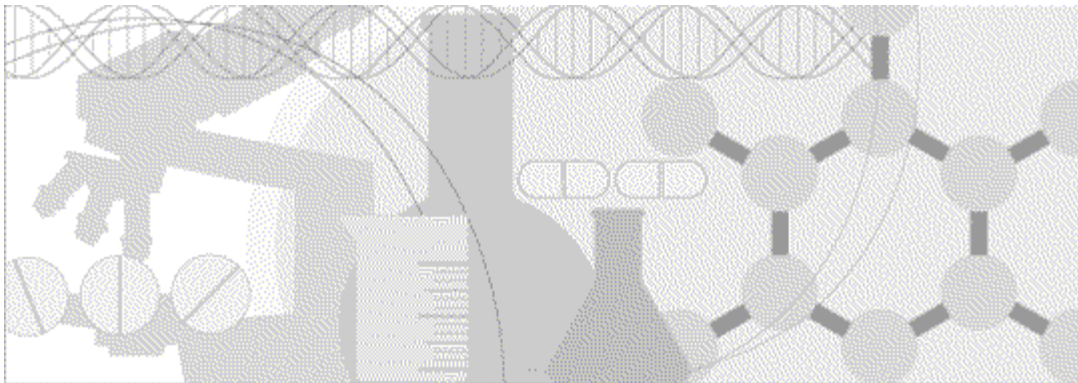


# InForm Design Guide

Oracle<sup>®</sup> Health Sciences Central Designer  
Release 2.1



ORACLE<sup>®</sup>

Part Number: E55017-01

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# About this guide

## In this preface

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## Overview of this guide

The *InForm Design Guide* describes how to design a study for deployment to the InForm application.

## Audience

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

| 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.   |
| 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.   |

## 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.               | <ul style="list-style-type: none"><li>• Understanding of C# or similar (for example, Java, C, or C++) expression syntax.</li><li>• Ability to incorporate functions in expressions.</li></ul> |
| User-defined functions.                  | <ul style="list-style-type: none"><li>• Ability to program in a .NET language (for example, C#) and create .NET assemblies.</li></ul>   |

# 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   |
|------------------------------|---|
| <i>Release Notes</i>         | The <i>Release Notes</i> document provides detailed information about the requirements, enhancements, and fixed issues in the current release.  |
| <i>Known Issues</i>          | The <i>Known Issues</i> document provides detailed information about the known issues in this release, along with workarounds, if available.  |
| <i>Installation Guide</i>    | The <i>Installation Guide</i> 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.   |
| <i>Administrator Guide</i>   | The <i>Administrator Guide</i> describes how to use the Oracle® Health Sciences Central Designer Administrator software to set up users, permissions, system configuration parameters, and catalog defaults.  |
| <i>User Guide</i>            | The <i>User Guide</i> 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: <ul style="list-style-type: none"> <li>• Work collaboratively.</li> <li>• Maximize study design efficiency by reusing study objects.</li> <li>• Manage collections of study objects.</li> </ul> |
| <i>InForm Design Guide</i>   | The <i>InForm Design Guide</i> describes how to design a study for deployment to the InForm application.  |
| <i>Rules Reference Guide</i> | The <i>Rules Reference Guide</i> is a reference to the tools that are available for creating rule expressions, including: <ul style="list-style-type: none"> <li>• Study object properties.</li> <li>• Functions.</li> <li>• Constants.</li> <li>• Data mappings.</li> <li>• Methods, operators, and literals.</li> </ul>   |

| Item                                    | Description   |
|---|---|
| <i>Secure Configuration Guide</i>       | The <i>Secure Configuration Guide</i> 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. |
| <i>Third Party Licenses and Notices</i> | The <i>Third Party Licenses and Notices</i> 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](http://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>).



## CHAPTER 1

# Setting up and administering a study

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## Creating a study

You can create a study from scratch or from a template. When you create a study, the Central Designer application creates a study project with the same name by default. You can change the study and project name when creating the study.

- 1 Select **File > New Study Project**.

The New Study dialog box appears.

- 2 Type a name and description.
- 3 From the **Templates** list, select a template. The list contains all templates that are saved in the repository. Because templates do not have versions, the template that you choose is the latest.

**Note:** To base the study on no template, choose <none>.

- 4 In the **Targets** section, select the target applications to which the study can be deployed.
- 5 To change the name of the associated study project, select the **Project** tab, and type a name, description, and template for the study project.
- 6 Click **OK**.

## Choosing the phase of a study

- 1 In the Project Explorer, select **Study Information**.
- 2 Select the study.  
The Study editor appears in the workspace.
- 3 Select the **General** tab.
- 4 From the **Phase** drop-down list, select the phase of the study.

## Choosing a sponsor for a study

- 1 In the Project Explorer, select **Study Information**.
- 2 Select the study.  
The Study editor appears in the workspace.
- 3 Select the **General** tab.
- 4 From the **Sponsor** drop-down list, select the sponsor to associate with the study.

## Editing the properties of a study

### To edit the properties of a study:

- 1 In the Project Explorer, select **Study Information**.
- 2 Select the study.
- 3 Open the **Properties Browser** (located by default at the far right of the application window).
- 4 Modify the properties as necessary.

### To edit the properties of a study project:

- 1 In the Project Explorer, select **Study Information**.
- 2 Select the study project.
- 3 Open the **Properties Browser** (located by default at the far right of the application window).
- 4 Modify the properties as necessary.

## Setting the primary layout for a study

Every layout requires a primary layout, or validation fails. An icon on the tab that contains the name of the layout (at the bottom of the Layout tab) indicates the primary layout.

You set the primary layout for a study at the study level. The first layout that you create for a form or item is given the name of the primary layout.

When you convert all layouts or a form with multiple layouts, you are prompted to choose the primary layout, and depending on the option you choose, it is or can be renamed to the name of the primary layout.

**Note:** Changing the name of the primary layout affects all forms. If a form has a layout named **Main**, and you choose to use the layout named **Spanish** as the primary layout, then all layouts named **Spanish** become the primary layouts.

- 1 Select **Tools > Layout Names Manager**.

The Layout Names Manager appears.

- 2 In the **Primary layout name** section, select one of the following options:

- **Use Main as the primary layout name**—The layout named Main is the primary layout.
- **Use the following as the primary layout name**—The layout that you choose from the drop-down list is the primary layout.

- 3 Click **OK**.



# Selecting locales

## Choosing the supported locales for a study

You must choose locales to create a layout, translate information, and create Help.

You choose the default locale for a study in the Central Designer application. For more information, see *Choosing the default locale for a study* (on page 9).

- 1 In the Project Explorer, select **Study Information**.
- 2 Select the study.
- 3 Select the **Languages** tab.
- 4 From the **Languages/Locales** list, select the locale or locales for the study.

**Note:** Only the locales selected in the Central Designer Administrator application appear in the list.

## About choosing the default locale for a study

### About the default locale

The default locale for a study is used to store study metadata that can be localized. For more information, see *Choosing the default locale for a study* (on page 9).

- After modifying the default locale, you do not need to restart the Central Designer application.
- If you do not set the default locale, the regional setting is used. The regional setting is set in the Control Panel > Regional and Language Options > Regional Options tab > Standards and formats section. If you modify the regional setting, you must close and reopen the Central Designer application to use the new locale.
- You select from the same list of locales that are available when you specify a regional setting.

### Display properties that the default locale affects

The default locale affects the display properties of the following:

- Some fields, such as the Default Question for a form, display the text for the default locale.
- The title bar in the workspace displays the default locale. For example: **Form : Demographics - - en-US**
- Float numbers are formatted according to the numeric standards for the default locale.  
For more information, see *Acceptable formatting for float values* (on page 11).

### Typing translated data

You can enter translated data in the following ways:

- You can enter translated data without specifying the locale, and the data is saved as data for the default locale. For example, you can enter the Default Question of an item in the Item Editor > Design tab > Default Question field.
- You can enter translated data explicitly for a locale, and the data is saved as data for the specified locale. For example, you can enter the Default Question of an item in the Item Editor > Design tab > Languages section > Question field.

For more information, see *Where to enter translated text* (on page 253).

### Making sure that the language in which you develop a study is the default locale for which study metadata is saved

To design a study for any locale, you must make sure that:

- In the Central Designer Administrator application, the locale is selected.
- In the Central Designer application, the locale is selected for the study.
- The user profiles in the Central Designer Administrator application list the locale as a skill.

## Choosing the default locale for a study

If you do not specify a locale for localizable study data, the data is saved according to the default locale for the study. Study data that is not localizable, such as a RefName, is not saved according to a locale. You specify a default locale in the Central Designer application. You do not need to restart the Central Designer application after selecting a default locale.

- 1 Select **Tools > Options**.

The Central Designer Options dialog box appears.

- 2 From the **Default locale** drop-down list, select a locale.

**Note:** If you do not select an option, the regional setting is used as the default locale. The regional setting is set in the Control Panel > Regional and Language Options > Regional Options tab > Standards and formats section.

- 3 Click **OK**.

## How to develop a study across multiple locales

You specify the default locale for a study in the Central Designer application. Localizable study metadata is saved according to the default locale.

### Language in which to type text values

You can enter item questions, labels, and text strings in any language, regardless of the default locale for the study. However, in some places, such as the Design tab of the Form Editor, you can enter labels and question text without specifying a locale. In these cases, the default locale determines the language or locale that is assigned to the entered text. If the default locale is not included in the list of supported locales for the study, the entered text is saved for the locale but is not deployed. Only the supported locales for the study are deployed.

### Typing text values using an explicit locale

If you work on a study with a locale that is different from the default locale, you can enter a study object's properties with an explicit locale. See the following table for places where the default locale is used and where you can specify an explicit locale.

| Study object | Property    | Specify a value in the default locale here | Specify a value in an explicit locale here |
|--------------|-------------|--|--|
| Study event  | Title       | Study Event Editor > General tab           | Study Event Editor > General tab           |
|              | Short Title | Study Event Editor > General tab           | Study Event Editor > General tab           |
| Form         | Short Title | Study Forms Editor                         | Form Editor > General tab                  |
|              | Form Title  | Not available.                             | Form Editor > Layout tab                   |

| Study object  | Property       | Specify a value in the default locale here  | Specify a value in an explicit locale here |
|---------------|----------------|---|--|
| Item          | Question       | <ul style="list-style-type: none"> <li>Form Editor &gt; Design tab</li> <li>Study Items Editor</li> </ul>   | Item Editor > Design tab                   |
|               | Short Question | <ul style="list-style-type: none"> <li>Form Editor &gt; Design tab</li> <li>Study Items Editor</li> </ul>   | Item Editor > Design tab                   |
|               | Caption        | Not available.  | Form Editor > Layout tab                   |
| Codelist item | Label          | <ul style="list-style-type: none"> <li>Item Editor &gt; Design tab</li> <li>Codelist Editor &gt; Design tab</li> <li>Study Codelist Items Editor</li> </ul> | Codelist Item Editor > Languages tab       |

| Rule component     | Specify a value in the default locale here | Specify a value in an explicit locale here |
|--------------------|--|--|
| Query text         | Not available.                             | Query Action dialog box.                   |
| Subject or Message | Not available.                             | Email Action dialog box.                   |

## Acceptable formatting for float values

You can enter float values according to numeric standards for:

- The *default locale for the study* (on page 9).

**Note:** Oracle recommends entering float data according to the numeric settings of the default locale for the study.

- The invariant locale. The invariant locale is a locale used by applications when a consistent and locale-independent result is required. The settings of the invariant locale are similar to English (United States).

For example, if French (France) is the default locale for a study and you want to type a number with a decimal point, you can:

- Type "123,45" according to French numeric standards.
- Type "123.45" according to numeric standards of the invariant locale.

The formatting of a float value depends on the default numeric settings for the default locale. For example, if the default locale is French (France), and you type a value of "123.45," the number appears as "123,45" after you navigate to a different part of the application and return.

If you change the numeric settings for the default locale—for example, if you change the decimal point character for the French locale from a comma to a period—the default settings are still used. In this example, a comma is still used as the decimal point character.

**Note:** Characters used to separate groups of digits for large numbers (in the United States, a comma is used) are never saved with float values.

You can type float values for:

- Codelists.
- Value list numbers for custom properties.
- Sequence numbers of workflow objects.

## Saving a study or library project

When you save a study or library project, any study objects that were modified are saved, along with any administrative modifications that were made to the project since it was last saved.

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

**Note:** If you uninstall a deployment system, you cannot save a project that contains study objects for that system.

## Deleting a study or project

When you delete a study, study project, or library project, the contents are permanently removed from the database.

**Note:** You cannot delete or archive the System Library or its project.

- 1 (Optional but highly recommended) Perform a full database backup.
- 2 (Optional) *Archive the study or project* (on page 313).
- 3 In the Project Explorer, right-click a study, study project, library, or library project, and select **Delete**.

A confirmation message appears.

The message indicates if the latest version of the selected study, or any of the studies or libraries in the selected project, has not been archived.

- 4 Click **Yes**.  
You receive a message that recommends performing a full database backup before deleting.
- 5 Click **Yes**.

# Selecting supported libraries

## Choosing the libraries to use for a study

Users who are designing a study can search for study objects only in the supported libraries.

**Note:** After choosing one or more libraries to use for a study, you can set the order of libraries in the Libraries List. For more information, see *Setting the order of libraries in the Libraries List for a study* (on page 13).

### To add a library to the Libraries List:

- 1 In the Project Explorer, select **Study Information**.
- 2 Select the study.
- 3 Select the **Libraries** tab.
- 4 Click **Add**.

The Add Study Library dialog box appears.

- 5 Select one or more libraries that you want to add to the study, and click **OK**.

### To remove a library from the Libraries List:

- 1 In the Project Explorer, select **Study Information**.
- 2 Select the study.
- 3 Select the **Libraries** tab.
- 4 In the **Libraries List**, select the library that you want to remove.
- 5 Click **Remove**.

You cannot remove the System Library.

## Setting the order of libraries in the Libraries list for a study

You must choose libraries before you can set their order in the Library List. For more information, see *Choosing the libraries to use for a study* (on page 13).

- 1 In the Project Explorer, select **Study Information**.
- 2 Select the study.
- 3 Select the **Libraries** tab.
- 4 In the **Libraries** list, select a library.
- 5 Click one of the following buttons:
  - **Up**—Move the library up in the list.
  - **Down**—Move the library down in the list.

# Setting up study teams

## Users Browser searches

To open the Users Browser:

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

| Characteristic                | Description   |
|-------------------------------|---|
| Use                           | <p>To find users and add them to:</p> <ul style="list-style-type: none"> <li>• A study team (in a study project), which an administrator creates as a role with a study scope in the Central Designer Administrator application.</li> <li>• A library team (in a library project), which an administrator creates as a role with a library scope in the Central Designer Administrator application.</li> </ul> <p><b>Note:</b> A user must be assigned to the corresponding role to be added to a team.</p> |
| Location of the Users Browser | By default, the browser is located to the right in the application window.  |
| Features                      | <p>You can:</p> <ul style="list-style-type: none"> <li>• Create and save search criteria for personal or global use.</li> <li>• Open, close, delete, rename, and switch to different searches.</li> </ul>   |
| Required search parameters    | No required parameters.   |
| Optional search parameters    | <p>Use one, several, or none of the following:</p> <ul style="list-style-type: none"> <li>• Text</li> <li>• Categories</li> <li>• Keywords</li> </ul> <p>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.</p>   |
| How the search is performed   | <p>Text, keywords, categories, and libraries are connected with the AND operator. Criteria within each parameter are connected with the OR operator. For example:</p> <ul style="list-style-type: none"> <li>• Text that you type<br/>AND</li> <li>• Keyword1 OR Keyword2<br/>AND</li> <li>• Category1 OR Category2</li> </ul>  |



| Characteristic                | Description  |
|-------------------------------|--|
| Which information is searched | <p>User names, display names, titles, first names, and last names of:</p> <ul style="list-style-type: none"> <li>• Active users</li> <li>• Inactive users</li> </ul> <p><b>Note:</b> You can add inactive but not terminated users to teams. View the status of users in the Central Designer Administrator application.</p> |
| Search results                | Users are listed in alphabetical order according to display name, with user names in parentheses.  |


## Finding and adding a user to a study team and saving the search

An administrator creates study teams as study 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 Rule Creation study role in the Central Designer Administrator application, the user must also be a member of the Rule Creation study team for a study to create rules in the study. 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 study team for the selected study only.

**Note:** To view all users, click **Find** without entering parameters. Depending on the size of the repository, this search might take several minutes. For more information on saving a Users Browser search, see the *User Guide*.

### To add a user to a study team:

- 1 Select the **Users Browser**.
- 2 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.
- 3 In the **Enter search text** field, type text that appears in the user's name or display name, title, first name, or last name.
- 4 To include categories and keywords 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**.

- 5 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 14).

- 6 In the Project Explorer, select **Study Information**.

- 7 Select a study.

- 8 Select the **Teams** tab.

All study roles created in the Central Designer Administrator application appear.

- 9 In the **[Study name] - Teams** section, select the team to which you want to add the user.

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

- 10 In the **Users Browser**, select the user that you want to add, and drag the user to the right section.

The user is added to the team.

**Note:** You can also add a user to a team by dragging the user directly to the team name in the left section.

- 11 Optionally, add the user to more teams, or add different users to teams.

**Note:** The user that you added must log out and log on again to have the privileges associated with the team.

## Saving a search in the Users Browser

- 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**.

## 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      | <ol style="list-style-type: none"> <li>1 Select <b>Attach file</b>.<br/>The Open dialog box appears.</li> <li>2 Navigate to the file that you want to attach, select the file, and click <b>Open</b>.<br/>A reference to the file appears in the Attachments section.</li> </ol> |

| To attach the following   | Perform these steps  |
|---------------------------|--|
| Physical copy of a file   | <ol style="list-style-type: none"> <li>1 Select <b>Copy and Attach File</b>.<br/>The Open dialog box appears.</li> <li>2 Navigate to the file that you want to attach, select the file, and click <b>Open</b>.<br/>The file appears in the Attachments section.</li> </ol> |
| Shortcut to a URL address | <ol style="list-style-type: none"> <li>1 Select <b>Attach URL</b>.<br/>The Attach URL dialog box appears.</li> <li>2 In the field, type the URL address.<br/>A shortcut to the URL appears in the Attachments section.</li> </ol>  |

**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**.

# Study administration data

## About study administration data

You can capture study administration data— item, query, rights, and signature groups, sponsor information, and system settings—that is associated with a study. When you deploy the study to the InForm application, you can include the administration data along with the study.

For more information, see *About deployment packages* (on page 276).

## Study administration data rights

To create, update, or remove study administration data, your administrator must assign you Modify Study Administration Data rights. If a user who navigates to an administration data editor does not have rights to modify study administration data, the information that appears in the editors is read-only.

## Study administration data editors

You capture administration data using the following editors:

- **Sponsor editor**—Defines the study sponsor and contact details.
- **System Settings editor**—Specifies system settings that are specific to an InForm release.
- **Item Groups editor**—Combines previously defined items into a group to set the group's display options within a rights group.
- **Query Groups editor**—Defines a query group.
- **Rights Group editor**—Combines previously defined items into groups to set the display options of the groups within a rights group.
- **Signature Groups editor**—Combines a set of users who can sign case report books and forms.

