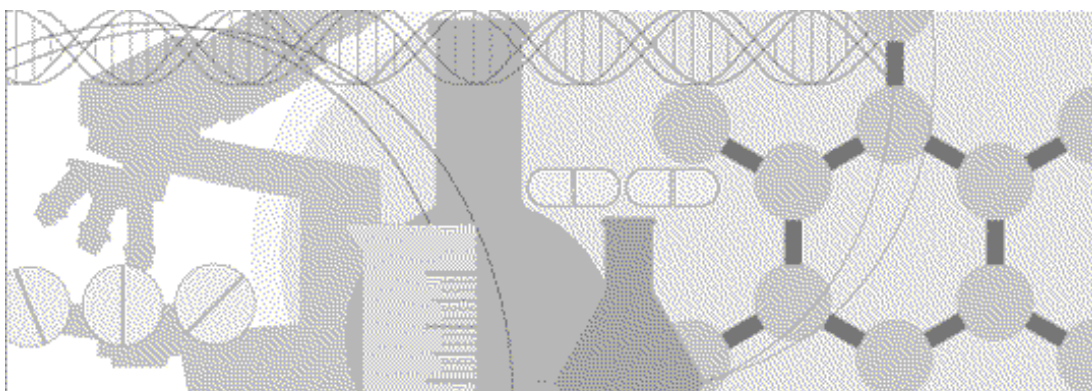


Reporting and Analysis Guide

InForm[™] ITM 4.6 SP3



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About this guide

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Overview of this guide

The *Reporting and Analysis Guide* provides an overview of the Reporting and Analysis module. It includes a brief overview of the Reporting and Analysis interface, illustrates how to access the Ad Hoc Reporting feature, and describes the study management and clinical data packages available for reporting. It also provides detailed descriptions of each standard report that is included with your installation.

Audience

This guide is for:

- Clinical Research Associates (CRAs).
- Clinical Data Managers (CDMs).
- Other clinical trial professionals who create and run reports.

Related information

Documentation

All documentation is available from the Phase Forward Download Center.

Item	Description
<i>Release Notes</i>	The <i>Release Notes</i> document describes enhancements introduced and problems fixed in the current release, upgrade considerations, release history, and other late-breaking information.
<i>Known Issues</i>	<p>The <i>Known Issues</i> document provides detailed information about the known issues in this release, along with workarounds, if available.</p> <p>Note: The most current list of known issues is available on the Phase Forward Extranet.</p> <p>To sign in to the Extranet, go to www.phaseforward.com and click Customer Login. Enter your email address and password, and navigate to the Known Issues section. Select a product, and then enter your search criteria.</p>
<i>Installation and Configuration</i>	<p>The <i>Installation and Configuration</i> guide describes how to install the software and configure the environment for the InForm application and Cognos 8 Business Intelligence.</p> <p>This document is also available from the Documentation CD.</p>
<i>Setting Up a Trial with InForm Architect and MedML</i>	<p>The <i>Setting Up a Trial with InForm Architect and MedML</i> describes how to design and implement trials in the InForm application using the InForm Architect application.</p> <p>This document is also available from the Documentation CD.</p>
<i>Step by Step for CRCs and CRAs</i>	<p>The <i>Step by Step for CRCs and CRAs Guide</i> describes how to use the InForm application to:</p> <ul style="list-style-type: none"> • Screen and enroll patients. • Enter, update, and monitor clinical data. • Enter and respond to queries. • Run trial management reports and clinical data listings. <p>This document is also available from the Documentation CD and the user interface.</p>

Item	Description
<i>Reporting and Analysis Guide</i>	<p>The <i>Reporting and Analysis Guide</i> provides an overview of the Reporting and Analysis module. It includes a brief overview of the Reporting and Analysis interface, illustrates how to access the Ad Hoc Reporting feature, and describes the study management and clinical data packages available for reporting. It also provides detailed descriptions of each standard report that is included with your installation.</p> <p>This document is also available from the Documentation CD and the user interface.</p>
<i>Utilities Guide</i>	<p>The <i>Utilities Guide</i> provides information about and step-by-step instructions for using the following utilities:</p> <ul style="list-style-type: none">• PFConsole utility• MedML Installer utility• InForm Data Import utility• InForm Data Export utility• InForm Performance Monitor utility• InForm Report Folder Maintenance utility <p>This document is also available from the Documentation CD.</p>
<i>Reporting Database Schema</i>	<p>The <i>Reporting Database Schema</i> Guide describes the InForm reporting database schema.</p> <p>This document is also available from the Documentation CD.</p>
<i>Portal Administration Guide</i>	<p>The <i>Portal Administration Guide</i> provides step-by-step instructions for setting up the InForm Portal software, and configuring and managing the InForm Portal application.</p> <p>This document is also available from the Documentation CD.</p>
Online Help	<p>The online Help describes how to use and administer the InForm application.</p> <p>This document is available only from the user interface.</p>
InForm Architect online Help	<p>The InForm Architect online Help describes how to design and implement trials in the InForm application using the InForm Architect application.</p> <p>This document is available only from the user interface.</p>
MedML Installer utility online Help	<p>The MedML Installer utility online Help provides information about, and step-by-step instructions for using, the MedML Installer utility, which is used to load XML that defines study components into the InForm database.</p> <p>This guide also provides reference information for the MedML elements and scripting objects that are used to import and export data to and from the InForm application, as well as sample data import XML.</p> <p>This document is available only from the user interface.</p>

Item	Description
InForm Data Export utility online Help	<p>The InForm Data Export utility online Help provides information about and step-by-step instructions for using the InForm Data Export utility, which is used to export data from the InForm application to the following output formats:</p> <ul style="list-style-type: none"> • AutoCode. • Customer-defined database (CDD). • Name value pairs. • Oracle Clinical. <p>This document is available only from the user interface.</p>
InForm Data Import utility online Help	<p>The InForm Data Import utility online Help provides information about and step-by-step instructions for using the InForm Data Import utility, which is used to import data into the InForm application.</p> <p>This document is available only from the user interface.</p>

Cognos documentation

The InForm application includes the Cognos 8 Business Intelligence reporting software, which is licensed from Cognos Corporation and includes a customized version of Cognos Report Studio. Report Studio provides advanced reporting capabilities and requires a separate license from Phase Forward. The Cognos 8 Business Intelligence and Report Studio software is licensed solely for use in connection with the InForm application and data contained in the Reporting and Analysis database. For advanced reporting using Report Studio, custom tables and extensions to the Reporting and Analysis database can be implemented and are covered under the InForm license.

A complete Reporting and Analysis module installation requires you to install both Cognos 8 Business Intelligence software and Sun ONE Directory Server. The following Cognos 8 Business Intelligence manuals are available from the InForm user interface.

Document	Description
Product documentation	
IBM Cognos 8 <i>Architecture and Deployment Guide</i>	Describes the Cognos 8 architecture from the perspectives of structure, communications, workflow, and security. Provides information for planning the Cognos 8 installation and configuration, and for maximizing its performance.
IBM Cognos 8 <i>New Features Guide</i>	Contains information about the new features and supported environments in this release of Cognos 8 Business Intelligence.
IBM Cognos 8 Reporting <i>Readme</i>	Provides late-breaking information about installation issues, limitations, and other known issues.
Installation and Configuration Documentation	

Document	Description
IBM Cognos 8 <i>Installation and Configuration Guide</i>	Contains instructions for installing, upgrading, configuring, and testing Cognos 8 Business Intelligence, changing application servers, and setting up samples.
IBM Cognos 8 BI Reporting <i>Getting Started Installation Guide</i>	Provides information for installing and configuring Cognos 8 on a single server with default settings.
Administration and Portal Documentation	
<i>Using IBM Cognos Series 7 and IBM Cognos BI in the Same Environment</i>	Provides information about using interoperability as part of the recommended migration strategy.
IBM Cognos 8 <i>Administration and Security Guide</i>	Contains step-by-step procedures and background information on Cognos 8 administration.
IBM Cognos Connection <i>User's Guide</i>	Explains how to use Cognos Connection and the Cognos 8 portal to view, edit, schedule, and distribute standard and complex reports.
Modeling Documentation	
Framework Manager <i>User's Guide</i>	Provides information about creating and publishing models using Framework Manager.
IBM Cognos Transformer <i>User's Guide</i>	Provides information about creating and publishing models and cubes using IBM Cognos Transformer.

Training

For information about training offerings, please see the course catalog on our website at <http://www.phaseforward.com/support/training/> or contact Phase Forward Educational Services at training@phaseforward.com.

If you need assistance

If you are a Phase Forward customer with a maintenance agreement, you can contact the Global Support Center for assistance with product issues.

Your maintenance agreement indicates the type of support you are eligible to receive and describes how to contact Phase Forward. Additionally, the Phase Forward website lists the toll-free support number for your product, location, and support level:

<http://www.phaseforward.com/support/>

In the event that our toll-free telephone service is interrupted, please use either of the following methods to contact the Global Support Center:

- Email
customer.support@phaseforward.com
- Telephone

In the US: 781-902-4900

Outside the US: +44 (0) 1628 640794

Phase Forward also provides assistance with User Management, Site Assessment, and Provisioning. Please refer to your Master Services Agreement and individual Statement of Work to determine if you are eligible to use these services.

CHAPTER 1
InForm overview

In this chapter

About the InForm application 2

About the Reporting and Analysis module 3

InForm users 4

InForm system configuration 5

Getting help 6

About the InForm application

The InForm application is a data collection and trial management application that uses a secure web browser to provide access to clinical trial data and management of the clinical trial process.

Embedded within the InForm user interface is the Reporting and Analysis module, which is a reporting application that was developed by the Cognos Corporation, and that has been customized and integrated into the InForm application by Phase Forward. The Reporting and Analysis module provides a library of configurable reports, predefined reports, and ad hoc reporting and charting tools. Both clinical and operational data are available in real time from a database that can be accessed using the Internet.

Note: You can install the InForm software without the Reporting and Analysis module if you want to use the data collection features of the InForm application without the reporting features.

About the Reporting and Analysis module

The Reporting and Analysis module is an optional part of the InForm application that provides a library of configurable reports, predefined reports, and ad hoc reporting and charting tools. Both clinical and operational data are available in real time.

The Reporting and Analysis module is based on the Cognos 8 Business Intelligence applications, which have been customized and integrated into the InForm application by Phase Forward, and embedded in the InForm user interface.

Note: You can install the InForm software without the Reporting and Analysis module if you want to use the data collection features of the InForm application without the reporting features.

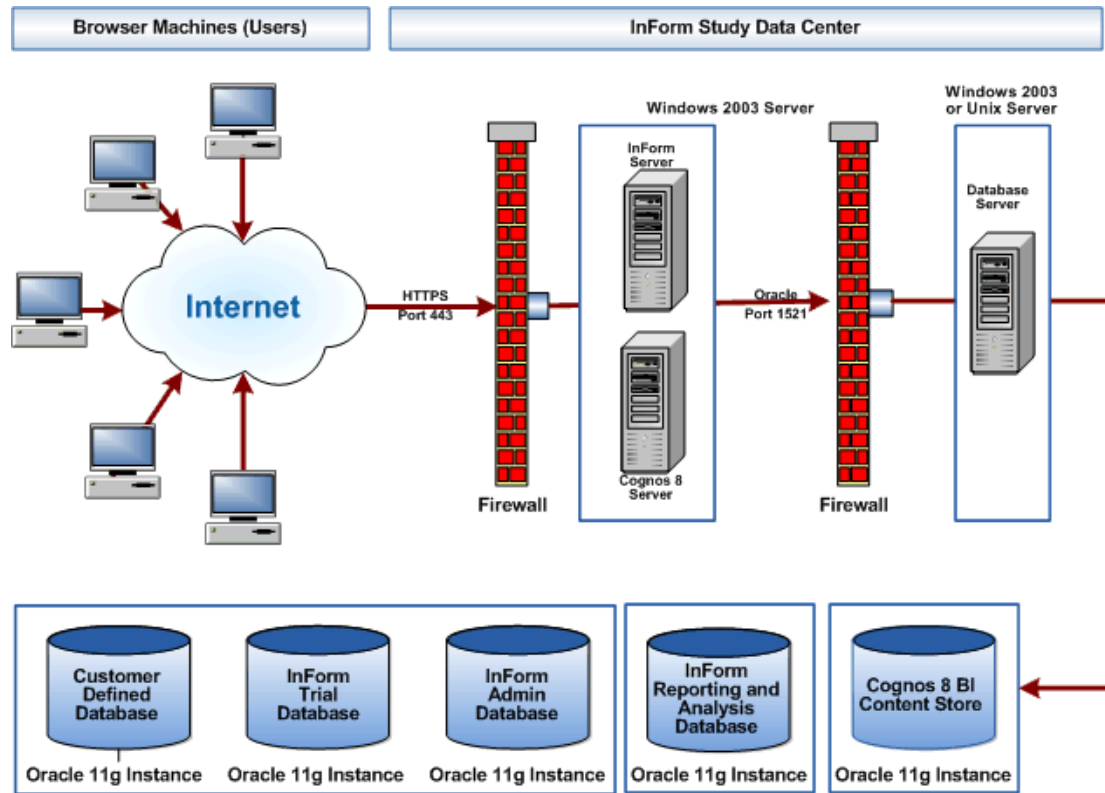
InForm users

The following are examples of InForm users:

User	Description
Clinical data manager (CDM)	A person who is responsible for preparing and maintaining a trial database and for reviewing data.
Clinical project manager	A person who is responsible for all aspects of one or more clinical trials or for the entire clinical plan for a drug, device, or procedure.
Clinical research associate (CRA)	A person who is hired by a sponsor to supervise and monitor the progress of sites that are participating in a trial. Also called <i>monitor</i> , <i>site monitor</i> .
Clinical research coordinator (CRC)	An assistant to the investigator at a site. Also called <i>site coordinator</i> , <i>trial coordinator</i> .
Principal investigator (PI)	The clinician who is responsible for treating subjects, executing the protocol of a study at a specific site, and filling out CRFs for subjects. Also called clinical investigator, investigator, primary investigator.
Medical monitor	A person who designs the trial protocol and reviews data.
Site user	An InForm user, typically a CRC or PI, who performs the following tasks: <ul style="list-style-type: none"> • Obtains an InForm site user name and password. • Screens and enrolls subjects into a trial. • Enters and changes clinical data in electronic case report forms. • Answers queries on clinical data. • Prepares for monitoring visits.
Sponsor user	An InForm user, typically a CRA, CDM, or medical monitor, who performs the following tasks: <ul style="list-style-type: none"> • Obtains an InForm sponsor user name and password. • Reviews clinical data queries. • Performs source verification. • Transfers subjects from one site to another. • Runs standard reports. • Creates ad hoc (custom) reports.

InForm system configuration

The InForm system configuration consists of the browser computers, application server, and database server.



Getting help

The following types of Help are available with the InForm application:

- **InForm application-specific Help, created by Phase Forward.**

To access the InForm application Help:

- In the navigation pane, select **Help > InForm and Trial Reporting**.

- **Cognos-specific Help, created by Cognos.**

To access the Cognos 8 Help:

- In the navigation pane, select **Help > Using Reporting Tools**.

An HTML page appears with links to the complete Cognos 8 Business Intelligence documentation set.

- From the Ad Hoc Reporting workspace, click **Ad Hoc Tools Help**.

The Cognos Query Studio User Guide appears. Query Studio is the Cognos tool that provides Ad Hoc Reporting capability.

Additional help for reporting

Two additional links provide reporting help.

- **Report help**—After you output any InForm standard report in HTML format, click the **Report Help** link to open detailed page-level help. This information is included on each standard report.
- **Ad Hoc tools help**—After you access Ad Hoc Reporting, click the **Ad Hoc tools** help link. This link provides access to the Cognos documentation for Query Studio. Query Studio is the Cognos application that provides Ad Hoc Reporting capability.

CHAPTER 2

Introduction to Reporting and Analysis

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About report data

Reporting and Analysis database

All data used for reporting resides in the Reporting and Analysis database, a database schema that is replicated from the InForm transactional database schema and updated in real time. Because data for reports is stored separately from InForm transactional data, you can write and run reports in the Reporting and Analysis module without affecting the performance of the InForm application.

Data in the Reporting and Analysis database is updated in real time, allowing you to access up-to-date information for your trial.

The Reporting and Analysis database contains two types of data:

- **Trial management data**

Trial management data includes metrics and status data for a trial. Use trial management data to report on the completion status of your trial. You can report on such things as the number of visits that are complete for a trial or the number of forms that are frozen or locked.

The Reporting and Analysis database study management schema is installed with each InForm installation. It is not specific to your trial.

- **Clinical reporting data**

Clinical data for reports includes data about each subject visit. Use clinical data to report on specific clinical questions and responses. You can report on such things as adverse events, vital signs information, and dosing records.

The Reporting and Analysis database clinical schema is built from the forms that are installed with your trial. Therefore, the clinical data available for reports is unique for each trial.

Basic relational database concepts

Term	Description	Example
Tables	Store collections of related data.	Subjects, Visits, and Forms tables.
Rows	Occurrences (records) of related data values. Each time you enter new data in a table, you create a row in that table.	Subjects, Visits, and Forms rows.
Columns	Store individual data values.	The columns in the Subjects table might store a Subject ID, Subject Number, Subject Initials, Current Status, and First Screened Date for each subject (row) in the trial.

Term	Description	Example
Primary keys	Special columns whose values uniquely identify a row in a table.	The Subject ID column in the Subjects table is a primary key because each Subject ID value can only occur one time in that table and is unique to each subject.
Foreign keys	Special columns that establish relationships with other tables in the database.	The Subject ID column in the Visits table is a foreign key that allows a relationship between the Visits table and the Subjects table as well as a relationship between the Visits table and the Forms table.
Joins	Expressions of relationships between database tables. A join occurs when you match the data value of a key (primary or foreign) in one table to the data value of a key in another table, thus retrieving related data.	<p>To retrieve a subject with the related visits and the related forms:</p> <ul style="list-style-type: none"> Join the Subject ID value in the Subjects table to the Subject ID value in the Visits table. Join the Subject ID value in the Visits table to the Subject ID value in the Forms table.

Reporting and Analysis terminology

Term	Description
Aggregate values	Quantitative (numeric) values that represent counts, averages, and totals.
Calculation	A report element that can perform many types of operations such as calculating the sum or average of the values in one column, or multiplying the values in two columns.
Chart	A report that shows patterns and trends in data using a graphical presentation: pie chart, bar chart, line chart, and so on.
Crosstab report	A report that shows summary data in rows and columns at the intersection points of rows and columns.
Data model	A logical representation of the data in the Reporting and Analysis database that describes data objects, structure, grouping, data relationships, and security.
Job	A group of ad hoc reports and/or other jobs that you can run and schedule as a batch.
List report	A report that shows detailed data in rows and columns.
Measure (or fact)	A report element that contains cumulative values that can be aggregated to produce meaningful results. Measures are quantitative performance indicators that give the numbers that usually appear in the cells of crosstab reports or in a chart.

Non-aggregate values	Non-numeric data representing string (text) or date values.
Package	A graphical representation (container) for one or more data models and reports.
Personal folder	A folder in the Reporting and Analysis portal that only the owner can access.
Portal	A Web site or page that provides a single presentation and a single starting point for a set of information.
Prompt	A feature that asks for parameter values before a report runs.
Public folder	A folder in the Reporting and Analysis portal that users with appropriate rights can access.
Report element	The equivalent of a column of data that contains the actual data from the Reporting and Analysis database. Note: Report elements are referred to as Query Items in Cognos.
Report palette	A workspace in the Reporting and Analysis module onto which the user drags and drops report elements to include in an ad hoc report.
Report topic	A category representing a reporting area in the Reporting and Analysis data model equivalent to a table of columns in the InForm database. Note: Report topics are referred to as Query Subjects in Cognos.
Report view	A version of an ad hoc report that keeps the underlying report specifications but allows the choice of another format, language, delivery method, or run option.
Shortcut	A pointer to another entry such as a report, report view, folder, job, or URL.

Data models and packages

Data models

A data model is a layer of the Reporting and Analysis database that describes the data objects, structure, grouping, data relationships, and security. The Reporting and Analysis module uses one or more data models to make the data in the Reporting and Analysis database available for your reports.

Two data models exist for every InForm trial.

Data model	Description
Trial management data model	Describes only the trial management portion of the Reporting and Analysis database.
Clinical data model	Describes only the clinical portion of the Reporting and Analysis database.

A data model is internal to the system; it is not directly visible to you until it is published to a package.

Clinical model security

Display override settings and site associations determine the clinical data that is available from the clinical model for use in reports. For example:

- If an item is not visible to you in the InForm application, when you create a report that contains the item, the cells in the row that corresponds to the item contain the text **N/A**.
- You can see and create reports using only information for the sites in the trial to which you have access.

The clinical model also contains relationships to the operational report topics. These relationships allow you to create reports in the Ad Hoc Reporting workspace by dragging and dropping clinical and operational report elements onto the report palette. This operation is conceptually similar to creating a SQL join directly between a clinical view and an operational view.

Packages

A package is a grouping of data from one or more data models. Two packages are installed with every InForm trial:

Package	Description
InForm Trial Management	Contains data from the Trial Management data model only. This package is installed with every InForm trial.
Trial-specific clinical	Contains data from both the Trial Management data model and the clinical data model (unique for each trial).

In the Ad Hoc Reporting workspace, you can see each package structure in the Ad Hoc Reporting tree.

InForm Trial Management package

The InForm Trial Management package is installed with every instance of the Reporting and Analysis module, and is identical across studies. It contains report topics and report elements from the Trial Management data model only.

Note: Use the InForm Trial Management package to create reports that contain only study management data. Reports that you create with the InForm Trial Management package can be shared across studies.

Trial-specific clinical package

The trial-specific clinical package provides access to both clinical and trial management data. It consists of report topics and report elements from both the clinical and Trial Management data models.

Note: Use the trial-specific package to create reports that include clinical data. Because clinical data is unique to each trial, report definitions using the trial-specific package might not be validated to work across different studies.

A trial-specific clinical package groups data in each report topic into four sub-folders: Basic Data, Additional Data, Incomplete Data Reasons, and Internal IDs.

Reporting basics and options

Reporting and Analysis portal

The Reporting and Analysis portal is the first page that appears after you click **Reports** in the navigation toolbar.








Report folders

From the Reporting and Analysis portal, you can use the folder tabs to navigate to specific reports.

Tab	Description
Public Folders	Provides access to the standard reports, and custom reports that are shared with all users.
My Folders	Provides access to reports that only you can access.

Report output icons

The icons that appear next to the name of a saved report indicate the format in which you can view the report.

Icon	Description
	View the report in HTML format.
	View the report in PDF format.
	View the report in Excel 2000 Single Sheet format.
	View the report in Excel 2000 format.
	View the report in Excel 2002 format.
	View the report in CSV format.
	View the report in XML format.

Portal icons

Icons in the upper-right corner of the Reporting and Analysis portal let you perform actions on public or personal folders.

- Navigate between list and detailed folder views.
- Create new folders.
- Cut and paste folders.
- Delete folders.
- Set folder properties.

Portal tools

The following options are available from the Reporting and Analysis portal, based on your InForm rights.


Option	Description
Log On menu	
Logoff	Log off of the namespace. Note: After you use the Logoff option, you must log off of the InForm application and log back in to access the Reporting and Analysis module.
Logon	Log on to other available namespaces.
Home menu	
Home	Navigate to your Home page.
Set View as Home	Set the current page as your Home page.
My Area	
My Watch Items	Navigate to the Alerts tab to monitor your watched items.
My Preferences	Change the default preferences for the Reporting and Analysis portal.
My Activities and Schedules	Navigate to the My Activities and Schedules page, where you can create and modify activities and job schedules.
Launch menu	
Ad Hoc Reporting	Launch the Ad Hoc Reporting workspace. The Cognos Query Studio application provides Ad Hoc Reporting capability for the InForm application.
Report Studio	Launch the Cognos Report Studio application. You must purchase the license for the Cognos Report Studio application separately from Phase Forward.

Option	Description
Drill-through Definitions	Create, edit, or delete drill-through definitions for packages in the Reporting and Analysis module.
Reporting Administration	<p>Manage styles, Cognos portlets, and third-party portlets in the Reporting and Analysis m</p> <ul style="list-style-type: none"> • Status—View and manage schedules, run a report, and view report outputs. • Security—Create and manage users, groups, and roles; capabilities; and user interface profiles. • Configuration—Create and manage data sources, content administration, distribution lists and contacts, styles, portlets, and dispatchers and services.

Renewing your credentials

If you set up scheduled reports and then change your account password, you must renew your credentials. Otherwise, the report fails at the next scheduled time after the password change.

To renew your credentials:

- 1 In the navigation pane, click **Reports**.
- 2 On the Reports pane, click the **My Area icon** () > **My Preferences**.
- 3 On the **Personal** tab, click **Renew the credentials**.
- 4 At the bottom-right corner of the window, click **Return**.

Personal pages


You can create up to 50 personal portal pages to organize the information that is most important to you. Using personal pages, you can access in one place the Reporting and Analysis features that you use the most, organized in the way that you want.

The personal page content consists of one or more frames that you display in a single-column, two-column, or three-column configuration. Each personal page frame can display:

- The contents of a public or a personal folder.
- Lists of public and private folders.
- Reports.

You can set up your personal pages to run your reports automatically during non-peak hours so that when you access your personal page at the beginning of the work day, the report output is ready for you to review.

- Bookmarks of URLs to web sites.
- Web pages that you visit often.
- RSS feeds.

A toolbar provides personal page configuration and management functions. Each page has a **Set Properties button** (). Use the Set Properties button to modify personal pages.

New Page wizard

Use the New Page Wizard to create and configure personal portal pages.

Page	Description
Specify a name and description	Provides basic properties for a personal page. <ul style="list-style-type: none">• Name• Description• Screen tip• Location (folder)
Set column and layout	Allows you to configure the columns on the personal page. <ul style="list-style-type: none">• Number of columns• Column width• Content organization
Set page style	Allows you to add titles and instructions to the page, and configure their style settings.

Report options

Report options for ad hoc reports

Ad hoc report option	Description
Set Properties	Set the characteristics of a report, including the report name, report options, and permissions.
Run with Options	Specify the output format and delivery options for an ad hoc report at runtime.
Open with Ad Hoc Reporting	Opens the report in the Ad Hoc Reporting workspace, where you can edit and modify report content and layout.
Create a report view of this report	<p>Create a report view of the report.</p> <p>Only users with Publisher rights or Report Administrator rights can access this option.</p> <p>Note: If you save a report view with the same name as the report, when you click the report name, the report does not re-generate and you only see the report view. To avoid overwriting data, save a report and its report view with different names.</p>
Schedule	Specify when to generate a report.
More link	Access the features that are listed in this table, as well as file management actions (Move, Copy, Create a shortcut, and Delete).

Report options for standard reports

Standard report option	Description
Set Properties	Set the characteristics of the standard report, including the report name, report options, and permissions.
Run with Options	Specify the output format and delivery options for the standard report at runtime.
Open with Report Studio	Available only if you have access to Report Studio. Opens the report in the Report Studio application.

Standard report option	Description
Create a report view of this report	<p>Create a report view of the report.</p> <p>Only users with Publisher rights or Report Administrator rights can access this option.</p> <p>Note: If you save a report view with the same name as the report, when you click the report name, the report does not re-generate and you only see the report view. To avoid overwriting data, save a report and its report view with different names.</p>
Schedule	Specify when to generate the standard report.
More link	Access the features that are listed in this table, as well as file management actions (Move, Copy, Create a shortcut, and Delete).

Run with options for ad hoc and standard reports

Run with option	Description
Format	<p>Specifies the delivery format for the report output:</p> <ul style="list-style-type: none"> • HTML (including the number of rows per page). • PDF (including the page orientation and paper size). • Microsoft Excel in single or multiple spreadsheet formats. • Delimited text (CSV). • XML. • Note: CSV and XML formats are only available for ad hoc reports, and are not supported for standard reports.
Language	Specifies the language in which to produce the report output. Only English is supported in this InForm release.
Delivery	<p>Any of the following delivery mechanisms:</p> <ul style="list-style-type: none"> • View the report now. • Save the report. <p>Saving the report output as a view produces a snapshot of the data at the time that you generate the report. This produces an archive that you can quickly review without having to regenerate the report output.</p> <p>Note: If you save a report view with the same name as the report, when you click the report name, the report does not re-generate and you only see the report view. To avoid overwriting data, save a report and its report view with different names.</p>

Run with option	Description
Prompt values	Specifies the range of data that is included in a report.
Advanced options	Specify additional options.

Run with advanced options for ad hoc and standard reports

Advanced option	Description
Time and mode	<p>Specifies when to generate the report.</p> <ul style="list-style-type: none"> • View the report now—Run the report immediately. • Run in the background—Specify whether to run the report immediately, or at a scheduled time. <p>Selecting Run in the background:</p> <ul style="list-style-type: none"> ▪ Displays the email options for a report. ▪ Allows you to set additional PDF formatting preferences.
Formats	<p>Specifies the delivery format for the report output.</p> <ul style="list-style-type: none"> • HTML—Allows you to specify: <ul style="list-style-type: none"> ▪ Number of rows per Web page ▪ Whether to enable selection-based interactivity. • PDF—Allows you to specify: <ul style="list-style-type: none"> ▪ Orientation ▪ Paper size • Excel 2007 • Excel 2002 • Excel 2000 single sheet • Excel 2000 • Delimited text (CSV) • XML <p>Note: CSV and XML formats are only available for ad hoc reports, and are not supported for standard reports.</p>
Language	<p>Specifies the language in which to produce the report output. Only English is supported in this InForm release.</p>

Advanced option	Description
Delivery	<p>Specifies the delivery mechanism:</p> <ul style="list-style-type: none"> • View the report now. • Save the report, save the report as a report view, print the report, or send a link to the report by email. <p>Note: To email a link to the report, you must first select Run in the background in the Time and mode section.</p>
Prompt values	Specify the range of data that is included in a report.

Considerations for running reports with advanced options

- When you run reports with advanced options and set new prompt values, clicking **Run Report** does not actually run the report. Instead, it saves the new prompt selections.
- You must have Publisher rights to email the link to a standard report from the Advanced Options menu. You must save the standard report to the Public Folder before you can email the link.

Report types

Ad hoc reports

You create ad hoc reports on both clinical and trial management data using the Ad Hoc Reporting workspace. Ad hoc reports allow limited use of Cognos features such as data output styles, report layout and formatting, summarizations and aggregations, mathematical functions, and prompts.

Note: References to *Query Studio* and *queries* have been removed from the Reporting and Analysis user interface and documentation to avoid confusion by clinical users to whom the term *query* means a clinical discrepancy, not a database operation. For example, in the Cognos documentation, report topics are referred to as query subjects and report elements are referred to as query topics.

InForm standard reports

The InForm application includes a set of management reports that provide information about the progress of a study. These reports show several categories of information. Several views of each report are available; for example, you can display the query status reports by site and by user, month by month or study-to-date, and in text or graphical formats. Standard reports are created using Cognos Report Studio and are validated and optimized for the InForm application.

Custom reports

Custom reports are advanced reports that are created by Phase Forward in Cognos Report Studio, which includes all Cognos features and functionality such as different data output methods, increased report layout and formatting options, summarizations and aggregations,

prompts, user-definable sorting, and drill-through reports.

Note: For more information on creating custom reports, contact your Phase Forward project manager to schedule mentoring.

Comparison of report types

The following table compares the available report types.

Report type	Ad Hoc	Standard	Custom
Design complexity	Simple to medium	Medium	Simple to advanced
Data source	Model	Model and SQL	Model and SQL
Database schema	Reporting	Reporting	Transactional and Reporting
Revisions	Current*	Current**	All
Data blinding	Inherent in model	In SQL	In SQL
Reporting tool	Cognos Query Studio	Cognos Report Studio	Cognos Report Studio

* For ad hoc reports you can see all revisions for operational data.

** The audit trail standard report covers all revisions.

Scheduling reports

Schedule a single report

You can schedule a saved ad hoc report or a standard report to run automatically at times that are convenient for you. If you choose to schedule a report:

- Avoid scheduling reports during peak periods for the study.
- If a study is complete, remember to cancel any associated scheduled reports.

Note: For more information, see the Cognos documentation, which is available from the Help icon in the upper-right of the InForm window.

Schedule multiple reports


To create a list of multiple reports, report views, or other items that you want to share schedule settings and run simultaneously, you create a job.

Using the job development tools, you can:

- Create a new job using the New Job wizard.
- Manage a job using the Set Properties button for the job.
- Run a job manually using the Run with options page.
- Manage jobs using the My Activities and Schedules page.

Note: Run with advanced options settings for a report take precedence over job settings. For example, if you use the Run with advanced options page to schedule the Query Cycle Times by Site report to run at a specific date and time, and you create a job that includes the same report, and is scheduled to run daily, the Query Cycle Times by Site report will run at the time you specified on the Run with advanced options page.

New Job wizard

You create jobs using the New Job wizard ()

- The job identification provides the following options:
 - The language in which to display the job identification information.
 - The name of the job.
 - An optional screen tip for a job.
 - An optional description of a job.
- Jobs contain job steps:
 - Steps reference the individual reports, jobs, and report views.
 - Submission of steps specifies whether to run the steps all at once or in sequence.

For more information, see the Cognos documentation.

Run with options page for an existing job


The Run with options page provides options for running a job manually. This page includes the same information as the Schedule page, which appears if you choose to schedule the job from the New Job wizard.

- **Time section**—Allows you to specify whether to run the job immediately or at a specified time.
- **Steps section**—Lists the components of the job.

Note: The settings that you implement on the Run with options page are in effect for this execution of the job only, and do not affect the original job definition.

For more information, see the Cognos documentation.

Set Properties page for an existing job


Click the **Set Properties** button () associated with a job to open the **Set properties** page and edit the job definition.

Comments in saved reports

To allow users to add comments to a report:

- 1 Save the report output in the Reporting and Analysis portal in one of the following output formats:
 - HTML
 - PDF
 - XML
- 2 Enable comments for the report.

Enabling comments in a saved report

- 1 For a saved report in HTML, PDF or XML output, click **Set Properties** ()
- 2 Do one of the following:
 - For an ad hoc report, select the **Query** tab.
 - For a standard report, select the **Report** tab.
- 3 Click **Advanced options**.
- 4 Select **Enable comments in saved output versions**.

Adding a comment to a report

- 1 Open a saved report in HTML, PDF or XML output.
- 2 Click **Add comments > Add comment**.
The Add a Comment dialog box appears.
- 3 In the **Name** field, type your name.
- 4 In the **Comment** field, type the comment text.
- 5 Click **Finish**.

Trial design considerations

Subject status requirements

The subject status that appears in reports depends on which InForm features you use to set the state. For instance, to display status data for a subject in the Randomized state, you must perform subject randomization through the InForm application.

This table outlines the requirements for subject status in the InForm application. If your organization does not take advantage of these InForm features, subject status reporting capabilities are limited in the Reporting and Analysis module.

Subject status	Required action in the InForm application
Screened	InForm Screening form (as designed per InForm requirements) must be successfully submitted for the subject.
Enrolled	InForm Enrollment form (as designed per InForm requirements) must be successfully submitted for the subject.
Screened Failed	A screening form (as designed per InForm requirements) must be submitted for the subject. The subject subsequently fails the InForm screening process.
Enrolled Failed	An enrollment form (as designed per InForm requirements) must be submitted for the subject. The subject subsequently fails the InForm enrollment process.
Enrolled Override	InForm Enrollment Override process must be successfully completed after subject initially fails screening or enrollment.
Randomized	Subject must be randomized in the InForm application.
Dropped Out	Trial Completion form (as designed per InForm requirements) must be completed for the subject. The form must indicate that the subject has dropped out of the trial.
Completed	Trial Completion form (as designed per InForm requirements) must be completed for the subject. The form must indicate that the subject has completed the trial.

DOV controls

Form aging and cycle time reports show the amount of time it takes to capture data throughout various steps of the electronic data entry process. These calculations begin with the date of visit (DOV).

There are several options for designing DOV controls. In general, the DOV control should:

- Have a specific Universal Unique Identifier (UUID).
- Appear within a form section that is identified with a specific UUID.
- Not appear on a common form.

Note: If you are designing a trial with the InForm Architect software, Phase Forward recommends that you design DOV controls in a particular way. For more information, see the *Setting Up a Trial with InForm Architect and MedML* guide.

The Reporting and Analysis module retrieves DOV data from the database, assuming that your trial uses the specific UUIDs mentioned above.

If your trial uses the special DOV UUIDs, you can leave the DOV blank during data entry. When the DOV is blank, DOV report columns and columns containing calculations that rely on a DOV are blank.

If an InForm user enters a DOV that is later than the data entry date, reports show negative values in cycle time columns.

Labels for clinical report elements

In the Central Designer application or the InForm Architect application, trial designers can specify a label in the Short Question or Itemset Column Header property for an item. For items in an itemset, this label appears as the column heading in the row and column representation of the itemset in the Reporting and Analysis module.

Note: If you are designing a trial with the InForm Architect application, do not use Subject Number as an itemset column header name. It will cause an error when you create the clinical model for the trial.

In the Reporting and Analysis module, the Itemset Column Header property is also the default short name for the field in the clinical reporting model, whether or not the item is in an itemset.

Optional trial elements

When you design a trial in the Central Designer application or the InForm Architect application, you can specify whether a study element is required or optional. Optional items that are included in the trial design and deployed to the InForm application may be left blank by InForm users. If an optional element does not contain data, the row that corresponds to the element in an ad hoc report contains blank cells.

For example, your trial may include a Sponsor Name element, for which you can choose not to enter data. In this case, ad hoc reports that contain the SponsorName report element will display an empty row for the item.

CHAPTER 3

Ad Hoc Reporting

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About Ad Hoc Reporting






The Ad Hoc Reporting workspace provides the flexibility to quickly create different types of reports:

- **List**—Data details in columns and rows.
- **Crosstab**—Summary data in columns and rows.
- **Charts**—Summary data using graphical presentations, such as pie charts and bar charts.

You create ad hoc reports on both clinical and trial management data using the Ad Hoc Reporting workspace. Ad hoc reports allow limited use of Cognos features such as data output styles, report layout and formatting, summarizations and aggregations, mathematical functions, and prompts.

Note: References to *Query Studio* and *queries* have been removed from the Reporting and Analysis user interface and documentation to avoid confusion by clinical users to whom the term *query* means a clinical discrepancy, not a database operation. For example, in the Cognos documentation, report topics are referred to as query subjects and report elements are referred to as query topics.

InForm to Cognos naming correspondence

Icon	Ad Hoc Reporting	Cognos Query Studio	Description
	Package		Subsets of a model that contain items you can add to a report.
	Folder		Organizer for data items. You cannot import a folder into a report.
		Namespace	Used to prevent naming conflicts within a package. Can contain a variety of objects such as dimensions, query subjects, and model filters.
	Report topic	Query Subject	Categories of different reporting areas representing tables in the database.
	Report element	Query Item	A representation of the data items to include in reports.
	Measure		Represents quantitative data such as counts, calculations, or aggregations.

Accessing the Ad Hoc Reporting workspace

- 1 From the navigation pane, select **Reports**.

The Reporting and Analysis portal appears.

- 2 Select **Launch > Ad Hoc Reporting**.

The Select a package page appears.

- 3 Click the link for the package with which you want to work:

In the **Recently used packages** section:

- Click the link for a package that was recently opened.

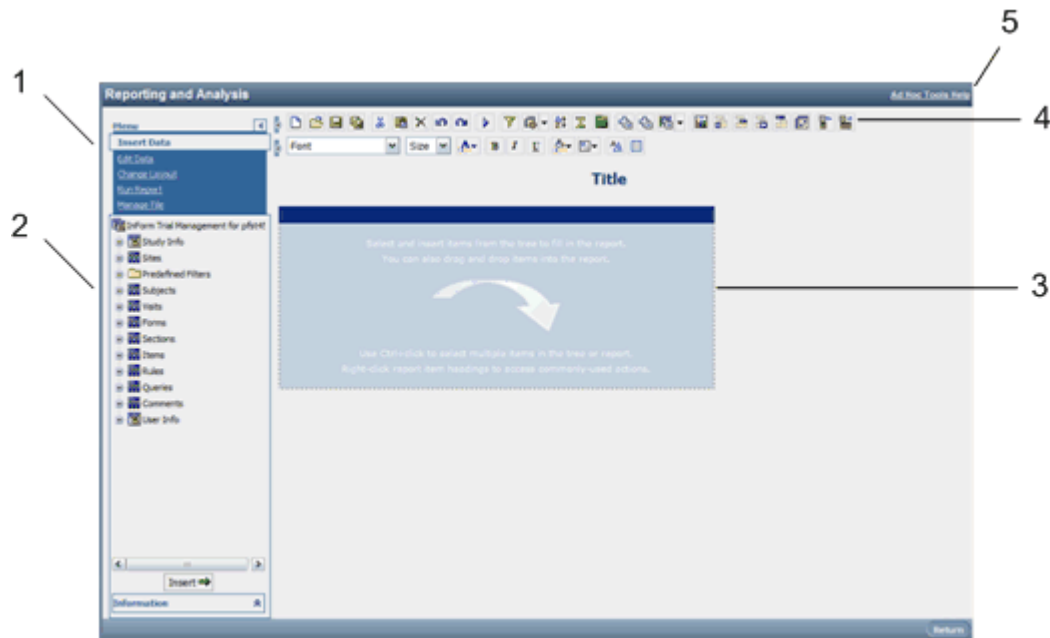
In the **List of all packages** section:

- **Trial-specific clinical package (containing both clinical and trial management data)**—Click the link with the name of your trial.
- **InForm Trial Management package**—Click **<trial name> InForm Trial Management**.

The InForm Ad Hoc Reporting workspace appears. The Ad Hoc Reporting tree reflects the package that you selected.

Ad Hoc Reporting workspace

The following illustration shows the Ad Hoc Reporting workspace.



- 1—Use the Ad Hoc Reporting menu to insert and edit data to a report, save reports, run reports, and change the layout of a report.
- 2—Use the Ad Hoc Reporting tree to add report topics to reports.
- 3—Drag report topics and elements to the Report palette to create ad hoc reports.
- 4—Use the Cognos 8 Business Intelligence toolbar to save reports, cut and paste data, apply filters, and summarize data.
- 5—Use the Ad Hoc Tools Help link to launch the online User Guide for Cognos Query Studio, which provides Ad Hoc Reporting capability to the InForm application.

Ad Hoc Reporting tree

The Ad Hoc Reporting tree is the graphical representation of a package structure that appears in the Ad Hoc Reporting workspace.

For more information, see:

- *Using the Ad Hoc Reporting tree to create reports* (on page 36).
- *InForm Trial Management reporting tree* (on page 64).
- *Clinical reporting tree* (on page 148).

Ad Hoc Reporting menu

Menu option	Description
Insert data	Adds report topics to the report palette for inclusion in an ad hoc report.
Edit data	Modify data on the report: <ul style="list-style-type: none"> • Apply filters. • Sort and summarize columns. • Add calculations. • Cut, paste, and delete data. • Undo and redo changes.
Change layout	Modify the presentation of a report: <ul style="list-style-type: none"> • Create charts. • Group, ungroup, and pivot columns. • Change font style. • Create sections in a report. • Swap rows and columns. • Collapse and expand groups.
Run report	Specify options for running the report: <ul style="list-style-type: none"> • Run the report with all data. • Run the report with limited or no data. • Specify an output format for your report. • Set advanced options.
Manage file	<ul style="list-style-type: none"> • Create and save reports. • Access Report Studio, if you have purchased it and have sufficient rights to access it. • Create reporting definitions. • Set preferences.

Running and saving ad hoc reports

Using the ad hoc reporting tree to create reports

To create an ad hoc report, do one of the following:

- Drag a report element or report topic from the Ad Hoc Reporting tree to the Ad Hoc Reporting workspace.
- Double-click a report element or report topic.
- Select the report element or report topic, and click Insert.

When you double-click or drag a report topic, all report elements it contains appear as columns in the ad hoc report.

When you double-click or drag a report element, a single element appears as a report column in the ad hoc report.

Note: By default, data is turned off in the Ad Hoc Reporting workspace. When you add report topics or report elements to the report palette, the columns are populated with **abcd**. When you click **Run with all data** or **Preview with limited data**, the report is populated with the actual data.

Running an ad hoc report from the Ad Hoc Reporting workspace

- 1 From the **Ad Hoc Reporting** menu, click **Run Report**.
- 2 Choose an option:
 - Run with all data.
 - Preview with limited data.
 - Preview with no data. (This option is selected by default.)

Running an ad hoc report in a new window

- Right-click the link for any report and click **Open in New Tab** to launch a new browser window in which to display the report.

Saving an ad hoc report

When you save an ad hoc report, you save the report definition. Each subsequent time you run the report, the data in the report reflects any changes in the Reporting and Analysis database.

- 1 Click **Save**.
- 2 If you are saving the report for the first time, specify:
 - **Name**—Name of the report.
 - **Description**—Descriptive text about the report.

- **Screen tip**—Hover text that appears for the report.
 - **Location**—Location in the Ad Hoc Reporting workspace in which to save the report.
- 3 Click **OK**.

Previewing report output with limited or no data

After you drag report topics on to the Ad Hoc Reporting palette, you can view a sample report output. From the Run Report menu, click **Preview with Limited Data**, or **Preview with No Data** to view a sample of the report.

- **Preview with Limited Data**—Displays a subset of the data for the ad hoc report you created.
- **Preview with No Data**—Displays the columns that you added to the Ad Hoc Reporting palette, populated with sample data.

For each option, the following appears in the Ad Hoc Reporting workspace:

- A jagged, torn-page look at the top of the report.
- A header with:
 - The report title that you created.
 - If you clicked **Preview with Limited Data**, a **Limited data** label.
 - If you clicked **Preview with No Data**, a **Data is turned off** label.
- A footer with:
 - The date when the preview was created.
 - The page number
 - The time when the preview was created.
 - A **Run once with all data** link, which allows you to run the report with all the data you added.

Preview formats

The Ad Hoc Reporting workspace provides Run Report menu selections to preview the output format for a report during report development:

- View in PDF Format.
- View in Excel 2007 Format.
- View in Excel 2002 Format
- View in Excel 2000 Single Sheet Format.
- View in Excel 2000 Format.
- View in CSV Format.
- View in XML Format.

Using the design-time report viewer

You can preview report output in several different formats using the Run Report menu. When you select an output format, a separate window opens (either the report viewer or another window) in which to display the output.

Preview output	Display utility
Adobe Acrobat Portable Document Format	Report Viewer
Microsoft Excel 2000 Format	Microsoft Excel
Comma-Separated Values Format	Microsoft Excel
XML Format (read-only)	Report Viewer

To access the design-time report viewer:

- 1 Open a saved report from the Reporting and Analysis portal.
- 2 From the **Menu** list in the Ad Hoc Reporting workspace, select **Run Report**.
- 3 From the **Run Report** menu, click one of the following:
 - View in PDF Format.
 - View in PDF Format.
 - View in Excel 2007 Format
 - View in Excel 2002 Format.
 - View in Excel 2000 Single Sheet Format.
 - View in Excel 2000 Format.
 - View in CSV Format.
 - View in XML Format.

Using the run-time report viewer

You can run a report from the Reporting and Analysis portal using the run-time report viewer. For each output format, the output appears in the report viewer or a separate window.

Preview output	Display utility
HTML Format	Report Viewer
Adobe Acrobat Portable Document Format	Report Viewer
Microsoft Excel 2000 Single Sheet Format	Microsoft Excel
Microsoft Excel 2000 Format	Microsoft Excel
Microsoft Excel 2002 Format	Microsoft Excel
Comma Separated Values Format	Microsoft Excel
XML Format (read-only)	Report Viewer

To access the run-time report viewer:

- 1 Access a saved report in a folder (public or personal).
- 2 From the folder, click the **Run with options** button that appears with the report name.
- 3 From the **Run with options** page, select a value from the **Format** drop-down list.
 - HTML
 - PDF
- 4 Click **Run**.

Opening an ad hoc report in Report Studio

If you have access to the Report Studio application, you can open a report in Report Studio from within the Ad Hoc Reporting workspace. You can then use the Report Studio application to add advanced functionality to the report.

- Click **Manage File > Open in Report Studio**.






Editing data in an ad hoc report

Opening an existing report

You can open an existing report from within the Ad Hoc Reporting workspace.

- 1 Click **Manage File**.
- 2 Click **Open**.
- 3 Select the report to open, and click **OK**.
- 4 To use the report as the basis of a new report, click **Save As**.

