



Online Help

**Oracle® Health Sciences
WebSDM and Empirica Study**

Release 3.1.2

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Release Notes and Other Documents

To view a page where you can access release notes, a printable version of the online help, the API WSDL file, customer-specific information (if applicable), and other pertinent documents for WebSDM™/Empirica™ Study, click [here](#).

To view documents provided as PDF files, you must have Adobe® Acrobat® Reader installed on your computer. Adobe Acrobat Reader is freely distributed software for viewing and printing PDF (Portable Document Format) files, and is available at www.adobe.com.

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Getting Started

Overview

WebSDM™/Empirica™ Study, provided by Oracle, is a web-based system designed to work with clinical trial data in the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) format.

The WebSDM (Web Submission Data Manager) component of WebSDM/Empirica Study allows you to validate case report data for compliance with the CDISC *Study Data Tabulation Model Implementation Guide* (SDTMIG) Version 3.1, 3.1.1, 3.1.2, or 3.1.3. Study data validation checking is done when data is loaded into WebSDM/Empirica Study. You can review checking results, browse, review and download the study metadata and clinical data. The following example shows high-level information about a study that has been loaded and checked:

Domain	Subjects	Description	Listings	Download Rows	Variables	Structure Checks	Consistency Checks
AE	509	Adverse Events		2860 rows	64	1	14
CM	609	Concomitant Medications		9483 rows	53	0	10
DM	613	Demographics		613 rows	33	0	8
DS	613	Disposition		613 rows	34	0	6

Note: All examples in the help system are examples only and are not representative of actual study data.

The Empirica Study component of WebSDM/Empirica Study is an additional set of features supporting the detection and evaluation of possible safety issues in study data. If you have licensed Empirica Study, you can:

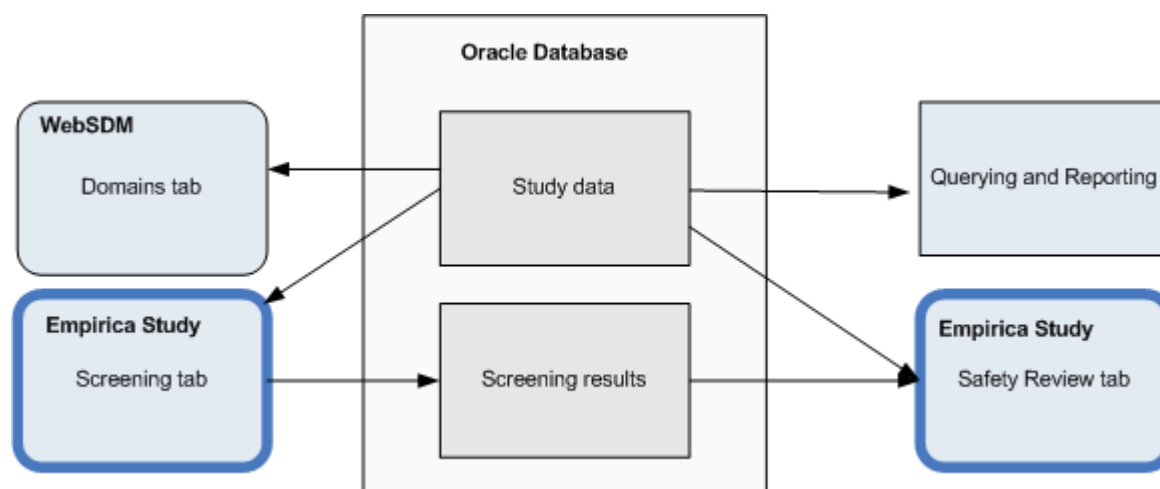
- Review study data from ongoing blinded studies or closed unblinded studies to review potential safety issues.
- Get a high-level overview of the study demographics and explore disposition events and exposure to the study drug.
- Review adverse event incidence statistics and drill down to detailed reports on events of interest.
- Explore clinical lab test results using a rich variety of graphical displays.
- For closed, unblinded studies, perform screening analysis to identify issues (adverse events or clinically significant laboratory, ECG or vital signs findings) related to the use of study treatment. Screening can be performed for pre-specified periods of time and for demographic subgroups, for example, white males over 50 who had adverse events after their run-in period).
- Use an innovative issue mining technique that combines standard cluster analysis techniques with Empirical Bayes adjusted odds ratio statistics to identify issue clusters, which are sets of three or more issues that tend to co-occur more for subjects in the treatment group than for subjects in the comparator group.

- Track and evaluate potential signals.
- Explore the effects of demographic factors, concomitant medications, medical history or other subject characteristics on issue occurrence using Bayesian logistic regression.

Features that are useful regardless of whether your focus is WebSDM or Empirica Study are:

- Viewing graphical displays of information.
- Drilling down on counts of subjects to subject details.
- Querying the study data based on specified criteria.
- Using summary and detailed reports to view study data in meaningful formats for analysis.

The following diagram shows how study data is used on various tabs:



Applications and studies

An application is a group of studies, which may be different studies or multiple versions of the same study. For example, an application may be a group of studies that is part of a regulatory submission. A *study* is clinical trial data about subjects being treated with an investigational drug.

For most activities, you are working within the context of a particular study, so your first step when you log in is to select an application and study. As a user preference, you can specify automatic selection of the application and study from your last session. During a session, you can switch easily between applications and studies by using the Select tab.

Related Topics

[Prerequisites and Usage Notes](#)

[Logging In](#)

[Selecting an Application](#)

[Selecting a Study or Study Pool](#)

[Changing Your Password](#)

[Setting User Preferences](#)

[Navigating](#)

[Using Help](#)

[Tips about Variables](#)

[Sending Feedback](#)

[Exiting](#)

Prerequisites and Usage Notes

Internet Explorer options

WebSDM/Empirica Study requires Windows® Internet Explorer version 7.0, or 8.0. The following steps configure Internet Explorer so that, in WebSDM/Empirica Study, you can print graphs and other outputs (such as tabular subject details) that use color, and download data. You can configure Internet Explorer at any time, and you need to do so only once.

1. Open Internet Explorer.
2. From the Tools menu, select **Internet Options**.
3. On the Advanced tab, scroll down to the Printing section.
4. Select the **Print background colors and images** check box. This setting allows WebSDM/Empirica Study to print the color key along with a graph, and print the shading for table column headers and grid lines.
5. Scroll down to the Security section.
6. Deselect the **Do not save encrypted pages to disk** check box, so that WebSDM/Empirica Study can download data.
7. Click **OK**.

Due to a limitation in Internet Explorer, when you download data you may not be able to use the **Open** button in the File Download dialog box. If you encounter problems opening a file, use the Save option and then open the saved file. Alternatively, clear Internet Explorer's cache: from Internet Explorer's Tools menu, select **Internet Options**, and then on the General tab, click **Delete Files**.

Also note that the IE option **Allow script-initiated windows without size or position constraints** affects the titles of pop-up windows (but not full browser pages) in WebSDM/Empirica Study. If this option is disabled, the window titles include the URL. This option should be enabled to display window titles without the URL. This is a security setting, that is enabled by default if you add the WebSDM/Empirica Study URL to the Local intranet zone on the Security tab of the Internet Options window.

Multiple sessions

Do not run more than one session of WebSDM/Empirica Study at the same time on your computer using different browser sessions or, in Internet Explorer 7 or 8, different tabs in the same browser session.

Back links

Do not use the Back button in Internet Explorer to navigate in WebSDM/Empirica Study. Use of the button may capture your choices on a page incorrectly or result in a message that a page cannot be found. Use other methods to navigate, such as clicking the **Back** link on a page or clicking another tab or hyperlink.

Pop-up windows

Some features of WebSDM/Empirica Study and Help rely on the use of pop-up windows. If you have pop-up blocking software installed on your computer, it might prevent these windows from opening. You might need to allow pop-up windows for the web site on which you run WebSDM/Empirica Study.

Adobe® Acrobat® Reader

If you will be downloading data from WebSDM/Empirica Study tables to Portable Document Format (PDF) files, you must have Adobe Acrobat Reader installed on your computer. Adobe Acrobat Reader is freely distributed software for viewing and printing PDF files, and is available at www.adobe.com.

You also need Adobe Acrobat Reader to view any PDF files that may be provided as links in this help system.

Note: In Adobe Acrobat Reader, select **Preferences** from the **Edit** menu. For the Internet category, deselect the **Display PDF in browser** check box.

ZIP file utility

If you will be creating ZIP archive files when downloading data or if you will be viewing archives of potential signals, you must have a ZIP file compression and extraction utility such as WinZip installed on your computer. WinZip is available at www.winzip.com. You must also have the file extension .zip associated with the ZIP file utility.

Installing a JRE for DataMontage

From within WebSDM/Empirica Study, you can use DataMontage™ to view graphical displays of subject data on a timeline. DataMontage is a third-party applet (provided by Stottler Henke) that has been customized and integrated into WebSDM/Empirica Study. The Run DataMontage as applet user preference determines whether DataMontage runs interactively as a Java™ Runtime applet. To use DataMontage interactively, you must install a Java Runtime Environment (JRE) as described in [Preparing to Use DataMontage](#).

PPD® Patient Profiles

From within WebSDM/Empirica Study, you can use PPD Patient Profiles Version 3.0 or above to view sophisticated graphical displays of data. PPD Patient Profiles is a third-party application provided and supported by Pharmaceutical Product Development (PPD); further information about PPD Patient Profiles and contact information is available at www.ppd.com.

If you want to use PPD Patient Profiles to view subject details in WebSDM/Empirica Study, purchase PPD Patient Profiles Version 3.0 or later from PPD (Pharmaceutical Product Development).

Note: Before installing PPD Patient Profiles, you must uninstall any previous versions of the product.

Once PPD Patient Profiles has been installed, you must [configure it](#) to work with WebSDM/Empirica Study.

Microsoft Excel

If you will be downloading data to Microsoft Excel®, make sure that Excel is installed on your computer.

SAS System Viewer

To view files that you created by downloading data to SAS Version 5 transport files (XPT files), you need the SAS® System Viewer. The SAS® System Viewer is freely distributed software for viewing and printing XPT files, and is available at <http://www.sas.com>.

Base SAS

To use files that you create by downloading data to SAS data step definition files (SAS files), you need Base SAS®. Base SAS is a third-party application that you can purchase at www.sas.com.

Sample studies and built-in reports

Installation instructions describe how to load the following sample studies:

- SAMP1_312 uses SDTM 3.1.2
- SAMP1_311 uses SDTM 3.1.1
- SAMP1 uses SDTM 3.1

Regardless of which SDTM version you use for your own study data, you must have loaded the SAMP1_312 study to use the [built-in report definitions](#). For more information, see the *WebSDM/Empirica Study Windows 2003/2008 Server Installation and Upgrade Instructions*.

Logging In

You log in to WebSDM/Empirica Study using the username and password that your site administrator provided. If your site administrator has enabled single sign-on, you can log in to WebSDM/Empirica Study using your single sign-on username and password. When you

log in to WebSDM/Empirica Study, the application authenticates your username using a case-insensitive match. For example, **jkelley** and **JKelley** both resolve to the **jkelley** username.

Before logging in, you must ensure that you have met the prerequisites described in [Prerequisites and Usage Notes](#). Although it is possible to log in to WebSDM/Empirica Study before performing the required installation and configuration tasks, you may be unable to perform some WebSDM/Empirica Study activities without their completion.

To log in initially:

1. Open Windows Internet Explorer.
2. Navigate to the WebSDM/Empirica Study web address provided by your user administrator. The login page appears.

Note: Do not run more than one session of WebSDM/Empirica Study at the same time using different browser sessions or different tabs in the same browser session.

3. Optionally bookmark the login page.
4. Enter your **Username** and **Password**, as provided by your user administrator.
5. Click **Log In**.

You may be prompted to [change your password](#). Oracle recommends that you change your initial password if you are not prompted automatically.

6. Select an application and a study or study pool.
7. Optionally set your [user preferences](#).

These user preferences can streamline your workflow:

- Start up with application and study from previous session
- Start in this tab

To log in with your WebSDM/Empirica Study username and password:

1. Open Windows Internet Explorer.
2. Navigate to the WebSDM/Empirica Study web address provided by your user administrator. The login page appears.

Note: Do not run more than one session of WebSDM/Empirica Study at the same time using different browser sessions or different tabs in the same browser session.

3. Enter your **Username** and **Password**.
4. Click **Log In**.

Password expiration warning

A message appears when your password is about to expire, providing a link to change your password at that time. If you choose not to change your password, a warning message continues to appear each time you log in until you change your password, or your password expires.

Password expired warning

If a message appears indicating that your password has expired, contact your user administrator to reset your password.

To log in with your single sign-on username and password:

Do one of the following:

- If you are currently logged in to your Oracle Access Manager environment:

No login page appears. You can access WebSDM/Empirica Study without re-entering your username and password.

- If you are not currently logged in:

The Oracle Access Manager single sign-on page appears. Enter your single sign-on username and password, and then click Log In.

Related Topics

[Navigating](#)

[Exiting](#)

Selecting an Application—Select tab

An application is the clinical trial data to be submitted to a regulatory authority for review and approval. Before you can use the Safety Review, Domains, Subject Lists, Reports, or Screening tabs, you must select an application, as well as a study or study pool within the application.

When at least one study in an application has been published to your login group, the application becomes available on the Select Application page.

Note: The phrase "currently selected application" or "currently selected study" refers to the application or study that you have selected on the Select tab.

To select an application:

1. Go to the Select tab. You can also click Select Another Application on the Select Study/Pool page.

If the site option Use FDA Look and Feel is not selected, the Select Application page provides a table of the following information for each application:

Column	Description
Name	Name of the application.

Description	Description of the application.
Created	Date and time at which the application was registered.
Drug Name	Name of the drug associated with the submission.

If the site option **Use FDA Look and Feel** is selected, the **Select Application** page provides a table of the following information for each application:

Column	Description
Application Name	Name of the application.
Description	Description of the application.
Sponsor	Name of the sponsor organization for the application.
Drug Name	Name of the drug associated with the submission.

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

- Click the row for an application and click **Select Application**. (Alternatively, double-click the row.) The **Select** page changes to list studies and pools that are part of the application so that you can [select a study or pool](#).
- If you have set your [user preference](#) Start up with application and study from previous session, the application that you select remains current until you select a different application.

Related Topics

[About Applications and Studies](#)

Selecting a Study or Study Pool

A study is clinical trial data about subjects being treated with an investigational drug. A study pool is a group of studies from which data is pooled. For a study pool, clinical data is treated as if it occurred in a single study.

When you have selected an application, the Select Study/Pool page appears and you must select a study or study pool. There may be multiple studies or study pools in an application. A study or study pool becomes visible on the Select tab when it has been published to your login group. However, you can select a study or study pool only if it has been loaded and checked.

To select a study or study pool:

- [Select an application](#). The Select Study/Pool page appears.

If the site option **Use FDA Look and Feel** is deselected, the Select Study/Pool page provides the following information for each study or study pool in the selected application:

Column	Description
--------	-------------

ID	Unique identifier of the study or study pool, assigned automatically when the study or pool was registered.
Name	Sponsor-assigned identifier of the study or study pool.
Type	Possible values are Study and Study Pool.
Description	Description of the study or study pool.
Last Update	Most recent date and time at which the study or pool was loaded and checked. If the study or pool has never been loaded and checked, Study Not Loaded is shown.
State	<p>Stage of the loading and checking process; assigned automatically as each stage of the loading and checking process is completed. Possible values are:</p> <ul style="list-style-type: none"> • Not Loaded—The study has been registered but has not been loaded or checked. • Initialized—The loading process has started. • Data Loaded-Not Checked—The loading process has completed but checking has not been performed. • Awaiting Reload—The loading process has completed, but a reload is required because of subsequent changes to the study or pool. • Data Structure Checks Run—Clinical data has been checked against the define.xml and metadata rules. • Within-Domain Checks Run—Clinical data has been checked against the define.xml and within-domain rules. • Cross-Domain Checks Run—Clinical data has been checked against the define.xml and cross-domain rules. • Ready to Use—The study or pool is ready to use. <p>Note: For study pools, there are no metadata structure checks or cross-domain checks, although these steps of the load and check process are performed.</p>
Standard	<p>One of the following values, indicating the version of the CDISC Study Data Tabulation Model (SDTM) associated with the study or pool:</p> <ul style="list-style-type: none"> • sdm313—Version 3.1.3 • sdm312—Version 3.1.2 • sdm311—Version 3.1.1 • sdm31—Version 3.1

If the site option **Use FDA Look and Feel** is selected, the Select Study/Pool page provides the following information about each study or study pool in the selected application:

Column	Description
Protocol	Name of the study.
Type	Possible values are Study and Study Pool.
Standard Version	One of the following values, indicating the version of the CDISC Study Data Tabulation Model (SDTM) associated with the study or pool: <ul style="list-style-type: none"> • sdm313—Version 3.1.3 • sdm312—Version 3.1.2 • sdm311—Version 3.1.1 • sdm31—Version 3.1

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

2. Click the row for a study and click **Select Study/Pool**. (Alternatively, double-click the row.) The page that appears next depends on the setting of your [user preference](#) **Start in this tab**.
3. If you have set your [user preference](#) **Start up with application and study from previous session**, the study or study pool that you select remains current until you select a different study or study pool.
4. To select a different application, click **Select Another Application**. The Select page changes to list applications so that you can select another application.

Related Topics

[About Applications and Studies](#)

Selecting a Directory

When registering an application, you must provide the path of the application directory, which is relative to the root directory specified as a [site option](#). When you subsequently register a study, you provide the name of the subdirectory, relative to the application directory, where the study metadata (and study data, for a SAS Transport data source) is located.

You can use the **Browse** link to navigate through the directory structure on the WebSDM/Empirica Study server and select directories. When you click **Browse**, the Select a Directory page appears. Then do the following to navigate through the directory structure:

- Click .. in the top row to go to the next higher directory after you have visited a child directory.
- Click a directory name in the left column to go to the directory.

- Click **Select** next to a directory name to select it.
- Click **Create** to create a new directory.

You can create and select a new directory for an application or for a study with an Oracle-based data source type by clicking on the **Create** link next to the new directory name. The option to create a new directory is offered when there is no directory named the same as the application or study being registered. Directory name collisions are avoided by appending a numeral and/or substituting an underscore for any special characters that are present in the application or study name.

Zooming In On a SOC

If you zoom in on a particular System Organ Class (SOC) when [viewing a sector map](#), data for only that SOC is displayed.

To zoom in on a term:

1. Click the tile representing a term in the main sector map.
2. Select **Zoom** from the menu that appears.

Once you have zoomed in on a term, you can do the following:

When you click a tile of the graph, a menu appears and you can do the following:

- [Drill down](#) to subjects (if any) with a combination of the treatment drug and the term represented by the tile.
- Click **2x2 Table** to [view 2x2 tables](#) if there are any subjects with the treatment or comparator drug and the term represented by the tile.

Changing Your Password

You can change your own password at any time. Your organization may require you to change it periodically for security reasons. If, when you log in, a message tells you that your password is due to expire in a certain number of days, ensure that you change your password within that time frame. You cannot log in with an expired password; if your password expires, ask your user administrator to reset it.

If you log in to WebSDM/Empirica Study using a single sign-on username and password, you cannot change your password in WebSDM/Empirica Study. Contact your user administrator for information on changing your password in Oracle Access Manager.

If you have the **Administer Users** permission, you can change other users' WebSDM/Empirica Study passwords. For more information, see [Changing User Passwords](#).

To change your password:

Note: If your password is due to expire, a warning message displays when you attempt to log in. Click the provided link and proceed to Step 3 below.

1. At the top of any page, click **Settings**.

2. Click **Change Password**. The Change Password page appears.

This link is unavailable if you log in to WebSDM/Empirica Study using a single sign-on username and password.
3. In the **Old Password** field, enter your old (existing) password.
4. Enter a value in the **New Password** field, up to a maximum of 64 characters. Minimum password requirements, if any, for length and character types are displayed. There may be restrictions on the re-use of old passwords.
5. In the **Confirm Password** field, enter your new password again.
6. Click **Change Password**. Your password is updated. The password expiration period, if one has been set, begins for the new password. The next time you log in to WebSDM/Empirica Study, you must use your new password.

Related Topics

[Logging In](#)

[Exiting](#)

Setting Your User Preferences

A user preference is a setting that customizes an aspect of WebSDM/Empirica Study for your username. Your user preference settings have no effect on any other WebSDM/Empirica Study users.

To set user preferences:

1. At the top of any page, click **Preferences**. The **Set User Preferences** page appears.
2. Modify any of the user preferences described below. You can set preferences for only features that you have permissions to use.

User Preference	Description
Start in this tab	Tab to display each time you log in and select an application and study. You must have appropriate permissions for the tab.
Default download file type	The default file type for download activities. The options are: <ul style="list-style-type: none">• Comma-separated file (.csv)• Tab-separated (.txt)• Excel spreadsheet (.xls)• SAS Version 5 transport file (.xpt)• SAS data step definition (.sas)

Start up with application and study from previous session	<p>Specify whether the application and study or study pool that you most recently selected (in your previous session) is selected automatically when you log in.</p> <ul style="list-style-type: none"> • If selected—WebSDM/Empirica Study starts with your most recently selected application and study. • If deselected—You must select an application and study or study pool when you log in.
Initialize Subject Details display with	<p>Specify the default display for the Subject Details page. The options are:</p> <ul style="list-style-type: none"> • All Domains—Displays a table for every domain in the study. By default, each table includes all columns. • Safety Domains—Displays a table for a subset of domains related to safety. By default, each table includes a subset of columns. <p>Note: This setting also determines the default setting in the Download window that appears when you download subject details.</p>
Locate table scrollbars on left side	<p>Specify the table scrollbar location.</p> <ul style="list-style-type: none"> • If selected—Vertical scrollbars appear on the left side of tables. • If deselected—Vertical scrollbars appear on the right side of tables. <p>Note: The availability of this user preference is determined by a site option.</p>
Display error-checking results	<p>Specify whether to include columns for Structure Errors and Consistency Errors and a View Checking Results Log link on the Study Data Domains page.</p> <ul style="list-style-type: none"> • If selected—Columns for structure and consistency errors appear and the View Checking Results Log link appears. • If deselected—Columns and the link do not appear.
Use long query variable names	<p>Specify whether to display variable descriptions in addition to the variable names on the Define Query page when you create a query-based subject list.</p> <ul style="list-style-type: none"> • If selected—Variable descriptions appear. • If deselected—Only the variable names appear.

Enable adverse event hierarchy browser	<p>Specify whether to use a hierarchy-based browser for selecting MedDRA terms when creating a query-based subject list.</p> <ul style="list-style-type: none"> • If selected—Uses a hierarchy-based browser. • If deselected—Uses a browser where events are in alphabetical order.
Enable drug hierarchy browser	Reserved for future use. Leave blank.
Run DataMontage as applet	<p>Specify whether to use Java-enabled interactive features when you display subject details in a DataMontage graph.</p> <ul style="list-style-type: none"> • If selected—Uses Java-enabled interactive features. • If deselected—Displays DataMontage graphs as static JPEG images. <p>Note: If you plan to use DataMontage interactively, you must also install a Java Runtime Environment (JRE). For more information, see Preparing to Use DataMontage.</p>
Display all lab values in DataMontage (even when within normal range)	<p>Specify whether to show lab values that are both within and outside normal ranges in the Labs section of DataMontage graphs.</p> <ul style="list-style-type: none"> • If selected—Shows lab values that are within and outside normal ranges. • If deselected—Shows only values outside normal ranges. Filtered to tests with abnormal values appears.
Maximum number of subjects to display in PPD Patient Profiles	Number of subjects that can be included in a PPD Patient Profiles graph for multiple subjects.
Display in DataMontage or PPD Patient Profiles	<p>Specify the data types to include in DataMontage or PPD Patient Profiles graphs.</p> <p>If you select Data Problems (applies to only DataMontage), problems that cause a domain's data to be omitted from the graph are reported above the graph.</p>

3. Click **Save**. The preferences become effective immediately for your username. Each time you log in to WebSDM/Empirica Study, your saved preferences are used.

Navigating

The basic navigation tool in WebSDM/Empirica Study is a set of tabs. Each tab provides a particular type of functionality and is accessible according to site options and user

permissions. You can set a [user preference](#) to select a tab by default when you have logged in and selected an application and study.

Other navigation tools are hyperlinks that cause another page to appear and menus that include a series of hyperlinks.

- A page in WebSDM/Empirica Study is a screen displayed as a web page in your browser.
- A window as used in this help system refers to a window or dialog box that pops up instead of displaying as a web page.

Tabs

WebSDM/Empirica Study includes the following tabs:

Tab	Use to
Home	Access customer-defined information on clinical trials. There may be multiple versions of the Home tab, each associated with a different group of users. Note: You can also go to the Home tab by clicking the graphic image in the upper lefthand corner of WebSDM/Empirica Study pages.
Select	Select an application and study or study pool. You must select an application and study or study pool before you can use the Domains, Subject Lists, Reports, or Screening tabs. You can also set your user preference Start up with application and study from previous session.
Domains	View clinical data, metadata, and the results of structure and consistency checking of data.
Safety Review	Available if your organization uses Empirica Study. View tables and graphs providing counts, percentages, and other information about subjects who received the treatment drug and comparator drug. View graphical and tabular displays of information about subjects in the study, including adverse events, lab and vital sign results, ECG results, exposures, disposition events, and so on. This tab also allows you to view the results of screening analysis.
Screening	Available if your organization uses Empirica Study. Perform screening analysis and view results, perform issue cluster mining and view results, and create and view potential signals.
Subject Lists	Query the study data and create lists of subjects of interest.
Reports	Create and run reports based on study data. You can use built-in reports or create your own.
Setup	Register and manage applications, studies, and study pools. Load and check studies and pools.
Run History	Review the status of loading and checking runs and screening analysis runs.

Standard hyperlinks

The following set of hyperlinks appears for all users in the upper corner of pages in WebSDM/Empirica Study:




Command	Use to
Preferences	Set user preferences for your username.
Settings	Change your password . If you have appropriate permissions, you can perform other activities related to user administration, applications and studies, rules, audit trails, the server, and so on.
Feedback	Send feedback (such as comments, suggestions, or requests) to an email address that is specified by your site administrator.
Exit	Exit WebSDM/Empirica Study
Help	Use online help .

Using Help

The WebSDM/Empirica Study Help provides conceptual and instructional topics. The help system is context-sensitive, meaning that you can click a **Help** link on a page (screen) to display information about that page. You can also go to the help Table of Contents and select topics to display. To find information in the help system, you can search for keywords or use the index.

To use help:

1. Click **Help**. Help for the page that you are viewing appears in a new browser window.
2. To view the main help page, click **Show Table of Contents** at the top of the help page. The main help window includes a help toolbar with the following buttons.

Button	Description
CONTENTS	<p>Display the Table of Contents for the help system.</p> <p>In the Table of Contents, expand a top-level entry by clicking either its name or the closed book icon  before its name. The icon changes to .</p> <p>Then click a topic name or the question mark icon  before its name to display the topic in the right-hand side of the help window.</p>
INDEX	<p>Display index entries for the help system. To go to the first occurrence of an index entry starting with particular characters, type in characters into the field above the index entries.</p> <p>When you click an index entry, if only one help topic is associated with an index entry, that topic is displayed. If multiple topics are associated with the entry, a pop-up window shows the topics and you can select one.</p>
SEARCH	<p>Display a search field. To find help topics containing a particular word or phrase, type in the word or phrase and click GO. Then click a listed</p>

topic to display it.

You can also use the following options:

- **Highlight search results:** When selected, highlights the word or phrase you specified in the topics returned from the search. To disable this option in topics, deselect this check box, and then click a topic in the search results.
- **Search results per page:** Indicates the number of topics to display per search result page. To view all topics on one page, specify a large number, such as **99**.

GLOSSARY Display a list of glossary terms. Click a glossary term to display a definition in the bottom left corner of the window.

BACK Redisplay the help page from which you navigated to the current page.

3. The help topics include underlined hyperlinks that you can click to display more information.

Help remains open until you close it. You can leave help open in the background while you are using WebSDM/Empirica Study.

Tips on Variables

Variable names

This help system sometimes refers to the names of variables in the source data. The following format is typically used for the variable name:

<two-character domain name>.<variable name>

For example, DM.RFSTDTC is the study reference start date in the Demographics domain.

Many variables names in different domains are the same except for their first two characters. For example, the Labs domain contains an LBDTC variable and the Vital Signs domain contains a VSDTC variable. In topics that cover both labs and vital signs, the help may refer to this variable as __DTC.

Derived variables

See [Derived Variables](#) for information about variables that are derived by WebSDM/Empirica Study from study data. The names of derived variables end in __.

Datetimes

For system-related datetimes (that is, datetimes that are not part of study data itself), the datetime of the WebSDM/Empirica Study server is used. This includes displayed dates and dates that you enter.

For example, when you submit a run, the start date will be in a server datetime. If you enter a specific date on which you want the run to start, your entry is interpreted as a server datetime.

For datetimes that are part of the study data and are ISO 8601-formatted text strings, WebSDM/Empirica Study derives Oracle datetimes representing the low and high end of the datetimes. For most computations involving datetimes from the study data, the derived datetimes are used. In this help system, descriptions of computations and algorithms typically refer to the study data variable (such as DM.RFSTDTC) and do not specify whether the derived low or high end (such as DM.RFSTDTL_ or DM.RFSTDTH_) for the datetime is used. When the variable represents a start date/time the derived low end is typically used, and when the variable represents an end date/time, the derived high end is typically used.

Sending Feedback

Oracle welcomes your comments, problem reports, suggestions, or requests about the product. This page enables you to send feedback to an e-mail address that is specified as a site option.

To send feedback:

1. At the top of any page, click Feedback.
2. In the Subject field, enter the subject of your message.
3. In the comments field, enter the text of your message.
4. Click Send This Now.
5. When informed that your message has been sent, click Continue. The user who is set up to receive feedback receives an e-mail message. In the e-mail message:
 - The date and time of the message is the date and time at which you clicked Send.
 - The From line shows the e-mail address associated with your username.
 - The Subject line shows the text you entered in the subject line of the feedback.
 - Before the message you typed in, a line identifies the application and your full name.

Exiting WebSDM/Empirica Study

You should ensure that you first exit WebSDM/Empirica Study before closing your browser. If you close your browser without exiting WebSDM/Empirica Study, your session continues to run and may use system resources unnecessarily.

If you logged in to WebSDM/Empirica Study using your single sign-on username and password, exiting WebSDM/Empirica Study may not log you out of your single sign-on environment. Depending on your WebSDM/Empirica Study configuration, exiting WebSDM/Empirica Study may log you out of your single sign-on environment, or from WebSDM/Empirica Study only.

To exit WebSDM/Empirica Study:

At the top of any WebSDM/Empirica Study page, click **Exit**. A message appears, indicating that you are logged out of WebSDM/Empirica Study.

If you logged in using your single sign-on username and password and your site administrator specified a custom logout page, that page appears.

To log in again:

Click the link provided on the logout page. The login page appears.

To log in as a different user:

- If you logged in with your single sign-on username and password, close your browser, and then open WebSDM/Empirica Study in a new browser session.
- If you logged in with your WebSDM/Empirica Study username and password, click the link that appears on the logout page.

Note: From outside of WebSDM/Empirica Study, the system administrator can specify the number of minutes before automated session timeouts occur in WebSDM/Empirica Study. The session timeout occurs if you have not performed any action within the time period, regardless of whether a job is running in the background.

Related Topics

[Logging In](#)

Basics

Selecting Entries from a List

In many places in WebSDM/Empirica Study, you are provided with a window to select entries from a list. The window includes a list of all available entries and a list of entries that you select. Depending on which functionality you are using, you might be selecting values, variables, terms (such as Preferred Terms), or table columns.





To select entries:

1. Scroll through the list to find entries. Alternatively, you can type a string into the Match String field then click **Find**. All entries containing that string are listed; the matching does not distinguish between cases (upper, lower, mixed). See below for tips on how to search for entries using the Match String field.

To list all entries again, click **Show All**.

When an entry is highlighted in the list, you can go to the next occurrence of an entry starting with a character that you type. For example, you can highlight the first entry in the list and type **H** to go to the first entry starting with **H**.

2. To highlight an entry, click the entry in the list of all entries. You can also do the following:
 - Highlight multiple non-contiguous entries: hold down the **Ctrl** key while clicking each entry.
 - Highlight multiple contiguous entries: click an entry, hold down the **Shift** key, and click another entry. Entries between and including those entries are highlighted.
 - Remove highlighting from an entry: hold down the **Ctrl** key while clicking the selected entry.
3. To move entries back and forth between the list of all entries and the list of selected entries, you can double-click a single highlighted entry or use the arrow button as follows:

Arrow	Use To
	Move highlighted entries from the list of all entries to the list of selected entries.
	Move all entries from the list of all entries to the list of selected entries.
	Move highlighted entries from the list of selected entries to the list of available entries.
	Move all entries from the list of selected entries to the list of available entries.

If a **Clear** button is available, you can click it to clear out the list of selected entries.

4. If up and down arrows are available for the list of selected entries, you can use them to move a highlighted entry or group of entries up or down in the list. For example, when specifying breakdown details in a report definition, you can order the selected values as you want them to appear in the report.
5. If there is a **Show Variables** link, you can click it to view variables for the currently selected study.
6. Click **OK**.
7. WebSDM/Empirica Signal wraps the entries in quotes automatically.

Special characters

To search for the following special characters, you must precede each special character with a backslash (\):

Character	
comma	,
backslash	\
double-quote	"

For example:

To Find	Specify
ECCHYMOSIS, ARMS BILATERALLY	ECCHYMOSIS\, ARMS BILATERALLY
IRON,VITAMIN,MINERAL	IRON\,VITAMIN\,MINERAL

Match string syntax

In the Match String field (or Find field), you can use the following syntax:

Syntax	What is Matched	Syntax Example	Syntax Finds
^	Letter(s) at the beginning of a value.	^V	VERTIGO VOMITING Does not find SEVERE VOMITING.
\$	Letter(s) at the end of a value.	on\$	AGITATION DEPRESSION Does not find ANEMIA IRON DEFIC.
.	Any single character.	D.stonia	DYSTONIA
[abcdef]	Any character included in the set.	[gq]	All terms that have any of the letters g or q, including: ANGINA

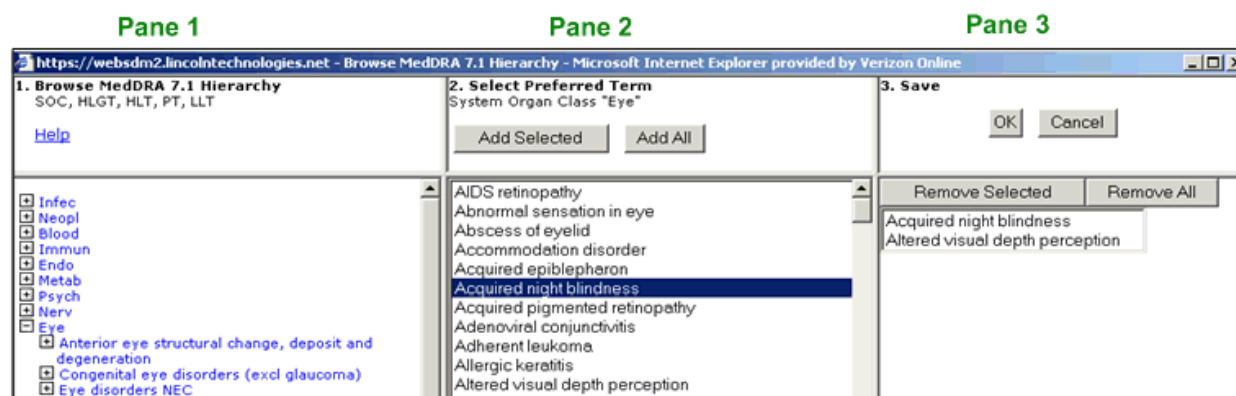
FREQUENT URINATION			
\b	A word boundary in a term.	\bDr	ABNORMAL DREAMS DRY MOUTH
\s	White space in a term.	en\s	PATHOGEN RESISTANCE SUDDEN INFANT DEATH SYNDROM
		\sen	ABDO ENLARGE

Using the Hierarchy Browser

Adverse events may be associated in WebSDM/Empirica Study with a dictionary, thesaurus, or other standardized terminology that organizes terms into a hierarchical structure. For example, adverse events terms may be associated with a version of the Medical Dictionary for Regulatory Activities (MedDRA).

If a variable is associated with a hierarchy, you can use the Hierarchy Browser to search for and select values from the hierarchy when creating a [query-based subject list](#) or creating or editing an [event list](#). You must set a user preference to enable use of the Hierarchy Browser.



The Browse Hierarchy window includes three panes (sections) that you use to browse, select, and save terms:



Browsing terms (pane 1)

Pane 1 displays terms at the highest, most general level of the hierarchy. For example, the MedDRA hierarchy shows SOC's in the left-hand section.

Note: The number of hierarchy levels that appear in pane 1 depends on the configuration. For example, for the MedDRA hierarchy, the levels SOC, HLGT, HLT, PT, and LLT typically appear in pane 1.

Click  before a term to show the next level of the hierarchy. For example, if you click  for a SOC, the HLGTs in that SOC are listed below the SOC.

If you point to a term in pane 1 so that the term becomes underlined, you can click the term to populate pane 2. You can click terms down to the level represented by the variable

with which you are working. Pane 2 then shows terms that are at the level represented by the variable and that are within the term you clicked in pane 1.

For example, suppose that you are working with a PT variable that is associated with MedDRA. If you click a SOC in pane 1, all PTs in that SOC appear in pane 2. If you click an HLGT or HLT, all PTs in that HLT or HLGT appear in pane 2. You can also click a specific PT to show that PT in pane 2.

Selecting terms (pane 2)

Pane 2 shows terms you selected by your actions in pane 1. Another way to list terms in pane 2 is by using the search field. Type in a text string and click **Find**. Only terms that include the text string are then listed.

Note: The hierarchy level for which terms appear in pane 2 depends on the variable for which you are selecting terms. For example, if the variable is PT, PTs appear in pane 2, and if the variable is HLT, HLTs appear in pane 2.

Once you have listed terms, you select which of those you want to include by moving them (up to 1,000 terms) to pane 3 as follows:

- To select all terms, click **Add All**.
- To select some terms, highlight them and click **Add Selected**. You can highlight multiple terms as follows:
 - Select multiple non-contiguous terms by holding down the **Ctrl** key while clicking each term.
 - To select multiple contiguous terms, click a term, hold down the **Shift** key, and click another term. Terms between and including those terms are highlighted.

You can also double-click a term to move it to pane 3.

To view the primary hierarchical path for a term, click the name of the term. The path displays in pane 1.

Saving terms (pane 3)

To remove terms from pane 3, you can do the following:

- Highlight terms and click **Remove Selected**. You can also remove a term by double-clicking it.
- Click **Remove All**.

When you are satisfied with the list of terms in pane 3, click **OK**. The Browse MedDRA Hierarchy window closes and you are returned to the task you were performing.

auspices of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

Specifying a SQL Where Clause

In some places, you can specify a SQL Where clause to restrict rows of a table or report. When specifying a SQL Where clause, do not enter **Where**. The **Where** is added internally to the start of the condition that you enter. For example, to view all results for which AGE is greater than 5, enter: AGE > 5

To connect conditions, use AND or OR. For example:

- AGE > 5 AND RESULT > 110
- AGE > 5 OR RESULT > 110

If you provide a SQL expression with invalid or unsupported syntax, an error message appears at the top of the page when you save the Where clause. Common errors are wrong or misspelled column names and unclosed or mismatched parentheses.

Data types

The way in which a variable is stored in the Oracle database determines how you can search for it. If you are uncertain of how a variable is stored, you can [view variable characteristics](#) on the Domains tab.

Text variables

If a variable is stored as a text field in the Oracle database, you must use single quotes around a text string, and capitalization must be exact within the quoted string.

To find a value that includes a single quotation mark or apostrophe, precede the quotation mark or apostrophe with another single quotation mark in the quoted string. For example, to find Bell's palsy for the MHTERM variable, enter: MHTERM like 'Bell's palsy'

You can use the following SQL operators:

AND, ANY, BETWEEN, IN, IS, LIKE, NOT, NULL, OF, OR, WHERE

The following table describes the more commonly used operators:

Operator	Action	Example
LIKE	matches	TEST LIKE 'WBC'
NOT	is not the condition that follows	TEST NOT LIKE 'WBC'

% is a wildcard character that you can use in a text string after LIKE; it matches any characters in its position, as follows:

Match Type	Example
Exact match	HLT LIKE 'Myopathies'
Starts with specified string	HLT LIKE 'Myo%'
Includes specified string	HLT LIKE '%path%'
Ends with specified string	HLT LIKE '%pathies'

Numeric variables

If a variable is stored as a number field in the Oracle database, you can use the following SQL operators:

(,) = , != <> > >= < <= + - * ? || /** /* */ --

The following table describes the more commonly used operators:

Operator	Action	Example
=	is equal to	AGE = 2
!= or <>	is not equal to	AGE != 2 AGE <> 2
>	is greater than	RESULT > 98.6
>=	is greater than or equal to	RESULT >= 98.6
<	is less than	RESULT < 8.5
<=	is less than or equal to	RESULT <= 8.5
BETWEEN	is between (inclusive of the starting and ending values)	RESULT BETWEEN 6.5 AND 8.0

Note: A stored value may be more precise than a displayed value. This situation can lead to non-intuitive results for a SQL Where clause. For example, if a stored value is 5.600004 and the displayed value is 5.6, the Where clause **value > 5.6** would find the value, but **value = 5.6** would not.

Date variables

If a date variable is stored as a text field in the Oracle database, you can search for it as you would search for any text string.

If a date variable is stored as a date field in the Oracle database, you can use the Oracle function TO_DATE to change a text string to an Oracle date. Then you can use the same

operators as for numeric variables. For example, suppose that you want to find dates later than 2001-01-17. You would use:

```
column-name > TO_DATE('2001-01-17', 'yyyy-mm-dd')
```

where *column-name* is the name of a database column corresponding to the date variable.

If you do not specify a time, the time is considered to be midnight of the specified date.

Note: [Derived variables](#) for dates are stored as Oracle dates.

Using Functions

You can use the following supported functions in your SQL Where clause:

Abs, acos, add_months, ascii, asciiStr, asin, atan, atan2, BitAnd, Ceil, Chr, Compose, concat, convert, cos, cosh, decompose, dump, exp, floor, from_tz, initcap, instr, last_day, length, ln, log, lower, lpad, ltrim, mod, months_between, new_time, next_day, NVL, power, remainder, replace, round, rpad, rtrim, sign, sin, sinh, soundex, sqrt, substr, tan, tanh, to_char, to_date, to_dsinterval1, to_multi_byte, to_number, to_single_byte, to_timestamp, to_timestamp_tz, to_ymininterval, translate, trunk, tz_offset, upper, vsize

Notes:

- Functions with no parameters, such as sysdate, are not restricted.
 - Functions with optional arguments, such as to_timestamp, require ALL arguments.
 - Functions with variable arguments, such as DECODE (), are not supported
-

Publishing an Object


You can publish the following objects:

- Subject lists
- Report definitions
- Report outputs
- Studies or study pools

By default, the Publication Level of a newly created object is **Private**. If you publish the object, it becomes available to other users.

In most cases, you can publish objects only to your own login group, unless you have the Administer Users permission, as noted below. The exception is that you do not need the Administer Users permission to publish studies or study pools to multiple login groups.

To publish an object:

1. Click the Action menu icon () for the object and then click **Publish <object>**. The Publish <object> page appears and includes the following. (This example is for a report definition.)

Definition '**Sample**' owned by Janet Smith [jsmith]

Publication Level:

This Definition is marked as Private

[Publish](#)

Note: If no publication level is displayed, the object has been published to a different login group than yours by someone with the Administer Users permission.

2. Click **Publish**. The object is published to other users who are in your login group. The page changes to show that the object is now **Public**:

Definition '**Sample**' owned by Janet Smith [jsmith]

Publication Level:

Marked as Public [Make Private](#)

3. To return the Publication Level to Private, click **Make Private**.

Note: If you have the Administer Users permission, you can publish an object to multiple login groups. Select login groups and click **Publish**. If you publish to **–All–** and then add a new login group, the object is published automatically to the new login group. To remove publication from a login group, click **Remove** for it.

Working with Graphs

This topic describes display options that are common to the various graphs, as well as how to copy or print a graph.

The following display options are available for all or most graphs:

Option	Check to
Use gray-scale instead of colors	Use shades of gray instead of colors in the graph.
Popup	Display each graph in an individual pop-up window. If you have pop-up blocking software installed on your computer, it may prevent these windows from opening. You may want to disable your pop-up blocking software.
Key	Display a color key below the graph to show which value each graph element (such as a bar or region of the graph) represents.
Notes	Display notes about the graph.
Links	Include the following, depending on the particular graph: <ul style="list-style-type: none"> • Information about what a graph component (such as a bar, cell, or region) represents that appears when you point to that component • A menu that allows you to drill down when you click a graph component

- A Print link that you can use to print the graph

Before copying a graph (for example, with copy and paste functions), you may want to clear this checkbox so that extraneous information is not included in the copy.

To print a graph:

1. Configure Internet Explorer to print background colors and images. See [Prerequisites and Usage Notes](#) for more information.
2. With the Internet Explorer Page Setup option, set up the print options, including headers and footers that you want to use for graphs. Note that you can enter "&p" to show the page number and "&P" to show the total number of pages. For example, you can enter "Page &p of &P". A single graph may span multiple pages, so Oracle recommends that you include page numbers in the header or footer of your printouts.
3. Check or clear the Key and Notes check boxes, depending on whether you want to include the graph key or notes in the printout.
4. For the graph(s) you want to print, click **Print**. The Internet Explorer Print window appears.
5. Optionally change the orientation of the paper (Portrait or Landscape) and make other choices. (Page range specification and number of copies are not supported.)

Note: For some graphs, you need to use Landscape orientation in order to fit the graph on a printed page.

6. Select a printer.
7. Click **Print**. The graph is printed; if multiple graphs display on the same page, all the graphs are printed.

To copy a graph:

1. Check or clear the Key and Notes check boxes, depending on whether you want to include the graph key or notes in the copy. Oracle recommends that you clear the Links check box.
2. Click **Display**. The graph displays on the right side of this page.
3. On the graph or graphs that you want to copy, right-click and click **Select All** from the shortcut menu that appears. Alternatively, hold down the left mouse button and drag over parts of the display that you want to copy.

Note: If the graph is large, you may want to copy sections of it from the window that is displayed when you click **Print**. The Print window breaks up the graph into "pages" in order to print it.

4. Right-click again and select **Copy**.

- Open the document to which you want to add the graph(s), and use the **Paste** command for that application.

Note: In some cases, you will need to use a third-party screen capture tool to capture an appropriate graph image for inclusion in another document.

Using Projects

A project is an organizational tool (similar to a folder) that allows you to group certain objects for reference and retrieval purposes. Projects are intended for you to use in whatever way suits your needs; they are not intended to map to any particular concept in clinical trials. Objects that you can assign to projects are subject lists, report definitions, report outputs, and screening analysis specifications.

You can assign an object to a new project or an existing project:



The list of existing projects includes projects that you have created or that other users have created for objects they have [published](#). Available projects are for any projects in the currently selected application. You can also choose not to use projects at all. By default, objects are unassigned.

Note: A project remains available until all objects assigned to the project have been deleted.

On the pages that list objects that can be assigned to projects, you can select a project to filter the list to only objects in that project. For example, suppose that you are working with two studies, HT-100 and HT-150, in the same application. You could create two projects, HT-100 and HT-150, and group objects related to each study in the appropriate project. Then, on the Subject Lists page, for example, you could select the project HT-150 to see only subject lists created for HT-150.

Tables

About Tables

Many pages use a tabular format for presenting information. To help you work with the data in a table more effectively, you can use the following features:

To	Click this link	Help Topic
Select, arrange, sort, and filter the columns that display in the table.	Columns or Columns and Rows	Arranging Table Columns
Print the contents of the table.	Print	Printing a Table

Download the contents of the table to a variety of file formats.

Download

[Downloading Data](#)

Navigating between pages

To specify the number of rows that should display at a time, enter a number in the **Rows per Page** field and press **Enter**. In general, you can display up to 999 rows on each page.

To go to another page, you can do the following:

- Click the right arrow (▶) to view the next page.
- Click the left arrow (◀) to view the previous page.
- Enter a number in the **Page** field and press **Enter** to view the specific page.

Finding text

To find specific text on a page, you can select **Edit>Find** from the Internet Explorer menu bar. For efficiency, you may want to set the **Rows per Page** to a large number before using the Find feature.

Vertical scrollbars

A site option determines whether vertical scroll bars for tables of information are always on the left side, always on the right side, or determined by the [user preference](#) **Locate table scroll bars on left side**.

tooltip

In some tables, when you hover your cursor over a column heading, a description of the column appears:

Domain	Subjects	Description	Listings	Download Rows
AE	278	Adverse Events	Description of the Domain - Click a link to view domain metadata	

Sorting a table

You can sort a table by up to three columns. The current sort order appears above the table. You can sort a column as follows:

- Click the Ascending sort ear (▲) to sort in ascending order, or click the Descending sort ear (▼) to sort in descending order.
- Click **Columns** or **Columns and Rows**. For more information, see [Arranging Table Columns](#).

When you click a sort ear to sort a column, that column is used for the primary sort order. For example, suppose that the current sort order is LBCAT, LBTEST, and VISIT, all in ascending order:

93922 rows Sorted by LBCAT, LBTEST, VISIT

	LBCAT	LBTEST	VISIT	LBSTRESN
	HEMATOLOGY	ACTIVATED PARTIAL THROMBOPLASTIN TIME	DAY_1	28

To sort by LBSTRESN in descending order, click the down arrow in that column heading. The sort order becomes:

93922 rows Sorted by LBSTRESN desc, LBCAT, LBTEST

	LBCAT	LBTEST	VISIT	LBSTRESN
	HEMATOLOGY	ACTIVATED PARTIAL THROMBOPLASTIN TIME	DAY_4	

Note that:

- The last sort order that you specify becomes the primary sort order.
- Other columns continue to be used for sorting (secondary and third sort orders).
- Null values, such as the LBSTRESN column in the above example, appear last if you sort the column in ascending order and first if you sort the column in descending order.

To clear a sort order or explicitly specify levels of sorting, open the [Columns \(or Columns & Rows\) window](#). For example, you could change the above sort order as follows:

Column Sort Order:

LBTEST	▼	Asc	▼
VISIT	▼	Asc	▼
	▼	Asc	▼

93922 rows Sorted by LBTEST, VISIT

	LBCAT	LBTEST	VISIT	LBSTRESN
	HEMATOLOGY	ACTIVATED PARTIAL THROMBOPLASTIN TIME	DAY_1	33

Arranging Table Columns

On pages that provide information in a tabular format, you can:

- Select the columns to include in the table.

- Reorder the columns.
- Sort the rows in the table using the values in up to three different columns.

Additionally, for some pages, you can filter rows in the table by [specifying a SQL Where clause](#).



Note: There are special considerations for tables on the Subject Details page. For more information, see [Viewing Subject Details](#) and [Viewing Domain-Specific Subject Details](#).

To arrange table columns:

1. Click **Columns** (or **Columns and Rows**) above the table. The **Columns** (or **Columns and Rows**) window appears.
2. Select the columns that you want to include in the table by moving them from the **Available Columns** list to the **Selected Columns** list. For more information, see [Selecting Entries from a List](#).

Note: Tables that include many columns or columns with long values may be longer than the real estate in your browser window. To view the remaining portion of the table, use the scroll bar.

3. Optionally change the order in which columns display by clicking the column name in the **Selected Columns** list, and then clicking:

- The Up arrow button () to move the column up in the list.
- The Down arrow button () to move the column down in the list.

To move multiple columns, hold down the **Ctrl** key while you click the column names, and then click the Up or Down arrow buttons.

4. Optionally select or deselect the **Hide empty columns** checkbox to exclude or include columns from the table where the rows contain no value.
5. Optionally sort the table by clicking the arrows next to the column headings. The resulting sort order appears in the **Column Sort Order** fields.

The **Column Sort Order** fields are blank if you do not click the sort arrows.

6. Optionally provide a [SQL Where clause](#) to filter rows of the table for tables where **Columns and Rows** appears. Click **Show Columns** to insert variable names into the Where clause by clicking them.
7. Click **OK**.

To replace column selections with the default value:

Click **Reset**.

Related Topics

[About Tables](#)

[Downloading Data](#)

[Printing a Table](#)

Printing a Table

1. Set up the displayed table as you want it to appear when printed. The table will be printed with the same columns and sort order as the displayed table.
2. Click **Print** above the table if you want to print the entire table (not just the page you are currently viewing).

To print only the data on the currently displayed page of the table, select **Print** from the Internet Explorer **File** menu. This option is available only if the table is displayed in an Internet Explorer window rather than a separate pop-up window.

The Windows Print window appears.

3. Optionally change the orientation of the paper (Portrait or Landscape) and make other printing choices. If all displayed columns do not print in Landscape mode, you can remove columns from the table before printing it.
4. Select a printer and click **Print**.

Related Topics

[About Tables](#)

[Arranging Table Columns](#)

[Downloading Data](#)

Downloading Data

When working with a table of information, you can download the information to various types of files. When viewing subject details, you can download the details to an Excel spreadsheet or a Rich Text Format file.

You can set your [user preference](#) **Default download file type** to a file type to be used by default; when downloading, you can override the default as needed.

Note: For floating point numbers that are downloaded, the precision of the numbers is accurate to the level of precision in the numbers as displayed.

To download data:

1. Ensure that you have configured Internet Explorer to download files properly. For more information, see [Prerequisites and Usage Notes](#).
2. Make sure you have [arranged table columns](#) as you want them.
3. Click **Download**. The Download Table window appears.

4. In the **Base filename** field, enter a file name without an extension. Oracle recommends that you use a file name that will help identify the content of the download.

Note: With Internet Explorer 7, a space in the file name is replaced automatically with an underscore (_).

5. Click one of the following file types, depending on how you intend to use the file. For some types of information, only certain file types may be available.

File Type	Description
Comma-separated file (.csv)	Text file in which values are separated by a comma. Can be used as input to a spreadsheet application such as Microsoft Excel.
Tab-delimited file (.txt)	Plain text file; typically the file extension .txt is associated with a text editor such as Microsoft Notepad.
Excel spreadsheet (.xls)	<p>Spreadsheet file that can be opened by Microsoft Excel. You must have Microsoft Excel installed on your computer. If you try to download a table of more than 64,000 rows, a message warns you that this exceeds the capacity of Excel.</p> <p>When you download subject details, which include data from multiple domains, each domain's data is on a separate worksheet in the .xls file.</p>
	<p>Note: If dates are not displayed appropriately in Excel, you may need to change the display format in Excel.</p>
SAS Version 5 transport (.xpt)	Industry-standard SAS transport file as defined for SAS Version 5 (XPORT format).
SAS data step definition (.sas)	SAS data step file, which can be used by SAS software to create a native SAS dataset.
Rich Text Format (.rtf)	<p>Available only for downloading subject details. File that includes formatting and layout information, as well as the data, and can be easily transferred between software products. Typically this file type is associated with Microsoft Word.</p> <p>For legibility reasons, you may need to limit the number of columns in tables displayed on the Subject Details page before you download to this format.</p>
Portable Document Format (.pdf)	This option requires the Adobe Acrobat Reader. File that includes formatting and layout information, as well as the data.

Note: When you download subject details, you can select only Excel spreadsheet (.xls) or Word Rich Text Format (.rtf).

6. In the **Limit to** field, optionally enter the number of rows that you want to download (instead of downloading the entire table). For example, if you specify 1000, only the first 1000 rows of the table are downloaded. If you do not fill in the Limit to field, all rows of the table are downloaded. Keep in mind that the way in which the table is sorted will determine which rows are downloaded.

The number of rows per page of the displayed table has no effect on downloading. For example, suppose that the table includes 100 rows and 25 rows are displayed per page. If you download the entire table, all 100 rows are downloaded.

Note: When you download subject details, Oracle recommends that you do not limit the number of rows. The limit would apply to each domain's data; for example, if you limit to 2 rows, only the first two adverse events and the first two lab tests for the subject would be downloaded.

7. If you select **Create a Zip archive file for download**, a file with the extension .zip is created to hold the file that contains the downloaded table. You must have a ZIP file compression and extraction utility such as WinZip installed on your computer, as described in [Prerequisites and Usage Notes](#).

The zip file also includes an id.txt file that provides the name of the user who downloaded the table and the date and time of the download.

Note: When you download the displayed results of a report definition to a WinZip file that you have run, the report definition file (definition.XML) is also downloaded. If you created an analysis script report definition, the analysis script file is included in the WinZip file as well.

8. When you download subject details, you can select one of the following:
 - **All Domains**—Downloads a table for every domain in the study. By default, each table includes all columns. If you customized subject details to show different columns, those columns are downloaded.
 - **Safety Domains**—Downloads a table for a subset of domains related to safety. By default, each table includes a subset of columns. If you customized subject details to show different columns, those columns are downloaded.

A [user preference](#) determines the default setting.

Note: If you are downloading from the **Subject Details** page, this option uses your setting from that page.

9. Click **OK**. The File Download dialog opens.

Related Topics

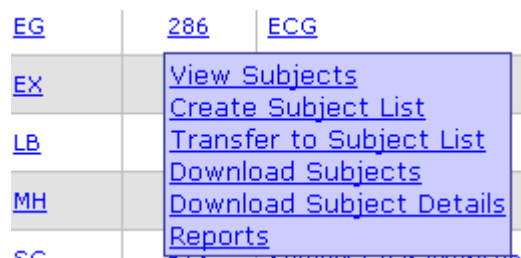
[About Tables](#)

[Printing a Table](#)

Drilling Down

About Drilldown

On many pages, the count (N or #) of subjects is a hyperlink that you can click to display a menu with drilldown options:



In most graphs, you can click a graph element, such as a bar or cell, to display the drilldown menu. For some graphs, drilldown is available only if the [Links option](#) for the graph is enabled.



On the drilldown menu, you can use the following options for subjects included in the count or represented by the graph element:

Option	Description
View Subjects	View a list of subjects . From the list of subjects, you can then drill down further to view subject details .
Create Subject List	Create a subject list .
Transfer to Subject List	Transfer the subjects to an existing subject list.
	Download the list of subjects .
Download Subjects	Note: This option functions the same as the Download link in the Subjects window. See Viewing a List of Subjects .
Download Subject Details	Download subject details for the subjects to an Excel spreadsheet or a Microsoft Word Rich Text Format File. You can download subject details only if the appropriate site option has been set. When viewing a particular subject, you can also download subject details for that one subject.
Reports	Run a report for the subjects. When running reports using this option, you can run only one report at a time.

Note: The options that are available on the drilldown menu are dependent on your user permissions.

Viewing Subjects

When you have [drilled down](#) into a list of subjects, subjects are listed in a tabular format. This is also referred to as "first-level drilldown". Each subject's site ID, sex, age, race, and study arm are displayed. In the Help, this window is referred to as the **Subjects** window, although the window title is often more informative.


USUBJID	Site ID	Sex	Age	Race	Planned Arm	Event(s)
39999-X42-AA81	X42	F	67	CAUCASIAN	OPC-45MG	 COUGH
39999-XX8-AA12	XX8	F	28	CAUCASIAN	OPC-15MG	 BLOOD IN STOOL


For information on viewing, printing, or downloading tables or changing the way data displays in the table in the Subjects window, see [About Tables](#).


Note: If you drilled down from a count that was affected by a time frame, only those subjects are represented on this page, although the page does not indicate the time frame.

The following columns are always available to include in the Subjects window:











Column	Description
USUBJID	Unique subject identifier (value of the USUBJID variable) for each subject. Click the subject ID hyperlink to view subject details . (This option is available only if your site administrator has set the appropriate site option.)
Site ID	Value of the SITEID variable for each subject.
Sex	Value of the SEX variable for each subject.
Race	Value of the RACE variable for each subject.
Planned Arm	Value of the ARM variable for each subject.

In some instances, the **Subjects** page includes an extra column, such as the Event(s) column in the above example. If the Adaptive Drilldown icon  appears next to the value, you can hover your mouse over it to view a tooltip, which provides additional information.

Column	Description
Event(s)	<p>This column appears on the Adverse Events page of the Safety Review tab when you drill down on subject counts for a row that represents multiple adverse events, or from an Incidence by . . . display (except a Box Plot for the Incidence by Day of Onset Graph) for such a row. The column includes adverse events that occurred within the time frame, including multiple occurrences of the same event. However, if you drill down from the Incidence by Recurrent display, events are listed only once.</p> <p>Your setting of All Events, Serious Events, or Events Causing Withdrawals on the Adverse Events page determines the adverse events that are listed.</p> <p>If more than one line is needed for any subject, you can click  to expand the column length for all subjects.</p>
Test Result(s)	<p>This column appears on the Lab Results page of the Safety Review tab if you select any radio button except All and you drill down on subject counts for a row that represents multiple lab test results. The column lists test results that occurred within the time frame, including results for multiple occurrences of the same lab</p>

	<p>test.</p> <p>Your setting of Clinically Significant, Outside 5x normal range, Outside 3x normal range, Outside normal range, or All on the Lab Results page determines the results that are listed.</p> <p>If more than one line is needed for any subject, you can click  to expand the column length for all subjects.</p>
Change from Baseline	<p>Appears when you drill down on one of the following:</p> <ul style="list-style-type: none"> • A Box Plot: Change from Baseline graph • A Delta Plot: Change from Baseline graph. <p>The column lists test results that occurred within the time frame.</p>
Result(s)	<p>Appears when you drill down on one of the following:</p> <ul style="list-style-type: none"> • A Box Plot: Distribution over Time graph. • A Distribution of QTc Change over Time display. Note that in this context, the displayed "result" value represents a change from baseline. <p>The column lists test results that occurred within the time frame.</p>
Results (BL, MAX)	Appears when you drill down on an LFT Scatter Plots: Shift from Baseline display. Lists test results that occurred within the time frame.
Results (BL, Post-BL)	Appears when you drill down on a Scatter Plot: Shift from Baseline display on the Labs page of the Safety Review tab. The column lists test results that occurred within the time frame.
Results (TEST1, TEST2)	Appears when you drill down on an LFT Scatter Plot Matrix: Maximum Results display. The column lists test results that occurred within the time frame.

The following example shows an expanded "Event(s)" column:

USUBJID	Site ID	Sex	Age	Race	Planned Arm	Event(s)
39999-X42-AA81	X42	F	67	CAUCASIAN	OPC-45MG	 COUGH,  FATIGUE,  HANGOVER,  SLEEP WALKING
39999-XX8-AA12	XX8	F	28	CAUCASIAN	OPC-15MG	 BLOOD IN STOOL,  CANDIDURIA,  CRYSTAL URINE PRESENT,  DIARRHOEA NOS,  HAEMOGLOBIN DECREASED,  PITTING OEDEMA

Note: If you print the table, the column lengths are always expanded. If you download the table, the multiple values are on one line, separated by the pipe character (|).

If your site administrator set the appropriate site option, you can click a subject ID hyperlink in the list of subjects to [view subject details](#) for that subject. You can also do the following:

Option	Description
Create Subject List	Create a subject list containing the listed subjects.
Transfer to Subject List	Transfer the subjects to an existing subject list.
Download Subject Details	<p>Download subject details for all subjects in the list to an Excel spreadsheet or a Word Rich Text Format File. You can download subject details only if your site administrator set the appropriate site option. In the Download Subject Details window, you can indicate whether to include data from all domains or only the safety domains. A user preference determines the default setting.</p> <hr/> <p>Note: This option differs from the Download option on this page, which downloads only the information displayed.</p>
Reports	Run a report for the subjects; you can run only one report definition at a time.
PPD Patient Profiles	Available if your site administrator has set the appropriate site option. View a PPD Patient Profiles graph for each of the listed subjects. A user preference determines how many subjects in the list will be graphed in PPD Patient Profiles.
Data Montage Graphs	View a DataMontage graph for each subject in the list.
Lab Profiles	View a Liver Function Test Patient Profile or view a Hematoxicity Patient Profile for each subject in the list.
Vital Signs Profiles	View a Vital Signs Patient Profile for each subject in the list.
Napoleon's March	View a Napoleon's March Graph that shows temporal relationships between duration of exposure and adverse event onset for the listed subjects.

Creating a Subject List from Drilldown Information

On pages and in reports that display a list of subjects identified by subject ID, you have the option to save the list of subjects for future use. A subject list is a named and saved list of subjects. You can also [transfer the subjects](#) to an existing subject list.

To create a subject list from drilldown information:

1. When viewing a list of subjects, click **Create Subject List**. Alternatively, click a count (N or #) of subjects in a table or click an element of a graph, and then click **Create Subject List** in the menu that appears. The Create Subject List window appears.
2. Enter a name for the new subject list. The name does not need to be unique, although Oracle recommends that you use a unique name.

3. Optionally, enter a description of the subject list in the Description field. A default description may be displayed. When you are working with screening results, by default, the description includes information about the subgroup for which the screening results were computed.
4. Optionally assign the subject list to a [project](#).
 - To assign the subject list to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
 - To create a new project and assign the subject list to it, click **Add to a new project named** and enter a project name.
5. Click **Create**.

Transferring Subjects to a Subject List

On pages that display a list of subjects identified by subject ID, you have the option to transfer the subjects to an existing subject list. You can also [create a new subject list](#) containing the subjects.

To transfer subjects to an existing subject list:

1. When viewing a list of subjects, click **Transfer to Subject List**. Alternatively, click a count (N or #) of subjects in a table or click the element of a graph, and then click **Transfer to Subject List** in the menu that appears. The Transfer to Subject List window appears.
2. Click the name of the subject list to which you want to transfer the subject IDs. Available subject lists are those to which you have access.
3. Click **Save**. The subject IDs are added to the subject list if they were not already in it. A message tells you how many subjects were added to the subject list.

Note: It is possible, but not recommended, to transfer subjects that do not meet query criteria to a query-based subject list. If the query is executed again, the transferred subjects will not be included because they will not meet the query criteria.

Viewing Subject Details

When a subject ID appears as a hyperlink, you can click (or "visit") the link to drill down to subject details. (This is sometimes referred to as "second-level drilldown".) The Subject Details window provides information about the subject, presented as a set of tables showing study data for the subject. This information is not restricted by any time frame that may be in effect.

If you are viewing subject details on the Subject Lists tab, you can indicate that you have reviewed the subject details and provide a comment.

Prerequisites

See [Prerequisites and Usage Notes](#) for information about configuring Internet Explorer for printing and downloading. Also see [Configuring PPD Patient Profiles](#) and [Preparing to Use DataMontage](#).

A site option determines whether drilling down to subject details is possible.

To review subject details:

1. Click a subject ID.
2. Click one of the following:
 - All Domains – Displays a table for every domain in the study. By default, each table includes all columns.
 - Safety Domains – Displays a table for a subset of domains related to safety. By default, each table includes a subset of columns.

A [user preference](#) determines the default setting.

Note: This setting does not affect the graphs that you can display from the Subject Details page.

3. In the "Contents" section, you can click a domain name to jump to the table of that domain's data on the page. If the domain exists in the study but has no data for the current subject, the "Contents" section includes the domain name but you cannot click it.



Standard domain names are used unless your organization has provided a define.xml file that uses non-standard domain names.

4. See [About Tables](#) for information about viewing, printing, or downloading tables.
5. Column headings are variable descriptions. If you hover the cursor over a column heading, the variable name appears as a tooltip.
6. The layout of a table in the Subject Details window consists of the included columns, the row sort order, and the number of rows per page. There are separate layouts depending on whether you are displaying all domains or only safety domains.

By default (that is, without customization), a system-defined set of columns is used in a layout.

To change the columns or the row sort order, click **Columns** and see [Arranging Table Columns](#). (You can also change the sort order by clicking arrows in the column heading.) If you customize the layout, your customizations affect second-level drill-down for all studies (for your username).

Keep in mind that columns in one study may not exist in another study. For example, suppose that Study1 includes the X and Y columns and you customize the layout to include them. Then you look at Study2, which includes only the X column. The Y column is no longer in the Columns window; if you save the layout again and then return to Study1, the Y column will not appear in second-level drill-down unless you add it again.

When you have customized a layout, a note informs you of this and a  icon is available above the table. If you click , the customizations are removed and the default layout (described above) is used for all studies. If there was a customized sort order, it is removed for all studies.

Note: If you click **Reset** in the Columns window, your changes to columns are removed and the default system-defined set of columns is used for all studies. The **Reset** button does not affect the row sort order.

7. If you click the domain name above a table, a window showing only that domain's data appears. See [Viewing Domain-specific Subject Details](#).
8. Tables may have a column (with a customized heading) that contains a __REFID or __SPID value from study data, an image file, or text that you can click to open a new browser window and go to a URL or external system such as InForm. For more information about InForm, see "Links to InForm" below.
9. You can also do the following on the Subject Details page:

Option	Description
PPD Patient Profiles	Available if the appropriate site option has been set. View a PPD Patient Profiles graph for the subject. If a message about memory occurs when PPD Patient Profiles is trying to show subject details, you may need to set the Windows environment variable CGPP_MEM described in About PPD Patient Profiles .
Data Montage Graph	View a DataMontage graph for the subject.
Lab Profile	View a Liver Function Test Patient Profile or view a Hematoxicity Patient Profile for the subject.
Vital Signs Profile	View a Vital Signs Patient Profile for the subject.

10. To print subject details, click **Print**. To [download subject details](#) to an Excel spreadsheet or a Word Rich Text Format File, click **Download**.
11. If you are on the Subject Lists tab: In the Reviewer Input section (available if the appropriate site option has been set) at the bottom of the window, you can do the following, and click **Save**:
 - Check the Reviewed check box if you want to indicate that study data for a subject has been reviewed.
 - Check the Excluded check box if you do not want the subject to appear on the Subjects page when you [hide excluded subjects](#).
 - Provide comments about the data.

Links to InForm

WebSDM/Empirica Study may also be set up to link to InForm™, which is an electronic data capture application provided by Oracle. Above the Contents section, there may be a hyperlink that you can click to access summary-level information available within InForm. The link, whose name is configurable, points to the InForm Time & Events Schedule for the selected subject.

There may also be linkable content in the columns that appear in the various tables on the Subject Details page. For studies whose data source is an InForm study, you can click the column content (a URL, an icon, or a text link) to access the corresponding InForm data for the subject.

Note: The first time you link to InForm during a WebSDM/Empirica Study session, you must provide an InForm user name and password. InForm then remains open until you log out of it.

Viewing Domain-specific Subject Details

From the Subject Details page, you can drill down further to a page that shows subject data for only a specific domain. (This is sometimes referred to as "third-level drilldown".)



When viewing domain-specific subject data, you can use a SQL Where clause to filter rows of the table and you can scroll through the table. (These features are not available for tables on the Subject Details page.)

To view domain-specific subject data:

1. On the Subject Details page, click the domain name above a table.
2. The layout of a domain-specific table consists of the included columns, the sort order, the number of rows per page, and a row filter if provided.

By default (that is, without customization), the layout of a domain-specific table includes the same columns and sort order as are used currently in the same table in second-level drilldown for the study.

To change the columns, row sort order, or row filter, click **Columns and Rows** and see [Arranging Table Columns](#). (You can also change the row sort order by clicking arrows in the column heading.) If you customize the layout for third-level drilldown, your customizations affect third-level drilldown for all studies (for your username). However, customizations of the layout for third-level drilldown do not affect second-level drilldown.

When you have customized a layout, a note informs you of this and a  icon is available above the table. If you click , the customizations are removed and the default layout (described above) is used for all studies. If there was a customized sort order or SQL Where clause, it is removed.

Note: If you click **Reset** in the Columns and Rows window, your changes to columns are removed and the set of columns that currently appear (at the time you click **Reset**) in second-level drilldown for the study are used for all studies. The **Reset** button does not affect the row sort order or row filter.

3. Tables may have a column (with a customized heading) that contains a __REFID or __SPID value from study data, an image file, or text that you can click to open a new browser window and go to a URL.

Common Graphs

DataMontage

About DataMontage

A DataMontage™ graph presents subject data on a timeline, offering a graphical view of the temporal relationships among data values. Colors, shapes, and other visual indicators in the graph plot subject data along time points, which are typically study days. Some types of data, such as adverse events, span a period of time. Other types of data, such as lab results, are collected at a specific point in time.

You can access a DataMontage graph from the [Subject Details page](#) and from the [Subjects page](#). When you access DataMontage from the Subjects page, you can scroll through a list of subjects, displaying the graph for each subject. DataMontage displays raw data from the study, except that some values in the QT Interval Prolongation section are computed change from baseline values. DataMontage graphs show all data for the subject and are not affected by any time frame that is in effect when you access the graphs.

DataMontage is a third-party applet provided by Stottler Henke that has been customized and integrated into WebSDM/Empirica Study.

Related Topics

[Preparing to Use DataMontage](#)

[Viewing a DataMontage Graph](#)

Preparing to Use DataMontage

A [user preference](#) determines whether DataMontage graphs are displayed with interactive features or as static JPEG images. Keep in mind that:

- The interactive version of DataMontage is more sensitive to firewall settings than the static version and as a result cannot be used in some environments.
- The static, JPEG version of DataMontage produces report output more quickly; no additional features are available.

To use DataMontage interactively, you must do the following:

- Install Java Runtime Environment (JRE) version 6 or 7 on your client computer as described below.
- Set your [user preference](#) **Run DataMontage as applet**.

One way to determine if a JRE is installed already is to set your user preference to run DataMontage as an applet and then view a DataMontage graph. If a JRE is installed, the interactive version of DataMontage will open by first displaying a Java logo and you will be able to use interactive features.

To install a JRE:

1. Remove all versions of Java Runtime Environment from your computer before you proceed. To do this, go to your Windows Control Panel, click **Add or Remove Programs**, and remove the JRE version(s).
2. Using Internet Explorer, go to the following URL: <http://www.java.com/en/download>
3. Click **Free Java Download**.
4. Click **Install**. The Java Installer downloads the JRE software then starts the installation.
5. Follow the prompts to complete the installation: on the Setup Type page, select Typical then click **Next**. Java Runtime Environment installation may take a few minutes.
6. When installation is complete, from the Internet Explorer Tools menu select **Internet Options** then go to the Advanced tab.
7. Under Java (Sun), verify that **Use JRE <version> for <applet>** is selected.
8. Go to the Security tab and click **Custom Level**.
9. Under **Scripting of Java Applets**, verify that **Enable** is selected then click **OK**.
10. In the Internet Options dialog box, click **OK**.
11. Close and re-open Internet Explorer before logging in to WebSDM/Empirica Study.

Viewing a DataMontage Graph

1. Click **DataMontage Graphs** on the [Subjects page](#) or click **DataMontage Graph** link on the [Subject Details page](#).

Note: The first time that you use DataMontage as an applet during a WebSDM/Empirica Study session, it may take a few moments to open.

2. If the DataMontage graph is for multiple subjects, use the controls above the graph to select another subject or go to the previous or next subject.
3. Demographic data for the subject displays above the graph. If you have set the [user preference](#) **Display in DataMontage or PPD Patient Profiles** to show data problems, notes on domains that could not be included as sections in the graph follow.
4. Scroll down to view subject data in each domain: in each section of the graph, the y-axis shows the values collected in a particular domain, such as each adverse event reported or vital sign.

You can specify the data domains to include on graphs with the **Display in DataMontage or PPD Patient Profiles** user preference.

5. Tick marks on the x-axis represent time points, which are typically study days. The 0 tick mark on the x-axis maps to the subject's reference start date (DM.RFSTDTC value). See [Time Point Computations and Tooltips](#) for information on how time points

and durations are determined for the various types of data in the graph. This graph is not affected by any currently selected time frame.

Additional features are available if you are [using DataMontage interactively](#).

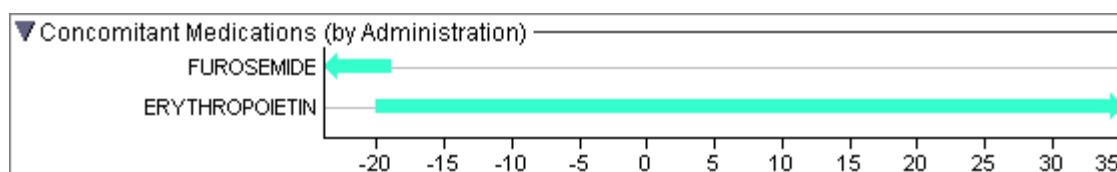
Viewing data with start and end dates

1. In the sections for Exposure, Adverse Events, Concomitant Medications, and Disposition, each value represents a period of time that is delineated by start and end dates. The DataMontage graph uses horizontal bars to represent duration. For example:

The length of each bar provides a visual indication of how long the event or intervention lasted, such as an adverse event or administration of a treatment. If an event or intervention occurred more than once, multiple bars display along the same y-axis line.

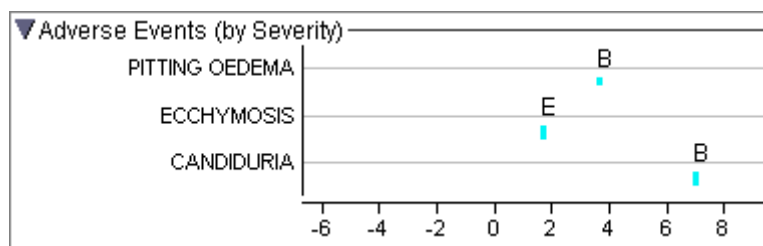
Note: If multiple durations for the same event or intervention have exactly the same duration on the timeline, only one is visible in the graph.

2. If the start date for a data value is prior to the earliest date plotted on the x-axis, the horizontal bar includes a left arrow to indicate the earlier start. Similarly, if the end date is after the last date on the x-axis, a right arrow displays at the end of the bar. For example:

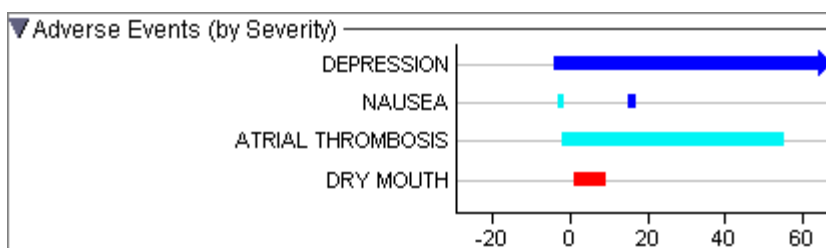


3. If an adverse event, exposure, or concomitant medication has a start date associated with it but no end date, a **B** may display on the graph above a short bar to indicate the recorded beginning. If there is an end date but no start date an **E** may display. See [Time Point Computations and Tooltips](#) for information about exactly when a **B** or **E** may appear.

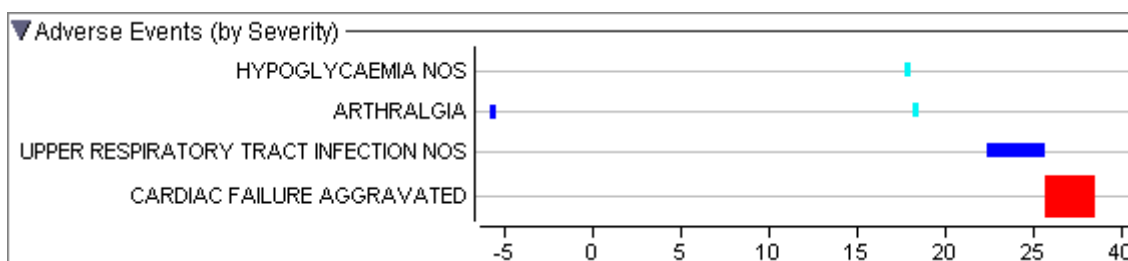
For example:



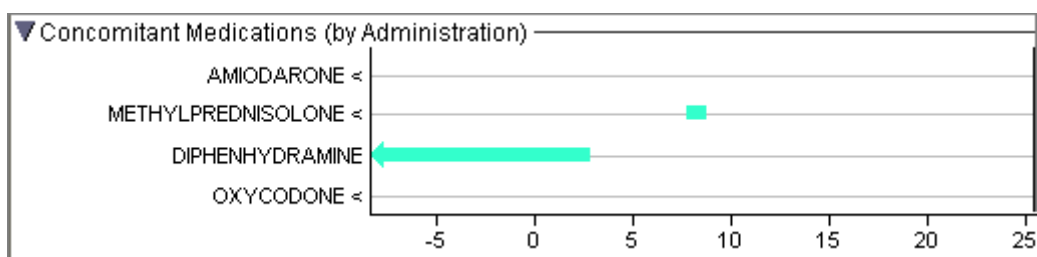
4. To indicate the severity of an adverse event, the graph assigns a different color to each value of the AESEV variable, such as Severe, Moderate, and Mild. For example, adverse events for this subject included Moderate (cobalt blue) depression, both Mild (cyan blue) and Moderate bouts of nausea, Mild atrial thrombosis, and Severe (red) dry mouth:



5. To indicate the seriousness of an adverse event the graph displays bars with different heights or thicknesses for each value of AESER. For example, adverse events for this subject include non-serious hypoglycaemia NOS, arthralgia, and upper respiratory tract infection NOS, and serious cardiac failure aggravated:



6. For a concomitant medication, if both the start date and the end date are prior to the earliest date on the x-axis, the value appears on the y-axis with a < symbol. For example:



If the medication was recorded with multiple start and end date values, including a period prior to the x-axis timeline and another period that does fall within the x-axis timeline, that value appears with both the < symbol and with a bar on the timeline, as for Methylprednisolone in the above example.

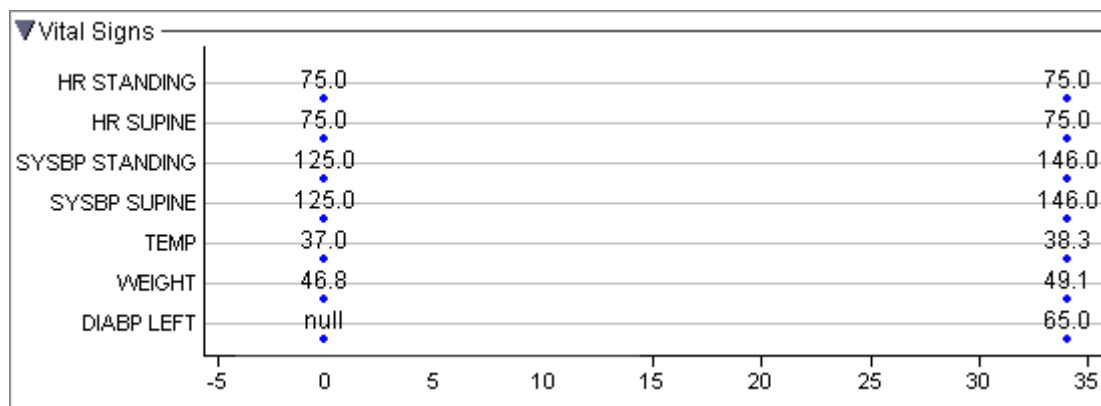
Note: A concomitant medication is omitted from the graph if the value of the CM.CMOCCUR variable is **N** or the value of the CM.CMSTAT variable is **NOT DONE**.

Viewing data collected at a point in time

1. In the sections for Vital Signs, Labs, and QTc Interval Prolongation, each measurement is collected at a specific point in time. The DataMontage graph places individual symbols on the timeline to represent when each recorded value was collected.

Note: If multiple time points for the same test or vital sign are possible, it may be that only one time point is visible in the graph.

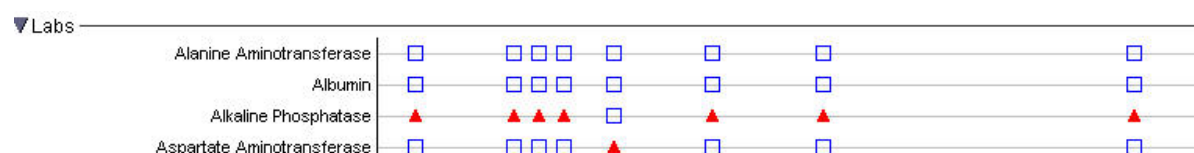
2. In the Vital Signs section, each data point displays as a blue dot with the value collected above it. For example:



The vital sign labels on the y-axis include the subject's position when the measurement was taken, if available.

If a date value is available but no measurement or result value was supplied for the vital sign, **null** appears above the time point, as illustrated for diastolic blood pressure (DIABP) left on the study start date (0).

3. In the Labs section, the graph uses different shapes and colors for the symbols as visual cues about the data collected.



The following symbols are used:

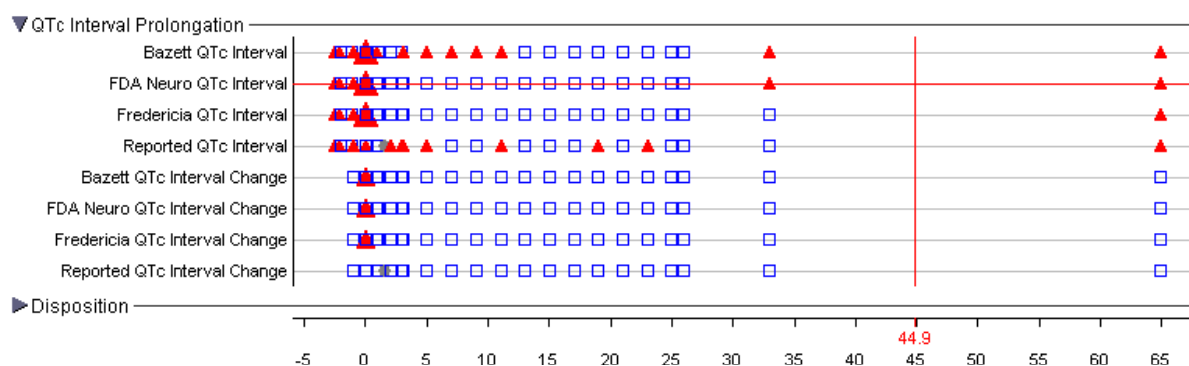
Symbol	Description
▲	A high value, above the supplied reference range upper limit (LBSTNRHI).
□	A normal value, within the reference range defined by LBSTNRHI and LBSTNRLO.
▼	A low value, below the supplied reference range lower limit (LBSTNRLO).
●	Indicates that a date value is available for the test, but no result value was supplied.
○	Indicates that date and result values are available for the test, but no reference range values were supplied.

Note: You can change the setting of the **Display all lab values in DataMontage (even when within normal range)** user preference to include or exclude values that fall in the normal range.

4. The QTc Interval Prolongation section may show the following, where *<correction-method>* is Reported, Bazett, FDA Neuro, or Fredericia:

- *<correction-method>* QTc Interval
- *<correction-method>* QTc Interval Change

Note: The rows for **QTc Interval Change** show increase or decrease from the baseline result. Also note that all post-baseline results are evaluated and counted, and that baseline is determined as described under **Baseline using baseline flag** in [Baseline Results](#).



Note: Findings are listed on the y-axis only if the required [test identifiers](#) have been defined and there are subjects with the finding. For the Reported findings, a test identifier for QTc INTERVAL must be defined. For the other types of findings, test identifiers for QT INTERVAL and RR INTERVAL must be defined.

Correction method computations are as follows. QT and RR tests must have the same date.

- Bazett's formula = $QT_{msec} / (RR \text{ sec})^{0.5}$
- FDA Neuropharmacological Division's formula = $QT_{msec} / (RR \text{ sec})^{0.37}$
- Fredericia's formula = $QT_{msec} / (RR \text{ sec})^{0.33}$

5. The following symbols are used:

Symbol	Description
□	A value that is normal, that is, it does not meet the other criteria below.
▲	Indicates either a QTc value of greater than 450.0 or a change in QTc of greater than or equal to 30.0.
▲	Indicates either a QTc value of greater than 480.0 or a change in QTc of greater than or equal to 60.0.
▲	Indicates a QTc value of greater than 500.0.
•	Indicates that a date value is available for the test, but no value was supplied.

Note that:

- For evaluations that use QT INTERVAL and RR INTERVAL, the results must have occurred at the same visit. For evaluations that use baseline, the later of the baseline values for QT or RR are used.
- It is assumed that RR is stored in milliseconds; thus, the RR value is divided by 1000 to obtain seconds.
- Computations rely on the value reported for RR to be non-negative. Records with a negative value for RR are excluded from the display.

Printing or downloading

To retain a copy of a DataMontage Graph for future reference, you can either print or download the graph:

- If you are using DataMontage interactively, click **Printable view** to open a printer-ready version of the graph in a new browser window. This image includes your interactive selections, such as reference lines or collapsed sections, if added to the graph.
- If you are viewing a static JPEG graph, click **Download to desktop** to save a JPEG image file to your local computer or network.

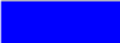
Note: Documentation for the DataMontage applet is available at: <http://www.stottlerhenke.com/datamontage>. This documentation is for the basic third-party product and is not customized for WebSDM/Empirica Study.

Using DataMontage interactively

1. When you hover the cursor over a bar or point in the graph, a tooltip provides more information as described in [Time Point Computations and Tooltips](#).
2. To display a key for the symbols used on the graph, right-click the graph and then click **Show Graph Key** in the menu that appears. Then select one of the following options:
 - **Container:** Displays a key for the entire graph.
 - **Module:** Displays a key for the section of the graph that you clicked on. For example:

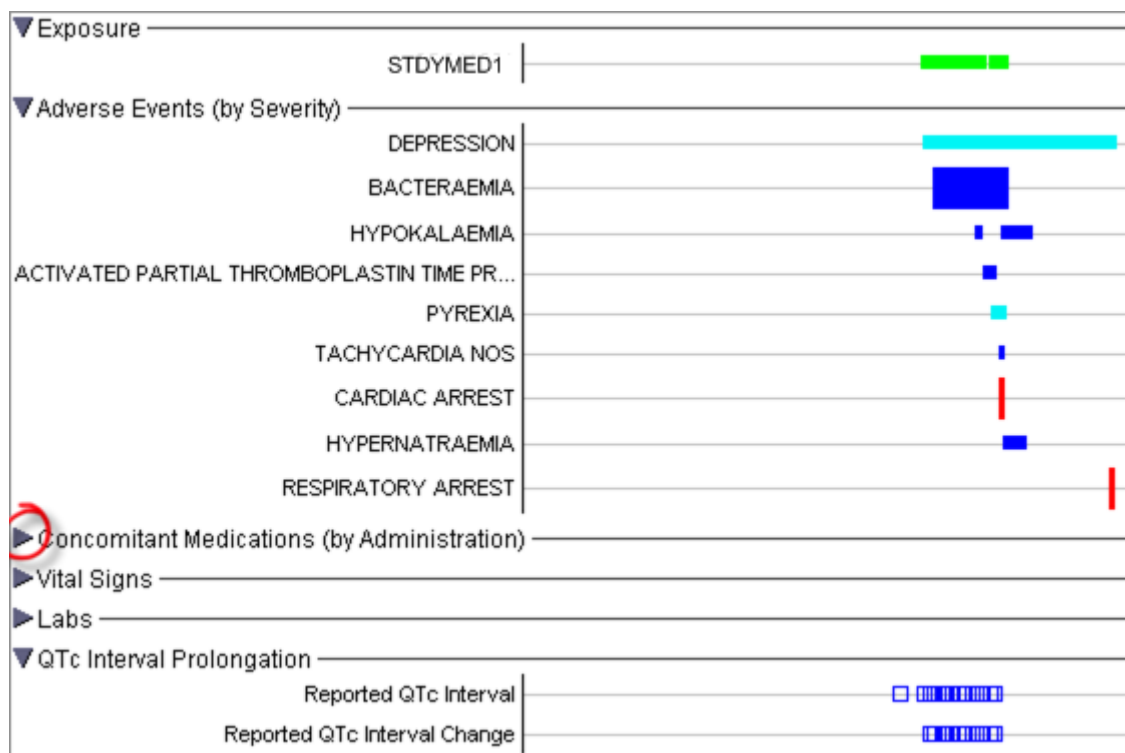
Labs	
<input type="checkbox"/>	In Range
<input checked="" type="checkbox"/>	Below Range
<input checked="" type="checkbox"/>	Above Range
<input checked="" type="checkbox"/>	Missing Value
<input type="checkbox"/>	Missing Range Values

- **Graph:** Displays a key for the y-axis bar or data point that you clicked on. For example:

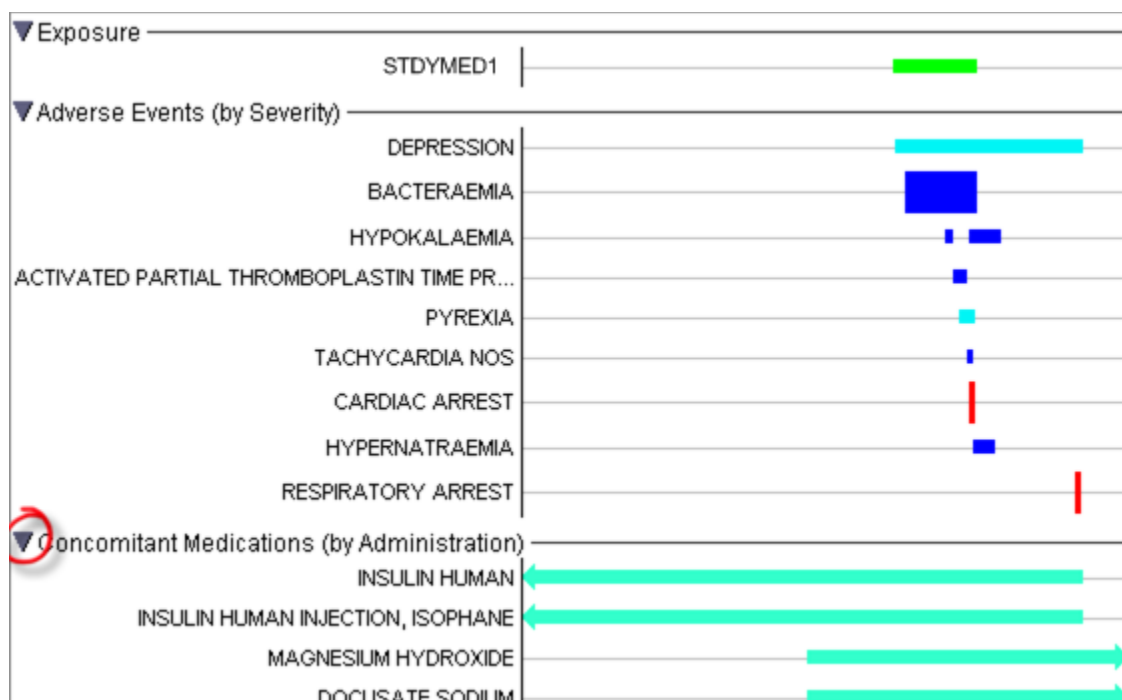
BACTERAEemia	
	MODERATE, SERIOUS

- Initially, the DataMontage graph displays complete detail for all of its sections. You may need to scroll down to see all of the sections. To focus on one or more sections of the graph and minimize others, you can collapse each section and expand it again when needed.

To collapse a section, click the down arrow that appears to the left of its section label:

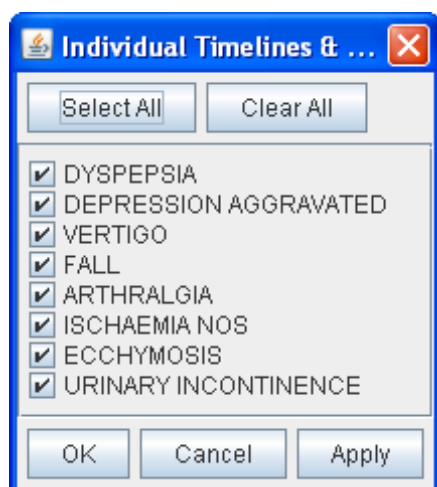


- To expand a collapsed section of the graph, click the right arrow to the left of the section label:



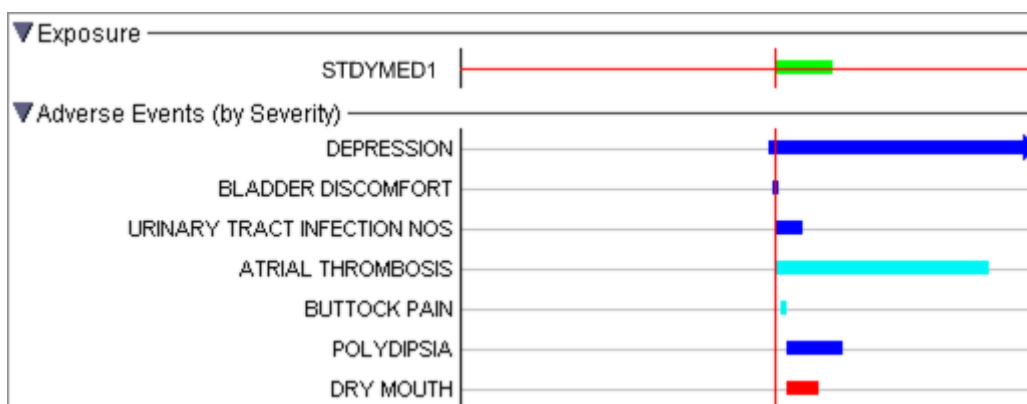
You can also right-click and check **Show All Data** to expand all previously collapsed sections at once.

- To reduce the amount of data shown in a graph section to a set of values that you specify, right-click within that section and click **Select Subsets**. Then click **Individual Timelines & Graphs**. A window opens with a check box for each value in that section of the graph:

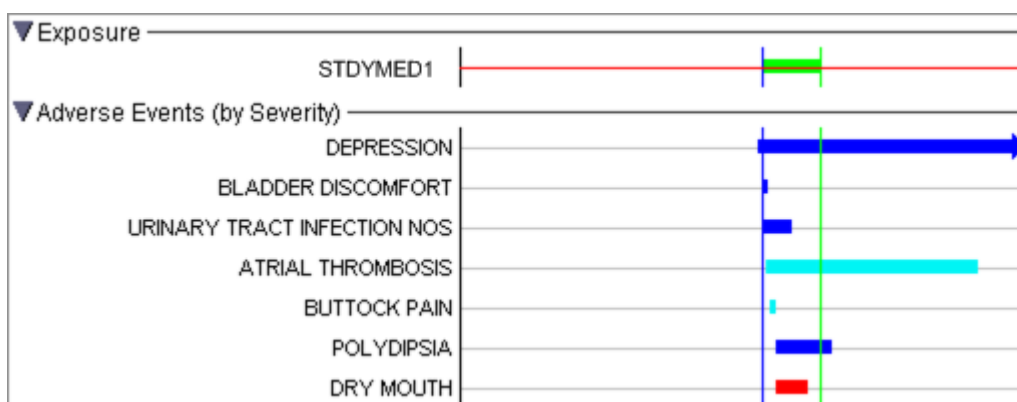


To prevent a value from displaying on the graph, clear its associated check box then click **OK**.

- To add reference lines to a graph, click on the graph. The graph adds red vertical and horizontal lines that intersect where you clicked.



7. You can save up to four vertical reference lines as visual aids. After adding the reference line, right-click and click **Fix Reference Line**. The line changes color to indicate that it is fixed in position.



8. To clear all reference lines, fixed or not, from the graph right-click and click **Clear Reference Lines**.
9. To expand the scale of the x-axis and view data from a particular section of the graph more closely, right-click and click **Zoom**. Then select one of the sub-options to zoom in on a section of the graph (Left, Middle, or Right relative to the position of the mouse), increase the scale by a percentage, or zoom in on a period of time.

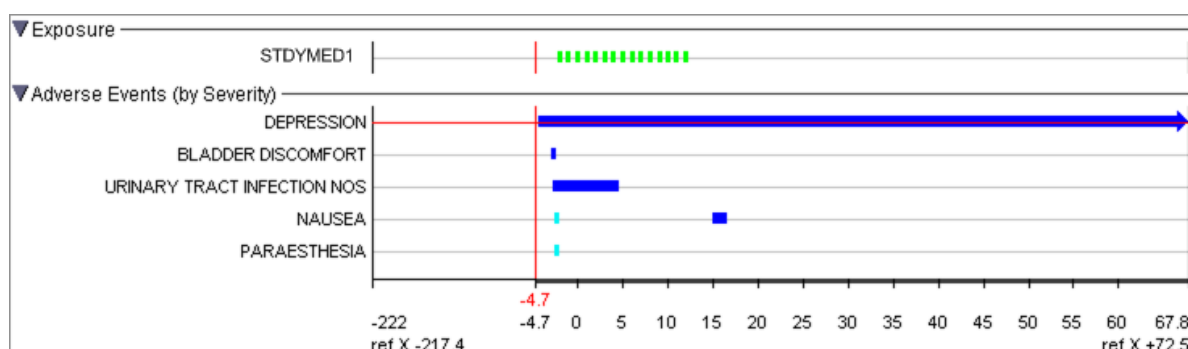
If you have added red (unfixed) reference lines to the graph, you can also position the mouse on the graph then right-click and select **Zoom Middle**. The graph rescales with the reference line as the x-axis starting point and the mouse position as the center of the graph.

When you zoom in using any of these options, the graph adds a horizontal scrollbar to the x-axis and may also update the values of the x-axis tick marks.

10. To return the x-axis to its original scale, right-click and click **Clear Zoom**.
11. To use more of the graph area to examine data collected during a particular period of time, add red reference lines to the graph then right-click and click **Non-linear X Axis**. Options to expand the graph based on the following appear:
 - **Right of 2 intervals**—Expands the time interval to the right of the x-axis reference line.

- **Right of 3**—Expands the right-most time interval of the three intervals created by the x-axis reference line and the position of the mouse.
- **Middle**—Expands the central interval of the three intervals created by the x-axis reference line and the position of the mouse.
- **Left of 2**—Expands the interval to the left of the x-axis reference line.
- **Left of 3**—Expands the left-most interval of the three intervals created by the x-axis reference line and the position of the mouse.
- **From Zoom Period**—If you have zoomed in on the graph, expands the interval covered by the zoom.
- **A Percentage**—Expands the x-axis by the selected percentage; after selecting a percentage you must position the mouse where you want the center of the graph to be, then right-click again and select Non-linear Middle.

When DataMontage displays data using a nonlinear x-axis, a thick line along the x-axis indicates the interval of interest.



To return the x-axis to its original format, right-click and click **Revert to Linear**.

Related Topics

[About DataMontage](#)

[Preparing to Use DataMontage](#)

[Time Point Computations and Tooltips](#)

Time Point Computations and Tooltips

The time points in a DataMontage graph are computed differently for each type of data and are plotted against the graphs x-axis. If you hover the cursor over a data point or bar in a DataMontage graph, a tooltip appears. The tooltip includes a specific time point or range of time points, depending on the type of data.

This graph is not affected by any time frame currently selected.

For durations that overlap, the bar showing duration in the graph starts at the start of the earliest duration and ends at the end of the latest duration. The Hover help for different regions of the bar show the different durations.

Data Type	y-axis Label	Information
Exposure	Study arm	<p>Start: Time point on which the exposure started. Computed as: (EX.EXSTDTC —DM.RFSTDTC)</p> <p>End: Time point on which the exposure ended. Computed as: (EX.EXENDTC—DM.RFSTDTC)</p> <p>Name of the exposure (EX.EXTRT).</p> <p>Route of administration (EX.EXROUTE) if available.</p> <p>Dose of administration (EX.EXDOSE) if available.</p> <p>Date on which the exposure started (EX.EXSTDTC); date on which the exposure ended (EX.EXENDTC). If EX.EXSTDTC is missing, shows Begin Date Not Specified and shows E above the interval. If EX.EXENDTC is missing, shows End Date Not Specified and shows B above the interval.</p>
Adverse Events (by Severity)	Adverse event	<p>Start: Time point on which the event started. Computed as: (AE.AESTDTC—DM.RFSTDTC). If AE.AESTDTC is missing, shows the same value as End.</p> <p>End: Study day on which the event ended. Computed as: (AE.AEENDTC—DM.RFSTDTC). If AE.AEENDTC is missing:</p> <ul style="list-style-type: none"> • If the event is ongoing (AE.AEENRF is AFTER), shows 99999. • Otherwise, shows same value as Start. <p>Name of the adverse event (AE.AEDECOD), seriousness (Serious, Not Serious, or Seriousness Unknown), and severity (AE.AESEV) of the event. Seriousness is Serious if AE.AESER is Y or Not Serious if AE.AESER is N; otherwise, shows Seriousness unknown.</p> <p>Date on which the event started (AE.AESTDTC); date on which the event ended (AE.AEENDTC). If AE.AESTDTC is missing, shows Begin Date Not Specified and shows E above the interval. If AE.AEENDTC is missing:</p> <ul style="list-style-type: none"> • If the event is ongoing (AE.AEENRF is AFTER), shows Ongoing. • Otherwise, shows End Date Not Specified and shows B above the interval.
Concomitant	Concomitant	Start: Time point on which the concomitant

Medications (by Administration) medication

medication was started. Computed as: (CM.CMSTDTC—DM.RFSTDTC). If CM.CMSTDTC is missing:

- If there is no prior medication (CM.CMSTDY is a negative value or null), shows the same value as End.
- Otherwise, shows -99999.

End: Time point on which the medication was stopped. Computed as: (CM.CMENDTC—DM.RFSTDTC). If CM.CMENDTC is missing:

- If the medication is not ongoing (CM.CMENRF is not AFTER or null), shows the same value as Start.
- Otherwise, shows 99999.

Name of the medication (CM.CMDECOD); if CM.CMDECOD is null, shows the value of CM.CMTRT. Route of administration (CM.CMROUTE) and dosage (CM.CMDOSE), if they are available. Then one of the following:

- Medication administered – Appears if CM.CMOCCUR is null or Y and CM.CMSTAT is null.
- Administration of medication is unknown – Appears if CM.CMOCCUR is other than Y, N, or null or CM.CMSTAT is other than NOT DONE or null.

Date on which the medication was started (CM.CMSTDTC); date on which the medication was stopped (CM.CMENDTC). If CM.CMSTDTC is missing:

- If there is a prior medication (CM.CMSTDY is a negative value or null), shows Present at start.
- Otherwise, shows Begin Date Not Specified and shows E above the interval.

If CM.CMENDTC is missing:

- If the medication is ongoing (CM.CMENRF is AFTER or null), shows Ongoing.
- Otherwise, shows End Date Not Specified and shows B above the interval.

Vital Signs	Vital sign	<p>Time Point: Time point of the vital sign result. Computed as: (VS.VSDTC —DM.RFSTDTC)</p> <p>refX: Displays only after you add a red reference line to the graph. Indicates the difference between the time points of the reference line and the vital sign result.</p> <p>Short name of the vital sign measurement (VS.VSTESTCD), followed by the position (VS.VSPOS), if any, in parentheses.</p> <p>Vital sign result (VS.VSSTRESN).</p> <p>Date of the vital sign result (VS.VSDTC).</p>
Labs	Lab test	<p>Time Point: Time point of the lab test result. Computed as: (LB.LBDTC —DM.RFSTDTC)</p> <p>refX: Displays only after you add a red reference line to the graph. Indicates the difference between the time points of the reference line and the test result.</p> <p>Long name of the lab test (LB.LBTEST) followed by the short name of the lab test (LB.LBTESTCD) in parentheses. If there are multiple long names for the same short name, then the alphabetically last name is shown here and on the y-axis.</p> <p>Lab test result (LB.LBSTRESN).</p> <p>Normal range (LB.LBSTNRLO and LB.LBSTNRHI).</p> <p>Date of the test result (LB.LBDTC).</p>
QTc Interval Prolongation	<p><correction-method> QTc Interval or <correction-method> QTc Interval Change where <correction-method> is Reported, Bazett, FDA Neuro, or Fredericia.</p>	<p>Time Point: Time point of the ECG test result. Computed as: (EG.EGDTC —DM.RFSTDTC)</p> <p>refX: Displays only after you add a red reference line to the graph. Indicates the difference between the time points of the reference line and test result.</p> <p>For QTc Interval findings, shows the value from the study data (EG.EGSTRESN).</p> <p>For QTc Interval Change findings, shows the change value, which can be positive or negative.</p> <p>Date of the test result (EG.EGDTC).</p>
Disposition	Disposition event	<p>Start: Time point on which the disposition event began. Computed as: DS.DSSTDTC—DM.RFSTDTC</p> <p>End: Study day on which the disposition event ended. Computed as: (DS.DSDTC—DM.RFSTDTC) + .01. The tooltip does not show decimal points and thus shows Start and End as equal.</p> <p>Name of the disposition event (DS.DSTERM).</p> <p>Date of the disposition event (DS.DSSTDTC).</p>

PPD Patient Profiles

About PPD Patient Profiles

PPD Patient Profiles is a third-party application provided and supported by Pharmaceutical Product Development (PPD). You can use PPD Patient Profiles when viewing subject details to view sophisticated graphical displays of data.

To use PPD Patient Profiles, you must purchase PPD Patient Profiles Version 3.0 or later from PPD and install it. When you have installed PPD Patient Profiles, you must [configure it](#) to work with WebSDM/Empirica Study.

Memory requirements

If PPD Patient Profiles indicates that more memory is required when it attempts to display subject details, you might need to create or modify the Windows environment variable CGPP_MEM. This environment variable represents the amount of RAM (in Mb) that PPD Patient Profiles uses for short-term tasks. The average optimum value is approximately 75% of available RAM. To set the environment variable, open your Windows Control panel, click **System**, go to the **Advanced** tab, and click **Environment Variables**.

Temporary files

When you use PPD Patient Profiles, the application creates temporary files on your computer with the following file extensions:

- .DAT
- .DSC
- DSN
- BIN

If you are using version 3.0 or later of PPD Patient Profiles, you can control the location of these files by using the CG_SERVER_TEMPDIR preference to specify a directory location. You should empty this directory occasionally to prevent the files from accumulating excessively.

You can obtain more information on PPD Patient Profiles at www.ppd.com.

Configuring PPD Patient Profiles

Use these procedures to configure Patient Profiles Version 3.0 or later for use with WebSDM/Empirica Study. Specifically, they describe how to register the PPD Patient Profiles XGC file type so that it will be recognized by your computer. This one-time setup process should be performed after PPD Patient Profiles is installed. The **PPD Patient Profile** link will not work properly in WebSDM/Empirica Study until this process is performed.

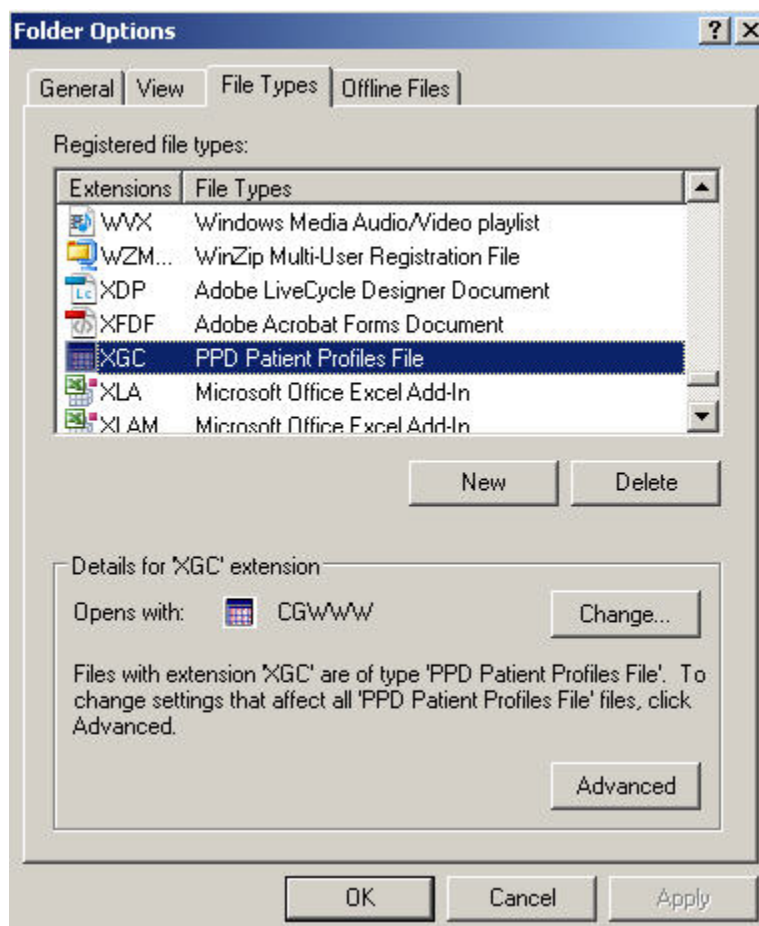
To configure the PPD Patient Profiles XGC file type:

1. Install PPD Patient Profiles Version 3.0 or later using materials and instructions provided by PPD. Oracle recommends that you accept the default for the installation

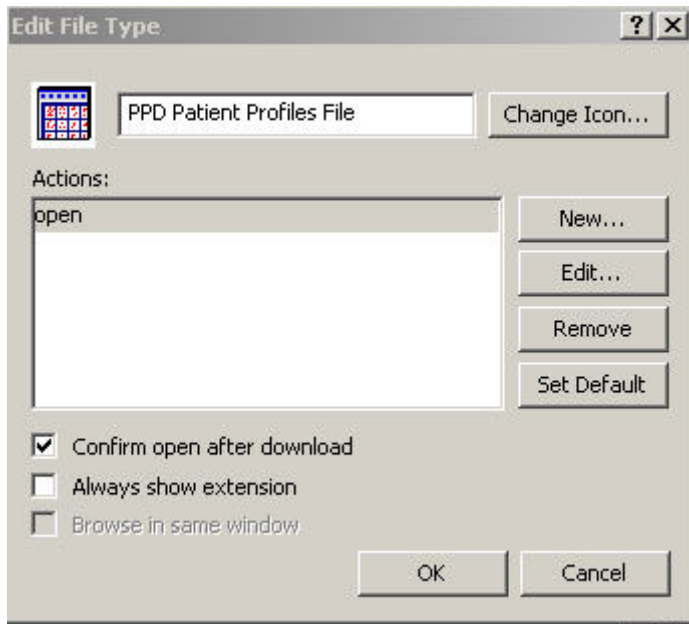
directory suggested by the install program so that the actual directory will match these instructions.

Note: Before installing PPD Patient Profiles, uninstall any earlier versions of it.