## Sponsor settings

Both you and the administrator can create sponsors and detailed sponsor information. Sponsor information is for documentation and reporting only; this information does not appear in the InForm application user interface.

When the administrator creates sponsors and sponsor details using the Central Designer Administration application, the study is propagated to the Central Designer application and is available for use in studies.

In the Central Designer application, when you create new sponsors and detail information, the sponsor names, but not the detail information, are propagated back to the Central Designer Administration application. You also can override sponsors and details that the administrator creates. The changes you make are not propagated back to the Central Designer Administration application.

## Selecting a sponsor to associate with a study

- 1 In the Project Explorer, select **Study Information > Administration**.  
The Study Administration workspace appears.
- 2 Select the **Sponsor** tab.  
The Sponsor editor appears.
- 3 From the **Sponsor Name** drop-down list, select a sponsor to associate with the study.  
The sponsor detail information appears in the fields.

## Adding a sponsor to a study

- 1 In the Project Explorer, click **Study Information > Administration**.  
The Study Administration workspace appears.
- 2 Select the **Sponsor** tab.  
The Sponsor editor appears.
- 3 Choose the information for the organization that is sponsoring the study.

**Note:** The only required field in the Sponsor editor is the Sponsor Name.

For more information, see *Sponsor tab of the Administration editor—Option descriptions* (on page 22).

## Editing sponsor detail information

- 1 In the Project Explorer, click **Study Information > Administration**.  
The Study Administration workspace appears.
- 2 Select the **Sponsor** tab.  
The Sponsor editor appears.
- 3 From the drop-down list, select the sponsor, and edit the detail information.

## Removing a sponsor from a study

- 1 In the Project Explorer, click **Study Information > Administration**.  
The Study Administration workspace appears.
- 2 Select the **Sponsor** tab.  
The Sponsor editor appears.
- 3 From the drop-down list, select the sponsor you want to remove from the study.
- 4 Click **Clear Sponsor**.

## Sponsor tab of the Administration editor—Option descriptions

| Option           | Description  |
|------------------|--|
| Sponsor Name     | Name of the organization that is sponsoring the study. |
| Program          | Name of the program.                                   |
| Therapeutic area | Medical area that is being investigated by the study.  |
| Note             | Additional information you may want to include.        |
| Address 1        | Sponsor street address.                                |
| Address 2        | Additional address information.                        |
| City             | City.  |
| State            | State (United States).                                 |
| Zip code         | Zip code (United States).                              |
| Province         | Province (outside the United States).                  |
| Postcode         | Postcode (outside the United States).                  |
| Country          | Country.   |
| Phone            | Telephone number.                                      |
| Alt phone        | Alternate telephone number.                            |
| Fax              | Fax number.  |
| Email address    | Email address.   |

## System settings

System settings specify information that is specific to the InForm release you are using.

The system settings are installed when the Central Designer application is installed. When you create a new study, it does not have system settings. You need to add the system settings to the study.

### About the System Settings editor

The System Settings editor has three columns. You can change only the fields in the Value column; the fields in the other columns are read-only.

The rows in the System Settings editor are fixed. You cannot add or delete any rows.

### Adding system settings to a study

- 1 In the Project Explorer, select **System Settings**.  
The Study Administration workspace appears.



- 2 Select the **System Settings** tab.  
The System Settings editor appears.
- 3 From the **Settings** drop-down list, select the settings for an InForm release.  
The System Settings editor is populated with settings for the InForm release you selected.

## Editing system settings

- 1 In the Project Explorer, select **System Settings > Administration**.  
The Study Administration workspace appears.
- 2 Select the **System Settings** tab.  
The System Settings editor appears. The editor is populated with the system settings for the InForm release you selected when you added the system settings to the study.
- 3 In the Value column, edit the settings either by typing or by selecting from the drop-down lists.  
For more information, see *System settings tab of the Administration editor—Option descriptions* (on page 24).

## Restoring default values

- 1 In the Project Explorer, select **System Settings > Administration**.  
The Study Administration workspace appears.
- 2 Select the **System Settings** tab.  
The System Settings editor appears and is populated with the system settings for the InForm release you selected when you loaded the system settings.
- 3 In the toolbar, click **Restore Defaults**.

## Deleting system settings

You can delete system settings only if they are not currently being used in a study.

- 1 In the Project Explorer, select **System Settings > Administration**.  
The Study Administration workspace appears.
- 2 Select the **System Settings** tab.  
The System Settings editor appears and is populated with the system settings for the InForm release you selected when you added the system settings.
- 3 From the **Settings** drop-down list, select the settings to delete.
- 4 Click **Remove Settings**.  
If the selected settings are not currently being used with a study, the Confirm Delete dialog box appears.
- 5 Click **Yes**.

## System settings tab of the Administration editor—Option descriptions

| Field                               | Description  |
|-------------------------------------|--|
| EnrollWithIncompleteForms           | Whether an InForm user can override a failed screening and enrollment.   |
| AutoAnswerManualQueries             | Whether the InForm application automatically answers a manual query when a data item change satisfies the rules on the data item.  |
| EmailForNewSiteAndUser Notification | Email address of an administrator who receives notification when a new site or new user is added.  |
| RequireCommentsForNA                | Whether a comment is required when NA is used.   |
| PatientSequence                     | Format for assigning subject numbers (read-only).  |
| TrialDateFormat                     | Format of the date that appears in the study   |
| ViewCRFSignList                     | Whether a list of required signatures is included on each form.  |
| QueryMaxLength                      | Maximum number of characters of query text.<br>Maximum characters: 350.  |
| InlineDuration                      | Number of seconds that the "Form submitted successfully" message remains visible in the header of the form before it fades.<br>Must be a value from 1 to 9.  |
| QuerySelection                      | State in which queries are created.  |
| EnforceVisitDate                    | Whether to require the use of Date of Visit on the first form of every visit.  |
| ScreeningSequence                   | Sequence number format for assigning screening numbers (read-only).  |
| UniqueIntDOBSwitch                  | Requirements for a subject initial/date of birth combination settings. <ul style="list-style-type: none"> <li>• Initials and DOB combination must be unique within a site.</li> <li>• Initials and DOB combination must be unique within a study.</li> </ul> |
| UniquePatIDSwitch                   | Requirements for a subject ID. <ul style="list-style-type: none"> <li>• Subject ID must be unique with a site.</li> <li>• Subject ID must be unique within a study.</li> </ul>   |
| SponsorEditFrozen                   | Whether a sponsor can edit a form after it is marked frozen.   |
| FormSaveMode                        | Location and format of the message that appears when a form is submitted successfully.   |
| VisitCalculatorEnabled              | Whether to enable the visit calculator.  |
| UserNameOrder                       | Order in which subjects appear in the Signature Details view.  |
| NavigationMode                      | Whether to allow users to change the order in which subjects appear in the InForm UI.  |

## Item groups

Item groups are sets of items you group together so you can assign a display override within a rights group to them.

Using display overrides, you can specify whether the group of items that make up an item group is hidden, editable, or read-only to the rights group with which the items are associated.

### About the Item Groups editor

The Item Groups editor has two sections. The top section has a list of item groups, and the bottom section has the items that are associated with an item group you select.

### Creating item groups

- 1 In the Project Explorer, select **Study Information > Administration**.  
The Study Administration workspace appears.
- 2 Select the **Item Groups** tab.  
The Item Groups editor appears.
- 3 In the toolbar, click **Create item groups(s)**.
- 4 Choose the settings for the item group.
- 5 Do one of the following:
  - To create one item group, click **Create**.
  - To create multiple item groups, click **Create/Next**. When you finish creating item groups, click **Create**.

### Editing an item group

- 1 In the Project Explorer, select **Study Information > Administration**.  
The Study Administration workspace appears.
- 2 Select the **Item Groups** tab.  
The Item Groups editor appears.
- 3 Select the row for the item group you want to edit, and do one of the following:
  - In the toolbar, click **Edit**.
  - Right-click and select **Edit**.The Edit Item Group dialog box appears.
- 4 Edit the item group.
- 5 Click **OK**.

## Deleting item groups

- 1 In the Project Explorer, select **Study Information > Administration**.  
The Study Administration workspace appears.
- 2 Select the **Item Groups** tab.  
The Item Groups editor appears.
- 3 Select one or more rows and do one of the following:
  - In the toolbar, click **Delete**.
  - Right-click and select **Delete**.
  - Press the **Delete** key.The Confirm Delete dialog box appears.
- 4 Click **Yes**.

## Adding items to an item group

- 1 In the Project Explorer, select **Study Information > Administration**.  
The Study Administration workspace appears.
- 2 Select the **Item Groups** tab.  
The Item Groups editor appears.
- 3 Select the row for the item group to which you want to add an item.
- 4 Select the item or items you want to add to the group.
- 5 Click **Add**.

## Removing items from an item group

- 1 In the Project Explorer, select **Study Information > Administration**.  
The Study Administration workspace appears.
- 2 Select the **Item Groups** tab.  
The Item Groups editor appears.
- 3 Select the row for the item group from which you want to remove an item.
- 4 Select the row for the item you want to remove.
- 5 Click **Remove**.  
The Confirm Delete dialog box appears.
- 6 Click **Yes**.

## Item Groups tab of the Administration editor—Option descriptions

| Option         | Description   |
|----------------|---|
| Group Name     | Name of the item group.                                 |
| Description    | Description of the item group.                          |
| Item Name      | Name of an item that is associated with the item group. |
| Question       | Question associated with the item group.                |
| Owner Form (s) | Form or forms in which the item group is defined.       |

## Query groups

A query group specifies a set of users who can work with queries that were created by other members of the same group.

### Creating query groups

- 1 In the Project Explorer, select **Study Information > Administration**.  
The Study Administration workspace appears.
- 2 Select the **Query Groups** tab.  
The Query Groups editor appears.
- 3 In the toolbar, click **Create query group**.  
The New Query Group dialog box appears.
- 4 Type a group name and description.
- 5 Click **Create**.

### Editing a query group

- 1 In the Project Explorer, select **Study Information > Administration**.  
The Study Administration workspace appears.
- 2 Select the **Query Groups** tab.  
The Query Groups editor appears.
- 3 Select the row you want to edit, and do one of the following:
  - In the toolbar, click **Edit**.
  - Right-click the row and select **Edit**.
 The Edit Query Group dialog box appears.
- 4 Edit the information, and click **OK**.

## Deleting one or more query groups

- 1 In the Project Explorer, select **Study Information > Administration**.  
The Study Administration workspace appears.
- 2 Select the **Query Groups** tab.  
The Query Groups editor appears.  
Select one or more rows to delete, and do one of the following:
  - In the toolbar, click **Delete**.
  - Press the **Delete** key.
 The Confirm Delete dialog box appears.
- 3 Click **Yes**.

## Query Groups tab of the Administration Editor—Option descriptions

| Option      | Description                     |
|-------------|---------------------------------|
| Group Name  | Name of the query group.        |
| Description | Description of the query group. |

## Rights groups

Rights groups allow you to create a set of rights and assign them to a set of item groups. Using display overrides, you can specify whether the group of items that make up an item group that is associated with a rights group is hidden, editable, or read-only.

### About the Rights Groups editor

The Rights Group editor has two sections. The top section has a list of rights groups, and the bottom shows the associated item groups for the selected rights group.

### Creating rights groups

- 1 In the Project Explorer, select **Study Information > Administration**.  
The Study Administration workspace appears.
- 2 Select the **Rights Groups** tab.  
The Rights Groups editor appears.
- 3 In the toolbar, click **Create rights group**.  
The New Rights Group dialog box appears.
- 4 Choose the settings for the rights group.

- 5 Do one of the following:
  - To create one rights group, click **Create**.
  - To create multiple rights groups, click **Create/Next**. When you finish creating rights groups, click **Create**.

## Editing a rights group

- 1 In the Project Explorer, select **Study Information > Administration**.  
The Study Administration workspace appears.
- 2 Select the **Rights Groups** tab.  
The Rights Groups editor appears.
- 3 Select the row for the rights group you want to edit.
- 4 In the toolbar, click **Edit**.  
The Edit Rights Group dialog box appears.
- 5 Edit the rights group you selected.
- 6 Click **OK**.

## Deleting a rights group

- 1 In the Project Explorer, select **Study Information > Administration**.  
The Study Administration workspace appears.
- 2 Select the **Rights Groups** tab.  
The Rights Groups editor appears.
- 3 Select the rights group to delete, and in the toolbar, click **Delete**.  
The Confirm Delete dialog box appears.
- 4 Click **Yes**.

## Adding item groups to a rights group

- 1 In the Project Explorer, select **Study Information > Administration**.  
The Study Administration workspace appears.
- 2 Select the **Rights Groups** tab.  
The Rights Groups editor appears.
- 3 Select the rights group to which you want to add item groups.
- 4 Click **Add**.  
The Rights Group – Add Item Groups dialog box appears.
- 5 Select the checkbox for each item group you want to add to the rights group.
- 6 Click **OK**.

## Deleting item groups from a rights group

- 1 In the Project Explorer, select **Study Information > Administration**.  
The Study Administration workspace appears.
- 2 Select the **Rights Groups** tab.  
The Rights Groups editor appears.
- 3 Select the rights group from which you want to remove an item group.
- 4 Select the item group you want to remove.
- 5 Click **Remove**.  
The Confirm Delete dialog box appears.
- 6 Click **Yes**.

## Setting the item group display override

- 1 In the Project Explorer, select **Study Information > Administration**.  
The Study Administration workspace appears.
- 2 Select the **Rights Groups** tab.  
The Rights Groups editor appears.
- 3 Select the rights group that has the item group for which you want to set a display override.  
The details appear for all the item groups that are assigned to the rights group you selected.
- 4 From the **Display Override** drop-down list, select an override.

## Rights Groups tab of the Administration Editor—Option descriptions

| Option           | Description  |
|------------------|--|
| Group Name       | Name of the item group.  |
| Description      | Description of the item group.   |
| Item Group Name  | Name of an item group that is associated with the rights group.                          |
| Description      | Description of an item group that is associated with the rights group.                   |
| Display Override | Whether the group of items that make up an item group is hidden, editable, or read-only. |



## Signature groups

A signature group specifies a set of users who can sign case report books and forms in the InForm application. You create signature groups and add forms to the group so that users in the signature group can sign the forms.

**Note:** Adding uses to groups occurs outside the Central Designer application.

For information about the validation checks for signature groups, see *Validation checks for InForm deployment* (on page 270).

### About the Signature Groups editor

The Signature Groups editor lists defined signature groups in the top section and details for the selected signature group in the middle section. The bottom section provides options for specifying the language to use for the signature meaning and affidavit text and for creating affidavit text.

### Creating signature groups

- 1 In the Project Explorer, select **Study Information > Administration**.  
The Study Administration workspace appears.
- 2 Select the **Signature Groups** tab.  
The Signature Groups editor appears.
- 3 In the toolbar, click **Create a signature group(s)**.  
The New Signature Group dialog box appears.
- 4 Choose the settings for the signature group.
- 5 Do one of the following:
  - To create one signature group, click **Create**.
  - To create multiple signature groups, click **Create/Next**. When you finish creating signature groups, click **Create**.

### Editing a signature group

- 1 In the Project Explorer, select **Study Information > Administration**.  
The Study Administration workspace appears.
- 2 Select the **Signature Groups** tab.  
The Signature Groups editor appears.
- 3 Select the row for the signature group you want to edit, and do one of the following:
  - In the toolbar, click **Edit**.
  - Right-click and select **Edit**.
 The Edit Signature Group dialog box appears.
- 4 Edit the information.
- 5 Click **OK**.

## Adding a form to a signature group

If a signature group is a case report book type, the following restrictions apply to forms that you add to the signature group:

- You cannot add a repeating form to the signature group.
- You can add only one form to the signature group.
- The form can belong to only one study event.
- The form cannot be used in a repeating study event.

To add a form to a signature group:

- 1 In the Project Explorer, select **Study Information > Administration**.  
The Study Administration workspace appears.
- 2 Select the **Signature Groups** tab.  
The Signature Groups editor appears.
- 3 Select the signature group to which to add a form.
- 4 Click **Add**.  
The Signature Group – Add Forms dialog box appears.
- 5 Select the checkbox for the form you want to add.
- 6 Click **OK**.

## About choosing settings for signature meaning and affidavit text

You can translate affidavit text if the language or languages in your skills profile are the same as those specified for the study.

For the signature meaning, if the translation language is English-United States, you can either select an option from the Signature Meaning drop-down list or type meanings of your own. For all other languages, you must type meanings.

If the translation language is English-United States, you can use the default text for the signature affidavit.

## Specifying translation text for a signature affidavit

- 1 In the Project Explorer, select **Study Information > Administration**.  
The Study Administration workspace appears.
- 2 Select the **Signature Groups** tab.  
The Signature Groups editor appears.
- 3 Select the signature group for which to specify translation text for the signature affidavit.
- 4 From the **Language** drop-down list, select the language to use for the **Signature Meaning** and **Signature Text**.

- 5 Do one of the following to specify the signature meaning:
  - If you are using the English-United States language, from the **Signature Meaning** drop-down list, select either **Approved** or **Reviewed**.
  - For any language, type a meaning that is appropriate to your study.
- 6 In the row for the language you are using, click **View/Edit**.

The Signature Text dialog box appears.
- 7 Do one of the following to specify the affidavit text:
  - If you are using the English-United States language and want to use the default affidavit text:

Select the **Use default text (available for English – United States Locale only)** checkbox. When the default text appears in the dialog box, click **OK**.
  - For any language, to create your own affidavit text:

Deselect the **Use default text (available for English – United States Locale only)** checkbox, type the text in the Signature Text dialog box, and click **OK**.

## Removing a form from a signature group

- 1 In the Project Explorer, select **Study Information > Administration**.

The Study Administration workspace appears.
- 2 Select the **Signature Groups** tab.

The Signature Groups editor appears.
- 3 Select the signature group from which to remove a form.
- 4 Select the form to remove.
- 5 Click **Remove**.
- 6 Click **OK**.

## Resetting the state of a form

You can specify whether associating a new signature group with a signed form resets the state of the form to unsigned in the InForm application.

If you reset the state, the original signatures remain valid. However, the form requires a signature from a member of the newly associated group in the InForm application.

- 1 In the Project Explorer, select **Study Information > Administration**.

The Study Administration workspace appears.
- 2 Select the **Signature Groups** tab.

The Signature Groups editor appears.
- 3 Select the signature group with which the form is associated.
- 4 In the **Reset Form State** column, select the checkbox.

## About the invalidation level of a signature

The InForm application invalidates a signature if any data items in the form change after signoff.

In cases in which the data items that changed are marked as hidden from a signer, you can prevent an invalidation by using one of the following options in the Invalidation Level drop-down list:

- **User**—The signature is invalidated only if the signer from whom the changes were hidden can view the data item that changed.
- **Group**—The signature is invalidated only if at least one signer in the signature group can view the data item that changed.

