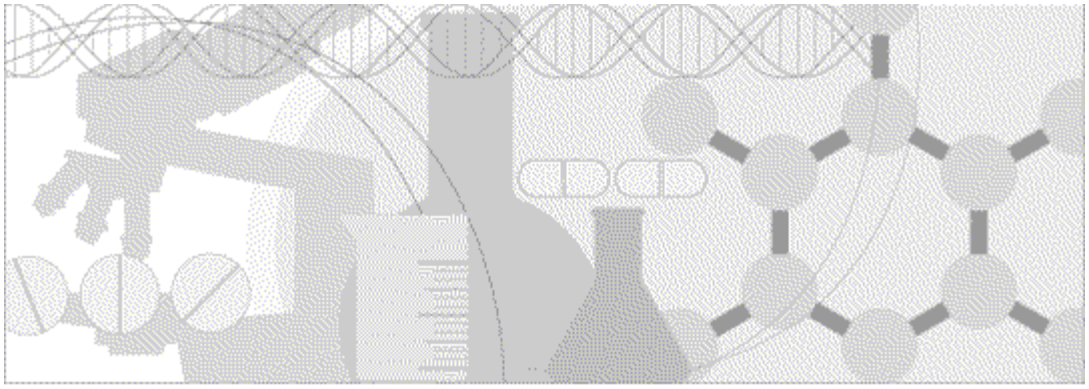
User Guide

Oracle® Health Sciences Central Designer Release 2.1



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About this guide

In this preface

Overview of this guide

The *User Guide* introduces the study design environment in the Central Designer application and describes how to work as a study design team in that environment, including how to:

- Work collaboratively.
- Maximize study design efficiency by reusing study objects.
- Manage collections of study objects.

Prerequisites

You should have experience in one or more of the following clinical areas:

- Data management
- Data analysis
- Study design
- Library management
- Project management

Additionally, rule developers must have the following levels of programming expertise, depending on the types of rules they will be creating.

Type of rule	Required programming expertise
Simple edit checks using rule templates.	None.
Comparisons, calculations.	• Understanding of C# or similar (for example, Java, C, or C++) expression syntax. • Ability to incorporate functions in expressions.
User-defined functions.	• Ability to program in a .NET language (for example, C#) and create .NET assemblies.

Users

This guide is for users of the Central Designer application, including:

User	Description
Clinical data manager	A user who is involved in the study design process.
Library administrator	A user with library administration privileges for one or more clinical areas.
Central Designer administrator	An IT representative who supports and maintains the application from a technology and infrastructure perspective.

User	Description
Study design team	Users who implement a study. This team includes several roles such as form designer, rule designer, and study workflow designer.
Medical project manager	A user who works with the CRF designer to create an annotated study protocol, usually based on existing CRFs for the therapeutic area. This user is concerned with the overall set of study questions and logic, not the individual details of form design.
Statistician	A user who interacts with study designers with respect to data collection needs for analysis.
Translator	A user who is responsible for translating text in clinical studies, forms, items, and rule queries to a specified language.

Documentation

The product documentation is available from the following locations:

- **Oracle Software Delivery Cloud** (https://edelivery.oracle.com)—The complete documentation set.
- **My Oracle Support** (https://support.oracle.com)—*Release Notes* and *Known Issues*.
- **Oracle Technology Network** (http://www.oracle.com/technetwork/documentation)—The most current documentation set, excluding the *Release Notes* and *Known Issues*.

All documents may not be updated for every Central Designer release. Therefore, the version numbers for the documents in a release may differ.

Item	Description
Release Notes	The *Release Notes* document provides detailed information about the requirements, enhancements, and fixed issues in the current release.
Known Issues	The *Known Issues* document provides detailed information about the known issues in this release, along with workarounds, if available.
Installation Guide	The *Installation Guide* provides system requirements and instructions for installing and upgrading the Oracle® Health Sciences Central Designer software and the Oracle® Health Sciences Central Designer Administrator software.
Administrator Guide	The *Administrator Guide* describes how to use the Oracle® Health Sciences Central Designer Administrator software to set up users, permissions, system configuration parameters, and catalog defaults.
User Guide	The *User Guide* introduces the study design environment in the Oracle® Health Sciences Central Designer application and describes how to work as a study design team in that environment, including how to: • Work collaboratively. • Maximize study design efficiency by reusing study objects. • Manage collections of study objects.
InForm Design Guide	The *InForm Design Guide* describes how to design a study for deployment to the InForm application.
Rules Reference Guide	The *Rules Reference Guide* is a reference to the tools that are available for creating rule expressions, including: • Study object properties. • Functions. • Constants. • Data mappings. • Methods, operators, and literals.

Item	Description
Secure Configuration Guide	The *Secure Configuration Guide* provides an overview of the security features provided with the Oracle® Health Sciences Central Designer application, including details about the general principles of application security, and how to install, configure, and use the Central Designer application securely.
Third Party Licenses and Notices	The *Third Party Licenses and Notices* document includes licenses and notices for third party technology that may be included with the Central Designer software.

Documentation accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc.

If you need assistance

Oracle customers have access to support through My Oracle Support. For information, visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=info, or if you are hearing impaired, visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs.

Finding Central Designer information and patches on My Oracle Support

The latest information about the Central Designer application is on the Oracle Support self-service website, My Oracle Support. Before you install and use the Central Designer application, check My Oracle Support for the latest information, including *Release Notes* and *Known Issues*, alerts, white papers, bulletins, and patches.

Creating a My Oracle Support account

You must register at My Oracle Support to obtain a user name and password before you can enter the site.

1 Open a browser to https://support.oracle.com.

2 Click the **Register** link.

3 Follow the instructions on the registration page.

Finding information and articles

1 Sign in to My Oracle Support at https://support.oracle.com.

2 If you know the ID number of the article you need, enter the number in the text box at the top right of any page, and then click the magnifying glass icon or press **Enter**.

3 To search the knowledge base, click the **Knowledge** tab, and then use the options on the page to search by:

- Product name or family.
- Keywords or exact terms.

Finding patches

You can search for patches by patch ID or number, product, or family.

1 Sign in to My Oracle Support at https://support.oracle.com.

2 Click the **Patches & Updates** tab.

3 Enter your search criteria and click **Search**.

4 Click the patch ID number.

The system displays details about the patch. You can view the Read Me file before downloading the patch.

5 Click **Download**, and then follow the instructions on the screen to download, save, and install the patch files.

Finding Oracle documentation

The Oracle website contains links to Oracle user and reference documentation. You can view or download a single document or an entire product library.

Finding Oracle Health Sciences documentation

For Oracle Health Sciences applications, go to the Oracle Health Sciences Documentation page at http://www.oracle.com/technetwork/documentation/hsgbu-clinical-407519.html.

Note: Always check the Oracle Health Sciences Documentation page to ensure you have the most up-to-date documentation.

Finding other Oracle documentation

1 Do one of the following:

- Go to http://www.oracle.com/technology/documentation/index.html.
- Go to http://www.oracle.com, point to the **Support** tab, and then click **Product Documentation**.

2 Scroll to the product you need, and click the link.

Finding prerequisite software for Oracle Health Sciences applications

Prerequisite software for Oracle Health Sciences applications is available from the following locations:

- Download the latest major or minor release from the Oracle Software Delivery Cloud (https://edelivery.oracle.com/).

  For information on the credentials that are required for authorized downloads, click **FAQs** on the main page of the Oracle Software Delivery Cloud portal.

- Download subsequent patch sets and patches from My Oracle Support (https://support.oracle.com).

  To find patch sets or patches, select the **Patches & Updates** tab.

If a previous version of prerequisite software is no longer available on the Oracle Software Delivery Cloud, log a software media request Service Request (SR). Previous versions of prerequisite software are archived and can usually be downloaded. After you open an SR, you can check its status:

- US customers: Call 1-800-223-1711.
- Outside the US: Check www.oracle.com/us/support/contact/index.html for your local Oracle Support phone number.

For more information on logging a media request SR, go to My Oracle Support for Document 1071023.1: Requesting Physical Shipment or Download URL for Software Media (https://support.oracle.com/epmos/faces/DocumentDisplay?id=1071023.1).

PART I

Introduction to the study design environment

CHAPTER 1

Product tour

In this chapter

About the Central Designer application

The Central Designer application provides a collaborative environment for developing clinical studies and addresses the need to significantly increase productivity in the study design process by:

- Providing one central environment for study design.
- Improving efficiency.
- Facilitating reuse.
- Supporting internal and external standards.

Applications

The Central Designer application provides a collaborative design environment that supports multiple users and roles from any location.

There are two client applications:

- **Central Designer**—Used for collaborative study development.
- **Central Designer Administrator**—Used to set up users, permissions, system configuration parameters, and catalog defaults.

An administrator must set up administration information before you can perform some tasks.

Deployment target applications

You can design a study in the Central Designer application and deploy the study to the InForm application.

Users, rights, and roles

An administrator sets up users and roles in the Central Designer Administrator application. When an administrator creates a role, the administrator chooses:

- The scope of the role. A role can have a library, study, or application scope.
- The rights to associate with the role.

The scope of a role, rights assigned to the role, and teams determine whether users can perform certain activities and view different application areas.

- **Library scope**—Roles created with the library scope become library teams in the Central Designer application.

  To perform activities in a library, you must be assigned to:

  - A role with a library scope in the Central Designer Administrator application.
  - The corresponding library team in the Central Designer application.
- **Study scope**—Roles created with the study scope become study teams in the Central Designer application.

  To perform activities in a study, you must be assigned to:

  - A role with a study scope in the Central Designer Administrator application.
  - The corresponding study team in the Central Designer application.
- **Application scope**—Activities associated with the application scope are always available to all users, whether or not the users are assigned to teams. Roles created with the application scope do not become teams in the Central Designer application.

First steps

Logging on and off

If your logon session is inactive for the amount of time set by the administrator, you are prompted to re-enter your password the next time you perform an activity.

To log on:

1 Navigate to the following address:

http://<*server name*>/CentralDesignerInstall

where <*server name*> is the name of the application server computer.

2 Click the **Start Central Designer Client** link.

A dialog box appears, indicating that the application is starting.

The logon window appears.

3 Type your **User Name** and **Password**.

Note: You might be prompted to change your password if your password has expired.

4 Click **Log On**.

You are logged on to the application, and the application opens. By default, the Home Page appears, but you can choose what you see after logon.

For more information, see *Choosing what appears on startup* (on page 21).

To log off and log on as a different user:

1 Select **File > Log on As Different User**.

If your project has unsaved changes, you are prompted to save.

The logon window appears.

2 Type your **User name** and **Password**, and click **Log On**.

To log off:

- Select **File > Exit**.

If you have unsaved changes, you are prompted to save them.

Changing your password

You can change your password at any time. You are prompted to change your password when you start the application if:

- The administrator has indicated that that you must change your password.
- Your password has expired.

To change your password after logging on:

1 Select **File > Change Password**.

The Change Password dialog box appears.

2 Type your old and new passwords. You must type your new password twice for confirmation.

3 Click **OK**.

To change your password because it is required:

1 Navigate to the following address:

http://<*server name*>/CentralDesignerInstall

where <*server name*> is the name of the application server computer.

2 Click the **Start Central Designer Client** link.

A dialog box appears, indicating that the application is starting.

The logon window appears.

3 Type your **User name** and **Password**, and click **Log On**.

The Change Password dialog box appears.

4 Type your old and new passwords. You must type your new password twice for confirmation.

5 Click **OK**.

Home Page

The Home Page displays deployment requests that you can approve, tasks that are assigned to you, and recently viewed projects.

- On the Pending Approvals tab, you can approve deployment requests and view a history of automated deployments.
- On the Recent Tasks tab, you can open a task, do the requested work, close the task, and go on to the next task.

The Home Page closes after you open a library project or study project. By default, the Home Page appears after you log on. For more information, see *Choosing what appears on startup* (on page 21).

For more information, see:

Home Page - Section descriptions (on page 149).

Pending Approvals tab - Option descriptions in the *InForm Design Guide*.

Task areas - Field descriptions (on page 145).

Opening the Home Page

Your startup options determine whether the Home Page appears by default after you log on.

You can view the Home Page at any time.

- On the toolbar, click the **Home Page** button ().

Opening a project from the Home Page

From the Home Page, you can:

- Open a study or library project by double-clicking the project or a task that is assigned to you.
- Open the application without opening a study or library project.

What to open	Procedure
Recently accessed library project or study project.	• In the Recent Projects List section, double-click a project.
Library project or study project, by selecting a task.	• In the My Tasks section or the Recent Tasks tab, double-click a task in the list.
Central Designer application. without selecting a task or project.	• On the toolbar, click the **Workspace** button ().

Note: You can also open study and library projects by selecting File > Open.

Getting Help

Using online Help

- Press **F1**, and then click the area of the application for which you want more information. A Help window appears with the relevant page displayed.
- To open a help document such as the *User Guide*, select **Help** and select the document.

If you need the version of the application, you can view it in the *About Central Designer* dialog box. The dialog box also contains copyright information.

The following help is also available:

- **Hover Help**—Point to a button, tab, or icon, and a tool-tip appears.
- **Oracle Help Desk**—Help is available from the Oracle Help Desk if you encounter system-related issues. For more information, see *If you need assistance* (on page xii).

Troubleshooting issues with Help

If any of the tabs do not appear when you open the Help from the Help menu, add the name of the application server to the list of trusted sites.

1 In Internet Explorer, select **Tools > Internet Options**.

2 Select the **Security** tab.

3 Select **Trusted Sites**, and click **Sites**.

4 In **Add this Web site to the zone**, type the address that the client application uses to connect to the application server.

5 Click **OK** until you return to Internet Explorer.

Setting your machine for different locales

Viewing Japanese characters

Perform these steps if you are unable to view Japanese characters.

1 Select **Start** > **Control Panel** > **Regional and Language Options**.

2 Select the **Languages** tab.

3 Select **Install files for East Asian languages**.

4 Click **OK**.

5 Restart your computer.

Setting up a keyboard to use different locales

When the Windows operating system starts in a specific locale, it updates the keyboard settings for that locale. If you will develop a study in a language other than the locale in which you are located, use this procedure to switch your keyboard settings and shortcuts between locales.

In each locale, set up the Windows operating system to support multiple text input languages—the

local language and the language in which the study is developed:

1 Select **Control Panel > Regional and Language Options > Languages** tab **> Details**.

2 In the **Settings** tab of the **Text Services and Input Languages** dialog box, make sure that both the local language and the study development language are included in the list of supported text input languages.

3 Activate the **Language Bar**.

4 Use the **Language Bar** to switch between the local language and the study development language. Always log on to the Central Designer application in the study development language.

Additional locale settings

You set the default locale for a study in the Central Designer application.

The Microsoft Windows operating system also provides the following language-related options.

Option location	Purpose
Control Panel > Regional and Language Options > Regional Options tab > Standards and formats section	Controls the formatting conventions for numeric data, including dates, times, numbers, and currencies. **Note:** If you do not set the default locale for a study in the Central Designer application, this setting is used as the default locale for a study. If you modify the regional setting, you must close and reopen the Central Designer application to use the new locale.
Control Panel > Regional and Language Options > Languages tab > Language used in menus and dialogs	Controls the language of text in menus and dialog boxes. The option appears only if you have one or more Multiple User Interface (MUI) packs installed. The Central Designer user interface supports only English.
Control Panel > Regional and Language Options > Languages tab > Details button > Default input language	Controls the language that you use to type information on the computer. For example, if the default locale for a study is set to French (France), all study metadata is saved as French metadata. Even if the input language is English (United States) and you type information in the English language, the information is saved as information entered for the French locale.

Project Explorer

The Project Explorer is the primary navigation tool in the Central Designer application. Located by default on the left side of the Central Designer application window, the Project Explorer consists of a set of hierarchical lists of the study objects in the design environment.

Lists of study objects appear in Explorer bars. When selected, each Explorer bar displays a list of study objects in a tree format. For example, when you select the Elements and Events Explorer bar, a tree listing of the study elements and study events in the open study or library appears in the Project Explorer. You can expand the tree listing to view the child study objects of each study object in the tree.

- When you select the icon for a group of study objects (for example, Forms) in the Project Explorer, the editor for that type of study object appears in the application workspace and lists the study objects of that type that have been defined for the open study or library.
- When you select a specific study object, the editor for that study object appears in the application workspace.

The Central Designer application has numerous options for finding, sorting, filtering, and displaying study objects in the Project Explorer.

Adjusting the view of the Explorer bars in the Project Explorer

You can choose between two Explorer bar groupings:

- **Bottom Grouping**—Explorer bars are grouped at the bottom of the Project Explorer. You can slide a splitter bar to control how many bars are visible in the Project Explorer. When an Explorer bar is not visible, an icon representing the Explorer bar appears at the bottom of the Project Explorer.
- **Zipper Grouping**—All Explorer bars appear in the Project Explorer. The Explorer bars before the selected Explorer bar appear at the top of the Project Explorer. The Explorer bars after the selected Explorer bar appear at the bottom of the Project Explorer.

To select an Explorer bar grouping:

1 At the top of the Project Explorer, select **Options > Explorer View**.

2 Select a grouping option.

To view a subset of Explorer bars in the Project Explorer:

- In the Project Explorer, do one of the following:
  - Click and drag the splitter bar up or down.
  - In the bottom right corner of the Project Explorer, click the arrow, and select **Show More Buttons** or **Show Fewer Buttons**.

Finding a study object in the Project Explorer

1 At the top of the Project Explorer, click **Find**.

The Find dialog box appears.

2 In the **Find what** field, type the text to search for.

3 In the **Fields to search** options, select the fields in which to search for the specified text.

4 To match the case used in the search, select **Match case**.

5 To search for the whole word, select **Match whole word**.

6 Click **Find Next**.

Starting with the selected study object, a search is performed. The first study object whose RefName or title matches the text that you type is selected.

Study objects filtered from view are ignored.

Sorting study objects

The Project Explorer for library projects and study projects has containers that hold study objects. For example, the Forms container holds all forms in the study or library. You can sort the study objects that appear in each container.

By default, study objects appear in the following order in the Project Explorer:

- Study objects added to a Study Design, Study Element, or Study Event appear in workflow order.
- Study objects added to a form appear in the order in which they are added.
- Study objects without children appear in alphabetical order.

1 In the Project Explorer, select **Options > Container Sorting**.

A menu appears.

2 Select one of the following options:

- **Ascending**—Sort the study objects in each study object container in alphabetical order.
- **Descending**—Sort the study objects in each study object container in reverse alphabetical order.

Note: If the order of the study objects is important, for example, the order of items on a form, these study objects cannot be sorted.

Filtering container objects

1 In the Project Explorer, select the Explorer bar for the study objects to view.

2 At the top of the Project Explorer, select **Filters**.

> **Note:** The Filters drop-down list is not enabled for the containers in the Study Information Explorer bar or the Visit Schedule Explorer bar.

3 Select one of the following:

- **All Objects**.
- **Modified Objects**—Study objects modified since the project was last saved.
- **Local Locks**—Study objects you locked.
- **Remote Locks**—Study objects locked by other users.

The workspace contains only the study objects specified by the filter. In addition, the header in the Project Explorer indicates that the workspace is filtered.

Viewing study object titles or RefNames in the Project Explorer

You can view either the RefNames or the titles of all study objects in the Project Explorer. When developing naming conventions, consider that all study objects (except study projects, library projects, libraries, and studies) have RefNames and titles, which can be different.

- RefNames are referenced in rules and are deployed to the target application. Therefore, they must:
  - Follow C# variable standards.
  - Start with a letter or an underscore.
  - Contain only letters, numbers, and underscores.
  - Be unique within a study or library. For example, you cannot have a form and an item with RefNames of DOV in the same study or library.
- Titles are the more readable display names for study objects. They can contain spaces and special characters, but are not referenced in rules and are not deployed to the target application.

To view titles or RefNames:

- At the top of the Project Explorer, select **Options > Display Names**, and select a display option.

  The option you select remains selected when you open a new session.

Editors

An editor allows you to work with study or library objects. The Central Designer application includes editors for each type of study object and for individual study objects. When you select a type of study object or a specific study object in the Project Explorer, the editor for that study object type or study object appears in the workspace.

- The editors for types of study objects (container editors) are organized as grids in which each study object of the type in the study or library appears in one row of the grid. Commands that allow you to perform actions on a selected study object appear at the top of the grid. You can arrange the columns of the grid in the order you prefer, and you can include or exclude columns as needed.

  For more information, see *Customizing the workspace* (on page 20).

- The information in editors for individual study objects is organized into tabs that give access to subsets of the functionality available for each type of study object. For example, when you create a form, item, or codelist, the Design tab in the Form, Item, or Codelist editor allows you to define the characteristics of the new study object.

Browsers

About browsers

Browsers enable you to perform specific study and library design, management, validation, and deployment activities. The following browsers are available in the Central Designer application:

- Project Explorer—View and navigate to study objects in the current study or library.
- Properties Browser—View and modify properties for a study object.
- Libraries Browser—View library objects, and drag them into a workspace.
- Users Browser—View users, and drag them into a workspace.
- Collaboration Notes Browser—View, create, and edit collaboration notes.
- Tasks Browser—View, create, edit, and manage tasks that you have created or that are assigned to you.
- Baselines Browser—View, edit, and delete validation baselines.
- Jobs Browser—View, edit, and delete jobs, including validation, deployment, and import jobs.
- Add To browser—View and add study objects that are available to be added to a workspace.

Opening and closing a browser

You can close the browsers that you do not need to work in. Your changes are saved for the next time you log on.

Note: If a browser name has a checkbox beside it in the View menu, it is open. If no checkbox appears, it is closed.

To open a browser:

- Select **View**, and then select a browser from the list.

To close a browser:

- Click the **X** button, located in the upper-right corner of the browser.

  or

  Select **View**, and deselect a browser from the list.

You can *reset the layout of the application window* (on page 20) to the default view.

Rearranging a browser in the application window

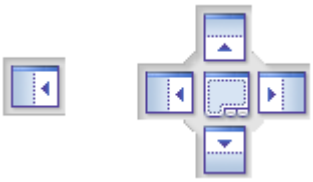
1 Click the title of the browser (located to the left of the **Auto-Hide** button () and the **X** button), and drag it away from its location. Do not release the mouse button.

The mouse cursor changes to a plus sign with arrows ().

Arrow buttons appear at the top, bottom, left, and right of the application window (for example: ).

2 Drag the browser (without releasing the mouse button) to the desired location in the application window.

Arrow buttons appear in the application area. For example:

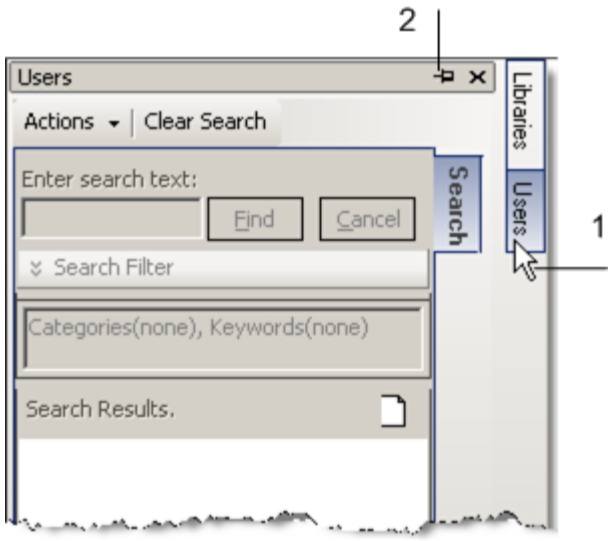


3 Point your mouse to an arrow button. The application area where the browser will appear is highlighted. After you find the desired location for the browser, release the mouse button.

Showing and hiding a browser

If a space holds multiple browsers and you can see only one at a time, hiding or showing one affects all of them.

Browser controls



1—When a browser is hidden, it does not appear automatically. You must point your cursor to the named tab for the browser to show it.

2—The Auto-Hide button is sideways, indicating that the browser is hidden.

To hide a browser:

- Click the **Auto-Hide** button (), located in the upper-right corner of the browser.

To view a hidden browser:

- Point your mouse to the name of the hidden browser. (The name of the browser appears along the outer edge—either the sides or the bottom—of the application window.)

  The browser appears and remains visible as long as the cursor is somewhere within the browser window. If you move the cursor away while the browser is temporarily shown, the browser becomes hidden again.

To show a browser:

1. Point your mouse to the name of the hidden browser. (The name of the browser appears along the outer edge—either the sides or the bottom—of the application window.)

   The browser appears.

2. Click the **Auto-Hide** button (), located in the upper-right corner of the browser. (The icon is sideways when the browser is hidden.)

Editing study object properties in the Properties Browser

1 Select the study object.

2 Select the **Properties Browser**.

> **Note:** If the Properties Browser is not visible, select View > Properties.

3 Edit the properties of the study object. After changing each property, press **Enter**, or tab to the next property.

> **Note:** The values of editable properties appear in bold, black text, and the values of non-editable properties appear in gray text.

For descriptions of the properties for study and library objects, see the Appendix.

Navigating to a specific Explorer bar, editor, or browser

1 From the application toolbar, select **Tools > Go to Window**.

The Go to Window dialog box appears.

2 Select an Explorer bar, editor, or browser.

3 Click **Go To**.

Customizing the workspace

Arranging fields, tabs, and browsers

You can arrange the order of:

- Fields in most grids.
- Tabs in editors.
- Browsers that are grouped.

To arrange the order of fields, tabs, or browsers:

- Drag a field, tab, or browser to a new position.

Resetting window layout and message boxes

You can reset the following information for yourself only:

- Window layout
  - Reset location and visibility of all browsers.
  - Reset the size of the application window (for example, minimized or maximized).
- Message boxes

  Deselect the **Do not show again** setting for all information messages. Messages that you chose not to see now appear.

To reset window layout or message boxes:

1 Select **Tools > Options**.

The Central Designer Options dialog box appears.

2 Click **Reset Window Layout** or **Reset Message Boxes**.

3 Click **OK**.

Showing and hiding the status bar

The Status bar and toolbar are at the bottom of the application window.

1 Select **Tools > Options**.

The Central Designer Options dialog box appears.

2 Select or deselect **Show Status Bar**.

3 Click **OK**.

For more information, see **Status toolbar - Option descriptions** (on page 149).

Changing the number of projects that appear in the Recent Projects list

By default, the six most recently viewed study and library projects appear on the Home Page.

1 Select **Tools > Options**.

The Central Designer Options dialog box appears.

2 In the [number] part of the **Display [number] projects in Recent Projects list** option, type the number of projects to appear.

3 Click **OK**.

Choosing what appears on startup

1 Select **Tools > Options**.

The Central Designer Options dialog box appears.

2 From the At Startup drop-down list, select one of the following options:

- **Show HomePage**—The Home Page appears after you log on.
- **Show Workspace**—A blank workspace with no project appears after you log on.
- **Load Most Recent Project**—The project you opened last appears in the workspace after you log on.

3 Click **OK**.

Filtering your view of system-specific study objects

The main toolbar contains a View Targets drop-down list that allows you to view objects for one target application or all target applications. Only the target applications that are enabled in the Targets workspace in the Central Designer Administrator application and selected in the Targets field in the General tab for a study appear in the list.

To filter your view of system-specific study objects:

- From the **View Targets** drop-down list on the main toolbar, select an option:
  - **All**—(Default selection in every project) All study objects appear.
  - **<target application name>**—Only study objects for the selected target application appear.

Viewing more than one tab in the workspace

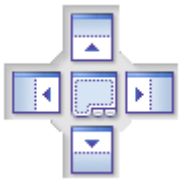
1 In the Project Explorer, select a study object.

The editor for the study object appears in the workspace.

2 Click one of the tabs, and drag it within the workspace, without releasing the mouse button.

The mouse cursor changes to a plus sign with arrows.

Arrow buttons appear in the workspace. For example:



Point your mouse to an arrow button, and the application area where the tab will appear is highlighted, as shown in the following example. After you find the desired location for the tab, release the mouse button.

Filtering data in a grid

You can filter data in most grids, such as the grid in the Collaboration Notes Browser.

For example, if you created multiple collaboration notes based on several collaboration note types, you can filter to view only the collaboration notes of a certain type.

To filter the data that appears in a grid:

1 In any grid, right-click a field, and select **Filter Row**.

Filtering fields appear at the top of every column in the grid.

2 To use a filtering operator, click the filter operators button (), and select an operator. If you do not select an operator, **Starts with** is used by default.

3 In the filter field, type the text to use for the filter.

As you type, an incremental filter of the column is performed.

4 To remove the filter, click the **Clear Filter Criteria** button, located at the end of the field.

To remove the filter row:

- In any grid, right-click any field, and deselect **Filter Row**.