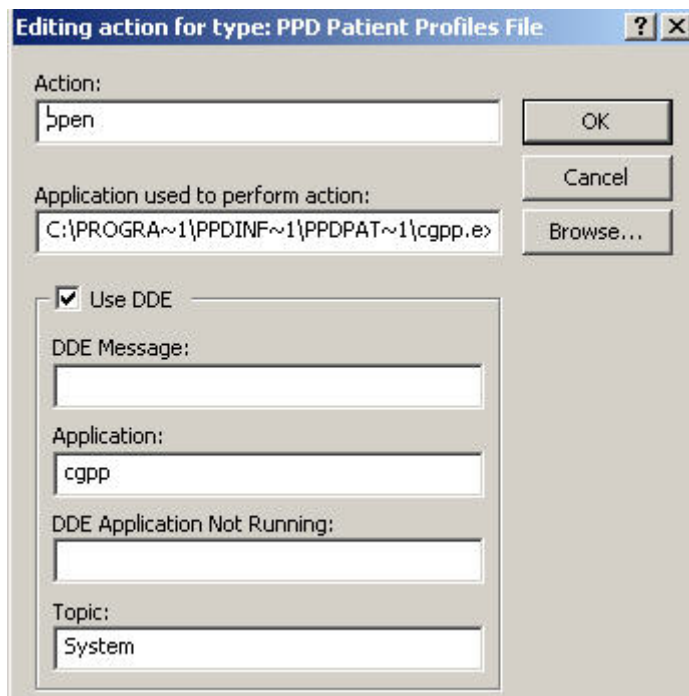
2. From the Windows Start menu, select **Settings** and then select **Control Panel**.
3. Double-click **Folder Options**, and then select the **File Types** tab. Scroll down until you find XGC (the file types are in alphabetical order). Select the XGC entry by single-clicking it:



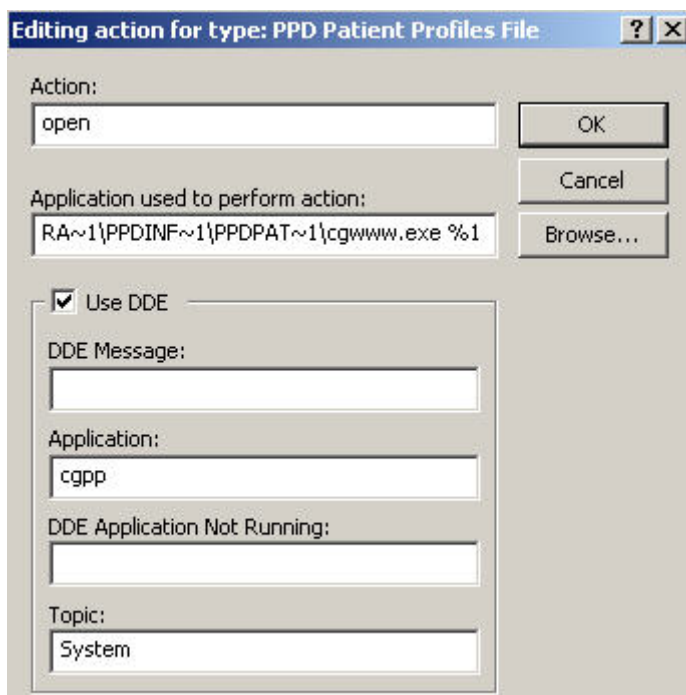
4. Click **Advanced**. The Edit File Type window appears:



5. In the Edit File Type window, clear the **Confirm open after download** check box.
6. In the Actions list, select the **open** action and click **Edit**. The Editing action for type window appears.
7. Type open in the Action field:



8. Using the mouse or arrow keys, scroll to the right-hand end of the text in the **Application used to perform action** field, and replace the text starting with **cgpp.exe** through the end of the line with **cgwww.exe %1**:







9. Click **OK** to close the Editing action for type window.
10. Click **OK** to close the Edit File Type window.
11. Click **Close** to close the Folder Options window.
12. To confirm that you can now use PPD Patient Profiles with WebSDM/Empirica Study, log in to WebSDM/Empirica Study and [view subject details](#). Then click **PPD Patient Profiles**. The Patient Profiles application should open and display a graph.

Documentation on how to use the PPD Patient Profiles application is provided on the PPD Patient Profiles installation CD, and is available on the PPD Patient Profiles download site.


Viewing a PPD Patient Profiles Graph

To view a PPD Patient Profiles graph:

1. Check the settings for the following [user preferences](#):
 - Maximum number of subjects to display in PPD Patient Profiles – Specifying the number of subjects that can be included in a PPD Patient Profiles graph for multiple subjects.
 - Display in DataMontage or PPD Patient Profiles – Check the types of data to include in PPD Patient Profiles graphs.
2. If you want to be able to view a graph in PPD Patient Profiles without first saving it to a file, make sure you have cleared the Internet Explorer option "Do not save encrypted pages to disk" as described in [Prerequisites and Usage Notes](#).

3. In the Subjects window or the Subject Details window, click **PPD Patient Profiles**. If you try to view a PPD Patient Profiles graph for more than the maximum number of subjects that is set as a user preference, a message informs you that only some of the subjects will be included.
4. If a message about memory occurs when PPD Patient Profiles is trying to show subject details, you may need to set the Windows environment variable CGPP_MEM described in [About PPD Patient Profiles](#).
5. To display the graph with all sections (domains) expanded, click .
6. To expand a section and leave other sections as they are, click  for the section.
7. To expand a section and collapse all other sections, click  for the section.
8. To collapse a section, click  for the section.
9. See the online help for PPD Patient Profiles. Additionally, documentation on how to use the PPD Patient Profiles application is provided on the PPD Patient Profiles installation CD, and is available on the PPD Patient Profiles download site.

Left and right arrows indicate the existence of data that does not appear in the graph. For example, if data for an entry (such as a concomitant medication) on the y-axis started before the period shown, the left end of the bar representing that medication is a left arrow against the y-axis:

PREDNISOLONE | 

Likewise, if data continues or starts (for example, late AEs) after the period shown, the right end of the bar is a right arrow:



Note: If there is a start date but no end date for a bar, a "B" appears at the start of the bar. If there is an end date but no start date, an "E" appears at the end of the bar. The "B" and "E" can be modified using a PPD Patient Profiles option for how to show missing start or end.

This graph is not affected by any currently selected time frame.

QTC Interval data

The QTc Interval data may show the following, where *<correction-method>* is Reported, Bazett, FDA Neuro, or Fredericia:

- *<correction-method>* QTc Interval
- *<correction-method>* QTc Interval Change

Note: The rows for "QTc Interval Change" show increase or decrease from the baseline result. Also note that all post-baseline results are evaluated and counted, and that baseline is determined as described under "Baseline using baseline flag" in [Baseline Results](#).

Note: Findings are listed on the y-axis only if the required [test identifiers](#) have been defined and there are subjects with the finding. For the Reported findings, a test identifier for QTC INTERVAL must be defined. For the other types of findings, test identifiers for QT INTERVAL and RR INTERVAL must be defined.

Correction method computations are as follows. QT and RR tests must have the same date.

- Bazett's formula = $QTmsec / (RR \text{ sec})^{0.5}$
- FDA Neuropharmacological Division's formula = $QTmsec / (RR \text{ sec})^{0.37}$
- Fredericia's formula = $QTmsec / (RR \text{ sec})^{0.33}$

Lab and Vital Sign Patient Profiles

Viewing a Liver Function Test Patient Profile

A Liver Function Test Patient Profile plots the results of the following four liver function tests (LFTs) over time:

- Alanine Aminotransferase (ALT)
- Aspartate Aminotransferase (AST)
- Alkaline Phosphatase (ALP)
- Bilirubin (BILI)

Note: The displayed names of the tests are not data-dependent. They correspond to the long names listed in [Where Test Identifiers are Used](#).

The x-axis of each graph represents study days. A red reference line along the x-axis shows the subject's exposure period. This graph is not affected by any currently selected time frame.

The results of different tests are represented by different line styles, as indicated in the graph key. The y-axis represents normalized values (that is, test values divided by the upper limit of normal) for the lab tests.

Note: The x- and y-axes for each subject's graph are computed independently and may vary by subject.

To view a Liver Function Test Patient Profile:

1. Click **Lab Profiles** and select **Liver Function Tests**.
2. [Configure the graph](#).
3. If the display includes graphs for multiple subjects, you can click anywhere on a graph to display the Subject Details window for that subject.
4. To print or copy the graph, see [Working with Graphs](#).

More detail

The following situations may prevent the graph from displaying or cause data points to be omitted from the graph. If you configure the graph to show notes, subjects for whom data points are omitted are listed.

Situation	Variables	Effect
A required variable is not found.	LB.LBSTRESN LB.LBSTNRHI LB.LBTESTCD LB.LBDY	Graph is not displayed.
An internal error occurred for the value of a variable, possibly because the variable does not have the expected data type.	LB.LBSTRESN LB.LBSTNRHI LB.LBDY	Graph is not displayed.
A Null value is found for a variable expected to have a non-null value.	LB.LBSTRESN LB.LBSTNRHI LB.LBDY	Data point is omitted from graph.
The value of ULN is 0, which makes normalization of the result impossible.	LB.LBSTNRHI	Data point is omitted from graph.
Encountered an internal error dividing the raw result by the upper limit of normal (possibly because the value of the ULN is extremely small).	LB.LBSTRESN / LB.LBSTNRHI	Data point is omitted from graph.

Study days on the x-axis are LB.LBDY values.

For the exposure line, the start of each exposure is EX.EXSTDTC—DM.RFSTDTC, and the end of the exposure is EX.EXENDTC—DM.RFSTDTC. A separate segment is drawn for each exposure record, so the exposure line may be a broken line.

Configuring a Liver Function Test Patient Profile

1. On the [graph display page](#), click **Configure**.
2. Specify up to three reference lines to appear in the graph to assist in graph interpretation. Enter a numeric value to indicate the y value at which each reference line will appear. For each reference line that you specify, a green line is drawn at the specified value on the y-axis.
3. Optionally check any other display options. See [Working with Graphs](#) for information about the following display options: Use gray-scale instead of colors; Popup; Key; Notes; and Links. Notes will include a list of any data problems that prevent data points from displaying in the graph.
4. Click **OK**. Your display options will be used for this type of graph for your username until you change them, log out, or select a different study.

Viewing a Hematoxicity Patient Profile

Three types of Hematoxicity Patient Profiles are available. Each type plots the results of a different set of lab tests over time:

Hematoxicity Type	Lab Tests Included
Standard Hematoxicity	<ul style="list-style-type: none"> • Hemoglobin (HGB) • Platelet (PLAT) • Neutrophils/Leukocytes (NEUTLE) • Leukocytes (WBC)
Anemia Hematoxicity	<ul style="list-style-type: none"> • Reticulocytes (RETI) • Hemoglobin (HGB) • Erythrocytes (RBC) • Ery. Mean Corpuscular Volume (MCV) • Ery. Mean Corpuscular HB Concentration (MCHC)
Hemolytic Anemia Hematoxicity	<ul style="list-style-type: none"> • Hemoglobin (HGB) • Bilirubin (BILI) • Indirect Bilirubin (BILIND) • Lactate Dehydrogenase (LDH) • Haptoglobin (HAPTOG)

Note: The displayed names of the tests are not data-dependent. They correspond to the long names listed in [Where Test Identifiers are Used](#).

The x-axis of each graph represents study days. A red reference line along the x-axis shows the subject's exposure periods. This graph is not affected by any currently selected time frame.

The results of different tests are represented by different line styles, as indicated in the graph key. The y-axis represents test results (actual values) from the study data. To see the test result for a dot, you can either point to the dot to display a tooltip or configure the graph to show data values.

You can configure the graphs to show gray reference lines indicating the upper and lower limits of normal values for the test. In order to show a single normal range area that can be used for all tests in a graph, the y-axis is scaled so that its height might represent 50 mg/dL for test 1, 200 U/L for test 2, and so on.

Note: The x- and y-axes for each subject's graph are computed independently and may vary by subject.

You can also configure the graph to use differently sized symbols to indicate toxicity grades.

The graph key shows units from the study data as follows:

- If all results have the same non-null value, the key shows that value.
- If all results have a null value for units, the key shows "Unknown units".
- If results have differing units (including null), the key shows "Multiple units". To see actual units, you can point to a dot and view the tooltip that appears.

To view a Hemotoxicity Patient Profile:

1. On the Subjects page (first-level drilldown) or the Subject Details window (second-level drilldown), click **Lab Profile** (or **Lab Profiles**) and select **Standard Hemotoxicity**, **Anemia Hemotoxicity**, or **Hemolytic Anemia Hemotoxicity**.
2. [Configure the graph](#).
3. When you point to a dot in the graph, details about the data point are displayed as a tooltip.
4. If the display includes graphs for multiple subjects, you can click anywhere on a graph to display the [Subject Details window](#) for that subject.
5. To print or copy the graph, see [Working with Graphs](#).

More detail

The following situations may prevent the graph from displaying or cause data points to be omitted from the graph. If you configure the graph to show notes, subjects for whom data points are omitted are listed.

Situation	Variables	Effect
A required variable is not found.	LB.LBSTRESN LB.LBSTRESU LB.LBTOXGR* LB.LBTESTCD LB.LBDY * If graph is configured to show toxicity grade.	Graph is not displayed.
An internal error occurred for	LB.LBSTRESN	Graph is not displayed.

the value of a variable, possibly because the variable does not have the expected data type.

LB.LBSTRESU
LB.LBTOXGR
LB.LBSTNRLO
LB.LBSTNRHI
LB.LBTESTCD
LB.LBDY

A Null value is found for a variable expected to have a non-null value.

LB.LBSTRESN, LB.LBDY

Data point is omitted from graph.

Study days on the x-axis are LB.LBDY values.

For the exposure line, the start of each exposure is EX.EXSTDTC—DM.RFSTDTC, and the end of the exposure is EX.EXENDTC—DM.RFSTDTC. A separate segment is drawn for each exposure record, so the exposure line may be a broken line.

Configuring a Hematotoxicity Patient Profile

1. On the [graph display page](#), click **Configure**.

Option	Description
Use log scale for Y axis	<p>Indicates whether logarithmic scale or linear scale is used for the Y axis.</p> <ul style="list-style-type: none"> • If selected—Uses log scale. • If deselected—Uses linear scale. <p>Deselected by default.</p>
Show data values	<p>Determines whether the graph shows the vital sign result for each visit. If standard units are not the same for all visits, the actual unit is displayed along with the result.</p> <ul style="list-style-type: none"> • If selected—Shows vital sign results. • If deselected—Does not show vital sign results.
Scale results for coincidence of normal range regions	<p>Indicates whether gray reference lines appear in the graph to indicate the lower limit of normal (LLN) and upper limit of normal (ULN).</p> <ul style="list-style-type: none"> • If selected—Reference lines appear. • If deselected—Reference lines do not appear. <p>For each subject and each test, a single normal range is computed, based on the lowest value of the LBSTNRLO variable and the highest value of the LBSTRNRHI value. An LLN appears in the graph if at least one test for the subject</p>

has a LBSTNRLO value. A ULN line appears if at least one test for the subject has a LBSTRNHI value.
The LLN or ULN line has a footnote if some tests for the subject have no LLN or no ULN.

Show test-specific reference lines	Reserved for future use. Leave blank.
Size plotting symbols by Toxicity Grade	<p>Available if toxicity grades are included in the study. Determines whether the symbols representing test results in the graph are sized differently depending on which toxicity grade criteria are met by the result. The options are:</p> <ul style="list-style-type: none">• Distinguish Toxicity Grade 1 (and above)• Distinguish Toxicity Grade 2 (and above)• Distinguish Toxicity Grade 3 (and above)• Distinguish Toxicity Grade 4 <p>If this option is deselected, all results will be plotted with a uniformly sized symbol.</p>

2. Optionally check any other display options. See [Working with Graphs](#) for information about the following display options: Use gray-scale instead of colors; Key; Notes; and Links.
3. Click **OK**.

Note: The configuration options are shared among the three types of Hematoxicity Patient Profiles and between the single-subject versions and multiple-subject versions of the graph.

Viewing Vital Signs Patient Profiles

The Vital Signs Patient Profiles plots the results of four different vital signs over time:

- Weight (WEIGHT)
- Heart Rate (HR)
- Systolic Blood Pressure (SYSBP)
- Diastolic Blood Pressure (DIABP)

Note: The displayed names of the vital signs are not data-dependent. They correspond to the long names listed in [Where Test Identifiers are Used](#).

The x-axis of each graph represents study days. A red reference line along the x-axis shows the subject's exposure periods. This graph is not affected by any currently selected time frame.

The results of different vital signs are represented by different line styles, as indicated in the graph key. The y-axis represents vital signs results (actual values) from the study data. To see the vital sign result for a dot, you can either point to the dot to display a tooltip or configure the graph to show data values.

You can configure the graphs to show gray lines indicating the upper and lower limits of normal values for the vital sign. In order to show a single normal range area that can be used for all vital signs in a graph, the y-axis is scaled so that its height might represent 150 mmHg for vital sign 1, 120 BEATS/MIN for vital sign 2, and so on.

Note: The x- and y-axes for each subject's graph are computed independently and may differ.

The graph key shows units from the study data as follows:

- If all results have the same non-null value, the key shows that value.
- If all results have a null value for units, the key shows "Unknown units".
- If results have differing units (including null), the key shows "Multiple units". To see actual units, you can point to a dot and view the tooltip that appears.

As indicated by the graph key, different line styles are used for different positions (that is, values of the VSPOS variable). If VSPOS is null, the key shows "position unspecified". However, there are only four available line styles, so if there are more than four values of VSPOS, the same line styles may be used for more than one position. Note that when you point to a dot in the graph, the information that appears includes the actual position.

To view a Vital Signs Patient Profile:

1. On the Subjects page (first-level drilldown) or the Subject Details window (second-level drilldown), click **Vital Signs Profile** (or **Vital Signs Profiles**).
2. [Configure the graph](#).
3. If the display includes graphs for multiple subjects, you can click anywhere on a graph to display the [Subject Details window](#) for that subject.
4. When you point to a dot in the graph, details about the data point are displayed as a tooltip.
5. If the same value represents multiple positions for the vital sign, multiple dots appear close together to represent each position.
6. To print or copy the graph, see [Working with Graphs](#).

More detail

The following situations may prevent the graph from displaying or cause data points to be omitted from the graph. If you configure the graph to show notes, subjects for whom data points are omitted are listed.

Situation	Variables	Effect
A required variable is not found.	VS.VSSTRESN VS.VSSTRESU VS.VSSTNRLO VS.VSSTNRHI VS.VSTESTCD VS.VSDY	Graph is not displayed.
An internal error occurred for the value of a variable, possibly because the variable does not have the expected data type.	VS.VSSTRESN VS.VSSTRESU VS.VSSTNRLO VS.VSSTNRHI VS.VSDY	Graph is not displayed.
A null value is found for a variable expected to have a non-null value.	VS.VSSTRESN VS.VSDY	Data point is omitted from graph.

Study days on the x-axis are VS.VSDY values.

For the exposure line, the start of each exposure is EX.EXSTDTC—DM.RFSTDTC, and the end of the exposure is EX.EXENDTC—DM.RFSTDTC. A separate segment is drawn for each exposure record, so the exposure line may be a broken line.

Configuring a Vital Signs Patient Profile

WebSDM/Empirica Study uses your display options for this graph type until you do one of the following:

- Change the options
- Log out
- Select a different study

To configure a Vital Signs Patient profile:

1. On the [graph display page](#), click **Configure**.

Option	Description
Use log scale for Y axis	<p>Determines whether a logarithmic scale is used y-axis.</p> <ul style="list-style-type: none"> • If selected—Uses a log scale. • If deselected—Uses a linear scale.

Show data values

Determines whether the vital sign result appears for each visit. If standard units are not the same for all visits, the unit is displayed along with the result.

- **If selected**—Vital sign result appears for each visit.
- **If deselected**—Vital sign result does not appear for each visit.

-
2. Optionally check any other display options. See [Working with Graphs](#) for information about the following display options: Use gray-scale instead of colors; Key; Notes; and Links.
 3. Click **OK**.

Exposure/Disposition

Viewing an Exposure Summary

The Exposure Summary shows counts of subjects who are exposed to treatment or comparator drugs over time. The x-axis represents the number of days since the start of the time period, which is described below under "More detail".

The duration on the x-axis is computed as follows: (exposure end—time period start) + 1.

To compute exposure end, the following occurs:

1. For each of a subject's exposures, find the earlier of the EX.EXENDTC value and the time period end. (If EX.EXENDTC is null, find the earlier of EX.EXSTDTC and the time period end.)
2. Find the latest of the dates determined in Step 1 for the subject's exposures, and use that value as the exposure end.

The start of the x-axis is 0 and the end of the x-axis is the latest of the time periods for subjects included in the graph.

The y-axis represents the number of subjects exposed.

"No. of Subjects" section

The "No. of Subjects" section below the graph shows the count of exposed subjects in the study at each number of days identified on the x-axis.

Over time, a subject is subtracted from these counts when either of the following occurs:

- The subject's exposure period ends.
- The time period for the subject ends before the end of the x-axis.


Notes

- Subjects for whom there is not enough information to compute days on the x-axis are excluded from the graph and the "No. of Subjects" counts.

- If an arm or dosing category contains fewer than two subjects for which days on the x-axis can be computed, data for that arm or dosing category is not shown. A note above the graph says that there is insufficient data for the arm or dosing category.
- If the graph plots data by Treatment and Comparator categories and one of those categories includes null ARM values, then the subjects with null ARM values are included in that category. However, subjects with null ARM values are not included if the graph plots data by ARM values.

To view an Exposure Summary:

1. Do one of the following:

Tab	Steps
Domains	Click  in the Listings column of the EX domain, and then click Exposure Summary Plot .
Safety Review	On the Overview page , click Exposure Summary .

2. To configure the graph, click **Configure**. Specify any of the following display options and click **OK**:

Option	Description
Add Note	Optionally enter text to display below the graph.
Use dosing breakdown instead of ARM values	Available on the Domains tab only, and available only if there is a default dosing category breakdown for the study. Check to use the default dosing category breakdown (Treatment and Comparator categories). Clear to use ARM values instead of the dosing category breakdown. If there are more than five ARM values, the graph cannot be displayed for ARM values.
Use gray-scale instead of colors	Check to use shades of gray instead of colors in the graph.
Show key/legend	Check to display a key for curves in the graph.
Show Links	Check to include Print and Help links for the graph. Before copying a graph (for example, with copy and paste functions), you may want to clear this check box.

3. If text in the graph is not legible, resize the graph window.
4. To print or copy the graph, see [Working with Graphs](#).

More detail

The "time period" for a subject depends on whether or not a time frame with a well-defined start or end is in effect.

If the time frame has a well-defined start and end, a subject's time period is from the time frame start to the time frame end.

If no time frame is in effect or if the time frame does not have a well-defined start or end, the start or end of a subject's time period is determined as described below.

A subject's time period start is determined as follows:

1. The time period start is the earliest SE.SESTDTC value.
2. If there is no SE.SESTDTC variable or it is null, the time period start is the earliest SV.SVSTDTC value.
3. If there is no SV.SVSTDTC variable or it is null, the time period start is the DM.RFSTDTC value.

A subject's time period end is determined as follows:

1. The time period end is the latest of the SE.SEENDTC and SE.SESTDTC values.
2. If both the SE.SEENDTC and SE.SESTDTC variables do not exist or are null, the time period end is the latest of the SV.SVENDTC and SV.SVSTDTC values.
3. If both the SV.SVENDTC and SV.SVSTDTC variables do not exist or are null, the time period end is the DM.RFENDTC value.

Viewing a Kaplan-Meier Plot

The Kaplan-Meier Plot shows the declining proportion of subjects in the study over time. Curves in the graph are Kaplan-Meier estimates.

The graph uses one disposition event per subject. To determine the disposition event, WebSDM/Empirica Study uses the algorithm described in [Disposition Events](#). If the algorithm finds multiple disposition events for a subject, WebSDM/Empirica Study tries to use the disposition event date to determine a disposition event to show in this display and a note appears below the graph.

The x-axis represents the number of days since the start of the time period, which is described below under "More detail". For subjects who complete or leave the study, the days on the x-axis are computed as: (DS.DSSTDTC value—time period start) + 1.

A subject is considered to have completed the study if the subject's disposition event contains the case-insensitive text string "COMPLETED". The subject is considered to have left the study if the subject's disposition event does not contain "COMPLETED".

The start of the x-axis is 0 and the end of the x-axis is the latest of the time periods for subjects included in the graph.

The y-axis represents the proportion of subjects remaining in the study, adjusted for censoring (that is, adjusted for subjects who completed or left the study).

When the continuation rate becomes less than 1, a 95% confidence interval is displayed for each study day tick mark on the x-axis. The confidence intervals are produced using the Greenwood method. To prevent overlapping of the confidence interval depictions for different arms, the confidence interval depictions are slightly offset from each other.

"Subjects at Risk" section

The "Subjects at Risk" section below the graph shows counts of subjects remaining in the study at each day identified on the x-axis. The initial count is the basis for the proportion of subjects remaining in the study.

Over time, a subject is subtracted from these counts when either of the following occurs:


- The subject completes or leaves the study.
- The time period for the subject ends before the end of the x-axis.

Notes

- If a time frame with a well-defined start is in effect, only subjects who did not [drop out](#) before the time frame start are included in the graph.
- Subjects for whom there is not enough information to compute days on the x-axis are excluded from the graph and the "Subjects at Risk" counts.
- If an arm or dosing category contains fewer than two subjects for which days on the x-axis can be computed, data for that arm or dosing category is not shown. A note says that there is insufficient data for the arm or dosing category.
- If the graph plots data by Treatment and Comparator categories and one of those categories includes null ARM values, then the subjects with null ARM values are included in that category. However, subjects with null ARM values are not included if the graph plots data by ARM values.

To view a Kaplan-Meier Plot:

1. Do one of the following:

Tab	Steps
Domains	Click  in the Listings column for the DS domain, and then click Kaplan-Meier Plot .
Safety Review	On the Disposition Summary page , click Kaplan-Meier Plot .
Screening	On the Analysis Results page: In the Disposition Summary by Dose Group window , click Kaplan-Meier Plot .

2. To configure the graph, click **Configure**. Specify any of the following display options and click **OK**:

Option	Description
Add Note	Optionally enter text to display below the graph.
Use dosing breakdown instead of ARM values	Available on the Screening tab: <ul style="list-style-type: none"> • Check to use the currently selected dosing category breakdown (Treatment and Comparator categories). • Clear to show the graph for ARM values instead of Treatment and Comparator categories. Note that only arms in the currently selected dosing category breakdown are used. If there

are more than five ARM values, the graph cannot be displayed by ARM values.

Available on the Domains tab if there is a default dosing category breakdown for the study:

- Check to use the default dosing category breakdown (Treatment and Comparator categories).
- Clear to show the graph for ARM values instead of Treatment and Comparator categories. If there are more than five ARM values, the graph cannot be displayed by ARM values.

Use gray-scale instead of colors	Check to use shades of gray instead of colors in the graph.
Show key/legend	Check to display a key for curves in the graph.
Show Links	Check to include Print and Help links for the graph. Before copying a graph (for example, with copy and paste functions), you may want to clear this check box.

3. If text in the graph is not legible, resize the graph window.
4. To print or copy the graph, see [Working with Graphs](#).

More detail

The "time period" for a subject depends on whether or not a time frame with a well-defined start or end is in effect.

If the time frame has a well-defined start and end, a subject's time period is from the time frame start to the time frame end.

If no time frame is in effect or if the time frame does not have a well-defined start or end, the start or end of a subject's time period is determined as described below.

A subject's time period start is determined as follows:

1. The time period start is the earliest SE.SESTDTC value.
2. If there is no SE.SESTDTC variable or it is null, the time period start is the earliest SV.SVSTDTC value.
3. If there is no SV.SVSTDTC variable or it is null, the time period start is the DM.RFSTDTC value.

A subject's time period end is determined as follows:

1. The time period end is the latest of the SE.SEENDTC and SE.SESTDTC values.

2. If both the SE.SEENDTC and SE.SESTDTC variables do not exist or are null, the time period end is the latest of the SV.SVENDTC and SV.SVSTDTC values.
3. If both the SV.SVENDTC and SV.SVSTDTC variables do not exist or are null, the time period end is the DM.RFENDTC value.

Napoleon's March Graph

Viewing a Napoleon's March Graph

A Napoleon's March Graph provides information about subjects' actual drug exposures (values of the EX.EXTRT variable) during the study, adverse events experienced by subjects, and the circumstances under which subjects completed or dropped out of the study. The temporal relationship between duration of exposure and the onset of an adverse event can be important in assessing causality. For example, a rare but serious adverse event that occurs more frequently in the treatment group might also occur earlier in the treatment group and be more likely in the treatment group to lead to dropout.

This graph is not affected by any currently selected time frame.

Each bar in the graph represents a subject's exposure over study days, and subjects are sorted by decreasing duration of treatment. Thus, the pattern formed by bars in the graph is informative; for example, a graph pattern of many short bars at the bottom of the graph and longer bars at the top may indicate that, although some subjects completed the study, many subjects could not tolerate the treatment.

Bars in the graph are colored according to exposure. At the end of each bar, there is:

- A disposition event, indicating the reason that the subject's participation in the study ended. See below for which disposition event is used. The graph does not indicate when the disposition event occurred on the timeline.
- The count and percentage of subjects in the study before that subject's participation ended.

You can choose to display a horizontal line (in the bar) representing the time period of any adverse events that occurred for the subject.

Brighter colors are used for drug exposures whose average dose is relatively high, and fainter colors are used for values whose average dose is relative low (or null). If the average dose is the same for multiple drug exposures, the drug exposures are ordered alphabetically in determining the color key.

For a study with more than one arm, a default dosing category breakdown may have been defined for the study. The Treatment and Comparator categories (groups) specified by that dosing category breakdown are used in the Napoleon's March graph. (If there is no default dosing category breakdown, all arms are shown in one group.) You can configure the graph to display information for treatment information and comparator information side-by-side, one below the other, or intermingled.

For background on the Napoleon's March Graph, see Szarfman, A., Levine, J. G., & Tonning, J. M. (2006). A New Paradigm for Analyzing Adverse Drug Events. In S. Ekins (Ed.),

Computer Applications in Pharmaceutical Research and Development (pp. 649-665). John Wiley & Sons, Inc.

Disposition events

Only one disposition event per subject is represented. To determine the disposition event, WebSDM/Empirica Study uses the algorithm described in [Disposition Events](#).

If the algorithm finds multiple disposition events for any subjects, WebSDM/Empirica Study tries to use the disposition event date to determine a disposition event to show in the graph and a note appears below the graph. If a disposition still cannot be determined, the disposition event is shown as "<Multiple Dispositions>".

To view a Napoleons' March graph:

1. On the Subjects page, click **Napoleon's March**. The graph can be displayed only if there are 500 or fewer subjects to be represented in the graph. Do not click on the graph until the whole graph is displayed.
2. [Configure the graph](#). The graph is displayed again with any configuration options you have modified.
3. When you point to a bar in the graph, the subject ID, sex, age, arm, and disposition are displayed.
4. To view subject details for a subject, click a bar for the subject (after the whole graph has displayed).
5. To print or copy the graph, see [Working with Graphs](#).

Variables used in this graph

The following situations may prevent the graph from displaying or cause data points to be omitted from the graph. If you configure the graph to show notes, subjects for whom data points are omitted for these reasons are listed.

Situation	Variables	Effect
A required domain table is not found.	DM, DS, EX domains	Graph is not displayed.
A required variable is not found.	DM.ARM DM.AGE DM.SEX DM.RFSTDTC DM.RFENDTC EX.EXTRT EX.EXSTDTC EX.EXENDTC EX.EXDOSE DS.DSDECOD	Graph is not displayed.
An internal error occurred for the value of a	DM.USUBJID	Data point is omitted

variable, possibly because the variable does not have the expected data type.	DM.ARM DM.AGE DM.SEX DM.RFSTDTC DM.RFENDTC EX.EXTRT EX.EXSTDTC EX.EXENDTC DS.DSDECOD AE.AEDECOD	from graph.
A Null value is found for a variable expected to have a non-null value.	DM.USUBJID EX.EXTRT EX.EXSTDTL AE.AEDECOD AE.AESTDTC	Data point is omitted from graph. Graph notes include: Null <variable-name>

More detail

The study day on the x-axis is computed as follows:

For exposure start:

- $(EXSTDTC - RFSTDTC) + 1$ if exposure starts after the study reference date
- $(EXSTDTC - RFSTDTC) - 1$ if exposure starts before the study reference date

For exposure end:

- $(EXENDTC - RFSTDTC) + 1$ if exposure ends after the study reference date
- $(EXENDTC - RFSTDTC) - 1$ if exposure ends before the study reference date

For event start:

- $(AESTDTC - RFSTDTC) + 1$ if event starts after the study reference date
- $(AESTDTC - RFSTDTC) - 1$ if event starts before the study reference date

For event end:

- $(AEENDTC - RFSTDTC) + 1$ if event ends after the study reference date
- $(AEENDTC - RFSTDTC) - 1$ if event ends before the study reference date

Configuring a Napoleon's March Graph

1. On the [graph display page](#), click **Configure**.
2. Specify the following display options:

Option	Description
Treatment-Comparator comparison style	<p>Determines the comparison style for Treatment and Comparator subjects. The options are:</p> <ul style="list-style-type: none"> • Side by side – A graph for treatment subjects and a graph for comparator subjects are displayed next to each other. • Treatment then comparator – Treatment and comparator subjects are displayed in the same graph, with all treatment subjects first and then all comparator subjects. • None – The graph does not show a comparison of treatment to comparator. Treatment subjects and comparator subjects are intermingled in the same graph. <p>The treatment and comparator categories are determined by the default dosing category breakdown for the study. For the Side by side or Treatment then comparator options, the study must have a default dosing category breakdown defined.</p>
Bar height in pixels	<p>Number of pixels to be used for the height of all bars in the graph. This is useful if there are many subjects in the graph and they cannot fit into a reasonably-sized display. If you change the bar height, the bar pattern is retained.</p>
Adjust bar heights to equalize heights of treatment and comparator displays	<p>Determines whether bar heights are adjusted to make the height of the treatment display the same as the height of the comparator display. This makes comparing the dropout patterns easier.</p> <ul style="list-style-type: none"> • If selected—Adjusts bar heights. • If deselected—Does not adjust bar heights.
Show subject ID's	<p>Determines whether the subject ID represented by each bar is shown along the y-axis.</p> <ul style="list-style-type: none"> • If selected—Shows the subject ID. • If deselected—Does not show the subject ID.
Show adverse events	<p>Available only if certain AE variables are in the study data. In each bar, determines whether a horizontal line appears, indicating the time period for any adverse events that occurred for the subject. If any serious adverse event occurred in the period represented by the line, the line is thicker.</p>

- **If selected**—Shows adverse events.
- **If deselected**—Does not show adverse events.

If this option is not available, you can hover your cursor over the option to display a tooltip about the reason for its unavailability.

Show count of subjects remaining in study

At the end of bars, determines whether the number of subjects remaining in the study before the subject's participation in the study ends appears.

- **If selected**—Shows count of subjects remaining.
- **If deselected**—Does not show count of subjects remaining.

Note: No count is shown for a bar if the count is the same as for the immediately preceding bar.

Show percentage of subjects remaining in study

At the end of bars, determines whether the percentage of subjects remaining in the study before the subject's participation in the study ends appears.

- **If selected**—Shows percentage of subjects remaining.
- **If deselected**—Does not show percentage of subjects remaining.

Note: No percentage is shown for a bar if the percentage is the same as for the immediately preceding bar.

Show disposition abbreviations

In the box that shows color-coded disposition at the end of each bar, determines whether the first character of the disposition value appears. If the disposition event is null, a question mark appears. If there are multiple dispositions, "***" appears instead of an abbreviation.

- **If selected**—Shows disposition abbreviations.
 - **If deselected**—Does not show disposition abbreviations.
-

- Optionally check any other display options. See [Working with Graphs](#) for information about the following display options: Use gray-scale instead of colors; Key; Notes; and Links. Notes will include a list of any subject IDs for which there are data problems that prevent data points from displaying in the graph
- Click **OK**. Your display options will be used for this type of graph for your username until you change them, log out, or select a different study.

Adverse Events

Viewing a Cumulative Incidence Plot

The Cumulative Incidence Plot shows the proportion of subjects with a particular adverse event over time. Curves in the graph are for the inverse of Kaplan-Meier estimates. The graph uses only the initial onset (and not subsequent occurrences) of the adverse event for a subject.

The x-axis represents the number of days since the start of the time period, which is described under **More detail**. Only adverse events that occurred within a subject's time period are included in the graph. The days on the x-axis are computed as: (AE.AESTDTC—period start) + 1.

The start of the x-axis is 0 and the end of the x-axis is the latest of the time periods for subjects included in the graph.

The y-axis represents the cumulative proportion of subjects with the adverse event, adjusted for subjects who experienced the adverse event.

A 95% confidence interval is displayed at each number of study days on the x-axis. The confidence intervals are produced using the Greenwood method. To prevent overlapping of the confidence interval depictions for different study arms, the confidence interval depictions are slightly offset from each other.

Subjects at Risk section

The **Subjects at Risk** section below the graph shows counts of subjects who have not yet experienced the adverse event. The initial count is the basis for the proportions in the graph.

Over time, a subject is subtracted from the initial count when either of the following occurs:





- The subject experiences an adverse event. If only serious events or events causing withdrawal are graphed, the subject is dropped only if the event is serious or caused withdrawal.
- The time period for the subject ends before the end of the x-axis.

Notes

- If a time frame with a well-defined start is in effect, only subjects who did not [drop out](#) before the time frame start are included in the graph.
- Subjects for whom there is not enough information to compute days on the x-axis are excluded from the graph and the **Subjects at Risk** counts.
- If an arm or dosing category contains fewer than two subjects for which days on the x-axis can be computed, data for that arm or dosing category is not shown. A note above the graph says that there is insufficient data for the arm or dosing category.
- If the graph plots data by Treatment and Comparator categories and one of those categories includes null ARM values, then the subjects with null ARM values are included in that category. However, subjects with null ARM values are not included if the graph plots data by ARM values.

To view a Cumulative Incidence Plot:

1. Do one of the following:

Tab	Steps to View the Cumulative Incidence Plot
Safety Review	<p>On the Adverse Events page, do one of the following:</p> <ul style="list-style-type: none"> • Click the Action menu icon () for a row and then click Cumulative Incidence Plot. • Click the Action menu icon () for a row and then click Incidence by Day of Onset. Click Cumulative Incidence Plot. • Click Sector Map. Click a tile and then click View Cumulative Incidence Plot from the menu that appears.
Screening	<p>On the Analysis Results page, select an issue for which the analysis type is MedDRA PT, MedDRA HLT, MedDRA HLGT, or MedDRA SOC. (If the analysis type is other than MedDRA PT, the graph will show PTs whose primary path includes the HLT, HLGT, or SOC. Only the first occurrence of each PT will be counted.) Then do either of the following:</p> <ul style="list-style-type: none"> • Click the Action menu icon () for an issue and then click View Cumulative Incidence Plot. • Click the Action menu icon () for an issue and then click View Day of Onset by Dose Group. Click Cumulative Incidence Plot. <p>Click View Sector Map. Click a tile and then click View Cumulative Incidence Plot from the menu that appears.</p>

2. To configure the graph, click **Configure**. Specify any of the following display options and click **OK**:

Option	Description
Add Note	Text to display below the graph.
Use dosing breakdown instead of ARM values	<p>Available on the Screening tab only. Specify whether to use the currently selected dosing category breakdown (Treatment and Comparator categories).</p> <ul style="list-style-type: none"> • If selected—The currently selected dosing category breakdown (Treatment and Comparator categories). • If deselected—Shows the graph for ARM values instead

of Treatment and Comparator categories. Note that only arms in the currently selected dosing category breakdown are used. If there are more than five ARM values, the graph cannot be displayed by ARM values.

Use gray-scale instead of colors	<p>Specify whether to use shades of gray instead of colors in the graph.</p> <ul style="list-style-type: none"> • If selected—Uses gray-scale. • If deselected—Uses color.
Show key/legend	<p>Specify whether to display a key for curves in the graph.</p> <ul style="list-style-type: none"> • If selected—Displays a key. • If deselected—Does not display a key.
Show Links	<p>Specify whether to include Print and Help links for the graph.</p> <ul style="list-style-type: none"> • If selected—Print and Help links appear. • If deselected—Print and Help links do not appear.
<p>Note: Before copying a graph (for example, with copy and paste functions), you may want to deselect this check box.</p>	

3. If text in the graph is not legible, resize the graph window.
4. To print or copy the graph, see [Working with Graphs](#).

More detail

The time period for a subject depends on whether or not a time frame with a well-defined start or end is in effect.

If the time frame has a well-defined start and end, a subject's time period is from the time frame start to the time frame end.

If no time frame is in effect or if the time frame does not have a well-defined start or end, the start or end of a subject's time period is determined as described below.

A subject's time period start is determined as follows:

1. The time period start is the earliest SE.SESTDTC value.
2. If there is no SE.SESTDTC variable or it is null, the time period start is the earliest SV.SVSTDTC value.
3. If there is no SV.SVSTDTC variable or it is null, the time period start is the DM.RFSTDTC value.

A subject's time period end is determined as follows:

1. The time period end is the latest of the SE.SEENDTC and SE.SESTDTC values.
2. If both the SE.SEENDTC and SE.SESTDTC variables do not exist or are null, the time period end is the latest of the SV.SVENDTC and SV.SVSTDTC values.
3. If both the SV.SVENDTC and SV.SVSTDTC variables do not exist or are null, the time period end is the DM.RFENDTC value.

Viewing a Sector Map

A *sector map* is a visual presentation of adverse event terms that appear in the study data and are MedDRA terms. Each System Organ Class (SOC) is represented by a large tile in the sector map. The tiles within each SOC tile represent another level of the MedDRA hierarchy, which is typically Preferred Terms (PTs). The primary path of a term is used to determine where it appears in the sector map.

The color, size, and ranking of tiles provide a "big picture" overview of the adverse event profile of a drug. Depending on how the graph is configured, tiles may be sized according to relative public health impact or they may be of equal size. Terms are ranked and colored in descending order of values of the one-tailed p-value associated with the Chi-statistic (the p-value is the same as the SCORE column of screening results).

If a time frame with a well-defined start is in effect, only subjects who did not [drop out](#) before the time frame start are included in the graph. If any time frame is in effect, only events that occurred within the time frame are shown.

To view a sector map:

1. Do one of the following:

Tab	Steps	Notes
Safety Review	As a safety review configuration option, select a dosing category breakdown (not ARM values) and time frame for which screening results exist. Then, on the Adverse Events page, click Sector Map .	The graph is for results of whichever standard analysis type is at the lowest MedDRA level in the \$\$\$BASIC\$\$\$SCREENING\$\$\$ specification.
	As a safety review configuration option, select a dosing category breakdown (not ARM values) and time frame for which screening results exist. Then, on the Screening Results page, select a standard or custom MedDRA PT, HLT, HLG, or SOC analysis type and click View	The graph is for the following: <ul style="list-style-type: none"> • The MedDRA level of the currently selected analysis type. • The currently selected category (such as Sex), if such fields are available. • For a custom analysis type,

Sector Map.

the criteria of that type.

Screening

On the Analysis Results page: Select a dosing category breakdown and time frame, and select a standard or custom MedDRA PT, HLT, HLGT, or SOC analysis type. Then click **View as Sector Map**.

The graph is for the following:

- The MedDRA level of the currently selected analysis type.
- The currently selected category (such as Sex), if such fields are available.
- For a custom analysis type, the criteria of that type.

2. [Configure the graph.](#)

3. Keep in mind that the following terms do not appear in the sector map:

- Terms not found in the MedDRA version – A note immediately below the graph key lists these terms. For example: **The following adverse event terms were not found in the MedDRA dictionary (MEDDRA60) "Hyperpyrexia NOS"**
- Terms excluded because of the number of times they occur in AERS – This is based on an option described in [Configuring a Sector Map](#). If you display notes for the graph, these terms are listed. For example: **Terms omitted due to number of times in AERS: Anaemia vitamin B12 deficiency(0), Gravitational oedema(5)**

In the notes, (n) indicates the number of times the terms occurs in the study data.

4. If you point to a tile, the MedDRA PT, HLT, HLGT, and SOC (depending on which level of term is represented by tiles in the sector map) appears. The following information is also provided for the term that the tile represents.

- A/B/C/D – Counts from the 2x2 table (for Observed Subjects) used to compute results.
- OR – Modified Odds Ratio
- Corrected OR – Corrected Odds Ratio
- Chi – Chi-statistic
- Chi p-value – p-value associated with the Chi-statistic. (This is the SCORE in the screening results table.)
- PRR – Proportional Reporting Ratio
- Color – Numeric indication of the relative intensity of the color, according to the color key below the sector map.

5. When you click on a tile of the graph, a menu appears and you can do the following:

- Click **Zoom** to display only the selected SOC tile; see [Zooming In on a SOC](#).
- Click **2x2 Table** to [view 2x2 tables](#) if there are any subjects with the treatment or comparator drug and the term represented by the tile.
- View a [cumulative incidence plot](#) of the adverse event.
- [Drill down](#) to subjects (if any) with a combination of the treatment drug and the term represented by the tile. (Drilldown options are not available if A = 0.)

6. To print or copy the graph, see [Working with Graphs](#).

Statistics

The following information appears below the sector map:

Field	Meaning
Rank	Ranking of the term according to the p-value associated with the Chi-statistic.
SOC	SOC containing the term.
Term (PT, HLT, HLGT, or SOC)	Specific PT, HLT, HLGT, or SOC, depending on which level of term is represented by tiles in the sector map.
Chi	Chi-statistic for the combination of the treatment drug and the term.
P-value	p-value associated with the Chi-statistic. (This value is the same as the SCORE column of screening results.) Terms are listed in ascending order of values of this column.
A/B/C/D	Counts from the 2x2 table (for observed subjects) used to compute results.

Note: If a note below the sector map tells you that "days on drug" was used as the denominator in computations, see [Scores for Disproportionality Analysis Types](#) for more information.

Configuring a Sector Map

1. On the [Sector Map page](#), click **Configure**.
2. Change any of the following display options.

Note: When MedDRA is prepared by Oracle for use in WebSDM/Empirica Study, counts of MedDRA terms are computed based on a version of AERS that is available at that time. Those counts are used by the configuration options described below.

Option	Description
Color controlled by	Currently, only the Chi option is supported. Other options are reserved for future use.
Term box size controlled by	Determines the term box size. The options are:

- Relative importance of term—Size of PT tiles is based on an algorithm that determines the relative public health impact of PTs. (If the tiles are for HLT, HLGT, or SOC, the tile size is determined by the PTs within that term.) Using AERS data, the public health impact for a PT is computed as:

$$(\text{number of times the PT occurs in serious cases}) * (\text{proportion of cases with that PT that are serious or fatal})$$
A higher Public Health Impact score corresponds to a larger tile in the sector map.

Note: For PTs that are new in the MedDRA version associated with the AERS data used to assess public health impact, the tile size cannot be determined. Such PTs are represented as small tiles.

- All terms have equal size—All PT tiles have the same size. If subjects taking the treatment drug have relatively few serious events, this option may be preferable because many non-serious events have low public health impact.

Note: AERS is the FOI (Freedom of Information) FDA spontaneous adverse event reports database, which is distributed by NTIS (National Technical Information Service) and prepared by Oracle for use with their products.

Display maximum intensity at signal score of	All tiles for which scores are above this value are displayed at the maximum-intensity color as shown in the color key below the graph.
Use gray-scale instead of colors	<p>Determines whether the color key appears in shades of gray or color to represent score ranking.</p> <ul style="list-style-type: none"> If selected—Uses only shades of gray. If deselected—Uses color.
Show low scores in green for color graph	<p>Determines the color that represents low signal scores.</p> <ul style="list-style-type: none"> If selected—Uses shades of green. If deselected—Uses black.
	<hr/> <p>Note: This setting has no effect if you display the sector map in gray-scale.</p> <hr/>
Include only terms used ___ or more times in AERS	<p>Number indicating how many times a PT must be in AERS in order for that PT to be shown in the sector map. Enter one of the following to indicate which terms to include:</p> <ul style="list-style-type: none"> 0—Include all terms (if they are in MedDRA), regardless of

whether or not they appear in AERS.

- **1** or higher—Include only terms (if they are in MedDRA) that appear *n* or more time in AERS.

If you leave this field blank, the default value of **100** is filled in when you click **OK**.

The number that you specify is applied to PTs. If the sector map is displayed at the HLT, HLGT, or SOC level, the number is applied to the total PTs in the HLT, HLGT, or SOC. For example, suppose that you set this option to 100. If an HLT contains two PTs that each occur 60 times, the PTs do not appear in the sector map when it is displayed at the PT level; however, they do appear in the sector map when it is displayed at the HLT level, because there are 120 PTs in the HLT. If an HLT, HLGT, or SOC has no PTs that meet the condition, the HLT, HLGT, or SOC is not in the sector map.

If you check Notes, a list of terms that were omitted because of this restriction is included in the notes below the sector map. If you specify a non-zero value in this field, you may want to check Notes so that you can see this list.

Group by HLT	If the sector map shows PTs, group together in a rectangular area the PTs that are within the same HLT, and show the HLT in the information that appears when you point to a tile.
Group by HLGT	If the sector map shows PTs, group together in a rectangular area the PTs that are within the same HLGT, and show the HLGT in the information that appears when you point to a tile.
List __ lowest p-values	<p>Number indicating how many (up to 1000) terms with the lowest p-values will be ranked and listed below the sector map. Terms are listed in ascending order of the p-value associated with the Chi-statistic.</p> <p>If multiple terms have the same score, each term is counted separately. For example, suppose that you enter 20 as the limit. If the 20th row has a score that other terms after that also have, those additional terms are shown as well.</p>
Show lowest p-value indexes	<p>Determines whether tiles in the sector map are numbered in ascending order of the p-value associated with the Chi-statistic, up to the number of scores specified in List __ lowest p-values. For this check box to take effect, there must be a value specified for List __ lowest p-values.</p> <ul style="list-style-type: none">• If selected—Shows lowest p-value indexes.• If deselected—Does not show lowest p-value indexes.

3. Optionally check any other display options. See [Working with Graphs](#) for information about the following display options: Key; Notes; and Links.
4. Click **OK**.

Related Topics

[Viewing a Sector Map](#)

[Zooming In On a SOC](#)

ECG Results

Viewing a Distribution of QTc Change Over Time Graph

The Distribution of QTc Change over Time graph provides the following information:

- The main graph of box plots shows changes from baseline in reported QTc interval values for subjects at a series of visits (the x-axis). Baseline is established as described under **Baseline using baseline flag** in [Baseline Results](#).
- The visit numbers (Visit values) represented on the x-axis are determined by [study visit descriptions](#) for the study. If the visit number cannot be determined for a value, the value is omitted from the graph.
- An area to the right of the main graph shows box plots of the minimum and maximum change from baseline in reported QTc interval values for all subjects in the study across visits (possibly including visits not represented in the main graph, depending on the setting of the **Compute max box plots over displayed visits only** configuration option for the graph). Minimum and maximum values for a subject are determined using the signed values of change from baseline instead of the absolute values of change from baseline; for example, if a subject's change from baseline values are -10, -3, 2, and 7, the minimum is -10 and the maximum is 7.
- For each visit, counts of subjects with results for the reported QTC interval are shown below the main graph.

Note: Only numeric results are plotted.


For information on interpreting box plots, see [Box Plots](#).

Time frames have no effect on this graph. All subjects and all ECG test results are included in the graph.

You must have defined a test identifier for the QTC INTERVAL test to view this graph.

To view a Distribution of QTC Change over Time of Change graph:

1. Do one of the following:

Tab	Steps to View Graph	Notes
Domains	Click the Action menu icon () in the Listings column for the EG domain, and then click Distribution of QTc Change over Time .	The graph shows arms or Treatment and Comparator categories, depending on how you configure the graph.

Safety Review

On the QT Prolongation Summary page, click **Distribution of QTc Change over Time**.

If you have [configured safety review](#) to use arms, the graph includes as a single group all arms; the arms are not restricted to those actually included in the Treatment and Comparator categories.

If you configured safety review to use a dosing category breakdown, the graph includes the Treatment category and Comparator category that are defined by that dosing category breakdown.

-
2. [Configure the graph](#).
 3. If you configure to show Links, you can point to a region of a graph to display the following:
 - The region of the box (Upper Outlier, Upper Whisker, Upper Box, Lower Box, Lower Whisker, or Lower Outlier).
 - The count of data points for the visit number and box plot region (only one QTc interval value is counted per subject and visit number).
 4. If you configure the graph to show Links: If you click a region (Upper Outlier, Upper Whisker, Upper Box, Lower Box, Lower Whisker, or Lower Outlier) of a box plot, a menu appears and you can [drill down](#) to subjects for that region. If you click the Upper Outlier region, all subjects with values that are upper outliers are listed when you drill down, including those with values outside the y-axis (shown in a separate area above the graph).

The counts of subjects with values outside the y-axis (above the main graph) and the subject counts in the **Subjects at Visit** section below the graph are hyperlinks that you can click to drill down.

If a subject has a value on the boundary between adjacent regions (not including the Upper Outlier or Lower Outlier regions), the subject ID is included when you drill down on either of the regions. Subjects with values on the boundary of the Upper Whisker or Lower Whisker are not included when you drill down on the Upper Outlier or Lower Outlier regions.

5. To zoom in on data for a study day or range of study days, double-click and draw a red rectangle around the data points for those days or the x-axis tick marks for those days, making sure that you do not include any of the gray background above or below the graph. When you then single-click, a zoom window appears.

Note: When you have zoomed in, the Min and Max section of the graph is based on only data points in the zoom window.

6. To print or copy the graph, see [Working with Graphs](#).

More detail

The following situations may cause the graph to not display or data points to be omitted from graph. If you configure the graph to show notes, subjects for whom data points are omitted for these reasons are listed. The notes do not pertain to data points that are omitted due to restrictions imposed by dosing category breakdowns.

Note: __DTC is checked only if the **Handling of multiple results at same visit** option is set to **Select first result** or **Select last result**.

Situation	Variables	Result
A required variable is not found.	__STRESN __BLNRS_ __TESTCD __DTC	Graph is not displayed.
No records for the test were found, as would be the case for an invalid test identifier.		Data point is omitted from graph.
An internal error occurred for the value of a variable, possibly because the variable does not have the expected data type.	USUBJID __STRESN __BLNRS_	
A null value is found for a variable expected to have a non-null value.	__STRESN __BLNRS_	Data point is omitted from graph.

Configuring a QTc Change over Time Graph

1. On the [graph display page](#), click **Configure**.
2. Specify the following display options:

Option	Description
Y axis low to include Y axis high to include	<p>You can modify the low or high values to be included on the y-axis to make the box plots more readable.</p> <hr/> <p>Note: The y-axis includes your specified values, but does not necessarily start or end with them.</p> <ul style="list-style-type: none"> • If the low value is blank, a default value is used. For linear axes, the default is 0. For log axes, the default is .1. • If the high value is blank, a high value that encompasses the highest value in the data is used. • If you set the y axis high and some values are above it, then a section above the graph shows counts of subjects

with those values. However, you cannot show counts of subjects with values below the Y axis low.

First reference line at Second reference line at Third reference line at	Define up to three reference lines to assist in graph interpretation. Enter a numeric value to indicate the y value at which each reference line will appear. For each reference line that you specify, a green line is drawn at the specified value on the y-axis.
Place visits along X axis	<p>Tick marks on the x-axis are always ordered according to their average study day value, as determined by the study visit descriptions. Use this option to indicate how much space will appear between tick marks on the x-axis. The options are:</p> <ul style="list-style-type: none"> • By study day—The space between tick marks will reflect the differences in average study day values for tick marks. For example, if the average study day value for Visit 3 is 1 less than the average study day value for Visit 4, there will be little space between Visit 3 and Visit 4 tick marks <p>If multiple tick marks have the same average study day value, a note tells you to configure the graph to show evenly spaced tick marks.</p> <ul style="list-style-type: none"> • Evenly spaced—All intervals between tick marks on the x-axis will be the same.
Handling of multiple results at the same visit	<p>Indicates which value to use if multiple QTc values occurred at the same visit. The options are:</p> <ul style="list-style-type: none"> • Select first result—Plot the result from the earliest test (EG.EGDTC value) for the subject visit. • Select last result—Plot the result from the latest test (EG.EGDTC value) for the subject visit. • Select maximum result—Plot the maximum result for the subject visit. • Select minimum result—Plot the minimum result for the subject visit. • Compute average—Plot the average of values for the subject visit. <p>Note: If multiple test results are recorded for the same test at the same visit and the same date and time, the option Select first result selects the first result arbitrarily and Select last result selects the last result arbitrarily.</p>
Compute min/max box plots over displayed visits	Determines whether maximum values (shown to the right of the main graph) are computed across only the visits displayed in the graph.

only

- **If selected**—Computes min/max box plots over displayed visits only.
- **If deselected**—Computes min/max box plots across all visits.

Note: Maximum values are the largest differences from baseline, where positive differences are always larger than negative differences.

Plot data for

Available on the Domains tab only. The options are:

- **Treatment and Comparator categories**—Include the Treatment category and Comparator category that are defined by the default dosing category breakdown for the study or study pool.
- **Arms in Treatment or Comparator categories combined**—Include as a single group those arms that are in the Treatment category and Comparator category defined by the default dosing category breakdown for the study or study pool.
- **All arms combined**—Include as a single group all arms; the arms are not restricted to the arms actually included in the Treatment and Comparator categories.

Note: The first two options are available only if there is a default dosing category breakdown for the study or pool.

- Optionally check any other display options. See [Working with Graphs](#) for information about the following display options: Use gray-scale instead of colors; Key; Notes; and Links.

If you check Notes, the following information will appear below the graph:

- Name of user who produced the graph, datetime the graph was produced, and the application/study.
- Configuration options specified for the graph.
- List of any subject IDs for which there are data problems that prevent data points from displaying in the graph.



- Click **OK**.

Lab Results/Vital Signs

Viewing a Lab or Vital Signs Graph

A *lab graph* or *vital signs graph* is a graphic display of lab test results or vital sign results, as compared to normal ranges, across the number of days since treatment began.



Note: In this context, the BMI value, if any, is from the study data; if it does not exist, it is not computed by WebSDM/Empirica Study.

The y-axis represents lab test or vital sign values and the x-axis represents the day relative to the start of treatment. If the graph represents two tests, the shape (a circle or triangle) of points indicates the lab test or vital sign. You can [configure the graph](#) to show normal range as a gray area in the graph, and to show clinically significant values as larger shapes in the graph. For example,  (as opposed to ) represents clinical significance.

If a time frame with a well-defined start is in effect, only subjects who did not [drop out](#) before the time frame start are included in the graph. If any time frame is in effect, only lab test or vital sign results that occurred within the time frame are shown.

To view a lab graph or vital signs graph:

1. Do one of the following:

Tab	Steps
Safety Review	On the Lab Results page: Click Lab Graph .
	On the Vital Signs page: Click Vital Signs Graph .
	On the Screening Results page: Click  for a result for a Lab Change from Baseline Analysis or a Clinically Significant Lab Analysis, and then click View Lab Graph .
Screening	On the Screening Results page: Click  for a result for a Vitals Change from Baseline Analysis or a Clinically Significant Vitals Analysis, and then click View Vitals Graph .
	On the Analysis Results page: Select a dosing category breakdown and time frame, and then click View Lab Graph .
	On the Analysis Results page: Select a dosing category breakdown and time frame, and then click View Vitals Graph .

2. [Configure the graph](#).
3. In the Test fields, select one or two tests. After the test name, units are shown in parentheses.
4. You can filter subjects to include in the graph by selecting values in the Dosing, Sex, Race, and Age Group list boxes. Available values depend on how the graph is [configured](#).

To select multiple values in a list box, hold down the Ctrl key. If you select more than one value, you can check "Separate plots" for the values. If you check "Separate plots", each combination of values (up to 8 combinations) is plotted separately in the graph, as shown in the color key below the graph.

Note: If you do not select anything in a list box, the graph does not filter subjects by that particular type of category. For example, suppose the dosing category breakdowns are listed and that they do not include all arms in the study. If you select none of them, the graph includes subjects with any arm in the study.

5. In the Subject List field, you can select a subject list to which you have access. The graph will include only subjects in the selected subject list.

If you are viewing a graph for a particular result generated by a custom analysis type using a subject list, then that subject list appears in this field as a default.
6. Click **Draw** (or **Redraw** if you have changed options). The categories and subject list (if any) used for the graph are shown above the graph display.
7. To [drill down](#) to subject information, point to the graph, click, and hold down the mouse button while you draw a red rectangle around the data points for which you want to drill down, making sure that you do not include any of the gray background above or below the graph. When you release the mouse button, a menu appears and you can drill down. Note that a single point in the graph may represent several data points.

Note: If you configure the graph to show actual values from the study data and you include a normal range region, there may be a difference between the number of subjects with data points plotted in the graph and the number of subjects that appear when you drill down. If the normal range for a data point cannot be determined, the data point is not plotted. However, when you drill down, you are drilling down on a range of actual values, so those data points are represented.

8. To zoom in on a particular region of the graph, click **Zoom** in the menu that appears when you drill down. Once you have zoomed in, a **Cancel Zoom** button is available.
9. To print or copy the graph, see [Working with Graphs](#).

Graph key

If you specify separate plots for your Dosing, Sex, Race, or Age Group selections, the key below the graph shows which color is used for points in the graph for each combination of selections.

If you represent two tests in the graph, the key shows which shape is used for points in the graph for that test.

Notes section

If a graph includes a test for which the normal range varies across subjects, you can configure the graph to use various means of showing normal range boundaries. If you also configure the graph to show Notes, the notes include an indication of what the normal range represents.

More detail

The following situations may cause data points to be omitted from the graph. If you configure the graph to show notes, subjects for whom data points are omitted for these reasons are listed. The notes do not pertain to data points that are omitted due to restrictions imposed by time frames or dosing category breakdowns.

Situation	Variables	Effect
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A null value is found for a variable expected to have a non-null value. The graph note is: Null <variable-name>	__STRESN __STNRLO __STNRHI __DY	Data point is omitted from graph.
The value of ULN is 0, which makes normalization of the result impossible.	__STNRHI	Data point is omitted from graph.

On the x-axis, the day relative to start of treatment is the value of the __DY variable, if that variable exists. Otherwise, the day relative to start of treatment is computed as: __DTC—DM.RFSTDTC.

In the list of lab tests or vital signs that you can select, each test name is composed of values from the study data in the following format: __TESTCD—__TEST (__STRESU). If there are multiple __STRESU values for the test, the alphabetically last one is used.

If there are multiple __TEST values for the same __TESTCD value, the alphabetically last one (among records where __STRESN is not null) is used.

Configuring a Lab or Vitals Graph

1. In the [Lab Graph or Vitals Graph window](#), click **Configure**.
2. Specify any of the following display options:

Option	Description
Basis for Categories—Dosing	<p>Determines the options that appear in the Dosing list box. On the Safety Review tab, the options are:</p> <ul style="list-style-type: none"> • Values of ARM—List all non-null arm values from the study data. • Dosing category breakdown—Available if you have configured safety review to use a dosing category breakdown; list categories from the breakdown. <p>On the Screening tab, the options are:</p> <ul style="list-style-type: none"> • Values of ARM—List all non-null arm values from the study data. • Dosing category breakdown—List categories from the currently selected dosing category breakdown.
Basis for Categories—Sex	<p>Determines the options that appear in the Sex list box. On the Safety Review tab, the options are:</p> <ul style="list-style-type: none"> • Values of SEX—List all non-null sex values from the study data.



- **Default breakdown**—Available if there is a default sex category breakdown; list categories from the breakdown.

On the Screening tab, the options are:

- **Values of SEX**—List all non-null sex values from the study data.
- **Analysis Specification**—Available if a sex category breakdown was specified in the analysis specification; list categories from the breakdown.

Basis for Categories—Race	<p>Determines the options that appear in the Race list box.</p> <p>On the Safety Review tab, the options are:</p> <ul style="list-style-type: none"> • Values of RACE—List all non-null race values from the study data. • Default breakdown—Available if there is a default race category breakdown; list categories from the breakdown. <p>On the Screening tab, the options are:</p> <ul style="list-style-type: none"> • Values of RACE—List all non-null race values from the study data. • Analysis Specification—Available if a race category breakdown was specified in the analysis specification; list categories from the breakdown.
Basis for Categories—Age	<p>Determines the options that appear in the Age Group list box.</p> <p>On the Safety Review tab, the options are:</p> <ul style="list-style-type: none"> • AGE quartiles—List automatically computed quartiles based on non-null age values from the study data. • Default breakdown—Available if there is a default age category breakdown; list categories from the breakdown. <p>On the Screening tab, the options are:</p> <ul style="list-style-type: none"> • AGE quartile—List automatically computed quartiles based on non-null age values from the study data. • Analysis Specification—Available if an age category breakdown was specified in the analysis specification; list categories from the breakdown.
Identify clinically	If a method of determining clinical significance has been

significant values
using

defined for the study, clinically significant values are shown as larger shapes in the graph. For example,  (as opposed to ) represents clinical significance. The options are:

- Built-in criteria
- Flag variable

These options are methods of determining clinical significance. Each option is available for this graph if the study was set up to support that method. If only one option is available, it is selected automatically. If an option is not available, you can hover the cursor over the option to display a tooltip explaining why the option is not available

For more information, see [Clinical Significance Criteria](#). For built-in criteria for clinical significance that measure change from baseline, the baseline is established as described under **Baseline using baseline flag** in [Baseline Results](#). Also note that when built-in criteria for clinical significance are used, all criteria are applied to all results in the time frame, even if they are baseline results. Thus, it is possible for a baseline result to appear in the graph as a clinically significant result. A note below the graph indicates whether the built-in criteria or a flag variable is used. If you have opted to base clinical significance on built-in criteria but there are no built-in criteria for the test, or there are built-in criteria but no test identifier has been defined, the note says that clinical significance is not defined.

Note that for a given result, clinical significance is shown as a larger shape only if the data needed to determine clinical significance is present for the test. For example, assume that clinical significance of Hemoglobin results is based on built-in criteria. For a subject with no Sex value, clinical significance of Hemoglobin results is never shown as a large shape because the built-in criteria depend on the subject's sex being **M** or **F**. However, for subjects with a Sex value of **M** or **F**, a larger shape may be used to indicate clinical significance for Hemoglobin results.

Jitter Factor Multiplier	Number that is greater than or equal to 0 and less than 2, indicating by how much points are "jittered" (offset) so that if two records have the same value, a point is more likely to be visible for each of them. Higher numbers represent more jittering than do lower numbers.
Display normalized values (/ULN)	Applies to the lab graph and available only if the study data includes the LBSTNRHI variable. <ul style="list-style-type: none">• If selected and there is there is at least one non-zero ULN for the result—Shows normalized values (that is, show values divided by ULN). The Notes section of the graph indicates when results could not be normalized.

- **If deselected**—Shows actual values.

Note: When normalized values are shown, results for which ULN is null or 0 are omitted from the graph. The Notes section of the graph tells you if results are omitted.

Include normal range region

Determines whether a normal test values section appears.

- **If selected**—Displays a section of normal test values with a gray background. If the study data does not include normal range values, the Notes section of the graph tells you that the normal range region cannot be displayed. If a normal range region can be determined for some subjects but not all subjects, the Notes section contains the subjects for which the normal range for the result cannot be determined.
- **If deselected**—Does not include a normal range region.

For wide normal range

This option is useful when normal range test values vary by age, gender, or race. Such tests are considered to have "wide" boundaries between normal and abnormal ranges. The options are:

- **Maximize normal range**—The normal range area of the graph uses the outer limits of the normal high and normal low values— that is, the greatest of the normal high values and the least of the normal low values.

Note: If normal range varies across subjects, this option is used automatically and a message appears in graph notes if you configure the graph to show notes. If you show normalized values in the graph, the upper limit of the normal range is always 1.0. The message appears only if the lower limit of the normal range varies across subjects.

- **Minimize normal range**—The normal range area of the graph uses the inner limits of the normal high and normal low values— that is, the least of the normal high values and the greatest of the normal low values.
 - **Use midpoints for normal range**—The normal range area of the graph uses the average of the inner and outer limits of the normal high and normal low values found in the data.
 - **Use hatches**—The inner and outer limits of the normal range are represented by hatched areas on the graph. This option applies only if there are two or more
-

possible normal ranges for the subjects represented in the graph. The gray area shows values common to all the normal ranges, and the hatched area shows values that are normal to some but not all of the normal ranges.

Note: The hatch option, if specified, is used only if a single test is shown in the graph.

For example, suppose that the normal range for a test varies by gender; for Males the normal range is 20-50 and for Females the normal range is 30-70. Suppose that the population whose results are being plotted includes both Males and Females. Then:

- If you click **Maximize Normal range**, the gray area will lie between 20 and 70.
- If you click **Minimize Normal range**, the gray area will lie between 30 and 50.
- If you click **Use Midpoints for Normal Range**, the gray area will lie between $(20+30)/2$ and $(50+70)/2$, that is, between 25 and 60.
- If you click **Use Hatches**, the gray area will lie between 30 and 50, and two hatched areas will also be drawn; one lying between 20 and 30, another between 50 and 70.

Include subject lines	Determines whether a line connecting data for the same subject appears. <ul style="list-style-type: none">• If selected—Includes subject lines. Not recommended for more than 12 subjects.• If deselected—Does not include subject lines.
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Include subject labels	Determines whether to label the first point for a subject with the subject ID. <ul style="list-style-type: none">• If selected—Includes subject labels.• If deselected—Does not include subject labels.
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3. Optionally check any other display options. See [Working with Graphs](#) for information about the following display options: Use gray-scale instead of colors; Key; Notes; and Links.

If you click Notes, information about the **Handle wide normal range boundaries by** option appears below the graph when the graph includes a test for which normal ranges vary across the set of included subjects.

Also included in Notes is a list of subjects for which data points are omitted.

- Click **OK**. The graph is redrawn.


Viewing a Lab Panel

A *lab panel* is a graphic display of lab test results, as compared to normal ranges, for each subject across study visits. The color of cells indicates the relationship of the lab test value to the normal range of values for that lab test, according to the key below the graph. Gray cells show test values that are within the normal range.

If a time frame with a well-defined start is in effect, only subjects who did not [drop out](#) before the time frame start are included in the graph. If any time frame is in effect, only lab test results that occurred within the time frame are shown.

To view a lab panel:

- Do one of the following:

Tab	Steps
Safety Review	On the Lab Results page: Click Lab Panel .
	On the Screening Results page: Click  for a result for a Lab Change from Baseline Analysis or a Clinically Significant Lab Analysis, and then click View Lab Panel .
Screening	On the Analysis Results page: Select a dosing category breakdown and time frame, and then click View Lab Panel .

- Configure the lab panel.
- Depending on how you configured the lab panel, in the Current Test or Current Subject field, select the test or subject for which you want to view results. You can also click **Next** or **Prev** to display the lab panel for the next or previous test or subject.
- Select a lab panel in the Panel field. Values in the Panel field depend on a lab category present in the study data.
- You can filter subjects to include in the lab panel by selecting values in the Dosing, Sex, Race, and Age Group list boxes. Available values depend on how the lab panel is [configured](#).

To select multiple values in a list box, hold down the Ctrl key.

Note: If you do not select anything in a list box, the lab panel does not filter subjects by that particular type of category. For example, suppose the dosing category breakdowns are listed and that they do not include all arms in the study. If you select none of them, the graph includes subjects with any arm in the study.

- In the Subject List field, you can select a subject list to which you have access. The Lab Panel will include only subjects in the selected subject list.

If you are viewing a Lab Panel for a particular result generated by a custom analysis type using a subject list, then that subject list appears in this field as a default.

7. Click **Draw** (or **Redraw** if you have changed options). The categories and subject list (if any) used for the lab panel are shown above the lab panel display.
8. Use the vertical scroll bar to scroll down and see all of the lab panel.
9. If you point to a cell, the following information appears:
 - Value – Lab test value.
 - NormalLo – Lower end of the normal range for the lab test.
 - NormalHi – Upper end of the normal range for the lab test.

If you point to a subject ID, the arm and last visit appear.
10. To view subject details for a subject, click the subject ID hyperlink.
11. You can click **Print** to print the lab panel. For more information, see [Working with Graphs](#).

Graph key

The key below the graph provides information about the lab test value as compared to the normal range. If there are multiple results for a subject's test during the same visit, cell colors are based on the most extreme result. The configuration option for handling multiple results during the same visit has no effect on how colors are determined.

Color Key Label	Meaning	Sample Test Values with Key if Normal Range is 20-30
Low = 1x	The lab test value is less than the lower end of the normal range and greater than or equal to half the lower end of the normal range.	10 through 19.999
Low = 2x	The lab test value is less than half the lower end of the normal range limit and greater than or equal to a third of the lower end of the normal range.	6.667 through 9.999
Low = 3x	The lab test value is less than a third of the lower end of the normal range.	0 through 6.666
High = 1x	The lab test value is greater than the upper end of the normal range and less than or equal to twice the upper end of the normal range.	30.001 through 60
High = 2x	The lab test value is greater than twice the upper end of the normal range and less than or equal to three times the upper end of the normal range.	60.001 through 90
High = 3x	The lab test value is greater than three times the upper end of the normal range.	90.001 and above
Indeterminate	Any of the following is true: <ul style="list-style-type: none"> • There is no upper or lower limit for the normal 	

range.

- There is no lower limit of normal and the result is not greater than or equal to the upper limit of normal.
- There is no upper limit of normal and the result is not less than or equal to the lower limit of normal.

More detail

Visits represented in the lab panel are distinct values of the LB.VISITNUM variable where the LB.LBCAT value matches the specified panel.

The test names shown in the display are in the following format: LBTESTCD —LBTEST. If there are multiple LBTEST values for the same LBTESTCD value, the alphabetically last one is used; if you are showing one page per subject, only the LBTEST values for the subject are considered.

Configuring a Lab Panel

1. In the [Lab Panel window](#), click **Configure**.
2. Change any of the following display options:

Option	Description
Basis for Categories—Dosing	<p>Determines the options that appear in the Dosing list box. On the Safety Review tab, the options are:</p> <ul style="list-style-type: none"> • Values of ARM—Lists all non-null arm values from the study data. • Dosing category breakdown—Available if you have configured safety review to use a dosing category breakdown; list categories from the breakdown. <p>On the Screening tab, the options are:</p> <ul style="list-style-type: none"> • Values of ARM—Lists all non-null arm values from the study data. • Dosing category breakdown—Lists categories from the currently selected dosing category breakdown.
Basis for Categories—Sex	<p>Determines the options that appear in the Sex list box. On the Safety Review tab, the options are:</p> <ul style="list-style-type: none"> • Values of SEX—Lists all non-null sex values from the study data.

- **Default breakdown**—Available if there is a default sex category breakdown; lists categories from the breakdown.

On the Screening tab, the options are:

- **Values of SEX**—Lists all non-null sex values from the study data.
- **Analysis Specification**—Available if a sex category breakdown was specified in the analysis specification; lists categories from the breakdown.

Basis for
Categories—Race

Determines the options that appear in the Race list box.
On the Safety Review tab, the options are:

- **Values of RACE**—Lists all non-null race values from the study data.
- **Default breakdown**—Available if there is a default race category breakdown; lists categories from the breakdown.

On the Screening tab, the options are:

- **Values of RACE**—Lists all non-null race values from the study data.
- **Analysis Specification**—Available if a race category breakdown was specified in the analysis specification; lists categories from the breakdown.

Basis for
Categories—Age

Determines the options that appear in the Age Group list box.
On the Safety Review tab, the options are:

- **AGE quartiles**—Lists automatically computed quartiles based on non-null age values from the study data.
- **Default breakdown**—Available if there is a default age category breakdown; lists categories from the breakdown.

On the Screening tab, the options are:

- **AGE quartile**—Lists automatically computed quartiles based on non-null age values from the study data.
 - **Analysis Specification**—Available if an age category breakdown was specified in the analysis specification;
-

lists categories from the breakdown.

For multiple results per visit, use	<p>Determines the value used when there are multiple results per visit. The options are:</p> <ul style="list-style-type: none"> • Highest value—If there are multiple values for a subject's test during the same visit, shows the highest of those values. • Average value—If there are multiple values for a subject's test during the same visit, shows the average of those values. • Lowest value—If there are multiple values for a subject's test during the same visit, shows the lowest of those values. <hr/> <p>Note: Regardless of this setting, if there are multiple results for a subject's test during the same visit, cell colors are based on the most extreme result.</p>
Display	<p>Determines data display. The options are:</p> <ul style="list-style-type: none"> • One subject per page—Lab data for each subject is shown on its own page. You can select the subject for which to show lab data. • One test per page—Lab data for each test is shown on its own page. You can select the test for which to show lab data. • All data on one page—Lab data for all subjects and tests is shown on the same page.
Show data values	<p>Determines whether lab test result values appear in cells of the lab panel.</p> <ul style="list-style-type: none"> • If selected—Data values are shown. • If deselected—Data values are not shown.

3. Optionally check any other display options. See [Working with Graphs](#) for information about the following display options: Use gray-scale instead of colors; Key; Notes; and Links.
4. If a lab panel is showing data values and there are multiple test results for the same subject and visit, the Notes tell you how the multiple test results are handled.
5. Click **OK**. The lab panel is redrawn.

Viewing an LFT Shift from Baseline Scatter Plot

The LFT Shift from Baseline to Maximum graph provides a way to identify elevations in post-baseline Liver Function Test values relative to baseline LFT values. A post-baseline result is one for which the value of LB.LBBLFL is not 'Y' and that occurs after the baseline result. Baseline is established as described in [Baseline Results](#).

The graph displays a scatter plot for each of the four liver function tests:

- Alanine Amniotransferase (ALT)
- Aspartate Amniotransferase (AST)
- Alkaline Phosphatase (ALP)
- Bilirubin (BILI)

In each scatter plot, the x-axis represents baseline values and the y-axis represents maximum post-baseline values. Only numeric values are plotted.

The graph plots normalized values, that is, values divided by the upper limit of normal. If a result has no upper limit of normal, it is omitted from the graph.


A key below the graph shows the colors and shapes used to plot values for different dosing categories.

If a time frame with a well-defined start is in effect, only subjects who did not [drop out](#) before the time frame start are included in the graph. If any time frame is in effect, only post-baseline lab test results that occurred within the time frame are shown. If the LBDTC data is missing, results for those subjects are not included.

You must have [defined test identifiers](#) for the appropriate lab tests to view the LFT Shift from Baseline Scatter Plot.

To view an LFT Shift from Baseline Scatter Plot:

1. Do one of the following:

Tab	Steps	Notes
Domains	Click  in the Listings column for the LB domain, and then click LFT Scatter Plots: Shift from Baseline.	The graph uses the default dosing category breakdown for the study or study pool. If there is no default dosing category breakdown, it groups all arms into one category named "Treatment: Any".
Safety Review	On the Lab Results page, click LFT Scatter Plots: Shift from Baseline.	The graph uses the currently selected dosing category breakdown. If there is no dosing category breakdown selected, it groups all arms into one category named "Treatment: Any".

2. [Configure the graph.](#)
3. To [drill down](#) to subject information, point to the graph, click, and hold down the mouse button while you draw a red rectangle around the data points for which you want to drill down, making sure that you do not include any of the gray background above or below the graph. When you release the mouse button, a menu appears and you can drill down. Note that a single plotted symbol in the graph may represent several data points if they have the same or similar values.
4. To display an individual graph enlarged in its own window, click **Zoom** in the menu described in the previous step.
5. To print or copy the graph, see [Working with Graphs](#).

More detail

The following situations may prevent the graph from displaying or cause data points to be omitted from the graph. If you configure the graph to show notes, subjects for whom data points are omitted for these reasons are listed. The notes do not pertain to data points that are omitted due to restrictions imposed by time frames or dosing category breakdowns.

Note: LBSTNRLO is checked only if the graph is restricted to subjects with normal baseline values.

Situation	Variables	Effect
A required variable is not found.	LB.LBSTRESN LB.LBSTNRLO LB.LBSTNRHI LB.LBTSTID_ LB.LBDTC	Graph is not displayed.
Test identifiers have not been defined.	All LB variables	Graph is not displayed.
An internal error occurred for the value of a variable, possibly because the variable does not have the expected data type.	LB.USUBJID LB.LBSTRESN LB.LBSTNRLO LB.LBSTNRHI	Data point is omitted from graph.
A Null value is found for a variable expected to have a non-null value.	LB.LBSTRESN LB.LBSTNRLO LB.LBSTNRHI	Data point is omitted from graph.
The value of ULN is 0, which makes normalization of the result impossible	LBSTNRHI	Data point is omitted from graph.
An internal error occurred when dividing the raw result by the upper limit of normal, possibly because the value of ULN is extremely small.	LB.LBSTRESN / LB.LBSTNRHI	Data point is omitted from graph.

Configuring an LFT Shift from Baseline Scatter Plot

1. In the [graph display window](#), click **Configure**.
2. Specify the following display options:

Option	Description
Axis type	<p>Indicates the axis type. The options are:</p> <ul style="list-style-type: none"> • Linear—The x-axis and y-axis are linear. • Log—The x-axis and y-axis are logarithmic. <p>The default value is Log.</p>
X and Y axis low to include X and Y axis high to include	<p>Allows you to modify the low or high values to be included on axes to make the scatter plots more readable.</p> <hr/> <p>Note: The axes include your specified values, but do not necessarily start or end with them.</p> <ul style="list-style-type: none"> • If the "low value" is blank, a default value is used. For linear axes, the default is 0. For log axes, the default is .1. • If the "high value" is blank, the graph uses a high value that encompasses the highest value in the data.
Points outside the range are:	<p>Determines how data points that fall outside the boundary of either axis are handled. The options are:</p> <ul style="list-style-type: none"> • Plotted at the axis boundary—Data points are plotted along the x or y axis. • Omitted from the display—Data points that fall outside the boundary of either axis do not appear in the graph. <p>No warning is issued in either of these situations.</p>
First reference line at Second reference line at Third reference line at	<p>Defines up to three reference lines to assist in graph interpretation. Enter a numeric value to indicate the x/y value at which each reference line will appear. For each reference line that you specify, a green line is drawn at the specified value on both the x-axis and the y-axis.</p>
Include linear regression lines	<p>Determines whether least-squares regression lines for treatment groups appear in each scatter plot.</p> <ul style="list-style-type: none"> • If selected—Linear regression lines appear.

- **If deselected**—Linear regression lines do not appear.

Include 45-degree line	Determines whether a 45-degree line ($x=y$) appears in each scatter plot. Points to the left of the 45-degree line represent LFT values that have increased as compared to baseline. Points to the right of the 45-degree line represent LFT values that have decreased as compared to baseline.
	<ul style="list-style-type: none"> • If selected—A 45-degree line appears. • If deselected—A 45-degree line does not appear.
Restrict to subjects normal at baseline	Determines whether to plot data only for subjects that had a normal result for the lab test at their baseline visit.
Display graph with all arms included in Treatment	Determines whether to plot data for all arms in the study data as a single group labeled Treatment and the graph key shows Treatment: Any . <ul style="list-style-type: none"> • If selected—Plots data with all arms included in Treatment. • If deselected—Plots data for the Treatment and Comparator categories. <p>For the Domains tab, you can deselect this option only if there is a default dosing category breakdown for the study or study pool.</p> <p>For the Safety Review tab, you can deselect this option only if there is a dosing category breakdown currently selected as a safety review configuration option.</p>

- Optionally check any other display options. See [Working with Graphs](#) for information about the following display options: Use gray-scale instead of colors; Key; Notes; and Links.
- If you check Notes, the following information will appear below the graph:
 - Name of user who produced the graph, datetime the graph was produced, and the application/study
 - Configuration options specified for the graph
 - List of any subject IDs for which there are data problems that prevent data points from displaying in the graph
- Click **OK**.

Viewing an LFT Scatter Plot Matrix

The Maximum LFT Results graph provides a way to identify maximum post-baseline LFT values that are elevated simultaneously in pairs of liver function tests. A post-baseline result

is one for which the value of LB.LBBLFL is not 'Y' and that occurs after the baseline result. Baseline is established as described in [Baseline Results](#). Note that a baseline is established separately for each test.

A scatter plot is displayed for each pairwise combination of the four liver function tests:

- Alanine Aminotransferase (ALT)
- Aspartate Aminotransferase (AST)
- Alkaline Phosphatase (ALP)
- Bilirubin (BILI)

Keep in mind that:


- Results for the pair of tests do not need to have occurred on the same date.
- In each scatter plot, the x-axis represents maximum values for one of the liver function tests, and the y-axis represents maximum values for another of the liver function tests. Only numeric values are plotted.
- The graph plots normalized values, that is, values divided by the upper limit of normal. If a test's upper limit of normal cannot be determined, the result is omitted from the graph.
- The range of values is determined by the lowest and highest value among all subjects' values across all post-baseline visits.

If a time frame with a well-defined start is in effect, only subjects who did not [drop out](#) before the time frame start are included in the graph. If any time frame is in effect, only post-baseline lab test results that occurred within the time frame are shown. If the LBDTC data is missing, results for those subjects are not included.

You must have [defined test identifiers](#) for the appropriate lab tests to view the LFT Scatter Plot Matrix graph.

To view an LFT Scatter Plot Matrix:

1. Do one of the following:

Tab	Steps	Notes
Domains	Click  in the Listings column for the LB domain, and then click LFT Scatter Plot Matrix: Maximum Results .	The graph uses the default dosing category breakdown for the study or study pool. If there is no default dosing category breakdown, it groups all arms into one category named "Treatment: Any".
Safety Review	On the Lab Results page , click LFT Scatter Plot Matrix: Maximum Results .	The graph uses the currently selected dosing category breakdown. If there is no dosing category breakdown

selected, it groups all arms into one category named "Treatment: Any".

2. [Configure the graph.](#)
3. To [drill down](#) to subject information, point to the graph, click, and hold down the mouse button while you draw a red rectangle around the data points for which you want to drill down, making sure that you do not include any of the gray background above or below the graph. When you release the mouse button, a menu appears and you can drill down. Note that a single plotted symbol in the graph may represent several data points if they have the same or similar values.
4. To display an individual graph enlarged in its own window, click **Zoom** in the menu described in the previous step.
5. To print or copy the graph, see [Working with Graphs](#).

More detail

The following situations may prevent the graph from displaying or cause data points to be omitted from the graph. If you configure the graph to show notes, subjects for whom data points are omitted for these reasons are listed. The notes do not pertain to data points that are omitted due to restrictions imposed by time frames or dosing category breakdowns.

Note: LBSTNRLO is checked only if the graph is restricted to subjects with normal baseline values.

Situation	Variables	Effect
A required variable is not found.	LB.LBSTRESN LB.LBSTNRLO LB.LBSTNRHI LB.LBTSTID_ LB.LBDTC	Graph is not displayed.
Test identifiers have not been defined.	All LB variables	Graph is not displayed.
An internal error occurred for the value of a variable, possibly because the variable does not have the expected data type.	LB.USUBJID LB.LBSTRESN LB.LBSTNRLO LB.LBSTNRHI	Data point is omitted from graph.
A Null value is found for a variable expected to have a non-null value.	LB.LBSTRESN LB.LBSTNRLO LB.LBSTNRHI	Data point is omitted from graph.
The value of ULN is 0, which makes normalization of the result impossible.	LBSTNRHI	Data point is omitted from graph.
An internal error occurred when dividing the raw result by the upper limit of normal, possibly	LB.LBSTRESN / LB.LBSTNRHI	Data point is omitted from

because the value of ULN is extremely small.

graph.

Configuring an LFT Scatter Plot Matrix

1. In the [graph display window](#), click **Configure**.
2. Specify the following display options:

Option	Description
Axis type	<p>Indicates the axis type. The options are:</p> <ul style="list-style-type: none"> • Linear—The x-axis and y-axis are linear. • Log—The x-axis and y-axis are logarithmic. <p>The default value is Log.</p>
X and Y axis low to include	Allows you to modify the low or high values to be included on axes to make the scatter plots more readable.
X and Y axis high to include	<p>Note: The axes include your specified values, but do not necessarily start or end with them.</p> <ul style="list-style-type: none"> • If the low value is blank, a default value is used. For linear axes, the default is 0. For log axes, the default is .1. • If the high value is blank, a high value that encompasses the highest value in the data is used.
Points outside the range are:	<p>Determines whether data points that fall outside the boundary of either axis are plotted. The options are:</p> <ul style="list-style-type: none"> • Plotted at the axis boundary—Data points appear along the x or y axis. • Omitted from the display—Data points do not appear in the graph. <p>No warning appears in either of these situations.</p>
Reference line(s) for Alanine Aminotransferase (ALT) at	Specify up to three reference lines for each test, or clear the fields if no reference lines should appear. Specify positive values delimited by commas. For example:
Reference line(s) for Alkaline Phosphatase (ALP)	<ul style="list-style-type: none"> • To include reference lines at 1x ULN and 2x ULN, specify 1, 2. • To include reference lines at 0.75x ULN, 1x ULN, and 2x ULN, specify 0.75, 1.0, 2.0.
Reference line(s) for Aspartate	WebSDM/Empirica Study ignores extra commas and additional

Aminotransferase (AST)	values specified beyond the third value. The default reference lines for each test are at:
Reference line(s) for Bilirubin (BILI) at	<ul style="list-style-type: none"> • ALT—3.0 • ALP—2.0 • AST—3.0 • BILI—2.0
Include linear regression lines	<p>Determines whether least-squares regression lines appear for treatment groups in each scatter plot.</p> <ul style="list-style-type: none"> • If selected—Linear regression lines appear. • If deselected—Linear regression lines do not appear.
Include ULN boundaries	<p>Determines whether a 1x ULN-bounded region appears at 1.0 on each axis.</p> <ul style="list-style-type: none"> • If selected—ULN boundaries appear. • If deselected—ULN boundaries do not appear.
Restrict to subjects normal at baseline	Determines whether to plot data for only subjects that had a normal result for the lab test at their baseline visit.
Display graph with all arms included in Treatment	<p>Select to plot data for all arms in the study data as a single group labeled "Treatment" and the graph key shows "Treatment: Any".</p> <p>Deselect to plot data for the Treatment and Comparator categories separately.</p> <p>For the Domains tab, this option can be cleared only if there is a default dosing category breakdown for the study or study pool.</p> <p>For the Safety Review tab, this option can be cleared only if there is a dosing category breakdown currently selected as a safety review configuration option.</p>
Use gray-scale instead of colors	Indicates whether the graph appears using shades of gray or color.
Key	Indicates whether a color key appears below the graph to indicate the values that each graph element represents.
Notes	<p>If you check Notes, the following information will appear below the graph:</p> <ul style="list-style-type: none"> • Name of user who produced the graph, datetime the graph was produced, and the application/study. • Configuration options specified for the graph. • List of any subject IDs for which there are data

problems that prevent data points from displaying in the graph.

Links	Indicates whether the following links and options appear:
	<ul style="list-style-type: none"> • Drilldown menu options when you point to a plot point. • Print link

3. Click **OK**.

Viewing a Change from Baseline Box Plot

The Change from Baseline Box Plot shows the values of changes in numeric lab or vital sign measurements from baseline measurements. Baseline is established as described in [Baseline Results](#). For information on interpreting box plots, see [Box Plots](#).


Note: Points in these box plots are "jittered" (displayed at small random offsets from the center line) so that if two results have the same value, a point is likely to be visible for each of them.

If a time frame with a well-defined start is in effect, only subjects who did not [drop out](#) before the time frame start are included in the graph. If any time frame is in effect, only post-baseline lab test results that occurred within the time frame are shown.

When displayed on the Safety Review tab, this graph uses values of the LB.LBTEST or VS.VSTEST variable. When displayed on the Screening tab, it uses values of the LB.LBTESTCD or VS.VSTESTCD variable.

To view a Change from Baseline Box Plot:

1. Do one of the following:

Tab	Steps to View the Box Plot	Notes
Safety Review	On the Lab Results page or Vital Signs page , click the Action menu icon () for a specific lab test or vital sign, and then click Box Plot: Change from Baseline .	The graph uses your safety review configuration options for Use maximum (instead of most recent) change from baseline .
	On the Screening Results page: For the result of a Lab or Vitals Change from Baseline analysis, click View as Box Plot to display the graph for Treatment and Comparator or View as Box Plot by Dose Group to display the graph for each arm in Treatment and	The graph uses the analysis specification's setting for Use maximum (instead of most recent) change from baseline . If the setting differs from your safety review configuration option, a warning message appears.

Comparator.		
Screening	On the Analysis Results page: For the result of a Lab or Vitals Change from Baseline analysis, click View as Box Plot to display the graph for Treatment and Comparator or View as Box Plot by Dose Group to display the graph for each arm in Treatment and Comparator.	The graph uses the analysis specification's setting for Use maximum (instead of most recent) change from baseline.

2. If you point to a region of a box plot, the region of the box and a count of data points for that region appears.

Note: The count of data points may be more than the count of subjects that will be listed when you drill down, because a subject may have multiple values for a lab test or vital sign.

3. If you click on a region of a graph, a menu appears and you can [drill down](#) to subjects represented by that region. You can drill down on the following box plot regions: Upper Outlier, Upper Whisker, Upper Box, Lower Box, Lower Whisker, Lower Outlier.

If a subject has a value on the boundary between adjacent regions (not including the Upper Outlier or Lower Outlier regions), the subject ID is included when you drill down on either of the regions. Subjects with values on the boundary of the Upper Whisker or Lower Whisker are not included when you drill down on the Upper Outlier or Lower Outlier regions.

4. To print or copy the graph, see [Working with Graphs](#).

Viewing a Change from Baseline Delta Plot

The Change from Baseline Delta Plot shows changes from baseline for the numeric results of lab tests or vital signs. Baseline is established as described in [Baseline Results](#).

The x-axis represents a change from baseline value. The change from baseline is computed for each subject and is represented by a horizontal line extending from the vertical line positioned at 0 on the x-axis. (If there are many subjects, lines may appear on top of each other because of space limitations.) If a subject has no change from baseline, a tiny horizontal line appears across the vertical line at 0 on the x-axis.

The horizontal lines that represent change from baseline are ordered starting with the greatest change from baseline (which appears at the top of each plot) and ending with the lowest change from baseline (which appears at the bottom of each plot).


The tick marks displayed along the y-axis are decile cutpoints indicating the percentage of subjects whose change from baseline is less than the value indicated by the horizontal line at that percentage.

If a time frame with a well-defined start is in effect, only subjects who did not [drop out](#) before the time frame start are included in the graph. If any time frame is in effect, only post-baseline lab test results that occurred within the time frame are shown.

When displayed on the Safety Review tab, this graph uses values of the LB.LBTEST or VS.VSTEST variable. When displayed on the Screening tab, it uses values of the LB.LBTESTCD or VS.VSTESTCD variable.

To view a Change from Baseline Delta Plot:

1. Do one of the following:

Tab	Steps to View the Delta Plot	Notes
Safety Review	On the Lab Results page or Vital Signs page : Click the Action menu icon () for a specific lab test or vital sign, and then click Delta Plot: Change from Baseline .	The graph uses your safety review configuration options for Use maximum (instead of most recent) change from baseline .
	On the Screening Results page: For the result of a Lab or Vitals Change from Baseline analysis, click View as Delta Plot or display the graph for Treatment and Comparator or View as Delta Plot by Dose Group to display the graph for each arm in Treatment and Comparator.	The graph uses the analysis specification's setting for Use maximum (instead of most recent) change from baseline . If the setting differs from your safety review configuration option, a warning message appears.
Screening	On the Analysis Results page: For the result of a Lab or Vitals Change from Baseline analysis, click View as Delta Plot to display the graph for Treatment and Comparator or View as Delta Plot by Dose Group to display the graph for each arm in Treatment and Comparator.	The graph uses the analysis specification's setting for Use maximum (instead of most recent) change from baseline .

2. If you point to a decile region of the graph, the number of the decile and a count of data points for that decile appears.

Note: The count of data points may be more than the count of subjects that will be listed when you drill down, because a subject may have multiple values for a lab test or vital sign.

3. If you click on a decile region of a graph, you can [drill down](#) to subjects represented by that region.

Note: If a subject has a value that is on the boundary between two decile regions, the subject ID is included when you drill down on either of the two regions.

4. To print or copy the graph, see [Working with Graphs](#).

Viewing a Shift from Baseline Scatter Plot

The Shift from Baseline Scatter Plot provides a way to identify shifts in post-baseline lab results or vital sign measurements relative to baseline values. A post-baseline result is one for which the value of LB.LBBLFL (for a graph showing lab tests) or VS.VSBLFL (for a graph showing vital signs) is not 'Y' and that occurs after the baseline result. Baseline is established as described in [Baseline Results](#).

The x-axis represents baseline values. You can choose to represent either minimum post-baseline values or maximum post-baseline values on the y-axis. Only numeric values are plotted.


If you display minimum versus baseline, results are divided by the lower limit of normal. If a result does not have a lower limit of normal, it is omitted from the graph. If no results for a test or vital sign have a lower limit of normal, then actual results from the study data are plotted.

If you display maximum versus baseline, results are divided by the upper limit of normal. If a result does not have an upper limit of normal, it is omitted from the graph. If no results for a test or vital sign have an upper limit of normal, then actual results from the study data are plotted.

A key below the graph shows the colors and shapes used to plot values for different dosing categories.

If a time frame with a well-defined start is in effect, only subjects who did not [drop out](#) before the time frame start are included in the graph. If any time frame is in effect, only post-baseline lab test results that occurred within the time frame are shown.

To view a Shift from Baseline Scatter Plot:

1. On the Safety Review tab: On the [Lab Results page](#) or [Vital Signs page](#), click  for a specific lab test or vital sign and then click **Scatter Plot: Shift from Baseline**. In the menu that appears, click **Minimum vs. Baseline** or **Maximum vs. Baseline**.
2. [Configure the graph](#).
3. To [drill down](#) to subject information, point to the graph, click, and hold down the mouse button while you draw a red rectangle around the data points for which you want to drill down, making sure that you do not include any of the gray background above or below the graph. When you release the mouse button, a menu appears and you can drill down. Note that a single plotted symbol in the graph may represent several data points if they have the same or similar values.
4. To print or copy the graph, see [Working with Graphs](#).

More detail

The following situations may prevent the graph from displaying or cause data points to be omitted from the graph. If you configure the graph to show notes, subjects for whom data points are omitted for these reasons are listed. The notes do not pertain to data points that are omitted due to restrictions imposed by time frames or dosing category breakdowns.

Note: __STNRHI is checked only if the graph is for Maximum vs. Baseline or is restricted to subjects with normal baseline values. __STNRLO is checked only if the graph is for Minimum vs. Baseline or is restricted to subjects with normal baseline values.

Situation	Variables	Effect
A required variable is not found.	__STRESN __DTC	Graph is not displayed.
An internal error occurred for the value of a variable, possibly because the variable does not have the expected data type.	USUBJID __STRESN __STNRLO __STNRHI	Data point is omitted from graph.
A Null value is found for a variable expected to have a non-null value.	__STRESN __STNRLO __STNRHI	Data point is omitted from graph.
The value of ULN or LLN (depending on which limit is used to normalize the raw result) is 0, which makes normalization of the result impossible.	__STNRLO __STNRHI	Data point is omitted from graph.
An internal error occurred when dividing the raw result by the lower or upper limit of normal, possibly because the value of LLN or ULN is extremely small.	__STRESN / __STNRHI or __STRESN / __STNRLO	Data point is omitted from graph.

Configuring a Shift from Baseline Scatter Plot

1. In the [graph display window](#), click **Configure**.
2. Specify the following display options:

Option	Description
Axis type	<p>Determines the x and y axis types. The options are:</p> <ul style="list-style-type: none"> • Linear—The x-axis and y-axis are linear. • Log—The x-axis and y-axis are logarithmic.
X and Y axis low to include X and Y axis high to include	<p>Allows you to modify the low or high values to be included on axes to make the scatter plots more readable.</p> <hr/> <p>Note: The axes include your specified values, but do not necessarily start or end with them.</p> <hr/> <ul style="list-style-type: none"> • If the low value is blank, a default value is used. For linear axes, the default is 0. For log axes, the default is .1. • If the high value is blank, a high value that encompasses the highest value in the data is used.
Points outside the	Determines the placement of data points that fall outside axis

range are:

boundaries. The options are:

- **Plotted at the axis boundary**—Data points that fall outside the boundary of either axis are plotted along that axis.
- **Omitted from the display**—Data points that fall outside the boundary of either axis do not appear in the graph.

No warning is issued in either of these situations.

First reference line at Second reference line at Third reference line at	Define up to three reference lines to assist in graph interpretation. Enter a numeric value to indicate the x/y value at which each reference line will appear. For each reference line that you specify, a green line is drawn at the specified value on both the x-axis and the y-axis.
Include linear regression lines	<p>Determines whether least-squares regression lines for treatment groups appear in each scatter plot.</p> <ul style="list-style-type: none"> • If selected—Linear regression lines are included. • If deselected—Linear regression lines are not included.
Include 45-degree line	<p>Determines whether a 45-degree line ($x=y$) appears in each scatter plot. Points to the left of the 45-degree line represent data values that have increased as compared to baseline. Points to the right of the 45-degree line represent LFT values that have decreased as compared to baseline.</p> <ul style="list-style-type: none"> • If selected—45-degree line is included. • If deselected—45-degree line is not included.
Restrict to subjects normal at baseline	<p>Determines whether to plot data only for subjects that had a normal result for the lab test at their baseline visit.</p> <ul style="list-style-type: none"> • If selected—Restricts to subjects normal at baseline. • If deselected—Does not restrict subjects.

3. Optionally check any other display options. See [Working with Graphs](#) for information about the following display options: Use gray-scale instead of colors; Key; Notes; and Links.

If you check Notes, the following information will appear below the graph:

- Name of user who produced the graph, datetime the graph was produced, and the application/study
- Configuration options specified for the graph

- List of any subject IDs for which there are data problems that prevent data points from displaying in the graph

4. Click **OK**.

Viewing a Box Plot of Distribution over Time

The lab or vitals Distribution over Time box plot provides the following information for lab test results or vital sign measurements:

- The main graph of box plots shows either change from baseline values, normalized raw values (that is, test values divided by the upper limit of normal), or raw values (actual results from the study data) for subjects at a series of visits (the x-axis). Baseline is established as described under **Baseline using baseline flag** in [Baseline Results](#).

The visit numbers (**Visit** values) represented on the x-axis are determined by [study visit descriptions](#) for the study. If the visit number cannot be determined for a value, the value is omitted from the graph.

- An area to the right of the main graph shows box plots of the minimum and maximum change from baseline values, normalized values, or raw values for all subjects in the study across visits (possibly including visits not represented in the main graph, depending on the setting of the **Compute max box plots over displayed visits only** configuration option for the graph). If the graph is showing change from baseline values, minimum and maximum values for a subject are determined using the signed values of change from baseline instead of the absolute values of change from baseline; for example, if a subject's change from baseline values are -10, -3, 2, and 7, the minimum is -10 and the maximum is 7.
- For each visit, counts of subjects with results for the lab test or vital sign are shown below the main graph.


Note: Only numeric results are plotted.

For information on interpreting box plots, see [Box Plots](#).

Time frames have no effect on this graph. All subjects and all test results are included in the graph.


To view a Distribution over Time Box Plot:

- Do one of the following:

Tab	Steps to View the Box Plot	Notes
Domains	Click the Action menu icon () in the Listings column for the LB domain, and then click LFT Box Plot: Distribution of <LFT> over Time .	The graph shows arms or Treatment and Comparator categories, depending on how you configure the graph. The graph always shows change from baseline values.

You must have [defined test identifiers](#) for the appropriate lab tests to view a Distribution over Time box plot from the Domains tab.

Safety Review

On the [Lab Results page](#) or [Vital Signs page](#), click the Action menu icon () for a specific lab test or vital sign, click **Box Plot: Distribution over Time**, and then click one of the following:

- **Normalized Raw Values**—Available if at least one result for the test has a non-null upper limit of normal. Show normalized values, that is, test values divided by the upper limit of normal. If a test's upper limit of normal cannot be determined, the result is omitted from the graph.
- **Change from Baseline**—Available if at least one result for the test has a non-null baseline flag. Show change from baseline values, that is, baseline values subtracted from the test values. If a test's baseline value cannot be determined, the result is omitted from the graph.
- **Raw Values**—Show actual results from the study data.

If you have [configured safety review](#) to use arms, the graph includes all arms as a single group; the arms are not restricted to those actually included in the Treatment and Comparator categories.

If you configured safety review to use a dosing category breakdown, the graph includes the Treatment category and Comparator category that are defined by that dosing category breakdown.

2. [Configure the graph](#).
3. If you configure the graph to show Links, you can point to a region of the graph to display the following:
 - The region of the box (Upper Outlier, Upper Whisker, Upper Box, Lower Box, Lower Whisker, or Lower Outlier).
 - The count of data points for the visit number and box plot region (only one lab test or vital sign value is counted per subject and visit number).

4. If you configure the graph to show Links: If you click a region (Upper Outlier, Upper Whisker, Upper Box, Lower Box, Lower Whisker, or Lower Outlier) of a box plot, a menu appears and you can [drill down](#) to subjects for that region. If you click the Upper Outlier region, all subjects with values that are upper outliers are listed when you drill down, including those with values outside the y-axis (shown in a separate area above the graph).

The counts of subjects with values outside the y-axis (above the main graph) and the subject counts in the **Subjects at Visit** section below the graph are hyperlinks that you can click to drill down.

If a subject has a value on the boundary between adjacent regions (not including the Upper Outlier or Lower Outlier regions), the subject ID is included when you drill down on either of the regions. Subjects with values on the boundary of the Upper Whisker or Lower Whisker are not included when you drill down on the Upper Outlier or Lower Outlier regions.

5. To zoom in on data for a study day or range of study days, double-click and draw a red rectangle around the data points for those days or the x-axis tick marks for those days, making sure that you do not include any of the gray background above or below the graph. When you then single-click, a zoom window appears.

Note: When you have zoomed in, the Min and Max section of the graph is based on only data points in the zoom window.

6. To print or copy the graph, see [Working with Graphs](#).

More detail

The following situations may prevent the graph from displaying or cause data points to be omitted from the graph. If you configure the graph to show notes, subjects for whom data points are omitted for these reasons are listed. The notes do not pertain to data points that are omitted due to restrictions imposed by dosing category breakdowns.

Note:

- ☐DTC is checked only if the **Handling of multiple results at same visit** option is set to **Select first result** or **Select last result**.
- ☐BLNRS is checked only if change from baseline values are shown or the graph is restricted to subjects with normal baseline values.
- ☐STNRHI is checked only if normalized values are shown or the graph is restricted to subjects with normal baseline values.
- ☐STRNLO is checked only if the graph is restricted to subjects with normal baseline values.

Situation	Variables	Result
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A required variable is not found.	__STRESN __BLNRS_ __STNRHI __TESTCD __DTC	Graph is not displayed.
No records for the test were found, as would be the case for an invalid test identifier.		Data point is omitted from graph.
An internal error occurred for the value of a variable, possibly because the variable does not have the expected data type.	USUBJID __STRESN __BLNRS_ __STNRHI	
A Null value is found for a variable expected to have a non-null value.	__STRESN __BLNRS_ __STNRHI	Data point is omitted from graph.
The value of ULN is 0, which makes normalization of the result impossible.	__STNRHI	Data point is omitted from graph.
An internal error occurred when dividing the raw result by the upper limit of normal, possibly because the value of ULN is extremely small.	__STRESN / __STNRHI	Data point is omitted from graph.

Configuring a Box Plot of Distribution over Time

1. On the [graph display page](#), click **Configure**.
2. Specify the following display options:

Option	Description
Y axis low to include	Modifies the low or high values to be included on the y-axis to make the box plots more readable.
Y axis high to include	<p>Note: The y-axis includes your specified values, but does not necessarily start or end with them.</p> <ul style="list-style-type: none"> • If the low value is blank, a default value is used. • If the high value is blank, a high value that encompasses the highest value in the data is used. • If you set the y axis high and some values are above it, a section above the graph shows counts of subjects with those values. However, you cannot show counts of subjects with values below the Y axis low.
First reference line at, Second	Defines up to three reference lines to assist in graph interpretation. Specify a numeric value to indicate the y value

reference line at, Third reference line at	at which each reference line will appear. For each reference line that you specify, a green line is drawn at the specified value on the y-axis.
Place visits along X axis	<p>Tick marks on the x-axis are always ordered according to their average study day value, as determined by the study visit descriptions. The following options indicate how much space will appear between tick marks on the x-axis. The options are:</p> <ul style="list-style-type: none"> • By study day—The space between tick marks will reflect the differences in average study day values for tick marks. For example, if the average study day value for Visit 3 is 1 less than the average study day value for Visit 4, there will be little space between Visit 3 and Visit 4 tick marks. <p>If multiple tick marks have the same average study day value, a note tells you to configure the graph to show evenly spaced tick marks.</p> <ul style="list-style-type: none"> • Evenly spaced—All intervals between tick marks on the x-axis will be the same.
Handling of multiple results at the same visit	<p>Indicates which value to use if multiple results occurred at the same visit. The options are:</p> <ul style="list-style-type: none"> • Select first result—Plot the result from the earliest test (LB.LBDTC or VS.VSDTC value) for the subject visit. • Select last result—Plot the result from the latest test (LB.LBDTC or VS.VSDTC value) for the subject visit. • Select maximum result—Plot the maximum result for the subject visit. • Select minimum result—Plot the minimum result for the subject visit. • Compute average—Plot the average of values for the subject visit. <p>Note: If multiple test results are recorded for the same test at the same visit and the same date and time, the option Select first result selects the first result arbitrarily and Select last result selects the last result arbitrarily.</p>
Compute max box plots over displayed visits only	<p>Indicates how max box plots are computed.</p> <ul style="list-style-type: none"> • If selected—Computes maximum values (shown to the right of the main graph) across only the visits displayed in the graph. • If deselected—Computes maximum values across all visits.
Restrict to subjects	Check to restrict the graph to only subjects whose test values

normal at baseline were normal at baseline.

Plot data for Available on the Domains tab only. The options are:

- **Treatment and Comparator categories**—Include the Treatment category and Comparator category that are defined by the default dosing category breakdown for the study or study pool.
- **Arms in Treatment or Comparator categories combined**—Include as a single group those arms that are in the Treatment category and Comparator category defined by the default dosing category breakdown for the study or study pool.
- **All arms combined**—Include as a single group all arms; the arms are not restricted to the arms actually included in the Treatment and Comparator categories.

Note: The first two options are available only if there is a default dosing category breakdown for the study or pool.

3. Optionally check any other display options. See [Working with Graphs](#) for information about the following display options: Use gray-scale instead of colors; Key; Notes; and Links.

If you check Notes, the following information will appear below the graph:

- Name of user who produced the graph, datetime the graph was produced, and the application/study.
- Configuration options specified for the graph.
- List of any subject IDs for which there are data problems that prevent data points from displaying in the graph.

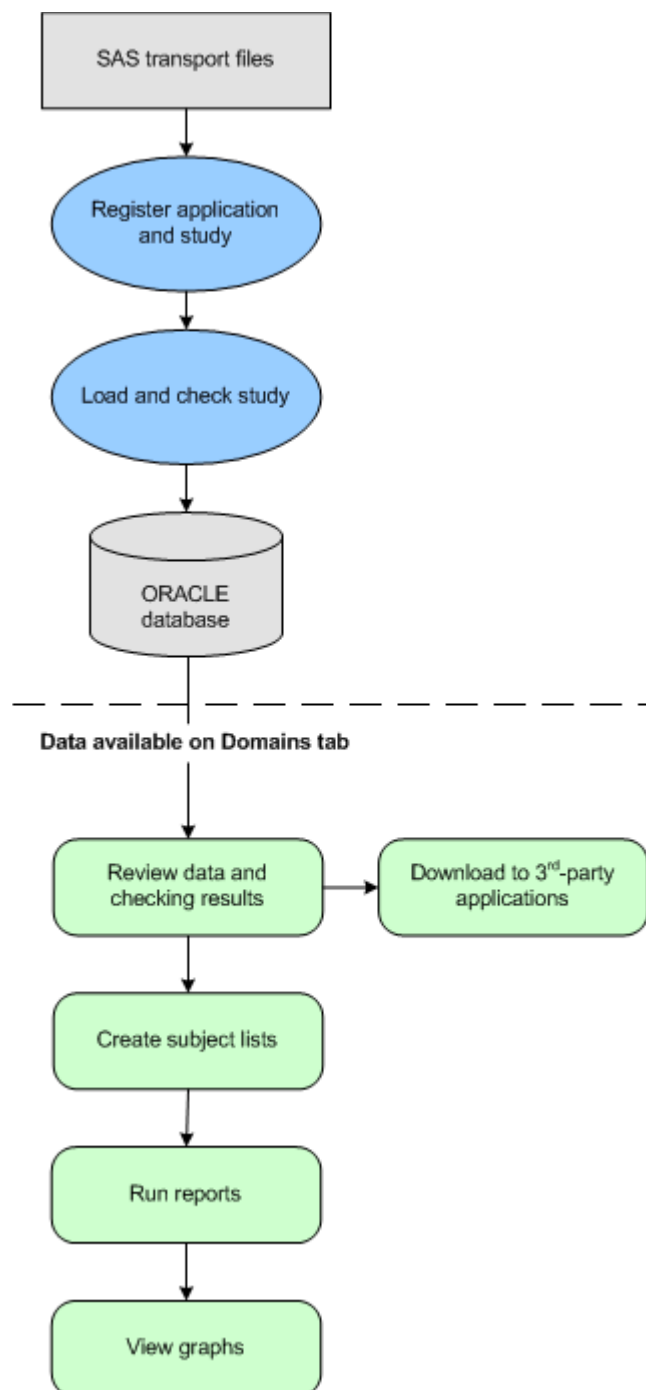
4. Click **OK**.

Domain Data

Domain Data Workflow

After an application and study (or studies) are registered, the study data is loaded and checked, which makes the clinical data, metadata, and any checking results (that is, failed validation checks) available for review on the Domains tab. During review, you can download data to third-party applications for further review and analysis. Within WebSDM/Empirica Study, you can also create lists of subjects based on specified criteria and then produce reports or view graphs. Options to use PPD Patient Profiles® or Stottler Henke DataMontage™ to view graphical representations of data are also available if appropriate [prerequisites](#) are met.

The following diagram shows the basic workflow for working with domain data. Tasks with a blue background are performed by users responsible for loading studies, and tasks with a green background are performed by medical and statistical reviewers.



Viewing Domain Data




A *domain* is a collection of data observations with a topic-specific commonality for clinical subjects; for example, demographics information or adverse events. Once you have [selected a study or study pool](#), you can use the Domains tab. The Study Data Domains page on the Domains tab provides information about the most recently loaded and checked data for all domains in the currently selected study (that is, the study you chose on the Select tab).

The following information appears at the top of the Study Data Domains page:


- Sponsor name, if provided when the application was [registered](#)
- Date and time that data for the study was last updated (that is, loaded and checked)
- For studies loaded from the [Oracle Life Sciences Data Hub](#), the “**Updated data available**” indicator

To view domain data:

1. Select an application and study, and go to the Domains tab. The Study Data Domains page provides a table of the following information about each domain. You can click the value or icon in each column to display further information.