Editing tools in the Ad Hoc Reporting workspace

Option	Description
 Filter	Select the data that should appear in a report.
Combine Filter	Combine two or more filters using AND or OR logical operators.
 Sort	Sort to reorder a column of data in ascending or descending order.
 Summarize	Include summaries (such as totals, averages, and counts) in the footer of the report.
Format Data	Change the appearance of numbers, dates, and times, as well as text, without changing the underlying data.
 Calculate	Create new report elements using data from one or more existing report elements.
Define Custom Groups	Produce new report elements containing values that are meaningful to you.
Go to	Access links to other reports. See your administrator about related links available in your study.
Rename Column Heading	Customize the column heading text.
	Perform typical editing functions.
Cut, Paste, Delete, Undo, and Redo	

Using predefined filters

Predefined filters let you limit your report to specific subjects, visits, and forms. These filters are shipped with the Reporting and Analysis module and can be used in all reports. The Predefined Filters folder is available in both the InForm Trial Management package and the clinical package.

You can also create filters. Each user-created filter is saved with the report in which it was created. The filter can be used only with that report and cannot be used globally across multiple reports.

Filter definitions

When you select a filter option for a column heading, the Filter pane appears. The following fields appear on the Filter pane:

- **Filter on**—Identifies the column on which to apply the filter.
- **Condition drop-down list**—Includes the following options:
 - **Show only the following**—Select values to include in the report.
 - **Do not show the following (NOT)**—Select values to exclude from the report.
- **Prompt every time the report runs checkbox**—Select whether to prompt every time the report is run.
- **Filter links**—Let you choose the way that you indicate your data selections:
 - Pick values from a list.
 - Search for values.
 - Type in values.
- **Data values section**—Indicate your selection values.
- **Apply the filter to individual values in the data source checkbox**—Allows you to apply the filter while retrieving the data from the database so that you retrieve only the data that you want. The alternative is to retrieve all the data from the database, then apply the filter to the retrieved data.
- **Missing values drop-down list**—Indicate whether to:
 - Include missing values.
 - Leave out missing values.
 - Show only missing values.

The following table shows which filters work with each type of reporting data.


Feature	Aggregate	Non-Aggregate	Date
Filter on	✓	✓	✓
Condition	✓	✓	✓
Prompt every time the report runs	✓	✓	✓

Feature	Aggregate	Non-Aggregate	Date
Links		✓	
Data values	✓	✓	✓
Apply the filter to individual values...		✓	✓
Missing values	✓	✓	✓

Adding a filter

- 1 Create a report.
- 2 In the Ad Hoc Reporting report palette, select the column header for a report topic on which to filter the report.
- 3 Right-click the report column header and select **Filter**.

Or

Click the **Filter** button () in the toolbar.

The Filter (Pick values from a list) pane appears.

- 4 Do one of the following:
 - From the Filter (Pick values from a list) pane, select a filter from a list.
 - Click **Search for values** to search for a filter using keywords.
 - Click **Type in values** to search for a filter using text in the filter name.

Adding a filter without adding a column

You can filter a report based on a particular report element without adding a column for that item to the report.

- 1 In the Ad Hoc Reporting tree, right-click the report element name.
- 2 Select **Filter for report**.
The Filter pane appears.
- 3 Specify the parameters by which to filter the report.
- 4 Click **OK**.

Removing a filter

When you add a filter on a report column, the report output includes a link to the filter just below the report title. If you click this link, you can change the filter parameters to produce different output.

To hide filter links from the title area of an ad hoc report:

- 1 Double-click the report title.
- 2 Deselect **Show filters**.

This removes the links but not the filters.

Note: You cannot modify the parameters for a predefined filter.

Combining filters

Combine two or more filters create a complex filter. For example, you can filter the columns Site Name, Visit Name, and Actual Date in a report.

- 1 From the Edit Data menu, select **Combine Filters**.
- 2 To add a filter, click **Add a filter line**.
- 3 To select a set of filters, click the names of the filters while holding down **Ctrl** or **Shift**.
- 4 Click **Group**.
- 5 Click the operator that appears between the filters and select **AND** or **OR** to combine them.
- 6 To convert a filter line or a combined filter into a NOT filter, click the filter line or combined filter and click **Apply NOT**.
- 7 Click **OK**.

Sorting the elements in a report

In the Sort Options section of the prompt page, you can choose the columns on which to sort a report.

Drop-down lists appear at the bottom of each report prompt page. Default sorting selections are automatically selected. You can change these to create your own report definition.

Each sort drop-down list includes **Ascending** and **Descending** radio buttons. Ascending sorts are automatically selected by default. Use the radio buttons to change the sort type.

Reports that include groupings, such as organization by user or by site, are sorted at the detail level within the grouping, according to the selections made in the drop-down lists. The grouping sort order can be modified (ascending or descending) but will always take precedence over other sorting settings.

Note: You can also sort data based on a report element without first adding the element to the report. For more information, see *Sorting data without adding a column* (on page 44).

Sorting data without adding a column

You can sort a report based on a particular report element without adding a column for that item to the report.

- 1 In the Ad Hoc Reporting tree, right-click the report element name.
- 2 Select **Sort for report**.
The Sort pane appears.
- 3 Specify whether to sort the report in ascending order, descending order, or not to sort the report at all.
- 4 Click **OK**.

Summarizing data

When you create an ad hoc report, you can include summary data in the report output. Summary data provides high-level information such as totals, counts, calculations, minimum and maximum values, and so forth. The summary data that is available depends on the report element for which you are providing summary data.

In addition to providing the option to summarize specific data in ad hoc report outputs, the Ad Hoc Reporting workspace automatically suppresses duplicate data in the report output, and displays only unique combinations of data.

Adding summary data to a report

- 1 In the report palette, select the column heading for the report element for which to configure summary data.
- 2 Select **Edit Data > Summarize**.
or
- 3 Right-click a column header and select **Summarize**.
The Summarize pane for the type of data in the selected column appears.
- 4 Specify the type of summary to add to the report.
- 5 Click **OK**.

Configuring summarization settings

- 1 Click **Run Report > Advanced Options**.
- 2 In the **Query Options** section, specify the following:
 - **Automatically generate footer summaries for measures** (selected by default)—Display a summary for each measure in the footer of the report output.
For example, if a report contains the Visit Mnemonic and Form Count report items, a row that contains the total number of forms for each visit exists in the report output.
 - **Automatically summarize detail values, suppressing duplicates** (selected by default)—Display only each unique combination of data, and display a summary of details.
For example, if you select this checkbox for a report that contains multiple combinations of Subject Number and Site data, the report displays only each unique combination of subject and site. If the report also contains the Visit Mnemonic and Form Count report items, a row that contains the total number of forms for each visit exists in the report output.
- 3 Click **OK**.

Configuring drill up, drill down, and drill through settings

- 1 Click **Run Report > Advanced Options**.
- 2 In the **Drill Options** section, select the following:
 - **Enable drill up and drill down in the report output** (selected by default)—Allows you to navigate a report output according to a specific report item.

For example, if a report displays query data, organized by form, you can drill up and down through the report data by form name.
 - **Enable drill through from a package in the report output** (selected by default)—Allows you to navigate between reports that exist in a report package, if a drill-through definition exists for the package.

For example, you can navigate from an ad hoc report to a standard report in the same package.
- 3 Click **OK**.

Lineage information for data

Before you add a report element to an ad hoc report, you can view its origin. The lineage information displays metadata such as the report package, visit, form, and so forth, associated with the report element. Use the lineage information to ensure that you include the correct report element to a report.

- Right-click the report element, and click **Lineage**.

Lineage information for the report element appears in two views:

- **Business View**—Displays information about the report element and the package in which it exists.
- **Technical View** includes two panes:
 - **Diagram pane**—Graphical representation of the package, the database table, and the database (either the InForm database or the Reporting and Analysis database) in which the report element exists. This information appears in two columns:
 - **Package**—Displays metadata including the report topic and database table associated with the report element.
 - **Data Sources**—Indicates the database in which the report element exists (the InForm database or the Reporting and Analysis database).
 - **Properties for <Report Element> pane**—Displays additional information about the item that you select in the **Package** column in the Diagram pane.

Note: Lineage information is not available for reports that are created in Report Studio and include an if-then-else-if-then-else construct. This includes, but is not limited to, most InForm standard reports, and Phase Forward custom reports.

Changing the display format for report elements

- 1 On the report palette, click the column heading for a report column, and do one of the following:
 - From the **Edit Data** menu, select **Format selection**.
 - Right-click the column heading, and select **Format**.
 The Format pane appears.
- 2 Specify the display characteristics for the selected column.
- 3 Click **OK**.

Renaming titles and headings

To customize a report title:


- Click the title in the report palette and enter data in the **Edit title area** pane.








To customize a report heading, do one of the following:

- Double-click the column heading in the report palette, and enter data in the **Rename** pane.

Changing the page layout for a report

Use the following Change Layout menu selections to change the look and feel of an ad hoc report.

Option	Description
 Chart	Present information graphically using one of several 2D and 3D formats.
Define Conditional Styles	Apply font styles depending on the data values in a column.
Change Font Styles	Specify font types and sizes for a report.
Change Border Styles	Specify the line weight and color for report borders.
Reset Font and Border Styles	Reset the report output to the default format.
Apply Template	Apply formatting that you create using Report Studio.
Edit Title area	Include meaningful report titles and optional subtitles.
Set Web Page Size	Specify the maximum number of rows of data that appear on any page of an ad hoc report.
Set Page Breaks	Specify page breaks on groups or report sections.

Option	Description
 Group	Organize a report so that identical values in a column appear together and suppress the display of duplicate values. <ul style="list-style-type: none"> • The grouped column automatically sorts in ascending order. • Duplicate values are suppressed. • A summary is generated for each distinct group value.
 Pivot	Convert a list report to a crosstab report.
 Ungroup	Revert to showing all values in a column including duplicates.
 Create Sections	Organize a report into a distinct section for each unique value within a column.
 Swap Rows and Columns	Interchange rows and columns in a crosstab, a chart based on a crosstab, or both.
 Collapse Group	Temporarily reduce progressive levels of detail to high-level summaries.
 Expand Group	Restore temporary collapsed levels from a Collapse Group action to the full detail levels.

Empty cells and deleted data in reports

The Ad Hoc Reporting module automatically suppresses empty cells and duplicate data from ad hoc reports. You can configure this functionality using the automatic summarization settings for a report.

The Ad Hoc Reporting module includes data from deleted records by default. To indicate that a form, visit, or subject and so forth is deleted, add the **Is Deleted** report item from the Properties folder for the report item to the report. You can also choose not to display deleted records to create reports for current data only.

Note: Calculations are performed before cells are hidden.

Internal IDs

About internal IDs

Each clinical topic contains an Internal IDs folder. These folders contain unique database identifiers for various study components.

Use the following internal IDs to enhance reports:

- **Subject ID**—Unique ID that identifies a subject when the Subject Number is not unique. The Subject ID is unique for each subject.
- **Form Index, Itemset Index, and Visit Index**—Use with repeating forms, items, and visits to report on status information for individual instances of repeating objects.

Note: Indexes are also known as sequence numbers.

Use internal IDs when you need to identify unique instances of clinical data when there are no other elements containing unique data values.

For example, if the subject numbers in a study are not unique, to uniquely identify a subject in a report, you can use the SUBJECTID element from the Internal IDs folder.

Note: Because internal IDs access database indexes directly, they can improve the efficiency of reports that you create with the Report Studio application. Knowledge of database principles and the Reporting and Analysis database schema is recommended.

Internal IDs in the Clinical Data by Form folder

In the Clinical Data by Form folder, the contents of the Internal IDs folder is the same for each report topic. Using the unique identifiers, you can focus a report on specific:

- Subjects
- Sites
- Trial versions
- Visits
- Forms

Note: If your trial does not enforce unique subject numbers, site mnemonics, or visit mnemonics, you can use the SUBJECTID, SITEID, or VISITID to uniquely identify a subject, site, or visit in a report.

Internal IDs in the Trial Management data model

In the Trial Management data model, the contents of the Internal IDs folder depend on the level of nesting for a report element. The more nested an element is, the more internal IDs are available.

For example, the Internal IDs folder for the Subjects report topic focuses primarily on subject identifiers (primary keys), whereas the Visits Internal IDs folder contains unique identifiers for both visits (primary keys) and subjects (secondary keys).

Calculation and conversion rules

About calculations and conversion rules

Some trials use calculations and conversions. Calculations and conversions set the value of data items by performing calculations that use the value in one or more related items. You can perform calculations such as:

- Aging on date time data.
- Concatenations and other string manipulation.
- Arithmetic and analytical operations on numeric data.

Note: You cannot edit a calculation. To modify a calculation, you must delete the calculated report element and recalculate it.



Calculations on date time elements

The Calculate page for date time elements allows you to perform the following operations.

Operation	Description
- (difference)	The difference between the date in the report and another specified date.
- (difference in days)	The number of days between the date in the report and another specified date.
- (difference in months)	The number of months between the date in the report and another specified date.
- (difference in years)	The number of years between the date in the report and another specified date.
Add days	Specify the number of days to add to a date.
Add months	Specify the number of months to add to a date.
Add years	Specify the number of years to add to a date.
Earliest	Determine the earliest date between the date in the report and another specified date.
Latest	Determine the latest date between the date in the report and another specified date.
Year	Extract the year number from a date
Month (number)	Extract the month number from a date.
Week	Extract the week number from a date.
Day	Extract the day value from a date

Operation	Description
Hour	Extract the hour value from a date
Minute	Extract the minute value from a date
Second	Extract the seconds value from a date

Creating a calculation

- On the report palette, click a column heading.
- Optionally, select additional column headings by clicking them while holding down the Shift key.
- Do one of the following:
 - From the **Edit Menu**, click **Calculate** ().
 - From the **Edit Data** toolbar, click the **Calculate** () button.
 - Right-click a highlighted column heading, and select **Calculate**.
- Complete the Calculate page:
 - Select the operations.
 - Select from other calculation parameters.
 - Optionally apply a new item name to the calculation.
- Click **Insert**.

Note: When you select more than one column upon which to base a calculation, you can only select columns that contain the same type of data (numeric, string, date time).

Dates with unknown date parts

If a date field allows unknown (**UNK**) values, the InForm application stores the following date values:

- For a complete date:
 - A date/time column.
 - A date string column.
 - A month column.
 - A day column.
 - A year column.
- If there is at least one unknown value, the InForm application stores the date values in a date string column only.

Calculations on string elements

The Calculate page for string elements enables operations on text and alphanumeric values.

Operation	Description
First characters	Specify the number of left-most characters to display in the report column.
Last characters	Specify the number of right-most characters to display in the report column.
Concatenation	Specify how to join single or multiple report values together including: <ul style="list-style-type: none"> • Preceding text • Following text • Separator between report elements
Remove trailing spaces	Delete the blank characters at the end (right) of a string value.

Calculations on numeric elements

The Calculate page for numeric elements allows arithmetic and other analysis operations.

Operation type	Operations	
Arithmetic	+ (sum)	Absolute value
	- (difference)	Round
	* (multiplication)	Round down
	/ (division)	Square root
	^ (power)	
Percentage	%	% difference (growth)
	% of total	
Analytic	Average	% of total
	Maximum	Percentile
	Minimum	Quartile
	Rank	Quantile

Calculating business days versus number of days

The **- (difference in days)** operation determines the total number of days between the date value in the report element and another specified date. To calculate the number of business days between two date values, use the following procedure:

- 1 Create a **- (difference in days)** calculation.
- 2 From the original calculation, create a new calculation (product) that multiplies the difference calculation by **.7142857142857** (this represents 5/7).
- 3 From the product calculation, create a new calculation that adds **.5** to the product.
- 4 From the addition calculation, create a new calculation that rounds the result.
- 5 Delete the difference, product, and addition calculations from the report.

Crosstab reports

About crosstab reports

Crosstab reports show summary information in a two-dimensional grid. Using crosstab reports, you can display large amounts of tabular data.

A crosstab report must contain at least three reporting elements:




- A non-aggregate report element that provides distinct categories of values that become row labels.
- A non-aggregate report element that provides distinct categories of values that become column labels.
- A measure (aggregate) report element that provides numeric values upon which to produce summaries.

Crosstab development tools

Use Change Layout options to:

- Create a new crosstab report.
- Convert a list report to a crosstab report.
- Convert a crosstab report back to a list report.
- Switch the column and row headers in a crosstab report.

Note: A crosstab report must contain at least three reporting elements: two non-aggregate elements for the categories and one measure for the summaries.

Option	Description
 Pivot	Converts a list report to a crosstab report.
 Ungroup	Reverts to a list report, showing all values in a column, including duplicates.
 Swap Rows and Columns	Interchanges rows and columns in a crosstab report, a chart based on a crosstab report, or both.

Charts

About charts

Charts show summary information graphically. Charts consist of at least two reporting elements:

- A non-aggregate report element that provides distinct categories of values.
- A measure (aggregate) report element that provides numeric values upon which to produce summaries.

Note: You can have up to two non-aggregate report elements and any number of measures in a chart.

Types of charts
















Chart Type	Chart Configurations	
Column	 Standard	 Stacked
	 100 Percent Stacked	 3-D Axis
Pie	 Standard	 100 Percent
	 100 Percent with 3-D Visual Effect	 Standard with 3-D Visual Effect
Bar	 Standard	 Stacked
	 100 Percent Stacked	
Line	 Standard	 Stacked
	 100 Percent Stacked	 3-D Axis











Chart Type	Chart Configurations	
Column-Line	 Standard	 Stacked
	 100 Percent Stacked	 Standard with 3-D Axis
Area	 Standard	 Stacked
	 100 Percent Stacked	 Standard with 3-D Axis
Radar	 Standard	 Stacked Area

Chart configurations

Chart configuration	Description
Standard	Plot the actual value of each measure from a common base line.
Stacked	Plot the relative value that each measure contributes to the total.
100 Percent stacked	Plot the relative contribution of each measure to the total, expressed as a percentage.
3-D Axis	Plot measures in three dimensions.




Choosing a chart type

Action	Chart type	Configuration
Show contributions of parts to a whole.	<ul style="list-style-type: none"> • Pie 	<ul style="list-style-type: none"> • Standard • 100% Stacked
Show trends in time or contrast values across different categories.	<ul style="list-style-type: none"> • Line • Area • Bar • Column 	
Compare groups of related information against actual values.	<ul style="list-style-type: none"> • Radar 	<ul style="list-style-type: none"> • Standard • Stacked • 3D
Compare different kinds of quantitative information.	<ul style="list-style-type: none"> • Column Line 	

Chart development tools

Using Change Layout tools, you can:

- Create a new chart.
- Convert a list report to a chart report.
- Convert a crosstab report to a chart.
- Convert a chart report back to a list report.
- Switch the category values to change the focus of a chart.

Option	Description
Change layout menu or toolbar buttons	
 Chart	Converts a list or crosstab report to a chart report.
 Ungroup	Reverts to a list report, showing all values in a column including duplicates.
 Swap Rows and Columns	Changes the focus of the chart by interchanging category values in a chart that is based on a crosstab report.
Chart page	

Option	Description
Chart type	Choose from: <ul style="list-style-type: none">• Seven available chart types (such as column and pie).• Four configuration options (such as standard and stacked).
Show the values on the chart	Includes the summary values in the chart.
Show the following in the report	Choose: <ul style="list-style-type: none">• Chart and table—displays both the chart and the list report upon which it is based.• Chart only—includes only the graphical display.

Note: You can use the Ungroup button only if you opted to display the table (crosstab report) along with the chart.

Custom groups

About custom groups

The Define Custom Groups selection in the **Edit Data** menu produces new report elements that contain special groupings of report values.

You can organize the data in a report using custom groups that create new report elements based on the values in a column. For example:

- Convert a list of numeric results into categories such as the number of open queries into New, Recent, and Old.
- Reduce the number of values into smaller, more meaningful sets such as organizing a list of sites into regions.

Customization type	Description	Numeric	Date Time	String
Ranges of values	Identify the ranges of values that constitute value groups.	✓	✓	✓
Individual values	Identify the lists of specific values that constitute value groups.			✓

Defining a custom group

- 1 On the report palette, click a column heading.
- 2 Select **Edit Data > Define Custom Groups**.
- 3 Complete the Define Custom Groups page:
 - a Select the customization type: Ranges (for any data type) or Individual Values (for string data only).
 - b Identify the group categories using the Create Range template (ranges) or the New Group template (individual values).
 - c Optionally apply a new item name to the custom group.
- 4 Click **OK**.

Custom groups on date time elements

The Define custom groups page for date time elements enables custom groups on ranges of values.

Customization type	Parameters	Description
Ranges	Ranges (in sequential order)	The name of the value ranges that you define.
	Create range:	A template that you complete to define a value range.
	<ul style="list-style-type: none"> • New range name • From • Earliest Date • To • Latest Date 	
	Item Name	An optional name that you can give to the custom group. Default value: column name followed by "(custom)".

Custom groups on numeric elements

The Define Custom Groups page for numeric elements enables custom groups on:

Customization type	Parameters	Description
Ranges	Ranges (in sequential order)	The name of the value ranges that you define.
	Create range	A template that you complete to define a value range.
	<ul style="list-style-type: none"> • New range name • From • Lowest Value • To • Highest Value 	
	Item Name	An optional name that you can give to the custom group. Defaults to the column name with a "(custom)" suffix.

Custom groups on string elements

The Define Custom Groups page for string elements enables custom groups on:

Customization type	Parameters	Description
Ranges	Ranges (in sequential order)	The name of the value ranges that you define.
	Create range <ul style="list-style-type: none"> • New range name • From • Lowest Value • To • Highest Value 	A template that you complete to define a value ranges.
	New Item Name	An optional name that you can give to the custom group. Defaults to the column name with a “(custom)” suffix.
Individual Values	New Group Name <ul style="list-style-type: none"> • Custom Group • Custom Group Values • Available Values 	A template that you complete to define a value group.
	New Item Name	An optional name that you can give to the custom group. Defaults to the column name with a “(custom)” suffix.

Reporting on trial management data

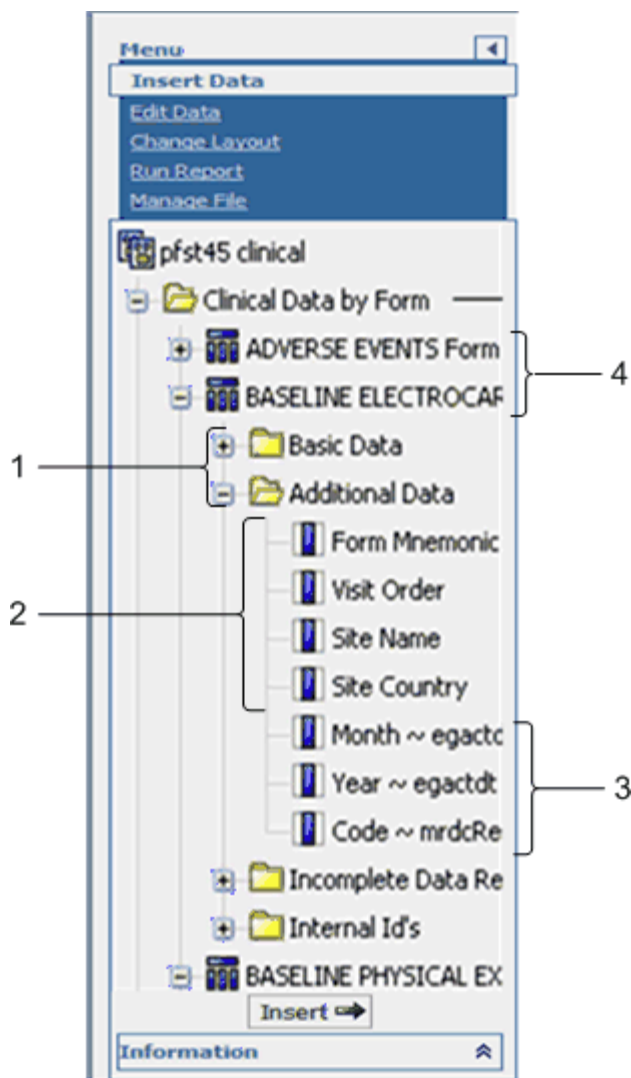
Trial management report elements

Trial management data includes the following topics or report elements:

Report elements	Description
Study info	Provide information about the trial, the trial sponsor, and trial version in your reports. Note: Many of these elements are optional in your trial design; report elements may return blank values.
Sites	Provide identifying and descriptive data for all sites in a given trial.
Subjects	Provide metrics and status information about subjects during the course of the trial. The elements and measures in this report topic return trial management data. You can use these elements and measures to access such data as current status, status dates, and counts.
Visits	Use to create reports on visit properties, status, and dates. All visit types are included in general visit counts for ad hoc reports. To limit your reports to clinical visit counts only, use a predefined filter.
Forms	Provide metrics and status information about forms in your trial. Use this report topic to include: Counts of different form types. Information about form properties and states. Information on when forms were initially created and changed.
Sections	Use to report on form sections.
Items	Provide metrics and status information about items on forms in the trial. Use this report topic to include counts of different item types, information about item properties, and information on when items were initially created and changed.
Rules	Provides information about rule types and the number of times rules have been triggered.
Queries	Use to see query text and type, to gather counts on manual and automatic queries, and to see query status.
Comments	Allow you to report on both item-level and form-level comments.
User Info	Allow you to gather information on your InForm users. Note: Many of these elements are optional in your trial design; report elements may return blank values.

The InForm Trial Management reporting tree

The trial management portion of the Ad Hoc Reporting tree contains report topics and elements related to non-clinical data such as subject numbers, visit and form mnemonics, query text, itemset indexes, comments, and so on.



- 1—The **report element folders** consist of clinical reporting elements.
- 2—To create reports with clinical data, include **trial management report elements** that identify the trial component (subject, visit, and so forth) on which you want to report. The Clinical Data by Form folder contains some report elements from the Trial Management package; you can use these elements to identify visit, subject, and site in your clinical reports, and to identify unique instances of repeating visits, forms, or itemsets.
- 3—Each **clinical form reporting topic** corresponds to a form or an itemset within your trial.
- 4—**Clinical report elements** reflect the item questions that appear on the forms within your trial. Labels for reporting elements may or may not have been customized for display in the reporting tree.

Element descriptions

The description of each element might include the following:

- **Data displayed**—The type of data returned in the report. Possible values are:
 - Numeric
 - String (text)
 - Date/Time
 - Y/N
- **Description**—A brief description of the element.
- **How calculated**—Information about how data is calculated. (Included only for counts.)
- **Data source**—A description of where the data came from. Possible values are:

Data source	Description
Replicated from the InForm Transactional database to the Reporting and Analysis database (not a derived value).	This data resides in both the InForm Transactional database and in the InForm Reporting and Analysis database.
Replicated from the InForm Transactional database to the Reporting and Analysis database. Database value has been decoded for display.	This data resides in both the InForm Transactional database and in the Reporting and Analysis database. The value has been derived for display. For example, a Y/N value that displays in a report may be stored as a 0/1 value in the database.
Derived by the Ad Hoc Reporting application. Not stored in the Reporting and Analysis database.	This data is derived when you run a report. The data does not appear in any InForm database.
Derived and stored in the Reporting and Analysis database.	This data is derived by the InForm Ad Hoc Reporting application and resides only in the Reporting and Analysis database.

- **Date type**—A description of the type of date displayed. (Included only for dates.) Possible values are:

Date type	Description
System date (GMT).	A date recorded by the InForm application at data entry.
System date and time (GMT).	A date and time recorded by the InForm application at data entry.

Date type	Description
System date (GMT), derived for display.	A date recorded by the InForm application, but derived for display. For example, the Form Status by Month, Year report element returns only the Month and Year portion of the date.
Reporting and Analysis database system date and time.	A system date on the Reporting and Analysis database server.
Clinical.	A date entered by an InForm user in local time.
Specified in trial design code.	A date specified in the trial MedML.
May be specified in trial design code. If not, this is a system date.	A date that may be specified in the trial MedML. If it is not, the date is a date recorded by the InForm application at data entry.

- **Tip**—Additional information about the report element.
- **Example**—An example to help illustrate a calculation or concept.

Study Info report elements

Use the Study Info report elements to include information about the study, the study sponsor, and study version in your reports.

Note: Many Study Info elements reflect data that is optional for each study. Reports do not display data for these elements if they have not been used for your study.

Study Info: Study

Study Info: Study report elements report on high-level specifics of the trial.

Study Info: Study	
Report element	Description
Study Name	<p>Data displayed: String</p> <p>Description: Name associated with the study, as specified in the study design code.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Trade Drug/Device Name	<p>Data displayed: String</p> <p>Description: The proprietary, trademark-protected name under which the drug, device, biologic, or compound is being marketed. This name is specified in the trial design code.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Study Info: Study	
Report element	Description
Generic Drug/Device Name	<p>Data displayed: String</p> <p>Description: The name used for the generic, therapeutic equivalent of the brand-name drug, device, biologic, or compound (if any). This name is specified in the trial design code.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Sponsor Drug/Device Name	<p>Data displayed: String</p> <p>Description: The name the sponsor uses to refer to the drug, device, biologic, or compound being studied. This name is specified in the trial design code.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Refresh Time	<p>Data displayed: Date/Time</p> <p>Description: The last date and time the reporting data was refreshed. This time reflects the last time data was refreshed in the Reporting and Analysis database, regardless of whether data was changed.</p> <p>Date type: Reporting and Analysis database system date and time.</p>
Transaction Time	<p>Data displayed: Date/Time</p> <p>Description: The most current InForm transaction time.</p> <p>Date type: System date and time (GMT).</p>

Study Info: Sponsor

Study Info: Sponsor report elements let you report on specifics about the sponsor of the trial.

Note: Many Study Info elements retrieve data that is optional; this data may or may not be specified in your trial design. If data is not specified, report elements return blank values.

Study Info: Sponsor	
Report element	Description
Sponsor Name	<p>Data displayed: String</p> <p>Description: The name of the sponsor of the study.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Study Info: Sponsor	
Report element	Description
Note	<p>Data displayed: String</p> <p>Description: An optional description of the study, specified in the trial design code.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Address 1	<p>Data displayed: String</p> <p>Description: The text stored in the Address 1 line for the trial sponsor.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Address 2	<p>Data displayed: String</p> <p>Description: The text stored in the Address 2 line for the sponsor.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
City	<p>Data displayed: String</p> <p>Description: The city in which the trial sponsor is located.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
State/Province	<p>Data displayed: String</p> <p>Description: The state or province in which the trial sponsor is located.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Country	<p>Data displayed: String</p> <p>Description: The country in which the trial sponsor is located.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Postal Code	<p>Data displayed: String</p> <p>Description: The postal code for the sponsor location.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Phone	<p>Data displayed: String</p> <p>Description: The primary telephone number for the sponsor.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Study Info: Sponsor	
Report element	Description
Alt Phone	<p>Data displayed: String</p> <p>Description: The secondary telephone number for the sponsor.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Fax	<p>Data displayed: String</p> <p>Description: The fax number for the sponsor.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Email	<p>Data displayed: String</p> <p>Description: An email address specified by the sponsor for a primary contact related to the study.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Therapeutic Area	<p>Data displayed: String</p> <p>Description: The medical area being investigated by the trial. Use of the Therapeutic Area field varies from sponsor to sponsor.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Program Name	<p>Data displayed: String</p> <p>Description: The name of the medical program into which the study can be categorized. Program names might be medical areas such as Oncology, Dermatology, and so forth. Use of the Program name field varies from sponsor to sponsor.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Study Info: Study Versions

Study Info: Study Versions reporting topics let you report on data about the particular trial versions.

Study Info: Study Versions	
Report element	Description
Version	<p>Data displayed: String</p> <p>Description: The name associated with a given study version, as specified in the trial design code. This report element returns all study versions.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Version Date	<p>Data displayed: Date/Time</p> <p>Description: The date the study version was defined for the trial.</p> <p>Date type: May be specified in trial design code. If not, this is a system date.</p>
Description	<p>Data displayed: String</p> <p>Description: Text used to describe what has changed in this study version. Study version description text is unique to each study version. Often, this field is used to reflect the iteration of a particular study. For example, a 2 in this field may indicate that the study version is the second revision.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Design Note	<p>Data displayed: String</p> <p>Description: Optional notes for the study version entered in the trial design code.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Sponsor Approval Date	<p>Data displayed: Date/Time</p> <p>Description: The projected date on which the Sponsor will be approved the InForm study version. This date is set by the trial designer. It does not necessarily reflect the actual date the study version goes live.</p> <p>Date type: Specified in trial design code.</p>

Sites report elements

Site report elements and measures allow you to create reports that provide identifying and descriptive data for all sites in a given study. Use the Sites report topic when you want to see information broken out by each site participating in the study.

Sites

Sites report elements return data specific to each site. Most of these elements reflect optional data. If data is not entered for any of these optional values, the resulting reports yield blank results.

Sites	
Report element	Description
Site Name	<p>Data displayed: String</p> <p>Description: The name of the site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Address 1	<p>Data displayed: String</p> <p>Description: First line of the site address, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Address 2	<p>Data displayed: String</p> <p>Description: Second line of the site address, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
City	<p>Data displayed: String</p> <p>Description: The city in which a site is located, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Sites	
Report element	Description
State/Province	<p>Data displayed: String</p> <p>Description: The state or province in which the site is located, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Country	<p>Data displayed: String</p> <p>Description: Country in which a site is located, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Postal Code	<p>Data displayed: String</p> <p>Description: The postal code for the site address, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Phone	<p>Data displayed: String</p> <p>Description: The primary telephone number for the study site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Alt Phone	<p>Data displayed: String</p> <p>Description: The site secondary telephone number, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Fax	<p>Data displayed: String</p> <p>Description: The fax number for a study site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Email	<p>Data displayed: String</p> <p>Description: The email address for a site contact, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Sites	
Report element	Description
Time Zone	<p>Data displayed: String</p> <p>Description: The time zone in which a study site is located, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Date Format	<p>Data displayed: Numeric</p> <p>Description: The format used for all references to dates for the site. Valid values are:</p> <p>1—Day/Month/Year</p> <p>2—Year/Month/Day</p> <p>3—Month/Day/Year</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Activation Date	<p>Data displayed: Date/Time</p> <p>Description: The projected date for the activation of the study by the site. It does not necessarily reflect the actual date on which the activation occurs.</p> <p>Date type: May be specified in trial design code. If not, this is a system date.</p>
Current Trial Version	<p>Data displayed: String</p> <p>Description: Displays a description of the most current study version, as specified in the trial design code. Many trial designers use this field to indicate study version iteration. For example, 2 indicates the second version of the study. The value may also be a text description for the study version.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Sites	
Report element	Description
Current Site Acceptance Date	<p>Data displayed: Date/Time</p> <p>Description: The date on which the site was assigned to the current study version.</p> <p>Date type: May be specified in trial design code. If not, this is a system date. The date that appears here depends on how the site was associated with the current study version:</p> <ul style="list-style-type: none">• If the site was associated with the study version through the InForm Administration interface, the Current Site Acceptance Date is the system date when the association took place.• If the site was associated with the study version through the MedML Installer utility, the Current Site Acceptance Date is the date specified in the MedML for the new study version.

Subjects report elements

Subject report elements and measures allow you to create reports that provide metrics and status information about subjects during the course of the study.

Note: The elements and measures in this report topic return trial management data. You can use these elements and measures to access such data as current status, status dates, and counts.

These elements and measures do not provide any clinical information about a subject. You can create reports that contain clinical data about subjects only if you have access to both trial management and clinical items and measures in your reporting package.

Subjects

Subjects report elements return identifying information about the subject. This report topic also includes a count element, allowing you to see totals for subjects, regardless of status.

Subjects	
Report element	Description
Subject Number	<p>Data displayed: String</p> <p>Description: Number that identifies the subject. This number may be changed after the subject is enrolled, if the study is configured to require a unique subject ID for a study or site.</p> <p>Note: Subject number might not be unique at your site.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Subject Initials	<p>Data displayed: String</p> <p>Description: The initials of the subject enrolled in the trial. These initials can be changed post enrollment.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Subject DOB (Screening)	<p>Data displayed: Date</p> <p>Description: The date of birth for the subject, as entered on the Screening form for the subject. The DOB field may or may not be used on the Screening form for your study.</p> <p>This date cannot be changed after the subject is enrolled. (It can be changed after the Screening form is submitted, as long as the subject has not yet been enrolled.)</p> <p>Many trial designers also include a date of birth field for the subject on other clinical forms in the study to correct data entry errors that might have occurred when the subject was screened. Unlike the DOB field on the screening form, a DOB field on a clinical form can be changed at any time.</p> <p>As a result, a subject may have two different dates of birth recorded in the Reporting and Analysis database; one recorded on the Screening form, and one recorded on another clinical form in the study. These dates may or may not match.</p> <p>You can report on clinical DOB dates using report element that appear in the Clinical Data by Form folder.</p> <p>Date type: Clinical.</p>

Subjects: Subject Status (text)

The elements in the Subjects: Subject Status (text) reporting topic allow you to create reports that describe subject status.

Note: The Subject states listed here are states internal to the InForm application. They may or may not correlate with clinical state definition, since events like screening and randomization are often performed outside of the InForm application.

Subjects: Subject Status	
Report element	Description
Subject Status	<p>Data displayed: String</p> <p>Description: The current InForm status assigned to the subject. This value reflects the InForm status of the subject; subjects can be in only one state at a time in InForm application. Valid values are:</p> <ul style="list-style-type: none"> • Screened—The Screening form for the subject was started, but the subject is not enrolled. This covers these cases: <ul style="list-style-type: none"> ▪ The subject is fully screened, but the enrollment form has not been started. ▪ The subject is fully screened and the enrollment process has started but not completed. • Screen Failed—The subject has failed the InForm screening process. • Enroll Failed—The subject has passed the InForm screening process, but failed the enrollment process. • Enrolled—The subject was properly enrolled in the InForm application, but has not reached the status of randomized, completed, or dropped out. • Randomized—The subject was enrolled and has been randomized in the InForm application, but is not yet completed or dropped out. • Complete—The subject has completed the study, as recorded in the Complete control of the Study Completion form for that subject. • Dropped out—The subject has dropped out of the study, as recorded in the Complete control of the Study Completion form for that subject. <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Subjects: Subject Status	
Report element	Description
Screen Failure Reason	<p>Data displayed: String</p> <p>Description: Text that indicates why the subject failed the screening process.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Enroll Failure Reason	<p>Data displayed: String</p> <p>Description: Text indicating why the subject failed enrollment.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Enroll Override Reason	<p>Data displayed: String</p> <p>Description: Text indicating why the screening or enrollment failure has been overridden for the subject.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Drop Out Reason	<p>Data displayed: String</p> <p>Description: Text that indicates why the subject dropped out of the study. The drop out reason is clinical data that is specified on the Study Completion form for the subject.</p> <p>Note: This report displays only those reasons that were specified when subjects dropped out of the study. If a drop out reason was never used, the reason does not appear in this report.</p> <p>UUIDs: PF_SC_COMPLETECTL, PF_SC_REASONCTL_internal_reason_value</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Subjects: Subject Status Counts

The Subjects: Subject Status Counts folder contains reporting elements that calculate counts of subjects based on subject state. The Subject states listed here are internal to the InForm application. Whether these states correlate to actual clinical states depends on your use of InForm application features.

About status counts

A subject can be in only one state at a time in the InForm application. Therefore, if a subject is randomized after being enrolled in the InForm application, the current state for the subject is randomized, not enrolled.

However, when you create reports on subjects who are still actively participating in the trial, you will likely need to see totals that reflect the number of subjects who have ever been enrolled in

the trial. For example, a count of enrolled subjects should include all subjects who have ever been enrolled in the InForm application, even if their status has changed to randomized, because in clinical terms, a subject who has been randomized is still considered enrolled. Therefore, these subject status counts return totals of subjects who have ever had these states:

- Screened
- Enrolled
- Enrolled Override
- Randomized

To report on subjects who are no longer active in the trial, use the Screened Failed, Enrolled Failed, Dropped Out, and Complete subject status counts. Unlike the other subject status counts, these report elements return totals of those subjects currently in any of these states. Subjects will have Dropped Out and Complete status only if the Trial Completion form is being used for your trial.

Note: The status assigned to a subject depends on the use of InForm application features. For more information, see *Subject status requirements* (on page 25).

Note: You can use any of the predefined subject filters to further qualify the Subject Status Count totals.

Subjects: Subject Status Counts

Report element	Description
Subject Count	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who have ever participated in the study.</p> <p>How calculated: All subjects, regardless of status, are included in this count. This count includes all screened, enrolled, randomized, dropped, and completed subjects.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p> <p>Note: You can use any of the predefined subject filters to further qualify this count.</p>

Subjects: Subject Status Counts	
Report element	Description
Screened	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who have ever been in the screened state in InForm application.</p> <p>How calculated: A subject is counted if the subject has ever been assigned a screened status in the InForm application. This count includes subjects whose states have changed from screened to a new state.</p> <p>Data source: Status is determined by InForm Screening form and stored in the Reporting and Analysis database. The status count is derived from the status and is set to 1 when the subject enters that status. This fact is stored in the Reporting and Analysis database.</p>
Screen Failed	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who have a current status of screened failed in the InForm application.</p> <p>How calculated: A subject is counted if the InForm screening process rejected the subject, based on some screening eligibility requirement that was not met. Subjects can have a status of screened failed in the InForm application only if screening eligibility requirements are being used for your study.</p> <p>A subject is not counted if the screen failure was overridden for the subject.</p> <p>Data source: Status is determined by InForm Screening form and stored in the Reporting and Analysis database. The status count is derived from the status and is set to 1 when the subject enters that status. This fact is stored in the Reporting and Analysis database.</p>
Enrolled	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who have ever been enrolled in the study through the InForm application.</p> <p>How calculated: A subject is counted if an Enrollment form was completed and successfully submitted for the subject. This count includes:</p> <ul style="list-style-type: none"> • Subjects whose states have changed from enrolled to a new state. • All subjects who have ever been in the enrolled state. • Subjects who have gone through the enroll-override process. <p>Data source: Status is determined by value on the InForm Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p>

Subjects: Subject Status Counts	
Report element	Description
Enrolled Failed	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who have a current status of enrolled failed in the InForm application.</p> <p>How calculated: A subject is counted if the InForm application rejected the enrollment form for the subject based on some eligibility requirement that was not met. This count includes subjects whose current states have changed from enrolled failed to a new state.</p> <p>A subject is not counted if the enroll failure was overridden for the subject.</p> <p>Subjects can have this status only if the enrollment eligibility requirements are being used in the InForm application for your study.</p> <p>Data source: Status is determined by value on the InForm Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p> <p>Note: You can use any of the predefined subject filters to further qualify this count.</p>
Enrolled Override	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who initially failed the InForm screening or enrollment process, but whose failure was overridden in the InForm application.</p> <p>How calculated: A subject is counted if the subjects were screened or enrolled successfully through the InForm Enrolled Override process. This count includes all subjects whose status has changed from enrolled override to a new status.</p> <p>Data source: Status is determined by InForm Screening/Enrollment override process and stored in the Reporting and Analysis database. The status count is derived from the status and is set to 1 when the subject enters that status. This fact is stored in the Reporting and Analysis database.</p>

Subjects: Subject Status Counts	
Report element	Description
Randomized	<p>Data displayed: Numeric</p> <p>Description: The number of subjects in the study who have ever been randomized in the InForm application. Subjects have a status of randomized immediately after they have been randomized with the InForm randomization feature.</p> <p>How calculated: A subject is counted if the subject has ever been randomized in the InForm application. This count includes subjects whose status has changed from randomized to a new status.</p> <p>If you randomize subjects outside of the InForm application, the randomized subject count will always be 0.</p> <p>Data source: Status is determined by InForm Randomization feature and stored in the Reporting and Analysis database. The status count is derived from the status and is set to 1 when the subject enters that status. This fact is stored in the Reporting and Analysis database.</p>
Dropped Out	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who have a current status of dropped out.</p> <p>How calculated: A subject is counted if the subject has dropped out of the study, as recorded in the Study Completion form for that subject.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Subject Complete	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who have a current status of complete.</p> <p>How calculated: A subject is counted if the current status for the subject is complete, as recorded in the Study Completion form for that subject.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Subjects: CRB Status Counts

The Subjects: CRB Status Counts return metrics on the number of casebooks in various states. CRB states are set at the casebook level only. A CRB state is not set by actions performed on individual forms within the casebook.

Subjects: CRB Status Counts	
Report element	Description
CRB Started	<p>Data displayed: Numeric</p> <p>Description: The number of casebooks that have been started in the InForm application.</p> <p>How calculated: A casebook is counted as started when a noncommon form from the first visit in the case book is started. (A form is started when any data, queries, or comments have been entered on the form.)</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
CRB SV Ready	<p>Data displayed: Numeric</p> <p>Description: The number of the casebooks with a current status of SV ready.</p> <p>How calculated: A casebook is counted if its current status is SV ready.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
CRB Frozen	<p>Data displayed: Numeric</p> <p>Description: The number of frozen casebooks.</p> <p>How calculated: A casebook is counted if its current status is frozen.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
CRB Signed	<p>Data displayed: Numeric</p> <p>Description: The number of casebooks that have been signed.</p> <p>How calculated: A casebook is counted if its current status is signed.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
CRB Locked	<p>Data displayed: Numeric</p> <p>Description: The number of locked casebooks.</p> <p>How calculated: A casebook is counted if its current status is locked.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Subjects: CRB Status Counts	
Report element	Description
CRB w/ Query	<p>Data displayed: Numeric</p> <p>Description: The number of the casebooks that have at least one opened or unanswered query.</p> <p>How calculated: A casebook is counted if at least one form in the casebook has at least one opened or answered query. A casebook is not counted if the only query associated with any of its forms is a candidate query.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Subjects: Subject Status Dates

The Subjects: Subject Status Dates report elements return dates when subjects were assigned to particular states in the InForm application.

You can use First and Last dates below to achieve different reporting purposes:

- Use Last dates to determine the current status of a subject and the date on which the status change occurred.
- Use the First and Last dates together to identify subjects who have been, but are no longer, in a particular state.

Subjects: Subject Status Dates	
Report element	Description
Subject Status Date	<p>Data displayed: Date/Time</p> <p>Description: The date the subject was assigned the current subject status. For example, if the current subject state is complete, the Subject Status date indicates the date on which the complete state was assigned to the subject.</p> <p>Date type: System date (GMT).</p>
InForm Screened Date	<p>Data displayed: Date/Time</p> <p>Description: The date on which the subject was screened for the study in the InForm application. A screened status indicates that the Screening form for the subject was started, but the subject is not yet enrolled. This covers these cases:</p> <ul style="list-style-type: none"> • The subject is fully screened, but the enrollment form has not been started. • The subject is fully screened and the enrollment process has started but not completed. <p>Date type: Clinical.</p>

Subjects: Subject Status Dates	
Report element	Description
InForm Enrolled Date	<p>Data displayed: Date/Time</p> <p>Description: The date on which the subject was enrolled in the InForm application. A status of enrolled indicates the subject was properly enrolled in the InForm application, but has not reached the status of randomized, completed, or dropped out.</p> <p>Date type: System date (GMT).</p>
InForm Screen Failure Date	<p>Data displayed: Date/Time</p> <p>Description: The date on which the subject failed the screening process.</p> <p>Date type: System date (GMT).</p>
InForm Randomized Date	<p>Data displayed: Date/Time</p> <p>Description: The date on which the subject was randomized through the InForm application. A status of randomized indicates that a subject was enrolled and randomized in the InForm application, but is not yet completed or dropped out.</p> <p>Note: If you perform randomization outside of the InForm application, this element returns a blank value.</p> <p>Date type: System date (GMT).</p>
First Dropped Date	<p>Data displayed: Date/Time</p> <p>Description: The date the subject first dropped out of the study, as recorded in the Study Completion form for that subject.</p> <p>Date type: System date (GMT).</p>
Last Dropped Date	<p>Data displayed: Date/Time</p> <p>Description: The date on which the subject most recently dropped out of the study, as recorded in the Study Completion form for that subject. If the subject is removed from the dropped out state, this element returns a blank value.</p> <p>Date type: System date (GMT).</p>
Subject First Complete Date	<p>Data displayed: Date/Time</p> <p>Description: The first date on which the subject completed the study, as recorded in the Study Completion form as designed per InForm requirements.</p> <p>Date type: System date (GMT).</p>

Subjects: Subject Status Dates	
Report element	Description
Subject Last Complete Date	<p>Data displayed: Date/Time</p> <p>Description: The most recent date on which the subject completed the study, as recorded in the Study Completion form as designed per InForm requirements. The value listed in the resulting ad hoc report is null if the subject is removed from the complete state.</p> <p>Date type: System date (GMT).</p>
CRB SV Ready Date	<p>Data displayed: Date/Time</p> <p>Description: The date the casebook was marked SV ready.</p> <p>Date type: System date (GMT).</p>
CRB Frozen Date	<p>Data displayed: Date/Time</p> <p>Description: The date the casebook was frozen in the InForm application. If the CRB is unfrozen, the report element returns a null value.</p> <p>Date type: System date (GMT).</p>
CRB Signed Date	<p>Data displayed: Date/Time</p> <p>Description: The date the casebook was signed in the InForm application. If the CRB is not signed, the report element returns a null value.</p> <p>Date type: System date (GMT).</p>
CRB Locked Date	<p>Data displayed: Date/Time</p> <p>Description: The date the casebook was locked in the InForm application. If the CRB is not locked, this report element returns a null value.</p> <p>Date type: System date (GMT).</p>

Subjects: Subject Status by Month and Year

The Subjects: Subject Status by Month and Year report elements let you create reports on subject status by month. Use these report elements with subject status counts to see the number of subjects who were assigned a particular status each month.