## Specifying the invalidation level of a signature

- 1 In the Project Explorer, select **Study Information > Administration**.  
The Study Administration workspace appears.
- 2 Select the **Signature Groups** tab.  
The Signature Groups editor appears.
- 3 Select the signature group.
- 4 From the **Invalidation Level** drop-down list, select either **User** or **Group**.

**Note:** If a study is integrated with the Central Coding application, to prevent signature invalidation when the Central Coding application updates an item, set the invalidation level to **User**.

## Deleting a signature group

- 1 In the Project Explorer, select **Study Information > Administration**.  
The Study Administration workspace appears.
- 2 Select the **Signature Groups** tab.  
The Signature Groups editor appears.
- 3 Select the signature group to delete.
- 4 In the toolbar, click **Delete**.  
The Confirm Delete dialog box appears.
- 5 Click **Yes**.

## Signature Groups tab of the Administration editor—Option descriptions

| Option      | Description                                  |
|-------------|--|
| Group Name  | Name of the signature group.                 |
| Description | Description of the signature group.          |
| Type        | Type of document a signature group can sign. |

| Option             | Description  |
|--------------------|--|
| Reset Form State   | Whether associating a new signature group with a form that is signed resets the state of the form to unsigned. |
| Invalidation Level | Invalidates a signature if items change after signoff.   |
| Title              | Name of the form a signature group can sign.   |
| Description        | Description of the form a signature group can sign.  |
| Language           | Language to use for meaning and signature text.  |
| Signature Meaning  | Whether the signature indicates that the form is Reviewed, Approved, or in a user-specified state.             |
| Signature Text     | The affidavit text.  |

## About exporting study administration data to a user management tool

You can export study administration data to a user management tool using the Export Wizard. The exported file contains the definitions of the study administration groups you created in the Central Designer application. The definitions are in a pipe-delimited format.

For more information, see Export Wizard options.

| Page                                  | Option           | Description  |
|---------------------------------------|------------------|--|
| Welcome                               |                  | Introduction page.   |
| Export Type                           | Data Type        | <p><b>CSML</b>—Export in Clinical Study Markup Language format.</p> <p><b>ODM</b>—Export in Operational Data Model-compliant format. The Central Designer application supports the ODM 1.3 standard.</p> <p><b>Administration data</b>—Export only study administration data for the User Management Tool application.</p> |
|                                       | Export Type      | <b>Local</b> —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.   |

## About importing study administration data

When you import CSML that includes study administration objects you can choose to import study objects and administration data, administration data only, or study objects only:

- **Import study objects and administration data**—The study objects (StudyAdministration, ItemGroups, SignatureGroups, Sponsor, SystemSettings, and RightsGroups) in the CSML you are importing overwrite the study objects in the existing study.

If a study object in the CSML data you are importing has the same identifier as an object in the study, the existing object is not deleted. Instead, a new study object is created and its version is incremented.

- **Import study administration data only**—The study objects are removed from the CSML before it is imported.

Because the study design has changed, some items and forms that the existing Study Administration objects reference cannot be part of the study workflow. These references are removed from the existing Study Administration objects in the study.

For more information, see 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.   |

| Page   | Option           | Description  |
|--|------------------|--|
| Rule Import Mode                               | Rule Import Mode | <p>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.</p> <p><b>Note:</b> 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.</p> |
| IPR Import Mode                                | Import IPR data  | <p>Select whether to import in-place revision objects.</p> <p><b>Note:</b> This page appears only if the file contains in-place revision objects.</p>  |
| Ready to Import<br>Data to Central<br>Designer |                  | <p>View a summary of the import options selected in the wizard.</p>  |

# Coding administration

## Administering coding tasks

To create coding maps in the Central Designer application, you must first perform the following administrative tasks.

- *Select dictionary types for a study or library* (on page 39).
- *Associate dictionary types with verbatim types for a study or library* (on page 40).

## Creating, modifying, and deleting a coding map

When you create a coding map, you specify:

- An item to code.
- One or more items that will receive code or term information from the Central Coding application.
- One or more items that contain context information. Context information provides assistance to the person who codes the item.
- A query target. When a Central Coding user creates a query, the query appears on the query target item in the InForm application.

**Note:** If you select a query target item for a coding map, you can only deploy the study to a version of the InForm application that supports coding query targets. For more information, see the InForm documentation.

**Note:** Only text items with no codelists are available for selection in the drop-down lists for Item to code and Target Item.

### To create a coding map:

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 Select a form.
- 3 Select the **Coding** tab.
- 4 Click **New Coding Map**.

The New Coding Map dialog box appears.

- 5 Fill in the fields in the dialog box.
- 6 Click **OK**.

### To modify a coding map:

**Note:** When you modify a coding map, you cannot modify the dictionary type or the verbatim (the item to code).

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 Select a form.



- 3 Select the **Coding** tab.
- 4 In the top panel, select a coding map, and click **Edit**.  
The Edit Coding Map dialog box appears.
- 5 Edit the coding map as necessary.  
You can modify information in the following fields:
  - Dictionary type.
  - Item to code.
  - Verbatim type.
  - Coding Results tab: Target Item and Target Question.
  - Context Information tab: Context Item and Context Question.
  - Assign queries to: Query target item.
- 6 Click **OK**.

**To delete a coding map:**

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 Select a form.
- 3 Select the **Coding** tab.
- 4 In the top panel, select a coding map, and click **Delete**.  
A confirmation dialog box does *not* appear.

## Selecting and removing dictionary types for a study or library

Only enabled dictionary types appear in the Dictionary types list. An administrator can import and enable additional dictionary types in the Central Designer Administrator application. For more information, see *Enabling and disabling a dictionary type* (in the *Administrator Guide*).

- 1 In the Project Explorer, select **Study Information**.
- 2 Select **InForm**.
- 3 Select the **Coding** tab.
- 4 In the **Dictionary Types** list, select or deselect the checkbox to select or remove a dictionary type.

**Note:** If a dictionary type is used in a coding map, **(In use)** appends the dictionary type, and you cannot deselect it.

After selecting a dictionary type, you can associate it with one or more verbatim types. For more information, see *Associating dictionary types with verbatim types for a study* (on page 40).

## Associating dictionary types with verbatim types for a study or library

Before you associate a dictionary type with a verbatim type, you must *select dictionary types for a study* (on page 39).

Only the selected dictionary types and their associated verbatim types are available for creating coding maps.

You define verbatim types in the Central Designer Administrator application. For more information, see *Adding, modifying, and deleting a verbatim type* (in the *Administrator Guide*).

- 1 In the Project Explorer, select **Study Information**.
- 2 Select **InForm**.
- 3 Select the **Coding** tab.
- 4 In the **Dictionary Types** list, select or deselect the checkbox to select or remove a dictionary type.

**Note:** If the checkbox for the dictionary type is not selected, you cannot associate verbatim types with the dictionary type.

The Verbatim Types list is populated with verbatim types.

- 5 In the **Verbatim Types** list, select the checkboxes for one or more verbatim types.

**Note:** If a verbatim type is used in a coding map for the selected dictionary type, **(in use)** appends the verbatim type, and you cannot deselect it.

## About coding setup activities in the Central Designer application

Some data that is collected in a study, such as a description of an adverse event, is free-form text. This item text is called a verbatim. A verbatim is the original reported text that describes the adverse event, disease, drug, or other item to be coded in the Central Coding application. The verbatim text must be converted to consistent terminology that is defined in either industry standard or customer-defined dictionaries for the purposes of statistical analysis. Coding is the process of selecting terms and codes from a dictionary for a given verbatim.

When you design a study in the Central Designer application, you can create items for which an InForm user provides a value—the verbatim text—and you can also create additional related items that are read-only in the InForm application.

A coding map is a study object that contains the necessary information to code an item. By creating a coding map in the Central Designer application, you can populate the values of the read-only fields with codes and terms that are selected in the Central Coding application.

After you deploy a study from the Central Designer application to the InForm application and begin collecting data, you can begin the coding process. All communication between the InForm application and the Central Coding application is initiated from the Central Coding application. The Central Coding application uses the InForm Adapter application to control communication between Central Coding servers and InForm studies.

For more information about the coding process in the Central Coding application, see the Central Coding *User Guide*.

## Coding terms and definitions

| Term              | Definition  |
|-------------------|---|
| Coding            | The process of selecting terms and codes from a dictionary for a verbatim.  |
| Verbatim          | The original reported text that describes the adverse event, disease, drug, or other item to be coded in the Central Coding application. A verbatim is typed in the InForm application.   |
| Coding map        | A study object that contains the necessary information to code an item.   |
| Target item       | An item that holds a term, code, or additional information after a verbatim is coded.<br><br>Also called a coding target.   |
| 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.  |
| Dictionary type   | A name or identifier for the metadata for a dictionary.   |
| Verbatim type     | A classification of a verbatim as defined in a coding dictionary.   |
| Query target item | An item in the InForm application that you designate as the item on which to place queries that are created in the Central Coding application. If you select a query target for a coding map, you can only deploy the study to a version of the InForm application that supports query targets. |

## Coding maps

| Characteristic           | Description   |
|--------------------------|---|
| Definition and purpose   | A coding map is a study object that contains the necessary information to code an item. You create a coding map for an item that needs to be coded in the Central Coding application.   |
| Where to view and create | <p>You can create, modify, and delete coding maps <i>only when a form is selected</i>. When a form is selected, the Coding tab displays all coding maps for the form. When a study event is selected, the Coding tab displays all coding maps for all of the forms in the study event, and so on.</p> <p>You can view, but not edit, coding maps in the Coding tab of the editors for the following study objects:</p> <ul style="list-style-type: none"> <li>• Study design</li> <li>• Study element</li> <li>• Study event</li> </ul> |

| Characteristic                      | Description   |
|-------------------------------------|---|
| Creation process                    | <p>To create a coding map, you assign an item to one or more dictionary levels and level types—the level type is the term, code, or additional information of the dictionary level.</p> <p>For more information, see <i>Creating, modifying, and deleting a coding map</i> (on page 38).</p>  |
| Information in a coding map         | <ul style="list-style-type: none"> <li>• Verbatim (the item to be coded).</li> <li>• Form on which the verbatim appears.</li> <li>• Verbatim type.</li> <li>• Dictionary type to use for coding.</li> <li>• Any specified context items and target items.</li> <li>• Query target item.</li> </ul>  |
| Multiple coding maps for a verbatim | <p>You can create multiple coding maps for a verbatim—one for each dictionary type that is installed and selected for a given study or library. Therefore, a verbatim, a target item, and a context item can all be part of multiple coding maps.</p>   |
| Reusing                             | <p>When you copy a form to a library or study, the coding maps that are defined for items on the form are copied with the form.</p>   |
| Deployment                          | <p>Coding maps are deployed to an InForm study as InForm TDE CODINGMAP objects.</p> <p>If you select a query target item for a coding map, you can only deploy the study to a version of the InForm application that supports coding query targets. For more information, see the InForm documentation.</p> <p><b>Note:</b> If you create or modify a coding map, use a full deployment package to deploy the changes. Changes to coding maps are not supported in incremental deployment packages.</p> |
| Requirements for repeating sections | <p>For repeating sections, the references in a coding map must all be either in the repeating section or outside the repeating section.</p>   |
| Multi-language studies              | <p>Coding maps are language neutral. You cannot create a language-specific coding map.</p>  |

## Dictionary types

| Characteristic                       | Description   |
|--------------------------------------|---|
| Definition and purpose               | <p>A dictionary type is a name or identifier for the metadata for a dictionary. You create a coding map for a verbatim using a dictionary type.</p> <p>The dictionary type specifies the metadata for all versions of a dictionary, including:</p> <ul style="list-style-type: none"> <li>• Verbatim types.</li> <li>• Dictionary levels.</li> <li>• Dictionary level types, such as Term or Code.</li> <li>• Where applicable, context meanings.</li> </ul>                |
| Dictionary types in the installation | <p>The following dictionary types are installed with the Central Designer application:</p> <ul style="list-style-type: none"> <li>• <b>MedDRA</b>—Medical Dictionary for Drug Regulatory Activities.</li> <li>• <b>MedDRAJ</b>—Japanese version of the MedDRA dictionary.</li> <li>• <b>WHO-DD</b>—World Health Organization Drug Dictionary (formerly WHO-DRL—World Health Organization Drug Reference List).</li> <li>• <b>JDrug</b>—Japanese drug dictionary.</li> </ul> |
| Importing                            | <p>You can import other standard dictionary types as well as custom dictionary types in the Central Designer Administrator application.</p> <p>For more information, see <i>Importing and overwriting a dictionary type</i> (in the <i>Administrator Guide</i>).</p>  |
| Multiple versions                    | <p>The Central Designer application supports multiple versions of a dictionary type.</p> <p>A version consists of dictionary metadata and dictionary data. In most cases, versions are different only in data, but new versions can also contain new metadata.</p>  |
| Using in a study or library          | <p>To use a coding dictionary in a study or library to create coding maps, you must use the following process:</p> <ol style="list-style-type: none"> <li>1 <b>Import the dictionary type</b> (in the <i>Administrator Guide</i>).</li> <li>2 <b>Enable the dictionary type</b> (in the <i>Administrator Guide</i>).</li> <li>3 <b>Select the dictionary type for a study or library</b> (on page 39).</li> </ol>   |
| Association with verbatim types      | <p>You can associate multiple verbatim types with a single dictionary type.</p>   |
| Deployment                           | <p>Dictionary types that are used in the coding maps are deployed to the InForm application as MedML DICTIONARY objects.</p>  |

## Verbatim types

| Characteristic                     | Description  |
|------------------------------------|--|
| Definition and purpose             | A verbatim type is a classification of a verbatim as defined in a coding dictionary.   |
| Verbatim types in the installation | <ul style="list-style-type: none"> <li>• <b>AE</b>—Adverse Event</li> <li>• <b>DISEASE</b>—Disease</li> <li>• <b>LABDATA</b>—Lab data</li> <li>• <b>MEDPROD</b>—Medical product</li> </ul> |
| Association with dictionary types  | You can associate multiple verbatim types with a single dictionary type.   |

## Verbatims, context items, target items, and query target items

| Characteristic         | Verbatims  | Context items   | Target items  | Query target items   |
|------------------------|--|---|---|--|
| Definition and purpose | <p>A verbatim is the original reported text that describes the adverse event, disease, drug, or other item to be coded in the Central Coding application.</p> <p>You can create multiple coding maps for a verbatim.</p> <p>A verbatim can have:</p> <ul style="list-style-type: none"> <li>• One or more target items.</li> <li>• One or more context items.</li> <li>• A coding map for each dictionary type.</li> </ul> | <p>A context item is 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.</p> | <p>A target item is an item that holds a term, code, or additional information after a verbatim is coded.</p> <p>It is a target for one and only one verbatim per dictionary type.</p> <p>Target items can hold dictionary level information or additional information that is defined by a dictionary.</p> | <p>A query target item is an item in the InForm application that you designate as the item on which to place queries that are created in the Central Coding application.</p> <p>When a Central Coding user creates a query, the query appears on the query target item in the InForm application.</p> <p>You must assign each verbatim a query target when you create a coding map for the verbatim.</p> <p><b>Note:</b> To select the verbatim item as the query target item, select <b>&lt;use verbatim&gt;</b> in the <b>Assign queries to</b> drop-down list in the New Coding Map dialog box.</p> |

| Characteristic               | Verbatims   | Context items   | Target items   | Query target items  |
|------------------------------|---|---|--|---|
| Source or result item        | A verbatim is a source item that provides information to the Central Coding application.  | A context item is a source item that provides information to the Central Coding application.  | A target item is a result item that receives a term or code from the Central Coding application.   | A target item is a result item that receives a query from the Central Coding application.   |
| Location in Project Explorer | Can be one of the following: <ul style="list-style-type: none"> <li>• Top-level item.</li> <li>• Child of a top-level compound item.</li> <li>• Child of a nested compound item.</li> </ul> | Can be one of the following: <ul style="list-style-type: none"> <li>• Top-level item.</li> <li>• Child of a top-level compound item.</li> <li>• Child of a nested compound item.</li> </ul> | Cannot be a child of a nested compound item.<br>Must be one of the following: <ul style="list-style-type: none"> <li>• Top-level item.</li> <li>• Child of a top-level compound item.</li> </ul> | Cannot be the child of a top-level compound item, but can be the top-level compound item itself.<br>Must be: <ul style="list-style-type: none"> <li>• A top-level item.</li> <li>• Visible and available for editing in the InForm application. Items designated as query targets must not have the Display Override property set to ReadOnly or Hidden in the Central Designer application.</li> </ul> |
| Conditional on another item  | Can be conditional on another item.   | Can be conditional on another item.   | Cannot be conditional on another item.   | Cannot be conditional on another item.  |

## Requirements:

- A verbatim (the item to code) and its target and context items must be on the same form.
- If a form has a repeating section, all items referenced in the coding map must all be either in the repeating section or outside the repeating section.
- All verbatims, context items, and target items must be text items. Query target items do not need to be text items.
- You can map each verbatim to only one coding dictionary. For example, to code to both Japanese and English dictionaries for the same item on the form, you must create two verbatims on the form.
- You can designate an item as a query target for only one verbatim.

- If you select a query target item for a coding map, you can only deploy the study to a version of the InForm application that supports coding query targets. For more information, see the InForm documentation.



# Setting up InForm review states

## About review states

In the InForm application, as many as five form-level customizable states, called review states, are available in the Data Viewer in addition to the standard InForm states. If defined, custom review states can provide users with greater flexibility in tracking the review progress.

Each custom review state has three customizable stages. For example, you can create two custom review states, labeled Medical Review and Data Management Review, each with three stages of Needs Review, Pending, and Reviewed. A custom review state is in one of its three stages at any time. The first stage is the default stage for a defined custom review state.

In the Central Designer application, you can create as many as five review states for a study, each having three review stages. You can perform the same actions on a review state as on other study objects. For example, you can lock, unlock, publish, unpublish, copy, and paste a review state, and you can mark it as a template and copy it from a library into a study.

Additionally, you can write rules that read and set the review stage of a form.

Review states appear in the Review States editor, which is active when you select the Study Information Explorer bar > InForm > Review States folder in the Project Explorer. You define a review state and its review stages in the Review State editor. The annotated study book for a study optionally includes a listing of the review states defined for the study, along with the review stages of each.

## Creating, modifying, and deleting a review state

**Note:** Review states are supported only in release 5.5 and later of the InForm application. If you attempt to deploy a study containing review states to an earlier release of the InForm application, deployment fails.

To create a review state:

**Note:** If you create a review state in the Central Designer application to replace a deleted review state, the new review state must have the same RefName and state number as the review state that was deleted.

- 1 In the Project Explorer, select **Study Information**.  
or  
In the Project Explorer, select the **Library Information** Explorer bar.
- 2 In the **InForm** folder, right-click **Review States**, and select **New Review State**.  
or
  - a In the **InForm** folder, select **Review States**.
  - b In the Review States editor, click **New**.
 The Object Name dialog box appears.

- 3 Enter a title, RefName, and description, and click **OK**.

The Review State editor appears.

- 4 Fill in the fields of the editor, and save the study project.