Column	Description
Domain	<p>Abbreviation of the domain. Click the hyperlinked abbreviation to view clinical data for each variable in the domain.</p> <hr/> <p>Note: This column does not show a hyperlink if clinical data was not loaded for the domain. This could occur if there was a problem loading the SAS transport file containing clinical data for the domain, or if the define.xml file referenced a domain for which there was no SAS transport file.</p>
Subjects	<p>Count of subjects with data in the domain. Click the hyperlinked count of subjects to display a pop-up menu that you can use to drill down.</p> <hr/> <p>Note: This column shows "Not Loaded" if clinical data was not loaded for the domain, and it is empty for domains that do not include subject-based data.</p>
Description	<p>Description of the domain. Click the hyperlinked domain description to view metadata for the domain, including the names of variables in the domain.</p> <p>If there is a customer-defined relationship between the domain's clinical data and another domain's data, the  icon appears after the description. For example, there may be a link from adverse event records to concomitant medications records. You can click the icon to display hyperlinks to other domains.</p> <p>If comments are attached to any clinical data in the domain, the  icon appears after the description. You can click the icon to view all comments attached to the clinical data. Comments are part of the study data and may assist you in interpreting the data.</p>
Listings	<p>Displays an icon () that you can click to select from a list of reports and graphs. These may include a Findings report, one of the built-in reports, or one of the following graphs:</p> <p>DS: Kaplan-Meier Plot</p> <p>EG: Distribution of QTc Change over Time</p> <p>EX: Exposure Summary Plot</p> <p>LB: LFT Scatter Plot: Shift from Baseline, LFT Scatter Plot Matrix:</p>

[Maximum Results](#), [LFT Box Plots: Distribution of <LFT> over Time](#)

For the TA, TE, and TV domains, click  to [view the trial design](#).

Download Rows	Count of rows of clinical data for the domain. Note that the number of rows may be greater than the number of subjects. For example, there might be multiple adverse events for the same subject. Click the hyperlinked count of rows to download all clinical data for the domain. See Downloading Data .
	Note: This column shows "Not Loaded" if clinical data was not loaded for the domain.
Variables	Count of variables in the domain. Click the count of variables to view a summary of the variable characteristics. You can also view simple graphs, such as bar graphs for categorical variables or box plots for continuous variables.
	Note: This column is blank if clinical data was not loaded for the domain.
Structure Checks	<p>Appears if you set your user preference "Display error-checking results" to Yes.</p> <p>Count of failed metadata checks found during the most recent loading and checking run for the study or pool. Click the hyperlinked count to view the failed checks included in the count. You can also resolve failed checks.</p> <p>If the number is 0 and is not a hyperlink, then no structure errors occurred for the domain. If the number is 0 and is a hyperlink, errors occurred for the domain but they have been resolved.</p> <p>This column is color-coded as described in About Checking Results.</p>
Consistency Checks	<p>Appears if you set your user preference "Display error-checking results" to Yes.</p> <p>Count of failed consistency checks during the most recent loading and checking run for the study or pool. Click the hyperlinked count to view the failed checks included in the count. You can also resolve failed checks.</p> <p>If the number is 0 and is not a hyperlink, then no consistency errors occurred for the domain. If the number is 0 and is a hyperlink, errors occurred for the domain but they have been resolved.</p> <p>This column is color-coded as described in About Checking Results.</p>

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

- The Study Data Domains page includes several hyperlinks for each domain. You can hover the cursor over a column heading to display a tooltip about which type of information will be displayed when you click a hyperlink in the column.

Description	Listings	Download Rows
Adverse Events	Description of the Domain - Click a link to view domain metadata	

3. Click a hyperlink or icon in the table (see below) to display more detailed information.
4. To [view checking results](#) for all domains in the study, you can click **View Check Results Log**.



Related Topics

[Domain Data Workflow](#)

Viewing Clinical Data for a Domain

1. On the [Study Data Domains page](#), click the hyperlinked name of a domain in the Domain column. The Clinical Data page appears, showing clinical data in a tabular format.

You can also click **View Clinical Data** on the [Checking Results page](#).

2. See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table. If you want to exclude empty columns from the display, click **Columns and Rows** to [arrange table columns](#).
3. Column headings are variable descriptions. If you hover the cursor over a column heading, the variable name appears as a tooltip.
4. To view subject details for a single subject, click the underlined subject ID.
5. If there is a customer-defined relationship between a row and clinical data in another domain, the  icon appears in the USUBJID column. For example, there may be a link from an adverse event record to a concomitant medications record for the same subject. You can click the icon to display a hyperlink to the other domain's clinical data.
6. If there are comments associated with a row, the  icon appears in the USUBJID column. You can click the icon to view comments. Comments are part of the study data and may assist you in interpreting the data.
7. If the __REFID or __SPID variable contains a full and valid internet address in the study data, the column displays a hyperlink that you can click to open a new browser window pointing to that internet address.

Datetime precision

A precision variable (in seconds) is derived for each datetime variable in the domain. The names of the precision variables end in "P_". For more information, see [Derived Variables](#).

On the Clinical Data page, color coding of the precision variable is used to show how much the datetime variable's precision level (seconds, minutes, hours, days, months, years) differs from the precision levels of other variables in the domain.

The color code of the precision variables is one of the following:

- No color – The datetime variable is the **same** precision level as the most precise datetime variable in the domain.

- Yellow – The datetime variable is **one** level less precise than the precision level of any datetime variable in the domain.
- Orange – The datetime variable is **two** levels less precise than the precision level of any datetime variable in the domain.
- Red – The datetime variable is **three or more** levels less precise than the precision level of any datetime variable in the domain.

Viewing Metadata for a Domain

On the [Study Data Domains page](#), click the hyperlinked value in the Description column for the domain.

The **Metadata** page provides the following information for each variable in the domain. To view a tooltip for each column, hover your mouse over a column heading.

Column	Description
VARIABLE	Name of the variable. Variable names ending with an underscore (_) are derived variables .
DESCRIPTION	Description of the variable.
DATATYPE	Character, Number, or Date.
SUPPLIED TERMINOLOGY	<p>Name of the sponsor-defined codelist, if any, associated with the variable. You can click the codelist name to view the contents of the codelist.</p> <p>This could be the name of a data-driven codelist generated when the study was registered, or the name of a codelist from a customer-provided define.xml file.</p> <p>The value ISO 8601 appears in this column when the value complies with the International Organization for Standardization (ISO) published standards for representation of dates and times.</p> <p>When you click the name of an external codelist, a message indicating that no definition is found appears.</p>
SDTM TERMINOLOGY	<p>Name of the standard codelist, if any, associated with the variable. This column contains a value for only those variables that are subject to CDISC controlled terminology. You can click the codelist name to view the contents of the codelist.</p> <hr/> <p>Note: If a standard codelist and a sponsor-defined codelist both exist for the variable, the loading and checking process checks data against the sponsor-defined codelist. In addition, the loading and checking process compares values in the sponsor-defined codelist to values in the standard codelist (if it is not extensible) and reports mismatches.</p>
DEPRECATED	Y— The variable was deprecated but is supported for the purpose of backward compatibility.

	Otherwise, blank.
ORIGIN	Source of the variable (for example: CRF, Derived, Sponsor Defined).
ROLE	Type of information that the variable provides about the observation (for example, Identifier, Timing, Topic), which determines how the variable is used.
COMMENTS	Comments associated with the variable. WebSDM/Empirica Study truncates comments to 200 characters when you load the study.
MANDATORY	Y — The variable is required by the CDISC SDTM. N — The variable is not required by the CDISC SDTM. Blank for derived variables.
ORDER_NUMBER	Used for sorting the list of variables consistent with the order in CDISC models.
ADDED_BY_SYSTEM_FLAG	1 if one of the following is true: <ul style="list-style-type: none"> • The variable was not in the original study data for that domain, but was added to the domain metadata by WebSDM/Empirica Study. • The variable is one that WebSDM/Empirica Study adds from the DM domain to other domains, such as AGE, SEX, and RACE. • The variable is derived. • The variable is a supplemental qualifier.
	Otherwise, empty.

For information on viewing, printing, or downloading tables or changing the way data displays in the table, see [About Tables](#).

Viewing the Define.xml

The *define.xml* file contains study metadata in XML (eXtensible Markup Language). To view the define.xml file, it must be in the directory indicated when the study was registered. You can view the define.xml in three different formats.

1. Hover your mouse over the **View Define.xml** link. A sub-menu appears.
2. Select one of the following:
 - **Using standard stylesheet** —Always available. Presents the metadata using a standard built-in style sheet.
 - **Using sponsor-provided stylesheet** —Available only if you loaded the study with a define.xml file that your organization provided (that is, it was not generated by WebSDM/Empirica Study), and the define.xml referenced a style sheet. The style sheet reference can be to a file location in the study data directory or a subdirectory in the study data directory.

- **RAW XML**—Always available. Presents the metadata without using a style sheet.

You cannot view this information for a study pool.

Notes:

- References to SAS transport files and an annotated CRF file (if any) must be to the study directory or to a subdirectory within the study directory.
- To view the annotated CRF, you must have Adobe Acrobat Reader installed.
- To view SAS transport files, you must have the SAS System Viewer or Base SAS installed. For more information, see [Prerequisites and Usage Notes](#).

Viewing Variable Characteristics

1. On the [Study Data Domains page](#), click the hyperlinked number (representing the number of variables in the domain) that appears in the Variables column. The Variable Characteristics page appears.
2. You can [graph a text variable](#) (a variable with a Type of Character) or [graph a numeric variable](#) (a variable with a Type of Number). To view a graph, click the variable name.

The following information is provided about each variable in the domain:

Column	Description
Variable	Short name of the variable. If you point to a variable name, a description of the variable appears. Note: Variable names ending in "_" are derived variables .
N	Count of non-null values for the variable.
Nulls	Count of null (empty) values for the variable.
Mean	For numeric values, mean of the values for the variable.
SD	For numeric values, standard deviation of the values for the variable.
Min	For numeric values, minimum value for the variable.
Max	For numeric values, maximum value for the variable.
Type	The type of the variable, expressed as one of Number, Character, or Date.

Graphing a Text Variable

1. On the [Variable Characteristics page](#), click the hyperlinked name of a variable whose type is Character. A one-variable detail bar graph appears. The y-axis represents values of the variable and the x-axis represents counts. Each bar shows the count of a particular value of the variable. At the end of each bar is:
 - The total count of times the value occurs across records in the domain.
 - The percentage of occurrences of the value relative to the total number of records in the domain.

Bars are ordered in descending order of their counts. If there are null values for the variable, a bar represents null values.

2. For a domain defined by the SDTM as a Findings domain, if the variable's SDTM role is Variable Qualifier or Result Qualifier, you can select a test and click **Redraw** to display the graph for just that test's values.
3. To [drill down](#) to a list of subjects with the value represented by a bar, click on the bar and then click **View Subjects**.

Note: When you drill down, there may be fewer subjects listed than are counted in the graph. This is because the same subject can have multiple occurrences of a value. For example, suppose that a subject has three occurrences of Headache. The subject would be counted three times in the graph, but would appear only once in the list of subjects.

Related Topics

[Graphing a Numeric Variable](#)

Graphing a Numeric Variable

1. When [viewing variable characteristics](#), if you click the hyperlinked name of a variable whose type is Number, a one-variable box plot appears. The box represents the middle 50% or so of the numeric values. A horizontal line within the box represents the median of all values (that is, the value that is exactly in the middle of all values). See [Box Plots](#).
2. For a domain defined by the SDTM as a Findings domain, if the variable's SDTM role is Variable Qualifier or Result Qualifier, you can select a test and click **Redraw** to display the graph for just that test's values.
3. You can point to a region of the box plot to view the number of times the value occurs for that region.
4. To [drill down](#) to a list of subjects with the values represented by a region of the box plot, click on a region of the box plot and then click **View Subjects**.

Related Topics

[Graphing a Text Variable](#)

Creating a Findings Report

A Findings Report uses a selection page that capitalizes on the standard structure of data in the CDISC SDTM Findings general class. It is available for each domain defined by CDISC as a Findings Domain, for example, Laboratory Tests. The Findings Report is intended to provide quick access to predefined formats of data; typically, the output of a Findings Report is not saved.

To create a Findings Report:

1. Do one of the following:

- On the Study Data Domains page, click  in the Listings column for a Findings domain and then click **Findings Report**.

Or

- On the Report Definitions page, click **Findings Report** or **Last Findings Report**.

The **Findings Report** page appears.

2. If you are creating the Findings Report from the **Report Definitions** page, provide a report name and description.
3. If you are creating a Findings Report from the **Report Definitions** page, select a domain. Available domains are those with the __TESTCD variable as the topic variable; usually these refer to general clinical observations like lab test results, vital signs, or questionnaire responses.

If you are creating a Findings Report from the **Domains** tab, the domain is displayed and is not modifiable.

4. Specify variables for the report. (If you clicked **Last Findings Report**, the settings for the most recent Findings Report that you created from the **Report Definitions** page appear during your current session, and you can change the settings as needed.) Next to variable fields, you can click **Select** to select variables for the Findings Report.

Timing variables group the data by time.

Topic variables describe the data topics, such as lab test names, to be included in the report. The report offers the option of selecting groups of tests together using the __CAT and __SCAT variables provided in the CDISC standard.

Qualifier, record qualifier, and demographic variables further describe the data in the report.

5. Select a report type, which determines the degree of report summarization. The options are:
 - **One row per subject x visit x ...** —The report will include one row for each unique combination of subject and visit.
 - **One row per subject, columns grouped by visit**—The report will include one row per subject, with columns grouped according to visit.
 - **One row per subject, columns grouped by test**—The report will include one row per subject, with the columns grouped by test.
6. Click **Apply**. The report definition appears on the **Edit Definition** page.
7. Edit the report definition further if needed and [save or run the report](#).

Running a Built-In Report


WebSDM/Empirica Study is delivered with a set of built-in report definitions, which require only that the SAMP1_312 study has been loaded. The installation instructions describe how to load the following sample studies:

- SAMP1_312 uses SDTM 3.1.2
- SAMP1_311 uses SDTM 3.1.1
- SAMP1 uses SDTM 3.1


Regardless of which SDTM version you use, the SAMP1_312 study must be loaded for you to use the built-in report definitions. When you load the study, you **MUST** name it **SAMP1_312**, and you must create it in the **LTI** application.

Only a Superuser can create or edit built-in reports. Depending on their permissions, other users may be able to create a new report by saving a built-in report with a different name.

To run a built-in report definition:

- On the [Study Data Domains page](#), when you click the Action menu icon () for a domain that has built-in reports, the built-in report definitions are listed in a menu and you can select one of them to run. The report is run against all subjects in that domain.

Or

- Click the Action menu icon () for the report definition on the [Report Definitions page](#), and then click **Run Report**. The report is run against the selected subject list or, if no subject list is selected, against all subjects in the study.

See [Running a Report](#) for general instructions.

WebSDM/Empirica Study is delivered with the following built-in report definitions:

Domain	Report Name	Report Description
AE	Summary by TERM and BODYSYS	For each combination of an adverse event body system and adverse event MedDRA Preferred Term, provides the count of subjects for each arm of the study.
CM	Summary by Decode	For each combination of concomitant medication (using standardized medication names), CMOCCUR value, and CMSTAT value, provides the count of subjects for each arm. Includes SQL Where clause for CMOCCUR and CMSTAT.
CM	Summary by Reported Name	For each combination of concomitant medication (using medication names as reported), CMOCCUR value, and CMSTAT value, provides the count of subjects for each arm. Includes SQL Where clause for CMOCCUR and CMSTAT.
DM	Demog Summary by ARM	For each arm, provides the following: subject count; mean and standard deviation of age; subject count by

		sex; and subject count by race.
EX	Summary by Total Exposure and ARM	For each arm, provides the subject count, median, minimum, and maximum for each exposure, using the derived variable DMDOSDY_ (Day taking study therapy) in the DM domain.
IE	Summary of Exceptions	For each inclusion/exclusion criterion, shows the unique count of subject by arm.
MH	Summary by Preferred Term	For each combination of a medical history MedDRA Preferred Term, medical history body system, MHOCCUR value, and MHSTAT value, provides the count of subjects. Includes SQL Where clause for MHOCCUR and MHSTAT.
MH	Summary by Reported Term	For each combination of a medical history reported term, medical history body system, MHOCCUR value, and MHSTAT value, provides the count of subjects. Includes SQL Where clause for MHOCCUR and MHSTAT.
SC	Subject Characteristics Listing	For each combination of subject, grouping qualifier, and characteristic, provides the characteristic result (the value of the SCSTRESC variable) and the datetime it was collected (the value of the SCDTC variable).
SU	Substance Use by Substance	For each combination of a substance, SUOCCUR value, and SUSTAT value, shows a unique subject count. Includes SQL Where clause for SUOCCUR and SUSTAT.
SU	Substance Use Listing	For each combination of subject, substance, substance category, SUOCCUR value, and SUSTAT value, provides descriptive information such as dosage and frequency. Includes SQL Where clause for SUOCCUR and SUSTAT.
VS	Vital Signs Horizontal	For each combination of subject and visit, provides the numerical result for each vital sign measurement.

Creating built-in report definitions

Only Superusers can create, edit, or delete built-in report definitions. For a built-in report definition:

- The report name must be prefaced by the two-letter name of the domain, followed by a colon.
- On the Report Descriptors page, the category must be Standard.
- On the Report Descriptors page, the **Built-in** check box must be checked. (This option is available only for Superusers.)

Viewing the Trial Design

For the following domains, which contain data about the structure of the clinical trial, you can view a graphical representation of the trial design: TA (Trial Arms); TE (Trial Elements); and TV (Trial Visits). For you to view trial design, the following variables must be in the source data:

- TE.ETCD and TE.ELEMENT
- TV.VISITNUM
- TV.VISIT, TV.TVSTRL, and TV.TVENRL

To view the trial design:

1. On the [Study Data Domains page](#), click  in the Listings column for the TA, TE, or TV domain. Then click **Trial Design**. The Trial Design page appears, showing the trial name as the value of the TA.STUDYID variable.

Note: The Trial Design display is not available for study pools.

2. Click **Print** if you want to print the trial design. If color does not appear properly in the printout, you may need to configure Internet Explorer to print background colors and images. See [Prerequisites and Usage Notes](#) for more information.
3. If you point to an arrow, the following information appears:
 - Value of the VISIT variable in the TV domain.
 - StartRule – Value of the TVSTRL variable in the TV domain.
 - EndRule – Value of the TVENRL variable in the TV domain.
4. If you point to a rectangle, the following information appears:
 - Value of the ELEMENT variable in the TE domain.
 - Code – Value of the ETCD variable in the TE domain.
 - Start Rule – Value of the TESTRL variable in the TE domain.
 - End Rule – Value of the TEENRL variable in the TE domain.
 - Duration – Value of the TEDUR variable in the TE domain.

For each arm (value of the ARM variable), the trial design diagram includes up arrows representing the start of each visit, and rectangles representing each trial element. The label on the rectangle is the value of the TE.ETCD. The label beneath the arrow is the value of the TV.VISITNUM variable. For each arm, elements are ordered according to the TA.TAETORD variable.

If TV.ARMCD and TV.ARM are both absent, visit numbers display along the bottom of the graph, rather than under each arm's row; this is especially apparent in crossover studies. In this case, arms are determined by DM.ARM, and visits (from TV.VISITNUM) are located on a certain arm using TV.VISITNUM and DM.ARM.

The widths of rectangles representing elements are related to the element (TE.TEDUR variable), but the relationship is not necessarily linear. Because elements within a single trial may vary widely in their duration, if there is a large difference between the duration of the shortest and longest trial element, the width of the rectangles varies on a logarithmic, rather than linear, scale.

Rectangles are colored as follows:

Trial element starts with	Color
Screen or Baseline	Green
Unscheduled	Red
FollowUp	Light blue-green
Termination	Blue
RunIn	Cyan
Discharge	Purple
Rest or Washout	Light yellow
Assessment	Orange
Any other characters	Olive

Linking visits and elements

In order to link information in the TV and TE domains, the variable ETCD_REL must be added to the TV domain during the preparation of data for use in WebSDM/Empirica Study. This value must match a value of the TE.ETCD variable.

If visits are linked to elements, the visits are displayed aligned with the start (left edge) of the corresponding element. If more than one visit corresponds to the same element, the multiple visit arrows are placed side-by-side, starting at the left edge of the corresponding element. Any visit not linked to an element is displayed at the right, just past the end of the display of elements.

If no visits are linked to elements (ETCD_REL is not defined), the visits are displayed spread out equally along the horizontal axis of the display. In this case, the fact that a particular visit arrow appears beneath a particular element rectangle is incidental, and does not indicate any relationship between the visit and the element.

If the visit schedule for all arms of the trial is identical, only one set of visit arrows is displayed (beneath the bottommost arm). If the visit schedule differs between arms, then a separate set of visit arrows is displayed for each arm.

Working with Checking Results

About Checking Results

When you perform a [loading and checking run](#) for a study or pool, the checking portion of the run applies rules to the study data. A rule is a predefined condition that must be met. If the rule fails, the check is considered to have failed. Checking results include the failed checks and are available on the [Checking Results page](#) on the Domains tab.

Note: Studies must be loaded and checked before they can be included in a study pool. When a study pool is loaded and checked, further checking is performed.

The **Study Data Domains** page on the Domains tab includes columns for Structure Checks and Consistency Checks that occurred for each domain when the study or pool was last loaded and checked. The columns are color coded, according to the color key that appears at the bottom of the page:



The failure of a check can have different levels of severity. If a check fails for a domain that is new for the SDTM version or is not fully supported by the SDTM version, the severity is always **Low**.

The severity level of a check-related cell indicates the most severe check failure (of the existing unresolved check failures) that occurred for the domain:

- **No Checks failed**—This can indicate two different situations:
 - No checks failed during the checking portion of the loading and checking run
 - or
 - Checks failed, but they have been resolved.
- **Low**—The most severe check failure for the domain is Low.
- **Medium**—The most severe check failure for the domain is Medium.
- **High**—The most severe check failure for the domain is High.

You can view and [resolve failed checks](#). When you resolve checks, you assign them a review status and annotate them, and they are no longer included in the count and the color of check-related cells in the table on the Study Data Domains page.

Validation checks

For descriptions of the validation checks (rules) that are executed in WebSDM/Empirica Study for some versions of the SDTM, see Appendix A in the *WebSDM/Empirica Study Release Notes Release 3.1*.

Viewing Checking Results

The Checking Results page lists checks that failed when the study was [loaded and checked](#).

When viewing checking results, keep in mind that the following variables from the DM domain are added to other subject-based domains when study data is loaded: AGE, ARM, ARMCD, COUNTRY, ETHNIC, INVID, RACE, SEX, SITEID, STUDYID, SUBJID, and USUBJID. If a checking result related to these variables occurs for the DM domain, it is not repeated for the other domains. (If your organization defines additional checks, there may be exceptions to this.)

To view checking results:

1. Make sure your [user preference](#) "Display error-checking results" is checked.
2. On the [Study Data Domains page](#):
 - To view checking results for a specific domain, click the hyperlinked count in the Structure Checks column or Consistency Checks column. The Checking Results page appears and shows checks that failed for the domain.
 - To view checking results for all domains, click **View Checking Results Log**. The Checking Results page appears and shows checks that failed for all domains.

For the specified domain (or for all domains), the Checking Results page provides a table of the following information about each failed check. Both [resolved](#) and unresolved checks are listed.

Column	Description
E_ID	Automatically assigned unique identifier of the check. (This is not the same as the rule ID or message ID.) You can click the hyperlinked E_ID to view rule details and resolve failed checks .
TABLENAME	Name of the domain for which the check failed.
CHECKTYPE	<p>Possible values are:</p> <ul style="list-style-type: none"> • Within-Domain – The check failure was caused by a "Within-Domain" rule, that is, a rule that applies to clinical data in one domain. This type of check is either built in or customer-defined. • Cross-Domain – The check failure was caused by a "Cross-Domain" rule, that is, a rule that applies to clinical data in multiple domains. This type of check is built in and cannot be customer-defined. • Structure – The check failure was caused by a "Metadata" rule that checks such issues as the presence or absence of columns or expected data types. This type of check is built in and cannot be customer-defined. (In the Rules Report, the STAGE column shows "Metadata".)
SEVERITY	<p>Severity of the check failure. This column is color coded as follows:</p> <ul style="list-style-type: none"> • Low – Yellow • Medium – Orange • High – Pink <p>Note: For the message "Too many rule failures", the severity is that of the check that failed.</p>

MESSAGE	<p>Message generated by the check failure. For example, "AESER and AETOXGR cannot both be non-null".</p> <p>Each check has a maximum number of times that it can fail. Check failures that occur more than the maximum appear on the Checking Results page only a limited number of times. In addition, the Checking Results page includes a row showing "Too many rule failures". The total number of times that the check failed for the domain appears in parentheses at the end of the message (inclusive of the check failures that are listed explicitly).</p>
R_ID	<p>Unique identifier of the rule that caused the check failure. If the rule ID starts with R or CR, it is a hyperlink that you can click to view rule detail. Rule IDs starting with CR are customer-defined rules. Rule IDs starting with R or IR are built-in rules.</p> <p>If a customer-defined rule has been deleted since the study was last loaded and checked, a message informs you of this.</p>
ESUBJECT	Subject ID for which the check failed. If the CHECKTYPE column is Within-Domain or Cross-Domain, ESUBJECT is a hyperlink that you can click to view subject details.
VISIT	Visit number for which the check failed.
E_COLUMN	Column(s) tested by the check.
EXPECTED, ACTUAL	For certain checks, WebSDM/Empirica Study reports the actual and/or expected values of the target variable or variables as a way of clarifying the nature of the failed check.
REVIEW_STATUS	<p>One of the following values (if any):</p> <ul style="list-style-type: none"> • annotated – The reviewer of the check marked it as "Annotated" and added the annotation that appears in the NOTE column. • consequence – The reviewer of the check marked it as "Consequence of other errors". • noterror – The reviewer of the check marked it as "Not an error".
NOTE	Note, if any, added by the reviewer of the check.

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

- Check failures are caused by rules that are applied to the study data. You can click **Generate Rules Report** to view a list of all rules (not just those that failed). From the Rules Report, you can access details of specific rules or the messages associated with them.

Note: The Rules Report is not available for study pools.

- If you are viewing checking results for a specified domain, you can click **View Clinical Data** to [view clinical data](#) for the domain. (This option is not present if clinical data was not loaded for the domain.)

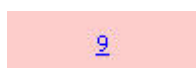
Resolving Failed Checks

You can resolve a failed check by assigning it a review status and annotating it. If a failed check has a review status other than **None**:

- The count of checks for the domain on the Study Data Domains page is decreased by 1.
- The color coding for the checks may change.

For example, suppose that the Consistency Checks column for the AE domain has nine failed checks; five of them are High severity, three are Medium severity, and one is Low severity.

- The cell for Consistency Checks for the AE domain shows as:



- You resolve the High checks. The cell is now:



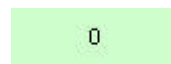
- You resolve the Medium checks. The cell is now:



- You resolve the Low checks. The cell is now:



If there were no failed checks in the checking results, the cell would be:



To see the full list of resolved and unresolved checks for the domain, you can click the hyperlinked count of checks.

One type of check is **Too many rule failures**. This check appears if a check fails more times than is allowed by a predefined limit. When this limit exists, even if you resolve the visible checks, there may still be checks that are not accessible from the Checking Results page. For example, suppose that 20 subjects in the DM domain have an invalid country code. If the limit of how many times this check can appear on the Checking Results page is 5, then the five checks plus the **Too many rule failures check** appear. Even if you resolve the five checks, the other 15 subjects still have the invalid country code.

To resolve a failed check:

1. On the [Checking Results page](#), click the hyperlinked E_ID. The Error Detail page appears, showing the following information about the failed check.

Note: WebSDM/Empirica Study informs you if a rule has been changed or deleted since the study was last loaded and checked. If the rule has been changed, the unmodified rule is displayed.

Field	Description
Error ID	Unique identifier of the check. (This is not the same as the rule ID or message ID.)
Message ID	Unique identifier of the message generated by the failed check.
Rule ID	Unique identifier of the rule that caused the failed check. Rule IDs starting with CR are customer-defined rules. Rule IDs starting with R or IR are built-in rules.
Severity	Possible values are: <ul style="list-style-type: none"> • Low • Medium • High
Message	Message generated by the failed check.
Description	Description of the failed check. For example: Age must be less than 18. Not displayed for checking results with the Too many rule failures error message.
Possible Causes	Available for some check failures. Description of possible reasons for the check failure.
Type of Check	Possible values are: <ul style="list-style-type: none"> • Within-Domain—The check failure was caused by a Within-Domain rule, that is, a rule that applies to clinical data in one domain. This type of check is either built in or customer-defined. • Cross-Domain—The check failure was caused by a Cross-Domain rule, that is, a rule that applies to clinical data in multiple domains. This type of check is built in and cannot be customer-defined. • Structure—The check failure was caused by a Metadata rule that checks such issues as the presence or absence of columns or expected data types. This type of check is built in and cannot be customer-defined. (In the Rules Report, the STAGE column shows Metadata.)
Table	Name of domain for which the check failed.
Column	For some check failures, column tested by the check. If the rule that generated the check failure refers to multiple columns, the name of one of those columns.
Subject	Subject ID for which the check failed.

Actual Value	Actual result. For example: 45 (if the rule checks whether age is less than 18)
--------------	---

2. In the **Review Status** field, select one of the following:

- Annotated
- Consequence of other errors
- Not an error
- None

If the review status is None and you add a note, the review status changes automatically to **Annotated**.

If you change the review status to None (from Annotated, Consequence of other errors, or Not an error), the failed check is counted again on the [Study Data Domains page](#) and the color coding of the cell may change.

3. In the Note field, optionally enter a note or modify an existing note.

4. Click **Save**. On the [Checking Results page](#), your annotation appears in the NOTE column and the Review Status appears in the REVIEW_STATUS column.

Viewing the Rules Report

The Rules Report shows all existing rules, including built-in rules and customer-defined rules, for the SDTM version used by the currently selected study. If a rule fails during the checking portion of a loading and checking run, a check failure appears on the Checking Results page. The Rules Report provides a means for you to view information about all rules, including those that did not fail during checking and those that have been added since the last loading and checking run.

A rule ID can start with:

- R – Built-in rule; always a Within-Domain rule.
- IR – Built-in rule; all Cross-Domain or Metadata rules and some Within-Domain rules have this prefix.
- CR – Customer-defined rule; always a Within-Domain rule.

Note: See the STAGE column described below for an explanation of Within-Domain, Cross-Domain, and Metadata.

A message ID can start with:

- M – Built-in message.
- CM – Customer-defined message.

To view a rules report:

1. On the [Checking Results page](#), click **Generate Rules Report**. The Rules Report page appears, showing all rules for all domains (for the SDTM version used by the study).

Note: The Rules Report is not available for study pools.

2. Under "Rule Description and Message View", click one of the following to indicate what to use in the RULE_DESCRIPTION and MESSAGE columns of the report:
 - Variable names from the SDTM
 - Variable labels from the SDTM

The Rules Report page provides the following information about each rule:

Field	Description
R_ID	Unique identifier of the rule. If the rule ID starts with R or CR, it is a hyperlink that you can click to view rule details .
M_ID	Unique identifier of the message associated with the rule. The ID is a hyperlink that you can click to view message details .
DOMAIN	Name of the domain (table) with which the rule is associated.
RULE_DESCRIPTION	Description of the rule.
SEVERITY	Severity of the rule failure. This column is color coded as follows: <ul style="list-style-type: none"> • Low – Yellow • Medium – Orange • High – Pink
MESSAGE	Message that appears on the Checking Results page when a rule fails.
CAUSES	Cause of the rule failure, as defined for the message associated with the rule.
STANDARD	Version of CDISC Study Data Tabulation Model against which the rule checks. For example, "sdm312" indicates Version 3.1.2.
ENABLED	Yes if the rule is enabled, or No if the rule is disabled. If the rule is disabled, it is not applied during the loading and checking process.
STAGE	One of the following values: <ul style="list-style-type: none"> • Within-Domain: The rule applies to clinical data in one domain. • Cross-Domain: The rule applies to clinical data in multiple domains. • Metadata: The rule checks such issues as the presence

or absence of columns or expected data types.

RULETYPE	<p>Possible values are:</p> <ul style="list-style-type: none"> RowSQL – The rule checks whether each row of clinical data for the domain meets a specified condition for a specified variable. Unique – The rule checks that the value of a specified column occurs only once in the domain. Codelist – The rule checks that the value in the specified column matches a coded value in the column's associated codelist. Built In – The rule is built in to WebSDM/Empirica Study. These rules include those that were created automatically to check data values against codelists provided in a define.xml file for variables that are not subject to controlled terminology.
ROWSWHERE	SQL Where clause that can be used to limit the rows to which the rule will be applied.
MAXMSGs	Maximum number of times the rule may fail before the message "Too many rule failures" is reported. If this field is blank, the number of times is unlimited.
COMMENTS	Further documentation of the rule.

- See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.
- By default, the Rules Report shows only enabled rules. To include disabled rules, you can click **Columns and Rows** and remove the SQL Where clause that filters the report to only enabled rules.

Viewing Rule Details

To view rule details:

On the [Rules Report page](#), click a value in the R_ID column, or, on the Checking Results page, click a rule ID that is a hyperlink. The Rule Details page appears.

Note: If the rule has been modified since the study was last loaded and checked, a message informs you of this. The current rule appears on this page and in the Rules Report.

The Rule Details page provides the following information about the rule:

Field	Description
Rule ID	Unique identifier of the rule. Rule IDs starting with CR are customer-defined rules. Rule IDs starting with R are built-in rules.

Standard	Version of CDISC Study Data Tabulation Model associated with the study. For example, "sdm312" indicates Version 3.1.2.
Enabled	Yes if the rule is enabled, or No if the rule is disabled. If the rule is disabled, it is not applied during the loading and checking process.
Message ID	ID of the message that will be generated if the rule fails.
Rule Type	<p>Possible values are:</p> <ul style="list-style-type: none"> RowSQL – The rule checks whether, for each row of clinical data for the domain, the value of the variable in the Column Name field meets the SQL condition that appears in the Test field. Unique – The rule checks that the values of columns in the Test field and the Column Name field are unique for the domain. Codelist – The rule checks that the value in the specified column matches a coded value in the column's associated codelist. Built-in – The rule is built in to WebSDM/Empirica Study. These rules may include rules that are created automatically to check data values against a codelist provided in a define.xml file for a variable that is not subject to controlled terminology.
Test	<p>SQL condition that must be met.</p> <p>If Rule Type is codelist, this column shows the name of the codelist against which data values will be checked.</p>
Processing Stage	Within-Domain.
Table	Domain to which the rule is applied.
Column Name	Columns tested by the rule.
Rows Where	SQL Where clause that limits the rows to which the rule will be applied.
Max Messages	Maximum number of times the rule may fail before the message "Too many rule failures" is reported. If this field is blank, the number of times is unlimited.
Comments	Further documentation of the rule.

Viewing Message Details

To view message details:

On the [Rules Report page](#), click a value in the M_ID column. The Message Details page appears.

Note: If the message has been modified since the study was last loaded and checked, WebSDM/Empirica Study informs you of this. The current message appears on this page and in the Rules Report.

The Message Details page provides the following information about the message.

Field	Description
Message	Unique identifier of the message.

ID	Note: The IDs of customer-defined messages begin with "CM".
Severity	Possible values are Low, Medium, and High. The severity of a failed check is indicated on the Checking Results page (on the Domains tab) by a color key.
Message	Text of the message, for example, "Begin date must be <= end date." The message appears on the Checking Results page (on the Domains tab) if the check fails.
Description	Description that appears on the Error Detail page if the check fails. For example, "A null value was found in a column where null is not allowed".
Causes	Text description of possible causes of the check failure.

Safety Review

About the Safety Review Tab

The Safety Review tab is designed specifically to meet the needs of clinical safety scientists and others who monitor and analyze the safety of products in clinical studies. It is intended to facilitate reviews that are systematic, efficient, consistent, and timely.

On the Safety Review tab, you can view a variety of tables and graphs providing counts and percentages of subjects who received the treatment drug and comparator drug and experienced particular events or tests. You can also review the study population by characteristics such as sex, race, and age. For example, you can view a disposition summary for the study, the cumulative incidence of adverse events over time, or lab test result changes from baseline.

In addition, the Safety Review tab provides access to the results of screening analysis, which provide statistical scores to help you evaluate the relationships between adverse events or test results and the study drug. For example, if subjects receiving the study treatment experience a higher occurrence of an adverse event than do subjects receiving the comparator treatment, this is considered more interesting than, and receives a lower score than, the situation in which the subjects receiving the study treatment experience a lower occurrence rate of the event. You can also assess the effect of characteristics such as age, sex, and race on the statistical scores.

From subject counts in tables or graphs, you can drill down to individual subject data as needed.

Viewing a Study Population Overview

The Overview page presents a table of statistics and four graphs for the dosing categories (or ARM values) and time frame that you select as [safety review options](#).

If no time frame is in effect, the table on the page includes the following rows for each dosing category:

- Subjects – Total count of subjects in the study or study pool.
- Subjects with adverse events – Total count of subjects in the study or pool who experienced an adverse event.
- Subjects with serious adverse events – If there is an AE.AESER variable, subjects with adverse events for which its value is "Y" are counted in this row. If there is no AE.AESER variable in the study data, "NA" appears for all columns.
- Subjects who dropped out – Subjects whose last disposition event is one for which:
1) the disposition event category does not contain the case-insensitive text string "MILESTONE" or "OTHER" and 2) the disposition event does not contain the case-insensitive text string "COMPLETED" and is not null. If there are multiple such disposition events with the same datetime, and none of them contains "COMPLETED", the subject is considered to have dropped out.

If any subjects have multiple disposition events, a note appears below the table.

If a [time frame](#) is in effect, the table on the page includes the following rows for each dosing category:

- Subjects in study/pool – Total count of subjects in the study or study pool (regardless of time frame).
- Subjects participating at start of time frame – If the time frame does not have a well-defined start, this is the same as the "Subjects in study" count. If the time frame has a well-defined start, this count excludes subjects who [dropped out](#) of the study before the start of the time frame.
- Subjects with adverse events during time frame – Among the subjects participating at the time frame start, these are subjects who experienced adverse events during the time frame.
- Subjects with serious adverse events during time frame – Among the subjects participating at the time frame start, these are subjects who experienced serious adverse events during the time frame. If there is an AE.AESER variable, subjects with adverse events for which its value is "Y" are counted in this row. If there is no AE.AESER variable in the data, "NA" appears for all columns.
- Subjects who dropped out during time frame – Among the subjects participating at the time frame start, those whose last disposition event within the time frame is one for which: 1) the disposition event category does not contain the case-insensitive text string "MILESTONE" or "OTHER" and 2) the disposition event does not contain the case-insensitive text string "COMPLETED" and is not null. If there are multiple such disposition events with the same datetime, and none of them contains "COMPLETED", the subject is considered to have dropped out.

If any subjects have multiple disposition events within the time frame, a note appears below the table.

Graphs

The four graphs show counts of subjects for each sex, race, age, and country. Only values that exist in the study data appear in a graph. If the time frame has a well-defined start, subjects who [dropped out](#) of the study prior to the start of the time frame are not included in these graphs.

Note the following:

- The band of color representing a dosing category that has very few members (relative to the total number of subjects) may not be visible in the graph.
- If a default category breakdown for Age or Race has been defined for the study, it is used for the Age or Race graph. Otherwise, age or race values from the study data are used. In this case, a box plot for Age appears rather than a bar graph because, typically, there are too many age values in the study data to present in a bar graph. See [Box Plots](#) for information about interpreting box plots.

To view a study population overview:

1. When you go to the Safety Review tab, the Overview page appears by default. If you are on another page of the Safety Review tab, you can click **Overview** to display the Overview page.
2. To [configure safety review](#), click **Configure**.
3. In the graphs, you can point to a segment of a bar (in a bar graph) or a region (in a box plot) to view information about what the segment or region represents.
4. You can click a count in the table to [drill down](#) to a list of subjects included in the count. You can click a bar (in a bar graph) or a region (in a box plot) to drill down to a list of subjects represented by the bar or region.
5. You can click **Print** to print the table or **Download** to [download the table](#).
6. To [view a Disposition Summary](#), click **Disposition Summary**.
7. To [view an Exposure Summary](#), click **Exposure Summary**.
8. Click **AEs**, **Labs**, **ECGs**, or **Vitals** at the top of the page to go to those pages.

Note: If you click **ECGs**, an up-to-date [issue list](#) must exist for the time frame that is selected as a safety review configuration option. If the issue list needs to be created or updated, a message informs you and provides the opportunity to create or update the issue list for that time frame and any other time frames.

9. If a preparatory analysis specification (named [\\$\\$\\$BASIC\\$\\$\\$SCREENING\\$\\$\\$](#)) has been run and you have configured safety review to use a dosing category breakdown and time frame for which screening results exist, you can click **Screening Results** to [view screening results](#).

Note: If the configuration option for maximum or most recent change from baseline is set differently than the setting that was used to generate screening results, a message warns you of this.

Configuring Safety Review

On the Overview page of the Safety Review tab, you set configuration options that may affect tables and graphs on any of the pages on the Safety Review tab. For example, you specify dosing categories and the time frame for which you want to review safety data. In some cases, a specific graph or tabular display may have its own **Configure** link that allows you to override the safety review configuration settings.

To configure safety review:

1. On the [Overview page](#), click **Configure**.
2. Specify any of the following:

Option	Description
Dosing category breakdown	Determines the dosing category breakdown to display. The options are:

- **None—use ARMs**—Information will be shown for each value (including null) of the ARM variable in the study data. All arms in the study are shown even if they are not included in any category breakdowns defined for the study.
- **Name of a dosing category breakdown** (if any) defined for the study or study pool—Information will be shown for the Treatment and Comparator categories defined by the selected breakdown. Keep in mind that subjects not included in those Treatment and Comparator categories are not included in displays that use this option.

If dosing category breakdowns have been defined, you can click **Browse** to [select](#) from a descriptive list of them.

Before you can view a sector map on the Adverse Events page or view screening results, you must select a dosing category breakdown for which screening results exist. If no screening results have been generated for a dosing category breakdown, the name of the breakdown is in parentheses. This situation can occur if a dosing category breakdown was added after the preparatory screening analysis specification for the Safety Review tab was run.

Before you can view an Odds Ratio Graph on the Adverse Events page, you must select a dosing category breakdown.

Note: It is possible for all screening results to be removed because of changes to study properties. In this case, the dosing category breakdown is not in parentheses.

If you use arm values, the order of arms is determined as follows:

- If there is a default dosing category breakdown for the study, arms are ordered by their order in the Treatment category, then by their order in the Comparator category. Then arms that are not in either category are ordered alphabetically by their ARM values.
- If there is no default dosing category breakdown for the study, arms are ordered alphabetically by ARMCD values.

Time frame

Determines the time frame to display. The options are:

- **None**—Does not display a time frame.
-

- **Name of a time frame** (if any) defined for the study or study pool. If time frames have been defined, you can click **Browse** to [select](#) from a descriptive list of them.

Before you can view a sector map on the AEs page or view screening results, you must select a time frame for which screening results exist. If no screening results have been generated for a time frame, the name of the time frame is in parentheses. This situation can occur if a time frame was added after the preparatory screening analysis specification for the Safety Review tab was run.

Note: It is possible for all screening results to be removed because of changes to study properties. In this case, the time frame is not in parentheses.

Use maximum (instead of most recent) change from baseline

Affects the following:

- The Vital Signs page, which shows change from baseline values.
- Only the following graphs on the Lab Results and Vital Signs pages of the Safety Review tab:
 - Box Plot: Change from Baseline
 - Delta Plot: Change from Baseline

When you view screening results on the Safety Review tab, the setting indicated in the analysis specification (named [\\$\\$\\$BASIC\\$\\$\\$SCREENING\\$\\$\\$](#)) when the specification was run is always used. If you set this option differently than the setting that was used to generate screening results, a message informs you of the different settings.

- **If selected**—The change from baseline value will be computed using the post-baseline result (within the time frame) whose value represents the greatest (positive or negative) change from the baseline result.
- **If deselected**—The change from baseline will be computed using the most recent, non-null, post-baseline result within the time frame. If there are multiple results with the same most recent date and time, the result (within the time frame) whose value represents the greatest (positive or negative) change from the baseline result is used.

Truncate Body System (on AEs page) and Group

On the [Adverse Events page](#), determines whether to display a truncated version of the body system; on the [Lab Results page](#), determines whether to display a truncated version of the

(on Labs page)	<p>group (that is, the panel of tests, such as Blood Chemistry).</p> <ul style="list-style-type: none"> • If selected—Displays a truncated version of the body system or group. • If deselected—Displays a full version of the body system or group.
Show summary for all subjects	<p>In tables of statistics, determines whether to include a Total column showing the total count of subjects in the dosing categories.</p> <ul style="list-style-type: none"> • If selected—Shows a summary. • If deselected—Does not show a summary.
Show number of subjects	<p>In tables of statistics, determines whether to include a column showing the count of subjects for each row.</p> <ul style="list-style-type: none"> • If selected—Shows number of subjects. • If deselected—Does not show number of subjects.
Show percent of subjects	<p>In tables of statistics, determines whether to include a column showing the percentage of subjects for each row.</p> <ul style="list-style-type: none"> • If selected—Shows percent of subjects. • If deselected—Does not show percent of subjects. <p>Note: This option does not apply to the table on the Overview page.</p>
Use gray-scale instead of colors	<p>In graphs, determines whether to use shades of gray instead of colors. This option does not affect graphs that have their own configuration option for using gray-scale.</p> <ul style="list-style-type: none"> • If selected—Uses gray-scale. • If deselected—Uses color.
Invert bar graphs	<p>Determines whether to change the orientation of bar graphs on the Overview page. For example, show Treatment/Comparator by Sex instead of Sex by Treatment/Comparator.</p> <ul style="list-style-type: none"> • If selected—Inverts bar graphs. • If deselected—Does not invert bar graphs.
Show counts on bar graphs	<p>In bar graphs on the Overview page, determines whether to show a count of subjects represented by each bar.</p>

- **If selected**—Shows counts on bar graphs.
- **If deselected**—Does not show counts on bar graphs.

Show percents on bar graphs	In bar graphs on the Overview page, determines whether to show the percentage of the total count of subjects that is represented by the entire bar.
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- **If selected**—Shows percentages.
 - **If deselected**—Does not show percentages.
-

3. Click **OK**. Your configuration options will be used for the selected study until you modify them again or exit WebSDM/Empirica Study.

Selecting a Category Breakdown

For some fields where you select a category breakdown from a drop-down list, you can also click **Browse** to select from a more descriptive list of category breakdowns for the study or pool.

To select a category breakdown:

1. Click **Browse**. The Select Category Breakdown window provides the following information about each category breakdown:


Column	Description
ID	Automatically assigned unique identifier of the category breakdown.
Name	Name of the category breakdown.
Categories	Categories included in the category breakdown.
Default?	Y if the category breakdown is the default for the study or pool. Otherwise, blank.
Category Type	Possible values are <ul style="list-style-type: none"> • Dosing • Age • Baseline Lab • Baseline Vital • Sex • Race • Medical History • Concomitant Medication

- Subject Characteristics
- Study Group (available for a study pool)

Unless you are creating a BLR run for a potential signal, the list includes only dosing category breakdowns.

Source Column	Name of the column in the study data that is referenced by the category breakdown.
Description	Description of the category breakdown.
Category Qualifier	More detail about the category type, if the type is Baseline Lab, Baseline Vital, or Subject Characteristics.

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

2. Click the Action menu icon () for a category breakdown and then click **Select**.

Selecting a Time Frame


For some fields where you select a time frame from a drop-down list, you can also click **Browse** to select from a more descriptive list of time frames for the study or pool.

To select a time frame:

1. Click **Browse**. The Select Time Frame window provides the following information about each time frame:

Column	Description
ID	Automatically assigned unique identifier of the time frame.
Based On	Possible values are: <ul style="list-style-type: none"> • Reference dates—The time frame is based on study reference start and/or end dates for subjects. • Epoch Range—The time frame is based on epochs for subjects.
Name	Name of the time frame.
Criteria	Criteria of the time frame.
Default?	Y if the time frame is the default for the study or pool. Otherwise, blank.
Description	Description of the time frame.
Impute Baseline?	Y if the time frame imputes baseline for displays that need a baseline value. Otherwise, blank. For more information, see Baseline Results .

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

- Click the Action menu icon () for a time frame and then click **Select**.

Viewing a Disposition Summary

The Disposition Summary shows counts of subjects with each disposition event (each value, including null, of the DS.DSDECOD variable). Only one disposition per subject is counted. To determine each subject's disposition event, WebSDM/Empirica Study uses the algorithm described in [Disposition Events](#).

If the algorithm finds multiple disposition events for any subjects, WebSDM/Empirica Study tries to use the disposition event date to determine a disposition event to show in the display and a note appears below the graph. If this is not possible for any subjects, the subjects are included in a row named **<Multiple Dispositions>**.

To view a Disposition Summary:

- On the [Overview page](#), click **Disposition Summary**.

The column heading for each dosing category shows N. If the time frame has a well-defined start, N is the total count of subjects for the dosing category who did not [drop out](#) before the time frame start. Otherwise, N is the total count of subjects for the dosing category. Other statistics in the table are for subjects included in N.

- For each dosing category, the table shows the following information for each disposition event:

Column	Description
#	Count of subjects with the disposition event during the time frame. Click to drill down to subjects included in the count.
%	Percentage of subjects with the disposition event during the time frame. Computed as $(\#/N) \times 100$

- Click **Print** to print the table.
- Click **Kaplan-Meier Plot** to [view a Kaplan-Meier Plot](#).

Adverse Events

Viewing Adverse Events

The Adverse Events page of the Safety Review tab shows incidence for adverse events. The first two columns are:

- Body System – Name of the body system containing the adverse event. There is also an entry for <Any Body System>. A [safety review configuration option](#) determines whether the body system name is truncated for display.
- Adverse Event – Name of the adverse event. There is also an entry for <Any Event> and entries for <Any Event in *body-system*>. If the Adverse Event column is empty, the row represents adverse event records in which the preferred term is blank.

To view adverse events:

Keep in mind that dosing categories and the time frame are determined by [safety review configuration options](#).

1. On the Safety Review tab, click **AEs**.
2. You can select an entry in the Body System field to limit the display to only events in that body system.
3. Under "Adverse Event Incidence for", click one of the following radio buttons to restrict the adverse events that are listed:
 - All Events
 - Serious Events
 - Events Causing Withdrawals

Events qualify as "Serious" if the AE.AESER variable is Y. Events qualify as "Causing Withdrawals" if the AE.AEACN variable contains the text string "WITHDRAW" (case-insensitive).

Note: The Body System field and the radio buttons affect which adverse events are listed on the page and the tables and graphs that you can display for a specific adverse event. They do not affect screening results or the sector map.

The column heading for each dosing category shows N. If the time frame has a well-defined start, N is the total count of subjects for the dosing category who did not [drop out](#) before the time frame start. Otherwise, N is the total count of subjects for the dosing category. Other statistics in the table are for subjects included in N.


For each dosing category, the table shows the following information for each adverse event:

Column	Description
#	Count of subjects with at least one occurrence of the adverse event during the time frame. You can click this value to drill down to subjects included in the count. Note: The same subject may be counted in multiple rows of the table.
%	Percentage of subjects with at least one occurrence of the adverse event during the time frame. Computed as: $(\#/N) \times 100$


4. To view the displayed information graphically, click **Graph**. The x-axis in the graph represents percentages of subjects, and the y-axis represents each adverse event. If the graph has a lot of data, there may be **Previous Part** and **Next Part** buttons, although the whole graph is printed if you click **Print**. The graph is affected by your [safety review configuration options](#).

You can point to a dot in the graph to display details about what the dot represents.

You can click a dot and then [drill down](#) to subjects represented by the dot.

5. If a preparatory analysis specification (named [\\$\\$\\$BASIC\\$\\$\\$SCREENING\\$\\$\\$](#)) has been run and you have configured safety review to use a dosing category breakdown and time frame for which screening results exist, you can click **AE Screening Results** to [view screening results](#).
6. To [view a sector map](#), click **Sector Map** (available only if you selected a dosing category breakdown and time frame for which results exist as a [safety review configuration option](#)).
7. If you click  for an adverse event, you can select the following options:
 - [Incidence by Day of Onset](#)
 - [AE Incidence by Severity, Toxicity Grade, Outcome, or Action Taken](#)
 - [Incidence by Recurrence](#)
 - [Demographic Distribution](#)
 - [Cumulative Incidence Plot](#)
 - [Odds Ratio Graph](#) (available only if you selected a dosing category breakdown as a safety review configuration option)

Viewing AE Incidence by Day of Onset

1. On the [Adverse Events page](#), click  for an event and then click **Incidence by Day of Onset**.

The column heading for each dosing category shows N. If the time frame has a well-defined start, N is the total count of subjects for the dosing category who did not [drop out](#) before the time frame start. Otherwise, N is the total count of subjects for the dosing category. Other statistics in the table are for subjects included in N.

For each dosing category, the table shows the following information for each adverse event:

Column	Description
#	Count of subjects with at least one occurrence of the event during the time frame. You can click this value to drill down to subjects included in the count.
%	Percentage of subjects with at least one occurrence of the event during the time frame.
Min Day	Minimum number of days to the onset of the adverse event. (See the "Base day of onset on" option below.)
Max Day	Maximum number of days to the onset of the adverse event. (See the "Base day of onset on" option below.)
Median Day	Median number of days to the onset of the adverse event. (See the "Base day of onset on" option below.)
Mean	Mean number of days to the onset of the adverse event. (See the "Base

Day day of onset on" option below.)

A note appears below the table if any subjects were omitted from the Min Day, Max Day, Median Day, and Mean Day columns because of missing dates that are needed to compute day of onset.

- Click **Configure**, set the following options, and click **OK**:


Option	Description
	One of the following:
	<ul style="list-style-type: none"> Reference start date – Use the following as the day of onset: $(AE.AESTDTC - DM.RFSTDTC) + 1$ Reference end date – Use the following as the day of onset: $(AE.AESTDTC - DM.RFENDTC) + 1$
Base day of onset on	<ul style="list-style-type: none"> Start of time frame – Available only if a time frame is in effect and it has a well-defined start. Use the following as the day of onset: $(AE.AESTDTC - \text{start of time frame}) + 1$
	<p>The result of the computation is rounded down. For example, 1.01, 1.50, and 1.99 are all rounded down to 1.</p> <p>Note: For subjects who experience an event more than once, the time to onset is based on the earliest occurrence of the event.</p>
Show minimum day of onset	Include the column "Min Day" to show the minimum number of days to onset for subjects who experienced the event.
Show maximum day of onset	Include the column "Max Day" to show the maximum number of days to onset for subjects who experienced the event.
Show median day of onset	Include the column "Median Day" to show the median number of days of onset for subjects who experienced the event.
Show mean day-of-onset	Include the column "Mean Days" to show the mean number of days to onset for subjects who experienced the event.

- Click **Print** to [print the table](#), or **Download** to [download the table](#).
- Click **Box Plot** to view a box plot showing the distribution of time to onset for each dosing category or arm. For information about interpreting a box plot, see [Box Plots](#).

Note: Points in these box plots are "jittered" (displayed at small random offsets from the center line) so that if two results have the same value, a point is likely to be visible for each of them.

- To [view a Cumulative Incidence Plot](#), click **Cumulative Incidence Plot**. The Cumulative Incidence Plot ignores the "Base onset on day of" option that is specified for the AE Incidence by Day of Onset tabular display.

Viewing AE Incidence by Severity, Toxicity Grade, Outcome, or Action Taken

1. On the [Adverse Events page](#), click  for an event and then click **Incidence by Severity**, **Incidence by Toxicity Grade**, **Incidence by Outcome**, or **Incidence by Action Taken**.

The column heading for each dosing category shows N. If the time frame has a well-defined start, N is the total count of subjects for the dosing category who did not [drop out](#) before the time frame start. Otherwise, N is the total count of subjects for the dosing category. Other statistics in the table are for subjects included in N.

For each dosing category, the table shows the following information for each adverse event:

Column	Description
#	Count of subjects with at least one occurrence of the event with the listed value for severity, toxicity grade, outcome, or action taken during the time frame. You can click this value to drill down to subjects included in the count.
%	Percentage of subjects with at least one occurrence of the event with the listed value for severity, toxicity grade, outcome, or action taken. Computed as: $(\#/N) \times 100$

The table columns (such as severity values) are from the corresponding [codelist](#), with the values shown in upper case. There are also columns for any values (including nulls) that exist in the data but are not in the codelist.

2. Click **Print** to [print the table](#), or **Download** to [download the table](#).
3. Click **Graph** to view the displayed information graphically. The x-axis represents percentages of subjects, and the y-axis represents combinations of the adverse event and each severity, toxicity grade, outcome, or action taken.

The color key below the graph shows colors used for Treatment/Comparator or arms, depending on your [safety review configuration options](#).

You can point to a dot to display information about what the dot represents. If you click a dot, a menu appears and you can [drill down](#) to subjects represented by the dot.

To print or copy the graph, see [Working with Graphs](#).

Note: If any component of the label for a name on the y-axis of the graph is too long to display, the name ends with ellipses after that component. You can hover the cursor over the truncated label to display the full label as a tooltip.

Viewing AE Incidence by Recurrence

To view AE Incidence by Recurrence:

1. On the [Adverse Events page](#), click  for an event and then click **Incidence by Recurrence**.

The column heading for each dosing category shows N. If the time frame has a well-defined start, N is the total count of subjects for the dosing category who did not [drop out](#) before the time frame start. Otherwise, N is the total count of subjects for the dosing category. Other statistics in the table are for subjects included in N.

For each dosing category, the table shows the following information for each adverse event:

Column	Description
#	<p>One of the following:</p> <p>1: Count of subjects with one occurrence of the event during the time frame.</p> <p>2: Count of subjects with two occurrences of the event during the time frame.</p> <p>3+: Count of subjects with three or more occurrences of the event during the time frame.</p> <p>You can click this value to drill down to subjects included in the count.</p>
%	<p>One of the following:</p> <p>1: Percentage of subjects with one occurrence of the event during the time frame.</p> <p>2: Percentage of subjects with two occurrences of the event during the time frame.</p> <p>3+: Percentage of subjects with three or more occurrences of the event during the time frame.</p> <p>Computed as: $(\#/N) \times 100$</p>


- Click **Print** to [print the table](#), or **Download** to [download the table](#).
- Click **Graph** to view the displayed information graphically. The x-axis represents percentage of subjects, and the y-axis represents the adverse event occurring one, two, or three or more times.

The color key below the graph shows colors used for Treatment/Comparator or arms, depending on your [safety review configuration options](#).

You can point to a dot to display information about what the dot represents. If you click a dot, a menu appears and you can [drill down](#) to subjects represented by the dot.

To print or copy the graph, see [Working with Graphs](#).

Viewing AE Demographic Distribution

- On the [Adverse Events page](#), click  for an event and then click **Demographic Distribution**.

The column heading for each dosing category shows N. If the time frame has a well-defined start, N is the total count of subjects for the dosing category who did not [drop out](#) before the time frame start. Otherwise, N is the total count of subjects for the dosing category. Other statistics in the table are for subjects included in N.

For each dosing category, the table shows the following information for each row, where the row is one of the following:

- *<adverse event>* – Statistics for this row are for subjects with at least one occurrence of the adverse event.
- *wo <adverse event>* – Statistics for this row are for subjects with no occurrences of the adverse event.

Column	Description
#<sex>	<p><sex> is any non-null value in the study data for the SEX variable.</p> <p>For the "with event" row, the count of <sex> subjects with at least one occurrence of the event in the time frame.</p> <p>For the "without (wo) event" row, the count of <sex> subjects with no occurrence of the event in the time frame.</p> <p>You can click this value to drill down to subjects included in the count.</p>
%	<p>For the "with event" row, the percentage of subjects with at least one occurrence of the event in the time frame.</p> <p>For the "without (wo) event" row, the percentage of subjects with no occurrence of the event in the time frame.</p> <p>Computed as: (sum of the #<sex> columns)/(N in the column heading) x 100</p>
Mean Age	<p>For the "with event" row, the mean age of subjects with at least one occurrence of the event in the time frame.</p> <p>For the "without (wo) event" row, the mean age of subjects with no occurrence of the event in the time frame.</p> <p>Mean age is computed using the SQL AVG function for values of the DM.AGE variable. Subjects with null age values are excluded from the computation.</p>
Mean Weight	<p>For the "with event" row, the mean weight of subjects with at least one occurrence of the event in the time frame.</p> <p>For the "without (wo) event" row, the mean weight of subjects with no occurrence of the event in the time frame.</p> <p>Mean weight is computed using the SQL AVG function for values of the VS.VSSTRESN variable where VS.VSTESTCD is the vital sign identifier for weight and the VS.VSBLFL variable is 'Y' (indicating baseline weight measurement). Subjects with null weight values are excluded from the computation.</p>
BMI	<p>Mean Body Mass Index of subjects.</p> <p>For the "with event" row, the mean Body Mass Index of subjects with at least one occurrence of the event in the time frame.</p> <p>For the "without (wo) event" row, the mean Body Mass Index of subjects with no occurrence of the event in the time frame.</p> <p>If no vital sign identifier for BMI is defined for the study, BMI is computed (for all subjects) using height and weight values found in the VS domain (if vital sign identifiers have been defined for height and weight and values exist for them). Subjects with null height or weight values are excluded</p>

from the computation.

If a vital sign identifier for BMI is defined for the study:

- If at least one subject has a non-null result for a test that matches the vital sign identifier for BMI, the value from the study data is used (for all subjects). BMI is not computed for any subjects.
- If no subjects have a non-null result for a test that matches the vital sign identifier for BMI, BMI is computed (for all subjects) using height and weight values found in the VS domain (if vital sign identifiers have been defined for height and weight and values exist for them)

2. Click **Configure**, set the following options, and click **OK**:

- Show mean subject age
- Show mean subject weight
- Show mean subject BMI
- Show demographics for subjects not experiencing events


3. Click **Print** to [print the table](#), or **Download** to [download the table](#).

Viewing an Odds Ratio Graph

The odds ratio graph shows **corrected** odds ratios and their lower and upper confidence bounds, which are in the [screening result columns](#) ODDS_RATIO_C, OR025_C, and OR975_C. For information about how the corrected odds ratio is computed, see [Scores for Disproportionality Analysis Types](#).

To view an odds ratio graph:

1. Do one of the following:

Tab	Steps	Notes
Safety Review	On the Adverse Events page: As a safety review configuration option, select a dosing category breakdown (not ARM values). Then click  for a row and click Odds Ratio Graph .	The graph is affected by your selection of a qualifier under "Adverse Event Incidence for" on the Adverse Events page. When displayed for a row containing "<Any Body System>" or "<Any Event>", the graph also includes bars for PTs.
	On the Screening Results page: For a screening result for any analysis type except a Lab or Vitals Change from Baseline	For a clinically significant lab or vitals result, if built-in criteria were used to determine clinical significance , the criteria are indicated below the table. No note appears if a flag variable was

	Analysis, click View Odds Ratio Graph .	used to determine clinical significance. When displayed for the result of an HLT, HLGT, or SOC Analysis, the graph also includes a bar for each PT that has the higher level term in its primary path.
Screening	On the Analysis Results page: For a screening result for any analysis type except a Lab or Vitals Change from Baseline Analysis, click View Odds Ratio Graph .	For a clinically significant lab or vitals result, if built-in criteria were used to determine clinical significance , the criteria are indicated below the table. No note appears if a flag variable was used to determine clinical significance. When displayed for the result of an HLT, HLGT, or SOC Analysis, the graph also includes a bar for each PT that has the higher level term in its primary path.

2. [Configure the graph](#).
3. You can point to a bar in the graph to display details about what the bar represents. Note that the details show the corrected odds ratios and their lower and upper confidence bounds.
4. Optionally click **Download Data for Graph to Excel**.

Configuring an Odds Ratio Graph

1. In the [graph display window](#), click **Configure**.
2. Specify the following display options:

Option	Description
Order by	<p>The options are:</p> <ul style="list-style-type: none"> • Event—PT. Applicable only if the graph includes multiple PTs. • Lower bound of CI—Lower bound of the confidence interval for the corrected odds ratio. • Corrected OR—Corrected odds ratio. When you view this graph on the Safety Review tab, the option is labeled OR, but refers to the corrected OR.
Color by	<p>Determines how the graph should be colored. The options are:</p> <ul style="list-style-type: none"> • Lower bound of CI—Lower bound of the confidence interval for the corrected odds ratio. • Corrected OR—Corrected odds ratio. When you view

this graph on the Safety Review tab, the option is labeled **OR**, but refers to the corrected OR.

- **None**—Do not use color in the graph.

Axis type	Indicates the axis type. The options are: <ul style="list-style-type: none"> • Linear—The x-axis and y-axis are linear. • Log—The x-axis and y-axis are logarithmic. <p>The default value is Log.</p>
Show number of subjects	Determines whether to show the total count of subjects participating in the study at the start of the selected time frame. <ul style="list-style-type: none"> • If selected—Shows number of subjects. • If deselected—Does not show number of subjects.
Show vertical reference line	Determines whether a vertical line appears at the corrected odds ratio 1.0 for reference purposes. <ul style="list-style-type: none"> • If selected—Shows a vertical reference line. • If deselected—Does not show a vertical reference line.

- Optionally check any other display options. See [Working with Graphs](#) for information about the following display options: Use gray-scale instead of colors; Key; and Links.
- Click **OK**.

Lab Test Results

Viewing Lab Test Results

The Lab Results page of the Safety Review tab shows lab test results. The first two columns are:

- **Group** – Name of the group containing the lab test. There is also an entry for <Any Group>. A [safety review configuration option](#) determines whether the group name is truncated for display.
- **Test** – Name of the lab test. There is also an entry for <Any Test> and entries for <Any *group-name* Test>. If the Test column is empty, the row represents lab test records in which the lab test name is blank. There is a row for each long name of a lab test. The result units are displayed in parentheses after the test name. If multiple units are found for any test, a note appears at the bottom of the page and you can click a hyperlink to view the multiple units.

To view lab test results:

1. Keep in mind that dosing categories and the time frame are determined by [safety review configuration options](#).
2. On the Safety Review tab, click **Labs**.
3. Optionally select an entry in the Group field to limit the display to only lab tests in a specific lab test category or panel.
4. Under "Lab Results", click one of the following radio buttons to restrict the lab tests that are listed. If multiple results exist for a subject/visit, the most extreme result is used.

Note: The Group field and the radio buttons affect which lab tests are listed on the page. They do not affect screening results or any graphs, including those available for a particular test and those available as hyperlinks at the top of the page.


Clinically significant	A post-baseline value is clinically significant according to a particular flag variable provided with the study data.
	Note: This option is available only if a lab test clinical significance flag variable has been defined for the study. This option never uses built-in criteria for clinical significance.
Outside 5x normal range	A post-baseline value is either of the following: <ul style="list-style-type: none"> • Less than a fifth of the lower end of the normal range • Greater than five times the upper end of the normal range.
Outside 3x normal range	A post-baseline value is either of the following: <ul style="list-style-type: none"> • Less than a third of the lower end of the normal range. • Greater than three times the upper end of the normal range.
Outside normal range	A post-baseline value is either of the following: <ul style="list-style-type: none"> • Less than the lower end of the normal range. • Greater than the upper end of the normal range. <p>Note: Options related to normal range are available only if normal ranges for lab tests are provided in the study data.</p>
All	Any value.

5. If you are showing values outside the normal range, check either or both of the "Above normal" and "Below normal" checkboxes.

The column heading for each dosing category shows N. If the time frame has a well-defined start, N is the total count of subjects for the dosing category who did not [drop out](#) before the time frame start. Otherwise, N is the total count of subjects for the dosing category. Other statistics in the table are for subjects included in N.

For each dosing category, the table shows the following information for each lab test:

Column	Description
#	Count of subjects with at least one occurrence of the lab test during the time frame, as qualified by the radio button under "Lab Results". If "All" results are displayed, the count includes subjects with null results for the test. You can click this value to drill down to subjects included in the count.
%	Percentage of subjects with at least one occurrence of the lab test during the time frame, as qualified by the radio button under "Lab Results". If "All" results are displayed, the percentage includes subjects with null results for the test. Computed as: $(\#/N) \times 100$

6. If a preparatory analysis specification (named [\\$\\$\\$BASIC\\$\\$\\$SCREENING\\$\\$\\$](#)) has been run and you have configured safety review to use a dosing category breakdown and time frame for which screening results exist, you can click **Lab Screening Results** to [view screening results](#).
7. To [view a Lab Graph](#) showing lab test values over the study timeline, click **Lab Graph**.
8. To [view a Lab Panel](#) showing lab test values, as compared to normal ranges, for each subject across study visits, click **Lab Panel**.
9. To [view an LFT Shift from Baseline Scatter Plot](#), click **LFT Scatter Plots: Change from Baseline**.
10. To [view an LFT Scatter Plot Matrix](#), click **LFT Scatter Plot Matrix: Maximum Results**.
11. To [view a Hy's Law and Liver Function Tests of Critical Concern](#) report, click **Hy's Law**.
12. If you click  for a lab test, you can select the following options:
 - [Results by High/Low/Normal Indicator](#) (available if you clicked All under "Lab Results")
 - [Box Plot: Change from Baseline](#) (available for rows associated with a specific test)
 - [Delta Plot: Change from Baseline](#) (available for rows associated with a specific test)
 - [Scatter Plot: Shift from Baseline](#) (available for rows associated with a specific test)
 - [Box Plot: Distribution over Time](#) (available for rows associated with a specific test). You can show raw values (actual results from the study data), normalized raw values (test values divided by the upper limit of normal), or change from baseline values.

More detail

The displayed units are the last alphabetically among units for all test records for which LB.LBSTRESN and LB.LBDTC are not null, without restriction by any time frame or dosing category breakdown.

Viewing Hy's Law and LFTs of Critical Concern

The Hy's Law and Liver Function Tests of Critical Concern reports on post-baseline results for the ALT, AST, BILI, and ALP tests that meet certain criteria. A post-baseline result is one for which the value of LB.LBBLFL is not 'Y' and that occurs after the baseline result. Baseline is established as described in [Baseline Results](#).

Notes

- For issues involving multiple criteria, the criteria must have occurred at the same post-baseline visit.
- If the same lab test occurred more than once for a post-baseline visit, all lab test values for the visit are considered in determining whether the finding-specific criteria are met.
- If there is no ULN value for a subject's test, the test result is not used.
- A subject is counted separately for each criterion that is met. The same subject could be counted in all six rows of the display.

To view Hy's Law and Liver Function Tests of Critical Concern:

1. On the [Lab Results page](#), click **Hy's Law**.

Note: WebSDM/Empirica Study checks for an up-to-date issue list for the time frame that is currently selected as a safety review configuration option. If an up-to-date issue list exists, it is used. If no issue list exists or it is out-of-date, the Hy's Law display is generated without an issue list. Report performance is faster when the issue list is used.

The column heading for each dosing category shows N. If the time frame has a well-defined start, N is the total count of subjects for the dosing category who did not [drop out](#) before the time frame start. Otherwise, N is the total count of subjects for the dosing category. Other statistics in the table are for subjects included in N.

For each dosing category, the table shows the following information for each lab test:

Column	Description
Finding	One of the following: <ul style="list-style-type: none"> • (ALT or AST) \geq 3x ULN, BILI \geq 2x ULN, ALP \leq 2x ULN • (ALT or AST) \geq 3x ULN, BILI \geq 1.5x ULN, ALP \leq 2x ULN • (ALT or AST) \geq 3x ULN, BILI \geq 1.5x ULN • (ALT or AST) \geq 20x ULN

- (ALT or AST) $\geq 10 \times$ ULN
- (ALT or AST) $\geq 5 \times$ ULN
- (ALT or AST) $\geq 3 \times$ ULN

Note: The above findings require that [lab test identifiers](#) for the following lab tests have been defined: Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Bilirubin (BILI), and Alkaline Phosphatase (ALP). However, you can display the report if test IDs for only ALT and/or AST have been defined.

#	Count of subjects who had at least one occurrence of the finding during the time frame. You can click this value to drill down to subjects included in the count.
%	Percentage of subjects who had at least one occurrence of the finding during the time frame. Computed as: $(\#/N) \times 100$

- To view the displayed information graphically, click **Graph**.

The x-axis in the graph represents percentages of subjects, and the y-axis represents each finding.

You can point to a dot to display details about what the dot represents. If you click a dot, a menu appears and you can [drill down](#) to subjects represented by the dot.

To print or copy the graph, see [Working with Graphs](#).

- To view the Drug Induced Liver Injury (DILI) plot, click **DILI Plot**.

For more information on the DILI Plot, see Viewing the Drug-Induced Liver Injury Plot.


- Click **Close**. The Hy's Law window closes.

Viewing Lab Test or Vital Sign Results by Range Indicators

If a normal range indicator variable for lab tests or vital signs is provided in the study data, you can view counts and percentages of subjects with results in high, low, and normal ranges (from the LB.LBNRIND or VS.VSNRIND values).

To view lab test or vital sign results by range indicators:

On the [Lab Results page](#), click the "All" radio button under "Lab Results". Then click  for a lab test and then click **Results by High/Low/Normal Indicator**.

On the [Vital Signs page](#), click  for a vital sign and then click **Results by High/Low/Normal Indicator**.

The column heading for each dosing category shows N. If the time frame has a well-defined start, N is the total count of subjects for the dosing category who did not [drop out](#) before

the time frame start. Otherwise, N is the total count of subjects for the dosing category. Other statistics in the table are for subjects included in N.

For each dosing category, the table shows the following information for each lab test or vital sign:

Column	Description
Test	Name of the lab test or vital sign.
#	Count of subjects with a lab test or vital sign result with the listed value for High/Low/Normal during the time frame. You can click this value to drill down to subjects included in the count.
%	Percentage of subjects with a lab test or vital sign result with the listed value for High/Low/Normal during the time frame. Computed as: $(\#/N) \times 100$

Viewing an LFT Scatter Plot Matrix

The Maximum LFT Results graph provides a way to identify maximum post-baseline LFT values that are elevated simultaneously in pairs of liver function tests. A post-baseline result is one for which the value of LB.LBBLFL is not 'Y' and that occurs after the baseline result. Baseline is established as described in [Baseline Results](#). Note that a baseline is established separately for each test.

A scatter plot is displayed for each pairwise combination of the four liver function tests:

- Alanine Aminotransferase (ALT)
- Aspartate Aminotransferase (AST)
- Alkaline Phosphatase (ALP)
- Bilirubin (BILI)

Keep in mind that:


- Results for the pair of tests do not need to have occurred on the same date.
- In each scatter plot, the x-axis represents maximum values for one of the liver function tests, and the y-axis represents maximum values for another of the liver function tests. Only numeric values are plotted.
- The graph plots normalized values, that is, values divided by the upper limit of normal. If a test's upper limit of normal cannot be determined, the result is omitted from the graph.
- The range of values is determined by the lowest and highest value among all subjects' values across all post-baseline visits.

If a time frame with a well-defined start is in effect, only subjects who did not [drop out](#) before the time frame start are included in the graph. If any time frame is in effect, only post-baseline lab test results that occurred within the time frame are shown. If the LB DTC data is missing, results for those subjects are not included.

You must have [defined test identifiers](#) for the appropriate lab tests to view the LFT Scatter Plot Matrix graph.

To view an LFT Scatter Plot Matrix:

1. Do one of the following:

Tab	Steps	Notes
Domains	Click  in the Listings column for the LB domain, and then click LFT Scatter Plot Matrix: Maximum Results .	The graph uses the default dosing category breakdown for the study or study pool. If there is no default dosing category breakdown, it groups all arms into one category named "Treatment: Any".
Safety Review	On the Lab Results page , click LFT Scatter Plot Matrix: Maximum Results .	The graph uses the currently selected dosing category breakdown. If there is no dosing category breakdown selected, it groups all arms into one category named "Treatment: Any".

2. [Configure the graph](#).
3. To [drill down](#) to subject information, point to the graph, click, and hold down the mouse button while you draw a red rectangle around the data points for which you want to drill down, making sure that you do not include any of the gray background above or below the graph. When you release the mouse button, a menu appears and you can drill down. Note that a single plotted symbol in the graph may represent several data points if they have the same or similar values.
4. To display an individual graph enlarged in its own window, click **Zoom** in the menu described in the previous step.
5. To print or copy the graph, see [Working with Graphs](#).

More detail

The following situations may prevent the graph from displaying or cause data points to be omitted from the graph. If you configure the graph to show notes, subjects for whom data points are omitted for these reasons are listed. The notes do not pertain to data points that are omitted due to restrictions imposed by time frames or dosing category breakdowns.

Note: LBSTNRLO is checked only if the graph is restricted to subjects with normal baseline values.

Situation	Variables	Effect
A required variable is not found.	LB.LBSTRESN LB.LBSTNRLO	Graph is not displayed.

	LB.LBSTNRHI LB.LBTSTID_ LB.LBDTC	
Test identifiers have not been defined.	All LB variables	Graph is not displayed.
An internal error occurred for the value of a variable, possibly because the variable does not have the expected data type.	LB.USUBJID LB.LBSTRESN LB.LBSTNRLO LB.LBSTNRHI	Data point is omitted from graph.
A Null value is found for a variable expected to have a non-null value.	LB.LBSTRESN LB.LBSTNRLO LB.LBSTNRHI	Data point is omitted from graph.
The value of ULN is 0, which makes normalization of the result impossible.	LBSTNRHI	Data point is omitted from graph.
An internal error occurred when dividing the raw result by the upper limit of normal, possibly because the value of ULN is extremely small.	LB.LBSTRESN / LB.LBSTNRHI	Data point is omitted from graph.

Configuring an LFT Scatter Plot Matrix

1. In the [graph display window](#), click **Configure**.
2. Specify the following display options:

Option	Description
Axis type	Indicates the axis type. The options are: <ul style="list-style-type: none"> • Linear—The x-axis and y-axis are linear. • Log—The x-axis and y-axis are logarithmic. <p>The default value is Log.</p>
X and Y axis low to include X and Y axis high to include	Allows you to modify the low or high values to be included on axes to make the scatter plots more readable. <p>Note: The axes include your specified values, but do not necessarily start or end with them.</p> <ul style="list-style-type: none"> • If the low value is blank, a default value is used. For linear axes, the default is 0. For log axes, the default is .1. • If the high value is blank, a high value that encompasses the highest value in the data is used.
Points outside the	Determines whether data points that fall outside the boundary

range are:

of either axis are plotted. The options are:

- **Plotted at the axis boundary**—Data points appear along the x or y axis.
- **Omitted from the display**—Data points do not appear in the graph.

No warning appears in either of these situations.

Reference line(s) for Alanine Aminotransferase (ALT) at	Specify up to three reference lines for each test, or clear the fields if no reference lines should appear. Specify positive values delimited by commas. For example: <ul style="list-style-type: none"> • To include reference lines at 1x ULN and 2x ULN, specify 1, 2. • To include reference lines at 0.75x ULN, 1x ULN, and 2x ULN, specify 0.75, 1.0, 2.0.
Reference line(s) for Alkaline Phosphatase (ALP)	
Reference line(s) for Aspartate Aminotransferase (AST)	WebSDM/Empirica Study ignores extra commas and additional values specified beyond the third value. The default reference lines for each test are at:
Reference line(s) for Bilirubin (BILI) at	<ul style="list-style-type: none"> • ALT—3.0 • ALP—2.0 • AST—3.0 • BILI—2.0
Include linear regression lines	Determines whether least-squares regression lines appear for treatment groups in each scatter plot. <ul style="list-style-type: none"> • If selected—Linear regression lines appear. • If deselected—Linear regression lines do not appear.
Include ULN boundaries	Determines whether a 1x ULN-bounded region appears at 1.0 on each axis. <ul style="list-style-type: none"> • If selected—ULN boundaries appear. • If deselected—ULN boundaries do not appear.
Restrict to subjects normal at baseline	Determines whether to plot data for only subjects that had a normal result for the lab test at their baseline visit.
Display graph with all arms included in Treatment	Select to plot data for all arms in the study data as a single group labeled "Treatment" and the graph key shows "Treatment: Any".

Deselect to plot data for the Treatment and Comparator categories separately.

For the Domains tab, this option can be cleared only if there is a default dosing category breakdown for the study or study pool.

For the Safety Review tab, this option can be cleared only if there is a dosing category breakdown currently selected as a [safety review configuration option](#).

Use gray-scale instead of colors	Indicates whether the graph appears using shades of gray or color.
Key	Indicates whether a color key appears below the graph to indicate the values that each graph element represents.
Notes	<p>If you check Notes, the following information will appear below the graph:</p> <ul style="list-style-type: none"> • Name of user who produced the graph, datetime the graph was produced, and the application/study. • Configuration options specified for the graph. • List of any subject IDs for which there are data problems that prevent data points from displaying in the graph.
Links	<p>Indicates whether the following links and options appear:</p> <ul style="list-style-type: none"> • Drilldown menu options when you point to a plot point. • Print link

3. Click **OK**.

ECG Results

Viewing a QT Prolongation Summary

The QT Prolongation Summary provides counts and percentages for findings about ECG tests. Rows in the summary are one of the following:

- *<correction-method>* QTc Interval > 450
- *<correction-method>* QTc Interval > 480
- *<correction-method>* QTc Interval > 500
- *<correction-method>* QTc Interval Increase >= 30
- *<correction-method>* QTc Interval Increase >= 60

where *<correction-method>* is Reported, Bazett, FDA Neuro, or Fredericia.

The QTc intervals are either as reported in the study data, or are computed using the following correction methods:

- Bazett's formula = $QT_{msec} / (RR \text{ sec})^{0.5}$
- FDA Neuropharmacological Division's formula = $QT_{msec} / (RR \text{ sec})^{0.37}$
- Fredericia's formula = $QT_{msec} / (RR \text{ sec})^{0.33}$

Note: For the above computations, the QT and RR test must have the same date.

If a [test identifier](#) for QTC INTERVAL (the reported, corrected QT interval) has been defined, the report includes checks for "Reported QTc Interval". If test identifiers for QT INTERVAL and RR INTERVAL have been defined, the report includes checks for "Bazett QTc Interval", "FDA Neuro QTc Interval", and "Fredericia QTc Interval".

Notes

- For evaluations based on actual values (that is, QTc Interval > 450, QTc Interval > 480, QTc Interval > 500), the display includes only subjects who had at least one QTc result.
- For evaluations based on increase from baseline (QTc Interval Increase >= 30 and QTc Interval Increase >= 60), the display includes only subjects who had a baseline QTc result and a post-baseline QTc result. See [Baseline Results](#) for information about how baseline is determined. Also note that the display does not use the safety review configuration option for "Use maximum (instead of most recent) change from baseline". All post-baseline results (within the time frame, if a time frame is in effect) are evaluated and counted.
- For evaluations that use QT INTERVAL and RR INTERVAL, the results must have occurred at the same visit. For evaluations that use baseline, the later of the baseline values for QT or RR are used.
- It is assumed that RR is stored in milliseconds; thus, the RR value is divided by 1000 to obtain seconds.
- Computations rely on the value reported for RR to be non-negative. Records with a negative value for RR are excluded from the display.

To view a QT Prolongation Summary:

1. Keep in mind that dosing categories and the time frame are determined by [safety review configuration options](#).
2. On the Safety Review tab, click **ECGs**.

Note: An up-to-date [issue list](#) must exist for the time frame that is selected as a safety review configuration option. To keep the list current, WebSDM/Empirica Study silently [submits an automatic screening run](#) when you perform certain actions that would cause the list to become out-of-date. However, if the issue list needs to be created or updated, for example, because a user cancelled the last autoscreening run, a message informs you and provides the opportunity to create or update the issue list for the selected time frame and any other time frames.

If you choose to update the issue list when WebSDM/Empirica Study prompts you and you do not have the Load and Check Studies permission, an error occurs. You must contact your system administrator to refresh the issue list.

The column heading for each dosing category shows N. If the time frame has a well-defined start, N is the total count of subjects for the dosing category who did not [drop out](#) before the time frame start. Otherwise, N is the total count of subjects for the dosing category. Other statistics in the table are for subjects included in N.

For each dosing category, the table shows the following information for each ECG result:

Column	Description
#	Count of subjects with at least one occurrence of the finding during the time frame. You can click this value to drill down to subjects included in the count.
%	Percentage of subjects with at least one occurrence of the finding during the time frame. Computed as: $(\#/N) \times 100$

- To view the displayed information graphically, click **Graph**. The x-axis in the dot plot represents percentages of subjects, and the y-axis represents each finding.

You can point to a dot in the graph to display details about what the dot represents.

You can click a dot and then [drill down](#) to subjects represented by the dot.

To print or copy the graph, see [Working with Graphs](#).

- If a preparatory analysis specification (named [\\$\\$\\$BASIC\\$\\$\\$SCREENING\\$\\$\\$](#)) has been run and you have configured safety review to use a dosing category breakdown and time frame for which screening results exist, you can click **ECG Screening Results** to [view screening results](#).
- To [view a QTc Change over Time graph](#), click **Distribution of QTc Change over Time**.

Vital Signs Results

Viewing Vital Signs Change from Baseline

The Vitals Signs page of the Safety Review tab shows the changes from baseline values for vital sign measurements. See [Baseline Results](#) for information about how baseline values are established. There is a row for each combination of the long name of the vital sign and position, if any. The position is displayed in parentheses, followed by the result units in parentheses. If multiple units are found for any test, a note appears at the bottom of the page and you can click a hyperlink to view the multiple units.

The change from baseline values in this display are one of the following, depending on your [safety review configuration option](#):

- Maximum difference between the baseline measurement and any post-baseline measurement

- Difference between the baseline measurement and the most recent measurement

The note below the table indicates whether the result uses "maximum change" or "most recent change".


To view vital signs results:

1. Keep in mind that dosing categories and the time frame are determined by [safety review configuration options](#).
2. On the Safety Review tab, click **Vitals**.

The column heading for each dosing category shows N. If the time frame has a well-defined start, N is the total count of subjects for the dosing category who did not [drop out](#) before the time frame start. Otherwise, N is the total count of subjects for the dosing category. Other statistics in the table are for subjects included in N.

For each dosing category, the table shows the following information for each vital sign:

Column	Description
Mean	Mean change from the baseline value during the time frame.
Min	Minimum change from the baseline value during the time frame.
Max	Maximum change from the baseline value during the time frame.

3. If a preparatory analysis specification (named [\\$\\$\\$BASIC\\$\\$\\$SCREENING\\$\\$\\$](#)) has been run and you have configured safety review to use a dosing category breakdown and time frame for which screening results exist, you can click **Vital Signs Screening Results** to [view screening results](#).
4. To [view a Vital Signs Graph](#) showing vital sign values over the study timeline, click **Vitals Signs Graph**.
5. If you click  for a vital sign, you can select the following options:
 - [Results by High/Low/Normal Indicator](#)
 - [Box Plot: Change from Baseline](#)
 - [Delta Plot: Change from Baseline](#)
 - [Scatter Plot: Shift from Baseline](#)
 - [Box Plot: Distribution over Time](#). You can show raw values (actual results from the study data), normalized raw values (test values divided by the upper limit of normal), or change from baseline values.

Variables used by this display

In order for a row to appear on this page, there must be a non-null value for each of the VS.VSTEST, VS.VSSTRESN, and VS.VSDTC variables.


The displayed units are the last alphabetically among units for all combinations of vital signs and position for which VS.VSSTRESN and VS.VSDTC are not null, without restriction by any time frame or dosing category breakdown.

Viewing Lab Test or Vital Sign Results by Range Indicators

If a normal range indicator variable for lab tests or vital signs is provided in the study data, you can view counts and percentages of subjects with results in high, low, and normal ranges (from the LB.LBNRIND or VS.VSNRIND values).

To view lab test or vital sign results by range indicators:

On the [Lab Results page](#), click the "All" radio button under "Lab Results". Then click  for a lab test and then click **Results by High/Low/Normal Indicator**.

On the [Vital Signs page](#), click  for a vital sign and then click **Results by High/Low/Normal Indicator**.

The column heading for each dosing category shows N. If the time frame has a well-defined start, N is the total count of subjects for the dosing category who did not [drop out](#) before the time frame start. Otherwise, N is the total count of subjects for the dosing category. Other statistics in the table are for subjects included in N.

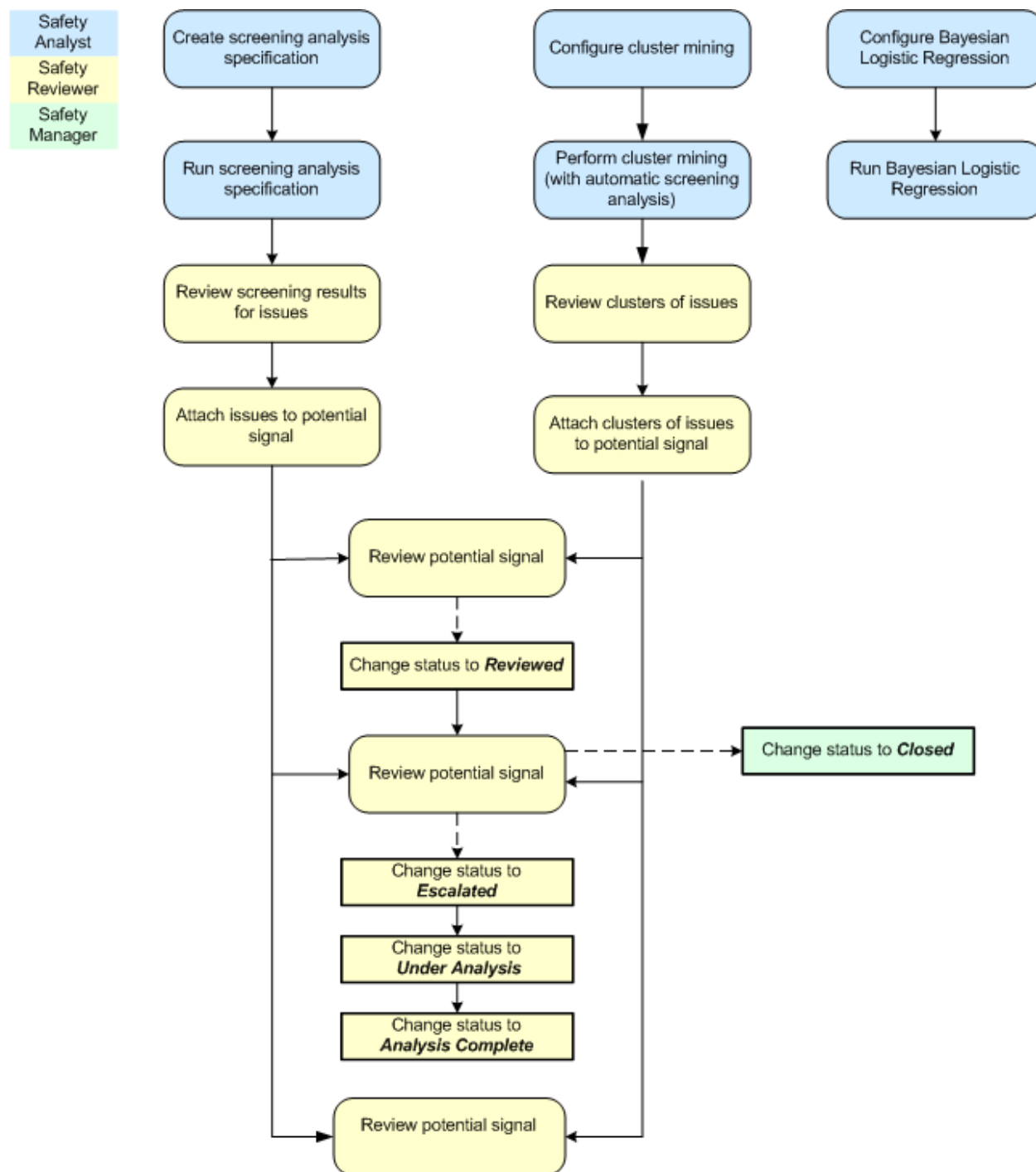
For each dosing category, the table shows the following information for each lab test or vital sign:

Column	Description
Test	Name of the lab test or vital sign.
#	Count of subjects with a lab test or vital sign result with the listed value for High/Low/Normal during the time frame. You can click this value to drill down to subjects included in the count.
%	Percentage of subjects with a lab test or vital sign result with the listed value for High/Low/Normal during the time frame. Computed as: $(\#/N) \times 100$

Screening Results

About the Screening Tab

The following diagram shows tasks that you perform on the Screening tab in WebSDM/Empirica Study. The job titles and roles of users who perform particular tasks may vary from organization to organization. For the purpose of clarity, the diagram assumes a specific model for tasks performed by safety analysts, safety reviewers, and safety managers:



About Screening Results

Screening results are statistical scores for associations of a treatment group (as compared to a comparator group) and safety issues. The issues vary depending on the type of screening analysis. For example, in a MedDRA PT Analysis, each PT is identified as an issue, whereas, in a Clinically Significant Lab Analysis, each lab test that has clinically significant values is identified as an issue. Screening analysis types may include disproportionality analyses, which compute Chi-statistics and p-values, and change-from-baseline analyses,

which compute t-statistics. For all analysis types, a score is computed to help you assess the issues.

Screening results are generated by screening analysis specifications that do the following:

- Specify the treatment and comparator categories and time frames for which to run the analysis.
- Define subgroups of subjects based on such factors as sex, race, age, medical history, and concomitant medications.
- Indicate the analysis types to run.

You can create and run analysis specifications and view their results on the Screening tab. If you run a screening analysis specification named [\\$\\$\\$BASIC\\$\\$\\$SCREENING\\$\\$\\$](#), you can also view screening results on the **Safety Review** tab.

The screening results are presented as a table in which each row is the result for a particular issue, treatment or comparator group, time frame, and subgroup. You can filter the results table in various ways to locate specific results.

Screening result columns

The three most significant columns are:

- **TYPE**—Identifies the type of analysis. For example, the TYPE column is a SOC for a MedDRA SOC Analysis and VSBL for a Vitals Change from Baseline.
- **ISSUE**—Identifies the safety issue being scored. For example, in results of a MedDRA PT Analysis, each PT is identified as the issue; in a Clinically Significant Lab Analysis, each lab test that has clinically significant values is identified as the issue. For a result generated for a custom MedDRA-based analysis type, the ISSUE is an event that meets the specified criteria; for example, serious, treatment-emergent events.
- **SCORE**—Shows the screening analysis score. For all analysis types except the two Change from Baseline Analyses, the score is the one-tailed p-value associated with the Chi statistic. For a Change from Baseline Analysis, the score is the one-tailed p-value associated with the t-statistic. For more information, see [Scores for Disproportionality Analysis Types](#) and [Lab or Vital Signs Change from Baseline Analysis](#).

For a description of each column, see [Screening Result Columns](#).

Related Topics

[Viewing Screening Results](#)

Viewing Screening Results

For information about values in the results, see [Screening Result Columns](#). You can also hover the cursor over a column heading to display a brief description of the column as a tooltip.

Score	Chi-square statistic	Odds Ratio	OR
0.99861	SCORE: Screening result score (one-tailed p-value associated with Chi-statistic or two-tailed p-value associated with t-statistic)		

To view screening results:

1. Do one of the following:

Tab	Steps	Notes
Safety Review	As a safety review configuration option , select a dosing category breakdown (not ARM values) and time frame for which screening results exist. Then click Screening Results. Depending on which page you are on, you can also click AE Screening Results , Lab Screening Results , ECG Screening Results , or Vital Signs Screen .	The screening results are for the analysis specification named \$\$\$BASIC\$\$\$SCREENING\$\$\$. If you go to screening results for a particular type of data, the Analysis Group field is set by default to that type of data.
Screening	For the analysis specification for which you want to view results, click the count in the "# Results" column.	

2. If warnings occurred when the specification was run, a message appears above the results with a link that you can click to [view the warnings](#).

Note: If the whole screening analysis specification run failed, a message informs you and enables you to view the errors that occurred.

If any of the results are marked as requiring review, a message appears below the table. The name of the issue for each of these results appears in red font. See [Marking a Result as Reviewed](#).

If the results for certain analysis types (EGQT, LBHY, LBCS, VSCS, LBBL or VSBL) were generated prior to Empirica Study 3.0, they are outdated because the way in which these analysis types compute results has changed. A message tells you that some results use outdated selection criteria and that results will be updated the next time you run the specification. For results that are outdated, you cannot drill down on counts and the only row-level action you can perform is viewing potential signals with the results attached.

3. On the Screening tab, you can select a different analysis specification in the Specification field to view results for that specification.
4. To [view information about the analysis specification](#), click **View Analysis Specification Details**.
5. Select values in fields as follows:

Field	Description
Dosing category breakdown	<p>On the Screening tab, select a breakdown in the "Dosing category breakdown" field. "--" indicates all breakdowns in the list. If a default dosing category breakdown is defined for the study or study pool, it appears in this field by default. Note that some hyperlinks are not available until you have selected a dosing category breakdown. Also note that if you select "--" in this field, you need to look at the Dosing Breakdown column to differentiate results in the table.</p> <p>On the Safety Review tab, the dosing category breakdown you selected as a safety review configuration option is used. This field does not appear.</p>
Time frame	<p>On the Screening tab, select a time frame in the "Time frame" field. "--" indicates all time frames in the list. If a default time frame is defined for the study or study pool, it appears in this field by default. Note that some hyperlinks are not available until you have selected a time frame. Also note that if you select "--" in this field, you need to look at the Time Frame column to differentiate results in the table.</p> <p>On the Safety Review tab, the time frame you selected as a safety review configuration option is used. This field does not appear.</p>
Analysis Group	<p>Select the type of data for which you want to view results. A group is available if there is at least one screening result for it. "--" indicates all groups in the list.</p> <hr/> <p>Note: This field appears only if there are results for more than one analysis group.</p>
Analysis Type	<p>Select the type of analysis for which you want to view results. A type is available if there at least one screening result for it. "--" indicates all types in the list.</p> <p>Depending on your analysis group selection, the following analysis types are available in this field:</p> <ul style="list-style-type: none"> • AES – MedDRA PT, HLT, HLGT, or SOC; Standardized MedDRA Query; Custom MedDRA Query • Disposition – Subject Disposition • ECGs – QT Interval Prolongation • Labs – Lab Change from Baseline, Clinically Significant Lab, Hy's Law • Vitals – Vitals Change from Baseline, Clinically Significant Vitals <hr/> <p>Note: This field appears only if there are results for more than one analysis type.</p>
<p>If the analysis specification used the following types of category breakdowns, there is a category "filter" field that you can use to restrict displayed results by category. Depending on how the analysis specification was set up, you can use only one of the category filter fields at a time or you can use them in combination. For more</p>	

information, see [Category Breakdowns and Time Frames](#). For each category filter field:


- " All" indicates the union of all categories defined in the breakdown.
- "—" indicates all categories in the list.

Sex	Available if the analysis specification used a sex category breakdown. Select the category for which you want to show results. Available categories are those for which there is at least one screening result.
Age	Available if the analysis specification used an age category breakdown. Select the category for which you want to show results. Available categories are those for which there is at least one screening result.
Race	Available if the analysis specification used a race category breakdown. Select the category for which you want to show results. Available categories are those for which there is at least one screening result.
Medical Hx	Available if the analysis specification used a medical history category breakdown. Select the category for which you want to show results. Available categories are those for which there is at least one screening result.
Con Med	Available if the analysis specification used a concomitant medication category breakdown. Select the category for which you want to show results. Available categories are those for which there is at least one screening result.
Study Group	Applies to study pools only. Available if the analysis specification used a study group category breakdown. Select the category for which you want to show results. Available categories are those for which there is at least one screening result.

- See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table. For screening results, you can specify up to 250 rows per page. For users with slow internet connections, reducing the number of rows per page is recommended so that the table refreshes quickly.

Note: If there are category filter fields, meaning that category breakdowns were used by the analysis specification, add the corresponding column to results if it is not there by default. For example, if there is a Medical Hx filter field, add the MEDHX_GROUP column to the table so that you can differentiate rows by medical history categories.

- For columns representing subject counts, you can click the count to [drill down](#) to subjects included in the count.
- If a screening result requires review, it appears in **red font** and its REVIEW_STATUS column shows **Needs Review**. To show only results that require review, select "Needs Review" in the Review Status field. If at least one result has been marked as reviewed, you can also select "Reviewed" to show only reviewed results. For more information, see [Marking a Result as Reviewed](#).
- If you are on the Screening tab, you can do the following once you have selected a dosing category breakdown and time frame:

- To [view a sector map](#), click **View as Sector Map**. This option is available for the following analysis types: MedDRA PT; MedDRA HLT; MedDRA HLGT; MedDRA SOC; or a custom analysis type based on one of those four analysis types.
 - To [view a Lab or Vitals Graph](#), click **View Lab Graph** or **View Vitals Graph**.
 - To [view a Lab Panel](#), click **View Lab Panel**.
 - To [view the Event Summary by Dose Group table](#), click **View Event Summary by Dose Group**.
 - To [view the Disposition Summary by Dose Group table](#), click **View Disposition Summary by Dose Group**.
10. On the Screening tab or Safety Review tab, if you click  for a specific screening result, you can view the following information:

View Options	PT, HLT, HLGT, SOC	SMQ, CMQ	LBCS, VSCS	LBHY	EGQT	DSPD	LBBL, VSBL
2x2 Table	X	X	X	X	X	X	
t-test Statistics							X
Box Plot							X
Delta Plot							X
Lab or Vitals Graph			X				X
Lab Panel			X				X
Events by Dose Group							
Day of Onset by Dose Group							
Severity, Toxicity Grade, Action Taken, or Outcome by Dose Group	X	X					
Recurrence by Dose Group							
Demographic Distribution by Dose Group							
Issues by Dose Group			X		X		
Cumulative Incidence Plot	X						
Odds Ratio Graph	X	X	X	X	X	X	

You can also do the following:

- To [view potential signals](#) to which a result is attached, click **View Potential Signals with this Result Attached**. This option is available only if you have the *Review Potential Signals* permission.

- To [attach a screening result to a potential signal](#) for the study, click **Attach to a Potential Signal** (if available).
- On the Screening tab: To indicate that you have [reviewed a result](#), click **Mark as Reviewed**. The REVIEW_STATUS column changes from **Needs Review** to **Reviewed** and the value in the ISSUE column no longer appears in **red font**. (This option is available only if you have the appropriate permission.)

Note: When an analysis specification is rerun, the status **Reviewed** is reset to **Needs Review**.

Viewing Analysis Specification Details

When viewing screening results, you may want to look at the various options used by the analysis specification that generated the results.

To view analysis specification details:

On the page displaying screening results, click **View Analysis Results**.

The information includes the categories (other than Dosing categories) that were used, as well as settings for the following options:

Option	Description
Use all combinations of categories	Checked if results were generated for all possible combinations of categories. If not checked, results were generated for one category at a time. See Category Breakdowns and Time Frames .
Use days on drug as denominator for MedDRA Analysis with no time frame	Applies to the following analysis types: MedDRA PT, HLT, HLGT, or SOC; Standardized MedDRA Query; Custom MedDRA Query. Checked if days on drug (instead of number of subjects) was used as the denominator in the odds ratio computation. This option applies to only results that are generated for the absence of a time frame. Results that are generated for a time frame ignore this option.
Use maximum (instead of most recent) change from baseline	This option affects the Lab Change from Baseline Analysis and Vitals Change from Baseline Analysis. If checked, the change from baseline value was computed using the post-baseline result (within the time frame) whose value represents the greatest (positive or negative) change from the baseline result. If not checked, the change from baseline was computed using the most recent, non-null, post-baseline result within the time frame. If there are multiple results with the same most recent date and time, the result (within the time frame) whose value represents the greatest (positive or negative) change from the baseline result was used.
Base CS Lab Analysis on flag variable	Applies to Clinically Significant Lab Analysis and Clinically Significant Vitals Analysis.
Base CS Vital Sign	If checked, clinical significance for the Lab or Vital Signs Change

Analysis on flag
variable

from Baseline Analysis was determined by a [flag variable](#). If unchecked, the clinical significance was determined by [built-in criteria](#).

Category Breakdowns and Time Frames

An analysis specification is run using selected dosing category breakdowns and time frames. In addition, the analysis specification may include category breakdowns for factors such as Sex and Race. A screening result is generated for each combination of the following:

- Each time frame for which the analysis specification was run.
- Each dosing category breakdown for which the analysis specification was run.
- Depending on the setting of "Use all combinations of categories" in the analysis specification, one of the following:
 - Each category (plus All) for a particular category breakdown (such as Sex) included in the analysis specification.
 - Each combination of categories (plus "All") for all the category breakdowns included in the analysis specification.

In the table of screening results, columns identify the above. The following example shows results if the following values are selected in fields on the page showing the table of screening results:

Dosing category breakdown: DCB1

Time frame: TF1

Sex: --

Race: --

The highlighted rows would appear only if the **Use all combinations of categories** option was checked in the analysis specification.

Issue	Score	Treatment Subjects	Comparator Subjects	Sex	Race	Dosing Breakdown	Time Frame
Anxiety	0.125090	248	112	Male	All	DCB1	TF1
Anxiety	0.148841	412	201	All	All	DCB1	TF1
Anxiety	0.202480	227	109	Male	White	DCB1	TF1
Anxiety	0.226506	377	194	All	White	DCB1	TF1
Anxiety	0.283738	13	4	All	Other	DCB1	TF1
Anxiety	0.329622	6	1	Male	Other	DCB1	TF1
Anxiety	0.342110	19	3	All	Black	DB1	TF1
Anxiety	0.348135	14	2	Male	Black	DCB1	TF1
Anxiety	0.459013	150	85	Female	White	DCB1	TF1
Anxiety	0.473170	164	89	Female	All	DCB1	TF1
Apnoea	0.236386	377	194	All	White	DCB1	TF1

Apnoea	0.242263	412	201	All	All	DCB1	TF1
Apnoea	0.243847	227	109	Male	White	DCB1	TF1
Apnoea	0.250487	248	112	Male	All	DCB1	TF1

For a screening result to be generated for a subgroup, there must be, in that subgroup, at least one subject receiving the treatment and at least one subject receiving the comparator. For the above example, there were no females with apnoea and no black males with apnoea, so no results were generated for those groups.

Viewing Warnings

When an [analysis specification](#) or [automatic screening](#) is run, warnings are generated if the study data fails certain diagnostic checks.

To view warnings:

If warnings are generated by the running of an analysis specification, a message appears in red on the page displaying screening results. Click the **here** link in the message to view the warnings. You can also click **Warnings** in the Execution Status column on the Analysis Specifications page or the Edit Analysis Specification page.

For warnings generated by automatic screening, you cannot view them except on the [Issue Clusters page](#), where a message appears in red and you can click the **here** link in the message to view the warnings.

The generation of warnings is not affected by dosing category breakdowns or time frames. For example, there may be warnings about AE.AEDECOD values for subjects who are not in the dosing category breakdowns or time frames for which results were generated.

Possible warnings

Warnings are generated in the situations listed below. For more information, see [About Analysis Types](#).

Note: The warnings for automatic screening also inform you of which analysis types were not run because requirements for the analysis type were not met. These are the same analysis types that would be unavailable for inclusion in a screening analysis specification for the study or pool.

Analysis Type	Message	Meaning of Message
MedDRA PT, HLT, HLGT, or SOC (standard or customized), Standardized MedDRA Query, Customized MedDRA Query	The following adverse event terms were not found in the MedDRA dictionary ([MedDRA account for the study]):	The AE.AEDECOD value is not in the MedDRA dictionary for the study. The terms that are not found are listed. Note: The case of the AE.AEDECOD value (upper case, lower case, or mixed) is ignored when matching to MedDRA terms is performed.
	The flag variable definition didn't identify any treatment emergent results	The flag variable for treatment emergence (used in a custom analysis type) is set to a value not

		found in the study data.
QT Prolongation (standard or customized)	No results were found for the following tests:	Results for the tests were not generated because the test identifier was missing or invalid.
	[N] records had invalid negative values for RR. These records will be excluded from screening analysis.	The computation of the corrected QT interval requires non-negative values for the RR interval. Records with negative RR values are excluded from the analysis.
Subject Disposition (standard or customized)	One or more subjects were found to have multiple disposition records.	The algorithm described in Disposition Events found multiple disposition events for the listed subjects and used disposition dates to differentiate them in order to determine one disposition event.
	One or more subjects were found to have multiple disposition records. When possible, the disposition was determined using disposition date but some subjects were omitted from consideration because no disposition could be determined for use in the analysis.	The algorithm described in Disposition Events found multiple disposition events for the listed subjects and used disposition dates to differentiate them in order to determine one disposition event. However, a disposition event could not be determined for some subjects so those subjects were omitted from the analysis. The subject IDs of the omitted subjects are preceded by "*"
Hy's Law (standard or customized)	No results were found for the following tests:	Results for the listed tests were not generated because the test identifier was missing or invalid.
Clinically Significant Lab or Vitals (standard or customized)	WARNING: [Lab or Vitals record]s may have incompatible units for built-in [LBCS OR VSCS] computations The message also indicates the test and the actual and expected units.	Built-in criteria for clinical significance were used, but the units of variables specified as test identifiers (i.e., the actual units) do not match (using case-insensitive matching) the units associated with the built-in criteria (i.e., the expected units). Results are generated for the test anyway (if the built-in criteria are met).
	When built-in criteria are used: The following tests have mappings that didn't match any short names found in the study data:	The test identifier for a test that is referenced by the built-in criteria is set to a value not found in the study data. Note: The warning does not occur if the test identifier is blank.
	When a flag variable is used: The flag variable definition didn't identify any clinically significant results	The lab flag variable or vital sign flag variable is set to a value not found in the study data. Note: The warning does not occur if

the flag variable is blank.

Screening Result Columns

For different analysis types, different columns of screening results are relevant and thus are included by default when you select a specific analysis type. To change which columns are displayed, the column order, or the sort order, or to use a SQL Where clause to filter rows of the screening results, you can click **Columns and Rows** and then [arrange the table](#). However, the default settings will be used again the next time you either select an analysis type or click **Reset** in the Columns and Rows window.

Note: You can also sort using the up and down arrows on either side of a column heading. By default, rows are sorted in ascending order of the SCORE column.

When viewing screening results, note that:

- You can hover the cursor over a column heading to display a brief description of the column as a tooltip. The name of the underlying column name (as stored in the database) precedes the description.
- For the Dosing Breakdown and Time Frame columns, you can hover the cursor over the content of a cell to display the composition of the particular dosing category or time frame as a tooltip.
- For columns representing subject counts, the count is a hyperlink that you can click to [drill down](#) to a list of subjects.
- In some cases, the column headings differ from the underlying column names (as stored in the database), which appear in the [Columns and Rows window](#). The Columns and Rows window includes a **Show Columns** link that provides both the column headings and the corresponding underlying names.
- Statistics in screening results may be computed to a greater precision level than the value displayed on the screening results page. To view statistics at their full precision levels, you can [download](#) results to an Excel format.

The following table describes all columns that are available to display in screening results. For information about how statistics are computed, see [Scores for Disproportionality Analysis Types](#) and [Lab or Vital Signs Change from Baseline Analysis](#).

Column	Analysis Type	Description
Time Frame	All	Name of the time frame for which the result was generated. You can hover the cursor over the value to display the composition of the time frame as a tooltip.
Dosing Breakdown	All	Name of the dosing category breakdown for which the result was generated. You can hover the cursor over the value to display the composition of the dosing category as a tooltip.
Row ID	All	Automatically assigned row identifier.

Spec ID	All	Automatically assigned ID of the analysis specification.
Type, Type Description	All	Abbreviation and description of the analysis type.
Issue	All	See Viewing Screening Results for a list of issues for the various analysis types. If a result requires review, the value in the ISSUE column appears in red font and the REVIEW_STATUS column shows "Needs Review".
Type ID	All	Automatically assigned identifier of the analysis type.
Type Name	All	Name of the standard or custom analysis type. This column is useful if you want to see the name of a custom analysis type that generated a result.
PT Code	PT	MedDRA code for the PT.
PT	PT	MedDRA Preferred Term.
HLT	PT, HLT, or HLGT	MedDRA High Level Term. If there is a PT value, this is the primary path HLT for the PT.
HLGT	PT, HLGT	MedDRA High Level Group Term. If there is a PT value, this is the primary path HLGT for the PT.
SOC	PT, HLT, HLGT, or SOC	MedDRA System Organ Class. If there is a PT value, this is the primary path SOC for the PT.
SOC Abbrev	PT, HLT, HLGT, or SOC	MedDRA short name for the System Organ Class.
Test Name	LBBL, LBCS, VSBL, or VSCS	Name of the lab test or vital sign.
Test Code	LBBL, LBCS, VSBL, or VSCS	Short name of the lab test or vital sign.
Application	All	Name of the application containing the study for which the result was generated.
Study	All	Name of the study or study pool for which the result was generated.
Configuration	All	Not used.
Drug	All	Always TestDrug in this implementation. Reserved for future use.
Review Status	All	"Needs Review" if the result requires review as specified by an event list or custom analysis type. Once the result is marked as reviewed, this column changes to "Reviewed".

		This column is empty if no review is required.
Review Date	All	If the REVIEW_STATUS is "Reviewed", date and time at which the result was marked as reviewed.
Reviewer	All	If the REVIEW_STATUS is "Reviewed", name of the user who marked the result as reviewed.
For the next six columns, if a category breakdown was defined, "All" indicates a union of all values in the defined categories. If no category breakdown was defined, "All" indicates that the value can be any value in the source data, including null.		
Sex	All	Sex category as defined in analysis specification.
Race	All	Race category as defined in analysis specification.
Age	All	Age category as defined in analysis specification.
Medical Hx	All	Medical history category as defined in the analysis specification.
Con Med	All	Concomitant medication category as defined in the analysis specification.
Study Group	All	Study Group category as defined in the analysis specification.
Values in the rest of this table are statistics for each subgroup. Note that if a time frame with a well-defined start is in effect, only subjects who did not drop out before the start of the time frame are included in the analysis.		
Total Subjects (N)	All	Total count of subjects who have sufficient data to determine if the issue occurred. $N = N_T + N_C$ If days on drug was used as the denominator, N is the total days on drug.
Treatment Subjects (N_T)	All	Total count of subjects who received the treatment and have sufficient data to determine if the issue occurred. $N_T = A + C$ If days on drug was used as the denominator, N_T is the total days on drug for subjects who received the treatment.
Comparator Subjects (N_C)	All	Total count of subjects who received the comparator and have sufficient data to determine if the issue occurred. $N_C = B + D$ If days on drug was used as the denominator, N_C is the total days on drug for subjects who received the comparator.
A	All except LBBL or VSBL	Count of subjects who received the treatment and experienced the issue.
B	All except LBBL or VSBL	Count of subjects who received the comparator and experienced the issue.
C	All	Count of subjects who received the treatment and did not

	except LBBL or VSBL	experience the issue. If days on drug was used as the denominator, C is computed as $(N_T - A)$ even though N_T is days on drug and A is a count of subjects.
D	All except LBBL or VSBL	Count of subjects who received the comparator and did not experience the issue. If days on drug was used as the denominator, D is computed as $(N_C - B)$ even though N_C is days on drug and B is a count of subjects.
chi-statistic	All except LBBL or VSBL	Chi-statistic.
Odds Ratio	All except LBBL or VSBL	Modified odds ratio statistic.
OR025	All except LBBL or VSBL	Lower confidence bound of the modified odds ratio statistic.
OR975	All except LBBL or VSBL	Upper confidence bound of the modified odds ratio statistic.
Corrected Odds Ratio	All except LBBL or VSBL	Corrected odds ratio statistic.
OR025_C	All except LBBL or VSBL	Lower confidence bound of the corrected odds ratio statistic.
OR975_C	All except LBBL or VSBL	Upper confidence bound of the corrected odds ratio statistic.
Shrunken Odds Ratio	All except LBBL or VSBL	Shrunken odds ratio statistic.
OR025_S	All except LBBL or VSBL	Lower confidence bound of the shrunken odds ratio statistic.
OR975_S	All except LBBL or	Upper confidence bound of the shrunken odds ratio statistic.