Grouping data in a grid

To view the grouping panel and group data in a grid:

1 In a grid, right-click any field, and select **Group**.

The grouping panel appears above the grid.

2 Drag a field to the grouping panel to group the grid by that field. You can group by one or more fields.

To remove the grouping panel:

- In a grid, right-click a field, and deselect **Group**.

Showing and hiding a field

To change the fields that appear in a grid:

1 In any grid, right-click any column, and select **Columns**.

The Columns dialog box appears.

2 Select fields that appear in the **Available Columns** or **Displayed Columns** lists, and use the **Add**, **Remove**, **Add All**, or **Remove All** buttons to move them to the correct list.

3 Optionally, to arrange the order of fields in the Displayed Columns list, select a field and click either **Move Up** or **Move Down**.

4 Click **OK**.

To hide a field:

- In any grid, right-click the field you want to remove, and select **Hide Column**.

Sorting data in a grid

1 In any grid, select a field one time.

The data from the field is sorted in ascending (if letters, alphabetical) order.

2 To sort the data in descending order (if letters, reverse alphabetical), select the field a second time.

CHAPTER 2

Planning

In this chapter

Planning teams and collaboration

In the Central Designer application, you can develop multiple studies simultaneously, and multiple users can work on the same study simultaneously.

Questions to consider	Notes
How will work be divided and assigned?	For example: • Who will work on each study? Do study designers in your organization specialize in particular therapeutic areas? • Do you want different users to manage study objects in libraries and study objects in studies? • Will different users create study objects and rules? • Do you want to assign supervisors to review the work of other users? • If your studies will be localized, is translation performed as a separate activity or by the user who creates study objects?
How will people work collaboratively when tasks are divided?	Which activities must be performed sequentially, and which can be performed concurrently? For example, the following activities depend on the existence of a study object but can be performed in any order after the study object has been created: • Defining study object properties. • Defining form layout. • Translating text. • Creating rules.
In how much detail do you want to break down tasks?	• What types of tasks do you want to define? • Which teams should perform particular task types?
How do you want to use collaboration notes? What types of collaboration notes do you want to define?	For example, you could use collaboration notes to communicate: • Design specifications for study objects. • Other information about study objects. • Instructions to other users. • Status information about study objects that are in the process of development.
How will the order in which you develop study objects affect your team assignments?	The Central Designer application supports building studies from the top down, from the bottom up, or a combination of approaches. In what order do you prefer to develop study objects? For example, you could have one team member build or copy all of the required codelists while another creates the study workflows.

Questions to consider	Notes
How will reuse affect your validation and formal testing plans?	After a study object has been validated, it should not be necessary to retest it in every study where it is used.

Example of collaboration

Note: The following table provides sample roles only. You can set up roles in a manner that is appropriate for your organization.

Role	Responsibilities	Collaboration actions
Clinical project manager	• Collects requirements. • Writes or co-writes the protocol document. • Decides the users who will work on each study.	Sets up study teams.
Study architect	Compiles a study by: • Collecting pre-approved form resources. • Defining study workflow. • Specifying where new forms are needed.	• Designs the workflow of the study. • Creates tasks for study objects requiring more work, such as forms that must be designed or rules that must be created. • Assigns the tasks to the study development team.
Study development team	Builds new forms specified by the study architect.	• Attaches collaboration notes to study objects to share information during study development. • As each form is completed, creates a task to translate the form into the required languages and assigns it to the study translation team.
Study translation team	Translates form resources for use in multiple language environments.	Completes the translation tasks.
Study development project manager	Manages the progress of the project.	Checks the statuses of tasks to ensure that the project is on schedule.

Example—Using a standard task

A study architect is creating a study event and has added several standard forms from the library. She needs a form for capturing test results but is unable to create it. She uses a standard task to assign the work.

a The study architect creates and names a blank form.

b On the form, the study architect creates a standard task that contains instructions to design the form, including the information that the form must capture. If the instructions are already written, she can attach the document to the task. The study architect assigns the task to the form design team.

c A member of the form design team sees the task in the Home Page. The form designer double-clicks the task, and the specified project and form open.

d The form designer accepts the task.

e The form designer uses the instructions in the task to build the form. If he needs help from rule designers, translators, or other specialists, he creates new tasks for the form and assigns them to the other teams.

f The form designer completes the form and changes the status of the task to Complete.

g After reviewing the work and verifying that it is complete, the study architect changes the status of the task to Closed.

Example—Using a translation task

A form designer is creating a form in English. He needs to translate the form into French (France) and Portuguese (Brazil), but he does not speak either language.

a The form designer creates the form in English and saves it.

b The form designer creates two translation tasks for the form. In each task, he chooses one language into which the form must be translated. The first task requests translation into French (France), and the second task requests translation into Portuguese (Brazil). He assigns both tasks to the translation team.

c A member of the translation team sees the task in the Home Page. The translator double-clicks the task and the specified project and form open.

d The translator accepts the task.

e The translator uses the instructions in the task to translate the form.

f After completing the translations, the translator changes the status of the task to Complete.

g After reviewing the work and verifying that it is complete, the form designer changes the status of the task to Closed.

Note: In general, create a translation task for each locale that requires translation. For example, if you create three tasks, for translation into French, Spanish, and Japanese, a different person can accept each task. If a single person performs all translations for all locales, you can create a single translation task for all locales.

Planning libraries

Guidelines for library development

Creating study objects

- Create study objects with reuse in mind, and reuse study objects as much as possible. Creating study objects takes some time, but you will save time in the long run when you reuse the study objects.
- Build study objects in a library using a top-down or bottom-up approach, just as you can for study objects in a study.
- Try to design study objects completely before adding them to a library. For example, add rules to study objects before adding the study objects to a library, so you do not need to recreate the rules every time you reuse the study objects.

Organizing libraries

Consider creating a different library for therapeutic areas, specific components, and the product that is being tested. For example:

- You can create an oncology library, a pediatrics library, and an infectious diseases library.
- You can create separate production libraries for approved user-defined functions and approved codelists.

Types to create

A library that has been built and maintained appropriately is a powerful tool that helps to decrease the time and effort needed for building a study. You can set up libraries as needed. Oracle recommends creating two different types of libraries, *staging libraries* (on page 29) and *production libraries* (on page 30).

Staging libraries

About staging libraries	
Use	Use a staging library to hold study objects before you add them to a production library. You can add categories and keywords and change the values of custom properties in the staging library. When you plan the study objects that will be reused, consider forms as well as other study objects that will help you build a study more quickly.
Users	Oracle recommends allowing only librarians to work in the library.
Number to create	One or many.
Adding study objects	A librarian can copy study objects as needed from production studies and test studies to a staging library.

About staging libraries	
Modifications to study objects	A librarian can add appropriate information needed for storing the study objects in a production environment. Oracle recommends allowing only the librarian to modify the study object.
Searches	Oracle recommends that you do not give users the rights to search staging libraries.

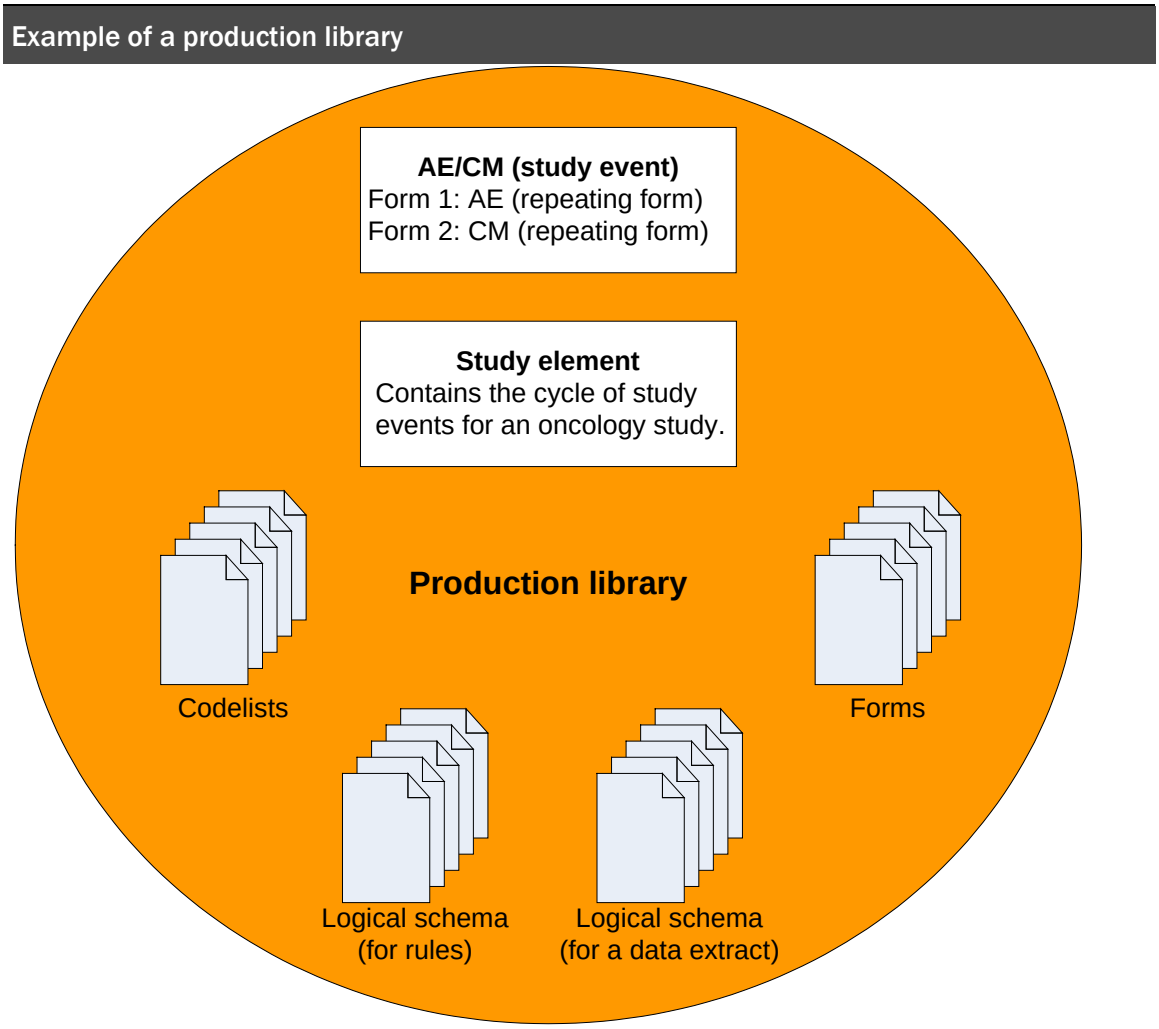
Production libraries

About production libraries	
Use	Use production libraries for study objects that have been tested in the target application and that will be reused in other studies.
Users	Oracle recommends allowing only librarians to work in the library.
Number to create	You can create one or many. Oracle recommends creating multiple production libraries to maximize scalability. When planning library development, encourage the use of standards. As the number of libraries grows, you can restrict searches to specific libraries so that you are searching only for study objects that are related to the study that you are developing.
Adding study objects	Oracle recommends that you develop an approval process for adding study objects to a production library. The approval process, which happens outside of the Central Designer application, might be conducted by a standards committee. After a study object has been tested, approved, and added to a production library, you can add the study object to additional production libraries without retesting it. Therefore, you can use the principles of reuse for building libraries as well as studies. If you use the Copy > Link option, the new study object retains a link to the original study object.
Modifications to study objects	To maintain the integrity of a production library, do not modify study objects that are in the library, except in unusual circumstances in which the change must be propagated to all studies that use the study object, or if the change: • Is trivial, such as a spelling mistake. • Does not affect testing. • Is necessary for all users. Oracle recommends modifying a study object outside the production library, and then adding the modified study object to the production library as a new study object.

About production libraries	
Searches	Oracle recommends that you allow users to search production libraries and view all published objects in them.
Questions to consider while planning	• How will you use categories and keywords to organize your study objects? A good categorization strategy will help you find study objects more efficiently. You can use categories for higher-level categorization and keywords for lower-level categorization. • What naming convention will you use for study objects, mappings, and functions? A naming convention will help you identify different types of study objects in your search results and will prevent you from giving the same name to two study objects in different libraries.

Illustrations of library workflow

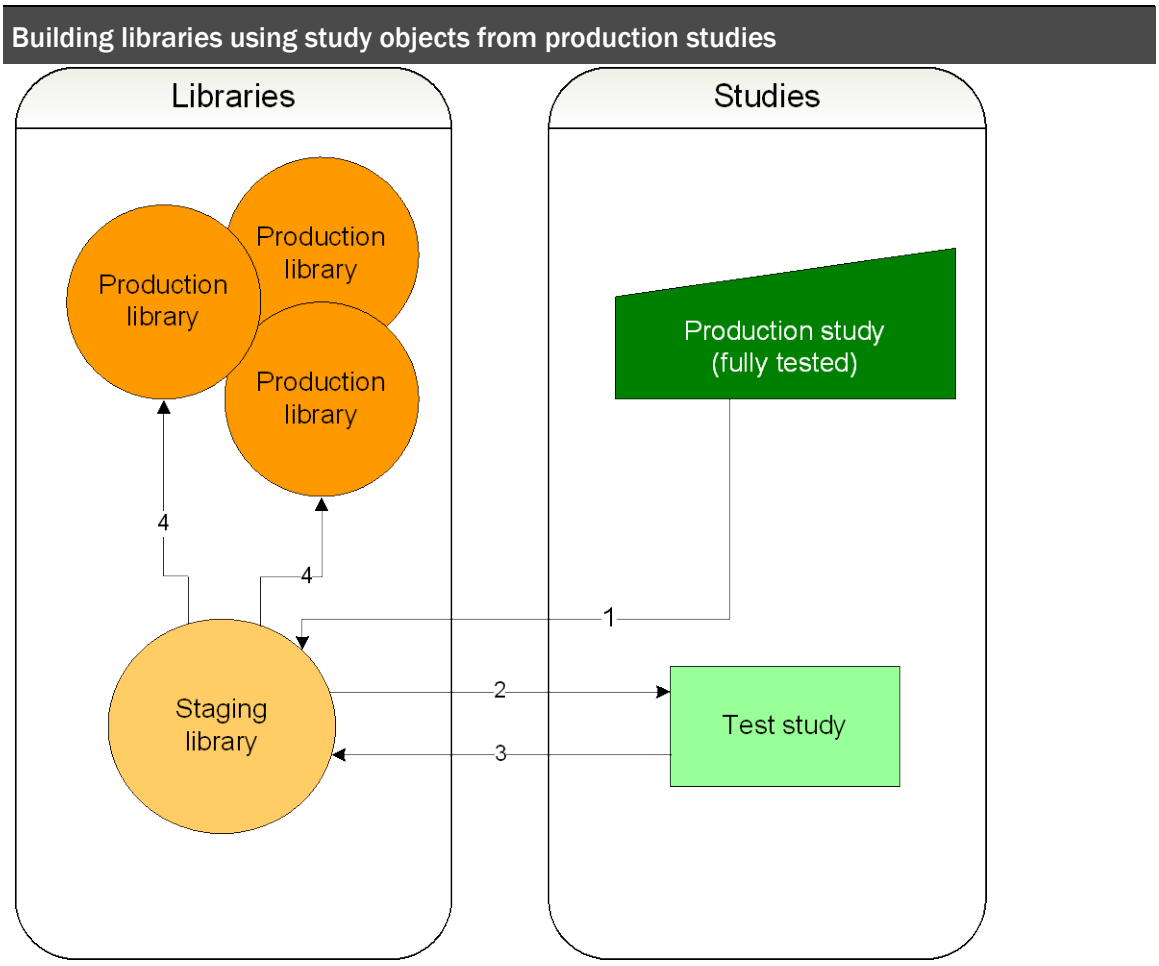
Illustration: Example of a production library



The illustration provides examples of content that you can include in a production library, including:

- Study elements.
- Study events.
- Forms (in or not in study events).
- Codelists.
- Mappings.

Illustration: Building libraries using study objects from production studies

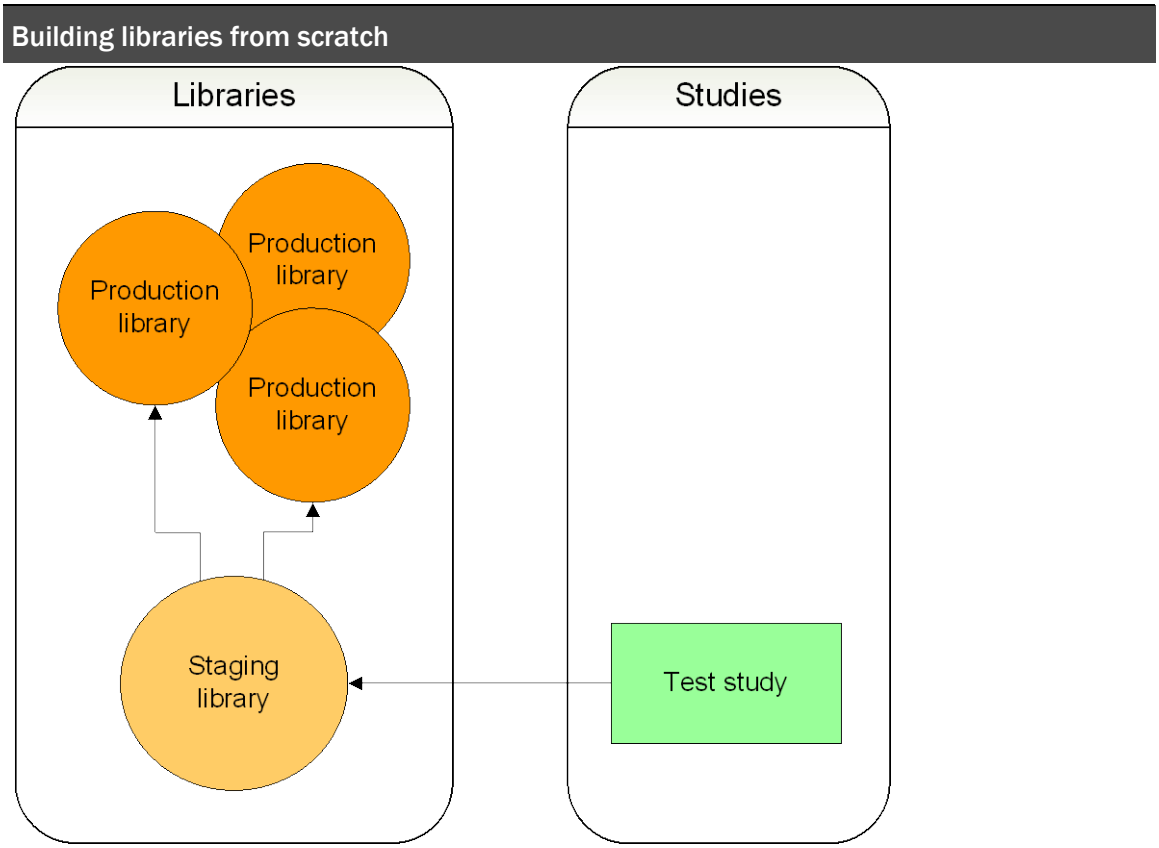


The illustration shows how you can add study objects from a production study to a production library. The production study has been validated in the Central Designer application and fully tested in the target application.

The numbers indicate the order in which study objects move among studies and libraries.

Oracle recommends implementing a process that requires study objects to be approved before they can be added to a production library. This task might be performed by a standards group.

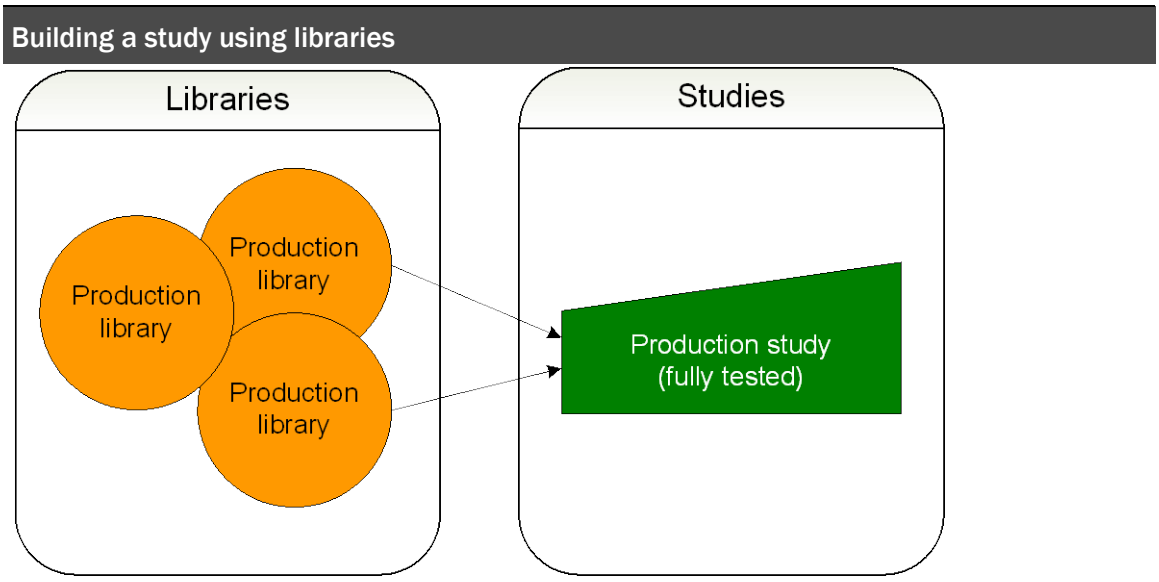
Illustration: Building libraries from scratch



The illustration shows how you can create study objects in a test study and then add them to a production library.

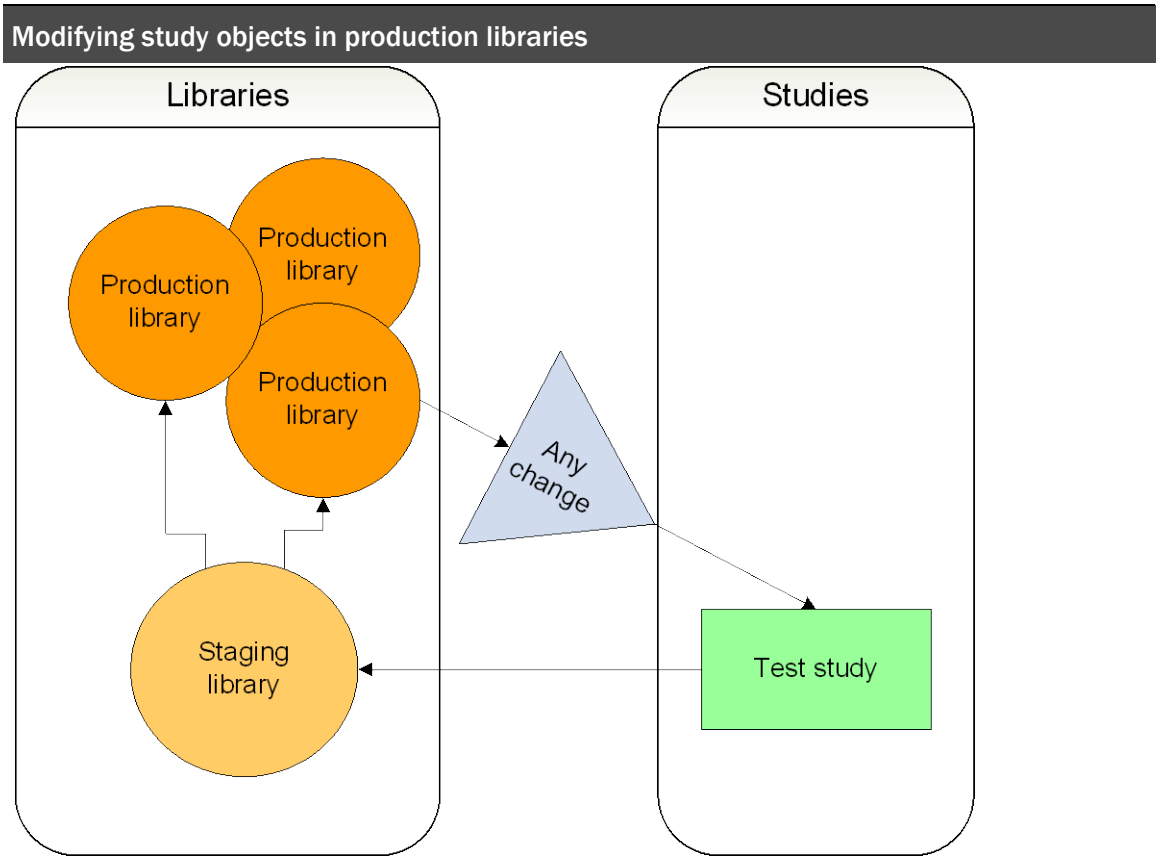
Oracle recommends implementing a process that requires study objects to be approved before they can be added to a production library. This task might be performed by a standards group.

Illustration: Building a study using libraries



The illustration shows how you can add study objects from a production library directly to a production study. The production study has been validated in the Central Designer application and fully tested in the target application.

Illustration: Modifying study objects in production libraries



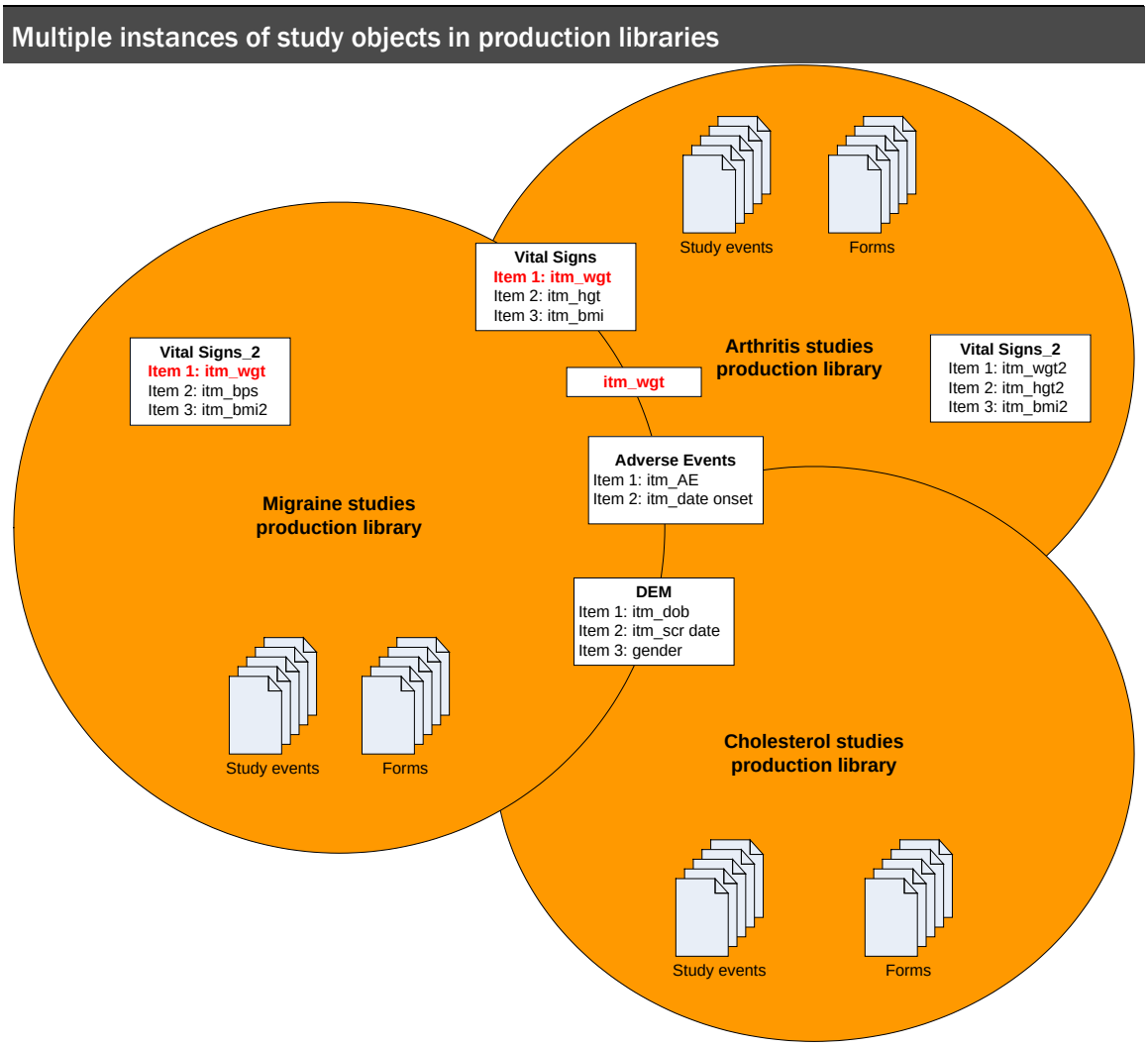
The illustration shows how you can modify study objects that are in a production library.