If the report is sorted by one of the Month/Year report elements, the resulting report displays each month, and you can then add the Subject Count element to see how many forms were assigned a particular status in each month. You can also apply a filter to specify a date range to one appropriate for your trial.

Subjects: Subject Status by Month and Year	
Report element	Description
Subject Status Month, Year	<p>Data displayed: Date/Time</p> <p>Description: Each month/year combination within a specific range. Use this column with Subject Count to see the month and year each subject was assigned the current InForm status.</p> <p>Date type: System date (GMT), derived for display.</p>
Screened Month, Year	<p>Data displayed: Date/Time</p> <p>Description: Each month/year combination within a specific range. Use this column with Subject Count to see how many subjects were screened in the InForm application each month.</p> <p>Date type: System date (GMT), derived for display.</p>
Enrolled Month, Year	<p>Data displayed: Date/Time</p> <p>Description: Each month/year combination within a specific range. Use this column with Subject Count to see how many subjects were enrolled each month.</p> <p>Date type: System date (GMT), derived for display.</p>
Randomized Month, Year	<p>Data displayed: Date/Time</p> <p>Description: Each month/year combination within a specific range. Use this column with Subject Count to see how many subjects were randomized in the InForm application each month.</p> <p>Date type: System date (GMT), derived for display.</p>
Subject Complete Month, Year	<p>Data displayed: Date/Time</p> <p>Description: Each month/year combination from January 1999 to December 2008. Use this column with Subject Count to see how many subjects were completed each month.</p> <p>Date type: System date (GMT), derived for display.</p>

Subjects: Subject Status by Month and Year	
Report element	Description
Dropped Month, Year	<p>Data displayed: Date/Time</p> <p>Description: Each month/year combination within a specific range. Use this column with Subject Count to see how many subjects dropped out of the InForm trial each month.</p> <p>Date type: System date (GMT), derived for display.</p>

Visits report elements

Visit report elements allow you to create reports on visit properties, status, and dates.

About visit types

Trials designed for InForm application are made up of a number of different visit types.

Visit type	Description
Clinical visit types	
Subject Visit	A visit used to gather clinical data within the casebook for the subject.
Common Visit	An internal mechanism used to contain common forms used in the study.
Non-clinical visit types	
Screening	The visit that contains the Screening form, used for InForm screening. Note that the Screening visit is not included in the casebook for the subject.
Enrollment	The visit that contains the Enrollment form, used for InForm enrollment. Note that the Enrollment visit is not included in the casebook for the subject.
Monitor (Reg Docs)	An internal mechanism used to record information about a review of the study documentation.
Monitor (Visit Report)	An internal mechanism used to record information about a visit to a site by a monitor.

All visit types are included in general visit counts for ad hoc reports. To limit your reports to clinical visit counts only, be sure to use a predefined filter. For more information, see

Predefined filters (on page 144).

Visits

Visits report elements return identifying information about the visit.

Visits	
Report element	Description
Visit Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation of the visit title, as specified in trial design code. For CRF visits, this name appears at the top of a collection of forms in the visit timeline. The visit mnemonic may not be a unique identifier.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Visit Name	<p>Data displayed: String</p> <p>Description: The complete name that identifies the visit in the InForm application, as specified in trial design code. The visit name is not a unique identifier.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Visits: Visit Properties

Visits: Visit Properties report elements return information about the type of visit.

Visits: Visit Properties	
Report element	Description
Visit Type	<p>Data displayed: String</p> <p>Description: The type of visit. Valid types are:</p> <ul style="list-style-type: none"> • Subject Visit—A visit used to gather clinical data within the casebook for the subject. • Common Visit—An internal mechanism used to contain common forms used in the study. • Screening—The visit that contains the Screening form, used for InForm screening. The Screening visit is not included in the casebook for the subject. • Enrollment—The visit that contains the Enrollment form, used for InForm enrollment. The Enrollment visit is not included in the casebook for the subject. • Monitor (Reg Docs)—An internal mechanism used to record information about a review of the study documentation. • Monitor (Visit Report)—An internal mechanism used to record information about a visit to a site by a monitor. <p>Tip: If you want to report on only clinical data, filter this column to include only common and subject visits.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Database value has been decoded for display.</p>
Start Hours	<p>Data displayed: Numeric</p> <p>Description: Number of hours from the subject enrollment to the start of the visit. This number is specified in the trial design code and is used to create the proposed schedule of visits shown in the Visit Calculator when a subject is enrolled.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Visits: Visit Properties	
Report element	Description
Is Scheduled Visit	<p>Data displayed: Y/N</p> <p>Description: Indicates whether the visit is a scheduled visit. Scheduled visits occur in a fixed relationship to the beginning of enrollment in a study by a subject. Scheduled visits start a specified number of hours after enrollment. Valid values are:</p> <ul style="list-style-type: none"> • Y—The visit is scheduled. • N—The visit is not a scheduled visit. <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Database value has been decoded for display.</p>
Is Repeating Visit	<p>Data displayed: Y/N</p> <p>Description: Indicates whether the visit is a repeating visit. Repeating visits are those that occur multiple times within a study. Repeating visits are always unscheduled. Valid values are:</p> <ul style="list-style-type: none"> • Y—The visit is a repeating visit. • N—The visit is not a repeating visit. <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Database value has been decoded for display.</p>
Is Dynamic Visit	<p>Data displayed: Y/N</p> <p>Description: Indicates whether the visit is a dynamic visit. Dynamic visits are created automatically when subject data satisfies certain criteria that you test by attaching a rule to a form item. Valid values are:</p> <ul style="list-style-type: none"> • Y—The visit is dynamic. • N—The visit is not dynamic. <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Database value has been decoded for display.</p>
Dynamic Projected Start Hours	<p>Data displayed: Numeric</p> <p>Description: The number of hours after the study starts that this visit is scheduled to take place. This value is used for dynamic scheduling of a visit.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Visits: Visit Properties	
Report element	Description
Visit Order	<p>Data displayed: Numeric</p> <p>Description: A number that indicates the relative order of the visit within the study.</p> <p>Tip: Use Visit Order to sort visits in a report. This is helpful when the visit order is not implied in the Visit Mnemonic or Visit Name.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Design Note	<p>Data displayed: String</p> <p>Description: Optional text containing special information about the visit, specified in the trial design code. This information is for documentation only and is not displayed in the InForm application.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Visits: Visit Counts by Property

Visits: Visit Counts by Property report elements return totals of different types of visits.

Note: These visit counts are totals of all subject visits, regardless of visit type. To report on clinical visits only, use the Clinical Visits filter, in the Predefined Filters folder.

Visits: Visit Counts by Property	
Report element	Description
Scheduled Visit	<p>Data displayed: Numeric</p> <p>Description: The number of scheduled subject visits, regardless of visit type.</p> <p>How calculated: This calculation includes:</p> <ul style="list-style-type: none"> • All scheduled visits. • All started dynamic visits. • All started unscheduled visits. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Visits: Visit Counts by Property	
Report element	Description
Repeating Visit	<p>Data displayed: Numeric</p> <p>Description: The number of started repeating (unscheduled) visits.</p> <p>How calculated: A visit is counted if it is repeating (unscheduled) and has been started.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Dynamic	<p>Data displayed: Numeric</p> <p>Description: The number of started dynamic visits.</p> <p>How calculated: A visit is counted if it is dynamic and has been started.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Visits: Visit Status Counts

Visits: Visit Status Count report elements return visit totals by their status. Visit states are derived from the state of each form within each visit. For example, a visit is considered completed only if all forms within the visit must have a status of complete.

Note: Visit status for several of the following items does not correlate to status indicators on the InForm patient list.

Visits: Visit Status Counts	
Report element	Description
Visit Count (Across subjects)	<p>Data displayed: Numeric</p> <p>Description: The total number of subject visits for the study.</p> <p>How calculated: All subject visit instances are counted, regardless of visit type or status. This count includes non-clinical visits. (You can apply a predefined filter if you want to limit visit counts to clinical visits only.)</p> <p>In addition to counting Visits that have expected forms (including activated dynamic visits), this count includes unscheduled visits.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Visits: Visit Status Counts	
Report element	Description
Visit Started	<p>Data displayed: Numeric</p> <p>Description: The number of visits that have a non-common form that has been started in the InForm application.</p> <p>How calculated: A visit is counted as started if at least one non-common expected form in the visit has been started.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Visit Complete	<p>Data displayed: Numeric</p> <p>Description: The number of visits where each expected form has a current status of complete.</p> <p>How calculated: A visit is counted as complete if all of the expected forms in the visit have a current status of complete.</p> <p>Note: Visit status reported here differs from visit status indicated by the traffic light icon in the InForm user interface.</p> <ul style="list-style-type: none"> • Visit complete in Ad Hoc Reporting—All expected forms must be complete for the visit to be considered complete. • Visit complete in the InForm user interface—At least one started form must be complete for the visit to be considered complete. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Visit Frozen	<p>Data displayed: Numeric</p> <p>Description: The number of visits where each expected form has a current status of frozen.</p> <p>How calculated: A visit is counted as frozen if all of the expected forms in the visit have a current state of frozen.</p> <p>Note: Visit status reported here differs from visit status indicated by the traffic light icon in the InForm user interface.</p> <ul style="list-style-type: none"> • Visit complete in Ad Hoc Reporting—All expected forms must be frozen for the visit to be considered frozen. • Visit complete in the InForm user interface—At least one started form must be frozen for the visit to be considered frozen. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Visits: Visit Status Counts	
Report element	Description
Visit SV Complete	<p>Data displayed: Numeric</p> <p>Description: The number of visits where each expected form has been source verified in the InForm application.</p> <p>How calculated: A visit is counted as source verified if all of the expected forms in the visit have a current status of source verified in the InForm application.</p> <p>Note: Visit status reported here differs from visit status indicated in the InForm user interface.</p> <ul style="list-style-type: none"> • Visit Source Verified in Ad Hoc Reporting—All expected forms must be source verified for the visit to be considered source verified. • Visit Source Verified in the InForm user interface—At least one started form must be source verified for the visit to be considered source verified. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Visit Locked	<p>Data displayed: Numeric</p> <p>Description: The number of visits where each expected form has a status of locked in the InForm application.</p> <p>How calculated: A visit is counted as locked if all of the expected forms in the visit have a current status of locked.</p> <p>Note: Visit status reported here differs from visit status indicated in the InForm user interface.</p> <ul style="list-style-type: none"> • Visit Locked in Ad Hoc Reporting—All expected forms must be locked for the visit to be considered locked. • Visit Locked in the InForm user interface—At least one expected form must be locked for the visit to be considered locked. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Visits: Visit Dates

Visits: Visit Dates report elements return dates associated with visits.

Visits: Visit Dates	
Report element	Description
Scheduled Date	<p>Data displayed: Date</p> <p>Description: The date on which the visit is scheduled.</p> <p>How calculated: This date is calculated by adding the value in the Start Hour property for the visit to the enrollment date.</p> <p>Date type: System date (GMT), derived for display.</p>
Actual Date (DOV)	<p>Data displayed: Date</p> <p>Description: The date recorded in a standard Date of Visit control in the InForm application.</p> <p>Date type: Clinical.</p> <p>Note: This report element retrieves a date stored when your DOV controls are designed in a specific way.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>For more information, see <i>DOV controls</i> (on page 26).</p>
Data Entry Date	<p>Data displayed: Date</p> <p>Description: The date data was entered for the visit. This date is equal to the first date any form is submitted for the visit.</p> <p>Date type: System date (GMT).</p>

Forms report elements

Forms report elements and measures allow you to create reports that provide metrics and status information about forms that comprise the study. Use this report topic to include:

- Counts of different form types.
- Information about form properties and states.
- Information on when forms were initially created and changed.

About Form elements and expected forms

Unless otherwise noted, all of the calculations and dates returned by elements in the Forms

report topic are based on expected form counts.

A form is counted as expected if it meets any of the following criteria:

- It appears within a scheduled visit (regardless of whether the form is started).
- It appears within a started unscheduled visit.
- It is a dynamic form that has been activated.

Expected forms are counted only for subjects who have been enrolled in the InForm application (includes enrolled, randomized, completed, and dropped subjects).

For subjects that have completed or dropped (as indicated by the Study Completion form), only forms in started visits or dynamic started forms are counted. Non-started common forms are not counted as expected.

The expected forms calculation assumes the following:

- Only subject visits and common visits are counted. Other special visits (such as screening/enrollment or monitor) are not included.
- **Alternate forms**—An alternate form is counted as expected only if it has been started.
- **Dynamic forms**—Dynamic forms are counted only when activated, unless the form has been deleted (removed).
- **Repeating forms**—For repeating forms that have not been started, one instance of the form is counted as expected. For repeating forms that have been started, each started instance counts as expected. Deleted form instances are not counted as expected.
- **Common forms**—A common form is counted only once, regardless of the number of visits in which it occurs. This count includes common forms that appear in unscheduled visits that have not started. Common forms that have not been started for subjects that have completed or dropped out of the trial are not included in the expected forms count.
- **Common repeating forms**—Each started instance is counted once. If no instances have been started, it is counted once.
- **Common dynamic forms**—Each activated or started instance is counted once.
- **Dynamic repeating forms**—Each activated or started instance is counted once.
- **Common dynamic repeating forms**—Each activated or started instance is counted once.

Forms

Forms report elements return identifying information about forms.

Forms	
Report element	Description
Form Mnemonic	<p>Data displayed: String</p> <p>Description: Short name or abbreviation for the form, as specified in the study design code. This name appears on the Visit Navigation tab and is used to access a specific form in the InForm application.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Form Name	<p>Data displayed: String</p> <p>Description: The complete name that identifies the form in the InForm application.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Forms: Properties

Forms: Properties report elements return information about the properties associated with forms.

Forms: Properties	
Report element	Description
Form Type	<p>Data displayed: String</p> <p>Description: Displays the type of form. Valid values are:</p> <ul style="list-style-type: none"> • CRF—Identifies a form used in a clinical subject visit. • Enrollment—Identifies forms used in Screening and Enrollment visits. • Monitor RegDoc—Identifies forms used in Regulatory Documentation visits. • Monitor Visit Report—Identifies forms used for Visit Reports. <p>Use the predefined form filters with this element to limit the data on your report to a particular form type.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database. Value decoded for display.</p>

Forms: Properties	
Report element	Description
Is Dynamic	<p>Data displayed: Y/N</p> <p>Description: Specifies whether the form is dynamic. Valid values are:</p> <ul style="list-style-type: none"> • Y—The form is dynamic. • N—The form is not dynamic. <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Database value has been decoded for display.</p>
Is Repeating	<p>Data displayed: Y/N</p> <p>Description: Specifies whether the form is a repeating form. Valid values are:</p> <ul style="list-style-type: none"> • Y—The form is a repeating form. • N—The form is not a repeating form. <p>A repeating form occurs multiple times in the same visit or trial. For example, if a protocol calls for multiple blood draws at intervals after administering a medication, you can capture the repeating data on multiple instances of a repeating form.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Database value has been decoded for display.</p>
Is Common	<p>Data displayed: Y/N</p> <p>Description: Specifies whether the form is a common form. Valid values are</p> <ul style="list-style-type: none"> • Y—The form is a common form. • N—The form is not a common form. <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Database value has been decoded for display.</p>
Is Alternate Form	<p>Data displayed: Y/N</p> <p>Description: Specifies whether the form is an alternate form. Valid values are:</p> <ul style="list-style-type: none"> • Y—The form is an alternate form. • N—The form is not an alternate form. <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Database value has been decoded for display.</p>

Forms: Properties	
Report element	Description
Contains SV Required Items	<p>Data displayed: Y/N</p> <p>Description: Specifies whether the form contains items that require Source Verification. Valid values are:</p> <ul style="list-style-type: none"> • Y—The form contains SV required items. • N—The form does not contain SV required items. <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Database value has been decoded for display.</p>
Contains Required Items	<p>Data displayed: Y/N</p> <p>Description: Specifies whether the form contains items that require data entry for the form to be complete. Valid values are:</p> <ul style="list-style-type: none"> • Y—The form contains required items. • N—The form does not contain required items. <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Database value has been decoded for display.</p>
Form Order	<p>Data displayed: Numeric</p> <p>Description: An ordinal that specifies the position of the form within the visit. For example, 3 indicates that the form is the third form in the visit.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Database value has been decoded for display.</p>
Design Note	<p>Data displayed: String</p> <p>Description: Optional text, specified in trial design code, used by trial designers for documentation purposes only. This note does not appear in the InForm application.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Forms: Properties	
Report element	Description
Form Note	<p>Data displayed: String</p> <p>Description: Optional text, specified in trial design code, that appears on the form.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Forms: Form Counts by Property

Forms: Form Counts by Property report elements return totals of different types of forms. Form counts here are expected form counts.

Note: When used by themselves, these report elements return form totals multiplied by the number of subjects participating in the trial. You can add other report elements to see different totals for specific subjects.

Forms: Form Counts by Property	
Report element	Description
Dynamic Form	<p>Data displayed: Numeric</p> <p>Description: The number of expected dynamic forms.</p> <p>How calculated: A form is counted if it is a dynamic form and has been activated or started. A dynamic form is not counted if it has been removed.</p> <p>Example: A subject (who is pregnant) is participating in a trial that requires the collection of additional information for subjects who are pregnant. A dynamic form is activated for the subject when data entered indicates that she is pregnant.</p> <p>Dynamic form count for this example = 1.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Forms: Form Counts by Property	
Report element	Description
Repeating Form	<p>Data displayed: Numeric</p> <p>Description: The number of started, non-started, and deleted repeating forms contained within the study.</p> <p>How calculated: A repeating form that has not been started is counted once. Each started instance of a repeating form is counted once.</p> <p>Example: Two subjects are participating in a trial with a repeating form that records blood draws at different intervals within the trial. Subject A has had one blood draw; therefore one instance of the repeating form has been started for the subject. Subject B has had two blood draws; therefore two instances of the repeating form have been started for Subject B.</p> <p>Repeating form count for this example =3.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Common Form	<p>Data displayed: Numeric</p> <p>Description: The number of possible common forms across all subjects.</p> <p>How calculated: A common form is counted once, regardless of the number of visits in which the form appears.</p> <p>Example: A trial contains a common form for Adverse Events, which appears in each visit. This form has been completed for a subject in three different visits.</p> <p>Common form count for this example = 1.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Alternate Form	<p>Data displayed: Numeric</p> <p>Description: The number of possible alternate forms across all subjects.</p> <p>How calculated: A form is counted if it is an alternate form and has been started.</p> <p>Example: An alternate form is completed for two subjects enrolled in the study.</p> <p>Alternate form count for this example=2.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Forms: Form Counts by Property	
Report element	Description
Has Required Items	<p>Data displayed: Numeric</p> <p>Description: The number of possible expected forms across all subjects that contain required items.</p> <p>How calculated: A form is counted if it is possible to be expected or started and it contains required items. This calculation includes dynamic and repeating forms with required items, as follows:</p> <ul style="list-style-type: none"> • Dynamic forms—A dynamic form is counted if it contains required items and it is activated or started. Dynamic forms are not counted if they have been removed. • Repeating forms—A repeating form that has not been started is counted once if it contains required items. Each instance of a repeating form that has been started is counted if it contains required items. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Has SV Required Items	<p>Data displayed: Numeric</p> <p>Description: The number of possible expected forms across all subjects that contain SV required items.</p> <p>How calculated: A form is counted if it is possible to be expected or started and it contains SV required items. This calculation includes dynamic and repeating forms with SV required items, as follows:</p> <ul style="list-style-type: none"> • Dynamic forms—A dynamic form is counted if it contains SV required items and is activated or started. Dynamic forms are not counted if they have been removed. • Repeating forms—A repeating form that has not been started is counted once if it contains SV required items. Each instance of a repeating form that has been started is counted if it contains SV required items. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Forms: Form Status Counts

Forms: Form Status Counts report elements return totals of forms according to their status.

Forms: Form Status Counts	
Report element	Description
Form Count	<p>Data displayed: Numeric</p> <p>Description: The total number of forms.</p> <p>How calculated: This calculation includes all forms, including expected forms, forms that have not been started, and unscheduled forms. Use this report element in combination with other predefined filters to narrow report results.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Expected	<p>Data displayed: Numeric</p> <p>Description: The number of expected forms in the study.</p> <p>How calculated: How calculated: A form is counted as expected if it meets any of the following criteria:</p> <ul style="list-style-type: none"> • It appears within a scheduled visit (regardless of whether the form is started). • It appears within a started unscheduled visit. • It is a dynamic form that has been activated. <p>Expected forms are counted only for subjects who have been enrolled in the InForm application (includes enrolled, randomized, completed, and dropped subjects).</p> <p>For subjects that have completed or dropped (as indicated by the Study Completion form), only forms in started visits or dynamic started forms are counted. Non-started common forms are not counted as expected.</p>

Forms: Form Status Counts	
Report element	Description
Expected (cont.)	<ul style="list-style-type: none"> • The expected forms calculation assumes the following: • Only subject visits and common visits are counted. Other special visits (such as screening/enrollment or monitor) are not included. • Alternate forms—An alternate form is counted as expected only if it has been started. • Dynamic forms—Dynamic forms are counted only when activated, unless the form has been deleted (removed). • Repeating forms—For repeating forms that have not been started, one instance of the form is counted as expected. For repeating forms that have been started, each started instance counts as expected. Deleted form instances are not counted as expected. • Common forms—A common form is counted only once, regardless of the number of visits in which it occurs. This count includes common forms that appear in unscheduled visits that have not started. Common forms that have not been started for subjects that have completed or dropped out of the trial are not included in the expected forms count. • Common repeating forms—Each started instance is counted once. If no instances have been started, it is counted once. • Common dynamic forms—Each activated or started instance is counted once. • Dynamic repeating forms—Each activated or started instance is counted once. • Common dynamic repeating forms—Each activated or started instance is counted once. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Started	<p>Data displayed: Numeric</p> <p>Description: Total count of all forms that are started across all subjects, by visit and by site.</p> <p>How calculated: An expected form is considered started if any type of data entry activity (form data, queries, or comments) has started on the form.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p> <p>Tip: To report on forms that are started but incomplete, subtract the complete count (Complete report element) from the started count (Started report element).</p>

Forms: Form Status Counts	
Report element	Description
Missing Required Items	<p>Data displayed: Numeric</p> <p>Description: The number of started forms for which at least one required item is empty.</p> <p>How calculated: A form is counted when all of the following are true:</p> <ul style="list-style-type: none"> • The form is started. • The form contains required items. • At least one required item does not contain data. <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Complete	<p>Data displayed: Numeric</p> <p>Description: Total count of all forms that are complete across all subjects, by visit and by site.</p> <p>How calculated: Counts forms that are expected and meet the following criteria:</p> <ul style="list-style-type: none"> • Are started. • Contain data for all required items. • Do not have open queries associated with any items on the form. • For a repeating form, the form is not in a deleted state. • For an itemset form, the form is complete even if all the instances are deleted. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Frozen	<p>Data displayed: Numeric</p> <p>Description: The number of expected forms that are currently marked frozen.</p> <p>How calculated: A form is counted if it is expected and has been frozen using any of the following InForm features:</p> <ul style="list-style-type: none"> • Freeze CRF • Freeze CRB • Freeze Visit <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Forms: Form Status Counts	
Report element	Description
SV Ready	<p>Data displayed: Numeric</p> <p>Description: The number of forms currently marked SV Ready.</p> <p>How calculated: A form is counted if one of the following is true:</p> <ul style="list-style-type: none"> • The form has been marked SV Ready in the InForm application. • The form is included within a case book that has been marked SV Ready in the InForm application. <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
SV Partial	<p>Data displayed: Numeric</p> <p>Description: The number of forms where source verification is partially complete.</p> <p>How calculated: A form is counted only if some of the SV-required items on the form are source verified and others are not. The InForm application automatically assigns a status of SV partial to any form for which some, but not all, SV-required items have been marked SV complete.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
SV Complete	<p>Data displayed: Numeric</p> <p>Description: The number of SV complete forms.</p> <p>How calculated: A form is counted if it is marked as SV complete, which means that all SV required items on the form have been source verified.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Signed	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of signed forms and the percentage of expected forms that are currently signed in the InForm application.</p> <p>How calculated: Counts forms that have been signed by all groups that are required to sign the form. This value appears as a whole number and as a percentage of expected forms that are signed:</p> $[\text{signed, \% of expected}] = [\text{signed forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Forms: Form Status Counts	
Report element	Description
Locked	<p>Data displayed: Numeric</p> <p>Description: The number of locked forms.</p> <p>How calculated: A form is counted if one of the following conditions is true:</p> <ul style="list-style-type: none"> • It has been locked in the InForm application at the form level or visit level. • It is contained within a casebook that has been locked in the InForm application. <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Marked Incomplete	<p>Data displayed: Numeric</p> <p>Description: The number of forms that have been marked incomplete.</p> <p>How calculated: A form is counted if a form comment exists for the form with an Incomplete Reason of Not Done, Not Applicable, or Unknown.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Has Data	<p>Data displayed: Numeric</p> <p>Description: The number of forms on which some data has been entered.</p> <p>How calculated: A form is counted if data has been entered in at least one item. The item with data does not need to be a required item.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Has Open Query	<p>Data displayed: Numeric</p> <p>Description: The number of forms with open queries.</p> <p>How calculated: A form is counted if it contains items that have open queries. This count does not include forms that contain items with queries in states other than open.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Forms: Form Status Counts	
Report element	Description
Has Answered Query	<p>Data displayed: Numeric</p> <p>Description: The number of forms with answered queries.</p> <p>How calculated: A form is counted if it contains at least one item with an answered query. This count does not include forms with items that have queries in states other than answered, including closed.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Candidate Query	<p>Data displayed: Numeric</p> <p>Description: The number of candidate queries. Use this report element in conjunction with Form Name to see the number of candidate queries associated with a particular form.</p> <p>How calculated: A query is counted if it is currently a candidate query.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Open Query	<p>Data displayed: Numeric</p> <p>Description: The number of open queries. Use this report element in conjunction with Form Name to see the number of open queries associated with a particular form.</p> <p>How calculated: A query is counted if it is currently open. This count includes reissued queries.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Answered Query	<p>Data displayed: Numeric</p> <p>Description: The number of answered queries. Use this report element in conjunction with Form Name to see the number of answered queries associated with a particular form.</p> <p>How calculated: A query is counted if it is currently answered.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Has Form Comment	<p>Data displayed: Numeric</p> <p>Description: The number of forms that contain form-level comments.</p> <p>How calculated: A form is included if it contains at least one form-level comment. This calculation includes forms that have been marked incomplete. This count does not include forms with only item-level comments.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Forms: Form Status Counts	
Report element	Description
Has Item Comment	<p>Data displayed: Numeric</p> <p>Description: The number of forms that contain items with item-level comments.</p> <p>How calculated: A form is counted if it contains at least one item-level comment. This calculation includes items that have been marked incomplete. This calculation does not include forms that include only form-level comments.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Deleted Repeating	<p>Data displayed: Numeric</p> <p>Description: The number of repeating forms that have been deleted.</p> <p>How calculated: A form is counted if it is a repeating form that has been deleted.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Forms: Form Dates

Forms: Form Dates report elements allow you to report on dates associated with form status.

About *First* and *Last* dates

Forms may be set to some states more than once. For these states, *First* and *Last* date report elements appear in the reporting tree. Use these report elements to identify when a form moved from one state to another, as follows:

- Use *Last* dates to determine the current status of a form, and the date on which the status change occurred.
- Use *First* and *Last* dates together to identify forms that had been but are no longer in a given state. You can also use these dates to identify forms that have changed since being set to a given state. For example, you can compare the Data Last Modified Date to the Last SV Complete date to see whether the form was changed since it was marked SV Complete.

Note: If a form has been in a particular state only once, the *First* and *Last* dates for that state display the same date.

If a form has never been assigned a particular status, the *First* and *Last* dates for that state return null values (resulting columns are empty).

Forms: Form Dates	
Report element	Description
Current Status Date	<p>Data displayed: Date/Time</p> <p>Description: The date on which the form was assigned to its current state. For instance, if the current state of a form is started, this element would return the date on which the form was started.</p> <p>Date type: System date (GMT).</p>
Data Last Modified Date	<p>Data displayed: Date/Time</p> <p>Description: The date on which data was last entered or modified on the form.</p> <p>Date type: System date (GMT).</p>
Form's Scheduled Visit Date	<p>Data displayed: Date</p> <p>Description: The date on which the scheduled visit containing the form should occur.</p> <p>Date type: System date (GMT).</p>
Form's Visit Data Entry Date	<p>Data displayed: Date/Time</p> <p>Description: The date on which data was first entered for the visit that contains the form.</p> <p>Date type: System date (GMT).</p>
DOV	<p>Data displayed: Date/Time</p> <p>Description: The date that is recorded in a standard Date of Visit control in the InForm application.</p> <p>Note: This report element assumes that your trial has been developed using a specific design for DOV controls.</p> <p>Date type: Clinical.</p> <p>Note: This report element assumes that your study was developed using a specific design for the DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>For more information, see <i>DOV controls</i> (on page 26).</p>
Started Date	<p>Data displayed: Date/Time</p> <p>Description: The date on which the form was started.</p> <p>Date type: System date (GMT).</p>

Forms: Form Dates	
Report element	Description
Complete Date	<p>Data displayed: Date/Time</p> <p>Description: The date on which the form was completed. Counts forms that are expected and meet the following criteria:</p> <ul style="list-style-type: none"> • Are started. • Contain data for all required items. • Do not have open queries associated with any items on the form. • For a repeating form, the form is not in a deleted state. • For an itemset form, the form is complete even if all the instances are deleted. <p>Date type: System date (GMT).</p>
Deleted Date	<p>Data displayed: Date/Time</p> <p>Description: The date on which the form was deleted.</p> <p>Date type: System date (GMT).</p>
First Frozen Date	<p>Data displayed: Date/Time</p> <p>Description: The date on which the status of the form was first set to frozen. A form is frozen if it has been frozen using any of these InForm features:</p> <ul style="list-style-type: none"> • Freeze CRF • Freeze CRB • Freeze Visit <p>This report element retrieves only those dates for forms frozen at the form or visit level. It does not retrieve a first frozen date for forms that were frozen at the casebook level.</p> <p>Date type: System date (GMT).</p>
Last Frozen Date	<p>Data displayed: Date/Time</p> <p>Description: The most recent date on which the status of the form was set to frozen. This report element retrieves only those dates for forms frozen at the form or visit level. It does not retrieve a last frozen date for forms that were frozen at the casebook level.</p> <p>Date type: System date (GMT).</p>

Forms: Form Dates	
Report element	Description
First SV Ready Date	<p>Data displayed: Date/Time</p> <p>Description: The date on which the status of the form was first considered SV ready. The status of a form is SV ready if one of the following conditions is true:</p> <ul style="list-style-type: none"> • The form was marked SV ready in the InForm application. • A casebook containing the form was marked SV ready in the InForm application. <p>Date type: System date (GMT).</p>
Last SV Ready Date	<p>Data displayed: Date/Time</p> <p>Description: The most recent date on which the status of the form was set to SV ready.</p> <p>Date type: System date (GMT).</p>
First SV Partial Date	<p>Data displayed: Date/Time</p> <p>Description: The date on which the form status was first set to SV partial. The InForm application automatically assigns a status of SV partial to any form for which some, but not all, SV-required items have been marked SV complete.</p> <p>Date type: System date (GMT).</p>
Last SV Partial Date	<p>Data displayed: Date/Time</p> <p>Description: The date on which the form was last considered SV partial.</p> <p>Date type: System date (GMT).</p>
First SV Complete Date	<p>Data displayed: Date/Time</p> <p>Description: The date on which the form was first considered SV complete. The status of a form is SV complete if all SV-required items on the form have been source verified.</p> <p>Date type: System date (GMT).</p>
Last SV Complete Date	<p>Data displayed: Date/Time</p> <p>Description: The most recent date on which the status of the form was considered SV complete.</p> <p>Date type: System date (GMT).</p>
First Signed Date	<p>Data displayed: Date/Time</p> <p>Description: The date on which the form was first signed.</p> <p>Date type: System date (GMT).</p>

Forms: Form Dates	
Report element	Description
Last Signed Date	<p>Data displayed: Date/Time</p> <p>Description: The date on which the form was last signed.</p> <p>Date type: System date (GMT).</p>
First Locked Date	<p>Data displayed: Date/Time</p> <p>Description: The date on which the form was first locked. This report element retrieves only those dates for forms locked at the form or visit level. It does not retrieve a first locked date for forms that were locked at the casebook level.</p> <p>Date type: System date (GMT).</p>
Last Locked Date	<p>Data displayed: Date/Time</p> <p>Description: The date on which the form was last locked. This report element retrieves only those dates for forms locked at the form or visit level. It does not retrieve a last locked date for forms that were locked at the casebook level.</p> <p>Date type: System date (GMT).</p>

Forms: Form Status by Month and Year

Forms: Form Status by Month and Year report elements let you create reports on form status by month. Use these report elements with form status counts to see the number of forms that were set to a particular status each month.

If the report is sorted by one of the Month/Year report elements, the resulting report displays each month, and you can add the Form Count element to see how many forms were assigned a particular status in each month.

Forms: Form Status by Month and Year	
Report element	Description
Started Month, Year	<p>Data displayed: Date</p> <p>Description: Each month/year combination within a specific range. Use this column with Form Count to see how many forms were started each month.</p> <p>Date type: System date (GMT), derived for display.</p>
Completed Month, Year	<p>Data displayed: Date/Time</p> <p>Description: Each month/year combination within a specific range. Use this report element with Form Count to see how many forms have been completed each month.</p> <p>Date type: System date (GMT), derived for display.</p>

Forms: Form Status by Month and Year	
Report element	Description
Frozen Month, Year	<p>Data displayed: Date/Time</p> <p>Description: Each month/year combination within a specific range. Use this report element with Form Count to see how many forms were frozen each month.</p> <p>Date type: System date (GMT), derived for display.</p>
SV Complete Month, Year	<p>Data displayed: Date/Time</p> <p>Description: Each month/year combination within a specific range. Use this report element with Form Count to see how many forms were source verified each month.</p> <p>Date type: System date (GMT), derived for display.</p>
Signed Month, Year	<p>Data displayed: Date/Time</p> <p>Description: Each month/year combination within a specific range. Use this report element with Form Count to see how many forms were signed each month.</p> <p>Date type: System date (GMT), derived for display.</p>
Locked Month, Year	<p>Data displayed: Date/Time</p> <p>Description: Each month/year combination within a specific range. Use this report element with Form count to see how many forms were locked each month.</p> <p>Date type: System date (GMT), derived for display.</p>

Forms: Aging

Forms: Aging report elements allow you to report on how long forms have been in an incomplete state.

Forms: Aging	
Report element	Description
Days Incomplete from DOV	<p>Data displayed: Numeric</p> <p>Description: The number of days the status of an incomplete form has been incomplete, beginning with the recorded date of visit.</p> <p>How calculated: This calculation begins on the recorded date of visit on the form and ends on the most recent date that the status of the form was set to incomplete.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Forms: Aging	
Report element	Description
Days Incomplete from Started	<p>Data displayed: Numeric</p> <p>Description: The number of days the status of an incomplete form has been incomplete, beginning with the date on which the form was started.</p> <p>How calculated: This calculation begins on the date the form was started and ends on the most recent date that the status of the form was set to incomplete.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

For more information, see *DOV controls* (on page 26).

Forms: Cycle Times

Forms: Cycle times report elements let you report on the amount of time it takes for forms to move from one state to another. These elements may return a specific value or an average, depending on other elements used in your report.

Forms: Cycle Times	
Report element	Description
DOV to Form Started	<p>Data displayed: Numeric</p> <p>Description: The number of days from the recorded date of visit to when the form was started in the InForm application.</p> <p>Note: This report element assumes that your trial has been developed using a specific design for DOV controls.</p> <p>How calculated: This calculation begins on the recorded date of visit for the form and ends on the date the status of the form was set to started.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Forms: Cycle Times	
Report element	Description
Started to Complete	<p>Data displayed: Numeric</p> <p>Description: The number of days from when the form was started to when it was completed.</p> <p>How calculated: This calculation begins on the date the status of the form was set to started and ends on the most recent date the status of the form was set to completed. Counts forms that are expected and meet the following criteria:</p> <ul style="list-style-type: none"> • Are started. • Contain data for all required items. • Do not have open queries associated with any items on the form. • For a repeating form, the form is not in a deleted state. • For an itemset form, the form is complete even if all the instances are deleted. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Complete to Frozen	<p>Data displayed: Numeric</p> <p>Description: The number of days from when a form was completed to when it was frozen.</p> <p>How calculated: This calculation begins on the first date the status of the form was set to complete and ends on the most recent date that the status of the form was set to frozen.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Complete to SV Ready	<p>Data displayed: Numeric</p> <p>Description: The number of days from when a form was completed to when it became SV ready in the InForm application.</p> <p>How calculated: This calculation begins on the first date the status of the form was set to complete and ends on the most recent date the status of the form was set to SV ready.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Forms: Cycle Times	
Report element	Description
Complete to SV Complete	<p>Data displayed: Numeric</p> <p>Description: The number of days from when a form was completed to when it became SV complete in the InForm application.</p> <p>How calculated: This calculation begins on the first date the status of a form is set to completed and ends on the most recent date the status of the form was set to SV complete.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Complete to Signed	<p>Data displayed: Numeric</p> <p>Description: The number of days from when a form was completed to when it was signed.</p> <p>How calculated: This calculation begins on the first date the status of the form was set to complete and ends on the most recent date the status of the form was set to signed.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Signed to SV Complete	<p>Data displayed: Numeric</p> <p>Description: The number of days from when a form was signed to when it became SV complete in the InForm application.</p> <p>How calculated: This calculation begins on the first date the status of the form was set to signed and ends on the most recent date the status of the form was set to SV complete.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
SV Ready to SV Complete	<p>Data displayed: Numeric</p> <p>Description: The number of days from when a form became SV ready to when it became SV complete in the InForm application.</p> <p>How calculated: This calculation begins on the first date the status of the form was SV ready and ends on the most recent date the status of the form was set to SV complete.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Forms: Cycle Times	
Report element	Description
Frozen to SV Complete	<p>Data displayed: Numeric</p> <p>Description: The number of days from when a form was frozen to when it became SV complete in the InForm application.</p> <p>How calculated: This calculation begins on the first date the status of the form was frozen and ends on the most recent date the status of the form was set to SV complete.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
SV Complete to Signed	<p>Data displayed: Numeric</p> <p>Description: The number of days from when a form became SV complete to when it was signed in the InForm application.</p> <p>How calculated: This calculation begins on the first date the status of the form was set to SV complete and ends on the most recent date the form was signed.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Signed to Locked	<p>Data displayed: Numeric</p> <p>Description: The number of days from when a form was signed to when it was locked.</p> <p>How calculated: This calculation begins on the first date the status of the form was set to signed and ends on the most recent date the status of the form was set to locked.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Complete to Locked	<p>Data displayed: Numeric</p> <p>Description: The number of days from when a form was completed to when it was locked.</p> <p>How calculated: This calculation begins on the first date the form became complete and ends on the most recent date that the status of the form was set to locked.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Sections report elements

Forms in your trial may be designed in sections. Section report elements let you report on these form sections in trial design.

Sections

Section report elements let you report on sections of forms in your trial.

Sections	
Report element	Description
Section Title	<p>Data displayed: String</p> <p>Description: The title of a section in a form as entered in the trial design code.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Items report elements

The Items report topic contains elements and measures that provide metrics and status information about items on forms that comprise the study. Use this report topic to include counts of different form types, information about form properties, and information on when items were initially created and changed.

About *First* and *Last* dates

Items may be set to some states more than once. For these states, *First* and *Last* date report elements appear in the reporting tree. Use these report elements to identify when an item moved from one state to another, as follows:

- Use *Last* dates to determine the current status for an item and the date on which the status change occurred.
- Use *First* and *Last* dates together to identify items that had been (but are no longer) in a given state. You can also use these dates to identify items that have changed since being set to a given state. For example, you can compare the Last Modified Date to the Last SV date to see whether the form was changed since it was last source verified.

Note: If an item has been in a particular state only once, the *First* and *Last* dates for that state display the same date.

If an item has never been assigned a particular status, the *First* and *Last* dates for that state return null values (resulting columns are empty.)

Items

Items report elements return metrics on the items in your trial.

Items	
Report element	Description
Item Name	<p>Data displayed: String</p> <p>Description: The itemset header text, specified in the trial design. Access to this data can be restricted in the InForm application. When users who have no access to this data run a report with this report element, the resulting report displays a series of asterisks (*****) rather than the actual itemset header text.</p> <p>InForm items that have never had data will not appear on reports that pair Item Name with Form Mnemonic or Form Name.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Item Question	<p>Data displayed: String</p> <p>Description: Text of the question or prompt that instructs the user to enter specific clinical data. Access to this data can be restricted in the InForm application. When users who have no access to this data run a report with this report element, the resulting report displays a series of asterisks (*****) rather than the actual item question.</p> <p>Items that have never contained data will not appear on reports that pair Item Question with Form Name or Form Mnemonic.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Reason for Change	<p>Data displayed: String</p> <p>Description: Text that explains the reason for the most recent clinical data change (if any) for the item. Text appears here only when the clinical data for the item has been changed since initial entry.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Incomplete Reason	<p>Data displayed: String</p> <p>Description: Text that explains why the item was marked incomplete. Text appears here only when the item has been marked incomplete. Use this report element with Subject Number to see incomplete reason text broken out by subject.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Items	
Report element	Description
Status Change User	<p>Data displayed: String</p> <p>Description: The user name of the InForm user who made the most recent change to the status of the item. A change to the SV status of the item is considered a status change for the item.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Data Change User	<p>Data displayed: String</p> <p>Description: The username of the InForm user who made the most recent change to clinical data for the item.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Items: Item Properties

Items: Item Properties report elements let you report on types of items.

Items: Item Properties	
Report element	Description
Is Required	<p>Data displayed: Y/N</p> <p>Description: Indicates whether the item requires a value for the form to be considered data entry complete. Valid values are:</p> <ul style="list-style-type: none"> • Y—The item is required. • N—The item is not required. <p>Note: Add Entry items cannot be required.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Database value has been decoded for display.</p>
Is SV Required	<p>Data displayed: Y/N</p> <p>Description: Indicates whether the item requires source verification.</p> <ul style="list-style-type: none"> • Y—The item requires InForm source verification. • N—The item does not require source verification. <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Database value has been decoded for display.</p>

Items: Item Counts by Property

Items: Item Counts by Property report elements let you report item totals based on their design characteristics.

Note: All item counts include only items that have at one time contained clinical data. These counts do not include items for which clinical data has never been entered.

Items: Item Counts by Property	
Report element	Description
Required	<p>Data displayed: Numeric</p> <p>Description: Indicates whether the item is required.</p> <ul style="list-style-type: none"> Y—A value must be entered for the item. N—Data entry is not required for the item. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
SV Required	<p>Data displayed: Numeric</p> <p>Description: The total number of items that require source verification and have ever contained clinical data.</p> <p>How calculated: An item is counted if both of these conditions are true:</p> <ul style="list-style-type: none"> The item is SV-required. The item contains (or has ever contained) clinical data. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Calculated	<p>Data displayed: Numeric</p> <p>Description: The total number of calculated items, as defined in the trial design.</p> <p>How calculated: An item is counted if:</p> <ul style="list-style-type: none"> The property for the item is set as a calculated control. The item has ever contained clinical data. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Items: Item Status Counts

Items: Item Status Counts return totals of items (relative to the number of subjects) in various states.

Items: Item Status Counts	
Report element	Description
Item Count	<p>Data displayed: Numeric</p> <p>Description: The total number of items, relative to the subjects participating in the study.</p> <p>How calculated: Each item is counted for each subject if it contains (or ever has contained) clinical data.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Empty	<p>Data displayed: Numeric</p> <p>Description: The total number of items that currently have no data.</p> <p>How calculated: An item is counted for each subject if both of these conditions are true:</p> <ul style="list-style-type: none"> • The item currently contains no clinical data. • The item contained clinical data at one time. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Source Verified	<p>Data displayed: Numeric</p> <p>Description: The total number of items with a current status of source verified.</p> <p>How calculated: An item is counted if its current status is source verified.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Marked Incomplete	<p>Data displayed: Numeric</p> <p>Description: The total number of items that are currently marked incomplete.</p> <p>How calculated: This calculation includes items with comments that have an Incomplete Reason of Not Done, Not Applicable, or Unknown.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Items: Item Status Counts	
Report element	Description
Deleted	<p>Data displayed: Numeric</p> <p>Description: The total number of items that have been deleted in the InForm application.</p> <p>How calculated: An item is counted if it is an add-entry item and has been removed.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Has Item Comment	<p>Data displayed: Numeric</p> <p>Description: The total number of items that have had an item-level comment associated with them.</p> <p>How calculated: This calculation includes:</p> <ul style="list-style-type: none"> • Items with item-level comments (item-level comments are manually entered by user). • Items that are marked not done (item-level comments are autogenerated). <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Has Query	<p>Data displayed: Numeric</p> <p>Description: The total number of items that have at least one open query associated with them.</p> <p>How calculated: An item is counted if it has at least one open query associated with it. An item is not counted if the only query associated with it is a candidate query.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Items: Item Dates

Items: Item Dates report elements let you report on when items were completed and modified.

Items: Item Dates	
Report element	Description
Original Value Date	<p>Data displayed: Date</p> <p>Description: The date on which data was originally entered into the item.</p> <p>Date type: System date (GMT).</p>

Items: Item Dates	
Report element	Description
Last Modified Date	<p>Data displayed: Date</p> <p>Description: The date on which data was most recently entered into the item.</p> <p>Date type: System date (GMT).</p>
First SV Date	<p>Data displayed: Date</p> <p>Description: The date on which the item was first source verified.</p> <p>Date type: System date (GMT).</p>
Last SV Date	<p>Data displayed: Date</p> <p>Description: The most recent date on which the item was source verified.</p> <p>Date type: System date (GMT).</p>

Rules report elements

Rule report elements and measures allow you to create reports using information about rules attached to the study. Use this report topic to include information about rule types and the number of times rules have been triggered.

Rules

Rules report elements return information on rules in your trial.

Rules	
Report element	Description
Rule Item RefName	<p>Data displayed: String</p> <p>Description: The name that uniquely identifies the item to which the rule is attached in the study design code. This corresponds to Short Question in the Central Designer application or Itemset Column Header in the InForm application. Access to this data can be restricted in the InForm application. When users who do not have access to this data run a report with this report element, the resulting report displays a series of asterisks (*****) rather than the actual text.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Rules	
Report element	Description
Rule RefName	<p>Data displayed: String</p> <p>Description: The name that uniquely identifies the rule in the trial design code.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Rule Description	<p>Data displayed: String</p> <p>Description: Description of the rule.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Rule Type	<p>Data displayed: String</p> <p>Description: The type of rule. Valid values are:</p> <ul style="list-style-type: none"> • Server Rule— Executes on the server. • Browser Rule— Executes on the browser. Two browser-side rule activities are supported in the InForm application: <ul style="list-style-type: none"> ▪ Checks for text entries in a numeric field or numeric entries in an alphabetic field. ▪ Smart controls, which provide automatic selection of radio buttons and check boxes when a user enters or selects a value in an associated text control or list. • Server Calc Rule—Provides the result for a calculated control whose value is based on the value of one or more other items. • Server conversion— Converts units from one standard to a different standard. • Server Rand Rule—Determines the randomized drug kit number to assign in a calculated control. • Clintrialderivation—Used in a Clintrial study to provide the result for a derived data item whose value is based on the value of one or more other items in the Clintrial database. • Clintrialrule—Used in a Clintrial study. <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Queries report elements

Query report elements allow you to include information about the queries that have been issued against clinical data. Use these report elements to see query text and type, to gather counts on manual and automatic queries, and to see query status.

Queries

Query report items return identifying information about queries and status.