For more information, see *Review State editor—Option descriptions* (on page 434).

**Note:** The Label and Mnemonic fields for the review state and each review stage are required for each InForm product locale (English and Japanese). If a required value is missing in a product locale tab, the value from the other locale (if it is defined) appears in the field in red, and an icon appears in the tab to indicate that translation is required. Study validation also checks for missing translated values. Because both English and Japanese locales are always required for review states, the study definition does not need to have the Japanese locale selected, and you do not need the Japanese language skill to translate the review state fields.

#### To modify a review state:

Before a review state is deployed to the InForm application, you can change any of its values and the values of its review stages.

**Note:** If you change the RefName property of a stage, you must update any rules that refer to the stage.

After deploying a review state to the InForm application, you cannot change the state number or any RefNames. You can only change labels, mnemonics, titles, descriptions, and activation state. If you change the RefName of a review state or the name of a review stage and redeploy the study, deployment fails.

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

or

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

- 2 In the Review States folder, select a review state.

The Review State editor appears.

- 3 Update the fields as needed.

#### To delete a review state:

You can delete a review state before or after the study is deployed to the InForm application. If you delete a review state in the Central Designer application for a deployed study and then redeploy, the review state is not removed from the InForm study. If you create a review state in the Central Designer application to replace a deleted review state, the new review state must have the same RefName and state number as the review state that was deleted.

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

or

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

- 2 Right-click a review state, and select **Delete**.

A confirmation dialog box appears.

- 3 Click **Yes**.

## CHAPTER 2

# Designing the study workflow

### **In this chapter**

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| Working with workflow diagrams .....                           | 54 |
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## About study objects in the study workflow

The study workflow contains:

- **Study design**—A study design is a container for the structure of a study. Each study has only one study design, which is created automatically when you *create a study* (on page 2). The study design study object is accessible only in a study, not in a library.
- **Study elements**—A study element is a 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

In the InForm application, a study element is a collection of visits (or, in Central Designer terminology, study events) that are scheduled as a unit. Although you are not required to use them, consider whether you might benefit from the following uses of study elements:

- If you want to simplify a complex workflow diagram, create a study element and include several study events in it. Your workflow diagram will have more layers but will be easier to navigate. A clinician might be better able to review a simplified workflow to determine if it accurately represents the study protocol.
- Study elements make it easy to reuse a collection of study events. If you add several study events to a study element and include the study element in a library, you can reuse all of the study events by reusing the study element.
- **Study events**—A study event is a subject evaluation checkpoint when data is collected. Study events usually correspond to visits, but one visit can span multiple study events. A study event can contain one or more forms.

A study event can be repeating. A repeating study event corresponds to a repeating visit in the InForm application.

## Creating and editing study objects in the study workflow

A study design is a container for the structure of a study. Each study has only one study design, which is created automatically when you **create a study** (on page 2). The study design study object is accessible only in a study, not in a library.

### To edit the properties of a study design in the Properties Browser:

- 1 In the Project Explorer, select the **Visit Schedule** Explorer bar.
- 2 Select the StudyDesign folder.
- 3 Select the **Properties Browser**.

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

- 4 Edit the properties of the study design. 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 more information, see *Study design properties* (on page 481).

You create a study object (study design, study element, study event, form, section, item, codelist, and codelist item) in a study or library. You can create a study object outside the hierarchy of a study or library, but the study object is not deployed until you add it to a parent study object in a study or library. To include a study object in the hierarchy of a study or library, add it to an existing parent in the study or library.

### To create a study element:

- 1 (Available only in a study) To create a study element on a study design:
  - a In the Project Explorer, select the **Visit Schedule** Explorer bar.
  - b Right-click the study design, and select **New Element**.

To create a study element outside the hierarchy of a study or library:

- c In the Project Explorer, select the **Elements and Events** Explorer bar.
- d Right-click the **Study Elements** folder, and select **New Element**.

The Object Name dialog box appears.

- 2 Type a title, RefName, and description, and click **OK**.

### To edit the properties of a study element in the Properties Browser:

- 1 In the Project Explorer, select a study element.
- 2 Select the **Properties Browser**.

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

- 3 Edit the properties of the study element. 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 more information, see *Study element properties* (on page 482).

You create a study object (study design, study element, study event, form, section, item, codelist, and codelist item) in a study or library. You can create a study object outside the hierarchy of a study or library, but the study object is not deployed until you add it to a parent study object in a study or library. To include a study object in the hierarchy of a study or library, add it to an existing parent in the study or library.

**To create a study event:**

- 1 Navigate to the parent study object, as indicated in the following table.

| Parent study object                   | Steps   |
|---------------------------------------|---|
| Study design (only in studies)        | <ol style="list-style-type: none"> <li>1 In the Project Explorer, select the <b>Visit Schedule</b> Explorer bar.</li> <li>2 Right-click the study design, and select <b>New Event</b>.</li> </ol>             |
| Study element                         | <ol style="list-style-type: none"> <li>1 In the Project Explorer, select the <b>Elements and Events</b> Explorer bar.</li> <li>2 Right-click the study element, and select <b>New Event</b>.</li> </ol>       |
| No parent (for example, in a library) | <ol style="list-style-type: none"> <li>1 In the Project Explorer, select the <b>Elements and Events</b> Explorer bar.</li> <li>2 Right-click the Study Events folder, and select <b>New Event</b>.</li> </ol> |

The Object Name dialog box appears.

- 2 Type a title, RefName, and description, and click **OK**.

**To edit the properties of a study event in the Properties Browser:**

- 1 In the Project Explorer, select a study event.
- 2 Select the **Properties Browser**.

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

- 3 Edit the properties of the study event. 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.

**To specify the short title of a study event:**

- 1 In the Project Explorer, select a study event.
- 2 Select the **General** tab.
- 3 Type a value in the **Short Title** field.

**To make a study event repeating or not repeating:**

- 1 In the Project Explorer, right-click a study event, and select **Repeating Event**.

If the study event was nonrepeating, it changes to a repeating study event. If the study event was repeating, it changes to a nonrepeating study event.

**To mark a study event as a special InForm visit:**

- 1 In the Project Explorer, select a study event.
- 2 Open the **Properties Browser**.

**Note:** If the **Properties Browser** is not visible, open the **View** menu and make sure **Properties** is selected.

- 3 From the **Special Visits** drop-down list, select a value.

# Working with workflow diagrams

## About study workflows

On paper, a study designer often charts the major events of a study by using a flow diagram that indicates the order in which a subject progresses from one step to another and also shows where any branches in the study occur. You can use the study workflow tools to map out the flow of a study in a similar way.

Study workflow tools provide a way to define:

- The major branches and events of a study.
- The forms used to collect clinical observations at each study event.
- Decision points that determine the path a subject follows through the study based on specific observations.

The process of designing the study workflow creates the actual study objects. A lead study designer can set up the outline by designing the study workflow and can assign the detail design tasks to other members of the team.

Use the Workflow Diagram tab to create a study workflow.

### About the Workflow Diagram tab

The Workflow Diagram tab enables you to create graphical study workflow diagrams that specify the sequence of steps in a study and the points where the study workflow can branch depending on the outcome of specific observations. The Central Designer application keeps the study objects in the Workflow Diagram and Workflow Grid tabs synchronized.

The Workflow Diagram tab appears in the Study Design, Study Element, and Study Event Editors in studies, and in the Study Element and Study Event Editors in libraries. Within each editor, the Workflow Diagram tab enables you to design a different level of a study workflow.

### Scope of the Workflow Diagram tab for each study object

| Editor        | Scope of workflow   |
|---------------|---|
| Study Design  | <ul style="list-style-type: none"> <li>• Study elements</li> <li>• Study element workflow rules</li> <li>• Study events</li> <li>• Study event workflow rules</li> <li>• Global conditions</li> </ul> |
| Study Element | <ul style="list-style-type: none"> <li>• Study events</li> <li>• Study event workflow rules</li> <li>• Global conditions</li> </ul>   |



| Editor      | Scope of workflow   |
|-------------|---|
| Study Event | <ul style="list-style-type: none"> <li>• Forms</li> <li>• Form workflow rules</li> <li>• Global conditions</li> </ul> |

### Where to create study workflows

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.

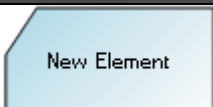
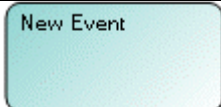
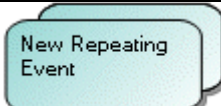
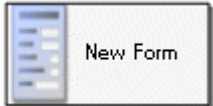

### Schedule of Events tab






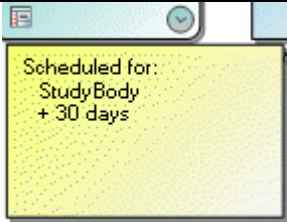
Another component of study workflow design is the *Schedule of Events* (on page 77) tab, which displays a schedule of events for the study. In the Schedule of Events tab, you can indicate the forms that appear in each study event.

### Workflow Grid tab

You can also use the *Workflow Grid tab* (on page 61) to create workflow information. The Central Designer application keeps the information in the Workflow Diagram and Workflow Grid tabs synchronized.

## Workflow diagram components

| Diagram component   | Purpose   |
|---|---|
|  New Element         | <b>Study element</b> —Can appear in the workflow for a study design.                                |
|  New Event           | <b>Study event</b> —Can appear in the workflow for a study design or for a study element.           |
|  New Repeating Event | <b>Repeating study event</b> —Can appear in the workflow for a study design or for a study element. |
|  New Form            | <b>Form</b> —Can appear in the workflow for a study event.  |
|  New Repeating Form  | <b>Repeating form</b> —Can appear in the workflow for a study event.                                |

| Diagram component  | Purpose  |
|--|--|
|   | <p><b>Workflow rule</b>—The color of the component indicates the study object that precedes the workflow rule in the workflow diagram:</p> <ul style="list-style-type: none"> <li>• <b>Blue</b>—Study element</li> <li>• <b>Green</b>—Study event</li> <li>• <b>Gray</b>—Form</li> </ul> |
|   | <p><b>Global condition</b>—Above a study object, this component indicates that a global condition is associated with the study object.</p>   |
|   | <p><b>Arrow</b>—Connects two workflow diagram components. The arrow indicates the order of the workflow between the components.</p>  |
|   | <p><b>Sequence number</b>—Indicates the order of workflow diagram components that are not at the endpoint of a connecting arrow.</p>   |
|   | <p><b>Data view icons</b>—In the lower-left corner of a workflow object, icons indicate the target application for which a study object and its children were designed.</p>  |
|  | <p><b>Schedule drop-down list</b>—When you click the clock (🕒) icon, a summary of the scheduling information for a study object appears.</p>   |

## Viewing a workflow diagram

To view a workflow diagram:

**Note:** You can view a workflow diagram for a study only in a study, not in a library.

- 1 In the Project Explorer, select a study design, study element, or study event.
- 2 Select the **Workflow Diagram** tab.

To adjust the size of a workflow diagram:

- 1 In the Project Explorer, select a study design, study element, or study event.
- 2 Select the **Workflow Diagram** tab.
- 3 Select the arrow to the right of the **Zoom** button.  
or  
Right-click the workspace.
- 4 Select a sizing option.

## Creating a study object in a workflow diagram

The editor in which the Workflow Diagram tab appears determines the study objects and components that you can create. When you create a study object, the study object is added to the Workflow Diagram tab, the Workflow Grid tab, and the Project Explorer.

Select one of the following Explorer bars and navigate to the Workflow Diagram tab to create the specified study object:

- Study element:
  - Visit Information Explorer bar
  - Elements and Events Explorer bar
- Study event:
  - Visit Information Explorer bar
  - Elements and Events Explorer bar
- Form:
  - Forms and Transactions Explorer bar

### To create the study object on the Workflow Diagram tab:

- 1 In the Workflow Diagram, click the **New <Study Object Type>** button.  
The Object Name dialog box appears.
- 2 In the **Title** field, type the title of the study object.  
As you type, the RefName field is filled in, using the Title text but omitting spaces and disallowed characters.
- 3 Optionally, in the **RefName** field, type a different RefName from the default.
- 4 Optionally, in the **Description** field, type a description of the study object.
- 5 Click **OK**.

### To change the repeating state of a study event:

- 1 In the Project Explorer, select the study design or study element on which the study event exists.
- 2 Select the **Workflow Diagram** tab.
- 3 Right-click a study event, and change the selection of **Repeating Event** as needed.

### To change the repeating or common state of a form:

- 1 In the Project Explorer, select the study event on which the form exists.
- 2 Select the **Workflow Diagram** tab.
- 3 Right-click a form in the workflow diagram, and select **Repeating Form** or **Common Form**.

## Connecting and ordering study objects in a workflow diagram

In a workflow diagram, when you connect:

- Two study objects—You specify the order of the study objects in the workflow.
- A rule and a study object—You specify the study object that comes next in the workflow based on the outcome of the rule.

When you make a connection to a study event, you can schedule the study event.

### To connect a study object to a study element or a study event:

- 1 In the Project Explorer, select the **Visit Schedule** Explorer bar.
- 2 Select a study design, study element, or study event.
- 3 Select the **Workflow Diagram** tab.
- 4 Move the cursor over the first of the two objects you want to connect until it changes to a pointing finger icon.
- 5 Drag the cursor to a connection node in the next component in the sequence, and release it.

A connection line points from the first object to the study element or study event, and the Edit Schedule dialog box appears.

- 6 Schedule the interval between study objects, and click **OK**.

**Note:** You can define multiple schedules leading into a study element or event. However, in the InForm application, the visit hours are always set to the schedule with the greatest amount of time.

### To connect two forms:

- 1 In the Project Explorer, select the **Visit Schedule** Explorer bar.
- 2 Select a study event.
- 3 Select the **Workflow Diagram** tab.
- 4 Move the cursor over the first of the two forms until it changes to a pointing finger icon.
- 5 Drag the cursor to a connection node in the next component in the sequence, and release it.

The two forms are linked by an arrow.

### To connect a rule to the next study object:

- 1 In the Project Explorer, select the **Visit Schedule** Explorer bar.
- 2 Select a study design, study element, or study event.
- 3 Select the **Workflow Diagram** tab.
- 4 Move the cursor over the rule workflow diagram object until it changes to a pointing finger icon.

- 5 Drag the cursor to a connection node in the next component in the sequence, and release it.  
A connection line points from the rule to the next object, and one of the following dialog boxes appears:
  - If you are connecting a rule to a study event or study element—Edit Schedule and Rule Action dialog box.
  - If you are connecting a rule to a form—Edit Rule Action dialog box.
- 6 In the **If the value is** section, select a value.
- 7 Click **OK**.
- 8 If the workflow branches differently for different outcomes of the rule, repeat the procedure for the other branch.

For more information, see:

**Edit Schedule dialog box—Option descriptions** (on page 411).

**Edit Rule Action dialog box—Option descriptions** (on page 410).

**Edit Schedule and Rule Action dialog box—Option descriptions** (on page 411).

## Changing the sequence number of a study object in a workflow diagram

Sequence numbers specify the order of disconnected study objects in the Workflow Diagram tab.

The first study object in each workflow sequence has a sequence number. If a workflow diagram has multiple workflow sequences, sequence numbers specify how the workflows are ordered in the InForm application, unless an unconnected study object is associated with a global condition. For clarity, and to make sure that dynamic study objects deploy in the correct order, connect all study objects in a workflow.

You can use whole numbers as well as numbers with decimal points as sequence numbers, and you are not required to use sequential numbers. For example, if you expect to add additional study objects to a workflow, you might use only even or odd numbers for existing study objects so you have additional whole numbers to use for new additions. Alternatively, you can use sequential numbers for existing study objects and use numbers with decimal points for inserted study objects.

- 1 In the Project Explorer, select the **Visit Schedule** Explorer bar.
- 2 Select a study design, study element, or study event.
- 3 Select the **Workflow Diagram** tab.
- 4 Double-click the sequence number (the numbered gray box that appears to the left of a study object).

The Modify Step Sequence dialog box appears.

- 5 In the **Step Sequence Number** field, type the new sequence number.

**Note:** The new sequence number cannot already exist in the workflow. To insert a new study object into the sequence, you must renumber other study objects to make the desired number available.


- 6 Click **OK**.

## Creating a reference copy of a study object in a workflow diagram

You can create a reference copy of a study element, study event, or form in a workflow. A reference copy is a duplicate image of a study object in a diagram; it is not a new link to the study object in the Central Designer repository. In a workflow diagram with many study objects and connecting lines, you can use a reference copy of a study object to separate the tangle of connecting lines and make the workflow diagram less cluttered.

- 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 study object in the workflow diagram, and select the **Create Reference Copy** command for the study element.

## Viewing scheduling information

- 1 In the Project Explorer, select the **Visit Schedule** Explorer bar.
- 2 Select a study design, study element, or study event.
- 3 Select the **Workflow Diagram** tab.
- 4 To view scheduling information for a single workflow object, click the clock icon  on the object.
- 5 To view scheduling information for the entire workflow, right-click the background of the workflow, and select **Show Scheduling**.
- 6 To hide scheduling information, press **Esc**.

# Working in the Workflow Grid tab

## Working with study objects in a workflow grid

In the Workflow Grid tab, you create the principal study objects in the workflow of a study by using a grid format.

You create only study objects (no workflow rules or global conditions) in the Workflow Grid tab. You can connect the study objects in a workflow and use workflow rules and global conditions in the Workflow Diagram tab. The Central Designer application keeps the study objects in the Workflow Diagram and Workflow Grid tabs synchronized.

The Workflow Grid tab appears in the Study Design, Study Element, and Study Event Editors in studies, and in Study Element and Study Event Editors in libraries.

The selected selection in the View Targets drop-down list determines the workflow objects that appear on the Workflow Grid tab.

## Creating a study object in a workflow grid

The editor in which the Workflow Grid tab appears determines the study objects and components that you can create.

Select one of the following Explorer bars and navigate to the Workflow Grid tab to create the specified study object:

- Study element:
  - Visit Information Explorer bar
  - Elements and Events Explorer bar
- Study event:
  - Visit Information Explorer bar
  - Elements and Events Explorer bar
- Form:
  - Forms and Transactions Explorer bar

### To create the study object on the Workflow Grid tab:

- 1 In the Project Explorer, select the study design, study element, or study event.
- 2 Select the **Workflow Grid** tab.
- 3 In the **Type** column, select the study object type from the drop-down list.
- 4 In the **Title** column, type the name of the study object.
- 5 Press **Enter**, or click the next row, or press the **Tab** key.

**Note:** You cannot reuse the same study event in multiple study elements in the same study.

**To change the repeating state of a study event:**

- 1 In the Project Explorer, select the study design or study element on which the study event exists.
- 2 Select the **Workflow Grid** tab.
- 3 Click within the gray box, located at the beginning of the row for a study event.
- 4 Right-click the study event, and change the **Repeating Event** selection as needed.

**To change the repeating or common state of a form:**

- 1 In the Project Explorer, select the study event on which the form exists.
- 2 Select the **Workflow Grid** tab.
- 3 Click within the gray box, located at the beginning of the row for a form.
- 4 Right-click the study form, and change the **Repeating Form** or **Common Form** selection as needed.