Oracle recommends updating the version number of the study object in the staging library to track changes.

The processes determined by your company determine whether trivial changes, such as a typo correction, need to be retested in the target application.

Oracle recommends implementing a process that requires study objects to be approved before they can be added to a production library, even if they have only been modified and have already been in a production library. This task might be performed by a standards group.

Illustration: Multiple instances of study objects in production libraries



Study objects, including forms and items, can appear multiple times in a single library and can also appear in other libraries. For example, in the illustration:

- The following forms were copied with the **Copy** > **Link** option:
  - **Vital Signs**—Appears in both the Arthritis and Migraine libraries.
  - **DEM**—Appears in both the Migraine and Cholesterol libraries.
  - **Adverse Events**—Appears in all three libraries.
- An item may be in a library in multiple places. For example, the itm_wgt is:
  - In the Migraine library as part of the Vital Signs_2 form.
  - In both the Migraine and Arthritis libraries as part of the Vital Signs form.
  - In both the Migraine and Arthritis libraries as a standalone item.

Planning how to manage study objects

Central Designer libraries make it possible to store and reuse the study objects that make up a study. When planning the development of a study, consider how you want to manage study objects.

Questions to consider	Notes
Do you prefer to develop studies based on your data analysis and reporting needs or based on the forms used to collect data?	The Central Designer application supports both approaches: • **Data-based**—You can start by developing mappings. • **Form-based**—You can start by developing forms, items, and other study objects, or by creating a study workflow. You can also work on both approaches simultaneously.
What types of libraries do you want to maintain?	For example, libraries for: • Therapeutic areas. • Functions. • Codelists and codelist items. • Customers (CRO). • Mappings for SDTM or ODM.
Do you have an existing library that you want to use?	You can import libraries in CSML or ODM format.
How do you want to be able to search for study objects? (How will you categorize study objects?)	For example: • By therapeutic area • By customer (CRO) • By study
What types of study objects will be reused in multiple studies?	For example: • Standard forms. • Study objects with rules.
Who will be responsible for setting up libraries and for determining the content of libraries?	Study object management tasks can include: • Naming (for example, enforcing adherence to a naming convention). • Categorizing. • Making changes. • Publishing (making study objects available for reuse).

Questions to consider	Notes
How do you want to use study templates?	Any part of study object definition can be stored in a template, including a whole study, and you can create templates from all types of study objects and from mappings. For example, a study template can include: • Standard study objects, including child study objects such as codelists. • Default settings of study object properties. • Team members. • Full or partial workflows. • Rules. • Mappings
How will study object reuse affect your testing of study designs?	If you perform formal testing on study objects before saving them in a library, it should not be necessary to retest them each time they are reused.

Will you develop naming conventions for study objects? How will your reporting needs affect naming conventions?	Consider that study objects have RefNames and titles:
	• A RefName is the formal name of a study object. RefNames are:
	  • Referenced in rules.
	  • Deployed to the InForm software.
	• A title is an additional name that you can make more readable than a RefName (for example, titles can contain spaces and special characters). Titles are:
	  • Not referenced in rules.
	  • Not deployed to the InForm application.
	Additionally, a data set and data series in a mapping can have an alias, which, if present, is used as the column heading in a customer-defined database (CDD).

How do you prefer to test study objects?	You could: • Create study objects in a study, validate and deploy the study, and move tested study objects to a library. • Create study objects in a test library, use them in a study to test them, and move tested study objects into a library for general use.

Planning rules and edit checks

Rule definition accommodates different levels of technical expertise.

Questions to consider	Notes
What types of rules and edit checks does the study require?	What types of rules can you create on standard study objects that can be reused?
What standard edit checks can be defined in a rule template?	
What types of functions do you require, in addition to the functions included with the Central Designer application?	
What types of additional functions would make the development of rules simpler or would make rules easier to reuse?	The functionality encapsulated in functions and rule templates does not need to be tested in every study object where it is used.
How do you want to assign the development of rules to the members of your team?	Consider: • Will one user create rule specifications and another user implement the rules? • Which rules can be created with templates or functions by users with no programming experience? • Which rules require users with programming experience?
How do you plan to test new data-entry rules?	You can use the Rule Test Cases dialog box to test data-entry rules, global conditions, and workflow rules.
How do you plan to test new functions that you develop?	

Planning the study workflow

Questions to consider	Notes
What is the structure of your study?	Does the study include: • Multiple treatment arms? • Unscheduled visits? • Repeating forms or visits? • Dynamic visits, forms or controls? • Common forms?
Do you prefer to develop a study from the top down or from the bottom up?	You can use the workflow tools to: • Summarize the flow of a study as a reference for the users who then develop the detailed definitions of study objects. This is a particularly useful communication device in complex studies. • Connect previously defined study objects.
When data is collected at multiple points in a study, do you want to reuse those study objects or make them repeating?	Repeating study objects (study events and forms) enable you to see all instances of the collected data in one location, or to navigate easily between instances.

Planning mappings and data extracts

You can group study data by using mappings. A mapping is a data grouping that provides an alternate data view of a study.

Questions to consider	Notes
What types of reports do you need to generate while the study is in process? What types study data will you need after the study is complete?	
How do you want to map data from an InForm study?	The Central Designer application supports: • Customer-Defined Database (CDD) mappings. • CIS mappings to the Clintrial application.
Do you want to use a mapping for rules?	A mapping for rules allows you to: • Write rules that are outside the scope of a study object. • Write rules that use arrays of data values.
Do you want to create data extracts that conform to a particular standard such as SDTM or ODM?	

PART II

Working in the study design environment

CHAPTER 3

Collaborating

In this chapter

Implementing collaboration

Creating and modifying tasks

Tasks

About tasks

A task is a request that you attach to a study object (a study, study element, study event, form, or item). A task is similar to a collaboration note except that you assign a task to an individual or to a whole study team. In a task, you can include detailed information and specify a due date and priority. You can format the text of a task and attach a file to it.

Example of using tasks

For example, a study workflow designer builds the framework for a study and includes information about the rules that will be required. A study architect can create rules to use as placeholders, without defining their expressions, and then create tasks for rule creation and assign them to the rule development team.

Level at which to create tasks

You can create a task on the study object, such as the form to be designed, or the parent study object, if the study object has not been created.

If the study object does not exist, consider creating a placeholder study object and then creating the task on the study object. For example, when the task assignee double-clicks the task in the Home Page, the Project Explorer opens, and the user is brought directly to the study object.

In general, create one task for each activity to be completed so that completed and remaining work can be assessed accurately.

Copying study objects with tasks

Tasks are not copied when a study object is copied from a library or published in a library.

Task types

When you create a task, you must choose a type on which to base it.

Task types

Administrators create task types in the Central Designer Administrator application. Task types are used to identify the type of the task and the way the task is used. Task types can be classified as Standard or Translation. Administrators select a default team to which tasks of each type are assigned. Selecting a default team is optional for standard tasks.

When you create a task, you choose a task type on which to base the task.

You can create multiple task types for each task classification. Task classifications are predefined and you cannot modify them.

Task classification	Description	Example
Standard	Used for all non-translation tasks assigned to an individual or team. When you create a standard task, you can override the default assignment.	• Task name: Create form • Default teams: Study designers, Form designers
Translation	Used for tasks that request translation of a study object into one or more languages. When you create a translation task, you choose the language into which the study object must be translated. **Note:** Oracle recommends selecting only one language for each translation task, unless you expect that the same person will translate into all of the selected languages.	• Task name: Translate form • Default team: Translation team.

Task statuses

Tasks appear in the Home Page and the Tasks Browser.

- Tasks that are assigned to you appear in the Home Page.
- All tasks appear in the Tasks Browser.

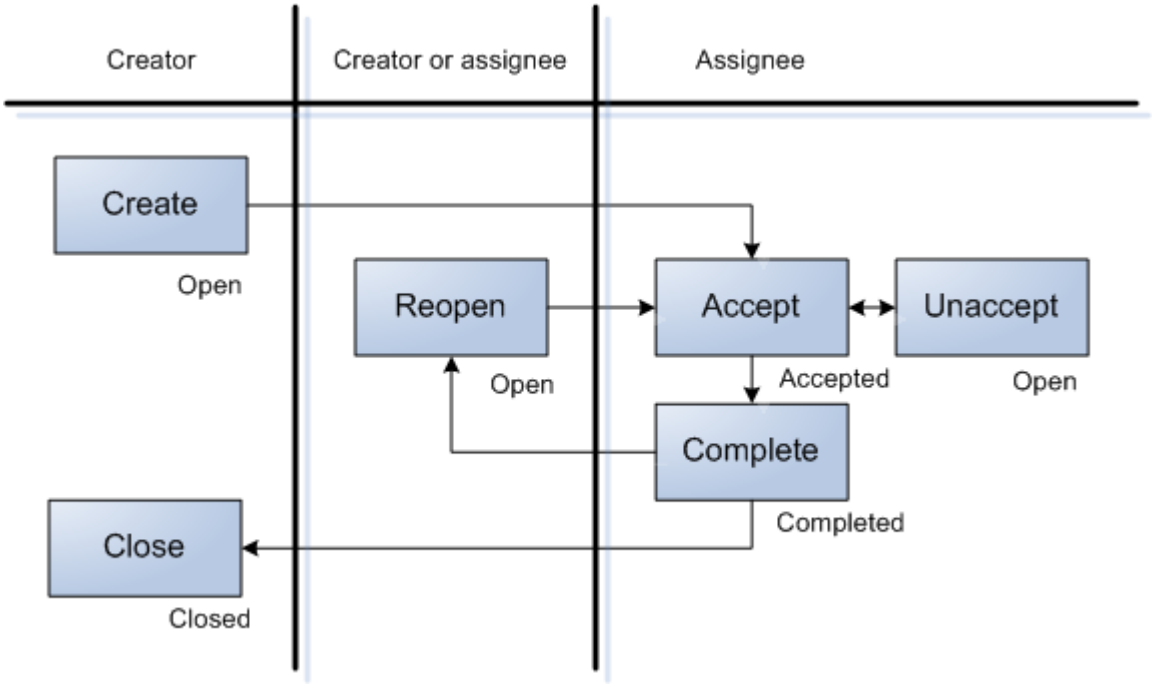
Note: If a task is overdue, the status displayed in the status field is Overdue—[Current status], such as Overdue—Accepted.

Procedure	Task status	Description
Creating a task (on page 49).	Open	When you create a task, you assign it to one or more individuals or teams.
Accepting a task (on page 59).	Accepted	When you accept a task, you take responsibility for completing the task. Only one person can accept a task, and you can only accept tasks that are assigned to you. After you accept a task, you can: • Mark it as Complete after you finish all required work. • Unaccept it if you will no longer work on the task.
Unaccepting a task (on page 59).	Open	You can unaccept a task that you have accepted but will no longer work on. An unaccepted task is assigned to the team to whom it was originally assigned. If no default team was selected, you are prompted to assign the task to a team or individual.

Procedure	Task status	Description
Completing a task (on page 59).	Completed	You can mark as Complete only those tasks that you have accepted. A completed task is assigned to the task creator. The task creator can do the following to a completed task: • Close it if work is complete. • Reopen it if work is not complete.
Closing a task (on page 59).	Closed	You can close completed tasks that you created. You close a task after you verify that all work has been completed. A closed task is assigned to the task creator.
Reopening a task (on page 59).	Open	Two people can reopen a task, the person who created it and the person who completed it. A reopened task is assigned to the individual or team to whom it was assigned by default. If no default team was selected, you are prompted to assign the task to a team or individual.

Task workflow

In the following illustration, activities appear in boxes with task statuses below them.



Creating a task

Note: You must save a study object before you can attach a collaboration note or task.

1 In the Project Explorer, select a study object (study design, study element, study event, form, section, item, codelist, codelist item, mapping, data set, or data series).

2 In the **Tasks Browser**, click **New Task**.

The Task Editor dialog box appears.

3 From the **Task Type** drop-down list, select the type of task to create. (Task types are defined in the Central Designer Administrator application.)

4 From the **Priority** drop-down list, choose a priority for the task.

5 From the **Due** drop-down list, choose the date that the task is due.

6 On the **Instructions** tab, type the instructions for the task.

7 To edit the appearance of the text, use the buttons on the toolbar.

8 To add an attachment, complete the following steps:

Note: The maximum size of the attachment is determined by a variety of factors, including information defined in the configuration file, available hard disk space, and available memory. To determine the approximate maximum attachment size, check the maxRequestLength attribute in the machine.config file.

a Click the **Attachments** button ().

The Attachments dialog box appears.

b Click **Add**.

The Open dialog box appears.

c Navigate to a file, and click **Open**.

Click **OK**.

9 If you are creating a Standard task, select the **Assignment** tab and choose the team (or teams) or user (or users) to assign the task to.

or

If you are creating a Translation task, select the **Languages** tab and choose the languages to which the task must be translated. (Only the languages configured as supported locales in the Central Designer Administrator application appear.)

Note: You must assign every task to at least one individual or team. For translation tasks, the default assignment for the task type is used.

10 Click **OK**.

For more information, see **Task Editor dialog box - Option descriptions** (on page 147).

Changing the assignees for a standard task

When the status of a task is open, you can change the assignees for a standard task, but you cannot remove all assignees from the task.

Note: You cannot change the assignees for translation tasks.

1 In the Project Explorer, select a study object (study design, study element, study event, form, section, item, codelist, codelist item, mapping, data set, or data series).

2 In the **Tasks Browser**, select a task.

3 On the toolbar, click **Edit**.

The Task Editor dialog box appears.

4 Click the **Assignment** tab.

5 Modify the users or teams to which the task is assigned. You must assign the task to at least one person or team.

6 Click **OK**.

For more information, see **Task Editor dialog box - Option descriptions** (on page 147).

Deleting a collaboration note or task

Only the creator of a task or a user with the necessary rights can delete a task. Consider deleting tasks that were created in error or that are no longer relevant. Tasks provide an audit trail for assigned activities, so you should not delete tasks if you want to maintain an audit trail of assigned activities.

If too many tasks appear on the Home Page, use filters to view, for example, only Open or Accepted tasks.

1 In the Project Explorer, select a study object (study design, study element, study event, form, section, item, codelist, codelist item, mapping, data set, or data series).

2 **For tasks**—In the **Tasks Browser**, select a task.

For collaboration notes—In the **Collaboration Notes Browser**, select a collaboration note.

3 Click **Delete**.

A message asks you to confirm the deletion.

4 Click **Yes**.

Editing a collaboration note or task

You can edit the text of collaboration notes and tasks, and you can remove attachments from collaboration notes.

To edit the text of a task:

1 In the Project Explorer, select a study object (study design, study element, study event, form, section, item, codelist, codelist item, mapping, data set, or data series).

2 In the **Tasks Browser**, select a task.

3 On the toolbar, click **Edit**, or double-click the task.

The Task Editor dialog box appears.

4 Edit the task as necessary, and click **OK**.

To edit the text of a collaboration note:

1 In the Project Explorer, select a study object (study design, study element, study event, form, section, item, codelist, codelist item, mapping, data set, or data series).

2 In the **Collaboration Notes Browser**, select the collaboration note that you want to edit.

3 On the toolbar, click **Edit**, or double-click the collaboration note.

The Collaboration Note Editor dialog box appears.

4 Edit the collaboration note as necessary, and click **OK**.

To remove an attachment from a collaboration note:

1 In the Project Explorer, select a study object (study design, study element, study event, form, section, item, codelist, codelist item, mapping, data set, or data series).

2 In the **Collaboration Notes Browser**, select a collaboration note, and click **Edit**.

The Collaboration Note Editor dialog box appears.

3 Click the **Attachments** button (a paperclip icon).

The Attachment dialog box appears.

4 Select the file that you want to remove, and click **Remove**.

5 Click **OK**.

For more information, see:

Collaboration Note Editor dialog box - Option descriptions (on page 144).

Task Editor dialog box - Option descriptions (on page 147).

Printing a collaboration note or task

1 In the Project Explorer, select a study object (study design, study element, study event, form, section, item, codelist, codelist item, mapping, data set, or data series).

2 Do one of the following:

- **For tasks**—In the **Tasks Browser**, select a task.
- **For collaboration notes**—In the **Collaboration Notes Browser**, select a collaboration note.

3 Click **Print**.

Tasks Browser

The Tasks Browser displays all tasks that are attached to the study object that is selected in the Project Explorer and, optionally, its child study objects. All users can see the tasks assigned to them.

In the Tasks Browser, you can:

- Create, view, sort, filter, and group tasks.
- Modify and delete a task.
- Print tasks.
- Select Show Children. You see all tasks attached to the selected study object and its children.
- Filter the tasks that appear. For more information, see *Filtering data in a grid* (on page 22).

By default, the browser is located at the bottom of the application window.

To open the Tasks Browser:

- Select the **View** menu, and make sure **Tasks** is selected.

For more information, see **Tasks Browser - Option descriptions** (on page 146).

Creating a collaboration note

You can create a collaboration note from the Project Explorer and from the Collaboration Notes Browser.

Note: You must save a study object before you can attach a collaboration note or task.

1 In the Project Explorer, select a study object (study design, study element, study event, form, section, item, codelist, codelist item, mapping, data set, or data series).

2 Right-click the study object, and select **Add Collaboration Note**.

or

In the **Collaboration Notes Browser**, click **New Note**.

The Collaboration Note Editor dialog box appears.

3 From the **Note Type** drop-down list, select a collaboration note type.

Note: Collaboration note types are defined in the Central Designer Administrator application.

4 On the **Instructions** tab, type the instructions for the task. To edit the appearance of the text, use the buttons on the toolbar.

5 To add an attachment, complete the following steps:

Note: The maximum size of the attachment is determined by a variety of factors, including information defined in the configuration file, available hard disk space, and available memory. To determine the approximate maximum attachment size, check the maxRequestLength attribute in the machine.config file.

a Click the **Attachments** button ().

The Attachments dialog box appears.

b Click **Add**.

The Open dialog box appears.

c Navigate to a file, and click **Open**.

Click **OK**.

6 Click **OK**.

For more information, see **Collaboration Note Editor dialog box - Option descriptions** (on page 144).

Collaboration notes

A collaboration note is a note that you attach to any study object, such as a project, study, study element, study event, form, or item. A collaboration note is like an electronic sticky note in which you include annotations, comments, messages, and file attachments. View the collaboration notes that are attached to a study object and, optionally, to its children, in the Collaboration Notes Browser.

When you create a collaboration note, you must choose a type on which to base it.

Collaboration note types

When you create a collaboration note, you choose a collaboration note type on which to base the collaboration note. Administrators define collaboration note types in the Central Designer Administrator application. Collaboration note types are used to identify the type and purpose of a collaboration note. You can filter the view of collaboration notes in the Collaboration Notes Browser according to type.

For example, an administrator might create a collaboration note type called Information to provide important information about study objects in a study and a Usage note type to tell where a study object can be used.

Collaboration Notes Browser

The Collaboration Notes Browser displays the collaboration notes that are attached to the study object that is selected in the Project Explorer and, optionally, its child study objects.

In the Collaboration Notes Browser, you can:

- Create, view, sort, filter, and group collaboration notes.
- Modify and delete a collaboration note.
- Print one or more collaboration notes.
- Select Show Children. You see all collaboration notes attached to the selected study object and its children.
- Filter the collaboration notes that appear. For more information, see *Filtering data in a grid* (on page 22).

By default, the browser is located at the bottom of the application window.

To open the Collaboration Notes Browser:

- Select the **View** menu, and make sure **Collaboration Notes** is selected.

For more information, see **Collaboration Notes Browser - Option descriptions** (on page 144).

About locking study objects

Determining whether a study object is locked

Only the user who holds the lock can modify a study object. The following types of locks are available:

- An **automatic lock**, also known as an implicit lock, is applied to a study object when you modify it and released when you save or close without saving.
- A **requested lock**, also known as an explicit lock, is applied to a study object when you explicitly lock a study object and released only when you unlock the study object. You might request a lock if you plan to work on a study object for an extended period of time.

To determine whether a study object is locked:

- In the Project Explorer, view the icon for the study object.
  - Normal icons appear for unlocked study objects.
  - Shaded icons appear for locked study objects.
    - If the lock icon is green, you hold the lock.
    - If the lock icon is red, someone else holds the lock. The tooltip for the study object has the name of the user who holds the lock.

      Note: The Modified property in the tooltip indicates whether you modified the study object since the last time you saved it. If someone else holds the lock, the property is set to False.

  or

  In the Properties Browser, check whether the Locked property is set to **True** or **False**.

Locking and unlocking a study object

You can lock and unlock a study object (study design, study element, study event, form, section, item, codelist, and codelist item).

To explicitly lock a study object:

- In the Project Explorer, right-click a study object, and select **Lock**.

  The study object is locked, and a green lock icon appears in the Project Explorer.

To unlock a study object:

Note: If you unlock a study object without saving, you are prompted to save changes, discard changes, or cancel.

- In the Project Explorer, right-click a study object, and select **Unlock**.

  The study object is unlocked, and the green icon in the Project Explorer is removed.

Locking and unlocking a deployment instance

1. In the Project Explorer, select the **Study Information** Explorer bar.
2. Select the study.
3. Select the **Deployment Setup** tab.
4. To explicitly lock a deployment instance, right-click a deployment instance, and select **Lock and Protect > Lock**.
5. To unlock a deployment instance that you explicitly locked, right-click a deployment instance, and select **Lock and Protect > Unlock**.

Locking and unlocking an in-place revision object

1 In the Project Explorer, select the **Visit Schedule** Explorer bar.

2 Select the study design.

The Study Design Editor appears.

3 Select the **IPR Summary** tab.

4 To explicitly lock an in-place revision, right-click an in-place revision, and select **Lock and Protect > Lock**.

5 To unlock an in-place revision that you explicitly locked, right-click an in-place revision, and select **Lock and Protect > Unlock**.

Locking and unlocking a StudyAdministration object

1 In the Project Explorer, select the **Study Information** Explorer bar.

2 To explicitly lock a StudyAdministration object, right-click the **Administration** folder, and select **Lock**.

3 To unlock a StudyAdministration object that you explicitly locked, right-click the **Administration** folder, and select **Unlock**.

Note: When you lock and unlock the StudyAdministration object, the following objects are also locked and unlocked: Sponsor, StudyConfiguration, ItemGroup, RightsGroup, QueryGroup, and SignatureGroup.

Locking and unlocking a workflow rule

To explicitly lock a workflow rule:

1 In the Project Explorer, select a study design, study element, or study event.

2 Select the **Workflow Diagram** tab.

3 Right-click a workflow rule, and select **Lock Rule**.

Note: Workflow rules appear as diamond-shaped objects in the workflow.

To unlock a workflow rule that you explicitly locked:

1 In the Project Explorer, select a study design, study element, or study event.

2 Select the **Workflow Diagram** tab.

3 Right-click a workflow rule, and select **Unlock Rule**.

Locking and unlocking a global condition

1 In the Project Explorer, select a study design, study element, or study event.

2 Select the **Workflow Diagram** tab.

3 On the toolbar, click **Global Conditions**.

The Edit Global Conditions dialog box appears.

4 To explicitly lock a global condition, right-click a global condition, and select **Lock**.

5 To unlock a global condition that you explicitly locked, right-click a global condition, and select **Unlock**.

Locking and unlocking a data-entry rule

A lock is automatically applied when you begin editing a rule and is released when you save the rule. If you want to work on a rule for an extended period of time, you can explicitly lock it to prevent others from working on it.

1 In the Project Explorer, select the study object on which the data-entry rule is created.

2 Select the **Rules** tab.

3 To explicitly lock a data-entry rule, right-click the data-entry rule, and select **Lock**.

4 To unlock a data-entry rule that you explicitly locked, right-click the data-entry rule, and select **Unlock**.

Revoking and transferring a lock on a study object

You can perform the following actions on a study object (study design, study element, study event, form, section, item, codelist, and codelist item):

- Revoke someone else's lock on a study object.
- For a study object that you locked in another session, such as on another computer, transfer the lock to your current session.

If a study object has a parent object that is locked by another user:

- You cannot revoke the lock on the study object.
- If you revoke the lock on the parent object, remote locks on the parent object's children are also revoked.

Note: When you revoke a lock, any unsaved changes made by the person who holds the lock are lost.

To remove another user's lock on a study object:

1 In the Project Explorer, right-click a study object that someone else has locked, and select **Revoke Lock**.

2 In the confirmation message, click **Yes**.

Any unsaved changes that the other user made are lost, and the lock is removed.

To transfer a lock from another session:

1 In the Project Explorer, right-click a study object that someone else has locked, and select **Transfer Lock**.

2 In the confirmation message, click **Yes**.

Working in a collaborative environment

Interacting with assigned tasks

Viewing all tasks assigned to you

You can view all tasks assigned to you in the Home Page in the Recent Tasks tab and the My Tasks section.

- On the toolbar, click the **Home Page** button ().

  The Home Page appears. The Recent Tasks tab and the My Tasks section display tasks assigned to you.

Accepting, unaccepting, completing, closing, and reopening a task

1. In the Project Explorer, select a study object (study design, study element, study event, form, section, item, codelist, codelist item, mapping, data set, or data series).
2. In the **Tasks Browser**, select a task.
3. On the toolbar, click an action.

   or

   Double-click the task. In the Task Editor dialog box, click an action.

For more information, see **Task Editor dialog box - Option descriptions** (on page 147).

CHAPTER 4

Reusing study objects

In this chapter

About projects, studies, and libraries

Characteristic	Description
About projects	Projects are containers used to hold study design building blocks. You can create two types of projects: • **Study project**—A project containing one or more studies that are related to each other. • **Library project**—A project containing a library.
Number of studies and libraries to create	You can create one library in each library project. There is no limit on the number of studies you can create in a study project. However, you might experience performance degradation if you have multiple studies in a single project, especially if the number of study objects is large.
Contents	Studies and libraries contain the same types of study objects. A study object is a study building block that appears in the Project Explorer.
Repository	All study objects and components are stored in a single database instance called the repository. The repository can be organized into multiple libraries, each of which can be managed differently and can serve a different purpose. For example, you can organize libraries by therapeutic area or by team. Central Designer libraries store study objects for reuse and help enforce standards. A library project is a project containing a library. A library is a container used to store related study objects and templates to be published for reuse in studies or other libraries. A library provides a logical view of the study objects in the repository. A librarian creates libraries within library projects and then includes resources from the repository or defines new resources within the library itself. If you have the appropriate rights (assigned in the Central Designer Administrator application) and you are a member of the library team, you can: • Create study objects and templates. • Publish study objects for other team members to use in study designs. • Search for study objects using categories and keywords.
Reuse	Study objects that are created in libraries can be copied easily into multiple studies. Additionally, study objects that are created and saved in studies are available for reuse when copied directly from the repository.

Characteristic	Description
System library	Oracle recommends that you do not modify information in the System Library. Instead, copy item types from the System Library to another library, and modify information in the new library. When you create an item, you can choose to base it on any of the types in the libraries in the Library List, so make sure you add the new library to the list. Optionally, if you do not want the item types in the System Library to appear as options, you can remove the System Library from the Library List.

Library administration

The study objects and components that are used to design studies are stored in the repository. A library is a container used to store related study objects and templates to be published for reuse in studies or other libraries. A library provides a view of the study objects in the repository

To set up a library in which users can develop and publish study objects, you use the tabs of the Library Editor in a library within a library project.

In the Library Editor, you define library properties, such as the supported locales and form layouts for deployment, the users who can work in the library, and the functions and constants that can be used when creating rules for study objects in the library.

Note: To define additional properties for a study object, consider using custom properties. In the Central Designer Administrator application, an administrator creates custom properties and can provide predefined values or allow Central Designer users to provide values. For more information, see the *Administrator Guide*.

Creating a library

When you create a library, the Central Designer application creates a library project with the same name by default. You can change the library project name when creating the library. Each library project can have only one library.

1 Select **File > New Library Project**.

The New Library dialog box appears.

2 Type a name and description.

3 In the **Targets** section, select the target applications for which you will create study objects in the library.

4 To change the name of the associated library project, select the **Library Project** tab, and type a name and description for the library project.

5 Click **OK**.

Opening and closing a study or library project

To open a study or library project:

- In the **Recent Projects List** of the **Home Page**, double-click a study or library project.

  or

  a Select **File > Open**, or press **Ctrl+O**.