Queries	
Report element	Description
Query Text	<p>Data displayed: String</p> <p>Description: The reason selected or text entered when a query was issued against an item.</p> <p>If the query state is open, answered, or closed, this element returns the text associated with the last time the query was opened. If the query is a candidate query, this element returns the text associated with the last candidate query.</p> <p>For automatic queries, query text is defined in the rule that triggers the query. Therefore, query text for automatic queries will be consistent. For manual queries, the query text reflects what an InForm user entered when issuing the query. Therefore, query text for manual queries will vary.</p> <p>Access to item questions can be restricted in the InForm application. If you do not have access to the item against which the query was issued, this report element returns a series of asterisks (*****) rather than the query text.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Query Response	<p>Data displayed: String</p> <p>Description: The text of the most recent response to the query. This text is entered when the query is answered. If the query is reopened after it is answered, the resulting column is blank in the report.</p> <p>Access to item questions can be restricted in the InForm application. If you do not have access to the item in the InForm application, this query element returns a series of asterisks (*****) rather than the query response.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Queries	
Report element	Description
Query Closure Text	<p>Data displayed: String</p> <p>Description: The text entered when the query was closed. Access to item questions can be restricted in the InForm application. If you have no access to the item against which the query was issued, this report element returns a series of asterisks (*****) rather than the query closure text.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Query Status	<p>Data displayed: String</p> <p>Description: The current status of the query. Valid values are:</p> <ul style="list-style-type: none">• Open• Answered• Closed• Candidate• Deleted <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Database value has been decoded for display.</p>
Originating User	<p>Data displayed: String</p> <p>Description: The username of the user who first entered the query. If the query has been reissued, this report element returns the username of the user who reissued the query.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Queries: Properties

Queries: Properties report elements let you report on different types of queries.

Queries: Properties	
Report element	Description
Query Type	<p>Data displayed: String</p> <p>Description: The type of query. Valid values are:</p> <ul style="list-style-type: none"> • Automatic—A query generated automatically in the InForm application. Automatic queries are triggered by rules in the trial design that check the data as it is entered. If the rule detects a discrepancy in the data, the InForm application issues an automatic query. • Manual—A query entered by an InForm user. • Conflict—A query generated automatically when different copies of the same trial are synchronized. Conflict queries flag discrepancies that can occur when users are working on two different copies of a trial. This query type exists only when the InForm application is used with CIS and/or InForm Unplugged. <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Database value has been decoded for display.</p>
Is Automatic	<p>Data displayed: Y/N</p> <p>Description: Indicates whether the query was automatically generated by the InForm application. Valid values are:</p> <ul style="list-style-type: none"> • Y—The query is automatic. • N—The query is either a manual or conflict query. <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Database value has been decoded for display.</p>
Is Manual	<p>Data displayed: Y/N</p> <p>Description: Indicates whether the query was entered manually by an InForm user. Valid values are:</p> <ul style="list-style-type: none"> • Y—The query is manual. • N—The query is either an automatic or a conflict query. <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Database value has been decoded for display.</p>

Queries: Query Counts

Queries: Query Counts report elements return totals of different types of queries.

Queries: Query Counts	
Report element	Description
Query Count	<p>Data displayed: Numeric</p> <p>Description: The number of unique queries, regardless of status or type.</p> <p>How calculated: All queries that have ever been triggered are counted, regardless of status and type.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Automatic	<p>Data displayed: Numeric</p> <p>Description: The number of queries automatically generated by the InForm application.</p> <p>How calculated: All automatic queries that have ever been triggered are counted, regardless of status. An automatic query is a query generated automatically in the InForm application. Automatic queries are triggered by rules in the trial design that check the data as it is entered. If the rule detects a discrepancy in the data, the InForm application issues an automatic query.</p> <p>This calculation does not include manual or conflict queries.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Manual	<p>Data displayed: Numeric</p> <p>Description: The number of queries entered manually by InForm users.</p> <p>How calculated: All manual queries that have ever been triggered are counted, regardless of status. A query entered by an InForm user. This calculation does not include automatic or conflict queries.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Queries: Query Counts	
Report element	Description
Conflict	<p>Data displayed: Numeric</p> <p>Description: The number of conflict queries that have ever been triggered.</p> <p>How calculated: All conflict queries that have ever been triggered are counted, regardless of status. A conflict query is a query generated automatically when different copies of the same trial are synchronized. Conflict queries flag discrepancies that can occur when users are working on two different copies of a trial. Conflict queries exist only when the InForm application is used with the CIS and/or InForm Unplugged application.</p> <p>This calculation does not include automatic or manual queries.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Candidate	<p>Data displayed: Numeric</p> <p>Description: The number of queries with a current status of candidate.</p> <p>How calculated: All queries with a current status of candidate are counted, regardless of query type.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Open	<p>Data displayed: Numeric</p> <p>Description: The number of queries with a current state of open.</p> <p>How calculated: All queries with a current status of open are counted, regardless of query type. Note that this total includes queries that have been reissued and are currently open.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p> <p>Tip: To see the total number of newly opened queries, create a calculation that subtracts the number of reissued queries from the number of open queries.</p>
Reissued	<p>Data displayed: Numeric</p> <p>Description: The number of currently open queries that were reissued.</p> <p>How calculated: All reissued queries that are currently open are counted. A query is reissued if it has been answered and then re-opened.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Queries: Query Counts	
Report element	Description
Answered	<p>Data displayed: Numeric</p> <p>Description: The number of queries with a current status of answered.</p> <p>How calculated: All queries with a current status of answered are counted, regardless of query type.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Deleted	<p>Data displayed: Numeric</p> <p>Description: The number of queries with a current status of deleted.</p> <p>How calculated: All queries with a current status of deleted are counted, regardless of query type.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Closed	<p>Data displayed: Numeric</p> <p>Description: The number of queries with a current status of closed.</p> <p>How calculated: All queries with a current status of closed are counted, regardless of query type.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Status Changes	<p>Data displayed: Numeric</p> <p>Description: The number of state changes for a query.</p> <p>How calculated: Each status change for each triggered query is counted. This count includes the initial entry of the query.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Queries: Query Dates

Query Dates report elements let you report query activity by date. You can also use this information to calculate how long queries have been in a particular state.

Queries: Query Dates	
Report element	Description
Query Status Date	<p>Data displayed: Date</p> <p>Description: The date a query was assigned its current status in the InForm application.</p> <p>Date type: System date (GMT).</p>

Queries: Query Dates	
Report element	Description
First Candidate Date	<p>Data displayed: Date</p> <p>Description: The date the query was first issued a candidate status.</p> <p>Date type: System date (GMT).</p>
Last Candidate Date	<p>Data displayed: Date</p> <p>Description: The date the query was last issued a candidate status.</p> <p>Date type: System date (GMT).</p>
Opened Date	<p>Data displayed: Date</p> <p>Description: The date a query was first opened in the InForm application.</p> <p>Date type: System date (GMT).</p>
First Reissued Date	<p>Data displayed: Date</p> <p>Description: The date a query was first reissued in InForm application.</p> <p>Date type: System date (GMT).</p>
Last Reissued Date	<p>Data displayed: Date</p> <p>Description: The date a query was last reissued.</p> <p>Date type: System date (GMT).</p>
First Answered Date	<p>Data displayed: Date</p> <p>Description: The date a query was first answered.</p> <p>Date type: System date (GMT).</p>
Last Answered Date	<p>Data displayed: Date</p> <p>Description: The date a query was last answered.</p> <p>Date type: System date (GMT).</p>
Closed Date	<p>Data displayed: Date</p> <p>Description: The date a query was closed.</p> <p>Date type: System date (GMT).</p>

Queries: Query Status by Month, Year

Queries: Query Status by Month, Year report elements let you create reports on query status by month. Use this report element with query counts to see the number of queries that were set to a particular status each month.

If the report is sorted by one of the Month/Year report elements, the resulting report displays each month within a specified ranged. You can then add the Query Count element to see how many Queries were assigned a particular status in each month.

Queries: Query Status by Month, Year	
Report element	Description
Query Status, Month, Year	<p>Data displayed: Date/Time</p> <p>Description: Each month/year combination that has occurred within a specified range. Use this report element with Query Count to see how many queries were opened each month.</p> <p>Date type: System date (GMT), derived for display.</p>
Opened Month, Year	<p>Data displayed: Date/Time</p> <p>Description: Each month/year combination that has occurred within a specified range. Use this report element with Query Count to see how many queries were opened each month.</p> <p>Date type: System date (GMT), derived for display.</p>
Answered Month, Year	<p>Data displayed: Date/Time</p> <p>Description: Each month/year combination that has occurred within a specified range. Use this report element with Query Count to see how many queries were answered each month.</p> <p>Date type: System date (GMT), derived for display.</p>
Closed Month, Year	<p>Data displayed: Date/Time</p> <p>Description: Each month/year combination that has occurred within a specified range. Use this report element with Query Count to see how many queries were closed each month.</p> <p>Date type: System date (GMT), derived for display.</p>

Queries: Cycle Times

Queries: Query Cycle Times report elements let you report on how long it takes for queries to move from one state to another.

Queries: Cycle Times	
Report element	Description
Days Opened to Answered	<p>Data displayed: Numeric</p> <p>Description: The number of days from when a query was first opened to the last time it was answered.</p> <p>How calculated: This calculation begins on the first date the status of a query was set to opened and ends on the most recent date the status of the query was set to answered. The value returned is either an exact count or an average, depending on other elements in your report. This value encompasses any re-issued and answer cycles that occurred from first open to last answered.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Days Opened to Closed	<p>Data displayed: Numeric</p> <p>Description: The number of days from when a query was first opened to last time it was closed.</p> <p>How calculated: This calculation starts on the first date the status of the query was set to open and ends on the most recent date the status of the query was set to closed. The value returned is either an exact count or an average, depending on other elements in your report.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Days Answered to Closed	<p>Data displayed: Numeric</p> <p>Description: The number of days from when a query was last answered to the last time it was closed.</p> <p>How calculated: This calculation begins on the first date the status of a query was set to answered and ends on the last date the status of the query was set to closed. The value returned is either an exact count or an average, depending on other elements in your report.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Queries: Aging

Queries: Aging report elements let you report the length of time that queries have been in particular states.

Queries: Aging	
Report element	Description
Days Candidate	<p>Data displayed: Numeric</p> <p>Description: The number of days a candidate query has been in the candidate state.</p> <p>How calculated: This calculation applies to only those queries that currently have a status of candidate. The value returned is either an exact count or an average, depending on other elements in the report.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Days Open	<p>Data displayed: Numeric</p> <p>Description: The number of days an open query has been in the open state.</p> <p>How calculated: This calculation applies only to queries with a current status of open. This value includes reissued queries. The value returned is either an exact count or an average, depending on other elements in your report.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Days Answered	<p>Data displayed: Numeric</p> <p>Description: The number of days an answered query has been in the answered state.</p> <p>How calculated: This report element returns values only for those queries currently in the answered state. The value returned is either an exact count or an average, depending on other elements in your report.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Comments report elements

Comment report elements allow you to report on comments entered in the course of the study. You can report on both item-level and form-level comments.

Comments

Comments: Comments report elements allow you to report on form-level and item-level comments recorded in your trial.

Comments	
Report element	Description
Comment Date	<p>Date type: Date</p> <p>Description: The date the comment was entered in the InForm application.</p> <p>Date type: Entered in the InForm application.</p>
Comment Text	<p>Date type: String</p> <p>Description: The text entered for the comment. Display of the comment text is limited to 255 characters.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Comment Type	<p>Date type: Text</p> <p>Description: The type of comment. Valid values are:</p> <ul style="list-style-type: none"> • Form—The comment is a form-level comment. • Item—The comment is an item-level comment. <p>Data source: Derived for the report; not stored in the Reporting and Analysis database. Database value decoded for display.</p>
Comment Count	<p>Date type: Numeric</p> <p>Description: The number of comments.</p> <p>How calculated: All item-level and form-level comments are counted.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Comments	
Report element	Description
Item Count	<p>Date type: Numeric</p> <p>Description: The number of item-level comments only. Item comments can be entered by an InForm user or automatically generated when an item is marked incomplete.</p> <p>How calculated: A comment is counted if it is an item-level comment only. Form-level comments are not counted.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Form Comment Count	<p>Date type: Numeric</p> <p>Description: The number of form-level comments only.</p> <p>How calculated: A comment is counted if it is a form-level comment only. Item-level comments are not counted.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

User Info report elements

User Info report elements allow you to gather information on your InForm users. Many of these elements are optional in your trial design; report elements may return blank values.

User Info: Users

User Info: Users report elements let you report on InForm users.

User Info: Users	
Report element	Description
User Name	<p>Data displayed: String</p> <p>Description: Username of the user.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
First Name	<p>Data displayed: String</p> <p>Description: First name of the user.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

User Info: Users	
Report element	Description
Last Name	<p>Data displayed: String</p> <p>Description: Last name of the user.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Title	<p>Data displayed: String</p> <p>Description: The job title of the InForm user.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Description	<p>Data displayed: String</p> <p>Description: Text that describes details of the InForm user. If no description has been entered for the user, the resulting data column is blank.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Rights Group	<p>Data displayed: String</p> <p>Description: Rights group to which the user belongs.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Email	<p>Data displayed: String</p> <p>Description: The email address of the InForm user.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Phone	<p>Data displayed: String</p> <p>Description: The phone number of the InForm user.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
User Count	<p>Data displayed: Numeric</p> <p>Description: The number of InForm users.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

User Info: Users	
Report element	Description
User Type	<p>Data displayed: String</p> <p>Description: User type. Valid values are:</p> <ul style="list-style-type: none"> • Site • Sponsor • System <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Database value has been decoded for display.</p>
Creation Date	<p>Data displayed: Date/Time</p> <p>Description: The date the user record was created in the InForm application.</p> <p>Date type: System date (GMT).</p>
Activation Date	<p>Data displayed: Date/Time</p> <p>Description: The date the user was activated in the InForm application.</p> <p>Date type: System date (GMT).</p>
User Status	<p>Data displayed: String</p> <p>Description: The current status of the InForm user. Valid values are:</p> <ul style="list-style-type: none"> • Active • Inactive • Terminated <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
User Status Date	<p>Data displayed: String</p> <p>Description: The date when the current status was assigned to the InForm user.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

User Info: Group Associations

Group Associations report elements let you report on the InForm groups with which users are associated.

User Info: Group associations	
Report element	Description
Group Name	<p>Data displayed: String</p> <p>Description: The InForm rights group to which the user belongs.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Group Type	<p>Data displayed: String</p> <p>Description: The type of the group with which the InForm user is associated. Valid values are:</p> <ul style="list-style-type: none">• Rights• Query• Signature• Reporting• Reportlist• Site• Manage User <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

User Info: Historical User Info

Historical User Info report elements allow you to see status information and group membership changes for users.

Note: To include the current first name, last name, and rights group for a user, use report elements from the User Info: Users folder.

There is also a standard report that shows the login history within a selected date range.

For more information, see *Historical Login Report* (on page 351).

User Info: Historical User Info	
Report element	Description
User ID	<p>Data displayed: String</p> <p>Description: User ID of the user whose audit information is displayed in the report.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Change Type	<p>Data displayed: String</p> <p>Description: Displays the following text, describing the type of change the user has undergone:</p> <ul style="list-style-type: none">▪ Group Change—The user has been added or removed from a group.▪ Status Change—The user has been activated, deactivated, terminated, or reinstated. <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

User Info: Historical User Info	
Report element	Description
Change Type Description	<p>Data displayed: String</p> <p>Description: Additional information about the type of change the user has undergone.</p> <ul style="list-style-type: none"> ▪ If the change type is Group Change: <ul style="list-style-type: none"> ▪ Addition ▪ Deletion ▪ If the change type is Status Change: <ul style="list-style-type: none"> ▪ Created ▪ Activated ▪ Deactivated ▪ Terminated ▪ Reinstated <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Change Date	<p>Data displayed: Date/Time</p> <p>Description: Date and time when the user status or group membership change took place.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Change Username	<p>Data displayed: String</p> <p>Description: Username of the user who updated the status or group membership information for the user whose status or group membership changed.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Reason for Change	<p>Data displayed: String</p> <p>Description: The reason for the user status or group membership change, as generated by the InForm application.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

User Info: Historical User Info	
Report element	Description
Change Group Name	<p>Data displayed: String</p> <p>Description: For users whose group membership information changed, the group name to which the user was added or from which the user was removed.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p> <p>Note: This column is blank if the user group membership information did not change.</p>
Change Group Type	<p>Data displayed: String</p> <p>Description: For users whose group membership information changed, the group type of the group to which the user was added or from which the user was removed.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p> <p>Note: This column is blank if the user group membership information did not change.</p>

Predefined Filters

Use predefined filters to narrow results in your ad hoc reports. These filters are shipped with the InForm application and can be used in all reports.

Note: You can also create filters to be used within reports. Each user-created filter is saved with the report in which it was created and can be used only with that report and cannot be used globally across multiple reports.

Filters

Predefined filters let you limit your report to specific subjects, visits, and forms.

Predefined Filters	
Filter	Description
All Enrolled Subjects	<p>Limits the report to subjects who have been enrolled in the study. The resulting report includes all active subjects who were ever enrolled in any of these states:</p> <ul style="list-style-type: none"> • Enrolled • Enroll Override • Randomized • Dropped Out • Complete
All Enrolled Subjects except Dropped	<p>Limits the report to subjects who were ever enrolled in the study, excluding those subjects who dropped out. The resulting report includes data about subjects in any of these states:</p> <ul style="list-style-type: none"> • Enrolled • Enroll Override • Randomized • Complete
Active Subjects	<p>Limits the report to active subjects; that is, all subjects who have been enrolled in the study, excluding those who have dropped out or completed the study. The resulting report includes data about subjects in any of these states:</p> <ul style="list-style-type: none"> • Enrolled • Enroll Override • Randomized
Clinical Visit	<p>Limits the report to data about only clinical, or subject visits. Use this filter when you want your report to include information only about clinical visits. This filter excludes data for these visit types:</p> <ul style="list-style-type: none"> • Screening • Enrollment • Reg Docs • Visit Report

Predefined Filters	
Filter	Description
Clinical Form	<p>Limits the report to information on clinical forms (forms whose type is CRF). This filter excludes these types of forms:</p> <ul style="list-style-type: none"> • Enrollment • Monitor RegDoc • Monitor Visit Report
Expected Forms: Scheduled Visits	Limits the report to those clinical forms that are expected because they appear in scheduled visits.
Expected Forms: Scheduled or Started Visits	Limits the report to expected forms that are expected because they appear in scheduled or started visits.
Expected Forms: Scheduled or Started Visits to Date	Limits the report to forms that are expected because they appear in visits that are scheduled to occur or have started by a particular date. (This filter prompts the report user to enter a date.)
Expected Forms: Scheduled Visits or Started Forms to Date	Limits the report to forms that have started by a given date or are expected because they appear in visits that are scheduled to occur by a given date. (This filter prompts the report user to enter a date.)
Data Complete (Queries Allowed)	Limits the report to forms that are data complete; that is, forms for which all required items have been completed. Note that this filter does not exclude forms that have queries (in any state) associated with them.
Data Complete, No Open Queries	Limits the report to data for forms that are data complete; that is, forms for which all required items have been completed. This filter excludes forms that have open queries and candidate queries associated with them. Note that this is comparable to a green traffic light in the InForm application.
Data Clean: Complete and SV	<p>Limits the report to forms that are data complete and clean. This filter includes forms for which:</p> <ul style="list-style-type: none"> • All required items have been completed. • All SV Required items have been source verified using the InForm application. <p>The filter excludes forms with open and answered queries associated with them.</p>

Reporting on clinical data

Clinical data reports

Use the Ad Hoc Reporting workspace to create reports that contain:

- **Trial management data**

The trial management portion of the Ad Hoc Reporting tree allows you to create reports on the progress of your trial.

- **Clinical data**

The clinical portion of the Ad Hoc Reporting tree allows you to create reports that display values entered into the clinical forms of your trial.

Reporting on clinical data

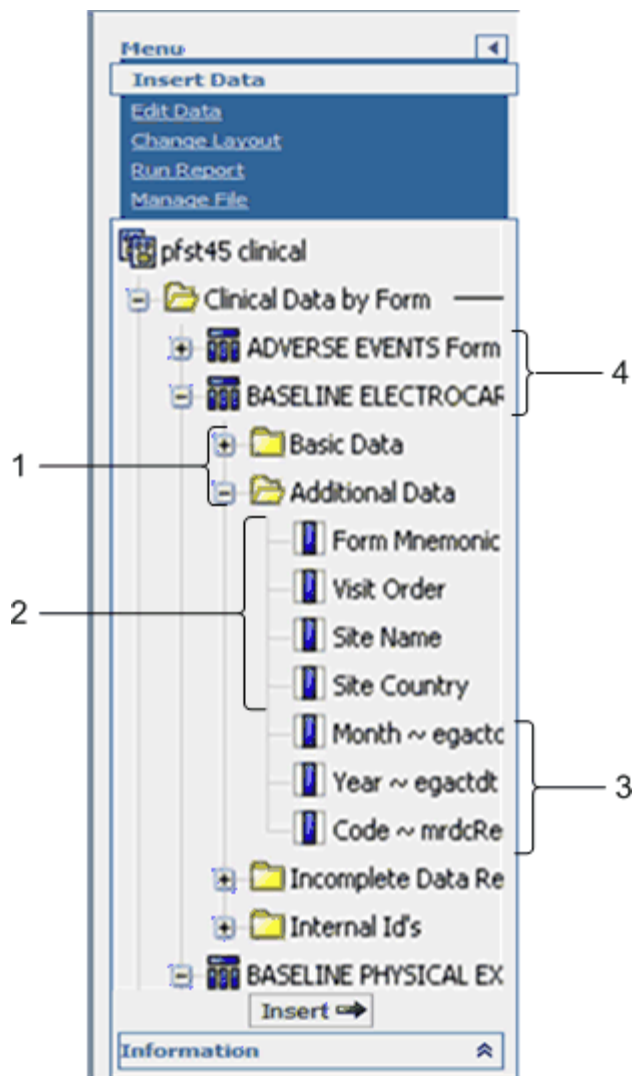
When you create reports using clinical data, keep in mind:

- Clinical data availability and organization are unique to each trial; for this reason, reports that contain clinical data may not be validated to use across trials.
- Data that is entered on clinical forms can be changed several times during the course of a trial. Although the InForm application captures audit trail data and stores it in the Reporting and Analysis database, the available clinical data elements in the Ad Hoc Reporting tree return only the most current values and revisions for any controls in clinical forms.
- A trial is likely to go through many versions. For example, forms and items might be added to or deleted from the original trial design. The Clinical Data by Form folder contains data elements for every form and item that have ever been used in any version of the trial.
- Your site associations and the display override settings on items determine the way reporting elements appear to you in the Ad Hoc Reporting workspace. For example, if an item is not visible to you in the InForm application, when you create a report that contains the item, the cells in the row that corresponds to the item contain the text **N/A**.
- When creating reports using clinical data, you must include a unique identifier for the trial component on which to report. For example, to create a clinical report about a particular patient, you must use whatever identifiers uniquely identify the patient in your trial. Depending on your trial design, you may use:
 - Patient Number, if unique Patient Numbers are assigned for your trial.
 - Patient Number and Patient Initials, if unique Patient Numbers are not assigned for your trial.
 - PatientID.
- When the same form is used in multiple visits, if a subject does not have any instances of the form, the resulting report may display extra rows that contain incomplete information. For more information, see ***Reporting on multi-instance forms and visits*** (on page 156).

Clinical reporting tree

The clinical portion of the Ad Hoc Reporting tree is built from the structure of the Reporting and Analysis database; reporting topics and elements are included for each form and control stored in the Reporting and Analysis database. The database structure is dependent on the trial design.

The clinical portion of the Ad Hoc Reporting tree resides in the Clinical Data by Form and Clinical Data by Associated Form folders. The following image illustrates the structure of the Clinical Data by Form folder. The Clinical Data by Associated Form folder includes the same data that is in the Clinical Data by Form folder for each form that is part of an association.



- **1**—The **report element folders** consist of clinical reporting elements.
- **2**—To create reports with clinical data, you must be sure to include **trial management report elements** that identify the trial component (subject, visit, and so forth) on which you want to report. The Clinical Data by Form folder contains some report elements from the Trial Management package; you can use these elements to identify visits, subjects, and sites in your clinical reports, and to identify unique instances of repeating visits, forms, or itemsets.
- **3**—Each **clinical form reporting topic** corresponds to a form or an itemset within your trial.
- **4**—**Clinical report elements** reflect the item questions that appear on the forms within your trial. Labels for reporting elements may or may not have been customized for display in the reporting tree.

Clinical reporting elements

Each clinical reporting element contains the following folders:

Clinical reporting element	Description
Basic Data	<p>The Basic Data folder is designed to provide easy access to meaningful reports. You can select the entire folder to create a basic report for a given form that includes easy-to read, meaningful data and appropriate key elements to ensure report accuracy.</p> <p>It contains:</p> <ul style="list-style-type: none"> • Clinical report elements that return clinical values associated with the form. • Display textual values of items rather than database codes as well as most of the available date formats. • Several reporting elements you can use to identify site, subject, and visit (these elements also appear in the Trial Management portion of the reporting tree.)
Additional Data	Contains report elements available for more advanced reports. Some of the elements included here return database codes, rather than textual values for fields, normalized values, and unit codes.
Incomplete Data Reasons	Contains reporting elements that return textual explanations of why an item on a form is not complete.
Internal IDs	Contains reporting elements that return values that uniquely identify a record in the database.

Note: When the clinical package is originally generated, the labels of each reporting element match the labels used within the trial design. Report topics are placed within default folders (Basic Data, Additional Data, Incomplete Data Reason, and Internal IDs). Labels and folder location for elements can be customized. This guide describes label naming conventions and element folder locations. Your clinical model labels and folders may vary.

Creating reports with both clinical and trial management data

If you create reports that use elements from both the clinical portion and the trial management portion of the Ad Hoc Reporting tree, keep the following restrictions in mind:

- You can include data from only one clinical form in any report that combines both clinical and trial management data.
- Do not use elements from the following trial management report topics in reports that also contain clinical elements:
 - Sections
 - Items
 - Rules
 - Queries
 - Comments

Report results will be difficult to interpret if you include these report elements.

- For best results, include only one element from the trial-specific clinical data model with no more than two elements from the Trial Management data model for each report that includes both clinical and trial management data.

Note: This suggestion does not apply to DOV elements.

Clinical data in the Ad Hoc Reporting tree

Forms and itemsets

When the clinical portion of the Reporting and Analysis database is generated, database views are created for each form and add entry form (itemset) in your study. When the InForm application generates the trial-specific clinical reporting package, each of these database views is represented as a report element.

Each report element that appears in the Clinical Data by Form folder corresponds to either a form, or an itemset on a form.

Note: Alternate forms are also represented by a report element.

Report elements are labeled with an appropriate suffix (Form or Itemset). In addition, the labels for itemset report topics begin with a prefix that identifies the form on which they appear.

Code report elements

Some clinical data is represented both by a text value and a code in the Reporting and Analysis database. The InForm application saves a unique, audited data record for the data (code) and a more readable display (text value) that can be adjusted if necessary. For example, a Yes answer to a question on a form is stored both as Yes and as 1 in the database.

Clinical report elements that appear in the Ad Hoc Reporting tree allow you to include either (or both) the text answer to a question or the code values in your reports. Text values are more readable in a report and are therefore included in the Basic Data folder for easy access. By default, the labels for report elements that return code values begin with the prefix **Code~** and appear in the Additional Data folder for any form in the Ad Hoc Reporting tree.

Data that require units of measure

Some answers to form questions are qualified by a unit of measurement. For example, the weight of a subject may be measured in kilograms or pounds.

For each question that requires a unit of measure qualifier, the following report elements appear in the Ad Hoc Reporting tree:

- Entered value.
- Unit of measure.
- Normalized value.

Itemsets, repeating visits, and repeating forms

Itemsets and repeating forms may capture data multiple times for a given subject. Forms may also appear in repeating visits. You can report on data that was collected at different iterations of itemsets, repeating forms, and repeating visits using index elements from the Ad Hoc Reporting tree to identify specific itemset, form, and visit instances.

Note: The Internal IDs folders also contain the following report elements: Form Index, Itemset Index, and Visit Index. While these elements also identify specific instances of repeating forms, visits, or items, they return the actual database value that is assigned to these instances.

- **Form index**—The report topic for any repeating form contains a Form Index report element. Use this element to separate data from each instance of the repeating form.
- **Itemset index**—The report topic for any Add Entry form contains an Itemset Index report element. Use this element to separate data from each instance of the itemset.
- **Visit index**—The report topic for any form or itemset that appears within a repeating (unscheduled) visit contains a Visit Index report element. Use this element to identify the visit instance in which data was gathered.

Deleted form instances and itemsets

InForm users can mark both itemset instances and instances of repeating forms for deletion. (By marking a form or itemset for deletion, the InForm application removes the form or itemset from the case book, but keeps a record of the form or itemset in the database.) The Ad Hoc

Reporting tree allows you to report on itemset and form instances that have been marked for deletion.

The report topic for any itemset or repeating form instance contains an element, **IsDeleted**, which returns data on whether the form or itemset was deleted in the InForm application. When you create reports on forms and itemsets, you may want to include these report elements to identify instances that have been marked for deletion, and add a filter to show information for forms or itemsets.

Date controls

Date controls in your trial are represented in different ways in the Ad Hoc Reporting tree. Some dates are stored as numeric values, and others are string values. For example, for a start date for an adverse event, the date control could appear as **Date ~ Start Date, Month Yr ~ Start Date**, and so forth, depending on your trial design. This format determines the data that appears in ad hoc reports.

In addition, the format for dates in the Reporting and Analysis module is determined by Cognos settings, and locale settings for your InForm trial.

Incomplete Data Reasons

Each clinical report topic contains an Incomplete Data Reasons folder. Report elements that appear in the folder return a textual value with the reason why an item question is marked Incomplete.

Default labeling

Default labels for clinical report elements come from properties that are established in the trial design code. Trial designers specified different pieces of information to identify each form, itemset, or control in your trial. The InForm application retrieves the text in these properties and uses it for default labeling of the clinical report elements.

The InForm application creates default labels for elements that appear in the Clinical Data by Forms folder as follows:

optional prefix~ control reference~ item reference

The following table describes each portion of the default label.

Report element label portion	Description
Optional prefix	<p>Defines the type of element. Possible prefixes include:</p> <ul style="list-style-type: none">• None• Code• Unit• Unit Code• Normalized• Date• Time• Month Yr• YYYY/MM/DD• HH24:MM:SS• Month• Year
Control reference	<p>Text that identifies the specific control for the item.</p> <p>If the control is not a checkbox control, the InForm application uses text that is in these properties for the second part of the control reference:</p> <ul style="list-style-type: none">• Caption property for the control, if it exists.• RefName property for the control, if no caption exists. <p>If the control is a checkbox, the InForm application uses text entered into these properties for this portion of the report element label:</p> <ul style="list-style-type: none">• Label property of the child control element, if it exists.• Caption property of the child control element, if no Label exists.• RefName property for the child control element, if no Label or Caption exists.

Report element label portion	Description
Item reference	<p>Text that identifies the item, as it appears in the trial. The InForm application uses text entered into these properties for this portion of the report element label:</p> <ul style="list-style-type: none"> Itemset Column Header property for the item, if it exists and is not the default. Question property for the item, if no Itemset Column Header exists.

Note: Trial designers should ensure that Itemset Column Header definitions are unique within a trial. If duplicate Itemset Column Header values exist, the Reporting and Analysis module combines the items into one row in reports.

Reference information for report elements

Report element (Default label)	Description	Default folder
Code report elements		
[control reference] Example: Cardiovascular ~ Cardiovascular	Returns the text value that was entered during data entry.	Basic Data
Code~ [control reference] Example: Code ~ Cardiovascular ~ Cardiovascular	Returns the database code that corresponds to the value entered during data entry.	Additional Data
Data that require units of measure		
[control reference] Example: Weight	Returns the value that was entered during data entry. For instance, if the InForm user entered 135 on the form, the Weight element would return 135.	Basic Data
Unit~ [control reference] Example: Unit~ Weight	Returns the specific unit of measure that was selected at data entry. The label for this element has the prefix Unit ~ . For example, the Unit ~ Weight element might return these values: kg or lbs.	Basic Data

Report element (Default label)	Description	Default folder
Normalized~ [control reference] Example: Normalized~Weight	Returns the normalized value; the InForm software converts measurements to the same, or normalized, unit of measure, based on a base unit of measure that is defined for your trial. For example, if the base unit of measure is kilograms, the InForm application converts all entered values to kilograms and stores that value as a normalized value.	Additional Data
Unit Code~ [control reference] Example: Unit Code~Weight	Returns the code value for the unit of measure, as it is stored in the database. The label for this element has the prefix Unit Code~ .	Additional Data
Itemsets, repeating visits, and repeating forms		
Visit Index	Returns a numeric value that indicates the instance of the visit in which data was entered for the form.	Basic Data
Form Index	Returns a numeric value that indicates each iteration of a repeating form.	Basic Data
Itemset Index	Returns a numeric value that indicates each iteration of an itemset.	Basic Data
Deleted itemsets and form instances		
Deleted form	Indicates whether the reported form instance was marked for deletion in the InForm application. Use this report element with the Form Index element to see form instances that have been deleted. Values are: <ul style="list-style-type: none"> • Y—Form was marked for deletion. • N—Form was not marked for deletion. 	Basic Data
Deleted itemset	Indicates whether the reported itemset was marked for deletion in the InForm application. Use this report element with the Itemset Index to see itemsets that have been deleted. Values are: <ul style="list-style-type: none"> • Y—Itemset was marked for deletion. • N—Itemset was not marked for deletion. 	Basic Data
Incomplete data reasons		
Not Done ~ [control label] Example: Note Done ~ Unit Dose	Returns a textual value that indicates why an item is marked Incomplete.	Incomplete Data Reasons

Reporting on multi-instance forms and visits

Your trial may include any number of multi-instance forms or items, including:

- Repeating forms.
- Non-repeating forms that occur within repeating visits.
- Itemsets (also called add entry forms).

When you create ad hoc reports, you can include data from more than one of these multi-instance forms, items, or visits on the same report.

A report can accurately provide data on the adverse events and concomitant medications for a subject. For example, it can accurately illustrate the relationships between:

- The subject and each adverse event.
- The subject and each medication.
- The adverse event and its associated concomitant medication.

Note: When the same form is used in multiple visits, if a subject does not have any instances of the form, the resulting report may display extra rows that contain incomplete information.

Filtering reports with more than one multi-instance form or itemset

You can apply filters to reports that contain data from more than one multi-instance form. However, results will vary depending on where you apply the filter. The table below describes how reporting behavior differs, depending on the filtered element.

You can filter on	For these results
A report element from a single-instance form	Rows for filtered-out items are removed. Example: Report contains: SubjectID, Gender, Adverse events, and Concomitant Medications Filter: Gender column = Male Results: Report removes all rows for female subjects.

You can filter on	For these results
A report element from a multi-instance form	<p>Rows for filtered-out items are not removed (they are set to blank values).</p> <p>Example:</p> <p>Report contains: SubjectID, Gender, Adverse events, and Concomitant Medications</p> <p>Filter: Adverse event = Depression</p> <p>Results: Report does not remove rows for other adverse events. Instead, the Adverse Events column displays blank values for all other adverse events.</p>

Reporting on forms with itemsets

For forms that contain a non-repeating section and an itemset, an association exists between the itemset and non-repeating section. You can create ad hoc reports to show the relationship between the data in a non-repeating section and its associated itemsets. The report output contains columns with data from the non-repeating section, and columns with data from each itemset.

For example, if an itemset exists on the Vital Signs form and the Demographics form, the itemset is associated with the non-repeating sections on each form.

- You can only create reports with data from a non-repeating section and itemsets that exist on the same form, and are therefore associated.
- You can create reports with data from a non-repeating section and itemsets that exist on non-repeating or repeating forms.
- For reports that contain a non-repeating section and multiple itemsets, there is no relationship between the itemsets.
- During trial versioning:
 - If a non-repeating section with an associated itemset is deleted, the association between the non-repeating section and the itemset remains for subjects with data in the non-repeating section. You can still generate reports using the existing data from the deleted section for those subjects. For subjects that do not have data in the non-repeating section, the columns in the report are empty.
 - If an itemset with an associated non-repeating section is deleted, the association between the itemset and the non-repeating section remains for subjects with data in the itemset. You can still generate reports using the existing data from the deleted itemset for those subjects. For subjects that do not have data in the itemset, the columns in the report are empty.
 - An association is created between a non-repeating section and an itemset when:
 - A non-repeating section is added to a form that contains an itemset
 - An itemset is added to a form that contains a non-repeating section.

Example 1: One non-repeating section and one itemset

This example shows the report output for patients AAA and AAB. In this example, the non-repeating section appears on a repeating form. Therefore, more than one instance of the non-repeating section exists in the study.

Subject Number for Flat portion	Subject Initials	Form Index	Deleted Form	Treatment Name	Subject Number from Itemset	Subject Initials	Itemset Index	Deleted Itemset	Date ~ New Dose Start	New Dose
100	AAA	1	N	Treat1	100	AAA	1	N	Jan 26, 2006	10
100	AAA	1	N	Treat1	100	AAA	2	N	Jan 25, 2006	20
100	AAA	2	N	Treat2	100	AAA	1	N	Jan 25, 2006	40
100	AAA	2	N	Treat2	100	AAA	2	N	Feb 27, 2005	41
100	AAA	2	N	Treat2	100	AAA	3	N	Feb 27, 2006	42
101	AAB	1	N	Treat6	101	AAB	1	N	Jan 25, 2006	41
101	AAB	1	N	Treat6	101	AAB	2	N	Feb 27, 2006	41

1—Data from the non-repeating section on each form for patients AAA and AAB.

2—Data for the itemsets on each form for patients AAA and AAB.

3—The Form Index column indicates that the non-repeating section appears on two forms for patient AAA, and one form for patient AAB.

4—The Itemset Index column indicates that:

- For patient AAA, the non-repeating section is associated with two itemset instances on Form 1 (rows 1 and 2), and three itemset instances on Form 2 (rows 3-5).
- For patient AAB, the non-repeating section is associated with two itemset instances on Form 1 only (rows 6 and 7).

Example 2: Incomplete non-repeating section and one itemset

This example shows the report output for patients AAA, AAB, and AAC when the data in the non-repeating section is incomplete for patient AAC.

Subject Number for Flat portion	Subject Initials	Form Index	Deleted Form	Treatment Name	Subject Number from Itemset	Subject Initials	Itemset Index	Deleted Itemset	Date ~ New Dose Start	New Dose
100	AAA	1	N	Treat1	100	AAA	1	N	Jan 26, 2006	10
100	AAA	1	N	Treat1	100	AAA	2	N	Jan 25, 2006	20
100	AAA	2	N	Treat2	100	AAA	1	N	Jan 25, 2006	40
100	AAA	2	N	Treat2	100	AAA	2	N	Feb 27, 2005	41
100	AAA	2	N	Treat2	100	AAA	3	N	Feb 27, 2006	42
101	AAB	1	N	Treat6	101	AAB	1	N	Jan 25, 2006	41
101	AAB	1	N	Treat6	101	AAB	2	N	Feb 27, 2006	41
					102	AAC	1	N	Jan 25, 2006	60
					102	AAC	2	N	Jan 24, 2006	61

1—The Form Index column indicates that the non-repeating section appears on two forms for patient AAA, and one form for patient AAB. For patient AAC, the non-repeating section does not contain data. However, its associated itemsets for patient AAC appear in rows 8 and 9.

2—The Itemset Index column indicates that:

- For patient AAA, the non-repeating section is associated with two itemset instances on Form 1 (rows 1 and 2), and three itemset instances on Form 2 (rows 3-5).
- For patient AAB, the non-repeating section is associated with two itemset instances on Form 1 (rows 6 and 7).
- For patient AAC, the non-repeating section is associated with two itemset instances (rows 8 and 9).

3—For patient AAC, the non-repeating section that is associated with Itemset Instance 1 and Itemset Instance 2 does not contain data. Therefore, blank cells appear for the columns that correspond to the data for the non-repeating section.

Example 3: Incomplete non-repeating section, one itemset, and an additional form

This example shows the report output for subjects AAA, AAB, and AAC when the data in the non-repeating section is incomplete for patient AAC, and data from the Demographics (DEM) form is included in the report.

For patients AAA and AAB, the itemset data is associated with the data in the non-repeating section, and the data in the non-repeating section is associated with the data on the DEM form. Therefore, in this instance, the itemset data is associated with the data on the DEM form for patients AAA and AAB. Because data is not entered in the non-repeating section for patient AAC, the data that exists for patient AAC on the DEM form is not associated with the itemset data, and therefore does not appear in the report, even if data for patient AAC exists on the DEM form.

Subject Number for Flat portion	Date ~ Date of Birth	Month Yr ~ Screening Date	Subject Initials	Form Index	Deleted Form	Treatment Name	Subject Number from Itemset	Subject Initials	Itemset Index	Deleted Itemset	Date ~ New Dose Start	New Dose
100	Feb 27, 1949	Feb 2010	AAA	1	N	Treat1	100	AAA	1	N	Jan 26, 2006	10
100	Feb 27, 1949	Feb 2010	AAA	1	N	Treat1	100	AAA	2	N	Jan 25, 2006	20
100	Feb 27, 1949	Feb 2010	AAA	2	N	Treat2	100	AAA	1	N	Jan 25, 2006	40
100	Feb 27, 1949	Feb 2010	AAA	2	N	Treat2	100	AAA	2	N	Feb 27, 2005	41
100	Feb 27, 1949	Feb 2010	AAA	2	N	Treat2	100	AAA	3	N	Feb 27, 2005	42
101	Jan 6, 1994	Feb 2010	AAB	1	N	Treat6	101	AAB	1	N	Jan 25, 2006	41
101	Jan 6, 1994	Feb 2010	AAB	1	N	Treat6	101	AAB	2	N	Feb 27, 2006	41
							102	AAC	1	N	Jan 25, 2006	80
							102	AAC	2	N	Jan 24, 2006	81

Diagram annotations: Brackets 1, 2, 3, and 4 group columns 1-3, 4-6, 7-9, and 10-12 respectively. Arrows 5 and 6 point to the Itemset Index and Form Index columns.

- 1—Non-repeating section data.
- 2—Demographics form data.
- 3—Non-repeating section data, continued.
- 4—For patient AAC, the non-repeating section that is associated with Itemset Instance 1 and Itemset Instance 2 does not contain data. Therefore, blank cells appear for the columns that correspond to the data for the non-repeating section, and the columns that correspond to the data for the SI form. An association cannot be made between the itemset data and the data on the SI form without data in the non-repeating section.
- 5—The Itemset Index column indicates that:
 - For patient AAA, the non-repeating section is associated with two itemset instances on Form 1 (rows 1 and 2), and three itemset instances on Form 2 (rows 3-5).
 - For patient AAB, the non-repeating section is associated with two itemset instances on Form 1 (rows 6 and 7).
 - For patient AAC, the non-repeating section is associated with two itemset instances (rows 8 and 9).
- 6—The Form Index column indicates that the non-repeating section appears on two forms for patient AAA, and one form for patient AAB. For patient AAC, the non-repeating section does not contain data. Therefore, data from the SI form does not appear for patient AAC; however, the itemset instances associated with the non-repeating section for patient AAC appear in rows 8 and 9.

Example 4: One non-repeating section with multiple itemsets

This example shows the report output for patient BBA when data in the non-repeating section is associated with multiple itemsets.

Note: No relationship exists between the itemsets.

Subject Number	Subject Initials	mdcYesNo1 ~ Are there any history and or physical findings	Subject Number	Itemset Index	Date ~ Start date	Date ~ Stop date	Subject Number	Itemset Index	Diagnosis	rdcMEDHxStatus ~ Status at Baseline
200	BBA	Yes	200	1	Feb 1, 2010	Feb 20, 2010	200	1	D1	Past
200	BBA	Yes	200	2	Feb 2, 2010	Feb 24, 2010	200	2	D2	Past
200	BBA	Yes	200	3	Feb 3, 2010	Feb 28, 2010				

1

2

3

- 1—Non-repeating section data.
- 2—Data for the first itemset that is associated with the non-repeating section. Three instances of the itemset exist in the trial.
- 3—Data for the second itemset that is associated with the non-repeating section. Two instances of the itemset exist in the trial.

Example 5: Incomplete non-repeating section with multiple itemsets

This example shows the report output for patients 200 and 201 when data in the non-repeating section is incomplete, and the non-repeating section is associated with multiple itemsets.

Note: No relationship exists between the itemsets.

1

Subject Number	Subject Initials	medxhistory1 ~ Are there any history and/or physical findings	Subject Number	Itemset Index	Date ~ Start date	Date ~ Stop date	Subject Number	Itemset Index	Diagnosis	rdxMEDHxStatus ~ Status at Baseline
200	BBA	Yes	200	1	Feb 1, 2010	Feb 28, 2010	200	1	D1	Past
200	BBA	Yes	200	2	Feb 2, 2010	Feb 24, 2010	200	2	D2	Past
200	BBA	Yes	200	3	Feb 3, 2010	Feb 28, 2010				
			201	1	Mar 1, 2010	Mar 24, 2010				
			201	2	Mar 2, 2010	Mar 30, 2010				
			201	3	Mar 3, 2010	Mar 30, 2010				
							201	1	D4	Past
							201	2	D5	Under Control

3

2

1—For patient 200, all items from the non-repeating section that appear in the report are complete, and data for five instances appears for two itemsets. Three instances of Itemset 1 exist, and two instances of Itemset 2 exist.

Because data in the non-repeating section is complete for patient 200, the data for all five itemset instances appears in three rows in the report output. The data for the two instances of Itemset 1 and the first two instances of Itemset 2 appears in the first two rows, and the data for the additional instance of Itemset 2 appears in the third row.

2—For patient 201, at least one of the three items that appear in the non-repeating section for the report is incomplete.

3—For patient 201, data for two itemset instances appears for one itemset.

Because the data from the non-repeating section that appears in the report is incomplete for patient 201, the data for both itemset instances appears in two rows in the report output, with each row corresponding to an itemset instance.

Note: If a non-repeating section contains incomplete data items, but the incomplete items are not included in the report, the report does not a row for each instance of each itemset.

Reporting on associated forms

You can create an ad hoc report to show the relationship between data in two associated forms.

- The associated forms must be repeating.
- The forms must be marked as associated in the trial design application (either the InForm Architect application or the Central Designer application).
- The report must only contain data from two associated forms.
- If the report topics in the report are not from associated forms, data does not display.
- If the report contains data from more than two associated forms, data does not display.

Use the report data in the Clinical Data by Associated Form package to create ad hoc reports with associated form data.

Note: You cannot create an ad hoc report that contains data from both the Clinical Data by Form report element and the Clinical Data by Associated Form package.

Example: Adverse Events and Concomitant Medications association

This example shows the report output for the association between the Adverse Events and Concomitant Medications forms for patients CCC, DDD, AAA, ASD, and BBB, for each of whom adverse event and concomitant medication data exists.

In this example, there is a one-to-one correspondence between each adverse event and each concomitant medication for each patient. If, for example, patient CCC reported two adverse events associated with Drug1, an additional row for patient CCC would exist with Event2 data in the Event column, and Drug1 data in the Drug name column.

Subject Initials	Event	Drug name	Site Name
CCC	SV2_JohnHop_Event1	SV2_JohnHop_Drug1	(04) Johns Hopkins Hospital
DDD	SV3_JohnHop_Event1	SV3_JohnHop_Drug1	(04) Johns Hopkins Hospital
AAA	SV1_Cleveland_Event1	SV1_Cleveland_Drug1	(02) Cleveland Clinic
ASD	SV1_MassGen_Event1	SV1_MassGen_Drug1	(01) Massachusetts General Hospital
BBB	SV1_JohnHop_Event1	SV1_JohnHop_Drug1	(04) Johns Hopkins Hospital
	1	2	

- 1—The Event column contains adverse event data for each patient.
- 2—The Drug name column contains concomitant medication data for each patient.

CHAPTER 4

Standard reports

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Standard reports

The InForm application includes a set of management reports that provide information about the progress of a study. These reports show several categories of information. Several views of each report are available; for example, you can display the query status reports by site and by user, month by month or study-to-date, and in text or graphical formats.

The reports comprise five categories:

- Query reports provide information about query aging, status, and cycle time.
- Case Report Form (CRF) reports provide information about the progress of data entry and query activity on started case books.
- Item reports provide information about the progress of item source verification, as well as listings of items on forms.
- Subject reports provide information on the progress of casebook completion for individual subjects. These reports also provide subject enrollment and dropout counts, as well as subject enrollment status.
- Audit trail reports provide auditing and operational information such as audit trail information and log in history.