VSBL		
Mean for Treatment	LBBL or VSBL	Mean of lab test or vital sign change from baseline values for subjects who received the treatment.
Mean for Comparator	LBBL or VSBL	Mean of lab test or vital sign change from baseline values for subjects who received the comparator.
Std. Deviation for Treatment	LBBL or VSBL	Standard deviation of lab test or vital sign change from baseline values for subjects who received the treatment.
Std. Deviation for Comparator	LBBL or VSBL	Standard deviation of lab test or vital sign change from baseline values for subjects who received the comparator.
Variance for Treatment	LBBL or VSBL	Variance of lab test or vital sign change from baseline values for subjects who received the treatment.
Variance for Comparator	LBBL or VSBL	Variance of lab test or vital sign change from baseline values for subjects who received the comparator.
T	LBBL or VSBL	t-statistic. See Lab or Vital Signs Change from Baseline Analysis .
Score	All	<p>For all analysis types except a Change from Baseline Analysis, the one-tailed p-value associated with the Chi-statistic.</p> <p>For a Change from Baseline Analysis, the two-tailed p-value associated with the t-statistic.</p> <p>For all analysis types, lower scores are considered more interesting. For analysis types based on 2x2 contingency tables, "interesting" means that subjects in the treatment group experience a disproportionately higher occurrence rate of an adverse event than do subjects in the comparator group. For the analysis types based on t-tests, "interesting" means that the treatment and comparator groups had a relatively large difference in their mean change from baseline.</p>

TYPE, TYPE_DESC, and ISSUE columns

TYPE	TYPE_DESC	ISSUE
PT	MedDRA PT Disproportionality	Specific Preferred Term.
HLT	MedDRA HLT Disproportionality	Specific High Level Term.
HLGT	MedDRA HLGT Disproportionality	Specific High Level Group Term.
SOC	MedDRA SOC Disproportionality	Specific System Organ Class.
SMQ	Standardized MedDRA Query (SMQ) Disproportionality	Specific SMQ, with narrow or broad added to name.

CMQ	Custom MedDRA Query Disproportionality	Name of the event list, followed by the level of event list in parentheses. For example: Cardiac events (Study-level Event List).
DSPD	Subject Disposition Disproportionality	Disposition of followed by the subject disposition from the clinical data.
EGQT	Tests for QT(c) Interval Prolongation and related Cardiac Conditions	<p>Possible values are:</p> <ul style="list-style-type: none"> • <i><correction-type></i> QTc Interval > 450 • <i><correction-type></i> QTc Interval > 480 • <i><correction-type></i> QTc Interval > 500 • <i><correction-type></i> QTc Interval Increase >= 30 • <i><correction-type></i> QTc Interval Increase >= 60 <p>where <i><correction-type></i> is Reported, Bazett's, FDA Neuro, or Fredericia's.</p>
LBBL	Laboratory Change from Baseline	Name of the laboratory test.
Depending on option for determining clinical significance: LBCS (Built-in criteria) or LBCS (Flag variable)	Clinically Significant Lab Results (post-baseline)	Clinically Significant followed by the lab test name.
LBHY	Laboratory Test Results that meet Hy's Law	<p>Possible values are:</p> <ul style="list-style-type: none"> • Alt 3x Upper Limit • Alt 3x Upper Limit, TBili 1.5x Upper Limit • Alt 3x Upper Limit, TBili 1.5x Upper Limit, AlkPhos Normal • Alt 5x Upper Limit • Alt 10x Upper Limit

- Alt 20x Upper Limit

VSBL	Vitals Change from Baseline	Name of the vital sign, followed by the value of the VSPOS variable (Vital signs position of subject), if any, in parentheses.
Depending on option for determining clinical significance: VSCS (Built-in criteria) or VSCS (Flag variable)	Clinically Significant Vitals Results (post-baseline)	Clinically Significant followed by the vital sign name, followed by the value of the VSPOS variable (Vital signs position of subject), if any, in parentheses.

Marking a Result as Reviewed


If a screening result requires review, the issue appears in **red text** and its REVIEW_STATUS column shows **Needs Review**. There are two reasons that a result might require review:

- The result is for a [custom analysis type](#) that is set up to [require review](#).
- The result is for a standard MedDRA PT Analysis and the PT is in a predefined [event list](#) that is set up to [require review](#). In this case, only results for which the SCORE column is less than 0.5 are flagged as needing review.

Empirica Study uses event lists that are at any level (system, application, study or study pool), that are either for the same MedDRA version as the current study or are based on the study data, and that are set up to require review. In the results, a PT is flagged as needing review if it is in any of these event lists.

Note: If an event list does not have **Must be reviewed** set, it has no effect on analysis results unless it is included in a custom analysis type.

To mark a result as reviewed:


1. On the page displaying screening results, you can select **Needs Review** in the **Review Status** field to list only results requiring review.
2. Click the Action menu icon () for the screening result and then click **Mark as Reviewed**. The REVIEW_STATUS column changes from **Needs Review** to **Reviewed** and the value in the ISSUE column no longer appears in red text.

Attaching a Screening Result to a Potential Signal

When you view screening results, you can attach a row of the screening results table to a [potential signal](#) associated with the current application selected. You can create a new potential signal, or select an existing one.

You cannot attach the same screening result with the same categories and generated by the same screening analysis specification to the same potential signal more than once.

To attach a screening result to a potential signal:

1. On the page displaying screening results, click  and then click **Attach to a Potential Signal**.
2. In the **Identify Potential Signal** window, you can:
 - Enter the name of a new potential signal to create.
 - Select an existing potential signal from a list of potential signals with the status **New**, **Escalated**, or **Reviewed** for the application. You can click **Browse** to view more information about the existing potential signals and select one.

You can also attach a screening result to a potential signal whose status is **Under Analysis** if the potential signal is currently assigned to you.

3. Click **OK**. The [Potential Signal page](#) appears with the result listed in the **Supporting Analysis Results** section.



Note: If you do not save changes to the potential signal, the screening result is not attached.

Viewing Dependent Potential Signals

When viewing screening results or issue clusters, you can view a list of potential signals to which a particular issue or issue cluster is attached.

To view dependent potential signals:

Do one of the following:

- On the page displaying screening results, click  and then click **View Potential Signals with this Result Attached**.
- On the [Issue Clusters page](#), click  and then click **View Potential Signals with this Issue Cluster Attached**.

The Dependent Potential Signals page appears, providing the following information about each potential signal to which the issue or issue cluster is attached:

Column	Description
ID	Automatically assigned numeric identifier of the potential signal.
Name	Name of the potential signal.
Application	Application name supplied during application registration.
Description	Description of the potential signal.
Status	Status assigned to the potential signal.

Assigned To	Name of the user expected to perform the next step in the workflow for the potential signal.
Created	Date and time at which the potential signal was created.
Modified	Date and time at which the potential signal was last modified.
Modified By	Name of the user who created or last modified the potential signal.
# Analysis Results	Number of screening results that have been attached to the potential signal. These may include both results from a screening analysis run and issues from an issue cluster that was attached to the potential signal.
# Issue Clusters	Number of issue clusters that have been attached to the potential signal.
# BLR Runs	Number of BLR runs that have been performed on the potential signal. This column is applicable only to BLR runs that were created prior to WebSDM/Empirica Study release 3.1.
# External Docs	Number of links to external documents that have been added to the potential signal.
# Comments	Number of comments for the potential signal as a whole. (This does not include annotations of specific supporting results or documents.)
SUBMISSION_ID	Automatically assigned unique identifier of the application (same as ID column on Applications page).

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

If you want to list only potential signals that are assigned to you or that have a particular status, use a SQL Where clause in the Columns & Rows window.

Viewing an Event Summary by Dose Group

- On the page displaying screening results, click **View Event Summary by Dose Group**. (You must first select a dosing category breakdown and time frame.) The graph uses the currently selected category (such as Sex), if such fields are available.
- Configure the dose group table as described below. The table includes columns for treatment and comparator categories, depending on how you configure the table. Each of these columns shows the following information for each row, where the row is one of the following:
 - All Events
 - Serious Events – The AE.AESER variable is "Y".
 - Non-Serious Events – The AE.AESER variable is "N" or Null.
 - Events Leading to Discontinuation – The AE.AEACN variable is "DRUG WITHDRAWN".

- Events Leading to Death – The AE.AESDTH variable is "Y".
- Subjects Treated/Days on drug – The N column shows the count of subjects. The Md or Mn column shows the median or mean for the number of days on drug (using the EX domain).

Column	Description
N	<p>Depends on the value in the Summary Statistic column as follows:</p> <ul style="list-style-type: none"> • For an event-based value in the Summary Statistic column: Total count of events that occurred during the time frame. If the time frame has a well-defined start, this count includes only subjects who did not drop out before the time frame start. • For the last row: Total count of subjects in the study; the time frame is ignored. <p>You can click this value to drill down to subjects included in the count. Note that the counts are of events, except for the last row. The displayed event count may be higher than the number of subjects displayed when you drill down on the event count.</p>
Md or Mn	<p>For all rows except the last row: Median or mean (depending on configuration options) number of events per subject during the time frame among subjects who did not drop out before the time frame start. To compute median and mean for all rows except the last row:</p> <ul style="list-style-type: none"> • Per-subject counts of events are computed. Multiple occurrences of an event for a subject are counted multiple times. Subjects with no events are assigned an event count of 0. • Then the SQL function PERCENTILE_CONT is used to compute the median number of event occurrences across subjects, and the SQL function AVG is used to compute the mean number of event occurrences across subjects. <p>For the last row: Mean or median (depending on configuration options) days on drug for all subjects in the study; the time frame is ignored. To compute median and mean:</p> <ul style="list-style-type: none"> • Days on drug for each subject are computed as the sum, over the subject's rows in the EX domain, of the difference between EX.EXENDTC and EX.EXSTDTC. • Then the SQL function PERCENTILE_CONT is used to compute the median number of days on drug across subjects, and the SQL function AVG is used to compute the mean number of days on drug across subjects.

3. Click **Print** to [print the table](#).

- Click **Dot Plot** to display a graph.

The color key below the graph shows colors used for treatment and comparator groups, or combinations of them, depending on how you configured the dose group table.

If you point to a dot in the graph, a description of the dot appears. If you click a dot in the graph, a menu appears and you can [drill down](#) to subjects represented by the dot. To print or copy the graph, see [Working with Graphs](#).

Configuring the dose group table

- Specify how to present treatment and comparator categories in the table:

Option	Description
Show breakdown by treatment group	Include statistics for each arm in the treatment category.
Show summary of all treatment groups	Include statistics for the combination of all arms in the treatment category.
Show breakdown by comparator group	Include statistics for each arm in the comparator category.
Show summary of all comparator groups	Include statistics for the combination of all arms in the comparator category.
Show summary for all subjects	Include statistics for all subjects.

- Specify the following options:

Option	Description
	Include the column "N" to show the following:
Show number of events in dose group	<ul style="list-style-type: none"> For all rows except the last row: Total number of events. For the last row (Subjects Treated/Days on drug): Total number of subjects treated.
	Click one of the following:
Show descriptive statistic per subject in dose group	<ul style="list-style-type: none"> Median events per subject – Include the "Md" column. Mean events per subject – Include the "Mn" column.

- Optionally check "Use gray-scale instead of colors when displaying graph".
- Click **OK**.

Viewing a Disposition Summary by Dose Group

1. On the page displaying screening results, click **View Disposition Summary by Dose Group**. (You must first select a dosing category breakdown and time frame.) The graph uses the currently selected category (such as Sex), if such fields are available.
2. Configure the dose group table as described below. The table includes columns for treatment and comparator categories, depending on how you configure the table. Each of these columns shows the following information for each row, where the row is one of the following:
 - **Randomized**—Subjects for which the ARM value is non-null and is not **Screen Failure** or **Not Assigned**, and the DM.ARMCD value is non-null and is not **Scrnfail** or **NOTASSGN**. The matching is case-insensitive.
 - **<Disposition event>**—Subjects with this DS.DSDECOD value. Only one disposition event per subject is counted. To determine the disposition event, WebSDM/Empirica Study uses the algorithm described in [Disposition Events](#).

If the algorithm finds multiple disposition events for any subjects, WebSDM/Empirica Study tries to use the disposition event date to determine a disposition event to show in the display and a note appears below the graph. Subjects for which this is not possible are included in a row named **<Multiple Dispositions>**.

- **Deaths**—Subjects with the AE.AESDTH value **Y** for any record in the AE domain.

Column	Description
#	<ul style="list-style-type: none"> • For the Randomized row, this is the same as N. • For a disposition event, count of subjects with the disposition event during the time frame. • For the Deaths row, count of subjects who died during the time frame. <p>Click to drill down to subjects included in the count.</p>
N	<p>Total count of subjects. If the time frame has a well-defined start, this is the total count of subjects who did not drop out before the time frame start. Other statistics in the table are for subjects who are included in N. Click to drill down to subjects included in the count.</p>
%	<ul style="list-style-type: none"> • For the Randomized row, this is 100%. • For a disposition event, percentage of subjects with the disposition event during the time frame. • For the Deaths row, percentage of subjects who died during the time frame.

Computed as (#/N) x 100

For the disposition row, a subject is counted for only one disposition event (or in the <Multiple Dispositions row). However, the same subject can be counted in the Randomized row, the disposition event row (or the <Multiple Dispositions> row), and the Deaths row.

3. Click **Print** to [print the table](#).
4. Click **Dot Plot** to display a graph. The color key below the graph shows colors used for treatment and comparator groups, or combinations of them, depending on how you configured the dose group table.

If you point to a dot in the graph, a description of the dot appears. If you click a dot in the graph, a menu appears and you can [drill down](#) to subjects represented by the dot. To print or copy the graph, see [Working with Graphs](#).

5. Optionally click **Kaplan-Meier Plot**. See [Viewing a Kaplan-Meier Plot](#).

Configuring the dose group table

1. Specify how to present treatment and comparator categories in the table:

Option	Description
Show breakdown by treatment group	<p>Specify whether to include statistics for each arm in the treatment category.</p> <ul style="list-style-type: none"> • If selected—Shows statistics by treatment group. • If deselected—Does not show statistics by treatment group.
Show summary of all treatment groups	<p>Specify whether to include statistics for the combination of all arms in the treatment category.</p> <ul style="list-style-type: none"> • If selected—Shows summary of all treatment groups. • If deselected—Does not show summary of all treatment groups.
Show breakdown by comparator group	<p>Specify whether to include statistics for each arm in the comparator category.</p> <ul style="list-style-type: none"> • If selected—Shows breakdown by comparator group. • If deselected—Does not show breakdown by comparator group.
Show summary of all	Specify whether to include statistics for the combination

comparator groups	of all arms in the comparator category.
	<ul style="list-style-type: none"> • If selected—Shows summary of all comparator groups. • If deselected—Does not show summary of all comparator groups.

Show summary for all subjects	Specify whether to include statistics for all subjects.
	<ul style="list-style-type: none"> • If selected—Shows summary of all subjects. • If deselected—Does not show summary of all subjects.

2. Specify the following options:

Option	Description
Show number of subjects with disposition	Specify whether to include the # column to show the count of subjects with the value in the Disposition column. <ul style="list-style-type: none"> • If selected—Shows number of subjects with disposition. • If deselected—Does not show number of subjects with disposition.
Show number of subjects receiving treatment or comparator	Specify whether to include the N column to show the total count of subjects. <ul style="list-style-type: none"> • If selected—Shows total count of subjects. • If deselected—Does not show total count of subjects.
Show percent of subjects with disposition	Specify whether to include the % column to show the percentage of subjects with the value in the Disposition column. <ul style="list-style-type: none"> • If selected—Shows percent of subjects with disposition. • If deselected—Does not show percent of subjects with disposition.

3. Optionally select **Use gray-scale instead of colors** when displaying graph.
4. Click **OK**.


Viewing Issue-specific Information

Viewing 2x2 Tables

For the results of disproportionately analysis types, you can display the 2x2 tables used in the analysis.

If the time frame has a well-defined start, subjects who [dropped out](#) before the time frame start are excluded from the analysis.

To view 2x2 tables:

1. On the page displaying screening results, click the Action menu icon () for a result (except a result for a Lab or Vitals Change from Baseline Analysis) and then click **View 2x2 Table**. (You can also view 2x2 tables for a tile in a sector map.)

Two [2x2 tables](#) appear, one for observed subject counts and one for expected subject counts. The following statistics appear below the 2x2 tables:

- Modified Odds Ratio (same as value of the ODDS_RATIO column in screening results)

Note: The modified odds ratio is followed by the lower and upper bounds of the confidence interval for the modified odds ratio (same as the values of the OR025 and OR975 columns in screening results).

- Corrected Odds Ratio (same as value of the ODDS_RATIO_C column in screening results)

Note: The corrected odds ratio is followed by the lower and upper bounds of the confidence interval for the corrected odds ratio (same as the values of the OR025_C and OR975_C columns in screening results).

- Shrunk Odds Ratio (same as the value of the ODDS_RATIO_SHRUNKEN column in screening results)

Note: The shrunk odds ratio is followed by the lower and upper bounds of the confidence interval for the shrunk odds ratio (same as the values of the OR025_S and OR975_S columns in screening results).

- Chi-statistic (same as the value of the CHI column in screening results)

For MedDRA-based analysis types, a note at the bottom of the display indicates whether odds ratios were computed using subject counts or days on drug. The latter option is available in an analysis specification and applies only to results for the absence of a time frame.

For the result of a [Clinically Significant Lab or Vitals Analysis](#), if built-in criteria were used to determine [clinical significance](#), the criteria are indicated below the table. No note appears if a flag variable was used to determine clinical significance.

2. If you click a count of subjects in a 2x2 table, you can [drill down](#) to a list of subjects included in the count. In the table for Expected Subjects, you can drill down on only the totals, because the A, B, C, and D values are not actual values.

If days on drug were used as the denominator, when you drill down on a value in the 2x2 table, WebSDM/Empirica Study behaves as if the standard computation was used. For example, if $N_T = 100$ days on drug and there are 67 subjects who received the study treatment, when you drill down on 100, those 67 subjects are listed.

Related Topics

[Scores for Disproportionality Analysis Types](#)

[Screening Result Columns](#)


Viewing t-test Statistics

The table's title indicates whether the result uses "maximum change" or "most recent change", as determined by the setting of the "Use maximum (instead of most recent) change from baseline" option in the analysis specification that generated the result.

Note: For screening results on the Safety Review tab, this table is not affected by the safety review configuration option for using the maximum or most recent change from baseline.

See [Lab or Vital Signs Change from Baseline](#) for information about the counts and statistics in this display. If the time frame has a well-defined start, subjects who [dropped out](#) before the time frame start are excluded from the analysis.

To view t-test statistics:

1. On the page displaying screening results, click  for a result from a Lab or Vitals Change from Baseline Analysis and then click **View t-test Statistics**.

A t-test statistics table provides the following information for the treatment and comparator groups:

- Count of subjects who had results for the test
- Mean change from baseline (same as the value of the U_T and U_C columns in screening results)
- Standard deviation of the change from baseline (same as the value of the S_T and S_C columns in screening results)


The following statistics appear below the t-test statistics table:

- The difference in the mean change from baseline between the treatment and comparator groups
 - The t-statistic followed by degrees of freedom, which is computed as $(N_T + N_C - 2)$
2. If you click a count of subjects in a t-test statistics table, you can [drill down](#) to a list of subjects included in the count.

Viewing Events by Dose Group

An Adverse Events by Dose Group table and graph are available for the results for any standard or customized MedDRA-based analysis type.

To view the dose group table:

1. On the page displaying screening results on the Screening tab, click  for a result and then click **View Events by Dose Group**.
2. Configure the dose group table as described below. The table includes columns for treatment and comparator categories, depending on how you configure the table. Each of these columns shows the following information for each row:

Column	Description
#	Count of subjects with at least one occurrence of the term during the time frame. You can click this value to drill down to subjects included in the count.
N	Total count of subjects. For a custom analysis type that includes a subject list, N includes only subjects in the list. If the time frame has a well-defined start, this is the total count of subjects who did not drop out before the time frame start. Other statistics in the table are for subjects who are included in N. You can click this value to drill down to subjects included in the count.
%	Percentage of subjects with at least one occurrence of the term during the time frame. Computed as: $(\#/N) \times 100$
RR	Relative Risk. Computed as: $\frac{(\# \text{ subjects with issue in dose group} / \# \text{ subjects in dose group})}{(\# \text{ subjects with issue in comparator group} / \# \text{ subjects in comparator group})}$

3. Click **Print** to [print the table](#).
4. Click **Dot Plot**.

The color key below the graph shows colors used for treatment and comparator categories, depending on how you configured the dose group table.

If you point to a dot in the graph, a description of the dot appears. If you click a dot in the graph, a menu appears and you can [drill down](#) to subjects represented by the dot. To print or copy the graph, see [Working with Graphs](#).

Configuring the dose group table

1. Specify how to present treatment and comparator categories in the table:

Option	Description
Show breakdown by treatment group	Include statistics for each arm in the treatment category.

Show summary of all treatment groups	Include statistics for the combination of all arms in the treatment category.
Show breakdown by comparator group	Include statistics for each arm in the comparator category.
Show summary of all comparator groups	Include statistics for the combination of all arms in the comparator category.
Show summary for all subjects	Include statistics for all subjects.

2. Specify which rows to include in the table, if the screening result was for a MedDRA PT, HLT, HGLT, or SOC Analysis or a Standardized MedDRA Query Analysis:

Option	Description
Show preferred term breakdown for HLT, HLGT, SOC, SMQ, CMQ tables	Applies to screening results of an HLT, HLGT, SOC, SMQ, or CMQ Analysis. Include a row for each PT whose primary path runs through the HLT, HLGT, SOC, SMQ, or CMQ.
Show higher level term for HLT, HLGT, SOC, SMQ, CMQ tables	Applies to screening results of an HLT, HLGT, SOC, SMQ, or CMQ Analysis. Include a row for the level of the analysis type that generated the screening result.

3. Specify the following options:

Option	Description
Show number of subjects having event	Include the column "#" to show the number of subjects with at least one occurrence of the event.
Show number of subjects receiving treatment or comparator	Include the column "N" to show the total number of subjects.
Show percent of subjects having event	Include the column "%" to show the percentage of subjects who have at least one occurrence of the event.
Show relative risk of treatment versus comparator	Include the column "RR" to show the Relative Risk.

4. Optionally check "Use gray-scale instead of colors when displaying graph".

5. Click **OK**.


Viewing Issues by Dose Group

An *<issue-type>* by Dose Group table and graph are available for the results of a standard or customized Clinically Significant Labs or Vitals Analysis or QT Prolongation Analysis. In

the name of the dose group table and graph, *<issue-type>* is one of the following: Clinically Significant Labs; Clinically Significant Vitals; or ECG QT.

Note: For the result of a [Clinically Significant Lab or Vitals Analysis](#), if built-in criteria were used to determine [clinical significance](#), the criteria are indicated below the table or graph. No note appears if a flag variable was used to determine clinical significance.

To view the dose group table:

1. On the page displaying screening results on the Screening tab, click  for a result and then click **View Issues by Dose Group**.
2. Configure the dose group table as described below. The table includes columns for treatment and comparator categories, depending on how you configure the table. Each of these columns shows the following information for each row, where the row is the name of the clinically significant lab test, the clinically significant vital sign measurement, or the QT interval issue.

Column	Description
Type	LBCS for a Clinically Significant Labs Analysis result, VSCS for a Clinically Significant Vitals Analysis result, or EGQT for a QT Prolongation Analysis result.
#	Count of subjects with at least one occurrence of the issue during the time frame. You can click this value to drill down to subjects included in the count.
N	Total count of subjects. For a custom analysis type that includes a subject list, N includes only subjects in the list. If the time frame has a well-defined start, this is the total count of subjects who did not drop out before the time frame start. Other statistics in the table are for subjects who are included in N. You can click this value to drill down to subjects included in the count.
%	Percentage of subjects with at least one occurrence of the term during the time frame. Computed as: $(\#/N) \times 100$
RR	Relative Risk. Computed as: $\frac{(\# \text{ subjects with issue in dose group})}{(\# \text{ subjects with issue in comparator group})} \div \frac{(\# \text{ subjects in dose group})}{(\# \text{ subjects in comparator group})}$

3. Click **Print** to [print the table](#).
4. Click **Dot Plot**.

The color key below the graph shows colors used for treatment and comparator groups, or combinations of them, depending on how you configured the dose group table.

If you point to a dot in the graph, a description of the dot appears. If you click a dot in the graph, a menu appears and you can [drill down](#) to subjects represented by the dot. To print or copy the graph, see [Working with Graphs](#).

Configuring the dose group table

- Specify how to present treatment and comparator categories in the table:

Option	Description
Show breakdown by treatment group	Include statistics for each arm in the treatment category.
Show summary of all treatment groups	Include statistics for the combination of all arms in the treatment category.
Show breakdown by comparator group	Include statistics for each arm in the comparator category.
Show summary of all comparator groups	Include statistics for the combination of all arms in the comparator category.
Show summary for all subjects	Include statistics for all subjects.

- Specify the following options:


Option	Description
Show number of subjects having issue	Include the column "#" to show the number of subjects with at least one occurrence of the issue.
Show number of subjects receiving treatment or comparator	Include the column "N" to show the total number of subjects.
Show percent of subjects having issue	Include the column "%" to show the percentage of subjects who have at least one occurrence of the issue
Show relative risk of treatment versus comparator	Include the column "RR" to show the Relative Risk.

- Optionally check "Use gray-scale instead of colors when displaying graph".
- Click **OK**.

Viewing Day of Onset by Dose Group

A Day of Adverse Event Onset by Dose Group table and graph are available for the results for any standard or customized MedDRA-based analysis type.

To view the dose group table:

- On the page displaying screening results, click the Action menu icon () for a result and then click **View Day of Onset by Dose Group**.
- The table includes columns for treatment and comparator categories, depending on how you configure the table. Each of these columns shows the following information for each row:

Column	Description
Min Day	Minimum number of days to the onset of the event during the time frame. (See the Base day of onset on option below.)
Max Day	Maximum number of days to the onset of the event during the time frame. (See the Base day of onset on option below.)
Median Day	Median number of days to the onset of the event during the time frame. (See the Base day of onset on option below.)
Mean Day	Mean number of days to the onset of the event during the time frame. If any of the derived values used in the computation are missing for a subject, the subject is not included in the computation of mean days of onset. (See the Base day of onset on option below.)
#	Count of subjects with at least one occurrence of the event during the time frame. Click to drill down to subjects included in the count.
N	Total count of subjects. For a custom analysis type that includes a subject list, N includes only subjects in the list. If the time frame has a well-defined start, this is the total count of subjects who did not drop out before the time frame start. Other statistics in the table are for subjects who are included in N. Click to drill down to subjects included in the count.

A note appears below the table if any subjects were omitted from the Min Day, Max Day, Median Day, and Mean Day columns because of missing dates that are needed to compute day of onset.

- Click **Print** to [print the table](#).
- Click **Box Plot** to view a box plot showing the distribution of time to onset for each dosing category or arm, depending on how you configured the table. For information about interpreting a box plot, see [Box Plots](#).

Note: Points in these box plots are jittered (displayed at small random offsets from the center line) so that if two results have the same value, a point is likely to be visible for each of them.

- Click **Cumulative Incidence Plot** to [view a Cumulative Incidence Plot](#). The Cumulative Incidence Plot ignores the **Base onset on day of** option that is specified for the Day of Adverse Event Onset by Dose Group tabular display.

Configuring the dose group table

- Specify how to present treatment and comparator categories in the table:

Option	Description
Show breakdown by treatment group	Specify whether to include statistics for each arm in the treatment category. <ul style="list-style-type: none"> If selected—Shows breakdown by treatment

group.

- **If deselected**—Does not show breakdown.

Show summary of all treatment groups	Specify whether to include statistics for the combination of all arms in the treatment category. <ul style="list-style-type: none"> • If selected—Shows summary of all treatment groups. • If deselected—Does not show summary.
Show breakdown by comparator group	Specify whether to include statistics for each arm in the comparator category. <ul style="list-style-type: none"> • If selected—Shows breakdown by comparator group. • If deselected—Does not show breakdown.
Show summary of all comparator groups	Specify whether to include statistics for the combination of all arms in the comparator category. <ul style="list-style-type: none"> • If selected—Shows summary of all comparator groups. • If deselected—Does not show summary.
Show summary for all subjects	Specify whether to include statistics for all subjects. <ul style="list-style-type: none"> • If selected—Shows summary for all subjects. • If deselected—Does not show summary.

- Specify which rows to include in the table, if the screening result was for a MedDRA PT, HLT, HGLT, or SOC Analysis or a Standardized MedDRA Query Analysis:

Option	Description
Show preferred term breakdown for HLT, HGLT, SOC, SMQ, CMQ tables	Applies to screening results of an HLT, HGLT, SOC, SMQ, or CMQ Analysis. Specify whether to include a row for each PT whose primary path runs through the HLT, HGLT, SOC, SMQ, or CMQ. <ul style="list-style-type: none"> • If selected—Shows preferred term breakdown. • If deselected—Does not show breakdown.

Show higher level term for HLT, HLGT, SOC, SMQ, CMQ tables	Applies to screening results of an HLT, HLGT, SOC, SMQ, or CMQ Analysis. Specify whether to include a row for the level of the analysis type that generated the screening result.
--	--

- **If selected**—Shows higher level term.
- **If deselected**—Does not show higher level term.

3. Specify the following options:

Option	Description
Base day of onset on	<p>The options are:</p> <ul style="list-style-type: none"> • Reference start date—Use the following as the day of onset: $(AE.AESTDTC - DM.RFSTDTC) + 1$ • Reference end date—Use the following as the day of onset: $(AE.AESTDTC - DM.RFENDTC) + 1$ • Start of time frame—Available only if a time frame is in effect and it has a well-defined start. Use the following as the day of onset: $(AE.AESTDTC - \text{start of time frame}) + 1$ <p>The result of the computation is rounded down. For example, 1.01, 1.50, and 1.99 are all rounded down to 1.</p> <hr/> <p>Note: For subjects who experience an event more than once, the time to onset is based on the earliest occurrence of the event.</p>
Show minimum day of onset	<p>Specify whether to include the Min Day column to show the minimum number of days to onset for subjects who experienced the event.</p> <ul style="list-style-type: none"> • If selected—Shows Min Day column. • If deselected—Does not show Min Day column.
Show maximum day of onset	<p>Specify whether to include the Max Day column to show the maximum number of days to onset for subjects who experienced the event.</p> <ul style="list-style-type: none"> • If selected—Shows Max Day column. • If deselected—Does not show Max Day column.
Show median day of onset	<p>Specify whether to include the Median Day column to show the median number of days to onset for subjects</p>

who experienced the event.

- **If selected**—Shows Median Day column.
- **If deselected**—Does not show Median Day column.


Show mean day-of-onset	Specify whether to include the Mean Days column to show the mean number of days to onset for subjects who experienced the event. <ul style="list-style-type: none"> • If selected—Shows Mean Days column. • If deselected—Does not show Mean Days column.
Show number of subjects having an event	Specify whether to include the # column to show the number of subjects with at least one occurrence of the event. <ul style="list-style-type: none"> • If selected—Shows # column. • If deselected—Does not show # column.
Show number of subjects receiving treatment or comparator	Specify whether to include the N column to show the total number of subjects. <ul style="list-style-type: none"> • If selected—Shows N column. • If deselected—Does not show N column.

4. Optionally select **Use gray-scale instead of colors** when displaying graph.
5. Click **OK**.

Viewing Severity, Toxicity Grade, Action Taken, or Outcome by Dose Group

An Adverse Event Severity, Toxicity Grade, Action Taken, or Outcome by Dose Group table and graph are available for the results for any standard or customized MedDRA-based analysis type.

To view the dose group table:

1. On the page displaying screening results, click  for a result and then click **View Severity by Dose Group**, **View Toxicity Grade by Dose Group**, **View Action Taken by Dose Group**, or **View Outcome by Dose Group**.

Missing Required Variable error

A message appears when variables required by the report are not present in the study data. You cannot view the report when required variables are missing.

- Configure the dose group table as described below. The table includes columns for treatment and comparator categories, depending on how you configure the table. Each of these columns shows the following information for each row:

Column	Description
#	Count of subjects with at least one occurrence of the term with the listed value for severity, toxicity grade, action taken, or outcome during the time frame. You can click this value to drill down to subjects included in the count.
N	Total count of subjects. For a custom analysis type that includes a subject list, N includes only subjects in the list. If the time frame has a well-defined start, this is the total count of subjects who did not drop out before the time frame start. Other statistics in the table are for subjects who are included in N. You can click this value to drill down to subjects included in the count.
%	Percentage of subjects with at least one occurrence of the term with the listed value for severity, toxicity grade, action taken, or outcome during the time frame. Computed as: $(\#/N) \times 100$

The table columns (such as severity values) are from the corresponding [codelist](#), with the values shown in upper case. There are also columns for any values (including nulls) that exist in the data but are not in the codelist.

- Optionally click **Print** to [print the table](#).
- Optionally click **Dot Plot**.

The color key below the graph shows colors used for treatment and comparator groups, or combinations of them, depending on how you configured the dose group table.

If you point to a dot in the graph, a description of the dot appears. If you click a dot in the graph, a menu appears and you can [drill down](#) to subjects represented by the dot. To print or copy the graph, see [Working with Graphs](#).

Configuring the dose group table

- Specify how to present treatment and comparator categories in the table:

Option	Description
Show breakdown by treatment group	Include statistics for each arm in the treatment category.
Show summary of all treatment groups	Include statistics for the combination of all arms in the treatment category.
Show breakdown by comparator group	Include statistics for each arm in the comparator category.
Show summary of all comparator groups	Include statistics for the combination of all arms in the comparator category.
Show summary for all	Include statistics for all subjects.

subjects

- Specify which rows to include in the table, if the screening result was for a MedDRA PT, HLT, HLGT, or SOC Analysis or a Standardized MedDRA Query Analysis:

Option	Description
Show preferred term breakdown for HLT, HLGT, SOC, SMQ, CMQ tables	Applies to screening results of an HLT, HLGT, SOC, SMQ, or CMQ Analysis. Include a row for each PT whose primary path runs through the HLT, HLGT, SOC, SMQ, or CMQ.
Show higher level term for HLT, HLGT, SOC, SMQ, CMQ tables	Applies to screening results of an HLT, HLGT, SOC, SMQ, or CMQ Analysis. Include a row for the level of the analysis type that generated the screening result.

- Specify the following options:


Option	Description
Show number of subjects having an event	Include the column "#" to show the count of subjects who have at least one occurrence of the term with that severity, toxicity grade, action taken, or outcome.
Show number of subjects receiving treatment or comparator	Include the column "N" to show the total count of subjects.
Show percent of subjects having an event	Include the column "%" to show the percentage of subjects who have at least one occurrence of the term with that severity, toxicity grade, action taken, or outcome.

- Optionally check "Use gray-scale instead of colors when displaying graph".
- Click **OK**.

Viewing Recurrence by Dose Group

An Adverse Event Recurrence by Dose Group table and graph are available for the results for any standard or customized MedDRA-based analysis type.

To view the dose group table:

- On the page displaying screening results, click  for a result and then click **View Recurrence by Dose Group**.
- Configure the dose group table as described below. The table includes columns for treatment and comparator categories, depending on how you configure the table. Each of these columns shows the following information for each row:

Column	Description
--------	-------------

- # One of the following:
- 1: Count of subjects with one occurrence of the term during the time frame.
 - 2: Count of subjects with two occurrences of the term during the time frame.
 - 3+: Count of subjects with three or more occurrences of the term during the time frame.

Note: An "occurrence" has a unique value of the AE.AESTDTC variable.

You can click this value to [drill down](#) to subjects included in the count.

- % One of the following:
- 1: Percentage of subjects with one occurrence of the term during the time frame.
 - 2: Percentage of subjects with two occurrences of the term during the time frame.
 - 3+: Percentage of subjects with three or more occurrences of the term during the time frame.

Computed as: $(\#/N) \times 100$

- N Total count of subjects. For a custom analysis type that includes a subject list, N includes only subjects in the list. If the time frame has a well-defined start, this is the total count of subjects who did not [drop out](#) before the time frame start. Other statistics in the table are for subjects who are included in N.
- You can click this value to [drill down](#) to subjects included in the count.
-

3. Click **Print** to [print the table](#).

4. Click **Dot Plot**.

The color key below the graph shows colors used for treatment and comparator groups, or combinations of them, depending on how you configured the dose group table.

If you point to a dot in the graph, a description of the dot appears. If you click a dot in the graph, a menu appears and you can [drill down](#) to subjects represented by the dot. To print or copy the graph, see [Working with Graphs](#).

Configuring the dose group table

1. Specify how to present treatment and comparator categories in the table:

Option	Description
Show breakdown by treatment group	Include statistics for each arm in the treatment category.

Show summary of all treatment groups	Include statistics for the combination of all arms in the treatment category.
Show breakdown by comparator group	Include statistics for each arm in the comparator category.
Show summary of all comparator groups	Include statistics for the combination of all arms in the comparator category.
Show summary for all subjects	Include statistics for all subjects.

- Specify which rows to include in the table, if the screening result was for a MedDRA PT, HLT, HGLT, or SOC Analysis or a Standardized MedDRA Query Analysis:

Option	Description
Show preferred term breakdown for HLT, HGLT, SOC, SMQ, CMQ tables	Applies to screening results of an HLT, HGLT, SOC, SMQ, or CMQ Analysis. Include a row for each PT whose primary path runs through the HLT, HGLT, SOC, SMQ, or CMQ.
Show higher level term for HLT, HGLT, SOC, SMQ, CMQ tables	Applies to screening results of an HLT, HGLT, SOC, SMQ, or CMQ Analysis. Include a row for the level of the analysis type that generated the screening result.

- Specify the following options:


Option	Description
Show number of subjects having an event	Include the column "N" to show the total count of subjects with the term.
Show number of subjects receiving treatment or comparator	Include the column "#" to show the count of subjects having the specified number of occurrences of the term.
Show percent of subjects having an event	Include the column "%" to show the percentage of subjects having the specified number of occurrences of the term.

- Optionally check "Use gray-scale instead of colors when displaying graph".
- Click **OK**.

Viewing Demographic Distribution by Dose Group

A Demographic Distribution for Adverse Events by Dose Group table and graph are available for the results for any standard or customized MedDRA-based analysis type.

To view the dose group table:

- On the page displaying screening results, click  for a result and then click **View Demographic Distribution by Dose Group**.

The table includes a column for each dosing category. Each of these columns shows the following information for each row, where the row is one of the following:

- *< term>* – Statistics for this row are for subjects with at least one occurrence of the term.

wo < term> – Statistics for this row are for subjects with no occurrences of the term.

2. Configure the dose group table as described below. The table includes columns for treatment and comparator categories, depending on how you configure the table. Each of these columns shows the following information for each row:

Column	Description
#	<p>For the "with term" row, the count of subjects with at least one occurrence of the term in the time frame.</p> <p>For the "without (wo) term" row, the count of subjects with no occurrence of the term in the time frame.</p> <p>You can click this value to drill down to subjects included in the count.</p>
N	<p>Total count of subjects. For a custom analysis type that includes a subject list, N includes only subjects in the list. If the time frame has a well-defined start, this is the total count of subjects who did not drop out before the time frame start. Other statistics in the table are for subjects who are included in N.</p> <hr/> <p>Note: This count includes subjects with no values for age, weight, or height.</p> <hr/> <p>You can click this value to drill down to subjects included in the count.</p>
%	<p>For the "with term" row, the percentage of subjects with at least one occurrence of the term in the time frame.</p> <p>For the "without (wo) term" row, the percentage of subjects with no occurrence of the term in the time frame.</p> <p>Computed as: $(\#/N) \times 100$</p>
Age	<p>For the "with term" row, the mean age of subjects with at least one occurrence of the term in the time frame.</p> <p>For the "without (wo) term" row, the mean age of subjects with no occurrence of the term in the time frame.</p> <p>Mean age is computed using the SQL AVG function for values of the DM.AGE variable. Subjects with null age values are excluded from the computation.</p>
Wgt	<p>For the "with term" row, the mean weight of subjects with at least one occurrence of the term in the time frame.</p> <p>For the "without (wo) term" row, the mean weight of subjects with no occurrence of the term in the time frame.</p> <p>Mean weight is computed using the SQL AVG function for values of the VS.VSSTRESN variable where VS.VSTESTCD is the vital sign identifier for weight and the VS.VSBLFL variable is 'Y' (indicating baseline weight measurement). Subjects with null weight values are excluded from the computation.</p>

- BMI** For the "with term" row, the mean Body Mass Index of subjects with at least one occurrence of the term in the time frame.
- For the "without (wo) term" row, the mean Body Mass Index of subjects with no occurrence of the term in the time frame.
- If no vital sign identifier for BMI is defined for the study, BMI is computed (for all subjects) using height and weight values (if vital sign identifiers have been defined for height and weight and values exist for them). Subjects with null height or weight values are excluded from the computation.
- If a vital sign identifier for BMI is defined for the study:
- If at least one subject has a non-null result for a test that matches the vital sign identifier for BMI, the value from the study data is used (for all subjects). BMI is not computed for any subjects.
 - If no subjects have a non-null result for a test that matches the vital sign identifier for BMI, BMI is computed (for all subjects) using height and weight values found in the VS domain (if vital sign identifiers have been defined for height and weight and values exist for them).

-
3. Click **Print** to [print the table](#).

Configuring the dose group table

1. Specify how to present treatment and comparator categories in the table:

Option	Description
Show breakdown by treatment group	Include statistics for each arm in the treatment category.
Show summary of all treatment groups	Include statistics for the combination of all arms in the treatment category.
Show breakdown by comparator group	Include statistics for each arm in the comparator category.
Show summary of all comparator groups	Include statistics for the combination of all arms in the comparator category.
Show summary for all subjects	Include statistics for all subjects.

2. Specify which rows to include in the table, if the screening result was for a MedDRA PT, HLT, HGLT, or SOC Analysis or a Standardized MedDRA Query Analysis:

Option	Description
Show preferred term breakdown for HLT, HLGT, SOC, SMQ, CMQ tables	Applies to screening results of an HLT, HLGT, SOC, SMQ, or CMQ Analysis. Include a row for each PT whose primary path runs through the HLT, HLGT, SOC, SMQ, or CMQ.

Note: Even if this option is checked, rows for PTs in a higher-level term are not included in the Demographic Distribution by Dose group information when it is part of a potential signal archive.

Show higher level term for HLT, HLGT, SOC, SMQ, CMQ tables

Applies to screening results of an HLT, HLGT, SOC, SMQ, or CMQ Analysis.
Include a row for the level of the analysis type that generated the screening result.

3. Specify the following options:

Option	Description
Show number of subjects having an event	Include the column "#" to show the count of subjects who either did or did not experience the term.
Show number of subjects receiving treatment or comparator	Include the column "N" to show the total count of subjects.
Show percent of subjects having an event	Include the column "%" to show the percentage of subjects who either did or did not experience the term.
Show mean subject age	Include the column "Age" to show the mean age of subjects who either did or did not experience the term.
Show mean subject weight	Include the column "Wgt" to show the mean weight of subjects who either did or did not experience the term.
Show mean subject BMI	Include the column "BMI" to show the mean Body Mass Index (BMI) of subjects who either did or did not experience the term.

4. Click **OK**.


Viewing an Odds Ratio Graph

The odds ratio graph shows **corrected** odds ratios and their lower and upper confidence bounds, which are in the [screening result columns](#) ODDS_RATIO_C, OR025_C, and OR975_C. For information about how the corrected odds ratio is computed, see [Scores for Disproportionality Analysis Types](#).

To view an odds ratio graph:

1. Do one of the following:

Tab	Steps	Notes
Safety Review	On the Adverse Events page: As a safety review	The graph is affected by your selection of a qualifier under "Adverse Event

	configuration option, select a dosing category breakdown (not ARM values). Then click  for a row and click Odds Ratio Graph .	Incidence for" on the Adverse Events page. When displayed for a row containing "<Any Body System>" or "<Any Event>", the graph also includes bars for PTs.
	On the Screening Results page: For a screening result for any analysis type except a Lab or Vitals Change from Baseline Analysis, click View Odds Ratio Graph .	For a clinically significant lab or vitals result, if built-in criteria were used to determine clinical significance , the criteria are indicated below the table. No note appears if a flag variable was used to determine clinical significance. When displayed for the result of an HLT, HLGT, or SOC Analysis, the graph also includes a bar for each PT that has the higher level term in its primary path.
Screening	On the Analysis Results page: For a screening result for any analysis type except a Lab or Vitals Change from Baseline Analysis, click View Odds Ratio Graph .	For a clinically significant lab or vitals result, if built-in criteria were used to determine clinical significance , the criteria are indicated below the table. No note appears if a flag variable was used to determine clinical significance. When displayed for the result of an HLT, HLGT, or SOC Analysis, the graph also includes a bar for each PT that has the higher level term in its primary path.

2. [Configure the graph](#).
3. You can point to a bar in the graph to display details about what the bar represents. Note that the details show the corrected odds ratios and their lower and upper confidence bounds.
4. Optionally click **Download Data for Graph to Excel**.

Configuring an Odds Ratio Graph

1. In the [graph display window](#), click **Configure**.
2. Specify the following display options:

Option	Description
Order by	The options are: <ul style="list-style-type: none"> • Event—PT. Applicable only if the graph includes multiple PTs. • Lower bound of CI—Lower bound of the confidence

interval for the corrected odds ratio.

- **Corrected OR**—Corrected odds ratio. When you view this graph on the Safety Review tab, the option is labeled **OR**, but refers to the corrected OR.

Color by	<p>Determines how the graph should be colored. The options are:</p> <ul style="list-style-type: none"> • Lower bound of CI—Lower bound of the confidence interval for the corrected odds ratio. • Corrected OR—Corrected odds ratio. When you view this graph on the Safety Review tab, the option is labeled OR, but refers to the corrected OR. • None—Do not use color in the graph.
Axis type	<p>Indicates the axis type. The options are:</p> <ul style="list-style-type: none"> • Linear—The x-axis and y-axis are linear. • Log—The x-axis and y-axis are logarithmic. <p>The default value is Log.</p>
Show number of subjects	<p>Determines whether to show the total count of subjects participating in the study at the start of the selected time frame.</p> <ul style="list-style-type: none"> • If selected—Shows number of subjects. • If deselected—Does not show number of subjects.
Show vertical reference line	<p>Determines whether a vertical line appears at the corrected odds ratio 1.0 for reference purposes.</p> <ul style="list-style-type: none"> • If selected—Shows a vertical reference line. • If deselected—Does not show a vertical reference line.

3. Optionally check any other display options. See [Working with Graphs](#) for information about the following display options: Use gray-scale instead of colors; Key; and Links.

4. Click **OK**.

Screening Analysis Types

About Analysis Types

An analysis type is a type of [screening analysis](#) that a screening analysis specification can execute. Analysis types include:

- Disproportionality analysis types that report on the relationship between the occurrence rate of events or certain results for subjects on the study treatment and subjects on the comparator treatment.
- Change-from-baseline analysis types that are based on a t-test of the mean change from baseline in the treatment group compared to the mean change from baseline in the comparator group for specific test or vital sign results.

You can also create [custom analysis types](#) that include events, subjects, or event characteristics, such as seriousness or outcome.

An analysis specification can include standard analysis types, custom analysis types, or both. Each analysis type is performed independently of other analysis types included in the specification.

The following standard analysis types are available:

Name	Abbreviation
MedDRA PT Analyses	PT
MedDRA HLT Analyses	HLT
MedDRA HLGT Analyses	HLGT
MedDRA SOC Analyses	SOC
Standardized MedDRA Query Analysis	SMQ
QT Interval Prolongation Analysis	EGQT
Clinically Significant Lab Analysis	LBCS
Clinically Significant Vitals Analysis	VSCS
Hy's Law Analysis	LBHY
Subject Disposition Analysis	DSPD
Lab Change from Baseline Analysis	LBBL
Vital Signs Change from Baseline Analysis	VSBL

All are disproportionality analysis types except Lab Change from Baseline Analysis and Vital Signs Change from Baseline Analysis.

All standard analysis types are listed in a [screening analysis specification](#). However, they are available to run only if certain variables are present. For more information, see [Variables Used in Screening Analysis](#).

Note: If the results of certain analysis types (EGQT, LBHY, LBCS, VSCS, LBBL or VSBL) were generated prior to WebSDM/Empirica Study 3.0, they are outdated. The way in which these analysis types compute results has changed. A message appears, indicating that some results use outdated selection criteria and that results will be updated the next time you run the specification.

Disproportionality Analysis Types

Scores for Disproportionality Analysis Types

Disproportionality analysis types report on the relationship between the occurrence rate of events or findings for subjects on the study treatment and subjects on the comparator treatment. All analysis types except Lab Change from Baseline and Vitals Change from Baseline are disproportionately analysis types.

To produce scores, WebSDM/Empirica Study does the following:

1. Computes 2x2 tables for observed and expected counts of the issue.
2. Computes a modified odds ratio for the issue.
3. Computes a corrected odds ratio for the issue.
4. Computes a shrunken odds ratio for the issue.
5. Computes a modified Chi-statistic for the issue.
6. Determines a score, which is a one-tailed probability for the signed Chi-statistic, computed with (1) degree of freedom.

For a time frame with a well-defined start, the screening analyses do not include subjects who [dropped out](#) before the start of the time frame.

2x2 tables

For each screening result, a 2x2 table of observed counts is constructed as follows:

	Treatment	Comparator	Total Subjects
Subjects who experienced the issue	A	B	A+B
Subjects who did not experience the issue	C	D	C+D
Total Subjects	A+C (N_T in results)	B+D (N_C in results)	N

A 2x2 table of expected counts is constructed as follows. It includes counts computed from the marginal totals of the observed counts, based on the assumption that whether or not a subject experienced an issue is independent of treatment.

	Treatment	Comparator	Total Subjects
Subjects who experienced the issue	$((A+B)(A+C))/(A+B+C+D)$	$((A+B)(B+D))/(A+B+C+D)$	A + B
Subjects who did not experience the issue	$((C+D)(A+C))/(A+B+C+D)$	$((C+D)(B+D))/(A+B+C+D)$	C + D
Total Subjects	A + C (N_T in results)	B + D (N_C in results)	N

In the 2x2 tables and in the analysis results:

- A = Count of subjects in the treatment group who experienced the issue in the time frame.
- B = Count of subjects in the comparator group who experienced the issue in the time frame.
- C = Count of subjects in the treatment group who did not experience the issue in the time frame.
- D = Count of subjects in the comparator group who did not experience the issue in the time frame.
- N_T = Total count of subjects in the treatment group.
- N_C = Total count of subjects in the comparator group.
- N = Total count of subjects.

Note that:

- For a time frame with a well-defined start, subjects who [dropped out](#) before the time frame start are excluded from the analysis and are thus excluded from all counts in the 2x2 table.
- Subjects are included in counts only if they have enough data to determine if the issue occurred. See the descriptions of specific analysis types for more information.
- In order for results to be generated for these analysis types, there must be at least one subject in each of the Treatment category and the Comparator category for the issue.
- Subjects are included in analysis results only if they are in a subgroup specified by categories, if any, in the analysis specification.
- For information about how counts are affected by the criteria of a custom analysis type, see [About Custom Analysis Types](#).

Days on drug as denominator

For cases where the average number of days on drug differs significantly between the treatment group and the comparator group, or for analyses run on a study pool where the average treatment duration varies significantly among the studies included in the study pool, more realistic analysis results may be obtained if the "Use days on drug for denominator for MedDRA Analysis with no time frame" option is checked when the analysis specification is created. However, other statistical approaches should be considered.

This option to use days on drug as the denominator applies to only MedDRA-based analysis types executed in the absence of a time frame. If this option is used, counts differ as follows, and a note below the 2x2 tables indicates that odds ratios were computed using days on drug as the denominator.

- N_T = Number of subject treatment days for subjects in the treatment group.
- N_C = Number of subject treatment days for subjects in the comparator group.
- $C = N_T - A$
- $D = N_C - B$
- $N = N_T + N_C$

The number of days on drug for a subject is computed as: $DM.RFENDTC - DM.RFSTDTC$

If one or both of these variables is null, days on drug is considered to be 0 for that subject.

Modified odds ratio

The modified odds ratio is computed as follows:

$$ODDS_RATIO = AD / BC$$

where:

- If A and B are both zero (no subjects experienced the issue), a neutral value of 1.0 is returned.
- If C and D are both 0 (all subjects experienced the issue), a neutral value of 1.0 is returned.
- If B (but not A) or C (but not D) is 0, the modified odds ratio is 100000000.

The lower confidence bound of the modified odds ratio statistic is computed as:

$$OR025 = \text{EXP}(\ln(OR) - 1.96 * \text{SQRT}(1 / A + 1 / B + 1 / C + 1 / D))$$

Note: If $\ln(OR)$ cannot be computed (that is, if A, B, C, or D is 0), then "???" is displayed for OR025.

The upper confidence bound of the modified odds ratio statistic is computed as:

$$OR975 = \text{EXP}(\ln(OR) + 1.96 * \text{SQRT}(1 / A + 1 / B + 1 / C + 1 / D))$$

Note: If $\ln(OR)$ cannot be computed (that is, if A, B, C, or D are 0), then "???" is displayed for OR975.

Corrected odds ratio

The corrected odds ratio is computed as:

$$ODDS_RATIO_C = [(A + 0.5)(D + 0.5)] / [(B + 0.5)(C + 0.5)]$$

The lower confidence bound of the modified odds ratio statistic is computed as:

$$OR025_C = \exp(\ln(OR) - 1.96 * \sqrt{((1 / (A + 0.5)) + (1 / (B + 0.5)) + (1 / (C + 0.5)) + (1 / (D + 0.5)))})$$

The upper confidence bound of the modified odds ratio statistic is computed as:

$$OR975_C = \exp(\ln(OR) + 1.96 * \sqrt{((1 / (A + 0.5)) + (1 / (B + 0.5)) + (1 / (C + 0.5)) + (1 / (D + 0.5)))})$$

Shrunken odds ratio

The shrunken odds ratio is a modification of the usual odds ratio for a two-by-two table of counts that has smaller variance than the raw odds ratio and also allows computation even when there are counts of 0. Suppose the counts (a, b, c, d) for a 2x2 table are defined as:

	Treatment	Control	Total
Event	a	b	a+b
No Event	c	d	c+d
Total	a+c	b+d	a+b+c+d

The raw odds ratio is $OR = ad/bc$. The shrunken odds ratio is computed by adding a total of n prior counts (a_0, b_0, c_0, d_0) to the raw counts and is computed as $SOR = (a+a_0)(d+d_0)/[(b+b_0)(c+c_0)]$. The prior counts are assumed to be of the form (where n is a positive number and p and q are between 0 and 1):

	Treatment	Control	Total
Event	$a_0 = n * p * q$	$b_0 = n * p * (1-q)$	$n * p$
No Event	$c_0 = n * (1-p) * q$	$d_0 = n * (1-p) * (1-q)$	$n * (1-p)$
Total	$n * q$	$n * (1-q)$	n

These definitions ensure that the prior odds ratio $a_0 d_0 / b_0 c_0 = 1$, and that the shrunken odds ratio will move the raw odds ratio toward 1. The quantity p is selected to be $p = (a+b)/(a+b+c+d)$ to maintain the same proportion of events as in the raw counts, and n is selected to be $= 1/\min(p, 1-p)$ so that the minimum of (a_0+b_0) and (c_0+d_0) will equal 1, ensuring that the prior counts are relatively small, so as not to overwhelm the actual data when the raw counts are not very small. The quantity q controls the allocation of the prior counts between Treatment and Control, and is computed as:

$$q = (a+c)^{1/2} / [(a+c)^{1/2} + (b+d)^{1/2}]$$

This is a compromise between always taking $q = 0.5$ [equal prior counts in both arms] and $q = (a+c)/(a+b+c+d)$ [allocation of prior counts to each arm in the same proportion as the raw counts].

Finally, both p and q are further constrained to be at least p_0 and at most $1-p_0$, where $p_0 = 0.5/(a+b+c+d)$. This ensures that p and q cannot be exactly 0 or 1, as might happen if two or three of the raw counts are 0.

The formulas for the SOR and its 90% confidence limits are:

$$\text{SOR} = (a+a_0)(d+d_0)/[(b+b_0)(c+c_0)]$$

$$\text{SOR}.025 = \text{SOR} \exp(-1.645\text{SE})$$

$$\text{SOR}.975 = \text{SOR} \exp(+1.645\text{SE})$$

$$\text{where SE} = [1/(a+a_0) + 1/(b+b_0) + 1/(c+c_0) + 1/(d+d_0)]^{0.5}$$

Modified Chi-statistic

The modified Chi-statistic is computed as:

$$\text{CHI} = \pm \sqrt{(A-E_A)^2 / E_A + (B-E_B)^2 / E_B + (C-E_C)^2 / E_C + (D-E_D)^2 / E_D)}$$

where:

- + is used if $A \geq E_A$ and "-" is used if $A < E_A$.
- If A and B are both zero (no subjects experienced the issue), a neutral value of 0.0 is returned.
- The square root of the chi-statistic is multiplied by -1 if disproportionately more subjects receiving the comparator treatment experience the issue, that is, when: $(A / (C + 1)) < (B / (D + 1))$

Score

The screening result score (the SCORE column of screening results) is the probability of obtaining a value for a test statistic that is as large as the observed value, given the null hypothesis that there is no treatment effect. The score is a one-tailed probability for the signed Chi-statistic, computed with (1) degree of freedom.

A one-sided alternate hypothesis is used because, from the point of view of safety signal detection, the situation is asymmetric. For example, if subjects receiving the study treatment experience a disproportionately higher occurrence rate of an issue than do subjects receiving the comparator, this is considered more interesting, and receives a lower score, than the situation in which the subjects receiving the study treatment experience a lower occurrence rate of the issue.

Note that:

- Computations are not corrected for multiple comparisons.

- If C and D are both 0 (all subjects experienced the issue), then the Chi-statistic is set to 0.0.

MedDRA PT, HLT, HLGT, or SOC Analysis

A MedDRA PT Analysis (type PT in screening results) performs a denominator-based disproportionality analysis that compares the following:

- Proportion of clinical trial subjects in the treatment group who experienced the PT.
- Proportion of clinical trial subjects in the comparator group who experienced the PT.

A MedDRA HLT, MedDRA HLGT, or MedDRA SOC Analysis (Type HLT, HLGT, or SOC in screening results) performs a denominator-based disproportionality analysis that compares the following:

- Proportion of subjects in the treatment group who experienced one or more PTs in the HLT, HLGT, or SOC.
- Proportion of subjects in the comparator group who experienced one or more PTs in the HLT, HLGT, or SOC.

The following example shows some results for a MedDRA PT analysis:

	Issue	Type	Score	chi-statistic	Corrected Odds Ratio	OR025_C	A	B	Treatment Subjects	Comparator Subjects
	Nausea	PT	0.000002	4.617	4.073	2.142	81	11	412	201
	Diarrhoea	PT	0.000084	3.762	2.499	1.526	98	22	412	201
	Dyspepsia	PT	0.001260	3.021	2.958	1.397	47	8	412	201

For more information, see [Scores for Disproportionality Analysis Types](#).

Note that an option is available to use days on drugs as the denominator for results generated for the absence of a time frame.

Included subjects

The analysis includes all subjects except that, for a time frame with a well-defined start, subjects who [dropped out](#) before the time frame start are excluded.

Notes




- The analysis includes only adverse events within the time frame.
- Counts of subjects who did not have an adverse event are determined using the DM domain in order to include subjects who have no data in the AE domain.
- These analysis types report only terms that are in the version of MedDRA associated with the study or study pool. If study data contains a term not in the MedDRA version, screening results are not generated for that term.
- Multiple occurrences of the same PT for the same subject are treated as one issue.

- In a MedDRA HLT, HLGT, or SOC Analysis, mapping of a PT to an HLT, HLGT, or SOC uses the primary path in the MedDRA Hierarchy. The occurrence of different PTs that map to the same HLT, HLGT, or SOC are treated as one issue.
- These analysis types are not available if the study is associated with MedDRA Versions 3.2 or 3.3. If you need to run these analysis types with these versions of MedDRA, contact Oracle.

Standardized MedDRA Query Analysis

A Standardized MedDRA Query Analysis (type **SMQ** in screening results) maps PTs to Standardized MedDRA Queries (SMQs), which are described below. Then a denominator-based disproportionality analysis compares the following:

- Proportion of subjects in the treatment group who experienced PTs meeting SMQ criteria
- Proportion of subjects in the comparator group who experienced PTs meeting SMQ criteria

	Issue	Type	Score	chi-statistic	Corrected Odds Ratio	OR025_C	A	B	Treatment Subjects	Comparator Subjects
	Pseudomembranous colitis [broad]	SMQ	0.000084	3.762	2.499	1.526	98	22	412	201
	Retroperitoneal fibrosis [broad]	SMQ	0.004100	2.644	1.858	1.161	90	26	412	201
	Parkinson-like events [broad]	SMQ	0.031540	1.859	7.454	0.424	7	0	412	201

For more information, see [Scores for Disproportionality Analysis Types](#).

Note that an option is available to use days on drugs as the denominator for results generated for the absence of a time frame.

SMQ definitions

The following description of Standardized MedDRA Queries is based on materials provided by the MSSO (Maintenance and Support Services Organization).

Standardized MedDRA Queries (SMQs) are intended to aid in the identification and retrieval of potentially relevant individual case safety reports; they are groupings of MedDRA terms, ordinarily at the Preferred Term (PT) level, that relate to a defined medical condition or area of interest. Terms included in a given SMQ may relate to relevant signs, symptoms, diagnoses, syndromes, physical findings, laboratory and other physiologic test data, etc. However, the methods used for SMQ development systematically exclude other parameters, such as timing of occurrence of an adverse event relative to drug administration, patient age, patient sex, disease severity, drug names, or case outcome. These other features may be essential elements of a given safety database search or an analysis of causality, but generally need to be considered separately from the adverse events of interest.

SMQs are not necessarily comprehensive, error-free, or universally applicable. However, results of performing a given SMQ search on a database should be reproducible and an identical search may be performed on any database utilizing the appropriate version of MedDRA. Thus, the overarching rationale for SMQs is to provide a framework for

reproducible searches and to avoid expensive duplication of effort. SMQs are not intended to provide a final answer to a regulatory question(s), but rather provide a standardized frame of reference for application when appropriate.

Conceptually, SMQs as described by MSSO may have a mixture of very specific terms and less specific terms that are consistent with a description of the overall clinical syndrome associated with a particular adverse event and drug exposure. Some SMQs are a straightforward collection of terms; others must be designed to accommodate combinations of terms from more than one group. To address these varied aspects, SMQs may have certain specific design features:

- **Narrow and Broad** – This approach accommodates those instances in which a user may need to identify cases that are highly likely to represent the condition of interest (a "narrow" scope) and those instances in which a user seeks to identify all possible cases, including some that may prove to be of little or no interest on closer inspection (a "broad" scope).
- **Algorithm** – For some SMQs, it may aid in case identification if the user applies an algorithmic approach to the terms in the SMQ. In other words, better case identification may result if cases are selected based on a defined combination of selected terms. For algorithmic SMQs, all selected terms are assigned a Category (e.g., A, B, ..., I) by MSSO. Categories are used in algorithmic formulas (e.g., A or (B and C)) to identify "broad" scope term combinations. For algorithmic SMQs only, Category A is synonymous with "narrow" scope.
- **Hierarchy** – Some SMQs are a series of queries related to one another in a hierarchical relationship similar to the hierarchical structure of MedDRA itself. These consist of one or more subordinate SMQs that could be combined to create a superordinate, more inclusive SMQ. For example, in MedDRA 9.1 the two-level hierarchy Haemorrhages (SMQ) includes two subordinate SMQs:

Haemorrhages

Haemorrhage terms (excl laboratory terms)

Haemorrhage laboratory terms

In the current implementation of the Standardized MedDRA Query Analysis, SMQs from all hierarchical levels may be generated for a study.

Implementation of the Standardized MedDRA Query Analysis is based on SMQs defined in the MSSO's *Introductory Guide for Standardized MedDRA Queries* for each MedDRA version beginning with MedDRA version 8.0. The SMQs generated by a Standardized MedDRA Query Analysis depend on the MedDRA version associated with the study.

Included subjects

The analysis includes all subjects except that, for a time frame with a well-defined start, subjects who [dropped out](#) before the time frame start are excluded.

Notes

- The analysis includes only adverse events within the time frame.
- Counts of subjects who did not have an SMQ are determined using the DM domain in order to include subjects who have no data in the AE domain.

- All PTs for a subject are used to determine whether the subject experienced the SMQ (including SMQs recorded for screening, baseline, and follow-up visits).
- Multiple occurrences of the same PT for the same subject are treated as one PT.
- Only MedDRA PTs (not LLTs) are used to determine whether the subject experienced the SMQ.
- This analysis type is not available if the study is associated with MedDRA versions prior to 8.0. If you need to run this analysis type with these early versions of MedDRA, contact Oracle.
- As a [custom analysis type](#), you can also create a Custom MedDRA Query Analysis (type **CMQ** in screening results). The custom analysis type must reference one or more predefined lists of events. This creates a screening result where the ISSUE column shows the name of the event list instead of the name of an SMQ.

QT Interval Prolongation Analysis

A QT Interval Prolongation Analysis (type EGQT in screening results) performs a denominator-based disproportionality analysis that compares the following for each type of abnormal QT interval:

- Proportion of subjects in the treatment group with one or more abnormal QT intervals
- Proportion of subjects in the comparator group with one or more abnormal QT intervals

In recent years, there has been increasing concern by regulatory agencies and by the public regarding detection and monitoring of drugs that delay cardiac repolarization, an effect that is manifest on a surface ECG as prolongation of the QT interval. QT interval prolongation favors the development of cardiac arrhythmias that can degenerate into life-threatening cardiac rhythms, such as ventricular fibrillation, which can result in sudden death.

The combination of the ability of a drug to prolong the QT interval and documented cases of cardiac events associated with the drug's use has resulted in a substantial number of regulatory actions, including withdrawal from the market and denial of marketing authorization. As a result, the FDA and Health Canada have jointly issued a recommendation saying that pre-marketing safety monitoring should include characterization of the drug effect on the QT interval and collection of clinical adverse event data that might represent cardiac arrhythmias. For more information, see *E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs* (Issued 6/10/2004, Posted 9/10/2004).

A QT Prolongation Analysis uses the reported, corrected QT interval from the study data, and it also computes corrected QTc intervals using the following three industry-standard formulas, which are the same except for the correction factor applied to the RR interval:

- QTcB is the length of the QT interval corrected for the RR interval by Bazett's formula: $QTcB = QTmsec / (RR \text{ sec})^{0.5}$
- QTcN is the length of the QT interval corrected for the RR interval by FDA Neuropharmacological Division's formula: $QTcN = QTmsec / (RR \text{ sec})^{0.37}$

- QTcF is the length of the QT interval corrected for the RR interval by Fredericia's formula: $QTcF = QTmsec / (RR \text{ sec})^{0.33}$

The following evaluations are performed for the reported QTc Interval and for each of the computed QTc intervals (QTcB, QTcN, and QTcF). If an evaluation is positive, the QTc result is considered to be abnormal.

- QTc Interval > 450
- QTc Interval > 480
- QTc Interval > 500
- QTc Interval Increase >= 30
- QTc Interval Increase >= 60

Issue	Type	Score	chi-statistic	Corrected Odds Ratio	OR025_C	A	B	Treatment Subjects	Comparator Subjects
FDA Neuro QTc Interval > 450	EGQT	0.170630	0.952	1.188	0.829	143	62	412	201
Reported QTc Interval > 450	EGQT	0.189435	0.880	1.166	0.825	169	75	412	201
Bazett QTc Interval Increase >= 30	EGQT	0.190595	0.876	1.178	0.811	126	55	405	199

For more information, see [Scores for Disproportionality Analysis Types](#).

Included subjects

The analysis includes only the following subjects:

- For issues not involving change from baseline, subjects who have an ECG test result within the time frame.
- For issues involving change from baseline, subjects who have both a post-baseline result within the time frame and a baseline result. The baseline result can be before the time frame start.

If the time frame has a well-defined start, subjects who [dropped out](#) before the time frame start are excluded from the analysis.

Test identifiers

The analysis relies on ECG [test identifiers](#) as follows:

- If a test identifier for QTC INTERVAL (the reported, corrected QT interval) has been defined, the screening results may include issues for Reported QTc Interval.

- If test identifiers for QT INTERVAL and RR INTERVAL have been defined, the screening results may include issues for Bazett QTc Interval, FDA Neuro QTc Interval, and Fredericia QTc Interval.

Notes

- The analysis includes results for the ECG test within the time frame. For issues that measure change from baseline, the post-baseline result must be within the time frame.
- Counts of subjects are determined using the EG domain.
- For evaluations based on actual values (that is, QTc Interval > 450, QTc Interval > 480, QTc Interval > 500), the analysis includes only subjects who had at least one QTc result.
- For evaluations based on increase from baseline (QTc Interval Increase >= 30 and QTc Interval Increase >= 60), the analysis includes only subjects who had a baseline QTc result and a post-baseline QTc result. See [Baseline Results](#) for information about how baseline values are established. Note that the analysis does not use the analysis specification's option for Use maximum (instead of most recent) change from baseline. All post-baseline results (within the time frame, if a time frame is in effect) are evaluated and counted.
- For evaluations that use QT INTERVAL and RR INTERVAL, the results must have occurred at the same visit. For evaluations that use baseline, the later of the baseline values for QT or RR are used.
- It is assumed that RR is stored in milliseconds; thus, the RR value is divided by 1000 to obtain seconds.
- Computations rely on the value reported for RR to be non-negative. Records with a negative value for RR are excluded from the analysis.

Clinically Significant Lab or Vitals Analysis

A Clinically Significant Lab Analysis (type **LBCS** in screening results) or Clinically Significant Vitals Analysis (type **VSCS** in screening results) performs a denominator-based disproportionality analysis that compares the following for each distinct lab test or vital sign:

- Proportion of subjects in the treatment group who have one or more post-baseline clinically significant results for the lab test or vital sign.
- Proportion of subjects in the comparator group who have one or more post-baseline clinically significant results for the lab test or vital sign.

A clinically significant value is a result that a clinician would consider to be medically meaningful. Clinically significant values may be more extreme than values that are simply outside normal ranges, and they may be age-dependent or sex-dependent.

There are two ways that clinical significance can be determined:

- If built-in criteria are used, the issues generated by this analysis type correspond to lab tests or vital signs for which there are built-in criteria and for which a test identifier has been defined.
- If a flag variable is used, the issues can be any lab tests or vital signs from the study data.

For more information see [Clinical Significance Criteria](#) and [Scores for Disproportionality Analysis Types](#).

Issue	Score	chi-statistic	Corrected Odds Ratio	OR025_C	A	B	Treatment Subjects	Comparator Subjects
Clinically Significant WBC	0.612437	-0.286	0.765	0.198	5	3	412	201
Clinically Significant HEMAT	0.683199	-0.477	0.867	0.503	40	22	412	201
Clinically Significant ALT	0.894895	-1.253	0.291	0.038	1	2	412	201

Included subjects

The analysis includes only subjects who have at least one result for the lab test or vital sign that occurs within the time frame and for which clinical significance can be determined. Note that built-in criteria involving clinical significance require both a post-baseline result and a baseline result. The baseline result does not need to be within the time frame.

If the time frame has a well-defined start, subjects who [dropped out](#) before the time frame start are excluded from the analysis.

Notes

- The analysis includes only results for the lab test or vital sign within the time frame. Note that built-in criteria involving clinical significance require both a post-baseline result and a baseline result. The baseline result does not need to be within the time frame.
- Counts of subjects are determined using the LB or VS domain.
- When built-in criteria for clinical significance are used, all criteria are applied to all results in the time frame. Thus it is possible for a pre-baseline result to appear in the screening results as a clinically significant result.
- For built-in criteria for clinical significance that measure change from baseline, the baseline is established as described under **Baseline using baseline flag** in [Baseline Results](#). Also note that the analysis specification's option for **Use maximum (instead of most recent) change from baseline** is not used. All results (within the time frame, if one is in effect) are evaluated and counted.
- If a flag variable (instead of built-in criteria) is used to determine clinical significance, there is no need to establish a baseline value.

- If Sex or Age is null for a subject, the subject is not included in counts for any test that requires a value of Sex or Age to determine clinical significance.
- For a Clinically Significant Lab Analysis, there is one potential issue per unique short name found in the LB domain. The Test Name column in the screening results table is set to the long name associated with the short name. If there are multiple long names associated with a short name, the alphabetically last long name is used.
- For a Clinically Significant Vitals Analysis, there is one potential issue per unique short name found in the VS domain, or, if the study includes the vital sign position, per unique combination of short name and position. If a position is present, it appears in parentheses after the vital sign name. The Test Name column of the screening results table is set to the long name associated with the short name (or combination of short name and position). If there are multiple long names associated with the short name (or combination of short name and position), the alphabetically last long name is used.

Hy's Law Analysis

A Hy's Law Analysis (type LBHY in screening results) performs a denominator-based disproportionality analysis that compares the following:

- Proportion of subjects in the treatment group with post-baseline results that meet the hepatotoxicity criteria (see below) at least once.
- Proportion of subjects in the comparator group with post-baseline results that meet the hepatotoxicity criteria (see below) at least once.

The analysis generates results for the following hepatotoxicity criteria:

- (ALT or AST) \geq 3x ULN, BILI \geq 2x ULN, ALP \leq 2x ULN
- (ALT or AST) \geq 3x ULN, BILI \geq 1.5x ULN, ALP \leq 2x ULN
- (ALT or AST) \geq 3x ULN, BILI \geq 1.5x ULN
- (ALT or AST) \geq 20x ULN
- (ALT or AST) \geq 10x ULN
- (ALT or AST) \geq 5x ULN
- (ALT or AST) \geq 3x ULN

Issue	Type	Score	chi-statistic	Corrected Odds Ratio	OR025_C	A	B	Treatment Subjects	Comparator Subjects
(ALT or AST) \geq 10x ULN	LBHY	0.670288	-0.441	0.541	0.055	1	1	164	89
(ALT or AST) \geq 5x ULN	LBHY	0.670288	-0.441	0.541	0.055	1	1	164	89
(ALT or AST) \geq 3x ULN	LBHY	0.670288	-0.441	0.541	0.055	1	1	164	89

For more information, see [Scores for Disproportionality Analysis Types](#).

Included subjects

The analysis includes only subjects who have lab test results needed to compute hepatotoxicity criteria within the time frame. If the time frame has a well-defined start, subjects who [dropped out](#) before the time frame start are excluded from the analysis.

Test identifiers

[Test identifiers](#) should be defined ahead of time for the following lab tests: Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Bilirubin (BILI), and Alkaline Phosphatase (ALP). However, the analysis type can be run if test IDs for only ALT and/or AST have been defined.

Notes

- The analysis includes results for lab tests meeting hepatotoxicity criteria within the time frame.
- A post-baseline result is one for which the value of LB.LBBLFL is not Y and that occurs after a result for which the value of LB.LBBLFL is Y.
- Counts of subjects are determined using the LB domain.
- For issues involving multiple tests, the test results must have occurred at the same post-baseline visit.
- If the same lab test occurred more than once for a post-baseline visit, all lab test values for the visit are considered in determining whether the finding-specific criteria are met.
- If there is no ULN value for a subject's test, the test result is not used.
- A subject is counted separately for each criterion that is met. The same subject could be counted in all six rows of screening results.

Subject Disposition Analysis

A Subject Disposition Analysis (type **DSPD** in screening results) performs a denominator-based disproportionately analysis that compares the following:

- Proportion of subjects in the treatment group with a particular disposition (DSDECOD value).
- Proportion of subjects in the comparator group with a particular disposition (DSDECOD value).

Issue	Type	Score	chi-statistic	Corrected Odds Ratio	OR025_C	A	B	Treatment Subjects	Comparator Subjects
Disposition of OTHER	DSPD	0.033028	1.838	2.660	0.838	18	3	412	201
Disposition of ADVERSE EVENT	DSPD	0.100545	1.278	1.316	0.855	90	35	412	201
Disposition of PROTOCOL VIOLATION	DSPD	0.192521	0.869	1.677	0.405	8	2	412	201

For more information, see [Scores for Disproportionality Analysis Types](#).

Only one disposition event per subject is counted. To determine the disposition event, WebSDM/Empirica Study uses the algorithm described in [Disposition Events](#).

If the algorithm finds multiple disposition events for any subjects, WebSDM/Empirica Study tries to use the disposition event date to determine a disposition event to use in the analysis and a message appears in the [warnings](#) for the analysis specification run. If this is not possible for a subject, the subject is omitted from the analysis and the message in the warnings tells you which subjects were omitted.

Included subjects

The analysis includes all subjects except that, for a time frame with a well-defined start, subjects who [dropped out](#) before the time frame start are excluded.




Notes

- The analysis includes disposition events within the time frame.
- Counts of subjects are determined using the DS domain.

Change from Baseline Analysis Types

Lab or Vital Signs Change from Baseline Analysis

The results of a Lab Change from Baseline Analysis (type LBBL in screening results) or Vital Signs Change from Baseline Analysis (type VSBL in screening results) are based on a t-test of the mean change from baseline in the treatment group compared to the mean change from baseline in the comparator group for the specific test or vital sign results. For information on how baseline results are established, see [Baseline Results](#).

	Issue	Type	Score	Mean for Treatment	Mean for Comparator	Treatment Subjects	Comparator Subjects	t-statistic
	AST	LBBL	0.003868	0.891111	3.984391	405	197	-2.900004
	CHLORIDE	LBBL	0.036133	0.159506	-0.576269	405	197	2.100144
	ALT	LBBL	0.060967	2.520691	12.846066	405	197	-1.877260

To determine which post-baseline result to use in computations, the analysis specification's setting for Use maximum (instead of most recent) change from baseline is used. If that option is checked, the change from baseline value is computed using the post-baseline

result (within the time frame) whose value represents the greatest (positive or negative) change from the baseline result. Otherwise, the change from baseline is computed using the most recent, non-null, post-baseline result (within the time frame); if there are multiple results with the same most recent date and time, the result (within the time frame) whose value represents the greatest (positive or negative) change from the baseline result is used.

Note: When you are viewing screening results on the Safety Review tab, this table is not affected by the safety review configuration option for using the maximum or most recent change from baseline.

Included subjects

The analysis includes only subjects who have both a post-baseline result within the time frame and a baseline result. The baseline result can be before the time frame start.

If the time frame has a well-defined start, subjects who [dropped out](#) before the time frame start are excluded from the analysis.

Notes

- The analysis includes only post-baseline results for the lab test or vital sign within the time frame.
- Counts of subjects are determined using the LB or VS domain.
- In order for results to be generated for these analysis types, there must be at least two subjects in each of the Treatment category and the Comparator category for the test.
- For a Lab Change from Baseline Analysis, there is one potential issue per unique short name found in the LB domain. The Test Name column in the screening results table is set to the long name associated with the short name. If there are multiple long names associated with a short name, the alphabetically last long name is used.
- For a Vital Signs Change from Baseline Analysis, there is one potential issue per unique short name found in the VS domain or, if the study includes the vital sign position, per unique combination of short name and position. If a position is present, it appears in parentheses after the vital sign name. The Test Name column of the screening results table is set to the long name associated with the short name. If there are multiple long names associated with a short name (or combination of short name and position), the alphabetically last long name is used.

Computations

For each screening result, the following counts are computed for subjects who had a baseline result and at least one post-baseline result for the test or vital sign in question. If a time frame is in effect, the post-baseline result must be within the time frame.

- N_T = Total count of subjects in the treatment group.
- N_C = Total count of subjects in the comparator group.
- N = Total count of subjects.

- U_T = Mean of change from baseline measurements for subjects in the treatment group.
- U_C = Mean of change from baseline measurements for subjects in the comparator group.
- S_T = Standard deviation of change from baseline results for subjects in the treatment group.
- S_C = Standard deviation of change from baseline results for subjects in the comparator group.
- V_T = Variance of change from baseline results for subjects in the treatment group.
- V_C = Variance of change from baseline results for subjects in the comparator group.

If U_T and U_C are identical or V_T or V_C is zero, no screening result is generated.

A t-statistic is computed as:

$$t = (U_T - U_C) / \sqrt{(((N_T - 1)V_T + (N_C - 1)V_C) / (N_T + N_C - 2)) (1/N_T + 1/N_C)}$$

Score

The screening result score (the SCORE column of screening results) is the probability of obtaining a value for a test statistic that is as large as the observed value, given the null hypothesis that there is no treatment effect. The score is based on a t-statistic derived from the difference in the mean change from baseline for the treatment and comparator groups.

The scores are p-values associated with the test statistics using a two-sided alternative hypothesis. A two-sided alternative is used because for some tests a negative outcome is associated with a positive change in the test result, while for other tests a negative outcome is associated with a negative change in the test result.

A two-tailed probability for the t-statistic is computed with $(N_T + N_C - 2)$ degrees of freedom. This probability (p-value) is used as the screening result score.

Bayesian Logistic Regression

About Bayesian Logistic Regression

Bayesian Logistic Regression (BLR) is an exploratory statistical technique provided with WebSDM/Empirica Study that analyzes clinical safety data. Using BLR analysis results, you can better determine how specific issues experienced by study subjects are related to treatment. Typically, you run BLR analysis for multiple medically-related issues in a study or study pool.

To perform BLR analysis, you create a BLR run and select predictors, or covariates, such as age and sex, and you select issues to use as responses. You then run the BLR, generating results that estimate the effects of treatment while accounting for the covariates. BLR runs provide results using both the Multivariate Bayesian Logistic Regression (MBLR) algorithm and the Regularized Logistic Regression (RLR) algorithm.


The results of a BLR run may help support any of the following conclusions:

- An issue appears related to treatment in a screening analysis, but is not related to treatment when covariates are included in a BLR run, and these covariates show a strong relationship to issue outcome. This may indicate that a randomization error has occurred.
- An issue is related to treatment, and that association is affected by covariates. For example, smokers over age 65 may be more vulnerable to experiencing the issue.

For more specific information on Bayesian Logistic Regression or the MBLR and RLR algorithms, see the *Multivariate Bayesian Logistic Regression for Analysis of Clinical Study Safety Issues* whitepaper available from Oracle upon request.

BLR Runs Created Prior to WebSDM/Empirica Study Release 3.1

Prior to WebSDM/Empirica Study release 3.1, you created Bayesian Logistic Regression (BLR) runs in the context of potential signals. In release 3.1, BLR runs are no longer created in this context; you now run them independently on the Bayesian Logistic Regression Runs page. However, when you upgrade WebSDM/Empirica Study from 3.0 to 3.1, the upgrade process retains any existing BLR runs that are attached to potential signals. These BLR runs remain accessible from the potential signals to which they are attached; you cannot access BLR runs created prior to 3.1 from the Bayesian Logistic Regression Runs page.

To allow you to manage BLR Runs created prior to release 3.1, some functionality remains accessible on the Potential Signal page. The following options are available for each existing BLR run from the Action menu icon ():

- View Results (available only if there were results generated by the most recent run of the BLR)
- View Configuration Options

- View Annotations
- Delete (availability is dependent on the status of the potential signal)

For information on working with BLR runs using the remaining options, see [Working with BLR Runs Attached to a Potential Signal](#).

Deprecated Functionality

You cannot create new BLR runs that are attached to potential signals in release 3.1. In addition, you cannot rerun existing BLR runs. Thus, the following options are no longer available on the Potential Signal page:

- The **Configure BLR** link in the Bayesian Logistic Regression Runs section.
 - The **Reconfigure/Rerun** option from the Action menu.

For information on creating and running new BLR runs, see [Creating BLR Runs](#).

Creating BLR Runs

Creating BLR Runs

You create BLR runs for the study or study pool that is currently selected. To create a BLR run, you must:

- Have at least the **Review Studies** and the **Manage BLRs** permissions.
- Have defined and run the \$\$\$\$BASIC\$\$\$\$SCREENING\$\$\$ screening analysis specification for the current study or study pool.

If you have not met these requirements, or if a screening analysis run for \$\$\$\$BASIC\$\$\$\$SCREENING\$\$\$ is currently queued or in process, the **Create BLR Run** link on the Bayesian Logistic Regression Runs page is unavailable.

To create a BLR run, do the following:

1. Click the Screening tab. The Bayesian Logistic Regression Runs page or the Analysis Specifications page appears.
2. If the Analysis Specifications page appears, click **BLRs**. The **Bayesian Logistic Regression Runs** page appears.
3. Click **Create BLR Run**. The **Configure BLR** page appears.

To create a BLR, an up-to-date issue list must exist. To keep the list current, WebSDM/Empirica Study silently [submits an automatic screening run](#) when you perform certain actions that would cause the list to become out-of-date. However, if the issue list needs to be created or updated, for example, because a user cancelled the last auto screening run, a message informs you and provides the opportunity to create or update the issue list.

If you choose to update the issue list when WebSDM/Empirica Study prompts you and you do not have the Load and Check Studies permission, an error occurs. You must contact your system administrator to refresh the issue list.

4. [Enter identifying information.](#)
5. [Select predictors.](#)
6. [Select a time frame.](#)
7. [Select issues.](#)
8. [Save and optionally run the BLR.](#)

Step 1: Enter Identifying Information

1. Specify the following in the Identifying Information section:

Field	Description
Name	Unique name for the BLR run, up to 40 characters long. REQUIRED
Description	Optional description for the BLR run. If you do not specify a description, WebSDM/Empirica Study inserts the BLR run creation date and time in this field automatically when you save the BLR run.
Add to existing project/ Add to a new project named	<p>Specify a project option. The options are:</p> <ul style="list-style-type: none"> • Add to existing project to assign the BLR run to a project you previously created, and then: <ul style="list-style-type: none"> • Select the project name from the drop-down list, or • Select Unassigned to leave the BLR run unassigned • Select Add to a new project named to create a new project to which WebSDM/Empirica Study should assign the BLR run, and then enter a unique name.

For more information on using projects, see [Using Projects](#).

2. Complete [Step 2: Select Predictors](#).

Step 2: Select Predictors

In this step, you select the predictors, or covariates, such as age, sex, and race, that define the subgroups included in the analysis. Minimally, you must select a dosing category breakdown and at least one other predictor. If your study administrator selected the **Use as default** option for any category breakdowns, those categories are pre-selected and included in the BLR run.

Select categories from the appropriate drop-down lists or multi-select lists for the appropriate predictors. To select multiple options or deselect an option selected in a multi-select list, such as Medical History, press **Ctrl+click** to select or deselect it.

Note: You should select a minimal number of predictors. Selecting many predictors may restrict BLR analysis to a subgroup in which no subjects have experienced the issue. In this situation, [an error occurs](#).

1. Optionally do any of the following when selecting predictors:

Action	Steps
View the category breakdowns for subgroups included in each category	Click Browse above each predictor.
Create additional category breakdowns	Click Add above each predictor. For more information on creating category breakdowns, see Defining a Category a Breakdown for Text Values or Defining a Category Breakdown for Numeric Values .

2. Complete [Step 3: Select a Time Frame](#).

Step 3: Select a Time Frame

Optionally, you can select a time frame to limit BLR analysis to adverse events that occurred during a specific time period. If your study administrator selected the **Use as default** option for a time frame, that time frame is pre-selected.

Select an appropriate time frame, or select **-None-** to indicate no time frame is necessary.

You can also click [Browse](#) to select from a more descriptive list of time frames.

Complete [Step 4: Select Issues](#).

Step 4: Select Issues

You must select at least one issue for a BLR run. Typically, you select multiple medically-related issues for a Bayesian Logistic Regression analysis.

Note: You do not need to select issues if you are simply saving the BLR run. However, to run the BLR, you must select at least one issue.

To select issues, click **Select Issues** below the Time Frame drop-down list. The [BLR Response Selector](#) appears.

Complete [Step 5: Save and Optionally Run the BLR Run](#).

Step 5: Save and Optionally Run the BLR Run

When you have finished creating your BLR run, do one of the following:

- Click **Save** to save the BLR without running it. You can run the BLR at a later time from the [Bayesian Logistic Regression Runs page](#).

- Click **Save & Run** to save the BLR and run it immediately.

If you previously ran the BLR, a message appears, indicating that all previously generated results for the BLR run will be replaced. Click **OK** to continue, or click **Cancel** to retain previous results.

WebSDM/Empirica Study displays the analysis results when the BLR run completes.

An error message may occur when your BLR run executes. Most error messages indicate that the data you are attempting to analyze is insufficient, or does not meet specific criteria. In this case, you must edit the BLR run criteria before you can view results. However, if specific error messages occur, WebSDM/Empirica Study still allows you to view results or subgroup statistics. For information on these error messages and viewing results, see [Viewing BLR Run Results](#).

For information on other BLR run error messages, see [BLR Run Error Messages](#).

Working with the BLR Response Selector

The BLR Response Selector allows you to select screening issues for which to run BLR analysis. The BLR Response Selector includes a list of issues generated during the most recent screening analysis run for the \$\$\$\$BASIC\$\$\$\$SCREENING\$\$\$ specification. However, the issue list does not include issues from the following analysis types:

- Subject Disposition (DSPD)
- Lab Change from Baseline (LBBL)
- Vitals Change from Baseline (VSBL)
- Custom MedDRA Query (CMQ) or any other custom analysis type

Using the options available in the BLR Response Selector, you can:

- Filter the screening issues shown using the drop-down lists.
- View additional graphs and summaries of the issues.
- Print or download issues.
- Configure columns and rows.
- Switch to multi-row selection mode.

To open the BLR Response Selector:

On the [Configure BLR page](#), click **Select Issues**. The BLR Response Selector opens.

The following table describes the columns available in the issue list:

Column	Description
Issue	The issue experienced by subjects in the treatment or comparator group.

Type	The analysis result type.
A	The total number of subjects in the treatment group who experienced the issue.
B	The total number of subjects in the comparator group who experienced the issue.
Treatment Subjects	The total number of subjects in the treatment group.
Comparator Subjects	The total number of subjects in the comparator group.


Filtering issues

WebSDM/Empirica Study filters the issues shown based on selections you make from drop-down lists. Select from the following:

- **Dosing category breakdown, Time frame:** Initially set to the default dosing category breakdown and time frame, if they exist, and if they were included in the most recent screening analysis run for the \$\$\$BASIC\$\$\$SCREENING\$\$\$ specification.
- **Analysis group, Analysis type:** Available only when screening results exist for multiple analysis groups and types.
- **Age, Sex, and so on:** Population subgroup selectors are available if they were included in the most recent screening analysis run for the \$\$\$BASIC\$\$\$SCREENING\$\$\$ specification.

Finding specific issues

When you know the specific issues that you want to add to the BLR run, you can more easily locate them in the BLR Response Selector issue list by using the Where Clause field in the Columns and Rows dialog box. In the Where Clause field, you can enter a string to limit the issues shown in the issues list to just those of interest.

1. Click **Show Issue Menus** to enable single-row selection mode. The Action menu icon  appears next to each issue.
2. Click **Columns and Rows** above the issue list. The Columns and Rows page appears.
3. Enter a string in the **Where Clause** field. For more information, see [Arranging Table Columns](#).
4. Click **OK**. The Columns and Rows dialog box closes, and the issues matching the WHERE clause appear in the issue list.

Viewing graphs and summaries

Additional reporting options become available when you select a dosing category breakdown and a time frame. Select from the following:

- [View as Sector Map](#)

- [View Lab Graph](#)
- [View Lab Panel](#)
- [View Vitals Graph](#)
- [View Event Summary by Dose Group](#)
- [View Disposition Summary by Dose Group](#)

Printing and downloading issues

Select from the following:

- [Print](#)
- [Download](#)

Selecting subject drilldown options


Subject drilldown options are available when you click the counts in the A, B, Treatment Subjects, and Comparator Subjects columns. To select a subject drilldown option, click a subject count, and then select from the following:

- [View Subjects](#)
- [Create Subject List](#)
- [Transfer to Subject List](#)
- [Download Subjects](#)
- [Download Subject Details](#)
- [Reports](#)

Note: The drilldown options that appear are dependent upon your user permissions.

Using selection modes

You can add issues to the BLR run using the following selection modes:

- **Single-row:** Allows you to add one issue at a time using the Action Menu icon . Enables drilldown options.
- **Multi-row:** Allows you to add multiple issues at once using checkboxes.

The BLR Response Selector uses multi-row selection mode by default.


To enable single-row selection mode, click **Show Issue Menus**.

To enable multi-row selection mode, click **Select Issues** when single-row selection mode is enabled.

Configuring columns and rows

Available in single-row selection mode only. Select [Columns and Rows](#).

Adding issues to the BLR run

To add issues in single-row selection mode, click the Action menu icon  next to an issue, and then click **Select**.

To add issues in multi-row selection mode, select the check boxes next to issues, and then click **Apply Selections**.

Selecting issue drill-down options

Issue drill-down options are available in single-row selection mode only. To select an issue drill-down option, enable single-row selection mode, and then select from the following:

Option	Analysis Type Availability			
	MedDRA-based Types	Clinically Significant Lab	Clinically Significant Vital	QT Interval Prolongation
View 2x2 Table	X	X	X	X
View Events by Dose Group	X			
View Issues by Dose Group		X	X	X
View Day of Onset by Dose Group	X			
View Severity by Dose Group	X			
View Toxicity Grade by Dose Group	X			
View Recurrence by Dose Group	X			
View Action Taken by Dose Group	X			
View Outcome by Dose Group	X			
View Demographic Distribution by Dose Group	X			
View Cumulative Incidence Plot	X			
View Lab Graph		X		
View Lab Panel		X		
View Vitals Graph			X	
View Odds Ratio Graph	X	X	X	X

[View Related Results](#)

X

BLR Run Error Messages

Message	Indication
There are <i><number-of-predictor-categories></i> predictor levels and 2 treatment levels for <i><number-of-subjects></i> subjects. At least 10 subjects required for each level: analysis cannot be run.	The minimum number of subjects required to run has not been met. This number is equal to the number of categories (including the two dosing categories) multiplied by 10. For example, if you use a category breakdown for sex (where there are two categories, Male and Female), the minimum number of subjects required is 40.
Analysis cannot be run because the following predictor(s) has/have no variability for subjects under analysis. <i><list of predictors></i>	<p>There is no variability in predictor levels. For example, suppose the Age predictor has the following levels:</p> <ul style="list-style-type: none"> • 0-18 years • 18-38 years • 38+ years <p>If all subjects fall into the 18-38 years subgroup, there is no variability for the Age predictor.</p>
Analysis cannot be run because the following issue(s) has/have no variability for subjects. You may have a study day window that excludes all issues, or a breakdown that excludes all subjects with issues. <i><list of issues></i>	<p>There is no variability in the number of subjects who experienced the issues included in the BLR run. At least one of the following conditions is true:</p> <ul style="list-style-type: none"> • No subjects experienced a specific issue. • All subjects experienced a specific issue.
The following subgroup(s) has/have no occurrences for any issue. <i><list of subgroups></i>	Also known as the "Perfect Predictor" warning. There is a predictor level in which no issues were experienced by subjects.
The following predictor terms are perfectly correlated with other terms. <i><list of terms></i>	Also known as the "Perfectly Correlated Terms" warning. A predictor other than Dosing has a constant value for all subjects.
Results from these analyses may depend on assumptions that cannot be verified with the current data. You may	<p>One of the following warnings occurred:</p> <ul style="list-style-type: none"> • The Perfect Predictor warning.

prefer to reformulate the model without using the predictor terms mentioned below.

Do you want to continue?

- The Perfectly Correlated Terms warning.

Though a condition was found that would normally prevent the BLR run from successfully producing results, WebSDM/Empirica Study allows you to view results. Do one of the following:

- Click **Continue** to view BLR run results.
- Click **Cancel** to discard the results and return to the Bayesian Logistic Regression Runs page.
- Click **Subgroup Statistics**. The subgroup statistics may assist you in adjusting your BLR model.

A/Some <u>subgroup/subgroups</u> has/have no occurrences for any issue.	Appears on the Bayesian Logistic Regression Results page when the Perfect Predictor warning occurs and you click Continue . Hover your mouse over the Subgroup hyperlink to view the subgroup that caused the error.
Some predictor <u>terms</u> are perfectly correlated with other terms.	Appears on the Bayesian Logistic Regression Results page when the Perfectly Correlated Terms warning occurs and you click Continue . Hover your mouse over the Terms hyperlink to view the predictor terms that caused the error.
Unable to execute Bayesian Logistic Regression run. For assistance, please contact your site administrator. Reference <i><name and location of zip file></i> .	In rare situations, appears on the Bayesian Logistic Regression Results page when the R program that computes BLR results fails to generate results. Write down the name and location of the .zip file indicated and send it to your site administrator. If you are a site administrator, review the contents of the .zip file to help diagnose the issue. The .zip file is located in C:\Lincoln\apps\websdm\webapps\web_root\graphgifs.

Running and Rerunning Bayesian Logistic Regression Runs

You can run BLR runs:

- For newly created BLR runs on the **Configure BLR** page.
- or
- For existing BLR runs on the **Bayesian Logistic Regression Runs** page.


When you rerun a BLR run for which analysis results exist, WebSDM/Empirica Signal replaces the existing results with the newly generated results.

In some cases, an error message may occur when your BLR run executes. Most error messages indicate that the data you are attempting to analyze is insufficient, or does not meet specific criteria. In this case, you must edit the BLR run configuration criteria before you can view results. However, if specific warning messages occur, WebSDM/Empirica Study still allows you to view results or subgroup statistics. For information on these and other error messages and viewing results, see [BLR Run Error Messages](#).

To run BLR runs on the Configure BLR page:

See [Creating BLR Runs](#).


To run BLR runs on the Bayesian Logistic Regression Runs page:

1. Click the Screening tab. The Bayesian Logistic Regression Runs page or the Analysis Specifications page appears.
2. If the Analysis Specifications page appears, click **BLRs**. The **Bayesian Logistic Regression Runs** page appears.
3. Click the Action Menu icon () next to a BLR run, and then select **Run**.
 - If you have not previously run the BLR run, a message appears, indicating that WebSDM/Empirica Study is generating results.
 - If you previously ran the BLR run, a message appears, indicating that all previous results will be replaced. Click **OK** or **Cancel**.

Working with BLR Run Results

Viewing BLR Run Results

To view BLR run results, do one of the following:

- [Run a BLR run](#).
- or
- On the [Bayesian Logistic Regression Runs page](#), click the Action menu icon () next to a BLR run, and then select **View Results**. The BLR Results page appears.

An error message may appear. For more information on BLR run error messages, see [BLR Run Error Messages](#).

Note: This topic describes viewing BLR Run results for runs that were created in WebSDM/Empirica Study release 3.1. For information on viewing results for BLR runs created prior to release 3.1 that are attached to potential signals, see [Viewing BLR Run Results for Runs Attached to a Potential Signal](#).

The following table describes the columns available in the BLR results table:

Column	Description
--------	-------------

Method	<p>The algorithm that generated the results.</p> <p>MBLR— Multivariate Bayesian Logistic Regression.</p> <p>RLR— Regularized Logistic Regression.</p> <hr/> <p>Note: A filter setting determines whether results for RLR, MBLR, or both are displayed.</p>
Response	<p>The response to treatment. Can be the value PRIOR_MEAN or the name of an issue used as a response. For example, PT: Thirst. PRIOR_MEAN is shown only for BLR runs that have more than one response issue. Estimates for PRIOR_MEAN are interpreted as summaries of the associations across all response issues.</p> <hr/> <p>Note: A filter setting determines the responses that are displayed.</p>
Term	<p>The term included in analysis. Can be:</p> <ul style="list-style-type: none"> • The value <Intercept> • A value representing the main effect of a covariate. For example, Sex: F. • A value representing the intersection of Treatment with a covariate. For example, Trt*Sex:F. • A value representing Treatment plus the interaction of Treatment with a covariate. For example, Trt + Trt*Sex:F. <hr/> <p>Note: A filter setting determines the terms that are displayed.</p> <p>Note: When you sort column data for a term, the sort may not perform as expected. Clicking the Ascending or Descending sort ear sorts the data in the order in which the subgroups were defined for each category, rather than in ascending or descending alphabetical order.</p>
OR	Odds Ratio describing the association between the Response and the Term, computed as the exponential of the corresponding logistic regression coefficient.
OR 05	Lower limit of the 90% confidence interval (Bayesian credible interval) for OR.
OR 95	Upper limit of the 90% confidence interval (Bayesian credible interval) for OR.
Effect Type	A classification for the Term. Can be Main , Interaction , or Treatment+ Interaction .
Predictor	The predictors included in the analysis.
Coefficient	Estimated logistic regression coefficient for the specified method, response and term.
SE of Coefficient	Standard Error (posterior standard deviation) of the Coefficient.

When viewing results, you can also do the following:

- [View Configuration Options](#)
- [Switch to Graphical View](#)

- [View Prior SDs](#)
- [View Compressed Input Data](#)
- [View Subgroup Statistics](#)
- [Filter Results](#)
- [Configure Columns](#)
- [Print](#) or [Download Data](#)

Filtering BLR Run Results

You can filter BLR run results to include or exclude results for specific terms, responses, and methods from the BLR results table or graph. If you select filter settings while viewing BLR run results in tabular format, the settings persist to the BLR run results graph, and vice versa.

To filter BLR run results:

1. [View BLR run results](#).
2. Optionally click [Switch to Graphical View](#).
3. Click **Filter Results**. The **Filter Results** dialog box opens.
4. Include and exclude the appropriate terms, responses, and methods.
5. Click **OK**. The Filter Results window closes, and WebSDM/Empirica Study filters the BLR run results accordingly.


To include one or more terms and responses:

1. Select one or more terms in the **Available Terms** list.


Or

Select one or more responses in the **Available Responses** list.

Note: Use **Ctrl** or **Shift** to select multiple terms or responses.

2. Click the right single-arrow button . The terms move to the **Included Terms** list, and the responses move to the **Included Responses** list.

To include all terms and responses:

Click the right double-arrow button . All terms move to the **Included Terms** list, and all responses move to the **Included Responses** list.

To exclude one or more terms and responses:

1. Select one or more terms in the **Included Terms** list.

Or

Select one or more responses in the **Included Responses** list.

Note: Use **Ctrl** or **Shift** to select multiple terms or responses.

2. Click the left single-arrow button . The terms move to the **Available Terms** list, and the responses move to the **Available Responses** list.

To exclude all terms or all responses:

Click the left double-arrow button . All terms move to the **Available Terms** list, and all responses move to the **Available Responses** list.

To select a method:

Select the appropriate **Method** radio button:

- MBLR
- RLR
- Both MBLR and RLR

When you select **RLR**, the BLR Results table includes only results for Effect Type **Main**. WebSDM/Empirica Study suppresses results for Effect Type **Interaction** and **Treatment+Interaction**.

To restore the default selections:

Click **Reset**. WebSDM/Empirica Study clears your selections and restores the default settings.

Viewing Prior SD Estimates

On the [BLR Results page](#), click **Prior SDs**. The **BLR Results Prior SDs** window appears.

This page provides some intermediate calculation results for the MBLR algorithm. The Bayesian model depends on certain prior standard deviations denoted (σ_A , σ_0 , σ_B , τ). [Only τ appears in the single-response model.] The final MBLR coefficient estimates are a weighted average of the coefficients estimated from assuming a range of particular values of the prior standard deviations, values that, according to the Bayesian model, are likely given the observed data. The multi-response model computes 33 sets of prior standard deviations across which to perform the averaging, while the single-response model computes just 9 values of τ . The top row of the table shows the prior standard deviations used for the RLR model, which are fixed in advance and not estimated from the data.

The remaining columns of this table show various intermediate results from the calculations relating to each particular set of PriorSDs. The bottom two rows of the table show means and standard deviation across all the PriorSDs, weighted according to the value of the PROB column.

The following table describes the columns present in the standard deviation data:

Column	Description
Sigma_A	Prior SD of coefficients of main effects of covariates, across responses.
Sigma_0	Prior SD of coefficients of main effects of Treatment, across responses.
Sigma_B	Prior SD of coefficients of Treatment-covariate interactions, across responses.
Tau	Prior SD of coefficients of Treatment-covariate interactions, across covariate categories.
PROB	Weight assigned to this combination of Prior SDs.
logLike	Log of the maximized joint posterior distribution of the coefficients, assuming that the Prior SDs are known to be the given values.
logDet2	0.5 times the log of the determinant of the approximate posterior covariance matrix of the coefficients, assuming that the Prior SDs are known to be the given value.
logBayesFactor	Sum of logLike plus logDet2. PROB is proportional to a slightly smoothed version of $\exp(\logBayesFactor)$.
Iters	Number of iterations of the Bayesian logistic regression calculations needed to maximize the posterior distribution of the coefficients for these specific Prior SDs. The final two rows of this column show, respectively, the sum of Iters for the 33 (or 9, if single-response) estimations shown immediately above, and the total number of estimation iterations required for a previous stage of the algorithm, involving a search for which sets of Prior SDs to use in the final calculations.
Converge	Value of convergence criterion achieved by the final iteration of the coefficient estimation algorithm. Should be less than 0.01 if the posterior distribution has been properly maximized.

Printing and downloading data

Select from the following:

- [Print](#)
- [Download](#)

Viewing Compressed Input Data

Compressed input data provides a summary of the number of subjects experiencing issues by predictor, subgroup, and issue. You can click the subject counts to access first-level drill-down options and work with the subject data.

To view compressed input data:

On the [BLR Results page](#), click **Compressed Input Data**. The **BLR Results Compressed Input Data** window appears.

Note: When you sort column data for a subgroup where the results are non-numeric, the sort may not perform as expected. Clicking the Ascending or Descending sort ear sorts the data in the order in which the subgroups were defined for the category, rather than in ascending or descending alphabetical order.

Printing and downloading data

Select from the following:

- [Print](#)
- [Download](#)

Selecting drill-down options

Click a hyperlinked count in an issue column, and then select from the following:

- [View Subjects](#)
- [Create Subject List](#)
- [Transfer to Subject List](#)
- [Download Subjects](#)
- [Download Subject Details](#)
- [Reports](#)

Note: The drill-down options that appear are dependent upon your user permissions.

Click **Close**. The **BLR Results Compressed Input Data** window closes.

Viewing Subgroup Statistics

The subgroup statistics table provides subject counts and odds ratios by issue and subgroup. Where the count is zero for Treatment Subjects or Comparator Subjects, cells are displayed with a pink background.

To view subgroup statistics:

On the [BLR Results page](#), click **Subgroup Statistics**. The **BLR Results Subgroup Statistics** window appears.

You can also view subgroup statistics when you run a BLR and the following warning appears:

Results from these analyses may depend on assumptions that cannot be verified with the current data.

For more information, see [BLR Run Error Messages](#).

The following table describes the columns available in the Subgroup Statistics table:

Column	Description
Issue	The response variable type and specific and issue. For example, PT: Anuria .
Subgroup	The predictor and subgroup. For example, Age: 51 to 65 .
Treatment Subjects	The total number of subjects in the treatment group.
Comparator Subjects	The total number of subjects in the comparator group.
Treatment Subjects with Issue	The total number of subjects in the treatment group who experienced the issue.
Comparator Subjects with Issue	The total number of subjects in the comparator group who experienced the issue.
OR (Shrunk)	Odds Ratio for the association of Issue versus Treatment based on the 2x2 table of 4 subject counts described above, with a small correction (shrinkage toward 1) to reduce variance in small samples.
OR (MBLR)	Odds Ratio for the same association based on the fitted MBLR model.
OR (RLR)	Odds Ratio for the same association based on the fitted RLR model.

Printing and downloading issues

Select from the following:

- [Print](#)
- [Download](#)

Click **Close**. The **BLR Results Subgroup Statistics** window closes.

Viewing a BLR Run Results Graph

A BLR run results graph shows confidence interval lines representing odds ratio estimates for the predictors, responses, and term groups included in BLR run results. The graph can help you better determine the association of treatment with issues, and the effect of the predictors on those issues.

The graph shows confidence interval lines for the following:

- **OR**—The odds ratio.
- **OR05**—A value such that there is approximately a 5% probability that the true odds ratio lies below it.
- **OR95**—A value such that there is approximately a 5% probability that the true odds ratio lies above it.

To view a BLR run results graph:

1. [View BLR run results](#).
2. Click **Switch to Graphical View**. The BLR Run Results graph appears.



Switching to Tabular View

To return to the BLR run results table, click **Switch to Tabular View**. The BLR run results table appears.

Configuring the graph

You can [configure BLR run results graphs](#) to customize the way that the graph is displayed.

Navigating results

If you configure the graph to page by method, response, or term group, the graph presents individual pages of statistics for those groups. You can then navigate through the pages by clicking the **Next**  and **Previous**  arrows available above the graph.

Filtering results

You can [filter BLR run results](#) to include or exclude results for specific terms, responses, and methods from the BLR run results graph.

Printing and downloading data

Select from the following:

- [Print](#)
- [Download](#)

Selecting subject drill-down options

Subject drill-down options are available when you point to a confidence interval line and click it. Select from the following:

- [View Statistics](#) (not available for response=PRIOR_MEAN)
- [View Subjects](#)
- [Create Subject List](#)
- [Transfer to Subject List](#)
- [Download Subjects](#)
- [Download Subject Details](#)
- [Reports](#)

Note: The drill-down options that appear are dependent upon your user permissions.

Configuring BLR Run Results Graphs

You can configure BLR run results graphs to customize the way that the graph is displayed. You can configure graphs for BLR runs that were created in WebSDM/Empirica Study release 3.1, and prior to release 3.1.

To configure BLR run results graphs for runs created in release 3.1:

1. On the [Bayesian Logistic Regression Results page](#), click **Switch to Graphical View**. The Odds Ratio Estimates graph appears.
2. Click **Configure**. The Configure Confidence Interval Graph dialog box opens.
3. Specify the information on this page using the descriptions in the table below.

To configure BLR run results graphs for runs created prior to release 3.1:

1. On the [Results for Bayesian Logistic Regression run on Potential Signal](#) page, click **Configure Graphs**. The Configure Confidence Interval Graph dialog box opens.
2. Specify the following:

Option	Description
Order by:	<p>Available only for BLR runs that were created prior to WebSDM/Empirica Study release 3.1. Indicates the order in which bars appear in the graph for each issue. The options are:</p> <ul style="list-style-type: none"> • Predictor—Covariate. • OR-05—A value such that there is approximately a 5% probability that the true Odds Ratio lies below it. • Odds Ratio—Odds ratio. • OR-95—A value such that there is approximately a 5% probability that the true Odds Ratio lies above it.
Color by:	<p>Indicates whether the graphs should include color, and, if so, indicates the values by which the graphs should be colored. The options are:</p> <ul style="list-style-type: none"> • OR-05—Uses color and draws the graph using the value of the lower bound of the confidence interval associated with the odds ratio. • Odds Ratio—Uses color and draws the graph using the odds ratio statistic. • None—Does not use color. This option is different from the Use gray-scale instead of color option.

Axis type Indicates the scale for the x-axis. The options are:

- **Linear**—The x-axis is linear.
- **Log**—The x-axis is logarithmic.

If you select Log, the confidence intervals for the predictor and response may appear more clearly. The default value is **Log**.

Page graphs by Available only for BLR runs that were created in WebSDM/Empirica Study release 3.1. Indicates whether the graph provides individual pages of statistics for each group or provides all group statistics on one page. The options are:

- **Method**—Provides one page of statistics per method.
- **Response**—Provides one page of statistics per response.
- **Term Group**—Provides one page of statistics per Effect Type and Predictor combination.
- **None**—Provides all statistics on one page.

The default value is **None**.

Group estimates on graph by Available only for BLR runs that were created in WebSDM/Empirica Study release 3.1. Indicates the sort order in which graph data is displayed. The options available are dependent on your selection in the **Page graphs by** field. The options are:

- When Page graphs by is **Method**:
 - Response, then Term Group
 - Term Group, then Response
 - When Page graphs by is **Response**:
 - Method, then Term Group
 - Term Group, then Method
 - When Page graphs by is **Term Group**:
 - Response, then Method
 - Method, then Response
 - When Page graphs by is **None**:
 - Method, then Response
 - Method, then Term Group
 - Response, then Method
-

- Response, then Term Group
- Term Group, then Method
- Term Group, then Response

Use gray-scale instead of color	<p>Indicates whether the graph appears using shades of gray or color.</p> <ul style="list-style-type: none"> • If selected—Uses gray-scale. • If deselected—Uses color.
Show vertical reference line	<p>Indicates whether the graph includes a vertical line at OR 1.0 for reference purposes.</p> <ul style="list-style-type: none"> • If selected—Shows a vertical reference line. • If deselected—Does not show a vertical reference line.
Key	<p>Indicates whether a color key appears below the graph to indicate the values that each graph element, such as a bar or region of the graph, represents.</p> <ul style="list-style-type: none"> • If selected—Includes a key. • If deselected—Does not include a key.
Links	<p>Indicates whether the following links and options appear:</p> <ul style="list-style-type: none"> • Tooltip that provides information and statistics for each response or term group. • Drilldown menu options when you click a bar. • Switch to Tabular View • Filter Results • Print • Download Data <p>Before copying the graph with copy and paste functions, you may want to clear this checkbox to ensure that unnecessary information is excluded.</p>

3. Click **OK**. The graph reappears using the options that you selected.

WebSDM/Empirica Study presents the graph using those options for subsequent displays of the same graph within a session.

Viewing Statistics for a Logistic Regression Results Graph

You can view statistics for a particular bar in a confidence interval graph of logistic regression results. The statistics are presented as a 2x2 table showing counts and percentages of subjects with and without the issue for treatment and comparator groups, corresponding to a particular predictor.

Below the 2x2 table, the following statistics are provided:

- Chi-statistic
- Fisher's Exact Test

The Chi statistic value is '??' when the total for the Treatment column or the Comparator column is **0**, indicating that the Chi statistic is not computable.

To view statistics for a logistic regression results graph:

1. When viewing a graph of BLR results, point to a bar, then click and select **View Statistics**.

This option is not available for all bars.
2. To display 2x2 tables for other bars in the graph, click **Show Other Levels**.
3. To hide the 2x2 tables for other bars in the graph, click **Hide Other Levels**.
4. If you click a count of subjects in a 2x2 table, you can [drill down](#) to a list of subjects included in the count.