## Opening a child study object from a workflow grid

From the Workflow Grid for a study object, you can open the Design tab of any of its child study objects. For example, from the Workflow Grid tab for a study design, you can edit its child study elements and study events.

- 1 Navigate to the study object, as indicated in the following table.

| Child study object | Parent Workflow Grid        | Steps  |
|--------------------|-----------------------------|--|
| Study element      | Study design (studies only) | 1 In the Project Explorer, select the <b>Visit Schedule</b> Explorer bar.      |
|                    |                             | 2 Select the <b>Workflow Grid</b> tab.   |
| Study event        | Study design (studies only) | 1 In the Project Explorer, select the <b>Visit Schedule</b> Explorer bar.      |
|                    |                             | 2 Select the <b>Workflow Grid</b> tab.   |
|                    | Study element               | 1 In the Project Explorer, select the <b>Elements and Events</b> Explorer bar. |
|                    |                             | 2 Select a study element.  |
|                    |                             | 3 Select the <b>Workflow Grid</b> tab.   |
| Form               | Study event                 | 1 In the Project Explorer, select the <b>Visit Schedule</b> Explorer bar.      |
|                    |                             | or   |
|                    |                             | 2 In the Project Explorer, select the <b>Elements and Events</b> Explorer bar. |
|                    |                             | 3 Select a study event.  |
|                    |                             | 4 Select the <b>Workflow Grid</b> tab.   |

- 2 Click within the gray box, located at the beginning of the row for the child study object.



- 3 Right-click the row of that study object, and select **Edit**.  
The Design tab for the selected study object appears.
- 4 Update the study object as needed.

# Study workflows and deployment to the InForm application

The design of a study workflow affects the following characteristics of the InForm study to which it is deployed:

- **Order of visits and forms** (on page 64)—The order of visits and forms in the InForm application depends on the order in which study objects are connected in a workflow and on the sequence numbers of study objects that are not connected.
- **Dynamic status of visits and forms** (on page 68)—Whether a visit or form is visible when a subject is enrolled in an InForm study depends on whether a study event or form is associated with a workflow rule or global condition in a study workflow. The outcome of the InForm rule that corresponds to a workflow rule or global condition determines whether a dynamic visit or form is activated.
- **Scheduling of visits** (on page 70)—The dates in the Visit Calculator that appears when a subject is enrolled in an InForm study and the MedML STARTHOUR value of a visit are generated from the scheduling information specified in a study workflow.

## InForm visits and forms

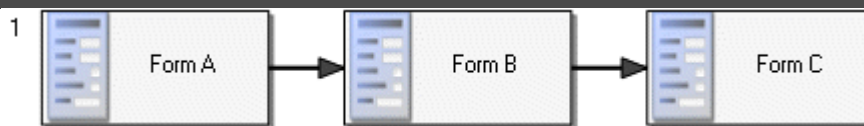
### Order of InForm visits and forms

The order of visits and forms in the InForm application depends on the order in which study objects are connected in a workflow and on the sequence numbers of study objects that are not connected.

**Note:** If the first object in a sequence is de-emphasized, the sequence number is also de-emphasized.

### Simple sequence of forms or study events

#### Simple sequence of forms or study events

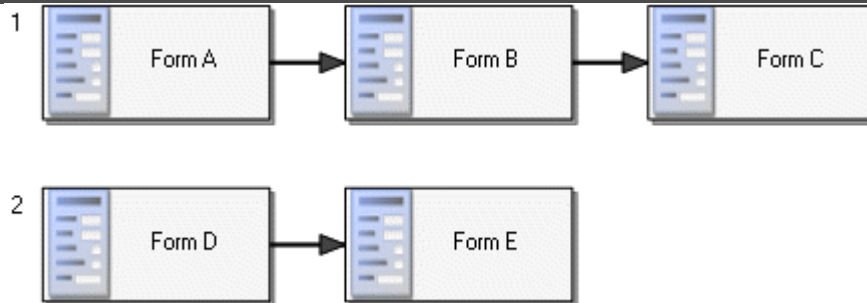


**Order in the InForm application:** Form A, Form B, Form C.

## Multiple sequences of forms or study events

A workflow can contain multiple sequences of connected study objects. The first study object in each sequence is labeled with a sequence number. For more information, see *Sequence numbers* (on page 75).

### Multiple sequences of forms or study events

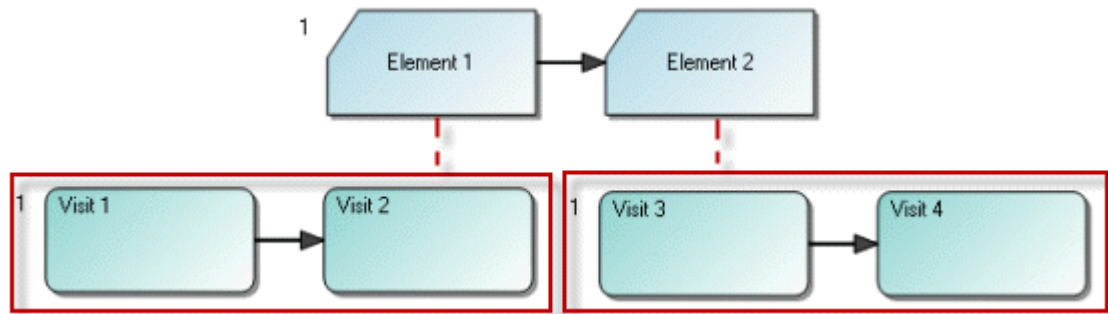


**Order in the InForm application:** Form A, Form B, Form C, Form D, Form E.

## Workflow with study elements

### Workflow with study elements

(Dotted lines indicate that the study elements contain the study events. These study objects do not appear together in the Workflow Diagram.)

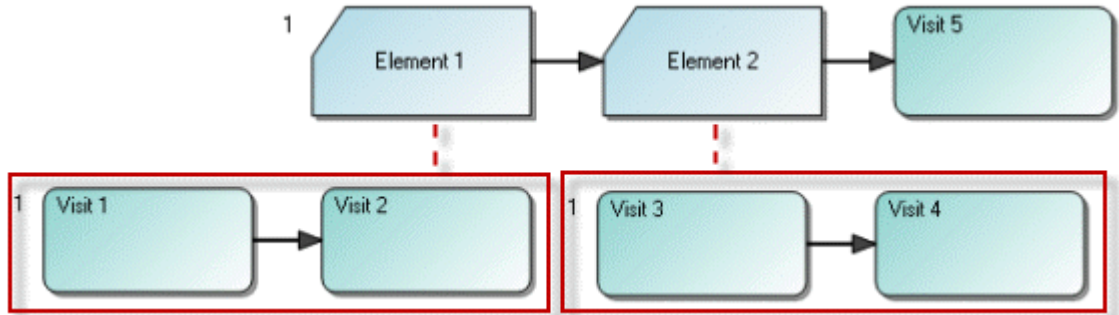


**Order in the InForm application:** Visit 1, Visit 2, Visit 3, Visit 4.

### Workflow with study elements and study events

#### Workflow with study elements and study events

(Dotted lines indicate that the study elements contain the study events. These study objects do not appear together in the Workflow Diagram.)

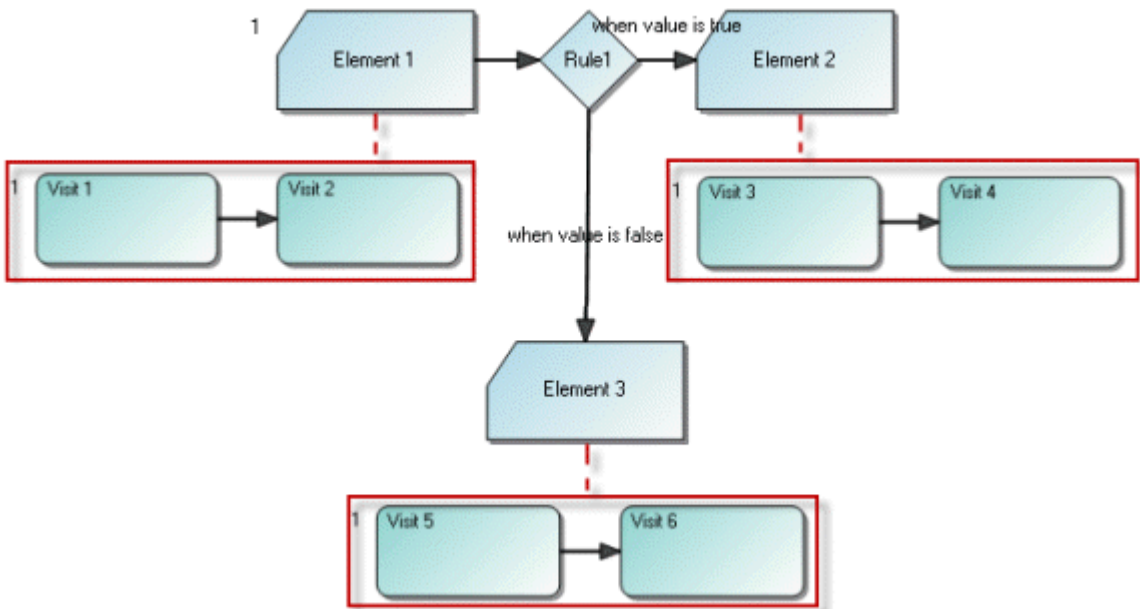


**Order in the InForm application:** Visit 1, Visit 2, Visit 3, Visit 4, Visit 5.

### Workflow with workflow rule

#### Workflow with workflow rule

(Dotted lines indicate that the study elements contain the study events. These study objects do not appear together in the Workflow Diagram.)



### Workflow with workflow rule

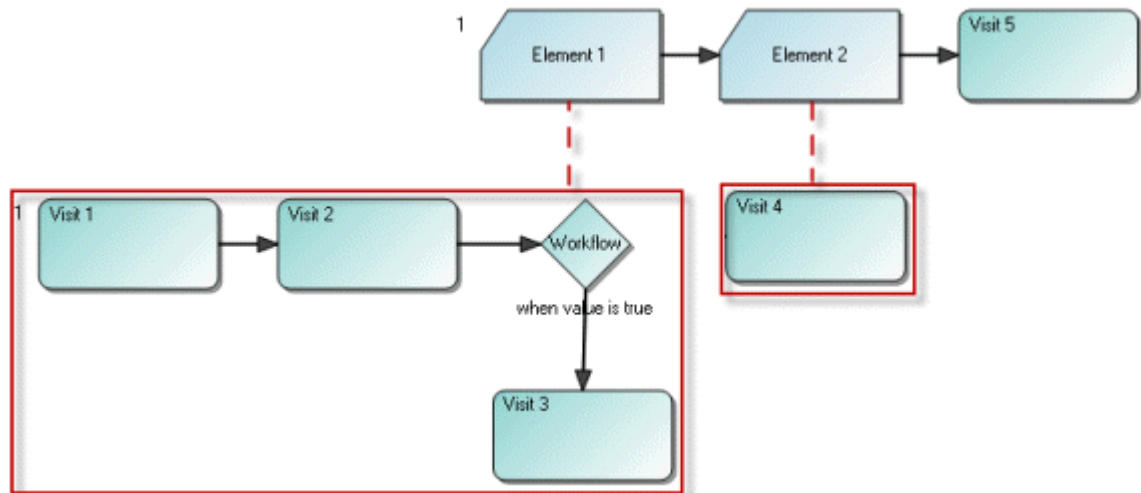
#### Order in the InForm application:

- **Initially**—Visit 1, Visit 2. Only Visit 1 and Visit 2 are in the Case Book. All other visits are dynamic and depend on the outcome of the rule.
- **If the rule evaluates to True**—Visit 1, Visit 2, Visit 3, Visit 4. Visit 5 and Visit 6 are dynamic and do not appear in the Case Book.
- **If the rule evaluates to False**—Visit 1, Visit 2, Visit 5, Visit 6. Visit 3 and Visit 4 are dynamic and do not appear in the Case Book.

#### Workflow with workflow rule (2)

### Workflow with workflow rule 2

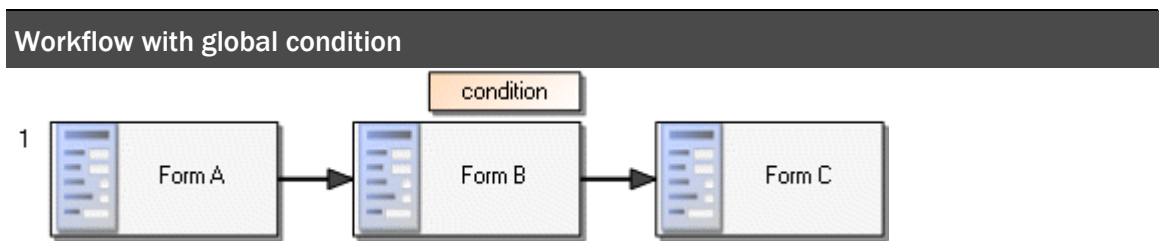
(Dotted lines indicate that the study elements contain the study events. These study objects do not appear together in the Workflow Diagram.)



#### Order in the InForm application:

- **Initially**—Visit 1, Visit 2, Visit 4, and Visit 5. Only Visit 3 is dynamic.
- **If the rule evaluates to True**—Visit 1, Visit 2, Visit 3, Visit 4, and Visit 5.
- **If the rule evaluates to False**—Visit 1, Visit 2, Visit 4, and Visit 5. Visit 3 is dynamic and does not appear in the Case Book.

## Workflow with global condition



## Order in the InForm application:

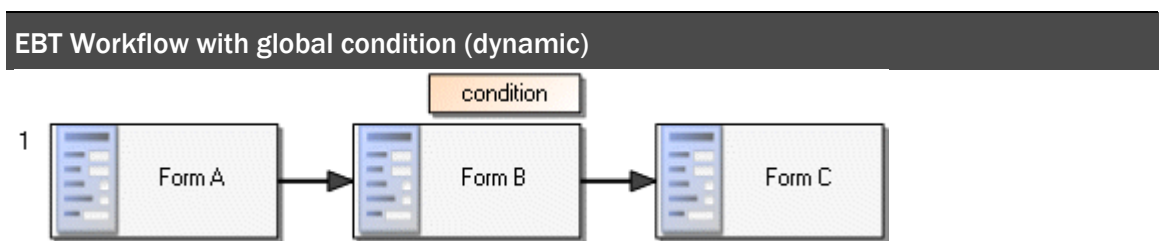
- **Initially, or if the condition evaluates to False**—Form A, Form C. Form B is dynamic and does not appear in the Case Book.
- **If the condition evaluates to True**—Form A, Form B, Form C.

## Dynamic status of InForm visits and forms

Whether a visit or form is visible when a subject is enrolled in an InForm study depends on whether a study event or form is associated with a workflow rule or global condition in a study workflow. The outcome of the InForm rule that corresponds to a workflow rule or global condition determines whether a dynamic visit or form is activated.

For information about a workflow with a workflow rule, see *Order of InForm visits and forms* (on page 64).

## Workflow with global condition



## Dynamic status in the InForm application:

- **Initially, or if the condition evaluates to False**—Form A and Form C are in the Case Book. Form B is dynamic and does not appear in the Case Book.
- **If the condition evaluates to True**—Forms A, B, and C are in the Case Book.

## Complex workflow with global conditions (Example 1)

### Study components

- Event1
  - Form1
    - Item1
    - Item2
- Event2 (with a global condition)
  - Form2 (with a global condition)

### Behavior

- Enter a value for Item1 and submit Form1 without entering a value for Item2: Event2 appears.
- Enter a value for Item2 and submit Form1 without entering a value for Item1: Neither Event2 nor Form2 appears.
- Subsequently enter a value for Item1 and submit Form1; Both Event2 and Form2 appear.

## Complex workflow with global condition (Example 2)

### Study components

- Event1
  - Form1
    - Item1
    - Item2
- Element1 (with a global condition)
  - Event2
  - Event3 (with a global condition)

### Behavior

- Enter a value for Item1 and submit Form1 without entering a value for Item2: All the visits in Element1 appear.
- Enter a value for Item2 and submit Form1 without entering a value for Item1: None of the visits in Element1 appear.
- Subsequently enter a value for Item1 and submit Form1: All the visits in Element1 appear.

## Scheduling of InForm visits

The dates in the Visit Calculator that appears when a subject is enrolled in an InForm study and the MedML STARTHOUR value of a visit are generated from the scheduling information specified in a study workflow.

A study element or study event in a workflow can be:

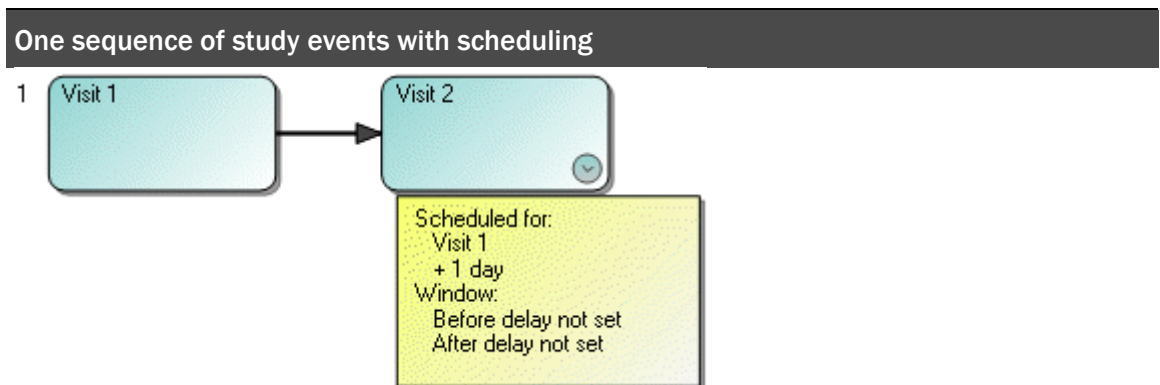
- **Scheduled**—You can schedule a study element or study event in the Workflow Diagram. The first study object in a sequence is considered to be scheduled by default.
- **Unscheduled**—If you do not schedule a study element or study event in the Workflow Diagram, the study element or study event is unscheduled in the InForm application. If a workflow has more than one sequence, the first study object in any sequence other than the first is considered to be unscheduled.

If a study object is unscheduled, its STARTHOUR value in the InForm application is set to 1 hour later than the previous study object in the sequence. This is to make sure that no two visits have the same STARTHOUR.

You can click the drop-down list in the lower-right corner of study elements and study events to view scheduling information.