InForm standard reports by category

Folder	Available reports
Query Reports	<ul style="list-style-type: none"> • Outstanding Queries by Site and Visit • Query Aging by Site • Query Cycle Times by Site • Query Cycle Times by User • Query Performance Summary by Site • Query Performance Summary by User • Query Status by Site • Query Status by Site and Subject • Query Status by Site and Visit • Query Status by User • Query Volume by Month by Site • Query Volume by Month by User • Query Volume by Rule • Subject Counts with Outstanding Queries
CRF Reports	<ul style="list-style-type: none"> • CRF Aging by Site • CRF Aging by User • CRF Cycle Time Detail by Site • CRF Cycle Time Detail by User • CRF Site Performance Summary by Site • CRF Site Performance Summary by User • CRF Status Detail by Site and Subject • CRF Status Detail by Visit and Site • CRF Status Summary by Site • CRF Status Summary by User
Item Reports	<ul style="list-style-type: none"> • CRF Item Listing • Source Verification Listing

Folder	Available reports
Subject Reports	<ul style="list-style-type: none">• Case Book Completion and Query Summary by Site• Case Book Completion and Query Summary by User• Cumulative Subject Enrollment by Month• Subject Dropout Count by Reason• Subject Enrollment Status by Site• Subject Enrollment Status by User
Audit Trail Reports	<ul style="list-style-type: none">• Audit Trail Report• Historical Login Report

Running a standard report from the Reporting and Analysis portal

- Click the link for the report.

Or

- 1 To specify additional options, click the **Run with Options** icon for the report.

Note: XML and CSV formats are *not* supported for standard reports.

- 2 Specify report parameters on the Selection Criteria page.
- 3 Click **Run Report**.

Running a report in a new window

- Right-click the link for any report and click **Open in New Tab** to launch a new browser window in which to display the report.

Note: Launching a new browser window is particularly helpful when you run reports that link back to the InForm software, such as the *CRF Item Listing* (on page 308) and the *Source Verification Listing* (on page 314).

Saving a standard report definition

When you save a report, the Reporting and Analysis module saves the report definition. A report definition includes the report elements and report topics that exist in the report you created, but does not include the report data. Each time you run a saved report, the Reporting and Analysis module creates a report with the report elements and report topics that exist in the report, and displays the most current data that exists in the Reporting and Analysis database.

- 1 Run the report.
- 2 Select **Keep this version > Save Report**.

The Reporting and Analysis module saves the report definition to the location from which you ran the report.

Saving a standard report as a report view

To save a report definition and the report data at the time when you ran the report, save the report as a report view. A report view allows you to save report data at specific times during the course of a study so that you can track study progress.

Note: To avoid overwriting report data, and to prevent confusion, save reports and report views with different names.

- 1 Run the report.
- 2 Select **Keep this version > Save as Report View**.
The **Save as report view** dialog box appears.
- 3 In the **Name** field, specify a name for the report view.
- 4 In the **Location** field, specify a location. By default, the home folder is specified.
 - To save the report view to a specific location:
 - a Click **Select another location**.
The Select a location (Navigate) dialog box appears.
 - b Specify the folder in which to save the report view.
 - c Click **OK**.
 - To save the report view to the My Folders page, click **Select My Folders**.

Opening a standard report in Report Studio

If you have access to the Report Studio application, you can open a standard report in Report Studio from the main InForm Reporting and Analysis portal page. You can then use Report Studio to add advanced functionality to the report.

- For the report, click the **Open with Report Studio** icon ().

Components of a standard report

Three types of pages comprise each standard report:

- Report prompt page.
- Report/Graph page.
- Summary page.

Report prompt page

On the report prompt page, you select criteria and choose sort options for your report. Prompt pages have three sections:

- Selection Criteria.
- Sort Options.
- Run Report/More options/Cancel buttons.

Reporting and Analysis **CRF Aging by Site**

Selection Criteria
Choose one or more items in each list to narrow report criteria.

Countries: ARGENTINA, CANADA, MEXICO, USA
 Update >>

Sites: (01) Massachusetts General Hospital, (02) Cleveland Clinic, (03) Bellevue Hospital, (04) Johns Hopkins Hospital, (05) University of California Hospital, (06) Clinic of the University of Michigan
 Select all Deselect all

Expected forms for: Scheduled Visits or Started Forms to Date
 Aging interval: 10
 Limit to forms with:
☒ Required Items
☐ SV Required Items
☒ Outstanding Queries
☐ Comments
 Select all Deselect all

Sort Options

First sort on: Site Mnemonic
☒ Ascending
☐ Descending

Then sort on: Completed Forms Count
☒ Ascending
☐ Descending

Then sort on: None
☒ Ascending
☐ Descending

Run Report Cancel

Return

Selection Criteria

In the Selection Criteria section of the prompt page, you can narrow criteria used to run your report. This section might contain:

- Cascading prompts
- Checkboxes
- Drop-down lists
- Calendars
- List boxes
- Text boxes

Unless a selection is required, you can choose not to make a selection, which means no criteria will be applied for a particular prompt to limit the report data. Not making a selection often causes a report to run faster than explicitly selecting all values in the prompt list.

Cascading prompts

Cascading prompts allow you to select criteria in one category to narrow the selections offered in another category.

In the following example, the Countries and Sites list boxes are cascading prompts. You can select one or more countries from the list and click Update to see only sites for selected countries in the Sites list.

Selection Criteria
Choose one or more items in each list to narrow report criteria.

Countries:

- ARGENTINA
- CANADA
- MEXICO
- USA**

Sites:

- (01) Massachusetts General Hospital
- (02) Cleveland Clinic
- (03) Bellevue Hospital
- (04) Johns Hopkins Hospital
- (05) University of California Hospital
- (06) Clinic of the University of Michigan

[Update >>](#)

[Select all](#)
[Deselect all](#)

[Select all](#) [Deselect all](#)

You can select one or more items in any of these lists to limit your report to your selections.

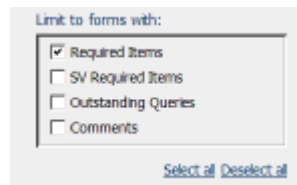
You can also choose to make no selection. However, making no selection means no criteria will be applied for this prompt to limit the reported data. This often will run a report faster than explicitly selecting all values in the prompt list.

Note: If you change a selection in one prompt, be sure to click Update to update all cascading prompts.

Some reports require you to make some selection before you can run the report. In these cases, the Run Report button is grayed out, and red dashes indicate the field in which you must make a selection.

Checkboxes

Checkboxes allow you to select one or several options for narrowing report criteria. You can select one or more checkbox items to limit your report to your selections.

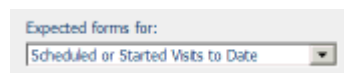


A screenshot of a software interface showing a selection prompt titled "Limit to forms with:". Below the title is a rectangular box containing four items, each with a checkbox: "Required Items" (checked), "SV Required Items" (unchecked), "Outstanding Queries" (unchecked), and "Comments" (unchecked). Below the box are two links: "Select all" and "Deselect all".

For some checkboxes, data must meet the criteria for **all** option selections to be contained in the report. For other checkboxes, data must meet criteria for **at least one** of the options selected to be contained in the report.

Selection Criteria section

Drop-down lists let you choose only one option. To choose an option, click the arrow on the drop-down list and move the cursor to the correct selection.





A screenshot of a software interface showing a selection prompt titled "Expected forms for:". Below the title is a drop-down menu with the text "Scheduled or Started Visits to Date" and a small downward-pointing arrow on the right side.

Calendars

When you need to specify a date range, you can click the calendar icon and then select the From and To dates in the calendar instead of typing them in.

Date range:

From: 

To: 

Then sort on:

☒ Ascending
☐ Descending

2009

Jan	Feb	Mar	Apr	May	Jun	
Jul	Aug	Sep	Oct	Nov	Dec	
Sun	Mon	Tue	Wed	Thu	Fri	Sat
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

List boxes

List boxes contain options that you can select.

- To select a single option, click the entry.
- To select more than one option at a time, hold down the **Ctrl** key while selecting each option.
- To select several options that appear together in the list, select the first option, and then press the **Shift** key while selecting the last option in the list to include.

Sites:

(01) Massachusetts General Hospital

(02) Cleveland Clinic

(03) Bellevue Hospital

[Select all](#) [Deselect all](#)

Text boxes

You enter data into a text box by typing the value to use.

Aging interval:

Sort Options section

In the Sort Options section of the prompt page, you can choose up to three columns on which to sort a report.

Drop-down lists appear at the bottom of each report prompt page. Default sorting selections are automatically selected. You can change these to create your own report definition.

Beneath each sort drop-down list are radio buttons labeled Ascending and Descending. Ascending sorts are automatically selected by default. Use the radio buttons to change the sort type.

Reports that include groupings, such as by user and by site, are sorted at the detail level within the grouping, according to the selections made in the drop-down lists. The grouping order can be modified (ascending vs. descending), but will always be the primary sort column.

Buttons - Run Report/More Options/Cancel buttons

The bottom-left corner of each prompt page contains buttons you can use to:

- Run the report.
- See more options (if available).
- Cancel the report.

Summary page

The summary page summarizes user selections from the report prompt page. Click the Bottom link on any report to see the summary page. This information is included for report printouts so readers will know what criteria were used.

Report/Graph page

The Report/Graph page displays the results of your report, based on the criteria you selected in the Prompt page.

The Report/Graph page can be made up of three parts:

- Show/Hide Report Selections (if applicable).
- Graphs, list, or crosstabs.
- Report footer.

Show/Hide Selections link

A Show/Hide Selections link appears for all reports. Click this link to turn on and off a list of the selections you chose on the prompt page, and to change the sort selections for the report.

Graphs and columns

Metrics/performance standard reports include:

- **Graphs**—Graphical representation of the report results. When a chart is included in a report, it appears on the first page. Use the Page Down link to navigate to the report columns.
- **Report columns**—Display report data in a table. Some columns include totals and subtotals.

Report header and footer

The report header displays the report title and trial name. The header can also display a logo. The report footer contains the following data.

Footer label	Description
Run at	Date and time the report was run.
Page	Page number appears centered in the footer. <ul style="list-style-type: none"> • In HTML reports, the page number appears. • In PDF reports, the page number and total page count appear.
Data as of	Date and time that data was last replicated to the InForm Reporting and Analysis database.

Data in standard reports

Standard reports show data for only clinical visits and clinical form types.

- **Subtotals and totals**—Standard reports display subtotals and totals for numeric columns, unless the column displays a median value. For reports that include median calculations, subtotals and totals are blank.
 - CRA-oriented reports that have grand totals calculate those totals based on unique sites and avoid reporting duplicate data when more than one CRA is associated with a site. When more than one CRA is associated with a site, the total on the report will be clearly labeled and the Prompt Page for the report will warn the user that site information will be duplicated due to CRAs sharing the same sites.
 - Minimum (Min), maximum (Max), and average values for subtotals and totals are calculated by taking the Min, Max, and Average of the sites.
- **Percentages**—When percentages are shown in a report, either the column head or a special footnote identifies what the number is a percentage of. When percentages appear in the same column as counts, sorting on that column is based on the percentage value and not the count value.
- **by User reports**—The by User reports in the InForm application are designed to provide information on the performance of primary monitors for your trial. The reports provide performance statistics about all roles within a trial. For sites with more than one person in a given role, you will see the same data multiple times, one row for each person. You can limit this by selecting specific individual users, such as primary CRAs, or establishing special rights groups that prohibit duplication by site.

To get the most out of the by User reports, follow these guidelines. When you can easily identify key rights groups and users, the by User reports will be manageable and will yield reliable results.

- Understand the rights group organization for your trial, and know how primary monitors fit into this organization. All primary monitors can be assigned to a single rights group, or to multiple rights groups. To target only primary monitors and avoid producing unwieldy reports, you must know which rights group to select.
- Know how to identify your primary monitors. This information is especially important if your organization has not designated a single rights group for all primary monitors.
- **UUIDs**—Trials created using the Central Designer application automatically specify the Universal Unique Identifiers (UUIDs) that are required to populate columns in certain reports.
 - If a column in a standard report does not contain any values, the InForm special fields may not have been specified when the trial was created in the Central Designer application.

Report folders

All standard reports included with the InForm application appear on the Public folders tab of the Reporting and Analysis portal.

Standard reports are organized into five folders. Click each folder name to access a complete list of standard reports for the chosen category.

- CRF Reports
- Item Reports
- Query Reports
- Subject Reports
- Audit Trail Reports

Note: You can toggle between a list view and a detail view of the standard reports folders. On the InForm navigation pane, select Help > Using Reporting Tools for more information.

Report actions

Each standard report folder lists Report Action icons. In list view, these icons appear under the label **Report Actions**.

Report action	Description
Set properties	Specify such items as report name and screen tip for the report.
View most recent report in HTML	Displays the latest saved HTML view of the latest version of the report. If you click this link, the report runs based on the last saved prompt values specified for the report.
View report output versions	Displays a list of all output versions created for the report, if report views have been saved. You can click these links to see each version. If you click this link, the report runs based on the last saved prompt values specified for the report.
Run with options	<p>Lets you specify output version and delivery mechanism when you run the report. Use this option to change any prompt values that may have been previously set for the report.</p> <p>Note: This release of the InForm application does not support selecting a language other than English.</p>
Note: Only users with Publisher rights or Report Administrator rights can access the following options.	
New schedule	Allows you to schedule the report.
View run history	Allows you to see the request time, start time, and completion time for each time the report was run.
Move	Allows you to move the report to another folder.
Copy	Allows you to copy the report to another folder.
Create shortcut to this entry	Allows you to create a shortcut to this report. You can specify any folder location (to which you have write access) for the shortcut.
Create report view of this report	Allows you to create a report view of the report.
Delete	Allows you to delete the report.

Query reports

About query reports

The Query reports provide information about the volume of query activity and the progress from query opening to resolution.

Outstanding Queries by Site and Visit

This cross-tab report shows the number of open or answered queries for each visit (columns) and each site (rows). Use this report to quickly spot open queries for older visits.

The report displays information only for countries that have sites with outstanding queries.

Selection criteria: Outstanding Queries by Site and Visit

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: Outstanding Queries by Site and Visit* (on page 182).

Selection criteria

Outstanding Queries by Site and Visit	
Selection criteria	Action
Countries	To report on specific countries, select their names from the list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.
Visits	Select a visit from the list.
Query Type	<p>To specify the type of queries to report on, select one of the following:</p> <ul style="list-style-type: none"> • Auto—Automatic queries generated by the InForm application when a rule in the study design detects a discrepancy in the data that is entered. • Manual—Manual queries created by InForm users. <p>If you leave all checkboxes blank, the report will include both of these options.</p>

Note: To include all available options in the report, leave the optional selection fields blank; that

is, do not select any individual options from the drop-down lists. For the best performance, do not select any optional filters.

Sort options

Sort options are: None, Country, Site Mnemonic, Total Open, Total Answered, Total Outstanding.

Use the Sort drop-down lists to change any of the default selections.

Outstanding Queries by Site and Visit	
Sort	Default selection
First level	Country
Second level	Site Mnemonic
Third level	None

Use the sort drop-down lists to change any of these selections.

Report/Graph page: Outstanding Queries by Site and Visit

Subtotals and totals

- **Subtotals**—By Country.
- **Totals**—Overall query count totals.

Column descriptions

Outstanding Queries by Site and Visit	
Report element	Description
Countries	<p>Data displayed: String</p> <p>Description: Country in which a site is located, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Outstanding Queries by Site and Visit	
Report element	Description
Visit Mnemonic	<p>Data displayed: String</p> <p>Description: An abbreviation of the visit title, as specified in the trial design. For CRF visits, this title appears at the top of a collection of forms in the visit timeline and may not be a unique identifier.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Open query counts by visit	<p>Data displayed: Numeric</p> <p>Description: For each visit, the number of queries with a current status of open.</p> <p>How calculated: Counts all open queries for each site and visit that are associated with items on any form in the visit. This calculation counts manual, automatic, or both types of open queries, based on your selection for the Query Type filter on the report prompt page. Note that this total includes queries that were opened, answered, and then reissued.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Answered query counts by visit	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of queries that were answered for each visit.</p> <p>How calculated: The sum of the values in the Open and Ans'd columns.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Total query counts by visit	<p>Data displayed: Numeric</p> <p>Description: For each site, the total number of open, answered, and closed queries in a given month.</p> <p>How calculated: The value displayed in this column is the sum of the values in the Open, Ans'd, and Closed columns.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Totals - Open query counts by visit	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of queries with a current status of Open.</p> <p>How calculated: The sum of the values for open queries for all visits at a given site.</p> <p>Data source: Derived for the report; not stored in the InForm Reporting and Analysis database.</p>

Outstanding Queries by Site and Visit	
Report element	Description
Totals - Answered query counts by visit	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of queries with a current status of Answered.</p> <p>How calculated: The sum of the values for answered queries for all visits at a given site.</p> <p>Data source: Derived for the report; not stored in the InForm Reporting and Analysis Reporting and Analysis database.</p>
Totals - Total query counts by visit	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of queries with a current status of Open or Answered.</p> <p>How calculated: The sum of the values for open or answered queries for all visits at a given site.</p> <p>Data source: Derived for the report; not stored in the InForm Reporting and Analysis Reporting and Analysis database.</p>

Query Aging by Site

This report shows the number of queries that are open, by site, for a given number of days. Use this report to help identify sites that are falling behind.

Selection criteria: Query Aging by Site

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: Query Aging by Site* (on page 185).

Selection criteria

Query Aging by Site	
Selection criteria	Action
Country	To report on specific countries, select their names from the list. Then, click Update to update the Sites list.

Query Aging by Site	
Selection criteria	Action
Sites	To report on specific sites, select the names of the sites from the list.

Aging Interval	<p>Enter a time duration (in days) to be used as the aging interval. The resulting report uses the aging interval to show how many open queries have been open for specific numbers of days.</p> <p>For example, if you specify 7, the resulting report shows the number of open queries that have been open for:</p> <ul style="list-style-type: none"> • Seven or fewer days. • More than 7 but fewer than 14 days. • More than 14 but fewer than 21 days. • More than 21 but fewer than 28 days. • More than 28 days.
----------------	---

Sort options

Sort options are: None, Country, Site Mnemonic, Enrolled Subject Count, Total Open Query Count, Average Age of Open, % of Queries Open 1st Period, % of Queries Open 2nd Period, % of Queries Open 3d Period, % of Queries Open 4th Period, % of Queries Open 5th Period.

Use the Sort drop-down lists to change any of the default selections.

Query Aging by Site	
Sort	Default selection
First level	Country
Second level	Site Mnemonic
Third level	None

Report/Graph page: Query Aging by Site

Subtotals and totals

- **Subtotals**—By Country.
- **Totals**—Overall query aging totals.

Column descriptions

Query Aging by Site	
Column	Description
Country	<p>Data displayed: String</p> <p>Description: Country in which a site is located, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Subject Count	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who have enrolled at the site.</p> <p>How calculated: For each site, counts subjects that have been enrolled in the InForm application. This count includes subjects who have enrolled and have moved on to other states, such as Randomized, Dropped Out, or Complete.</p> <p>Note: The Enrollment form, designed according to InForm specifications, must be completed for the subject.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Status is determined by value on the InForm Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p>
Total Open	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of queries with a current state of open.</p> <p>How calculated: For each site, all queries with a current status of open are counted, regardless of query type. Note that this total includes queries that were opened, answered, and then reissued.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Query Aging by Site	
Column	Description
Average Age of Open	<p>Data displayed: Numeric</p> <p>Description: For each site, the average number of days that open queries have been in the open state.</p> <p>How calculated: This calculation applies only to queries with a current status of Open. The calculation begins on the date when a query was last opened and ends on the current date.</p> <p>This value is calculated in multiples of 24 (hours). For example, if the query is opened at 10 a.m. on day 1 and the report is run 10 days later at 9 a.m., the days open is 9.</p> <p>You specify the aging interval (in days) on the report prompt page.</p> <p>For example, if you specify 7, the resulting report shows the number of queries that have been open for:</p> <ul style="list-style-type: none">• Seven or fewer days.• More than 7 but equal to or fewer than 14 days.• More than 14 but equal to or fewer than 21 days.• More than 21 but equal to or fewer than 28 days.• More than 28 days. <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Query Aging by Site	
Column	Description
Queries Open (% of Total Open for Country)	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of open queries that have been open for specific intervals of time. You specify the aging interval (in days) on the report prompt page.</p> <ul style="list-style-type: none">• 7 or fewer days.• More than 7 days but fewer than 14 days.• More than 14 days but fewer than 21 days.• More than 21 days but fewer than 28 days.• More than 28 days. <p>How calculated: This value is calculated in multiples of 24 (hours). For example, if the query is opened at 10 a.m. on day 1 and the report is run 10 days later at 9 a.m., the days open is 9.</p> <p>The number of queries in the date range is followed by a percentage of the total open query count per country. For each country, the percentage is calculated as follows:</p> $[open\ queries\ within\ aging\ interval] * 100 / [total\ number\ of\ open\ queries]$ <p>Data source: Derived and stored in the Reporting and Analysis database. Percentage derived for display.</p>

Query Cycle Times by Site

This report shows the minimum, maximum, and median number of days for queries to move from open to answered to closed. This report is grouped by site or sponsor. Use the report to help you see whether a given site or sponsor is having issues resolving queries in a timely way.

The report includes only those sites that have queries.

Selection criteria: Query Cycle Times by Site

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: Query Cycle Times by Site* (on page 190).

Selection criteria

Query Cycle Times by Site	
Selection criteria	Action
Countries	To report on specific countries, select their names from the list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.
Query Types	<p>To specify the type of queries to report on, select one of the following:</p> <ul style="list-style-type: none"> • Auto—Automatic queries generated by the InForm application when a rule in the study design detects a discrepancy in the data that is entered. • Manual—Manual queries created by InForm users. <p>If you leave all checkboxes blank, the report will include both of these options.</p>
Date Range	<p>Enter the From and To dates or use the calendar icons to select the dates.</p> <p>Default From date: 2000-01-01</p> <p>Default To date: Current date</p>

Note: To include all available options in the report, leave the optional selection fields blank; that is, do not select any individual options from the drop-down lists. For the best performance, do not select any optional filters.

Sort options

Sort options are: None, Country, Site Mnemonic, Subject Count, Query Count, Open to Answered–Min, Open to Answered–Max, Open to Answered–Median, Answered to Closed–Min, Answered to Closed–Max, Answered to Closed–Median, Open to Closed–Min, Open to Closed–Max, Open to Closed–Median.

Use the Sort drop-down lists to change any of the default selections.

Query Cycle Times by Site	
Sort	Default selection
First level	Country
Second level	Site Mnemonic
Third level	None

Report/Graph page: Query Cycle Times by Site

Graphs

A combination line/bar graph appears on the first page of the Query Cycle Times by Site report, plotting the median time from query open to answered, and the minimum time answered to closed, by sites within countries.

Subtotals and totals

- Subtotals—By country.
 - Min—Lowest minimum value for any site in the country.
 - Max—Highest maximum value for any site in the country.
 - Median—No value.
- Totals—Overall query cycle time totals.
 - Min—Lowest minimum value for any site in the country.
 - Max—Highest maximum value for any site in the country.
 - Median—No value.

Column descriptions

Query Cycle Times by Site	
Column	Description
Country	<p>Data displayed: String</p> <p>Description: Country in which a site is located, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Subject Count	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who have enrolled at the site.</p> <p>How calculated: For each site, counts subjects that have been enrolled in the InForm application. This count includes subjects who have enrolled and have moved on to other states, such as Randomized, Dropped Out, or Complete.</p> <p>Note: The Enrollment form, designed according to InForm specifications, must be completed for the subject.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Status is determined by value on the InForm Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p>
Query Count	<p>Data displayed: Numeric</p> <p>Description: The total number of number of open, answered, and closed queries.</p> <p>How calculated: This calculation counts all open, closed, and answered queries based on the Query Type filter specified on the report prompt page. This count does not include queries that have never been opened (candidate queries or deleted candidate queries).</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Query Cycle Times by Site	
Column	Description
Open to Answered (Days): Min, Max, Median	<p>Data displayed: Numeric</p> <p>Description: Data on the number of days from when queries are opened to when they are answered. For each site, the column displays:</p> <ul style="list-style-type: none"> • Minimum—The fewest number of days for an opened query to be answered at the site. • Maximum—The greatest number of days for an opened query to be answered at the site. • Median—The median of the opened-to-answered range for all answered queries at the sites. <p>How calculated: The calculation begins on the first day when the status of a query was set to Open and ends on the most recent day when the status of a query was set to Answered. This value is calculated in multiples of 24 (hours) and is rounded down to the nearest whole number.</p> <p>For example, if a query is opened on day 1 at 10 a.m. and answered on day 3 at 9 a.m., the Open to Answered value is 1 day.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Answered to Closed (Days): Min, Max, Median	<p>Data displayed: Numeric</p> <p>Description: Data on the number of days from when queries are answered to when they are closed. For each site, the columns display:</p> <ul style="list-style-type: none"> • Minimum—The fewest number of days for an answered query to be closed at the site. • Maximum—The greatest number of days for an answered query to be closed at the site. • Median—The median of the answered-to-closed range for all closed queries at the site. <p>How calculated: The calculation begins on the first day when the status of a query was set to Answered and ends on the most recent day when the status of a query was set to Closed. This value is calculated in multiples of 24 (hours) and is rounded down to the nearest whole number.</p> <p>For example, if a query is answered on day 1 at 10 a.m. and closed on day 3 at 9 a.m., the Answered to Closed value is 1 day.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Query Cycle Times by Site	
Column	Description
Open to Closed (Days): Min, Max, Median	<p>Data displayed: Numeric</p> <p>Description: Data on the number of days from when queries are opened to when they are closed. For each site, the column displays:</p> <ul style="list-style-type: none"> • Minimum—The fewest number of days for an opened query to be closed at the site. • Maximum—The greatest number of days for an opened query to be closed at the site. • Median—The median of the opened-to-closed range for all closed queries at the site. <p>How calculated: The calculation begins on the first day when the status of a query was set to Open and ends on the most recent day when the status of a query was set to Closed. This value is calculated in multiples of 24 (hours) and is rounded down to the nearest whole number.</p> <p>For example, if a query is opened on day 1 at 10 a.m. and closed on day 3 at 9 a.m., the Answered to Closed value is 1 day.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Query Cycle Times by User

This report shows the minimum, maximum, and median number of days for queries to move from open to answered to closed. This report is grouped by site or sponsor. Use the report to help you see whether a given site or sponsor is having issues resolving queries in a timely way.

Selection criteria: Query Cycle Times by User

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: Query Cycle Times by User* (on page 195).

Selection criteria

Query Cycle Times by User	
Selection criteria	Action
Rights groups	Select the rights group or groups used for CRAs that are primary in your study and click Update to update the Users list.
Users	Select specific usernames from the list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.
Date Range	<p>Enter the From and To dates or use the calendar icons to select the dates.</p> <p>Default From date: 2000-01-01</p> <p>Default To date: Current date</p>
Query Types	<p>To specify the type of queries to report on, select one of the following:</p> <ul style="list-style-type: none"> Auto—Automatic queries generated by the InForm application when a rule in the study design detects a discrepancy in the data that is entered. Manual—Manual queries created by InForm users. <p>If you leave all checkboxes blank, the report will include all of these options.</p>

Note: To include all available options in the report, leave the optional selection fields blank; that is, do not select any individual options from the drop-down lists. For the best performance, do not select any optional filters.

Sort options

Sort options are: None, Group Name, User Name, Site Mnemonic, Subject Count, Query Count, Open to Answered–Min, Open to Answered–Max, Open to Answered–Median, Answered to Closed–Min, Answered to Closed–Max, Answered to Closed–Median, Open to Closed–Min, Open to Closed–Max, Open to Closed–Median.

Use the Sort drop-down lists to change any of the default selections.

Query Cycle Times by User	
Sort	Default selection
First level	Group Name
Second level	User Name
Third level	Site Mnemonic

Report/Graph page: Query Cycle Times by User

Subtotals and totals

- **Subtotals**—By User Name and Rights Group.
Min—Lowest minimum value for any site for this user.
Max—Highest maximum value for any site for this user.
Median—No value.
- **Totals**—Overall query cycle time totals.
Min—Lowest minimum value for any site for this user.
Max—Highest maximum value for any site for this user.
Median—No value.

Column descriptions

Query Cycle Times by User	
Column	Description
Rights Group	<p>Data displayed: String</p> <p>Description: The InForm rights group to which the user belongs.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
User Name	<p>Data displayed: String</p> <p>Description: Username of the user.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Query Cycle Times by User	
Column	Description
Subject Count	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who have enrolled at the site.</p> <p>How calculated: For each site, counts subjects that have been enrolled in the InForm application. This count includes subjects who have enrolled and have moved on to other states, such as Randomized, Dropped Out, or Complete.</p> <p>Note: The Enrollment form, designed according to InForm specifications, must be completed for the subject.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Status is determined by value on the InForm Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p>
Query Count	<p>Data displayed: Numeric</p> <p>Description: The total number of number of open, answered, and closed queries.</p> <p>How calculated: This calculation counts all open, closed, and answered queries based on the Query Type filter specified on the report prompt page. This count does not include queries that have never been opened (candidate queries or deleted candidate queries).</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Query Cycle Times by User	
Column	Description
Open to Answered (Days): Min, Max, Median	<p>Data displayed: Numeric</p> <p>Description: Data on the number of days from when queries are opened to when they are answered. For each user, the column displays:</p> <ul style="list-style-type: none"> • Minimum—The fewest number of days for an opened query to be answered for this user. • Maximum—The greatest number of days for an opened query to be answered for this user. • Median—The median of the opened-to-answered range for all answered queries for this user. <p>How calculated: The calculation begins on the first day when the status of a query was set to Open and ends on the most recent day when the status of a query was set to Answered. This value is calculated in multiples of 24 (hours) and is rounded down to the nearest whole number.</p> <p>For example, if a query is opened on day 1 at 10 a.m. and answered on day 3 at 9 a.m., the Open to Answered value is 1 day.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Answered to Closed (Days): Min, Max, Median	<p>Data displayed: Numeric</p> <p>Description: Data on the number of days from when queries are answered to when they are closed. For each user, the column displays:</p> <ul style="list-style-type: none"> • Minimum—The fewest number of days for an answered query to be closed for this user. • Maximum—The greatest number of days for an answered query to be closed for this user. • Median—The median of the answered-to-closed range for all closed queries for this user. <p>How calculated: The calculation begins on the first day when the status of a query was set to Answered and ends on the most recent day when the status of a query was set to Closed. This value is calculated in multiples of 24 (hours) and is rounded down to the nearest whole number.</p> <p>For example, if a query is answered on day 1 at 10 a.m. and closed on day 3 at 9 a.m., the Answered to Closed value is 1 day.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Query Cycle Times by User	
Column	Description
Open to Closed (Days): Min, Max, Median	<p>Data displayed: Numeric</p> <p>Description: Data on the number of days from when queries are opened to when they are closed. For each user, the column displays:</p> <ul style="list-style-type: none">• Minimum—The fewest number of days for an opened query to be closed for this user.• Maximum—The greatest number of days for an opened query to be closed for this user.• Median—The median of the opened- to-closed range for all closed queries for this user. <p>How calculated: The calculation begins on the first day when the status of a query was set to Open and ends on the most recent day when the status of a query was set to Closed. This value is calculated in multiples of 24 (hours) and is rounded down to the nearest whole number.</p> <p>For example, if a query is opened on day 1 at 10 a.m. and closed on day 3 at 9 a.m., the Answered to Closed value is 1 day.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Query Performance Summary by Site

This report provides a summary collection of query statistics: the volume of queries by CRF and CRB, the average and range of days to resolve, and the current ages of unresolved queries.

The report lists only sites that have open queries.

Selection criteria: Query Performance Summary by Site

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: Query Performance Summary by Site* (on page 200).

Selection criteria

Query Performance Summary by Site	
Selection criteria	Action
Countries	To report on specific countries, select their names from the list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.
Query Types	<p>To specify the type of queries to report on, select one of the following:</p> <ul style="list-style-type: none"> • Auto—Automatic queries generated by the InForm application when a rule in the study design detects a discrepancy in the data that is entered. • Manual—Manual queries created by InForm users. <p>If you leave all checkboxes blank, the report will include both of these options.</p>
Aging interval	<p>Enter a time duration (in days) to be used as the aging interval. The resulting report uses the aging interval to show how many open queries have been open for specific numbers of days.</p> <p>For example, if you specify 7, the resulting report shows the number of open queries that have been open for:</p> <ul style="list-style-type: none"> • Seven or fewer days. • More than 7 but fewer than 14 days. • More than 14 but fewer than 21 days. • More than 21 but fewer than 28 days. • More than 28 days.

Note: To include all available options in the report, leave the optional selection fields blank; that is, do not select any individual options from the drop-down lists. For the best performance, do not select any optional filters.

Sort options

Sort options are: None, Country, Site Mnemonic, Enrolled Count, Queries/CRB Max, Queries/CRB Median, Queries/CRF Max, Queries/CRF Median, Resolve Days Min, Resolve Days Max, Resolve Days Median, Days Period 1, Days Period 2, Days Period 3, Days Period 4, Days Period 5.

Use the Sort drop-down lists to change any of the default selections.

Query Performance Summary by Site	
Sort	Default selection
First level	Country
Second level	Site Mnemonic
Third level	None

Report/Graph page: Query Performance Summary by Site

Graphs

A bar graph appears on the first page of the Query Performance Summary by Site report, plotting the median query count for casebooks and forms by site and by country.

A second graph shows the median days to resolve queries, by site within country.

A third graph shows the median days queries have been open, by site within country.

Subtotals and totals

- **Subtotals**—By Country.
- **Totals**—Overall query count totals.

Column descriptions

Query Performance Summary by Site	
Column	Description
Country	<p>Data displayed: String</p> <p>Description: Country in which a site is located, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Query Performance Summary by Site	
Column	Description
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Enrolled	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who have enrolled at the site.</p> <p>How calculated: For each site, counts subjects that have been enrolled in the InForm application. This count includes subjects who have enrolled and have moved on to other states, such as Randomized, Dropped Out, or Complete.</p> <p>Note: The Enrollment form, designed according to InForm specifications, must be completed for the subject.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Status is determined by value on the InForm Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p>
Queries per CRB	<p>Data displayed: Numeric</p> <p>Description: The maximum and median number of all queries per casebook for all enrolled subjects within each site.</p> <p>How calculated: For each site, this calculation counts manual, automatic, or both types of queries based on the Query Type filter specified on the report prompt page. This count includes all queries, regardless of status. This calculation includes all subjects who were ever enrolled, regardless of current status.</p> <p>For each site, the column displays:</p> <ul style="list-style-type: none"> • Maximum—The maximum number of all queries per case book for all enrolled subjects at the site. • Median—The median number of all queries per case book for all enrolled subjects at the site. <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Query Performance Summary by Site	
Column	Description
Queries per CRF	<p>Data displayed: Numeric</p> <p>Description: The maximum and median number of all queries per form for all started forms for all enrolled subjects within each site.</p> <p>How calculated: For each site, this calculation counts manual, automatic, or both types of queries based on the Query Type filter specified on the report prompt page. This count includes all queries, regardless of status. This calculation includes all started clinical forms.</p> <p>For each site, the report displays:</p> <ul style="list-style-type: none"> • Maximum—The maximum number of all queries per form for all started forms at the site. • Median—The median number of all queries per form for all started forms at the site. <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Days to Resolve (Open to Close)	<p>Data displayed: Numeric</p> <p>Description: The minimum, maximum, and median number of days for queries to be opened and closed.</p> <p>How calculated: For each query, the calculation starts on the first date when the status of the query was set to Open and ends on the most recent date when the status of the query was set to Closed. The number of days from the Open to the Closed state is rounded down to the nearest whole number.</p> <p>For example, if a query is opened on day 1 at 10 a.m. and closed on day 3 at 9 a.m., the Answered to Closed value is 1 day.</p> <p>For each site, columns display:</p> <ul style="list-style-type: none"> • Minimum—The fewest number of days taken for a query to be opened and closed at the site. • Maximum—The maximum number of days taken for a query to be opened and closed at the site. • Median—The median number of days for all queries at the site. <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Query Performance Summary by Site	
Column	Description
Days Open	<p>Data displayed: Numeric</p> <p>Description: For each site, the average number of days that open queries have been in the open state.</p> <p>How calculated: This calculation applies only to queries with a current status of Open. The calculation begins on the date when a query was last opened and ends on the current date.</p> <p>This value is calculated in multiples of 24 (hours). For example, if the query is opened at 10 a.m. on day 1 and the report is run 10 days later at 9 a.m., the days open is 9.</p> <p>You specify the aging interval (in days) on the report prompt page.</p> <p>For example, if you specify 7, the resulting report shows the number of queries that have been open for:</p> <ul style="list-style-type: none"> • Seven or fewer days. • More than 7 but equal to or fewer than 14 days. • More than 14 but equal to or fewer than 21 days. • More than 21 but equal to or fewer than 28 days. • More than 28 days. <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Query Performance Summary by User

This report provides a summary collection of query statistics: the volume of queries by CRF and CRB, the average and range of days to resolve, and the current ages of unresolved queries.

Selection criteria: Query Performance Summary by User

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- ***Running a standard report from the Reporting and Analysis portal*** (on page 167).
- ***Running a standard report in a new window*** (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see ***Report/Graph page: Query Performance Summary by User*** (on page 205).

Selection criteria

Query Performance Summary by User	
Selection criteria	Action
Rights groups	Select the rights group or groups used for CRAs that are primary in your study and click Update to update the Users list.
Users	To report on specific users, select them from the drop-down list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.
Query Types	<p>To specify the type of queries to report on, select one of the following:</p> <ul style="list-style-type: none"> • Auto—Automatic queries generated by the InForm application when a rule in the study design detects a discrepancy in the data that is entered. • Manual—Manual queries created by InForm users. <p>If you leave all checkboxes blank, the report will include all of these options.</p>
Aging Interval	<p>Enter a time duration (in days) to be used as the aging interval. The resulting report uses the aging interval to show how many open queries have been open for specific numbers of days.</p> <p>For example, if you specify 7, the resulting report shows the number of open queries that have been open for:</p> <ul style="list-style-type: none"> • Seven or fewer days. • More than 7 but fewer than 14 days. • More than 14 but fewer than 21 days. • More than 21 but fewer than 28 days. • More than 28 days.

Note: To include all available options in the report, leave the optional selection fields blank; that is, do not select any individual options from the drop-down lists. For the best performance, do

not select any optional filters.

Sort options

Sort options are: None, Rights Group, User Name, Site Mnemonic, Enrolled Count, Queries/CRB Max, Queries/CRB Median, Queries/CRF Max, Queries/CRF Median, Resolve Days Min, Resolve Days Max, Resolve Days Median, Days Period 1, Days Period 2, Days Period 3, Days Period 4, Days Period 5.

Use the Sort drop-down lists to change any of the default selections.

Query Performance Summary by User	
Sort	Default selection
First level	Group Name
Second level	User Name
Third level	Site Mnemonic

Report/Graph page: Query Performance Summary by User

Subtotals and totals

- **Subtotals**—By User Name and Rights Group.
- **Totals**—Overall query count totals.

Column descriptions

Query Performance Summary by User	
Column	Description
Rights Group	<p>Data displayed: String</p> <p>Description: The InForm rights group to which the user belongs.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
User Name	<p>Data displayed: String</p> <p>Description: Username of the user.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Query Performance Summary by User	
Column	Description
Enrolled	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who have enrolled at the site.</p> <p>How calculated: For each site, counts subjects that have been enrolled in the InForm application. This count includes subjects who have enrolled and have moved on to other states, such as Randomized, Dropped Out, or Complete.</p> <p>Note: The Enrollment form, designed according to InForm specifications, must be completed for the subject.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Status is determined by value on the InForm Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p>
Queries per CRB	<p>Data displayed: Numeric</p> <p>Description: The maximum and median number of all queries per casebook for all enrolled subjects within each site.</p> <p>How calculated: For each site, this calculation counts manual, automatic, or both types of queries based on the Query Type filter specified on the report prompt page. This count includes all queries, regardless of status. This calculation includes all subjects who were ever enrolled, regardless of current status.</p> <p>For each site, the column displays:</p> <ul style="list-style-type: none">• Maximum—The maximum number of all queries per case book for all enrolled subjects at the site.• Median—The median number of all queries per case book for all enrolled subjects at the site. <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Query Performance Summary by User	
Column	Description
Queries per CRF	<p>Data displayed: Numeric</p> <p>Description: The maximum and median number of all queries per form for all started forms for all enrolled subjects within each site.</p> <p>How calculated: For each site, this calculation counts manual, automatic, or both types of queries based on the Query Type filter specified on the report prompt page. This count includes all queries, regardless of status. This calculation includes all started clinical forms.</p> <p>For each site, the report displays:</p> <ul style="list-style-type: none"> • Maximum—The maximum number of all queries per form for all started forms at the site. • Median—The median number of all queries per form for all started forms at the site. <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Days to Resolve (Open to Close)	<p>Data displayed: Numeric</p> <p>Description: The minimum, maximum, and median number of days for queries to be opened and closed.</p> <p>How calculated: For each query, the calculation starts on the first date when the status of the query was set to Open and ends on the most recent date when the status of the query was set to Closed. The number of days from the Open to the Closed state is rounded down to the nearest whole number.</p> <p>For example, if a query is opened on day 1 at 10 a.m. and closed on day 3 at 9 a.m., the Answered to Closed value is 1 day.</p> <p>For each site, columns display:</p> <ul style="list-style-type: none"> • Minimum—The fewest number of days taken for a query to be opened and closed at the site. • Maximum—The maximum number of days taken for a query to be opened and closed at the site. • Median—The median number of days for all queries at the site. <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Query Performance Summary by User	
Column	Description
Days Open	<p>Data displayed: Numeric</p> <p>Description: For each site, the average number of days that open queries have been in the open state.</p> <p>How calculated: This calculation applies only to queries with a current status of Open. The calculation begins on the date when a query was last opened and ends on the current date.</p> <p>This value is calculated in multiples of 24 (hours). For example, if the query is opened at 10 a.m. on day 1 and the report is run 10 days later at 9 a.m., the days open is 9.</p> <p>You specify the aging interval (in days) on the report prompt page.</p> <p>For example, if you specify 7, the resulting report shows the number of queries that have been open for:</p> <ul style="list-style-type: none">• Seven or fewer days.• More than 7 but equal to or fewer than 14 days.• More than 14 but equal to or fewer than 21 days.• More than 21 but equal to or fewer than 28 days.• More than 28 days. <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Query Status by Site

This report shows the current total queries in each state by site, subject, and visit. This report can also show the number of queries that entered a given state within a specified time period.

Selection criteria: Query Status by Site report

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: Query Status by Site* (on page 210).

Selection criteria

Query Status by Site	
Selection criteria	Action
Countries	To report on specific countries, select their names from the list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.
Query type	<p>To specify the type of queries to report on, select one of the following:</p> <ul style="list-style-type: none"> • Auto—Automatic queries generated by the InForm application when a rule in the study design detects a discrepancy in the data that is entered. • Manual—Manual queries created by InForm users. <p>If you leave all checkboxes blank, the report will include both of these options.</p>

Note: To include all available options in the report, leave the optional selection fields blank; that is, do not select any individual options from the drop-down lists. For the best performance, do not select any optional filters.

Sort options

Sort options are: None, Country, Site Mnemonic, Subject Count, Candidate Query Count, Deleted Query Count, Open Query Count, Answered Query Count, Closed Query Count, % Total within Country.

Use the Sort drop-down lists to change any of the default selections.

Query Status by Site	
Sort	Default selection
First level	Country
Second level	Site Mnemonic

Query Status by Site	
Sort	Default selection
Third level	None

Report/Graph page: Query Status by Site

Subtotals and totals

- **Subtotals**—By Country
- **Totals**—Overall query count totals

Drill down reports

This report contains links to two drill down reports:

- Click the value in the Site Mnemonic column to drill down to Query Status by Site and Visit report for the site.
- Click the value in the Subject Count column to drill down to the Query Status by Site and Subject report for the subject.

Column descriptions

Query Status by Site	
Column	Description
Country	<p>Data displayed: String</p> <p>Description: Country in which a site is located, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Query Status by Site	
Column	Description
Subject Count	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who have enrolled at the site.</p> <p>How calculated: For each site, counts subjects that have been enrolled in the InForm application. This count includes subjects who have enrolled and have moved on to other states, such as Randomized, Dropped Out, or Complete.</p> <p>Note: The Enrollment form, designed according to InForm specifications, must be completed for the subject.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Status is determined by value on the InForm Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p>
Avg Queries per Patient	<p>Data displayed: Numeric</p> <p>Description: The average number of queries associated with each subject at the site.</p> <p>How calculated: Counts the average number of unique queries per subject for the site, regardless of status, by dividing the number of queries for the site by the subject count for the site. This calculation counts manual, automatic, or both types of queries, based on your selection for the Query Types prompt.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Query Count: Candidate	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of queries with a current status of candidate.</p> <p>How calculated: Counts queries with the current status of Candidate. Counts manual, automatic, or both types of candidate queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Deleted	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of queries with a current status of Deleted.</p> <p>How calculated: Counts queries with a current status of Deleted. Counts manual, automatic, or both types of deleted queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Query Status by Site	
Column	Description
Query Count: Open	<p>Data displayed: Numeric</p> <p>Description: For each site and visit, the number of queries with a current status of Open.</p> <p>How calculated: Counts all open queries for each site. Counts manual, automatic, or both, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Answered	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of queries with a current status of Answered.</p> <p>How calculated: Counts all answered queries for each site. Counts manual, automatic, or both types of answered queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Closed	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of queries with a current status of Closed.</p> <p>How calculated: Counts all closed queries for each site. Counts automatic, manual, or both types of closed queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Total (% of Total within Country)	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The total number of queries at the site, regardless of status. For each site total, this column also displays the percentage of total queries for the country at the site.</p> <p>How calculated: Counts automatic, manual, or both types of closed queries, based on your selection in the Query Type filter on the report prompt page. The percentage is calculated as follows:</p> <p>$[\% \text{ of total within country}] = [\text{query count for the site}] * 100 / [\text{query count for the country}]$</p> <p>Data source: Derived and stored in the Reporting and Analysis database. Percentage derived for display.</p>

Query Status by Site and Subject

This report shows CRAs and trial managers the number of queries to date in each query state for one or more subjects within selected sites. This report is a drill-through target for the Query Status by Site and Query Status by User reports.

Selection criteria: Query Status by Site and Subject

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: Query Status by Site and Subject* (on page 214).

Selection criteria

Query Status by Site and Subject	
Selection criteria	Action
Countries	To report on specific countries, select their names from the list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.
Subjects	Select specific subjects from the list.
Query Type	<p>To specify the type of queries to report on, select one of the following:</p> <ul style="list-style-type: none"> • Auto—Automatic queries generated by the InForm application when a rule in the study design detects a discrepancy in the data that is entered. • Manual—Manual queries created by InForm users. <p>If you leave all checkboxes blank, the report will include both of these options.</p>

Note: To include all available options in the report, leave the optional selection fields blank; that is, do not select any individual options from the drop-down lists. For the best performance, do not select any optional filters.

Sort options

Sort options are: None, Country, Site Mnemonic, Subject Number, Current Status, Started Visits Count, Candidate Query Count, Deleted Query Count, Open Query Count, Answered Query Count, Closed Query Count, % of all Queries.

Use the Sort drop-down lists to change any of the default selections.

Query Status by Site and Subject	
Sort	Default selection
First level	Country
Second level	Site mnemonic
Third level	Subject Number

Report/Graph page: Query Status by Site and Subject

Subtotals and totals

- **Subtotals**—By Site and Country.
- **Totals**—Overall query count totals.

Column descriptions

Query Status by Site and Subject	
Column	Description
Country	<p>Data displayed: String</p> <p>Description: Country in which a site is located, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Query Status by Site and Subject	
Column	Description
Subject Number	<p>Data displayed: String</p> <p>Description: The subject number, followed by the subject initials.</p> <p>The subject number identifies the subject. The subject number and subject initials can be changed post enrollment, if this is configured in the study.</p> <p>Note: Subject number may or may not be unique at your site.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Current Status	<p>Data displayed: String</p> <p>Description: The current status for the subject, which must be <i>enrolled</i>. (This report includes data for only enrolled subjects.)</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Started Visits Count	<p>Data displayed: Numeric</p> <p>Description: For each subject, the number of visits that have a current status of started.</p> <p>How calculated: For each subject, a visit is counted as started if at least one expected form in the visit has been started. A form is started when any data, queries, or comments have been entered on the form.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Candidate	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of queries with a current status of candidate.</p> <p>How calculated: Counts queries with the current status of Candidate. Counts manual, automatic, or both types of candidate queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Deleted	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of queries with a current status of Deleted.</p> <p>How calculated: Counts queries with a current status of Deleted. Counts manual, automatic, or both types of deleted queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Query Status by Site and Subject	
Column	Description
Query Count: Open	<p>Data displayed: Numeric</p> <p>Description: For each site and visit, the number of queries with a current status of Open.</p> <p>How calculated: Counts all open queries for each site. Counts manual, automatic, or both, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Answered	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of queries with a current status of Answered.</p> <p>How calculated: Counts all answered queries for each site. Counts manual, automatic, or both types of answered queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Closed	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of queries with a current status of Closed.</p> <p>How calculated: Counts all closed queries for each site. Counts automatic, manual, or both types of closed queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Total (% of Queries within Country)	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The total number of queries at the site, regardless of status. For each site total, this column also displays the percentage of total queries for the country at the site.</p> <p>How calculated: Counts automatic, manual, or both types of closed queries, based on your selection in the Query Type filter on the report prompt page. The percentage is calculated as follows:</p> <p>$[\% \text{ of total within country}] = [\text{query count for the site}] * 100 / [\text{query count for the country}]$</p> <p>Data source: Derived and stored in the Reporting and Analysis database. Percentage derived for display.</p>

Query Status by Site and Visit

This report shows CRAs and trial managers the number of queries to date in each query state for one or more visits for selected sites. This report is a drill-through target for the Query Status by Site and Query Status by User reports.