  The Open dialog box appears.

  b Optionally, in the **Filter** field, specify the text to use for filtering the list of study or library projects.

  The list of study or library projects changes to include only projects whose name or description includes the specified text (not case-sensitive).

  c Optionally, in the **Project Types** field, select whether to show only study or only library projects.

  > **Note:** To appear in the list of study and library projects, a project must match both the text in the Filter field and the project type selected in the Project Types field.

  d Select a study or library project, and click **Open**.

To close a study or library project:

1 Select **File > Close**.

2 If prompted, confirm that you want to save changes.

Setting up library teams

Users Browser searches

To open the Users Browser:

- Select the **View** menu, and make sure **Users** is selected.

Characteristic	Description
Use	To find users and add them to: • A study team (in a study project), which an administrator creates as a role with a study scope in the Central Designer Administrator application. • A library team (in a library project), which an administrator creates as a role with a library scope in the Central Designer Administrator application. **Note:** A user must be assigned to the corresponding role to be added to a team.
Location of the Users Browser	By default, the browser is located to the right in the application window.

Characteristic	Description
Features	You can: • Create and save search criteria for personal or global use. • Open, close, delete, rename, and switch to different searches.
Required search parameters	No required parameters.
Optional search parameters	Use one, several, or none of the following: • Text • Categories • Keywords The asterisk (*), percent sign (%), and underscore (_) are wildcard operators, which are inserted before and after text. For example, dem automatically becomes *dem*. Use a comma as a delimiter.
How the search is performed	Text, keywords, categories, and libraries are connected with the AND operator. Criteria within each parameter are connected with the OR operator. For example: • Text that you type AND • Keyword1 OR Keyword2 AND • Category1 OR Category2
Which information is searched	User names, display names, titles, first names, and last names of: • Active users • Inactive users **Note:** You can add inactive but not terminated users to teams. View the status of users in the Central Designer Administrator application.
Search results	Users are listed in alphabetical order according to display name, with user names in parentheses.

Finding and adding a user to a library team and saving the search

An administrator creates library teams as library roles in the Central Designer Administrator application. A user must be assigned to the corresponding role to be added to a team.

For example, if a user is assigned to the Librarian library role in the Central Designer Administrator application, the user must be a member of the Librarian library team for a library (in the Central Designer application) to work in the library. You assign users to roles in the Central Designer Administrator application and to study and library teams in the Central Designer application. You assign a user to a library team for the selected library only.

Note: To view all users, click **Find** without entering parameters. Depending on the size of the repository, this search might take several minutes.

To add a user to a library team:

1 Open a library project and select the library containing the team to which you want to add a user.

2 Select the **Users Browser**.

3 Optionally, to name the search:

   a Select **Actions > New Search**. The Actions menu is located at the top of the browser.

   The New search dialog box appears.

   b Type a name for the search, and click **OK**.

   The name of the search appears on a tab to the right of the browser.

4 In the **Enter search text** field, type text that appears in the user's name or display name, title, first name, or last name.

5 To include *categories and keywords* (on page 74) as parameters, click the down arrows button ( ) next to the **Search Filter**, and then:

   - Optionally, select the **Categories** tab, and select one or more categories.
   - Optionally, select the **Keywords** tab, and select one or more keywords.

   The parameters you select appear in the field below the **Search Filter**.

6 Click **Find**.

   The Central Designer application performs a search based on your search criteria. For more information about how searches work, see *Users Browser searches* (on page 65).

7 In the Project Explorer, select the **Library Information** Explorer bar.

8 Select the library.

9 Select the **Teams** tab.

   All teams created in the library scope in the Central Designer Administrator application appear in the workspace.

10 In the **[Study name] - Teams** section, select a team.

   The name of the team appears above the right section on the tab.

11 In the **Users Browser**, select a user, and drag the user to the right section.

The user is added to the team. You can add the user to more teams or add different users to teams.

> **Note:** You can also add a user to a team by dragging the user directly to the team name in the left section.
>
> **Note:** The user that you added must log out and log on again to have the privileges associated with the team.

To save the search:

1 Select **Actions > Save Search to Repository**. The Actions menu is located at the top of the browser.

The Save Search to Repository dialog box appears.

2 Optionally, type a description for the search.

3 Select an option:

- **Just me**—Only you can see and use the search.
- **Everyone**—Everyone can see and use the search.

4 Click **Save**.

Opening a search saved in the repository

All saved searches are stored in the repository, which contains all data created and saved in the application.

1 Select either the **Libraries Browser** (for a study object search) or **Users Browser** (for a user search).

2 Select **Actions > Open Search from Repository**. The Actions menu is located at the top of the browser.

The Open Search from Repository dialog box appears.

3 Select a search, and click **Open**.

The search opens. A tab with the name of the search appears to the right of the browser.

Clearing search parameters

> **Note:** If you clear the parameters of a saved search but do not save after clearing, the search is saved with parameters.

- In the **Libraries Browser** or **Users Browser**, click **Clear Search**, which is located at the top of the browser.

  The following information is cleared:

  - Text in the Enter search text field.
  - Selected categories and keywords.
  - Selected libraries (in the Libraries Browser only).

Closing an active search

All saved searches are stored in the repository, which contains all data created and saved in the application. If you close a saved search, the search is removed from your view but is not deleted.

1 Select either the **Libraries Browser** (for a study object search) or **Users Browser** (for a user search).

2 Select a tab. Tabs are located along the right side of the browser.

3 Select **Actions > Close Active Search**. The Actions menu is located at the top of the browser.

The search is closed. If it is a saved search, it remains in the repository. If it is not saved, it is removed and cannot be reopened.

Deleting a search from the repository

1 Select either the **Libraries Browser** (for a study object search) or **Users Browser** (for a user search).

2 Select **Actions > Delete Search from Repository**. The Actions menu is located at the top of the browser.

The Delete Search from Repository dialog box appears.

3 Select a search, and click **Delete**.

Removing a user from a study or library team

1 In a study, select the **Study Information** Explorer bar.

or

In a library, select the **Library Information** Explorer bar.

2 Select the study or library.

3 Select the **Teams** tab.

4 In the left section, right-click the user, and select **Remove from Team**.

Library security

Access to a library is determined by the following library security features.

Security feature	Where to perform	Description
Assign rights and roles (in the *Administrator Guide*)	Central Designer Administrator	Libraries contain published and unpublished resources for reuse within studies. The librarian manages the users who are granted access to a library.
Assign users to library teams (on page 67)	Library	An administrator must add you to a library study team before you can create or modify objects in that library.

Security feature	Where to perform	Description
Enable and disable a library (on page 70)	Library	Libraries are enabled (or made accessible to other users) by default. The librarian can enable or disable the library at any time. For example, a librarian might disable a library to create and organize its resources before making the library visible to other users. When the library is ready for use, the librarian enables it. **Note:** You cannot search a disabled library.
Publish library objects (on page 73)	Library	You must publish a study object that was created in a library to allow other users to search for it in the Libraries Browser.
Create a library list (in the *InForm Design Guide)*	Study	You can search only libraries that appear in a study's library list for study objects to include in the study.
Protect and unprotect study objects (on page 71)	Study or library	• You can: • Protect study objects in studies and libraries to prevent users from making changes. • If you protect a study object, all of its children are also protected. • Protect an entire study or library.

Disabling and enabling a library

You can disable a library to:

- Prevent users from using library resources while you are working on them.
- Close a library that you no longer use.

Members of a library team can work in a disabled library if they have the necessary rights. However:

- Study administrators cannot add the library to the Library List for a study.
- Study designers cannot search for study objects in the library, even if it is already in the Library List for the study.

To disable or enable a library:

1 In the Project Explorer, select the **Library Information** Explorer bar.

2 Right-click a library, and select or deselect **Enable Library**.

Protecting and unprotecting a library

To protect a library:

1 In the Project Explorer, select the **Library Information** Explorer bar.

2 Right-click the library and select **Protect**.

The selected library and all of the study objects within the library are protected.

The icons to the left of the library and all of the study objects within the library change to reflect a protected status.

Note: You cannot delete study objects that are the direct children of a protected study object. After you protect a study object, you cannot select Undo, but you can select Unprotect.

To unprotect a library:

1 In the Project Explorer, select the **Library Information** Explorer bar.

2 Right-click the library and select **Unprotect**.

The selected library is unprotected.

The icon to the left of the library changes to reflect an unprotected status.

Note: Unprotecting a library or a study object in a library does not affect study objects that you copied from the library into a study.

Publishing, republishing, and unpublishing

About publishing, republishing, and unpublishing

You must publish study objects that were created in a library to allow users to search for them in the Libraries Browser. You can publish, republish, and unpublish study objects only in a library. You must save a study object before you publish or republish it.

In a library, you can publish any of the following.

What to publish	Notes
A single study object.	When you publish a study object, you publish its most recent version or revision.
A study object and its child study objects.	• When you publish a form and its children, sections on the form are also published. • Publishing child study objects is not supported for mappings. • If you modify a study object or one of its children, you can use the republish option to publish the study object and its children again. • If you copy a study object with child study objects from the Libraries Browser to a study or library, the child study objects are also copied, regardless of whether they are published.
All study objects.	

Note: To prevent users from finding study objects using the Libraries Browser, unpublish the study objects.

Guidelines for publishing, republishing, and unpublishing

- Publish and reuse study objects at the highest-level study object that makes sense. For example, consider publishing and reusing forms rather than individual items, unless you specifically need individual items to be available in a library. A reused form can save you more time than a reused item.
- Where possible, consider publishing and reusing study events and study elements rather than forms.
- Consider publishing codelists and codelist items so they can be shared and reused.

Workflows and published study objects

You can develop study workflows in either a study or a library, and you can use study objects found in a Libraries Browser search to define a workflow in a study in the following ways:

- **Adding a published study object to a workflow**—You can drag a published study object from the Libraries Browser to a workflow tab in a study (for example, you can drag a published study event to the Workflow Diagram tab in the Study Editor or Study Element Editor). When you do this, the study object from the Libraries Browser is added to the workflow in the study.
- **Replacing a published study object in a workflow**—You can drag a published study object from the Libraries Browser onto a study object in a study (for example, you can drag a published form from the Libraries Browser and drop it onto a form object in the Workflow Diagram tab in the Study Event Editor of a study). When you do this, the study object from the Libraries Browser replaces the definition of the study object. This method enables you to create an outline of a study workflow without defining the properties of the study objects and then to replace the placeholder study objects with fully defined, published study objects.

Publishing, unpublishing, and republishing a study object

Publishing a study object (a study element, study event, form, section, item, codelist, and codelist item) created in a library makes it available for copying into a study. Unpublishing a study object makes it unavailable for future copying unless you republish it.

To publish or republish a study object (with or without child study objects):

1 In a library project, save the study object that you want to publish or republish.

2 In the Project Explorer, right-click a study object, and:

- **To publish**—Select **Publishing > Publish**.
- **To republish**—Select **Publishing > Republish**.

3 If prompted, confirm whether to publish or republish the child study objects.

To publish or republish all study objects in a library:

1 Select **File > Save Project**.

2 Do one of the following:

- **To publish**—In the Project Explorer, right-click a library, and select **Publish Study > Publish**.
- **To republish**—In the Project Explorer, right-click a library, and select **Publish Study > Republish**.

To unpublish a study object (with or without child study objects):

1 In the Project Explorer of a library project, right-click a study object, and select **Publishing > Unpublish**.

2 If prompted, confirm whether to unpublish the child study objects.

To unpublish all study objects in a library:

- In the Project Explorer of a library project, right-click a library, and select **Publish Study > Unpublish**.

Publishing a template

After creating or modifying a template, you must do the following to make your changes available:

- For study project templates and study templates, save the template.
- For all other study object templates, save and publish the template at any time. Your changes are not available to others until you publish the template.

1 Open a library project.

2 In the Project Explorer for a library, select the **Types and Templates** Explorer bar.

3 Expand the **Templates** folder, and expand the folder for the type of study object (for example, the **Study Events** folder).

4 Right-click the template, and select **Publish**.

Publishing a type

After you create or modify a type, save and publish the type. Your changes are not available to others until you publish the type.

1 Open a library project.

2 In the Project Explorer for a library, select the **Types and Templates** Explorer bar.

3 Right-click a type, and select **Publish**.

Categorizing study objects

Categorization of study objects

You can categorize a study object with keywords and categories to facilitate searching for study objects in the Libraries Browser. You must save a study object before categorizing it.

Usefulness of categorization

Categories and keywords are especially helpful in libraries with many study objects. When study objects are categorized, you can find a study object by selecting categories or keywords when you search rather than scanning study objects in the search results list.

Types of keywords and categories

The following keywords and categories are available.

Type of keyword or category	Location in Libraries Browser
System keywords are keywords that are installed by default with the Central Designer application or that an administrator creates in the Central Designer Administrator application.	Keywords tab > System list
User keywords are keywords that a Central Designer user creates. You cannot view keywords that other users create, and other users cannot view your user keywords.	Keywords tab > User list

Type of keyword or category	Location in Libraries Browser
Automatically generated categories are categories that automatically catalog study objects by auditing information (for example, the study object type, original author, creation date, and library in which the study object was created).	Categories tab > Automatically Generated tree
Manually generated categories are categories that you create by dragging keywords to the Categories tree.	Categories tab > Manually Generated tree

All study objects are categorized in the following way:

- In a study: **[Study Project Name] > Study > [Study Name]**.
- In a library: **[Library Project Name] > Library > [Library Name]**.

The categorization information appears below a **Project** category. When you change the name of a project, library, or study, the corresponding category is automatically updated.

When to categorize

If you have a categorization plan, consider categorizing study objects as you create them. If you expect your categorization plan to change, consider categorizing study objects after creating most of them.

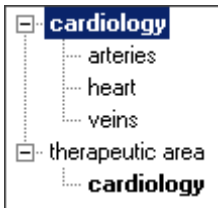
Note: You can categorize multiple study objects at once in study object container editors.

Example

In the following example, **cardiology** appears as a category. The categories of **heart**, **arteries**, and **veins** appear below **cardiology**, and **cardiology** also appears below the **therapeutic area** category.

You can search for a study object that has been categorized with **cardiology**:

- No matter where **cardiology** appears in the Categories tree.
- When **cardiology** appears only under **therapeutic area**.
- When **cardiology** appears with **arteries**, **heart**, and veins below it.



Categorizing a study object

You categorize a study object (study design, study element, study event, form, section, item, codelist, and codelist item) with keywords and categories to facilitate searching for study objects in the Libraries Browser.

1 In the Project Explorer, right-click a study object, and select **Categorize**.

The Categorize dialog box appears.

2 Optionally, select one or more the categories on the **Categories** tab.

> **Note:** If you select a category, all child categories beneath it are also selected.

3 Click **Next**, or select the **Keywords** tab.

The **Keywords** tab appears.

a Optionally, select the keywords from the list of system keywords or the list of user-defined keywords.

b To create a keyword, type the keyword in the **Keywords** field, and press **Enter**. Separate multiple keywords with a comma.

The keyword is added to the list of **User** keywords.

4 Click **Apply**.

Finding and using study objects in a library

Searching for study objects

Libraries Browser searches

To open the Libraries Browser:

- Select the **View** menu, and make sure **Libraries** is selected.

Libraries Browser searches	
Use	To find items, forms, and other study objects in a study or library, and then copy the study objects into a study or library.
Location of the Libraries Browser	By default, the browser is located to the right in the application window.
Features	• Create and save search criteria for personal or global use. • Open, close, delete, rename, and switch to different searches.
Required search parameters	• In a study project, you must select at least one library. • In a library project, selecting a library is optional.
Optional search parameters	Use one, several, or none of the following: • Text • Categories • Keywords • Libraries **Note:** You can select libraries in study projects only. Choose from the libraries in the Libraries tab. The asterisk (*), percent sign (%), and underscore (_) are wildcard operators, which are inserted before and after text. For example, dem automatically becomes *dem*. Use a comma as a delimiter.

Libraries Browser searches	
How the search is performed	Text, keywords, categories, and libraries are connected with the AND operator. Criteria within each parameter are connected with the OR operator. For example: • Text that you type AND • Keyword1 OR Keyword2 AND • Category1 OR Category2 AND • Library1 OR Library2

Libraries Browser searches	

Information that is searched	Titles, RefNames, and descriptions of:
	• Study elements and study events.
	• Forms and items.
	• Codelists and codelist items.
	• Mappings.
	Titles and RefNames of:
	• Templates and types.
	RefNames of:
	• Functions.
	• Constants.
	Additionally:
	• **In a study project**
	  • In selected libraries, only published study objects are searched.
	  • In libraries you do not select, no study objects are searched.
	  • Studies are not searched.
	  For more information about publishing, see ***Publishing, republishing, and unpublishing*** (on page 72).
	• **In a library project**
	  • In selected libraries, only published study objects are searched, unless you select **Include latest object revisions in Repository**.
	  If you select **Include latest object revisions in Repository**:
	  • The *latest revisions* of study objects in libraries are searched.
	  • *All* study objects in all studies are searched.
	  If you leave the checkbox unselected, studies are not searched.
	  • In libraries you do not select, only the latest revisions of study objects are searched.
	Note: The **Include latest object revisions in Repository** checkbox is available in the Search Filter section only in a library project.

Libraries Browser searches	

Search results	• **In a study project**
	• Results include only published study objects, which appear below the **Objects Found** container and are organized by library.
	• **In a library project**
	Study objects are grouped according to whether they are the published versions or the latest revisions.
	  • Below the **Objects Found** container, published study objects are organized by library and then study object type, such as form or item.
	  • If you select **Include latest object revisions in Repository**, the **Repository** container appears below all library containers and holds the latest revisions of study objects, organized by study or library and then study object type, such as form or item.
	  • If the published version of a study object is different from the latest revision, the study object appears in two places—in the container for the library that holds it (for the published version), and below the Repository container (for the latest revision).
	  • If the latest revision is the same as the published version, the study object appears as a published study object, in the top section, organized by library.
	Study objects appear as follows:
	Title (RefName): Description

Copied study objects	If you copy a study object with child study objects from the Libraries Browser to a study or library, the child study objects are also copied, regardless of whether they are published. When you drag a study object that is in a library from the Libraries Browser to another library, you are prompted to choose whether you want to link to the existing study object and its children or create new copies of the study object and its children. When you drag a study object that is in a library from the Libraries Browser to a study, or drag a study object that is in a study from the Libraries Browser to a library, new copies of the study object and its children are created. When you copy a template from the Libraries Browser, a study object without a link to the template is created.

About searching for a template or type

To create a study object from a template, find the template in the Libraries Browser and copy it to a study. To narrow your Libraries Browser search, you can select categories that limit the search.

You can select one or more of the following categories, which are automatically applied to templates and types, to narrow your search.

Category type	Where the categories appear in the Categories tab of the Libraries Browser
Template categories	Template categories appear below Automatically Generated > Template.
Type categories	Type categories appear below Automatically Generated > Types: • **Item**—User-created items and System Library types, including Integer Item, Text Item, Float Item, Compound Item, and Date Time Item. • **Primitive Type**—Items that are installed with the Central Designer application, including Integer Variable, Text Variable, Float Variable, Compound Variable, and Date Time Variable.

Finding and adding a study object to a study or library and saving the search

In a library, you can create, save, and publish study objects, and then use the Libraries Browser to copy them into studies or other libraries. You can also copy study objects created in studies into libraries.

To search using the Libraries Browser, select a library, study, or study object in the Project Explorer.

Note: To view all results, search without entering criteria. Depending on the size of the repository, this search might take several minutes.

To add a study object to a study or library from the Libraries Browser:

1 Open a study or library.

2 In the Project Explorer, select any study object except the library project or study project.

3 Select the **Libraries Browser**.

4 Optionally, to name the search:

a Select **Actions > New Search**. The Actions menu is located at the top of the browser.

The New search dialog box appears.

b Type a name for the search, and click **OK**.

The name of the search appears on a tab to the right of the browser.

5 To search by title, RefName, or description of the study object, type text in the **Enter search text** field.

6 To include categories, keywords, and libraries as parameters:

   a Click the double down arrows ( ) next to the **Search Filter**.

   b Optionally, select the **Categories** tab, and select one or more categories.

   c Optionally, select the **Keywords** tab, and select one or more keywords. For more information about categories and keywords, see *Categorization of study objects* (on page 74).

   d If you are in a study project, select the **Libraries** tab, and select the libraries to search. You must select at least one library. This step is optional if you are in a library project.

   The parameters you select appear in the field below the Search Filter.

7 Click **Find**.

   The Central Designer application performs a search based on your search criteria.

   For more information about how searches work, see *Libraries Browser searches* (on page 77).

8 Make sure the Project Explorer is selected.

9 From the Libraries Browser, do one of the following:

- **To add the study object to a parent** (for example, add an item to a form)—Drag the study object to the parent study object.
- **To add the study object outside the hierarchy of the study** (available in a library)—Drag the study object to the folder for the study object. For example, drag a study event to the Events folder.

   The result depends on the type of project to which you added the study object. For more information, see *Results of adding study objects to studies and libraries from the Libraries Browser* (on page 85).

> **Note:** Study objects are added to the bottom of the list of child study objects under the parent.

To save the search:

1 Select **Actions > Save Search to Repository**. The Actions menu is located at the top of the browser.

   The Save Search to Repository dialog box appears.

2 Optionally, type a description for the search.

3 Select an option:

- **Just me**—Only you can see and use the search.
- **Everyone**—Everyone can see and use the search.

4 Click **Save**.

Clearing search parameters

Note: If you clear the parameters of a saved search but do not save after clearing, the search is saved with parameters.

- In the **Libraries Browser** or **Users Browser**, click **Clear Search**, which is located at the top of the browser.

  The following information is cleared:

  - Text in the Enter search text field.
  - Selected categories and keywords.
  - Selected libraries (in the Libraries Browser only).

Closing an active search

All saved searches are stored in the repository, which contains all data created and saved in the application. If you close a saved search, the search is removed from your view but is not deleted.

1 Select either the **Libraries Browser** (for a study object search) or **Users Browser** (for a user search).

2 Select a tab. Tabs are located along the right side of the browser.

3 Select **Actions > Close Active Search**. The Actions menu is located at the top of the browser.

The search is closed. If it is a saved search, it remains in the repository. If it is not saved, it is removed and cannot be reopened.

Opening a search saved in the repository

All saved searches are stored in the repository, which contains all data created and saved in the application.

1 Select either the **Libraries Browser** (for a study object search) or **Users Browser** (for a user search).

2 Select **Actions > Open Search from Repository**. The Actions menu is located at the top of the browser.

The Open Search from Repository dialog box appears.

3 Select a search, and click **Open**.

The search opens. A tab with the name of the search appears to the right of the browser.

Deleting a search from the repository

1 Select either the **Libraries Browser** (for a study object search) or **Users Browser** (for a user search).

2 Select **Actions > Delete Search from Repository**. The Actions menu is located at the top of the browser.

The Delete Search from Repository dialog box appears.

3 Select a search, and click **Delete**.

Reusing study objects

About reusing an item on a form

You can reuse an item on a form as long as the item's reuse does not create identical context paths for the item. A context path is created with only the visit, form, section, and top-level item, even if the top-level item has child items or has items that are conditional on it. For instance, consider the following hierarchies in the Central Designer application and InForm application:

Hierarchy in the Central Designer application	Becomes the following in the InForm application
Study event > Form or section >	Visit > Form > Section >
Item 1	Item 1
Item 2 (conditional on Item 1)	Item 2 (Conditional on Item 1)
Item 3 (Compound item, conditional on Item 2)	Item 3 (Conditional on Item 2)
Item 4 (Has a rule, conditional on Item 3)	Item 4 (Has a rule, conditional on Item 3)
Item 4 (Has a rule, conditional on Item 1)	Item 4 (Has a rule, conditional on Item 1)

In this example, using Item 4 in two places creates the following identical context paths, causing validation to fail. The context paths appear below in bold; the non-bold information is the additional information that makes the item's placement unique but, that information is not visible to the Central Designer application when it tries to determine when rules run:

- **Visit > Form > Section > Item 1** > Item 2 > Item 3 > Item 4
- **Visit > Form > Section > Item 1** > Item 4

If Item 4 were not conditional on Item 1, you could reuse the item without issues because the hierarchy would appear in the following way:

Hierarchy in the Central Designer application	Becomes the following in the InForm application
Study event > Form > Section (optional) >	Visit > Form > Section >
Item 1	Item 1
Item 2 (conditional on Item 1)	Item 2 (Conditional on Item 1)
Item 3 (Compound item, conditional on Item 2)	Item 3 (Conditional on Item 2)
Item 4 (Has a rule, conditional on Item 3)	Item 4 (Has a rule, conditional on Item 3)
Item 4 (Has a rule)	Item 4 (Has a rule)

In this example, the following context paths would exist for Item 4. Because the information in the context paths is unique down to the first-level item, the reuse is acceptable.

- **Visit > Form > Section > Item 1** > Item 2 > Item 3 > Item 4
- **Visit > Form > Section > Item 4**

Results of adding study objects to studies and libraries from the Libraries Browser

The following table describes the results of searching for a study object in the Libraries Browser and then adding it to a library or study.

Note: In the following sections, the library or study that contains the study object is the *source location*. The library or study to which you are adding a study object is the *target location*.

Process	Results of adding the study object
Library to library (The study object is in a **library**, and you are adding the study object to a **library**.)	You are prompted to choose one: • Link to the existing study object and its children. The study object and its children are added to the target location as links. Each study object is a single study object that exists in multiple libraries. If you change a study object in either library, the change is reflected in the other library. • Copy the study object and its children to the target location. If the study object or any of the child objects have already been copied into the target location, new copies of the study objects are not created. The existing study objects are referenced correctly by other study objects that are copied in. For the study object or any children that have not been copied into the target location, new copies are created. If you change a study object in either library, the study object in the other library is not updated.

Process	Results of adding the study object
Library to study (The study object is in a **library**, and you are adding the study object to a **study**.) or Study to library (The study object is in a **study**, and you are adding the study object to a **library**.)	Copies of the study object and its children are created in the target location. If you change a study object in either the target or original location, the study object in the other location is not updated. Because two study objects in a study cannot have the same RefName, the Central Designer application renames study objects in a study when you: • Drag a study object from a library to a study, and its RefName is identical to an existing study object in the study. • Use the **Copy > With Children** and the **Copy > Without Children** options. When a study object is renamed, it is appended with "_1" (or similar). **Note:** Study object names in a library might not be unique. Additionally, a study object can appear in multiple places in a study if it is copied using the **Copy > Link** option. **Note:** If you drag and drop a study object that is mapped to a data series, and the study object already exists in the library, the database contains a data point for the study object, and the drop operation reuses that data point as is. The application warns you that the drag and drop operation is not supported. If you continue, any data mappings in the dropped study object that are different from the data mappings that are associated with the study object that already exists in the library are removed.

Note: You cannot have duplicate RefNames in a study. Duplicate RefNames are allowed in a library with the following exceptions:

- All children of a study object must have unique RefNames. For example, a form can contain only one item with the RefName of Item1. However, a library can contain multiple study objects with the RefName of Item1.
- Below any given parent, such as a study event, all child study objects must have unique names. For example, a library cannot contain two nonlinked items named Weight on two forms that are on the same study event.

  Note: A linked item can appear on two forms in the same study event.

Results of modifying study objects that have been copied to studies and libraries

The following table describes the results of modifying a study object after you drag the study object from the Libraries Browser to a study or library.

Note: In the following sections, the library or study that contains the study object is the *source location*. The library or study to which you are adding a study object is the *target location*.

Action	Result	Example
After you add a study object from a library to a library using the Libraries Browser:		
If you modify the study object or one of its children in the source location and drag the modified study object objects to the target location:	You are prompted to choose one of the following: • Update the study object in the target location. If you choose this option, the study object and any modified children are updated, but unchanged study objects are not updated. • Create a link to the updated study object and its children in the target location. If you choose this option, a new RefName is created for the study object in the target location.	After you add a form from LibraryA to LibraryB using the Libraries Browser, if you modify the form or one of its items in LibraryA and drag the modified form or item to LibraryB, you are prompted to choose one of the options described above.
If you modify the study object in the target location and then drag the study object to the source location:	You are prompted to choose one of the following: • Update the study object in the source location. • Create a link to the modified study object.	After you add a form from LibraryA to LibraryB using the Libraries Browser, if you modify the form in LibraryB and then drag the form to LibraryA, you are prompted to choose one of the options described above.
After you add a study object from a library to a study or from a study to a library using the Libraries Browser:		

Action	Result	Example
If you create a new study object in the target location and drag a child of the original study object to the new study object:	The two child study objects in the target location are automatically linked.	After you add FormA from a library to a study using the Libraries Browser, if you create FormB in the study and drag ItemA (a child of FormA) to FormB using the Libraries Browser, ItemA on FormA and ItemA on FormB are automatically linked in the study.
If you modify the original study object in the source location and then drag it to the same parent in the target location:	You are prompted with the following two options: • Update the study object and its children in the target location. The study object and any modified children are updated to the study object that you previously added. Unchanged study objects are not updated. • Cancel adding the original study object and its children to the target location.	After you add FormA from a library to EventA in a study using the Libraries Browser, if you modify FormA in the library and then drag it again to EventA in the study, you are prompted to choose one of the options described above.
If you modify the original study object in the source location and then drag it to a different parent (that does not already contain the study object) in the target location:	You are prompted with the following two options: • Update the study object and its children in the target location. The study object and any modified children are linked to the study object in the target location, and the study object in the target location is updated. • Cancel adding the original study object and its children to the target location.	After you add FormA from a library to EventA in a study using the Libraries Browser, if you modify FormA in the library and then drag it to EventB (which does not yet contain FormA), you are prompted with the options described above.