Managing BLR Runs

Viewing BLR Runs

You can view BLR runs that you created for the current study or study pool on the Bayesian Logistic Regression Runs page.

Note: This topic describes viewing BLR runs created in WebSDM/Empirica Study release 3.1. For information on viewing BLR runs created prior to release 3.1 that are attached to potential signals, see [Working with BLR Runs Attached to a Potential Signal](#).

To view BLR runs:


1. Click the Screening tab. The Bayesian Logistic Regression Runs page or the Analysis Specifications page appears.
2. If the Analysis Specifications page appears, click **BLRs**. The **Bayesian Logistic Regression Runs** page appears.
3. The following table describes the columns available in the BLR Runs table:

Column	Description
ID	The BLR run ID. WebSDM/Empirica Study assigns an ID automatically when you save or run a BLR run.
Name	The BLR run name that you specified when you created the run.
Description	The description for the BLR run. If you did not specify a description when you created the BLR run, WebSDM/Empirica Study inserts the BLR run creation date and time in the Description field automatically.
Results?	Indicates whether results exist for the BLR run. Y —A user executed the BLR run and results exist. N —Indicates one of the following: <ul style="list-style-type: none"> The run has not yet been executed. or <ul style="list-style-type: none"> A user executed the run, but results could not be produced. This is most likely due to a BLR run error message.
Modified By	The username of the user who last modified the BLR run.
Created	The date on which the BLR run was first saved.
Modified	The date and time on which the user in the Modified By field modified the BLR run configurations.
Executed	The date and time on which the BLR run was last executed, regardless of whether the run successfully produced results.
Project	The project to which the BLR run is assigned.

Editing BLR Runs

You can edit a BLR run at any time. However, when you edit and then save changes to a BLR run, WebSDM/Empirica Study deletes all previously generated results for that run. You must then re-run it to obtain results.

To edit a BLR run:

- On the [Bayesian Logistic Regression Runs page](#), click the Action menu icon () next to a run, and then select **Edit**. The **Configure BLR** page appears.
- Edit the BLR run as necessary. For field information, see [Creating BLR Runs](#).
- [Save and optionally run the BLR run](#).

Results Will Be Deleted message


A message appears, indicating that all previously generated results for the BLR run will be deleted. Click **OK**. Your changes are saved.

Deleting BLR Runs

When you delete a BLR run, WebSDM/Empirica Study deletes the BLR and its results.

Note: This topic describes deleting BLR runs created in WebSDM/Empirica Study release 3.1. For information on deleting runs created prior to release 3.1 that are attached to potential signals, see [Working with BLR Runs Attached to a Potential Signal](#).


To delete a BLR run:

1. On the [Bayesian Logistic Regression Runs page](#), click the Action menu icon () next to a run, and then select **Delete**. A confirmation prompt appears.
2. Click **OK** to delete the BLR and its results, or click **Cancel** to return to the **Bayesian Logistic Regression Runs** page.

Copying BLR Runs

You can create a copy of a BLR run to duplicate its configuration settings. You can then edit the settings, and save the copy as a new BLR run.

To copy a BLR run:

1. On the [Bayesian Logistic Regression Runs page](#), click the Action menu icon () next to a run, and then select **Copy**. The Configure BLR page opens.
2. Specify a name for the BLR run in the **Name** field. By default, WebSDM/Empirica Study populates this field with "Copy of <existing BLR run name>".
3. Optionally edit configuration settings for the BLR run.
4. [Save and optionally run the BLR run](#).

Viewing BLR Run Configuration Options

To view configuration options for BLR runs created in release 3.1:


- On the [Bayesian Logistic Regression Runs page](#), click the Action menu icon () next to a BLR run, and then select **View Configuration Options**.

or

- On the [Bayesian Logistic Regression Results page](#), click the **View Configuration Options** link at the top.

The Configuration Options dialog box appears.

To view configuration options for BLR runs created prior to release 3.1:

On the [Potential Signal](#) page, click the Action menu icon () next to a BLR run, and then select **View Configuration Options**. The Configuration Options dialog box appears.

BLR Runs and Compound Issues

About Issue Clusters and Compound Issues

The results from an issue cluster mining run are a set of issues that tend to co-occur more than expected for subjects in the treatment group. The Bayesian adjustment to estimates and confidence intervals provided by WebSDM/Empirica Study provides good compensation for large numbers of hypothesis tests and the resulting problem of type I error inflation. However, simply including the set of individual issues that resulted from a cluster mining run does not test hypotheses specific to the cluster itself; such an approach would only test hypotheses about the individual items and their correspondence to the other factors in the regression (treatment and one or more predictors).

An issue cluster is found on the basis of greater than expected co-occurrence among its member issues for subjects in the treatment group. This implies that a subject with any two of the member issues "experienced" the cluster as far as cluster mining is concerned. To test logistic regression hypotheses about the relationship of the issue cluster to other predictors, a compound issue must be created. A *compound issue* is an issue that you have defined as occurring if a specified set of conditions are met; the conditions can be joined by the SQL logical operators AND and OR. By default, a compound issue identifies subjects who experienced any two of the issues in the cluster. However, you may want to specify more complex criteria. For example, you might specify that Syndrome X exists if at least three of the PTs Abnormal dreams, Anxiety, Neuralgia, or Sleep Disorder occurred and Depression did not occur. A compound issue is necessary to test hypotheses about the issue cluster itself; individual issues from the cluster may be included in the BLR run as well, but tests corresponding to such issues would be specific to these issues, not the cluster itself.

In contrast to clusters generated by an issue cluster mining run, compound issues are generated by the analyst and should be informed by medical knowledge and theory. Compound issues based on lax combinatorial criteria using issues collected only because of their relationship to treatment will produce statistically significant results of questionable validity.

Prior to WebSDM/Empirica Study release 3.1, you created compound issues for a specific Bayesian Logistic Regression (BLR) run attached to a potential signal. In release 3.1, compound issue functionality has been deprecated. However, when you upgrade WebSDM/Empirica Study from a previous release to 3.1, the upgrade process retains any existing compound issues. Existing compound issues remain attached to the BLR run for which you created them, and can be viewed only in BLR results. You cannot add, edit, or delete compound issues in release 3.1.

Working with BLR Runs Created Prior to WebSDM/Empirica Study 3.1


Working with BLR Runs Attached to a Potential Signal

BLR runs may be attached to a potential signal if they were created prior to release 3.1. For information on allowable actions for these runs, see [BLR Runs Created Prior to WebSDM/Empirica Study Release 3.1](#).

To work with BLR runs attached to a potential signal:

1. On the [Potential Signal page](#), scroll down to the **Bayesian Logistic Regression Runs** section. The following information is available for each BLR run:

Column	Description
ID	Automatically assigned identifier of the BLR run.
Description	Description of the BLR run. A default description is provided for the BLR run; when results are saved, the default description can be modified.
Results	Y if results were saved for the logistic regression run. Otherwise, N.
Modified By	Name of the user who submitted the BLR run.
Created	Date and time at which the BLR run was submitted.
Modified	Date and time at which the BLR run was last annotated.
# Annotations	Number of annotations for the BLR run. You can click the number to view or add annotations .

2. Click the Action menu icon  next to a BLR run, and then select one of the following:
 - To [view results of the BLR run](#), click **View Results**. This option is available only if the results of the run were saved.
 - To [view the configuration options](#) for the BLR run, click **View Configuration Options**.
 - To [view or add annotations](#) for the BLR run, click **View Annotations**, or click the number in the # Annotations column. If the column is not included in the table of supporting logistic regression runs, click **Columns** and include it.
 - To remove the BLR run from the potential signal, click **Delete**, and then click **Delete** at the prompt.
3. Click **Save** on the Potential Signal page to save any changes.

Viewing a Combined Graph

A combined graph for Bayesian Logistic Regression results shows, for each response, the Empirical Bayesian and unadjusted odds ratio and confidence interval for the treatment group versus the comparator group.

This topic is applicable only for BLR runs that were created prior to WebSDM/Empirica Study release 3.1. You cannot view a combined graph for BLR runs that were created in WebSDM/Empirica Study release 3.1.

Note: An additional odds ratio bar appears in the graph for the PRIOR_MEAN response for BLR runs created prior to release 3.1. You can ignore this bar and its data.

To view a combined graph:

1. On the [Results for Bayesian Logistic Regression Run on Potential Signal page](#), click **Combined Graph**.
2. If you point to a confidence interval bar, the following statistics for the issue pair appear: EBOR, EBOR05, EBOR95, OR, OR05, and OR95.
3. To download the graph data to a comma-separated file, click **Download Data for Graph(s) to Excel**. You must have Excel installed on your computer. See [Prerequisites and Usage Notes](#) for information about configuring Internet Explorer for downloading.
4. To print or copy the graph, see [Working with Graphs](#).

Analysis Specifications

About Screening Analysis

WebSDM/Empirica Study supports the detection and evaluation of possible safety issues in clinical trials. Screening analysis is the process of generating statistical scores for associations of a treatment group as compared to a comparator group and issues. The issue depends on the type of analysis. For example, for a MedDRA PT disproportionately analysis, the issue is a specific adverse event Preferred Term (PT); for a clinically significant lab analysis, the issue is a specific lab result.

The following list describes the screening analysis process:

1. Create a screening analysis specification by defining subgroups of subjects (based on such factors as sex, race, age, medical history, and concomitant medications) and including one or multiple analysis types (such as a MedDRA PT Analysis and a Clinically Significant Lab Analysis) in the analysis specification. You can also create custom analysis types.
2. Run the screening analysis specification, specifying the dosing category breakdowns and time frames for which you want to generate results. Screening runs are batch jobs and appear in the [Run History](#).
3. Review screening results, which contain statistical scores for issues.
4. Explore results by:
 - Viewing 2x2 tables.
 - Viewing dose group information, such as severity and recurrence.
 - Viewing graphs, including lab graphs, vitals graphs, and sector map graphs.

Interpretation of results

Because screening uses many independent statistical tests to highlight potential issues, it is expected that by chance alone there will be a number of positive screening results in situations where there is in fact no causal relationship between the treatment and a safety problem. This "multiple comparisons" problem is inherent in screening, and care must be taken not to consider the occurrence of positive individual screening results as statistically significant. Also, the simple analysis steps required for screening do not embody all of the statistical sophistication and consideration of alternative explanations and confounding factors that would be required in a targeted analysis. Expert human interpretation and thorough statistical and medical follow-up are required to evaluate any positive results from screening.

SDTM

The primary data sources used by an analysis type come from the clinical data for a study or study pool that has been loaded in to WebSDM/Empirica Study. Production studies are

represented using clinical data converted to the CDISC SDTM standard. The following clinical data domains are used in screening analysis:

Domain	Description
DM	Demographics
AE	Adverse Events
LB	Laboratory Tests
DS	Disposition
EG	ECG
MH	Medical History
CM	Concomitant Medications

About Analysis Specifications

An analysis specification determines:

- The screening analyses (for example, MedDRA PT or Clinically Significant Lab Values) to perform.
- The factors (such as age and sex) to control.

An analysis specification can include multiple analysis types, including:

- **Standard analyses**—Included with WebSDM/Empirica Study by default.
- **Custom analyses**—Optionally created by your organization based on one of the standard analysis types.

When multiple analysis types are included in an analysis specification, WebSDM/Empirica Study generates screening results for each analysis type independently of the other analysis types. You can filter the screening results to view only results for a particular type.

An analysis specification must:

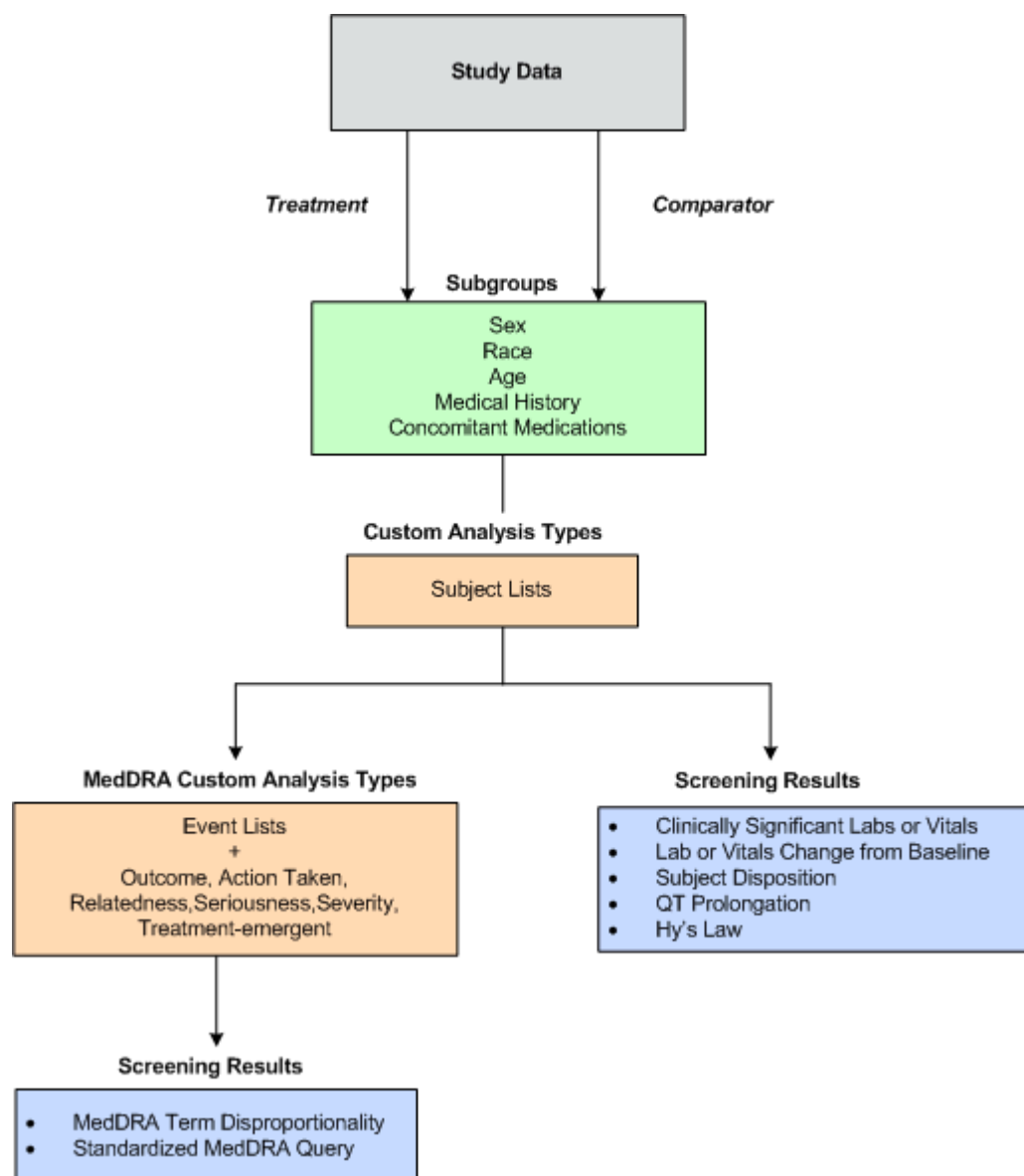
- Specify at least one standard or custom analysis type.
- Be run using at least one dosing category breakdown.

Optionally, you can specify control factors and custom analysis types.

The following must have occurred before you can perform certain activities:

- An [automatic screening](#) run.
- A run of an analysis specification named [\\$\\$\\$BASIC\\$\\$\\$SCREENING\\$\\$\\$](#).

Analysis specification functions



Related Topics

[Viewing Existing Analysis Specifications](#)

\$\$\$BASIC\$\$\$SCREENING\$\$\$ Analysis Specification

\$\$\$BASIC\$\$\$SCREENING\$\$\$ is an analysis specification. Like other analysis specifications, you can run the \$\$\$BASIC\$\$\$SCREENING\$\$\$ specification for any or all of the existing dosing category breakdowns and time frames. You must create the \$\$\$BASIC\$\$\$SCREENING\$\$\$ analysis specification before you can:

- View screening results on the Safety Review tab.
- View a sector map on the Adverse Events page of the Safety Review tab.
- Create BLR runs on the Safety Review tab.

An analysis specification includes the **Use maximum (instead of most recent) change from baseline** option. You can specify a similar option as a [safety review configuration option](#). If you set the safety review configuration option differently than the \$\$\$\$BASIC\$\$\$\$SCREENING\$\$\$ specification, a message appears, indicating the different settings.

Viewing Existing Analysis Specifications

The Analysis Specifications page lists existing [analysis specifications](#) for the currently selected study or study pool.

To view existing analysis specifications:

1. Go to the Screening tab. The Analysis Specifications page appears, listing all analysis specifications created for the study by any users.

Note: If you are on another page on the Screening tab, you can return to the Analysis Specifications page by clicking **Specifications**.

2. In the Project field, select the [project](#) for which you want to view analysis specifications. "--" indicates "All".

The Analysis Specifications page provides the following information about each analysis specification:

Column	Description
ID	Automatically assigned identifier of the analysis specification.
Name	Name of the analysis specification.
Description	Description of the analysis specification.
# Results	<p>One of the following values:</p> <ul style="list-style-type: none"> • Not Run – The analysis specification has never been run. • Number of screening results – Screening results exist and this number is a hyperlink that you can click to view them. • 0 – Either no results were generated because the data did not meet the criteria of any analysis types in the analysis specification, or all screening results were removed because of changes to study or pool properties. <p>This column is shaded in pink if some or all of the results of the analysis specification are marked as requiring review. When all such results are reviewed, the pink shading will be removed. See Marking a Result as Reviewed.</p>
Created	Date and time at which the analysis specification was created.
Modified	Date and time at which the analysis specification was created or last modified. This field is updated when Save or Save & Run is clicked for the analysis specification.
Executed	Date and time at which the last run of the analysis specification was

completed.

If the analysis specification has been saved but not submitted, or if it has been submitted but has not yet finished running, this column is empty.

If the results for certain analysis types (EGQT, LBHY, LBCS, VSCS, LBBL or VSBL) were generated prior to Empirica Study 3.0, they are outdated because the way in which these analysis types compute results has changed. In this case, this column is shaded in pink and a message tells you that some results use outdated selection criteria and that results will be updated the next time you run the specification.

Warnings	<p>The text "Warnings" as a hyperlink if warnings were generated because the source data failed certain diagnostic checks. Click the link to view the warnings.</p> <p>Blank if any of the following is true:</p> <ul style="list-style-type: none"> • The analysis specification has never been run. • The analysis specification has been run but no warnings were generated for any of the included analysis types. • The analysis specification has been run but results produced by analysis types with warnings were removed.
	<p>The warnings are generated each time the analysis specification is run. The only other time they change is when changes to study or pool properties cause screening results to be removed; in this case, the associated warnings are removed along with the results.</p>
Rerun to Update	<p>This column is intended to alert you that existing screening results for the specification will differ if you re-run the specification.</p> <p>This column shows "Y" if any of the following is true:</p> <ul style="list-style-type: none"> • A dosing category breakdown or time frame has been added to the study or study pool since the last time the analysis specification was run. • A dosing category breakdown or time frame for the study or study pool has been modified since the last time the analysis specification was run. • The analysis specification was last run without the option to generate results for the absence of a time frame, and all time frames for the study or study pool have been deleted since then. • When last run, the analysis specification included the analysis type EGQT, and ECG test identifiers for the study or study pool have been added, modified, or deleted since then. • When last run, the analysis specification included the analysis types LBHY or LBCS (using built-in criteria), and lab test identifiers for the study or study pool have been added, modified, or deleted since then. • When last run, the analysis specification included the analysis type

VSCS (using built-in criteria) and vital sign identifiers for the study or study pool have been added, modified, or deleted since then.

- When last run, the analysis specification included a customized MedDRA-based analysis type that uses the treatment-emergent flag variable and the treatment-emergent flag variable has been modified or deleted since then.
- When last run, the analysis specification included the analysis type LBCS (using the lab flag variable), and the lab flag variable has been modified or deleted since then.
- When last run, the analysis specification included the analysis type VSCS (using the vital sign flag variable), and the vital sign flag variable has been modified or deleted since then.
- When last run, the analysis specification included a custom analysis type that referenced an event list for the study, study pool, or application, and that event list has been modified or deleted since then.
- When last run, the analysis specification included a custom analysis type that referenced a subject list, and that subject list has been modified since then.
- When last run, the analysis specification included a custom analysis type, and that custom analysis type has been modified or deleted since then.


Note that this column does not indicate "Y" when:

- An analysis type is no longer available in the specification.
- Dosing category breakdowns or time frames have been deleted.

Age Cutpoints	Age categories defined in the analysis specification.
Annotations Table	For system internal purposes; Oracle recommends that you exclude this column from the table display.
Application	Name of the application that was selected at the time the analysis specification was created.
Modified By	Name of the user who created or last modified the analysis specification. This field is updated when Save or Save & Run is clicked for the analysis specification. Note: If you save an analysis specification and another user runs it, your name continues to be associated with the specification.
Project	Name of the project with which the analysis specification is associated.
Sex Categories	Sex categories defined in the analysis specification.

Signal Table	For WebSDM/Empirica Study internal purposes; Oracle recommends that you exclude this column from the table display.
Study	Name of the study that was selected at the time the analysis specification was created.

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

3. To create a new analysis specification, click **Create Analysis Specification**. The [Edit Analysis Specification page](#) appears.
4. To create a copy of the analysis specification that you most recently created or modified, click **Last Analysis Specification**. The Edit Analysis Specification page appears, showing the content of that last analysis specification. By default, the name is prefaced with "Copy of".
5. To create or manage custom analysis types, click **Manage Custom Screening Analysis Types**. You must have the *Manage Custom Analysis Types* permission.
6. To [view the results](#) of the last run of an analysis specification, click the hyperlinked value in the "# Results" column.
7. If the Execution Status column shows **Warnings**, click the link to [view the warnings](#) generated by the analysis specification because the source data failed certain diagnostic checks.
8. If you click  for an analysis specification, you can do the following:
 - To [edit an analysis specification](#), click **Edit**. The Edit Analysis Specification page appears.
 - To copy an analysis specification, click **Copy**. The Edit Analysis Specification page appears. Name the analysis specification, edit it as necessary, and save it. (By default, the name is prefaced with "Copy of".) This is the only way to rename an analysis specification.

If you copy an analysis specification that uses a custom analysis type, the custom analysis type is also copied if its visibility is limited to the analysis specification. Otherwise, the custom analysis type is not copied.

- To run the analysis specification, click **Run** and [specify run options](#). If no dosing category breakdowns have been defined for the study or study pool, you cannot run the specification.
- To delete an analysis specification and its results, click **Delete**. When you delete an analysis specification, information about all runs of that analysis specification is deleted automatically from the Run History.

If you re-run or delete an analysis specification that generated results when it was last run, a message informs you that results will be deleted if you continue. If you continue, *all* results for the analysis specification are deleted.


You cannot edit, re-run, or delete an analysis specification if either of the following is true:

- There is an existing run of the analysis specification either currently re-running or in the queue to be run, and it has not been cancelled.
- Screening results for the analysis specification are attached to a potential signal or used by a BLR run.

Creating/Editing an Analysis Specification

The Edit Analysis Specification page appears when you are creating a new [analysis specification](#) or editing an existing one. If you edit an analysis specification for which there are screening results, all of those results will be deleted when you save your changes.

To create or edit an analysis specification:

1. On the Analysis Specifications page, click **Create Analysis Specification**.
Alternatively, click the Action menu icon () for an analysis specification and then click **Edit**. The **Edit Analysis Specification** page appears.

You can also click **Last Analysis Specification** to create a copy of the analysis specification that you most recently created or modified.
2. Enter a name for the screening analysis specification. Each analysis specification for a study must have a unique name. You cannot change the name of an analysis specification once you have saved it.
3. Optionally enter a description of the analysis specification. Oracle recommends that you provide an informative description so that other users can easily identify the analysis specification.
4. Optionally assign the analysis specification to a [project](#).
 - To assign the analysis specification to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
 - To create a new project and assign the analysis specification to it, click **Add to a new project named** and enter a project name.
5. For a new analysis specification, the default categories for Sex, Race, Age, Medical History, and Concomitant Medications are determined by the default category breakdowns (if any), which are defined as properties of the study or study pool. You can change the categories as needed in the analysis specification.

To create or modify categories, click the corresponding hyperlink (such as **Sex Categories**). Then create or modify categories as described in [Defining a Category Breakdown for Text Values](#) or [Defining a Category Breakdown for Numeric Values](#).

Note: If a type of category is not available to select, you can hover the cursor over the category to display a tooltip explaining the reason for the unavailability.

6. Specify the following:

Option	Description
Use all combinations of categories	<p>Generates results for all possible combinations of categories.</p> <ul style="list-style-type: none"> • If selected—Results are generated for all combinations of categories. • If deselected—Results are generated for one category at a time. See Category Breakdowns and Time Frames.
Use days on drug as denominator for MedDRA Analysis with no time frame	<p>Applies to the following analysis types: MedDRA PT, HLT, HLG, or SOC; Standardized MedDRA Query; Custom MedDRA Query.</p> <ul style="list-style-type: none"> • If selected—Use days on drug as the denominator in the odds ratio computation. Applies to only results that are generated for the absence of a time frame. Results that are generated for a time frame ignore this option. • If deselected—Uses number of subjects as the denominator in the odds ratio computation.
Use maximum (instead of most recent) change from baseline	<p>Affects the Lab Change from Baseline Analysis and Vitals Change from Baseline Analysis.</p> <ul style="list-style-type: none"> • If selected—The change from baseline is computed using the post-baseline result (within the time frame) whose value represents the greatest (positive or negative) change from the baseline result. • If deselected—The change from baseline is computed using the most recent, non-null, post-baseline result within the time frame. If there are multiple results with the same most recent date and time, the result (within the time frame) whose value represents the greatest (positive or negative) change from the baseline result is used.
Base CS Lab Analysis on flag variable (will use built-in criteria if unchecked)	<p>Applies to a Clinically Significant Lab Analysis.</p> <p>Available if any lab test identifiers referenced by built-in criteria have been defined or a flag variable for lab clinical significance has been defined. If only one of these methods of determining clinical significance has been set up, this check box is selected or deselected automatically and cannot be changed.</p> <p>If neither method has been defined, the check box is deselected and unavailable. If you point to an unavailable check box for this option, an explanatory message appears as a tooltip.</p>
Base CS Vital Sign Analysis on flag	<p>Applies to a Clinically Significant Vitals Analysis.</p> <p>Available if any vital sign identifiers referenced by built-in</p>

variable (will use built-in criteria if unchecked) [criteria](#) have been defined or a [flag variable](#) for vital sign clinical significance has been defined. If only one of these methods of determining clinical significance has been set up, this check box is selected or deselected automatically and cannot be changed.

If neither method has been defined, the check box is deselected and unavailable. If you point to an unavailable check box for this option, an explanatory message appears as a tooltip.

7. Optionally click **Create Custom Analysis Type** to create an analysis type for selected events, subjects, or event criteria (such as seriousness or outcome).
8. In the list of Analysis Types, check at least one [analysis type](#) to include. Below the list, you can click **Select All** to check all available analysis types, click **Select All Standard** to select all available [standard analysis types](#), or click **Clear All** to clear all analysis types.

If the analysis specification was previously run, you cannot deselect the check box for an analysis type that generated a result that is attached to an existing potential signal.

Analysis types are available only if appropriate variables are present and, in some cases, only if test identifiers and flag variables have been set. If an analysis type is unavailable, you can point to its check box to display the reason for the unavailability. For more information, see [Variables Used in Screening Analysis](#).

The following information is provided about each analysis type:

Column	Description
Included	Select each analysis type that you want to perform. If you are editing the analysis specification, analysis types that were included in the last run and are still available are checked by default.
Name	Name of the analysis type.
Description	Description of the analysis type. The names of standard (non-customized) analysis types delivered with WebSDM/Empirica Study are preceded by "Default".
Configuration Options	Description of which event list, subject list, and event criteria were selected for the analysis type. This description is generated automatically.
Warnings	If this column shows Warnings , the analysis type was included in the last run of the analysis specification and one or more warning messages occurred. Click Warnings to view the warnings .
# Results	Number of screening results for the analysis type. The number is a hyperlink that you can click to view results for the analysis type. If any results for the analysis type require review, this column has a pink background for the analysis type. (In the results, the value in the ISSUE column will appear in red font for any result requiring review). This column shows 0 if either no results were generated because the data did not meet the criteria of any analysis types in the analysis specification, or screening results were removed because of changes

to study or pool properties.

9. Do one of the following:
 - To save the analysis specification without running it, click **Save**. The specification is saved and is listed on the Analysis Specifications page with the # Findings column showing "Not Run".
 - To run an analysis specification and save any changes you have made, click **Save & Run** and then [specify run options](#).

If you have edited an analysis specification for which there are screening results, a message informs you that all of those screening results will be deleted if you continue.

10. You may want to [view screening analysis warnings](#) for the analysis types that were included in the analysis specifications.

Defining a Category Breakdown for Text Values (analysis specification)

This topic describes defining a category breakdown for text values from within an analysis specification.

Sex, Race, and Study Group

1. To create a new category, click **New**, enter the category name, and click **OK**.
2. To rename the selected category, click **Rename**, enter a new category name, and click **OK**.
3. To delete the selected category, select the category, click **Delete**, and click **OK**.
4. To add or modify values in the selected category, select one or more values in the **All Values** list. See [Selecting Entries from a List](#) for information about searching or selecting values. Note that null values appear in the list as "(NULL)" and can be included in a category. In the Selected Values list, you can use the up and down arrows to order the values.
5. Click **OK**.

Medical History and Concomitant Medications

For medical history and concomitant medications, you can define only one category. A second category is created automatically to include subjects not having values in the first category. For example, suppose that you define the **Pneumonia** category to include **Pneumonia, bact**, **Pneumonia, viral**, and **Pneumonia, other**. A **No Pneumonia** category is created automatically to include all subjects who do *not* have a history of **Pneumonia, bact**, **Pneumonia, viral**, or **Pneumonia, other**.

1. To rename the default **Key CMs** or **Key MHs** category, click **Rename**, enter a new category name, and click **OK**.

- In the **All Values** list, select one or more values to include in the category. See [Selecting Entries from a List](#) for information about searching or selecting values.
- Click **OK**.

Defining a Category Breakdown for Numeric Values (analysis specification)

This topic describes defining a category breakdown for numeric values from within an analysis specification.

To define a category breakdown for numeric values:

- Click **View Column Statistics** to [view statistics](#) about the distribution of values in the study data.
- In the first value field (after **VALUE <=**), enter the maximum value for the first category. Also, enter a category name.
- In the next row, in the Value field, enter the maximum value for the second category. (The cutpoint values must be in ascending order.) Also enter a category name.
- Continue defining categories until you are ready to define the last category.
- For the last category, enter only a category name. (Do not enter a value.) This is the category for all values above the previous cutpoint. For example:

	Value	Category
	VALUE <= 18	Up to 18
18	< VALUE <= 50	19 to 50
50	< VALUE	Over 50

- To add more categories than you can currently fit on the page, select **Add additional cutpoints on saving**.
- Optionally, enter a minimum and/or maximum value. This option is useful to exclude extreme values from categories.

Note: Values equal to the minimum or maximum value are included. Only values less than the minimum value or greater than the maximum value are excluded.

- Click **OK**.

Specifying Run Options for an Analysis Specification

- Select the time frames and dosing category breakdowns for which you want to generate screening results. You must select at least one time frame (or **-None-**) and at least one dosing category breakdown.

By default, all time frames (not including **None**) and all dosing category breakdowns are selected for the initial run of an analysis specification. If there are no time frames for the study or pool, **None** is checked automatically and cannot be cleared.

You can hover the cursor over the name of a time frame or dosing category breakdown to display its definition as a tooltip.

Note: In a re-run, the time frames and dosing category breakdowns used for the previous run are checked by default. However, all existing screening results are removed and regenerated. For example, if you selected Time Frame 1 in the initial run, and you re-run the specification with the addition of Time Frame 2, results for Time Frame 1 are regenerated.

2. Specify a name for the run. By default, the run name is the same as the analysis specification name. The name of the run does not need to be unique, although Oracle recommends that you use a unique name. Each run will also have an automatically assigned ID that is unique.
3. Specify a description of the run. Oracle recommends that you provide an informative description so that you can easily identify the run.
4. To perform the run now, click **Run as soon as possible**.
5. To schedule the run for a future date or time, click **Do not run until** and then supply a date and time. To supply a date, enter it in mm/dd/yyyy format or click **<icon>** to display a calendar from which you can select a date. To supply a time, enter it in hh:mm:ss am/pm format.
6. To receive e-mail notification when the run is complete (as successful or failed), select **E-mail me when complete** and specify one or more email addresses (separated by commas) to receive notification. By default, the address (or addresses) associated with your username appears. If you want to change this default address, see your user administrator.
7. Click **Next**. The [Confirm Run Parameters page](#) appears.

Submitting a Run

1. On the **Confirm Run Parameters** page that appears when you load a study, load a study pool, or run an analysis specification, review the parameters to make sure that they are correct.
2. To change any parameters, click **Back** until you are on the appropriate page and modify the run. Then click **Next** until you are on the **Confirm Run Parameters** page again.
3. If you are satisfied with the parameters, click **Submit**. A message tells you that the run (or runs) are in the process of being submitted. After a few seconds, you can click **Continue** or click any available tab or command.

If a run fails (as indicated on the [Run History page](#)), you can view log files to help diagnose the error. To do so, [view jobs for the run](#) and then [view job detail](#). In the Output Files section, click load_log.txt and error_log.txt.

Customizing Screening Analysis Types

About Custom Analysis Types

A custom analysis type is a customized version of a standard analysis type. In some cases, you can specify only a subject list as part of the custom criteria. For customized MedDRA-based analysis types, you can also specify criteria of the events to be included in the analysis. For example, you might want to specify that only serious events are included in a MedDRA PT Analysis. For a customized Subject Disposition Analysis, you can also specify epochs to be included in the analysis.

When you create a custom analysis type, it has a specified visibility to a particular analysis specification, study, or application, or to all applications. It becomes available as another entry in the list of analysis types within an analysis specification. For example, if you create a Serious MedDRA PT analysis type, it is available to include in an analysis specification.

Depending on your permissions, you can create and manage custom analysis types of any visibility. Some users can create custom analysis types only for the analysis specifications that they create.

Additionally, you can create a Customized MedDRA Query (CMQ), which is similar to a Standardized MedDRA Query. A CMQ looks for events that you have specified, rather than events that the MSSO defined as SMQs. For example, you could create a CMQ for PTs that involve cerebral events. There is always one result per event list referenced by a CMQ. If you want to generate statistics for individual PTs representing cerebral events, you need to create a customized MedDRA PT Analysis.

Counts in screening results

For results of a custom analysis type, counts are qualified by the criteria of the custom analysis type as follows:

- A subject list or list of epochs that is referred to by a custom analysis type acts as a filter on the whole analysis (that is, the counts A, B, C, D, N_T, N_C, and N for a [disproportionality analysis](#) and U_T, U_C, S_T, S_C, V_T, V_C, N_T, N_C, and N for a [change-from-baseline analysis](#)).
- For a MedDRA-based custom analysis type, other criteria, such as event seriousness or an event list, qualify events. They affect the counts A and B, but not other counts.

Example

Suppose that a customized MedDRA PT Analysis specifies a fatal outcome, an event list that contains Cardiac Disorder, and a subject list. The AND operator connects the outcome criteria and the event list. In the results table, counts will be as follows:

- A = Count of treatment subjects in the subject list who have Cardiac Disorder with a fatal outcome.
- B = Count of comparator subjects in the subject list who have Cardiac Disorder with a fatal outcome.

- C = Count of treatment subjects in the subject list who have do not have Cardiac Disorder with a fatal outcome.
- D = Count of comparator subjects in the subject list who have do not have Cardiac Disorder with a fatal outcome.
- N_T = Total count of treatment subjects in the subject list.
- N_C = Total count of comparator subjects in the subject list.
- N = Total count of subjects in the subject list.

If, in this example, you edit the logic of the custom analysis type so that the OR operator connects the outcome criteria and the event list, counts will be as follows:

- A = Count of treatment subjects in the subject list who have Cardiac Disorder or a fatal outcome.
- B = Count of comparator subjects in the subject list who have Cardiac Disorder or a fatal outcome.
- C = Count of treatment subjects in the subject list who have neither Cardiac Disorder nor a fatal outcome.
- D = Count of comparator subjects in the subject list who have neither Cardiac Disorder nor a fatal outcome.
- N_T = Total count of treatment subjects in the subject list.
- N_C = Total count of comparator subjects in the subject list.
- N = Total count of subjects in the subject list.

Related Topics

[Viewing Existing Custom Analysis Types](#)

Viewing Existing Custom Analysis Types

If you have the appropriate [user permission](#), you can view and manage custom analysis types.

To view existing custom analysis types:

1. Select an application and study, and go to the Screening tab.
2. On the [Analysis Specifications page](#), click **Manage Custom Analysis Types**. The Custom Analysis Types page lists custom analysis types (created by all users) for which the visibility is set to global, the current application, or the currently selected study.

The Custom Analysis Types page provides a table of the following information about each analysis type:

Column	Description
ID	Automatically assigned identifier of the custom analysis type.
Name	Name of the custom analysis type.
Description	Description of the custom analysis type.
Flag Criteria	One of the following values: <ul style="list-style-type: none"> Always – All of the results generated by the analysis type require review. Never – None of the results generated by the analysis type require review. Score – Results generated by the analysis type require review if the result score is less than the score shown in the Flag Threshold column. IncidenceRate – Results generated by the analysis type require review if the difference between the incidence rate of the issue for the treatment drug (A/N_T) and the incidence rate of the issue for the comparator drug (B/N_C) is more than a specified percentage (shown in the Flag Threshold column).
Flag Threshold	If the Flag Criteria column shows "Score", this column shows a score. If the Flag Criteria column shows "IncidenceRate", this column shows a percentage.
Base Type	One of the following values: <ul style="list-style-type: none"> PT– MedDRA PT Disproportionality HLT– MedDRA HLT Disproportionality HLGT– MedDRA HLGT Disproportionality SOC– MedDRA SOC Disproportionality SMQ– Standardized MedDRA Query CMQ– Customized MedDRA Query DSPD – Premature Study Discontinuation Disproportionality EGQT– Tests for QT(c) Interval Prolongation and related Cardiac Conditions LBBL– Laboratory Change from Baseline LBCS– Clinically Significant Lab Results LBHY– Hy's Law VSCS – Clinically Significant Vitals Analysis

- VSBL– Vitals Change from Baseline Analysis


Configured Options	Description of which epoch, event list, subject list, and/or event qualifiers were specified by the custom analysis type. This description is generated automatically.
Application	Name of the application that was selected (on the Select tab) when the custom analysis type was created.
Study	Name of the study that was selected (on the Select tab) when the custom analysis type was created. When a study is deleted, analysis types with certain values for visibility are retained, but this column becomes null.
Analysis Specification	Name of the analysis specification, if any, that was being created or edited when the custom analysis type was created.
Modified By	Name of the user who created or last modified the custom analysis type.
Created	Date and time at which the custom analysis type was created.
Modified	Date and time at which the custom analysis type was created or last modified.
Visibility	One of the following values, showing whether the custom analysis type is available for selection: <ul style="list-style-type: none"> • Hidden – Not available for selection in any analysis specifications for any application or study. • Analysis Specification – Available for selection during editing of the screening analysis specification shown in the Analysis Specification column. • Study/Study Pool – Available for selection in screening analysis specifications created or modified when the currently selected study (or study pool) is the one shown in the Study column. • Application – Available for selection in screening analysis specifications created or modified when the currently selected application is the one shown in the Application column. • Global – Available for selection in any screening analysis specification for any application and any study.
Status	One of the following values: <ul style="list-style-type: none"> • Included – The analysis type has been used in at least one screening analysis specification that has not been run. • Results generated – The analysis type has been used in at least one analysis specification that has been run, and results have been generated for the analysis type. • Results requiring review – The analysis type has been used in

at least one screening analysis specification that has been run, and review is required for at least some of the results for the analysis type.

- Results reviewed – The analysis type has been used in at least one screening analysis specification that has been run, review was required for screening results of the analysis type, and all such results have been marked as reviewed.
- Results attached – The analysis type has been used in at least one screening analysis specification that has been run, and results for the analysis type have been attached to a potential signal.

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

Note: The additional columns CREATED_FOR_SCREEN_SPEC_ID, CREATED_FOR_STUDY_ID, and CREATED_FOR_SUBMISSION_ID provide information used internally by WebSDM/Empirica Study and are excluded from the page by default.

3. To see other custom analysis types, you can click **Columns and Rows** and change the [SQL Where clause](#). If you remove the SQL Where clause, all custom analysis types are listed, including those for which the visibility is a particular analysis specification or "hidden". If you modify or remove the Where clause, the change remains in effect for your current session.
4. To create a new custom analysis type, click **Create Custom Analysis Type**. The Create Custom Analysis Type page appears and you [select a base analysis type](#).
5. If you click  for a custom analysis type specification, you can do the following:
 - To view a list of analysis specifications that include the custom analysis type, click **View Dependencies**.
 - To [modify the configuration options](#) of a custom analysis type, click **Configure analysis options**. If you configure analysis options for an analysis type for which results have been generated, the results will be lost.
 - To [edit the attributes](#) (the description, review requirements, or visibility) of a custom analysis type, click **Edit analysis attributes**.
 - To copy a custom analysis type, click **Copy**. You can then change the configuration options and attributes as needed.
 - To delete a custom analysis type, click **Delete**.

You can configure, edit, or delete custom analysis types for which any of the following is true:

- The Study column shows the currently selected study.

- The Study column is empty, the Application column shows the currently selected application, and the visibility is Application or Global.
- The Application and Study columns are empty and the visibility is Global.

When you configure, edit, or delete a custom analysis type, the following messages may occur:

- If screening results for the custom analysis type are attached to potential signals, a message informs you that you cannot perform the action.
- If there are existing results for the custom analysis type, a message informs you that the results will be deleted. Note that only the results for the affected analysis types will be removed.

Creating a Custom Analysis Type

The first step in creating a [custom analysis type](#) is to select the standard analysis type on which the custom analysis type will be based. The custom analysis type behaves the same way as the standard analysis type except that it includes only subjects or events that meet the criteria of the custom analysis type.

The Custom MedDRA Query Disproportionality Analysis is a special type of analysis that is custom-only. There is no standard version of it, although it is similar to the Standardized MedDRA Query Analysis in its behavior. The Standardized MedDRA Query Analysis uses MSSO's definition of Standardized MedDRA Queries, each of which is associated with a group of PTs. In a Custom MedDRA Query Analysis, you define your own Customized MedDRA Queries by specifying one or more event lists. The screening results include one row for each event list.

When creating or editing an analysis specification, you can create a custom analysis type that is available for use within that analysis specification. If you have the *Manage Custom Analysis Types* permission, you can make the custom analysis type available for the current study, the current application, or globally, and you can also create a custom analysis type outside of an analysis specification.

To create a custom analysis type from within an analysis specification:

1. On the [Edit Analysis Specification page](#), click **Create Custom Analysis Type**. The Create Custom Analysis Type page appears.
2. Select the analysis type to use as a basis for the new analysis type.
3. Click **Next**. The Configure <analysis-type> page appears and you can [configure the custom analysis type](#).


To create a custom analysis type outside of an analysis specification:

1. On the [Analysis Specifications page](#), click **Manage Custom Analysis Types**.
2. On the [Custom Analysis Types page](#), click **Create Custom Analysis Type**. The Create Custom Analysis Type page appears.
3. Select the analysis type to use as a basis for the new analysis type.

4. Click **Next**. The Configure <analysis-type> page appears and you can [configure the custom analysis type](#).
5. If you do not immediately see the new custom analysis type listed on the Custom Analysis Types page, you may need to click **Columns and Rows** and modify or remove the [SQL Where clause](#) that is in effect.

Configuring a Custom Analysis Type

Use these procedures to configure a custom analysis type that is not based on MedDRA.

1. On the [Create Custom Analysis Type page](#), click **Next**.
2. Alternatively, on the [Custom Analysis Types page](#), click the Action menu icon () and then click **Configure analysis options**. The Configure Custom Analysis Type page appears.


For an existing custom analysis type that you configure, the following messages may appear:

- If there are screening results for the custom analysis type and they are attached to potential signals, a message informs you that the event list cannot be edited and lists the pertinent potential signals.
 - If there are screening results for the custom analysis type, a message informs you that the results will be deleted. Note that only the results for the affected analysis types will be removed.
3. For a Subject Disposition Analysis, you can select values of the EPOCH variable (if any) in the DS domain. Only records in the specified epochs will be included in the analysis.
 4. In the Subject List field, highlight one subject list to restrict the analysis to only subject IDs that are in the subject list. Available subject lists are those that you created or that have been *published to your login group*.

Note: Even if you refer to a subject list that is private (you created it and have not published it), the custom analysis type may be available to other users, depending on its visibility.

5. If you are creating a custom analysis type, click **Next** and you can [set visibility and review criteria](#).
6. If you are editing an existing custom analysis type, click **OK**. The new analysis type appears in the list of custom analysis types. It is available in analysis specifications (during creation or editing) according to its specified visibility.

To configure a MedDRA-based custom analysis type:

1. On the [Create Custom Analysis Type page](#), click **Next**.
2. Alternatively, on the [Custom Analysis Types page](#), click the Action menu icon () and then click **Configure analysis options**. The Configure Custom Analysis Type page appears.

3. In the following fields, optionally highlight one or more values for the following:

- Outcome
- Action Taken
- Relatedness
- Seriousness
- Severity

Note: You can click **Clear** or **Clear All** to clear selections from these fields.

4. Optionally check the **Serious** check boxes that indicate the seriousness of the event.

5. In the Event Lists field, optionally highlight one event list. (For a Customized MedDRA Query Analysis, you *must* select one or more event lists, which can be at different levels.) The event lists available to select are those that are for the version of MedDRA associated with the currently selected study, or those that were based on the study data.

An [event list](#) is a list of PTs defined at the level of the system, application, or study (or study pool). The available lists include:

- All global event lists.
- Application-level event lists for the current application.
- Study-level event lists for the current study (or study pool event lists for the current study pool).

6. In the Subject List field, optionally highlight one subject list to restrict the analysis to only subject IDs that are in the subject list. You can refer to any published or unpublished subject lists for the study.

Note: Even if you refer to a subject list that is private (you created it and have not published it), the custom analysis type may be available to other users, depending on its visibility.

7. Optionally check **Treatment Emergent Events**. Only events that are flagged as treatment-emergent (that is, the [derived variable](#) AE.AETE_ is **Y**) will be included in the analysis.

8. If you specify multiple criteria, the default logic appears near the bottom of the page. You can click **Edit** to [edit the logic](#).

9. If you are creating a custom analysis type, click **Next** and you can [set visibility and review criteria](#).

If you are editing an existing custom analysis type, click **OK**. The new analysis type appears in the list of custom analysis types. It is available in analysis specifications (during creation or editing) according to its specified visibility.

Variables used by custom analysis types

The variables for **Outcome**, **Action Taken**, and **Severity** (AE.AEOUT, AE.AEACN, and AE.AESEV) are associated (respectively) with non-extensible codelists OUT, ACN, and AESEV. It is recommended that you not add values to these codelists, but use instead the SDTM standard codelist for each variable. You can also select any values (excluding nulls) that exist in the data but not in the codelist.

For **Relatedness**, available values are from the customer-provided codelist associated with the AE.AEREL variable. If there is no such codelist, system-defined values are used. You can also select for values (excluding nulls) that exist in the data but are not in the codelist (or not among the system-defined values).

For **Seriousness**, system-defined values are available.

The **Serious** check boxes are based on the following variables in the AE domain: AESCAN, AESCONG, AESDISAB, AESDTH, AESHOSP, AESLIFE, AESOD, and AESMIE.

Editing Custom Analysis Type Logic

When you are configuring a custom analysis type and you select more than one configuration option, the default logic connecting the options appears. You can click **Edit** if you want to modify the logic.

On the Configure page, each option for configuring a custom analysis type is numbered from 1 to 9, with the Serious checkboxes as 6.1 through 6.8. The default logic connects the Serious checkboxes 6.1 through 6.8 by OR and connects other options by AND.

For example, suppose that you select the outcome **RECOVERED/RESOLVED**, the severity **SEVERE**, the Serious checkboxes for **Life-threatening** and **Results in or Prolongs Hospitalization**, the event list **DME**, and the subject list **Males**. By default, the logic is:

1 and 5 and (6.5 or 6.6) and 7

Note that when you include Option 8 (a subject list) in the custom analysis type, results for the custom analysis type will include only subjects in the list. You cannot reference Option 8 in the logic.


To edit custom analysis type logic:

1. On the [Configure page](#), click **Edit**. The **Edit Logic** page appears.
2. Specify any changes to the logic that appears in the Logic field. Note that:
 - The only supported operators are AND and OR. Although other operators are available for query-based subject list construction, they are not available for custom analysis type logic.
 - You can use parentheses to adjust the effects of a series of operators. For example, you could change the above example to: 1 or (5 and 6.5) or (6.6 and 7)
3. Click **OK**. The [Identify Custom Analysis Type page](#) appears.

Setting Visibility and Review Criteria for a Custom Analysis Type

1. On the [Configure page](#), click **Next**.

Or

On the [Custom Analysis Types page](#), click the Action menu icon () and then click **Edit analysis attributes**. The Identify Custom Analysis Type page appears.

When you edit an existing custom analysis type, the following messages may appear:

- If there are existing screening results for the custom analysis type and they are attached to potential signals, a message informs you that the event list cannot be edited and lists the pertinent potential signals.
 - If there are existing results for the custom analysis type, a message informs you that the results will be deleted. (The message also tells you if the results required review.) Note that only the results for the affected analysis types will be removed.
2. Enter a name for the custom analysis type. The name must differ from that of any other custom analysis type that could be used in the same analysis specification. For example, if the type's visibility is study, its name must differ from that of any type for which visibility is global, the currently selected application, or the currently selected study; however the name could be the same as that of a type whose visibility is a different study.
 3. Optionally enter a description of the analysis type. Oracle recommends that you provide an informative description so that other users can easily identify the analysis type.
 4. Specify a review requirement. The options are:
 - **Never**—None of the results generated by the analysis type will require review.
 - **When Score is less than __** —Results generated by the analysis type will require review if the score is less than the specified number.
 - **When Treatment incidence rate is __ % greater than Comparator incidence rate**—Results generated by the analysis type will require review if the difference between the incidence rate of the issue for the treatment drug (A/N_T) and the incidence rate of the issue for the comparator drug (B/N_C) is more than the specified percentage. This option is not available for a Change from Baseline analysis type.
 - **Always**—All of the results generated by the analysis type will require review.

When a [result requires review](#), its REVIEW_STATUS column initially shows **Needs Review**.

Note: If the custom analysis type refers to an event list that is set up to require review, results for PTs in the event list (or for HLTs, HLGs, SOC, SMQs, or CMQs

containing PTs in the event list) are flagged for review, regardless of the review criteria specified for the custom analysis type.

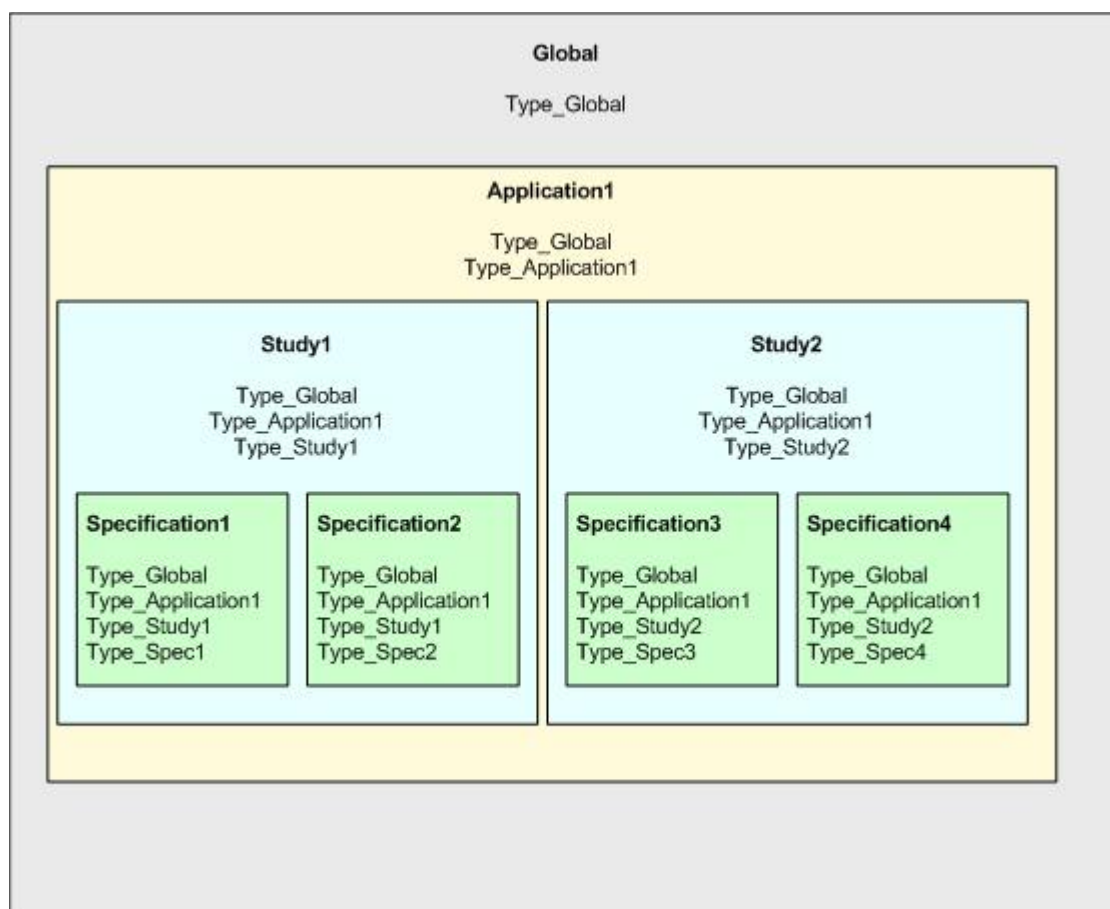
5. If you are creating the custom analysis type from within an analysis specification, the visibility must be Current Analysis Specification, which means that the custom analysis type will be available to only the current analysis specification.

If you are creating or copying a custom analysis type from outside a particular analysis specification (from the Custom Analysis Types page, which requires special permissions), specify a visibility. The options are:


- **Analysis Specification**—The custom analysis type will be available for selection in only the named analysis specification, which is the last one you edited (if any).
 - **Study/Study Pool**—The custom analysis type will be available for selection in analysis specifications for the currently selected study or study pool.
 - **Application**—The custom analysis type will be available for selection in analysis specifications for the currently selected application. Available only if the custom analysis type does not refer to a subject list.
 - **Global**—The custom analysis type will be available for selection in any analysis specification for any study or study pool and any application. Available only if the custom analysis type does not refer to a subject list.
 - **Hidden**—The custom analysis type will not be available for selection in any analysis specification. Specify this visibility if the custom analysis type is not yet ready for use.
6. Click **Save**. The new analysis type appears in the list of custom analysis types. It is available in analysis specifications (during creation or editing) according to its specified visibility.

Visibility

The following illustration shows which custom analysis types are available in analysis specifications, depending on the type's visibility:



Viewing Dependencies of a Custom Analysis Type

On the [Custom Analysis Types page](#), click  for the custom analysis type and then click **View Dependencies**. A list of analysis specifications that use the custom analysis type appears.

The Dependencies page shows the following information:

Column	Description
Application	Name of the application associated with the analysis specification that includes the custom analysis type.
Study/Study Pool	Name of the study or study pool associated with the analysis specification that includes the custom analysis type.
Analysis Specification	Name of the analysis specification that includes the custom analysis type.
Status	One of the following values: <ul style="list-style-type: none"> Type is included in Analysis Specification – The custom analysis type is included in an existing analysis specification, but no results were generated for the type. This could be because the analysis specification has not been run, or because there were no

results for the analysis type (for example, if the analysis type looks for treatment-emergent events and there are no such events).

- **Results are generated** – Results were generated for the analysis type.
- **Generated results require review** – Results requiring review were generated for the analysis type; the results may or may not have been marked as reviewed.
- **Results are attached to Potential Signals** – Results were generated for the analysis type and are attached to potential signals.

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

Issue Clusters

About Cluster Mining

An issue cluster is a set of three or more issues that tend to co-occur more for subjects in the treatment group than for subjects in the comparator group. Issue cluster mining uses standard cluster analysis techniques along with a distance metric based on a comparison of Empirical Bayesian adjusted odds ratio statistics for pairs of issues and the treatment drug.

When a cluster mining run has completed, you can view issue cluster results as heatmaps or confidence interval graphs and save relevant issue clusters. When you have saved an issue cluster, you can add it to a potential signal, causing the individual issues in the cluster to be added to the potential signal as supporting results.

Generally, cluster analysis is an exploratory technique. The clusters obtained differ depending on the algorithm and configuration options selected, and there are no clearly objective criteria for determining which solution is most informative. It is up to the analyst to determine if a cluster solution "makes sense".

When you perform cluster mining, you select from an issue list that is generated by [automatic screening](#). All available standard analysis types are included in cluster mining, with the exception of the following:

- Subject Disposition Analysis
- Lab Change from Baseline Analysis
- Vitals Change from Baseline Analysis

You can [view a summary](#) of these issues when creating a cluster mining run.

When you initiate issue cluster mining, WebSDM/Empirica Study determines whether an automatic screening run has been performed for the study. If an automatic screening run has not been performed, or if [test identifiers](#) or [flag variables](#) have been modified since the last automatic screening run was performed (and thus new or revised analysis types are available), you are prompted to submit an automatic screening run before you can perform issue cluster mining.

As with the execution of screening analysis specifications, some analysis types do not generate results during automatic screening if you have not defined test identifiers and flag variables. For more information, see [About Analysis Types](#).

Note: [Time frames](#) are not used in issue cluster mining runs.

Cluster Mining Computations

Issue cluster mining (or "cluster mining") is based on a statistic called the Syndromic Odds Ratio (SOR). To compute the SOR statistic, WebSDM/Empirica Study computes Empirical Bayesian adjusted proportions, which are then used to produce Empirical Bayesian odds ratios (EBOR statistics) for each issue and then for each issue pair. Then the SOR for each

issue pair is computed. The computations use Empirical Bayesian techniques to adjust statistics and improve confidence in results.

To perform cluster mining, WebSDM/Empirica Study does the following for the treatment group and comparator group, as determined by the dosing category breakdown selected for the cluster mining run:

1. For each issue, shrinks the observed probability toward the expected probability based on Empirical Bayes estimates.
2. For each issue, computes an odds ratio based on the shrunken probability from Step 1. This statistic is the EBOR (Empirical Bayesian Odds Ratio) for the individual issue.
3. For each issue pair, shrinks the observed probability to the expected probability (which is based on the shrunken probability estimates for the individual issues).
4. For each issue pair, computes an odds ratio based on the shrunken probability from Step 3. This statistic is the EBOR (Empirical Bayesian Odds Ratio) for the issue pair.
5. For each issue pair, computes a syndromic odds ratio (SOR) as follows: issue pair odds ratio / <highest of 1 or the odds ratios of the two issues that constitute the pair or the odds ratio based on expected probabilities for the pair>

As with any statistical technique, the reliability of results depends to a great extent on the number of subjects observed. The more subjects sampled, the more reliable the results. Although the confidence interval for SOR is not defined, the EBOR values for each issue pair do have confidence intervals that should be considered when determining the relevance of a cluster as a potential safety signal.

Empirical Bayesian adjusted proportions

The EBOR values are based on proportions adjusted using an Empirical Bayes method.

- There are issues 1 through k for subjects in the treatment group or comparator group.
- There are n total subjects, n_t subjects are in the treatment group, and $(n - n_t)$ subjects in the comparator group.
- There are N_k total subjects with issue k, N_{kt} subjects with issue k in the treatment group, and $(N_k - N_{kt})$ subjects with issue k in the comparator group.
- P_k is the probability of issue k occurring in a subject in the treatment group [= N_{kt} / n_t].
- Q_k is the probability of issue k occurring in a subject in the comparator group [= $(N_k - N_{kt}) / (n - n_t)$].

An Empirical Bayes method is used to shrink both P_k and Q_k toward N_k/n . The "Beta-binomial" Bayesian model is used:

- $EBP_k = (N_{kt} + \beta_{nt}/n) / (N_k + \beta_{nt}/N_k)$ [estimate β by Empirical Bayesian method]
- $EBQ_k = (N_k - N_{kt} + \beta(n - n_t)/n) / (n - N_k + \beta(n - n_t)/N_k)$ [same β for all k]

The same process is used to generate adjusted probabilities for co-occurring issues j and k , except that instead of shrinking P_{jk} and Q_{jk} towards N_{jk}/n , P_{jk} is shrunk towards $EBP_j EBP_k$ and Q_{jk} is shrunk towards $EBQ_j EBQ_k$.

- N_{jk} is the number of subjects with both issue j and issue k .
- N_{jkt} subjects with the issue pair are in the treatment group, and $(N_{jk} - N_{jkt})$ with the issue pair are in the comparator group.
- P_{jk} is the probability of both issue j and issue k occurring in a subject in the treatment group.
- Q_{jk} is the probability of both issue j and issue k in a subject in the comparator group.
- If issues are independent, $P_{jk} = P_j P_k$ and $Q_{jk} = Q_j Q_k$, so the EB versions of the probabilities are used.
- There is a beta-binomial model that shrinks N_{jkt}/n_t toward $EBP_j EBP_k$ and another beta-binomial model to shrink $(N_{jk} - N_{jkt})/(n - n_t)$ toward $EBQ_j EBQ_k$. The first model computes the observed co-occurrence of the issue pair shrunk to the expected co-occurrence, which is based on Empirical Bayes estimates for the individual issues. The second model computes the observed absence of co-occurrence of the issue pair shrunk to the expected absence of co-occurrence, which is based on Empirical Bayes estimates for the individual issues.

The odds ratio (EBOR) for each issue and issue pair is computed as follows:

- $EBOR_j = EBP_j(1 - EBQ_j) / EBQ_j(1 - EBP_j)$
- $EBOR_k = EBP_k(1 - EBQ_k) / EBQ_k(1 - EBP_k)$
- $EBOR_{ind} = EBP_j EBP_k(1 - EBQ_j EBQ_k) / EBQ_j EBQ_k(1 - EBP_j EBP_k)$
- $EBOR_{jk} = EBP_{jk}(1 - EBQ_{jk}) / EBQ_{jk}(1 - EBP_{jk})$

The Syndromic Odds Ratio (SOR) indicates whether issue pairs occur in the treatment group more strongly than can be explained by the occurrences of single issues. The SOR is computed as follows:

$$SOR_{jk} = EBOR_{jk} / \max(1, EBOR_j, EBOR_k, EBOR_{ind})$$

The SOR is an indicator of treatment-related issue co-occurrence above that expected from any treatment-related increase for the individual issues. The higher the SOR value, the stronger the treatment-related correspondence. Thus, the reciprocal of SOR indicates a sort of "distance". The reciprocal of SOR is used as a distance metric in an issue cluster mining run.

Cluster algorithm

The cluster algorithm will do the following:

- Determine the distance between each issue pair (j and k). The distance between issue pairs is computed as: $d_{jk} = 1/SOR_{jk}$

- Find the shortest distance between issue pairs and join that pair together in a cluster.
- Iterate this process until all issues are in a single cluster or until the shortest distance between issue pairs is larger than a specified stopping distance. (See Step 7 in the example below).

For example, suppose that issues are:

Issue	Distance from A	Distance from B	Distance from C	Distance from D
A	0	1	2	6
B	1	0	3	5
C	2	3	0	4
D	6	5	4	0

The cluster mining algorithm does the following:

1. Determines that the shortest distance between issues is between A and B.
2. Creates a cluster of: AB
3. Determines the distance between AB and C. In determining this distance, looks at the distances between:
 - A and C
 - B and C
4. If the Average method has been specified, uses the average of the two distances (in this case, 1.5). If the Complete method has been specified, uses the farther of the two distances (in this case, 2).
5. Determines the distance between AB and D. In determining this distance, WebSDM/Empirica Study looks at the distances between:
 - A and D
 - B and D

If the Average method has been specified, use the average of the two distances (in this case, 5.5). If the Complete method has been specified, uses the farther of the two distances (in this case, 6).
6. Determines the shorter of the following distances (assuming that the Average method has been specified):
 - Distance between AB and C is 1.5
 - Distance between AB and D is 5.5
7. Of issue C and issue D, add the issue with the shortest distance from AB to the cluster. The cluster is now ABC, and the overall SOR for the cluster is 1/1.5. (If the Complete method had been specified, the overall SOR for the cluster would be 1/2.)

The Overall Syndromic Odds Ratio (SOR) statistic for an issue cluster is a rough indication of whether issue pairs in the cluster occur together more frequently than can be explained by the occurrences of individual issues in the cluster. Its specific meaning depends on the clustering method used. For the Complete clustering method, the overall SOR is the reciprocal of the largest distance between any two issues in the new cluster. For the Average method, the overall SOR is the reciprocal of the average distance between the set of issue pairs composed of each issue from the existing cluster paired with the last issue added to the cluster.

8. If there were more issues, clustering would continue until the stopping distance between issues was reached. The stopping distance between issues is measured as 1/minimum SOR specified for the cluster mining run.

Creating an Issue Cluster Mining Run

1. On the Issue Clusters page, click **Create Issue Cluster Mining Run**.

Note: An up-to-date [issue list](#) must exist before you can perform cluster mining. If the issue list needs to be created or updated, a message informs you and provides the opportunity to create or update the issue list. If you choose to update the issue list when WebSDM/Empirica Study prompts you and you do not have the Load and Check Studies permission, an error occurs. You must contact your system administrator to refresh the issue list.

2. Optionally click **View Summary of All Issues** to [view a summary](#) of all issues from results generated by the [automatic screening](#) run. The summary may help you in deciding how to select issues in Step 4.
3. Select the issue types from which you want to select on the next page (the [Configure Issue Cluster Mining Run page](#)). You can check the following types of issues, although some of the types may not have been generated by the automatic screening. The options are:
 - **Adverse Events**—Click the MedDRA level (PT, HLT, HLGT, OR SOC) for the analysis. Issues from a MedDRA PT, HLT, HLGT, or SOC Analysis, depending on your choice, will be available for selection.
 - **Standardized MedDRA Query**—Issues from a [Standardized MedDRA Query Analysis](#), Narrow or Broad, will be available for selection.
 - **QT Prolongation**—Issues from a [QT Interval Prolongation Analysis](#) will be available for selection.
 - **Hy's Law**—Issues from a [Hy's Law Analysis](#) will be available for selection.
 - **Clinically Significant Labs**—Issues from a [Clinically Significant Lab Analysis](#) will be available for selection. You can choose issues for which clinical significance is based on a flag variable or on built-in criteria. For more information, see [Clinical Significance Criteria](#).
 - **Clinically Significant Vitals**—Issues from a [Clinically Significant Vitals Analysis](#) will be available for selection. You can choose issues for which clinical significance is

based on a flag variable or on built-in criteria. For more information, see [Clinical Significance Criteria](#).

If you want to reset the selected screening analysis types to the default (all types), click **Set to Default Types**.

4. Specify which issues (from the automatic screening run) will be selected by default for inclusion in the cluster mining run. The issues will be selected by default on the next page (the Configure Issue Cluster Mining Run page), and you can modify the selection. The options are:
 - **Custom Select**—No issues are selected by default.
 - **___ most frequently occurring issues**—The specified number of the most frequently occurring issues will be selected by default.
 - **Issues occurring in at least ___% of subjects**—Issues that occur for at least the specified percentage of subjects will be selected by default.
 - **Issues occurring in at least ___ subjects**—Issues that occur for at least the specified number (2 or above) of subjects will be selected by default.
5. Click **Next**. The [Configure Issue Cluster Mining Run page](#) appears.

Viewing an Issue Summary

The Issue Summary page lists issues that were generated by automatic screening and occurred for at least one subject. Automatic screening runs all standard analysis types except the Subject Disposition Analysis, the Lab Change from Baseline Analysis, and the Vitals Change from Baseline Analysis. For information about automatic screening runs, see [About Cluster Mining](#).

Note: Only issues that occurred in at least two subjects will be available to include in an issue cluster mining run.

To view an issue summary:

On the [Create Issue Cluster Mining Run page](#), click **View Summary of All Issues**. The Issue Summary page appears.

The Issue Summary page provides information about each issue. The "# Subjects" column shows the count of subjects who experienced the issue.

The following table shows possible values in the Issue Type and Issue Name columns:

Issue Type	Issue Name
PT	Specific Preferred Term.
HLT	Specific High Level Term.
HLGT	Specific High Level Group Term.
SOC	Specific System Organ Class.

SMQ	Specific SMQ, with "narrow" or "broad" added to name.
EGQT	<p>One of the following:</p> <ul style="list-style-type: none"> • <correction-type> QTc Interval > 450 • <correction-type> QTc Interval > 480 • <correction-type> QTc Interval > 500 • <correction-type> QTc Increase from Baseline >= 30 • <correction-type> QTc Increase from Baseline >= 60 <p>where <correction-type> is Reported, Bazett's, FDA Neuro, or Fredericia's.</p>
LBBL	Name of the laboratory test.
<p>Depending on option for determining clinical significance:</p> <p>LBCS (Built-in criteria) or LBCS (Flag variable)</p>	<p>"Clinically Significant" followed by the lab test name.</p> <p>Depending on how a study is set up, results using one or both methods of determining clinical significance may be available. For more information, see Derived Variables.</p>
LBHY	<p>One of the following values:</p> <ul style="list-style-type: none"> • Alt 3x Upper Limit • Alt 3x Upper Limit, TBili 1.5x Upper Limit • Alt 3x Upper Limit, TBili 1.5x Upper Limit, AlkPhos Normal • Alt 5x Upper Limit • Alt 10x Upper Limit • Alt 20x Upper Limit
VSB�	Name of the vital sign, followed by the value of the VSPOS variable (Vital signs position of subject), if any, in parentheses.
<p>Depending on option for determining clinical significance:</p> <p>VSCS (Built-in criteria) or VSCS (Flag variable)</p>	<p>"Clinically Significant" followed by the vital sign name, followed by the value of the VSPOS variable (Vital signs position of subject), if any, in parentheses.</p> <p>Depending on how a study is set up, results using one or both methods of determining clinical significance may be available. For more information, see Derived Variables.</p>

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

Configuring an Issue Cluster Mining Run

On the Configure Issue Cluster Mining Run page, you specify options to be used for the run and the issues to be included in the run. If you click **View Configuration Options** for an issue cluster on the Issue Clusters page, a read-only version of the Configure Issue Cluster Mining Run page appears.

To configure a cluster mining run:

1. On the [Create Issue Cluster Mining Run page](#), click **Next**. The **Configure Issue Cluster Mining Run** page appears.
2. Select a dosing category breakdown. If there is a default dosing category breakdown for the study, it is selected automatically. You can also do one of the following:
 - Click **Browse** to [select](#) from a descriptive list of dosing category breakdowns

Or

 - Click **Add** to [define a new dosing category breakdown](#).

The dosing category breakdown determines the treatment and comparator groups for the cluster mining run.
3. Select a clustering method. The options are:
 - **Average**—Issues are added into a cluster on the basis of the average distance of an issue from all other issues in the cluster.
 - **Complete**—Issues are added into a cluster on the basis of the furthest distance from an issue to any other issue in the cluster. This method produces smaller and tighter clusters.
4. Optionally check **Issue Cluster Allowed to Share Issues** to allow an issue to appear in multiple issue clusters for the run. See below for an example of sharing issues.
5. Specify the minimum Syndromic Odds Ratio (SOR) for issue clusters. The specified value will have a strong influence on clustering. This value must be at least 1. The value of 1.5 is provided as a good default starting point, but exploration of values above and below 1.5 is recommended. Consider the following:
 - Entering a high SOR value will result in smaller clusters of more highly correlated issues; however, if the value is too large, no clusters will be generated.
 - Entering a low SOR value will generate larger clusters of more loosely related issues; however, if the value is too small, the generated clusters will be more noise than signal. Clusters of more than 10 issues may be difficult to interpret due to the complex patterns of interrelatedness that emerge. A cluster of more than 15 issues cannot be attached to a potential signal.

For information on how SOR is computed, see [Cluster Mining Computations](#).

6. Specify the minimum number (3 or higher) of issues that must be included in an issue cluster.
7. Select issues to be included in cluster mining. Depending on your specifications on the [Create Issue Cluster Mining Run page](#), there may be issues selected by default. You can modify the default selection as needed. You must select at least as many issues as the number you specified as the minimum number of issues to include. You cannot select more than 300 issues. Keep in mind that issue clustering is a resource-intensive procedure.

The issues that are available for selection are the issues generated by [automatic screening](#). They are listed by descending order of the number of subject occurrences. Only issues that occurred in at least two subjects are available to include in cluster mining.

8. Click **Run**. The [Results for Cluster Mining Run page](#) appears.

Note: If every subject has one or more of the selected issues, if no subject has one or more of the selected issues, or if all subjects are in the treatment group or all subjects are in the comparator group, a message informs you that cluster mining cannot be performed.

Example: Sharing issues

Suppose that a cluster analysis is performed with the following options:

- The minimum SOR is 1.5.
- The minimum number of issues that must be included in the issue cluster is 3.
- Clusters do not share issues.

The following clusters are generated:

A: Issue2, Issue4, Issue6, Issue8

B: Issue3, Issue5, Issue7

There are also three two-issue clusters that are suppressed because they have fewer than the specified minimum number of issues (3):

C: Issue1, Issue11

D: Issue9, Issue19

E: Issue10, Issue12

The cluster mining run is run again with the same issues and options, except that issue clusters are allowed to share issues. Issue 8 from cluster A is close enough to be in cluster C, but also issue 19 from one of the suppressed two-issue clusters is close enough to be in cluster B. So the following clusters are generated:

A: Issue2, Issue4, Issue6, Issue8

B: Issue3, Issue5, Issue7, Issue19

C: Issue1, Issue11, Issue8

These two-issue clusters remain suppressed:

D: Issue9, Issue19

E: Issue10, Issue12

Issue19 appears in Cluster B even though it does not appear in either the previously existing clusters or the new cluster, since it comes from a two-issue cluster that remains suppressed.

Defining a Dosing Category Breakdown (issue cluster mining)

This topic describes creating a dosing category breakdown during the creation of an issue cluster mining run.

To define a dosing category breakdown:

1. In the **Categories** list, click a category name (Treatment or Comparator).
2. In the **All Values** list, select one or more values to include in the selected category. See [Selecting Entries from a List](#) for information on searching or selecting values. Note that null values appear in the list as "(NULL)" and can be included in a category.
3. In the **Selected Values** list, you can use the up and down arrows to order the values. You may want to order dosages in increasing order for the best presentation in the **by dose group** tables for screening results.
4. Optionally select **Use as default**. When you select this option, the breakdown becomes the default and this option is deselected automatically from another breakdown (if any) for which the option was selected.
5. Click **Next** and [identify the category breakdown](#).

Viewing Issue Cluster Mining Results

A cluster mining run generates as many issue clusters as possible based on how you configured the run. In the results, the issue clusters are numbered sequentially starting with

1. For example:

Cluster #1 (Overall Syndromic Odds Ratio=1.56):

PT: Chronic obstructive airways disease
PT: Blood alkaline phosphatase increased

Cluster #2 (Overall Syndromic Odds Ratio=1.52):

PT: Dyspnoea
PT: Epistaxis
PT: Anaemia
PT: Hepatic enzyme increased

The Overall Syndromic Odds Ratio is displayed for each issue cluster. If you used "Average" as the clustering method, the overall Syndromic Odds Ratio (SOR) is the average SOR among issues in the cluster. If you used "Complete" as the clustering method, the Overall Syndromic Odds Ratio is the smallest (complete) SOR among issues in the cluster.

To view cluster mining results:

1. On the Configure Issue Cluster Mining Run page, click **Run**. When the run completes, the results are displayed on the Results for Issue Cluster Mining Run page.
2. To view statistics for an issue, click the issue name.
3. To configure heatmaps and confidence interval graphs available for these cluster mining results, click **Configure Heatmaps and Graphs**.
4. To [view a confidence interval graph](#) for *all* clusters generated by the cluster mining run, click **View as Graph**.
5. To [save an issue cluster](#), click **Save Issue Cluster** for the cluster. The issue cluster is saved and appears on the [Issue Clusters page](#), so that it can be attached to a potential signal.
6. To [view a heatmap](#) for a particular cluster, click **View Heatmap** next to the cluster.
7. To [view a confidence interval graph](#) for a particular cluster, click **View Graph** next to the cluster.

Saving an Issue Cluster

1. Enter a name for the issue cluster. Each issue cluster for a study must have a unique name. You cannot change the name of an issue cluster once you have saved it.
2. Optionally enter a description of the issue cluster. Oracle recommends that you provide an informative description.
3. Optionally assign the issue cluster to a [project](#).
 - To assign the issue cluster to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
 - To create a new project and assign the issue cluster to it, click **Add to a new project named** and enter a project name.
4. Click **Save**. The issue cluster is saved and appears on the [Issue Clusters page](#), so that it can be attached to a potential signal.

Reviewing Issue Clusters

Viewing Existing Issue Clusters

To view existing issue clusters:

1. Go to the Screening tab and click **Issue Clusters**. The Issue Clusters page appears, listing existing issue clusters created by all users for the currently selected study or study pool.

2. When an [automatic screening run](#) is performed, it generates warnings if the study data fails certain diagnostic checks. If warnings were generated the last time the automatic screening was run, the following message appears:

Warnings were generated when the issue list was last updated. Click [here](#) to view them.

To [view the warnings](#), click **here** in the message. The warnings also include information about analysis types that could not be run at all because certain variables were not present or test identifiers or flag variables were not set; for more information, see [About Analysis Types](#).


Note: If the whole automatic screening run failed, a message informs you and enables you to view the errors that occurred.

3. Optionally select the [project](#) for which you want to view issue clusters. "--" indicates "All".

The Issue Clusters page provides the following information about each issue cluster:

Column	Description
ID	Automatically assigned identifier of the issue cluster.
Name	Name of the issue cluster.
Description	Description of the issue cluster.
Application	Name of the application.
Study	Name of the study.
Created	Name of the user who created the issue cluster.
Modified	Date and time at which the issue cluster was last modified.
Modified By	Name of the user who created or last modified the issue cluster.
Project	Name of the project with which the issue cluster is associated.

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

4. To [create an issue cluster mining run](#) that identifies issue clusters, click **Create Issue Cluster Mining Run**.
5. If you click  for an issue cluster, you can do the following:
- To change the description or project associated with an issue cluster, click **Edit**.
 - To view the [configuration options](#) used for the issue cluster mining run that produced the issue cluster, click **View Configuration Options**.
 - To [view statistics](#) for issues in the cluster, click **View Statistics**.
 - To [view a heatmap](#) for issues in the cluster, click **View Heatmap**.
 - To [view a confidence interval graph](#) for issues in the cluster, click **View Graph**.

- To [view potential signals](#) to which an issue cluster is attached, click **View Potential Signals with this Issue Cluster Attached**.
- To [attach the cluster to a potential signal](#), click **Attach to a Potential Signal**. You cannot attach an issue cluster with more than 15 issues to a potential signal.
- To delete an issue cluster, click **Delete**. You cannot delete an issue cluster that is attached to a potential signal, or that has any component issues attached to a potential signal. (If the issue cluster had been attached to a potential signal and then detached, its component issues would still be attached to the potential signal unless you explicitly detached them.)

Viewing Statistics for an Issue Cluster


You can view the following statistics for an issue cluster:

- The counts and percentages of subjects who experienced each issue in the cluster
- The actual and expected counts of subjects who experienced each possible number of issues in the cluster. For example, if the cluster includes three issues, a subject may have experienced no issues (N=0), one issue (N=1), two issues (N=2), or three issues (N=3).

Note: The expected counts are not computed if there are more than 15 issues in the issue cluster.

The statistics are provided for subjects in the treatment group, subjects in the comparator group, and overall subjects. The treatment and comparator groups are based on the dosing category breakdown used in the cluster mining run that generated the issue cluster.

To view statistics for an issue cluster:

On the [Issue Clusters page](#), click  and then click **View Statistics**. The Issue Cluster Statistics page appears.

In the tables of counts and percentages, each issue is identified as follows:

Issue Type	Issue Name
One of the following types of issues:	One of the following issues, depending on the issue type:
<ul style="list-style-type: none"> • PT – MedDRA PT Disproportionality • HLT – MedDRA HLT Disproportionality • HLGT – MedDRA HLGT Disproportionality • SOC – MedDRA SOC Disproportionality 	<ul style="list-style-type: none"> • PT – Specific Preferred Term. • HLT – Specific High Level Term. • HLGT – Specific High Level Group Term. • SOC – Specific System Organ Class. • Specific SMQ, with "narrow" or "broad" added to name.


- LBCS – Clinically Significant Lab Results (post-baseline)
- VSCS – Clinically Significant Vitals Results (post-baseline)
- LBHY – Laboratory Test Results that meet Hy's Law
- EGQT – Tests for QT(c) Interval Prolongation and related Cardiac Conditions
- SMQ – Standardized MedDRA Query (SMQ) Disproportionality
- LBCS – "Clinically Significant" followed by the lab test name.
- VSCS – "Clinically Significant" followed by the vital sign name, followed by the value of the VSPOS variable (Vital signs position of subject), if any, in parentheses.
- LBHY – One of the following:
 - Alt 3x Upper Limit
 - Alt 3x Upper Limit, TBili 1.5x Upper Limit
 - Alt 3x Upper Limit, TBili 1.5x Upper Limit, AlkPhos Normal
 - Alt 5x Upper Limit
 - Alt 10x Upper Limit
 - Alt 20x Upper Limit
- EGQT – One of the following:
 - <correction-type> QTc Interval > 450
 - <correction-type> QTc Interval > 480
 - <correction-type> QTc Interval > 500
 - <correction-type> QTc Increase from Baseline >= 30
 - <correction-type> QTc Increase from Baseline >= 60

where <correction-type> is Reported, Bazett's, FDA Neuro, or Fredericia's.

Viewing a Heatmap

A heatmap is a graph that provides a concise view of information about the counts and Syndromic Odds Ratio (SOR) of each pair of issues in the cluster. Occurrences of issues are represented as two diagonals of diamonds, with each diamond representing a combination of two issues.

To view a heatmap:

1. On the [Issue Clusters page](#), click the Action menu icon () and then click **View Heatmap**. You can also click **View Heatmap** for an issue cluster on the [Results for Issue Cluster Mining Run page](#). The Heatmap page appears.
2. Click **Configure** to [configure heatmaps and confidence interval graphs](#).
3. If you point to an issue, the diamonds associated with the issue are highlighted.
4. If you point to a diamond, the two issues represented by the diamond are highlighted. Additionally, the following statistics for the issue pair are displayed: count (N) of subjects, EBOR, OR05, OR95, and SOR. For more information, see [Cluster Mining Computations](#).
5. If you click a diamond, you can then [view statistics](#) or [drill down](#) to subjects with the issue pair.

Note: Do not click a diamond until the whole heatmap, including the key, has appeared.


6. To print or copy the graph, see [Working with Graphs](#).
7. To save the issue cluster (if you are viewing it from the Results for Issue Cluster Mining Run page), click **Save Issue Cluster**. The issue cluster is saved and appears on the [Issue Clusters page](#), so that it can be attached to a potential signal.

Viewing a Confidence Interval Graph (for issue cluster)

A confidence interval graph for an issue cluster shows the 5% and 95% confidence limits for the Empirical Bayesian odds ratio (EBOR) statistic for each pair of issues in the cluster. OR05 is a value such that there is approximately a 5% probability that the true Odds Ratio lies below it. OR95 is a value such that there is approximately a 5% probability that the true Odds Ratio lies above it. The interval from OR05 to OR95 can be considered to be the 90% confidence interval.

The graph title shows the overall SOR statistic for all issue pairs in the cluster. You can also choose to order issue pairs or color confidence interval lines by the SOR statistic for issue pairs.

To view a confidence interval graph:

1. On the [Issue Clusters page](#), click the Action menu icon () and then click **View Graph** to view a confidence interval graph for all issue clusters on the page. You can also click **View Graph** for an issue cluster on the [Results for Issue Cluster Mining Run page](#). The Confidence Interval Graph page appears.
2. Click **Configure** to [configure heatmaps and confidence interval graphs](#).
3. When you point to a confidence interval line, the following statistics are displayed: count (N) of subjects, EBOR, OR05, and OR95. For an issue pair ("Co-occurrence of both issues"), the SOR is also displayed. For more information, see [Cluster Mining Computations](#).

4. If you click a confidence interval line for an issue pair, you can then [view statistics](#) or [drill down](#) to subjects with the issue pair. If you click a confidence interval line for an issue, you can then view statistics or drill down to subjects with the issue.
5. To print or copy the graph, see [Working with Graphs](#).
6. You can download values that appear in the graph to Microsoft Excel (if you have Excel installed on your computer). See [Prerequisites and Usage Notes](#) for information about configuring Internet Explorer for downloading.

Click **Download data for graph(s) to Excel**. In the File Download window that appears, indicate whether you want to open the file or save the file to your computer.

The file is always downloaded to a comma-separated (CSV) file. If you open the file from within WebSDM/Empirica Study, the file always opens in Excel. If you save the file and open it from your desktop, the file will open in whichever application is associated (in Microsoft Windows) with the file extension **CSV**.

7. To [save an issue cluster](#) (if you are viewing it from the Results for Issue Cluster Mining Run page), click **Save Issue Cluster** for the cluster. The issue cluster is saved and appears on the [Issue Clusters page](#), so that it can be attached to a potential signal.

Configuring Heatmaps and Confidence Interval Graphs

You can configure heatmaps and confidence interval graphs as described below. The configuration options that you choose affect all heatmaps and confidence interval graphs that are related to issue clusters.

To configure heatmaps and confidence interval graphs:

1. On the [Heatmap page](#) or the [Confidence Interval Graph page](#) for an issue cluster, click **Configure**. The Configure Heatmaps and Graphs page appears.
2. Specify the following options:

Option	Description
Order by	<p>For confidence interval graphs, indicates the order of issue pairs in the graph. The options are:</p> <ul style="list-style-type: none"> • OR05—Value such that there is approximately a 5% probability that the true odds ratio lies below it • EBOR—Empirical Bayesian Odds Ratio • OR95—Value such that there is approximately a 5% probability that the true odds ratio lies above it • SOR—Syndromic Odd Ratio • N—Subject count for each pair

For more information, see [Cluster Mining Computations](#).

Color by	<p>Determines how the graph is colored. The options are:</p> <ul style="list-style-type: none"> • OR05—Value such that there is approximately a 5% probability that the true Odds Ratio lies below it • EBOR—Empirical Bayesian Odds Ratio • SOR—Syndromic Odds Ratio • None— No color is used in the graph; differs from the gray-scale option
Axis type	<p>For confidence interval graphs, determines the axis type. When you use a logarithmic axis, the confidence intervals for the issue pairs may appear more clearly. The options are:</p> <ul style="list-style-type: none"> • Linear—The axis type is linear. • Log—The axis type is log. <p>The default value is Log.</p>
Show number of subjects	<p>Determines whether to include subject counts for each issue pair in heatmaps and confidence interval graphs.</p> <ul style="list-style-type: none"> • If selected—Shows number of subjects. • If deselected—Does not show number of subjects.
Show vertical reference line	<p>For confidence interval graphs, displays a vertical line at SOR 1.0 for reference purposes.</p> <ul style="list-style-type: none"> • If selected—Shows a vertical reference line. • If deselected—Does not show a vertical reference line.

3. Optionally select any other display options. See [Working with Graphs](#) for information about the following display options: Use gray-scale instead of colors; Key; and Links.
4. Click **OK**. The configuration options are used for all heatmaps or confidence interval graphs (related to issue clusters) that you view, until you change the options.

Viewing Statistics for an Issue

When viewing a heatmap or a confidence interval graph, you can view the following statistics for each issue:

- **Observed** – Percentage of subjects observed to experience the issue

- Empirical Bayes Estimate – Percentage of subjects expected to experience the issue, using empirical Bayesian estimates
- Empirical Bayes Odds Ratio (EBOR) for the issue, followed by the OR05 and OR95 in parentheses

The first two statistics are provided for subjects in the treatment group and comparator group. The treatment and comparator groups are based on the dosing category breakdown used in the cluster mining run that generated the issue cluster.

To view statistics for an issue:

Do one of the following:

- On the Results for Issue Cluster Mining Run page, click the name of an issue that is listed as part of one of the clusters.
- When viewing a confidence interval graph for an issue cluster, point to a confidence interval line and then click **View Statistics**.

Viewing Statistics for an Issue Pair

When viewing a heatmap or confidence interval graph, you can view the following statistics for each issue pair:

- Observed – Percentage of subjects observed to experience the pair of issues
- Empirical Bayes Estimate Under independence – Percentage of subjects expected to experience the pair of issues based on the shrunken probability estimates for the individual issues
- Empirical Bayes Estimate with Secondary Shrinkage – Percentage of subjects observed to experience the pair of issues shrunken to the expected percentage for issue pairs (which are based on shrunken probability estimates for the individual issues)
- Empirical Bayes Odds Ratio (EBOR) for the issue pair, followed by the OR05 and OR95 in parentheses
- Syndromic Odds Ratio (SOR) for the issue pair

The first three statistics are provided for subjects in the treatment group and comparator group. The treatment and comparator groups are based on the dosing category breakdown used in the cluster mining run that generated the issue cluster.

To view statistics for an issue pair:

Do one of the following:

- When viewing a heatmap for an issue cluster, point to a diamond and then click **View Statistics**.
- When viewing a confidence interval graph for an issue cluster, point to a confidence interval line and then click **View Statistics**.


Attaching a Cluster to a Potential Signal

When you view issue clusters, you can attach a cluster to a [potential signal](#) associated with the current application selected. You can create a new potential signal, or select an existing one.

You cannot:

- Attach the same issue cluster, generated by the same cluster mining run, to the same potential signal more than once.
- Attach clusters of more than 15 issues to a potential signal.

To attach an issue cluster to a potential signal:

1. On the [Issue Clusters page](#), click the Action menu icon () and then click **Attach to a Potential Signal**.
2. In the **Identify Potential Signal** window, you can:
 - Enter the name of a new potential signal to create.
 - Select an existing potential signal for the application from a list of potential signals with the status **New**, **Reviewed**, **Escalated**, or **Under Analysis**. You can click **Browse** to view more information about the existing potential signals and select one.

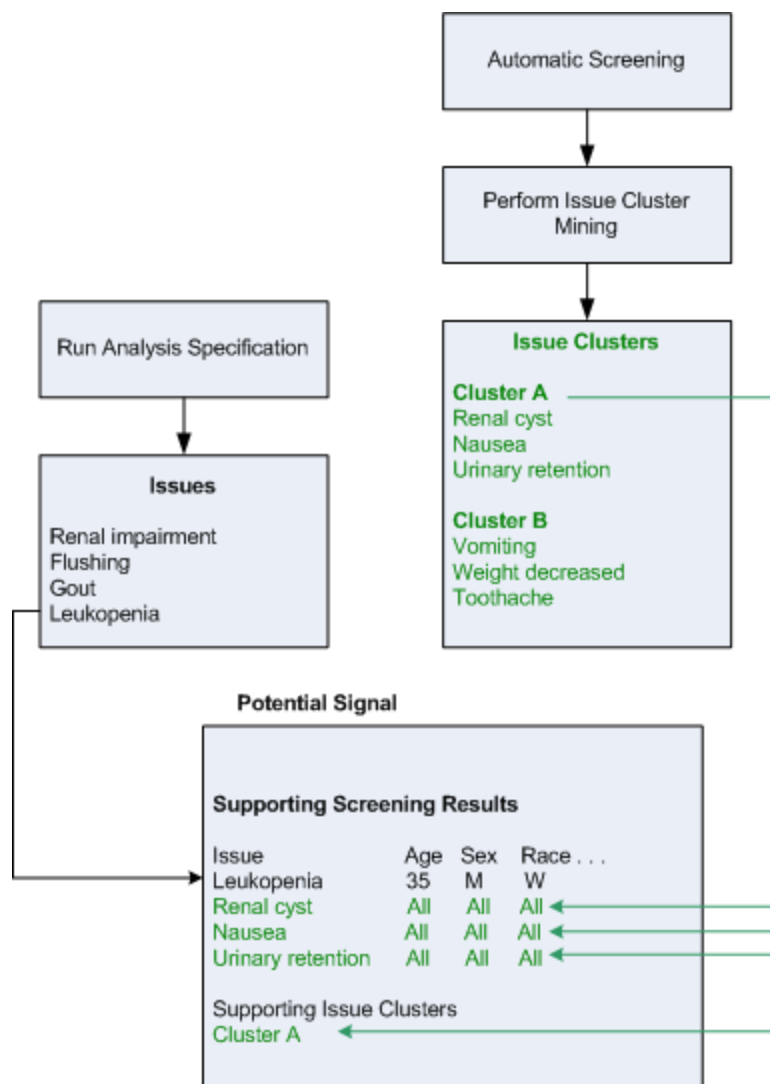
You can attach an issue cluster to a potential signal whose status is **Under Analysis** only if the potential signal is currently assigned to you.

3. Click **OK**. The [Potential Signal page](#) appears, with the issue cluster listed in the **Issue Clusters** section and the cluster's constituent issues in the **Supporting Analysis Results** section.

Note: If you do not save changes to the potential signal, the issue cluster is not attached.

Only the issues are attached. WebSDM/Empirica Study does not attach the dosing categories. There are no categories such as Age, Sex, and Race; thus, category columns contain the value **All**.

The following diagram shows the attachment of screening results and issue clusters to a potential signal:





Viewing Dependent Potential Signals

When viewing screening results or issue clusters, you can view a list of potential signals to which a particular issue or issue cluster is attached.

To view dependent potential signals:

Do one of the following:

- On the page displaying screening results, click  and then click **View Potential Signals with this Result Attached**.
- On the [Issue Clusters page](#), click  and then click **View Potential Signals with this Issue Cluster Attached**.

The Dependent Potential Signals page appears, providing the following information about each potential signal to which the issue or issue cluster is attached:

Column	Description
ID	Automatically assigned numeric identifier of the potential signal.
Name	Name of the potential signal.
Application	Application name supplied during application registration.
Description	Description of the potential signal.
Status	Status assigned to the potential signal.
Assigned To	Name of the user expected to perform the next step in the workflow for the potential signal.
Created	Date and time at which the potential signal was created.
Modified	Date and time at which the potential signal was last modified.
Modified By	Name of the user who created or last modified the potential signal.
# Analysis Results	Number of screening results that have been attached to the potential signal. These may include both results from a screening analysis run and issues from an issue cluster that was attached to the potential signal.
# Issue Clusters	Number of issue clusters that have been attached to the potential signal.
# BLR Runs	Number of BLR runs that have been performed on the potential signal. This column is applicable only to BLR runs that were created prior to WebSDM/Empirica Study release 3.1.
# External Docs	Number of links to external documents that have been added to the potential signal.
# Comments	Number of comments for the potential signal as a whole. (This does not include annotations of specific supporting results or documents.)
SUBMISSION_ID	Automatically assigned unique identifier of the application (same as ID column on Applications page).

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

If you want to list only potential signals that are assigned to you or that have a particular status, use a SQL Where clause in the Columns & Rows window.

Potential Signals

About Potential Signals

A potential signal is a collection of information that could indicate a drug safety concern, and thus is intended for subsequent statistical and medical evaluation. Potential signals can include results from any studies in a particular application. You can continue to add information to a potential signal over time. The following information can be added to a potential signal as supporting evidence:

- Issues from [screening results](#) or [issue clusters](#) for any study in the application.
- [Supporting issue clusters](#).
- [Supporting documentation](#).
- [Annotations of the above components](#).
- [Comments](#) about the potential signal.

Typically, a potential signal is first created when a concerning issue or issue cluster is found by a reviewer of screening results or issue cluster mining results. Information is then added to the potential signal as the signal goes through stages of medical and statistic evaluation.

Each potential signal has a status. The status:

- Provides information on the current position of the potential signal in the workflow.
- Controls the activities that can be performed with the signal.

For information on changing the status, see [Changing the Status of a Potential Signal](#).

Attached results or issue clusters

Actions that could modify screening results, such as reloading a study or re-running an analysis specification, are not allowed when screening results or issue clusters are attached to a potential signal. If you detach the screening results or issue clusters from the potential signal, these actions are then possible.

Viewing Existing Potential Signals

To view existing potential signals:

1. Go to the Screening tab and click **Potential Signals**. The Potential Signals page appears, listing existing potential signals created by all users *for the currently selected application*. The following information is provided about each potential signal:


Column	Description
ID	Automatically assigned numeric identifier of the potential signal.
Name	Name of the potential signal.

Application	Application with which the potential signal is associated.
Description	Description of the potential signal.
Status	Status assigned to the potential signal.
Assigned To	Name of the user expected to perform the next step in the workflow for the potential signal.
Created	Date and time at which the potential signal was created.
Modified	Date and time at which the potential signal was last modified.
Modified By	Name of the user who created or last modified the potential signal.
# Analysis Results	Number of screening results that have been attached to the potential signal. These may include both results from a screening analysis run and issues from an issue cluster that was attached to the potential signal.
# Issue Clusters	Number of issue clusters that have been attached to the potential signal.
# BLR Runs	Number of Bayesian Logistic Regression runs that have been performed on the potential signal. This column is applicable only to BLR runs that were created prior to WebSDM/Empirica Study release 3.1.
# External Docs	Number of links to external documents that have been added to the potential signal.
# Comments	Number of comments for the potential signal as a whole. (This does not include annotations of specific supporting results or documents.)
SUBMISSION_ID	Automatically assigned unique identifier of the application (same as ID column on the Applications page).

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

- If you want to list only potential signals that are assigned to you or that have a particular status, click **Columns and Rows** and use a [SQL Where clause](#).

Note: To list signals for all applications, you can click **Columns and Rows** and remove the SQL Where clause that restricts potential signals to only those for the currently selected application.


- To create a potential signal, click **Create Potential Signal** (available if you have the *Manage Potential Signals* permission). Typically, new potential signals are not created this way, but are created in the process of attaching the first screening result or issue cluster to a signal.
- If you click  for a potential signal, you can do the following:
 - To [review a potential signal](#), click **Review** (available only if the potential signal is for the currently selected application.) If the potential signal status is *Closed*, click **View History**.
 - To view the most recent [archive](#) of the potential signal, click **View Latest Archive**.

Reviewing a Potential Signal

The Potential Signal page lists and provides access to various types of information that have been attached to the potential signal. The page appears when you are creating or reviewing an existing potential signal.

No changes to a potential signal are saved unless you click **Save** on the Potential Signal page. Also note that each time you save changes to a potential signal, an archive of the potential signal is created automatically.

To review a potential signal:

1. On the Potential Signals page, click the Action menu icon () for a potential signal and then click **Review**. (If the potential signal status is **Closed**, click **View History** instead.) From the Potential Signals page, you can review only potential signals for the currently selected application.

The Potential Signal page includes the following information to identify the potential signal:

Field	Description
Application	Name of the application with which the potential signal is associated. This field cannot be changed.
Name	Name of the potential signal. The name must be unique within the application.
Description	Description of the potential signal.
Assigned To	Name of the user expected to perform the next step in the workflow for the potential signal. Available users are those who are in login groups and have the Manage Potential Signals permission. If you have the Administer Users permission, you can also select from users in other login groups to which any study in the application is published and who have the Manage Potential Signals permission, as well as users in other login groups who have both the Manage Potential Signals permission and the Administer Users permission, whether or not a study in the application is published to them.
Status	Status of the potential signal. When you first create a potential signal, this is set automatically to New .

2. See [About Tables](#) for information about viewing, printing, or downloading tables that appear on the Potential Signal page, or changing the way data is displayed in the tables.
3. [View supporting screening results](#).
4. [View supporting issue clusters](#).
5. [Work with Bayesian Logistic Regression \(BLR\) runs](#).

The Bayesian Logistic Regression Runs section is available only if the potential signal has BLR runs that were created prior to WebSDM/Empirica Study release 3.1.

6. If you have the Manage Potential Signals permission, you can [add supporting documents](#) to the potential signal.
7. [Annotate components](#) of the potential signal.
8. [Add comments to the potential signal](#), if the status of the potential signal is not **Closed**.
9. If you have the Manage Potential Signals permission, you can:
 - Change the name or description of the potential signal.
 - Assign a potential signal to other users who have access to the application for which the potential signal exists, are in the same login group as you, and have the Manage Potential Signals permission.
 - [Change the status of the potential signal](#).

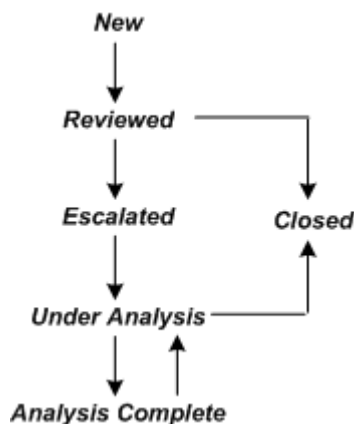
Note: If you have the Administer Users permission or are a Superuser, you can assign a potential signal to users (in any login groups) who have access to the currently selected application and have the Manage Potential Signals permission.

10. Click **View History** if you want to [view the history](#) (and [archives](#)) of the potential signal.
11. If you have modified a potential signal, click **Save** if you want to save your changes or **Cancel** if you do not want to save the changes. You can then click **Back** to go to the previous page.

Note: An archive of the potential signal is created automatically each time you click **Save**.

Changing the Status of a Potential Signal

There are six possible statuses for a potential signal. Signal statuses can be changed as follows:



The following table describes each status. Your organization can match its own processes to potential signal statuses and workflows that are built into WebSDM/Empirica Study. The only automatic status setting is **New**.

Note: For a potential signal of any status except **Closed**, a user with permission to review potential signals can add comments to the potential signal or annotate components of the potential signal (even if the potential signal is not assigned to that user).

Status	Description
New	The potential signal has been created. Screening results and issue clusters can be attached/detached, and supporting documents can be added/deleted.
Reviewed	The potential signal has been reviewed and its status has been changed manually from New to Reviewed . Screening results and issue clusters can be attached/detached, and supporting documents can be added/deleted.
Escalated	The status has been changed manually from Reviewed to Escalated so that the potential signal can be analyzed further. Screening results and issue clusters can be attached/detached, and supporting documents can be added/deleted. For BLR runs created prior to WebSDM/Empirica Study release 3.1, Bayesian Logistic Regression results can be viewed for the potential signal.
Under Analysis	<p>Only the user to whom the potential signal is assigned can change the potential signal, attach/detach screening results or issue clusters, and add/delete supporting documents. (Note: The exception is that a Superuser or user with the Administer Users permission can assign the potential signal to another user.)</p> <p>The status can be changed manually from Escalated or Analysis Complete to Under Analysis. For example, you may want to change the status manually from Escalated to Under Analysis if you are assigning the potential signal to a user other than yourself.</p> <hr/> <p>Note: This status is applicable only for BLR runs that were created prior to WebSDM/Empirica Study release 3.1.</p>
Analysis Complete	The status has been changed manually from Under Analysis to Analysis Complete . Screening results and issue clusters cannot be attached/detached and supporting documents cannot be added.
Closed	<p>The status has been changed manually from Reviewed or Under Analysis to Closed to indicate that no further investigation or analysis is necessary. No further activities are possible with the potential signal, except that the signal history archives can be viewed. The status cannot be changed.</p> <hr/> <p>Note: When a potential signal is closed, screening results, issue clusters, and Bayesian Logistic Regression runs that were created prior to WebSDM/Empirica Study 3.1 are detached automatically.</p>

To change the status of a potential signal:

1. On the [Potential Signal page](#), select a status. The Change Status of Potential Signal window appears.
2. Enter a reason for the status change. The reason will appear in the potential signal archive.
3. Click **OK**.
4. When you have finished making any other changes to the potential signal, click **Save** on the Potential Signal page to save the changes.

Viewing Supporting Screening Results in a Potential Signal

To view supporting screening results in a potential signal:

1. On the [Potential Signal page](#), you can view the information in the table below about screening results that are attached to the potential signal. In this context, a screening result can be either a result from running an analysis specification or an issue from an issue cluster that was attached to the potential signal.

If the results of some analysis types were generated prior to Empirica Study 3.0, they are outdated because the way in which these analysis types compute results has changed. In this case, a message appears above the table of supporting screening results. For more information, see [About Analysis Types](#).

Note: The same issue may be listed multiple times in the "Supporting Analysis Results" section of a potential signal. The issues may be associated with different categories, may be from the results of different analysis specifications, or may be from both screening results and issue clusters attached to the potential signal.

Column	Description
ID	Automatically assigned identifier of the result.
Description	Automatically assigned description that indicates the analysis type for which the result was generated. If the result is a screening result that was attached to the potential signal, the description includes the name of the analysis specification. If the result was added automatically when an issue cluster was attached to the potential signal, the description includes the name of the issue cluster.
Issue Type	Abbreviation of the type of analysis that generated the issue. For the result of a screening analysis specification or an issue from an issue cluster, the issue type may be: <ul style="list-style-type: none"> • PT – MedDRA PT • SOC – MedDRA SOC • HLGT – MedDRA HLGT • HLT – MedDRA HLT

- SMQ – Standardized MedDRA Query
- HY – Hy's Law
- EGQT – QT Prolongation
- LBCS (Built-in criteria) – Clinically Significant Lab Results
- LBCS (Flag variable) – Clinically Significant Lab Results
- VSCS (Built-in criteria) – Clinically Significant Vitals Results
- VSCS (Flag variable) – Clinically Significant Vitals Results


For the result of a screening analysis specification, the issue type may also be:

- LBBL – Lab Change from Baseline
- VSBL – Vitals Change from Baseline
- CMQ – Custom MedDRA Query
- DSPD – Subject Disposition

Issue Name	Name of the issue.
Age	Age category of the result. For an issue that came from an issue cluster that was attached to the potential signal, Age is always All.
Sex	Sex category of the result. For an issue that came from an issue cluster that was attached to the potential signal, Sex is always All.
Race	Race category of the result. For an issue that came from an issue cluster that was attached to the potential signal, Race is always All.
Medical Hx	Medical history category of the result. For an issue that came from an issue cluster that was attached to the potential signal, Medical Hx is always All.
Con Med	Concomitant medication category of the result. For an issue that came from an issue cluster that was attached to the potential signal, Con Med is always All.
Study Group	Study Group category of the result. For an issue that came from an issue cluster that was attached to the potential signal, Study Group is always All. (Applies to only screening results for a study pool.)
Study	Name of the study for which the result was generated.
Modified By	Name of the user who attached the result to the potential signal or last annotated the result.
Created	Date and time at which the result was attached to the potential signal.
Modified	Date and time at which the result was last annotated.
# Annotations	Number of annotations for the result. You can click the number to view or add annotations .

Drug	Always TestDrug in this implementation. Reserved for future use.
Dosing Breakdown	Dosing category breakdown associated with the result.
Time Frame	Time frame associated with the result.

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

- To [view or add annotations](#) for a supporting result, click the number in the "# Annotations" column. (If the column is not included in the table of supporting results, click **Columns** and include it.) To add an annotation, enter the text of the annotation and click **Add**.
- If you click  for a result on the Potential Signal page, you view the following information:

View Options	PT, HLT, HLG, SOC	SMQ, CMQ	LBCS, VSCS	LBHY	EGQT	DSPD	LBBL, VSBL
2x2 Table	X	X	X	X	X	X	
t-test Statistics							X
Box Plot							X
Delta Plot							X
Lab or Vitals Graph			X				X
Lab Panel			X				X
Events by Dose Group	X	X					
Day of Onset by Dose Group							
Severity, Toxicity Grade, Action Taken, or Outcome by Dose Group							
Recurrence by Dose Group							
Demographic Distribution by Dose Group							
Issues by Dose Group			X		X		
Cumulative Incidence Plot	X						
Odds Ratio Graph	X	X	X	X	X	X	

You can also do the following:

- To [view related results](#), that is, screening results that are in the same primary path as the current result, click **View Related Results**. Applies to only a MedDRA PT, HLT, or HLG Analysis. This option is not available for issues that were attached automatically to the potential signal when an issue cluster was attached.

- To view a description of the analysis specification that generated the result, click **View Analysis Specification Details**.
- To [view or add annotations](#) for the result, click **View Annotations**.
- To detach the result from the potential signal, click **Detach**. If the result was attached automatically when an issue cluster was attached to the potential signal, the issue cluster is not affected when you detach the result.


You cannot detach any results if a BLR run exists for the potential signal (regardless of whether BLR results were saved and regardless of whether that particular result was used in the BLR run).

4. When you have finished making any other changes to the potential signal, click **Save** on the Potential Signal page to save the changes.

Viewing Related Results in a Potential Signal or BLR Run

The Related Analysis Results page lists all screening results having the same PT, HLT, HLGT, or SOC in their primary path as the screening result selected in the potential signal or BLR run.

To view related results in a potential signal:

1. For screening results of a MedDRA PT, HLT, HLGT, or SOC Analysis, click  for the result and then click **View Related Results**. The Related Analysis Results page appears.

Note: This option is not available for issues that were attached automatically to the potential signal when an issue cluster was attached.

The columns for the related results are a subset of the [screening result columns](#) that appear on the Analysis Results page. When you are working with related results, any SQL Where clause that you use in the Columns & Rows window is not retained beyond the current display. For related screening results, you can specify up to 250 rows per page.

For columns representing subject counts, the count is a hyperlink that you can click to [drill down](#) to a list of subjects.


2. In the Result Type field, select another analysis type. This field appears only if multiple analysis types (of MedDRA PT, HLT, HLGT, and SOC Analyses) were generated by the analysis specification that generated the attached result.
3. In the MedDRA layer field, you can select higher level terms along the MedDRA primary path of the term in the attached result. For example, suppose that the attached result is for a MedDRA PT Analysis and the issue is Arthralgia. In the MedDRA Layer field, the default is: PT='Arthralgia'. You can also select any of the following:

HLT='Joint related signs and symptoms'

HLGT='Joint disorders'


SOC='Musculoskeletal and connective tissue disorders'

If you select HLGT='Joint disorders', results for all PTs with the HLGT in their primary path are displayed. The related results are always from the set of screening results generated by the analysis specification that generated the attached result.

4. If you click  for a related result, you can select options to view the following:
 - [2x2 Table](#)
 - [Events by Dose Group](#)
 - [Day of Onset by Dose Group](#)
 - [Severity, Toxicity Grade, Action Taken, or Outcome by Dose Group](#)
 - [Recurrence by Dose Group](#)
 - [Demographic Distribution by Dose Group](#)
 - [Cumulative Incidence Plot](#)
 - [Odds Ratio Graph](#)
 - If you have the *Manage Potential Signals* permission, you can also click **Attach to a Potential Signal: <signal-name>** to attach a related result to the same potential signal.
5. When are you done viewing related results, click **Close**.

To view related results in a BLR run:

Note: This procedure describes viewing related results in BLR runs created in WebSDM/Empirica Study 3.1.

1. In the [BLR Response Selector](#), click **Show Issue Menus**. Single-row selection mode is enabled.
2. Click the Action menu icon  next to an issue of type PT, HLT, HLGT, or SOC, and then select **View Related Results**. The Related Analysis Results page appears.
3. Select any of the following options below, and then click **Close** when you are finished.
 - Configuring columns and rows
 - Select **Columns and Rows** to include or exclude columns from the results list or add a WHERE clause to limit rows.
 - Printing and downloading issues
 - Select from the following:
 - [Print](#)
 - [Download](#)

Filtering issues

WebSDM/Empirica Study filters the issues shown based on selections you make from drop-down lists. Select from the following:

- **Result Type:** Select the analysis type. This field appears only if the \$\$\$BASIC\$\$\$SCREENING\$\$\$ analysis specification generated results for multiple analysis types (of type MedDRA PT, HLT, HLGT, and SOC).
- **MedDRA Layer:** Select higher level terms along the MedDRA primary path of the selected issue. For example, suppose that the issue is the MedDRA PT **Arthralgia**. In this field, the default value is **PT='Arthralgia'**. You could then select any of the following:

HLT='Joint related signs and symptoms'

HLGT='Joint disorders'

SOC='Musculoskeletal and connective tissue disorders'

If you select HLGT='Joint disorders', results for all PTs with the HLGT in their primarypath are displayed. The related results are always from the set of screening results generated by the \$\$\$BASIC\$\$\$SCREENING\$\$\$ analysis specification.

- **Age, Sex, and so on:** Predictors are available if they were included in the most recent screening analysis run for the \$\$\$BASIC\$\$\$SCREENING\$\$\$ analysis specification.


Selecting subject drill-down options

Subject drilldown options are available when you click the counts Total Subjects, Treatment Subjects, and Comparator Subjects columns. To select a subject drilldown option, click a subject count, and then select from the following:

- [View Subjects](#)
- [Create Subject List](#)
- [Transfer to Subject List](#)
- [Download Subjects](#)
- [Download Subject Details](#)
- [Reports](#)

Note: The options that appear are dependent upon your user permissions.

Selecting issue drill-down options

Click the Action menu icon  next to an issue, and then select from the following:

- [View 2x2 Table](#)
- [View Events by Dose Group](#)
- [View Day of Onset by Dose Group](#)

- [View Severity by Dose Group](#)
- [View Toxicity Grade by Dose Group](#)
- [View Recurrence by Dose Group](#)
- [View Action Taken by Dose Group](#)
- [View Outcome by Dose Group](#)
- [View Demographic Distribution by Dose Group](#)
- [View Cumulative Incidence Plot](#)
- [View Odds Ratio Graph](#)

In addition, you can select **Use as BLR response** to attach the issue to your BLR run.

Adding all issues to the BLR run

Click **Use all as BLR responses** below the table to add all issues in the list to your BLR run.

Viewing Supporting Issue Clusters in a Potential Signal

To view supporting issue clusters in a potential signal:


1. On the [Potential Signal page](#), you can view the following information about each issue cluster that has been attached to the potential signal:

Column	Description
ID	Automatically assigned identifier of the issue cluster.
Name	Name of the issue cluster.
Study	Name of the study for which the issue cluster was generated.
Modified By	Name of the user who attached the issue cluster to the potential signal or last annotated the issue cluster.
Created	Date and time at which the issue cluster was attached to the potential signal.
Modified	Date and time at which the issue cluster was last annotated.
# Annotations	Number of annotations for the issue cluster. You can click the number to view or add annotations

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

2. To [view or add annotations](#) for a supporting issue cluster, click the number in the "# Annotations" column. (If the column is not included in the table of supporting results,

click **Columns** and include it.) To add an annotation, enter the text of the annotation and click **Add**.