Only countries and sites with subject queries appear in the report.

Selection criteria: Query Status by Site and Visit

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: Query Status by Site and Visit* (on page 218).

Selection criteria

Query Status by Site and Visit	
Selection criteria	Action
Countries	To report on specific countries, select their names from the list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.
Visits	Select a visit from the list.
Query type	<p>To specify the type of queries to report on, select one of the following:</p> <ul style="list-style-type: none"> • Auto—Automatic queries generated by the InForm application when a rule in the study design detects a discrepancy in the data that is entered. • Manual—Manual queries created by InForm users. <p>If you leave all checkboxes blank, the report will include both of these options.</p>

Note: To include all available options in the report, leave the optional selection fields blank; that is, do not select any individual options from the drop-down lists. For the best performance, do not select any optional filters.

Sort options

Sort options are: None, Country, Site Mnemonic, Visit Order, Subject Count, Candidate Query Count, Deleted Query Count, Open Query Count, Answered Query Count, Closed Query

Count, % of all Queries.

Use the Sort drop-down lists to change any of the default selections.

Query Status by Site and Visit	
Sort	Default selection
First level	Country
Second level	Site Mnemonic
Third level	Visit Order

Report/Graph page: Query Status by Site and Visit

Subtotals and totals

- **Subtotals**—By Site and Country.
- **Totals**—Overall query count totals.

Column descriptions

Query Status by Site and Visit	
Column	Description
Country	<p>Data displayed: String</p> <p>Description: Country in which a site is located, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Query Status by Site and Visit	
Column	Description
Subject Count	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who have enrolled at the site.</p> <p>How calculated: For each site, counts subjects that have been enrolled in the InForm application. This count includes subjects who have enrolled and have moved on to other states, such as Randomized, Dropped Out, or Complete.</p> <p>Note: The Enrollment form, designed according to InForm specifications, must be completed for the subject.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Status is determined by value on the InForm Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p>
Visit Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation of the visit title, as specified in trial design code. For CRF visits, this name appears at the top of a collection of forms in the visit timeline. The visit mnemonic may not be a unique identifier.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Query Count: Candidate	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of queries with a current status of candidate.</p> <p>How calculated: Counts queries with the current status of Candidate. Counts manual, automatic, or both types of candidate queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Deleted	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of queries with a current status of Deleted.</p> <p>How calculated: Counts queries with a current status of Deleted. Counts manual, automatic, or both types of deleted queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Query Status by Site and Visit	
Column	Description
Query Count: Opened	<p>Data displayed: Numeric</p> <p>Description: For each site and visit, the number of queries with a current status of Open.</p> <p>How calculated: Counts all open queries for each site. Counts manual, automatic, or both, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Answered	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of queries with a current status of Answered.</p> <p>How calculated: Counts all answered queries for each site. Counts manual, automatic, or both types of answered queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Closed	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of queries with a current status of Closed.</p> <p>How calculated: Counts all closed queries for each site. Counts automatic, manual, or both types of closed queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Total (% Queries within Country)	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The total number of queries at the site, regardless of status. For each site total, this column also displays the percentage of total queries for the country at the site.</p> <p>How calculated: Counts automatic, manual, or both types of closed queries, based on your selection in the Query Type filter on the report prompt page. The percentage is calculated as follows:</p> <p>$[\% \text{ of total within country}] = [\text{query count for the site}] * 100 / [\text{query count for the country}]$</p> <p>Data source: Derived and stored in the Reporting and Analysis database. Percentage derived for display.</p>

Query Status by User

This report shows CRAs and trial managers the raw numbers of queries to date in each query state for one or more sites, by user, with the option to drill-down into the list of queries for visits and subjects for a specific site.

Selection criteria: Query Status by User

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- ***Running a standard report from the Reporting and Analysis portal*** (on page 167).
- ***Running a standard report in a new window*** (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see ***Report/Graph page: Query Status by User*** (on page 222).

Selection criteria

Query Status by User	
Selection criteria	Action
Rights groups	Select one or more rights groups from the list and click Update to update the Users list.
Users	To report on specific users, select them from the drop-down list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.
Query types	<p>Select one or more options to filter the report to include only these queries:</p> <ul style="list-style-type: none"> • Auto—Automatic queries generated by the InForm application when a rule in the study design detects a discrepancy in the data that is entered. • Manual—Manual queries created by InForm users. <p>If you leave all checkboxes blank, the report will include all of these options.</p>

Note: To include all available options in the report, leave the optional selection fields blank; that is, do not select any individual options from the drop-down lists. For the best performance, do not select any optional filters.

Sort options

Sort options are: None, Rights Group, User Name, Site Mnemonic, Subject Count, Candidate Query Count, Deleted Query Count, Open Query Count, Answered Query Count, Closed Query

Count, % Total within Country.

Use the Sort drop-down lists to change any of the default selections.

Query Status by User	
Sort	Default selection
First level	Rights Group
Second level	User Name
Third level	Site Mnemonic

Use the sort drop-down lists to change any of these selections.

Report/Graph page: Query Status by User

Subtotals and totals

- **Subtotals**—None.
- **Totals**—Overall query count totals.

Drill-through reports

This report contains links to two drill-through reports:

- Click the value in the site mnemonic column to drill down to the Query Status by Site and Visit report for the selected site.
- Click the value in Subject Count column to drill down to the Query Status by Site and Subject report for the subjects included in the count.

Column descriptions

Query Status by User	
Column	Description
Rights Group	<p>Data displayed: String</p> <p>Description: Rights group to which the user belongs.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
User Name	<p>Data displayed: String</p> <p>Description: Username of the user.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Query Status by User	
Column	Description
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Subject Count	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who have ever participated in the study.</p> <p>How calculated: All subjects, regardless of status, are included in this count. This count includes all screened, enrolled, randomized, dropped, and completed subjects.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p> <p>Note: You can use any of the predefined subject filters to further qualify this count.</p>
Avg Queries per Patient	<p>Data displayed: Numeric</p> <p>Description: The average number of queries associated with each subject at the site.</p> <p>How calculated: Counts the average number of unique queries per subject for the site, regardless of status, by dividing the number of queries for the site by the subject count for the site. This calculation counts manual, automatic, or both types of queries, based on your selection for the Query Types prompt.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Query Count: Candidate	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of queries with a current status of candidate.</p> <p>How calculated: Counts queries with the current status of Candidate. Counts manual, automatic, or both types of candidate queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Query Status by User	
Column	Description
Query Count: Deleted	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of queries with a current status of Deleted.</p> <p>How calculated: Counts queries with a current status of Deleted. Counts manual, automatic, or both types of deleted queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Open	<p>Data displayed: Numeric</p> <p>Description: The number of queries that were opened in a given month.</p> <p>How calculated: Counts all open queries for each site. Counts manual, automatic, or both, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Query Count: Answered	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of queries with a current status of Answered.</p> <p>How calculated: Counts all answered queries for each site. Counts manual, automatic, or both types of answered queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Query Count: Closed	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of queries with a current status of Closed.</p> <p>How calculated: Counts all closed queries for each site. Counts automatic, manual, or both types of closed queries, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Query Status by User	
Column	Description
Query Count: Total (% of all Queries)	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The total number of queries at the site, regardless of status. For each site total, this column also displays the percentage of total queries for the country at the site.</p> <p>How calculated: Counts automatic, manual, or both types of closed queries, based on your selection in the Query Type filter on the report prompt page. The percentage is calculated as follows:</p> $[\% \text{ of total within country}] = [\text{query count for the site}] * 100 / [\text{query count for the country}]$ <p>Data source: Derived and stored in the Reporting and Analysis database. Percentage derived for display.</p>

Query Volume by Month by Site

This report shows and plots the number of queries opened, answered, and closed in each month for a range of months. Use the report to see if query volume or query handling is changing negatively over the course of a trial.

Selection criteria: Query Volume by Month by Site

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: Query Volume by Month by Site* (on page 227).

Selection criteria

Query Volume by Month by Site	
Selection criteria	Action
Countries	To report on specific countries, select their names from the list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.

Query Volume by Month by Site	
Selection criteria	Action
Query status	<p>To filter the report by query status, select one or more of the following options:</p> <ul style="list-style-type: none"> • Open—Query status is Open. • Answered—Query status is Answered. • Closed—Query status is Closed. <p>If you leave all checkboxes blank, the report will include all these options.</p>
Limit to Reissued	<p>To filter the report to include data for queries in the Reissued Queries state, select this option. The results will be limited to reissued queries only.</p>
Query type	<p>To specify the type of queries to report on, select one of the following:</p> <ul style="list-style-type: none"> • Auto—Automatic queries generated by the InForm application when a rule in the study design detects a discrepancy in the data that is entered. • Manual—Manual queries created by InForm users. <p>If you leave all checkboxes blank, the report will include all of these options.</p>
Date range	<ul style="list-style-type: none"> • To specify the date range, enter the From and To dates, or use the calendar icons to select the dates. • To automatically select the earliest and latest possible dates, use the Earliest Date and Latest Date radio buttons. <p>The resulting report shows query volume for the specified date range.</p>

Note: To include all available options in the report, leave the optional selection fields blank; that is, do not select any individual options from the drop-down lists. For the best performance, do not select any optional filters.

Sort options

Sort options are: None, Country, Site Mnemonic.

Use the Sort drop-down lists to change any of the default selections.

Query Volume by Month by Site	
Sort	Default selection
First level	Country
Second level	Site Mnemonic
Third level	None

Use the sort drop-down lists to change any of these selections.

Report/Graph page: Query Volume by Month by Site

Graphs

A bar graph appears on the first page of the report, plotting the query volume by month and site.

Subtotals and totals

- **Subtotals**—By Country.
- **Totals**—Overall query count totals.

Column descriptions

Query Volume by Month by Site	
Column	Description
Country	<p>Data displayed: String</p> <p>Description: Country in which a site is located, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Query Volume by Month by Site	
Column	Description
Open Counts by Month	<p>Data displayed: Numeric</p> <p>Description: The number of queries that were opened in a given month.</p> <p>How calculated: Counts all open queries for each site. Counts manual, automatic, or both, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Answered Counts by Month	<p>Data displayed: Numeric</p> <p>Description: The number of queries that were answered in a given month.</p> <p>How calculated: A query is counted if it has been answered in a given month. This calculation counts queries based on the Query Status and Query State filters on the report prompt page.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Closed Counts by Month	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of queries that were closed in a given month.</p> <p>How calculated: A query is counted if it has a status of closed in a given month. This calculation counts queries based on the Query Status and Query State filters on the report prompt page.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Totals by Month	<p>Data displayed: Numeric</p> <p>Description: For each site, the total number of open, answered, and closed queries in a given month.</p> <p>How calculated: The value displayed in this column is the sum of the values in the Open, Ans'd, and Closed columns.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Query Volume by Month by User

This report shows and plots the number of queries opened, answered, and closed in each month for a range of months.

Selection criteria: Query Volume by Month by User prompt page

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: Query Volume by Month by User* (on page 230).

Selection criteria

Query Volume by Month by User	
Selection criteria	Action
Rights groups	Select one or more rights groups from the list and click Update to update the Users list.
Users	To report on specific users, select them from the drop-down list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.
Limit to Reissued	To filter the report to include data for queries in the Reissued Queries state, select this option. The results will be limited to reissued queries only.
Query state	To filter the report to include data for queries in the Reissued Queries state, select this option. The results will be limited to reissued queries only.
Query type	<p>Select one or more options to filter the report to include only these queries:</p> <ul style="list-style-type: none"> • Auto—Automatic queries generated by the InForm application when a rule in the study design detects a discrepancy in the data that is entered. • Manual—Manual queries created by InForm users. <p>If you leave all checkboxes blank, the report will include all of these options.</p>

Query Volume by Month by User	
Selection criteria	Action
Date range	<p>Enter the From and To dates or use the calendar icons to select the dates.</p> <p>Default From date: 2000-01-01</p> <p>Default To date: Current date</p> <p>The resulting report shows query volume for the specified date range.</p>

Sort options

Query Volume by Month by User	
Sort	Default selection
First level	Rights Group
Second level	User Name
Third level	Site Mnemonic

Use the sort drop-down lists to change any of these selections.

Report/Graph page: Query Volume by Month by User

Subtotals and totals

- **Subtotals**—None.
- **Totals**—Overall query count totals.

Column descriptions

Query Volume by Month by User	
Column	Description
Rights Group	<p>Data displayed: String</p> <p>Description: The InForm rights group to which the user belongs.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Query Volume by Month by User	
Column	Description
Open counts by Month	<p>Data displayed: Numeric</p> <p>Description: The number of queries that were opened in a given month.</p> <p>How calculated: Counts all open queries for each site. Counts manual, automatic, or both, based on your selection in the Query Type filter on the report prompt page.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Answered counts by Month	<p>Data displayed: Numeric</p> <p>Description: The number of queries that were answered in a given month.</p> <p>How calculated: A query is counted if it has been answered in a given month. This calculation counts queries based on the Query Status and Query State filters on the report prompt page.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Closed counts by Month	<p>Data displayed: Numeric</p> <p>Description: The number of queries that were answered in a given month.</p> <p>How calculated: A query is counted if it has been answered in a given month. This calculation counts queries based on the Query Status and Query State filters on the report prompt page.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Totals	<p>Data displayed: Numeric</p> <p>Description: The total number of open, answered, and closed queries for each month.</p> <p>How calculated: For each site, this calculation adds open, answered, and closed queries for each month.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Query Volume by Rule

This report shows the number of times that each rule triggered a query. This information can help a trial designer identify problem areas as well as unnecessary query rules.

Selection criteria: Query Volume by Rule report

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: Query Volume by Rule* (on page 233).

Selection criteria

Query Volume by Rule	
Selection criteria	Action
Rule trigger count	<p>Select a trigger count range for your report. The trigger count is the number of times a rule triggered a query in the InForm application.</p> <p>Use the radio buttons to do the following:</p> <ul style="list-style-type: none"> • Specify a From and To value. • Select the lowest and highest trigger counts in the study by using the data in the Lowest value and Highest value fields. <p>Default: Lowest to highest value</p> <p>Note: If no selection is made, the bar graph will be hard to read because rule names are very long. Phase Forward recommends that you specify From and To values.</p>

Sort options

Sort options are: None, Rule Name, Form Mnemonic, Item Name, Trigger Count, % of Total Trigger Count.

Use the Sort drop-down lists to change any of the default selections.

Query Volume by Rule	
Sort	Default selection
First level	Trigger Count.

Query Volume by Rule	
Sort	Default selection
Second level	Form Mnemonic.
Third level	None.

Report/Graph page: Query Volume by Rule

Graphs

A bar graph appears on the first page of the Query Volume by Rule report, illustrating the number of times each rule triggered a query.

Subtotals and totals

- **Subtotals**—By Rule.
- **Totals**—Overall rule trigger count totals.

Column descriptions

Query Volume by Rule	
Column	Description
Rule name	<p>Data displayed: String</p> <p>Description: The name that uniquely identifies the rule in the trial design code.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Form Mnemonic	<p>Data displayed: String</p> <p>Description: Short name or abbreviation for the form, as specified in the study design code. This name appears on the Visit Navigation tab and is used to access a specific form in the InForm application.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Item Name	<p>Data displayed: String</p> <p>Description: The name that uniquely identifies the item to which the rule is attached in the study design code. This corresponds to Short Question in the Central Designer application or Itemset Column Header in the InForm application. Access to this data can be restricted in the InForm application. When users who do not have access to this data run a report with this report element, the resulting report displays a series of asterisks (*****) rather than the actual text.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Query Volume by Rule	
Column	Description
Trigger Count	<p>Data displayed: Text</p> <p>Description: The total number of times that the rule has triggered a query.</p> <p>How calculated: Counts rules that have triggered a query.</p> <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

Subject Counts with Outstanding Queries

This report shows the number of subjects at each site that have open or answered queries at a specified time. The report includes countries and sites regardless of whether they have subjects or queries.

Selection criteria: Subject Counts with Outstanding Queries report

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: Subject Counts with Outstanding Queries* (on page 235).

Selection criteria

Subject Counts with Outstanding Queries	
Selection criteria	Action
Countries	To report on specific countries, select their names from the list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.
Query Type	<p>To specify the type of queries to report on, select one of the following:</p> <ul style="list-style-type: none"> • Auto—Automatic queries generated by the InForm application when a rule in the study design detects a discrepancy in the data that is entered. • Manual—Manual queries created by InForm users. <p>If you leave all checkboxes blank, the report will include all of these options.</p>

Subject Counts with Outstanding Queries	
Selection criteria	Action
Minimum Days 'Open' or 'Answered'	Specify the minimum number of days a query must be opened or answered to be included in this report. Default: 0 (days)

Note: To include all available options in the report, leave the optional selection fields blank; that is, do not select any individual options from the drop-down lists. For the best performance, do not select any optional filters.

Sort options

Sort options are: None, Country, Site Mnemonic, Subject Count, Subjects w/Open Queries, Subjects w/Answered Queries.

Use the Sort drop-down lists to change any of the default selections.

Subject Counts with Outstanding Queries	
Sort	Default selection
First level	Country
Second level	Site Mnemonic
Third level	None

Report/Graph page: Subject Counts with Outstanding Queries

Subtotals and totals

- **Subtotals**—By Country.
- **Totals**—Overall subject count totals.

Column descriptions

Subject Counts with Outstanding Queries	
Column	Description
Country	<p>Data displayed: String</p> <p>Description: Country in which a site is located, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Subject Counts with Outstanding Queries	
Column	Description
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Subjects	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who have enrolled at the site.</p> <p>How calculated: For each site, counts subjects that have been enrolled in the InForm application. This count includes subjects who have enrolled and have moved on to other states, such as Randomized, Dropped Out, or Complete.</p> <p>Note: The Enrollment form, designed according to InForm specifications, must be completed for the subject.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Status is determined by value on the InForm Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p>
Subjects with Open Queries	<p>Data displayed: Numeric</p> <p>Description: The number of subjects with open queries.</p> <p>How calculated: Counts subjects with at least one open query against the entered data for the subject. The open query must have been open for at least the number of days that you specified in the Minimum Days Opened or Answered filter on the report prompt page. The calculation begins on the date when the query was last opened and ends on today's date. The number of days is rounded down to the nearest whole number.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Subjects with Answered Queries	<p>Data displayed: Numeric</p> <p>Description: The number of subjects with answered queries.</p> <p>How calculated: Counts subjects with at least one answered query against the entered data for the subject. The answered query must have been answered for at least the number of days that you specified in the Minimum Days Opened or Answered filter on the report prompt page. The calculation begins on the date when the query was last answered and ends on today's date. The number of days is rounded down to the nearest whole number.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Case Report Form (CRF) reports

About Case Report Form (CRF) reports

Case Report Form (CRF) reports provide information about the progress of data entry and query activity on Case Books that have been started.

CRF Aging by Site

This report shows:

- The number of forms that are expected at any point in the trial.
- The number of forms that are incomplete.
- The length of time that incomplete forms have been incomplete, beginning with the date of visit.

Note: This calculation relies on the use of specified DOV elements in the form design. For more information, see *DOV controls* (on page 26).

Selection criteria: CRF Aging by Site prompt page

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: CRF Aging by Site* (on page 240).

Selection criteria

CRF Aging by Site	
Selection criteria	Action
Countries	To report on specific countries, select their names from the list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.

CRF Aging by Site	
Selection criteria	Action
Expected forms for	<p>Filter the report by expected forms. Choose one of these options from the drop-down list.</p> <ul style="list-style-type: none"> • All forms—All clinical forms (forms of type CRF) are considered. • Scheduled visits—All expected forms that are in scheduled visits are considered. • Scheduled or started visits—All clinical forms that are in either expected or started visits are considered. • Scheduled or started visits to date—All the expected forms that are in scheduled visits whose expected start date is earlier than the report run date, and all the expected forms that are present in started visits when the actual date of the visit is on or before the report run date are considered. • Scheduled visits or started forms to date—All the expected forms that are in scheduled visits whose expected start date is on or before the report run date, and all the expected forms that were started on or before the report run date are considered.
Aging Interval	<p>Enter a time duration (in days) to be used as the aging interval. The resulting report uses the aging interval to show how many forms have been incomplete during specific ranges of calendar days after the date of visit.</p> <p>For example, if you specify 7 here, the resulting report shows the number of forms that have been incomplete for:</p> <ul style="list-style-type: none"> • Seven or fewer days after the date of visit. • More than 7 days but fewer than 14 days after the DOV. • More than 14 days but fewer than 28 days after the DOV. • More than 28 days after the DOV. <p>Default: 7 (days)</p>

CRF Aging by Site	
Selection criteria	Action
Limit to forms with	<p>To filter the report, select one or more of the following options:</p> <ul style="list-style-type: none"> • Required items—Forms that have items marked as required are considered. • SV required items—Forms that have items marked as source verification required are considered. • Outstanding queries—Forms that have open or answered queries against the form items are considered. • Comments—Forms that have either form level or item level comments are considered. <p>If you leave all checkboxes blank, this prompt is not applied. In that case, the results are determined by your selections in the previous prompts.</p> <p>If one or more checkboxes are selected, the counts are limited by the selection(s) in this prompt. Most likely, this results in decreased counts. For example, selecting both Required items and SV required items limits the report results to only those forms that have both required items and SV required items.</p>

Sort options

Sort options are: None, Country, Site Mnemonic, Subject Count, Expected Forms Count, Completed Forms Count, Incomplete Forms Count, Not Started Forms Count, % of Incomplete Forms 1st Period, % of Incomplete Forms 2nd Period, % of Incomplete Forms 3d Period, % of Incomplete Forms 4th Period, % of Incomplete Forms 5th Period.

Use the Sort drop-down lists to change any of the default selections.

CRF Aging by Site	
Sort	Default selection
First level	Country
Second level	Site Mnemonic
Third level	None

Report/Graph page: CRF Aging by Site

Subtotals and totals

- **Subtotals**—By Country.
- **Totals**—Overall form count totals.

Column descriptions

CRF Aging by Site	
Column	Description
Country	<p>Data displayed: String</p> <p>Description: Country in which a site is located, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Subject Count	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who have enrolled at the site.</p> <p>How calculated: For each site, counts subjects that have been enrolled in the InForm application. This count includes subjects who have enrolled and have moved on to other states, such as Randomized, Dropped Out, or Complete.</p> <p>Note: The Enrollment form, designed according to InForm specifications, must be completed for the subject.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Status is determined by value on the InForm Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p>
Form Counts: Expected	<p>Data displayed: Numeric</p> <p>Description: The number of expected forms in the trial.</p> <p>How calculated: This number reflects the number of expected forms for the site based on the option selected for the Expected forms for filter on the report prompt page.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

CRF Aging by Site	
Column	Description
Form Counts: Complete	<p>Data displayed: Numeric</p> <p>Description: Total count of all forms that are complete across all subjects, by visit and by site.</p> <p>How calculated: Counts forms that are expected and meet the following criteria:</p> <ul style="list-style-type: none"> • Are started. • Contain data for all required items. • Do not have open queries associated with any items on the form. • For a repeating form, the form is not in a deleted state. • For an itemset form, the form is complete even if all the instances are deleted. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Form Counts: Incomplete	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number (and percentage) of expected forms that are started but not complete.</p> <p>How calculated: For each site, calculates the following:</p> $[\text{incomplete forms count}] = [\text{started forms count}] - [\text{completed forms count}]$ $[\text{incomplete, \% of expected}] = [\text{incomplete forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Form Counts: Not Started	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number (and percentage) of expected forms that are not started in the InForm application.</p> <p>How calculated: A form is started if any data, queries or comments have been entered. Each instance of a repeating form counts as a separate started form. A dynamic form may be Activated but not Started.</p> <p>This value displays as a whole number and as the percentage of expected forms that are not started:</p> $[\text{not started, \% of expected}] = [\text{not started forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

CRF Aging by Site	
Column	Description
Incomplete (from DOV) Form Counts:	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The total count of all forms across all subjects that have been incomplete for specific ranges of calendar days after the date of visit. You specify the aging interval (in days) on the report prompt page.</p> <p>For example, if you specify 7 on the report filter page, the resulting report shows the number of forms that have been incomplete for:</p> <ul style="list-style-type: none"> • Seven or fewer days after the date of visit. • More than 7 days and less than 14 days. • More than 14 days and less than 21 days. • More than 21 days and less than 28 days. • More than 28 days. <p>How calculated: This value is displays as a whole number, followed by a percentage of the total incomplete form count. The percentage is calculated as follows:</p> $[\text{count of incomplete forms within the aging interval}] * 100 / [\text{count of incomplete forms}]$ <p>Note: This report element assumes that your trial has been developed using a specific design for DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

CRF Aging by User

This report shows how many forms are expected at any point in the trial as well as how many are incomplete. It also shows how long incomplete forms have been incomplete beginning with the date of visit.

This calculation relies on the use of specified DOV elements in the form design. For more information, see *DOV controls* (on page 26).

Note: User reports can return a large amount of data. User reports are more manageable if you select one rights group, or a set of specific users, such as primary CRAs, for each report.

Selection criteria: CRF Aging by User prompt page

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: CRF Aging by User* (on page 245).

Selection criteria

CRF Aging by User	
Selection criteria	Action
Rights groups	<p>Select the rights group or groups used for CRAs that are primary in your study and click Update to update the Users list.</p> <p>Note: For optimal performance, if you want to include all rights groups in your report, do not select any rights groups from the list.</p>
Users	To report on specific users, select them from the drop-down list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.
Expected forms for:	<p>Select the clinical forms (forms that have a type of CRF) that are expected to appear.</p> <ul style="list-style-type: none"> • All forms—All expected forms are considered. • Scheduled visits—Expected forms that appear in scheduled visits are considered. • Scheduled or started visits—Expected forms that appear in scheduled or started visits are considered. A started visit is a visit in which at least one non-common expected form is started. • Scheduled or started visits to date—Expected forms that appear in visits that are scheduled to start or have been started by the date the report is run are considered. • Scheduled visits or started forms to date—Expected forms for which either of the following is true are considered: <ul style="list-style-type: none"> ▪ The forms appear in visits that are scheduled to occur by the date the report is run. ▪ The forms have been started by the date the report is run. ▪ Default: Scheduled or started visits

CRF Aging by User	
Selection criteria	Action
Aging interval	<p>Enter a time duration (in days) to be used as the aging interval. The resulting report uses the aging interval to show how many forms have been incomplete during specific ranges of calendar days after the date of visit.</p> <p>For example, if you specify 7 here, the resulting report shows the number of forms that have been incomplete for:</p> <ul style="list-style-type: none"> • Seven or fewer days after the date of visit. • More than 7 days but fewer than 14 days after the DOV. • More than 14 days but fewer than 28 days after the DOV. • More than 28 days after the DOV. • Default: 7 (days)
Limit to forms with	<p>To filter the report, select one or more of the following options:</p> <ul style="list-style-type: none"> • Required items—Forms that have items marked as required are considered. • SV required items—Forms that have items marked as source verification required are considered. • Outstanding queries—Forms that have open or answered queries against the forms items are considered. • Comments—Forms that have either form level or item level comments are considered. <p>If you leave all checkboxes blank, this prompt is not applied. In that case, the results are determined by your selections in the previous prompts.</p> <p>If one or more checkboxes are selected, the counts are limited by the selection(s) in this prompt. Most likely, this results in decreased counts. For example, selecting both Required items and SV required items limits the report results to only those forms that have both required items and SV required items.</p>

Sort options

CRF Aging by User	
Sort	Default selection
First level	Rights Group
Second level	User Name
Third level	Site Mnemonic

Use the sort drop-down lists to change any of these selections.

Report/Graph page: CRF Aging by User

Subtotals and totals

- **Subtotals**—By User Name and Rights Group.
- **Totals**—Overall form count totals.

Column descriptions

CRF Aging by User	
Column	Description
Rights Group	<p>Data displayed: String</p> <p>Description: Rights group to which the user belongs.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
User Name	<p>Data displayed: String</p> <p>Description: Username of the user.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Subject Count	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who have enrolled at the site.</p> <p>How calculated: For each site, counts subjects that have been enrolled in the InForm application. This count includes subjects who have enrolled and have moved on to other states, such as Randomized, Dropped Out, or Complete.</p> <p>Note: The Enrollment form, designed according to InForm specifications, must be completed for the subject.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Status is determined by value on the InForm Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p>

CRF Aging by User	
Column	Description
Form Counts: Expected	<p>Data displayed: Numeric</p> <p>Description: The number of expected forms in the study.</p> <p>How calculated: This number reflects the number of expected forms for the site based on the option selected for the Expected forms for filter on the report prompt page.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Form Counts: Complete	<p>Data displayed: Numeric</p> <p>Description: Total count of all forms that are complete across all subjects, by visit and by site.</p> <p>How calculated: Counts forms that are expected and meet the following criteria:</p> <ul style="list-style-type: none"> • Are started. • Contain data for all required items. • Do not have open queries associated with any items on the form. • For a repeating form, the form is not in a deleted state. • For an itemset form, the form is complete even if all the instances are deleted. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Form Counts: Incomplete	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number (and percentage) of expected forms that are started but not complete.</p> <p>How calculated: For each site, calculates the following:</p> $[\text{incomplete forms count}] = [\text{started forms count}] - [\text{completed forms count}]$ $[\text{incomplete, \% of expected}] = [\text{incomplete forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

CRF Aging by User	
Column	Description
Form Counts: Not Started	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number (and percentage) of expected forms that are not started in the InForm application.</p> <p>How calculated: A form is started if any data, queries or comments have been entered. Each instance of a repeating form counts as a separate started form. A dynamic form may be Activated but not Started.</p> <p>This value displays as a whole number and as the percentage of expected forms that are not started:</p> $[\text{not started, \% of expected}] = [\text{not started forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

CRF Aging by User	
Column	Description
Incomplete (From DOV) Form Counts	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The total count of all forms across all subjects that have been incomplete for specific ranges of calendar days after the date of visit. You specify the aging interval (in days) on the report prompt page.</p> <p>For example, if you specify 7 on the report filter page, the resulting report shows the number of forms that have been incomplete for:</p> <ul style="list-style-type: none">• Seven or fewer days after the date of visit.• More than 7 days and less than 14 days.• More than 14 days and less than 21 days.• More than 21 days and less than 28 days.• More than 28 days. <p>How calculated: This value is displays as a whole number, followed by a percentage of the total incomplete form count. The percentage is calculated as follows:</p> $[\text{count of incomplete forms within the aging interval}] * 100 / [\text{count of incomplete forms}]$ <p>Note: This report element assumes that your trial has been developed using a specific design for DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none">• DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674• Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674• Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

CRF Cycle Time Detail by Site

This report shows the measures of data-entry performance by showing the number of days, from:

- Date of visit to form started.
- Date of visit to form completed.
- Form completed to form source verified.
- Form completed to form locked.

Note: This calculation relies on the use of specified DOV elements in the form design. For more information, see *DOV controls* (on page 26).

Selection criteria: CRF Cycle Time Detail by Site prompt page

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: CRF Cycle Time Detail by Site* (on page 250).

Selection criteria

CRF Cycle Time Detail by Site	
Selection criteria	Action
Countries	To report on specific countries, select their names from the list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.
Visits	Select a visit from the list.

Note: To include all available options in the report, leave the optional selection fields blank; that is, do not select any individual options from the drop-down lists. For the best performance, do not select any optional filters.

Sort options

Sort options are: None, Country, Site Mnemonic, Visit Order, Started Forms Count, Completed Forms Count, Expected Forms Count, DOV to Form Started–Min, DOV to Form Started–Max, DOV to Form Completed–Min, DOV to Form Completed–Max, Form Completed to SDV Completed–Min, Form Completed to SDV Completed–Max, Form Completed to Form

Locked—Min, Form Completed to Form Locked—Max.

Use the Sort drop-down lists to change any of the default selections.

CRF Cycle Time Detail by Site	
Sort	Default selection
First level	Country
Second level	Site Mnemonic
Third level	Visit Order

Report/Graph page: CRF Cycle Time Detail by Site

Graphs

This report does not contain a graph.

Subtotals and totals

- **Subtotals**—By site and country.
 Min—Lowest minimum value for any site in the country.
 Max—Highest maximum value for any site in the country.
 Median—No value.
- **Totals**—Overall form count totals.
 Min—Lowest minimum value for any site in the country.
 Max—Highest maximum value for any site in the country.
 Median—No value.

Column descriptions

CRF Cycle Time Detail by Site	
Column	Description
Country	<p>Data displayed: String</p> <p>Description: Country in which a site is located, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

CRF Cycle Time Detail by Site	
Column	Description
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Visit Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation of the visit title, as specified in trial design code. For CRF visits, this name appears at the top of a collection of forms in the visit timeline. The visit mnemonic may not be a unique identifier.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Form Counts: Expected	<p>Data type: Numeric</p> <p>Description: The total count of all forms that are expected across all patients, by visit and by site.</p> <p>How calculated: This number reflects the number of expected forms for the site based on the definition of Expected forms.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Form Counts: Started	<p>Data displayed: Numeric</p> <p>Description: Total count of all forms that are started across all subjects, by visit and by site.</p> <p>How calculated: An expected form is considered started if any type of data entry activity (form data, queries, or comments) has started on the form.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

CRF Cycle Time Detail by Site	
Column	Description
Form Counts: Completed	<p>Data displayed: Numeric</p> <p>Description: Total count of all forms that are complete across all subjects, by visit and by site.</p> <p>How calculated: Counts forms that are expected and meet the following criteria:</p> <ul style="list-style-type: none"> • Are started. • Contain data for all required items. • Do not have open queries associated with any items on the form. • For a repeating form, the form is not in a deleted state. • For an itemset form, the form is complete even if all the instances are deleted. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
DOV to Form Started (Days): Min, Max, Median	<p>Data displayed: Numeric</p> <p>Description: The number of days from the date entered on the DOV form to the first day on which any data entry activity (item data, comments, or queries) started. For each visit, this section displays:</p> <ul style="list-style-type: none"> • Minimum number of days taken by InForm users, across all forms and all patients for each visit at every site, to start a form from the date entered in the DOV form. • Maximum number of days taken by InForm users, across all forms and all patients for each visit at every site, to start a form from the date entered in the DOV form. • Median value for the number of days taken by InForm users, across all forms and all patients for each visit at every site, to start a form from the date entered in the DOV form for all forms in the visit. <p>Note: This report element assumes that your trial has been developed using a specific design for DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>

CRF Cycle Time Detail by Site	
Column	Description
DOV to Form Completed (Days): Min, Max, Median	<p>Data displayed: Numeric</p> <p>Description: The number of days from the date entered on the DOV form to the most recent date on which all of the required items on the form contain data. For each visit, this section displays:</p> <ul style="list-style-type: none"> • Minimum number of days taken by InForm users, across all forms and all patients for each visit at every site, to complete a form from the date entered in the DOV form. • Maximum number of days taken by InForm users, across all forms and all patients for each visit at every site, to complete a form from the date entered in the DOV form. • Median value for the number of days taken by InForm users, across all forms and all patients for each visit at every site, to complete a form from the date entered in the DOV form for all forms in the visit. <p>How calculated: For each completed form, the DOV to Form Completed calculation begins on the recorded date of visit for the visit and ends on the last day a form was assigned a status of complete.</p> <p>Note: This report element assumes that your trial has been developed using a specific design for DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>

CRF Cycle Time Detail by Site	
Column	Description
Form Completed to SV Complete (Days): Min, Max, Median	<p>Data displayed: Numeric</p> <p>Description: The number of days from when a form was completed to when it was marked SV complete in the InForm application. For each visit, this column displays:</p> <ul style="list-style-type: none"> • Minimum number of days, across all forms and all patients for each visit at every site, to complete the source verification process from the date of form completion. • Maximum number of days, across all forms and all patients for each visit at every site, to complete the source verification process from the date of form completion. • Median value of number of days, across all forms and all patients for each visit at every site, to complete the source verification process from date of form completion. <p>How calculated: For each SV Complete form, the Completed to SV complete calculation begins on the first day a forms status was set to completed and ends on the most recent day the forms status was set to SV complete.</p> <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>
Form Completed to Form Locked (Days): Min, Max, Median	<p>Data displayed: Numeric</p> <p>Description: The number of days from when a form was completed to when it was locked in the InForm application. This report displays the minimum, maximum, and median number of days for forms in each visit. For each visit, this column displays:</p> <ul style="list-style-type: none"> • Minimum number of days, across all forms and all patients for each visit at every site, to lock the form from the date of form completion. • Maximum of days, across all forms and all patients for each visit at every site, to lock the form from the date of form completion. • Median value of number of days, across all forms and all patients for each visit at every site, to lock the form from the date of form completion. <p>How calculated: For each locked form, the Completed to locked calculation begins on the first day a forms status is set to completed and ends on the most recent day the forms status was set to locked.</p> <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>

CRF Cycle Time Detail for a Site

This report shows the measures of data-entry performance by showing the number of days, from:

- Date of visit to form started.
- Date of visit to form completed.
- Form completed to form source verified.
- Form completed to form locked.

Note: This calculation relies on the use of specified DOV elements in the form design. For more information, see *DOV controls* (on page 26).

Selection criteria: CRF Cycle Time Detail for a Site prompt page

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: CRF Cycle Time Detail for a Site* (on page 256).

Selection criteria

CRF Cycle Time Detail by Site	
Selection criteria	Action
Countries	To report on specific countries, select their names from the list. Then, click Update to update the Sites list.
Sites	Select the name of the site from the list.
Visits	Select a visit from the list.

Sort options

Sort options are: None, Country, Site Mnemonic, Visit Order, Started Forms Count, Completed Forms Count, Expected Forms Count, DOV to Form Started–Min, DOV to Form Started–Max, DOV to Form Completed–Min, DOV to Form Completed–Max, Form Completed to SDV Completed–Min, Form Completed to SDV Completed–Max, Form Completed to Form Locked–Min, Form Completed to Form Locked–Max.

Use the Sort drop-down lists to change any of the default selections.

CRF Cycle Time Detail by Site	
Sort	Default selection
First level	Country
Second level	Site Mnemonic
Third level	Visit Order

Report/Graph page: CRF Cycle Time Detail for a Site

Graphs

A combination line/bar graph appears on the first page of the CRF Cycle Time Detail for a Site report, plotting the median time from DOV to form complete against expected forms.

Subtotals and totals

- **Subtotals**—By site and country.
Min—Lowest minimum value for any site in the country.
Max—Highest maximum value for any site in the country.
Median—No value.
- **Totals**—Overall form count totals.
Min—Lowest minimum value for any site in the country.
Max—Highest maximum value for any site in the country.
Median—No value.

Column descriptions

CRF Cycle Time Detail by Site	
Column	Description
Country	<p>Data displayed: String</p> <p>Description: Country in which a site is located, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

CRF Cycle Time Detail by Site	
Column	Description
Visit Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation of the visit title, as specified in trial design code. For CRF visits, this name appears at the top of a collection of forms in the visit timeline. The visit mnemonic may not be a unique identifier.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Form Counts: Expected	<p>Data type: Numeric</p> <p>Description: The total count of all forms that are expected across all patients, by visit and by site.</p> <p>How calculated: This number reflects the number of expected forms for the site based on the definition of Expected forms.</p> <p>Data source: Derived for the report; not stored in the InForm Reporting and Analysis database.</p>
Form Counts: Started	<p>Data displayed: Numeric</p> <p>Description: Total count of all forms that are started across all subjects, by visit and by site.</p> <p>How calculated: An expected form is considered started if any type of data entry activity (form data, queries, or comments) has started on the form.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Form Counts: Completed	<p>Data displayed: Numeric</p> <p>Description: Total count of all forms that are complete across all subjects, by visit and by site.</p> <p>How calculated: Counts forms that are expected and meet the following criteria:</p> <ul style="list-style-type: none"> • Are started. • Contain data for all required items. • Do not have open queries associated with any items on the form. • For a repeating form, the form is not in a deleted state. • For an itemset form, the form is complete even if all the instances are deleted. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

CRF Cycle Time Detail by Site	
Column	Description
DOV to Form Started (Days): Min, Max, Median	<p>Data displayed: Numeric</p> <p>Description: The number of days from the date entered on the DOV form to the first day on which any data entry activity (item data, comments, or queries) started. For each visit, this section displays:</p> <ul style="list-style-type: none">• Minimum number of days taken by InForm users, across all forms and all patients for each visit at every site, to start a form from the date entered in the DOV form.• Maximum number of days taken by InForm users, across all forms and all patients for each visit at every site, to start a form from the date entered in the DOV form.• Median value for the number of days taken by InForm users, across all forms and all patients for each visit at every site, to start a form from the date entered in the DOV form for all forms in the visit. <p>Note: This report element assumes that your trial has been developed using a specific design for DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none">• DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674• Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674• Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>

CRF Cycle Time Detail by Site	
Column	Description
DOV to Form Completed (Days): Min, Max, Median	<p>Data displayed: Numeric</p> <p>Description: The number of days from the date entered on the DOV form to the most recent date on which all of the required items on the form contain data. For each visit, this section displays:</p> <ul style="list-style-type: none"> • Minimum number of days taken by InForm users, across all forms and all patients for each visit at every site, to complete a form from the date entered in the DOV form. • Maximum number of days taken by InForm users, across all forms and all patients for each visit at every site, to complete a form from the date entered in the DOV form. • Median value for the number of days taken by InForm users, across all forms and all patients for each visit at every site, to complete a form from the date entered in the DOV form for all forms in the visit. <p>How calculated: For each completed form, the DOV to Form Completed calculation begins on the recorded date of visit for the visit and ends on the last day a form was assigned a status of complete.</p> <p>Note: This report element assumes that your trial has been developed using a specific design for DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>

CRF Cycle Time Detail by Site	
Column	Description
Form Completed to SV Complete (Days): Min, Max, Median	<p>Data displayed: Numeric</p> <p>Description: The number of days from when a form was completed to when it was marked SV complete in the InForm application. For each visit, this column displays:</p> <ul style="list-style-type: none"> • Minimum number of days, across all forms and all patients for each visit at every site, to complete the source verification process from the date of form completion. • Maximum number of days, across all forms and all patients for each visit at every site, to complete the source verification process from the date of form completion. • Median value of number of days, across all forms and all patients for each visit at every site, to complete the source verification process from date of form completion. <p>How calculated: For each SV Complete form, the Completed to SV complete calculation begins on the first day a forms status was set to completed and ends on the most recent day the forms status was set to SV complete.</p> <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>
Form Completed to Form Locked (Days): Min, Max, Median	<p>Data displayed: Numeric</p> <p>Description: The number of days from when a form was completed to when it was locked in the InForm application. This report displays the minimum, maximum, and median number of days for forms in each visit. For each visit, this column displays:</p> <ul style="list-style-type: none"> • Minimum number of days, across all forms and all patients for each visit at every site, to lock the form from the date of form completion. • Maximum of days, across all forms and all patients for each visit at every site, to lock the form from the date of form completion. • Median value of number of days, across all forms and all patients for each visit at every site, to lock the form from the date of form completion. <p>How calculated: For each locked form, the Completed to locked calculation begins on the first day a forms status is set to completed and ends on the most recent day the forms status was set to locked.</p> <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>

CRF Cycle Time Detail by User

This report shows the cycle time performance from:

- Date of visit to form started.
- Date of visit to form completion.
- Form completion to source verification.
- Form completion to form locked.

Note: User reports can return a large amount of data. User reports are more manageable if you select one rights group, or a set of specific users, such as primary CRAs, for each report.

Selection criteria: CRF Cycle Time Detail by User prompt page

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: CRF Cycle Time Detail by User* (on page 262).

Selection criteria

CRF Cycle Time Detail by User	
Selection criteria	Action
Rights groups	Select the rights group or groups used for CRAs that are primary in your study and click Update to update the Users list. Note: For optimal performance, if you want to include all rights groups in your report, do not select any rights groups from the list.
Users	To report on specific users, select them from the drop-down list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.
Visits	Select a visit from the list.

Sort options

CRF Cycle Time Detail by User	
Sort	Default selection
First level	Rights Group

CRF Cycle Time Detail by User	
Sort	Default selection
Second level	User Name
Third level	Site Mnemonic

Use the sort drop-down lists to change any of these selections.

Report/Graph page: CRF Cycle Time Detail by User

Subtotals and totals

- **Subtotals**—By Site, User, and Rights Group.
- **Totals**—Overall form count totals.

Column descriptions

CRF Cycle Time Detail by User	
Column	Description
Rights Group	<p>Data displayed: String</p> <p>Description: The InForm rights group to which the user belongs.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
User Name	<p>Data displayed: String</p> <p>Description: Username of the user.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Visit Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation of the visit title, as specified in trial design code. For CRF visits, this name appears at the top of a collection of forms in the visit timeline. The visit mnemonic may not be a unique identifier.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

CRF Cycle Time Detail by User	
Column	Description
Form Counts: Expected	<p>Data displayed: Numeric</p> <p>Description: The number of expected forms in the study.</p> <p>How calculated: This number reflects the number of expected forms for the site based on the option selected for the Expected forms for filter on the report prompt page.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Form Counts: Started	<p>Data displayed: Numeric</p> <p>Description: Total count of all forms that are started across all subjects, by visit and by site.</p> <p>How calculated: An expected form is considered started if any type of data entry activity (form data, queries, or comments) has started on the form.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Form Counts: Completed	<p>Data displayed: Numeric</p> <p>Description: Total count of all forms that are complete across all subjects, by visit and by site.</p> <p>How calculated: Counts forms that are expected and meet the following criteria:</p> <ul style="list-style-type: none"> • Are started. • Contain data for all required items. • Do not have open queries associated with any items on the form. • For a repeating form, the form is not in a deleted state. • For an itemset form, the form is complete even if all the instances are deleted. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>

CRF Cycle Time Detail by User	
Column	Description
DOV to Forms Started (Days): Min, Max, and Median	<p>Data displayed: Numeric</p> <p>Description: The number of days from the date entered on the DOV form to the first day on which any data entry activity (item data, comments, or queries) started. For each visit, this section displays:</p> <ul style="list-style-type: none">• Minimum number of days taken by InForm users, across all forms and all patients for each visit at every site, to start a form from the date entered in the DOV form.• Maximum number of days taken by InForm users, across all forms and all patients for each visit at every site, to start a form from the date entered in the DOV form.• Median value for the number of days taken by InForm users, across all forms and all patients for each visit at every site, to start a form from the date entered in the DOV form for all forms in the visit. <p>Note: This report element assumes that your trial has been developed using a specific design for DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none">• DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674• Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674• Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>

CRF Cycle Time Detail by User	
Column	Description
DOV to Forms Completed (Days): Min, Max, and Median	<p>Data displayed: Numeric</p> <p>Description: The number of days from the date entered on the DOV form to the most recent date on which all of the required items on the form contain data. For each visit, this section displays:</p> <ul style="list-style-type: none"> • Minimum number of days taken by InForm users, across all forms and all patients for each visit at every site, to complete a form from the date entered in the DOV form. • Maximum number of days taken by InForm users, across all forms and all patients for each visit at every site, to complete a form from the date entered in the DOV form. • Median value for the number of days taken by InForm users, across all forms and all patients for each visit at every site, to complete a form from the date entered in the DOV form for all forms in the visit. <p>How calculated: For each completed form, the DOV to Form Completed calculation begins on the recorded date of visit for the visit and ends on the last day a form was assigned a status of complete.</p> <p>Note: This report element assumes that your trial has been developed using a specific design for DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>

CRF Cycle Time Detail by User	
Column	Description
Forms Completed to Forms SV Completed (Days): Min, Max, and Median	<p>Data displayed: Numeric</p> <p>Description: The number of days from when a form was completed to when it was marked SV complete in the InForm application. For each visit, this column displays:</p> <ul style="list-style-type: none"> • Minimum number of days, across all forms and all patients for each visit at every site, to complete the source verification process from the date of form completion. • Maximum number of days, across all forms and all patients for each visit at every site, to complete the source verification process from the date of form completion. • Median value of number of days, across all forms and all patients for each visit at every site, to complete the source verification process from date of form completion. <p>How calculated: For each SV Complete form, the Completed to SV complete calculation begins on the first day a forms status was set to completed and ends on the most recent day the forms status was set to SV complete.</p> <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>
Forms Completed to Forms Locked (Days): Min, Max, and Median	<p>Data displayed: Numeric</p> <p>Description: The number of days from when a form was completed to when it was locked in the InForm application. This report displays the minimum, maximum, and median number of days for forms in each visit. For each visit, this column displays:</p> <ul style="list-style-type: none"> • Minimum number of days, across all forms and all patients for each visit at every site, to lock the form from the date of form completion. • Maximum of days, across all forms and all patients for each visit at every site, to lock the form from the date of form completion. • Median value of number of days, across all forms and all patients for each visit at every site, to lock the form from the date of form completion. <p>How calculated: For each locked form, the Completed to locked calculation begins on the first day a forms status is set to completed and ends on the most recent day the forms status was set to locked.</p> <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>

CRF Site Performance Summary by Site

This report provides a snapshot of how well sites are managing to keep up with entering and completing form data entry activities by listing average time from visit to entry start and complete, combined with aging for incomplete forms.