### Workflows with scheduled and unscheduled study objects

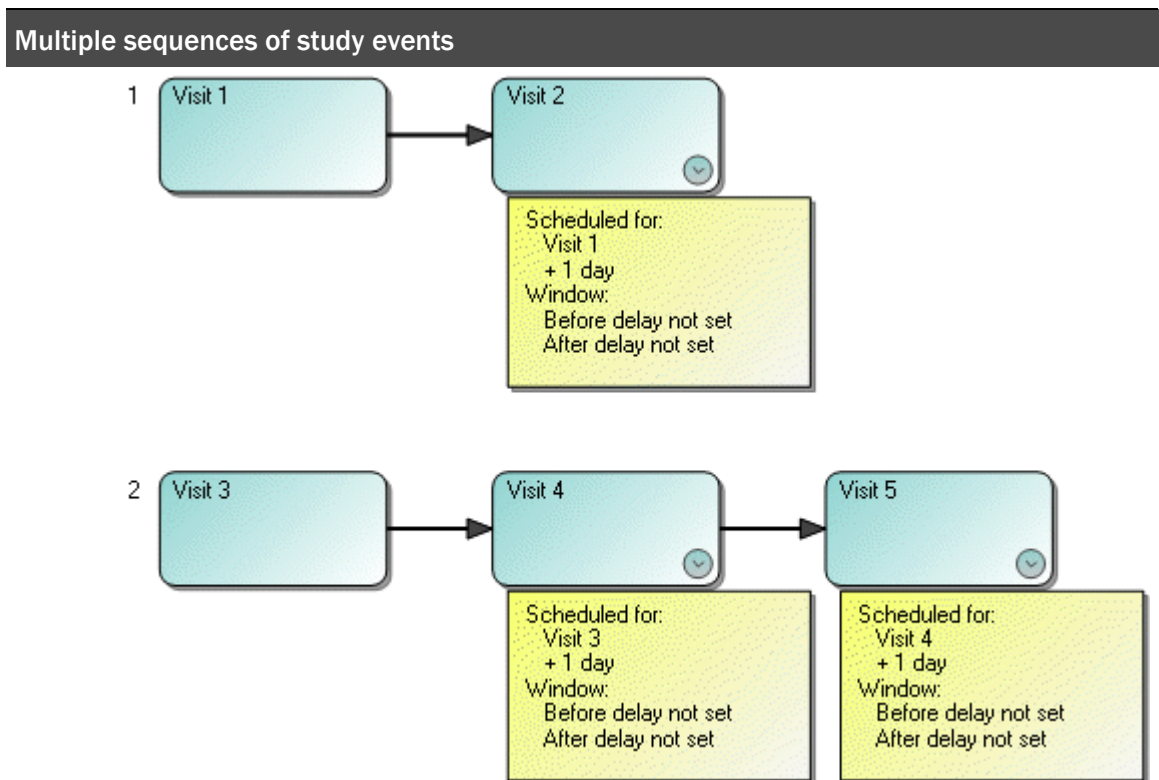
#### One sequence of study events with scheduling



**Scheduling in the InForm application:** Visit 1 and Visit 2 are scheduled. Visit 2 is scheduled one day after Visit 1.



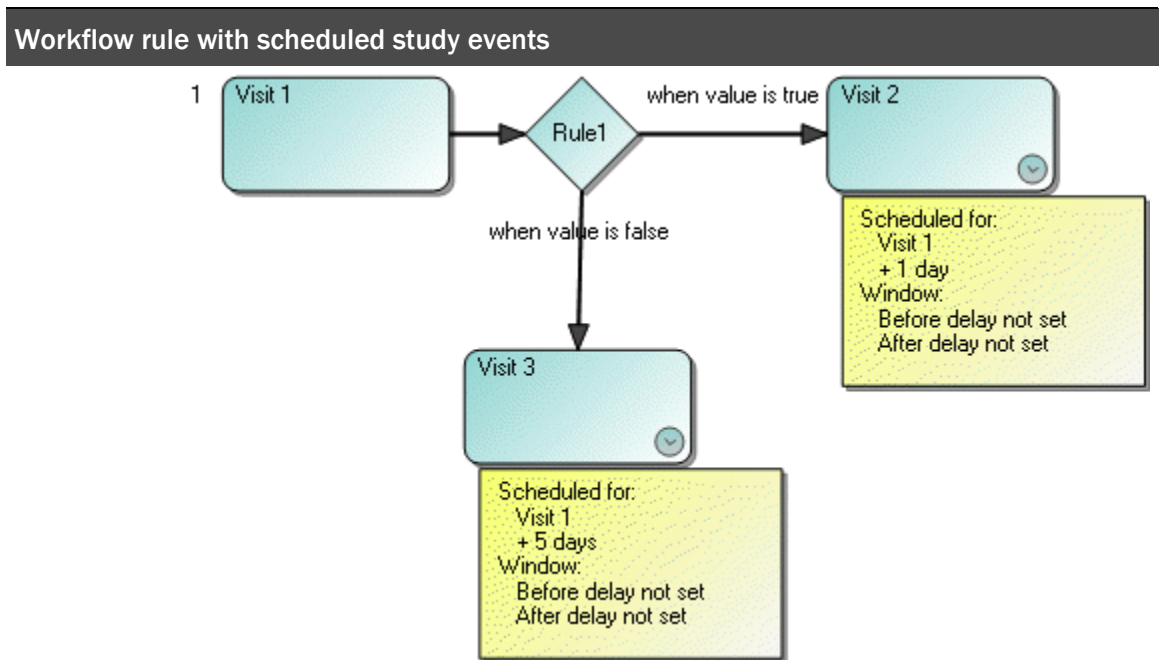
## Multiple sequences of study events



### Scheduling in the InForm application:

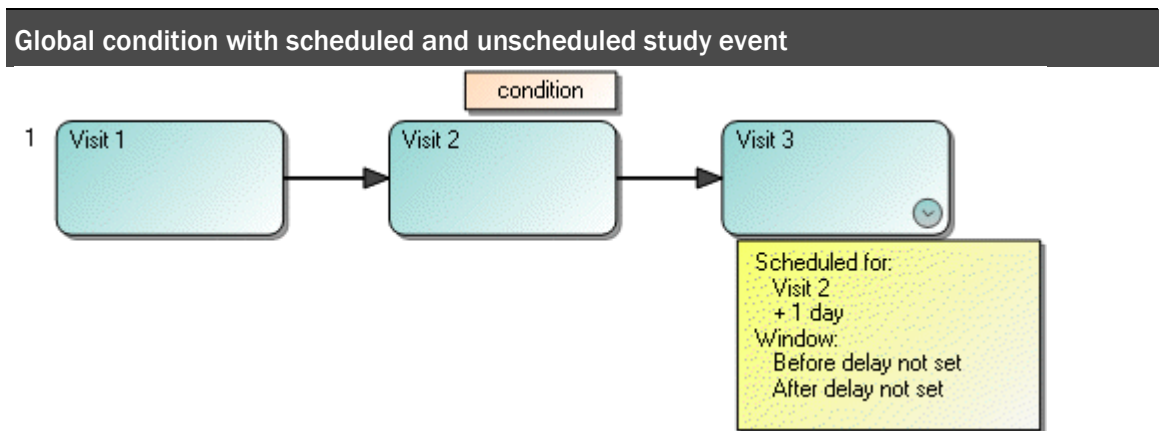
- All visits except Visit 3 are scheduled. Visits 2, 4, and 5 are scheduled one day after the previous visit.
- The STARTHOUR attribute of Visit 3 is one hour after Visit 2.
- Visit 5 is scheduled three days plus one hour after Visit 1.

Workflow rule with scheduled study events



**Scheduling in the InForm application:**

- Visit 1 is scheduled.
- The STARTHOUR attribute of Visit 2 is calculated to be one day after Visit 1, but Visit 2 does not appear in the Visit Calculator when the value of Rule1 is true.
- The STARTHOUR attribute of Visit 3 is calculated to be five days after Visit 1, but Visit 3 does not appear in the Visit Calculator when the value of Rule1 is false.

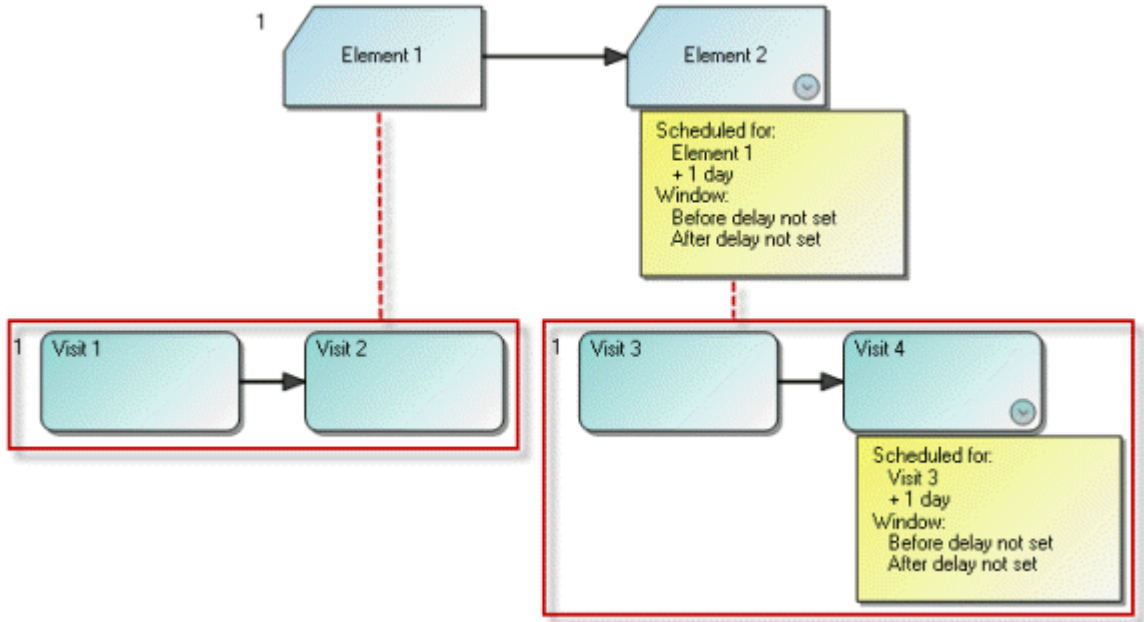
**Global condition with scheduled and unscheduled study event****Scheduling in the InForm application:**

- Visit 1 is scheduled.
- The STARTHOUR attribute of Visit 2 is calculated to be one hour after Visit 1, but Visit 2 does not appear in the Visit Calculator.
- Visit 3 is scheduled as one day after Visit 2 and one day plus one hour after Visit 1.

Scheduled study elements

**Scheduled study elements**

(Dotted lines indicate that the study elements contain the study events. These study objects do not appear together in the Workflow Diagram.)



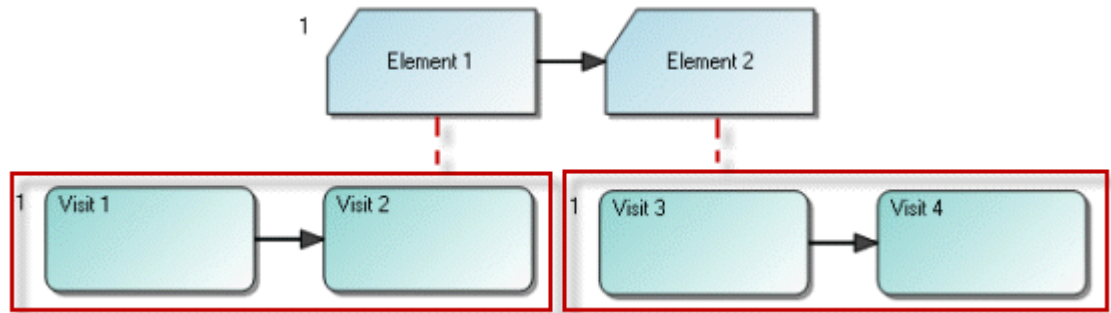
**Scheduling in the InForm application:**

- Visit 1 is scheduled.
- Visit 2 is unscheduled. Its STARTHOUR value is one hour after Visit 1.
- Visit 3 is scheduled as one day after Visit 2.
- Visit 4 is scheduled as one day after Visit 3, or two days plus one hour after Visit 1.

## Unscheduled study elements

### Unscheduled study elements

(Dotted lines indicate that the study elements contain the study events. These study objects do not appear together in the Workflow Diagram.)



### Scheduling in the InForm application:

- Visit 1 is scheduled.
- Visits 2, 3, and 4 are unscheduled. The STARTHOUR value of each is one hour after the preceding visit.

## Deploying to the InForm application

### Sequence numbers

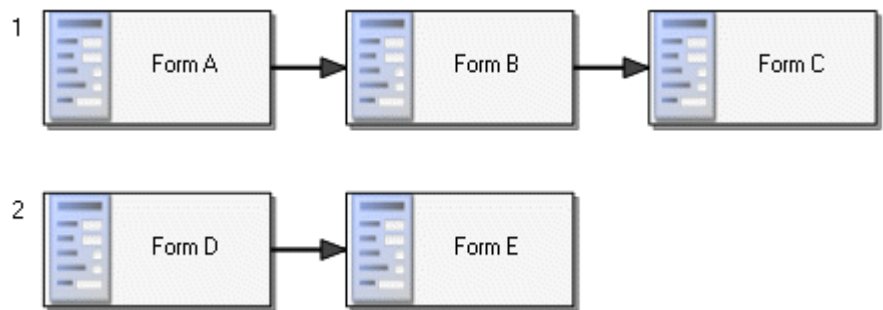
When you create a study object in the Workflow Diagram tab, a sequence number appears in a box near the upper left corner of the object. Initially, the sequence number indicates the order in which you created each study object.



As you connect study objects in a workflow, the sequence number disappears for each connected study object after the first.



A workflow can contain multiple sequences of study objects. The sequence numbers of the first study object in each sequence determine the order in which the sequences appear in a deployed study. In the following example, the order in which the forms appear when deployed is Form A, Form B, Form C, Form D, Form E.



You can change the sequence number for a study object in a workflow diagram. Changing the sequence number of a study object affects only the order in which multiple sequences are deployed. Changing the sequence number does not affect the order in which a study object appears in the Project Explorer or in the Workflow Diagram tab.

**Note:** The new sequence number cannot already exist in the workflow. To insert a new study object into the sequence, you must renumber other study objects to make the desired number available.

## Invalid workflows

To prevent the creation of an invalid workflow, the Central Designer application enforces the following rules:

- The sequence of workflow steps cannot be circular. The last step cannot point back to the first step.
- A study object that is associated with a global condition can have only one prerequisite step, and you cannot associate a global condition with a study object that has more than one prerequisite step.
- A study object can have only one outgoing arrow. Branching to two different study objects requires a workflow rule.
- The workflow action for each branch of a workflow rule outcome must be unique. For example, if a step follows a workflow rule when the expression evaluates to True, the other branch of the workflow cannot also be based on the expression evaluating to True.

# Working in the Schedule of Events tab

## Using the Schedule of Events tab to update the study workflow

The Schedule of Events tab is a matrix that lists the study events in a study and indicates the forms that are included in each study event. The Schedule of Events tab is available in studies and not in libraries.

The Schedule of Events tab enables you to create or update a study workflow quickly by selecting (with checkboxes) the forms to include in each study event. When you select or deselect the forms in a study event and save the study design, the Central Designer application updates the contents of the study event and also updates the study event workflow.

You can also navigate to the Form editor or delete forms from a study using the Schedule of Events tab.

## Adding or removing a form in the Schedule of Events

- 1 In the Project Explorer, select the **Visit Schedule** Explorer bar.
- 2 Select the study design.  
The Study Design Editor appears.
- 3 Select the Schedule of Events tab.
- 4 For each study event in which the form should be added or be removed, select or deselect the checkbox where the row of the study object and the column of the study event intersect.

The form is added or removed under each applicable Study Event container in the Project Explorer and is added to the Workflow Diagram and Workflow Grid tabs of the Study Event Editor.

## Deleting a form from the Schedule of Events

- 1 In the Project Explorer, select the **Visit Schedule** Explorer bar.
- 2 Select the study design.  
The Study Design Editor appears.
- 3 Select the Schedule of Events tab.
- 4 Right-click the row of the form, and select **Delete InForm form**.  
A message appears, prompting you to confirm the deletion.

- 5 Click one of the following:
  - **Yes**—Delete the study object.
  - **Yes, Always Delete**—Delete this study object, and do not prompt for confirmation in subsequent deletions.
  - **No**—Do not delete the study object.

**Note:** If you click **Yes, Always Delete**, and later decide that you want to be prompted before deletions, you can reset the prompt in the **Central Designer Options dialog box**, which is available from the **Tools** menu.

## Editing a form in the Schedule of Events

- 1 In the Project Explorer, select the **Visit Schedule** Explorer bar.
- 2 Select the study design.  
The Study Design Editor appears.
- 3 Select the Schedule of Events tab.
- 4 Right-click the row of the form, and select **Edit InForm form**.  
The Form Editor appears in the workspace and displays the definition of the study object you selected.
- 5 Edit the form.



# CHAPTER 3

## Designing forms

### In this chapter

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# Forms design activities

## About forms

A form is a container for one or more items. A form can contain one or more sections and supports multiple locales and layouts. (A section is a form embedded within a form.)

### Order in which to create forms

The order in which you can create forms and items depends on the current view of a study:

- In the Form editor, a form must first exist before you can create or copy its items or sections.
- In the Study Forms editor, you can create forms and items, or copy them into the study from a library, in any order.

### Working with multiple forms

The topics in this section focus on working with a single form. The Workflow Diagram and the Workflow Grid tabs of the Study Event Editor enable you to specify how forms relate to each other in the workflow of a study event. For more information, see *About study workflows* (on page 54).

### Naming conventions

Sometimes lists of forms in the Central Designer application include sections, and in the Study Forms Container Editor, sections and forms have the same icon. To more easily identify sections and forms, Oracle recommends that you use a naming convention. For example, you can preface a form name with **frm** and a section name with **sect**.

### Repeating, common, and associated forms

Certain types of forms have specialized characteristics when deployed in a study.

| Type of form  | Characteristic  | Property used to define form   |
|---|---|--|
| Repeating   | The form holds multiple instances of the same set of data.                                      | Repeating.<br>If this property is set to True, the form is repeating.  |
| Common  | The same data is visible in all study events that contain the form.                             | Common.<br>If this property is set to True, the form is common.  |
| Associated<br>(Two repeating forms in the same study event) | Data from both forms in the association is accessible when a study user works with either form. | AssociatedForm. (This property is visible only in the Structured view of a study.)<br>Two repeating forms in the same study event are associated if the AssociatedForm property of one form is set to the Title of the other form. |

## Creating and editing a form

You create a study object (study design, study element, study event, form, section, item, codelist, and codelist item) in a study or library. You can create a study object outside the hierarchy of a study or library, but the study object is not deployed until you add it to a parent study object in a study or library. To include a study object in the hierarchy of a study or library, add it to an existing parent in the study or library.

### To create a form:

- 1 To create a form on an existing study event:
  - In the Project Explorer, right-click a study event, and select **New > Form**.
 To create a form outside the hierarchy of a study or library:
  - a In the Project Explorer, select the **Forms and Transactions** Explorer bar.
  - b Right-click the Study Forms container, and select **Form**.
 The Object Name dialog box appears.
- 2 Type a title, RefName, and description, and click **OK**.

### To edit the properties of a form in the Properties Browser:

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 In the Forms folder, select a form.
- 3 Select the **Properties Browser**.

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

- 4 Edit the properties of the form. 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.