Action	Result	Example
If you modify one or more children of the study object in the source location and then drag the study object to the target location:	You are prompted with the following two options: • Update the children in the target location. The child study objects that were modified are updated in the target location. • Cancel adding the original study object and its children to the target location.	After you add FormA from a library to a study using the Libraries Browser, if you modify one or more items on FormA in the library and then copy FormA to the study again, you are prompted with the options described above.
If you drag the study object that you already added to the same parent in the target location:	You receive a message indicating that the study object cannot be added to the same parent more than once if the study object has not been updated.	After you add FormA from a library to a study using the Libraries Browser, if you have not modified FormA and try to add FormA to the study again using the Libraries Browser, a message appears, indicating that the study object cannot be added to the parent more than once if the study object has not been updated.

Notes:

If you create a study object in the source location, add it to a target location, and then drag the study object back to the source location without modifying the study object in the target location, you are asked if you want to update the study object.

For example, if you create a study object in LocationA (either a study or library), copy it to LocationB (either a study or library), and then drag the study object from LocationB back to LocationA without modifying it in LocationB, you are asked if you want to overwrite the study object in LocationA or cancel. If you updated the study object in LocationA and you choose to overwrite, you lose the changes when the study object from LocationB is added to LocationA.

If you add a study object to a study from a library, copy and paste the study object within the study, and then add the study object from the library to the study again, none of the copies is updated.

The RefNames of study objects are never updated when a study object is updated.

You cannot use the Libraries Browser to create multiple copies of a study object within a target location. Use the Copy option to create multiple copies of a study object within a study or library.

To determine whether a study object is a link or a copy of another study object, check the Identifier field in the Properties Browser. If the identifiers are identical, the study objects are links; otherwise, they are copies.

Results of adding templates to studies and libraries

The children of templates are treated like regular study objects unless they are also marked as templates. For example, if you add a codelist template from a library to two different items in another library, the codelist items are links as long as they are not marked as templates.

You can add study objects to a study template using the Libraries Browser. If you copy a study object from a library to a study template and then create a study from the study template, the study objects in the study are linked to the original study objects in the library.

Copying, cutting, and pasting

When you *copy and paste a study object* (on page 92), all of its child study objects are copied with it. The method of copying that you choose determines whether the new study object and new child study objects retain links to the original study objects.

When you copy a study object into a study twice, the two study objects are links to each other.

You can cut linked study objects but not instances of study objects. Cutting a link is the same as deleting the link to (but not the instance of) the study object. After cutting, you must paste the link on the correct parent study object. For example, you can cut an item that is on a form and then paste it on another form.

The following copying options are available.

Copying option	Description
Link	• The new study object retains a link to the original. If either the original or the new study object is modified, the other study object is modified, and all other reference copies of it *within the study* are also modified. • All child study objects are copied with links to the original study objects.
With children	• The new study object has no link to the original. If either the original or the new study object is modified, the other study object is not affected. • All child study objects are also copied and do not retain links to the original study objects. Therefore, a change to either the original or new child study objects does not affect the other.
Without children	• The new study object has no link to the original. If either the original or the new study object is modified, the other study object is not affected. • All child study objects are copied with links to the original study objects. Therefore, if either an original or a new child study object is modified, the other study object is modified, and all other reference copies of it *within the study* are also modified.

Note: Advanced copying options (Link, With children, and Without children) are not available for codelist items. When you copy a codelist item, a copy of the original codelist item is created with a new identifier.

Renamed RefNames

Because two study objects in a study cannot have the same RefName, the Central Designer application renames study objects in a study when you:

- Drag a study object from a library to a study, and its RefName is identical to an existing study object in the study.
- Use the **Copy > With Children** and the **Copy > Without Children** options.

When a study object is renamed, it is appended with "_1" (or similar).

Note: Study object names in a library might not be unique. Additionally, a study object can appear in multiple places in a study if it is copied using the Copy > Link option.

Copying and pasting a study object

1 In the **Project Explorer**, right-click a study object and select **Copy**. Select one of the following copying options from the menu that appears:

Link: (Not available for study elements and study events)

- The new study object retains a link to the original. If either the original or the new study object is modified, the other study object is modified, and all other reference copies of it *within the study* are also modified.
- All child study objects are copied with links to the original study objects. Therefore, if either an original or a new child study object is modified, the other study object is modified, and all other reference copies of it *within the study* are also modified.

With children:

- The new study object has no link to the original. If either the original or the new study object is modified, the other study object is not affected.
- All child study objects are also copied and do not retain links to the original study objects. Therefore, a change to either the original or new child study objects does not affect the other.

Without children:

- The new study object has no link to the original. If either the original or the new study object is modified, the other study object is not affected.
- All child study objects are copied with links to the original study objects. Therefore, if either an original or a new child study object is modified, the other study object is modified, and all other reference copies of it *within the study* are also modified.

2 In the **Project Explorer**, right-click a parent study object, and then select **Paste**.

Note: You cannot copy study objects as links from one study to another within the same study project.

When you copy a template from the Libraries Browser, a study object without a link to the template is created.

Dragging and dropping study objects

You can drag and drop a study object in the Project Explorer to copy a study object as a link.

When you drag a study object that is in a library from the Libraries Browser to another library, you are prompted to choose whether you want to link to the existing study object and its children or create new copies of the study object and its children.

When you drag a study object that is in a library from the Libraries Browser to a study, or drag a study object that is in a study from the Libraries Browser to a library, new copies of the study object and its children are created.

Note: Before you copy a study object by dragging and dropping it, you must first navigate to the Explorer bar and folder in which the target study object exists.

The following table describes the target study objects onto which you can copy each study object type.

Study object	Location of available target study objects
Study element	Visit Schedule Explorer bar > Study Design folder.
Study event	• Visit Schedule Explorer bar > Study Design folder > Element name. or • Elements and Events Explorer bar > Elements folder > Element name.
Form	Elements and Events Explorer bar > Events folder > Event name.
Items	• Forms and Transactions Explorer bar > Target application folder > Forms folder > Form name. or • Forms and Transactions Explorer bar > Target application folder > Forms folder > Non-Clinical folder > Form name.
Codelist	Items Explorer bar > InForm items folder > Item name. **Notes:** For the item, the Use Codelist option must be selected. The codelist must match the type of the item. For example, you can drag an integer codelist only to an integer item.

Cutting and pasting a study object

You can cut linked study objects but not instances of study objects.

1 In the Project Explorer, right-click a study object, and select **Cut**.

The study object is removed from the Project Explorer.

2 Right-click a parent study object (such as a form, if you cut an item), and select **Paste**.

The study object appears under its parent study object in the Project Explorer.

Copying and moving data-entry rules

To copy and paste a data-entry rule:

1 In the Project Explorer, select a study design (in a study only), study element, study event, form, section, or item.

The editor for the study object appears in the workspace.

2 Select the **Rules** tab.

3 In the grid, select a rule.

4 Right-click the rule, and select **Copy**.

5 In the Project Explorer, select a study object onto which to copy the rule.

6 Right-click the study object and select **Paste**.

The pasted data-entry rule appears in the grid, and the row containing the pasted data-entry rule is selected.

Note: You can also copy and paste a data-entry rule by holding down the Ctrl key, dragging the rule from the Rules tab, and dropping it onto a study object.

To move a data-entry rule:

1 In the Project Explorer, select a study design (in a study only), study element, study event, form, section, or item.

The editor for the study object appears in the workspace.

2 Select the **Rules** tab.

3 In the grid, select a rule.

4 Right-click the rule, and select **Cut**.

The data-entry rule is grayed out.

Note: When you select Cut, the data-entry rule is not immediately deleted from its parent study object. The rule is only deleted when you paste it onto another study object. If you do not paste a cut rule, it remains associated with its original parent study object. This behavior is different from the cut and paste functionality that is used when you move a study object in the Project Explorer. In the Project Explorer, when you cut a study object, it is immediately deleted from its parent study object.

5 In the Project Explorer, select a study object.

6 Right-click the study object and select **Paste**.

The data-entry rule is removed from the original study object on which it was created, the pasted data-entry rule appears in the grid, and the row containing the pasted data-entry rule is selected.

Note: You can also move a data-entry rule by dragging the rule from the Rules tab, and dropping it onto a study object without holding down the Ctrl key.

About copying study objects grouped by data mappings

The following table explains how study objects are copied when they are part of a data mapping. You can copy study objects from a library to a study or another library as well as from a study to another study. You also can copy study objects in the Project Explorer.

When you copy a data mapping, data set, or data series within a study or library, the new study object contains item mappings.

Copied study object	Copied within a study or library	Copied from one study or library to another
Data mapping, data set, or data series	Mappings to items that are part of the data series are retained in the new study object.	Item mappings are not copied to the new study object.
Item, Form, or study event that is mapped to a data series	The new study object is mapped to the data series. If you break the link between the original and the new study object, the new study object is still mapped to the data series.	The study object is copied, but data mappings are not copied. **Note:** If you drag and drop a study object that is mapped to a data series, and the study object already exists in the library, the database contains a data point for the study object, and the drop operation reuses that data point as is. The application warns you that the drag and drop operation is not supported. If you continue, any data mappings in the dropped study object that are different from the data mappings that are associated with the study object that already exists in the library are removed.

Note: When a data series is copied within a study or library, the items that are part of a data series are not copied, but data series mappings to items are copied. For example, if an item is added to a data series, and the item is mapped to be part of the data series only when the item appears in a specific form, the mapping of the item to the data series for the form is copied. Similarly, if you copy a data set or mapping definition containing a data series, the mappings are also copied. If you use the new data series in another study, the mappings are retained. If you later add the item and form that are mapped to the data series to the study containing the data series, the mapping appears in the Data Series Summary tab.

Working with templates and types

About templates

Characteristic	Description
Definition	A template is study object that is either partially or fully defined and that can be used to create other study objects.
Available for	You can create templates for the following study objects: • Study projects • Studies • Study elements • Study events • Forms • Items • Codelists • Mappings
Purpose of study templates	Study templates can decrease the time and effort required to build a study. Think about how to set up study templates to minimize work that users might need to perform. For example, you might create templates for different therapeutic areas, compounds, devices, and biologic areas.
After creating	After you create and publish a template, users can create study objects from the template. You do not need to publish study project templates and study templates to make them available. When you create a study object, you can (but are not required to) create it from a template.
History links	A study object created from a template inherits the characteristics of the template but has no history link to the template. Therefore, changing the template does not affect the study object, and the reverse is also true.
Versions	Templates do not have versions; therefore: • For study project templates and study templates, the last **saved** version of a template is used when you create a study project or study from the template. • For other study object templates, the last **published** version of a template is used when you create a study object from a template.

Characteristic	Description
Where to view templates	Study project and study templates are viewable when you create a study project or study. You can view all other templates in the library project in which they are created in the following places in the Project Explorer: • Under the **Templates** container. For example, within the Templates container, the Forms container has all form templates. • Under the containers for each study object.
Rule templates	You can also create rule templates.

Note: You can protect templates and types. However, if you create a new study object from a protected template or type, the newly created study object is not protected.

About types

A type is a study object that is either partially or fully defined and can be used to create other study objects. Types are like templates except that types appear as options in the Actions menu and in the Project Explorer menu when you create a new study object. Types are used only for items. Some commonly used types, including Float, Text, and Integer, are included in the system library.

Marking an item as a type automatically marks it as a template, as well.

Types have the following requirements:

- You can create types for items only.
- You can create types in libraries only.
- An item marked as a type is automatically marked as a template (and you cannot remove the template categorization).

After you create an item type and publish it, other users can create items from the type.

When you create an item, you must select a type on which to base it, and you choose from types that are in:

- The System Library. These types are installed with the Central Designer application.
- Libraries that appear in the Library List for the study.

If a type with the same name appears in both the System Library and another library, the type from the non-System Library is used for creating the item.

An item created from a type inherits the characteristics of the type on which it was based, but the item has no history link to the type. Therefore, a change to the type does not affect the item, and the reverse is also true. Additionally, types do not have versions, so the last published version of a type is always used.

Types appear in the following places in the Project Explorer:

- In a library, types appear under the Types container. For example, the Items container contains all item types in the library.
- In studies and libraries, item types appear under the container for items.

Note: You can protect templates and types. However, if you create a new study object from a template or type, the newly created study object is not protected.

Differences between templates and types

Characteristic	Templates	Types
Purpose	To provide predefined information about a study object. You are not required to base new study objects on templates.	To provide predefined information about an item. When you create an item, you must choose a type on which to base it.
You can create templates and types for the following study objects	Study projects, studies, study elements, study events, forms, items, codelists, and mappings.	Items only.
How to create study objects from a template or type	**Creating a study project or study:** You are allowed but not required to choose a template. **Creating all other study objects:** To create a study object based on a template, find the template in the Libraries Browser and then copy it to your study. For more information, see *Creating a study object from a template* (on page 102).	**Creating an item:** You must choose an item type. For more information, see *Creating an item from a type* (on page 104).

Information you can define for templates and types

The following table contains examples of the kinds of information that you can define for templates and type. All study objects created from a template or type inherit the characteristics of the template or type.

Note: You can create a study object, such as a study or study event, copy study objects to it from a library, and then mark the study object as a template. If you use the template to create a study object, the study objects that were copied from the library do not retain history information from the study objects in the library.

Study object	Information you can define
Templates	
Study project	• The references required for creating studies in the project, such as protocols or goals. • Any studies or study objects that are contained in the project.

Study object	Information you can define
Study	• Study deployment requirements, including languages and form layouts. • Study language requirements. • A defined Library List containing the libraries from which study objects and templates will be taken to build the study. • The references required for building a study, such as a protocol or study goals. • The users (assigned to study teams) who will be working on the study. • The instructions and Help information for the study. • The functions and constants that will be used in the study. • Workflow components, including commonly used forms, special forms, and any other commonly used study objects. • Mappings, including items and mappings to items, forms, and study events.
Study element	• The study objects contained in the study element and their workflow. • Instructions and Help for the study element.
Study event	• The study objects contained in the study event and their workflow. • Instructions and Help for the study event.
Form	• A designed layout. • The study objects contained in the form. • Instructions and Help for the form.
Item	• Design information, including a question, title, units, and length. • A codelist including codes and labels. • Data entry rules, such as a range check. • A designed layout. • Instructions and Help for the item.
Codelist	• The codes and labels contained in the codelist.
Mapping	• A name, RefName, and description of the mapping. • The data sets, data series, and items contained by the mapping.
Types	
Item	• Design information, including a question, title, units, and length. • A codelist including codes and labels. • Data entry rules, such as a range check. • A designed layout. • Instructions and Help for the item.

Marking a study object as a template

1 Do one of the following:

- **For study projects and studies**—Open a study project.
- **For all other study objects**—Open a library project.

2 In the Project Explorer, right-click a study project, study, or study object, and select **Set Advanced Options**.

The Advanced Options dialog box appears.

3 Select **Mark as Template**, and click **OK**.

> **Note:** You cannot mark a project as a template if it contains hidden studies, which are studies on which you are not a team member.

4 (*Not for study project templates and study templates*) Optionally, to make the template available for others to use, right-click the template, and select **Publish**. Only published study objects appear in the search results for the library in which they are created.

> **Note:** Study project templates and study templates are available to be used by default.

After creating or modifying a template, you must do the following to make your changes available:

- For study project templates and study templates, save the template.
- For all other study object templates, save and publish the template at any time. Your changes are not available to others until you publish the template.

Modifying a template

After creating or modifying a template, you must do the following to make your changes available:

- For study project templates and study templates, save the template.
- For all other study object templates, save and publish the template at any time. Your changes are not available to others until you publish the template.

To modify a study project template or study template:

1 Select **File > Open**.

The Open Project dialog box appears.

2 Select the study project template or the study project that contains the study template, and click **Open**.

> **Note:** Only users with rights to modify templates can see templates in the Open Project dialog box.

3 Modify the template, and save the changes.

To modify other study object templates:

1 In the Project Explorer for a library, select a study object template.

2 Modify the template, and save the changes.

3 To make the template available for use, right-click the template, and select **Publish**.

Removing a template categorization from a study object

To remove a template categorization from a study project or study template:

1 Select **File > Open**.

The Open Project dialog box appears.

2 Select the study project template or the study project that contains the study template, and click **Open**.

> **Note:** Only users with rights to modify templates can see templates in the Open Project dialog box.

3 In the Project Explorer, right-click the study project or study, and select **Set Advanced Options**.

The Advanced Options dialog box appears.

4 Deselect **Mark as Template**, and click **OK**.

To remove a template categorization from other study objects:

1 In the Project Explorer for a library, select the **Types and Templates** Explorer bar.

2 Right-click a template, and select **Set Advanced Options**.

The Advanced Options dialog box appears.

3 Deselect **Mark as Template**, and click **OK**.

Creating a study object from a template

To create a study element, study event, form, item, codelist, codelist item, or mapping from a template, you search for the template in the Libraries Browser and then copy it into your study or library.

A study object created from a template inherits the characteristics of the template but has no history link to the template. Therefore, changing the template does not affect the study object, and the reverse is also true.

1 Open a study or library, and make sure a library, study, or other study object (but not a library project or study project) is selected.

2 Select the **Libraries Browser**.

3 To search by title, RefName, or description of the study object, type text in the **Enter search text** field.

4 To include categories, keywords, and libraries as parameters:

   a Click the double down arrows ( ) next to the **Search Filter**.

   b Optionally, select the **Categories** tab, and select one or more categories.

   c Optionally, select the **Keywords** tab, and select one or more keywords. For more information about categories and keywords, see *Categorization of study objects* (on page 74).

   d If you are in a study project, select the **Libraries** tab, and select the libraries to search. You must select at least one library. This step is optional if you are in a library project.

   The parameters you select appear in the field below the Search Filter.

   Note: For more information about narrowing your search using template categories, see ***About searching for a template or type*** (on page 81).

5 Click **Find**.

   The Central Designer application performs a search based on your search criteria.

6 In the Libraries Browser, select a template from the search results, and drag it to the appropriate location in the Project Explorer.

   A new study object is created in the Project Explorer from the template. The new study object has the same name as the template but is editable.

7 Type a name for the study object, and press **Enter**.

Marking an item as a type

1 In the Project Explorer for a library, right-click an item, and select **Set Advanced Options**.

   The Advanced Options dialog box appears.

2 Select **Mark as Type**, and click **OK**.

3 To make the type available for others to use, right-click the type, and select **Publish**.

Modifying a type

1 In the Project Explorer for a library, select the **Types and Templates** Explorer bar.

2 Select and modify the type.

3 To make the type available for others to use, right-click the type, and select **Publish**.

Removing a type categorization from an item

After you remove a type categorization from an item, the item type is no longer listed with the item types that appear when you create a new item.

1 In the Project Explorer for a library, select the **Types and Templates** Explorer bar.

2 Right-click a type, and select **Set Advanced Options**.

   The Advanced Options dialog box appears.

3 Deselect **Mark as Type**, and click **OK**.

Creating an item from a type

When you create an item, you must choose a type on which to base it. You can create items in studies and libraries.

Note: If you are working in a study project, the only types available to you are the types in the libraries in the Library List for the study.

1 In the Project Explorer, select the **Items** Explorer bar.

2 Right-click the **InForm Items** node, and select **New Item > [Item type]**.

The Object Name dialog box appears.

3 Enter the Title, RefName, and optionally, a Description, and click **OK**.

Note: You can protect templates and types. However, if you create a new study object from a template or type, the newly created study object is not protected.

CHAPTER 5

Managing study objects

In this chapter

Creating, replacing, updating, and deleting

About creating study objects

Characteristic	Description
Naming conventions	Oracle recommends developing naming conventions, which help you identify study objects that appear in search results in the Libraries Browser.
Parents	You can create study objects on the following parents. You create a: • Study element on a study design. • Study event on a study design or study element. • Form on a study event. • Section on a form. **Note:** You cannot create a section outside the hierarchy. You must create a section on a form. • Item on a form or section. • Codelist on an item. • Codelist item on a codelist.

RefNames and titles	When developing naming conventions, consider that all study objects (except study projects, library projects, libraries, and studies) have RefNames and titles, which can be different.
	• RefNames are referenced in rules and are deployed to the target application. Therefore, they must:
	  • Follow C# variable standards.
	  • Start with a letter or an underscore.
	  • Contain only letters, numbers, and underscores.
	  • Be unique within a study or library. For example, you cannot have a form and an item with RefNames of DOV in the same study or library.
	• Titles are the more readable display names for study objects. They can contain spaces and special characters, but are not referenced in rules and are not deployed to the target application.

Characteristic	Description
Automatically generated RefNames	When you create a new study object (not by copying an existing study object), its title and RefName are automatically generated. For example, the title of a new integer item is *Integer Item*, and the RefName is *IntegerItem*. The first time you rename the study object, both the title and RefName are updated. Subsequent changes to the study object name change the title but not the RefName. Some words cannot be used for RefNames. For more information, see ***Reserved words for RefNames*** (on page 138).
Viewing RefNames or titles	In the Project Explorer, you can select whether to display RefNames or titles for study objects, and this selection is reflected in most tabs in the workspace.

Order to create study objects	You can create study objects in any order. Consider the following options:
	
	• Start by determining whether any required study objects already exist in libraries.
	
	• If you are working from the study protocol, you might want to start with the study workflow to create an overview of the study.
	
	• If you are working from CRF specifications:
	
	  • Determine whether the study contains study objects and components that can be reused in multiple locations.
	
	  • Create these study objects and components (for example, codelists, constants, date time items) first.

Renaming a study object

1 In the Project Explorer, right-click a study object, and select **Rename**.

The study object name becomes editable.

2 Type a name for the object, and press **Enter**.

Note: You can also rename a study object by clicking the name of the study object once. The name becomes editable.

Renaming a study object in a workflow diagram

1 In the Project Explorer, select the study object.

2 Select the **Workflow Diagram** tab.

3 Right-click the workspace, and select the Rename option for the study object.

In the workflow diagram, the name becomes selected.

4 Type the new name for the study object, and press **Enter**, or click outside the study object.

About deleting

The way a study object and its children are deleted depends upon whether the study object is an instance or a link. Before deleting a study object, make sure that you understand the implications of the deletion.

For more information, see:

- *Instances and links* (on page 109).
- *How instances are deleted* (on page 111).
- *How links are deleted* (on page 112).

When you delete a study object from a library, the study object is removed from the database only if it is not in any other library.

Deleting a study object

You can delete any study object, including a study (the study design is also deleted), study event, study element, form, section, item, codelist, and codelist item. The way that study objects are deleted depends on whether they are instances or links.

Note: If you delete a study object that has been copied as a link, only the selected study object is deleted. No copies of it are deleted. For more information, see ***Copying, cutting, and pasting*** (on page 91).

- In the Project Explorer, right-click a study object, and select **Delete**.

  If a confirmation message appears, select the appropriate option. For more information, see *About deleting* (on page 108).

Deleting a study object in a workflow diagram

1 In the Project Explorer, select a study design (in a study only), study element, or study event.

2 Select the **Workflow Diagram** tab.

3 Right-click a study object, and select **Delete**.

Deleting a study object in a workflow grid

1 In the Project Explorer, select a study design (in a study only), study element, or study event.

2 Select the **Workflow Grid** tab.

3 Right-click the gray box located at the beginning of a row, and select **Delete**.

Note: To delete multiple study objects, select multiple rows.

Deleting a workflow rule from a workflow diagram

1 In the Project Explorer, select a study design (in a study only), study element, or study event.

2 Select the **Workflow Diagram** tab.

3 Right-click the rule in the workflow diagram, and select **Delete Rule**.

Deleting a global condition

1 In the Project Explorer, select a study design (in a study only), study element, or study event.

2 Select the **Workflow Diagram** tab.

3 On the toolbar, click **Global Conditions**, or right-click in the workflow, and select **Global Conditions**.

The Edit Global Conditions dialog box appears.

4 Select a global condition in the list, and click **Delete**.

5 Click **OK**.

Deleting one or more rules

1 In the Project Explorer, select a study design (in a study only), study element, study event, form, section, or item.

The editor for the study object appears in the workspace.

2 Select the **Rules** tab.

3 Select one or more rules, pressing CTRL or Shift to select multiple rules.

4 On the toolbar, click **Delete**.

Note: If any of the selected rules are locked by someone else or on a study object that is protected by someone else, the Delete options are grayed out.

About instances and links

Instances and links

Type	Description	Appearance in the Project Explorer
Instance	An actual study object in a study	Study objects that are **instances** appear in study object containers. For example, all study elements in the Elements container are instances.
Link	A link to a study object in a study.	Study objects that are **links** appear as children in study object containers. For example, if a study event is a child of a study element in the Elements container, the study element is an instance, and the study event is a link.

Viewing the parents of a linked form

You can view the parents of a form, section, item, codelist, or codelist item that:

- You copied using the Copy > Link option.
- You use on multiple parents.

To view the parents of a linked study object:

1 In the Project Explorer, select a study object, and confirm that a blue icon () appears in the upper-left corner of the study object's icon.

> **Note:** If the icon does not appear, the study object could be used multiple times in the study but always on the same parent.

2 Right-click the study object, and select **Show Parents**.

The Show Parents dialog box appears.

3 Review the paths of the parent study objects in the current project.

The paths begin with the project name and work down; the last study object listed is the parent.

4 To copy paths to the Microsoft Windows clipboard:

a To copy one path, select it and click **Copy**.

or

Click **Copy All**.

b Paste the information in a text editor.

Notes:

- Show Parents is available in both a study and library, but it lists only the parents in the current project.
- Show Parents is not available for a study object on a single parent that appears multiple times, such as an item on a form that is used multiple times in a study.

Breaking the link of a study object

Breaking the link of a study object creates a new study object in the place of the original study object.

- The new study object is identical to the original, except it has a new study object identifier.
- The original study object remains in the study, but the link to it is removed from the study object tree in the Project Explorer.

You must choose whether to break the links of child study objects. Child study objects for which links are not broken become the children of the new study object and are no longer the children of the original study object.

> **Note:** You can break links for study objects that are links only. You cannot break the links of study objects that are instances. For more information, see ***Instances and links*** (on page 109).

To break the link of a study object:

- In the Project Explorer, right-click a study object and point to **Break link**, and select one of the following options:

  With new children:

  - The original study object is removed from the study object tree in the Project Explorer (but not the study), and an identical study object (with a new identifier) is created in its place.
  - If the original study object has child study objects, the child study objects are also removed from the study object tree in the Project Explorer, and identical study objects (with new identifiers) are created in their places. The new child study objects are children of the new study object, and the original children are no longer associated with the original parent study object.

  With links to children:

  - The original study object is removed from the study object tree in the Project Explorer (but not the study), and an identical study object (with a new identifier) is created in its place.
  - If the original study object has child study objects, the child study objects are not changed. However, they are no longer associated with the original study object. Instead, they become the children of the new study object.

How instances are deleted

Description	Example	When you delete the Gender item
No child study objects. Not used by other study objects in the study.	Item name—PregnancyTest • No codelist. • Not used on any form.	The instance of the PregnancyTest item is removed from the study.
No child study objects. Used by one or more study objects in the study.	Item name—PregnancyTest • No codelist. • Used on the Visit1 and Visit2 forms.	A dialog box informs you that the delete will remove all links to the instance. You can continue or cancel. If you continue: • The instance of the PregnancyTest item is removed from the study. • The links to the PregnancyTest item are removed from the Visit1 and Visit2 forms.
One or more child study objects that are not used by any other study object. Not used by other study objects in the study.	Item name—PregnancyTest • Has a codelist. • Not used on any form.	The instance of the PregnancyTest item is removed from the study. You are asked if you want to include the child study objects in the delete. • If you select Yes, the codelist is deleted. • If you select No, the codelist is not deleted.