Selection criteria: CRF Site Performance Summary by Site

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: CRF Site Performance Summary by Site* (on page 268).

Selection criteria

CRF Site Performance Summary by Site	
Selection criteria	Action
Countries	To report on specific countries, select their names from the list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.
Aging Interval	<p>Enter a time duration (in days) to be used as the aging interval. The resulting report uses the aging interval to show how many forms have been incomplete during specific ranges of calendar days after the date of visit.</p> <p>For example, if you specify 7 here, the resulting report shows the number of forms that have been incomplete for:</p> <ul style="list-style-type: none"> • 7 or fewer days after the date of visit. • More than 7 days and fewer than 14 days after the DOV. • More than 14 days and fewer than 21 days after the DOV. • More than 21 days and 28 or fewer days after the DOV. • More than 28 days after the DOV. <p>Default: 7 (days)</p>

Note: To include all available options in the report, leave the optional selection fields blank; that is, do not select any individual options from the drop-down lists. For the best performance, do not select any optional filters.

Sort options

Sort options are: None, Country, Site Mnemonic, DOV to Form Started–Min, DOV to Form Started–Max, DOV to Form Started–Median, DOV to Form Completed–Min, DOV to Form Completed–Max, DOV to Form Completed–Median, Form Completed to SDV Completed–Min, Form Completed to SDV Completed–Max, Form Completed to SDV Completed–Median, Form Completed to Form Locked–Min, Form Completed to Form Locked–Max, Form Completed to Form Locked–Median, Incomplete Forms–1st Period, Incomplete Forms–2nd Period, Incomplete Forms–3rd Period, Incomplete Forms–4th Period, Incomplete Forms–5th Period.

Use the Sort drop-down lists to change any of the default selections.

CRF Site Performance Summary by Site	
Sort	Default selection
First level	Country
Second level	Site Mnemonic
Third level	None

Report/Graph page: CRF Site Performance Summary by Site

Graphs

Two bar graphs appear on the first page of the CRF Site Performance Summary by Site report. The first graph plots the median time from DOV to form started and median DOV to form complete times for selected sites against expected forms. The second graph plots incomplete form count for selected sites.

Subtotals and totals

Subtotals—By Country.

- Min—Lowest minimum value for any site in the country.
- Max—Highest maximum value for any site in the country.
- Median—No value.

Totals—Overall cycle time totals.

- Min—Lowest minimum value for any site in the country.
- Max—Highest maximum value for any site in the country.
- Median—No value.

Drilldown reports

You can click the value in the site mnemonic column to drill down to the Cycle Time Detail by Site report.

Column descriptions

CRF Site Performance Summary by Site	
Column	Description
Country	<p>Data displayed: String</p> <p>Description: Country in which a site is located, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
DOV to Forms Started (Days): Min, Max, Median	<p>Data displayed: Numeric</p> <p>Description: The number of days from the date entered on the DOV form to the first day on which any data entry activity (item data, comments, or queries) started. For each visit, this section displays:</p> <ul style="list-style-type: none"> • Minimum number of days taken by InForm users, across all forms and all patients for each visit at every site, to start a form from the date entered in the DOV form. • Maximum number of days taken by InForm users, across all forms and all patients for each visit at every site, to start a form from the date entered in the DOV form. • Median value for the number of days taken by InForm users, across all forms and all patients for each visit at every site, to start a form from the date entered in the DOV form for all forms in the visit. <p>Note: This report element assumes that your trial has been developed using a specific design for DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>

CRF Site Performance Summary by Site	
Column	Description
DOV to Forms Completed (Days): Min, Max, Median	<p>Data displayed: Numeric</p> <p>Description: The number of days from the date entered on the DOV form to the most recent date on which all of the required items on the form contain data. For each visit, this section displays:</p> <ul style="list-style-type: none"> • Minimum number of days taken by InForm users, across all forms and all patients for each visit at every site, to complete a form from the date entered in the DOV form. • Maximum number of days taken by InForm users, across all forms and all patients for each visit at every site, to complete a form from the date entered in the DOV form. • Median value for the number of days taken by InForm users, across all forms and all patients for each visit at every site, to complete a form from the date entered in the DOV form for all forms in the visit. <p>Note: This report element assumes that your trial has been developed using a specific design for DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>
Forms Completed to Forms SV Complete (Days): Min, Max, Median	<p>Data displayed: Numeric</p> <p>Description: The number of days from the earliest date on which the form was complete to the most recent date on which all of the form items that are SVRequired were source verified. For each visit, this section displays:</p> <ul style="list-style-type: none"> • Minimum number of days, across all forms and all patients for each visit at every site, to complete the source verification process from the date of form completion. • Maximum number of days, across all forms and all patients for each visit at every site, to complete the source verification process from the date of form completion. • Median value of number of days, across all forms and all patients for each visit at every site, to complete the source verification process from date of form completion. <p>Note: This report element assumes that your trial has been developed using a specific design for DOV controls.</p>

CRF Site Performance Summary by Site	
Column	Description
Forms Completed to Forms Locked (Days): Min, Max, Median	<p>Data displayed: Numeric</p> <p>Description: The number of days from the earliest date on which the form was complete to the most recent date on which form was locked. For each visit, this section displays:</p> <ul style="list-style-type: none">▪ Minimum number of days, across all forms and all patients for each visit at every site, to lock the form from the date of form completion.▪ Maximum of days, across all forms and all patients for each visit at every site, to lock the form from the date of form completion.▪ Median value of number of days, across all forms and all patients for each visit at every site, to lock the form from the date of form completion. <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>

CRF Site Performance Summary by Site	
Column	Description
Forms Incomplete (Days)	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The total count of all forms across all subjects that have been incomplete for specific ranges of calendar days after the date of visit. You specify the aging interval (in days) on the report prompt page.</p> <p>For example, if you specify 7 on the report filter page, the resulting report shows the number of forms that have been incomplete for:</p> <ul style="list-style-type: none">• Seven or fewer days after the date of visit.• More than 7 days and less than 14 days.• More than 14 days and less than 21 days.• More than 21 days and less than 28 days.• More than 28 days. <p>How calculated: This value is displays as a whole number, followed by a percentage of the total incomplete form count. The percentage is calculated as follows:</p> $[\text{count of incomplete forms within the aging interval}] * 100 / [\text{count of incomplete forms}]$ <p>Note: This report element assumes that your trial has been developed using a specific design for DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none">• DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674• Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674• Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

CRF Site Performance Summary by User

This report provides a snapshot of how well sites are managing to keep up with entering and completing form data entry activities by listing average time from visit to data entry start and complete, combine with aging for incomplete forms.

Note: User reports can return a large amount of data. User reports are more manageable if you select one rights group, or a set of specific users, such as primary CRAs, for each report. For more information, see *Data in Standard Reports* (on page 178).

Selection criteria: CRF Site Performance Summary by User prompt page

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: CRF Site Performance Summary by User* (on page 274).

Selection criteria

CRF Site Performance Summary by User	
Selection criteria	Action
Rights groups	<p>Select the rights group or groups used for CRAs that are primary in your study and click Update to update the Users list.</p> <p>Note: For optimal performance, if you want to include all rights groups in your report, do not select any rights groups from the list.</p>
Users	To report on specific users, select them from the drop-down list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.

CRF Site Performance Summary by User	
Selection criteria	Action
Aging interval	<p>Enter a time duration (in days) to be used as the aging interval. The resulting report uses the aging interval to show how many forms have been incomplete during specific ranges of calendar days after the date of visit.</p> <p>For example, if you specify 7 here, the resulting report shows the number of forms that have been incomplete for:</p> <ul style="list-style-type: none"> • Seven or fewer days after the date of visit. • More than 7 days but fewer than 14 days after the DOV. • More than 14 days but fewer than 28 days after the DOV. • More than 28 days after the DOV. • Default: 7 (days)

Sort options

CRF Site Performance Summary by User	
Sort	Default selection
First level	Rights Group
Second level	Site Mnemonic
Third level	None

Use the sort drop-down lists to change any of these selections.

Report/Graph page: CRF Site Performance Summary by User

Subtotals and totals

- **Subtotals**—By Site, User, and Rights Group.
- **Totals**—Overall cycle time totals.

Drilldown reports

You can click the value in the site mnemonic column to drill down to the CRF Cycle Time Detail by User report.

Column descriptions

CRF Site Performance Summary by User	
Column	Description
Rights Group	<p>Data displayed: String</p> <p>Description: The InForm rights group to which the user belongs.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
User Name	<p>Data displayed: String</p> <p>Description: Username of the user.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
DOV to Forms Started (Days): Min, Max, Median	<p>Data displayed: Numeric</p> <p>Description: The number of days from the date entered on the DOV form to the first day on which any data entry activity (item data, comments, or queries) started. For each visit, this section displays:</p> <ul style="list-style-type: none"> • Minimum number of days taken by InForm users, across all forms and all patients for each visit at every site, to start a form from the date entered in the DOV form. • Maximum number of days taken by InForm users, across all forms and all patients for each visit at every site, to start a form from the date entered in the DOV form. • Median value for the number of days taken by InForm users, across all forms and all patients for each visit at every site, to start a form from the date entered in the DOV form for all forms in the visit. <p>Note: This report element assumes that your trial has been developed using a specific design for DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>

CRF Site Performance Summary by User	
Column	Description
DOV to Forms Completed (Days): Min, Max, Median	<p>Data displayed: Numeric</p> <p>Description: The number of days from the date entered on the DOV form to the most recent date on which all of the required items on the form contain data. For each visit, this section displays:</p> <ul style="list-style-type: none"> • Minimum number of days taken by InForm users, across all forms and all patients for each visit at every site, to complete a form from the date entered in the DOV form. • Maximum number of days taken by InForm users, across all forms and all patients for each visit at every site, to complete a form from the date entered in the DOV form. • Median value for the number of days taken by InForm users, across all forms and all patients for each visit at every site, to complete a form from the date entered in the DOV form for all forms in the visit. <p>Note: This report element assumes that your trial has been developed using a specific design for DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>
Forms Completed to Forms SV Completed (Days): Min, Max, Median	<p>Data displayed: Numeric</p> <p>Description: The number of days from the earliest date on which the form was complete to the most recent date on which all of the form items that are SVRequired were source verified. For each visit, this section displays:</p> <ul style="list-style-type: none"> • Minimum number of days, across all forms and all patients for each visit at every site, to complete the source verification process from the date of form completion. • Maximum number of days, across all forms and all patients for each visit at every site, to complete the source verification process from the date of form completion. • Median value of number of days, across all forms and all patients for each visit at every site, to complete the source verification process from date of form completion. <p>Note: This report element assumes that your trial has been developed using a specific design for DOV controls.</p>

CRF Site Performance Summary by User	
Column	Description
Forms Completed to Forms Locked (Days): Min, Max, Median	<p>Data displayed: Numeric</p> <p>Description: The number of days from the earliest date on which the form was complete to the most recent date on which form was locked. For each visit, this section displays:</p> <ul style="list-style-type: none">▪ Minimum number of days, across all forms and all patients for each visit at every site, to lock the form from the date of form completion.▪ Maximum of days, across all forms and all patients for each visit at every site, to lock the form from the date of form completion.▪ Median value of number of days, across all forms and all patients for each visit at every site, to lock the form from the date of form completion. <p>Data source: Minimum, maximum, and median values are derived for the report, and are not stored in the Reporting and Analysis database.</p>

CRF Site Performance Summary by User	
Column	Description
Incomplete (from DOV) Form Count (Days)	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The total count of all forms across all subjects that have been incomplete for specific ranges of calendar days after the date of visit. You specify the aging interval (in days) on the report prompt page.</p> <p>For example, if you specify 7 on the report filter page, the resulting report shows the number of forms that have been incomplete for:</p> <ul style="list-style-type: none"> • Seven or fewer days after the date of visit. • More than 7 days and less than 14 days. • More than 14 days and less than 21 days. • More than 21 days and less than 28 days. • More than 28 days. <p>How calculated: This value is displays as a whole number, followed by a percentage of the total incomplete form count. The percentage is calculated as follows:</p> $[\text{count of incomplete forms within the aging interval}] * 100 / [\text{count of incomplete forms}]$ <p>Note: This report element assumes that your trial has been developed using a specific design for DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

CRF Status Detail by Site and Subject

This report shows the number of forms in each possible status. Forms can be counted based on the definition selected for **expected**.

Selection criteria: CRF Status Detail by Site and Subject prompt page

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: CRF Status Detail by Site and Subject* (on page 281).

Selection criteria

CRF Status Detail by Site and Subject	
Selection criteria	Action
Countries	To report on specific countries, select their names from the list. Then, click Update to update the Sites list.
Sites	Select specific sites from the list and click Update to update the Subjects list with Subject IDs.
Subjects	Select specific subjects from the list.
Visits	Select a visit from the list.

CRF Status Detail by Site and Subject	
Selection criteria	Action
Expected forms for	<p>Filter the report by expected forms. Choose one of these options from the drop-down list.</p> <ul style="list-style-type: none"> • All forms—All clinical forms (forms of type CRF) are considered. • Scheduled visits—All expected forms that are in scheduled visits are considered. • Scheduled or started visits—All clinical forms that are in either expected or started visits are considered. • Scheduled or started visits to date—All the expected forms that are in scheduled visits whose expected start date is earlier than the report run date, and all the expected forms that are present in started visits when the actual date of the visit is on or before the report run date are considered. • Scheduled visits or started forms to date—All the expected forms that are in scheduled visits whose expected start date is on or before the report run date, and all the expected forms that were started on or before the report run date are considered. <p>Default: Scheduled or started visits</p>
Visits	To report on one or more visits, select the visits from the list.
Limit to forms with	<p>To filter the report, select one or more of the following options:</p> <ul style="list-style-type: none"> • Required items—Forms that have items marked as required are considered. • SV required items—Forms that have items marked as source verification required are considered. • Outstanding queries—Forms that have open or answered queries against the forms items are considered. • Comments—Forms that have either form level or item level comments are considered. <p>If you leave all checkboxes blank, this prompt is not applied. In that case, the results are determined by your selections in the previous prompts.</p> <p>If one or more checkboxes are selected, the counts are limited by the selection(s) in this prompt. Most likely, this results in decreased counts. For example, selecting both Required items and SV required items limits the report results to only those forms that have both required items and SV required items.</p>

Note: To include all available options in the report, leave the optional selection fields blank; that is, do not select any individual options from the drop-down lists. For the best performance, do not select any optional filters.

Sort options

Sort options are: None, Country, Site Mnemonic, Subject Number, Visit, Subject Count, Expected Forms Count, % of Not Started Forms, % of Incomplete Forms, % of Completed Forms, % of Frozen Forms, % of SV Partial Forms, % of SV Complete Forms, % of Signed Forms, % of Locked Forms, % of Forms with Comments, % of Forms with Queries.

Use the Sort drop-down lists to change any of the default selections.

CRF Status Detail by Site and Subject	
Sort	Default selection
First level	Country
Second level	Site Mnemonic
Third level	Subject Number

Use the sort drop-down lists to change any of these selections.

Report/Graph page: CRF Status Detail by Site and Subject

Subtotals and totals

- **Subtotals**—By Subject, Site, and Country.
- **Totals**—Overall form count totals.

Column descriptions

CRF Status Detail by Site and Subject	
Column	Description
Country	<p>Data displayed: String</p> <p>Description: Country in which a site is located, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

CRF Status Detail by Site and Subject	
Column	Description
Subject Number	<p>Data displayed: String</p> <p>Description: The subject number, followed by the subject initials.</p> <p>The subject number identifies the subject. The subject number and subject initials can be changed post enrollment, if this is configured in the study.</p> <p>Note: Subject number may or may not be unique at your site.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Visit Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation of the visit title, as specified in trial design code. For CRF visits, this name appears at the top of a collection of forms in the visit timeline. The visit mnemonic may not be a unique identifier.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
DOV	<p>Data displayed: Date/Time</p> <p>Description: The date that is recorded in a standard Date of Visit control in the InForm application.</p> <p>Note: This report element assumes that your trial has been developed using a specific design for DOV controls.</p> <p>Date type: Clinical.</p> <p>Note: This report element assumes that your study was developed using a specific design for the DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>For more information, see <i>DOV controls</i> (on page 26).</p>
Form Count (% of Expected): Expected	<p>Data displayed: Numeric</p> <p>Description: The number of expected forms in the study.</p> <p>How calculated: This number reflects the number of expected forms for the site based on the option selected for the Expected forms for filter on the report prompt page.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

CRF Status Detail by Site and Subject	
Column	Description
Form Count (% of Expected): Not Started	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number (and percentage) of expected forms that are not started in the InForm application.</p> <p>How calculated: A form is started if any data, queries or comments have been entered. Each instance of a repeating form counts as a separate started form. A dynamic form may be Activated but not Started.</p> <p>This value displays as a whole number and as the percentage of expected forms that are not started:</p> $[\text{not started, \% of expected}] = [\text{not started forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Form Count (% of Expected): Incomplete	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of expected forms that are started but incomplete, and the percentage of expected forms that are incomplete.</p> <p>How calculated: For each site, calculates the following:</p> $[\text{incomplete forms count}] = [\text{started forms count}] - [\text{completed forms count}]$ $[\text{incomplete, \% of expected}] = [\text{incomplete forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

CRF Status Detail by Site and Subject	
Column	Description
Form Count (% of Expected): Completed	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of completed forms, and the percentage of expected forms that are complete in the InForm application.</p> <p>How calculated: Counts forms that are expected and meet the following criteria:</p> <ul style="list-style-type: none"> • Are started. • Contain data for all required items. • Do not have open queries associated with any items on the form. • For a repeating form, the form is not in a deleted state. • For an itemset form, the form is complete even if all the instances are deleted. <p>This value displays as a whole number and as a percentage of the total number of expected forms that are complete:</p> $[\% \text{ complete}] = [\text{complete forms}] * 100 / [\text{expected forms}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>
Form Count (% of Expected): Frozen	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of frozen forms, and the percentage of expected forms that are currently marked frozen in the InForm application.</p> <p>How calculated: Counts expected forms that have been frozen using any of these InForm features:</p> <ul style="list-style-type: none"> • Freeze CRF • Freeze CRB • Freeze Visit <p>This value displays as a whole number (number of frozen forms), followed by the percentage of expected forms that are currently marked frozen:</p> $[\% \text{ frozen}] = [\text{frozen forms}] * 100 / [\text{expected forms}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>

CRF Status Detail by Site and Subject	
Column	Description
Form Count (% of Expected): SV Partial	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of SV Partial forms, and the percentage of expected forms where source verification is not complete.</p> <p>How calculated: Counts forms as SV partial if they are expected and if only some of the SV required items on the forms have been source verified, and others have not. The InForm application automatically assigns a status of SV partial to any form for which some, but not all, SV required items have been marked SV complete.</p> <p>This value is displayed as a whole number and as a percentage of the total number of expected forms that are marked SV partial:</p> $[\% \text{ SV partial}] = [SV \text{ partial form count}] * 100 / [\text{expected forms}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>
Form Count (% of Expected) SV Completed	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of SV complete forms, and the percentage of expected forms where source verification is complete.</p> <p>How calculated: Counts forms as SV complete if all SV required items on the form have been source verified. This value displays as a whole number and as a percentage of the total number of expected forms that are marked SV complete. This value displays as a whole number and as a percentage of the total number of expected forms that are marked SV complete:</p> $[\% \text{ SV complete}] = [SV \text{ complete form count}] * 100 / [\text{expected form count}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Form Count (% of Expected): Signed	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of signed forms and the percentage of expected forms that have been signed in the InForm application.</p> <p>How calculated: Counts forms that have been signed. This value displays as a whole number and as a percentage of the total number of expected forms that are signed.</p> $[\% \text{ signed}] = [\text{signed form count}] * 100 / [\text{expected form count}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>

CRF Status Detail by Site and Subject	
Column	Description
Form Count (% of Expected): Locked	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of locked forms, and the percentage of expected forms that are locked.</p> <p>How calculated: Counts forms for which any of the following conditions is true:</p> <ul style="list-style-type: none"> • The form has been locked. • The form is contained within a case book that has been locked. • The form is contained within a visit that has been locked. <p>This value displays as a whole number and as a percentage:</p> $[\% \text{ locked}] = [\text{locked form count}] * 100 / [\text{expected form count}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>
Form Counts (% of Expected): Forms with Comments	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of expected forms with form-level comments, and the percentage of expected forms that have form-level comments.</p> <p>How calculated: Counts forms that contain form-level comments. Does not count forms with item-level comments only. This value displays as a whole number and a percentage of the total number of expected forms that have comments:</p> $[\% \text{ forms with comments}] = [\text{forms with comments}] * 100 / [\text{expected form count}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>
Form Counts (% of Expected): Forms with Queries	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of forms with open queries, and the percentage of expected forms that contain open queries.</p> <p>How calculated: Counts forms that contain an item with an open query. This value displays as a whole number and a percentage of the total number of expected forms that have open queries:</p> $[\% \text{ forms with open queries}] = [\text{forms with open queries}] * 100 / [\text{expected form count}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>

CRF Status Detail by Visit and Site

This report shows the number of forms in each possible status, organized by visit across sites.

Selection criteria: CRF Status Detail by Visit and Site report prompt page

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: CRF Status Detail by Visit and Site* (on page 289).

Selection criteria

CRF Status Detail by Visit and Site	
Selection criteria	Action
Countries	To report on specific countries, select their names from the list. Then, click Update to update the Sites list.
Sites	Select specific sites from the list and click Update to update the Subjects list with Subject IDs.
Subjects	Select specific subjects from the list.
Visits	Select a visit from the list.

CRF Status Detail by Visit and Site	
Selection criteria	Action
Expected forms for	<p>Filter the report by expected forms. Choose one of these options from the drop-down list.</p> <ul style="list-style-type: none"> • All forms—All clinical forms (forms of type CRF) are considered. • Scheduled visits—All expected forms that are in scheduled visits are considered. • Scheduled or started visits—All clinical forms that are in either expected or started visits are considered. • Scheduled or started visits to date—All the expected forms that are in scheduled visits whose expected start date is earlier than the report run date, and all the expected forms that are present in started visits when the actual date of the visit is on or before the report run date are considered. • Scheduled visits or started forms to date—All the expected forms that are in scheduled visits whose expected start date is on or before the report run date, and all the expected forms that were started on or before the report run date are considered.
Limit to forms with	<p>To filter the report, select one or more of the following options:</p> <ul style="list-style-type: none"> • Required items—Forms that have items marked as required are considered. • SV required items—Forms that have items marked as source verification required are considered. • Outstanding queries—Forms that have open or answered queries against the forms items are considered. • Comments—Forms that have either form level or item level comments are considered. <p>If you leave all checkboxes blank, this prompt is not applied. In that case, the results are determined by your selections in the previous prompts.</p> <p>If one or more checkboxes are selected, the counts are limited by the selection(s) in this prompt. Most likely, this results in decreased counts. For example, selecting both Required items and SV required items limits the report results to only those forms that have both required items and SV required items.</p>

Note: To include all available options in the report, leave the optional selection fields blank; that is, do not select any individual options from the drop-down lists. For the best performance, do not select any optional filters.

Sort options

Sort options are: None, Country, Visit, Site Mnemonic, Subject Number, Expected Forms

Count, % of Incomplete Forms, % of Completed Forms, % of Frozen Forms, % of SV Partial Forms, % of SV Complete Forms, % of Signed Forms, % of Locked Forms, % of Forms with Comments, % of Forms with Queries.

Use the Sort drop-down lists to change any of the default selections.

CRF Status Detail by Visit and Site	
Sort	Default selection
First level	Country
Second level	Visit Order
Third level	Site Mnemonic

Use the sort drop-down lists to change any of these selections.

Report/Graph page: CRF Status Detail by Visit and Site

Subtotals and totals

- **Subtotals**—By Site, Visit, and Country.
- **Totals**—Overall form count totals.

Column descriptions

CRF Status Detail by Visit and Site	
Column	Description
Country	<p>Data displayed: String</p> <p>Description: Country in which a site is located, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Visit Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation of the visit title, as specified in trial design code. For CRF visits, this name appears at the top of a collection of forms in the visit timeline. The visit mnemonic may not be a unique identifier.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

CRF Status Detail by Visit and Site	
Column	Description
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Subject Number	<p>Data displayed: String</p> <p>Description: Number that identifies the subject. This number may be changed after the subject is enrolled, if the study is configured to require a unique subject ID for a study or site.</p> <p>Note: Subject number might not be unique at your site.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
DOV	<p>Data displayed: Date/Time</p> <p>Description: The date that is recorded in a standard Date of Visit control in the InForm application.</p> <p>Note: This report element assumes that your trial has been developed using a specific design for DOV controls.</p> <p>Date type: Clinical.</p> <p>Note: This report element assumes that your study was developed using a specific design for the DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>For more information, see <i>DOV controls</i> (on page 26).</p>
Form Count (% of Expected) :Expected	<p>Data displayed: Numeric</p> <p>Description: The number of expected forms in the study.</p> <p>How calculated: This number reflects the number of expected forms for the site based on the option selected for the Expected forms for filter on the report prompt page.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

CRF Status Detail by Visit and Site	
Column	Description
Form Count (% of Expected): Incomplete	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of expected forms that are started but incomplete, and the percentage of expected forms that are incomplete.</p> <p>How calculated: For each site, calculates the following:</p> $[incomplete\ forms\ count] = [started\ forms\ count] - [completed\ forms\ count]$ $[incomplete,\ \%\ of\ expected] = [incomplete\ forms\ count] * 100 / [expected\ forms\ count]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Form Count (% of Expected): Completed	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of completed forms, and the percentage of expected forms that are complete in the InForm application.</p> <p>How calculated: Counts forms that are expected and meet the following criteria:</p> <ul style="list-style-type: none"> • Are started. • Contain data for all required items. • Do not have open queries associated with any items on the form. • For a repeating form, the form is not in a deleted state. • For an itemset form, the form is complete even if all the instances are deleted. <p>This value displays as a whole number and as a percentage of the total number of expected forms that are complete:</p> $[\% \ complete] = [complete\ forms] * 100 / [expected\ forms]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>

CRF Status Detail by Visit and Site	
Column	Description
Form Count (% of Expected): Frozen	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of frozen forms, and the percentage of expected forms that are currently marked frozen in the InForm application.</p> <p>How calculated: Counts expected forms that have been frozen using any of these InForm features:</p> <ul style="list-style-type: none"> • Freeze CRF • Freeze CRB • Freeze Visit <p>This value displays as a whole number (number of frozen forms), followed by the percentage of expected forms that are currently marked frozen:</p> $[\% \text{ frozen}] = [\text{frozen forms}] * 100 / [\text{expected forms}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>
Form Count (% of Expected): SV Partial	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of SV Partial forms, and the percentage of expected forms where source verification is not complete.</p> <p>How calculated: Counts forms as SV partial if they are expected and if only some of the SV required items on the forms have been source verified, and others have not. The InForm application automatically assigns a status of SV partial to any form for which some, but not all, SV required items have been marked SV complete.</p> <p>This value is displayed as a whole number and as a percentage of the total number of expected forms that are marked SV partial:</p> $[\% \text{ SV partial}] = [\text{SV partial form count}] * 100 / [\text{expected forms}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>

CRF Status Detail by Visit and Site	
Column	Description
Form Count (% of Expected) SV Completed	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of SV complete forms, and the percentage of expected forms where source verification is complete.</p> <p>How calculated: Counts forms as SV complete if all SV required items on the form have been source verified. This value displays as a whole number and as a percentage of the total number of expected forms that are marked SV complete. This value displays as a whole number and as a percentage of the total number of expected forms that are marked SV complete:</p> $[\% \text{ SV complete}] = [\text{SV complete form count}] * 100 / [\text{expected form count}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Form Count (% of Expected): Signed	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of signed forms and the percentage of expected forms that have been signed in the InForm application.</p> <p>How calculated: Counts forms that have been signed. This value displays as a whole number and as a percentage of the total number of expected forms that are signed.</p> $[\% \text{ signed}] = [\text{signed form count}] * 100 / [\text{expected form count}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>
Form Count (% of Expected): Locked	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of locked forms, and the percentage of expected forms that are locked.</p> <p>How calculated: Counts forms for which any of the following conditions is true:</p> <ul style="list-style-type: none"> • The form has been locked. • The form is contained within a case book that has been locked. • The form is contained within a visit that has been locked. <p>This value displays as a whole number and as a percentage:</p> $[\% \text{ locked}] = [\text{locked form count}] * 100 / [\text{expected form count}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>

CRF Status Detail by Visit and Site	
Column	Description
Form Counts (% of Expected): Forms with Comments	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of expected forms with form-level comments, and the percentage of expected forms that have form-level comments.</p> <p>How calculated: Counts forms that contain form-level comments. Does not count forms with item-level comments only. This value displays as a whole number and a percentage of the total number of expected forms that have comments:</p> $[\% \text{ forms with comments}] = [\text{forms with comments}] * 100 / [\text{expected form count}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>
Form Counts (% of Expected): Forms with Queries	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of forms with open queries, and the percentage of expected forms that contain open queries.</p> <p>How calculated: Counts forms that contain an item with an open query. This value displays as a whole number and a percentage of the total number of expected forms that have open queries:</p> $[\% \text{ forms with open queries}] = [\text{forms with open queries}] * 100 / [\text{expected form count}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>

CRF Status Summary by Site

This report shows the total number and percentage of expected forms that are incomplete, complete, frozen, and locked. This report is grouped by site.

Selection criteria: CRF Status Summary by Site prompt page

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: CRF Status Summary by Site* (on page 296).

Selection criteria

CRF Status Summary by Site	
Selection criteria	Action
Countries	To report on specific countries, select their names from the list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.
Expected forms for	<p>Select the clinical forms (forms that have a type of CRF) that are expected to appear.</p> <ul style="list-style-type: none"> • All forms—All expected forms are considered. • Scheduled visits—Expected forms that appear in scheduled visits are considered. • Scheduled or started visits—Expected forms that appear in scheduled or started visits are considered. A started visit is a visit in which at least one non-common expected form is started. • Scheduled or started visits to date—Expected forms that appear in visits that are scheduled to start or have been started by the date the report is run are considered. • Scheduled visits or started forms to date—Expected forms for which either of the following is true are considered: <ul style="list-style-type: none"> ▪ The forms appear in visits that are scheduled to occur by the date the report is run. ▪ The forms have been started by the date the report is run. ▪ Default: Scheduled or started visits

CRF Status Summary by Site	
Selection criteria	Action
Limit to forms with	<p>To filter the report, select one or more of the following options:</p> <ul style="list-style-type: none"> • Required items—Forms that have items marked as required are considered. • SV required items—Forms that have items marked as source verification required are considered. • Outstanding queries—Forms that have open or answered queries against the forms items are considered. • Comments—Forms that have either form level or item level comments are considered. <p>If you leave all checkboxes blank, this prompt is not applied. In that case, the results are determined by your selections in the previous prompts.</p> <p>If one or more checkboxes are selected, the counts are limited by the selection(s) in this prompt. Most likely, this results in decreased counts. For example, selecting both Required items and SV required items limits the report results to only those forms that have both required items and SV required items.</p>

Note: To include all available options in the report, leave the optional selection fields blank; that is, do not select any individual options from the drop-down lists. For the best performance, do not select any optional filters.

Sort options

Sort options are: None, Country, Site Mnemonic, Subject Count, Expected Forms Count, % of Not Started Forms, % of Incomplete Forms, % of Completed Forms, % of Frozen Forms, % of SV Complete Forms, % of Signed Forms, % of Locked Forms.

Use the Sort drop-down lists to change any of the default selections.

CRF Status Summary by Site	
Sort	Default selection
First level	Country
Second level	Site Mnemonic
Third level	None

Report/Graph page: CRF Status Summary by Site

Graphs

A bar graph appears on the first page of the CRF Status Summary by Site report, plotting a

summary of form completion status across all sites.

Subtotals and totals

- **Subtotals**—By Country.
- **Totals**—Overall form count totals.

Drill-down reports

Click the value in the Site Mnemonic column to drill down to the CRF Status Detail by Visit and Site report for the selected site.

Click the value in the Subject Count column to drill down to the CRF Status Detail by Visit and Site report for the subjects included in the subject count.

Column descriptions

CRF Status Summary by Site	
Column	Description
Country	<p>Data displayed: String</p> <p>Description: Country in which a site is located, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Subject Count	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who have enrolled at the site.</p> <p>How calculated: For each site, counts subjects that have been enrolled in the InForm application. This count includes subjects who have enrolled and have moved on to other states, such as Randomized, Dropped Out, or Complete.</p> <p>Note: The Enrollment form, designed according to InForm specifications, must be completed for the subject.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Status is determined by value on the InForm Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p>

CRF Status Summary by Site	
Column	Description
Form Count (% of Expected: Expected)	<p>Data displayed: Numeric</p> <p>Description: The number of expected forms in the study.</p> <p>How calculated: This number reflects the number of expected forms for the site based on the option selected for the Expected forms for filter on the report prompt page.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Form Count (% of Expected: Not Started)	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number (and percentage) of expected forms that are not started in the InForm application.</p> <p>How calculated: A form is started if any data, queries or comments have been entered. Each instance of a repeating form counts as a separate started form. A dynamic form may be Activated but not Started.</p> <p>This value displays as a whole number and as the percentage of expected forms that are not started:</p> $[\text{not started, \% of expected}] = [\text{not started forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Form Count (% of Expected) Incomplete	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of expected forms that are started but incomplete, and the percentage of expected forms that are incomplete.</p> <p>How calculated: For each site, calculates the following:</p> $[\text{incomplete forms count}] = [\text{started forms count}] - [\text{completed forms count}]$ $[\text{incomplete, \% of expected}] = [\text{incomplete forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

CRF Status Summary by Site	
Column	Description
Form Count (% of Expected): Completed	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of completed forms, and the percentage of expected forms that are complete in the InForm application.</p> <p>How calculated: Counts forms that are expected and meet the following criteria:</p> <ul style="list-style-type: none"> • Are started. • Contain data for all required items. • Do not have open queries associated with any items on the form. • For a repeating form, the form is not in a deleted state. • For an itemset form, the form is complete even if all the instances are deleted. <p>This value displays as a whole number and as a percentage of the total number of expected forms that are complete:</p> $[\% \text{ complete}] = [\text{complete forms}] * 100 / [\text{expected forms}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>
Form Count (% of Expected) Frozen	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of frozen forms, and the percentage of expected forms that are currently marked frozen in the InForm application.</p> <p>How calculated: Counts expected forms that have been frozen using any of these InForm features:</p> <ul style="list-style-type: none"> • Freeze CRF • Freeze CRB • Freeze Visit <p>This value displays as a whole number (number of frozen forms), followed by the percentage of expected forms that are currently marked frozen:</p> $[\% \text{ frozen}] = [\text{frozen forms}] * 100 / [\text{expected forms}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>

CRF Status Summary by Site	
Column	Description
Form Count (% of Expected) SV Complete	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of SV complete forms, and the percentage of expected forms that are currently SV complete in the InForm application.</p> <p>How calculated: Counts forms marked SV complete in the InForm application if all SV required items on the form have been source verified.</p> <p>This value appears as a whole number and as a percentage of expected forms that are marked SV complete:</p> $[\text{SV complete, \% of expected}] = [\text{SV complete forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Form Count (% of Expected) Signed	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of signed forms and the percentage of expected forms that are currently signed in the InForm application.</p> <p>How calculated: Counts forms that have been signed by all groups that are required to sign the form. This value appears as a whole number and as a percentage of expected forms that are signed:</p> $[\text{signed, \% of expected}] = [\text{signed forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Form Count (% of Expected) Locked	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of locked forms and the percentage of expected forms that are locked in the InForm application.</p> <p>How calculated: Counts forms for which any of the following conditions is true:</p> <ul style="list-style-type: none"> • The form has been locked. • The form is contained within a case book that has been locked. • The form is contained within a visit that has been locked. <p>This value displays as a whole number and as a percentage:</p> $[\text{locked, \% of expected}] = [\text{locked forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

CRF Status Summary by User

This report shows, by site, the total number and percentage of expected forms that are incomplete, complete, frozen, locked, SV complete, and signed. This report is grouped by user within rights group.

Selection criteria: CRF Status Summary by User prompt page

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: CRF Status Summary by User* (on page 303).

Selection criteria

CRF Status Summary by User	
Selection criteria	Action
Rights Groups	Select the rights group or groups used for CRAs that are primary in your study and click Update to update the Users list.
Users	To report on specific users, select them from the drop-down list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.

CRF Status Summary by User	
Selection criteria	Action
Expected forms for	<p>Select the clinical forms (forms that have a type of CRF) that are expected to appear.</p> <ul style="list-style-type: none"> • All forms—All expected forms are considered. • Scheduled visits—Expected forms that appear in scheduled visits are considered. • Scheduled or started visits—Expected forms that appear in scheduled or started visits are considered. A started visit is a visit in which at least one non-common expected form is started. • Scheduled or started visits to date—Expected forms that appear in visits that are scheduled to start or have been started by the date the report is run are considered. • Scheduled visits or started forms to date—Expected forms for which either of the following is true are considered: <ul style="list-style-type: none"> ▪ The forms appear in visits that are scheduled to occur by the date the report is run. ▪ The forms have been started by the date the report is run. ▪ Default: Scheduled or started visits
Limit to forms with	<p>To filter the report, select one or more of the following options:</p> <ul style="list-style-type: none"> • Required items—Forms that have items marked as required are considered. • SV required items—Forms that have items marked as source verification required are considered. • Outstanding queries—Forms that have open or answered queries against the forms items are considered. • Comments—Forms that have either form level or item level comments are considered. <p>If you leave all checkboxes blank, this prompt is not applied. In that case, the results are determined by your selections in the previous prompts.</p> <p>If one or more checkboxes are selected, the counts are limited by the selection(s) in this prompt. Most likely, this results in decreased counts. For example, selecting both Required items and SV required items limits the report results to only those forms that have both required items and SV required items.</p>

Note: To include all available options in the report, leave the optional selection fields blank; that is, do not select any individual options from the drop-down lists. For the best performance, do not select any optional filters.

Sort options

Sort options are: None, Rights Group, User Name, Site Mnemonic, Subject Count, Expected Forms Count, % of Not Started Forms, % of Incomplete Forms, % of Completed Forms, % of Frozen Forms, % of SV Complete Forms, % of Signed Forms, % of Locked Forms.

Use the Sort drop-down lists to change any of the default selections.

CRF Status Summary by User	
Sort	Default selection
First level	Rights Group
Second level	User Name
Third level	Site Mnemonic

Report/Graph page: CRF Status Summary by User

Subtotals and totals

- **Subtotals**—None.
- **Totals**—Overall form count totals.

Drill down reports

Click the value in the Site Mnemonic column to drill down to the CRF Status Detail by Visit and Site report for the selected site.

Click the value in the Subject Count column to drill down to the CRF Status Detail by Site and Subject report for the selected user.

Column descriptions

CRF Status Summary by User	
Column	Description
Rights Group	<p>Data displayed: String</p> <p>Description: Rights group to which the user belongs.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

CRF Status Summary by User	
Column	Description
User Name	<p>Data displayed: String</p> <p>Description: Username of the user.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Subject Count	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who have enrolled at the site.</p> <p>How calculated: For each site, counts subjects that have been enrolled in the InForm application. This count includes subjects who have enrolled and have moved on to other states, such as Randomized, Dropped Out, or Complete.</p> <p>Note: The Enrollment form, designed according to InForm specifications, must be completed for the subject.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Status is determined by value on the InForm Enrollment form, which is stored in the Reporting and Analysis database. Status is set to 1 when the subject is enrolled.</p>
Form Count (% of Expected): Expected	<p>Data displayed: Numeric</p> <p>Description: The number of expected forms in the study.</p> <p>How calculated: This number reflects the number of expected forms for the site based on the option selected for the Expected forms for filter on the report prompt page.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

CRF Status Summary by User	
Column	Description
Form Count (% of Expected): Not Started	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number (and percentage) of expected forms that are not started in the InForm application.</p> <p>How calculated: A form is started if any data, queries or comments have been entered. Each instance of a repeating form counts as a separate started form. A dynamic form may be Activated but not Started.</p> <p>This value displays as a whole number and as the percentage of expected forms that are not started:</p> $[\text{not started, \% of expected}] = [\text{not started forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Form Count (% of Expected): Incomplete	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number (and percentage) of expected forms that are started but not complete.</p> <p>How calculated: For each site, calculates the following:</p> $[\text{incomplete forms count}] = [\text{started forms count}] - [\text{completed forms count}]$ $[\text{incomplete, \% of expected}] = [\text{incomplete forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

CRF Status Summary by User	
Column	Description
Form Count (% of Expected): Completed	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of completed forms, and the percentage of expected forms that are complete in the InForm application.</p> <p>How calculated: Counts forms that are expected and meet the following criteria:</p> <ul style="list-style-type: none"> • Are started. • Contain data for all required items. • Do not have open queries associated with any items on the form. • For a repeating form, the form is not in a deleted state. • For an itemset form, the form is complete even if all the instances are deleted. <p>This value displays as a whole number and as a percentage of the total number of expected forms that are complete:</p> $[\% \text{ complete}] = [\text{complete forms}] * 100 / [\text{expected forms}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>
Form Count (% of Expected) Frozen	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of frozen forms, and the percentage of expected forms that are currently marked frozen in the InForm application.</p> <p>How calculated: Counts expected forms that have been frozen using any of these InForm features:</p> <ul style="list-style-type: none"> • Freeze CRF • Freeze CRB • Freeze Visit <p>This value displays as a whole number (number of frozen forms), followed by the percentage of expected forms that are currently marked frozen:</p> $[\% \text{ frozen}] = [\text{frozen forms}] * 100 / [\text{expected forms}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>

CRF Status Summary by User	
Column	Description
Form Count (% of Expected): SV Complete	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of SV complete forms, and the percentage of expected forms that are currently SV complete in the InForm application.</p> <p>How calculated: Counts forms marked SV complete in the InForm application if all SV required items on the form have been source verified.</p> <p>This value appears as a whole number and as a percentage of expected forms that are marked SV complete:</p> $[\text{SV complete, \% of expected}] = [\text{SV complete forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Form Count (% of Expected): Signed	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of signed forms and the percentage of expected forms that are signed in the InForm application.</p> <p>How calculated: Counts forms that have been signed. This value displays as a whole number and as a percentage of the total number of expected forms that are signed.</p> $[\text{signed, \% of expected}] = [\text{signed forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Form Count (% of Expected): Locked	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of locked forms and the percentage of expected forms that are locked in the InForm application.</p> <p>How calculated: Counts forms for which any of the following conditions is true:</p> <ul style="list-style-type: none"> • The form has been locked. • The form is contained within a case book that has been locked. • The form is contained within a visit that has been locked. <p>This value displays as a whole number and as a percentage:</p> $[\text{locked, \% of expected}] = [\text{locked forms count}] * 100 / [\text{expected forms count}]$ <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Item reports

About item reports

Item reports provide information about the progress of item source verification, as well as listings of items on forms.

CRF Item Listing

This report shows a list of form items that are in a given state or that entered a given state as of a specified point in time. The report is organized by site, subject, visit, and form. Selection can be filtered for missing items or for items that were changed since a given time.

Selection criteria: CRF Item Listing

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

Note: You must make a selection from the Visits drop-down list before you can access the More Options page or run the report.

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: CRF Item Listing* (on page 310).

Selection criteria

CRF Item Listing	
Selection criteria	Action
Countries	To report on specific countries, select their names from the list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.
Visits	Select a visit from the list.

CRF Item Listing	
Selection criteria	Action
Limit to forms that are	<p>To filter the report to include only items in specific states, select one or more of the following options:</p> <ul style="list-style-type: none"> • SV ready—Forms marked SV Ready are considered. • Not SV complete—Forms that are neither source verified nor partially source verified are considered. • Partially SV complete—Forms that are partially source verified (only some of the SV Required items on the form are source verified) are considered. • SV complete—Forms that are completely source verified are considered. • Frozen—Forms in a frozen state are considered. • Signed—Forms that are signed are considered. • Locked—Forms that are locked are considered. <p>The resulting report includes items in all form states you select. If you leave all checkboxes blank, the report includes all applicable forms.</p>
Limit to items that are	<p>Select one or more options to filter the report to include only items that are:</p> <ul style="list-style-type: none"> • Required—Items that are marked required are considered. • SV required—Items for which source verification is required are considered. • With queries—Items that have open queries against them are considered. • With comments—Items that have comments against them are considered. • Unverified—Items that are not yet source verified are considered. • Verified—Items that are source verified are considered. • No longer verified—Items that were modified after source verification was done and for which the source verification for the changes is not complete are considered. • Empty—Items that have no data are considered. • Modified—Items that were modified after initial data entry are considered. • Filled—Items that have data are considered. <p>The resulting report includes data for only the types of items you select. If you leave all checkboxes blank, the report will include all applicable items.</p>

CRF Item Listing	
Selection criteria	Action
Date last modified date range	Specify a From and To date by entering dates or by using the calendar icons to select the date range to include in your report. The resulting report includes data for items that were last modified within the date range specified. Default: Current Date

Note: To include all available options in the report, leave the optional selection fields blank; that is, do not select any individual options from the drop-down lists. For the best performance, do not select any optional filters.

Sort options

Sort options are: None, Site, Subject Number, Visit, Form, Item Question, Form Dates–SV Ready, Form Dates–Frozen, Form Dates–SV Complete, Form Dates–Signed, Form Dates–Locked, Item–Verified, Item–SV Required, Item–Required, Item–Has Query, Item–Has Comment, Item–Original Value Date, Item–Data Change User, Item–Data Last Modified.

Use the Sort drop-down lists to change any of the default selections.

CRF Item Listing	
Sort	Default selection
First level	Site.
Second level	Subject Number.
Third level	Visit.
Fourth level	Form.

Use the sort drop-down lists to change any of these selections.

Report/Graph page: CRF Item Listing

Link to form items

Click the value in the Form column to link directly to the item question on the InForm form.