### To add one or more items to a form or section:

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 In the Forms folder, select a form.
- 3 Select the **Design** tab.
- 4 On the toolbar, click **Columns**, and display the columns that you need in the grid, including **Codelist** and **Item Properties**.
- 5 In the grid, create items on the form or section by typing values in each field. Press **Tab** to advance to the next field and, when you have reached the end of a row, to the next item.

Your changes are added to the grid after you move the cursor away from the row but are not saved in the database until you explicitly save them.

**Note:** To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add *HTML formatting characters* (on page 244) to a text field to control its appearance when deployed.

- 6 To modify the properties of an item:
  - a In the **Item Properties** field, click **Edit**, or on the toolbar, select **Item Properties**.  
The Item Properties dialog box appears.
  - b Define the *properties of the item* (on page 379). The fields that appear in the dialog box depend upon the type of item that you select. These properties are also available on the **Design** tab for an item.

**To add a codelist to an item:**

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 In the **Forms** folder, select the form or section that contains the item, and select the **Design** tab.
- 3 In the grid, select an integer, text, or float item.
- 4 Do one of the following:
  - If the codelist already exists, select it from the drop-down list in the **Codelist** field.
  - *Create a codelist* (on page 124) on the item.

## Making a form common or not common

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 In the **Forms** folder, right-click a form, and select **Common Form**.  
If **Common Form** is selected, the form is common. If **Common Form** is not selected, the form is not common.

## Making a form or section repeating or nonrepeating

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 In the **Forms** folder, right-click a form or section, and select **Repeating Form** or **Repeating Section**.  
If **Repeating Form** or **Repeating Section** is selected, the form or section is repeating.

## Marking a form for source verification

You can indicate that a form requires source verification or that a repeating form is critical for source verification in the InForm application by setting its SDV Required and SDV Critical properties.

**Note:** All forms that are marked SDV Critical automatically are marked SDV Required.

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 In the Forms folder, select a form.
- 3 Select the **Design** tab.
- 4 To indicate that the form requires source verification, select the **SDV Required** checkbox.
- 5 To indicate that the form is critical for source verification, select both the **SDV Required** and the **SDV Critical** checkboxes.

## Marking a form as a special InForm form

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 In the Forms folder, select a form.
- 3 Open the **Properties Browser**.

**Note:** If the Properties Browser is not visible, open the View menu and select Properties, if it is not already selected.

- 4 From the **Special Forms** drop-down list, select the type of special form.

## Associating two forms

You can associate two repeating forms that are in the same study event. You can associate a form with only one other form.

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 Select a form.
- 3 In the **Properties Browser**, select the form you want to associate from the drop-down list in the **Associated** property, and press **Enter**.

The Associated property for both forms is updated.

## Creating and translating instructions and Help for a form

You can create study documents that are specific to a target application or locale for study designs, study elements, study events, forms, sections, and items.

You can provide instructions and Help information if the study or library supports one or more locales, and if you have been given skills to work in the locales (in the Central Designer Administrator application).

### To create and delete instructions and Help:

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

The editor for the study object appears in the workspace.

- 2 Select the **Instructions & Help** tab.
- 3 To select a locale for the study documents, select the tab for the locale. The tabs are located along the bottom of the workspace.
- 4 To create or edit study documents:
  - a Type in the text area.
  - b Optionally, use the toolbar to format the appearance of the text. Additionally, you can use HTML formatting characters. For more information, see *Supported HTML formatting tags* (on page 244).
- 5 To delete study documents:
  - a On the toolbar, click the **Delete** button.  
or  
Select all of the text, and press **Delete**.  
A dialog box appears.
  - b Choose one of the following options:
    - Delete the study documents for only the selected locale.
    - Delete the study documents for all locales.

**To translate instructions and Help:**

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

The editor for the study object appears in the workspace.


- 2 Select the **Instructions & Help** tab.
- 3 To select a locale for the study documents, select the tab for the locale. The tabs are located along the bottom of the workspace.
- 4 Optionally, copy and paste study documents from a locale for which the information is already written.
- 5 Select the locale to which you want to translate.
- 6 Translate the study documents.
- 7 Optionally, use the toolbar to format the appearance of the text.

**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.

## Special InForm forms and items

In the InForm application, certain forms are required, and others have special design requirements to make sure that their data is handled correctly in an InForm study:

- **Screening** (on page 86).
- **Enrollment** (on page 88).
- **Patient Identification** (on page 89).
- **Study Completion** (on page 91).

Special InForm items are required for some forms. You can include the following additional special InForm items in a regular form:

- **Date of Visit** (on page 96).
- **Randomization** (on page 97).

If you do not include special InForm forms and items in your study design, the Central Designer application includes default versions of some forms and items when you deploy the study to the InForm application. Default versions are included for the following:

- **Screening form** (on page 86).
- **Enrollment form** (on page 88).
- **Date of Visit item** (on page 96).

### Screening form

The Screening form is included in the special InForm Screening visit as the system Screening form.

| Design consideration                         | Description  |
|--|--|
| Form title (value of Special Forms property) | Screening.   |
| Purpose in the InForm application            | Captures subject screening data.   |
| Required form?                               | Yes. If you include a custom screening form, select <b>Screening</b> in the Special Forms custom property list in the Properties Browser.  |
| Default version generated?                   | Yes. If you do not include a screening form, a default form is generated during deployment to the InForm application. The default form contains the item listed as a Required item. If you include a custom screening form, it must contain the required item.<br><br><b>Note:</b> Default forms and items appear in English in the InForm application. Create custom forms and items if you do not want to use the default information or if you want to translate an item or form. |



| Design consideration | Description  |
|----------------------|--|
| Required items?      | <ul style="list-style-type: none"> <li>• <b>Item</b>—Initials.</li> <li>• <b>Item type</b>—Text.</li> <li>• <b>Special Fields property</b>—Initials (Screening).</li> </ul>  |
| Optional items       | <ul style="list-style-type: none"> <li>• <b>Item</b>—Date of birth.</li> <li>• <b>Item type</b>—Date time.</li> <li>• <b>Special Fields property</b>—DOB (Screening).</li> </ul> <hr/> <ul style="list-style-type: none"> <li>• <b>Item</b>—Screening date.</li> <li>• <b>Item type</b>—Date time.</li> <li>• <b>Special Fields property</b>—Screening date (Screening).</li> </ul>  |
| Hidden items         | <p>During deployment, the Central Designer application creates two hidden items, itmWorkflow and itmVisitHours, which are used internally by Central Designer dynamics calculations to store data. These data items are not visible during form design or in the annotated study book.</p>   |
| Other requirements   | <ul style="list-style-type: none"> <li>• The Screening form must have the Special Forms custom property value of <b>Screening</b> and must be the only form in the study with this custom property value.</li> <li>• The study event that contains the Screening form must have the Special Visits custom property of <b>Screening</b> and must be the only study event in the study with this custom property value. The Screening study event must contain only the Screening form and no other forms.</li> <li>• The Screening study event must be a standalone study event that is not connected to the rest of the workflow.</li> <li>• The Screening study event must be the first study event in the workflow diagram.</li> <li>• Items with the following Special Fields custom property values can occur only once in a study and must be in a form with the Special Forms custom property value of <b>Screening</b>: <ul style="list-style-type: none"> <li>▪ Initials (Screening)</li> <li>▪ DOB (Screening)</li> <li>▪ Screening Date (Screening)</li> </ul> </li> <li>• The Screening form must not contain a repeating section.</li> </ul> |

## Enrollment form

The Enrollment form is included in the special InForm Enrollment visit as the system Enrollment form.

| Design consideration                         | Description   |
|--|---|
| Form title (value of Special Forms property) | Enrollment.   |
| Purpose in the InForm application            | Captures subject enrollment data.   |
| Required form?                               | Yes. If you include a custom enrollment form, select <b>Enrollment</b> in the Special Forms custom property list in the Properties Browser.   |
| Default version generated?                   | <p>Yes. If you do not include an enrollment form, a default form is generated during deployment to the InForm application. The default form contains an item with a text control called <b>Subject Number</b>. This item allows InForm users to specify a patient number.</p> <p><b>Note:</b> Default forms and items appear in English in the InForm application. Create custom forms and items if you do not want to use the default information or if you want to translate an item or form.</p>       |
| Required items?                              | No.   |
| Optional items                               | <p>If you include an optional Patient Number item, it must conform to the listed specifications.</p> <p><b>Note:</b> If you include the optional Patient Number item <b>and</b> you create a Patient Identification form, the Patient Identification form must include the same Patient Number item.</p> <ul style="list-style-type: none"> <li>• <b>Item</b>—Patient Number.</li> <li>• <b>Item type</b>—Text or Integer.</li> <li>• <b>Special Fields property</b>—Patient No. (Enrollment).</li> </ul> |

| Design consideration | Description  |
|----------------------|--|
| Other requirements   | <ul style="list-style-type: none"> <li>The Enrollment form must have the Special Forms custom property value of <b>Enrollment</b> and must be the only form in the study with this custom property value.</li> <li>The study event that contains the Enrollment form must have the Special Visits custom property of <b>Enrollment</b> and must be the only study event in the study with this custom property value. The Enrollment study event must contain only the Enrollment form and no other forms.</li> <li>The Enrollment study event must be a standalone study event that is not connected to the rest of the workflow.</li> <li>The Enrollment study event must be the second study event in the workflow diagram.</li> <li>The Enrollment form must not contain a repeating section.</li> </ul> |

## Patient Identification form

| Design consideration                         | Description  |
|--|--|
| Form title (value of Special Forms property) | Patient Identification.  |
| Purpose in the InForm application            | <p>Captures subject identification information that users can edit after a subject is enrolled.</p> <p>In the InForm application, the items on the special InForm Screening or Enrollment forms are not editable after a subject is screened or enrolled. If you want users to be able to change the patient initials or patient number, you must include those items on a form with a Special Forms property value of Patient Identification.</p> <p>When a subject is enrolled, the Patient Initials or Patient Number data is transferred from the Screening or Enrollment form to the Patient Identification form. Subsequently, when a user changes the patient identification fields on the Patient Identification form, the new information updates the patient object in the study database. The updated information is not reflected on the Screening and Enrollment forms.</p> <p>To transfer other data (for example, to transfer Date of Birth to a Demographics form), create a calculation rule to populate the item on the target form with the value of the item on the screening or enrollment form. When a subject is enrolled, the calculation runs in the InForm application.</p> <p><b>Note:</b> The ability to transfer screening and enrollment data other than Patient Initials or Patient Number is not available with some releases of the InForm application.</p> |
| Required form?                               | No.  |

| Design consideration       | Description   |
|----------------------------|---|
| Default version generated? | No.   |
| Required items?            | <p>The Patient Number item is required if either of the following is true:</p> <ul style="list-style-type: none"> <li>• You have created an Enrollment form with the Special Forms custom property of <b>Enrollment</b>, and that Enrollment form includes an item with the Special Fields custom property of <b>Patient No. (Enrollment)</b>.</li> <li>• You have not created an Enrollment form with the Special Forms custom property of <b>Enrollment</b>. In this case a default Enrollment form is generated.</li> </ul> <p>Otherwise, all items are optional.</p>  |
| Optional items             | <p>The following items, if included, must conform to the listed specifications.</p> <p><b>Note:</b> The Patient Identification form can also have other items, including items copied from the Screening or Enrollment special forms. If you copy Screening or Enrollment items, note the other requirements that apply.</p> <ul style="list-style-type: none"> <li>• <b>Item</b>—Initials.</li> <li>• <b>Item type</b>—Text.</li> <li>• <b>Special Fields property</b>—Initials (Patient Identification).</li> <li>• <b>Item</b>—Patient Number.</li> <li>• <b>Item type</b>—Text or Integer.</li> <li>• <b>Special Fields property</b>—Patient No. (Enrollment).</li> </ul> |

| Design consideration | Description  |
|----------------------|--|
| Other requirements   | <ul style="list-style-type: none"> <li>The Patient Identification form must have the Special Forms custom property value of <b>Patient Identification</b> and must be the only form in the study with this custom property value.</li> <li>If the <b>Patient Number</b> and <b>Initials</b> items are included on the <b>Patient Identification</b> form, the items must be together in either a section or the top-level form.</li> <li>You can copy the Initials item from the Screening form into the Patient Identification form. If you copy the Initials item: <ul style="list-style-type: none"> <li>Do not use the Copy &gt; Link command. Use Copy &gt; With new children or Copy &gt; With links to children.</li> <li>Change the Special Fields property value from <b>Initials (Screening)</b> to <b>Initials (Patient Identification)</b>.</li> </ul> </li> <li>If the Enrollment form contains a Patient Number item with the Special Fields property of <b>Patient No. (Enrollment)</b>, the Patient Number item on the Patient Identification form must be the same item. You can copy this item with the Copy &gt; Link command.</li> <li>If you copy the Date of Birth or Screening date items from the Screening form: <ul style="list-style-type: none"> <li>Do not use the Copy &gt; Link command. Use Copy &gt; With new children or Copy &gt; With links to children.</li> <li>Change the Special Fields property value from <b>DOB (Screening)</b> or <b>Screening date (Screening)</b> to <b>None</b>.</li> </ul> </li> <li>If you copy screening or enrollment items other than Initials, Date of Birth, or Screening date, you can copy them with the Copy &gt; Link command.</li> <li>The Patient Number and Randomization items cannot be on the same section or on the same form, outside a section. If one item is on a section, the other item is allowed to be outside the section on the same form.</li> </ul> |

## Study Completion form

| Design consideration                         | Description  |
|--|--|
| Form title (value of Special Forms property) | Study Completion.  |
| Purpose in the InForm application            | Records the completion of a study by a subject or the reason the subject dropped out of the study. |
| Required form?                               | No.  |
| Default version generated?                   | No.  |

| Design consideration   | Description  |
|--|--|
| Required items?  | <p>If a form is marked as the Study Completion form, the Completion Status or Drop-out Reason special field must also be present:</p> <ul style="list-style-type: none"> <li>• <b>Item</b>—Study completion status.</li> <li>• <b>Item type</b>—Integer or Text.</li> <li>• <b>Special Fields property</b>—Completion status (Study Completion).</li> </ul> <hr/> <ul style="list-style-type: none"> <li>• <b>Item</b>—Drop-out reason.</li> <li>• <b>Item type</b>—Integer or Text.</li> <li>• <b>Special Fields property</b>—Drop out reason (Study Completion).</li> </ul>  |
| Other requirements   | <ul style="list-style-type: none"> <li>• The Study Completion form cannot be repeating.</li> <li>• The Study Completion form must have the Special Forms custom property value of <b>Study Completion</b> and must be the only form in the study with this custom property value.</li> <li>• The item with the <b>Completion status (Study Completion)</b> Special Fields custom property must have a codelist that has two codelist items: <ul style="list-style-type: none"> <li>▪ <b>Yes codelist item</b>—The value of the Study Completion Status Items custom property for this codelist item must be <b>Complete Study (Study Completion)</b>.</li> <li>▪ <b>No codelist item</b>—The value of the Study Completion Status Items custom property for this codelist item must be <b>Incomplete Study (Study Completion)</b>.</li> </ul> </li> <li>• The item with the <b>Drop out reason (Study Completion)</b> Special Fields custom property must have a codelist that has at least one codelist item. The code on all codelist items must not have more than 47 characters. During deployment, the codelist item values are converted to InForm resources that are available in the InForm application for Reporting and Analysis. The item must be able to accept only one value.</li> </ul> |
| Designing for a CDD  | <p>If you are implementing a Custom-Defined Database (CDD), note that you can map the item with the <b>Drop out reason (Study Completion)</b> property to only one column. For mapping each drop-out reason to a separate CDD column, Oracle suggests the following design:</p>  |
| <ul style="list-style-type: none"> <li>• Compound item: Did the subject complete the study?</li> </ul> | <p>Create a compound item in which the No response to the study completion status question has multiple-selection child items for each drop-out reason. The compound item and its child items do not have a value for the Special Fields custom property.</p>  |

| Design consideration  | Description  |
|---|--|
| <ul style="list-style-type: none"> <li>Hidden Yes No item: Did the subject complete the study?</li> </ul> | <p>Create a hidden item with a codelist that has Yes and No codelist items.</p> <p>Custom properties:</p> <ul style="list-style-type: none"> <li><b>Item</b>—Special Fields property value is <b>Completion status (Study Completion)</b>.</li> <li><b>Yes codelist item</b>—Study Completion Status Items value is <b>Complete Study (Study Completion)</b>.</li> <li><b>No codelist item</b>—Study Completion Status Items value is <b>Incomplete Study (Study Completion)</b>.</li> </ul>   |
| <ul style="list-style-type: none"> <li>Hidden item: Reason for noncompletion</li> </ul>                   | <p>Create a hidden item with a codelist in which each codelist item corresponds to a child item in No response of the visible compound item.</p> <p>Custom property:</p> <ul style="list-style-type: none"> <li><b>Item</b>—Special Fields property value is <b>Drop out reason (Study Completion)</b>.</li> </ul>   |
| <ul style="list-style-type: none"> <li>Calculation rules</li> </ul>                                       | <p>Create calculation rules that map:</p> <ul style="list-style-type: none"> <li>The Yes response in the compound item to the Yes codelist item in the hidden Yes No item.</li> <li>The No response in the compound item to the No codelist item in the hidden Yes No item.</li> <li>The selected child item in the No response of the compound item to the corresponding codelist item in the hidden Reason for noncompletion item.</li> </ul> <p><b>Note:</b> Because the compound item allows multiple selections, and the hidden item requires a single selection, the rule must contain logic that prioritizes the noncompletion reason to select in the hidden item if multiple reasons are selected in the compound item.</p> |
| <ul style="list-style-type: none"> <li>Mapping</li> </ul>   | <p>In a CDD mapping, map each child item in the compound item to a different data series. Each data series maps to a separate CDD column.</p>  |

Illustration of Study Completion form design for CDD

| STUDY 2: STUDY COMPLETION FORM (SC) [frmSC]     |  |
|---|--|
| Study Completion Form [sctSC01]                 |  |
| 1. * Did the subject complete the study?        | <p>[COMPLETE]</p> <p>[1] <input type="radio"/> Yes</p> <p>[0] <input type="radio"/> [COMPREAS] _____ 2</p> <p>[REAS01]</p> <p>No, specify primary reason(s):</p> <p>[1] <input type="checkbox"/> Investigator's decision</p> <p>[REAS02]</p> <p>[2] <input type="checkbox"/> Subject withdrew consent</p> <p>[REAS03]</p> <p>[3] <input type="checkbox"/> Subject lost to follow-up</p> <p>[REAS05]</p> <p>[5] <input type="checkbox"/> Subject non-compliance</p> <p>[REAS06]</p> <p>[6] <input type="checkbox"/> Lack of efficacy</p> <p>[REAS08]</p> <p>[8] <input type="checkbox"/> Protocol violation</p> <p>[REAS12]</p> <p>[12] <input type="checkbox"/> Adverse event</p> <p>[REAS99]</p> <p>[99] <input type="checkbox"/> [OTHSP]</p> <p>Other, specify</p> <p>A100</p> |
| Study Completion Form (Report Fields) [sctSC02] |  |
| 2. Did the subject complete the study? [hidden] | <p>[COMPLETR]</p> <p>[1] <input type="radio"/> Yes [0] <input type="radio"/> No</p>  |
| 3. Primary reason [hidden]                      | <p>[COMPREAR]</p> <p>[1] <input type="radio"/> Investigator's decision</p> <p>[2] <input type="radio"/> Subject withdrew consent</p> <p>[3] <input type="radio"/> Subject lost to follow-up</p> <p>[5] <input type="radio"/> Subject non-compliance</p> <p>[6] <input type="radio"/> Lack of efficacy</p> <p>[8] <input type="radio"/> Protocol violation</p> <p>[12] <input type="radio"/> Adverse event</p> <p>[99] <input type="radio"/> Other</p>  |
| * Item is required.                             |  |



1—sctSC01 section with study completion data entry items.