Description	Example	When you delete the Gender item
One or more child study objects that are used by one or more other study objects. Not used by other study objects in the study.	Item name—PregnancyTest • Has a codelist. • Not used on any form.	The instance of the PregnancyTest item is removed from the study. The codelist on the item is not affected because it is being used by one or more other study objects in the study.
One or more child study objects that are not used by any other study object. Used by one or more study objects in the study.	Item name—PregnancyTest • Has a codelist. • Used on the Visit1 and Visit2 forms.	A dialog box informs you that the delete will remove all links to the instance. You can continue or cancel. If you continue: • You are asked if you want to include the child study objects in the delete. ▪ If you select Yes, the codelist is removed from the study. ▪ If you select No, the codelist is not affected. In addition: • The instance of the PregnancyTest item is removed from the study. • The links to the PregnancyTest item are removed from the Visit1 and Visit2 forms

How links are deleted

Description	Example	Results of deleting the item
Has child study objects or has no child study objects. Is used by multiple study objects.	Item name—PregnancyTest • Has a codelist or has no codelist. • Used on the Visit1 and Visit2 forms.	When you delete the PregnancyTest item from a form (for example, the Visit2 form): • The link to the PregnancyTest item is deleted from the Visit2 form. • The link to the PregnancyTest item remains on the Visit1 form. The PregnancyTest item can be used on other forms.
Has no child study objects. Is used by a single study object.	Item name—PregnancyTest • No codelist. • Used on the Visit2 form only.	The link to the PregnancyTest item is deleted from the Visit2 form, and the instance of the PregnancyTest item is removed from the study.

Description	Example	Results of deleting the item
Has one or more child study objects. Is used by a single study object.	Item name—PregnancyTest • Has a codelist. • Used on the Visit2 form only.	The link to the PregnancyTest item is removed from the Visit2 form. If the codelist on the item is used by only the PregnancyTest item, then you are asked if the child study objects should be included in the delete: • If you select Yes, the instances of the codelist and its codelist items are removed from the study. • If you select No, only the PregnancyTest item is removed from the study. The codelist still exists and can be used by other items.

Note: When you delete the final link of a study object, you receive a message that only a single link to the study object exists in the study or library, and you are asked if you want to delete the study object from the study or library after the link is removed. If you click:

- Yes—Both the link to the study object and the study object itself are deleted from the study or library.
- No—The link to the study object is removed from the study or library, but the study object remains in the study or library.

Adding study objects

If a study object exists in a study but has not been added to the study object hierarchy, you can use the Add To browser to locate the study object and add it to a parent study object.

About the Add To browser

The Add To browser displays the list of study objects, within the current study, that you can add to the selected study object. For example, if you select a form, the Add To browser contains a list of items and sections that you can add to the selected form.

In the Add To browser, you can:

- Filter the list of available study objects by:
  - Typing a keyword.
  - Specifying the fields on which to apply the filter (RefName, Title, Description, or Labels).
- Display the filtered list of study objects by RefName or Title.
- Do the following for the selected study object:
  - Copy a study object with or without its children.
  - Add a link to a study object.

Before you add a study object using the Add To browser, you can also view details about the study object, including:

- Study object properties.
- Parent study objects.
- Form layout (available for InForm forms only).

Adding study objects to a study from the Add To browser

In the Project Explorer, select a study object.

To open the Add To browser

- In the upper-right corner of the application window, select **Add To**.

To filter study objects in the Add To browser

1 Do one of the following:
   - In the **Filter** field, type a keyword.
   - Click **Advanced Filtering**.
     a Specify the properties on which to apply the filter.
     b Specify the display format for the filtered results.
2 Click **Refresh Results** ().

To view details for a study object in the Add To browser

1 In the Add To browser, select the study object.

2 Click **Show Details**.

The Show Details dialog box appears.

3 Do one of the following:

- To view the form layout for forms, select the **Preview Form** tab.
- To view properties for the study object, select the **Object Details** tab.
- To view the parent study objects for the study object, select the **Referenced By** tab.

To add a study object from the Add To browser

- Select the study object and do one of the following:
  - Drag the study object from the Add To browser and drop it onto the study object selected in the Project Explorer.
  - Select the **Add link** drop-down list, and select one of the following:
    - **Add as link**—Adds a link to the study object.
    - **Add with children**—Adds a copy of the study object and the study object's children.
    - **Add without children**—Adds a copy of the study object without the study object's children.

Previewing study objects in the Add To browser

1 In the Project Explorer, select a study object.

2 To open the Add To browser, in the upper-right corner, select **Add To**.

3 In the Add To browser, select a study object to preview.

4 Click **Preview**.

The Preview Object dialog box appears.

5 If the study object you selected is an InForm form, select **Preview Form** to view the form layout.

Saving study objects

About saving study objects

Characteristic	Description
What you can save	• A study object and its child study objects. • All study objects in a study. • All study objects in a study project.
Study objects that are saved	Only the study objects that have been modified since the last save are saved.
Level at which to save	• If you are working on multiple study objects and are not finished with all of them, you might want to save individual study objects after you finish working on them using Actions > Save. • If you are working at a global level (for example, on mappings) you might want to save at the project level (File > Save Project or Ctrl+S).
Locks that are released	Saving releases the locks that you hold on all study objects that you have edited. • If you are collaborating with users who need access to study objects you are working on, consider saving as soon as you are finished with each study object. • If you are working on multiple related study objects and do not want to release the locks until the related work is completed, consider not saving until you exit the study or library, or apply explicit locks.
Undoing	You cannot undo after a save action. **Note:** Although you cannot undo after a save, you can revert to a previous version or revision. If you are unsure whether you want to keep the changes you are making, you might not want to save so you can still undo your changes.
Revisions	When you save a study object, a ***revision*** (on page 121) is created.

Saving one or more study objects

To save a study object:

- In the Project Explorer, right-click a study object, and select **Save**.

To save all study objects in a study:

1 In the Project Explorer, select the **Study Information** Explorer bar.

2 Right-click a study, and select **Save Study**.

To save all study objects in a study project:

- Select **File > Save Project**, or press **Ctrl+S**.

Saving a rule

You can save a rule at any stage of development. For example, you can save a rule after providing only the name and description, and a more technical user can create the expression. You can also save a rule that has errors and return to it later. Validation checks the syntax of all rules.

- At any time in the Rule Wizard, click **Finish**.

References

A reference is a text note, a link to a Web page or file (URL), a document, or a combination of all three, that is attached to a study project for users to consult during the development of a study.

You can attach a reference to a study or study project and view references already attached to a study or project.

References include standard operating procedures, protocols, naming or project standard documents, and other relevant documents. Study designers can use reference information to construct a study.

You can attach the following references:

- **A shortcut that references a file.**

  For example, you can attach a shortcut to a file if the file is checked in to a version-control application and you want all users to view the most recent version.

- **A physical file.**

  You can attach a physical file if the file is stored in a location that everyone cannot access.

- **A shortcut that references a URL address.**

  You can attach the address of a web site that contains information relevant to a study.

References attached to a study project are available for all studies in the project, but references attached to a study are available only for the study.

Note: Version control is available only for study objects and is not available for references.

Attaching a reference to a study

1 In the Project Explorer, select **Study Information**.

2 Select a study.

3 Select the **References** tab.

4 In the **Title** field in the top grid, type a name for the reference.

5 In the **Attachments** section (located in the lower-right corner), click the drop-down arrow next to the **Add File** button.

A menu of attachment options appears.

6 Attach one of the following references.

To attach the following	Perform these steps
Shortcut to a file	1 Select **Attach file**. The Open dialog box appears. 2 Navigate to the file that you want to attach, select the file, and click **Open**. A reference to the file appears in the Attachments section.

To attach the following	Perform these steps
Physical copy of a file	1 Select **Copy and Attach File**. The Open dialog box appears. 2 Navigate to the file that you want to attach, select the file, and click **Open**. The file appears in the Attachments section.
Shortcut to a URL address	1 Select **Attach URL**. The Attach URL dialog box appears. 2 In the field, type the URL address. A shortcut to the URL appears in the Attachments section.

Note: The maximum size of the attachment is determined by a variety of factors, including information defined in the configuration file, available hard disk space, and available memory. To determine the approximate maximum attachment size, check the maxRequestLength attribute in the machine.config file.

Removing a reference from a study

1 In the Project Explorer, select **Study Information**.

2 Select a study.

3 Select the **References** tab.

4 In the **Attachments** section, select a reference.

5 Click **Remove**.

Maximum attachment size

By default, the maximum size of a file that is attached as a reference is 10 MB. When a user copies or attaches a file in the References editor, an error message appears if the size exceeds the configured maximum.

The maximum file size is set in the DesignerUI.config file, in the <ReferencesEditor> section. To change it, update the <MaxFileAttachmentSize> value, using an integer value in megabytes.

About versions and revisions

Versions

A version is an explicitly requested audit history record for a study object. Every study object has a version that is composed of three numbers: the major number, the minor number, and the revision number, which appear in the following format:

<Major number>.<Minor number>.<Revision number>

For example, for version 1.2.34, the major number is 1, the minor number is 2, and the revision number is 34.

When you version a study object, you can choose to increment either the major or minor number. When you increment the major number, the minor number and revision number are both reset to 0. When you increment the minor number, the revision number is reset to 0. For example, for version 1.2.34:

- If you increment the major number, the new version is 2.0.0.
- If you increment the minor number, the new version is 1.3.0.

Versioning and revising a study object

You can version and revise a study object (study design, study element, study event, form, section, item, codelist, and codelist item).

To version a study object:

1 In the Project Explorer, right-click a study object, and select **Create Version**.

The Create Version dialog box appears.

2 Select one of the following increment options:

- **Increment major number**—Increment the major number by one and reset minor and revision numbers to 0.

  For example, version **1.2.34** changes to **2.0.0**.

- **Increment minor number**—Increment the minor number by one and reset revision number to 0.

  For example, version **1.2.34** changes to **1.3.0**.

3 Type a version label and description.

4 Click **Create**.

Note: The version or revision of a study object is saved in the Revision property in the Properties Browser.

To revise a study object:

- Save your changes.

  Revisions are generated automatically when you save a study object with changes. The revision number for all saved study objects is incremented by 1 automatically.

Note: The version or revision of a study object is saved in the Revision property in the Properties Browser.

Reverting to a previous version or revision of a study object

You can revert to a previous version or revision of a study object (study design, study element, study event, form, section, item, codelist, and codelist item) if the study object is not locked by another user.

Note: A revision is created automatically every time someone edits a study object and saves the changes. A version is created only when you explicitly request it.

1 In the Project Explorer, right-click a study object, and select **Audit History**.

  The History Viewer dialog box appears.

2 Select one of the following options:

  - **View Versions**—All versions of the selected study object appear in the top grid.
  - **View Every Edit**—All revisions of the study object appear in the top grid.

3 Double-click the version or revision to which you want to revert.

4 Click **Revert to**.

  The study object reverts to the selected version or revision.

For more information, see *History Viewer dialog box - Option descriptions* (on page 151).

Revising study objects

Revisions

A revision is an audit history record that is created automatically when a user edits a study object and saves the changes. Study objects are revisioned automatically when you save them, and their versions are updated automatically. Every study object has a version that is composed of three numbers: the major number, the minor number, and the revision number, which appear in the following format:

<Major number>.<Minor number>.<Revision number>

For example, for version 1.2.34, the major number is 1, the minor number is 2, and the revision number is 34.

When you save a study object after making changes, the revision number increases by 1. When you version a study object, the revision number is automatically reset to 0.

Object revisions in the InForm application

Object revisions are created in the InForm application when you perform the following actions:

- Modify study objects.
- Use linked study objects multiple times in a study.
- Deploy a study that was previously deployed in earlier releases of the Central Designer application.

Only some object revisions are visible in the InForm application, but all revisions are reported during submission by the CRF Submit application.

How modifying study objects affects revisions in the InForm application

In a study that has already been deployed, object revisions are created for modified study objects.

Modified study object	Result in the InForm application
Study event	A new revision is created for the visit.
Form	A new form revision is created.
Section	New revisions are created for both the section and the form on which it is used.
Item	New revisions are created for the item as well as the section and form on which it is used. **Note:** Sections are created for all items in the InForm application by default, so a revision is created for the default section if the item is not in a section in the Central Designer application.
Control portion of an item (for example, the information that appears in the right column of a layout).	New revisions are created for the control and item as well as the section and form on which the item is used.

How using linked study objects affects revisions in the InForm application

Object revisions are sometimes created during the initial deployment of a study when an item, section, or form is used as a link (that is, it is used multiple times in a study).

Because the presentation of a study object (its layout) is separated from the data of study objects, you can create different layouts for each instance of the study object. Object revisions are created for the study objects with modified layouts.

For example, if the Dem form is used on two study events and each form has a different form title in the Layout tab, a form revision is created for one of the Dem forms in the InForm application.

The following table provides examples of information that, when you modify it for a linked study object, results in the creation of object revisions.

Form modifications	Section modifications	Item modifications
• Form title	• Section note • Section header • Section title	• Caption override • Codelist item label override • Size of a text box • Width of the question column • Orientation of radio buttons, checkboxes, or a group control

How deployment of a study created with an earlier release of the Central Designer application affects revisions in the InForm application

If you deploy a study using release 1.0 or 1.1 and then upgrade to a later release, revisions are created for study events, forms, sections, and items that existed during the deployment from release 1.0 or 1.1.

Study object deployed in release 1.0 or 1.1	Result in the InForm application when the study is deployed
Study event	A new revision is created for the visit.
Form	A new form revision is created.
Section	New revisions are created for both the section and the form on which it is used.
Item	New revisions are created for the item as well as the section and form on which it is used. **Note:** Sections are created for all items in the InForm application by default, so a revision is created for the default section if the item is not in a section in the Central Designer application.
Control portion of an item (for example, the information that appears in the right column of a layout).	New revisions are created for the control and item as well as the section and form on which the item is used.

Post-production revision management

A study design represents the root of the study workflow, including study events, forms, and rules that govern the behavior of study events and forms. The study workflow is independent of locale; therefore, there are special considerations for designing a single study with different workflows for different sites or locales in the target application.

For example, consider the case where you want to add a form to a visit in some sites or locales but not to others. Because the study has only one study workflow, the form must be added to all sites. Your options are:

- Create a workflow rule or global condition for the form that causes the form to never appear unless the site code or locale is one that has been specified. This approach might work for simple cases, but the approach can create maintenance problems if there are many similar customizations, or if different sites require different versions of the form.
- Create a separate workflow for the different sites. This approach would normally require having two study designs in the study, which is not supported by the Central Designer application.

Many production multi-site studies undergo different maintenance paths, in which some changes are distributed to all sites and others are limited to only a few sites. The Central Designer application does not allow you to create a single study with multiple study designs (in other words, multiple workflows) that you maintain in parallel.

However, you can split the different maintenance paths into separate copies of the study, each of which can be maintained separately, as follows:

1 Create a study that will be used in production. Consider this study to be the 1.0 study.

2 Create a deployment package and deploy and install it in all study sites.

3 Export the study and import it into a new study (which can be, but does not have to be, part of the same study project). The new study is comparable to a 1.1 branch. The new study will be maintained separately from the existing study.

4 Before making any changes to the new study, create a baseline and deployment package. This package is identical to the original study package. The new package will be the basis for incremental deployment packages in the 1.1 study.

5 Add study objects to or modify the 1.1 study.

6 Create an incremental deployment package, and deploy the package to the specific sites that require the changes.

This approach requires you to maintain both studies independently of each other. For example, if you modify a form in one study, the change is not propagated to the form in the other study unless the study object is in a library and is used in both studies.

Viewing audit history for a study object

You can view the audit history for a study object (study design, study element, study event, form, section, item, codelist, and codelist item) in the History Viewer dialog box. The History Viewer shows the properties and structure of the study object, including its children, but it does not show associated rules or layout information.

1 In the Project Explorer, right-click a study object, and select **Audit History**.

The History Viewer dialog box appears.

2 Select one of the following options:

- **View Versions**—All versions of the selected study object appear in the top grid.
- **View Every Edit**—All revisions of the study object appear in the top grid.

3 Click among the versions or revisions to view the structure of the study object (in the lower-left grid) and the properties for the study object selected in that grid (in the lower-right grid).

For more information, see *History Viewer dialog box - Option descriptions* (on page 151).

Viewing the differences between two versions or revisions of a study object

In the History Differences dialog box, you can view the differences between two versions or revisions of a study object, including the child study objects and properties, for each version or revision. A revision is created automatically every time someone edits a study object and saves the changes. A version is created only when you explicitly request it.

1 In the Project Explorer, right-click a study object, and select **Audit History**.

The History Viewer dialog box appears.

2 Select one of the following options:

- **View Versions**—All versions of the selected study object appear in the top grid.
- **View Every Edit**—All revisions of the study object appear in the top grid.

3 In the **Revision/Version** grid, select the two versions or revisions that you want to compare:

a To select the first version or revision, double-click within the gray box at the left end of the row.

b To select the second version or revision, click within any field in the row.

4 Click **Differences**.

The History Differences dialog box appears.

5 In the top grid, compare the child study objects that appeared in each version or revision. In the bottom grid, compare the properties of the study object in each version or revision.

For more information, see *History Viewer dialog box - Option descriptions* (on page 151).

Exporting and importing text for translation

About exporting and importing text

You can export all text strings for a target application and locale into a CSV file, translate them locally, and then re-import the translated strings.

This option is useful for outsourcing translations. After exporting the text strings for a selected target application and locale to a CSV file, you can send the file to a third-party translation vendor to translate the strings. When the translated strings are returned, you import them back into the Central Designer database. You perform the export and import separately for each locale to be translated.

You can export and import text strings at any time during the development of a study, including updates after a study has gone live. For example, to generate a test file to validate the process with a translation vendor, you can export the text strings for a partially developed study. When the study is completely developed, you can export the strings again, have the vendor translate the remaining strings, and import the completed translation file.

Note: The text string export and import feature works only with the current format of layouts. If your study contains layouts that were created in release 1.2 or earlier of the Central Designer application, you must convert the layouts to the current format before exporting or importing text strings. For more information, see Converting layouts (in the *InForm Design Guide*).

Exporting text strings from a study or library

1 In the Project Explorer, right-click a study or library, and select **Translations > Export**.

The Export Translations dialog box appears.

2 Fill in the fields of the dialog box. For more information, see *Export Translations dialog box—Option descriptions* (on page 150).

3 Click **Export**.

The Central Designer application exports all of the text strings that match the selected criteria and saves them in CSV format in the location you specified. Status messages appear in the Export log results field.

4 To save the export log file, click **Save Log Results As** and select a location.

5 To interrupt the export process, click **Stop**.

The export process stops, and no further records are written to the output file.

Note: You can undo a string export.

Importing translated text strings

To import translated text strings successfully, make sure that the translation file is in the correct format and that all requirements for character formatting are met.

For more information, see:

- *Translation file format* (on page 128).
- *Translation file requirements* (on page 129).

1 In the Project Explorer, right-click a study or library, and select **Translations > Import**.

The Import Translations dialog box appears.

2 Browse to the location of the CSV file containing translated strings to import.

3 Click **Import**.

The Central Designer application imports each text string to the study object specified in the CSV file. Status messages appear in the Import log results field. If an entry cannot be imported (for example, if the import process cannot acquire a lock on the target study object), a message is written to the import log, and the import continues with the next entry. You can re-import the file to process modified or corrected entries.

4 To save the import file messages, click **Save Log Results As**, and select a location.

5 To interrupt the import process, click **Stop**.

The import process stops, and no further records are updated in the study. Records that were updated before the stop remain in the study.

Note: You can undo a string import.

Translating exported text strings

After the text strings for a study or library are exported, a translator adds translated strings to the exported file.

- In the exported file, provide translated values for each text string, and save the file.

Note: If you use Microsoft Excel spreadsheet software as the CSV file editor, you must import the exported file as Unicode UTF-8; you cannot simply open the file and edit it. Additionally, you must export the edited file as Unicode UTF-8 CSV; you cannot save it and preserve the correct formatting. You might want to develop a Microsoft Excel macro specification or other tool that performs this processing. For guidance, see the Microsoft Excel documentation.

For more information, see:

- *Translation file format* (on page 128).
- *Translation file requirements* (on page 129).

Translation file format

The translation export and import CSV file consists of a header and translation records in the following formats.

Header

The header contains the following values: RefName,OwnerType,SrType, Id,Revision, <*ReferenceLocaleValue*>,< *LocaleToTranslate*>

- <*ReferenceLocaleValue*>—Locale of the strings from which to translate, as specified in the Locale to translate from field of the Export Translations dialog box. Example: en-US.
- <*LocaleToTranslate* >—Locale to which text strings are being translated, as specified in the Locale to translate field of the Export Translations dialog box. Example: fr-FR.

Example of file header

```
RefName,OwnerType,SrType,Id,Revision,en-US,fr-FR
```

Records

Each translation record contains the following fields: <RefName>,<OwnerType>,<SrType, <Id>,<Revision>,<*ReferenceLocaleValue*>,< *LocaleToTranslate*>, as described in the following table.

Field	Description
RefName	RefName of the study object that owns the string.
OwnerType	Internal type of the study object that owns the string resource.
SrType	Internal type of the field that references the string resource.
Id	GUID of the string resource in CSML.
Revision	Revision number of the study object for which the text string is defined.
ReferenceLocaleValue	Text string in the locale to translate.
LocaleToTranslate	Translated text string. This value is empty when you export the file. The translator fills in the value before you import the file. **Note:** The LocaleToTranslate is the only value that may be changed in each record.

Examples of file records

```
Layout_5fxx,LayoutPlan,ItemCaption,d067b170-8885-11e1-b0c4-0800200c9a66,12, "DOV
Form","Forme pour la date de visite"
Itm_DOB,DateTime,Question,26beca46-663e-4841-ab8b-03ff6b7a78f9,5,"Date of
Birth","Date de naissance"
```

Translation file requirements

- Do not change any values in the translation file except the strings in the LocaleToTranslate position (last field in each record).
- The header record must be present.
- Each record must conform to the following standards:
  - All records must have the same number of fields.
  - RefName and Id fields must not be empty.
  - RefName length must be less than or equal to 63 characters.
  - Revision and OwnerType lengths must be less than or equal to 255 characters.
  - ReferenceLocaleValue and LocaleToTranslate lengths must be less than or equal to 32000 characters.
- Double quotation marks (") are required for any field that contains a line break, double quote, or comma and are optional for any other field.
- If a field contains a double quotation mark character [for example, Dizzy ("Groggy")], you must include another double quotation mark as an escape character, as follows: "Dizzy (""Groggy"")"
- Lines must end with a Windows-style (CRLF) line terminator.

Checking for empty strings

You can generate a list of the empty strings in a study for a specified locale.

1 In the Project Explorer, select a study.

2 Do one of the following:

- Select **Actions > Translations > Check for Empty Strings**.

or

a Select **Actions > Translations > Export Strings for Translation**.

The Export Strings for Translation dialog box appears.

b Click **Check for Empty Strings**.

The Check for Empty Strings dialog box appears.

3 In the **Locale** drop-down list, select the locale to check.

4 Click **Run**.

The empty strings in the study appear in the **Empty strings for study < study name>** grid.

5 To navigate to the location of an empty string, click the button at the left of the **Owner RefName** column, and select **Goto empty string**.

Importing and exporting a study

Importing and exporting are useful for:

- Working with customer support to analyze problems in a study.
- Moving a study from one server to another.

Note: Exporting and importing do not preserve notes, categorization, or ancestry.

About importing

You can import study objects into a library or study. For example, if a study contains many study objects that you expect to reuse, you can use the import feature to create the study objects quickly in a library or study. After a study has been imported, you can revise, add, or delete study objects as needed.

You can import a file in CSML or ODM format

- Clinical Study Markup Language (CSML) is an XML-based markup language developed by Oracle for representing and exchanging clinical data definitions created in the Central Designer application.
- Operational Data Model (ODM) is an XML-based standard developed by the Clinical Data Interchange Standards Consortium (CDISC) for representing and exchanging clinical data.

  For example, you can use the CSML option to import an exported Central Designer study into another study.

Note: You cannot import a CSML file into a library if the file contains a study design. A CSML file contains a study design if you exported the CSML from a study. To add study objects that are in a CSML file to a library, import the CSML file into a study, use the Libraries Browser to search for the study objects, and then drag them to the library.

Importing study objects

Note: You cannot import a CSML file into a library if the file contains a study design. A CSML file contains a study design if you exported the CSML from a study. To add study objects that are in a CSML file to a library, import the CSML file into a study, use the Libraries Browser to search for the study objects, and then drag them to the library.

1 In the Project Explorer, right-click a study or library, and select **Import Study**.

  The Central Designer Import Wizard appears.

2 Complete the pages of the **Central Designer Import Wizard**. Click **Next** after you finish filling in each page. On the **Import Type** page, select the source of the data to import.

Based on your selection, the Central Designer Import Wizard prompts for different information as you progress through the wizard.

After you select a file to import and click Next, the wizard reviews all the study objects in the file. This process might take several minutes.

3 On the final page of the **Central Designer Import Wizard**, click **Finish**.

If you are importing a CSML file containing study objects for a system that is not selected as a Deployment System for the study or library, a message appears; choose one of the following options:

- Continue with the import, and select all the systems in the CSML file as Deployment Systems. If you choose this option, continue to the next step.
- Cancel the import.

A slide-up message appears in the lower-right corner to indicate when the job starts and completes.

4 When the job completes, check the status in the **Jobs Browser**.

5 Review the imported study objects, and add, delete, or modify them as necessary.

Note: If you uninstall a deployment system, you cannot import a CSML file that contains study objects for that system.

For more information, see:

Import Wizard options - CSML or ODM file (on page 153).

Import Wizard options - InForm resources (on page 154).

Viewing import job results

1 In the Project Explorer, select a study or library.

2 In the row of browser tabs, select the **Jobs Browser**.

The Jobs Browser appears.

Note: In the Jobs Since list, you can select the period for which you want to view job results. You can also sort the list by the Name or Start Time column to locate a job quickly by a specific starting date.

3 Click **Refresh**.

The list of jobs is refreshed from the database.

4 On the toolbar, click **Show Job Results**, and expand the results for an individual job.

Information, warning, and error messages appear for the jobs run in the selected period.

Note: To view the complete text of a message that is truncated because of column size, hold the cursor over the portion of text that is visible. Alternately, select a row, and then right-click it and select **Properties**.

CSML metadata imports

If you export and then re-import a study using the CSML format, the Study Design object is overwritten. (Each study has only one Study Design object.) The following rules apply when an imported study object and an existing study object have the same object ID.

Import target	Imported study object has the same ID as a study object in...	Result
Study	Any other study.	The ID of the imported study object is changed to a new ID. All references to the imported study object in the import are updated to refer to the new ID.
Study	The same study.	The ID of the imported object does not change.
Library	Any library.	The ID of the imported object does not change.
Library	Any study.	The ID of the imported study object is changed to a new ID. All references to the imported study object in the import are updated to refer to the new ID.

When functions are declared in the study CSML, functions are imported except under the following circumstances:

- When you import CSML in a study, and a function in the CSML already exists in a library that is in the Library List for the study. The function is already available for use. You do not receive an error or warning.
- When the function assembly does not exist in the database. You receive a warning.

ODM metadata imports

The Operational Data Model (ODM) is an XML-based standard developed by the Clinical Data Interchange Standards Consortium (CDISC) for representing and exchanging clinical data. ODM is a vendor-neutral, platform-independent format used for importing, exporting, and archiving clinical study data and metadata.

The Central Designer import feature supports a subset of the ODM standard, using only the metadata that fits into the Central Designer CSML schema.

You can import metadata in ODM format into the Central Designer application as long as the metadata:

- Complies with version 1.3 of the ODM standard.
- Contains only standard ODM objects with no extensions.
- Has a file type of Snapshot and contains only one study, one metadata version, and one protocol.
- Includes measurement units that are present in the Central Designer Units definition in the database.

> **Note:** If the metadata contains units that are not present in the Central Designer database, a warning occurs, and the units are not imported.

ODM mappings

The following table describes how ODM elements are mapped to Central Designer study objects during import.

ODM element	Central Designer study object
Study	Study design
StudyEventDef	Study event
FormDef	Form
ItemGroupDef	Section
ItemDef (datatype=INTEGER)	Integer item
ItemDef (datatype=FLOAT)	Float item
ItemDef (datatype=DATE, TIME, DATETIME)	Date time item
ItemDef (datatype=TEXT, STRING)	Text item
CodeList	CodeList
CodeListItem	CodeListItem

Considerations for ODM import in InForm studies

You can reuse ODM-formatted study design metadata that is exported from a third-party application. Consider the following if you are importing metadata in ODM format into the Central Designer application to use in the creation of InForm studies or libraries.