Column descriptions

CRF Item Listing	
Column	Description

CRF Item Listing	
Column	Description
Site	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Subject Number/Initials	<p>Data displayed: String</p> <p>Description: The subject number, followed by the subject initials. The subject number identifies the subject. The subject number and subject initials can be changed post enrollment, if this is configured in the study.</p> <p>Note: Subject number may or may not be unique at your site.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Visit	<p>Data displayed: String</p> <p>Description: Abbreviation of the visit title, as specified in trial design code. For CRF visits, this name appears at the top of a collection of forms in the visit timeline. The visit mnemonic may not be a unique identifier.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
DOV	<p>Data displayed: Date/Time</p> <p>Description: The date that is recorded in a standard Date of Visit control in the InForm application.</p> <p>Note: This report element assumes that your trial has been developed using a specific design for DOV controls.</p> <p>Date type: Clinical.</p> <p>Note: This report element assumes that your study was developed using a specific design for the DOV controls.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>For more information, see <i>DOV controls</i> (on page 26).</p>

CRF Item Listing	
Column	Description
Form	<p>Data displayed: String</p> <p>Description: Short name or abbreviation for the form, as specified in the study design code. This name appears on the Visit Navigation tab and is used to access a specific form in the InForm application.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Form index	<p>Data displayed: Numeric</p> <p>Description: For repeating forms, a numeric ordinal value that indicates each iteration of the form. For other forms, the value is 1.</p> <p>Data source: Calculated in the Reporting and Analysis database and is an ordinal number based on the FORMINDEX.</p>
Item Question	<p>Data displayed: String</p> <p>Description: Text of the question or prompt that instructs the user to enter specific clinical data.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Form State Dates: SV Ready	<p>Data displayed: Date/Time</p> <p>Description: The most recent date on which the status of the form was set to SV ready in the InForm software. Note that a value displays here only if the form has a current status of SV ready.</p> <p>Date type: System date (GMT).</p>
Form State Dates: Frozen	<p>Data displayed: Date/Time</p> <p>Description: The most recent date on which the status of the form was set to frozen in the InForm application. Note that a value displays here only if the form has a current status of frozen.</p> <p>Date type: System date (GMT).</p>
Form State Dates: SV Complete	<p>Data displayed: Date/Time</p> <p>Description: The most recent date on which all of the SV required items on the form are source verified.</p> <p>Date type: System date (GMT).</p>
Form State Dates: Signed	<p>Data displayed: Date/Time</p> <p>Description: The most recent date on which the form was signed in the InForm application. Note that a value displays here only if the form has a current status of Signed.</p> <p>Date type: System date (GMT).</p>

CRF Item Listing	
Column	Description
Form State Dates: Locked	<p>Data displayed: Date/Time</p> <p>Description: The most recent date on which the form was locked in the InForm application. Note that a value displays here only if the form has a current status of Locked.</p> <p>Date type: System date (GMT).</p>
Item Properties: Required	<p>Data displayed: Numeric</p> <p>Description: Indicates whether the item is required.</p> <ul style="list-style-type: none"> • Y—A value must be entered for the item. • N—Data entry is not required for the item. <p>Data source: Derived and stored in the Reporting and Analysis database.</p>
Item Properties: SV Required	<p>Data displayed: Y/N</p> <p>Description: Indicates whether the item requires source verification.</p> <ul style="list-style-type: none"> • Y—The item requires InForm source verification. • N—The item does not require source verification. <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Database value has been decoded for display.</p>
Item Properties: Verified	<p>Data displayed: Y/N</p> <p>Description: Indicates whether the item has been source verified:</p> <ul style="list-style-type: none"> • Y—The item is verified. • N—The item is not verified. <p>Note: This field is not supported in Add Entry items.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Database value has been decoded for display.</p>
Item Properties: Has Query	<p>Data displayed: Y/N</p> <p>Description: Indicates whether the item has an open query associated with it.</p> <ul style="list-style-type: none"> • Y—The item has a query. • N—The item does not have a query. <p>Note: This field is not supported in Add Entry items.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Database value has been decoded for display.</p>

CRF Item Listing	
Column	Description
Item Properties: Has Comment	<p>Data displayed: Y/N</p> <p>Description: Indicates whether the item has a comment associated with it.</p> <ul style="list-style-type: none"> • Y—The item has a comment. • N—The item does not have a comment. <p>Note: This field is not supported in Add Entry items.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Database value has been decoded for display.</p>
Item Properties: Data Modified	<p>Data displayed: Date</p> <p>Description: The date on which data was most recently entered into the item.</p> <p>Date type: System date (GMT).</p>
Item Properties: Original Value Date	<p>Data displayed: Date</p> <p>Description: The date on which data was originally entered into the item.</p> <p>Date type: System date (GMT).</p>
Item Properties: Data Change User	<p>Data displayed: String</p> <p>Description: The username of the InForm user who made the most recent change to clinical data for the item.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Source Verification Listing

This report shows form items based on date range and SV status. Use this report to compile a list of items to source verify when visiting a site, or to view those items that were source verified in a given time period.

Selection criteria: Source Verification Listing

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: Source Verification Listing* (on

page 316).

Selection criteria

Source Verification Listing	
Selection criteria	Action
Countries	To report on specific countries, select their names from the list. Then, click Update to update the Sites list.
Sites	Select specific sites from the list and click Update to update the Subjects list with Subject IDs.
Subjects	Select specific subjects from the list.
Visit	<p>To report on a visit, select it from the list. You can only select one visit at a time.</p> <p>Note: You must select a visit.</p>
Forms	<p>To report on specific forms, select one or more forms from the list of form mnemonics.</p> <p>Note: You must select at least one form.</p>
Data entry completion status	<p>To filter the report by data entry completion status, select one of the following options:</p> <ul style="list-style-type: none"> • Any Forms—Includes all data entry incomplete and data entry complete expected forms. • Only Incomplete Forms—Includes only expected forms that have been started by are not yet data entry complete • Only Complete Forms—Includes only expected forms that are data entry complete. <p>The resulting report includes data for the form completion status selected.</p> <p>Default: Any Forms</p>
Visit start date range	<p>Select a date range for the visit start date. Use the calendar icons to select the date range to include in your report. The resulting report will include data for all visits that were started within the selected range.</p> <p>Default start date: 01-JAN-2009</p> <p>Default end date: Report run date</p>

Source Verification Listing	
Selection criteria	Action
Limit to	<p>To report based on item type, select from the following options:</p> <ul style="list-style-type: none"> • Items with queries—Items that have open queries against them are considered. • Items with comments—Items that have comments against them are considered. • Unverified items—Items that are not yet source verified are considered. • Verified items—Items that are source verified are considered. • No longer verified items—Items that were modified after source verification was done and for which the source verification for the changes is not complete are considered. <p>The resulting report displays data items that have all of the selected criteria. If you leave all checkboxes blank, the report will include all applicable forms.</p>

Sort options

Sort options are: None, Site, Subject Number, Visit, Form, Item Question, Verified, Status Change User, Last Verified, Data Change User, Data Last Modified.

Use the sort drop-down lists to change any of these selections.

Source Verification Listing	
Sort	Default selection
First level	Site
Second level	Subject Number
Third level	Visit
Fourth level	Form

Report/Graph page: Source Verification Listing

Link to form items

Click the value in the Form column to link directly to the item question on the InForm form. From here, you can see the data entered for the item.

Column descriptions

Source Verification Listing	
Column	Description
Site	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Subject Number	<p>Data displayed: String</p> <p>Description: Number that identifies the subject. This number may be changed after the subject is enrolled, if the study is configured to require a unique subject ID for a study or site.</p> <p>Note: Subject number might not be unique at your site.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Visit	<p>Data displayed: String</p> <p>Description: Abbreviation of the visit title, as specified in trial design code. For CRF visits, this name appears at the top of a collection of forms in the visit timeline. The visit mnemonic may not be a unique identifier.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
DOV	<p>Data displayed: Date</p> <p>Description: The date recorded in a standard Date of Visit control in the InForm application.</p> <p>Date type: Clinical.</p> <p>Note: This report element retrieves a date stored when your DOV controls are designed in a specific way.</p> <p>UUIDs:</p> <ul style="list-style-type: none"> • DateTimeControl—BD991BC0-B0A4-11D2-80E3-00A0C9AF7674 • Item—BD991BBF-B0A4-11D2-80E3-00A0C9AF7674 • Section—BD991BBE-B0A4-11D2-80E3-00A0C9AF7674 <p>For more information, see <i>DOV controls</i> (on page 26).</p>

Source Verification Listing	
Column	Description
Form	<p>Data displayed: String</p> <p>Description: Short name or abbreviation for the form, as specified in the study design code. This name appears on the Visit Navigation tab and is used to access a specific form in the InForm application.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Form Index	<p>Data displayed: Numeric</p> <p>Description: For repeating forms, a numeric ordinal value that indicates each iteration of the form. For other forms, the value is 1.</p> <p>Data source: Calculated in the Reporting and Analysis database and is an ordinal number based on the FORMINDEX.</p>
Item Question	<p>Data displayed: String</p> <p>Description: Text of the question or prompt that instructs the user to enter specific clinical data. Access to this data can be restricted in the InForm application. When users who have no access to this data run a report with this report element, the resulting report displays a series of asterisks (*****) rather than the actual item question.</p> <p>Items that have never contained data will not appear on reports that pair Item Question with Form Name or Form Mnemonic.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Status Change User	<p>Data displayed: String</p> <p>Description: The user name of the InForm user who made the most recent change to the status of the item. A change to the SV status of the item is considered a status change for the item.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Verified	<p>Data displayed: Y/N</p> <p>Description: Indicates whether the item has been source verified:</p> <ul style="list-style-type: none"> • Y—The item is verified. • N—The item is not verified. <p>Note: This field is not supported in Add Entry items.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Database value has been decoded for display.</p>

Source Verification Listing	
Column	Description
Last Verified	Data displayed: Date Description: The most recent date on which the item was source verified. Date type: System date (GMT).
Data Change User	Data displayed: String Description: The username of the InForm user who made the most recent change to clinical data for the item. Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.
Data Last Modified	Data displayed: Date Description: The date on which data was most recently entered into the item. Date type: System date (GMT).

Subject reports

About subject reports

Subject reports provide information on the progress of casebook completion for individual subjects. These reports also provide subject enrollment and dropout counts, as well as subject enrollment status.

Case Book Completion and Query Summary by Site

This report shows how many subject case books are complete and how many have no outstanding queries.

Selection criteria: Case Book Completion and Query Summary by Site report

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: Case Book Completion and Query Summary by Site* (on page 322).

Selection criteria

Case Book Completion and Query Summary by Site	
Selection criteria	Action
Countries	To report on specific countries, select their names from the list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.

Case Book Completion and Query Summary by Site	
Selection criteria	Action
Expected forms	<p>Select the clinical forms (forms that have a type of CRF) that are expected to appear.</p> <ul style="list-style-type: none"> • All forms—All expected forms are considered. • Scheduled visits—Expected forms that appear in scheduled visits are considered. • Scheduled or started visits—Expected forms that appear in scheduled or started visits are considered. A started visit is a visit in which at least one non-common expected form is started. • Scheduled or started visits to date—Expected forms that appear in visits that are scheduled to start or have been started by the date the report is run are considered. • Scheduled visits or started forms to date—Expected forms for which either of the following is true are considered: <ul style="list-style-type: none"> ▪ The forms appear in visits that are scheduled to occur by the date the report is run. ▪ The forms have been started by the date the report is run. ▪ Default: Scheduled or started visits

Note: To include all available options in the report, leave the optional selection fields blank; that is, do not select any individual options from the drop-down lists. For the best performance, do not select any optional filters.

Sort options

Sort options are: None, Country, Site Mnemonic, Enrolled Subject Count, Count of Incomplete CRBs, % of Incomplete CRBs, Count of Incomplete CRBs with Queries, % of Incomplete CRBs with Queries, Count of Incomplete CRBs without Queries, % of Incomplete CRBs without Queries, Count of Completed CRBs, % of Completed CRBs, Count of Completed CRBs with Queries, % of Completed CRBs with Queries, Count of Completed CRBs without Queries, % of Completed CRBs without Queries.

Use the Sort drop-down lists to change any of the default selections.

Case Book Completion and Query Summary by Site	
Sort	Default selection
First level	Country.
Second level	Site Mnemonic.
Third level	None.

Report/Graph page: Case Book Completion and Query Summary by Site

Subtotals and totals

- Subtotals—By Country.
 - Numeric columns—Total for each country.
 - % columns—Percent for each country.
- Totals—Overall subject count totals.
 - Numeric columns—Total for all countries.
 - % columns—Percent for all countries.

Column descriptions

Case Book Completion and Query Summary by Site	
Column	Description
Country	<p>Data displayed: String</p> <p>Description: Country in which a site is located, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Enrolled Subject Count	<p>Data displayed: Numeric</p> <p>Description: The number of subjects with started CRBs who have enrolled at the site and have not dropped out.</p> <p>How calculated: For each site, counts subjects with started CRBs who have been enrolled in the InForm application and have not dropped out of the study.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Case Book Completion and Query Summary by Site	
Column	Description
Incomplete CRBs (% of Incomplete CRBs)	<p>Data displayed: Numeric</p> <p>Description: The number of started CRBs that are not complete.</p> <p>How calculated: Counts Case Report Books that have been started and have at least one expected form without a status of Data Entry Completed.</p> <p>$[\% \text{ incomplete CRBs}] = [\text{incomplete CRBs}] * 100 / [\text{started CRBs}]$</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Incomplete CRBs with Queries (% of Incomplete CRBs with Queries)	<p>Data displayed: Numeric</p> <p>Description: The number of started CRBs that are not complete and that have open queries.</p> <p>How calculated: Counts Case Report Books that meet all of the following criteria:</p> <ul style="list-style-type: none"> ▪ Have been started. ▪ Have at least one expected form without a status of Data Entry Completed. ▪ Have at least one expected form with at least one open or answered query. <p>This value displays as both a total and a percentage of all started CRBs for subjects that have not dropped out:</p> <p>$[\% \text{ incomplete CRBs with queries}] = [\text{incomplete CRBs with queries}] * 100 / [\text{started CRBs}]$</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Case Book Completion and Query Summary by Site	
Column	Description
Incomplete CRBs without Queries (% of Incomplete CRBs without Queries)	<p>Data displayed: Numeric</p> <p>Description: The number of started CRBs that are not complete and that have no open queries.</p> <p>How calculated: Counts Case Report Books that meet all of the following criteria:</p> <ul style="list-style-type: none"> • Have been started. • Have at least one expected form without a status of Data Entry Completed. • Do not have any expected forms with any open or answered queries. <p>This value displays as both a total and a percentage of all started CRBs for subjects that have not dropped out:</p> $[Incomplete\ CRBs\ w/out\ queries] = [Incomplete\ CRBs] - [Incomplete\ CRBs\ with\ Queries]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Completed CRBs (% of Completed CRBs)	<p>Data displayed: Numeric</p> <p>Description: The number of started CRBs that are complete.</p> <p>How calculated: Counts Case Report Books that meet all of the following criteria:</p> <ul style="list-style-type: none"> • Have been started. • Have all expected forms with a status of Data Entry Completed. <p>This value displays as both a total and a percentage of all started CRBs for subjects that have not dropped out:</p> $[complete\ CRBs] = [CRB\ count] - [incomplete\ CRBs]$ $[%\ complete\ CRBs] = [complete\ CRBs] * 100 / [started\ CRBs]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Case Book Completion and Query Summary by Site	
Column	Description
Completed CRBs with Queries (% of Completed CRBs with Queries)	<p>Data displayed: Numeric</p> <p>Description: The number of started CRBs that are complete and that have open or answered queries.</p> <p>How calculated: Counts Case Report Books that meet all of the following criteria:</p> <ul style="list-style-type: none"> • Have been started. • Have all expected forms with a status of Data Entry Completed. • Have at least one expected form with at least one open or answered query. <p>This value displays as both a total and a percentage of all started CRBs for subjects that have not dropped out:</p> $[\text{completed CRBs with queries}] = [\text{total CRBs with queries}] - [\text{incomplete CRBs with queries}]$ $[\% \text{ complete CRBs with queries}] = [\text{complete CRBs with queries}] * 100 / [\text{started CRBs}]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Completed CRBs without Queries (% of Completed CRBs without Queries)	<p>Data displayed: Numeric</p> <p>Description: The number of started CRBs that are complete and that have no open or answered queries.</p> <p>How calculated: Counts Case Report Books that meet all of the following criteria:</p> <ul style="list-style-type: none"> • Have been started. • Have all expected forms with a status of Data Entry Completed. • Do not have any expected forms with any open or answered queries. <p>This value displays as both a total and a percentage of all started CRBs for subjects that have not dropped out:</p> $[\text{complete CRBs without queries}] = [\text{complete CRBs}] - [\text{complete CRBs with queries}]$ $[\% \text{ complete CRBs without queries}] = [\text{complete CRBs without queries}] * 100 / [\text{started CRBs}]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Case Book Completion and Query Summary by User

This report shows how many subject case books are complete and how many have no outstanding queries.

Selection criteria: Case Book Completion and Query Summary by User report

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: Case Book Completion and Query Summary by User* (on page 328).

Selection criteria

Case Book Completion and Query Summary by User	
Selection criteria	Action
Rights Groups	Select the rights group or groups used for CRAs that are primary in your study and click Update to update the Users list. Note: For optimal performance, if you want to include all rights groups in your report, do not select any rights groups from the list.
Users	To report on specific users, select them from the drop-down list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.

Case Book Completion and Query Summary by User	
Selection criteria	Action
Expected forms	<p>Select the clinical forms (forms that have a type of CRF) that are expected to appear.</p> <ul style="list-style-type: none"> • All forms—All expected forms are considered. • Scheduled visits—Expected forms that appear in scheduled visits are considered. • Scheduled or started visits—Expected forms that appear in scheduled or started visits are considered. A started visit is a visit in which at least one non-common expected form is started. • Scheduled or started visits to date—Expected forms that appear in visits that are scheduled to start or have been started by the date the report is run are considered. • Scheduled visits or started forms to date—Expected forms for which either of the following is true are considered: <ul style="list-style-type: none"> ▪ The forms appear in visits that are scheduled to occur by the date the report is run. ▪ The forms have been started by the date the report is run. ▪ Default: Scheduled or started visits

Sort options

Case Book Completion and Query Summary by User	
Sort	Default selection
First level	Group Name
Second level	User Name
Third level	Site Mnemonic

Use the sort drop-down lists to change any of these selections.

Report/Graph page: Case Book Completion and Query Summary by User

Subtotals and totals

- **Subtotals**—By User and Rights Group.
- **Totals**—Overall subject count totals.

Column descriptions

Case Book Completion and Query Summary by User	
Column	Description
Rights Group	<p>Data displayed: String</p> <p>Description: Rights group to which the user belongs.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
User Name	<p>Data displayed: String</p> <p>Description: Username of the user.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Enrolled Subject Count	<p>Data displayed: Numeric</p> <p>Description: The number of subjects with started CRBs who have enrolled at the site and have not dropped out.</p> <p>How calculated: For each site, counts subjects with started CRBs who have been enrolled in the InForm application and have not dropped out of the study.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Case Book Completion and Query Summary by User	
Column	Description
Incomplete CRBs	<p>Data displayed: Numeric</p> <p>Description: The number of started CRBs that are not complete.</p> <p>How calculated: Counts Case Report Books that have been started and have at least one expected form without a status of Data Entry Completed.</p> $[\% \text{ incomplete CRBs}] = [\text{incomplete CRBs}] * 100 / [\text{started CRBs}]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Incomplete CRBs with Queries	<p>Data displayed: Numeric</p> <p>Description: The number of started CRBs that are not complete that have open or answered queries.</p> <p>How calculated: A case book is counted if it meets both of the following criteria:</p> <ul style="list-style-type: none"> • It has been started and at least one expected form does not have a status of Data Entry Completed. • At least one expected form has at least one open or answered query. <p>This value displays as both a total and a percentage of all started CRBs that are incomplete and that have queries:</p> $[\% \text{ incomplete CRBs with queries}] = [\text{incomplete CRBs with queries}] * 100 / [\text{started CRBs}]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Incomplete CRBs without Queries	<p>Data displayed: Numeric</p> <p>Description: The number of started CRBs that are not complete that have no open or answered queries.</p> <p>How calculated: A case book is counted if it meets both of the following criteria:</p> <ul style="list-style-type: none"> • It has been started and no expected forms have a status of Data Entry Completed. • No expected forms have any open or answered queries. <p>This value displays as both a total and a percentage of started CRBs that are incomplete and have no queries:</p> $[\% \text{ incomplete CRBs w/out queries}] = [\text{incomplete CRBs w/out queries}] * 100 / [\text{started CRBs}]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Case Book Completion and Query Summary by User	
Column	Description
Completed CRBs	<p>Data displayed: Numeric</p> <p>Description: The number of started CRBs that are complete.</p> <p>How calculated: Counts Case Report Books that meet all of the following criteria:</p> <ul style="list-style-type: none"> • Have been started. • Have all expected forms with a status of Data Entry Completed. <p>This value displays as both a total and a percentage of all started CRBs for subjects that have not dropped out:</p> $[\text{complete CRBs}] = [\text{CRB count}] - [\text{incomplete CRBs}]$ $[\% \text{ complete CRBs}] = [\text{complete CRBs}] * 100 / [\text{started CRBs}]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Completed CRBs with Queries	<p>Data displayed: Numeric</p> <p>Description: The number of started CRBs that are complete and that have open or answered queries.</p> <p>How calculated: Counts Case Report Books that meet all of the following criteria:</p> <ul style="list-style-type: none"> • Have been started. • Have all expected forms with a status of Data Entry Completed. • Have at least one expected form with at least one open or answered query. <p>This value displays as both a total and a percentage of all started CRBs for subjects that have not dropped out:</p> $[\text{completed CRBs with queries}] = [\text{total CRBs with queries}] - [\text{incomplete CRBs with queries}]$ $[\% \text{ complete CRBs with queries}] = [\text{complete CRBs with queries}] * 100 / [\text{started CRBs}]$ <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Case Book Completion and Query Summary by User	
Column	Description
Completed CRBs without Queries	<p>Data displayed: Numeric</p> <p>Description: The number of started CRBs that are complete and that have no open or answered queries.</p> <p>How calculated: Counts Case Report Books that meet all of the following criteria:</p> <ul style="list-style-type: none"> • Have been started. • Have all expected forms with a status of Data Entry Completed. • Do not have any expected forms with any open or answered queries. <p>This value displays as both a total and a percentage of all started CRBs for subjects that have not dropped out:</p> <p>[complete CRBs without queries] = [complete CRBs] - [complete CRBs with queries]</p> <p>[% complete CRBs without queries] = [complete CRBs without queries] * 100 / [started CRBs]</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Cumulative Subject Enrollment by Month

This report charts the cumulative counts of enrolled, dropped, and completed subjects over time.

Selection criteria: Cumulative Subject Enrollment by Month report

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: Cumulative Subject Enrollment by Month* (on page 332).

Selection criteria

Cumulative Subject Enrollment by Month	
Selection criteria	Action
Countries	To report on specific countries, select their names from the list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.
Date range	Enter the From and To dates or use the calendar icons to select the dates. Default From date: 2000-01-01 Default To date: Current date

Note: To include all available options in the report, leave the optional selection fields blank; that is, do not select any individual options from the drop-down lists. For the best performance, do not select any optional filters.

Sort options

Sort options are: None, Site Mnemonic, Date.

Use the Sort drop-down lists to change any of the default selections.

Cumulative Subject Enrollment by Month	
Sort	Default selection
First level	Site Mnemonic.
Second level	Date.

Report/Graph page: Cumulative Subject Enrollment by Month

Graphs

A bar graph appears on the first page of the Cumulative Subject Enrollment by Month report, illustrating the enrolled, dropped, and completed subject count by month.

Subtotals and totals

- **Subtotals**—None.
- **Totals**—Overall subject count totals.

Column descriptions

Cumulative Subject Enrollment by Month	
Column	Description
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Enrolled count by month	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who were enrolled at the site within a given month.</p> <p>How calculated: For each site, the enrolled subject count is incremented if a new subject has become enrolled during the month. If there are no new subjects enrolled during a particular month, the count is the same as the previous month.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Dropped count by month	<p>Data displayed: Numeric</p> <p>Description: The number of subjects in each site who dropped out of the study during a given month.</p> <p>How calculated: For each site and month, the dropped subject count is incremented if a subject drops out of the study during the month. If no subjects drop out during a particular month, the count is the same as the previous month.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Completed count by month	<p>Data displayed: Numeric</p> <p>Description: The number of subjects at the site who completed the study during a given month.</p> <p>How calculated: For each site and month, the complete subject count is incremented when a subject completes the study in a particular month. If no subjects complete the count in a given month, the count is the same as the previous month.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Subject Dropout Count by Reason

This report shows the number of subjects who have left the trial for each reason used in the trial design. It is not limited to the reasons provided in the InForm application.

Selection criteria: Subject Dropout Count by Reason report

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: Subject Dropout Count by Reason* (on page 335).

Selection criteria

Subject Dropout Count by Reason	
Selection criteria	Action
Countries	To report on specific countries, select their names from the list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.
Date range	Enter the From and To dates or use the calendar icons to select the dates. Default From date: 2000-01-01 Default To date: Current date

Sort options

Sort options are: None, Country, Site Mnemonic, Enrolled Count, Total Dropouts.

Use the Sort drop-down lists to change any of the default selections.

Subject Dropout Count by Reason	
Sort	Default selection
First level	Country.
Second level	Site Mnemonic.
Third level	None.

Report/Graph page: Subject Dropout Count by Reason

Graphs

A bar graph appears on the first page of the Subject Dropout Count by Reason report, illustrating how many subjects dropped out by drop out reason.

Subtotals and totals

- **Subtotals**—By Country and Site.
- **Totals**—Overall subject count totals.

Column descriptions

Subject Dropout Count by Reason	
Column	Description
Country	<p>Data displayed: String</p> <p>Description: Country in which a site is located, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Enrolled	<p>Data type: Numeric</p> <p>Description: The number of subjects that were enrolled at the site in the InForm application during the specified date range.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Subject Dropout Count by Reason	
Column	Description
Dropout Reason	<p>Data displayed: String</p> <p>Description: Text that indicates why the subject dropped out of the study. The drop out reason is clinical data that is specified on the Study Completion form for the subject.</p> <p>Note: This report displays only those reasons that were specified when subjects dropped out of the study. If a drop out reason was never used, the reason does not appear in this report.</p> <p>UUIDs: PF_SC_COMPLETECTL, PF_SC_REASONCTL_internal_reason_value</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Total Dropouts	<p>Data type: Numeric</p> <p>Description: The total number of subjects that dropped out of the trial, by site. This total is a sum of all dropout counts in the row plus the count of subjects who dropped out but for whom the reason was not specified.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Subject Enrollment Status by Site

This report shows the number and percentage of subjects screened, enrolled, randomized, active, completed, or dropped by site.

Selection criteria: Subject Enrollment Status by Site

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: Subject Enrollment Status by Site* (on page 337).

Selection criteria

Subject Enrollment Status by Site	
Selection criteria	Action
Countries	To report on specific countries, select their names from the list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.
Date range	Enter the From and To dates or use the calendar icons to select the dates. Default From date: 2000-01-01 Default To date: Current date

Sort options

Sort options are: None, Country, Site Mnemonic, Screened, Screen Failed, % Enrolled, Enroll Failure, Screen Override, Enroll Override, % Randomized, % Active, % Completed, % Dropped.

Use the Sort drop-down lists to change any of the default selections.

Subject Enrollment Status by Site	
Sort	Default selection
First level	Country.
Second level	Site Mnemonic.
Third level	None.

Report/Graph page: Subject Enrollment Status by Site

Graphs

A bar graph appears on the first page of the Subject Enrollment Status by Site report, illustrating the number of enrolled subjects at each site.

Subtotals and totals

- **Subtotals**—By Country.
- **Totals**—Overall subject count totals.

Column descriptions

Subject Enrollment Status by Site	
Column	Description
Country	<p>Data displayed: String</p> <p>Description: Country in which a site is located, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Screened	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who have been successfully screened in the InForm application without a screen failure during the screening process.</p> <p>How calculated: For each site, counts each subject who was successfully screened without a screen failure during the screening process and who meets one of the following conditions:</p> <ul style="list-style-type: none"> • The enrollment process was not started. • The enrollment process was started but not completed because either an enrollment failure occurred or the user completed the enrollment form but chose not to enroll the subject. • The enrollment process was completed successfully and the subject moved on to another state (Enrolled, Randomized, Dropped Out, or Incomplete). <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Screen Failure	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who were successfully screened (no screen failure reason generated), but failed the enrollment process by entering an invalid character (hyphen or a slash). The failure generates the enroll failure reason in the InForm application.</p> <p>How calculated: For each site, counts the number of subjects who failed the InForm enrollment process. This count excludes the Enroll Override values.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Subject Enrollment Status by Site	
Column	Description
Enroll Failure	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who have failed the enrollment process in the InForm application.</p> <p>How calculated: For each site, a subject is counted if he/she failed the InForm enrollment process within the date range specified. This count includes subjects whose enrollment failure has been overridden in InForm application.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Screen Override	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of subjects who have been screened in InForm application due to the screening override process within the date range specified on the report prompt page.</p> <p>How calculated: For each site, counts the number of subjects who failed the InForm screening process and subsequently were screened through the InForm screening override process. This count includes subjects who may have moved on to other states (such as Enrolled, Randomized, Dropped out, or Complete).</p> <p>Subjects screened and enrolled through PF Admin Import: Subjects who are added to the trial through PF Admin Import are never counted in Screen/Enroll Override counts, even if they initially failed screening or enrollment.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Enroll Override	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of subjects who have been enrolled in InForm application due to the enrollment override process within the date range specified on the report prompt page.</p> <p>How calculated: For each site, counts subjects who have ever failed the InForm enrollment process, but have subsequently been enrolled through the InForm enroll override process. This count includes subjects who may have moved on to other states (such as Randomized, Dropped out, or Complete).</p> <p>Subjects screened and enrolled through PF Admin Import: Subjects who are added to the trial through PF Admin Import are never counted in Screen/Enroll Override counts, even if they initially failed screening or enrollment.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Subject Enrollment Status by Site	
Column	Description
Enrolled (% of Screened + Screen Override)	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of subjects that were ever enrolled at the site.</p> <p>How calculated: For each site, the count includes subjects who were initially screen failed or enroll failed but subsequently enrolled or moved from the Enrolled state to other states (Randomized, Dropped out, or Completed).</p> <p>Percent value is calculated as $(\text{Enrolled} / (\text{Screened} + \text{Screen Override})) * 100$</p> <p>Subjects screened and enrolled via PF Admin Import: Subjects who are added to the trial via PF Admin Import are not counted in Screen/Enroll Override counts, even if they initially failed screening or enrollment.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>
Randomized (% of Enrolled)	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of enrolled subjects who have been randomized in the InForm application.</p> <p>How calculated: For each site, counts subjects who have ever been in the randomized state.</p> <p>Percent value is calculated as $(\text{Randomized} / \text{Enrolled}) * 100$</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>
Active in Trial (% of Enrolled)	<p>Data displayed: Numeric (Percentage)</p> <p>Description: For each site, the number of subjects currently participating in the trial as of the report run date.</p> <p>How calculated: For each site, counts every subject in the Enrolled or Randomized state within the specified date range. Excludes subjects in the Completed or Dropped out state.</p> <p>Percent value is calculated as $(\text{Active in trial} / \text{Enrolled}) * 100$</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Subject Enrollment Status by Site	
Column	Description
Completed (% of Enrolled)	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of enrolled subjects who have completed the study.</p> <p>How calculated: For each site, counts subjects who have completed the study, as recorded on the Subject Completion in the InForm application.</p> <p>Percent value calculated as $(\text{Completed} / \text{Enrolled}) * 100$</p> <p>UUIDs: PF_SC_COMPLETECTL, PF_SC_STUDY_COMPLETE, PF_SC_STUDY_INCOMPLETE</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>
Dropped (% of Enrolled)	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of enrolled subjects who have dropped out of the study.</p> <p>How calculated: For each site, counts subjects who have dropped out of the study, as recorded on the Subject Completion form in the InForm application.</p> <p>Percent value calculated as $(\text{Dropped} / \text{Enrolled}) * 100$</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>

Subject Enrollment Status by User

Selection criteria: Subject Enrollment Status by User

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: Subject Enrollment Status by User* (on page 342).

Selection criteria

Subject Enrollment Status by User	
Selection criteria	Action
Rights groups	<p>Select the rights group or groups used for CRAs that are primary in your study and click Update to update the Users list.</p> <p>Note: For optimal performance, if you want to include all rights groups in your report, do not select any rights groups from the list.</p>
Users	To report on specific users, select them from the drop-down list. Then, click Update to update the Sites list.
Sites	To report on specific sites, select the names of the sites from the list.
Date range	<p>Enter the From and To dates or use the calendar icons to select the dates.</p> <p>Default From date: 2000-01-01</p> <p>Default To date: Current date</p>

Sort options

Subject Enrollment Status by User	
Sort	Default selection
First sort	Rights Group.
Second sort	User Name.
Third sort	Site Mnemonic.

Use the sort drop-down lists to change any of these selections.

Report/Graph page: Subject Enrollment Status by User

Subtotals and totals

- **Subtotals**—None.
- **Totals**—Overall subject count totals.

Column descriptions

Subject Enrollment Status by User	
Column	Description
Rights Group	<p>Data displayed: String</p> <p>Description: The InForm rights group to which the user belongs.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
User Name	<p>Data displayed: String</p> <p>Description: Username of the user.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Screened	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who have been successfully screened in the InForm application without a screen failure during the screening process.</p> <p>How calculated: For each site, counts each subject who was successfully screened without a screen failure during the screening process and who meets one of the following conditions:</p> <ul style="list-style-type: none"> • The enrollment process was not started. • The enrollment process was started but not completed because either an enrollment failure occurred or the user completed the enrollment form but chose not to enroll the subject. • The enrollment process was completed successfully and the subject moved on to another state (Enrolled, Randomized, Dropped Out, or Incomplete). <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Subject Enrollment Status by User	
Column	Description
Screen Failure	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who were successfully screened (no screen failure reason generated), but failed the enrollment process by entering an invalid character (hyphen or a slash). The failure generates the enroll failure reason in the InForm application.</p> <p>How calculated: For each site, counts the number of subjects who failed the InForm enrollment process. This count excludes the Enroll Override values.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Enroll Failure	<p>Data displayed: Numeric</p> <p>Description: The number of subjects who have failed the enrollment process in the InForm application.</p> <p>How calculated: For each site, a subject is counted if he/she failed the InForm enrollment process within the date range specified. This count includes subjects whose enrollment failure has been overridden in InForm application.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Screen Override	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of subjects who have been screened in InForm application due to the screening override process within the date range specified on the report prompt page.</p> <p>How calculated: For each site, counts the number of subjects who failed the InForm screening process and subsequently were screened through the InForm screening override process. This count includes subjects who may have moved on to other states (such as Enrolled, Randomized, Dropped out, or Complete).</p> <p>Subjects screened and enrolled through PF Admin Import: Subjects who are added to the trial through PF Admin Import are never counted in Screen/Enroll Override counts, even if they initially failed screening or enrollment.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Subject Enrollment Status by User	
Column	Description
Enroll Override	<p>Data displayed: Numeric</p> <p>Description: For each site, the number of subjects who have been enrolled in InForm application due to the enrollment override process within the date range specified on the report prompt page.</p> <p>How calculated: For each site, counts subjects who have ever failed the InForm enrollment process, but have subsequently been enrolled through the InForm enroll override process. This count includes subjects who may have moved on to other states (such as Randomized, Dropped out, or Complete).</p> <p>Subjects screened and enrolled through PF Admin Import: Subjects who are added to the trial through PF Admin Import are never counted in Screen/Enroll Override counts, even if they initially failed screening or enrollment.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Enrolled (% of Screened + Screen Override)	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of subjects that were ever enrolled at the site.</p> <p>How calculated: For each site, the count includes subjects who were initially screen failed or enroll failed but subsequently enrolled or moved from the Enrolled state to other states (Randomized, Dropped out, or Completed).</p> <p>Percent value is calculated as $(\text{Enrolled} / (\text{Screened} + \text{Screen Override})) * 100$</p> <p>Subjects screened and enrolled via PF Admin Import: Subjects who are added to the trial via PF Admin Import are not counted in Screen/Enroll Override counts, even if they initially failed screening or enrollment.</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>
Randomized (% of Enrolled)	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of enrolled subjects who have been randomized in the InForm application.</p> <p>How calculated: For each site, counts subjects who have ever been in the randomized state.</p> <p>Percent value is calculated as $(\text{Randomized} / \text{Enrolled}) * 100$</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>

Subject Enrollment Status by User	
Column	Description
Active in Trial (% of Enrolled)	<p>Data displayed: Numeric (Percentage)</p> <p>Description: For each site, the number of subjects currently participating in the trial as of the report run date.</p> <p>How calculated: For each site, counts every subject in the Enrolled or Randomized state within the specified date range. Excludes subjects in the Completed or Dropped out state.</p> <p>Percent value is calculated as (Active in trial / Enrolled) * 100</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Completed (% of Enrolled)	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of enrolled subjects who have completed the study.</p> <p>How calculated: For each site, counts subjects who have completed the study, as recorded on the Subject Completion in the InForm application.</p> <p>Percent value calculated as (Completed / Enrolled) * 100</p> <p>UUIDs: PF_SC_COMPLETECTL, PF_SC_STUDY_COMPLETE, PF_SC_STUDY_INCOMPLETE</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>
Dropped out (% of Enrolled)	<p>Data displayed: Numeric (Percentage)</p> <p>Description: The number of enrolled subjects who have dropped out of the study.</p> <p>How calculated: For each site, counts subjects who have dropped out of the study, as recorded on the Subject Completion form in the InForm application.</p> <p>Percent value calculated as (Dropped / Enrolled) * 100</p> <p>UUID: PF_SC_COMPLETECTL</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Percentage is derived for display.</p>

Audit Trail reports

About Audit Trail reports

The following Audit Trail standard reports are available in the Reporting and Analysis module:

- Audit Trail Report
- Historical Login Report

Audit Trail Report

This report shows the fields for which data was entered, modified, or cleared within a selected date range.

Selection criteria: Audit Trail Report

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: Audit Trail Report* (on page 348).

Selection criteria

Audit Trail Report	
Selection criteria	Action
Sites	Select specific sites from the list and click Update to update the Subjects list with Subject IDs.
Subjects	Select specific subjects from the list and click Update to update the Visits list.
Visits	Select a visit from the list and click Update to update the Forms list.
Forms	Select one or more forms from the list of form mnemonics and click Update to update the Item Questions list.
Item Questions	Select specific item display labels from the list.
Initial Entry or Modification	Select whether to narrow the report by initial data entered, or modified data.
Rights Groups	Select one or more rights groups and click Update to update the Usernames list.
Usernames	Select specific usernames from the list.

Audit Trail Report	
Selection criteria	Action
User Types	Select specific user types from the list.
Current Value Date / Time range	Enter the From and To dates or use the calendar icons to select the dates. Default From date: 2000-01-01 Default To date: Current date

Sort options

None. Automatically sorted by Site Mnemonic, Patient Number, Visit Mnemonic, Visit Index, Form Mnemonic, Form Index, Itemset Index, Item Question, Control RefName, Audit Order.

Report/Graph page: Audit Trail Report

Column descriptions

Audit Trail Report	
Column	Description
Trial Name	<p>Data displayed: String</p> <p>Description: Name associated with the study, as specified in the study design code.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Site Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation used to identify a site, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Subject Number	<p>Data displayed: String</p> <p>Description: Number that identifies the subject. This number may be changed after the subject is enrolled, if the study is configured to require a unique subject ID for a study or site.</p> <p>Note: Subject number might not be unique at your site.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Audit Trail Report	
Column	Description
Visit Mnemonic	<p>Data displayed: String</p> <p>Description: Abbreviation of the visit title, as specified in trial design code. For CRF visits, this name appears at the top of a collection of forms in the visit timeline. The visit mnemonic may not be a unique identifier.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Visit Index	<p>Data displayed: Numeric</p> <p>Description: Value that indicates the instance of the visit in which data was entered for the form.</p> <p>Data source: Calculated in the Reporting and Analysis database and is an ordinal number based on the VISITINDEX.</p>
Form Mnemonic	<p>Data displayed: String</p> <p>Description: Short name or abbreviation for the form, as specified in the study design code. This name appears on the Visit Navigation tab and is used to access a specific form in the InForm application.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Form Index	<p>Data displayed: Numeric</p> <p>Description: For repeating forms, a numeric ordinal value that indicates each iteration of the form. For other forms, the value is 1.</p> <p>Data source: Calculated in the Reporting and Analysis database and is an ordinal number based on the FORMINDEX.</p>
Itemset Index	<p>Data displayed: Numeric</p> <p>Description: Value that indicates each iteration of an itemset.</p> <p>Data source: Calculated in the Reporting and Analysis database and is an ordinal number based on the ITEMVISITINDEX.</p>
Item Question	<p>Data displayed: String</p> <p>Description: Text of the question or prompt that instructs the user to enter specific clinical data.</p> <p>Items that have never contained data will not appear on reports that pair Item Question with Form Name or Form Mnemonic.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p> <p>Note: User rights and display override settings determine whether you can see this data. If you do not have access to this data, the resulting report column will be empty.</p>

Audit Trail Report	
Column	Description
Changed Control Ref-name	<p>Data displayed: String</p> <p>Description: Name of the modified field.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Audit Order	<p>Data displayed: Numeric</p> <p>Description: Value that indicates the audit order for item changes from the earliest to the latest.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Initial Entry or Modification	<p>Data displayed: String</p> <p>Description: Text that explains whether the clinical data is an initial entry or a modification.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Entered Reason	<p>Data displayed: String</p> <p>Description: Text that explains the reason for the most recent clinical data change (if any) for the item. Text appears here only when the clinical data for the item has been changed since initial entry.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Current Value	<p>Data displayed: String</p> <p>Description: Current value of the item.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Current Value Date / Time	<p>Data displayed: String</p> <p>Description: Current date/time value for the item.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Previous Value	<p>Data displayed: String</p> <p>Description: Value of the item before it was modified.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>
Previous Value Date / Time	<p>Data displayed: String</p> <p>Description: Date/time value of the item before it was modified.</p> <p>Data source: Derived for the report; not stored in the Reporting and Analysis database.</p>

Audit Trail Report	
Column	Description
Rights Group	<p>Data displayed: String</p> <p>Description: Rights group to which the user who entered or modified the data belongs.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Username	<p>Data displayed: String</p> <p>Description: Username of the user who entered or modified the data.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
User Type	<p>Data displayed: String</p> <p>Description: User type. Valid values are:</p> <ul style="list-style-type: none"> • Site • Sponsor • System <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Database value has been decoded for display.</p>

Historical Login Report

This report shows the login history within a selected date range.

Note: Historical login information is only available after you run a report.

You can also create an ad hoc report that shows user status and group membership information.

For more information, see *User Info: Historical User Info* (on page 141).

Selection criteria: Historical Login Report

Use the report prompt page to select criteria and specify sort options for your report.

For general instructions about how to run a standard report:

- *Running a standard report from the Reporting and Analysis portal* (on page 167).
- *Running a standard report in a new window* (on page 168).

For information about data that appears on this report, such as the data source, how data is calculated, and how it is displayed, see *Report/Graph page: Historical Log In Report* (on page 352).

Selection criteria

Historical Login Report	
Selection criteria	Action
Country	Select specific countries from the list.
Rights Group	Select one or more rights groups.
Username	Select specific usernames from the list.
User Type	Select specific user types from the list.
Login Date / Time	<ul style="list-style-type: none"> • To specify the date range, enter the From and To dates, or use the calendar icons to select the dates. • To automatically select the earliest and latest possible dates, use the Earliest Date and Latest Date radio buttons.

Sort options

None. Automatically sorted by the Login Date / Time in descending order.

Report/Graph page: Historical Login Report

Column descriptions

Historical Login Report	
Column	Description
Login Date / Time	<p>Data displayed: String</p> <p>Description: Login date/time value.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>

Historical Login Report	
Column	Description
Username	<p>Data displayed: String</p> <p>Description: Username of the user.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
First name	<p>Data displayed: String</p> <p>Description: First name of the user.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Last name	<p>Data displayed: String</p> <p>Description: Last name of the user.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Country	<p>Data displayed: String</p> <p>Description: Country in which a user is located, as entered in the InForm Administration interface.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
Rights Group	<p>Data displayed: String</p> <p>Description: Rights group to which the user belongs.</p> <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database.</p>
User Type	<p>Data displayed: String</p> <p>Description: User type. Valid values are:</p> <ul style="list-style-type: none"> • Site • Sponsor • System <p>Data source: Replicated from the InForm Transactional Database to the Reporting and Analysis database. Database value has been decoded for display.</p>

Glossary

A

Ad Hoc Reporting

The Reporting and Analysis module, which allows you to create, run, and save customized reports on clinical and trial-management data.

adverse event (AE)

An undesirable symptom or occurrence that a trial subject experiences during or after a clinical trial.

association

The many-to-many relationship that can exist between two repeating forms.

audit trail

A complete record of changes that are made in the trial database.

C

case book

The collection of all case record forms (CRFs) for a single trial participant. Also called a *case record book* (CRB).

case record form (CRF)

A form that is used to record clinical data about trial participants.

clinical data

The data that is entered on a CRF.

clinical data manager (CDM)

A person who is responsible for preparing and maintaining a trial database and for reviewing data.

clinical project manager

A person who is responsible for all aspects of one or more clinical trials or for the entire clinical plan for a drug, device, or procedure.

clinical reporting package

An Ad Hoc Reporting package that provides access to both clinical and trial-management data for reporting. Clinical reporting packages are unique for each trial.

clinical research associate (CRA)

A person who is hired by a sponsor to supervise and monitor the progress of sites that are participating in a trial.

Also called *monitor*, *site monitor*.

clinical research coordinator (CRC)

An assistant to the investigator at a site.

Also called *site coordinator*, *trial coordinator*.

clinical trial

See ***trial*** (on page 358).

coding dictionary

A standardized collection of terms and the codes that correspond to those terms.

common form

A form that occurs in multiple visits and contains cumulative data.

content pane

The area that is located on the right side of the InForm window that displays CRFs, summary lists, CRF item details, and so on.

content-specific pane

The bar that is located at the bottom of the page that displays command buttons and navigation controls, which vary depending on what is displayed in the content pane.

control

A generic term for a form component, such as a radio button, checkbox, or drop-down list, in which you select or enter data.

control path

A sequence of IDs that define the physical location of a data point in the InForm database.

CRF help

A study document that contains details about how to complete the items on a form.

customer-defined database (CDD)

An extract of the trial database that gives sponsor personnel access to the clinical data that is collected before the trial is completed.

D**design note**

A comment about a form component.

display override

A property of items that can be set to Editable, Read-Only, or Hidden. Also called *item blinding*.

dynamic form

A form that is created in a trial only if certain conditions are met.

E**element**

An option that you can select from a drop-down list, checkbox group, or radio group.

event

A component that specifies the action to take

when a rule fails.

exclusion criteria

A list of admission criteria, any one of which excludes a potential subject from participation in a clinical trial.

execution plan

A script that is associated with an event, and that sends an email message or writes to the Windows event log.

expected form

A form that appears in the Time and Events Schedule for a subject, based on current known subject data. An expected form is a dynamic form that has been activated, or appears within a scheduled visit or a started unscheduled visit.

F**form**

The data collection mechanism that is used in a clinical trial to gather patient data.

G**generic rule**

A rule that the trial developer can attach to multiple items.

H**home page**

The page that appears when you log on to an application.

I**inclusion criteria**

A list of admission criteria that potential subjects must meet to be eligible for participation in a trial.

InForm Reporting and Analysis

A reporting application, developed by Cognos Corporation, which has been customized and integrated into the InForm software by Phase

Forward.

InForm Trial Management package

An Ad Hoc Reporting package that provides access to trial management data for reporting and allows users to share reports across trials.

Institutional Review Board (IRB)

A group that reviews biomedical research that involves human subjects.

investigator

The clinician who is responsible for treating subjects, executing the protocol of a study at a specific site, and filling out CRFs for subjects.

Also called clinical investigator, investigator, primary investigator.

itemset

A collection of repeating items on a form.

M

medical monitor

A person who designs the trial protocol and reviews data.

N

navigation pane

The left side of the InForm window, which displays navigation buttons that you use to enter the functional areas of the InForm software.

P

package

A grouping of reporting elements from one or more data models. Two reporting packages are installed with every InForm trial: the InForm Trial Management package and a trial-specific clinical reporting package.

protocol

The detailed plan for a clinical study.

Q

query

A question that is automatically generated by the InForm software or manually issued by a CRA.

R

RefName

A name that uniquely identifies a trial component definition.

regular form

A CRF that is used to collect data that is specific to the visit in which the form occurs.

repeating form

A form that can have multiple instances within a visit.

rule

A script that checks whether data is valid or that sets the value of an item based on a calculation.

rule dependency

An additional item that is required for rule processing.

S

screening and enrollment

The process of adding a subject to a study.

serious adverse event

An adverse medical occurrence that is life-threatening, or results in death or persistent or significant disability or incapacity; involves an overdose or the development of cancer, a congenital anomaly, or a birth defect; requires inpatient hospitalization, or lengthens a hospital stay.

signature group

A group of users who are authorized to sign a specific set of CRFs.

source verification

The process of comparing data that is on forms to data on source documents, checking for inconsistencies or errors, and recording the results of the review.

sponsor

The individual, company, or organization that is responsible for the initiation, management, or financing of a clinical study.

standard report

A report that is included within all Reporting and Analysis installations.

started form

A CRF that is submitted or that contains data, a query, or a comment.

started visit

A visit in which at least one non-common expected form has been started.

SV Report

A printed version of one or more CRFs that CRAs use to perform offline source verification.

T**trial**

The systematic study of a test article (a treatment, drug, or device) in human subjects.

trial management data

The metric and status data pertaining to a study, which is used to report on the status of a study relative to its completion.

trial-specific clinical model

An Ad Hoc Reporting data model that is specific to a trial, and that contains references to subject data that site users enter on forms.

U**unscheduled visit**

A visit that occurs in addition to the visits prescribed by the study protocol.

V**visit**

A subject evaluation checkpoint when data is collected.

visit calculator

A scheduling aid that enables you to compute and print suggested visit dates based on the patient start date. The visit calculator page appears when a patient is enrolled and is also available as part of the trial documents.

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