3. If you click  for an issue cluster on the Potential Signal page, you can do the following:
 - To view the [configuration options](#) used for the issue cluster mining run that produced the issue cluster, click **View Configuration Options**.
 - To [view statistics](#) for the issue cluster, click **View Statistics**.
 - To [view a heatmap](#) for the issue cluster, click **View Heatmap**.
 - To [view a confidence interval graph](#) for the issue cluster, click **View Graph**.
 - To [view or add annotations](#) for the issue cluster, click **View Annotations**.
 - To remove the issue cluster result from the potential signal, click **Detach**. The issues that were added to the potential signal when the cluster was attached to the potential signal remain, even though the cluster is detached. You can detach the issues separately.

You cannot detach any issue clusters if a BLR run that was created prior to WebSDM/Empirica Study 3.1 exists for the potential signal (regardless of whether BLR results were saved and regardless of whether any issues from the issue cluster were used in the BLR run).
4. When you have finished making any other changes to the potential signal, click **Save** on the Potential Signal page to save the changes.

Adding Documents to a Potential Signal

If you have the Manage Potential Signals permission, you can add supporting documents and images, including Microsoft® Word or Adobe® Acrobat Portable Document (PDF) files, to a potential signal with any status except **Closed**. You can either add the file from your desktop, or add it by entering a URL that points to the file.


For most graphs produced in WebSDM/Empirica Study, to attach the graph to a potential signal, take a screen capture of the graph using any third-party screen capture tool, and then attach the resulting image as a supporting document. For some graph types, the graph is included automatically in the archive of the potential signal.

To add a supporting document to a potential signal:

1. On the [Potential Signal page](#), click **Add**. The **Edit Other Supporting Documentation** window appears.
2. Enter a link label and description for the supporting document.
3. Click **WWW** or **Local File System** to indicate the location of the document you are adding.
4. If you click **WWW**, enter an entire internet address, including the protocol, such as `http://` or `https://`. Keep in mind that the internet address is live, and the content of it

may change over time. If you are uncertain whether the internet address will remain valid on a long-term basis, capture information from the internet address in a durable format such as an Adobe Acrobat® Portable Document Format (PDF) file or a GIF or JPEG image file, and attach it to the potential signal as a local file.

If the internet address points to a downloadable file, such as a PDF file or an HTML file, the file will be copied to the ZIP file each time the **Archive** (or **View Latest Archive**) link is clicked.

5. If you click **Local File System**, enter the file name of the document, or click **Browse** to locate the document. Supported document types include, but are not limited to:
 - Microsoft® Word.
 - Microsoft® PowerPoint.
 - Adobe Acrobat® Portable Document (PDF) files.
 - GIF or JPEG image files.
6. Click **Add**.
7. To view the document, click the document name hyperlink in the Link column.
8. You can click the Action menu icon () for a supporting document and do the following:
 - To change the document label or description, click **Edit**. If the document location changes, you must delete and re-add the document to the potential signal.
 - To delete the document from the potential signal, click **Delete**.
 - To [view or add annotations of a supporting document](#), click **View Annotations**.
 - To download a document to your desktop, click **Download to desktop**. This option is available only for documents that were added from your local file system.
9. Click **Save** on the **Potential Signal** page to save the changes.

In the **Other Supporting Documentation** section, the following information is provided about each supporting document that is currently attached to the potential signal:

Column	Description
ID	Automatically assigned identifier of the document.
Description	Description of the document.
Link	Link to the document.
Modified By	Name of the user who added the document, last modified the document label or description, or last annotated the document.
Created	Date and time at which the document was added.
Modified	Date and time at which the document label or description was last

	modified, or the document was last annotated.
# Annotations	Number of annotations for the document. You can click the number to view or add annotations
File Origin	For a supporting document added from a local file system, the exact path that was supplied when the document was added to the potential signal.

Annotating Components of a Potential Signal


When you view or edit a potential signal, you can annotate a component, such as a screening result, issue cluster, or document, of the potential signal. If the potential signal has attached BLR runs that were created prior to WebSDM/Empirica Study release 3.1, you can also annotate the BLR runs. You can also [add comments](#) to the potential signal as a whole.

You cannot edit or delete existing annotations. When you annotate a component, WebSDM/Empirica Study adds your annotation to the list of existing annotations for the component.

To annotate a component of a potential signal:

1. On the [Potential Signal page](#), click the number in the # Annotations column. If the column is not included in the table of supporting results, click **Columns** to include it.

or

Click the Action menu icon () for the component, and then click **View Annotations**.

The **Potential Signal Detail Annotations** window appears, listing existing annotations for that supporting result or document. For each annotation, the following information is available:

- The date that the annotation was added.
 - The name of the user who added the annotation.
 - The text of the annotation.
2. Enter the annotation and then click **Add**.
 3. Click **Save** on the **Potential Signal** page.

Adding Comments to a Potential Signal


You can add comments to a potential signal with any status except **Under Analysis** (by another user) or **Closed**. Comments are listed in the Comments section of the potential signal. You can also [annotate components](#) of a potential signal.

To add a comment to a potential signal:

1. On the [Potential Signal page](#), you can view the following information about comments that have been added to the potential signal:

Column	Description
ID	Automatically assigned identifier of the comment.
Text	Text of the comment.
Modified By	Name of the user who created or last modified the comment.
Created	Date and time at which the comment was added.
Modified	Date and time at which the comment was last modified.

For information on viewing, printing, or downloading tables or changing the way data displays in the table see [About Tables](#).

2. To add a comment, click **Add**. The Comment Editor window appears.
3. Enter the text of the comment.
4. Click **Add**. The comment is added and appears on the **Potential Signal** page.
5. On the **Potential Signal** page, you can click  for a comment and then do the following:
 - To edit the comment, click **Edit**.
 - To delete the comment, click **Delete**.
6. When you have finished making any other changes to the potential signal, click **Save** on the **Potential Signal** page to save the changes.

Viewing the History of a Potential Signal

Each time that you click **Save** on the Potential Signal page, an archive of the potential signal is created automatically. The Potential Signal History page lists the archives and allows you to [view them](#).

To view the history of a potential signal:

1. On the Potential Signal page, click **View History**. The Potential Signal History page appears, providing the following information about each archive of the potential signal:

Column	Description
ARCHIVE	The hyperlink " Archive " that you can click to view the archive .
MODIFIED	Date and time that the potential signal was last saved.

STATUS	Status of the potential signal at the time the archive was created.
SIGNED	"Yes" if the potential signal was signed electronically, which is required for certain status changes (changes to Escalated, Analysis Complete, or Closed).
ASSIGNED_TO	Name of the user to whom the potential signal was assigned at the time the archive was created.
ID	Automatically assigned numeric identifier of the potential signal.
NAME	Name of the potential signal at the time the archive was created.
DESCRIPTION	Description of the potential signal at the time the archive was created.
MODIFIER	Name of the user who last saved the potential signal.
CREATED	Date and time at which the potential signal was created originally.
REASON_FOR_STATUS_CHANGE	Applies only if the STATUS column for the archive shows a different value than the STATUS column for the last saved archive. Reason for change that was entered when the status of the potential signal was changed.
APPLICATION	Name of the application with which the potential signal is associated.

2. To [view a particular archive](#), click **Archive**.

Viewing an Archive of a Potential Signal

The *archive* of a potential signal is a saved WinZip file containing PDF files of information about the potential signal. The name of the WinZip file containing the archive is:


<signal-name><date-archive-created><time-archive-created>.zip

where *time-archive-created* is in 24-hour format as HH#MI#SS. For example, mysignal01-JUN-200616#30#15.zip is an archive of "mysignal" created on June 1, 2006, at 16:30:15.

Note: If you access a potential signal archive from the Potential Signals page (instead of from the Potential Signal History page), the WinZip file name does not include a date and time.

To view an archive of a potential signal:

1. See [Prerequisites and Usage Notes](#) for information about WinZip and Adobe® Reader, third-party applications that you need to open the archive WinZip and Portable Document Format (PDF) files.

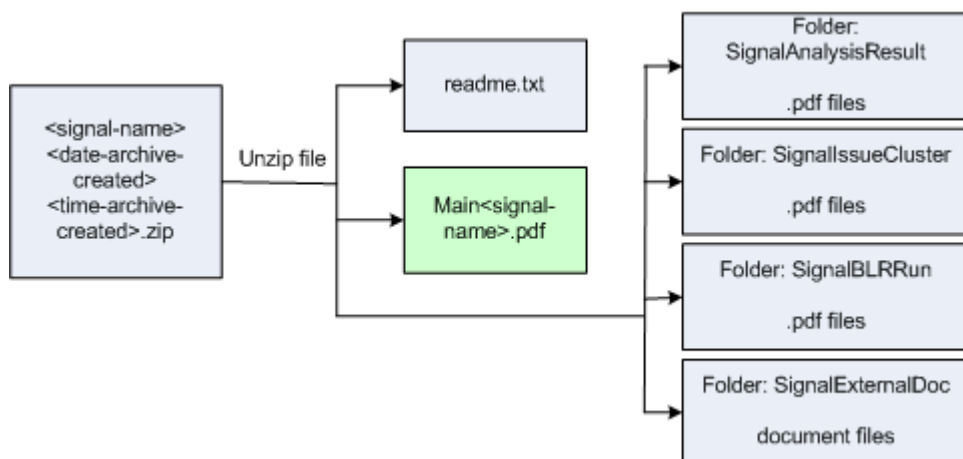
2. On the [Potential Signal page](#), click **View History** to [view the history](#) of the potential signal.
3. On the Potential Signal History page, click **Archive** for the archive that you want to view. To view the most recent archive, you can also click  for a potential signal on the Potential Signals page and then click **View Latest Archive**.

The File Download window appears.

4. Click **Open** to open the archive ZIP file, or click **Save** to download the file to a specified location on your desktop. If you need to be able to view details in the archive, save it to your desktop. Links to details in the archive work only if you have saved the archive.
5. If you are opening the file immediately, open the Main<signal-name>.pdf file in the ZIP file. If you saved the ZIP file to your desktop, open it and extract its contents to a specified location on your desktop. In the Extract window, check "Use folder names".

The archive file (that is, the ZIP) file includes the following files:

- readme.txt, which indicates the name of the potential signal, the audit version date, and the name of the user who downloaded the archive; the audit version date is the Modified date on the Potential Signal History page.
- Main<signal-name>.pdf, whose components are described in Step 7.
- <number>.pdf for each screening result, issue cluster, and Bayesian Logistic Regression run (created prior to WebSDM/Empirica Study release 3.1) that is part of the potential signal; these files are placed in default folders.
- Document files that are attached to the potential signal.



6. Open the Main<signal-name>.pdf file.
7. View components of the potential signal archive as described in the following table:

Section	Contents
Page 1	Provides the following: potential signal name; date and time the version of

the potential signal was saved (audit version date); name of user who saved the version of the potential signal; application with which the potential signal is associated; description of the potential signal; name of the user to whom the potential signal was assigned; status of the potential signal and reason for the status change (if any).

Provides links to other sections of the archive.

Analysis Results	<p>Screening results (and associated annotations) attached to the potential signal. Screening results include screening results, and issues from issue clusters that have been attached to the potential signal.</p> <p>To view details for a screening result, click <ID> Details, where <ID> is the automatically assigned identifier of the screening result.</p> <p>To view annotations for a screening result, click <ID> Notes, where <ID> is the automatically assigned identifier of the screening result.</p>
Issue Clusters	<p>Issue clusters (and associated annotations) attached to the potential signal.</p> <p>To view details for an issue cluster, click <ID> Details, where <ID> is the automatically assigned identifier of the issue cluster.</p> <p>To view annotations for an issue cluster, click <ID> Notes, where <ID> is the automatically assigned identifier of the issue cluster.</p>
BLR Runs	<p>BLR runs (and associated annotations) for the potential signal.</p> <p>To view details for a BLR run, click <ID> Details, where <ID> is the automatically assigned identifier of the BLR run.</p> <p>To view annotations for a BLR run, click <ID> Notes, where <ID> is the automatically assigned identifier of the BLR run.</p> <p>Note: This information is included only for BLR runs that were created prior to WebSDM/Empirica Study 3.1. In release 3.1, BLR runs are created independently from potential signals, and thus are not included in an archive file.</p>
External Documents	<p>External documents (and associated annotations) attached to the potential signal as "other supporting documentation".</p> <p>If a local file was added to the potential signal as a supporting document, a copy of the file is stored in the ZIP file.</p> <p>To view an external document, click <ID> Details, where <ID> is the automatically assigned identifier of the external document. If the link is to an internet address, keep in mind that the internet address is live and its content may have changed since it was attached to the potential signal. If the supporting document is an internet address pointing to a document file that is downloadable, the file is copied to the ZIP file each time the Archive (or View Latest Archive) link is clicked.</p> <p>To view annotations for an external document, click <ID> Notes, where <ID> is the automatically assigned identifier of the external document.</p>
Comments	Comments attached to the potential signal.

Subject Lists

About Subject Lists

A subject list is a saved list of subjects of interest. For example, you might want to save a list of all subjects with a particular demographic profile involving a particular class of drugs. From a subject list, you can access detailed data for a particular subject. You can also:

- Select a subject list before running a report, to include only subjects in the subject list in the report.
- Specify that a screening analysis be restricted only to those subjects in a specific subject list.

You can create a subject list on the Subject Lists tab, or from various pages that list subject IDs or counts of subject IDs; for example, drilldown information or certain reports. To create a subject list based on specified criteria of the study data, you can use a [Query Wizard](#) to build a SQL query and retrieve subjects for the subject list.

Viewing Existing Subject Lists

The Subject Lists page shows [subject lists](#) that are based on the currently selected study (that is, the study you chose on the Select tab). For the selected project, the Subject Lists page shows subject lists that you have created or that have been published to your login group.

To view existing subject lists:



1. Select an application and study, and go to the Subject Lists tab.
2. In the Project field, select the [project](#) for which you want to view subject lists. "--" indicates "All".

The Subject Lists page provides a table of the following information about each subject list:

Column	Description
Name	Name of the subject list.
Description	Description of the subject list.
Project	Name of the project with which the subject list is associated.
Configuration	Name of the configuration on which the subject list is based. A configuration is a detailed specification that makes study data available for various activities. A configuration name is in the format application-name_study-name_CONFIG.
# of Subjects	Number of subjects in the subject list.
Created By	Name of the user who created the subject list.

Created	Date and time on which the subject list was created.
As Of	Reserved for future use.

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

3. To [look up a particular subject](#), click **Subject Lookup**.
4. If you click  for any subject list that is listed, you can do the following:
 - To [view a subject list](#), click **View Subjects**.
 - To [view the query logic](#) for a query-based subject list, click **View Query Logic**. (This option shows variables and values that make up the query, as well as the query logic.)
 - To [email a subject list](#), click **E-mail**.
 - To [view report definitions](#) with the subject list selected, click **Report**.
 - To [copy a subject list](#), click **Copy**.
5. If you click  for a subject list that you created, you can also do the following:
 - To edit the query portion of a subject list that was created with the Query Wizard, click **Edit**.
 - If there are screening results for a custom analysis type that uses the subject list, a message informs you that screening results will be deleted if you continue. Note that only the results for the affected analysis types will be removed.
 - To [rename a subject list](#), click **Rename**. You can also change its description or assign it to a different project.
 - To [publish a subject list](#), click **Publish**.
 - To [delete a subject list](#), click **Delete**. You cannot delete a subject list if it used by a custom analysis type that is included in an analysis specification (even if there are no screening results for the custom analysis type).
 - To define a query-based subject list based on specified criteria, click **Create using Query Wizard**.
 - To [create an empty subject list](#) to which you will manually add subject IDs, click **Create Empty Subject List**.
 - To [create a subject list from XML](#), such as XML provided by another reviewer, click **Create Subject List from XML**.


Looking Up a Subject

At any time, you can look up subject details for a specified subject ID in the currently selected study. Subject details are a tabular subject profile, presented as a set of tables showing study data for the subject.

To look up a subject:

1. On the **Subject Lists** tab, click **Subject Lookup**. The **Subject Lookup** page appears.
2. Either type in a subject ID or select a subject identifier from the displayed list.
3. Click **Display Subject**. If there is one subject ID that matches the value in the Subject ID field, the **Subject Details** page appears.
 - If there are multiple matches to the character string you typed in, all subject IDs containing that character string are listed. Select one of them and click **Display Subject** again.
 - If the Subject ID field was empty when you clicked **Display Subject**, all subject IDs are listed. Select one of them and click **Display Subject** again.

Viewing a Subject List

1. On the [Subject Lists page](#), click  for the subject list and then click **View Subjects**. The Subjects page provides the following information about each subject:

Column	Description
USUBJID	Unique subject identifier, that is, the value of the USUBJID variable, for each subject. Click the subject ID hyperlink to view subject details . When viewing subject details, you will be able to mark subjects as "Reviewed" and "Excluded" and add comments.
Site ID	Value of the SITEID variable for each subject.
Sex	Value of the SEX variable for each subject.
Race	Value of the RACE variable for each subject.
Planned Arm	Value of the ARM variable for each subject.
Reviewed	Displays a checkmark if the subject has been marked as "Reviewed".
Excluded	Displays a checkmark if the subject has been marked as "Excluded".
Comments	Comment (if any) associated with the subject details.

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

See [Viewing Subject Details](#) for information about marking a subject as reviewed or excluded, or adding a comment to subject details.


2. If any subjects have been marked as excluded, you can click **Hide Excluded**. Excluded subjects are then not visible on the Subjects page. If you click **Show Excluded**, such subjects are visible.
3. The following options are available:

Option	Description
Manually Enter IDs	Add subjects manually to the list. This link is available only if you have the Manage Subject Lists permission.
Report	Display the Report Definitions page with the subject list selected.
Download Subject Details	Download subject details for all subjects in the list to an Excel spreadsheet or a Word Rich Text Format File. In the Download Subject Details window, you can indicate whether to include data from all domains or only the safety domains. A user preference determines the default setting. Note: This option differs from the Download option on this page, which downloads only the displayed information.
PPD Patient Profiles	Available if the appropriate site option has been set. A user preference determines how many subjects in the list will be graphed in PPD Patient Profiles.
Data Montage Graphs	View a DataMontage graph for each subject in the list.
Lab Profiles	View a Liver Function Test Patient Profile or view a Hematoxicity Patient Profile for each subject in the list.
Vital Signs Profiles	View a Vital Signs Patient Profile for each subject in the list.
Napoleon's March	View a Napoleon's March graph that shows temporal relationships between duration of exposure and adverse event onset for the listed subjects.

Viewing Query Logic

For a [query-based subject list](#), you can view the query logic specified as part of the query on which the subject list is based.


To view selection criteria:

On the [Subject Lists page](#), click  for the subject list and then click **View Query Logic**. The Query Logic window appears. See [Defining a Query](#) and [Specifying Query Logic](#) for more information.

Renaming a Subject List

Renaming allows you to modify the identifying attributes of a [subject list](#), including its name, description, and project. You can rename any subject list that you have created.

To rename a subject list:

1. On the [Subject Lists page](#), click the Action menu icon () for the subject list and then click **Rename**. The Rename Subject List page appears.
2. Enter a new name for the subject list. The name does not need to be unique, although Oracle recommends that you use a unique name.

3. Optionally enter a description of the subject list. Oracle recommends that you provide an informative description. For example, if the subject list includes female subjects whose medical history includes smoking, you could explain that in the description.
4. Optionally assign the subject list to a [project](#).
 - To assign the subject list to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
 - To create a new project and assign the subject list to it, click **Add to a new project named** and enter a project name.
5. Click **Save**. The **Subject Lists** page appears, listing the renamed subject list.

Note: When you rename a subject list, the name attached to any existing report outputs is not changed.

Emailing a Subject List


When a [query-based subject list](#) is created, the definition of the subject list is stored as XML (eXtensible Markup Language). If you email the subject list, its XML definition is included in the email and a user with appropriate permissions can [use the XML to create another subject list](#) from it.

Note: If the query-based subject list had subjects added to it (in addition to subjects found by the query), those subjects will not be included in the new subject list created from the XML.

If you email a subject list that was created manually (that is, it was created as an empty subject list and then had subjects added to it), only a list of subject IDs is included in the email. Another user with appropriate permissions can create an empty subject list and paste in that list of subjects.

You can email XML for subject lists that you have created or that have been published to your login group. An email address must be set up for your username before you can email a subject list.

To email a subject list:

1. On the [Subject Lists page](#), click the Action menu icon () for the subject list and then click **Email**. The **E-Mail Definition** page appears.
2. In the **To** field, enter an email address. If a default email address is associated with the currently selected application, it appears here by default.
3. In the **Subject** field, modify the subject as needed. The default subject is **Subject List: *subject-list-name***.
4. Do not change the XML that appears in the text of the message for a query-based subject list.
5. Click **Send**.

Using XML to Create a Subject List

When you create and save a [query-based subject list](#), the definition of the subject list is saved in XML. This XML representation can be sent to other users, who can create a new subject list using the XML.

To create a subject list from XML:

1. Obtain the XML that you want to use. You can copy it from your email if another user sent you the XML via email. (See [Emailing a Subject List](#).)

Note: If you are copying XML from email, copy only the XML (not information about the report). The XML begins below the line XML Definition.

2. On the [Subject Lists page](#), click **Create Subject List from XML**. The Create from XML page appears.
3. In the XML Definition field, paste in the copied XML.

XML Definition:

```
<?xml version="1.0" encoding="UTF-8"?>
<QueryXml version="3"
accountName="S_LTI2SAMP1"
caseTable="" caseCaseColumn=""
logicString="1"
componentCount="1"><LogicalGroup
operator="AND"><QueryField
tableName="RAW_AE"
columnName="AEBODSYS"
```

Cancel Next >>

4. Click **Next**. The Define Query page appears and is filled in as specified by the copied XML. You can modify the query as needed.

Creating an Empty Subject List

One way to create a [subject list](#) is to create an empty subject list and then manually add (type in or paste in) a list of subject IDs to it, or transfer subjects to the empty subject list.

To create an empty subject list:

1. On the [Subject Lists page](#), click **Create Empty Subject List**. The Create Empty Subject List page appears.
2. Provide a name for the new subject list. Though not required, Oracle recommends that you provide a unique name.
3. In the Description field, optionally enter a description of the subject list. Oracle recommends that you provide an informative description. For example, if the subject list will include female subjects whose medical history includes smoking, you could explain that in the description.

4. Optionally assign the subject list to a [project](#).
 - To assign the subject list to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
 - To create a new project and assign the subject list to it, click **Add to a new project named** and enter a project name.
5. Click **Save**.
6. [View the empty subject list](#) and [manually add subjects](#) to the subject list or [transfer subjects](#) to it.

Manually Adding Subjects to a Subject List

You can add subjects manually to an empty subject list or to a subject list that already includes subjects. You can add subjects manually to any subject list that you created or that has been published to your login group. You must have the Manage Subject Lists permission to manually add subjects to a subject list.

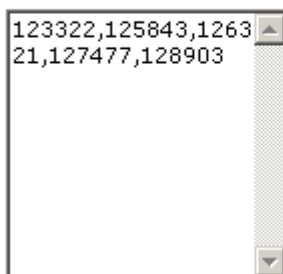
Note: For a [query-based subject list](#), it is possible to add subjects that do not meet the query criteria. However, this is not recommended: if the query is applied again, the added subjects will not be included because they will not meet the query criteria.

To add subjects to a subject list manually:

1. On the [Subject Lists page](#), [view the subject list](#) to which you want to add subjects. (The subject list may be empty or may already include subjects.)
2. On the **Subjects** page, click **Manually Enter IDs**. The Append Manually Entered Subject IDs window appears.
3. Type in or paste in a list of subject IDs. They must be on separate lines or separated by a comma.

Note: If another user emailed you a subject list that was created manually, you can copy the list of subject IDs from your e-mail and paste them in.

Please enter one or more subject IDs, on separate lines or separated by commas



4. Click **Append**. WebSDM/Empirica Study searches the study data for the subjects. The window displays the number of subject IDs that you manually entered, the number of subject IDs that were actually added to the subject list, and the total number of subjects now included in the subject list. If a manually added subject ID does not exist in the study data, that subject ID is not added to the subject list.
5. Click **Close**.


Copying a Subject List

One way to create a new subject list is to use an existing subject list as the basis for a new one. If you copy a [query-based subject list](#), you can then edit the copy to make any necessary changes.

When you copy a query-based subject list, the list of subjects is copied along with the query conditions and logic. To refresh the list of subjects retrieved by the query, click **Edit** for the new subject list and then save it. If the source data has changed, results of the new subject list may differ from the results of the original subject list.

Note: Any indication of subjects as Reviewed or Excluded on the [Subjects page](#) and any attached comments are included in the copy.

To copy a subject list:

1. On the [Subject Lists page](#), click the Action menu icon () for the subject list and then click **Copy**. The Copy Subject List page appears.
2. Enter a name for the new subject list. The name does not need to be unique, although Oracle recommends that you use a unique name.
3. In the Description field, optionally enter a description of the subject list. Oracle recommends that you provide an informative description. For example, if the subject list will include female subjects whose medical history includes smoking, you could explain that in the description.
4. Optionally assign the subject list to a [project](#). To assign the subject list to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you. To create a new project and assign the subject list to it, click **Add to a new project named** and enter a project name.
5. Click **Save**. A message tells you that the subject list has been copied and shows the names of the original subject list (Source), the copy of the subject list (Destination), and the number of subjects in the two lists.

Copy Subject List successfully copied

	Copy Subject List Name	# of Subjects
Source:	test	129
Destination:	Copy of test	129


[Continue](#)

6. Click **Continue**. The Subject Lists page appears, showing the new subject list.
7. If you copied a query-based subject list, refresh the list of subjects by clicking **Edit** for the new subject list and then saving it.
8. Optionally [publish](#) the subject list. (The publication level of the original subject list is not copied to the new subject list.)

Deleting a Subject List

You can delete any [subject list](#) that you have created, unless it is used by a [custom analysis type](#).

To delete a subject list:

1. On the [Subject Lists page](#), click the Action menu icon () for the subject list and then click **Delete**.

Note: You cannot delete a subject list if it is used by an existing custom analysis type (even if no screening results exist for the custom analysis type).

2. At the message asking if you want to delete the subject list, click **OK**. The subject list is deleted and no longer appears on your Subject Lists tab.

When you delete a subject list that was used for reports, the following occurs:

- Any report definition associated with the subject list is no longer associated with a subject list. Thus, when the report is next run, the results may differ from when the report was originally run.
- Any report output associated with the subject list continues to be associated with the subject list and is viewable, even though the subject list no longer exists.

Creating Query-based Subject Lists

About Query-based Subject Lists

One way to create a [subject list](#) is to use the Query Wizard to define a query that retrieves subject IDs from source data on the basis of specified criteria. For example, you could query for females between age 17 and 45 who have taken DrugA and experienced events in the Respiratory SOC (System Organ Class). WebSDM/Empirica Study includes a Query Wizard that facilitates the query creation process. To enable the Query Wizard, your site administrator must have set the appropriate site option.

To create a query, you select variables from the source data and then select values for each variable. To connect the variables, you can use logical operators (AND, OR, and NOT) or set operators (INTERSECT, UNION, and MINUS) to construct a logical expression. The query retrieves a list of subjects, and the subject IDs of those subjects constitute the subject list. If a subject is retrieved multiple times by the query, its subject ID is included only once in the subject list.

Defining a Query

When you create or edit a query-based subject list, the Define Query page appears. On the Define Query page, you specify conditions (variables and their values) and link them with operators. This topic describes how to specify conditions. For information on operators, see [Specifying Query Logic](#).

To define a query:

1. On the [Subject Lists page](#), click **Create using Query Wizard**. The **Define Query** page appears.
2. Click **Select Variables**. The Select Variables window appears.
3. For more information on variables, click **Show Variables**. The Configuration Variables window appears, showing a description of each variable.
4. [Select one or multiple variables](#) on which you will base conditions. A number is assigned automatically to each variable that you select. In the [query logic](#), you use that number to refer to the condition that is based on that variable.
5. When you select a variable, a field for that variable appears on the **Define Query** page. To specify a condition, you specify values for that variable. The way in which you specify values depends on the type of variable, as follows.

Note: You do not need to specify values immediately after adding a variable. For example, you could first select all variables on which you want to base conditions, and then specify their values.

Selecting values

- If the **Select** link appears for a variable, click the link to [select entries from a list](#) of values. Only exact matches to the selected values, including the case (upper, lower, or mixed), will be found by the query.
- If the **Select <hierarchy> Terms** link appears for a variable, click the link to select terms from the [Hierarchy Browser](#). (You can set a user preference to enable a hierarchy for use during query creation.) For example, if a variable is associated with a MedDRA version and your [user preference Enable adverse event hierarchy browser](#) is set to Yes, you can click **Select MedDRA Terms**. Only exact matches will be found.

Note: If the **Select** link or the **Select <hierarchy> Terms** link appears, you can also type in values separated by a comma. However, it is preferable to select values from a list. If you type in a value that contains a comma, you must enclose the entire value in double quotation marks (for example, **Diabetes, Type II**). If you type in a value that includes a backslash or double quotation mark, you must precede the backslash or double quotation mark with a backslash (for example, **Cold\\flu**).

Specifying ranges

For numeric or date variables, specify a range by entering values in the From and To fields. Values equal to or greater than the From value and equal to or less than the To value will be found.

- If you leave the From field empty, there is no lower bound.
- If you leave the To field empty, there is no upper bound.
- If a date variable is stored as a date field in the source data, you must enter the date in the format MM/DD/YYYY. WebSDM/Empirica Study uses the Oracle function TO_DATE to change the entered date to an Oracle date. For example, suppose that you enter 03/26/2004 in the From field for the FDA_DATE variable. In the SQL that is generated, you will see: FDA_DATE >= to_date('2004-03-26 00:00:00', 'yyyy-mm-dd hh24:mi:ss').
- If you do not specify a time, the time is considered to be midnight of the specified date.

Note: If a date variable is stored as a text field in the Oracle database, you can search for it as you would search for any text string.

6. Optionally select Include Null values to include null (empty) values along with the other values that you specify for a variable. For more information, including how the NOT operator works if you include null values, see [Specifying Query Logic](#).
7. Optionally select Ignore Case to return subjects irrespective of case. Deselect this check box to return only exact case matches. This option is available only if the Select <hierarchy> Terms link or the Select MedDRA Terms link appears for the variable.
8. To select additional variables, repeat Step 4. Conditions are connected by default operators, which you can modify.
9. Each condition that you specify must be referenced by the query logic. Thus, if you are not going to reference a condition, you must remove the condition from the query. To remove a condition, click the delete symbol [X] in the upper right corner of the box containing the variable. (After deleting a condition, you may need to respecify values for variables in the other conditions.)

Note: You can include the same variable in the query multiple times. For example, suppose that you want subjects for which age is between 17 and 25 or above 65. You would include the AGE variable and set it to 17-25, include the AGE variable again and set it to above 65, then connect the variables with the OR operator.

10. After adding all variables that you need for specifying conditions, [specify query logic](#). If you add or delete another query variable after this step, the query logic will be reset to a default.
11. Click **Next**. The Confirm Query page appears.
12. On the **Confirm Query** page, view the following information about the query:
 - The "data source, which is the name of the configuration on which the query is based

- The logic of the query and a description of each condition in the query
- The number of subjects to be retrieved by the query
- The Oracle SQL that is constructed from the query and will be used to retrieve subjects

13. Click **Next** and then [save the subject list](#).

Specifying Query Logic

When you specify conditions in a query, they are connected using operators. You can modify the supplied default operators as needed. When specifying query logic, you refer to conditions by the numbers that were assigned automatically to the variables on which the conditions are based. For example, the query logic **1 AND 2** means **Condition 1 AND Condition 2**.

To specify query logic:

1. On the [Define Query page](#), click **Edit**. The Edit Logic window appears.
2. Specify logical operators, set operators, and parentheses as needed. See below for more information.

The conditions in a query must be joined by the AND, OR, INTERSECT, UNION, or MINUS operator. The NOT operator is available to negate a condition (for example, 1 AND NOT 2).

Each condition must be referenced by the query logic at least once. You can refer to the same condition multiple times in a query. For example, you can specify: (1 AND NOT 2) OR 2

3. Click **OK**.

Logical operators

Logical operators act on individual rows of source data tables. You can use the following logical operators between conditions:

- **AND**—Find subjects for which both conditions occurred simultaneously.
- **OR**—Find subjects for which either of the conditions occurred.

You can use the logical operator NOT to negate a condition. (You cannot use NOT alone to connect conditions.)

Set operators

Set operators act on sets of subjects that are retrieved by the conditions on each side of the set operator. You can use the following set operators between conditions:

- **INTERSECT**—Find subjects that are in both sets.

- **UNION**—Find subjects that are in either set.
- **MINUS**—Find subjects that are in the set to the left of the operator and subtract from that list the subjects that are in the set to the right of the operator.

Sometimes it is possible to specify the same query using either logical operators or set operators. It is preferable to use logical operators because they are generally more efficient.

Operator priority

Operators are applied in the following order when the query expression is interpreted:

- NOT
- AND
- OR
- INTERSECT, UNION, MINUS (same priority)

The only restriction on how logical and set operators can interact is that logical operators cannot act on the results of set operators. For example, the following query is invalid: 1 AND (2 INTERSECT 3)

You can use parentheses to change the way in which a query expression is interpreted. If you do not use parentheses explicitly, the query is interpreted as if there are parentheses, based on the default order of operators.

For example, suppose the query is:

1 AND 2 OR 3 INTERSECT 4

With no supplied parentheses, WebSDM/Empirica Study reads the query as follows:

((1 AND 2) OR 3) INTERSECT 4

If you explicitly use parentheses as follows, the meaning of the query is different:

1 AND (2 OR 3) INTERSECT 4

Examples

Suppose that you specify the following conditions:

The image shows three screenshots of the WebSDM/Empirica Study interface. The first two are titled '1 AEDECOD (in AE)' and '2 AEDECOD (in AE)'. Both have a list box containing 'Tardive dyskinesia' and 'Tremor' respectively, with a 'Select' button to the right. Below each list box is a checkbox labeled 'Include Null values'. The third screenshot is titled '3 AESTDY (in AE)' and shows a 'From:' field with the value '18' and an empty 'To:' field. It also has an 'Include Null values' checkbox.

For illustrative purposes in the following examples, the query logic does not always refer to all three conditions. When you are creating a query within WebSDM/Empirica Study, the query logic must reference all conditions in the query.

Also note that a condition can refer to multiple values. For example, you could include the AEDECOD variable once and select Tardive dyskinesia and Tremor as one condition. The AEDECOD variable is included twice in this example so that complex logic can be illustrated.

Suppose that the source data includes subjects A through G with the following data:

USUBJID	AEDECOD	AESTDY
A	Tardive dyskinesia	21
A	Tremor	11
B	Tardive dyskinesia	11
B	Tremor	21
C	Movement disorder	11
D	Tardive dyskinesia	11
E	Tardive dyskinesia	21
F	Tremor	21
G	Movement disorder	21

1 AND 3

The query retrieves subjects with rows in which Tardive dyskinesia occurred and AESTDY \geq 18 for that row:

A
E

1 OR 3

The query retrieves subjects with rows in which either Tardive dyskinesia occurred or AESTDY \geq 18 for any PT:

A
B
D
E
F
G

If OR is used between variables from different tables, only subjects that are in each of those tables will be retrieved. For example, suppose that a query specifies that DSDECOD is **Death** OR AEDECOD is **Death**. Only subjects that meet the criteria and are in both tables will be retrieved. You may want to use SET operators instead of logical operators. For example, replace OR with UNION in the query to find subjects where DSDECOD is **Death** plus subjects where AEDECOD is **Death**.

1 AND 2

No subjects are retrieved because no one row for a subject can have both Tardive dyskinesia and Tremor for a PT.

You can use the set operator INTERSECT if you want to find subjects for which both Tardive dyskinesia and Tremor occurred. See the 1 INTERSECT 2 example below.

1 AND 2 OR 3

The query retrieves subjects with rows in which Tardive dyskinesia occurred and, for that row, Tremor occurred (not possible, because a row can have only one PT), or AESTDY \geq 18 for any PT:

A
B
E
F
G

1 AND (2 OR 3)

The query retrieves subjects with rows in which Tardive dyskinesia occurred and, for the same row, either Tremor occurred (not possible, since a row can have only one PT) or AESTDY \geq 18:

A
E

1 AND NOT 3

The query retrieves subjects with rows in which Tardive dyskinesia occurred and AESTDY is not ≥ 18 for that row:

B
D

NOT 1 AND 3

The query retrieves subjects with rows in which Tardive dyskinesia did not occur and AESTDY ≥ 18 :

B
F
G

NOT (1 AND 3)

The query retrieves subjects with rows in which Tardive dyskinesia with AESTDY ≥ 18 did not occur:

A
B
C
D
F
G

NOT 1 AND NOT 3

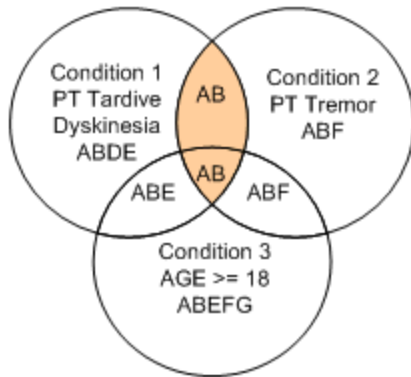
The query retrieves subjects with rows in which Tardive dyskinesia did not occur and, for the PT that occurred, AESTDY is not ≥ 18 occurred:

A
C

1 INTERSECT 2

The query finds the intersection of the two sets, which results in the following subjects:

A
B

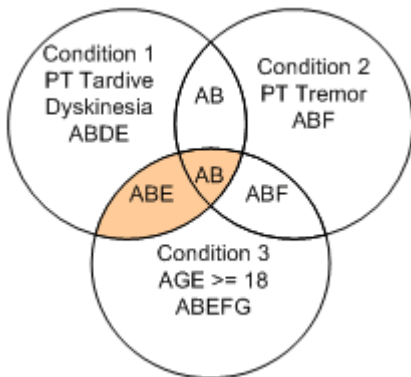


1 INTERSECT 3

The query finds the intersection of the two sets, which results in the following subjects:

A
B
E

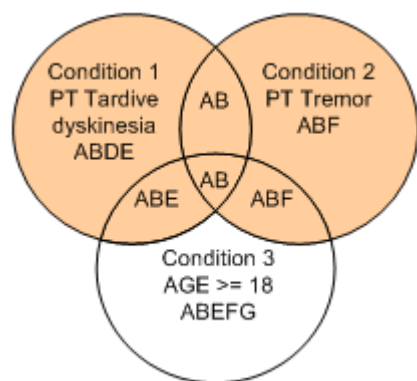
Note that for subject B, there is no occurrence of Tardive dyskinesia where AESTDY >= 18, but subject B was in the set created by Condition 3, as well as the set created by condition 1, so the query retrieves it.



1 UNION 2

The query finds the union of the two sets, which results in the following subjects:

A
B
D
E
F



3 MINUS 1

The query finds the subjects that remain when subjects in set 1 are removed from set 3:

F
G

1 INTERSECT 2 AND 3

The query finds the following subjects:

B

1 UNION 2 AND 3

The query finds the following subjects:

A
B
D
E
F

Null values

If you select **Include Null values** for a condition, the condition finds subjects with rows for which the condition is true or the variable referenced by the condition is null. If you precede the condition with NOT, the condition finds subjects with rows for which the condition is not true or the variable referenced by the condition is not null.

For example, suppose that the source data has four null values for AESTDY:

USUBJID	AEDECOD	AESTDY
A	Tardive dyskinesia	
A	Tremor	11
B	Tardive dyskinesia	
B	Tremor	21

C	Movement disorder	
D	Tardive dyskinesia	11
E	Tardive dyskinesia	21
F	Tremor	
G	Movement Disorder	21

If you specify the condition AESTDY \geq 18 and select **Include Null values**, the following subjects are found:

A
B
C
E
F
G

When you specify that values for a query should include nulls and then you precede the condition with the NOT operator, the query retrieves subjects with rows for which the condition is not true and the variable used in the condition is not null.


If you specify NOT 3 (meaning not condition 3, which is AESTDY \geq 18) and you have selected **Include Null values**, the following subjects are found:

A
D

Editing a Query-based Subject List

You can edit any [query-based subject list](#) that you have created using the Query Wizard. You cannot edit a subject list that was created in any other way.

To edit a subject list:

1. On the [Subject Lists page](#), click the Action menu icon () for the query-based subject list and then click **Edit**. The **Define Query** page appears.
2. See [Defining a Query](#) and [Specifying Query Logic](#). Make changes to the query definition and logic as appropriate.
3. Click **Next**. The **Confirm Query** page appears.
4. Verify that the query has searched for the information as you expected. When you are satisfied with the query, you can either click **Save** to save the subject list with the same name or **Save As** to [save the subject list](#) with a different name.

Saving a Subject List

1. In the **Name** field, enter a name for the subject list. The name does not need to be unique, although Oracle recommends that you use a unique name to avoid confusion when referring to this subject list later.
2. In the **Description** field, optionally enter a description of the subject list. Oracle recommends that you provide an informative description. For example, if the subject list will include female subjects whose medical history includes smoking, you could explain that in the description.
3. Optionally assign the subject list to a [project](#).
 - To assign the subject list to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
 - To create a new project and assign the subject list to it, click **Add to a new project named** and enter a project name.
4. Click **Save**. A message tells you that the subject list is being saved. If you press **Cancel** at this point or navigate to another page, the subject list is not created.

Reports

About Reports

The WebSDM/Empirica Study reporting feature allows you to:

- Retrieve study data and present it in a tabular format.
- View graphs of the report data.

In creating a report, you can:

- Determine the variables that define the rows and columns of the report.
- Break down variables at multiple levels (such as counts of adverse events for Males and counts of adverse events for Females within each age group).
- Indicate how to aggregate multiple values for a variable in the report.

You can create various types of reports, including line listings, and summary reports showing statistics for cross-tabulations of variables. If a report includes subject IDs or counts, you can use the drill-down feature to view subject details.

A report definition determines the format of a report and any restrictions on the data that the report will display. Only users with appropriate permissions can create report definitions and publish them to other users. Additionally, WebSDM/Empirica Study includes [built-in report definitions](#) that are delivered with the product to facilitate safety review. You can use these report definitions as is, or copy and modify them as needed.

A report output is the result of applying a report definition to all subjects in the study, or to those subjects in a selected subject list, and saving the result. A report output is static. If there is a change in a report definition or a subject list against which the report was run, you might want to run the report again and save another report output.

Related Topics

[Report Structure](#)

[Creating/Editing a Report Definition](#)

[Running a Report](#)

[Running a Built-in Report](#)

[Viewing a Report Output](#)

Report Structure

A report is a tabular display of study data, presented according to the specifications of a report definition. A report includes one row for each variable (or combination of variables) that have been specified as row variables in the report definition. For each row, the report

includes columns that have been identified as column variables in the report definition; each column is referred to as an analysis variable.

The report definition may include multiple levels of column variables, as in the following example. A variable that groups values for another variable is referred to as a *breakdown variable*. Any row variable can be a breakdown variable, and the uppermost column variable can be a breakdown variable.

Age	Sex	Body System		
		CARDIOVASCULAR	GASTROINTESTINAL	RESPIRATORY
		Subjects	Subjects	Subjects
		N	N	N
37	F	3	3	2
37	M	7	7	10
38	F	1	1	1
38	M	14	26	15
39	F	2	3	2
39	M	24	40	23
40	F	1	1	1
40	M	28	34	19

Viewing Existing Report Definitions

A report definition specifies:

- Which variables from the source data will appear as columns in the report, and how they will be broken down based on other variables
- Which variable or combination of variables will provide a unique key for the report; the report will include one row for each unique key value (or key value combination)
- How to aggregate multiple values in individual cells
- The subset of rows to appear in the report, based on conditions specified by a SQL Where clause

The Report Definitions page lists report definitions that are compatible with the currently selected study. A study and a report definition are compatible if the study includes all variables (with the same name and data type) as the variables used in the report definition. (The study may also contain more variables than are used in any one report definition.)

For the selected project, the Report Definitions page shows report definitions that you have created or that have been published to your login group.

Valid report definitions

On the Report Definitions page, the names of valid report definitions are bolded. A report definition is valid (and therefore can be run) if it includes at least one row variable and one column variable, and no error messages appear for report variables.

To view existing report definitions:

1. Select an application and study, and go to the Reports tab. (The Report Definitions page appears by default.) You can also click **Report Definitions** while on any other report-related page.

Another way to display the Reports Definitions page is from the [Subject Lists page](#).

Click  for a subject list and then click **Report**.


2. In the Project field, select the [project](#) for which you want to view report definitions. Available projects are those that you created, as well as those that other users associated with objects they published. If "--" is in the Project field, report definitions for all available projects appear.
3. If you have not already selected a subject list, optionally click **Browse** to [select a subject list](#). A report that you run will include only subjects in the subject list. If you do not select a subject list, the report will be for all subjects in the study.

The Report Definitions page provides a table of the following information about each report definition:

Column	Description
Definition	Name of the report definition. Only the names of report definitions that are valid to run are bolded.
Description	Description of the report definition.
Project	Name of the project with which the report definition is associated.
Configuration	Name of the configuration on which the report definition is based. A configuration is a detailed specification that makes study data available for various activities. A configuration name is in the format application-name_study-name_CONFIG.
Created	Date and time at which the report definition was created.
Created By	Name of the user who created the report definition.
Modified	Date and time at which the report definition was last modified.
Modified By	Name of the user who last modified the report definition.
Category	Category of the report, if specified.

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

4. To [create a new report definition](#), click **Create Definition**.

5. To [create a Findings Report](#), click **Create Findings Report**. If you click **Last Findings Report**, the settings for the most recent Findings Report that you created from the Report Definitions page are used as defaults; you can change the settings as needed.
6. To create a Standard Demographics Report, click **Create with Standard Demographics**.
7. To [create a report definition from XML](#), click **Create Definition from XML**.
8. If you click  for a report definition, you can do the following:
 - To [run a report](#), click **Run Report** (available for only reports that have a valid definition.)
 - To edit a report definition, click **Edit**. The [Edit Definition page](#) appears.
 - To [copy a report definition](#), click **Copy**. If you have the *Manage Reports* permission, this option is available for report definitions created by other users; although you cannot edit such report definitions, you can copy them and modify the copy.
 - To [email report definition XML](#), click **Email**.
 - To [publish](#) a report definition, click **Publish**.
 - To delete a report definition that you have created, click **Delete**. At the message asking if you want to delete the report definition, click **OK**. The report definition is deleted. Any report output that was created using the report definition remains accessible on the Report Outputs page.

Creating Report Definitions

Selecting a Subject List for a Report

On the Report Definitions page, you have the option to select a subject list. If you select a subject list and then run a report definition, the report will include only subjects in the subject list. If you have not selected a subject list, the report will be for all subjects in the study.

Note: Subjects who have been marked as excluded as part of reviewer input will not be included in the report.

To select a subject list for a report:

1. On the **Report Definitions** page, click **Browse** next to **Subject List**. The **Select Subject List** page appears, showing all subject lists for studies that you have created or that have been published to your login group.

The following information is provided for each subject list:

Column	Description
Name	Name of the subject list.
Description	Description of the subject list.

Project	Project with which the subject list is associated.
Configuration	Configuration used by the subject list.
# of Subjects	Number of subjects in the subject list.
Created By	Name of the user who created the subject list.
Created	Date and time at which the subject list was created.

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

- In the Project field, select the [project](#) for which you want to view subject lists. Available projects are those that you created, as well as those that other users associated with objects they published. If -- is in the Project field, subject lists for all available projects appear.
- Select the radio button next to a subject list and then click **Select**. The Report Definitions page shows the name of the selected subject list and the number of subjects in it. Subjects marked as excluded as part of reviewer input are included in the number, but a report that you run will not include those subjects.

Creating/Editing a Report Definition

- Select an application and study, and go to the **Reports** tab.
- Optionally [select a subject list](#). If you do not select a subject list, then when you run the new report, it will be for all subjects in the study.
- On the [Report Definitions page](#), do one of the following:
 - To create a new report definition, click **Create Definition**.
 - To [create a Findings Report](#), click **Create Findings Report**. If you click **Last Findings Report**, the settings for the most recent Findings Report that you created from the Report Definitions page are used as defaults; you can change the settings as needed.
 - To create a Standard Demographics Report, click **Create with Standard Demographics**.
 - To [create a report definition from XML](#), click **Create Definition from XML**.

The Create Definition page appears.

- [Name the report definition](#). The Edit Definition page appears.
- On the Edit Definition page, [specify column attributes](#).
- Optionally [edit report attributes](#).

7. Optionally [edit report descriptors](#).
8. [Save or run the report definition](#).

Related Topics

[Copying a Report Definition](#)

Naming a Report Definition

When you have clicked **Create Definition** on the [Report Definitions page](#) or you have clicked **Save As** on the [Edit Definition page](#), you must name the report definition.

To name a report definition:

1. Enter a report name. The name does not need to be unique, although Oracle recommends that you provide a unique and meaningful name.
2. Optionally enter a report description. Oracle recommends that you provide a description that will help differentiate the report definition from others on the Report Definitions page.
3. Optionally assign the report definition to a [project](#). To assign the report definition to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you. To create a new project and assign the report definition to it, click **Add to a new project named** and enter a project name.
4. Click **Save**. The [Edit Definition page](#) appears. If you choose not to specify attributes for the report now, the report definition is saved and listed on the **Report Definitions** page so that you can edit it later.

Note: You cannot run a report until at least one row variable and one column variable have been defined and no error messages appear for report variables.

Specifying Column Attributes

On the Edit Definition page, you define the rows and columns to appear in the report. The Edit Definition page displays when you create or edit a report definition. By default, the Edit Definition page appears with Column Attributes selected:

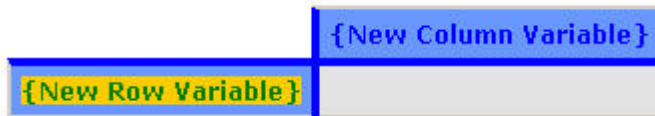
☒ **Column Attributes** ☐ **Report Attributes** ☐ **Report Descriptors**

Column attributes include the variables and source values (from study data) to define rows and columns in the reports, the labels of report columns, and the aggregation method (such as actual value, count, percentage, or mean) to be used to show values in the report.

A report can include columns from multiple tables. WebSDM/Empirica Study assumes that the tables can be linked by the subject ID. As a result, only tables containing a subject ID column are suitable for use with reports.

Note: If you are defining a Findings Report or a Standard Demographics Report, some column variables are already selected and you can change them as needed.

A new report definition presents the placeholders for the variables that define rows and columns for the report in a tabular display like this:



When specifying columns and rows, you can use the following tools:

- Click **Save** frequently to [save the report](#), especially when building a complex report definition. The report definition is saved and the Edit Definition page remains open.
- Click **Preview** to [preview the report](#).
- Click **Undo** to remove the last change you made to the report definition since you last saved the report definition. Click **Redo** to add back the last undone change. You can click **Undo** and **Redo** successive times.

To specify column attributes:

1. On the Edit Definition page, click **Column Attributes**.
2. Add rows and columns as described below.
3. To select an aggregation method for a variable, highlight the N (or other value) in the cell and click **Select** next to **Content Details**. Then [specify content details](#).
4. To select which source values for a variable will appear in the report, click **Select** next to **Breakdown Details**. Then you [define breakdown details](#).
5. To [view a histogram](#) showing the distribution of values for a numeric variable, click **View Column Statistics**.
6. To delete a variable, highlight the variable and click **Delete**. At the message asking if you are sure you want to delete the variable, click **OK**. You cannot delete the last row variable or last column variable.
7. You can [edit report attributes](#), [edit report descriptors](#), or [save or run the report definition](#).

Adding rows and columns to a report definition

The following instructions do not include [changing the labels](#) of row and column variables or changing the [aggregation method](#). The default labels, which are the variable names, are used and the default aggregation method (Value) is used.

To define the first row variable and column variable:

1. Click {New Row Variable} or {New Column Variable} to highlight it in yellow.

- To specify the corresponding source data variable, click **Select** next to **Data Source**. The [Edit Data Source page](#) appears.
- In the following example, AEBODSYS (in AE) has been defined as the row variable and USUBJID (in AE) as the column variable:

	USUBJID (in AE)
AEBODSYS (in AE)	Value

To add a row variable:

- Click the name of an existing row to highlight it in yellow.

	USUBJID (in AE)
AEBODSYS (in AE)	Value

- Click **Insert Left** or **Insert Right**.
- Select the source data variable for the added row variable. The new row variable is included in the report definition. In following example, AEDECOD (in AE) has been inserted as a row variable to the right of AEBODSYS (in AE).

		USUBJID (in AE)
AEBODSYS (in AE)	AEDECOD (in AE)	Value

To add a column variable:

- Click the name of an existing column variable to highlight it in yellow.
- Click **Insert Left**, **Insert Right**, **Insert Below**, or **Insert Above**.
- Select the source data variable for the added column variable. The new column variable is included in the report definition. In the following example, SEX is inserted as a breakdown variable above USUBJID.

		SEX (in AE)
		USUBJID (in AE)
AEBODSYS (in AE)	AEDECOD (in AE)	Value

Note: For a column breakdown variable, you are required to specify breakdown values. If there are 10 or fewer distinct values for the variable in the source data, those values are used automatically as breakdown values; you can modify them as needed. If there are more than 10 distinct values, a message informs you that breakdown details are missing and you must specify them.

- To add another column to the right of SEX, highlight SEX and click **Insert Right**.

		SEX (in AE)	
		USUBJID (in AE)	LBTEST (in LB)
AEBODSYS (in AE)	AEDECOD (in AE)	Value	Value

- To insert another column below SEX and at the same level as USUBJID, highlight USUBJID and click **Insert Right**:

		SEX (in AE)		
		USUBJID (in AE)	EGTEST (in EG)	LBTEST (in LB)
AEBODSYS (in AE)	AEDECOD (in AE)	Value	Value	Value

- To insert another column breakdown variable below SEX, highlight SEX and click **Insert Below**:

		SEX (in AE)		
		SITEID (in AE)		
		USUBJID (in AE)	EGTEST (in EG)	LBTEST (in LB)
AEBODSYS (in AE)	AEDECOD (in AE)	Value	Value	Value

Specifying a Data Source

The data source of a report column or row is the name of the variable in the study data from which data is retrieved for the report. You also specify the label that identifies the variable in the report.

Note: If a row variable's underlying column has the same name as any column in an analysis variable's table, then a SQL inner join of the same-named columns occurs in addition to the usual join on report ID.

To specify the data source for the highlighted column or row variable:

- On the [Edit Definition page](#), click **Select** next to **Data Source**, or click an **Insert** button to insert a column. The Edit Data Source window appears.
- In the **Table** field, select the name of the database table that contains the variable that you want to use, or select **All Tables**.

Note: To include all subject IDs, use the subject ID from the demographics table. It is possible that a subject ID has no record in the other database tables. Otherwise, to include subject IDs that have records in the table from which you are getting other data, use the subject ID from that table.

- Select a variable. For more information, see [Selecting Entries from a List](#).

When you highlight a variable in the list, the Label field shows the variable name by default. You can type in a different label, which will appear in the report as the column heading for the variable.

For example, suppose that you use default labels for the USUBJID (in AE) and the AEACN (in AE) variables. The column headings in the report look like this:

USUBJID (in AE)	AEACN (in AE)
CD-00015	DOSE NOT CHANGED

For clarity, you could modify the labels as follows:

Subject ID	Action Taken
CD-00015	DOSE NOT CHANGED

- To change the label, select the default label and change it.
- Click **OK**. On the **Edit Definition** page, the name of the domain containing the variable appears in parentheses after the variable name. If you chose a numeric value, you can click **View Column Statistics** to [view a histogram](#) showing the distribution of values for the variable in the study data.
- Optionally click **Save** to save your report definition so far.

Saving/Running a Report Definition

If you have made changes to a report definition since the last time it was saved:

- You can click **Save** to save the report definition without running it. If you are working on a complex report definition, you may want to click **Save** periodically. The Edit Definition page remains open so that you can continue working on the report definition.

Note: If you are editing a report definition that you did not create, the **Save** button is not available.

- You can click **Save As** to save the report definition with a different name, without running it. Then [name the new report definition](#). The Edit Definition page remains open so that you can continue working on the report definition.
- For a valid report definition, you can click **Save & Run** to save the report definition and run it. A report is considered valid if it includes at least one row variable and one column variable, and there are no error messages for the report definition.

If you have not made changes to a report definition since it was last saved:

- You can click **Save As** to save the report definition with a different name, without running it. Then name the new report definition. The Edit Definition page remains open so that you can continue working on the report definition.

- For a valid report definition, you can click **Run** to run the report definition. A report is considered valid if it includes at least one row variable and one column variable, and there are no error messages for the report definition.

Error messages

An error message appears if any of the following are true:

- You have not specified breakdown details for a column breakdown variable that has more than 10 values. (If there are 10 or fewer values, they are used automatically as distinct values for the breakdown variable.)
- You have specified breakdown details for an analysis variable.
- In a SQL Where clause for the report definition, one of the variables referenced by the Where clause has been removed from the report definition.
- You specified breakdown details as grouped values, but there is at least one group that includes no values.

Creating a Findings Report

A Findings Report uses a selection page that capitalizes on the standard structure of data in the CDISC SDTM Findings general class. It is available for each domain defined by CDISC as a Findings Domain, for example, Laboratory Tests. The Findings Report is intended to provide quick access to predefined formats of data; typically, the output of a Findings Report is not saved.

To create a Findings Report:

1. Do one of the following:
 - On the Study Data Domains page, click  in the Listings column for a Findings domain and then click **Findings Report**.

Or

- On the Report Definitions page, click **Findings Report** or **Last Findings Report**.

The **Findings Report** page appears.

2. If you are creating the Findings Report from the **Report Definitions** page, provide a report name and description.
3. If you are creating a Findings Report from the **Report Definitions** page, select a domain. Available domains are those with the __TESTCD variable as the topic variable; usually these refer to general clinical observations like lab test results, vital signs, or questionnaire responses.

If you are creating a Findings Report from the **Domains** tab, the domain is displayed and is not modifiable.

4. Specify variables for the report. (If you clicked **Last Findings Report**, the settings for the most recent Findings Report that you created from the **Report Definitions** page appear during your current session, and you can change the settings as needed.) Next to variable fields, you can click **Select** to select variables for the Findings Report.

Timing variables group the data by time.

Topic variables describe the data topics, such as lab test names, to be included in the report. The report offers the option of selecting groups of tests together using the ___CAT and ___SCAT variables provided in the CDISC standard.

Qualifier, record qualifier, and demographic variables further describe the data in the report.

5. Select a report type, which determines the degree of report summarization. The options are:
 - **One row per subject x visit x ...** —The report will include one row for each unique combination of subject and visit.
 - **One row per subject, columns grouped by visit**—The report will include one row per subject, with columns grouped according to visit.
 - **One row per subject, columns grouped by test**—The report will include one row per subject, with the columns grouped by test.
6. Click **Apply**. The report definition appears on the **Edit Definition** page.
7. Edit the report definition further if needed and [save or run the report](#).

Specifying Variable Breakdowns

Defining Breakdown Details

Breakdown details are the specification of values for a [breakdown variable](#). If a breakdown variable is a text or date variable, you can define breakdown details using individual selected values, distinct values, or grouped values. If a breakdown variable is a numeric variable, you define breakdown details using cutpoints.

In the following example, the breakdown values for Visit are BASELINE, POST STUDY, SCREENING, and STUDY VISIT:

Arm	Visit			
	BASELINE	POST STUDY	SCREENING	STUDY VISIT
	Subjects	Subjects	Subjects	Subjects
	N	N	N	N
TREATMENT A 15.0 MG/15.0 MG	238	234	578	1638
TREATMENT A 15.0 MG/PLACEBO	210	210	528	1462
TREATMENT A 7.5 MG/7.5 MG	336	326	816	2296
TREATMENT A 7.5 MG/PLACEBO	224	220	553	1532

Note that if there are 10 or fewer values for a column breakdown value, they are used by default as distinct values for the breakdown variable. For a row variable, all values are used by default as distinct values for the breakdown variable. You can modify these default breakdowns as needed.

Report performance with breakdown details

The performance of a report with breakdown details can depend on whether the analysis variable that you use comes from the same source table as the row variables. If the analysis variable is from the same table as the row variables, the performance of a report definition with breakdown details is much faster; this may be important when you are working with a sizeable subject list (5,000 subjects or more). The speed difference is several orders of magnitude. When possible, select the analysis variable from the same table as the row variables.

All column

For a breakdown variable, you can include a category for All values. The All column is *not* based on values for other columns in the report. For example, if the report shows counts, the All column is not a total of counts for the other columns.

In the following example, the same subject may have PTs in both the Card SOC and Other SOC:

SOC				
	Card	Other	Null	All
Sex	Subjects	Subjects	Subjects	Subjects
	N (U)	N (U)	N (U)	N (U)
F	5000	11000	0	12000
M	6000	13000	0	16500

The N (U) value for the All column and F row is *not* 5000 + 11000. The value in the All column is:

4000 who have a PT in the Card SOC and a PT in other SOC
+ 1000 who have a PT in the Card SOC only

+ 7000 (computed as 11000—4000) who have a PT in any SOC's except Card
12000

To specify breakdown details:

1. On the **Edit Definition** page, select a breakdown variable and click **Select** next to Breakdown Details. The Breakdown Details window appears.
2. For a text or date variable, you can do any of the following:
 - [Define breakdown details by all distinct values](#). The report will include a column or row for every distinct (unique) value of the variable. This option uses the values available at the time you run the report, not at the time you define it. As a result, each time you run a report that has this option selected, it will include any new data values that have been added to the source data.
 - [Define breakdown details by individual values](#). The report will include a column or row for every value that you select. This option results in a static list of breakdown values that does not automatically adjust to changing source data.
 - [Define breakdown details by grouped values](#). The report will include a column or row for every group that you define.

For a numeric variable, you can [define breakdown detail by cutpoints](#). The exception to this is the VISITNUM variable, which behaves like a text variable even if it is numeric. This option uses the values available at the time you run the report, not at the time you define it.

Defining Breakdown by Distinct Values

If you click Every Distinct Value on the [Breakdown Details window](#), the report includes a column or row for every distinct (unique) value of the variable. This option uses the values available at the time you run the report, not at the time you define the report.

This type of breakdown is useful if you expect to be running the report definition for other studies.

- If you define breakdown by individual values, those values might not be present in the other studies.
- If you define breakdown by distinct values, the report definition will use the distinct values present in the other studies automatically.

To define breakdown by distinct values:

1. In the Breakdown Details window, click **Every Distinct Value**.
2. Optionally select **Include a category for ALL selected values**. A column or row is included in the report to represent all values for the variable (including null values if **Include a category for Null values** is checked). For reports that display percentages, the report must include a row or column for **All**.
3. Optionally select **Include a category for Null values** to include a column or row to represent null (missing) values for the variable.

The following example shows a report that includes a column for each distinct (unique) value of Country:

Sex	Country				
	CAN	MEX	USA	NULL	All
	Subjects	Subjects	Subjects	Subjects	Subjects
	N	N	N	N	N
F	191	0	967	55	1213
M	106	2	1594	49	1751
All	297	2	2561	104	2964

In this example, the **All** row shows the number of subjects with any of the Sex values for each Country. The All column shows the number of subjects with any of the Country values for each Sex. Also, the NULL column shows the number of subjects with no Country value for each Sex.

Note: See [Specifying Content Details](#) for information on the behavior of the All row when unique counts are shown for column variables.

Defining Breakdown by Individual Values

If you click Individual Values on the [Breakdown Details window](#), the report includes a column or row for every value that you select. This option results in a static list of breakdown values that does not automatically adjust to changing study data.

To define breakdown by individual values:

1. In the Breakdown Details window, click **Individual Values**.
2. Select values for the variable; see [Selecting Entries from a List](#). You can use up and down arrows for selected entries to order them as you want them to appear in the report.
3. For the **Breakdown values order** field:
 - To sort the values in ascending order, click **Sorted**.
 - To show values in the order in which they appear in the Selected Values list, click **Listed order**.
4. Optionally select **Include a category for Null values** to include a column or row to represent null (missing) values for the variable.
5. Optionally select **Include a category for ALL selected values** if there are values in the **Selected Values** list. A column or row is included in the report to represent all selected values for the variable (including null values if **Include a category for Null values** is selected). For reports that display percentages, the report must include a row or column for All.

- Optionally select Include a category for all deselected values to include a column or row for values that are not represented by any other columns.
- Click **OK**. The **Edit Definition** page shows the selected values. You may want to click **Save** to save your report definition so far.
- To [edit value labels](#) for breakdown values, click **Edit Labels** in the **Breakdown Details** section. The **Edit Labels** page appears.

The following example shows a report in which eight different AE terms were selected:

Sex	AE Term							
	ALLERGIES	ASTHMA	ASTHMA ATTACK	ASTHMA EXACERBATION	SINUS CONGESTION	SORE THROAT	STREPTOCOCCAL THROAT INFECTION	TONSILLITIS
	Subjects	Subjects	Subjects	Subjects	Subjects	Subjects	Subjects	Subjects
	1	1	1	1	1	1	1	1
F	1	0	0	0	4	2	1	1
M	0	2	6	1	0	4	0	0

In the following example, the All row shows the number of subjects with any of the Sex values for each AE term. The All column shows the number of subjects with any of the AE Term values for each Sex.

Sex	AE Term								
	ALLERGIES	ASTHMA	ASTHMA ATTACK	ASTHMA EXACERBATION	SINUS CONGESTION	SORE THROAT	STREPTOCOCCAL THROAT INFECTION	TONSILLITIS	All
	Subjects	Subjects	Subjects	Subjects	Subjects	Subjects	Subjects	Subjects	Subjects
	1	1	1	1	1	1	1	1	1
F	1	0	0	0	4	2	1	1	9
M	0	2	6	1	0	4	0	0	13
All	1	2	6	1	4	6	1	1	22

Note: See [Specifying Content Details](#) for information on the behavior of the All row when unique counts are shown for column variables.

In the following example, the NULL column shows the number of subjects with no AE Term for each Sex:

Sex	AE Term									
	ALLERGIES	ASTHMA	ASTHMA ATTACK	ASTHMA EXACERBATION	SINUS CONGESTION	SORE THROAT	STREPTOCOCCAL THROAT INFECTION	TONSILLITIS	NULL	All
	Subjects	Subjects	Subjects	Subjects	Subjects	Subjects	Subjects	Subjects	Subjects	Subjects
	1	1	1	1	1	1	1	1	1	1
F	1	0	0	0	4	2	1	1	3	12
M	0	2	6	1	0	4	0	0	5	18
All	1	2	6	1	4	6	1	1	8	30

In the following example, all adverse events terms that are not in any of the eight selected AE terms are represented by the Other column:

Sex	AE Term										
	ALLERGIES	ASTHMA	ASTHMA ATTACK	ASTHMA EXACERBATION	SINUS CONGESTION	SORE THROAT	STREPTOCOCCAL THROAT INFECTION	TONSILLITIS	NULL	All	Other
	Subjects	Subjects	Subjects	Subjects	Subjects	Subjects	Subjects	Subjects	Subjects	Subjects	Subjects
	1	2	3	4	5	6	7	8	9	10	11
F	1	0	0	0	4	2	1	1	3	12	114
M	0	2	5	1	0	4	0	0	5	18	202
All	1	2	5	1	4	6	1	1	8	30	316

Editing Individual Value Labels

If you define breakdown details using individual values, the default labels for values are the exact values from the source data. You can modify the labels that appears in the report. Editing the labels has no effect on the actual source data.

To edit value labels:

1. On the [Edit Definition page](#), click **Edit Labels** in the **Breakdown Details** section. The Edit Labels window appears. Each value that you have selected appears in the Value column.
2. In the **Label** field for any of the values, type in a different label.
3. Click **OK**. The modified labels are shown on the **Edit Definition** page.

Defining Breakdown by Grouped Values

If you click Grouped Values in the [Breakdown Details window](#), the report includes a column or row for every group that you define. This option results in a static list of breakdown values that does not automatically adjust to changing source data.

To define breakdown by grouped values:

1. In the Breakdown Details window, click **Grouped Values**.
2. Next to the Groups field, click **New**. A message asks for the new group's name.
3. Enter a name for the new group and click **OK**.
4. In the **All Values** list, select one or more values to include in the group. See [Selecting Entries from a List](#) for information on searching or selecting values.
5. For the **Breakdown values order** field:
 - Click **Sorted** to sort the groups in ascending order.
 - Click **Listed** order to show groups in the order in which they appear in the Groups list.
6. Create other groups and select values to be included in them. Ensure that each group includes at least one value.
7. To rename or delete groups, click **Rename** or **Delete** next to the groups.

8. Optionally select **Include a category for Null values** to include a column or row to represent null (missing) values for the variable.
9. Optionally select **Include a category for ALL selected values** if there are values in the Selected Values list. A column or row is included in the report to represent all selected values for the variable (including null values if Include a category for Null values is checked). For reports that display percentages, the report must include a row or column for **All**.
10. Optionally select Include a category for all deselected values to include a column or row for values that are not in any of the groups.
11. Click **OK**. The **Edit Definition** page shows the groups. You may want to click **Save** to save your report definition so far.

Note: You cannot save the report definition if all groups have no values in them. If some groups are empty, the report definition is saved and the empty groups are ignored.

Defining Breakdown by Cutpoints

If you are [defining breakdown details](#) for a numeric variable, you must define cutpoints. To define cutpoints, you specify ranges of numbers by indicating their boundaries. This option uses the values available at the time you run the report, not at the time you define it.

With the numeric variable highlighted on the Edit Definition page, you can click **View Column Statistics** to [view a histogram](#) of variable values.

To define cutpoints:

1. In the Breakdown Details window, in the first value field (after **VALUE <=**), enter the maximum value for the first category. Also, enter a label.
2. In the next row, in the **Value** field, enter the maximum value for the second category. (The cutpoint values must be in ascending order.) Also, enter a label.
3. Continue defining categories until you are ready to define the last category.
4. For the last category, enter only a label. (Do not enter a value.) This is the label for all values greater than the previous cutpoint. For example:

	Value	Label
	VALUE <= 18	18 or younger
18	< VALUE <= 65	19 through 65
65	< VALUE	over 65

5. Optionally select **Include a category for Null values** to include a column or row to represent null values for the variable.
6. Optionally select **Include a category for ALL selected values** if there are values in the Selected Values list. A column or row is included in the report to represent all values for the variable (including null values if **Include a category for Null values** is

selected). For reports that display percentages, the report must include a row or column for **All**.

- Click **Save**. The **Edit Definition** page shows the selected values. You may want to click **Save** to save your report definition so far.

Viewing Column Statistics (in report definition)

On the Edit Definition page, if you highlight a numeric variable, you can click **View Column Statistics** to view a histogram showing the distribution of values for the variable. A *histogram* is a graph of grouped (binned) data showing frequency distribution. The x-axis represents values from the study data and the y-axis represents counts of subjects. A shaded rectangular block in the graph represents each bin; a bin is a range of x-axis values. The top of each block indicates the count of subjects for the bin.

The following information is also provided, based on values of the variable for the study:

- Minimum – Minimum value.
- Maximum – Maximum value.
- Distinct Values – Number of distinct values.
- Total Values – Total number of values.
- Average – Average value.
- Standard Deviation – Standard deviation of values.
- Variance – Variance of values.

If you rest on a block in the histogram, the following information appears:

- The range of x-axis values for the bin
- The cumulative count of subject IDs with that range of values
- The cumulative percentage of subject IDs with that range of values

Specifying Content Details

Content details specify the aggregation method for the values of an [analysis variable](#), that is, the aggregation method for its values. For example, you may want to show an actual value, a count of records that have a value, a percentage of records that have the value, and so on. You can specify multiple aggregation methods for an analysis variable.

When you add an analysis variable to a report, **Value** appears by default as the aggregation method:

	USUBJID (in AE)
SEX (in AE)	Value

Value stands for **First value**. When you change the aggregation method, an abbreviation for the aggregation method that you select appears in the table cell. For example, if you select Count as the aggregation method, N displays in the table cell:

	USUBJID (in AE)
SEX (in AE)	N

You can choose one or multiple aggregation method for a variable.

The aggregation methods that you can select for an analysis variable include counts and unique counts. If you choose both of these aggregation methods for a variable that is unique in the selected table, the count and unique count will be the same. If the variable is not unique in the selected table, the count and unique count may differ. For example, demographics data typically includes only one record for each subject ID, so the count and unique count would be the same. Adverse events data often includes multiple records for each subject ID, so the count and unique count would differ.

To specify content details for an analysis variable:

1. Highlight the aggregation method (not the column heading) for the analysis variable. For example, highlight **Value** in the above example.
2. Click **Select** next to **Content Details**. The Content Details window appears.
3. Optionally select one or more aggregation methods and click **OK**. Available aggregation methods depend on the data type of a variable.

Aggregation methods for text or date variables

For an analysis variable with a data type of text or date, select one or more of the following check boxes. The abbreviation appears in the report column heading and on the Edit Definition page.

Check box	Abbreviation	Definition
Count	N	The number of non-NULL values.
Count (Unique)	N (U)	<p>The number of unique non-NULL values.</p> <p>For source database tables in which each record has a unique value, the Count and Count (Unique) values are the same. For example, a demographics table typically includes one record for each subject ID, so the Count and Count (Unique) of the subject ID are the same.</p> <p>For source database tables in which multiple records may have the same value, the Count and Count (Unique) may differ. For example, an adverse events table may have multiple records for each subject ID, so the Count and Count (Unique) of the subject ID may differ.</p>
Row %	Row %	Count of non-unique values for the row and column/Count of non-unique values for the row for all columns. (There must be a column for All.)

Column %	Col %	Count of non-unique values for the column and row/Count of non-unique values for the column for all rows. (There must be a row for All.)
Overall %	%	Count of non-unique values for the column and row/Count of non-unique values for all columns and all rows. (There must be a column for All and a row for All.)
Row % (Unique)	Row % (U)	Count of unique values for the row and column/Count of unique values for the row for all columns. (There must be a column for All.)
Column % (Unique)	Col % (U)	Count of unique values for the column and row/Count of unique values for the column for all rows. (There must be a row for All.)
Overall % (Unique)	% (U)	Count of unique values for the column and row/Count of unique values for all columns and all rows. (There must be a column for All and a row for All.)
All values	ALL	All values, including null values, separated by commas. Null values are shown as blanks, so you may see a list of values like "DrugA, , DrugC".
All values and counts	ALL (N)	All values including null values, separated by commas; after each value is the count of the value. Null values are represented in the list by the string "null".
All values (excluding NULLs)	All	All values except null values, separated by commas.
All values and counts (Excluding NULLs)	All (N)	All values except null values, separated by commas; after each value is the count of the value.
First value	Value	First non-NULL value from the database (for the subject list being used). If you do not specify an aggregation method, this method is used by default.

Aggregation methods for numeric variables

For an analysis variable with a data type of number, check one or more of the following check boxes. The abbreviation appears in the report column heading and on the Edit Definition page.

Option	Abbreviation	Definition
Count	N	The number of non-NULL values.
Count (Unique)	N (U)	The number of unique non-NULL values.
Row %	Row %	Count of non-unique values for the row and column/Count of non-unique values for the row for all columns. (There must be a column for All.)
Column %	Col %	Count of non-unique values for the column and row/Count of non-unique values for the column for all

		rows. (There must be a row for All.)
Overall %	%	Count of non-unique values for the column and row/Count of non-unique values for all columns and all rows. (There must be a column for All and a row for All.)
Row % (Unique)	Row % (U)	Count of unique values for the row and column/Count of unique values for the row for all columns. (There must be a column for All.)
Column % (Unique)	Col % (U)	Count of unique values for the column and row/Count of unique values for the column for all rows. (There must be a row for All.)
Overall % (Unique)	% (U)	Count of unique values for the column and row/Count of unique values for all columns and all rows. (There must be a column for All and a row for All.)
All values	ALL	All values including null values, separated by commas. Null values are shown as blanks, so you may see a list of values like 60, , 105 .
All values and counts	ALL (N)	All values including null values, separated by commas; after each value is the count of the value. Null values are represented in the list by the string null .
All values, excluding NULLS	All	All values except null values, separated by commas.
All values and counts, Excluding NULLS	All (N)	All values except null values, separated by commas; after each value is the count of the value.
Sum	Sum	The sum of the values.
Mean	Mean	The mean of the values.
Median	Median	The median of the values.
Standard Deviation	SD	The standard deviation of the values.
1st Quartile	Q1	The first quartile of the values.
3rd Quartile	Q3	The third quartile of the values.
Min	Min	The minimum value.
Max	Max	The maximum value.

For example, suppose that a report includes counts like this:

	Severity			
	Mild	Mod	Severe	All
	Subject	Subject	Subject	Subject
Male	200	300	500	1000
Female	100	600	700	1400
All	300	900	1200	2400

If you replaced the counts in the report with row, column, and overall percentages, the report display would change to this:

	Severity											
	Mild			Mod			Severe			All		
	Subject			Subject			Subject			Subject		
	Row %	Col%	%	Row%	Col%	%	Row%	Col%	%	Row%	Col%	%
Male	200/1000	200/300	200/2400	300/1000	300/900	300/2400	500/1000	500/1200	500/2400	1000/1000	1000/2400	1000/2400
Female	100/1400	100/300	100/2400	600/1400	600/900	600/2400	700/1400	700/1200	700/2400	1400/1400	1400/2400	1400/2400
All	300/2400	300/300	300/2400	900/2400	900/900	900/2400	1200/2400	1200/1200	1200/2400	2400/2400	2400/2400	2400/2400

Previewing a Report

When creating or editing a report definition, you can click **Preview** on the [Edit Definition page](#) to check that the report definition is set up as you want it before you save or run the report. A portion of the report is displayed. The preview is intended as an aid in testing the report format, and not as a reliable way to view data without running the report definition.

You can preview only a valid report definition. A report definition is valid if it includes at least one row variable and one column variable, and there are no errors for report variables.

Using XML to Create a Report Definition

A report definition is stored as XML (eXtensible Markup Language). Its XML representation can be sent to other users, who can create a new report using the XML.

To create a report using XML:

1. Obtain the XML that you want to use. You can copy it from your e-mail if another user sent you the XML of a report definition via e-mail. (See [Emailing Report Definition XML](#).) You can also click the Report Descriptors radio button on the [Edit Definition page](#) and then copy the text from the XML field. (Do not attempt to use the XML that appears when you click **View XML Representation** on the Edit Report Attributes page.)

Note: If you are copying XML from e-mail, copy only the XML (not information about the report). The XML begins below the line **XML Definition**.

2. On the **Report Definitions** page, click **Create Definition from XML**. The Create from XML page appears.
3. Provide the name, category, and XML as described below. The values that you specify appear on the Reports tab, where users can sort by them. For example, you can group reports into categories; then users of the Reports tab can sort by category so that all reports of that category are listed together.

Column	Description
Name (required)	Name of the report.
Description	Description of the report.
Category	Category containing the report. By default, this value is Ad Hoc. You

<i>(required)</i>	can modify the category as needed.
Creator	Cannot be modified. Name of the user who created the report.
Data	Cannot be modified. Description of the source data. If you are creating a report from XML that you have pasted in to the XML Definition field, you must provide a value for this field in order for the report to appear on the Reports page.
Status	Under Development , indicating that the report is not ready to be run until you have saved it.

- In the XML Definition field, paste in the copied XML.

XML Definition:

```
<?xml version="1.0" encoding="UTF-8"?>
<CompositeTable Version="2.0b1" Account="S_LTISAMP1"
Name="Sample">
  <RowDefs>
    <BreakdownSequence>
      <VariableGroup>
        <Variable ID="1" Type="Data" DataType="VARCHAR2"
Label="CMDECOD">
          <Source Table="RAW_CM" Column="CMDECOD"
DataType="VARCHAR2" ConfigurationVariable="CMDECOD (in CM)" />
          <Expansion Type="Discrete" SpecialType="All" />
        </Variable>
      </VariableGroup>
    </BreakdownSequence>
  </RowDefs>
  <ColumnDefs>
    <BreakdownSequence>
      <VariableGroup>
        <Variable ID="2" Type="Data" DataType="VARCHAR2"
Label="ARMCD">
```

- Click **Save**.
- To assign the new report definition to a project, edit the report definition to provide a project name on the Report Descriptors page.

Specifying Report Attributes/Descriptors

Editing Report Attributes

To edit attributes of a report definition as a whole, including supplying a SQL Where clause, click **Report Attributes** on the [Edit Definition page](#).

☐ Column Attributes ☒ **Report Attributes** ☐ Report Descriptors

To edit report attributes:

- By default, you can [drill down](#) on counts of subjects in a report or elements of graphs based on the reports. To disable drilldown for the report, click **Generate drilldown Information** and click **No** in the window that appears. Even if this attribute is set to **No**, you can still drill down to subject details by clicking a subject ID that appears as a row variable in a report.

2. To restrict the report to a subset of data that meets a specified condition, such as AGE > 18 AND AGE < 65, click **Restrict by SQL Where Clause**. The Restrict by [SQL Where Clause page](#) appears. Only data that meets the condition that you specify will be included in the report.
3. To view the XML (eXtensible Markup Language) representation for a report definition, click **View XML Representation**. Do *not* attempt to copy and reuse this representation of the XML to [create a report definition using XML](#).
4. You can [edit column attributes](#), [edit report descriptors](#), or [save or run the report definition](#).

Specifying Report Restrictions

You can restrict a report to a subset of data that meets a specified condition by using a SQL Where clause. For example, you might want the report to include only Males who reside in the United States and are between 18 and 55 years old.

Note: A report restriction is applied, if specified, after the report is generated and before the report is displayed.

To specify a report restriction:

1. On the Edit Definition page, click Report Attributes.
2. Click **Restrict by SQL WHERE Clause**. The Restrict by SQL WHERE Clause page appears.
3. Next to the SQL WHERE Clause field, click **Show columns**. The Select Table Columns window appears.
4. Click the name of the column that you want to include in the Where clause. Note the column type, so that you know what syntax is valid for that column in the Where clause.

The column you selected appears in the SQL Where Clause field in square brackets. (The square brackets are required.) The Select Table Columns page remains open, so that you can select other columns.

5. In the SQL Where clause field, complete the SQL condition. You might, for example, select the AGE column (placing AGE into the field), and then specify **>=65** to restrict the report to subjects that are at least 65.

As another example, if you want to omit displaying rows that contain all zeroes in an aggregate report, supply a SQL Where clause of the form {columnVar1} + {columnVar2} + ... + {columnVarN} > 0. To omit rows where all column values are null, supply a clause of the form {columnVar1} is not null or {columnVar2} is not null or

You must enter a valid SQL Where clause using only supported syntax. For information on supported syntax, see [Specifying a SQL WHERE Clause](#).

6. Click **Apply**. The Edit Definition page appears, showing the SQL Where clause.

If there are errors in the SQL syntax, an error message will appear when you try to run the report.

Editing Report Descriptors

1. On the Edit Definition page, click **Report Descriptors**.

☐ Column Attributes ☐ Report Attributes ☒ Report Descriptors

2. View or modify the following information. You can change only the Name, Description, and Category.




Field	Description
Name of Report	Name of the report definition.
Description of Report	Description of the report definition.
Category	<p>Category containing the report definition. The options are:</p> <ul style="list-style-type: none"> • Ad Hoc • Standard <p>Typically, Standard reports are intended for publication to other users.</p>
Built-in	<p>Available for Superusers only. Intended for use by Oracle when creating built-in report definitions, which are predefined reports supplied with WebSDM/Empirica Study and available if the appropriate configuration has been set up during installation. For more information see Running a Built-In Report.</p> <p>Note: The category of a built-in report is Standard and should not be changed.</p>
Add to existing project Add to a new project named	<p>Optionally assign the run to a different project.</p> <ul style="list-style-type: none"> • To assign the report to an existing project, click Add to existing project and select from a list of projects that you created or that are published to you. • To create a new project and assign the report to it, click Add to a new project named and enter a project name.
Status	<ul style="list-style-type: none"> • Ready if the report definition can be run, that is, the report definition is valid. A report definition is considered valid if it has at least one row variable, at least one column variable, and none of the variables are shown in <i>italicized red</i>. • Under Development if the report definition is not ready



to be run.

Configuration	Description of the source data of the report definition.
XML	XML representing the report definition. You can copy and paste this XML to create a report using XML .



3. Click **Save**.

Running a Report

1. Do one of the following:
 - On the **Edit Definition** page, click **Save & Run** or **Run**. See [Saving or Running a Report Definition](#).
 - On the [Report Definitions page](#), optionally [select a subject list](#). Click the Action menu icon () for the report definition and then click **Run Report**. If you do not select a subject list, the report is run against all subjects in the study.
 - You can [drill down](#) on a count or graph element elsewhere in WebSDM/Empirica Study to run a report definition against subjects included in the count or represented by the graph element.
 - On the **Domains** tab, [run a built-in report](#)
2. If the report includes a count (N) of subjects that is a hyperlink, you can click the hyperlink to display a menu from which you can [drill down](#). If specific subject IDs appear in the report as a hyperlink, you can click a subject ID to view subject details.
3. You can sort a report by up to three columns of the report. The current sort order appears above the report. You can sort a column as follows:
 - Click  to sort in Ascending order.
 - Click  to sort in descending order.

When you click  or  to sort a column, that column is used for the primary sort order. The previous primary sort order (if any) becomes the secondary sort order. The previous secondary sort order (if any) becomes the tertiary sort order.

Note: In displayed reports, sorting is case-insensitive.

4. To specify how many rows should display at a time, enter a number in the Rows per Page field and press the **Enter** key. You can display up to 999 rows on each page.
5. To go to another page, you can do the following:
 - Click  to view the next page.
 - Click  to view the previous page.
 - Enter a number in the Page field and press the **Enter** key to view the specific page.

6. To find specific text on a page, you can select **Find** on the browser's (Internet Explorer's) **Edit** menu. For efficiency, you may want to set the **Rows per Page** to a large number before using the Find feature.
7. To show a **Notes** section below the report, click **Show Notes**. If you print the report while the **Notes** section is displayed, the report printout includes the **Notes** section.
8. If you have the Manage Reports permission, you can click **Edit Definition**. The Edit Report page appears and you modify the definition as needed.
9. To [save report output](#) so it can be viewed later, click **Save Output**.
10. To [choose a graph](#) to show data in the report, click **Choose Graph**. This option appears only if any graphs are available.
11. To create a new subject list containing subjects in the report, click **Create Subject List**. This option is available only if the report contains hyperlinked subject IDs in the first column.
12. To [print the table](#) (that is, the report), click **Print**.
13. To [download report data](#), click **Download**. The column names will be created from the labels in the report definition, followed by the breakdown specifications.

Notes section of report

The Notes section includes the following information:

Field	Description
Output Name	Always Not yet saved .
Definition Name	Name of the report definition.
Description	Description of the report definition.
Where Clause	SQL restriction Where clause, if any, used in the report definition.
Breakdowns	Details for grouped values breakdowns, if any, used in the report definition.
Subject List Name	For a report run against a selected subject list: Name of the subject list for which the report definition was run. The number of subjects in the subject list appears in square brackets after the subject list name. For a report run from the popup drilldown menu: (None)
Subject List Description	Description of the subject list, if any, for which the report definition was run.
Data Source	Name of the application and study for which the report definition was run.
Event Hierarchy	Name of the adverse event coding dictionary (typically MedDRA and its version number), if any, for the study shown as the Data Source.
Drug Hierarchy	Reserved for future use.
User	Name of the user running the report.

Date Date and time at the report was run.

Running a Built-In Report


WebSDM/Empirica Study is delivered with a set of built-in report definitions, which require only that the SAMP1_312 study has been loaded. The installation instructions describe how to load the following sample studies:

- SAMP1_312 uses SDTM 3.1.2
- SAMP1_311 uses SDTM 3.1.1
- SAMP1 uses SDTM 3.1


Regardless of which SDTM version you use, the SAMP1_312 study must be loaded for you to use the built-in report definitions. When you load the study, you **MUST** name it **SAMP1_312**, and you must create it in the **LTI** application.

Only a Superuser can create or edit built-in reports. Depending on their permissions, other users may be able to create a new report by saving a built-in report with a different name.

To run a built-in report definition:

- On the [Study Data Domains page](#), when you click the Action menu icon () for a domain that has built-in reports, the built-in report definitions are listed in a menu and you can select one of them to run. The report is run against all subjects in that domain.

Or

- Click the Action menu icon () for the report definition on the [Report Definitions page](#), and then click **Run Report**. The report is run against the selected subject list or, if no subject list is selected, against all subjects in the study.

See [Running a Report](#) for general instructions.

WebSDM/Empirica Study is delivered with the following built-in report definitions:

Domain	Report Name	Report Description
AE	Summary by TERM and BODYSYS	For each combination of an adverse event body system and adverse event MedDRA Preferred Term, provides the count of subjects for each arm of the study.
CM	Summary by Decode	For each combination of concomitant medication (using standardized medication names), CMOCCUR value, and CMSTAT value, provides the count of subjects for each arm. Includes SQL Where clause for CMOCCUR and CMSTAT.
CM	Summary by Reported Name	For each combination of concomitant medication (using medication names as reported), CMOCCUR

		value, and CMSTAT value, provides the count of subjects for each arm. Includes SQL Where clause for CMOCCUR and CMSTAT.
DM	Demog Summary by ARM	For each arm, provides the following: subject count; mean and standard deviation of age; subject count by sex; and subject count by race.
EX	Summary by Total Exposure and ARM	For each arm, provides the subject count, median, minimum, and maximum for each exposure, using the derived variable DMDOSDY_ (Day taking study therapy) in the DM domain.
IE	Summary of Exceptions	For each inclusion/exclusion criterion, shows the unique count of subject by arm.
MH	Summary by Preferred Term	For each combination of a medical history MedDRA Preferred Term, medical history body system, MHOCCUR value, and MHSTAT value, provides the count of subjects. Includes SQL Where clause for MHOCCUR and MHSTAT.
MH	Summary by Reported Term	For each combination of a medical history reported term, medical history body system, MHOCCUR value, and MHSTAT value, provides the count of subjects. Includes SQL Where clause for MHOCCUR and MHSTAT.
SC	Subject Characteristics Listing	For each combination of subject, grouping qualifier, and characteristic, provides the characteristic result (the value of the SCSTRESC variable) and the datetime it was collected (the value of the SCDTC variable).
SU	Substance Use by Substance	For each combination of a substance, SUOCCUR value, and SUSTAT value, shows a unique subject count. Includes SQL Where clause for SUOCCUR and SUSTAT.
SU	Substance Use Listing	For each combination of subject, substance, substance category, SUOCCUR value, and SUSTAT value, provides descriptive information such as dosage and frequency. Includes SQL Where clause for SUOCCUR and SUSTAT.
VS	Vital Signs Horizontal	For each combination of subject and visit, provides the numerical result for each vital sign measurement.

Creating built-in report definitions

Only Superusers can create, edit, or delete built-in report definitions. For a built-in report definition:

- The report name must be prefaced by the two-letter name of the domain, followed by a colon.
- On the Report Descriptors page, the category must be Standard.

- On the Report Descriptors page, the **Built-in** check box must be checked. (This option is available only for Superusers.)

Saving Report Output

While viewing report output, you can save the output so that it can be viewed later without regenerating the report.

To save report output:


1. On the page displaying the report, click **Save Output**. The **Save Output** page appears.
2. Enter a name for the saved output. The name does not need to be unique, although Oracle recommends that you provide a unique and meaningful name.
3. Optionally enter a description of the saved output. Oracle recommends that you provide a description that will help differentiate the report output from others on the Report Outputs page.
4. Optionally enter a report description.
5. Optionally enter a category for the saved output.
6. Optionally assign the report output to a [project](#).
 - To assign the report output to an existing project, click **Add to existing project** and select a project from a list of projects that you have created or that other users have created for objects they have published.
 - To create a new project and assign the report output to it, click **Add to a new project named** and enter a project name.
7. Click **Save**. The report output is saved. Modification or deletion of the report definition does not affect the saved report output.

Note: The current sort order of a report is not saved as part of the report output.

Copying a Report Definition

If you cannot edit a report definition, you can copy it and modify it as needed.

To copy a report definition:


1. Select an application and study, and go to the **Reports** tab.
2. On the Report Definitions page, click the Action menu icon () for the report and then click **Copy**.
3. Enter a report name. The name does not need to be unique, although Oracle recommends that you provide a unique and meaningful name.

4. Optionally enter a report description. Oracle recommends that you provide a description that will help differentiate the report definition from others on the Report Definitions page.
5. Click **Save**.
6. If you want to assign the report definition to a project, edit the report definition to provide a project name on the Report Descriptors page.
7. [Edit](#) the copy of report definition as needed.

E-mailing Report Definition XML

A report definition is stored as XML (eXtensible Markup Language). If you send the XML definition of a report via e-mail, a user with appropriate permissions can [use that XML to create a new report definition](#). You can e-mail XML for report definitions that you have created or that have been published to your login group.

To e-mail the XML of report definition:

1. Select an application and study, and go to the **Reports** tab.
2. On the [Report Definitions](#) page, click the Action menu icon () for the report and then click **Email**. The **E-Mail Definition** page appears.
3. In the **To** field, enter the e-mail address to which you want to send the XML definition. If a default e-mail address is associated with the currently selected application, it appears here and you can change it as needed.
4. In the **Subject** field, modify the subject as needed. The default subject is **Report: report-name**. You cannot modify the **From** or **Date** fields.
5. The text field shows information about the report followed by the XML definition. Do not change any of the information in the text field.
6. Click **Send**.

Viewing Report Outputs

Viewing Existing Report Outputs

When a report is run from the Report Definitions page, the output can be named and saved. The saved output appears on the Saved Output page and can be viewed without any need to rerun the report.

Note: Once a report output is saved, it remains available until it is explicitly deleted. Modification or deletion of the report definition on which the report was based does not affect the saved report output.


The Report Outputs page lists report definitions for the currently selected study. For the selected project, the Report Outputs page shows report outputs that you have created or that have been published to your login group.

To view existing report outputs:

1. Select an application and study, go to the Reports tab, and click **Report Outputs**.
2. In the Project field, select the [project](#) for which you want to view report outputs. Available projects are those that you created, as well as those that other users associated with objects they published. If "--" is in the Project field, report outputs for all available projects appear.
3. The Report Outputs page provides a table of the following information about each report output:

Column	Description
Output	Name of the saved output.
Description	Description of the saved output.
Project	Name of the project with which the report output is associated.
Configuration	Name of the configuration on which the report definition that generated the report output is based. A configuration is a detailed specification that makes source data available in WebSDM/Empirica Study. A configuration name is in the format application-name_study-name_CONFIG.
Subject List	Name of the subject list, if any, on which the report definition used by the output is based. The report was run against only subjects in that subject list. If blank, the report was run on all subjects.
Created By	Name of the user who saved the report output.
Created	Date and time at which the report output was saved.
Category	Category of the report, if specified by the report creator.
Definition	Name of the report definition that generated the report output.

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

4. If you click  for a report output, you can do the following:
 - To [view the report output](#), click **View Report Output**.
 - To [edit attributes of a report output](#), click **Edit**.
 - To [publish a report output](#), click **Publish**.
 - To delete a report output, click **Delete** and, at the prompt asking if you want to delete the report output, click **OK**.




Viewing a Report Output



When interpreting the information in a report, you may want to view help topics on:

- [Specifying Column Attributes](#)



- [Defining Breakdown Details](#)
- [Specifying Content Details](#)
- [Specifying Report Restrictions](#)

To view a report output:

1. Do one of the following:
 - On the [Report Outputs page](#), click  for the report output and then click **View Report Output**.
 - You can [drill down](#) on a count or graph element elsewhere in WebSDM/Empirica Study to run a report definition against subjects included in the count or represented by the graph element.
 - On the Domains tab, [run a built-in report](#)
2. If the report includes a count (N) of subjects that is a hyperlink, you can click the hyperlink to display a menu from which you can [drill down](#). If specific subject IDs appear in the report as a hyperlink, you can click a subject ID to view subject details.
3. You can sort a report by up to three columns of the report. The current sort order appears above the report. You can sort a column as follows:
 - Click  to sort in Ascending order.
 - Click  to sort in descending order.

When you click  or  to sort a column, that column is used for the primary sort order. The previous primary sort order (if any) becomes the secondary sort order. The previous secondary sort order (if any) becomes the tertiary sort order.

Note: In displayed reports, sorting is case-insensitive.

4. To specify how many rows should display at a time, enter a number in the Rows per Page field and press the **Enter** key. You can display up to 999 rows on each page.
5. To go to another page, you can do the following:
 - Click  to view the next page.
 - Click  to view the previous page.
 - Enter a number in the Page field and press the **Enter** key to view the specific page.
6. To find specific text on a page, you can select Find on the browser's (Internet Explorer's) Edit menu. For efficiency, you may want to set the Rows per Page to a large number before using the Find feature.
7. To show a Notes section below the report, click **Show Notes**. If you print the report while the Notes section is displayed, the report printout includes the Notes section.

- To [choose a graph](#) to show data in the report, click **Choose Graph**.
- To [download report data](#), click **Download**. The column names will be created from the labels in the report definition, followed by the breakdown specifications.

Notes section of report


The Notes section includes the following information:

Output Name	Name of the saved report output.
Description	Description of the saved report output.
Saved By	Name of the user who saved the report output.
Saved Date	Date and time at which the report output was saved.
Definition Name	Name of the report definition that was run to produce the report output.
Where Clause	SQL restriction Where clause, if any, used in the report definition.
Breakdowns	Details for grouped values breakdowns, if any, used in the report definition.
Subject List Name	Name of the subject list, if any, for which the report definition was run.
Data Source	Name of the application and study for which the report was run.
Event Hierarchy	Name of the adverse event coding dictionary (typically MedDRA and its version number), if any, for the study shown as the Data Source.
Drug Hierarchy	Reserved for future use.
User	Name of the user viewing the report output.
Date	Date and time at which the report output was viewed.

Editing Attributes of a Report Output

You can edit the identifying attributes of a report output that you created.

To edit a report output:

- Select an application and study, go to the **Reports** tab, and click **Report Outputs**.
- On the **Report Outputs** page, click the Action menu icon () for the report and then click **Edit**. The **Edit Output** page appears.
- Modify the report name, description, or category.
- Click **Save**.

The following information also displays but you cannot modify it:

Column	Report
Data	Name of the study on which the output's associated subject list was based.
Subject List	Name of the subject list, if any, for which the report was run.
Report	Name of the report definition that was run to create the output.

Viewing Report Graphs

Choosing a Report Graph

When displaying a report or saved report output that includes multiple column variables, you have the option to view a graphical representation of the report data. When you click **Choose Graph** on the Display Report or the Display Output page, the Choose Graph page appears. Different graphs are available depending on the type of variables in the report, as follows:

Graph Type	Report Variables
Aggregate bar graph	All column variables or all column variables except one are numeric. The subject ID does not need to be in the report. Link name: Bar graph (where rows are aggregate values)
Detail bar graph	The row variable in the report is the subject ID. Link name: Bar graph (where rows are detail records)
Box plot	The row variable in the report is the subject ID. At least one column variable is numeric. Link name: Box plot (where rows are detail records)
Scatter plot	The row variable in the report is the subject ID. At least two column variables are numeric. Link name: Scatter plot (where rows are detail records)
Histogram	The row variable in the report is the subject ID. At least one column variable is numeric. Link name: Histogram (where rows are detail records)

Note: A numeric variable is one for which source data is numeric or a numeric value such as count or percentage is specified as content detail.

Aggregate Bar Graphs

About Aggregate Bar Graphs

In an aggregate bar graph:

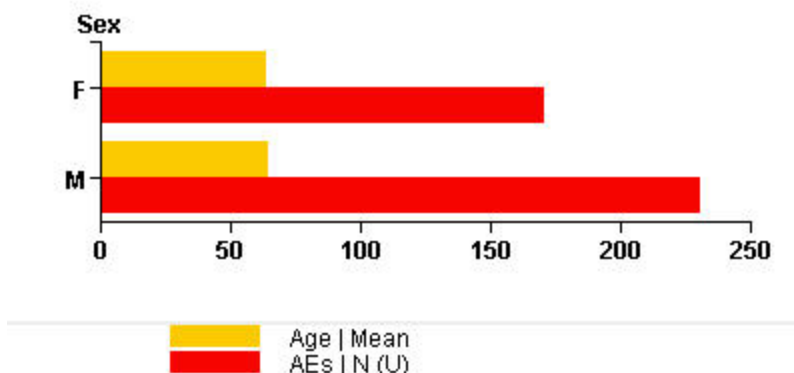
- The row variable of the report is represented on the y-axis.
- Each numeric column variable in the report is represented on the x-axis.

A key appears below the graph, indicating the values that the bars represent.

For example, suppose that a report includes the mean age and count of AEs for each sex:

SEX (in DM)	Age	AEs
	Mean	N (U)
F	64.6	171
M	65.11	231

Depending on the [display options](#) that you specify, the graph may look like this:



Related Topics

[Choosing a Report Graph](#)

[Working with Graphs](#)

[Viewing an Aggregate Bar Graph](#)

Viewing an Aggregate Bar Graph

For an overview of aggregate bar graphs, see [About Aggregate Bar Graphs](#).

To view an aggregate bar graph:

1. On the [Choose Graph page](#), click **Bar graph (where rows are aggregate values)**.
2. Enter X and Y labels to clarify what is represented by the axes.
3. Check "Show counts at the ends of bars" if the report shows subject counts and you want to show the subject counts at the ends of bars. If the report shows numeric values that are not subject counts and you check this option, the values are shown instead of counts.
4. Check "Transpose rows and columns" if you want to switch the roles of the rows and columns in displaying the graph.
5. Optionally check any other display options. See [Working with Graphs](#) for information about copying or printing a graph, and information about the following display options: Use gray-scale instead of colors; Pop-up; Key; Notes; and Links.

6. The Notes section is the same as for the report display. The Notes provide different information, depending on whether the report is displayed by [running a report](#) or [viewing a report output](#).
7. Click **Display**. The display options are used for only the current display of the graph.
8. If a bar represents subject counts, you can point to the bar to see the exact values represented by the bar.
9. If you click on a bar that represents subject counts, you can then [drill down](#) to subjects for the bar. If you are displaying multiple graphs on the same page, do not click any graph until all the graphs are displayed.

Detail Bar Graphs

About Detail Bar Graphs

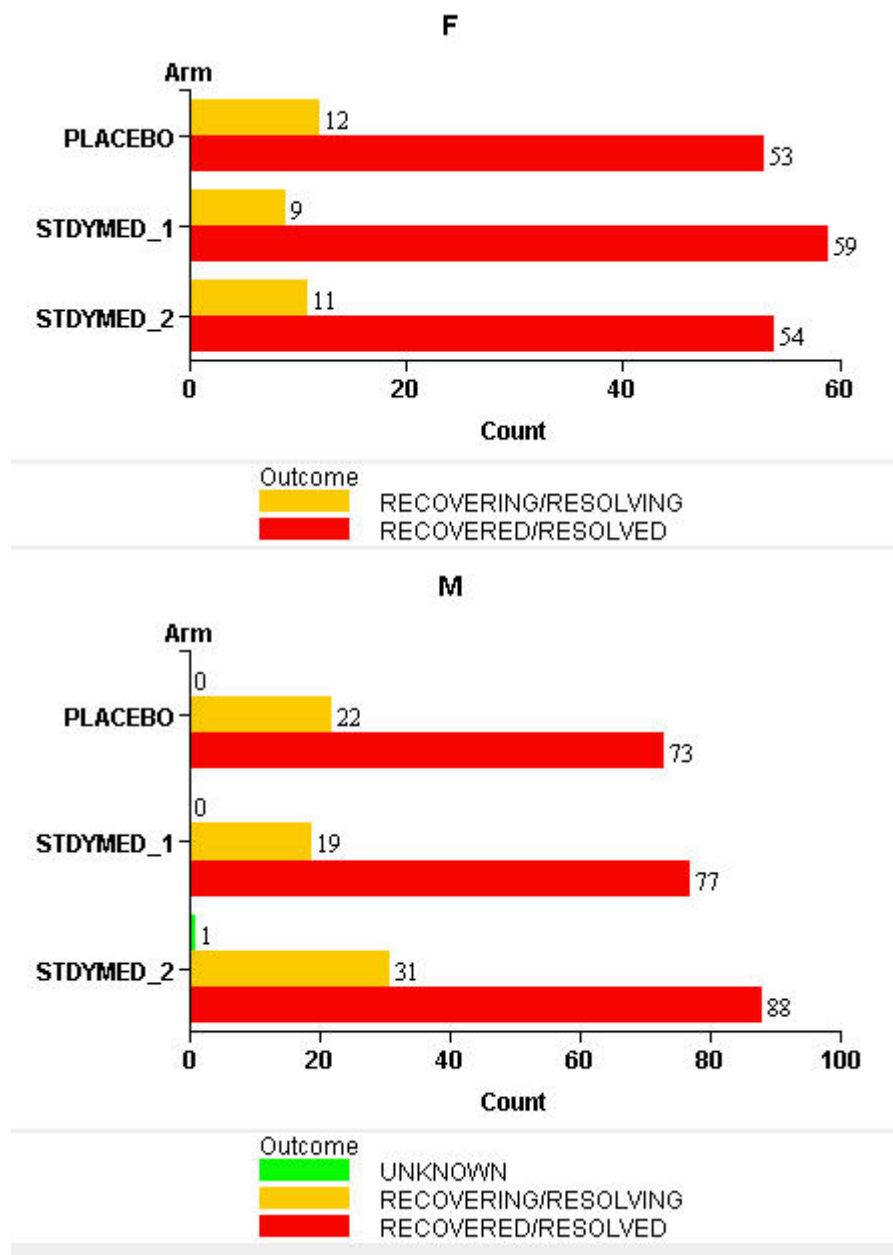
With a detail bar graph, you can choose which row variables and column variables of the report are represented by the y-axis, and subject counts are represented on the x-axis. There is a subject count for each primary variable that you select as a display option; you can break down the subject counts for the primary variable by specifying a secondary variable. If you specify a secondary variable, a key below the graph shows the meaning of each bar.

You can also create multiple graphs, one for each value of a row or column variable that you specify as a subset variable.

For example, suppose that a report shows sex, arm, and outcome for each subject ID:

USUBJID	Sex	Arm	Outcome
CD-09042	M	STDYMED_2	RECOVERING/ RESOLVING
CD-09051	M	PLACEBO	RECOVERED/ RESOLVED
CD-09055	M	STDYMED_1	RECOVERED/ RESOLVED
CD-09060	M	STDYMED_2	RECOVERED/ RESOLVED
CD-09069	M	STDYMED_2	RECOVERED/ RESOLVED
CD-09073	M	PLACEBO	RECOVERED/ RESOLVED
CD-09077	M	PLACEBO	RECOVERED/ RESOLVED

Depending on the [display options](#) that you specify, the graph may look like this, where sex is the subset variable, treatment arm is the primary variable, and outcome is the secondary variable:



Related Topics

[Choosing a Report Graph](#)

[Working with Graphs](#)

[Viewing a Detail Bar Graph](#)

Viewing a Detail Bar Graph

For an overview of detail bar graphs, see [About Detail Bar Graphs](#).

To view a detail bar graph:

1. On the [Choose Graph page](#), click **Bar graph (where rows are detail records)**. For this graph type to be available, the first column in the report must be subject ID.
2. Optionally select a subset variable. There will be one graph for each value of the subset variable.
3. Select a primary variable, which will be represented on the x-axis.
4. Optionally select a secondary variable. Each bar in the graph will represent a value of the secondary variable, as identified by the color key below the graph.
5. Optionally set the following display options:

Option	Description
Labels X and Y	Labels the x-axis and y-axis to clarify what is represented by the axes.
Show counts at the ends of bars	Specify whether to show subject counts at the end of bars in the graph. <ul style="list-style-type: none"> • If selected—Shows subject counts. • If deselected—Does not show subject counts.

6. Optionally select any other display options. See [Working with Graphs](#) for information about copying or printing a graph, and information about the following display options: Use gray-scale instead of colors; Popup; Key; Notes; and Links.

The Notes section is the same as for the report display. The Notes provide different information, depending on whether the report is displayed by [running a report](#) or [viewing a report output](#).

7. Click **Display**. The display options are used for only the current display of the graph.
8. To see the exact values represented by a bar in the graph, point to the bar.
9. If you click on a bar, you can then [drill down](#) to subjects for the bar. If you are displaying multiple graphs on the same page, do not click any graph until all the graphs are displayed.

Box Plots

About Report Box Plots

A box plot (also known as a box-and-whisker plot) is the plotting of data points against horizontal and vertical axes to show the distribution of a continuous variable. In a box plot:

- The box represents the middle 50% or so of the numeric values.
- A horizontal line within the rectangle represents the median of all values (that is, the value that is exactly in the middle of all values).
- The top end of the box represents the upper quartile (that is, the median of the ordered set of values that are greater than the overall median).

- The bottom end of the box represents the lower quartile (that is, the median of the ordered set of values that are less than the overall median).

The interquartile range, which is the difference between the upper quartile and the lower quartile, is a measure of the spread of the distribution. The relative distances of the upper and lower quartiles from the median describe the shape of the distribution of data.

Note: For information about how quartiles are computed, see [Box Plots](#).

In a box plot:

- The whisker above the box plot extends from the upper quartile to the highest actual value that is within the (75th percentile + 1.5 * (interquartile range)).
- The whisker below the box plot extends from the lower quartile to the lowest actual value that is within the (25th percentile—1.5 * (interquartile range)).
- Outliers are plotted as individual points in the graph. An outlier is considered to be a value that falls outside of the upper or lower whisker.

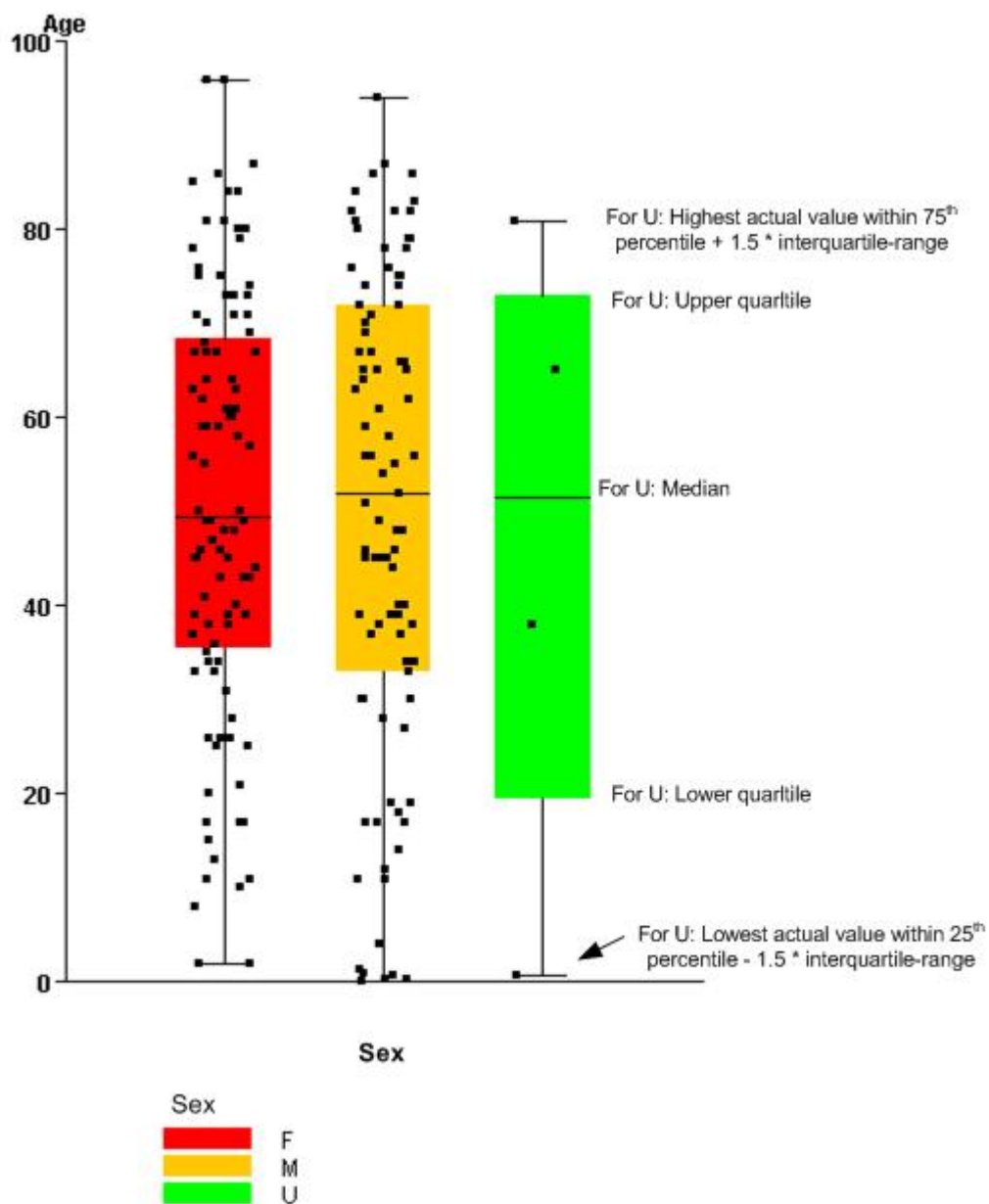
Note: Points in a box plot are jittered, or displayed at small random offsets from the center line. This ensures that if two records have the same value, a point is likely to be displayed for each of them.

Several box plots may be shown in a single graph if a secondary variable is selected. In that case, a key is provided below the box plot to relate the individual box plots to the values of the secondary variable.

For example, suppose that a report shows age and sex for each subject ID:

USUBJID (in DM) ▾	AGE (in DM) ▾	SEX (in DM) ▾
CD-00015	75	M
CD-00019	49	M
CD-00024	81	M
CD-00033	69	F

Depending on the [display options](#) that you specify, the graphs may look like this:



Related Topics

[Choosing a Report Graph](#)

[Working with Graphs](#)

[Viewing a Box Plot](#)

Viewing a Box Plot (for a report)

For an overview of box plots, see [About Box Plots](#).

To view a box plot:

1. On the [Choose Graph page](#), click **Box plot (where rows are detail records)**.
2. Optionally select a subset variable. There will be one box plot for each value of the subset variable.
3. Select a primary variable from the list of numeric variables in the report definition. Each point in the box plot will represent a value of the primary variable.
4. Optionally select a secondary variable from the list of all variables in the report definition. Each box will represent a value of the secondary variable, as identified by the color key below the box plot.
5. Optionally set the following display options:

Option	Description
Labels X and Y	Labels for the x-axis and y-axis.
Show all points as overlay	<p>Specify whether to show all points on the box plot.</p> <ul style="list-style-type: none"> • If selected—Shows all points. • If deselected—Shows only points outside the upper and lower whiskers. <hr/> <p>Note: Points in a box plot are jittered, so that if two records have the same value, a point is likely to be displayed for each of them.</p>

6. Optionally check any other display options. See [Working with Graphs](#) for information on copying or printing a graph, and information about the following display options: Use gray-scale instead of colors; Popup; Key; Notes; and Links.