- **Common visits**—The ODM specification allows multiple common StudyEventDefs, while the Central Designer application allows only one common visit.

  All common StudyEventDefs in an ODM import file are consolidated into a single common visit after import. The forms defined for the common visits in the ODM import file appear in the single common visit in the Central Designer application.

  The CommonVisit definition for the common visit that appears in the Central Designer application contains a LongTitle and ShortTitle, which are populated by the Description and Name defined in the first common StudyEventDef in the ODM import file.

- **Units**—The MeasurementUnit in the ODM import file is matched with entries in the Central Designer database based on unit symbols, but not unit names. If a unit in the ODM import file is not recognized as a unit in the Central Designer database, a warning message appears and the unit is not imported.

- **Metadata**—The Central Designer application does not recognize some ODM metadata (for example, the attribute SDSVarName). Any element or attribute in the ODM import file that is not recognized by the Central Designer application is ignored, and is not imported. You cannot recover this metadata after import.

- **Rules**—RangeCheck is the ODM simple range-checking attribute. Because the Central Designer application uses rules for range checking, ODM RangeChecks are imported as collaboration notes so that you can create the appropriate RangeCheck rules after importing.

- **Import file type**—Snapshot ODM represents a complete picture of a study at a point in time. Transactional ODM represents the life of the study over time. The Central Designer application supports standard ODM with a file type of Snapshot.

  The Central Designer application does not support ODM file chaining. The ODM specification allows files to be chained together through the FileOID and PriorFileOID attributes. File chaining is primarily used in Transactional ODM, but can also be used in Snapshot ODM to break up study metadata into multiple files that are chained together. Transactional ODM uses file chaining to create a final end state of a study upon import completion. Because the Central Designer application does not support file chaining, if you import Transactional ODM, an error occurs.

  Note: You cannot import InForm metadata that you extracted from the InForm Adapter application with a Transactional file type. You must specify Snapshot as the file type parameter when you export data from the InForm Adapter application. For more information see the InForm Adapter *User Guide*.

- **Workflow**—Because the OrderNumber attribute is optional for StudyEventDefs in an ODM import file, the order in which the StudyEventDefs appear in the ODM is the order in which they appear in the Central Designer workflow.

  - A study event with an OrderNumber attribute is assigned a sequence number, unless its predecessor in the workflow has a type of Scheduled.
  - A study event with no OrderNumber attribute is placed at the end of the workflow, in the order in which it is read from the ODM import file.

  Note: Any study event, with or without an OrderNumber attribute, is assigned a sequence number of zero if its predecessor in the workflow has a type of Scheduled.

- **Localization**—The Central Designer application imports localized data specified in an ODM import file. The translated data appears in the Central Designer application in the language to which it was localized. For more information, see the ODM specification for the TranslatedText element on the CDISC web site.

  The following localized study objects can be imported:

  - Forms.
  - Sections.
  - Items (Question, Text, and Description).
  - The decoded value for codelist items.
  - Symbols for measurement units.

- **Granularity**—Granularity is an optional ODM file attribute. If present, it must be set to All or Metadata. If Granularity is set to Metadata, the document cannot contain AdminData , ClinicalData, or ReferenceData sections.

- **Naming uniqueness**—The Central Designer application enforces naming uniqueness with Universal Unique Identifiers (UUIDs). A UUID is a Global Unique Identifer (GUID) that is created using the Object Identifier (OID) for a study object. If the OID is not a valid GUID or is already used by another object, the import process generates a GUID using Microsoft's GUID generation algorithm.

  For example, during the import, to create a StudyEventOID, the Central Designer application:

  1 Truncates the OID to the maximum allowed length.

  2 Removes disallowed characters.

  In addition, within an ODM import file, ODM allows the reuse of RefNames if the RefName is for a different type of study object. However, the Central Designer application requires unique RefNames for all study objects in a study, and for all study objects in an import file. To enforce the uniqueness of RefNames in the import file, the Central Designer application adds prefixes to the imported study object RefNames according to the study object type.

  If an ODM import file contains study objects with the same RefName, the Central Designer application uses the following logic:

  - For study objects of the same type, the Central Designer application creates a new object with a different ID but the same RefName, and adds a prefix to the RefName.
  - For study objects not of the same type, the Central Designer application imports the study object and displays a warning that duplicate RefNames exist.

  Note: If you import multiple ODM files, and duplicate RefNames exist between the files, the Central Designer application allows you to import the study objects. You must resolve RefName conflicts after import in order to validate the study.

  The Central Designer application applies the following prefixes for study objects with duplicate RefNames within an ODM import file.

CSML object type	Prefix
StudyDesign	SD_
StudyEvent	SE_
DataView (from the FormDef definition in the ODM import file)	DF_
DataView (from the ItemGroupDef definition in the ODM import file)	DI_
IntegerVariable, FloatVariable, DateTimeVariable, or TextVariable	VR_
CodeList	CL_
CodeListItem	CI_

Pre-import checking

Pre-import checking verifies that the following conditions are met before ODM is transformed to CSML for import into the Central Designer application.

- All requirements are met. For more information, see *Considerations for ODM import in InForm studies* (on page 133).
- The input file is a well-formed XML file and is fully compliant with the ODM 1.3 schema.

Note: Error and warning messages appear as Job Results in the Central Designer Job Browser.

Post-import modifications

After you import a study from an external source, you should review the imported study object definitions to identify the additions and changes they require. For example:

- If you import a file in CSML format, Central Designer rules are created. If any rule refers to a user-defined function that does not exist in the target study, import the user-defined function to the study. If a required constant does not exist in the study or in a library that the study uses, add the constant or add the appropriate library to the Library List.
- If you import from a source other than CSML, imported rules are not converted to Central Designer rules; instead, they appear as collaboration notes. You must create a rule for each rule in the import file that you want to use in the library or study.
- In order to use imported study objects as valid deployable Central Designer study objects, you should review the imported study objects to add additional information that is not contained in the ODM format. For example, you must:
  - Create form layouts for imported forms.
  - Translate study object labels and text strings as needed for multi-lingual studies.
  - Create a range check rule for each imported ODM RangeCheck that you want to use in the library or study. For more information, see the *Rules Reference Guide*.
  - Resolve RefName conflicts for all study objects you want to deploy to a target application.
  - Connect any scheduled imported events or elements in the proper order with arrows, and provide hours between the visits.

- If studies or study objects were marked as templates, you must re-mark the study objects as templates.

Note: If you harvest InForm resources and publish them in a library, both forms and sections appear in the forms group when you search for study objects. However, in the Project Explorer, forms and sections have different icons. Using naming conventions that clearly distinguish forms from sections is recommended.

About exporting

The export feature enables you to export a study or library to a file, for archiving or for importing back into the Central Designer application or to an ODM-compliant system. With the export feature, you can generate export files in Clinical Study Markup Language (CSML) or in Operational Data Model (ODM)-compliant format:

- Clinical Study Markup Language (**CSML**) is an XML-based markup language developed by Oracle for representing and exchanging clinical data definitions created in the Central Designer application.
- Operational Data Model (**ODM**) is an XML-based standard developed by the Clinical Data Interchange Standards Consortium (CDISC) for representing and exchanging clinical data. The Central Designer application exports XML that is compliant with the 1.3 version of the ODM standard.

Note: When you export a study or library, you export the entire study or library. You cannot selectively export certain study objects.

Exporting study objects

1 In the Project Explorer, right-click the study or library from which you want to export study objects, and select **Export Study**.

The Central Designer Export Wizard appears.

2 Complete the pages of the **Central Designer Export Wizard**. Click **Next** when you finish filling out each page.

3 On the final page of the **Central Designer Export Wizard**, click **Finish**.

An export file is created in the location you specified in the wizard.

Note: If errors result when you export to the ODM format, a dialog box containing the errors appears.

For more information, see **Export Wizard options** (on page 151).

Reserved words for RefNames

The following keywords and reserved words cannot be used as RefNames. You can use the following words as part of a RefName; for example, **abstract_1** is allowed.

Note: You cannot use non-English characters in RefNames.

C# keywords					
• abstract	• decimal	• float	• long	• sbyte	• typeof
• as	• default	• for	• namespace	• sealed	• uint
• base	• delegate	• foreach	• new	• short	• ulong
• bool	• do	• goto	• object	• sizeof	• unchecked
• break	• double	• public	• operator	• stackalloc	• unsafe
• byte	• else	• if	• out	• static	• ushort
• case	• enum	• implicit	• override	• string	• using
• catch	• event	• in	• params	• struct	• virtual
• char	• explicit	• int	• private	• switch	• volatile
• checked	• null	• interface	• protected	• this	• void
• class	• extern	• internal	• readonly	• throw	• while
• const	• false	• is	• ref	• true	
• continue	• fixed	• lock	• return	• try	

Oracle keywords		
• AFROWID	• ITEMSETID	• SUBJECTVISITID
• CD_COUNT	• ITEMSETIDX	• SUBJECTVISITREV
• DATETIME	• ITEMSETINDEX	• SUBJECTID
• DELETEDFORM	• NOTDONE	• SUBJECTINITIALS
• DELETEDITEM	• SECTIONID	• VISITID
• FORMID	• SITECOUNTRY	• VISITINDEX
• FORMIDX	• SITEID	• VISITMNEMONIC
• FORMINDEX	• SITEMNEMONIC	• VISITORDER
• FORMMNEMONIC	• SITENAME	
• FORMREV	• STUDYVERSIONID	

Rules-related keywords

- Current
- CurrentIndex
- CurrentValuesIndex
- CurrentAllValuesIndex
- CurrentObjectsIndex
- CurrentAllObjectsIndex

Oracle reserved words

A, ABORT, ACCESS, ACCESSED, ACCOUNT, ACTIVATE, ADD, ADMIN, ADMINISTER, ADMINISTRATOR, ADVISE, ADVISOR, AFTER, ALGORITHM, ALIAS, ALL, ALLOCATE, ALLOW, ALL_ROWS, ALTER,ALWAYS, ANALYZE, ANCILLARY, AND, AND_EQUAL, ANTIJOIN, ANY, APPEND, APPLY, ARCHIVE, ARCHIVELOG, ARRAY, AS, ASC, ASSOCIATE, AT, ATTRIBUTE, ATTRIBUTES, AUDIT, AUTHENTICATED, AUTHENTICATION, AUTHID, AUTHORIZATION, AUTO, AUTOALLOCATE, AUTOEXTEND, AUTOMATIC, AVAILABILITY, BACKUP, BECOME, BEFORE, BEGIN, BEHALF, BETWEEN, BFILE, BIGFILE, BINARY_DOUBLE, BINARY_DOUBLE_INFINITY, BINARY_DOUBLE_NAN, BINARY_FLOAT, BINARY_FLOAT_INFINITY, BINARY_FLOAT_NAN, BINDING, BITMAP, BITS, BLOB, BLOCK, BLOCKS, BLOCKSIZE, BLOCK_RANGE, BODY, BOTH, BOUND, BROADCAST, BUFFER, BUFFER_CACHE, BUFFER_POOL, BUILD, BULK, BY, BYPASS_RECURSIVE_CHECK, BYPASS_UJVC, BYTE, CACHE, CACHE_CB, CACHE_INSTANCES, CACHE_TEMP_TABLE, CALL, CANCEL, CARDINALITY, CASCADE, CASE, CAST, CATEGORY, CERTIFICATE, CFILE, CHAINED, CHANGE, CHAR, CHARACTER, CHAR_CS, CHECK, CHECKPOINT, CHILD, CHOOSE, CHUNK, CIV_GB, CLASS, CLEAR, CLOB, CLONE, CLOSE, CLOSE_CACHED_OPEN_CURSORS, CLUSTER, CLUSTERING_FACTOR, COALESCE, COARSE, COLLECT, COLLECTIONS_GET_REFS, COLUMN, COLUMNS, COLUMN_STATS, COLUMN_VALUE, COMMENT, COMMIT, COMMITTED, COMPACT, COMPATIBILITY, COMPILE, COMPLETE, COMPOSITE_LIMIT, COMPRESS, COMPUTE, CONFORMING, CONNECT, CONNECT_BY_ISCYCLE, CONNECT_BY_ISLEAF, CONNECT_BY_ROOT, CONNECT_TIME, CONSIDER, CONSISTENT, CONSTRAINT, CONSTRAINTS, CONTAINER, CONTENT, CONTENTS, CONTEXT, CONTINUE, CONTROLFILE, CONVERT, CORRUPTION, COST, CPU_COSTING, CPU_PER_CALL, CPU_PER_SESSION, CREATE, CREATE_STORED_OUTLINES, CROSS, CUBE, CUBE_GB, CURRENT, CURRENT_DATE, CURRENT_SCHEMA, CURRENT_TIME, CURRENT_TIMESTAMP, CURRENT_USER, CURSOR, CURSOR_SHARING_EXACT, CURSOR_SPECIFIC_SEGMENT, CYCLE, DANGLING, DATA, DATABASE, DATAFILE, DATAFILES, DATAOBJNO, DATE, DATE_MODE, DAY, DBA, DBA_RECYCLEBIN, DBTIMEZONE, DDL, DEALLOCATE, DEBUG, DEC, DECIMAL, DECLARE, DECREMENT, DEFAULT, DEFERRABLE, DEFERRED, DEFINED, DEFINER, DEGREE, DELAY, DELETE, DEMAND, DENSE_RANK, DEREF, DEREF_NO_REWRITE, DESC, DETACHED, DETERMINES, DICTIONARY, DIMENSION, DIRECTORY, DISABLE, DISASSOCIATE, DISCONNECT, DISK, DISKGROUP, DISKS, DISMOUNT, DISTINCT, DISTINGUISHED, DISTRIBUTED, DML, DML_UPDATE, DOCUMENT, DOMAIN_INDEX_NO_SORT, DOMAIN_INDEX_SORT, DOUBLE, DOWNGRADE, DRIVING_SITE, DROP, DUMP, DYNAMIC, DYNAMIC_SAMPLING, DYNAMIC_SAMPLING_EST_CDN, EACH, ELEMENT, ELSE, EMPTY, ENABLE,

ENCRYPTED, ENCRYPTION, END, ENFORCE, ENFORCED, ENTRY, ERROR, ERROR_ON_OVERLAP_TIME, ESCAPE, ESTIMATE, EVENTS, EXCEPT, EXCEPTIONS, EXCHANGE, EXCLUDING, EXCLUSIVE, EXECUTE, EXEMPT,EXISTS, EXPAND_GSET_TO_UNION, EXPIRE, EXPLAIN, EXPLOSION, EXPORT, EXPR_CORR_CHECK, EXTEND, EXTENDS, EXTENT, EXTENTS, EXTERNAL, EXTERNALLY, EXTRACT, FACT, FAILED, FAILED_LOGIN_ATTEMPTS, FAILGROUP, FALSE, FAST, FBTSCAN, FIC_CIV, FIC_PIV, FILE, FILTER, FINAL, FINE, FINISH, FIRST, FIRST_ROWS, FLAGGER, FLASHBACK, FLOAT, FLOB, FLUSH,FOLLOWING, FOR, FORCE, FORCE_XML_QUERY_REWRITE, FOREIGN, FREELIST, FREELISTS, FREEPOOLS, FRESH, FROM, FULL, FUNCTION, FUNCTIONS, GATHER_PLAN_STATISTICS, GBY_CONC_ROLLUP, GENERATED, GLOBAL, GLOBALLY, GLOBAL_NAME, GLOBAL_TOPIC_ENABLED, GRANT, GROUP, GROUPING, GROUPS, GROUP_BY, GUARANTEE, GUARANTEED, GUARD, HASH, HASHKEYS, HASH_AJ, HASH_SJ, HAVING, HEADER, HEAP, HIERARCHY, HIGH, HINTSET_BEGIN, HINTSET_END, HOUR, HWM_BROKERED, ID, IDENTIFIED, IDENTIFIER, IDENTITY, IDGENERATORS, IDLE_TIME, IF, IGNORE, IGNORE_ON_CLAUSE, IGNORE_OPTIM_EMBEDDED_HINTS, IGNORE_WHERE_CLAUSE, IMEDIATE, IMPORT, IN, INCLUDE_VERSION, INCLUDING, INCREMENT, INCREMENTAL, INDEX, NDEXED, INDEXES, INDEXTYPE, INDEXTYPES, INDEX_ASC, INDEX_COMBINE, INDEX_DESC, INDEX_FFS, INDEX_FILTER, INDEX_JOIN, NDEX_ROWS, INDEX_RRS, INDEX_SCAN, INDEX_SKIP_SCAN, INDEX_SS, INDEX_SS_ASC, INDEX_SS_DESC, INDEX_STATS, INDICATOR, INFINITE, INFORMATIONAL, INITIAL, INITIALIZED, INITIALLY, INITRANS, INLINE, INNER, INSERT, INSTANCE, INSTANCES, INSTANTIABLE, INSTANTLY, INSTEAD, INT, INTEGER, INTEGRITY, INTERMEDIATE, INTERNAL_CONVERT, INTERNAL_USE, INTERPRETED, INTERSECT, INTERVAL,INTO, INVALIDATE, IN_MEMORY_METADATA, IS, ISOLATION, ISOLATION_LEVEL, ITERATE, ITERATION_NUMBER, JAVA, JOB, JOIN, KEEP, KERBEROS, KEY, KEYFILE, KEYS, KEYSIZE,KEY_LENGTH, KILL, LAST, LATERAL, LAYER, LDAP_REGISTRATION, LDAP_REGISTRATION_ENABLED, LDAP_REG_SYNC_INTERVAL, LEADING, LEFT, LENGTH, LESS, LEVEL, LEVELS, LIBRARY, LIKE, LIKE2, LIKE4, LIKEC, LIKE_EXPAND, LIMIT, LINK, LIST, LOB, LOCAL, LOCALTIME, LOCALTIMESTAMP, LOCAL_INDEXES, LOCATION, LOCATOR, LOCK, LOCKED, LOG, LOGFILE, LOGGING, LOGICAL, LOGICAL_READS_PER_CALL, LOGICAL_READS_PER_SESSION, LOGOFF, LOGON, LONG, MAIN, MANAGE, MANAGED, MANAGEMENT, MANUAL, MAPPING, MASTER, MATCHED, MATERIALIZE, MATERIALIZED, MAX, MAXARCHLOGS, MAXDATAFILES, MAXEXTENTS, MAXIMIZE, MAXINSTANCES, MAXLOGFILES, MAXLOGHISTORY, MAXLOGMEMBERS, MAXSIZE, MAXTRANS, MAXVALUE, MEASURES, MEMBER, MEMORY, MERGE, MERGE_AJ, MERGE_CONST_ON, MERGE_SJ, METHOD, MIGRATE, MIN, MINEXTENTS, MINIMIZE, MINIMUM, MINUS, MINUTE, MINVALUE, MIRROR, MLSLABEL, MODE, MODEL,MODEL_DONTVERIFY_UNIQUENESS, MODEL_MIN_ANALYSIS, MODEL_NO_ANALYSIS, MODEL_PBY, MODEL_PUSH_REF, MODIFY, MONITORING, MONTH, MOUNT, MOVE, MOVEMENT, MULTISET, MV_MERGE, NAME, NAMED, NAN, NATIONAL, NATIVE, NATURAL, NAV, NCHAR, NCHAR_CS, NCLOB, NEEDED, NESTED, NESTED_TABLE_FAST_INSERT, NESTED_TABLE_GET_REFS, NESTED_TABLE_ID, NESTED_TABLE_SET_REFS, NESTED_TABLE_SET_SETID, NETWORK, NEVER, NEW, NEXT, NLS_CALENDAR, NLS_CHARACTERSET, NLS_COMP, NLS_CURRENCY, NLS_DATE_FORMAT, NLS_DATE_LANGUAGE, NLS_ISO_CURRENCY, NLS_LANG, NLS_LANGUAGE, NLS_LENGTH_SEMANTICS, NLS_NCHAR_CONV_EXCP, NLS_NUMERIC_CHARACTERS, NLS_SORT, NLS_SPECIAL_CHARS, NLS_TERRITORY,

NL_AJ, NL_SJ, NO, NOAPPEND, NOARCHIVELOG, NOAUDIT, NOCACHE, NOCOMPRESS, NOCPU_COSTING, NOCYCLE, NODELAY, NOFORCE, NOGUARANTEE, NOLOGGING, NOMAPPING, NOMAXVALUE, NOMINIMIZE, NOMINVALUE, NOMONITORING, NONE, NOORDER, NOOVERRIDE, NOPARALLEL, NOPARALLEL_INDEX, NORELY, NOREPAIR, NORESETLOGS, NOREVERSE, NOREWRITE, NORMAL, NOROWDEPENDENCIES, NOSEGMENT, NOSORT, NOSTRICT, NOSWITCH, NOT, NOTHING, NOVALIDATE, NOWAIT, NO_ACCESS, NO_BASETABLE_MULTIMV_REWRITE, NO_BUFFER, NO_CPU_COSTING, NO_EXPAND, NO_EXPAND_GSET_TO_UNION, NO_FACT, NO_FILTERING, NO_INDEX, NO_INDEX_FFS, NO_INDEX_SS, NO_MERGE, NO_MODEL_PUSH_REF, NO_MONITORING, NO_MULTIMV_REWRITE, NO_ORDER_ROLLUPS, NO_PARALLEL, NO_PARALLEL_INDEX, NO_PARTIAL_COMMIT, NO_PRUNE_GSETS, NO_PUSH_PRED, NO_PUSH_SUBQ, NO_QKN_BUFF, NO_QUERY_TRANSFORMATION, NO_REF_CASCADE, NO_REWRITE, NO_SEMIJOIN, NO_SET_TO_JOIN, NO_STAR_TRANSFORMATION, NO_STATS_GSETS, NO_SWAP_JOIN_INPUTS, NO_UNNEST, NO_USE_HASH, NO_USE_MERGE, NO_USE_NL, NO_XML_QUERY_REWRITE, NULL, NULLS, NUMBER, NUMERIC, NVARCHAR2, OBJECT, OBJNO, OBJNO_REUSE, OF, OFF, OFFLINE, OID, OIDINDEX, OLD, ON, ONLINE, ONLY, OPAQUE, OPAQUE_TRANSFORM, OPAQUE_XCANONICAL, OPCODE, OPEN, OPERATOR, OPTIMAL, OPTIMIZER_FEATURES_ENABLE, OPTIMIZER_GOAL, OPTION, OPT_ESTIMATE, OR, ORA_ROWSCN, ORDER, ORDERED, ORDERED_PREDICATES, ORGANIZATION, OR_EXPAND, OUTER, OUTLINE, OUT_OF_LINE, OVER, OVERFLOW, OVERFLOW_NOMOVE, OVERLAPS, OWN, PACKAGE, PACKAGES, PARALLEL, PARALLEL_INDEX, PARAMETERS, PARENT, PARITY, PARTIALLY, PARTITION, PARTITIONS, PARTITION_HASH, PARTITION_LIST, PARTITION_RANGE, PASSWORD, PASSWORD_GRACE_TIME, PASSWORD_LIFE_TIME, PASSWORD_LOCK_TIME, PASSWORD_REUSE_MAX, PASSWORD_REUSE_TIME, PASSWORD_VERIFY_FUNCTION, PCTFREE, PCTINCREASE, PCTTHRESHOLD, PCTUSED, PCTVERSION, PERCENT, PERFORMANCE, PERMANENT, PFILE, PHYSICAL, PIV_GB, PIV_SSF, PLAN, PLSQL_CODE_TYPE, PLSQL_DEBUG, PLSQL_OPTIMIZE_LEVEL, PLSQL_WARNINGS, POLICY, POST_TRANSACTION, POWER, PQ_DISTRIBUTE, PQ_MAP, PQ_NOMAP, PREBUILT, PRECEDING, PRECISION, PREPARE, PRESENT, PRESERVE, PRIMARY, PRIOR, PRIVATE, PRIVATE_SGA, PRIVILEGE, PRIVILEGES, PROCEDURE, PROFILE, PROGRAM, PROJECT, PROTECTED, PROTECTION, PUBLIC, PURGE, PUSH_PRED, PUSH_SUBQ, PX_GRANULE, QB_NAME, QUERY, QUERY_BLOCK, QUEUE, QUEUE_CURR, QUEUE_ROWP, QUIESCE, QUOTA, RANDOM, RANGE, RAPIDLY, RAW, RBA, READ, READS, REAL, REBALANCE, REBUILD, RECORDS_PER_BLOCK, RECOVER, RECOVERABLE, RECOVERY, RECYCLE, RECYCLEBIN, REDUCED, REDUNDANCY, REF, REFERENCE, REFERENCED, REFERENCES, REFERENCING, REFRESH, REF_CASCADE_CURSOR, REGEXP_LIKE, REGISTER, REJECT, REKEY, RELATIONAL, RELY, REMOTE_MAPPED, RENAME, REPAIR, REPLACE, REQUIRED, RESET, RESETLOGS, RESIZE, RESOLVE, RESOLVER, RESOURCE, RESTORE_AS_INTERVALS, RESTRICT, RESTRICTED, RESTRICT_ALL_REF_CONS, RESUMABLE, RESUME, RETENTION, RETURN, RETURNING, REUSE, REVERSE, REVOKE, REWRITE, REWRITE_OR_ERROR, RIGHT, ROLE, ROLES, ROLLBACK, ROLLUP, ROW, ROWDEPENDENCIES, ROWID, ROWNUM, ROWS, ROW_LENGTH, RULE, RULES, SAMPLE, SAVEPOINT, SAVE_AS_INTERVALS, SB4, SCALE, SCALE_ROWS, SCAN, SCAN_INSTANCES, SCHEDULER, SCHEMA, SCN, SCN_ASCENDING, SCOPE, SD_ALL, SD_INHIBIT, SD_SHOW,SECOND, SECURITY, SEED, SEGMENT, SEG_BLOCK, SEG_FILE, SELECT, SELECTIVITY, SEMIJOIN, SEMIJOIN_DRIVER, SEQUENCE, SEQUENCED, SEQUENTIAL, SERIALIZABLE,

SERVERERROR, SESSION, SESSIONS_PER_USER, SESSIONTIMEZONE, SESSIONTZNAME, SESSION_CACHED_CURSORS, SET, SETS, SETTINGS, SET_TO_JOIN, SEVERE, SHARE, SHARED, SHARED_POOL, SHRINK, SHUTDOWN, SIBLINGS, SID, SIMPLE, SINGLE, SINGLETASK, SIZE, SKIP, SKIP_EXT_OPTIMIZER, SKIP_UNQ_UNUSABLE_IDX, SKIP_UNUSABLE_INDEXES, SMALLFILE, SMALLINT, SNAPSHOT, SOME, SORT, SOURCE, SPACE, SPECIFICATION, SPFILE, SPLIT, SPREADSHEET, SQL, SQLLDR, SQL_TRACE, STANDBY, STAR, START, STARTUP, STAR_TRANSFORMATION, STATEMENT_ID, STATIC, STATISTICS, STOP, STORAGE, STORE, STREAMS, STRICT, STRIP, STRUCTURE, SUBMULTISET, SUBPARTITION, SUBPARTITIONS, SUBPARTITION_REL, SUBSTITUTABLE, SUCCESSFUL, SUMMARY, SUPPLEMENTAL, SUSPEND, SWAP_JOIN_INPUTS, SWITCH, SWITCHOVER, SYNONYM, SYSAUX, SYSDATE, SYSDBA, SYSOPER, SYSTEM, SYSTIMESTAMP, SYS_DL_CURSOR, SYS_FBT_INSDEL, SYS_OP_BITVEC, SYS_OP_CAST, SYS_OP_COL_PRESENT, SYS_OP_ENFORCE_NOT_NULL$, SYS_OP_MINE_VALUE, SYS_OP_NOEXPAND, SYS_OP_NTCIMG$, SYS_PARALLEL_TXN, SYS_RID_ORDER, TABLE, TABLES, TABLESPACE, TABLESPACE_NO, TABLE_STATS, TABNO, TEMPFILE, TEMPLATE, TEMPORARY, TEST, THAN, THE, THEN, THREAD, THROUGH, TIME, TIMEOUT, TIMESTAMP, TIMEZONE_ABBR, TIMEZONE_HOUR, TIMEZONE_MINUTE, TIMEZONE_REGION, TIME_ZONE, TIV_GB, TIV_SSF, TO, TOPLEVEL, TRACE, TRACING, TRACKING, TRAILING, TRANSACTION, TRANSITIONAL, TREAT, TRIGGER, TRIGGERS, TRUE, TRUNCATE, TRUSTED, TUNING, TX, TYPE, TYPES, TZ_OFFSET, UB2, UBA, UID, UNARCHIVED, UNBOUND, UNBOUNDED, UNDER, UNDO,UNDROP, UNIFORM, UNION, UNIQUE, UNLIMITED, UNLOCK, UNNEST, UNPACKED, UNPROTECTED, UNQUIESCE, UNRECOVERABLE, UNTIL, UNUSABLE, UNUSED, UPDATABLE, UPDATE, UPDATED, UPD_INDEXES, UPD_JOININDEX, UPGRADE, UPSERT, UROWID, USAGE, USE, USER, USER_DEFINED, USER_RECYCLEBIN, USE_ANTI, USE_CONCAT, USE_HASH, USE_MERGE, USE_NL, USE_NL_WITH_INDEX, USE_PRIVATE_OUTLINES, USE_SEMI, USE_STORED_OUTLINES, USE_TTT_FOR_GSETS, USE_WEAK_NAME_RESL, USING, VALIDATE, VALIDATION, VALUE, VALUES, VARCHAR, VARCHAR2, VARRAY, VARYING, VECTOR_READ, VECTOR_READ_TRACE, VERSION, VERSIONS, VIEW, WAIT, WELLFORMED, WHEN, WHENEVER, WHERE, WHITESPACE, WITH, WITHIN, WITHOUT, WORK, WRITE, XID, XMLATTRIBUTES, XMLCOLATTVAL, XMLELEMENT, XMLFOREST, XMLPARSE, XMLSCHEMA, XMLTYPE, X_DYN_PRUNE, YEAR, ZONE

APPENDIX A

Option and property descriptions

In this appendix

Collaboration

Collaboration Notes Browser—Option descriptions

Option	Description
Fields	
Author	Person who created the collaboration note.
Created Date	Date and time the collaboration note was created. READ-ONLY
Description	Description of the collaboration note.
ID	Unique identifier of the collaboration note.
Object Name	Study object to which the collaboration note is attached.
Object Type	Type of study object (such as form or study event) to which the collaboration note is attached.
Type	Collaboration note type on which the collaboration note was based. Collaboration note types are defined in the Central Designer Administrator application.
Toolbar options	
New Note Edit Print Delete	Create, edit, print, or delete the selected collaboration note.
Show Children	• **Selected**—You see all collaboration notes attached to the selected study object and its children. • **Not selected**—You see the collaboration notes that are attached to the selected study object only.
Refresh	Refresh the information in the Collaboration Notes Browser with information from the database.