The Notes section is the same as for the report display. The Notes provide different information, depending on whether the report is displayed by [running a report](#) or [viewing a report output](#).
7. Click **Display**. The display options are used for only the current display of the graph.
8. If you point to a region of the graph, the following information appears:
 - The region of the box (Upper Outlier, Upper Whisker, Upper Box, Lower Box, Lower Whisker, or Lower Outlier).
 - The value of the secondary variable, if any.
 - The count of data points for the primary variable (and secondary variable, if any) for that region of the box.

The count may be more than the number of subjects because there may be more than one data point for the same subject. For example, a subject may have multiple adverse events, where each adverse event is a separate data point.
9. If you click on a region (Upper Outlier, Upper Whisker, Upper Box, Lower Box, Lower Whisker, or Lower Outlier) of a box plot, you can then [drill down](#) to subjects for that

region. If you are displaying multiple graphs on the same page, do not click any graph until all the graphs are displayed.

If a subject has a value on the boundary between any regions (not including the Upper Outlier or Lower Outlier regions), the subject ID is included when you drill down on either of the regions. Subjects with values on the boundary of the Upper Whisker or Lower Whisker are not included when you drill down on the Upper Outlier or Lower Outlier regions.

Histograms

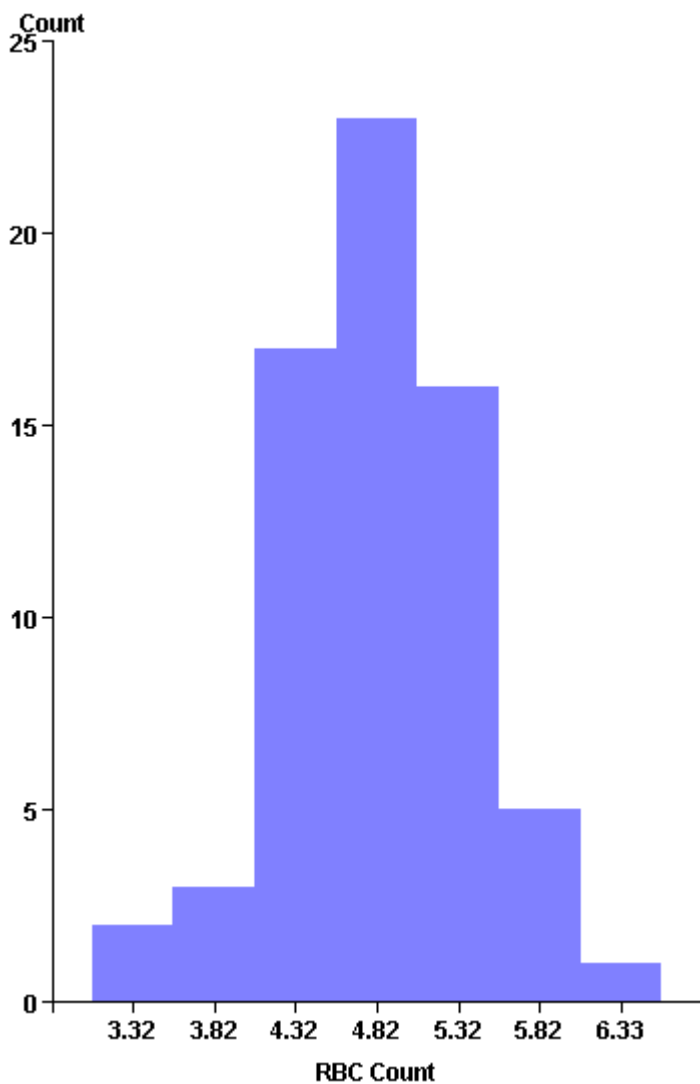
About Report Histograms

A histogram is a graph of grouped (binned) data showing frequency distribution. The x-axis represents values of a selected variable and the y-axis represents counts of subjects. A shaded rectangular block in the graph represents each bin; a bin is a range of x-axis values. The top of each block indicates the count of subjects for the bin.

For example, suppose that a report looks like this:

	LBTEST (in LB)	
	Red Blood Cell Count	White Blood Cell Count
▾ USUBJID (in LB) ▴	▾ LBSTRESN (in LB) ▴	▾ LBSTRESN (in LB) ▴
CD-00015	4.7775	9.8475
CD-00019	4.8175	6.6625
CD-00024	3.9	6.1425
CD-00033	3.315	7.1175
CD-00042	4.29	6.7275

Depending on the [display options](#) that you specify, the graph may look like this:



Related Topics

[Choosing a Report Graph](#)

[Working with Graphs](#)

[Viewing a Histogram](#)

Viewing a Histogram (for a report)

For an overview of histograms, see [About Histograms](#).

To view a histogram:

1. On the [Choose Graph page](#), click **Histogram (where rows are detail records)**.
2. Optionally select a subset variable. There will be one histogram for each value of the subset variable.

3. Select a histogram variable from the list of numeric variables in the report definition. Each point in the histogram will represent a value of the primary variable.
4. Enter X and Y labels to clarify what is represented by the axes.
5. Enter the number of bins (up to 100) to include in the histogram. A shaded rectangular block in the graph represents each bin; a bin is a range of x-axis values.
6. Optionally check any other display options. See [Working with Graphs](#) for information about copying or printing a graph, and information about the following display options: Use gray-scale instead of colors; Popup; Key; Notes; and Link.

The Notes section is the same as for the report display. The Notes provide different information, depending on whether the report is displayed by [running a report](#) or [viewing a report output](#).

7. Click **Display**. The display options are used for only the current display of the graph.
8. If you point to a block, the following information appears:
 - The range of x-axis values for the bin
 - The count of subjects for the histogram variable for that bin
9. If you click on a block of the graph, you can then [drill down](#) to subjects for that region. If you are displaying multiple graphs on the same page, do not click any graph until all the graphs are displayed.

Note: If a subject has a value that is on the boundary between two blocks, the subject ID is included when you drill down on either of the regions.

Scatter Plots

About Report Scatter Plots

A scatter plot is the plotting of data points against horizontal and vertical axes to show the correlation between two or more continuous variables. You select a variable to plot against the x-axis of the scatter plot, and one or two variables to plot against the y-axis.

For scatter plots, you can:

- Select a variable by which to subset data. For example, you might want to view a different scatter plot for each treatment arm.
- Specify an inner breakdown variable to use a color key to associate each dot on the graph with a particular value. For example, if you want to know the particular subject ID associated with each dot, you can use the subject ID as the inner breakdown variable.

Note that:

- No data point is plotted for a record if either the X variable or the Y variable is empty.

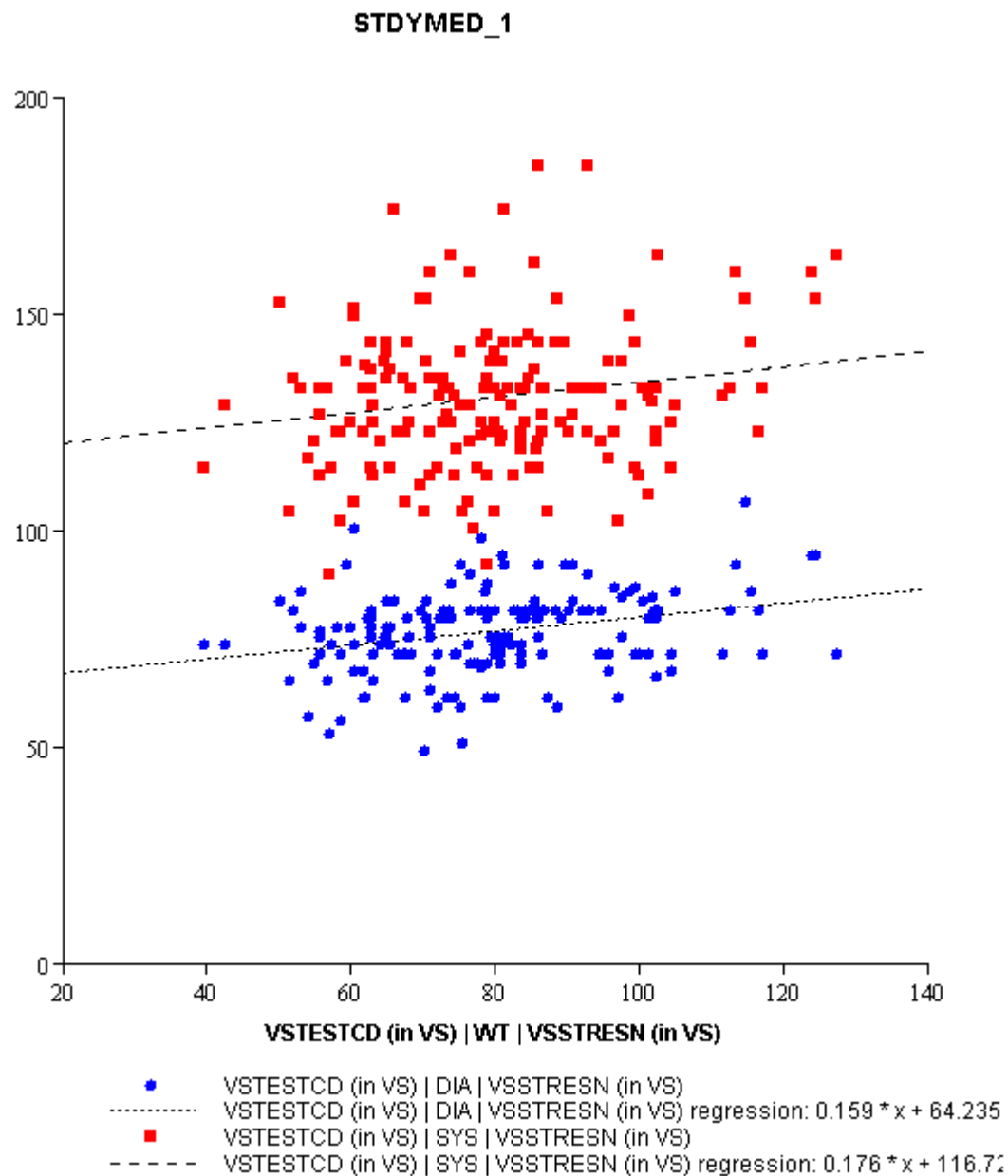
- If you select two y-axis variables, each of them uses a different shape, as shown in the color key below the scatter plot.
- If the X and Y values for one record coincide with the X and Y values for another record, the two data points are plotted in the same position. It is not possible to distinguish whether that data point represents one record or several records.

The color key below the scatter plot indicates the value of the inner breakdown variable that each dot represents.

For example, suppose that a report shows arm, sex, and vital sign measurements for each subject ID:

USUBJID	Arm	Sex	VSTESTCD (in VS)				
			DIA	HT	PUL	SYS	WT
			VSSTRESN (in VS)	VSSTRESN (in VS)	VSSTRESN (in VS)	VSSTRESN (in VS)	VSSTRESN (in VS)
CD-00015	STDYMED_2	M	67.275	161.85	65.325	135.525	61.9125
CD-00019	STDYMED_1	M	68.675	172.2	88.15	121.975	78.105
CD-00024	PLACEBO	M	63.375	153.66	92.625	113.1	57.915

Depending on the [display options](#) that you specify, the graph may look like this:



Related Topics

[Choosing a Report Graph](#)

[Working with Graphs](#)

[Viewing a Scatter Plot](#)

Viewing a Scatter Plot (for a report)

For an overview of scatter plots, see [About Scatter Plots](#).

To view a scatter plot:

1. On the [Choose Graph page](#), click **Scatter plot**.
2. Optionally select a subset variable. There will be one scatter plot for each value of the subset variable.
3. Select an X variable, that is, a numeric variable to be plotted against the x-axis.
4. Select a Y variable, that is, a numeric variable to be plotted against the y-axis.
5. Optionally select another Y variable. Each of the two Y variables will be plotted against the y-axis. Each Y variable corresponds to a different-shaped point, as shown in the key below the scatter plot.
6. Optionally select a text variable as an inner breakdown variable. The color key will associate each point on the scatter plot with a particular value of the inner breakdown variable.
7. Optionally set the following display options:

Option	Description
Labels X and Y	Label the x-axis and y-axis to clarify what is represented by the axes.
Include linear regression lines	Include a linear regression line to help identify trends in the data.
Include 45-degree line and matched axes	Include a 45-degree line in the scatter plot; useful if you are plotting two similar variables and you are interested in the differences.

8. Optionally check any other display options. See [Working with Graphs](#) for information about copying or printing a graph, and information about the following display options: Use gray-scale instead of colors; Popup; Key; Notes; and Links.

The Notes section is the same as for the report display. The Notes provide different information, depending on whether the report is displayed by [running a report](#) or [viewing a report output](#).
9. Click **Display**. The display options are used for only the current display of the graph.
10. To [drill down](#) to subject information, point to the graph, click, and hold down the mouse button while you draw a red rectangle around the data points for which you want to drill down. When you release the mouse button, a menu appears and you can drill down. Note that a single point in the graph may represent several data points.

Note: If you are displaying multiple graphs on the same page, do not try to drill down until all the graphs are displayed.

Preparing Study Data

Managing Applications/Studies

About Applications and Studies

The first step in preparing study data for use in WebSDM/Empirica Study is to register an application. An application is a group of studies, which may be different studies, or multiple versions of the same study. For example, an application may be a group of studies that is part of a regulatory submission. A study is clinical trial data about subjects being treated with an investigational drug; an application may include multiple studies.

When you register an application, you specify the directory containing the source data for that application's studies. When you register a study, you specify the directory containing that study's source data and/or metadata relative to the application directory. If the application directory and study directories conform to certain structures, you have the option to register selected studies automatically when you register the application. You always have the option to register studies manually. For more information, see [Directory Structure for Applications and Studies](#).

When you have registered a study, you must [load and check](#) the clinical data for the study before you can review it in WebSDM/Empirica Study. You load clinical data from SAS transport files (.xpt files) that you provide, or from an Oracle source identified to WebSDM by a DB link. WebSDM/Empirica Study checks the data according to predefined rules (validation checks) that evaluate compliance with the CDISC Study Data Tabulation Model (SDTM).

A study pool is a group of studies from which data is pooled. Only studies for which data has been loaded and checked can be included in a study pool. Study pools cannot be registered automatically. You register a study pool by selecting loaded and checked studies to include in the pool. You then load the study pool to combine the data from the component studies. Clinical data for a study pool is treated as if it occurred in a single study. Domain data for the combination of studies is displayed for the study pool, and screening analysis statistical computations are performed on the combined data.

The steps in preparing study data are:

1. If the data source is SAS Transport files, place SAS .xpt files in the study subdirectory.
2. **Register application.**
Creates an Oracle account for the application.
3. **Register study.**
Creates an Oracle account for the study.
Generates a [define.xml](#) file, unless you specify an existing one in the study subdirectory.
4. **Load study.**
Loads study data into the Oracle account for the study.
If the data source is Oracle Health Sciences [InForm](#) or Oracle Life Sciences Data Hub, the load process extracts the study data from Oracle tables or views, and loads that

data into WebSDM's Oracle database.

If the data source is SAS transport files, the load process extracts the study data from these files and loads that data into WebSDM's Oracle database.

5. **Register study pool.**

Creates an Oracle account for the study pool.

6. **Load study pool.**

Combines study data from the Oracle accounts for component studies and loads it into the Oracle account for the study pool.

Directory Structure for Applications and Studies

When you register an application, you specify the "application directory" to serve as parent directory for studies in that application. A site option must be set to indicate a root directory (on the WebSDM/Empirica Study server) for all application directories. The application directory path that you specify is relative to that root directory.

Similarly, when you register a study, you specify a "study directory" whose path is relative to the application directory. Each study has its own subdirectory within the application directory. When you load a study, its metadata is obtained from a define.xml file in the study subdirectory. In addition, if the study's data source type is SAS transport files, then the study's data is also obtained from the study subdirectory.

You can create new application and study directories for Oracle-based data sources from within WebSDM/Empirica Study. That is, the directories do not need to exist before you register a new application or a new study whose data source type is Oracle-based. For a study whose data source type is SAS transport files, however, the study directory must exist before you register the study, and the study's data files must be placed in that directory before you load the study.

Regardless of a study's data source type, it is required to identify a study directory that will store certain files such as study metadata. Metadata is specified in a CDISC Case Report Tabulation Data Definition Specification (define.xml file). When you register a study, you can either:

- Generate a define.xml file whose content is guided by the data source files, tables, or views, and that will be placed in the study directory.
- Use your own define.xml file that you have placed manually in the study directory.

During application registration, you have the option to register studies for that application automatically if the structure of the application directory conforms to the following electronic submission standard directory structures:

Standard eNDA directory structure

\<application-name>

\crt

\datasets

\<study-name>

Contains define.xml. For SAS transport-based studies, contains files for each domain and supplemental qualifiers.

Standard eCTD directory structure

\<application-name>	
\0000	Initial submission; next submission is labeled 0001, and so on.
\m5	
\datasets	
\<study-name>	
\tabulations	Contains define.xml. For SAS transport-based studies, contains files for each domain and supplemental qualifiers.

Related Topics

[Selecting a Directory](#)

Managing Applications

Viewing Registered Applications

1. Go to the Setup tab. The Applications page provides the following information about each application.


Note: If you are on another page on the Setup tab, you can return to the Applications page by clicking **Applications**.

Column	Description
ID	Automatically assigned unique identifier of the application.
Name	User-specified name of the application.
# Studies/Pools	<p>Number of studies and study pools that have been registered for the application. The count is a hyperlink that you can click to go to the Studies and Study Pools page.</p> <p>Note: Depending on your permissions and on whether studies or pools have been published, this number may be greater than the number of studies or pools that you see listed on the page.</p>
Description	User-specified description of the application.
Created	Date and time at which the application was registered.
Modified	Date and time at which the application was last updated. (The date and time changes each time you click Save during editing, regardless of whether or not changes were made.)
Default Codelists in Metadata	<p>This option determines the default value of the Metadata field for studies in the application if there are no define.xml files or multiple define.xml files in the study directory. One of the following:</p> <ul style="list-style-type: none"> • Standard codelists – Create a new define.xml file that includes a standard, CDISC-compliant codelist for each variable that is subject to SDTM controlled terminology. See Codelists for more information.

- **Standard and data-driven codelists** – Create a new define.xml that includes: 1) for each variable subject to SDTM controlled terminology, a standard, CDISC-compliant codelist and 2) for each variable subject to sponsor-defined controlled terminology, a codelist containing all unique non-null values from the study data for that variable. See [Codelists](#) for more information.

Drug Name	User-specified name of the drug associated with the submission.
Oracle Account	Name of the Oracle account representing the application; assigned automatically when the application was registered. The Oracle account for the application is not used by the current version of WebSDM/Empirica Study and is reserved for future use.
Owner	Name of the user who registered the application.
Path	File system path, on the WebSDM/Empirica Study server, to the location of the application folder, which contains the study data. See Directory Structure for Applications and Studies for more information about directory structure.
Sponsor	User-specified name of the sponsor organization.

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

2. To [register an application](#), click **Register Application**.
3. If you click  for an application, you can do the following:
 - To [edit an application](#), click **Edit**.
 - To set up or modify [Event Lists](#) or [Test Identifiers](#), click **Manage Properties>Event Lists**, or **Manage Properties>Test Identifiers**. For more information on properties, see [About Properties](#).
 - To [load selected studies or study pools](#) in the application, click **Load**.
 - To [delete an application](#), click **Delete**. Only a *Superuser* can delete an application. If screening results or issue clusters for studies in the application are attached to any potential signals, the application cannot be deleted.

Registering an Application

For information about editing an already-registered application, see [Editing/Deleting an Application](#).

To register an application:

1. Ensure that the application directory exists on the WebSDM/Empirica Study server.
2. On the [Applications page](#), click **Register Application**. The Register Application page appears.

3. Provide the following information. Much of the information on this page appears on the **Select** page from which users select an application. Required fields are highlighted in yellow.

Field	Description
Sponsor	Name of the sponsor organization for the application. If a sponsor name is specified as a site option , that default appears here; if it is also set up as overrideable, you can change it.
Name	Name of the application. REQUIRED
Description	Description of the application.
FDA review division	FDA review division responsible for the application.
Application number	FDA application number associated with the application (that is, the submission).
Default e-mail address	Email address to be used by default as the To address when the XML definition of a subject list or report created for this application is emailed. The sender can change the default value to a different email address.
Application type	Type of regulatory document with which the clinical data is associated (for example, NDA or IND).
Drug name	Name of the drug associated with the submission.
Submission type	Version of the clinical data that is part of the submission (for example, Original Application or Amendment).
Document ID	Reference ID from an external system.
Path	File system path, on the WebSDM/Empirica Study server, to the location of the application directory. Click Browse next to this field to navigate through the directory structure (up to the root directory specified as a site option) and select a directory . REQUIRED For more information, see Directory Structure for Applications and Studies .
Default codelists in metadata	Determines the default value of the Metadata field for studies in the application if there are no define.xml files or multiple define.xml files in the study directory. REQUIRED The options are: <ul style="list-style-type: none"> • Standard Codelists—Create a new define.xml file that includes a standard, CDISC-compliant codelist for each variable that is subject to SDTM controlled terminology. For more information, see Codelists. • Standard and Data-Driven Codelists—Create a new define.xml that includes: 1) for each variable subject to SDTM controlled terminology, a standard, CDISC-compliant codelist and 2) for each variable subject to sponsor-defined controlled terminology, a codelist containing all unique non-null values from the study data

for that variable. For more information, see [Codelists](#).

Default MedDRA account	Name of the Oracle account containing MedDRA data to be associated by default with studies that are registered subsequently for the application. You can change this value for each study. REQUIRED
Default SDTM version	Select a version of CDISC Study Data Tabulation Model to be associated by default with studies that are registered subsequently for the application. For example, sdm312 indicates Version 3.1.2. REQUIRED

4. If you are registering a new application, click **OK**. If you are editing an existing application, click **Save**.

For a new application, if the structure of the application directory conforms to the structure described in [Directory Structure for Applications and Studies](#), the Auto-Register Studies page appears. For each study, select one of the following:

- **Defer study registration**—If you choose this option, you will need to [register the study](#) later manually. This is the default if there are multiple define.xml files in the study directory.
- **Generate a new metadata file with standard codelists**—Create a new define.xml file (named in the format **define_YYYYMMDDhhmmss.xml**) that includes, for each variable that is subject to CDISC controlled terminology, a standard CDISC-compliant codelist. See [Codelists](#) for more information.
- **Generate a new metadata file with standard and data-driven codelists**—Create a new define.xml (named in the format **define_YYYYMMDDhhmmss.xml**) that includes: 1) for each variable subject to CDISC controlled terminology, a standard, CDISC-compliant codelist and 2) for each variable subject to sponsor-defined controlled terminology, a codelist containing all unique non-null values from the study data for that variable. For more information, see [Codelists](#).
- **Use Define.xml**—Available if the study directory (indicated in the Data location field) contains one or more files named like *define*.xml. There may be multiple define.xml files.

Note: If there is only one define.xml in the study directory, that file is the default in this field. If there are no define.xml files in the study directory, the default in this field is determined by the application's setting for Default codelists in metadata.

Then click **OK**.

When you register an application, the following occurs:

- An Oracle account is created for the application and an Oracle account is created for each study (if any) that you registered automatically; the account names and passwords are based on the application name or the study names.
- The application is available on the Select tab. However, studies in the application cannot be selected until they have been loaded.

Note: Study pools cannot be registered automatically.


5. Oracle recommends that you check the [test identifiers](#) for the newly registered application and any newly registered studies. If global-level test identifiers exist, a copy of them is associated with the application and they can be modified for the application. If application-level identifiers exist, a copy of them is associated with newly registered studies and they can be modified for the studies.

Editing/Deleting an Application


The following restrictions apply to deleting an application:

- Only a Superuser can delete an application.
- You cannot delete an application that is currently selected (on the Select tab) by you or another user. If you have the application selected yourself, the message that appears gives you the option to click **OK** to de-select the application.
- If screening results or issue clusters for studies in the application are attached to any potential signals, you cannot delete the application.
- The **Delete** option is not available if your database administrator has not granted the DROP_USER permission to the WebSDM master account. For more information, see the **Setting Up the Oracle tablespaces and master account** section in the *WebSDM/Empirica Study Windows 2003/2008 Server Installation and Upgrade Instructions*.

To edit an application:

1. On the [Applications page](#), click the Action menu icon () for the application and then click **Edit**. The **Register Application** page appears and you can change any information except the Path field.
2. Click **Save**.

To delete an application:

1. On the [Applications page](#), click the Action menu icon () for the application and then click **Delete**. If there are screening results or issue clusters (or their component issues) for the study, a message informs you. If you continue, the results and issue clusters will be deleted.

If screening results or issue clusters for studies in the application are attached to any potential signals, you cannot delete the application.

2. For the confirmation message that appears, click **OK** if you are sure you want to continue with deletion. All studies in the application will also be deleted. For more information, see [Editing/Deleting a Study](#) and [Editing/Deleting a Study Pool](#).

When you delete an application, the following occurs:

- All studies and study pools associated with the application are deleted. For the effects of study deletion, see [Editing or Deleting a Study](#).

- The application and associated studies are no longer available for selection on the Select tab.
- The Oracle accounts for the application and all studies for the application are deleted from the database. You can register the application again if the source files are still in appropriate locations on the WebSDM/Empirica Study server.
- The application tablespace is deleted (if applications each have their own tablespace, as determined by a site option.)

Note: If WebSDM/Empirica Study cannot remove all the datafiles associated with the Oracle tablespace for the application and its studies, a warning message appears. In this case, the datafiles listed by the warning message need to be deleted manually from the server. If a datafile is not deleted and a new application is later created with the same name as that of the deleted application, an error message redisplay the names of the datafiles that must be deleted.

- Custom analysis types for which the visibility is the application, a study within the application, or Hidden are deleted.
- Custom analysis types for which the visibility is Global but that were created for this application are deleted if they are not referenced by analysis specifications for other applications. If they are so referenced, they are retained but they are no longer associated with the application. (The Application column on the **Custom Screening Analysis Types** page is empty.)
- Any potential signals associated with the application are deleted.

Managing Studies/Pools

Viewing Registered Studies/Pools

1. On the Setup tab, click **Studies/Pools**. Alternatively, click the hyperlinked number in the "# Studies/Pool" column for an application on the Applications page. The Studies and Study Pools page provides the following information about each study or study pool in the selected application:

Column	Description
ID	Automatically assigned unique identifier of the study or pool.
Name	User-specified name of the study or pool.
State	<p>Stage of the loading and checking process; assigned automatically as each stage of the loading and checking process is completed. Possible values are:</p> <ul style="list-style-type: none"> • Not Loaded – The study or pool has been registered but has not been loaded or checked. • Initialized – The loading process has started. • Data Loaded—Not Checked – The loading process has completed, but structure and consistency checks have not been run yet.

- Awaiting Reload – The loading process has completed, but a reload is required because of subsequent changes to the study or pool.
- Data Structure Checks Run – Clinical data has been checked against the define.xml and metadata rules.
- Within-Domain Checks Run – Clinical data is checked against the define.xml and within-domain rules.
- Cross-Domain Checks Run – Clinical data is checked against the define.xml and cross-domain rules.
- Ready to Use – The study or pool is ready to use.


Note: For study pools, there are no metadata structure checks or cross-domain checks, although these steps of the load and check process are performed.

The status of a study is related to loading and checking, and does not provide information about whether properties have been defined for a study or pool. Thus, a status or pool with the status "Ready to Use" may still require the defining of properties before it can be used for certain activities.

Description	User-specified description of the study or pool. Note: A study that is registered automatically is given the description "Study <study-name> for Application <application-name>"; you can modify the description by editing the study.
Standard	Version of CDISC Study Data Tabulation Model associated with the study. For example, "sdm312" indicates Version 3.1.2. For studies, this property is specified by the user. For pools, this property is assigned automatically when the pool is saved; it corresponds to the latest of the SDTM versions associated with the studies that are included in the pool.
MedDRA Account	Name of the Oracle account containing the MedDRA dictionary used by the study. For studies, this property is specified by the user. For pools, this property is assigned automatically when the pool is saved; it corresponds to the latest of the MedDRA dictionaries used by studies that are included in the pool.
Created	Date and time at which the study or pool was registered.
Modified	Date and time at which the study or pool was last modified.
Data Location	Applies to studies only. User-specified name of the study directory relative to the application directory. See Directory Structure for Applications and Studies for more information.
Metadata Location	Applies to studies only. User-specified location of the define.xml file for the study.
Type	"Study" for a study or "Pool" for a study pool.

Application	Name of the application to which the study or pool belongs.
Check Variable Labels	<p>Applies to studies only. One of the following values:</p> <ul style="list-style-type: none"> • yes – A rule will check whether the variable descriptions in the define.xml file match the standard variable description according to the SDTM version for the study. If any descriptions do not match, a checking result is reported on the Study Data Domains page of the Domains tab. • no – Variable descriptions will not be checked against the SDTM. • N/A – The option does not apply. The option can be set for only studies that use SDTM Version 3.1.1 or 3.1.2.
Indication	Applies to pools only. User-specified study group, if any, for the pool.
Oracle Account	Name of the Oracle account containing the clinical data and metadata for the study or pool; assigned automatically when the study or pool was registered.
Owner	Name of the user who registered the study or study pool.

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

- In the Application field, you can select another application for which you want to view studies and pools. You can click **Browse** to select from a descriptive list of applications.
- To [register a study](#), click **Register Study**.
- To [register a study pool](#), click **Register Study Pool**.
- To [load studies and study pools](#) for the application selected on the page, click **Load Studies/Pools**.
- If you click  for a study or pool, you can do the following:
 - To [edit the study](#) or [edit the study pool](#), click **Edit**.
 - For a study or pool that has been loaded and checked, click **Manage Properties** to set up or modify:
 - [Category Breakdowns](#)
 - [Time Frames](#)
 - [Event Lists](#)
 - [Test Identifiers](#)
 - [Flag Variables](#)
 - [Study Visit Descriptions](#)

For more information on properties, see [About Properties](#).

- To [load the study or study pool](#), click **Load**.
- To [publish](#) a study or pool so that it can be viewed by other users, click **Publish**. You can publish a study or pool if you are its owner or you have the *Manage Applications and Studies* permission. Also note that you can publish the study or pool to multiple login groups. A published study or study pool appears on the Select tab although it cannot be selected until the study (or all studies in the pool) has been loaded and checked. Note that publication affects only the study or pool's availability on the Select tab; it does not affect the Setup tab.
- To [delete a study](#), click **Delete**. In order to delete a study a pool, you must either be its owner or have the *Delete Studies* permission.
- To [delete a study pool](#), click **Delete**. In order to delete a pool, you must either be its owner or have the *Delete Studies* permission.

You cannot edit, load, or delete a study or pool for which screening results or issue clusters are attached to a potential signal.

Note that you cannot perform certain actions if the study or pool is currently selected (on the Select tab) by you or another user. If you have the study or pool selected yourself, the message that appears gives you the option to click **OK** to de-select the study or pool, so you do not have to navigate to the Select tab.

Registering a Study

When you register an application that has been set up according to the eCTD or eNDA directory structure specifications (see [Directory Structure for Applications and Studies](#)), you can register studies automatically. If you defer the registration, you must register each study manually. You can also add a new study to a previously registered application at any time by registering the study manually.

For information about editing an already-registered study, see [Editing/Deleting a Study](#).

ODM versions

A generated define.xml file uses the CDISC Operational Data Model (ODM) Version 1.2.1. If you provide your own define.xml file, it can use ODM Version 1.2.1 or 1.3.

To register a study:

1. On the [Studies and Study Pools page](#), click **Register Study**. The **Register Study** page appears.

Note: Fields highlighted in yellow are REQUIRED.

2. Specify the following.

Note: If the study contains REFID values that are links to an external system, click **Show Details** next to the Reference ID Options field.

Field	Description
Name	Name of the study. If a study is registered automatically, the study name is the name of the study directory. REQUIRED
Description	Description of the study. If the study is registered automatically, it has the default description Study <study-name> for Application <application-name> . You can modify the default description.
SDTM version	Version of CDISC Study Data Tabulation Model associated with the study. For example, sdm312 indicates version 3.1.2. The default is the value of the application's SDTM version field. If a study is loaded with a define.xml that your organization provided and the file references an SDTM version, WebSDM/Empirica Study assigns that SDTM version to the study when the study is loaded and checked. This overrides the value specified in this field. REQUIRED
MedDRA account	<p>Name of the Oracle account containing MedDRA dictionary used by the study. The default is the value of the application's MedDRA account.</p> <p>If a study is loaded with a define.xml file that your organization provided and the AEDECOD variable's External Codelist element references a MedDRA version (account) that exists, WebSDM/Empirica Study assigns that MedDRA version to the study when the study is loaded and checked. This overrides the value specified in this field. REQUIRED</p> <p>Note: If your organization has supplied a define.xml file, you might want to view it before registering the study to determine the MedDRA version (if any) specified by the define.xml so that you can set this field to match. See the description of the Metadata field below for instructions on viewing the define.xml file.</p>
Indication	Indication, if any, associated with the study. If you will be pooling studies, this might be helpful to include.
Check variable labels against SDTM	<p>Available if you are using SDTM Version 3.1.1, 3.1.2, or 3.1.3.</p> <ul style="list-style-type: none"> • If selected—A rule will check whether the variable descriptions in the define.xml file match the standard variable description according to the SDTM version for the study. If any descriptions do not match, a checking result is reported on the Study Data Domains page of the Domains tab. • If deselected—The variable descriptions are not checked.
Reference ID Options	<p>The following options appear if you click Show Details.</p> <p>Reference ID variable—The options are:</p> <ul style="list-style-type: none"> • REFID – The value of __REFID variable from the study

data appears by default on the left of the [Subject Details page](#) for each relevant domain.

- **SPID** – The value of __SPID variable from the study data appears by default on the left of the Subject Details page for each relevant domain.

If the __REFID or __SPID variable contains a full and valid internet address in the study data, the Subject Details page displays a hyperlink that opens a new browser window pointing to that internet address.

Column header for 2nd level drilldown—Specify the column heading for the reference ID variable as you want it to appear on the Subject Details page (that is, second-level drilldown). If you leave this field blank, __REFID or __SPID will be used as the column heading.

Root for URLs—Root URL to be added as a prefix to all values of the __REFID or __SPID variable from the study data. This value is needed only if the study data contains only partial URLs for an external system, such as InForm.

Note: This option affects only the Subject Details page and tables accessed from that page. It does not affect the Clinical Data page.

Display content as—One of the following, indicating what will appear in the reference ID variable column (depending on your selection) on the Subject Details page if there is a __REFID or __SPID value in the study data:

- **Value in REFID/SPID column**—The value of __REFID or __SPID from the study data.
- **Image file**—The graphic from the specified file. Specify only the file name. The file must be located in the image subdirectory of the web_root directory that was established for the instance during installation. For standard installations, this is C:\Lincoln\apps*<instance-name>*\webapps\web_root\image.
- **Fixed label**—The specified text string.

Data source type	<p>Available only if the site option Allow data import from Oracle Health Sciences InForm or Allow data import from Oracle Life Sciences Data Hub is selected. The Data Source Details required to register a study vary depending on the data source type selected:</p> <ul style="list-style-type: none"> • SAS Transport Files – The study data is in .xpt files that are located in the specified data location. • Oracle Health Sciences InForm – The study data is
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from InForm, and is in an accessible Oracle database account.

- **Oracle Life Sciences Data Hub** – The study data is in an existing database account, mapped by a Business Area Schema, in an Oracle Life Sciences Data Hub instance.

When using Oracle views for InForm or Life Sciences Data Hub data, the efficiency of the views has a major impact on how long it will take to generate the define.xml.

Note: All data sources, regardless of type, must be formatted for SDTM compliance.

Data location	<p>Name of the study directory relative to the application directory. Click Browse to navigate to the application directory and select a directory. For more information, see Directory Structure for Applications and Studies.</p> <p>If there are any define.xml files in this location, they will be available to select in the Metadata field. If you generate a new define.xml file, it will be placed into this location.</p> <p>If the study's data source type is SAS transport files, you must place the *.xpt files in this location before loading the study. For information on loading a domain's data from multiple xpt files, see Split Domains.</p>
Metadata	<p>Specifies metadata generation method, or an existing metadata file. The options are:</p> <ul style="list-style-type: none"> • Generate a new metadata file with standard codelists—Create a new define.xml file that includes a standard CDISC compliant codelist for each variable that is subject to CDISC controlled terminology. For more information, see Codelists. • Generate a new metadata file with standard and data-driven codelists—Create a new define.xml that includes: <ul style="list-style-type: none"> • A standard, CDISC-compliant codelist for each variable subject to CDISC controlled terminology. • A codelist containing all unique non-null values from the study data for that variable for each variable subject to sponsor-defined controlled terminology. For more information, see Codelists. • Use Define.xml—Available if the study directory (indicated in the Data location field) contains a file named define.xml. There may be multiple define.xml files. When a define.xml file is generated, the file name includes the date and a numeric identifier.

Note: If there is only one define.xml in the study directory, that file is the default in this field. If there are no define.xml files in the study directory, the default in this field is determined by the application's setting for **Default codelists in metadata**.

When a define.xml file name appears in this field, you can hover your mouse over the **View** link to view the define.xml file in one of the following formats:

- **Using standard stylesheet**—Always available. Presents the metadata using a standard built-in style sheet.
- **Using sponsor-provided stylesheet**—Available only if you loaded the study with a define.xml file that your organization provided (that is, it was not generated by WebSDM/Empirica Study), and the define.xml referenced a style sheet. The style sheet reference can be to a file location in the study data directory or a subdirectory in the study data directory.
- **RAW XML**—Always available. Presents the metadata without using a style sheet.

References to SAS transport files and an annotated CRF file (if any) must be to the study directory or to a subdirectory within the study directory. **REQUIRED**

Note: To view the annotated CRF, you must have Adobe Acrobat Reader installed. To view SAS transport files, you must have the SAS System Viewer or Base SAS installed. For more information, see [Prerequisites and Usage Notes](#).

3. If you are generating a new metadata file (that is, a define.xml file), click **Generate Metadata**.

A message warns you that the generation of a new metadata file may be time-consuming and gives you the opportunity to continue or cancel. When the metadata file has been generated, the name of the new file appears in the Metadata field and the button label changes to **OK**. The file name is in the format **define_YYYYMMDDhhmmss.xml**.

4. If you have generated a metadata file using data-driven codelists, you may want to view the codelists in the define.xml file before completing study registration. To do so, you can click **View** for the Metadata field

.xpt file warning

If the data source type is [SAS Transport files](#), xpt files must be present in the Data location directory when you opt to generate a define.xml file. A message appears if there are no xpt files present.

5. Click **OK** to register the study with the currently selected define.xml file. The following occurs:
 - An Oracle account is created for it; the account name is based on the study name.

- The study appears on the Select tab. However, it cannot be selected until it has been [loaded and checked](#). You will also need to [publish](#) the study as appropriate.
6. Before the study data can be accessed, you must [load and check the study](#) and [publish the study](#).
 7. Oracle recommends that you check the [test identifiers](#) for the newly registered study. If application-level identifiers exist, a copy of them is associated with the study and they can be modified for the study.

Registering a Study Pool

To register a study pool, you select loaded studies to include in the pool. The pooled data will include all variables from all studies in the pool. The sets of variables do not need to be the same across the constituent studies of the pool.

If variables have different data types among constituent studies, the least restrictive type is used for the variable in the pool. For example, if a variable has the type NUMBER in one study and the type VARCHAR2 in another study, the pool defines that variable as having the type VARCHAR2. If variables have different descriptions, origins, roles, or comments, the one that comes last alphabetically is used for the variable in the pool.

For information about editing an already-registered study pool, see [Editing/Deleting a Study Pool](#).

To register a study pool:

1. Before registering a study pool, assign test identifiers and flag variables to each of the studies in the pool. You cannot assign test identifiers and flag variables for a pool. Also, once you have registered a study, you cannot add, edit, or delete test identifiers or flag variables for the pool's component studies.

Note: See [Defining/Editing Test Identifiers](#) for information about how tests are identified in pooled data.

2. On the [Studies and Study Pools page](#), click **Register Study Pool**. The Register Study Pool page appears.
3. Provide the following information about the study pool. Required fields are highlighted in yellow.

Field	Description
Name	Name of the study pool. REQUIRED
Description	Description of the study pool. You may want to include the names of the studies included in the study pool.

4. Move the studies that you want to include in the pool from the **All Available Studies** list to the **Currently Selected Studies** list. See [Selecting Entries from a List](#). The **All Available Studies** list includes studies that meet the following conditions:
 - They are registered for the selected application.

- They have been loaded and checked.
- Either you created them or they have been published to your login group.

If an indication has been specified for a study, it appears after the study name.

Studies in the pool do not need to use the same version of MedDRA or the SDTM. For the study pool, the highest version of MedDRA and the SDTM among included studies is used.

5. If you are registering a new study pool, click **OK**. If you are editing an existing study pool, click **Save**.

When you register a study pool, an Oracle account is created for the study pool; the account name is based on the study pool name. As soon as you register a study pool, it appears on the Select tab. However, it cannot be selected until it has been [loaded and checked](#). You will also need to [publish](#) the study pool as appropriate.

Editing/Deleting a Study


You cannot edit or delete a study that is part of a pool. You also cannot edit or delete a study if any of the following are true:

- Screening results or issue clusters for the study are attached to a potential signal.
- The study is currently selected (on the Select tab) by you or another user. If you have the study selected yourself, the message that appears gives you the option to click **OK** to de-select the study.
- The study is part of any type of run in the Run History that is currently running or is scheduled to run.

A study can be deleted by a user who owns it or has the *Delete Studies* permission.

Note: The **Delete** option is not available if your database administrator has not granted the DROP_USER permission to the WebSDM master account. For more information, see the **Setting Up the Oracle tablespaces and master account** section in the *WebSDM/Empirica Study Windows 2003/2008 Server Installation and Upgrade Instructions*.


To edit a study:

1. On the [Studies and Study Pools page](#), click the Action menu icon () for the study, and then click **Edit**. The [Register Study page](#) appears.
2. You can change any information except the application. If you change the following options, the study will need to be reloaded:
 - SDTM version
 - MedDRA account
 - Check variable labels against SDTM
 - Data source type

- Data location
 - Metadata
 - Oracle Health Sciences InForm database or account
 - Oracle Life Sciences Data Hub database or business area schema
3. Generate a new define.xml file (as described in [Registering a Study](#)) if necessary. For example, if you have modified the SDTM version or MedDRA account, you will need to generate (or provide) a new define.xml file.
 4. Click **OK**.
 5. If a confirmation message appears, review it before you click **OK** to continue. Before saving changes that will require the study to be reloaded, consider the consequences of a reload. Loading and checking results, as well as screening results, analysis specifications, and so on are always removed when you reload. See [Loading Studies/Pools](#) for more information.

If you save changes that require a reload, the status of the study becomes **Awaiting Reload**.

To delete a study:

1. On the [Studies/Pools page](#), click the Action menu icon () for the study and then click **Delete**.
2. When a message asks if you want to delete the study, click **OK**. When you delete a study, the following occurs:
 - The study is no longer available for selection on the **Select** tab.
 - The Oracle account for the study is deleted from the database. You can register the study again if the source files are still in appropriate locations in the application directory.
 - Runs of all types for the deleted study are deleted from the Run History.
 - Results of the most recent loading and checking run for the study are no longer accessible on the **Domains** tab.
 - All subject lists, report definitions, and report outputs for the study are deleted.
 - Analysis specifications defined for the study and the results of those analysis specifications are deleted.
 - Custom analysis types for which the visibility is the study, an analysis specification in the study, or **Hidden** are deleted.
 - Custom analysis types for which the visibility is global or application (but that were created for the study) are deleted if they are not referenced by analysis specifications for other studies or pools. If they are so referenced, they are retained but they are no longer associated with the study, so the Study column on the **Custom Screening Analysis Types** page is empty.

- Issue clusters and automatic screening runs for the study are deleted.
- Bayesian Logistic Regression (BLR) runs for the study are deleted.

Editing/Deleting a Study Pool


You cannot edit or delete a study pool if:

- Screening results or issue clusters for the pool are attached to a potential signal.
- The pool is currently selected (on the Select tab) by you or another user. If you have the pool selected yourself, the message that appears gives you the option to click **OK** to de-select the pool.
- The pool is part of any type of run in the Run History that is currently running or is scheduled to run.

A study pool can be deleted by a user who owns it or has the Delete Studies permission.

Note: The **Delete** option is not available if your database administrator has not granted the DROP_USER permission to the WebSDM master account. For more information, see the *WebSDM/Empirica Study Windows 2003/2008 Server Installation and Upgrade Instructions*.

To edit a study pool:


1. On the [Studies and Study Pools page](#), click the Action menu icon () for the study pool, and then click **Edit**. The **Register Study Pool** page appears.
2. You can change the pool description and which studies are in the study pool. If you change which studies are in a loaded pool, the pool will need to be reloaded.

Note: If you remove all of the studies from a pool, the pool is deleted automatically.

3. Click **Save**. If a confirmation message appears, review it before you click **OK** to continue. Before saving changes that will require the pool to be reloaded, consider the consequences of a reload. Loading and checking results, as well as screening results, analysis specifications, and so on are always removed when you reload. For more information, see [Loading Studies/Pools](#).

If you save changes that require a reload, the status of the pool becomes **Awaiting Reload**.

To delete a study pool:

1. On the [Studies/Pools page](#), click the Action menu icon () for the study pool and then click **Delete**.
2. When a message asks if you want to delete the study pool, click **OK**. When you delete a study pool, the following occurs:
 - The study pool is no longer available for selection on the **Select** tab.
 - The Oracle account for the study pool is deleted from the database.

- All subject lists, report definitions, and report outputs associated with the study pool are deleted.
- Runs of all types for the deleted study pool are deleted from the Run History.
- Analysis specifications and screening results for the study pool are deleted.
- Custom analysis types for which the visibility is the study pool, an analysis specification in the pool, or **Hidden** are deleted.
- Custom analysis types for which the visibility is global or application (but that were created for the pool) are deleted if they are not referenced by analysis specifications for other studies or pools. If they are so referenced, they are retained but they are no longer associated with the pool, so the Study column on the **Custom Screening Analysis Types** page is empty.
- Event lists for the study pool are deleted.
- Issue clusters and automatic screening runs for the study pool are deleted.

Split Domains

A split domain is one for which data is in multiple, physically separate datasets. Split domains were introduced with SDTM 3.1.2.

If a study uses SDTM 3.1.2, WebSDM/Empirica Study can load data from split domains and load split supplemental qualifier data for the split domains.

For the main domain datasets, the names of the .xpt files can have up to four characters. WebSDM/Empirica Study interprets the .xpt file names as follows:

- The first two characters indicate the domain.
- The last two characters, which can be alphabetic or numeric, indicate a split domain.
- File names are ordered alphabetically and loaded in that order. For example, QS1, QS2, ..., QS9, QS10 would sort to QS1, QS10, QS2, ..., QS9. However, QS01, QS02, ..., QS09, QS10 would sort in correct numerical order.

For example, LB01.xpt and LB02.xpt contain study data for the LB domain and LB01.xpt is loaded first.

In order for WebSDM/Empirica Study to recognize the names of supplemental qualifier datasets, the .xpt file names must start with SUPPxx, where xx is the two-character domain identifier. For example, you might have the following .xpt files:

SUPPLB01.xpt
SUPPLB02.xpt
SUPPLB03.xpt

Variables of the same name in separate datasets should have the same SAS Length attribute.

Data Source Types

You can load data into WebSDM from three different data source types: SAS Transport Files, Oracle Health Sciences InForm, and Oracle Life Sciences Data Hub. Each of the latter two data source types is available only if the respective [site option](#) (**Allow data import from Oracle Life Sciences Data Hub** or **Allow data import from Oracle Health Sciences Inform**) is selected.

If the data source type choices do not appear for a new study that you are registering, the data source is SAS transport files. If the choices do not appear for a study that you are editing, then either 1) the data source is SAS transport files, or 2) the data source is Oracle-based, but the relevant site option was cleared after the study was registered.

Note: When the data source is switched from SAS transport files to an Oracle-based source, the associated define.xml can still be used for reloading study data if there is no difference in study domains.

SAS Transport Files

The SAS Transport Files contain study data in SDTM format. The source data files are version 5 transport (*.xpt) files located in the specified data location.

While registering a study, if you specify the SAS Transport Files source type, you must complete the **Data Location** field. The **Data Location** field in this case specifies the directory where both study data files and the study metadata (define.xml) reside.

Oracle Health Sciences InForm

Oracle Health Sciences InForm database contains study data in SDTM format. If you specify the InForm source type, you must complete the following fields:

- **Data Location** – Name of the directory where metadata (define.xml) for the study resides.
- **Database** – Reference to the Oracle database in which the InForm study resides. If the InForm study is hosted in the same database as WebSDM/Empirica Study, **<local>** is the appropriate choice. In other cases, the appropriate choice corresponds to the name of a database link that is defined on the WebSDM/Empirica Study database and points to the InForm database.
- **Account** – Name of the Oracle account that owns the InForm data structures. You can click **Select** to select an account from a list of accounts containing a table or view named CV_SDTM<SDTM version>_DM, where <SDTM version> is **31**, **311**, **312**, or **313** (depending on the SDTM version specified for the study).

The following fields may be specified when registering a study whose data source type is Oracle Health Sciences Inform:

- **URL** – Optional specification of a URL that can be accessed from the Subject Details page. For example, a URL pointing to InForm.
- **Label** – If a URL is provided, the label of the hyperlink that will appear on the Subject Details page. For example, **InForm T & E Schedule**. If you leave this field blank, the label **Subject Summary** will be used.

- You can also specify the `_REFID` or `_SPID` attributes as described in [Registering a Study](#). The **URL** field and the **Root for URLs** fields will be concatenated to point to specific types of InForm records for a subject. You may want to set the **Column header for 2nd level drill down** field to **InForm**. Users will be able click that column's contents (for example, an image) on the Subject Details page to go to InForm.

Oracle Life Sciences Data Hub

Oracle Life Sciences Data Hub (LSH) contains study data in SDTM format. If you specify the LSH source type, you must complete the following fields:

- **Data Location** – Name of the directory where metadata (define.xml) for the study resides.
- **Database** – Reference to the Oracle database for the Life Sciences Data Hub. The appropriate choice corresponds to the name of a database link that is defined on the WebSDM/Empirica Study database and points to the Oracle Life Sciences Data Hub database.
- **Business Area Schema** – Name of the Business Area schema that owns the LSH data structures of the study. You can query from LSH for the selected database.

For studies whose data source type is Oracle Life Sciences Data Hub, the "**Updated data available**" indicator displays on the Register Study page when it is opened to edit a loaded study. This indicator shows whether the study data in LSH has been updated since the last data load of that study to WebSDM. Possible values for the indicator are "Yes", "No", or "UNK". The "UNK" value displays when the LSH database is not accessible. A value of "Yes" indicates that new data is available in LSH; the WebSDM user may want to request or initiate a reload of that study from the Oracle Life Sciences Data Hub source.

Loading and Checking Data

About Loading and Checking

When you have registered a study, you must perform a loading and checking run for the study before you can review it in WebSDM/Empirica Study. Loading and checking a study requires the following:

A define.xml file, which is a CDISC Case Report Tabulation Data Definition Specification based on the CDISC ODM. The define.xml file can be generated by WebSDM/Empirica Study, or provided by your organization.

Study data provided as SAS transport (.xpt) files, or as tables or views in an Oracle database. Rules that check compliance with the appropriate version of the Study Data Tabulation Model (SDTM) prepared by the CDISC (Clinical Data Interchange Standards Consortium) Submission Data Standards Group.

Loading and checking runs are performed as batch jobs and appear in the [Run History](#). A study is not available for use until it has been loaded and checked. The results of a loading and checking run appear on the Domains tab for the study. If your [user preference Display error-checking results](#) is set to **Yes**, failed checks are included on the Domains tab. Each

time you reload a study (and thus, the loading and checking are performed again), the most recent results replace previous results for the study on the Domains tab.

When you have loaded and checked studies, you can include them in a study pool. You then need to load and check the study pool before you can review the pool data in WebSDM/Empirica Study. For a study pool, the checking process reports on consistency across studies in the pool.

For more information on the loading and checking process, see [Results of Loading and Checking](#).

Loading Studies/Pools

You can load studies and pools from the Applications page or the Study/Pools page. You cannot reload a study that is part of a pool. You also cannot reload a study or pool if any of the following are true:

- Screening results or issue clusters for the study or pool are attached to a potential signal.
- The define.xml file for a study is not in the location specified when the study was registered.
- The study or pool is currently selected (on the Select tab) by you or another user. If you have the study or pool selected yourself, the message that appears gives you the option to click **OK** to de-select the study or pool.
- The study or pool is part of any type of run in the Run History that is currently running or is scheduled to run.
- You do not have the appropriate permissions.
- You do not own the study, or it is not published to your login group.


If you need to reload a study for which there have been certain types of changes to study data, you need to [edit the study](#) in order to generate (or provide) a new define.xml file for the study. For example, if domains or variables were added to or removed from the study data, you need a new define.xml file. If you do not use a new define.xml file, then checking results may include failed checks related to discrepancies between the study data and the define.xml.

To load a study or study pool:


1. If you are loading a previously loaded study, make sure that you understand the consequence of the reload. Although you can retain some properties such as test identifiers during a reload, all checking results and some other information will be deleted. For more information, see [Results of Loading and Checking](#).

Also note that even if you retain properties from the previously loaded study or pool, you will need to review and possibly edit properties for the reloaded study or pool.


2. To load one study or pool, do one of the following:

- On the [Studies and Study Pools page](#), click the Action menu icon () for the study or pool and then click **Load**.

Or

- On the [Run History page](#), locate the latest load and check run for the study or pool, click the Action menu icon () for it, and then click **Re-run**.

- To load one or more studies in an application at the same time, do one of the following:

- On the [Applications page](#), click the Action menu icon () for an application, and then click **Load**.

Or

- On the [Studies and Study Pools page](#), select the application and click **Load Studies/Pools**.

A page on which you select study or pools to load appears (unless you have clicked **Re-run** on the Run History page.) Only the studies that have been published to your login group are displayed. The following information is provided about each study or pool:

Column	Description
Include	<p>Do one of the following:</p> <ul style="list-style-type: none"> Select Include in the column heading to load and check all studies or study pools. Available only if there are multiple studies that can be loaded. <p>Or</p> <ul style="list-style-type: none"> Select Include for the individual studies and pools that you want to load. Selected by default if you are loading an individual study. <p>If a study or pool is unavailable to load, you can hover the cursor over its check box to display a tooltip describing the reason for its unavailability.</p>
ID	Automatically assigned unique identifier of the study or pool.
Name	Name of the study or pool.
Description	Description of the study or pool.
Type	<p>Possible values are:</p> <ul style="list-style-type: none"> Study Pool

State	<p>Stage of the loading and checking process. Assigned automatically as each stage of the loading and checking process is completed. Possible values are:</p> <ul style="list-style-type: none"> • Not Loaded—The study or pool has been registered but has not been loaded or checked. • Initialized—The loading process has started. • Study Loaded—The loading process has completed. • Awaiting Reload—The loading process has complete, but a reload is required because of subsequent changes to the study or pool. • Data Structure Checks Run—Clinical data has been checked against the define.xml and metadata rules. • Within-Domain Checks Run—Clinical data has been checked against the define.xml and within-domain rules. • Cross-Domain Checks Run—Clinical data has been checked against the define.xml and cross-domain rules. • Ready to Use—The study or pool is ready to use.
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Location	Name of the study directory relative to the application directory.
Standard	Version of CDISC Study Data Tabulation Model associated with the study or pool. For example, sdm312 indicates Version 3.1.2.
Created	Date and time at which study or pool was registered.
Screening Results	<p>Possible values are:</p> <ul style="list-style-type: none"> • N/A—The study or pool has not been loaded and checked, or the study or pool has been edited since it was last loaded and checked. The study or pool is not currently selectable on the Select tab. • None—There are no screening results for any analysis specifications for the study or pool and no saved issue clusters for the study. • Screening results generated—There are screening results for one or more analysis specifications for the study or pool. There are no saved issue clusters for the study. • Issue clusters generated—There are one or more saved issue clusters for the study or pool. There are no screening results for the study or pool. • Issue clusters and screening results generated—There are one or more saved issue clusters and screening results of

one or more analysis specifications for the study or pool.

- **Screening results generated – review required**—There are screening results for one or more analysis specifications for the study or pool, and at least one result is flagged as needing review (and may or may not have been reviewed). There may be saved issue clusters for the study or pool.
- **Issue clusters and screening results generated-review required**—There are one or more saved issue clusters for the study or pool. Additionally, there are screening results for one or more analysis specifications for the study or pool, and at least one result is flagged as needing review (and may or may not have been reviewed).
- **Screening results attached to potential signals**—At least one screening result (but no issue clusters) for the study or pool is attached to a potential signal, so you cannot reload the study or pool unless you first detach results from potential signals. To see the potential signals to which results are attached, point to the check box before the name of the study or pool.
- **Issue clusters attached to potential signals**—At least one issue cluster (but no screening results) for the study or pool is attached to a potential signal, so you cannot reload the study unless you first detach issue clusters from potential signals. To see the potential signals to which issue clusters are attached, point to the check box before the name of the study or pool.
- **Issue clusters and screening results attached to potential signals**—At least one issue cluster and at least one screening result for the study or pool is attached to a potential signal, so you cannot reload the study or pool unless you first detach issue clusters and results from potential signals. To see the potential signal to which issue clusters and results are attached, point to the check box before the study name.

Distribute
Supplemental
Qualifiers

Applies to studies, but not to study pools. Do one of the following:

- Select **Distribute Supplemental Qualifiers** in the column heading to distribute supplemental qualifiers for all studies.

Or

- Select **Distribute Supplemental Qualifiers** for individual studies.

If you choose to distribute supplemental qualifiers,
WebSDM/Empirica Study will use domain-specific supplemental

qualifier datasets if it finds at least one of them in the study directory; otherwise, it will use a single dataset of supplemental qualifier data. In order to be recognized by WebSDM/Empirica Study, the datasets must conform to the CDISC SDTM file naming conventions for the SDTM version specified for the study.

Retain Properties	<p>Applies to studies or study pools that were loaded previously. If metadata has changed since the last load of the study or pool, Oracle recommends that you do not retain properties.</p> <ul style="list-style-type: none"> • If selected—You must review and possibly modify the properties for the reloaded study or pool. For more information, see Editing Retained Properties. The following properties of the study or pool are retained during the load: <ul style="list-style-type: none"> • Category breakdowns • Time frames • Test identifiers • Flag variables • Study visit descriptions • Event lists • If deselected—The above properties are deleted and you will need to redefine them after the load.
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If you reload a study or pool with this setting checked, subsequent reloads of the study or pool will have this setting selected by default. If you reload from the Setup tab, you can change that default. However, if you reload from Run History, you cannot change the default.

4. Click **Next**.
5. If a confirmation message appears, review it before you click **OK** to continue.
6. For the consequences of reloading a study or pool, see [Results of Loading and Checking](#).
7. [Specify run options](#).

Results of Loading and Checking

When you load and check a study, the following occurs:

- If the [data source type](#) of the study is Oracle Health Sciences InForm or Oracle Life Sciences Data Hub, the load process extracts the study data from Oracle tables or views, and loads that data into the WebSDM/Empirica Study database.

- If the data source type of the study is SAS transport files, clinical data is loaded from the SAS transport files (xpt files) in the study directory (identified when the study was registered) into the WebSDM/Empirica Study database.
- Certain variables are [derived](#) and added to the study data.
- A default time frame (named **Study Reference Period**) is created for the study.
- Data structure checking and data consistency checking are performed by checking clinical data and metadata against the define.xml file and [rules](#).

When you load and check a study pool, the following occurs:

- The load fails and an error message appears in the Run History if USUBJID values are not unique across all studies in the pool. Note that this is not a check of the combination of USUBJID and STUDYID values.
- Metadata and clinical data for each domain is pooled. All domains in any of the studies, and all variables in each domain for any of the studies, are included.

For information about codelists for study pools, see [Codelists](#).

- For the AE domain, a built-in Within Domain rule checks whether all values of AEDECOD are found in the MedDRA version associated with the pool. If the studies in a pool use different MedDRA versions, the highest among those versions are used for the pool. Thus, a study that used a lower version of MedDRA might contain AEDECOD values that no longer exist in the higher level of MedDRA.
- For domains including __TESTCD and __STRESU variables, a built-in Within Domain rule checks that for each value of __TESTCD that is in all studies in the pool, the value of __STRESU must be the same in all studies. (There is a similar rule at the study level. This rule is applied for a pool only if it produced no errors for any studies in the pool.)
- For domains including __TESTCD and __STRESN variables, a built-in Within Domain rule checks that for each value of __TESTCD that is in all studies in the pool, the value of __TEST must be the same for all studies. (There is a similar rule at the study level. This rule is applied for a pool only if it produced no errors for any studies in the pool.)
- The STUDYID_ variable is [derived](#) for studies in the pool
- Data from the component studies of the pool is copied to the Oracle account for the study pool.
- A default time frame (named **Study Reference Period**) is created for the pool.
- Automatic screening runs occur for the **-None-** time frame, the Study Reference Period time frame, and other time frames that exist when you load the study. If you are reloading a study and you selected the **Retain Properties** option on the **Select Studies/Pools to Load** page, automatic screening runs also occur for each time frame defined previously.

Reloading

When you reload a study or pool, the following occurs:

- All activities described above for loading and checking are performed, with the exception that if you chose to retain properties, the default time frame (named **Study Reference Period**) is retained as is.
- All checking results for the study or pool are deleted.
- If you did not choose to retain properties, then properties for the study or pool are deleted. If you do not retain properties, you will need to define properties again for the reloaded study or pool. If you do retain properties, you will need to review and possibly modify the properties for the reloaded study or pool. For more information, see [Editing Retained Properties](#).


Note that subject lists, report definitions, and report outputs for the study or pool are not deleted.

If your organization uses Empirica Study (not only WebSDM), the following also occurs when you reload:

- All analysis specifications and screening results for the study or pool are deleted.
- Custom analysis types for which the visibility is hidden, the study, or an analysis specification (for the study or pool) are deleted.
- Custom analysis types for which the visibility is global or application (but that were created for the study or pool) are deleted if they are not referenced by analysis specifications for other studies or pools. If they are so referenced, they are retained but they are no longer associated with the study or pool, so the Study column on the Custom Screening Analysis Types page is empty.
- All issue lists for the study or pool are removed.
- All issue clusters for the study or pool are deleted.
- Bayesian Logistic Regression (BLR) runs are deleted.

Specifying Run Options for a Load & Check Run

1. Specify a name for the run. By default, the run name is the same as the study (or study pool) name. The name of the run does not need to be unique, although Oracle recommends that you use a unique name. Each run will also have an automatically assigned ID that is unique.
2. Specify a description of the run. Oracle recommends that you provide an informative description so that you can easily identify the run.
3. To perform the run now, click **Run as soon as possible**.

To schedule the run for a future date or time, click **Do not run until** and then supply a date and time. To supply a date, enter it in mm/dd/yyyy format or click  to display a calendar from which you can select a date. To supply a time, enter it in hh:mm:ss am/pm format.

4. To receive e-mail notification when the run is complete (as successful or failed), select **E-mail me when complete** and specify one or more email addresses (separated by commas) to receive notification. By default, the address (or addresses) associated with your username appears. If you want to change this default address, see your user administrator.

Note: For a load and check run that fails, the error_log.txt file will be attached to the e-mail.

5. Click **Next**. The [Confirm Run Parameters page](#) appears.

Submitting a Run

1. On the **Confirm Run Parameters** page that appears when you load a study, load a study pool, or run an analysis specification, review the parameters to make sure that they are correct.
2. To change any parameters, click **Back** until you are on the appropriate page and modify the run. Then click **Next** until you are on the **Confirm Run Parameters** page again.
3. If you are satisfied with the parameters, click **Submit**. A message tells you that the run (or runs) are in the process of being submitted. After a few seconds, you can click **Continue** or click any available tab or command.

If a run fails (as indicated on the [Run History page](#)), you can view log files to help diagnose the error. To do so, [view jobs for the run](#) and then [view job detail](#). In the Output Files section, click load_log.txt and error_log.txt.

Managing Rules/Error Messages

About Rules and Error Messages

A rule indicates a specific condition that must be met by study data that has been loaded. WebSDM/Empirica Study applies rules during the checking portion of a [loading and checking](#) run.

Each rule is associated with an error message. If a rule fails during checking, an error message appears on the [Checking Results page](#).

WebSDM/Empirica Study includes built-in rules and error messages that cannot be edited. However, a user with appropriate permissions can add rules to supplement the built-in rules and error messages. You can add rules for studies only. You cannot add rules for study pools.

Built-in rules and customer-defined rules are applied system-wide. When you load and check any study in any application, all rules for the SDTM version used by the study are applied. The [Rules Report](#) provides descriptions of these rules.

There are three rule types:

- **Within-Domain rules**—Apply to clinical data in a single domain. For example, a Within-Domain rule might check that the end date of an adverse event is later than the start date of the adverse event. This is the only rule type that you can add as a customer-defined rule.
- **Cross-Domain rules**—Compare clinical data values that are stored in separate domains. For example, a rule can validate that a subject ID is found in the DM domain for subject IDs in every domain other than DM.
- **Metadata rules**—Validate metadata issues, such as the presence or absence of columns or expected data types.

Within-Domain and Cross-Domain rule failures are reported on the [Study Data Domains page](#) as failed consistency checks. Metadata rule failures are reported as failed structure checks.

Validation checks

For descriptions of the validation checks (rules) that are executed in WebSDM/Empirica Study for some versions of the SDTM, see Appendix A in the *WebSDM/Empirica Study Release Notes Release 3.1*.

Related Topics

[Viewing Customer-defined Rules](#)

[Viewing Customer-defined Error Messages](#)

Viewing Customer-defined Error Messages

From the Settings page, you can view and edit only customer-defined [rules and error messages](#). You can also create new rules and error messages.


When [viewing checking results](#) for a particular study, you can also [view a Rules Report](#) that shows all built-in and customer-defined rules and their associated error messages.

To view customer-defined error messages:

1. Click **Settings** and then click **Edit Error Messages**. The Edit Error Messages page provides the following information about each error message:

Column	Description
M_ID	Automatically assigned unique identifier of the message.
SEVERITY	Possible values are Low, Medium, and High.
MESSAGE	Text of the message. For example: Null value. The message appears on the Errors page (on the Domains tab) if the rule fails and thus generates an error.
EDESC	Description of the message.
CAUSES	Causes of the error message.
STAGE	Within-Domain.


See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

2. To [add an error message](#), click **Add New Message**.
3. If you click  for an error message, you can do the following:
 - To [edit an error message](#), click **Edit**. When you edit an error message, the existing results of loading and checking runs are not affected. The next time the study is loaded and checked, the modified error message is used.
 - To delete an error message, click **Delete**. You can delete an error message only if it is not attached to a rule.

Adding/Editing an Error Message

If you have the appropriate [user permission](#), you can add or edit customer-defined error messages that are associated with customer-defined rules. You cannot edit the error messages that are built in to WebSDM/Empirica Study.

To add or edit an error message:

1. Click **Settings**, and then click **Edit Error Messages**. The **Edit Error Messages** page opens.
2. Do one of the following:
 - To add a message, click **Add New Message**.
 - To edit a message, click  and then click **Edit**. The Edit Error Message page appears.

If you are adding a new message, all fields are blank. A unique message ID is assigned automatically.

3. Enter the following:

Field	Description
Message ID	Automatically assigned unique identifier of the error message, beginning with CM . Error message identifiers are assigned sequentially; if error messages are deleted, their identifiers are re-assigned.
Severity	Indicates the severity of the error message. The options are: <ul style="list-style-type: none"> • Low • Medium • High
Message	Text of the message. For example, Begin date must be <= end

<i>(required)</i>	date. The message appears on the Errors page on the Domains tab if the rule fails.
Description	Description of the error. For example, A null value was found in a column where null is not allowed. The description appears on the Error Detail page if the rule fails.
Causes	Text description of possible causes for the error.

- Click **Save**. The error message is used during the next loading and checking run.

Viewing Customer-defined Rules

From the Settings page, you can view and edit only customer-defined [rules and error messages](#). You can also create new rules and error messages.

When [viewing checking results](#) for a particular study, you can also [view a Rules Report](#) that shows all built-in and customer-defined rules and their associated error messages.


To view customer-defined rules:

- Click **Settings** and then click **Edit Rules**. The Edit Rules page provides the following information about each rule:

Field	Description
R_ID	Automatically assigned unique identifier of the rule.
M_ID	ID of the error message that will be generated if the rule fails.
RULETYPE	Possible values are: <ul style="list-style-type: none"> RowSQL – The rule checks whether each row of clinical data for the domain meets the SQL condition specified in the TEST column. Unique – The rule checks that the values of variables in the TEST column and the COLNAME column are unique. Codelist – Reserved for future use.
TEST	SQL condition that must be met.
TABLERNAME	Domain to which the rule is applied.
COLNAME	Column tested by the rule. If the rule refers to multiple columns, the name of one of those columns.
ROWSWHERE	SQL Where clause that limits the rows to which the rule will be applied.
MAXMSG	Maximum number of times the rule may fail before the error "Too many rule failures" is reported.
COMMENTS	Further documentation of the rule.
ENABLED	Yes if the rule is enabled, or No if the rule is disabled. If the rule is disabled, it is not applied during the loading and checking process.

STAGE	Within-Domain.
STANDARD	SDTM version against which the rule will check. For example, "sdm312" indicates Version 3.1.2. During the loading and checking process, the rule will run if the study has this SDTM version.

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

- To [add a rule](#), click **Add New Rule**.
- If you click  for a rule, you can do the following:
 - To [edit the rule](#), click **Edit**. When you edit a rule, the existing results of loading and checking runs are not affected. The next time a study is loaded and checked, the modified rule is used.
 - To delete the rule, click **Delete**. When you delete a rule, any errors that were generated by a previous loading and checking run are not affected.

Adding/Editing a Rule


If you have the appropriate [user permission](#), you can add or edit customer-defined rules. You cannot add or edit the rules that are built in to WebSDM/Empirica Study. To model a rule after an existing built-in rule, you can view the Rules report, and then [view rule details](#).

Customer-defined rules apply only within a domain; only built-in rules can apply across domains or to metadata. In addition, customer-defined rules are applied to studies. They do not apply to study pools.

To add or edit a rule:

- Obtain the error message ID of the error message that you want to associate with the rule.
- Click **Settings**, and then click **Edit Rules**. The Edit Rules page appears.
- To add a rule, on the **Edit Rules** page, click **Add New Rule**.

or

To edit a rule, on the **Edit Rules** page, click the Action menu icon () and then click **Edit**. The Edit Rule page appears.

If you are adding a new rule, all fields are blank. A unique rule ID is assigned automatically.

- Enter the following:

Field	Description
Rule ID	Automatically-assigned unique identifier of the rule, beginning with CR . Rule identifiers are assigned sequentially; if rules are deleted, their identifiers are re-assigned.

Standard	SDTM version against which the rule will check. For example, sdm312 indicates Version 3.1.2. During the loading and checking process, the rule will run if the study has this SDTM version.
Enabled	Indicates whether the rule is enabled or disabled. The options are Yes and No . If the rule is disabled, it is not applied during the loading and checking process.
Message ID	ID of the error message that will be generated if the rule fails. You can refer to an error message that you have added or that is built-in. REQUIRED Note: You cannot view built-in error messages on the Edit Error Messages page. To see built-in messages, you can view the Rules Report and then view message detail .
Rule Type	Indicates the rule type. The options are: <ul style="list-style-type: none"> • RowSQL – The rule checks whether each row of clinical data for the domain meets the SQL condition specified in the Test field. • Unique – The rule checks that the values of columns in the Test field and the Column Name field are unique. • Codelist – Reserved for future use.
Test	If the Rule Type is RowSQL , the SQL condition that must be met for the rule to succeed. For example, if this field is A > B , then if A is greater than B , the loading and checking process will succeed and will not result in an error. If the Rule Type is Unique , the names of the columns whose values are checked for uniqueness. REQUIRED
Processing Stage	The type of rule. Always Within-Domain for a customer-defined rule.
Table	Domain to which the rule is applied. REQUIRED
Column Name	Columns tested by the rule. If the rule refers to multiple columns, separate column names by commas. The rule is not executed for studies that do not contain all of the variables listed here. REQUIRED
Rows Where	SQL Where clause to limit the rows to which the rule will be applied. You must enter a valid SQL Where clause using only supported syntax. For information on supported syntax, see Specifying a SQL WHERE Clause .
Max Messages	Maximum number of times the rule may fail before the Too many rule failures error is reported. If you leave this field blank, WebSDM/Empirica Study automatically assigns a value of 1000 when you save the rule.
Comments	Additional rule documentation.

5. Click **Save**. WebSDM/Empirica Study uses the new or changed rule during the next loading and checking run.

Oracle recommends that you test any rules that you have added. The Message column on the [Checking Results page](#) informs you if a rule does not execute. This may occur, for example, if the SQL for the rule is invalid, or the rule references a table that does not exist.

Loading Rules or Error Messages

You can load a tab-delimited file (.txt file) of customer-defined rules or error messages in to WebSDM/Empirica Study. This allows you to define rules and error messages outside of WebSDM/Empirica Study and load them in to WebSDM/Empirica Study. You can also [download](#) existing rules and messages from WebSDM/Empirica Study to a .txt file and then load them into a different instance of WebSDM/Empirica Study.

The loaded rules or error messages replace any existing customer-defined rules or error messages. Built-in rules are not affected when you load customer-defined rules or error messages.

TXT file

All values in the .TXT file will be loaded in to Oracle database columns of the data type VARCHAR(200).

For a rule, the TXT file must include the following columns (in any order). For most columns, a value must also be in the TXT file.

R_ID – Must be **CR** followed by four digits (CRnnnn)
STANDARD
ENABLED
M_ID
RULETYPE
TEST
TABLENAME
COLNAME
ROWSWHERE (value not required)
MAXMSGs
COMMENTS (value not required)

For an error message, the TXT file must include the following columns (in any order):

M_ID – Must be **CM** followed by four digits (CMnnnn)
SEVERITY
MESSAGE
EDESC (value not required)
CAUSES (value not required)

To load rules or error messages:

1. Log in as a user with the Add to Standard Metadata permission.
2. Place the TXT file of rules or error messages on your client computer.
3. Click **Settings** and then click **Load Customer-defined Rules and Messages**.
4. Select a file type. The options are:

- **Rules**—Load a TXT file of rules. If you load rules that refer to existing message IDs, you do not need to load the error messages.
- **Messages**—Load a TXT file of error messages. If you load error messages used by existing rules, make sure that the .TXT file uses the appropriate message IDs.

In some cases, you may need to load both the rules and error messages (in either order).

5. Specify the name of the TXT file containing rules or error messages. (You can click **Browse** to locate the file.)
6. Click **Load**.

Properties

About Properties

Properties include a variety of definitions that are needed to perform analysis and review of safety data. For example, they determine:

- How data is organized into subgroups based on dosing categories and other factors, such as age or sex.
- How data is organized into time frames.
- How clinical significance is assessed.

In general, you should define properties before a study or study pool becomes available for use. If the study or pool is available for use and you need to set properties, ensure that no users are currently using the study or pool when you modify the properties.

You cannot set properties for a study or pool if either of the following are true:

- The status of the study or pool is not Ready to Use.
- The study or pool is part of any run type in the Run History that is currently running or is scheduled to run.

Note: Setting certain properties —time frames, test identifiers, and flag variables—queues one or more automatic screening runs for the study or pool. These queued runs may inhibit your rapidly setting properties in sequence.

For example, you may want to create two time frames and set test identifiers for a newly loaded study. Creating the first time frame will queue an automatic screening run which, while queued or running, will inhibit your setting any other properties (the second time frame, or test identifiers) for the study.

To avoid this delay, the following sequence is recommended:

1. Create the first time frame.
2. On the Run History tab, [cancel](#) the automatic screening run queued for the study.
3. Create the second time frame.
4. On the Run History tab, [cancel](#) the automatic screening run queued for the study.
5. Set test identifiers.
6. Allow all automatic screening runs to complete. If you examine the Run History tab at this point, you will find an automatic screening run queued for each named time frame, plus an extra run for the '-None-' time frame. This collection of runs must be allowed to complete, else the issue list will be out-of-date.

Property levels

Some properties can be set only at the study or study pool level. Other properties can be set at the study or study pool level, at the level of an application, or globally. The following table indicates the levels at which each type of property can be defined:

Property	Study Level	Pool Level	Application Level	Global Level
Category breakdowns	X	X		
Time frames	X	X		
Event lists	X	X	X	X
Test identifiers	X		X	X
Flag variables	X			
Study visit descriptions	X			

For test identifiers, the relationship among test identifiers defined at different levels is as follows:

- When an application is first registered, a copy of the global-level test identifiers is associated with the application. Subsequent changes to global-level test identifiers do not affect the application-level test identifiers. Subsequent changes to the application-level test identifiers do not affect the global-level properties.
- When a study or pool is first registered, a copy of the application-level test identifiers is associated with the study or pool. Subsequent changes to application-level test identifiers do not affect the study-level or pool-level properties. Subsequent changes to the study-level or pool-level test identifiers do not affect the application-level properties.

You can also explicitly copy test identifiers from the global level to the application level, or from the application level to the study level or pool level.

Category Breakdowns

About Category Breakdowns

A category breakdown is the specification of named categories that include values of a particular variable in the study data. Category breakdowns organize data into useful subgroups of subjects, such as males and females, for analysis and display. They also filter subjects included in analysis to ensure that results are generated only for subjects with values in the selected categories.

Dosing category breakdowns

The dosing category breakdown is the most critical category breakdown. The dosing category breakdown defines a Treatment category and a Comparator category based on values of the DM.ARM variable. The ARM variable, along with other variables from the DM domain, is propagated to other subject-oriented tables during a load and check run. A subject is assumed to belong to a single treatment or comparator dose group, even for a

crossover or extension study where the actual treatment received by a subject may vary over time.

A dosing category breakdown is required for screening results generation and can be used for other displays on the Safety Review tab and the Screening tab.

Note: There are always exactly two categories in a dosing category breakdown. The categories are Treatment and Comparator.

A dosing category breakdown is required for screening results generation. When running a screening analysis specification, you can choose the dosing category breakdowns for which to generate screening results. Then, when viewing the screening results, you can select a dosing category breakdown and view just that breakdown's results.

For example, suppose that the arms of the study are 10MG, 20MG, 50MG, and PLACEBO. To compare 10MG and 20MG with PLACEBO, both separately and together, you could define the following category breakdowns:

Dosing Category Breakdown	Categories	ARM Values
10MG	Treatment	10MG
	Comparator	PLACEBO
20MG	Treatment	20MG
	Comparator	PLACEBO
10-20MG	Treatment	10MG, 20MG
	Comparator	PLACEBO

Note: In this example, the 50MG arm does not appear in any of the breakdowns.

Dosing category breakdowns are predefined by a user with appropriate permissions as a property of a study or study pool. You can also define dosing category breakdowns when you create an issue cluster mining run or a Bayesian Logistic Regression run. You can define multiple category breakdowns for a study or study pool.

Other category breakdown types

Other category breakdown types are not required, but can be used on the Safety Review tab and the Screening tab. Category breakdowns do not affect the Domains tab, Subject Lists tab, or Reports tab, with the exception that some graphs on the Domains tab can be filtered by a default dosing category breakdown, if one exists. The following table lists the other (non-dosing) category breakdown types:


Type	Description
Sex	Categories based on values of the DM.SEX variable.
Race	Categories based on values of the DM.RACE variable.
Age	Categories based on values of the DM.AGE variable.

Medical History	A category based on values of the MH.MHDECOD, MH.MHTERM, MH.MHCAT, or MH.MHBODSYS variable, and a category based on the absence of those values.
Concomitant Medications	A category based on values of the CM.CMDECOD, CM.CMTRT, or CM.CMCAT variable, and a category based on the absence of those values.
Study Group	Create categories based on values of the DM.STUDYID_ variable. Available for study pools only.
Baseline Labs	Categories for specific findings based on baseline values of the LB.LBSTRESN variable. Also uses values of LB.LBTEST and LB.LBTESTCD. Baseline for this type of category breakdown is the lowest LB.LBSTRESN value among those for which LB.LBBLBFL = 'Y'. Available for use only during creation of a BLR run.
Baseline Vitals	Categories for specific findings based on baseline values of the VS.VSSTRESN variable. Also uses values of VS.VSTEST and VS.VSTESTCD. Baseline for this type of category breakdown is the lowest VS.VSSTRESN value among those for which VS.VSBLBFL = 'Y'. Available for use only during creation of a BLR run.
Subject Characteristics	Categories for specific findings based on values of the SC.SCORRES and SC.SCSTRESC variable. Also uses values of SC.SCTEST and SC.SCTESTCD. Available for use only during creation of a BLR run.

Except where noted, these category breakdown types can be defined by a user with appropriate permissions as a property of a study or study pool or during creation of a BLR run. They are used as defaults (which can be overridden) in an analysis specification and they are available for use in a BLR run.

Note: If you create a screening analysis specification with different category breakdowns, you can generate screening results for each breakdown separately, or for combinations of breakdowns. For example, if you define both a Sex category breakdown and an Age category breakdown, you can generate results for each sex and for each age, or you can generate results for each combination of sex and age. For more information, see [Category Breakdowns and Time Frames](#).


Viewing Existing Category Breakdowns

- On the [Studies and Study Pools page](#), click  for the loaded study and select **Manage Properties > Category Breakdowns**. The Category Breakdowns window provides the following information about each category breakdown:

Column	Description
ID	Automatically assigned unique identifier of the category breakdown.
Category Type	Factor for which the category breakdown was defined. Possible values are Age, Baseline Lab, Baseline Vital, Dosing, Sex, Race, Medical

	History, Concomitant Medication, Subject Characteristics, or Study Group (available for a study pool only).
Name	Name of the category breakdown.
Source Column	Name of the column in the data that is referenced by the category breakdown.
Description	Description of the category breakdown.
Categories	Categories included in the category breakdown.
Default?	Y if the breakdown is the default breakdown for the study or pool. Otherwise, blank.
Category Qualifier	For Baseline Lab, Baseline Vitals, or Subject Characteristics, more detail about the breakdown.

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

2. To [create a new category breakdown](#), click **Create Category Breakdown**.
3. If you click  for a category breakdown, you can do the following:
 - To [edit the category breakdown](#), click **Edit**.
 - To rename the category breakdown, click **Rename** and [identify the category breakdown](#).
 - To delete the category breakdown, click **Delete**.

Note: Restrictions and effects of editing or deleting category breakdowns are described in [Creating/Editing a Category Breakdown](#).

Creating/Editing a Category Breakdown

If you add a dosing category breakdown, existing screening results are not affected. However, the next time the analysis specification that generated the results is run, results for the additional category breakdown can be generated. This has the most significance for the Safety Review tab. On that tab, users can select any existing dosing category breakdown, which means they can select a new breakdown for which results do not exist. They cannot then view a sector map or screening results for that breakdown. Thus, when you add a dosing category breakdown, consider re-running the [\\$\\$\\$BASIC\\$\\$\\$SCREENING\\$\\$\\$](#) analysis specification.

Note: When you reload data that has changed since the previous load of the study or pool and you retain properties during the reload, the retained category breakdowns may refer to values that are no longer in the data. For more information, see [Editing Retained Properties](#).

Restrictions and effects of changes to category breakdowns

Note: "Editing" in the following context does not include changes to the **Use as default** check box or the name or description of a category breakdown.


You cannot:

- Edit or delete a dosing category breakdown if screening results or issue clusters for the breakdown are attached to a potential signal.
- Delete any type of category breakdown if the breakdown is used by an existing BLR run.

If you edit or delete a dosing category breakdown for which there are screening results or issue clusters, a message informs you that the screening results or issue clusters for the breakdown will be deleted.

The issue list (that is, the results of automatic screening) is not affected by modification or deletion of category breakdowns.

To create or edit a category breakdown:

1. On the [Studies and Study Pools page](#), click the Action menu icon () for the study and select **Manage Properties> Category Breakdowns**.

Note: You can also define a dosing category breakdown when creating an issue cluster mining run, and any category breakdowns when creating a Bayesian Logistic Regression run.

2. In the Category Breakdowns window, click **Create Category Breakdown**.
3. Select the type of breakdown. See [About Category Breakdowns](#) for information about the types.
4. Click **Next**. If you are defining a category breakdown for Baseline Labs, Baseline Vitals, or Subject Characteristics, select a type of finding and click **Next** again.
5. Define the breakdown as described in [Defining a Category Breakdown for Text Values](#) and [Defining a Category Breakdown for Numeric Values](#).
6. [Identify the category breakdown](#).

Defining a Category Breakdown for Text Values

This topic describes defining various types of category breakdowns for text values in the following two places:

- As a property of a study or study pool.
- During creation of a Bayesian Logistic Regression run.

Separate instructions are provided for:

- [Defining a Category Breakdown for Text Values \(analysis specification\)](#)
- [Defining a Dosing Category Breakdown \(issue cluster mining\)](#)

Dosing

1. In the Categories list, click a category name (Treatment or Comparator).
2. In the **All Values** list, select one or more values to include in the selected category. See [Selecting Entries from a List](#) for information on searching or selecting values. Note that null values appear in the list as "(NULL)" and can be included in a category.
3. In the **Selected Values** list, you can use the up and down arrows to order the values. The order of arms affects the following:
 - The order of arms displayed in the **by dose group** tables for a row of screening results.
 - The order of arms for displays on the **Safety Review** tab when safety review is configured to use ARM values

Note: You can create multiple dosing category breakdowns that are the same except for the order of arms in the categories.

4. Optionally select **Use as default**. When you check this option, the breakdown becomes the default and this option is deselected automatically from another breakdown (if any) for which the option was selected.

The default category breakdown affects the following:

- The default breakdown will be selected by default when screening results are viewed on the **Screening** tab (if results have been generated for that breakdown).
 - The default breakdown will be selected by default as a configuration option for the **Safety Review** tab.
 - If there is no default dosing category breakdown, a Napoleon's March graph cannot be [configured](#) to show treatment and comparator information side by side or one after the other.
 - Some graphs available on the **Domains** tab may use the default dosing category breakdown, depending on graph configuration options.
5. Click **Next** and [identify the category breakdown](#).

Sex, Race, and Study Group

1. To create a new category, click **New**, enter the category name, and click **OK**.
2. To rename the selected category, click **Rename**, enter a new category name, and click **OK**.
3. To delete the selected category, select the category, click **Delete**, and click **OK**.
4. To add or modify values in the selected category, select one or more values in the All Values list. See [Selecting Entries from a List](#) for information about searching or selecting values. Note that null values appear in the list as "(NULL)" and can be included in a category. In the Selected Values list, you can use the up and down arrows to order the values.

5. Optionally select **Use as default**. When you select this option, the breakdown becomes the default and this option is deselected automatically from another breakdown (if any) for which the option was selected.

New screening analysis specifications will use the category breakdown as the default, but users can create their own categories.

If a default category breakdown for Race is defined, it is used for the Race graph on the [Overview page](#) on the **Safety Review** tab.

6. Click **Next** and [identify the category breakdown](#).

Medical History and Concomitant Medications

For medical history and concomitant medications, you can define only one category. A second category is created automatically to include subjects not having values in the first category. For example, suppose that you define the **Pneumonia** category to include **Pneumonia, bact**, **Pneumonia, viral**, and **Pneumonia, other**. A **No Pneumonia** category is created automatically to include all subjects who do *not* have a history of **Pneumonia, bact**, **Pneumonia, viral**, or **Pneumonia, other**.

1. In the **Based on values of** field, select the variable on which to base the category breakdown.
2. To rename the default **Key CMs** or **Key MHs** category, click **Rename**, enter a new category name, and click **OK**.
3. In the **All Values** list, select one or more values to include in the category. See [Selecting Entries from a List](#) for information about searching or selecting values.
4. Optionally check **Use as default**. When you select this option, the breakdown becomes the default and this option is deselected automatically from another breakdown (if any) for which the option was selected.

New screening analysis specifications will use the category breakdown as the default, but users can create their own categories.

5. Click **Next** and [identify the category breakdown](#).

Subject Characteristics

1. Select a type of subject characteristic finding.
2. To create a new category, click **New**, enter the category name, and click **OK**.
3. To rename the selected category, click **Rename**, enter a new category name, and click **OK**.
4. To delete the selected category, select the category, click **Delete**, and click **OK**.
5. To add or modify values in the selected category, select one or more values in the **All Values** list. See [Selecting Entries from a List](#) for information on searching or selecting values. In the **Selected Values** list, you can use the up and down arrows to order the values.

6. Optionally select **Use as default**. When you select this option, the breakdown becomes the default and this option is deselected automatically from another breakdown (if any) for which the option was selected.
7. Click **Next** and [Identify the category breakdown](#).

Defining a Category Breakdown for Numeric Values

Category breakdowns for age, baseline labs, and baseline vitals are based on numeric cutpoints. This topic describes creating or editing a category breakdown for numeric values in the following two places:

- As a property of a study or study pool
- During creation of a Bayesian Logistic Regression run

Separate instructions are provided for [Defining a Category Breakdown for Numeric Values \(analysis specification\)](#).

To define a category breakdown for numeric values:

1. If you are creating a Baseline Labs or Baseline Vitals category breakdown, select a finding type.
2. Click **View Column Statistics** to [view statistics](#) about the distribution of values in the study data.
3. In the first value field (after **VALUE <=**), enter the maximum value for the first category. Also, enter a category name.
4. In the next row, in the Value field, enter the maximum value for the second category. (The cutpoint values must be in ascending order.) Also enter a category name.
5. Continue defining categories until you are ready to define the last category.
6. For the last category, enter only a category name. (Do not enter a value.) This is the category for all values above the previous cutpoint. For example:

	Value	Category
	VALUE <= 18	Up to 18
18	< VALUE <= 50	19 to 50
50	< VALUE	Over 50

7. To add more categories than you can currently fit on the page, select **Add additional cutpoints on saving**.
8. Optionally, enter a minimum and/or maximum value. This option is useful to exclude extreme values from categories.

Note: Values equal to the minimum or maximum value are included. Only values less than the minimum value or greater than the maximum value are excluded.

9. Optionally select **Use as default**. When you select this option, the breakdown becomes the default and this option is deselected automatically from another breakdown (if any) for which the option was selected.

For an age category breakdown, new screening analysis specifications will use the category breakdown as the default, but users can create their own categories. For all numeric breakdowns, the breakdown is also selected by default when a new BLR run is configured.

If a default category breakdown for Age is defined, it is used for the Age graph on the [Overview page](#) on the **Safety Review** tab.

10. Click **Next** and [identify the category breakdown](#).

Viewing Column Statistics (in category breakdown)

If you click **View Column Statistics** when defining a category breakdown, the Column Value Statistics page appears. This page shows a histogram of the variable's distribution for the study. A *histogram* is a graph of grouped (binned) data showing frequency distribution. The x-axis represents the variable's values from the study data and the y-axis represents counts of subjects. A shaded rectangular block in the graph represents each bin; a bin is a range of x-axis values. The top of each block indicates the count of subjects for the bin.

The following information is also provided, based on values of the variable for the study:

- Minimum – Minimum value.
- Maximum – Maximum value.
- Distinct Values—Number of distinct values.
- Total Values – Total number of values.
- Average – Average value.
- Standard Deviation – Standard deviation of value.
- Variance – Variance of value.

When you point to a block, the following information appears:

- The range of x-axis values for the bin
- The cumulative count of subject IDs with that range of values
- The cumulative percentage of subject IDs with that range of values

Identifying a Category Breakdown

1. Enter a name and description that will help to identify the breakdown.
2. Click **Save**. The category breakdown is listed on the [Category Breakdowns page](#).

Note: If you create a category breakdown within the context of a potential signal, the category breakdown is not saved unless you save changes to the potential signal.

Time Frames

About Time Frames

A time frame is a period of time based on either subjects' study epochs or subjects' study reference start and end dates. For example, you can set up different time frames to match periods for screening through run-in, treatment with the experimental drugs, and follow-up. You can use time frames to filter data displays and analyses to include only events or results that occurred during a particular period.

Time frames are not required, but can be used on the Screening tab and the Safety Review tab. They do not affect the Domains tab, Subject Lists tab, or Reports tab.

Time frames are predefined by a user with appropriate permissions as a property of a study or study pool. Multiple time frames can be defined for a study or study pool. The definition of a time frame indicates the parameters that will be used as boundaries; for example, the number of days before or after a subject's study reference start and end dates that the time frame starts and ends.

Note: As described in [Variables Used by Time Frames](#), Oracle recommends that you ensure that variables used by time frames are populated in the study data.

A time frame is an abstract concept that is based on study data but whose start and end dates are not stored in the database. A time frame based on epochs always has a start and end, which are defined as a number of days before or after specified epochs. A time frame based on study reference dates has a start, an end, or both; the start and end are defined as a number of days before or after the study reference start or end dates.

Also note that a time frame is only a set of parameters until it is applied to study data. The actual start and end of a time frame are determined when you select a time frame for use and will differ from subject to subject.

Well-defined start

A time frame is considered to have a "well-defined" start if its start is based on a number of days following the start of an epoch or a number of days after a study reference date.

An epoch-based time frame must be created with a well-defined start. A time frame based on a study reference date can be created with or without a well-defined start.

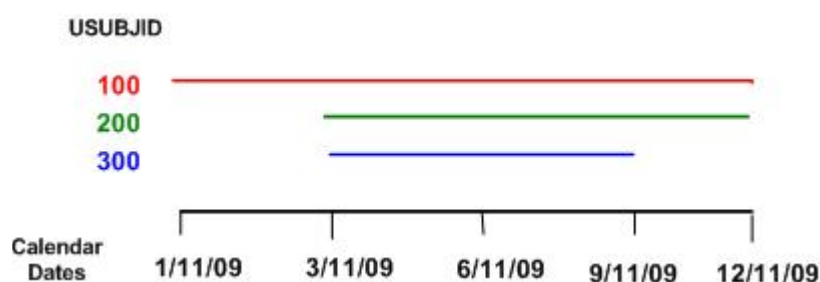
Note: Even if a time frame has a well-defined start, it is possible that the time frame start cannot be determined for a subject. For example, if the time frame start is based on the study reference start date and a subject is missing a study reference start date, the time frame start cannot be determined for that particular subject.

Time frame example

Suppose that the DM domain includes the following data:

USUBJID	Study Reference Start Date	Study Reference End Date
100	2009-01-01 12:00:00	2009-09-01 12:00:00
200	2009-03-01 12:00:00	2009-12-01 12:00:00
300	2009-03-01 12:00:00	2009-09-01 12:00:00

Then suppose that the time frame is defined as starting 10 days after the study reference start date (DM.RFSTDTC) and ending 10 days after the study reference end date (DM.RFENDTC).



Related Topics

[Variables Used by Time Frames](#)

[How Time Frames Are Used](#)

Variables Used by Time Frames

If you plan to use time frames for reviewing and analyzing data, it is recommended that you ensure that variables that are used by those time frames are populated in the study data. Time frames function most consistently if the variables that they use are non-null. These variables include the following:

- Variables that are used to determine the start and end of time frames.
- Variables that record when observations occurred and thus are used to determine whether an observation occurs within a time frame.

For an epoch-based time frame, the following variables are always used:

- SE.SESTDTC
- SE.SEENDTC

For a time frame based on study reference dates, the following variables are used:

- DM.RFSTDTC if the start or end of the time frame is based on the study reference start date.

- DM.RFENDTC if the start or end of the time frame is based on the study reference end date. (*Note:* This type of time frame can be defined to include in counts of events or findings those subjects who have a missing study reference end date.)

In determining whether an observation occurred within a time frame, WebSDM/Empirica Study uses the following date variables, depending on the type of data in the display or analysis:

Domain	Variable
AE	AESTDTC
DS	DSSTDTC
EG	EGDTC
LB	LBDTC
VS	VSDTC

Note: The variables that are actually used when a time frame is applied are the high and low dates that are [derived](#) from the above dates when they contain an ISO 8601-formatted text string.

Related Topics

[About Time Frames](#)

[How Time Frames Are Used](#)

How Time Frames Are Used

When generating screening results by running a screening analysis specification, you can choose the time frames for which to generate screening results. Then, when viewing the screening results, you can select a time frame and view just that time frame's results. You can also select a time frame when viewing other types of displays. The currently selected time frame may affect displays and analyses as follows:

- The display or analysis may include only observations that occurred within the current time frame.
- Subjects who [dropped out](#) before the start of the current time frame may be excluded from the display or analysis.
- In some cases, the baseline value is established depending on whether a time frame is in effect and whether that time frame was set up to impute baseline using its start. See [Baseline Results](#) for information about how baseline values are established.

Observations in time frame

For displays that show only observations that occur within a time frame, only observations for which it can be determined that they occurred within the time frame are included. For information about which variables are used to determine an observation's datetime, see [Variables Used by Time Frames](#).

The start and end of a time frame are inclusive, that is, an observation is considered to have occurred within the time frame if it occurred on or after the time frame start and on or before the time frame end.

If it cannot be determined if an observation occurred within a time frame, then the observation is treated as if it did not occur within the time frame. For example, suppose that the time frame is based on study reference start. If a subject has no study reference start date, no observations for the subject are considered to have occurred within the time frame.

Note: For time frames whose start is based on the study reference end date, there is an option to include observations for subjects that have no study reference end date. See [Creating/Editing a Time Frame](#).

Example

Suppose that a time frame is defined as running from 3 days after the study reference start date to 10 days after the study reference end date. The following table shows study data plus the computed time frame boundaries for each of four subjects, as well as timing information on adverse events:

USUBJID	RFSTDTC	<Start of Time Frame>	RFENDTC	<End of Time Frame>	AEDECOD	AESTDTC
100	2009-01-12 12:00:00	2009-01-15 12:00:00	2009-01-12 12:00:00	2009-01-22 12:00:00	Dry mouth	2009-01-18 20:00:00
100	2009-01-12 12:00:00	2009-01-15 12:00:00	2009-01-12 12:00:00	2009-01-22 12:00:00	Sinusitis	2009-01-23 14:00:00
101	2009-02-12 18:00:00	2009-02-15 18:00:00	2009-03-12 01:00:00	2009-03-22 01:00:00	Headache	2009-03-22 02:00:00
102					Rash	2009-04-01 12:00:00
103	2009-03-12 12:00:00	2009-03-15 12:00:00	2009-04-12 12:00:00	2009-04-22- 12:00:00	Nausea	

If you view adverse events with this time frame in effect:

- Only Dry mouth appears for subject 100. Sinusitis does not appear for subject 100 because the event occurred outside the time frame.
- No adverse events appear for subject 101 because no events occurred within the time frame.
- No adverse events appear for subjects 102 and 103 because there is not enough data to determine if the events occurred within the time frame.

Related Topics

[About Time Frames](#)


[Variables Used by Time Frames](#)

Viewing Existing Time Frames

- On the [Studies and Study Pools page](#), click  for a loaded study or pool and then select **Manage Properties> Time Frames**. The Time Frames window provides the following information about each time frame:

Column	Description
ID	Automatically assigned unique identifier of the time frame.
	One of the following values:
Based On	<ul style="list-style-type: none"> Reference Dates – The time frame is based on the study reference start and end dates. Epoch Range – The time frame is based on a range of epochs.
Name	Name of the time frame.
Description	Description of the time frame.
Criteria	Automatically provided description of criteria specified for the time frame.
	Indication of how baseline is established for the displays and analysis types that require the identification of a baseline result:
Impute Baseline?	<ul style="list-style-type: none"> If Y, baseline is imputed using the lower boundary of the time frame. If this column is blank, the baseline flag variable in the study data is used.
	See Baseline Results for more information.
Default	Y if the time frame is the default time frame for the study or pool. Otherwise, blank.

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

- To [create a time frame](#), click **Create Time Frame**.
- If you click  for a time frame, you can do the following
 - To [edit the time frame](#), click **Edit**.
 - To rename the time frame, click **Rename** and [identify the time frame](#).
 - To delete the time frame, click **Delete**.

Note: Restrictions and effects of editing or deleting time frames are described in [Creating/Editing a Time Frame](#).

Creating/Editing a Time Frame

When a study or study pool is loaded, a default time frame named **Study Reference Period** is created automatically. You can edit or delete that time frame and create additional time frames.

If you add a time frame, existing screening results are not affected. However, the next time an analysis specification is run, an option to generate results for the new time frame will be available. The relationship between screening results and time frames has the most significance for the Safety Review tab. On that tab, users can select any existing time frame, which means they can select a new time frame for which `$$$BASIC$$$SCREENING$$$` results do not exist; if they do so, they cannot then view a sector map or screening results for that time frame. Thus, when you add a time frame, consider re-running the [\\$\\$\\$BASIC\\$\\$\\$SCREENING\\$\\$\\$](#) analysis specification.

Note: When you reload data that has changed since the previous load of the study or pool and you retain properties during the reload, the retained time frames may refer to values that are no longer in the data. For more information, see [Editing Retained Properties](#).

Restrictions and effects of changes to time frames

Note:

"Editing" in the following context does not include changes to:

- The **Use as default** check box.
- The name of a time frame.
- The description of a time frame.


You cannot edit or delete a time frame if screening results for the time frame are attached to a potential signal.


If you edit or delete a time frame for which:

- There are screening results, a message informs you that screening results for the time frame will be deleted.
- There are BLR runs, a message informs you that BLR runs for the time frame will be deleted.

If you add or edit a time frame, WebSDM/Empirica Study silently [submits one automatic screening run](#) per time frame as a background process to update the issue list.

To create or edit a time frame:

1. Go to the [Studies and Study Pools page](#) on the **Setup** tab. Click the Action menu icon () for a loaded study or pool and then select **Manage Properties> Time Frames**.

- Click **Create Time Frame**. Alternatively, click the Action menu icon () for a time frame and then click **Edit**. The Configure Time Frame page appears.
- To base the time frame on study reference dates, click **Based on reference dates** and specify the following:

Field	Description
Starting	<p>Provides a start of the time frame. Click Study reference start date or Study reference end date. Specify the number of days after the start or end date as a positive or negative integer. You can enter 0.</p> <p>This option uses the value of a subject's DM.RFSTDTC (if Study reference start date is in effect) or DM.RFENDTC (if Study reference end date is in effect). Subjects with null DM.RFSTDTC/DM.RFENDTC values are not included.</p>
Ending	<p>Provides an end of the time frame. Click Study reference start date or Study reference end date. Specify the number of days after the start or end date as a positive or negative integer. You can enter 0.</p> <p>This option uses the value of a subject's DM.RFSTDTC (if Study reference start date is in effect) or DM.RFENDTC (if Study reference end date is in effect). Subjects with null DM.RFSTDTC values are not included. Subjects with null DM.RFENDTC values are not included unless you select Include subjects whose study reference end date is missing.</p>
Include subjects whose study reference end date is missing	<p>Applies only if the time frame is defined with an end based on the study reference end date.</p> <ul style="list-style-type: none"> • If selected—Counts of observations within the time frame include subjects who do not have a study reference end date. The observations will be considered to have occurred within the time frame. • If deselected—The counts within the time frame do not include these subjects. <p>Note: This option has no effect on the determination of who dropped out before the start of a time frame.</p>

To base the time frame on epochs, click **Based on range of epochs**. You must specify the following:

- For the time frame start, an epoch and the number of days following the start of the epoch
- For the time frame end, an epoch and the number of days following the end of the epoch

The number of days can be a positive or negative integer or 0. See below for information about which variables are used for an epoch-based time frame.

4. Select **Impute baseline result using start of time frame** if you want displays and analysis types that require the identification of baseline values to impute the baseline values using the lower boundary of the time frame. Otherwise, the baseline flag variable in the data is used. See [Baseline Results](#) for more information about these two methods and where they are used.
5. Optionally select **Use as default**. When you check this option, the time frame becomes the default and this option is cleared automatically from another time frame (if any) for which the option was checked. The time will be selected by default when screening results are viewed on the Screening tab.
6. If you are creating a new time frame, click **Next** and [identify the time frame](#).

If you are editing a time frame, click **Save**.

Note: Each type of time frame must be unique for the study or study pool. To determine whether a time frame is unique, every attribute of the time frame except the name, description, and **Use as default** check box is considered.

Variables used by an epoch-based time frame

You can create an epoch-based time frame only if the SE and TA domains exist and all of the following is true:

- The SE domain contains the USUBJID, ARM, ETCD, SESTDTC, and SEENDTC variables, and has at least one record where all five variables have non-null values.
- The TA domain contains the ARM, EPOCH, ETCD, and TATEORD variables, and has at least one record where all four variables have non-null values.

For each subject and ETCD value, the earliest SE.SESTDTC value is mapped to the lowest value of TA.TAETORD, the second earliest SE.SESTDTC value is mapped to the second lowest value of TA.TAETORD, and so on. The epochs in the drop-down list for epochs are ordered according to values of TA.TAETORD for all subjects.

When the time frame is computed, for each subject:

- The start of the time frame is the earliest SE.SESTDTC value for the specified epoch plus the specified number of days following the start of the epoch.
- The end of the time frame is the latest SE.SEENDTC value for the specified epoch plus the specified number of days following the end of the epoch.

Identify a Time Frame

When you are creating or renaming a time frame, you must identify the time frame.

To identify a time frame:

1. Enter a name and description that will help to identify the time frame.
2. Click **Save**. The time frame is listed on the [Time Frames page](#).

Event Lists

About Event Lists

An event list is a saved list of preferred terms (PTs) selected from study data or directly from the MedDRA dictionary. Users with appropriate permissions can define event lists at the level of the system, application, or study (or study pool). An event list can be set up to require review, meaning that screening results for PTs in the event list will be flagged as [needing review](#).

You can [create event lists](#) globally, for an application, or for a study or study pool.

Event lists can be used during screening analysis in the following ways:



- When creating a [custom analysis type](#) based on a MedDRA PT, HLT, HLGT, or SOC, or on a Standardized MedDRA Query Analysis, users can specify one event list as part of the criteria for the specific PTs to include in screening results. The custom analysis type may be set up to require review, regardless of whether the event list itself is set up to require review.
- When creating a Custom MedDRA Query Analysis, users must specify one or more event lists.
- For a standard MedDRA PT analysis, event lists set up to require review may flag results as needing review.

The following event lists are used for a custom analysis type or Custom MedDRA Query Analysis, and to determine the standard MedDRA PT Analysis results to flag as needing review:

- All global event lists.
- Application-level event lists for the current application.
- Study-level event lists for the current study, or study pool event lists for the current study pool.

Viewing Existing Event Lists


To view existing event lists:

1. Do one of the following:
 - To view global event lists, go to the Settings page and click **Manage Global Properties**.
 - To view event lists for an application, go to the [Applications page](#) on the Setup tab. Click  for the application and select **Manage Properties> Event Lists**.
 - To view event lists for a study or study pool, go to the [Studies and Study Pools page](#) on the Setup tab. Click  for the loaded study or pool and select **Manage Properties> Event Lists**.

The Event Lists window appears, providing the following information about each event list:

Field	Description
ID	Automatically assigned unique identifier of the event list.
Name	Name of the event list.
Description	Description of the event list.
Term Source	MedDRA Dictionary or Study.
MedDRA Account	Name of the Oracle account containing the version of MedDRA, if the value of Term Source is MedDRA Dictionary.
Created	Date and time at which the event list was created.
Modified	Date and time at which the event list was last modified.
Modified By	Name of the user who created or last modified the event list.
# Terms	Number of terms in the event list.
Terms Require Review?	Y if the event list is set up to require review. Blank if the event list is not set up to require review.

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.


2. If you click  for an event list, you can do the following
 - To [edit the event list](#), click **Edit**.
 - To delete the event list, click **Delete**. You cannot delete an event list if it is used by a custom analysis type (regardless of whether or not the custom analysis type is included in an analysis specification).
3. To [create an event list](#), click **Create Event List**.
4. To [copy an existing event list](#), click **Copy Event List**.



Related Topics

[About Event Lists](#)

[Marking a Result as Reviewed](#)

Creating/Editing an Event List

1. To create or edit a global event list, click **Manage Global Properties**.
 - A. To create or edit an event list for an application, go to the [Applications page](#) on the **Setup** tab. Click the Action menu icon () for an application and then select **Manage Properties> Event Lists**.

- B. To create or edit an event list for a study or pool, go to the [Studies and Study Pools page](#) on the **Setup** tab. Click the Action menu icon () for a loaded study or pool and then select **Manage Properties> Event Lists**.
2. Click **Create Event List**. Alternatively, click the Action menu icon () for an event list and then click **Edit**. The **Event List** page appears.

The following messages may appear:

 - For study-level event lists: If the study belongs to a pool, a message informs you event list cannot be edited (added, modified, or deleted).
 - If the event list is used by screening results that are attached to potential signals, a message informs you that the event list cannot be edited and lists the pertinent potential signals.
 - If the event list is used by an analysis type for which there are screening results, a message informs you that the results will be deleted. Note that only the results for the affected analysis types will be removed.
3. Enter a name and optionally enter a description of the event list. Oracle recommends that you provide an informative name and description so that users can easily identify the event list when limiting events for a screening analysis specification. The combination of the name and description are shown together with a total of about 50 characters displayed.
4. To create a list based on MedDRA terms:
 - A. Click MedDRA Dictionary for **Source for Terms**.
 - B. In the MedDRA Account field, select the Oracle account containing the MedDRA dictionary. The account names include the MedDRA version. By choosing an account you are determining which version of MedDRA will be used. By default, the MedDRA version associated with the study or pool is selected. If you select a MedDRA version that does not match that of the study or pool, a warning message appears. When a custom analysis type is created, only event lists based on the same MedDRA version as the one used by the study will be available.
 - C. Next to the Terms field, click **Select Terms**. The Browse MedDRA Hierarchy window appears.
 - D. [Select MedDRA terms](#) for the list.
5. To create a list based on terms in the study data (for a study-level event list):
 - A. Click Study Data for **Source for Terms**.
 - B. Next to the Terms field, click **Select Terms**.
 - C. Select terms for the list.
6. Select **Must be Reviewed** if you want MedDRA PT Analysis results for any PTs in the list to be flagged as needing review. This flagging for review is independent of custom analysis types, and occurs only if the SCORE column for the result is less than 0.5. See [Marking a Result as Reviewed](#).

7. Click **Add**. The event list is created and is available for use in analysis specifications.

Copying an Event List

One way to [create an event list](#) is to copy an existing event list, modify it as needed, and save it with a different name.

To copy an event list:

1. In the Event Lists window, click **Copy Event List**.
2. Select an event list and click **Copy**. A new event list is created with the same name preceded by "Copy of".
3. [Edit the event list](#), including its name, as needed.
4. Click **Save**. The copy of the event list is created and is available for use in analysis specifications.

Test Identifiers

About Test Identifiers

In running specific analysis types and displaying other information, WebSDM/Empirica Study must identify certain lab tests, ECG tests, and vital signs. However, the test names in study data are not constrained by a controlled vocabulary, and may vary from study to study. Thus, you must map names that WebSDM/Empirica Study expects to names that are in the study data. This mapping is called a test identifier. For example, WebSDM/Empirica Study uses the HEMATOCRIT lab test for certain displays. In one study, this test might map to HCT and in another study, it might map to HEMA.

When test identifiers are defined, WebSDM/Empirica Study [derives](#) standardized test identifiers—the LB.LBTSTID_, VS.VSTSTID_, and EG.EGTESTID_ variables.

For a list of the analysis types and displays that use test identifiers, see [Where Test Identifiers Are Used](#). Also note that one method of determining clinical significance is to use [built-in criteria](#). In this case, a test identifier must be set for the test or measurement to which the built-in criteria apply.

You can [define test identifiers](#) globally, for an application, or for a study or study pool. Additionally, you can do the following:

- Copy identifiers from a higher level.
- Save identifiers to a higher level.

If test identifiers are defined globally, they are used by default for a newly registered application and can be overridden at the application level.

If test identifiers exist at the application level, they are used by default for a newly registered study (in the application) and can be overridden at the study level.

Defining/Editing Test Identifiers

When you define test identifiers, you map names of lab tests, ECG tests, or vital signs that are expected by WebSDM/Empirica Study to names that occur in the study data. The expected names, followed by the standard short name (in parentheses), and the expected units are displayed. When you click **Select**, test names in the study data are listed.

If you edit test identifiers used by a Hy's Law Analysis or a QT Interval Prolongation Analysis, or associated with a lab test or vital sign for which built-in criteria are defined, WebSDM/Empirica Study silently [submits an automatic screening run](#) to keep the [issue list](#) current.

For a list of which analysis types and displays use test identifiers, see [Where Test Identifiers Are Used](#).



Study pools

The test identifiers do not need to be the same in all the component studies. The displays and analysis types that rely on test identifiers ignore the short names and long names used by the constituent studies.

However, keep in mind that some displays and analysis types ignore test identifiers and operate on either distinct short names (for example, the LBBL, VSBL, LBCS (flag variable), and VSCS (flag variable) analysis types) or on distinct long names (for example, the Lab Results and Vital Signs pages of the Safety Review tab). To the extent that the studies included in a pool use different short or long names to refer to the same test, these displays and analysis types will tend to separate issues that should be combined. To the extent that the studies included in a pool use the same short or long names to refer to different tests, these displays and analysis types will tend to combine issues that should be distinguished.

To define or edit test identifiers:

1. Do one of the following:

- To define global test identifiers, go to the [Settings page](#) and click **Manage Global Properties**. Then click **Test Identifiers**.
- To define test identifiers for an application, go to the [Applications page](#). Click the Action menu icon () for the application and select **Manage Properties> Test Identifiers**.
- To define test identifiers for a study, go to the [Studies and Study Pools page](#). Click the Action menu icon () for the loaded study or pool and select **Manage Properties>Test Identifiers**.

The following messages may occur:

- For study-level test identifiers: If the study belongs to a pool, a message informs you that the test identifiers cannot be edited (added, modified, or deleted).
- If the type of test identifier (lab, ECG, or vital signs) is used by screening results or issue clusters that are attached to potential signals, a message informs you that the identifiers cannot be edited and lists the pertinent potential signals.

- If the type of test identifier (lab, ECG, or vital signs) is used by an analysis type that has screening results, a message informs you that the results will be deleted. Note that only the results for the affected analysis types will be removed.
- If the type of test identifier (lab, ECG, or vital signs) is used by issues included in an issue cluster, a message informs you that the issue clusters will be deleted. Note that all the saved issue clusters (not only the ones containing issues for the affected analysis types) will be removed.
- If the type of test identifier (lab, ECG, or vital signs) is used by issues included in a BLR run, a message informs you that the BLR run will be deleted.

Note: Each type of test identifier (lab, ECG, and vitals) is treated as a collection. For example, even if you edit only one lab test identifier, all results that reference any of the lab test identifiers will be deleted.