Collaboration Note Editor dialog box—Option descriptions

Option	Description
Study	(READ-ONLY.) Study with the study object to which the collaboration note is attached.
Object Name	(READ-ONLY.) Study object to which the collaboration note is attached.
Object Type	(READ-ONLY.) Type of study object to which you are attaching the collaboration note, such as a form or study event.

Note Type	(REQUIRED.) Type of the collaboration note. An administrator defines collaboration note types in the Central Designer Administrator application.
Author	(READ-ONLY.) User who created the collaboration note.
Instructions text field	Text for the collaboration note.

Task areas—Field descriptions

The following fields appear in:

- Recent Tasks tab of the Home Page.
- My Tasks section of the Home Page.
- Tasks Browser.

Note: Some fields appear on the Home page, but not in the Tasks Browser. In addition, not all fields appear in the default view. Optionally, you can add the other fields to the browser view, and you can rearrange the order of fields. For more information, see *Showing and hiding a field* (on page 23).

Field	Description
Completed By	Person who completed the task.
Completed Date	Date and time the task was completed. READ-ONLY
Created Date	Date and time the task was created.
Description	Description of the task.
Due Date	Deadline for the task, selected by the task requester. If the task is overdue, the date is red. READ-ONLY
Id	Unique identifier for the task.
Object Name	Study object to which the task is attached.
Object Type	Task type.
Owner	User or team responsible for the task: • Assigned task—The assignee (or assignees). • Accepted task—The accepter. • Completed task—The creator.
Priority	Priority of the task. Options are Critical, High, Medium, and Low.
Project Id	Unique identifier for the project that contains the task.
Project Name	Project that contains the task.
Requested By	Person who created the task.

Field	Description
Status	Status of the task.
Study Id	Unique identifier for the study that contains the task.
Study Name	Study that contains the task.
Type	Task type on which the task is based. An administrator defines task types in the Central Designer Administrator application.

Tasks Browser—Option descriptions

Note: Some fields appear on the Home page, but not in the Tasks Browser. In addition, not all fields appear in the default view. Optionally, you can add the other fields to the browser view, and you can rearrange the order of fields. For more information, see ***Showing and hiding a field*** (on page 23).

Field	Description
Completed By	Person who completed the task.
Completed Date	Date and time the task was completed. READ-ONLY
Created Date	Date and time the task was created.
Description	Description of the task.
Due Date	Deadline for the task, selected by the task requester. If the task is overdue, the date is red. READ-ONLY
Id	Unique identifier for the task.
Object Name	Study object to which the task is attached.
Object Type	Task type.
Owner	User or team responsible for the task: • Assigned task—The assignee (or assignees). • Accepted task—The accepter. • Completed task—The creator.
Priority	Priority of the task. Options are Critical, High, Medium, and Low.
Project Id	Unique identifier for the project that contains the task.
Project Name	Project that contains the task.
Requested By	Person who created the task.
Status	Status of the task.
Study Id	Unique identifier for the study that contains the task.

Field	Description
Study Name	Study that contains the task.
Type	Task type on which the task is based. An administrator defines task types in the Central Designer Administrator application.

Option	Description
New Task Edit Print Delete	Create, edit, print, or delete a task.
Accept Complete Close Reopen Unaccept	Accept, complete, close, reopen, and unaccept a task.
Show Children	• **Selected**—You see all tasks attached to the selected study object and its children. • **Not selected**—You see the tasks that are attached to the selected study object only.
Refresh	Refresh the information in the Tasks Browser with information from the database.

Task Editor dialog box—Option descriptions

The second tab that appears in the Task Editor dialog box depends on the type of task that is selected. For standard tasks, the dialog box has an Instructions tab, and for translation tasks, the dialog box has an Assignment tab.

Option	Description
Top toolbar	
Accept, Complete, Close, Reopen, Unaccept	Accept, complete, close, reopen, and unaccept a task.
Top section	
Study	(READ-ONLY) Study with the study object to which the task is attached.
Object Name	(READ-ONLY) Study object to which the task is attached.
Object Type	(READ-ONLY) Type of study object on which the task was created.
Created	(READ-ONLY) Date and time the task was created.
Requested By	(READ-ONLY) User who created the task.
Status	(READ-ONLY) Status of the task (Open, Accepted, Completed, or Closed).

Option	Description
Task Type	(REQUIRED.) Type of the task. An administrator defines task types in the Central Designer Administrator application.
Priority	(REQUIRED.) Priority of the task. Options are Critical, High, Medium, and Low.
Due	(REQUIRED.) Deadline for when the task must be completed. **Default value**—Current date and time.
Owner	(READ-ONLY) Person or team to which the task is assigned.
Completed By	(READ-ONLY) User who completed the task.
Completed Date	(READ-ONLY) Date and time the task was completed.
Instructions tab	(Appears for standard tasks only)
Instructions text field	Text for the task.
Assignment tab	(Appears for translation tasks only)
[List of roles]	List of roles to which the task can be assigned. If an administrator specified a default role to which the task type is assigned, the role is selected.

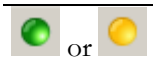
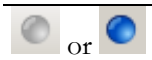
Note: Use the buttons on the toolbar to add an attachment and format the text.

Home page

Home Page—Section descriptions

Section	Description
Recent Projects List	Projects you opened recently. For more information, see *Changing the number of projects that appear in the Recent Projects list* (on page 21).
Pending Approvals Tab	Deployment requests that you can approve. Use the toolbar buttons to approve or reject requests, and view a history of automated deployments.
Recent Tasks Tab	Tasks that are open and assigned to you. Use the drop-down list to see tasks added since yesterday, in the last three days, in the last week, and so on.
My Tasks	All tasks assigned to you.

Status toolbar—Option descriptions

Option	Description
	Appears when study objects are loading.
	You are logged on, and the application is connected to the application server.
	• (Green circle icon)—The application is pulling information from the application server. • (Yellow circle icon)—The application is unable to pull information from the application server. For example, network connectivity might be unavailable, or the server might have stopped responding.
	• (Gray circle icon)—The server is not processing information, and you can work. • (Blue circle icon)—The server is processing information. Wait until the process completes before performing another activity.

Study objects

Export Translations dialog box—Option descriptions

Option	Description
Field	
Locale to translate from	Name of the locale in which the text strings to translate have been defined. **Note:** The Locale to translate from is not the global default locale that is defined in the Tools > Options dialog box, but rather any locale in which the text strings to export exist.
Translate <*locale name*> to	Locale into which strings will be translated.
Target	Target application for which to translate strings.
Export file location	Location and file name in which to store the file of strings to translate. By default the file name has the format: <*StudyName*>_ExportTranslations_<*TargetSystem*>_<SelectedLocale>.csv For example: TestStudy_ExportTranslations_InForm_fr-FR.csv The Browse button enables you to browse to the location.
Include empty locale values	• **If selected**, the file of strings to translate includes strings that are empty in the locale to translate from. • **If not selected**, the export process skips empty strings.
Export log results	Displays messages that are generated during the export. Optionally, you can save these results to a file by clicking the Save Log Results As button.
Button	
Check for Empty Strings	Opens a window listing all strings that are empty in the locale to translate from.
Save Log Results As	Specifies the location of a log file containing the messages that are generated in the Export log results box during the export.

Export Wizard options

Page	Option	Description
Welcome		Introduction page.
Export Type		Select the output format and export type.
	Data Type	**CSML**—Export in Clinical Study Markup Language format. **ODM**—Export in Operational Data Model-compliant format. The Central Designer application supports the ODM 1.3 standard. **Administration data**—Export only study administration data for the User Management Tool application.
	Export Type	**Local**—Export to the computer where the Central Designer application is installed.
Export File Path	Export Directory	Specify the path name and file in which to save the export file, or click Browse to browse for the path name and file in which to save the export file.
Ready to Export Central Designer Data		View a summary of the parameters that will be used for the export.

History Viewer dialog box—Option descriptions

Field	Description
Top section	
Object	Name of the study object.
Unlocked or Locked icon	Indicates whether study object is locked or unlocked.
Object [name of study object] section	
Revision/Version	Revision or version number of the study object, with either *Version* or *Revision* in parentheses to indicate if it is a version or revision. **Note:** This value is for the selected study object only, not for the study in which the study object exists. This value may differ from the value that appears for the Revision property at the bottom of the History Viewer dialog box.
Label	• **If you are viewing versions**—Label given to the version when it was created. • **If you are viewing revisions**—Study Revision.

Field	Description
Altered By	Name of the user who modified the study object for the version or revision.
Date	Day and time when the study object was modified for the version or revision.
Description	• **If the last save created a version**—The label and description applied for the version. • **If the last saved created a revision**—Auto-generated description text.
View changing radio buttons	
View Versions	All versions of the selected study object appear in the top grid.
View Every Edit	All revisions of the study object appear in the top grid.
Buttons	
Differences	(Enabled when you select two versions or revisions.) View the differences between two versions or revisions of a study object.
Revert to	Revert to a previous version or revision of a study object.

Import Wizard options - CSML or ODM file

Page	Option	Description
Welcome		Introduction page.
Import Type		Select the source of the data to import.
	Import CSML or ODM file	Generate study objects from a file in CSML or ODM format.
	Harvest InForm Resources	Generate study objects from the components of an InForm study.
File Location	Path of file to import	Specify the path of the CSML or ODM import file, or click Browse to locate the import file.
Study Administration Import Mode		This page appears only for the CSML import type, if the CSML file contains study administration objects.
	Import study objects and administration data.	Import both study objects and study administration objects.
	Import administration data only.	Import only study administration objects.
	Import study objects only.	Import only study objects.
Rule Import Mode	Rule Import Mode	Only the Import as Collaboration Notes option is supported. With this option, each imported rule is converted to a collaboration note in the Central Designer application. **Note:** This option applies only if the Import Type is ODM; if the Import Type is CSML, the import process creates a Central Designer rule for each imported rule.
IPR Import Mode	Import IPR data	Select whether to import in-place revision objects. **Note:** This page appears only if the file contains in-place revision objects.
Ready to Import Data to Central Designer		View a summary of the import options selected in the wizard.

Import Wizard options - InForm resources

Page	Option	Description
Welcome		Introduction page.
Import Type		Select the source of the data to import.
	Import CSML or ODM file	Generate study objects from a file in CSML or ODM format.
	Harvest InForm Resources	Generate study objects from the components of an InForm study.
InForm File Location		Select the file or trial from which to harvest resources.
	RSP or XML file	Specify the full path of the RSP or XML file containing MedML definitions of InForm trial components to import, or click Browse to browse to the file.
Rule Import Mode	Rule Import Mode	Only the Import as Collaboration Notes option is supported. With this option, each imported rule is converted to a collaboration note in the Central Designer application.
Ready to Import Data to Central Designer		View a summary of the import options selected in the wizard.

References tab—Option descriptions

Option	Description
Top section	
Title	Name of the file or URL attachment.
Preview	Text that appears in the Description section.
(Paper clip button)	Indicates whether the reference has an attachment (a file, shortcut to a file, or URL address).
Details section	
Description	Description of the attachment.
Attachments	All file and URL attachments. **Note:** The default maximum file size is 10 MB. This value can be configured. For more information, see ***Maximum attachment size*** (on page 119) (in the *User Guide*).

Glossary

A

annotated study book

A form-by-form summary of the design of a study. Optionally, it includes a time and events schedule, a preview of each form, and selected annotations that list design details.

See also ***study book*** (on page 162).

application role

A role associated with administrative activities.

arm

See ***study arm*** (on page 162).

authentication

The method of ensuring that you are using the correct user name and password to log on.

authorization

The method of giving users access to information or functionality. Access is controlled using rights, roles, and teams.

automated deployment

The process through which a deployment package is sent directly from the Central Designer application to the InForm application and installed without additional action required.

B

baseline

A snapshot of all components in a study. Validation creates a baseline.

Baselines Browser

A browser in which you view the results of validation and make temporary baselines public so that other users can work with them.

branch

See ***study branch*** (on page 162).

C

calculation rule

A rule that sets the value of an item based on a calculation.

catalog

A collection of categories and keywords that can be attached to users and study objects to facilitate searching in the Libraries Browser and Users Browser.

catalog administration

The process of creating keywords and categories and assigning them to users and study objects for faster and more sophisticated searching.

category

A hierarchical grouping of keywords. You can create categories only from existing keywords.

CDISC

Clinical Data Interchange Standards Consortium. CDISC is an open, multidisciplinary, non-profit organization committed to the development of industry standards to support the electronic acquisition, exchange, submission and archiving of clinical trials data and metadata for medical and biopharmaceutical product development.

checkbox

A type of data entry control in which you can select one or more options by selecting the box that represents each option.

clinical project

See *study project* (on page 162).

clinical protocol

See *protocol* (on page 160).

clinical study

See *study* (on page 161).

codelist

A collection of code-label pairs that gather together the entry choices for an item. A code-label pair consists of a single code (the value that is used for analysis) and a label (the value that is visible to users).

See also *codelist item* (on page 156).

codelist item

A code-label pair consisting of a single code (the value that is used for analysis) and a label (the value that is visible to users). Multiple codelist items make up a codelist.

See also *codelist* (on page 156).

coding

The process of selecting terms and codes from a dictionary for a verbatim.

coding dictionary

A standardized collection of terms and the codes that correspond to those terms.

coding map

A study object that contains the necessary information to code an item.

coding target

See *target item* (on page 163).

collaboration

The process by which users with different roles and specialties can work together to create, validate, and deploy a study.

collaboration note

A note that you attach to any study object.

collaboration note type

A classification used to identify the type and purpose of a collaboration note.

Collaboration Notes Browser

A browser in which you work with collaboration notes.

common form

A form that is designed for use with multiple study events. The same data appears in the form in all study events in which the form is used.

component

Any design building block that is configured in a study or library. Design components include study objects (such as a project, study, study element, study event, form, or item) as well as rules, individual items selected from drop-down lists, and controls (such as checkboxes and radio buttons).

compound item

An item that has one or more child items that can have different data types.

constant

A value that is defined in a library or study and that can be referenced by any rule.

constraint rule

A rule that checks whether data is valid. Constraint rules are used to confirm that clinical data meets the requirements of the clinical protocol.

container

A node in the Project Explorer that contains zero or more study objects or components.

context item

An item that provides additional coding information, such as the indication and route of administration

for drugs, that can be displayed with an item coded using the WHO-DD dictionary.

CSML

Clinical Study Markup Language. CSML is an XML-based markup language developed by Oracle for representing and exchanging clinical data definitions created in the Central Designer application.

See also *MedML* (on page 160).

custom data dimension

See *data dimension* (on page 157).

custom property

A user-defined or default characteristic of a study object.

D

data dimension

A key item for a data set. A data dimension specifies the additional information that will be saved when study data is collected. You can specify standard data dimensions (Study, Subject, Event and Event Index, Form and Form Index, and Item) and custom data dimensions.

data series

A grouping of one or more items with the same clinical meaning, such as one or more items that measure weight.

See also *data set* (on page 157), *mapping* (on page 159).

data set

A grouping of one or more related data series.

See also *data series* (on page 157), *mapping* (on page 159).

data type

An attribute for items and data series. For an item, the data type determines the type of entry an item will accept. For a data series, the data type determines which items can be added to it. Data types include date time, integer, float, and text.

data-entry rule

A rule that checks whether data is valid or that sets the value of an item based on a calculation.

See also *workflow rule* (on page 164).

date time item

An item used to collect date and time information on a form.

deployment

The process of sending a study to a target application. To collect data, a study must be deployed into a target application as a complete deployment package.

deployment approval

The optional process by which a study deployment is approved by a user with the appropriate rights.

deployment instance

The server to which you deploy a study.

deployment request

A request from a user with the appropriate rights to initiate an automated deployment to the InForm application.

dictionary metadata item

An identifier that describes administrative data about a dictionary and that you can use to create a coding map.

dictionary type

A name or identifier for the metadata for a dictionary.

drop-down list

A data entry format in which you select an option from a list.

dynamic form

A form that is automatically generated in the InForm application when subject data satisfies certain criteria tested in another form.

dynamic visit

A visit that is automatically generated in the InForm application when patient data satisfies certain criteria tested in another visit.

E

edit check

A data-entry rule that checks whether entered data is valid.

See *data-entry rule* (on page 157).

element

See *study element* (on page 162).

event

See *study event* (on page 162).

explicit lock

A lock that you request and that does not expire.

See also *implicit lock* (on page 158).

expression

The part of a rule that specifies what to evaluate.

F

field

The area in a data-entry window where the value for an item is entered or displayed.

float item

An item used to collect numerical values with decimal points.

form

A container for one or more items. A form can contain one or more sections and supports multiple locales and layouts. A form is deployed to a target application as a data-entry form used to collect subject information and other clinical data.

full installation deployment package

A deployment package that contains everything needed to deploy a complete study.

function

A reusable piece of code that extends the behavior of a rule. A function can be predefined or user-defined.

G

global condition

A logical construct that, when applied to a study object, determines whether the study object will appear for a particular subject. A global condition does not affect other study objects in the workflow.

See also *workflow rule* (on page 164).

globals

Study objects and properties that are related to mappings.

grouping

A default or user-provided value used to organize custom properties of a study object.

I

implicit lock

A type of lock used when you edit a study object. An implicit lock is automatically applied when you select or open a study object and is automatically released when you close or save a study object.

See also *explicit lock* (on page 158).

incremental deployment package

A deployment package that contains a complete study based on a previously created deployment package, plus any additions or changes.

in-place revision (IPR)

A study design change that is applied to existing study versions previously deployed to the InForm application.

integer item

An item used to collect a numerical value without a decimal point.

internationalization

The process of configuring a study for translation into different languages or for different regional requirements.

intrinsic rule

A constraint rule or calculation rule based on a predefined rule template.

item

A study object used as a container for the collection of clinical data.

item group

A study object used to combine items so that you can set their display override options in the InForm application.

J

Job Log Browser

A browser in which you view the results of asynchronous jobs, such as validation or import.

K

keyword

An identifier that is associated with users and study objects to facilitate more powerful and efficient searches.

L

Libraries Browser

A browser in which you search the repository for study objects and then add them to studies or libraries.

library

A container used to store related study objects and templates to be published for reuse in studies or other libraries. A library provides a view of the study objects in the repository.

See also *repository* (on page 161).

Library List

A hierarchical list of libraries from which resources can be used. The hierarchy determines the order in which libraries are searched. The Library List is defined for each study in the Study Editor.

library project

A project containing a library.

library role

A role associated with library activities.

library team

A group of users who have rights granted by a certain role to perform tasks in a particular library.

locale

A supported language or language variation.

localization

The process of designing a study for a specific locale.

locked

A state in which only the user who created the lock can modify a study object. Locks can be implicit or explicit.

See also *implicit lock* (on page 158), *explicit lock* (on page 158).

M

mapping

A data grouping that provides an alternate data view of a study. Mappings were previously called logical schemas.

See also *data series* (on page 157), *data set* (on

page 157).

MedML

An XML-based markup language developed by Oracle for representing and exchanging clinical data definitions created in the InForm application..

See also ***CSML*** (on page 157).

method

A block of code that is called by a rule and that is used to manipulate data.

N

normalization

The process of converting data to a required format.

O

object

See ***study object*** (on page 162).

ODM

Operational Data Model. ODM is an XML-based standard developed by the Clinical Data Interchange Standards Consortium (CDISC) for representing and exchanging clinical data.

P

precondition

The part of a rule that specifies when to evaluate the rule expression.

project

See ***library project*** (on page 159) and ***study project*** (on page 162).

Project Explorer

A browser that displays a view of the open project and the study objects it contains.

Properties Browser

A browser in which you can view and modify the properties of the study object selected in the Project Explorer.

property

A defining characteristic of a study object.

protocol

A detailed plan that describes how investigators conduct a study. The clinical protocol sets the guidelines for the study, describes the conditions of the study, and contains a set of forms on which clinical data is collected.

publish

The action that makes a study object created in a library available to other users.

See also ***unpublish*** (on page 163).

Q

query

A text string that appears on a CRF item in the InForm application when a rule on that item fails. When designing a rule in the Central Designer application, you can specify the query text and the circumstances under which a rule results in a query.

query group

A study object used to specify the users who can act on queries created by other members of the group in the InForm application.

R

radio button

A type of data entry format in which you must select a single item from a list of choices.

reference

A text note, a link to a Web page or file (URL), a document, or a combination of all three, that is attached to a study project for users to consult during the development of a study.

RefName

A unique identifier for a study object.

repeating form

A type of form for which the *Repeating* property is

set to true. You use a repeating form to collect multiple instances of the same data at different dates and times.

repository

A single database instance that contains all Central Designer study objects, components, and users.

revision

An audit history record that is created automatically when a user edits a study object and saves the changes.

right

A predefined permission that controls access to a specific feature or activity in the Central Designer client or Central Designer Administrator client and that can be assigned to one or more roles.

See also *role* (on page 161).

rights group

A study object used to create a set of predefined InForm rights in the InForm application.

role

A collection of rights. When a user is assigned to a role, the rights associated with the role are granted to the user.

See also *library role* (on page 159), *study role* (on page 162), and *user role* (on page 163).

role administration

The process of managing tasks that users perform in the Central Designer and Central Designer Administrator applications, assigning rights to roles, and assigning roles to users.

rule

See *data-entry rule* (on page 157), *workflow rule* (on page 164).

rule action

The action, or actions, that takes place as a result of the evaluation of a rule expression.

rule scope

The set of study objects that a rule can reference. The scope of a rule is determined by the study object on which the rule is defined.

rule template

A function that is defined on a study object, study object template, or study object type and can be used as the expression clause of a rule.

rule type

See *calculation rule* (on page 155), *constraint rule* (on page 156), and *intrinsic rule* (on page 159).

S

SDTM

Study Data Tabulation Model. SDTM is a CDISC model used to standardize data structures in data extracts.

shared form

See *common form* (on page 156).

signature group

A study object used to specify the forms that require signature and the signature type in the InForm application.

site

A location that participates in a study.

sponsor

A study object used to define the sponsor properties of a study, such as name or address, in the InForm application.

standard data dimension

See *data dimension* (on page 157).

standard task type

A task type that is typically used for all non-translation tasks assigned to an individual or team.

study

The definition of the workflow, data-entry, and data-management system for a clinical study.

study administration object

A collection of study objects that are used to capture study administration data for deployment to the InForm application.

See also *item group* (on page 159), *query group* (on page 160), *rights group* (on page 161), *signature group* (on page 161), *sponsor* (on page 161), *study configuration* (on page 162).

study arm

The CDISC term for a study branch consisting of a planned sequence of study elements. A study arm is typically equivalent to a treatment group.

study book

The set of forms used to collect clinical data.

See also *annotated study book* (on page 155).

study branch

A path for which data is collected for certain subjects. A study can contain multiple branches as different conditions are assessed, and a branch is followed depending on the subject and other circumstances.

study configuration

A study object used to specify the value of an InForm configuration variable in the InForm application.

study design

A container for the structure of a study.

study element

The CDISC term for a basic building block of a study. A study element represents a segment of a study and can consist of one or more study events. Study elements are optional.

study event

A subject evaluation checkpoint when data is collected. Study events usually correspond to visits, but one visit can span multiple study events.

study object

A study building block that appears in the Project Explorer. Study objects include study projects, library projects, studies, libraries, study elements, study events, forms, sections, items, codelists, codelist items, deployment instances, in-place revisions, and study administration objects.

See also *component* (on page 156) and *study administration object* (on page 162).

study object editor

An editor for each study object, such as a project, study, study element, study event, form, or item. A study object editor appears in the workspace when you select a study object.

study project

A project containing one or more studies that are related to each other.

study role

A role associated with study activities.

study team

A group of users who perform tasks granted by a certain role for a particular study.

study workflow

See *workflow* (on page 164).

subject

An individual who participates in a clinical study.

system

An application to which you deploy a study from the Central Designer application.

system configuration administration

The process of creating, configuring, and managing

internationalization, collaboration, and customization information using the Central Designer Administrator application.

T

target item

An item that holds a term, code, or additional information after a verbatim is coded.

task

A request that you attach to a study object and assign to an individual or a study team.

task classification

The classification of a task. You can choose either standard (used for all non-translation tasks assigned to an individual or team) or translation (used for tasks that request translation of a study object into one or more languages). You define the classification for task types in the Central Designer Administrator application.

task type

A classification used to identify the type of the task and the way the task is used.

Tasks Browser

A browser in which you work with tasks.

team

See *study team* (on page 162), *library team* (on page 159).

template

A study object that is either partially or fully defined and that can be used to create other study objects. You can create templates for study projects, studies, study elements, study events, forms, items, codelists, and mappings.

text box

A data-entry format in which you type data.

text item

An item used to collect alphanumeric information.

translation task type

A task type that is used for tasks that request translation of a study object into one or more languages.

type

A study object that is either partially or fully defined and can be used to create other study objects. Types are like templates except that types appear as options in the Actions menu and in the Project Explorer menu when you create a new study object.

U

unpublish

The action that makes a study object in a library no longer available to other users.

See also *publish* (on page 160).

user

A person who works in the Central Designer or Central Designer Administrator application.

user administration

The process of managing users.

user role

A role associated with user activities.

Users Browser

A browser in which you search the repository for users and then add them to study teams or library teams.

V

validation

The process of checking the status of a study to indicate if the study is ready for deployment. The study validation process determines whether all essential components exist and are consistent.

verbatim

The original reported text that describes the adverse event, disease, drug, or other item to be coded in the Central Coding application.

verbatim type

A classification of a verbatim as defined in a coding dictionary.

version

An explicitly requested audit history record for a study object.

visit

See *study event* (on page 162).

W

workflow

The progression of work for a study, as determined by the study designers.

workflow rule

A logical construct that tests data values to determine the study element, study event, or form to which a subject progresses next. A workflow rule prevents study objects in the workflow from appearing until the rule is evaluated.

See also *data-entry rule* (on page 157), *global condition* (on page 158).

workspace

The work area of the Central Designer and Central Designer Administrator applications. The contents of the workspace depend on the type of activity you are performing and the rights that you have been granted. The workspace displays the editor for the study object that is selected in the Project Explorer.

Y

yes no item

An item used to collect yes or no answers to questions. A yes no item contains a predefined codelist with Yes and No options.

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