2. If you hover the cursor over the name of a test, a description of the test appears as a tooltip.
3. In the **Short Name** field for each test, specify a value in the study data. If you are defining identifiers for a study, you can click **Select** to [select a term](#) from the study data. On the **Select from List** page that appears, you can filter available values by category or subcategory if they exist in the study data. The same value cannot be mapped to more than one test

The units that WebSDM/Empirica Study expects appear in the Units column. Certain analysis types require that test names have been mapped to study variables that use the expected units. See [Viewing Warnings](#) for more information.

4. When defining identifiers for an application, you can click **Copy from Global Properties**.
5. When defining identifiers for a study, you can click **Copy from Application Properties**.
6. When defining identifiers for an application, you can select **Save as global properties?** (This option is available only if you have the *Manage Global Properties* permission.)
7. When defining identifiers for a study, you can select **Save as application properties?**
8. You can click **Print**, or click **Download** to [download](#) the test identifiers.
9. Click **Save**. For a study-level identifier, if you typed in a value that does not exist in the study data, a warning message appears and you have the option to save the value anyway.

If changes to study-level test identifiers will cause an analysis type to become unavailable, a message informs you of which specifications include that analysis type (regardless of whether there are results). If you continue, the type's **Included** check box will be deselected and becomes unavailable in those specifications.

Selecting Terms for Test Identifiers

When [defining or editing test identifiers](#) for a study, you can click **Select** to select values for the test identifiers. The Select from List window appears. The top of the window shows the "built-in" test name and units that WebSDM/Empirica Study expects; see [Where Test Identifiers Are Used](#) for more information.

In the **All Terms** list, there is an entry for each unique combination of the __TESTCD value, __TEST value, and __STRESU value that is found in the study data. .

To select terms for test identifiers:

1. Select a category (value of the __CAT variable). If there are none in the study data, **ALL** is the only available value.
2. Select a subcategory (value of the __SCAT variable). If there are none in the study data, **ALL** is the only available value.
3. Scroll through the **All Terms** list to find an entry. Alternatively, you can type a string into the **Show Match to** field then click **Find**. All entries containing that string are listed; the matching does not distinguish between cases (upper, lower, mixed). See below for tips on how to search for entries using the **Show Match to** field.

To list all entries again, click **Show All**.

When an entry is highlighted in the list, you can go to the next occurrence of an entry starting with a character that you type. For example, you can highlight the first entry in the list and type **H** to go to the first entry starting with **H**.

4. To select an entry from the list, either highlight the entry and click **OK** or double-click the entry.

Special characters

To search for the following special characters, you must precede each special character with a backslash (\):

+
*
?
.
\
(
)
[
]

Where Test Identifiers are Used

This topic lists the displays that use the various types of test identifiers.

ECG Test Identifiers

The ECG test identifiers are used by the following analysis types and displays:

ECG Test	EGQT Analysis	Distrib. of QTc Change over Time	QT Prolongation Summary	DataMontage	PPD Patient Profiles
QT INTERVAL	X	X	X	X	X
QTC INTERVAL	X	X	X	X	X
RR INTERVAL	X	X	X	X	X

Lab Test Identifiers

The lab test identifiers are used by the following analysis types and displays. ***Scroll to the right for the whole list.***

Lab Test	LBCS Analysis*	Lab Graph*	LBHY Analysis	Hy's Law on Safety Review/Labs page	LFT Scatter Plot	LFT Profile	Std. Hema tox. Profile	Anemia Hema tox. Profile	Hemolytic Anemia Hemat ox. Profile
Eosinophils/Leukocytes (EOSLE)	X	X							
Ery. Mean Corpuscular HB Concentration (MCHC)								X	
Ery. Mean Corpuscular Volume (MCV)								X	
Erythrocytes (RBC)								X	
Haptoglobin (HAPTOG)									X
Hematocrit (HCT)	X	X							
Hemoglobin (HGB)	X	X					X	X	X
Leukocytes (WBC)	X	X					X		
Neutrophils/Leukocytes (NEUTLE)	X	X					X		

Platelet (PLAT) Units: /mm**3	X	X				X	
Platelet, Estimated (PLAT) Units: THOU/mm**3	X	X					
Reticulocytes (RETI)							X
Alanine Aminotransferase (ALT)	X	X	X	X	X	X	
Alkaline Phosphatase (ALP)	X	X	X	X	X	X	
Aspartate Aminotransferase (AST)		X	X	X	X	X	
Bilirubin (BILI)	X	X	X	X	X	X	X
Blood Urea Nitrogen (BUN)	X	X					
Creatine Kinase (CK)	X	X					
Creatinine (CREAT)	X	X					
Indirect Bilirubin (BILIND)							X
Lactate Dehydrogenase (LDH)	X	X					X
URIC ACID	X	X					

* The test identifiers are used only to [derive](#) the LBSGABC_ variable for clinical significance.

Vital Sign Identifiers

The vital sign identifiers are used by the following analysis types and displays:

Vital Sign	VSCS Analysis*	Vitals Graph*	Vital Signs Profiles	Demographic Distribution
Body Mass Index (BMI)				X
Diastolic Blood Pressure (DIABP)	X	X	X	

Heart Rate (HR)	X	X	X	
Height (HEIGHT)				X
Systolic Blood Pressure (SYSBP)	X	X	X	
Temperature (TEMP)	X	X		
Weight (WEIGHT)	X	X	X	X

* The test identifiers are used only to [derive](#) the VSSGABC_ variable for clinical significance.
0

Defining/Editing Flag Variables


If the site option **Enable Empirica Study Features** is selected, you can define flag variables for a study. A flag variable is a source data variable that has been identified as a way to indicate the clinical significance of lab test or vital sign values or to indicate whether adverse events are treatment-emergent. Often, the specified value is for a supplemental qualifier variable in study data.

Flag variables are used in the following places:

- As an option for determining [clinical significance](#) for the purposes of a [Clinically Significant Lab Analysis](#), a [Clinically Significant Vitals Analysis](#), and a [Lab or Vitals Graph](#).
- To determine clinical significance for the [Lab Results page](#) on the **Safety Review** tab.
- To determine treatment-emergence for an event-based [custom analysis type](#).

If you edit flag variables for lab test clinical significance or vital sign clinical significance, WebSDM/Empirica Study silently [submits an automatic screening run](#) for each time frame defined to keep the [issue list](#) current.

To define or edit flag variables:

1. On the [Studies and Study Pools page](#), click the Action menu icon () for the loaded study and then click **Manage Properties> Flag Variables**. The following messages may occur:
 - If the study belongs to a pool, a message informs you that flag variables cannot be edited (added, modified, or deleted).
 - If any flag variable is used by screening results or issue clusters (or their component issues) that are attached to potential signals, a message informs you that the flag variables cannot be edited and lists the pertinent potential signals.

- If any flag variable is used by analysis types for which there are screening results, a message informs you that the results will be deleted. Note that only the results for the affected analysis types will be removed.
 - If any flag variable is used by issues included in issue clusters (or their component issues), a message informs you that the issue clusters will be deleted. Note that all saved issue clusters (not just the ones containing issues for the affected analysis types) will be removed.
 - If any flag variable is used by issues included in BLR runs, a message informs you that the BLR runs will be deleted.
2. To specify a source variable (typically a binary variable) from the study data, enter the variable name or click **Select** and [select the variable from a list](#).
 3. To specify a source variable value from the study data, enter the value or click **Select** to [select values from a list](#).

The flag variable for records that have the values you select will be derived to Y. For records that do not have the values you select, the derived variable will be derived to N.

If you enter variable values, you must precede the double-quote character (") and the backslash character (\) with a backslash to ensure the characters remain literal. For example:

```
\TERRIBLE\ HEADACHE
INCREASED THIRST\DRY MOUTH
```

If you do not precede the backslash and double-quote with a backslash, WebSDM/Empirica Study removes the backslash and quote during the save process.

4. You can click **Print**, or click **Download** to [download](#) the flag variables.
5. Click **Save**.

If changes to a flag variable will cause an analysis type to become unavailable, a message informs you of which specifications include that analysis type (regardless of whether there are results). If you continue, the type's **Included** check box will be deselected and becomes unavailable in those specifications.

Describing Study Visits

In the following graphs which show distribution over time, the x-axis represents time points (typically, these are study visits):

Tab	Graph
Domains	Study Domains page: <ul style="list-style-type: none"> • For the EG domain—Distribution of QTc Change over Time • For the LB domain—LFT Box Plot: Distribution of <test-name> over Time


Safety Review

- QT Prolongation Summary page – Distribution of QTc Change over Time
- Lab Results page—Box Plot: Distribution over Time
- Vitals Signs page—Box Plot: Distribution over Time

For each of the EG, LB, and VS domains, you can specify which visits (values of the VISITNUM variable) will appear on the x-axis of these graphs.

Note: By default, study visits are selected for inclusion based on the number of subjects for each visit number. If you do not describe study visits, the default settings are used.

To describe study visits:

1. On the [Studies and Study Pools page](#), click the Action menu icon () for the loaded study and select **Manage Properties> Study Visit Descriptions>Lab Visits, ECG Visits, or Vital Signs Visits**.

The Study Visit Descriptions window appears, providing the following information. You can modify the Visit Label and Include in Graphs columns.

Column	Description
Visit Number	Shows all values of the VISITNUM variable. Non-integer visit numbers are combined with integer visit numbers; for example, visit numbers 4, 4.1, 4.2, 4.8 would all be counted as visit number 4. The non-integer visit numbers are truncated because they typically indicate either a repeated occurrence of a scheduled visit or a visit that occurs between two scheduled visits.
Visit Name	Shows the value in the VISIT variable for each value of the VISITNUM variable. If multiple values of VISIT are found for a VISITNUM value, they are separated by commas.
Visit Day (average)	Shows the average study day value for the visit number. This value is used for ordering tick marks on the x-axis. The average is computed as follows: <ul style="list-style-type: none"> • For each record, get the non-null value of the VISITDY variable, if present. Otherwise, get the non-null value of the __DY variable, if present. Otherwise, get the non-null value of the VISITNUM variable, if present. • Average these values across all records. • Round the average to the nearest integer.
# Subjects	Shows the count of subjects having data for each visit number. May be useful in determining which visit numbers you want to include in the graph.

Visit Label	By default, the value of the VISITNUM variable. You can modify the visit labels. To avoid spacing problems in the graph, use a short label or configure the graph to evenly space the visits along the x-axis.
Include in Graphs	Checked by default for the visit numbers that have the ten highest number of subjects (in the # Subjects column). You can check or clear the checkboxes to indicate which visit numbers you want to include in the graph. You can include up to ten visit numbers. If more than ten visit numbers are checked to be included, only the first ten such visit numbers will be included in the graphs.

2. Click **Save**.

Editing Retained Properties

When you reload a study or study pool, you can retain properties associated with the existing study or pool that you are reloading. If you do so, it is critical that you review and possibly modify the properties for the newly loaded study or pool. Some comparisons to reloaded data are performed when you save properties; for this reason, you should use the Edit option for the properties and save them even if you have not made changes.

For a reloaded study, review the retained category breakdowns, time frames, event lists, test identifiers, flag variables, and study visit descriptions.

For a reloaded pool, review the retained category breakdowns, time frames, and event lists.

Note: If metadata has changed since the last load of the study or pool, Oracle recommends that you do not retain properties for a reload.

Category breakdowns

A category breakdown that is retained from a previous load may include values that are no longer present in the study data. In this case, when you edit the category breakdown, a message informs you that one or more of the values are no longer in the data. You can click **Repair** to remove those values from the category breakdown.

Note: There may be times when you want to leave in the category breakdown those values that do not exist in the currently loaded data—for example, if you anticipate that there may be a future reload in which those values will be re-introduced in the data.

If a retained category breakdown is based on a variable that no longer exists in the metadata, you need to edit the category breakdown to use a different variable.

In the following situations, when you try to edit the category breakdown, a message informs you that the breakdown cannot be edited:

- The domain referenced by the retained category breakdown does not exist in the reloaded data. For example, there is a Medical History breakdown but the reloaded data has no MH domain.
- A variable needed by the retained category breakdown (for example, the LB.LBBLFL variable for a Baseline Labs breakdown) is not in the reloaded data.

- A particular lab test (for a Baseline Labs breakdown), vital sign (for a Baseline Vitals breakdown), or subject characteristic (for a Subject Characteristics breakdown) is not in the reloaded data.

Time frames

A retained time frame that is based on epochs may be incompatible with a reloaded study or pool as follows:

- If the TA and SE domains in the reloaded data do not contain the information needed to convert a named epoch into a date range, then when you edit the time frame, a message informs you the time frame cannot be edited. You can delete it and create a new time frame to replace it.
- If one or more of the epochs referenced by the retained time frame is not in the reloaded data, you need to edit the time frame to refer to different epochs.

Event lists

Neither a new event list nor a retained event list is compared to the study data.

Test identifiers

When you save new or retained test identifiers, a warning message appears if the values you specified are not in the study data.

Flag variables

If the variable on which a new or retained flag variable is based is not in the study metadata, you cannot save flag variables until you choose a variable that does exist.

Study visits

If a visit number is not in the reloaded study data, the Visit Name, Visit Day, and # Subjects columns that appear when you edit study visits contain **N/A**. A message indicates that these visits will be removed.

For visit numbers that are retained in the reloaded study data and new visit numbers in the reloaded study data, the contents of Visit Name, Visit Day, and # Subjects columns are established using the reloaded study data.

Run History

Viewing the Run History

The Run History provides summary and detailed information about batch jobs that you have submitted, which include loading and checking runs and screening analysis runs. You can use the Run History tab to monitor and manage submitted runs, including runs that have failed or have been cancelled. The Run History refreshes when you select the Run History tab and also if you use the browser's Refresh command while on the Run History tab.

If you do not have the *Administer Users* permission, the Run History lists only runs that you have created. If you have the *Administer Users* permission, the Run History lists runs created by all users.

To view the Run History:

1. Go to the Run History tab. The Run History page appears.
2. To list only runs for a particular application, study (or pool), or run type, select an entry in the Application, Study, or Run Type fields. You can select entries for all three fields; however, your selection for each field does not affect which entries are available to select in the other two fields.


The Run History provides the following information about each run:

Column	Description
ID	Run identifier that was assigned automatically to the run when it was submitted. Run IDs are unique and are not re-used if the run is deleted.
Name	<p>For a study loading and checking run, name of the run as provided by the user. If multiple studies were loaded and checked at the same time, the run name is the same for each study.</p> <p>For a study pool loading and checking run, name of the run as provided by the user. If multiple study pools were loaded at the same time, the run name is the same for each pool.</p> <p>For a screening analysis run, name of the analysis specification as provided by the user. If the name is "\$\$\$ BASIC\$\$\$SCREENING\$\$\$", this is a special required run for the safety review feature.</p> <p>For an automatic screening run, this column shows "AutoScreen" and there is a separate entry in the Run History for each time frame for which the issue list is generated.</p> <p>You can click the run name to view constituent jobs for the run.</p>
Description	Description of the run, as provided when the run was created. Click the description to view the run parameters.
Application	Name of the application.
Study/Pool	Name of the study or study pool.
Run Type	One of the following:

- Load&Check – For a loading and checking run of a study.
- Pool Loader – For a loading run of a study pool.
- Screening Analysis – For a screening analysis run.
- Automatic Screening – For an [automatic screening run](#).

Created By	Name of the user who submitted the run.
Created	Date and time at which the run was submitted.
Start Date	Date and time at which the run started. For a scheduled run, the start date may be substantially later than the submission date of the run. Note: If a run that you submitted does not start when expected, it may be because other runs are currently executing, although they are not visible to you on the Run History tab.
End Date	Date and time at which the run ended. This column is empty until all jobs that constitute the run have completed.
Status	Empty until all jobs for the run have completed. If all jobs for the run have completed successfully, then the run has completed successfully and this column shows Completed. If the run has failed, this column shows Error Occurred. To learn more about the error, click the run name to view jobs for the run and look at the Status column. If the run was cancelled, this column shows Cancelled.

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

3. If you click  for a run, you can do the following:
- To [cancel or delete a run](#), click **Cancel** or **Delete**. You can cancel a run that is currently running or is scheduled to run. You can delete any completed or cancelled run except the most recent load and check run for a study or study pool.

If you cancel an [automatic screening](#) run, issue lists may become out-of-date. For more information, see [About Properties](#).

- To [re-run a run](#), click **Re-run**. This option is available for only the most recent load and check run for a study or study pool and for the most recent version of a particular analysis specification. It is not available for a screening analysis run or automatic screening.
- To [view run details](#), click **Details**.

Viewing Run Details

Do one of the following:

- On the [Run History page](#), click  for a run and then click **Details**.

- On the [Job Details page](#), click **Details**.

The run details depend on the type of run, as described below.

Screening analysis specification run

Field	Description
ID	Automatically assigned identifier of the run.
Description	Description of the run.
Created By	Name of the user who submitted the run.
Created On	Date and time at which the run was submitted.
Application	Name of the application for which the run was submitted.
Study	Name of the study for which the run was submitted.
Dosing category breakdowns	Name of the dosing category breakdowns for which the screening analysis specification was run. If a dosing category breakdown was deleted since screening analysis was performed, its ID is listed and followed by "(deleted)".
Time frames	Names of the time frames for which the screening analysis specification was run. If a time frame was deleted since screening analysis was performed, its ID is listed and followed by "(deleted)".
Generate result set with no time frame in effect	Yes if the screening analysis specification was run for the absence of a time frame. Otherwise, No.

Automatic screening run

Field	Description
ID	Automatically assigned identifier of the run.
Description	Description of the run.
Created By	Name of the user who submitted the run.
Created On	Date and time at which the run was submitted.
Application	Name of the application for which the run was submitted.
Study	Name of the study for which the run was submitted.
Time frame	Names of the time frames for which automatic screening was run. If a time frame was deleted since screening analysis was performed, its ID is listed and followed by "(deleted)".

Load and check run for study

Field	Description
ID	Automatically assigned identifier of the run.
Description	Description of the run.

Created By	Name of the user who submitted the run.
Created On	Date and time at which the run was submitted.
Application	Name of the application containing the study that was loaded.
Study	Name of the study that was loaded.
Supplemental Qualifier Processing	One of the following, depending on whether the option to distribute supplemental qualifiers was checked for the load and check run: <ul style="list-style-type: none"> Distribute supplemental qualifier data to target domains Do not distribute supplemental qualifier data to target domains
Properties retained	Y if the option to retain properties of the previously loaded study was checked for the load and check run. Otherwise, N.

Study Pool loading run

Field	Description
ID	Automatically assigned identifier of the run.
Description	Description of the run.
Created By	Name of the user who submitted the run.
Created On	Date and time at which the run was submitted.
Properties retained	Y if the option to retain properties of the previously loaded pool was checked for the pool loading run. Otherwise, N.

Viewing Jobs for a Run

The Jobs for Run page presents information about jobs that constitute a run and provides access to input and output files for the jobs. In the current release, each run consists of only a single job.

The name and owner of the run is provided at the top of the Jobs for Run page. If a run was scheduled, the scheduled date and time are shown. To view details about the run parameters, click **Description**.

The Jobs for Run page refreshes automatically, with the Status column providing information about the progress of a job.

To view jobs for a run:

1. On the [Run History page](#), click the name of the run that has the job you want to view. The Jobs for Run page appears.

Run 'CAT DISP/OT' owned by Jennifer Hurwitz [jennifer.hurwitz] [Details](#)

ID	Name	Description	Server	Created	Start Date	End Date	Runnable	Status
245	Task 1 For Run 245	Part of Run 245	any	05/05/2006 13:42:11 EDT	05/05/2006 13:42:11 EDT	05/05/2006 13:42:17 EDT	YES	Completed

2. To [view run details](#), click **Details**.
3. To view the job parameters and access input and output files for jobs, click the name of the job. The [Job Detail page](#) appears.

The Jobs for Run page provides the following information about each job:

Column	Description
ID	Automatically assigned unique ID of the job. When runs are deleted, the job IDs are not re-used.
Name	The name of each job includes a descriptor followed by the number of the run.
Description	"Task1 For" followed by the run ID.
Server	If multiple servers are in use, the unique ID of the server on which the job is performed.
Created	Server date and time at which the job was created. For a scheduled run, the creation of the job may be substantially later than the creation date of the run.
Start Date	Server date and time at which the job was started.
End Date	Server date and time at which the job ended.
Runnable	YES.
Status	"Cancelled" if the run was cancelled when the job was being performed. An error message (and red background) appears if the job failed. "Completed" if the job succeeded.
Error	YES if an error occurred for the job, otherwise NO.
Error Msg	If Error is YES, a message about the error.

Viewing Job Detail

The Job Detail page provides a list of parameters used for the job, and a list of input and output files.

To view job detail:

1. If you have not already done so, [configure Internet Explorer](#) to download files properly.
2. On the [Run History page](#), click the name of the run that has the components you want to view. The [Jobs for Run page](#) appears.
3. Click the job name. The Job Detail page appears.
4. Optionally click the name of a file in the Job Parameters section. The File Download window appears.
5. Choose to either save the file to disk or open it. Each file is a .zip file containing a plain text file. To view the file, you must have a ZIP file compression and extraction utility such as WinZip installed on your computer, as described in [Prerequisites and Usage Notes](#).

For a loading and checking run, the Job Parameters include the following:

Parameter	Description
Process Supplemental Qualifier Data	<p>Applies to a load and check run for a study (not a study pool). One of the following values:</p> <ul style="list-style-type: none"> 2 – Do not distribute supplemental qualifier data to target domains. 3 – Distribute supplemental qualifier data to target domains. <p>For loading and checking runs executed prior to WebSDM/Empirica Study 3.0, values may be:</p> <ul style="list-style-type: none"> 0 – Distribute supplemental qualifier data from SUPPQUAL table to target domains. 1 – Distribute supplemental qualifier data from domain-specific tables to target domains. 2 – Do not distribute supplemental qualifier data to target domains.
Update Existing Configuration	Always 10. Reserved for future use.
Study ID	Unique, automatically-assigned identifier of the study.
Retain properties	<p>One of the following values:</p> <ul style="list-style-type: none"> 0 if properties were not retained when the study or pool was loaded. 1 if properties were retained when the study or pool was loaded.
Input Files	Always blank. Reserved for future use.
Output Files	Four files that are useful in error diagnosis: load_log.txt, error_log.txt, filtered_define.xml, PROC_job-id_log-id.log.

For a screening analysis run, the Job Parameters include the following:

Parameter	Description
Study ID	Unique, automatically-assigned identifier of the study.
Signal Loader Spec Description	Description of the screening analysis specification that was run.
Included time frames	IDs of the time frames for which screening analysis was performed.
Signal Loader Spec Name	Name of the screening analysis specification that was run.

Signal Loader Spec ID	Automatically assigned ID used for internal purposes.
Included dosing category breakdowns	IDs of the dosing category breakdowns for which screening analysis was performed.
Include Unrestricted time frame	One of the following values: <ul style="list-style-type: none"> 0 if screening analysis was not performed for the absence of a time frame. 1 if screening analysis was performed for the absence of a time frame.
Input Files	Always blank. Reserved for future use.
Output Files	Three files that are useful in error diagnosis: load_log.txt, error_log.txt, PROC_job-id_log-id.log.

For an automatic screening run, the Job Parameters include the following:


Parameter	Description
Do all time frames	1 if automatic screening was performed for all time frames. Otherwise, 0.
Study ID	Unique, automatically-assigned identifier of the study.
Time Frame	Always -1, indicating that automatic screening was performed for the absence of a time frame.
Input Files	Always blank. Reserved for future use.
Output Files	Three files that are useful in error diagnosis: load_log.txt, error_log.txt, PROC_job-id_log-id.log.

Cancelling/Deleting a Run

On the Run History page, you can cancel and delete runs that you have submitted.


You can cancel a run that is currently running or has not yet been started. When a run has completed, the run status becomes either **Complete** or **Error Occurred**. At this point, the **Cancel** option in the menu is replaced by a **Delete** option, which you can use to delete a run (including a run that has been cancelled).

To cancel a run:

1. On the [Run History page](#), click  for the run and then click **Cancel**.
2. At the message asking if you want to cancel the run, click **OK**. The Status of the run changes to **Cancelled**, and the run can be deleted or [re-run](#).

When you cancel a loading and checking run, the status of the study or study pool becomes **Study Initialized**. The study cannot be selected on the Select tab until another loading and checking run has been performed.

To delete a run:

1. On the [Run History page](#), click  for the run and then click **Delete**. The delete option is available only if the run has been completed or cancelled. Thus, if you want to delete a run that is currently running or is scheduled to run in the future, you must first cancel it.
2. At the message asking if you want to delete the run, click **OK**. The run is removed from the Run History.

Note: You cannot delete the most recently submitted loading and checking run for a study.


Re-running a Run

From the Run History page, you can re-run the most recent load and check run for a study or the most recent pool loading run. You cannot re-run an analysis specification or an automatic screening run.

You can re-run runs that are currently running, completed successfully, failed, were cancelled, or have not started.

Note: When you reload a study from the Setup tab, you can choose different settings for distributing supplemental qualifiers or retaining study properties. You cannot change these settings when you re-run a load and check run from the Run History.

To re-run a run:

1. On the [Run History page](#), click the Action menu icon () for a loading and checking run or a pool loading run and then click **Re-run**.

You cannot re-run if the study or pool is currently selected (on the **Select** tab) by you or another user. If you have the study or pool selected yourself, the message that appears gives you the option to click **OK** to de-select the study the pool.

You cannot reload a study if any screening results or issue clusters for the study are attached to a potential signal. Also, you cannot reload a study that is part of a pool.

You cannot reload a pool if any screening results or issue clusters for the pool are attached to a potential signal.

If you select a study or pool that has already been loaded and checked (that is, its State is **Ready to Use**), a message informs you that reloading will remove data checking results and so on. For information about what occurs when you reload a study or pool, see [Results of Loading and Checking](#).

2. The [Run Options page](#) appears and you can change run options as needed.
3. Confirm run parameters and [submit the run](#). A new entry for the run is created in the Run History.

Administration

Managing Users

About Managing Users

A user with the Administer Users permission is responsible for setting up usernames and permissions.

Users and permissions

Each user must have a username and password, permissions, and a login group. Permissions control the activities, such as study loading or report creation, that a user can perform.

A user role is a set of permissions that may be needed by a particular type of user, such as a reviewer. WebSDM/Empirica Study includes several [predefined user roles](#), and you can add additional user roles to meet your organization's needs.

To assign permissions to users, you assign user roles, individual permissions, or both.

A login group is a group of users. Each login group may have its own version of the **Home** tab, with links to customer-specific information.

Access to objects

A user with the **Administer Users** permission can:

- Select any applications, regardless of whether the application has been published.
- Act on subject lists, report definitions, and report outputs that other users have created, regardless of whether the objects have been published.

Users without this permission can perform certain activities with these objects only if they created the object or the object is published to their login group.

Related Topics

[Viewing Existing Users](#)

[Viewing Existing User Roles](#)

[Viewing Existing Login Groups](#)

User Permissions

Permissions can be assigned to a user or to a user role (which is then assigned to a user). The following table shows each permission, the tabs the permission enables, and the activities the permission allows.

Permission	Rights Granted
Review Studies (Needed by most users)	View all information on the Domains tab; view subject lists that have been published to the user's login group; and view report definitions or report outputs that have been published to the user's login group. Most users need the Review Studies permission. The exception might be users who have only the Administer Users permission. Tabs enabled: Select, Domains, Subject Lists (view only), Reports (view only)
Download Study Data	Download clinical data from the Clinical Data page; download a report that displays when a report definition is run or a report output is viewed; Download Subject Details.
Manage Subject Lists	Create, copy, rename, or delete subject lists.
Manage Reports	Create, edit, or copy report definitions, and e-mail the XML of a report definition.
Manage Report Outputs	Create report outputs and edit their attributes. Users do not need this permission in order to run report definitions or view report outputs.
Review Analysis Results	View the results of analysis specifications; mark analysis results as reviewed; and manage screening result views. This permission does not allow users to create analysis specifications, attach results to a potential signal, or manage custom analysis types. Tabs enabled: Screening (Specifications and Issue Clusters links), Safety Review
Manage Analysis Specifications	Create, edit, copy, delete, and run analysis specifications; create and manage custom analysis types whose visibility is the current analysis specification; and perform all actions that can be performed by users with the Review Analysis Results permission. Tabs enabled: Screening (Specifications link), Safety Review, Run History
Manage Custom Analysis Types	View existing custom analysis types; create custom analysis types; and manage custom analysis types visible to all applications to which the user has access. Tabs enabled: Screening, Safety Review
Review Potential Signals	Users with this permission can: view all information on the Potential Signal page; add comments to the potential signal; annotate attached results, issue clusters, Bayesian Logistic Regression runs (for runs created prior to WebSDM/Empirica Study release 3.1), or documents in a potential signal; view a potential signal's history and archives; and perform all actions that can be performed by users with the Review Analysis Results permission. They cannot: change the status of the potential signal; \ or attach results, issue clusters, or documents to a potential signal. Tabs enabled: Screening (Specifications and Potential Signals links), Safety Review
Manage Potential Signals	Users with this permission can mark screening results as reviewed; attach results, issue clusters, or documents to a potential signal; create a new potential signal; perform all activities on the Potential

Signal page, including creating category breakdowns ; view a potential signal's history and archives; and perform all actions that can be performed by users with the Review Analysis Results permission.

Tabs enabled: Screening (**Specifications** and **Potential Signals** links), Safety Review, Run History

Manage Issue Clusters	Create issue cluster mining runs; save, edit, view, and delete issue clusters. Tabs enabled: Screening (Issue Clusters link).
Manage BLRs	Create, Edit, Run, Copy, and Delete BLR runs; view a list of BLR runs; view results of BLR runs. Tabs enabled: Screening (BLRs link).
Load and Check Studies	Load and check study data and view the Run History. Note: Users who have this permission but not the Manage Applications and Studies permission can load only studies that are visible to them on the Studies and Study Pools page. Additionally, they can load any studies in the selected application if they use the Load Studies/Pools link at the top of that page.
Add to Standard Metadata	Load and edit customer-defined rules and error messages.
Manage Applications and Studies	Perform activities on the Applications page and the Studies and Study Pools page, with the following exceptions: <ul style="list-style-type: none"> • The Load and Check Studies permission is required for loading studies. • An application can be deleted by only a Superuser. • A study or pool can be deleted only by a user who owns it or has the Delete Studies permission.
Manage Global Properties	At the system level, create and manage event lists and define test identifiers.
Delete Studies	Delete studies and study pools. Additionally, a user who is the owner of a study or study pool can delete the study or pool. The user must also have the Manage Applications and Studies permission in order to delete studies or pools.
Administer Users	Create and edit users; create login groups; create user roles; send a message to users; view the User Activity Audit Trail; view currently logged in users; and set site options related to user passwords. (Other site options are available to only Superusers.) Users with this permission can also act on objects (including unpublished objects), such as queries, that have been created by other users.

Safety review permissions

To use the Safety Review tab, you must have either the Review Studies or Administer Users permission as well as one of the following permissions: Review Analysis Results; Manage Analysis Specifications; Manage Custom Analysis Types; Review Potential Signals; or Manage Potential Signals. Additionally, the appropriate [site option](#) must be set.

Superuser permissions

A user designated as a Superuser can perform any activities. Only a Superuser can perform the following activities:


- Delete an application.
- Restart the listener process.
- Set up a database connection.
- Set any site options, including those related to user passwords.
- View the server status.
- View free disk space.
- Create or edit built-in report definitions.

Changing User Passwords

If you are a Superuser or you have the **Administer Users** permission, you can change other users' passwords.

If you have implemented single sign-on, you cannot change user passwords in WebSDM/Empirica Study. You must use Oracle Access Manager to change or reset user passwords.

To change a user password:

1. On the [Users page](#), click  next to the user whose password you want to change, and then click **Edit**. The Add/Edit User page appears.
2. Select the user whose password you want to change, and then click **Edit User**.
3. Click **Change Password**.
4. Enter a value in the New Password field, up to a maximum of 64 characters. Site options determine the required password length and the types of characters allowed (alphabetic, numeric, non-alphanumeric, lowercase, uppercase). Password requirements, if any, for length and character types are displayed. There may be restrictions on the re-use of old passwords.

Note: To log in to WebSDM/Empirica Study, the user's exact password must be entered in the correct case (upper, lower, or mixed).

5. Enter the same value in the Confirm Password field.

- Click **Change Password**. The password is updated. The password expiration period, if one has been set as a [site option](#), begins for the new password. The next time the user logs in to WebSDM/Empirica Study, the user must use the new password.

Managing Users

Viewing Existing Users


To view existing users:

- Click **Settings** and then click **Edit Users**. The Users page appears.
- In the Login Group field, select the login group for which you want to view users. If "--" is in the Login Group field, all users from all login groups appear.
- In the Status field, select Enabled if you want to view only usernames that are currently enabled. If "--" is in the Status field, enabled and disabled usernames appear.

The Users page provides a table of the following information about each user:

Column	Description
Username	Unique name of the user account.
Name	Full name associated with the username.
Email	E-mail address (or addresses, separated by commas) for the user. This address is the default address used when the user sends feedback or requests e-mail notification about run completion. For a user with appropriate permissions, it is also used if the user sends a message to all users or receives notification of a user account lockout due to login failures.
Login Group	Login group to which the user belongs.
Status	Enabled if the user can log in to WebSDM/Empirica Study. Disabled if the user cannot log in. Note: This value is determined by the "Account disabled" check box on the Edit User page.
Quota	This option is reserved for future use and should be left blank.
SSO Login	Indicates whether single sign-on is enabled for the username. You must add this optional column using the Columns link. <ul style="list-style-type: none"> Enabled —Single sign-on authentication is enabled. Disabled —Single sign-on authentication is disabled. The user is locally authenticated.

- See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.
- To [add a user](#), click **Add a New User**.

6. If you click  for a user, you can do the following:
7. To [edit a user](#), click **Edit**.
8. To [delete a user](#), click **Delete**.

Related Topics

[Adding/Editing a User](#)

[Renaming a User](#)

[About Single Sign-On](#)

Adding/Editing a User


You create a username for each user who logs in to WebSDM/Empirica Study. When you create usernames, you must ensure that each username is unique in its composition. WebSDM/Empirica Study converts usernames to lowercase automatically upon creation, and thus does not allow duplicate usernames that differ only in case. For example, if you create user **jkelly** and then attempt to create user **JKelly**, a message appears, indicating that the user already exists.

When you create a new user, WebSDM/Empirica Study sends an email message to the user if you have provided an email address for the user. The message includes the new username and password, and the URL from which to access WebSDM/Empirica Study. The From address is the address associated with the [site option Feedback Email](#).

If you have enabled single sign-on, the WebSDM/Empirica Study usernames that you create must be identical to their associated single sign-on usernames in Oracle Access Manager. In addition, you must still provide a WebSDM/Empirica Study password. When single sign-on is enabled, WebSDM/Empirica Study usernames and passwords are applicable if, for example, a Superuser logs in to WebSDM/Empirica Study natively using a remote desktop connection. You create WebSDM/Empirica Study passwords according to the password restrictions you specified on the [Site Options](#) page.

This procedure describes adding and editing WebSDM/Empirica Study users only. For information on creating single sign-on users in Oracle Access Manager, refer to your Oracle Access Manager documentation.

To add or edit a user:

1. On the [Users page](#), do one of the following:
 - To **add** a user, click **Add a New User**.
 - To **edit** a user, click  next to the user that you want to edit, and then click **Edit**.

The **Add/Edit User** page appears.

2. Enter the following:

Field	Description
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Username	Unique name (up to 100 characters) of the user account. You can also re-use deleted usernames. This field appears only if you are creating a new username. If you are using single sign-on, this username must be identical to the associated single sign-on username in Oracle Access Manager.
First Name	The user's first name.
Last Name	The user's last name
Email	Optional e-mail address (or addresses, separated by commas) for the user. This is the default email sender address when the user sends feedback, and the default recipient address when the user requests email notification about run completion. For a user with appropriate permissions, it is also used if the user sends a message to all users, or receives notification of a user account lockout due to login failures.
Password	<p>Password for the user, up to a maximum of 64 characters. Note that users can also modify their own WebSDM/Empirica Study passwords. Follow any recommendations by your organization related to creating secure passwords. Site options affect allowed passwords.</p> <p>Note: If you are using single sign-on, you must still provide a WebSDM/Empirica Study password.</p>
Confirm Password	Re-enter the password.
Login Group	Name of the login group to which the user belongs.
Quota	Reserved for future use. Leave blank.

3. Select or deselect any of the following:

Field	Description
Superuser	<p>Indicates whether the user is a Superuser. Available only if you are logged in as a Superuser.</p> <ul style="list-style-type: none"> • If selected—The user is a Superuser. • If deselected—The user is not a Superuser.
User must change password at next login	<p>Indicates whether the user must change his or her password during the next login.</p> <ul style="list-style-type: none"> • If selected—A window appears during the login process, requiring the user to enter a new password. WebSDM/Empirica Study then deselects this option automatically when the user has reset his or her password. • If deselected—The user is not required to enter a new password.

Password never expires	Indicates whether the user's password never expires. At least one user should have a password that does not expire, and can access all users. Generally, this is user is the user with the Administer Users permission.
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- **If selected**—The user's password never expires.
- **If deselected**—The user's password expires after the number of days specified in the Password Expiration site option.

Account disabled	Indicates whether the user's account is disabled.
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- **If selected**—The account is disabled and the user cannot log in. WebSDM/Empirica Study selects this checkbox automatically for users who attempt to log in with an incorrect password more than the number of times allowed by the **Number of Attempts Allowed** [site option](#).
- **If deselected**—The account is enabled and the user can log in.

When a user's password has expired, the user's account becomes disabled. To allow the user to log in again, you must:

- Assign a new password to the user.
- Re-enable the user's account.

Note: If a potential signal is assigned to a user account that you disable, the potential signal is re-assigned automatically to a user who is in the same login group and has the required permissions.

4. Click **Save**. When you have saved the username, links to assign roles, assign permissions, change the user password, and rename the user appear on the page.

Note: If you do not click Save before continuing the next steps, the changes you made in previous steps are not saved.

5. Optionally [assign roles](#) to the user.
6. Optionally [assign permissions](#) to the user.
7. Optionally [change the user's password](#).
8. Optionally [rename the user](#) if you selected the **Enable SSO Login when SSO is configured** check box.

This link is available only if you are a Superuser or you have the **Administer Users** permission.

Related Topics

[About Single Sign-On](#)

[Deleting a User](#)

Assigning Roles to a User

A user role is the name of a set of permissions for a group of users. WebSDM/Empirica Study provides [predefined user roles](#), which you can modify or supplement. When you create a user, you can assign one or more user roles to the username. You can also [assign individual permissions](#) to the username.

To assign roles to a user:

1. On the [Add/Edit Users page](#), click **Assign Roles**. The **Assign Roles** page appears.
2. Select or deselect the appropriate checkboxes to assign roles to or unassign roles from the username.
3. Click **Save**. WebSDM/Empirica Study grants the permissions associated with the role to the user. The changes take effect the next time the user logs in.

Assigning Permissions to a User

You can assign permissions to users by:

- Assigning the users to roles.
- Selecting individual permissions.

If the user has permissions that were assigned by a user role, those permissions are pre-selected on the Assign Permissions page. You can assign additional permissions as necessary. However, you cannot disable the permissions that were assigned via a user role.

To assign or unassign permissions:

1. On the [Add/Edit Users page](#), click **Assign Permissions**. The **Assign Permissions** page appears, listing all possible [permissions](#).
2. Select or deselect the appropriate check boxes to assign permissions to or unassign permissions from the user.
3. Click **Save**. The changes take effect the next time the user logs in.

Deleting a User

If you delete a user who has never logged in, the username is removed from the database. It is possible to create another user with the same username as the deleted user.


When you delete a user who has logged in at least once:

- The username can no longer be used to log in; however, the username is not removed from the database.

- The only place where the username is visible is the [User Activity Audit Trail](#), where you can view activities performed by the deleted user. (The username is followed by "deleted".)

When you delete a user, your username becomes the owner of any applications, studies, subject lists, report definitions, or report outputs that were created by that user, and your username appears in the Run History instead of the deleted username. You cannot delete a user to whom any potential signals are assigned currently.

To delete a user:

1. On the [Users page](#), click the Action menu icon () for the user and then click **Delete**.
2. Click **Yes, delete this user**. The user is deleted. If the deleted user is currently logged in, that user can continue working; however, once the user logs out, the user cannot log in again.

Renaming a User


When you enable single sign-on, you must ensure that your WebSDM/Empirica Study usernames are identical to their associated single sign-on usernames in Oracle Access Manager. If the usernames are not identical, you must rename your Empirica Study users to allow single sign-on to function properly.

When you rename your users:

- Users can no longer use their original username to log in to Empirica Study.
- Empirica Study converts usernames to lowercase automatically upon creation, and thus does not allow duplicate usernames that differ only in case.

For example, if you create user **jkelley** and then attempt to create user **JKelley**, a message displays, indicating that the user already exists.

To rename a user:

1. On the [Users page](#), click the Action menu icon () next to the user that you want to rename. A sub-menu appears.
2. Click **Edit**. The **Add/Edit User** page appears.
3. Click **Rename User**. The **Rename User** page appears.
4. Enter a new username. The name must be unique, and can be up to 100 characters long.
5. Click **Save**. The **Add/Edit User** page re-appears.

Related Topics

[About Single Sign-On](#)

[Configuring Single Sign-On for WebSDM/Empirica Study](#)

Managing User Roles

Predefined User Roles

WebSDM/Empirica Study is delivered with the following predefined user roles that have the indicated user permissions:

Permission	Reviewer role	Advanced Reviewer role	Study Loader role	Customer Administrator role
Review Studies	X	X	X	X
Download Study Data	X	X	X	X
Manage Subject Lists	X	X		X
Manage Reports	X	X		X
Manage Report Outputs	X	X		X
Review Analysis Results	X	X		X
Manage Analysis Specifications		X		X
Manage Custom Analysis Types		X		X
Review Potential Signals	X	X		X
Manage Potential Signals		X		X
Manage Issue Clusters				
Manage BLRs				
Load and Check Studies			X	X
Add to Standard Metadata				X
Manage Applications and Studies		X	X	X
Manage Global Properties		X	X	X
Delete Studies			X	X
Administer Users				X

Viewing Existing User Roles

A *user role* is a set of permissions that may be needed by a particular type of user. WebSDM/Empirica Study is delivered with a set of predefined user roles, which you can modify or supplement.

When a user is created, one or more roles may be assigned to the user. Permissions can also be assigned individually and explicitly to a user. Individually assigned permissions are in addition to any permissions granted by a role.

To view existing user roles:

1. Click **Settings** and then click **Edit Roles**. The Edit Roles page appears.
2. To [create a user role](#), click **Create New Role**.
3. To [assign permissions to a user role](#), click **Edit** for the role.
4. To delete a user role, click **Delete** for the role. When a message asks if you are sure you want to delete the role, click **OK**. The role is deleted. Users currently logged in with that role can continue with their current session; however, once they log out, their permissions will no longer include those that had been granted solely through the deleted role.

Creating a User Role

1. On the [Edit Roles page](#), click **Create New Role**. The Create New Role page appears.
2. Enter a unique name for the user role.
3. Click **Save**. To assign permission to the user role, click **Edit** for the new role on the **Edit Roles** page.

Assigning Permissions to a User Role

1. On the [Edit Roles page](#), click **Edit** for the name of the user role. The **Permissions for Roles** page appears.
2. Select or deselect the appropriate check boxes to assign permissions to or unassign permissions from the user role. For more information on the WebSDM/Empirica Study activities that are made available by each permission, see [User Permissions](#).
3. Click **Save**. For users in the login group, the changes take effect the next time they log in.

Managing Login Groups

Viewing Existing Login Groups

A *login group* is a group of users. When you [add a new user](#), you associate the user with a login group.

To view existing login groups:

1. Click **Settings** and then click **Edit Login Groups**. The Edit Login Groups page appears.
2. To [create a login group](#), click **Create New Login Group**.
3. To [edit a login group](#), click **Edit** for the login group. The Login Group Settings page includes a list of which users are currently in the login group and which studies and study pools are currently published to the login group.
4. To delete a login group, click **Delete** for the login group. When a message asks if you are sure you want to delete the login group, click **OK**.

If the login group includes usernames (even if they are disabled), you cannot delete the login group unless you first delete those usernames.

Creating a Login Group

1. On the [Edit Login Groups page](#), click **Create New Login Group**. The Create Login Group page appears.
2. Enter a unique name for the login group.
3. Click **Save**. The [Login Group Settings page](#) appears for the new login group so that you can provide information about the new login group.

Editing a Login Group

1. On the [Edit Login Groups page](#), click **Edit** for the login group. The Login Group Settings page appears.

Note: The Login Group Settings page also appears when you are creating a new login group, after you enter a login group name and click **Save**.

2. In the **Logo Image** field, enter the name of an image file. (You cannot use a text file.) The image will be forced to be 150 x 100 pixels in size. The image file must exist in the \image subdirectory of the server location to which WebSDM/Empirica Study was installed.

If Empirica Study is not enabled (via a site option), the Logo Image field shows W_logo.bmp by default for a new login group. If Empirica Study is enabled, it shows E_logo.bmp by default.

3. In the **Home Page** field, enter the name of the file that contains the customized .html for the Home page. The .html file must exist in the \customhomes subdirectory of the server location to which WebSDM/Empirica Study was installed.

If Empirica Study is not enabled (via a site option), the **Home Page** field shows W_home.inc by default for a new login group. If Empirica Study is enabled, it shows EStudy_home.inc by default.

4. The Users list includes all users who are currently in the login group, including user accounts that are disabled. The number in parentheses indicates the total number.

5. The Studies and Pools list includes all studies and study pools that are currently published to the login group. The number in parentheses indicates the total number. The list format is application name, forward slash (/), and study name.

Note: Studies or pools published to **All** login groups are published automatically to new login groups.

6. Click **Save**. For users in the login group, the changes take effect the next time they log in.

Using Single Sign-On

About Single Sign-On

Single Sign-On is an optional authentication method that allows users to log in to WebSDM/Empirica Study and other applications in a single sign-on environment using one username and password. With single sign-on enabled, users log in to your single sign-on environment once, and can then access all applications within the environment without having to re-enter their credentials.

As a system administrator, single sign-on simplifies your user administration across applications by reducing the number of user accounts that must be managed. Single sign-on also eliminates the need for users to remember multiple usernames and passwords.

To enable single sign-on, you must have installed and configured Oracle Access Manager, and installed and configured the Webgate agent on the Empirica Study application server. Contact Oracle for assistance in installing and configuring these components.

WebSDM/Empirica Study supports single sign-on using Oracle Access Manager only.

For more information on configuring single sign-on, see [Configuring Single Sign-On for WebSDM/Empirica Study](#).

Configuring Single Sign-On for WebSDM/Empirica Study

To add WebSDM/Empirica Study to a single sign-on environment, several configuration tasks outside of the WebSDM/Empirica Study application are necessary before enabling single sign-on for your WebSDM/Empirica Study users. Your application environment determines whether your site administrator or Oracle performs the configuration tasks.

Single Sign-On Configuration—Hosted Installations

If Oracle hosts your WebSDM/Empirica Study installation, contact Oracle to perform all single sign-on configuration tasks.

Single Sign-On Configuration—Self-Hosted Installations

If you self-host your WebSDM/Empirica Study installation, your site administrator performs most configuration tasks. Your site administrator must also contact Oracle for assistance in

configuring Oracle Access Manager and the Webgate agent. See the installation checklist below for specific task responsibilities.

Task	Responsibility	Source for Instructions
Install Oracle Access Manager, if it is not already installed.	Oracle/Site Administrator	Contact Oracle for assistance.
Configure a Webgate agent on the Oracle Access Manager server.	Oracle/Site Administrator	Contact Oracle for assistance.
Install and configure Webgate on the WebSDM/Empirica Study application server.	Oracle/Site Administrator	Contact Oracle for assistance.
Uncomment the single sign-on properties in the <code>website.properties</code> file.	Site Administrator	WebSDM/Empirica Study Windows 2003/2008 Server Installation and Upgrade Instructions
Optionally specify the URL for a custom logout page.	Site Administrator	WebSDM/Empirica Study Windows 2003/2008 Server Installation and Upgrade Instructions
Modify the WebSDM/Empirica Study application session timeout to ensure that it is longer than the single sign-on session timeout.	Site Administrator	WebSDM/Empirica Study Windows 2003/2008 Server Installation and Upgrade Instructions
Configure the WebSDM/Empirica Study application server for native logins.	Site Administrator	WebSDM/Empirica Study Windows 2003/2008 Server Installation and Upgrade Instructions
Exclude specific URLs from single sign-on authentication.	Site Administrator	WebSDM/Empirica Study Windows 2003/2008 Server Installation and Upgrade Instructions
Restart the WebSDM/Empirica Study service.	Site Administrator	WebSDM/Empirica Study Windows 2003/2008 Server Installation and Upgrade Instructions
Validate your single sign-on configuration by logging in with your Oracle Access Manager single sign-on username and password.	Site Administrator	WebSDM/Empirica Study Windows 2003/2008 Server Installation and Upgrade Instructions
Create single sign-on users in Oracle Access Manager if you installed Oracle Access Manager for the first time.	Site Administrator	Oracle Access Manager documentation.
Rename existing WebSDM/Empirica Study usernames to match their associated Oracle Access Manager single sign-on usernames.	Site Administrator	Renaming a User
Select the Enable SSO Login when SSO is configured check box for WebSDM/Empirica Study usernames.	Site Administrator	Adding/Editing a User

Related Topics

[About Single Sign-On](#)

[Logging In](#)

[Exiting](#)

Renaming a User


When you enable single sign-on, you must ensure that your WebSDM/Empirica Study usernames are identical to their associated single sign-on usernames in Oracle Access Manager. If the usernames are not identical, you must rename your Empirica Study users to allow single sign-on to function properly.

When you rename your users:

- Users can no longer use their original username to log in to Empirica Study.
- Empirica Study converts usernames to lowercase automatically upon creation, and thus does not allow duplicate usernames that differ only in case.

For example, if you create user **jkelley** and then attempt to create user **JKelley**, a message displays, indicating that the user already exists.

To rename a user:

1. On the [Users page](#), click the Action menu icon () next to the user that you want to rename. A sub-menu appears.
2. Click **Edit**. The **Add/Edit User** page appears.
3. Click **Rename User**. The **Rename User** page appears.
4. Enter a new username. The name must be unique, and can be up to 100 characters long.
5. Click **Save**. The **Add/Edit User** page re-appears.

Related Topics

[About Single Sign-On](#)

[Configuring Single Sign-On for WebSDM/Empirica Study](#)

Managing the Server

Specifying Settings

When you click the **Settings** link at the top of any page, the **Settings** page appears. Your user permissions determine the options that are available on the **Settings** page. For most users, this page includes only the [Change Password](#) link. However, if you log in to WebSDM/Empirica Study using a single sign-on username and password, the Change

Password link is unavailable. You change your single sign-on password in Oracle Access Manager.

Depending on your user permissions, the options listed below may also be available.

Manage Users

- [Edit Users](#)
- [Edit Login Groups](#)
- [Edit Roles](#)

Monitor System

- [View User Activity Audit Trail](#)
- [View Currently Logged In Users](#)
- [View Server Status](#)
- [View Free Space](#)

Administer System

- [Set Site Options](#)
- [Send Message to All Users](#)
- [Restart Listener](#)
- [Set Database Connection](#)

Configure System

- [Manage Global Properties](#)
- [Edit Error Messages](#)
- [Edit Rules](#)
- [Load Customer-defined Rules and Messages](#)
- [Manage Configurations](#) (for use only by Oracle when setting up the system for your organization)

Sending a Message to All Users

You can send an e-mail message to all enabled users whose usernames have an associated e-mail address. For example, you might want to send a message announcing an upgrade or scheduling maintenance. You provide user e-mail addresses when you add or edit users on the [Add/Edit User page](#).

To send a message to all users:

1. Click **Settings** and then click **Send Message to All Users**. The Send Message to All Users page appears.
2. In the **Subject** field, enter the subject of your message.
3. In the **Comments** field, enter the text of your message.
4. Click **Send**. Users to whom the message was sent are listed. WebSDM/Empirica Study sends the message to all enabled users, regardless of whether they are currently logged in.
5. Click **Continue**.

In the e-mail message:

- The date and time of the message is the date and time at which you clicked **Send**.
- The From line shows the e-mail address associated with the **admin** username, if one is associated. If no e-mail address is associated, the From line shows the e-mail address associated with the **Feedback Email** field on the [Set Site Options page](#).
- The Subject line shows the text you entered in the subject line.

Viewing the User Activity Audit Trail


The *User Activity Audit Trail* provides information about activities for selected users, activities, and dates. Also see [User Activity Audit Trail](#).


To view the User Activity Audit Trail:

1. Click **Settings** and then click **View User Activity Audit Trail**. The User Activity Audit Trail Options page appears.
2. In the User field, select a username or select "– all –".
3. Check the activities that you want to include in the User Activity Audit Trail. The activities that you can include in the Audit Trail do not represent every type of activity that can be performed; they represent activities that are most likely to need monitoring.

To check all activity check boxes, click **Check All**. To clear all activity check boxes, click **Clear All**.

4. If you do not need audit trail information before or after a certain date, you can specify start and end dates.

In the Start Date field, type in a date in mm/dd/yyyy format or click  next to the date field to display a calendar. Specified activities that occurred on or after the Start Date will appear in the User Activity Audit Trail. If you leave this field blank, there is no limit on the Start Date.

In the End Date field, type in a date in mm/dd/yyyy format or click  next to the date field to display a calendar. Specified activities that occurred on or before the End Date will appear in the User Activity Audit Trail. If you leave this field blank, there is no limit on the End Date.

- Click **View User Activity**. The settings that you specified are used for this version of the User Activity Audit Trail, but are not saved. To modify the settings, click **Back** and respecify them.

User Activity Audit Trail

The User Activity Audit Trail provides the following information:

Column	Description
ID	Automatically assigned numeric activity identifier.
USER_NAME	Username of the user who performed the activity. (The username is followed by "deleted" if the username has been deleted.)
SESSID	Automatically assigned identifier of the user's WebSDM/Empirica Study session.
IP	IP address of the computer used to connect to WebSDM/Empirica Study.
Activity	Name of the activity. Only activities that you specified on the previous page appear in the audit trail.
Activity Start	Date and time at which user activity started. The date and time format is determined by a site option .
Activity End	Date and time at which the user activity ended. The date and time format is determined by a site option.
INFO	More information on the activity that was performed.

See [About Tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

Applications and studies

When an application is registered, studies for the application may be registered automatically. The application registration and each study registration are separate entries in the audit trail.

When a study is deleted, other objects may be deleted automatically. The study deletion and the deletion of each object are separate entries in the audit trail.

Related Topics

[Viewing the User Activity Audit Trail](#)

Viewing Currently Logged In Users

To view information about users who are currently logged in:

Click **Settings** and then click **View Currently Logged In Users**. The Currently Logged In Users page provides the following information about each user who is currently logged in:

Column	Description
User Name	Full name followed by the username in brackets.
Login Date	Date and time at which the user logged in. The date and time format is determined by a site option .
Session ID	Automatically assigned identifier of the user's WebSDM/Empirica Study session.
IP	IP address of the computer from which the user is connected.

If a user closes the browser before logging out, the session becomes inaccessible to the user but persists within WebSDM/Empirica Study (that is, the session remains listed on the Currently Logged In Users page) until the session timeout period passes. (Setting the timeout period is described in the WebSDM/Empirica Study installation instructions.) Depending on the activity the user was performing just before closing the browser, the persistence of this "orphaned" session may prevent others from performing certain activities. For instance, a study or study pool that had been selected cannot be reloaded; also, a potential signal that was being edited is not accessible by any other user. You can cancel an "orphaned" session from the Currently Logged In Users page by clicking **Cancel Session** on the appropriate row.

Note: The **Cancel Session** link is displayed for every session (because WebSDM/Empirica Study cannot distinguish "orphaned" sessions from active ones) so you should take great care when using this feature. It is not intended as a means to cancel current user sessions.

Related Topics

[Viewing the User Activity Audit Trail](#)

Restarting the Listener Process

The WebSDM/Empirica Study listener process is responsible for identifying background work and assigning it to processes for execution. The listener process starts when WebSDM/Empirica Study starts up, and updates an associated "heartbeat" date and time value every 2-30 seconds while WebSDM/Empirica Study is running.

Occasionally, the listener process terminates unexpectedly (either because it encounters an error or is stopped by a system operator).

When a run is submitted, WebSDM/Empirica Study checks the heartbeat value to determine if the listener process is still running. If the listener process is not running, it is restarted automatically.

You can restart the listener process manually from within WebSDM/Empirica Study at any time.

To restart the listener process:

1. Log in as a Superuser.

- Click **Settings** and then click **Restart Listener**. A message tells you that the listener was started.

Note: You can restart the listener process only if the listener is running as part of the WebSDM/Empirica Study web site. If the listener is running outside of the web site, clicking **Restart Listener** has no effect.

Setting Up a Database Connection

- Log in as a Superuser.
- Click **Settings** and then click **Set Database Connection**. The Set Database Connection page appears.
- Enter values in the following required fields:
 - User Name**—Username for the Oracle account that contains the WebSDM/Empirica Study support tables. The account must have been set up and configured to support WebSDM/Empirica Study.
 - Password**—Password for the Oracle account.
 - Confirm Password**—Re-enter the password for the Oracle account.
 - Connection String**— Database connection string for the Oracle account that contains the WebSDM/Empirica Study support tables.
- Optionally select the **Encrypt Password** check box.
 - If selected**—Encrypts the password in the text file that WebSDM/Empirica Study uses to store the database connection information. Oracle recommends encrypting the password for security reasons.
 - If deselected**—Does not encrypt the password.
- Click **Save**.

To modify the database connection information further, click **Edit Again**. To log in to WebSDM/Empirica Study (for example, to test the connection), click **Login to site**.

Setting Site Options

A site option is a setting that customizes an aspect of WebSDM/Empirica Study for all users of the website from which WebSDM/Empirica Study is run.

Note: The password restriction site options are not applicable to single sign-on passwords. You set password restrictions for single sign-on users in Oracle Access Manager.

To specify site options:

- Click **Settings**. The **Settings** page appears.
- Click **Set Site Options**. The Site Options page appears.

If you have the Administer Users permission but you are not a Superuser, you can set only the site options related to password restrictions.

Site Option	Description
Sponsor Name	Name of the application sponsor, to be used by default for newly registered applications.
Submissions Can Override	<p>Determines whether the default sponsor name that appears during application registration can be overridden.</p> <ul style="list-style-type: none"> • If selected—You can override the default sponsor name. • If deselected—You cannot override the default sponsor name.
System Name	Short identifier for the software. For example, WebSDM .
System Description	Text to appear as the page name on the Home tab. For example, Web Submission Data Manager .
System Version Description	Software version to appear on the Home tab. For example, Version 3.1.
Profile for new Accounts	<p>The database account profile. The default value is DEFAULT. If your Database Administrator has defined an alternative profile, you can select that value from the drop-down list.</p> <p>Your Database Administrator must define an alternative database profile if one of the following is true:</p> <ul style="list-style-type: none"> • Your database is configured with a DEFAULT profile that imposes limits on the duration of passwords. <p>Or</p> <ul style="list-style-type: none"> • The DEFAULT profile uses a password verification function that is more restrictive than the passwords that WebSDM/Empirica Study normally generates and assigns to the application database accounts and study database accounts. <p>For information and instructions on creating an alternative profile, see Appendix A, Profile for Study Accounts, in the <i>WebSDM/Empirica Study System Administration Guide</i>.</p>
Default Tablespace for new Accounts	Default tablespace for study data tables. The options are:

- **Create a new tablespace for each Application**—WebSDM/Empirica Study creates a new default tablespace automatically for each new application. Oracle recommends selecting this option.
- **Use this tablespace for all Application and Study accounts**—WebSDM/Empirica Study uses the selected default tablespace for all applications. If you use one tablespace for all applications, Oracle recommends that you use **WebSDM**.

Temporary Tablespace for new Accounts	Temporary tablespace for application-level accounts and study-level accounts.
Root directory of source data for all applications and studies	<p>Root directory that contains the application directory and its study subdirectories. Click Browse next to this field to navigate through the directory structure and select a directory.</p> <p>If you change this value from a previously specified directory, applications that have already been registered are not affected.</p> <p>For more information, see Directory Structure for Applications and Studies.</p>
Expiration	<p>The number of days after which user passwords expire. This affects passwords for all new and existing users. The expiration period is the number of days from when:</p> <ul style="list-style-type: none"> • The user was created. <p>Or</p> <ul style="list-style-type: none"> • The password was last changed. <p>The default value is 0, indicating no password expiration.</p> <p>Note: It is possible that passwords for existing users will expire when you set this option. In this instance, a message informs each user that his or her password has expired. At least one user should have the Password never expires option selected before you set or change the this setting.</p>
Expiration Warning	<p>The number of days prior to password expiration that a warning message begins to appear when users log in. This optional setting affects passwords for all new and existing users. The default value is 7.</p> <p>The expiration warning period is the number of days</p>

from when:

- The user was created.

Or

- The user's password was last changed.

For example, if you enter **5**, then 5 days before a user's password is due to expire, a warning message appears when the user logs in. The user can then [change the password](#). If the user continues without changing the password, the message continues to appear upon login for the number of days you specified until:

- The user changes his or her password.

Or

- The password expires.

Minimum Length	The minimum length (up to a maximum of 64 characters) of new passwords. Existing passwords are not affected by this value. The default value is 8 .
Number of Attempts Allowed	<p>The number of times that each user can attempt to log in with an incorrect or missing password before WebSDM/Empirica Study disables the user account. When this limit is reached, WebSDM/Empirica Study sends a lockout notification email to all users with the Administer Users permission. The default value is Unlimited.</p> <hr/> <p>Note: When a user account is disabled due to excessive login attempts, the Account disabled check box is selected automatically for the username. To re-enable the user account, edit the username, deselect the check box, and reset the user's password.</p>
Number of Passwords Retained	<p>The number of unique passwords that WebSDM/Empirica Study should retain in the username history. Passwords retained in a username's history cannot be reused.</p> <p>For example, suppose that you set this option to 20. When the user changes his or her password, WebSDM/Empirica Study retains 20 old passwords. When the user selects a new password the password cannot match any of the 20 passwords in the username history.</p> <p>To allow password re-use, set this value to 0. To prevent password re-use, set this value to a high number, such as 1000.</p>

The default value is 0 .	
Alphabetic Numeric Non-alphanumeric Lowercase Uppercase	Requirements for password content. Specify the number of each character type that must be present when a user creates a new password, or specify 0 to indicate there are no password character requirements. The default value for all fields is 0 .
SMTP Server	<p>The name of the SMTP server to use for the following email notifications:</p> <ul style="list-style-type: none"> • Run completion • Feedback email • Error email
<p>Note: The SMTP mailer must be enabled on the WebSDM/Empirica Study server to support email functions within the application.</p>	
Feedback Email	<p>The email address to which feedback submitted by WebSDM/Empirica Study users is sent. You can enter one address, or multiple addresses separated by commas. The default email address is websdm_bugs@phaseforward.com. This email address appears in email messages as follows:</p> <ul style="list-style-type: none"> • In the To address in emails sent using the Feedback link. • In the From address in the email notification that Web SDM/Empirica Study sends when you create a new user. • In the From address in emails sent to all users if no email address exists for the system administrator.
Error Email	<p>The email address for system error notifications. You can enter one address or multiple addresses separated by commas. The default value is websdm_bugs@phaseforward.com. This email address appears in email messages as follows:</p> <ul style="list-style-type: none"> • In the To and From addresses in emails sent in response to system errors. • In the From address in the email notification that WebSDM/Empirica Study sends to system administrators when user account lockouts

occur.

Date & Time Format	<p>Select the format to use for server datetimes that are displayed. Note that the current datetime is displayed in the format examples.</p> <hr/> <p>Note: UTC is Coordinated Universal Time (abbreviated as UTC).</p>
Auto-Start Local Listener	<p>Determines whether a listener process will be started automatically when a batch run is submitted. The options are Yes and No.</p> <p>This option should be set to Yes unless the listener process does not run on the Web server.</p>
Log Level	<p>Indicates the type of information to be included in the weberror.log file on the WebSDM/Empirica Study server. The options are:</p> <ul style="list-style-type: none"> • Error • Warning • Information • DEBUG
Max Memory Per Report	<p>Defines the maximum amount (MB) of memory that a single report is allowed to use when executing. Typically, set to a value that is no larger than 768 MB. Before changing this option, you may want to consult with Oracle.</p> <hr/> <p>Tip: One way to decrease the amount of memory used by reports is to edit report attributes to set the Generate Drilldown Information option to No.</p>
Allow data import from Oracle Health Sciences InForm	<p>Select to allow import from InForm. If selected, the Register Study page includes Oracle Health Sciences InForm as an available data source type.</p> <hr/> <p>Note: Changes to this option affect only new studies.</p>
Allow data import from Oracle Life Sciences Data Hub	<p>Select to allow import from an Oracle Life Sciences data warehouse. If selected, the Register Study page includes Oracle Life Sciences Data Hub as an available data source type.</p> <hr/> <p>Note: Changes to this option affect only new studies.</p>
Allow Subject Comment/Review/Exclusion	<p>Indicates whether the Reviewer Input section appears on the Subject Details page.</p> <hr/> <ul style="list-style-type: none"> • If selected—The Reviewer Input section appears.

- **If deselected**—The Reviewer Input section does not appear.

Note: This affects only the [Subject Details page](#) that you access on the Subject Lists tab.

Enable PPD Patient Profiles	<p>Indicates whether PPD Patient Profiles is enabled.</p> <ul style="list-style-type: none"> • If selected—PPD Patient Profiles is enabled. • If deselected—PPD Patient Profiles is not enabled. <p>For information on configuring PPD Patient Profiles, see Configuring PPD Patient Profiles.</p>
Enable Advanced Tab	Reserved for future use. Leave blank.
Use FDA Look and Feel	<p>Determines whether additional columns appear on the following pages:</p> <p>The Select Application page: Application Name; Description; Sponsor; and Drug Name.</p> <p>The Select Studies and Study Pools page: Protocol, Type, Standard Version.</p>
Enable Empirica Study Features	<p>Indicates whether Empirica Study features (the Screening tab and the Safety Review tab) are enabled.</p> <ul style="list-style-type: none"> • If selected—Empirica Study features are enabled. • If deselected—Empirica Study features are not enabled.
Enable Second Level Drilldown on Subjects Page	<p>Indicates whether second-level drilldown is enabled on the Subjects page. Second-level drilldown allows users to drill down to view subject details for a particular subject when they are viewing a list of subjects.</p> <ul style="list-style-type: none"> • If selected—Second-level drilldown on the Subjects page is enabled. • If deselected—Second-level drilldown on the Subjects page is not enabled. <p>This option does not apply to the Subject Lists tab or to a subject ID hyperlink in a report; you can always drill down to subject details from these locations.</p>
Enable Download Subject Details	<p>Indicates whether users with the appropriate permission (Download Study Data) can download subject details.</p> <ul style="list-style-type: none"> • If selected—Download of subject details is enabled.

- **If deselected**—Download of subject details is not enabled.

This option does not apply to downloading of information on the Subject Lists tab, or to downloading of subject details that you access from a subject ID hyperlink in a report; users can always download subject details from these locations.

Scrollbar Location for Tables	Indicates the scrollbar location for tables. The options are: <ul style="list-style-type: none"> • Right side—Display vertical scrollbar on the right side of tables of information. • Left side—Display vertical scrollbar on the left side of tables of information. • User's Preference—Make available the user preference Locate table scrollbars on left side so that each user can decide whether to display vertical scrollbars on the left or right side of tables of information.
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3. Click **Save**.
4. Click **Review Changes** or **Continue**.
5. Oracle recommends that you exit WebSDM/Empirica Study and log back in after changing site options. Some site options do not take effect until you have done so.

Viewing the Server Status

WebSDM/Empirica Study supports two different kinds of computer processing:

- Foreground or interactive processing, such as the specification of runs
- Background or batch processing, such as the execution of runs

If you are running on a single-processor server, that processor must perform both kinds of processing. If you are running on a multi-processor server, you can control how the available processors are used to perform foreground or background processing.

The Server Status page allows you to set the maximum number of processors to use for **background processing**, that is, the number of concurrent runs that can be performed. For a dedicated WebSDM/Empirica Study server, Oracle recommends that you set the maximum number of processors to one less than the number of processors that are on the server. For a shared server, a smaller number of maximum processors is recommended.

For example, if there are three processors on a dedicated WebSDM/Empirica Study server, and you set the maximum number of processors to 2, then two runs can run at the same time.

To specify the maximum number of processors:

1. Log in as a *Superuser*.
2. Click **Settings** and then click **View Server Status**. The Server Status page appears.
3. Change the value in the Maximum Processors field.
4. Click **Save**. A message tells you that your update was successful.
5. Click **Continue**.

Viewing Free Disk Space

The option to view free disk space is intended for users who are familiar with Oracle storage mechanisms. This feature may be useful for monitoring the Max Utilization level of a tablespace. When it approaches a threshold predefined by your installation, such as 75%, additional datafiles may need to be allocated.

This option displays information for tablespaces used to store study data only. To review the utilization of tablespaces used to store system data, Oracle DBA tools must be used.

Note: The "Disk information" section of this page is reliable only in configurations where the database and the application server are running on the same server.

To view disk space:

1. Log in as a *Superuser*.
2. Click **Settings** and then click **View Free Space**. The View Free Space page appears.
3. Select an Oracle tablespace. Information about remaining space for each file in the selected tablespace appears.

Reference

About Automatic Screening and Issue Lists

Automatic screening is a process that inspects study data and creates a list of issues that occur for each subject. Automatic screening generates issue lists from the following standard analysis types across all subjects in the study:

- MedDRA PT, HLT, HLGT, and SOC Analysis
- [Standardized MedDRA Query Analysis](#)
- [QT Interval Prolongation Analysis](#)
- [Hy's Law Analysis](#)
- [Clinically Significant Lab Analysis*](#)
- [Clinically Significant Vitals Analysis*](#)

* If you defined [test identifiers](#), clinical significance is determined by [built-in criteria](#). If you defined [flag variables](#), clinical significance is determined by the flag variables. If you defined test identifiers and flag variables, results are generated for both methods of determining clinical significance.

Issue Lists in Analysis

WebSDM/Empirica Study uses the issue list in analysis performed by the following:

- The QT Prolongation Summary.
- Hy's Law and LFTs of Critical Concern.
- Issue cluster mining runs.
- Bayesian Logistic Regression runs.

When you open the QT Prolongation Summary or Hy's Law and LFTs of Critical Concern, and when you create BLR runs or issue cluster mining runs, WebSDM/Empirica Study checks for the existence of an up-to-date issue list. The issue list may have become out-of-date if:

- The last automatic screening run did not complete successfully.
- A user cancelled the last automatic screening run.

In these instances, WebSDM/Empirica Study prompts you to submit a screening run that will update the issue list. The [Run Options page](#) appears.

Automatic screening is a batch job and appears in [Run History](#).

Automatically Submitted Screening Analysis Runs

WebSDM/Empirica Study silently queues automatic screening runs when you set specific [properties](#)—time frames, test identifiers, and flag variables. WebSDM/Empirica Study also silently queues automatic screening runs when you load a study.

Automatic Issue List Regeneration

Some WebSDM/Empirica Study actions require an up-to-date issue list. If the issue list is not already up-to-date and you perform the actions, WebSDM/Empirica Study notifies you and provides you the opportunity to initiate an automatic screening run. WebSDM/Empirica Study notifies you when you perform the following:

Tab	Link	Action
Safety Review	ECGs	<ul style="list-style-type: none"> Add, edit, or delete test identifiers and time frames. Add, edit, or delete a time frame (or delete the option). <p>When you create or update the issue list option, you also have the option to update the issue list. If you choose to update the issue list without the Create Studies permission, an error message is displayed.</p> <p>Note: When a time frame is deleted, the issue list is regenerated.</p>
	Hy's Law on the Lab Results page	<ul style="list-style-type: none"> Add, edit, or delete test identifiers and time frames. Add, edit, or delete a time frame (or delete the option). <p>If no issue list exists or it is out-of-date, an error message is displayed. However, report performance is calculated.</p> <p>Note: When a time frame is deleted, the issue list is regenerated.</p>
Screening	Create Issue Cluster Mining Run on the Issue Clusters page.	<ul style="list-style-type: none"> Add, edit, or delete test identifiers and time frames.
	Create BLR Run on the Bayesian Logistic Regression Runs page.	<ul style="list-style-type: none"> Add, edit, or delete test identifiers and time frames. Add, edit, or delete test identifiers and flag variables. Add, edit, or delete a time frame (or delete the option). <p>If you choose to update the issue list without the Create Studies permission, an error message is displayed.</p>

and Check Studies permission, an error list.

Keep in mind that:

- The only way to create or update issue lists is by running automatic screening.
- Automatic screening simply identifies the issues observed for each subject in the study or study pool. It does not generate summary statistics.
- Automatic screening does not include:
 - Custom analysis types.
 - Lab Change from Baseline Analysis.
 - Vitals Change from Baseline Analysis.
 - Subject Disposition Analysis.
- Automatic screening does not use dosing category breakdowns or other category breakdowns.
- There is no screening analysis specification associated with automatic screening.
- For MedDRA-based analysis types, WebSDM/Empirica Study never uses **days on drug** as the denominator in computations; this is an option in an analysis specification.
- In Run History, this type of run is listed with the run type **Automatic Screening**. You cannot re-run automatic screening from Run History.
- Automatic screening may generate [warnings](#) that you can view on the **Issue Clusters** page only.
- As with the execution of analysis specifications, certain analysis types do not generate results during automatic screening if required test identifiers and flag variables have not been defined. This information is included in the warnings.
- Issue lists generated by automatic screening are removed when you reload a study, but are recreated during the automatic screening run that WebSDM/Empirica Study executes during the reload.

Note that when you modify test identifiers or flag variables, all existing issue clusters and BLR runs are deleted.

Baseline Results

Some computations and displays (listed below) use baseline results and thus require WebSDM/Empirica Study to establish one of the results in the study data as the baseline result. There are two methods of establishing a baseline result. In general, one method imputes baseline from the start of the [time frame](#) and the other method uses a baseline flag (the __BLFL variable) reported in the study data. Details are provided below.

In the following descriptions, the date on which a result (a test or vital sign value) occurred is determined by the __DTC variable.

Baseline using time frame

When a time frame is defined, its option to **Impute baseline result using start of time frame** can be checked. If this option is checked, then when the time frame is in effect, WebSDM/Empirica Study establishes the baseline value as follows for each combination of subject and test or vital sign:

- If the time frame start is well-defined, the baseline result is the latest one that occurred before the time frame start. If no result occurred before the time frame start, the baseline result is the one with the earliest date on or after the time frame start.
- If the time frame start is not well-defined, the baseline result is the earliest result found for the test or vital sign.

If there are multiple results that have the same datetime and qualify as baseline, the lowest result is used as baseline.

Baseline using baseline flag

If no time frame is in effect, or if a time frame is in effect but its option to **Impute baseline result using start of time frame** was not checked, baseline values are established using the [derived](#) variable __BLNRS_. To derive this variable, WebSDM/Empirica Study first establishes a result as the baseline (described below), and then derives the __BLNRS_ variable to be the value of __STRESN for that result.

The baseline result is established as follows:

1. If any subject has a result with a non-null value of the __BLFL variable, the __BLFL variable is used to determine baseline for all subjects.

For each subject:

- If the subject has one result for which __BLFL = 'Y', that one is the baseline result.
- If the subject has multiple results for which __BLFL = 'Y', the earliest one of them is the baseline result.
- If there are multiple results that have the same datetime and qualify as baseline, the lowest result is used as baseline.

2. If no subjects have a non-null value for __BLFL, the DM.RFSTDTC variable is used to establish baseline for all subjects.

For each subject:

- The baseline result is the latest one that occurred before the subject's DM.RFSDTC value. If no result occurred before the subject's DM.RFSTDTC value, the baseline result is the earliest one that occurred on or after the subject's DM.RFSTDTC value.
- If there are multiple results that have the same datetime and qualify as baseline, the lowest result is used as baseline.

Where these methods are used

For the following displays and analyses, one of the above methods of establishing baseline is used depending on the current time frame:

- Lab or Vital Signs Change from Baseline Analysis
- EGQT Analysis
- Hy's Law Analysis
- LFT Shift from Baseline Scatter Plot
- LFT Scatter Plot
- LFT Scatter Plot Matrix
- Change from Baseline Box Plot
- Change from Baseline Delta Plot
- Shift from Baseline Scatter Plot
- Hy's Law and Liver Function Tests of Critical Concern on Lab Results page of Safety Review tab
- QT Prolongation Summary display on Safety Review tab

For the following displays and analyses, only the second of the above two methods (baseline flag) is ever used:

- Clinically Significant Lab or Vitals Analysis using built-in criteria
- Lab or Vitals Signs Graph for screening results if clinical significance is based on built-in criteria
- Lab or Vitals Signs Graph on Lab Results or Vital Signs page of Safety Review tab if clinical significance is based on built-in criteria
- QTc findings in DataMontage or PPD Patient Profiles
- QTc Distribution over Time Box Plot
- Lab/Vitals Distribution over Time Box Plot showing change from baseline values

Box Plots

A box plot (also known as box-and-whisker plot) in WebSDM/Empirica Study is the plotting of data points that shows the distribution, central value, and spread of a continuous variable.

The box represents the middle 50% or so of the numeric values. A horizontal line within the box represents the median of all values (that is, the value that is exactly in the middle of all values).

The top end of the box represents the upper quartile (that is, the median of the ordered set of values that are greater than the overall median). The bottom end of the box represents the lower quartile (that is, the median of the ordered set of values that are less than the overall median). The interquartile range, which is the difference between the upper quartile and the lower quartile, is a measure of the spread of the distribution. The relative distances of the upper and lower quartiles from the median describe the shape of the distribution of data.

The whisker above the box plot extends from the upper quartile to the highest actual value that is within the $(75\text{th percentile} + 1.5 * (\text{interquartile range}))$. The whisker below the box plot extends from the lower quartile to the lowest actual value that is within the $(25\text{th percentile} - 1.5 * (\text{interquartile range}))$.

Outliers are plotted as individual points in the graph. An outlier is considered to be a value that falls outside of the whiskers.

Quartile computations

1. The median (50th percentile) is computed by creating a list of the values, ordered from minimum to maximum, and then:
 - If the number of values in the list (N) is odd, taking the value that appears in the middle of the list (that is, taking the value of element $(N+1)/2$)
 - If the number of values in the list (N) is even, taking the average of the two middle-most values (that is, taking the average of the values of element $N/2$ and element $(N/2) + 1$)
2. The first quartile (25th percentile) is computed by creating a list of the values, ordered from minimum to maximum, and then:
 - If the number of values in the list (N) is odd, taking the first $(N-1)/2$ values and computing the median of this subset (using the rules described in Step 1)
 - If the number of values in the list (N) is even, the first $(N)/2$ values and computing the median of this subset (using the rules described in Step 1)
3. The third quartile (75th percentile) is computed by creating a list of the values, ordered from minimum to maximum, and then:
 - If the number of values in the list (N) is odd, taking the last $(N-1)/2$ values and computing the median of this subset (using the rules described in Step 1)
 - If the number of values in the list (N) is even, the last $(N)/2$ values and computing the median of this subset (using the rules described in Step 1)

Clinical Significance Criteria

Clinical significance for lab tests or vital signs, which is relevant for certain analysis types and displays, can be determined according to built-in criteria that are part of WebSDM/Empirica Study, or according to a study data variable that has been designated. Depending on whether [test identifiers](#), [flag variables](#), or both are set up, one or both methods (built-in criteria or a flag variable) of determining clinical significance are available.

The built-in criteria for clinical significance are listed below. For WebSDM/Empirica Study to determine clinical significance using these criteria, a test identifier for the test or measurement must have been defined and other criteria (such as ULN) may be necessary.

Some built-in criteria for clinical significance involve change from baseline values and thus require a baseline value and a post-baseline value. These criteria never impute the baseline result relative to the time frame. They determine baseline as described in [Baseline Results](#) under **Baseline using baseline flag**.

Lab clinical significance criteria (built-in)

Analyte	Clinical Significance Criterion
Alkaline Phosphatase (ALP)	$\geq 3 \times$ Upper Limit of Normal (ULN)
Alanine Aminotransferase (ALT)	$\geq 3 \times$ ULN
Aspartate Aminotransferase (AST)	$\geq 3 \times$ ULN
Bilirubin (BILI)	≥ 2.0 mg/dL
Blood Urea Nitrogen (BUN)	≥ 30 mg/dL
Creatine Kinase (CK)	$\geq 3 \times$ ULN
Creatinine (CREAT)	≥ 2.0 mg/dL
Eosinophils/Leukocytes (EOSLE)	$\geq 10\%$
Hematocrit (HCT)	Female: $\leq 32\%$ AND $\geq 3\%$ decrease from baseline Male: $\leq 37\%$ AND $\geq 3\%$ decrease from baseline
Hemoglobin (HGB)	Female: ≤ 9.5 mg/dL Male: ≤ 11.5 mg/dL
Lactic Dehydrogenase (LDH)	$\geq 3 \times$ ULN
Neutrophils/Leukocytes (NEUTLE)	$\leq 15\%$
Platelet (PLAT)	Low: $\leq 75,000/\text{mm}^3$

	High: $\geq 700,000/\text{mm}^3$
Platelet, Estimated (PLAT)	Low: $\leq 75 \text{ THOU}/\text{mm}^3$ High: $\geq 700 \text{ THOU}/\text{mm}^3$
URIC ACID	Female: $\geq 8.5 \text{ mg/dL}$ Male: $\geq 10.5 \text{ mg/dL}$
Leukocytes (WBC)	Low: $\leq 2.8 \text{ THOU}/\mu\text{L}$ High: $\geq 16 \text{ THOU}/\mu\text{L}$

Vital signs clinical significance criteria (built-in)

Analyte	Age	Clinical Significance Criterion
Weight (WEIGHT)	Any	Increase of $\geq 7\%$ from baseline
Temperature (TEMP)	Any	Increase of $\geq 1.1^\circ\text{C}$ to $\geq 38.3^\circ\text{C}$
Heart Rate (HR)	5 to 14 years	$\leq 50 \text{ bpm}$ $\geq 140 \text{ bpm}$
	15 to 18 years	$\leq 50 \text{ bpm}$ $\geq 120 \text{ bpm}$
	18 and above	$\leq 50 \text{ bpm}$ $\geq 110 \text{ bpm}$
	Any	Decrease of $\geq 15 \text{ bpm}$ from baseline Increase of $\geq 15 \text{ bpm}$ from baseline
Systolic Blood Pressure (SYSBP)	7 to 12 years	$\leq 117 \text{ mmHg}$ $\geq 130 \text{ mmHg}$
	13 to 17 years	$\leq 120 \text{ mmHg}$ $\geq 144 \text{ mmHg}$
	18 and above	$\leq 90 \text{ mmHg}$ $\geq 150 \text{ mmHg}$
	Any	Decrease of $\geq 20 \text{ mmHg}$ from baseline Increase of $\geq 20 \text{ mmHg}$ from baseline
Diastolic Blood Pressure (DIABP)	7 to 12 years	$\leq 75 \text{ mmHg}$ $\geq 86 \text{ mmHg}$
	13 to 17 years	$\leq 80 \text{ mmHg}$ $\geq 92 \text{ mmHg}$
	18 and above	$\leq 50 \text{ mmHg}$ $\geq 100 \text{ mmHg}$
	Any	Decrease of $\geq 15 \text{ mmHg}$ from baseline

Increase of ≥ 15
mmHg from baseline

Codelists

A codelist is a list of valid codes and decoded values for a variable. The purpose of a codelist is to ensure that data values comply with controlled terminology. The SDTM defines some variables as subject to CDISC controlled terminology, and other variables as subject to optional, sponsor-defined controlled terminology. Additionally, your organization may choose to define codelists for variables that the SDTM does not regard as subject to controlled terminology.

Codelist creation

When a new define.xml file is generated during study registration, the following occurs:

- Standard codelists, which are compliant with CDISC, are always created for variables (except AEBODSYS) that are subject to CDISC controlled terminology. These codelists do not depend on the version of SDTM associated with the study.
- "Data-driven" codelists can be created for variables that are subject to sponsor-defined terminology. This type of codelist is a compilation of all unique non-null values of the variable for the study.

The user who generates the define.xml from within WebSDM/Empirica Study indicates whether to include standard codelists or both standard codelists and data-driven codelists in the define.xml.

Note that your organization may provide its own define.xml file instead of generating one. In this case, the define.xml can include codelists for any variable, whether or not the variable is subject to controlled terminology. A sponsor-provided codelist for a field always overrides a standard codelist for that field.

Codelist checking

When a study is loaded and checked, the data values are checked against the codelists that have been defined, and rules related to codelists are executed. When a rule fails, a checking result is generated. Study data may need to be modified and reloaded and rechecked.

Checking results are reported on the [Study Data Domains page](#) if any of the following is true:

- Values in the study data are not in the codelist. For a variable subject to CDISC controlled terminology, if a sponsor-defined codelist is provided, that codelist is used instead of the standard codelist.
- The define.xml references a codelist that is not in the define.xml.
- For a variable subject to CDISC controlled terminology, the define.xml does not reference a codelist.

- For a variable subject to CDISC controlled terminology with a non-extensible codelist, the define.xml references a sponsor-defined codelist containing values that are not in the standard codelist.

Support for extensible codelists

The CDISC controlled terminology identifies certain codelists as “Extensible.” That is, the user may extend these codelists by including additional values.

There are 22 extensible codelists used by the SDTM variables in WebSDM/Empirica Study. The table lists the extensible codelists along with the domain(s) and variables with which they are associated. Note that the following restrictions to extensibility apply:

- No coded values containing ‘OTHER’ or ‘MILESTONE’ should be added to codelist DSCAT
- No coded values containing ‘COMPLETED’ should be added to codelist NCOMPLT

CODELIST	DOMAIN	VARIABLE
DSCAT	DS	DSCAT
EGMETHOD	EG	EGMETHOD
EGSTRESC	EG	EGSTRESC
EGTEST	EG	EGTEST
EGTESTCD	EG	EGTESTCD
ETHNIC	DM	ETHNIC
FREQ	<INTERVENTIONS>	__DOSFRQ
FRM	CM	CMDOSFRM
FRM	EX	EXDOSFRM
LBTEST	LB	LBTEST
LBTESTCD	LB	LBTESTCD
LOC	<FINDINGS>	__LOC
LOC	<INTERVENTIONS>	__LOC
LOC	AE	AELOC
NCOMPLT	DS	DSDECOD
POSITION	<FINDINGS>	__POS
RACE	DM	RACE
ROUTE	<INTERVENTIONS>	__ROUTE
SCCD	SC	SCTESTCD
TSPARM	TS	TSPARM
TSPARMCD	TS	TSPARMCD
UNIT	<FINDINGS>	__ORRESU
UNIT	<FINDINGS>	__STRESU
UNIT	<INTERVENTIONS>	__DOSU
VSRESU	VS	VSORRESU
VSRESU	VS	VSSTRESU

VSTEST	VS	VSTEST
VSTESTCD	VS	VSTESTCD

Viewing codelists

When data is ready for use, you can view codelists on the [Metadata page](#) of the Domains tab. You also have the option to click **View Define.xml** and look at the codelists in the define.xml.

Codelists for study pools

For a study pool, there may be different codelists associated with the same variable. For the Metadata page, the codelist name is a hyperlink and contents are displayed as described below.

- If only one of the studies in the pool has a codelist associated with the variable, the codelist name is used as the hyperlink.
- If multiple studies in the pool have a codelist associated with the variable and all those codelist names are the same (regardless of content), the codelist name is used as the hyperlink. The codelist content appears as the union of values from the codelists across the studies.
- If multiple studies in the pool have a codelist associated with the variable and the codelist names are different, the hyperlink is **MULTIPLE**. The codelist content appears as a separate table for each distinctly named codelist.

If different versions of a codelist with the same name are used by multiple and different variables in the studies in the pool, a variant of the codelist is used for each of the variables. The codelist name followed by a number in parentheses is used as the hyperlink. The codelist content is a union of values from the codelist across the studies. For example, suppose that, in a pool with two studies, CodelistA has values 1, 2, and 3 for one study and values 4 and 5 for another study. If the codelist is attached to multiple variables in each study, for the first variable that uses it the hyperlink name will be "CodelistA (2)" and the codelist content will be 1, 2, 3, 4, and 5. For the second variable, the hyperlink name will be CodelistA (3), and so on. (Note that 1 is skipped in the numbering of the hyperlink names.)

Derived Variables

WebSDM/Empirica Study derives the variables described below. All derived variables except those that depend on test identifiers or flag variables are added to study data during the [loading and checking](#) of a study. Derivations that depend on the existence of test identifiers or flag variables are added to study data when the test identifiers or flag variables are defined for the loaded study.

Note: A study pool uses the derived variables from its component studies. Additionally, the STUDYID_ variable is derived for each study in a study pool when the pool is loaded.

Oracle datetimes from ISO 8601-formatted text strings

For each datetime variable, the following variables are derived:

- *<variable-name>P_* – The number of absolute seconds in the most precise element of the datetime value. The value of this variable is 1 plus the number of seconds between the low and high ends of the datetime value.
- *<variable-name>L_* – An Oracle datetime representing the low end of the datetime value, implied by the precision as shown in the table below.
- *<variable-name>H_* – An Oracle datetime representing the high end of the datetime value, implied by the precision as shown in the table below.

WebSDM/Empirica Study first identifies any missing intermediate date components (denoted using a hyphen). For example, 2008-10-31T-:15 represents a missing hour component and 2008-10--T09:-:32 represents missing day and minute components. When a missing intermediate date component is identified, WebSDM/Empirica Study truncates the ISO 8601-formatted text string based on the leftmost missing intermediate date component. Using the preceding examples, 2008-10-31T-:15 is truncated to 2008-10-31 and 2008-10--T09:-:32 is truncated to 2008-10.

Then values of the low and high datetimes are derived as follows:

Precision	<i><variable-name>L_</i>	<i><variable-name>H_</i>
Year	00:00:00 on January 1 of the specified year	23:59:59 on December 31 of the specified year
Month	00:00:00 on the first day of the specified month	23:59:59 on the last day of the specified month
Day	00:00:00 on the specified day	23:59:59 on the specified day
Hour	00:00 of the specified hour	59:59 of the specified hour
Minute	00 of the specified minute	59 of the specified minute
Second	Content of the ISO 8601-formatted string	Content of the ISO 8601-formatted string

For example, if the AESTDTC value is **2006-07-16**, then:

AESTDTP_ = 86400 // number of seconds in the most precise element of AESTDTC, which is Day

AESTDTL_ = 07/16/2006 00:00:00 EDT

AESTDTH_ = 07/16/2006 23:59:59 EDT

Durations and elapsed times from ISO 8601-formatted text strings

For each duration or elapsed time variable whose name ends in DUR or ELTM, the following variables are derived:

- *<variable-name>P_* – The number of absolute seconds in the most precise element of the duration or elapsed time value.

- *<variable-name>L_* – The low value in absolute seconds, implied by the precision. The low value is computed as the sum of the number of seconds in each element of the duration or elapsed time value.
- *<variable-name>H_* – The high value in absolute seconds, implied by the precision. The high value is computed as the sum of the number of seconds in each element of the duration or elapsed time value.

Note: If the *<variable-name>L_* and *<variable-name>H_* variables are null, then the *<variable-name>P_* variable is set to null.

For example, an AEDUR value of P3Y6M4DT12H30M indicates the duration **3 years, 6 months, 4 days, 12 hours and 30 minutes**. The actual value could range from a low of 3 years, 6 months, 4 days, 12 hours and 30 minutes, to a high of 3 years, 6 months, 4 days, 12 hours and 30 minutes plus the number of seconds in one minute, minus 1 second. Thus, the derived values are:

Variable	Value	Computation
AEDURP_	60 seconds	Number of seconds in one minute, the most precise element of AEDUR.
AEDURL_	109254600 seconds	(3 years * 31104000 seconds/year) + (6 months * 2592000 seconds/month) + (4 days * 86400 seconds/day) + (12 hours * 3600 seconds/hour) + (30 minutes * 60 seconds/minute)
AEDURH_	109254659 seconds	(3 years * 31104000 seconds/year) + (6 months * 2592000 seconds/month) + (4 days * 86400 seconds/day) + (12 hours * 3600 seconds/hour) + (30 minutes * 60 seconds/minute) + (60 seconds/minute)—(1 second)

For example, an AEELTM value of -P2H indicates an elapsed time **2 hours before a baseline time**. The actual value could range from a high of the 2 hours, to a low of the 2 hours plus the number of seconds in one hour, minus 1 second. Since it is negative, the final value is negated; the low value is the most negative value and the high value is the least negative value. Thus, the derived values are:

Variable	Value	Computation
AEELTMP_	3600 seconds	Number of seconds in one hour, the most precise element of AEELTM.
AEELTML_	-10799 seconds	(2*3600 seconds/hour) + (3600 seconds/hour)—1 second
AEELTMH_	-7200seconds	(2*3600 seconds/hour)

Exposure summary variables

If data in the EX domain contains consistent values for Dose Units (EXDOSU) and Dose Description (EXDOSTXT), cumulative exposure levels for certain domain-specific critical

dates are derived. For example, in the LB domain the total exposure as of the LBDTC date is derived to be the value of LBDOSCU_. This derivation is based on the sum of the values of the Total Daily Dose (EXDOSTOT), starting at the first day of therapy and continuing to the value of the domain-specific critical date.

Along with the cumulative dosage measure, WebSDM/Empirica Study derives other variables for the LB, EG, and AE domains:

Derived Variable	Description	Comment
__DOSCU_	Cumulative dose of study therapy as of the date of the observation.	Based on the low end of the date range implied by the ISO 8601-formatted observation date.
__DOSUN_	Units in which __DOSCU_ is expressed.	Taken from the EXDOSU variable in the EX domain.
__DOSDY_	Number of exposure days before the observation.	Based on the low end of the date range implied by the ISO 8601-formatted observation date
__DOSPV_	Number of days since the last dose prior to the observation.	Based on the low end of the date range implied by the ISO 8601-formatted observation date.

Baseline results

For each Findings domain, an __BLNRS_ variable is derived as the baseline result. WebSDM/Empirica Study first establishes a result as the baseline, and then derives the __BLNRS_ variable to be the value of __STRESN for that result.

The baseline result is established as described under Baseline using baseline flag in [Baseline Results](#).

Comments

Long comments are stored in the sponsor-provided Comments (CO) domain in the set of variables named COVAL, COVAL1, COVAL2,..., COVAL9, each of which has a length of no more than 200 bytes. In the CO domain, a variable named COVAL_ is derived to be a concatenation of the contents of COVAL and any of the COVAL1, COVAL2,...,COVAL9 variables that are present in the sponsor-provided data.

Total days on therapy

In the DM domain, a variable named DMDOSDY_ is derived to contain the total number of days that a subject was treated with the study therapy. This derivation is based on the same logic used to populate the __DOSDY_ variables (described above) that are derived for the AE, EG, and LB domains.

Study indication

For study pools, a STUDYID_ variable is derived as the identifier of each study in the pool. The value assigned to STUDYID_ is the numeric ID assigned by WebSDM/Empirica Study

when the study is registered. The derived variable is added to study pool data when the pool is loaded.

Standardized test identifiers

A variable is derived to contain a system-wide numeric code for each specified [test identifier](#). The derived variable is assigned a value automatically when test identifiers are defined for a study.

For the EG domain, the EGTSTID_ variable is derived by assigning a system-wide numeric code to each record that has a value that was assigned as an ECG test identifier. For a record with a value not assigned as an ECG test identifier, the EG.EGTSTID_ variable is null.

For the LB domain, the LBTSTID_ variable is derived by assigning a system-wide numeric code to each record that has a value that was assigned as a lab test identifier. For a record with a value not assigned as a lab test identifier, the LB.LBTSTID_ variable is null.

For the VS domain, a VSTSTID_ variable is derived by assigning a system-wide numeric code to each record that has a value that was assigned as a vital sign identifier. For a record with a value not assigned as a vital sign identifier, the VS.VSTSTID_ variable is null.

See [Defining Test Identifiers](#) for more information.

Clinically significant lab tests or vital signs

Clinical significance for lab test or vital signs, which is relevant for certain analysis types and displays, can be determined according to [built-in criteria](#) that are part of WebSDM/Empirica Study or according to a study data variable that you designate. Depending on whether test identifiers, flag variables, or both are set up, one or both methods of determining clinical significance will be available to users.

When [test identifiers](#) for the lab tests or vital signs that have built-in criteria are defined, WebSDM/Empirica Study derives the LB.LBSGABC_ or VS.VSSGABC_ variable. The variable is set to Y for a lab test or vital sign if the built-in criteria are met for that lab test or vital sign. When defining test identifiers, it is possible to specify null values or values that are not in the study data; in this case, the LB.LBSGABC_ or VS.VSSGABC_ variable will be null.

Note: Derivation of the LB.LBSGABC_ or VS.VSSGABC_ variable for any lab test or vital sign requires the presence of the following variables in the LB or VS domains: AGE, SEX, __TEST, __TESTCD, __STRESN, and __STRESU. Also note that if the SEX variable is other than 'M', 'F', or null or the AGE variable is below 0, above 150, or null, the derived variable is set to ?.

When a [flag variable](#) for lab test or vital signs is defined, WebSDM/Empirica Study derives the LB.LBSGABF_ or VS.VSSGABF_ variable. A flag variable is defined by selecting a variable (for example, LB.LBCLSIG or VS.VSCLSIG) from the study data and specifying which values of it (such as Y) indicate clinical significance. The derived variable is set to Y for a lab test or vital sign if the flag variable criteria is met for that lab test or vital sign. When defining flag variables, it is possible to specify values that are not in the study data; in this case, the LB.LBSGABF_ or VS.VSSGABF_ variable will be null.

A study can be set up to use either or both methods for indicating clinically significant results. If both methods have been set up:

- Both methods are available to a user who is creating an analysis specification or viewing a Lab Graph or Vitals Graph.
- In [automatic screening](#), issues are generated using both methods.

Note: For the display on the Lab Results page of the Safety Review tab, only the flag variable is used to determine clinical significance.

Treatment-emergent events

In a customized MedDRA-based analysis type Treatment emergent events can be specified as one of the event criteria. An AE.AETE_ variable is derived to indicate (Y or null) whether an adverse event is considered to be treatment-emergent. This derivation is based on the value of the sponsor-defined [flag variable](#) for treatment-emergent adverse events. The derived variable is added to study data when the flag variables are defined (instead of during loading and checking.)

Disposition Events

This topic describes how WebSDM/Empirica Study determines a subject's disposition event for the purposes of the following:

- [Subject Disposition Analysis](#)
- [Kaplan-Meier Plot](#)
- [Napoleon's March Plot](#)
- [Disposition Summary](#) on the Overview page of the Safety Review tab
- [Disposition Summary by Dose Group](#) for a screening result

To determine which of a subject's disposition events to use, WebSDM/Empirica Study does the following:

1. If a time frame is in effect, finds disposition records in the DS domain that occurred within the time frame. If no time frame is in effect, this step is skipped.
2. Excludes disposition records for which the disposition event category (DS.DSCAT value) contains the case-insensitive text string OTHER or MILESTONE.
3. If there is one remaining disposition record, uses its disposition event (DS.DSDECOD value).
4. If there are multiple remaining disposition records, finds the latest disposition record (using the DS.DSSTDTC value) and uses that record's disposition event.
5. If the latest disposition record cannot be determined (for example, if there is no disposition event date or there are multiple latest disposition records with the same datetime), see the help topic for the specific graph or display for information about the behavior.

Screening Analysis References

Oracle used the following documents in designing WebSDM/Empirica Study:

- *Study Data Tabulation Model and Study Data Tabulation Model Implementation Guide*, available at <http://www.cdisc.org/standards/index.html>
- MedDRA terminology and supporting user documentation, obtained under license from the MedDRA Maintenance and Support Services Organization (MSSO) and available at www.meddramsso.org
- *Standardized MedDRA Queries – Overview of Development Concepts Proposed by the Working Group*, obtained under license from the MedDRA Maintenance and Support Services Organization (MSSO) and available at www.meddramsso.org
- *Introductory Guide for Standardized MedDRA Queries (SMQs)* for various MedDRA versions, obtained under license from the MedDRA Maintenance and Support Services Organization (MSSO) and available at www.meddramsso.org
- *SMQ Distributed File Format* obtained under license from the MedDRA Maintenance and Support Services Organization (MSSO), available at www.meddramsso.org
- *Safety Reporting Requirements for Human Drug and Biological Products: Proposed rule* (Federal Register, March 14, 2003; Volume 67, Number 50).
- U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), *Reviewer Guidance: Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review*, February 2005.
- *E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs* (Issued 6/10/2004, Posted 9/10/2004)
- Kaplan, E.L., and Meier, P. (1958). Nonparametric estimation from incomplete observations, *Journal of the American Statistical Association*, 53:457-481.
- Greenwood, M. (1926). The natural duration of cancer. *Reports on Public Health and Medical Subjects*. 33:1-26. Her Majesty's Stationery Office, London.
- U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), *Guidance for Industry: Drug-Induced Liver Injury: Premarketing Clinical Evaluation*, July 2009.

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Study Dropouts

When a time frame with a well-defined start (described in [About Time Frames](#)) is in effect, most displays and analyses exclude subjects who dropped out before the start of the time frame. In general, WebSDM/Empirica Study considers subjects to have dropped out before the time frame start if their latest disposition event occurred before the time frame start. (Specifics are provided below.) The date of the disposition event, rather than its actual value, is the main consideration.

A subject is considered to have dropped out before the time frame start if the subject's latest disposition record in the DS domain (excluding those with a disposition event category containing the case-insensitive text string **MILESTONE** or **OTHER**) has a disposition event date that is earlier than the time frame start. Otherwise, the subject is not considered to have dropped out before the time frame start.

If values needed to determine whether the subject dropped out before the time frame start are missing, the subject is not considered to have dropped out and is thus included in the display or analysis.

Example of study dropouts

Suppose that the disposition data and time frames for six subjects are as follows:

USUBJID	DSCAT	DSSTDTC	Time Frame Start
100	DISPOSITION EVENT	01/01/2009 12:00:00	02/01/2009 12:00:00
100	PROTOCOL MILESTONE	02/01/2009 12:00:00	02/01/2009 12:00:00
101	OTHER EVENT	01/01/2009 12:00:00	03/01/2009 12:00:00
101	DISPOSITION EVENT	05/01/2009 12:00:00	03/01/2009 12:00:00
102	OTHER EVENT	01/01/2009 12:00:00	Indeterminate
102	DISPOSITION EVENT		Indeterminate
103		02/01/2009 12:00:00	03/01/2009 12:00:00
104	OTHER EVENT	03/01/2009 12:00:00	04/01/2009 12:00:00
105	DISPOSITION EVENT		02/01/2009

Only subjects 100 and 103 are considered to be dropouts and are thus excluded from the display or analysis.

Variables Used in Screening Analysis

The following table describes which variables are used by analysis type. The variable names are shown as `<table-name>.<variable-name>`. The names of [derived variables](#) end in `_`.

Analysis Type	Required Variables	Notes
MedDRA PT, HLT, HLG, or SOC	<ul style="list-style-type: none"> DM.USUBJID DM.ARM DM.RFSTDTC DM.RFSENDTC AE.USSUBJID AE.ARM AE.DECOD 	DM.RFSTDTC and DM.RFSENDTC are required only if days on drug is used as the denominator in computations.
Standardized MedDRA Query Analysis	<ul style="list-style-type: none"> DM.USUBJID DM.ARM DM.RFSTDTC DM.RFSENDTC AE.USSUBJID AE.ARM AE.DECOD 	DM.RFSTDTC and DM.RFSENDTC are required only to specify days on drug as the denominator.

QT Interval Prolongation	<ul style="list-style-type: none"> • DM.RFSTDTC • EG.USUBJID • EG.ARM • EG.TESTCD • EG.EGTSTID_ • EG.DTL_ • EG.EGBLFL • EG.EGBLNRS_ • EG.EGSTRESN 	<p>ECG test identifiers must be defined for QT INTERVAL, QTC INTERVAL, and RR INTERVAL. However, the analysis type can be run if test IDs for only QTC INTERVAL have been defined or if only test identifiers for QT INTERVAL and RR INTERVAL have been defined.</p> <hr/> <p>Note: For a study pool, ECG test identifiers must be defined for at least one study in the pool.</p> <hr/> <p>DM.RFSTDTC may be used to establish baseline results.</p>
Subject Disposition	<ul style="list-style-type: none"> • DS.USUBJID • DS.ARM • DS.DSCAT • DS.DSDECOD 	
Hy's Law	<ul style="list-style-type: none"> • LB.USUBJID • LB.ARM • LB.LBTESTCD • LB.LBTEST • LB.LBTSTID_ • LB.LBDTL_ • LB.LBSTRESN • LB.LBSTNRLO • LB.LBSTNRHI 	<p>Lab test identifiers should be defined for Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Bilirubin (BILI), and Alkaline Phosphatase (ALP). However, the analysis type can be run if test IDs for only ALT and/or AST have been defined.</p> <hr/> <p>Note: For a study pool, lab test identifiers must be defined for at least one study in the pool.</p>
Clinically Significant Labs	<ul style="list-style-type: none"> • LB.USUBJID • LB.ARM • LB.LBTEST • LB.LBTESTCD • LB.LBTSTID_ • LB.LBDTL_ • LB.LBSGABC_ • LB.LBSGABF_ 	<p>To use built-in criteria for clinical significance, lab test identifiers must be defined to derive LBSGABC_.</p> <p>To use flag variables for clinical significance, a lab flag variable must be defined to derive LBSGABF_.</p> <p>To run this analysis type, there must be at least one record with a non-null value for one of these variables.</p>
Clinically Significant Vitals	<ul style="list-style-type: none"> • VS.USUBJID • VS.ARM • VS.VSTEST • VS.VSTESTCD • VS.VSPOS • VS.VSTSTID_ • VS.VSDTL_ • VSSGABC_ • VSSGABF_ 	<p>To use built-in criteria for clinical significance, vital sign identifiers must be defined to derive VSSGABC_.</p> <p>To use flag variables for clinical significance, a vital sign flag variable must be defined to derive VSSGABF_.</p> <p>To run this analysis type, there must be at least one record with a non-null value for one of these variables.</p>
Lab Change from Baseline	<ul style="list-style-type: none"> • DM.RFSTDTC • LB.USUBJID • LB.ARM 	<p>DM.RFSTDTC may be used to establish baseline results.</p>

	<ul style="list-style-type: none">• LB.LBTEST• LB.LBTESTCD• LB.LBDTL_• LB.LBSTRESN• LB.LBBLNRS_• LB.LBBLFL	
Vitals Change from Baseline	<ul style="list-style-type: none">• DM.RFSTDTC• VS.USUBJID• VS.ARM• VS.VSTEST• VS.VSTESTCD• VS.VSPOS• VS.VSDTL_• VS.VSSTRESN• VS.VSBLNRS_• VS.VSBLFL	DM.RFSTDTC may be used to establish baseline results .

Glossary

\$

\$\$\$BASIC\$\$\$SCREENING\$\$\$ specification: Preparatory analysis specification that must be run before you can view screening results or a sector map on the Safety Review tab.

2

2x2 table: Contingency table that shows frequency data classified according to two categorical variables

A

aggregate bar graph: Type of bar graph that uses horizontal bars to show numeric values of column variables in a report for each value of the row variable in the report.

aggregation method: Way in which values for an analysis variable are displayed in a report, e.g., count of unique values, percentage, mean, etc.

analysis specification: Series of user choices that determine which types of screening analysis to perform and the factors (such as age or sex) for which to control.

analysis type: Specific type of screening analysis, such as a MedDRA PT Analysis.

analysis variable: In a report, column variables for which values are displayed for each combination of row variables, e.g., adverse event counts (analysis variable) for each row (Gender).

application: Group of studies, which may be different studies or multiple versions of the same study. For example, an application may be a group of studies that is part of a regulatory submission.

archive: Saved WinZip file containing PDF files of information about a potential signal.

automatic screening: Run that generates issues for standard analysis types for use in certain activities, such as issue cluster mining.

B

BLR: Bayesian Logistic Regression

box plot: Graph that plots data points that shows the distribution, central value, and spread of a continuous variable; also known as a box-and-whisker plot.

breakdown variable: Variable used in a report to group values for another variable; e.g., subject counts might be grouped by the breakdown variable AEBODSYS.

built-in report: Report definition that is predefined by Lincoln Technologies and delivered with the product.

C

category: For use in screening analysis, a group defined for a factor such as sex or age; a subgroup is a combination of categories, e.g., males over age 65.

category breakdown: .Specification of named categories that include values of a particular variable in the study data. Category breakdowns organize data into useful subgroups of subjects (such as males and females) for analysis and display.

cluster mining: Process that identifies clusters (or sets) of issues that co-occur under treatment more often than the occurrence rates for the component individual issues under treatment would lead one to expect; cluster mining is based on a comparison of Empirical Bayesian adjusted odds ratio statistics for issue pairs and the treatment drug.

CMQ: Customized MedDRA Query Analysis

codelist: List of valid codes and decoded values for a variable. The purpose of a codelist is to ensure that data values comply with controlled terminology.

compound issue: Issue that is defined as occurring if a specified set of conditions are met; used in Bayesian logistic regression of a potential signal.

configuration: Definition of which variables from study data are available for use, and how they can be used.

content details: Part of a report definition that specifies the aggregation method for values of a column, for example, actual values, counts, percentages, and so on.

custom analysis type: Analysis type that your organization creates and that is based on one of the standard analysis types, as well as additional criteria; it may also be a Customized MedDRA Query (CMQ).

D

define.xml: CDISC Case Report Tabulation Data Definition Specification for a study.

derived variable: Variable computed by WebSDM and added to study data, typically during the loading and checking process.

detail bar graph: Type of bar graph that uses horizontal bars to show subject counts for one or two variables in a report.

domain: Collection of data observations with a topic-specific commonality for clinical subjects; for example, demographics information or adverse events.

domain data: Metadata and clinical data for a domain.

dosing category breakdown: Definitions of a Treatment category and a Comparator category based on values of the DM.ARM variable.

drilldown: The process of uncovering more detailed information about the subjects that are included in screening analysis results, in a subject list, or in a report.

E

EBOR: Empirical Bayesian Odds Ratio

Empirica Study: Component of the system that supports the detection and evaluation of possible safety issues in study data.

error message: Message describing a rule that appears on the Errors page if a rule fails during checking.

event list: Saved list of PTs, selected from study data or directly from MedDRA, that can be set up to require review when they occur in screening analysis results, or can be used in a custom analysis type.

F

flag variable: Derived variable that, based on the existence of specified values in source data, determines clinical significance of lab test or vital sign values or determines if events are treatment-emergent.

H

heatmap: Graph that provides a concise view of information about the counts and Syndromic Odds Ratio(SOR) of each pair of issues in the cluster.

histogram: Graph of grouped (binned) data showing frequency distribution.

I

InForm: Phase Forward Integrated Trial Management platform.

issue cluster: A set of three or more issues that tend to co-occur more for subjects in the treatment group than for subjects in the comparator group.

issue cluster mining: Process that uses standard cluster analysis techniques along with a distance metric based on a comparison of Empirical Bayesian adjusted odds ratio statistics for pairs of issues and the treatment drug.

issue list: List of issues generated by an automatic screening run, which generated results for some standard analysis types and is required before certain activities can be performed.

issue pair: Co-occurrence of two issues in the same subject.

L

loading and checking run: Batch run that loads study data from SAS transport files and checks for compliance with CDISC SDTM.

logical operators: AND, OR, NOT operators that you can use when building a subject list.

login group: A group of users who perform similar activities.

M

MedDRA: Medical Dictionary for Regulatory Activities developed by the International Conference on Harmonisation (ICH).

P

potential signal: Collection of information that could indicate a drug safety concern, and thus is intended for subsequent statistical and medical evaluation.

project: Organizational tool (similar to a folder) that allows you to group certain objects for reference and retrieval purposes.

property: Definitions that are global or that are attached to a study, study pool, or application and that are needed to perform analysis and review of safety data. Properties include category breakdowns, time frames, test identifiers, flag variables, event lists, and study visit descriptions.

Q

Query Wizard: Series of pages that guide you through the process of retrieving subject IDs that meet specified conditions and creating a subject list containing those subject IDs.

query-based subject list: Subject list that was created by finding subject IDs that meet the conditions of a specified query of study data.

R

report definition: Specification of which columns and rows from the study data will appear in the report; a report definition is run to produce a report.

report output: Saved, static results of running a report definition.

rule: Specified condition that must be met in study data that has been loaded; rules are applied during the checking portion of a loading and checking run.

S

scatter plot: Graph that plots data points against horizontal and vertical axes to show the correlation between two or more continuous variables.

score: Probability of obtaining a value for a test statistic that is as large as the observed value, given the null hypothesis that there is no treatment effect.

screening analysis run: Execution of a screening analysis specification.

screening result: Row of the table of screening results; a row represents a combination of an analysis type, an issue, and a subgroup.

screening results: Tabular presentation of statistical values for combinations of the issue under consideration and the treatment drug; each row is a "screening result".

SDTM: Study Data Tabulation Model developed by the CDISC (Clinical Data Interchange Standards Consortium) Submission Data Standards Group.

sector map: Graph that presents data as tiles representing terms at a particular level of the MedDRA hierarchy, with the color, size, and ranking of tiles providing a "big picture" overview of the adverse event profile of a drug.

set operators: INTERSECT, UNION, MINUS operators that you can use when building a subject list.

site option: One of many system-wide options that control such elements as password restrictions, date and time formats, and so on.

standard analysis type: One of the analysis types that is delivered with the product for performing screening analysis.

study: Clinical trial data about subjects being treated with an investigational drug.

study pool: Combined data from multiple studies; only studies for which data has been loaded and checked can be included in a study pool.

subject list: Saved list of subjects of interest.

Superuser: Attribute that can be set for a username to enable the user to perform any activity.

supplemental qualifier: SDTM-compliant variables that capture values for which there are no standard variables in the general observation classes.

T

test identifier: The mapping of the system name for a lab test, ECG test, or vital sign measurement to a variable in the study data.

time frame: Period of time based on either subjects' study epochs or subjects' study reference start and end dates.

U

user activity audit trail: Report on user activities for selected usernames, activities, and dates.

user preference: Setting that customizes an aspect of the system for only your username.

user role: Set of permissions that can be granted to users performing a particular job function.

V

VSBL: Vitals Change from Baseline Analysis

VSCS: Clinically Significant Vitals Analysis

W

WebSDM: Component of the system that enables you to verify that customer-provided case report data conforms to the CDISC Study Data Tabulation Model (SDTM Version 3.1, 3.1.1, or 3.1.2).

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