2—COMPREAS compound item with multi-select integer items mapped to separate columns in the CDD.

3—sctSC02 section with special item and controls required for Reporting and Analysis.

4—COMPLETR hidden item with special custom properties:

- **Item**—Special Fields property value is **Completion status (Study Completion)**.
- **Yes codelist item**—Study Completion Status Items value is **Complete Study (Study Completion)**.
- **No codelist item**—Study Completion Status Items value is **Incomplete Study (Study Completion)**.

This item is populated with a calculation rule.

5—COMPREAR hidden item with dropout reason codelist. Special Fields property value is **Drop out reason (Study Completion)**. This item is populated with a calculation rule.

## Date of Visit item

| Design consideration              | Description   |
|-----------------------------------|---|
| Item                              | Date of visit.  |
| Purpose in the InForm application | Captures the visit date for any visit.  |
| Required form?                    | <p>A Date of Visit form is not required; however, a special Date of Visit item must be present on:</p> <ul style="list-style-type: none"> <li>• The first form of each visit, if you want to enable the <b>Enforce visit date entry</b> system configuration option in the InForm application.</li> <li>• The first form of each instance of a repeating visit in the InForm application, regardless of whether the <b>Enforce visit date entry</b> system configuration option is enabled in the InForm application.</li> </ul>  |
| Default version generated?        | <p>Yes. Validation checks for a Date of Visit item on the first form of each repeating study event. If a Date of Visit item is not present, a default Date of Visit form containing a Date of Visit item is generated for each repeating study event when you deploy a study to the InForm application.</p> <p><b>Note:</b> Default forms and items appear in English in the InForm application. Create custom forms and items if you do not want to use the default information or if you want to translate an item or form.</p> |
| Required items?                   | <ul style="list-style-type: none"> <li>• <b>Item</b>—Date of visit.</li> <li>• <b>Item type</b>—Date time.</li> <li>• <b>Special Fields property</b>—DOV (Date of Visit).</li> </ul>  |
| Other requirements                | A study can contain only one Date of visit item. To use the same item in multiple forms, use the Copy > Link command.   |

## Randomization item

| Design consideration              | Description  |
|-----------------------------------|--|
| Item                              | Randomization.   |
| Purpose in the InForm application | Holds a sequence and drug kit number generated by InForm randomization processing.   |
| Required form?                    | No. The special randomization item can appear on any form.   |
| Default version generated?        | No.  |
| Required items?                   | <ul style="list-style-type: none"> <li>• <b>Item</b>—Randomization.</li> <li>• <b>Item type</b>—Text. The field appears in the InForm application in the format <i>sequence / drug_kit_number</i>.</li> <li>• <b>Special Fields property</b>—Randomization field (Randomization).</li> </ul>   |
| Other requirements                | <ul style="list-style-type: none"> <li>• An item with the Special Fields custom property value of <b>Randomization field (Randomization)</b> can occur only once in a study.</li> <li>• The following configuration is required on the computer hosting the InForm study: <ul style="list-style-type: none"> <li>▪ Define a randomization sequence for each different list of drug kits used in the study and install it in the study database using the MedML Installer tool.</li> <li>▪ Configure the randomization data source manager.</li> <li>▪ Configure the format of each randomization sequence.</li> <li>▪ Set up a randomization source database.</li> <li>▪ Create an ODBC connection for the randomization source database.</li> </ul> <p>For more information, see the InForm documentation (<i>Study and Reporting Setup Guide</i>).</p> </li> <li>• In the Central Designer application, a randomization rule is required to generate the sequence and drug kit number. The Randomize function is available to help you create the rule. For more information, see <b>Randomize</b> (in the <i>Rules Reference Guide</i>).</li> <li>• The Patient Number and Randomization items cannot be on the same section or form. If one item is on a section, the other item is allowed to be outside the section on the same form.</li> </ul> |

## Deciding whether to create custom special InForm forms or use the default forms

Oracle recommends using the default forms if the items they contain meet your needs. You must create custom screening and enrollment forms if:

- You want to collect additional data (other than the default items) in the screening or enrollment form or to copy that data into another form in the study.
- You want users to be able to edit the screening or enrollment form after a subject is enrolled.
- You do not want to collect the default data on the screening or enrollment form.
- You want to translate the screening and enrollment forms.

You must create a form with the special Patient Identification Special Forms property if you want users to be able to update the patient number or initials and have the updated information stored in the patient object in the study database. If you create a form with the special Patient Identification Special Forms property, the form must include the special Patient Number item with a Special Fields property value of Patient No. (Enrollment) if:

- You include the special Patient Number item in a custom enrollment form.
- You use the default enrollment form containing the special Patient Number item.

## Validation for special InForm forms and items

| Validation area  | Error or warning   |
|--|--|
| All special forms<br>(Screening, Enrollment,<br>Patient Identification, and<br>Study Completion) | <p>Error if:</p> <ul style="list-style-type: none"> <li>• The study contains multiple instances of the form.</li> <li>• The form contains multiple instances of any item.</li> <li>• Required fields are not on the form.</li> <li>• The form is marked as repeating or appears in a repeating study event.</li> <li>• The Special Forms property is defined on a section that is on the form.</li> </ul>  |
| Screening and Patient<br>Identification forms  | <p>Error if:</p> <ul style="list-style-type: none"> <li>• (For a Screening form only) The form is used in multiple study events.</li> <li>• (For a Screening form only) The form contains a repeating section.</li> <li>• (For a Patient Identification form only) The Patient Number and Initials items are included on the form and are not together in either a section or the top-level form.</li> <li>• All items are not on the same section or form.</li> <li>• The item types for special items are not correct.</li> </ul> <p>Warning if the special items are on a non-special form.</p> |
| Enrollment form  | <p>Error if the:</p> <ul style="list-style-type: none"> <li>• Form is used in multiple study events.</li> <li>• Item types for special items are not correct.</li> <li>• Form contains a repeating section.</li> </ul> <p>Warning if the special items are on a non-special form.</p>  |
| Study Completion form  | <ul style="list-style-type: none"> <li>• Error if all items are not in the same form.</li> <li>• Warning if the special items are on a non-special form.</li> </ul>  |

| Validation area       | Error or warning   |
|-----------------------|--|
| DOV item              | <p>Error if the item:</p> <ul style="list-style-type: none"> <li>• Is used multiple times in a study, unless it was copied using Copy &gt; Link.</li> </ul> <p><b>Note:</b> You can use the Copy &gt; Link option to reuse the DOV item in a study. However, an error occurs if you use the DOV item multiple times in a study event, even if you copied it using Copy &gt; Link.</p> <ul style="list-style-type: none"> <li>• Was copied using the Copy &gt; Link option and pasted onto a form in the same study event.</li> <li>• Has an incorrect item type.</li> <li>• Is not on the first form in a study event.</li> <li>• Is in a repeating section or form.</li> <li>• Is in a common form or a section of a common form.</li> <li>• Is in a section in a repeating study event.</li> </ul> |
| Randomization item    | <ul style="list-style-type: none"> <li>• Error if the item appears multiple times in a study.</li> <li>• Error if the Patient Number and Randomization items are on the same section or form. If one item is on a section, the other item is allowed to be outside the section on the same form.</li> </ul>  |
| Patient Initials item | Warning if the item has 4 characters.  |
| Drop Out Reason item  | Error if the code for its codelist item has more than 47 characters.   |

## Custom properties for special InForm forms and items

The following custom properties identify special InForm visits (study events), forms, items, and codelist items:

- Special Visits (for study events).
- Special Forms (for a form).
- Special Fields (for an item).
- Study Completion (for the codelist items used in the Completion Status special item in a Study Completion form).

After defining a special InForm study event, form, item, or codelist item, you indicate how the study event, form, item, or codelist item will be used in the InForm study by selecting the appropriate custom property definition in the Properties Browser.

When a study event, form, item, or codelist item is defined as a specific type of Special Study Event, Form, Special Field, or Study Completion codelist item, the deployment process generates the MedML definitions for the required InForm study components, including forms, sections, or items, along with the required Universally Unique IDs (UUIDs).

**Note:** You can apply the Special Forms custom property only to a form, not to a section. If you apply the Special Forms custom property to a section, validation fails.

## Non-clinical forms

Regulatory documents and visit reports, which are monitoring forms, are custom forms used by monitors when they visit sites. You are not required to create monitoring forms. If you do not create the forms, default forms are created and deployed with the study.

- **Visit report form**—A form that a CRA uses to report findings from a site visit. A visit report form cannot be repeating but can contain a repeating section.
- **Regulatory document form**—A form that a CRA uses to record whether required regulatory documentation, such as the study protocol, IRB approvals, and electronic signature reporting documentation, is available and up to date. A regulatory document form is not repeating by default, but you can mark it as repeating.

During deployment, a study event is created for each monitoring form.

You can create one of each type of form in a study, and you can create multiple forms in a library.

**Note:** You can create monitoring forms only in the NonClinical container in the Project Explorer.

### Creating a regulatory document form

You can create only one regulatory document form in a study. You can create multiple forms in a library. When you create a regulatory document or visit report form in the NonClinical container, the Special Forms custom property in the Properties Browser is automatically set to the appropriate value (either Reg Docs or Visit Report).

A regulatory document form is not repeating by default, but you can mark it as repeating.

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 Select the **Non-Clinical** folder.
- 3 In the workspace, click **New > Reg Docs Form**.

The Object Name dialog box appears.

- 4 In the **Title** field, type the title of the study object.

As you type, the RefName field is filled in, using the Title text but omitting spaces and disallowed characters.

- 5 Optionally, in the **RefName** field, type a different RefName from the default.
- 6 Optionally, in the **Description** field, type a description of the study object.
- 7 Click **OK**.



## Creating a visit report form

You can create only one visit report form in a study. You can create multiple forms in a library. The form must contain a ***Date of Visit (DOV) item*** (on page 96) that is marked as a Date of Visit special item and is the first item on the form. The item does not have to be in its own section. When you create a regulatory document or visit report form in the NonClinical container, the Special Forms custom property in the Properties Browser is automatically set to the appropriate value (either Reg Docs or Visit Report).

A visit report form cannot be repeating but can contain a repeating section.

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 Select the **Non-Clinical** folder.
- 3 In the workspace, click **New > Visit Report Form**.

The Object Name dialog box appears.

- 4 In the **Title** field, type the title of the study object.

As you type, the RefName field is filled in, using the Title text but omitting spaces and disallowed characters.

- 5 Optionally, in the **RefName** field, type a different RefName from the default.
- 6 Optionally, in the **Description** field, type a description of the study object.
- 7 Click **OK**.

## Validation for monitoring forms

If you create a custom regulatory document form and a visit report form, the following must be true for the study to pass validation:

- Only one regulatory document form and one visit report form exist in the study.
- (For visit report forms only) The form contains a Date of Visit item that is marked as a Date of Visit special item and is the first item on the form.
- If the study supports multiple locales, the regulatory document form and visit report form are translated for all locales. A warning occurs if the forms are missing translations for one or more locales.
- The visit report form is not repeating.

# Designing sections

## About sections

If you want to group a set of related items together in a form, you can create a section for those items. Sections are not required components of a form. If you do include a section in a form, the section must have at least one item.

In a repeating section, multiple instances of the same set of data appear in the section.

In a fixed repeating section, multiple instances of the same set of data appear in the section, organized by one or more fixed items. For more information, see *Designing fixed repeating sections* (on page 108).

Sections are managed as forms. When you select a form that has one or more sections in the Project Explorer, the Form Editor for the form includes information about the sections in the form.

## Creating and editing a section

You create a study object (study design, study element, study event, form, section, item, codelist, and codelist item) in a study or library. You can create a study object outside the hierarchy of a study or library, but the study object is not deployed until you add it to a parent study object in a study or library. To include a study object in the hierarchy of a study or library, add it to an existing parent in the study or library.

### To create a section:

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 In the **Study Forms** folder, right-click a form, and select **New Section**.

The Object Name dialog box appears.

- 3 Fill in the fields as necessary, and click **OK**.

The section is created and appears in the Project Explorer, and the Design tab of the Section Editor appears in the workspace.

### To add one or more items to a form or section:

- 1 In the Project Explorer, select a form or section, and select the **Design** tab.
- 2 On the toolbar, click **Columns**, and display the columns that you need in the grid, including **Codelist** and **Item Properties**.
- 3 In the grid, create items on the form or section by typing values in each field. Press **Tab** to advance to the next field and, when you have reached the end of a row, to the next item.

Your changes are saved after you move the cursor away from the row.

**Note:** To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add *HTML formatting characters* (on page 244) to a text field to control its appearance when deployed.

- 4 To modify the properties of an item:
  - a In the **Item Properties** field, click **Edit**, or, on the toolbar, select **Item Properties**.  
The Item Properties dialog box appears.
  - b Define the *properties of the item* (on page 379). The fields that appear in the dialog box depend upon the type of item that you select. These properties are also available on the **Design** tab for an item.

**To add a codelist to an item:**

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 In the **Forms** folder, select the form or section that contains the item, and select the **Design** tab.
- 3 In the grid, select an integer, text, or float item.
- 4 Do one of the following:
  - If the codelist already exists, select it from the drop-down list in the **Codelist** field.
  - *Create a codelist* (on page 124) on the item.

**To make a form or section repeating:**

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 In the **Forms** folder, right-click a form or section, and select **Repeating Form** or **Repeating Section**.  
If **Repeating Form** or **Repeating Section** is selected, the form or section is repeating.

**To mark a repeating section as fixed:**

- 1 Navigate to a repeating section.
- 2 Do one of the following:
  - In the Project Explorer, right-click the repeating section and select **Fixed Repeating Section**.
  - In the *<Section name>* editor, select the **Fixed** checkbox.

**To edit the properties of a section in the Properties Browser:**

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 In the **Study Forms** folder, select a section.
- 3 Select the **Properties Browser**.

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

- 4 Edit the properties of the section. 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.

## Reordering the sections on a form

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 In the Study Forms folder, select a form with two or more sections, and then select the **Design** tab.
- 3 On the toolbar, click **Reorder Sections**.  
The Reorder Sections dialog box appears.
- 4 Select a section, and use the **Move Up** and **Move Down** buttons to reorder the form.
- 5 Click **OK**.

## Creating and translating instructions and Help for a section

You can create study documents that are specific to a target application or locale for study designs, study elements, study events, forms, sections, and items.

You can provide instructions and Help information if the study or library supports one or more locales, and if you have been given skills to work in the locales (in the Central Designer Administrator application).

### To create and delete instructions and Help:

- 1 In the Project Explorer, select a study object (study design, study element, study event, form, section, item, codelist, or codelist item).  
The editor for the study object appears in the workspace.
- 2 Select the **Instructions & Help** tab.
- 3 To select a locale for the study documents, select the tab for the locale. The tabs are located along the bottom of the workspace.
- 4 To create or edit study documents:
  - a Type in the text area.
  - b Optionally, use the toolbar to format the appearance of the text. Additionally, you can use HTML formatting characters. For more information, see *Supported HTML formatting tags* (on page 244).
- 5 To delete study documents:
  - a On the toolbar, click the **Delete** button.  
or  
Select all of the text, and press **Delete**.  
A dialog box appears.
  - b Choose one of the following options:
    - Delete the study documents for only the selected locale.
    - Delete the study documents for all locales.

**To translate instructions and Help:**

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

The editor for the study object appears in the workspace.


- 2 Select the **Instructions & Help** tab.
- 3 To select a locale for the study documents, select the tab for the locale. The tabs are located along the bottom of the workspace.
- 4 Optionally, copy and paste study documents from a locale for which the information is already written.
- 5 Select the locale to which you want to translate.
- 6 Translate the study documents.
- 7 Optionally, use the toolbar to format the appearance of the text.

**Viewing the parents of a linked section**

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.

# Designing fixed repeating sections

## About fixed repeating sections

You might want to design a form that allows a user to enter the same piece of data multiple times for the same item. For example, a user might need to record a subject's heart rate while the subject is sitting and then standing, at specified time intervals after the subject receives a drug.

To do this, you can create a fixed repeating section in the Central Designer application. A fixed repeating section includes items for which predefined values are configured by using codelists at study design time, and cannot be modified at runtime. For the above example, the fixed repeating section contains the following study objects:

| Study object         | Type                      | Description   |
|----------------------|---------------------------|---|
| TimePoint item       | Text, Integer, or Float   | The amount of time before or after a drug is administered when data is collected.<br>Contains predefined values.  |
| Time points codelist | Text, Integer, or Float   | Codelist items for each required time point. <ul style="list-style-type: none"> <li>• <b>Codelist item 1</b>—Pre-dose</li> <li>• <b>Codelist item 2</b>—15 minutes post dose</li> <li>• <b>Codelist item 3</b>—30 minutes post dose</li> <li>• <b>Codelist item 4</b>—45 minutes post dose</li> <li>• <b>Codelist item 5</b>—60 minutes post dose</li> </ul> The codelist items are the predefined values for the TimePoint item. |
| Position item        | Text, Integer, or Float   | The subject's position when the data is collected.<br>Contains predefined values.   |
| Position codelist    | Text, Integer, or Float   | Codelist items for each required subject position: <ul style="list-style-type: none"> <li>• <b>Codelist item 1</b>—Sitting</li> <li>• <b>Codelist item 2</b>—Standing</li> </ul> The codelist items are the predefined values for the Position item.  |
| HeartRate item       | Any type, other than Date | The subject's heart rate at each time point, for each position.<br>Does not contain predefined values.  |

In the Edit Fixed Table dialog box for this example, you might create the following rows:

| Row | itmTime value | itmPosition value | itmHeartRate |
|-----|---------------|-------------------|--------------|
| 1   | Pre-dose      | Sitting           |              |

| Row | itmTime value        | itmPosition value | itmHeartRate |
|-----|----------------------|-------------------|--------------|
| 2   | Pre-dose             | Standing          |              |
| 3   | 15 minutes post dose | Sitting           |              |
| 4   | 15 minutes post dose | Standing          |              |
| 5   | 30 minutes post dose | Sitting           |              |
| 6   | 30 minutes post dose | Standing          | BLANK        |
| 7   | 45 minutes post dose | Sitting           |              |
| 8   | 45 minutes post dose | Standing          |              |
| 9   | 60 minutes post dose | BLANK             |              |
| 10  | 60 minutes post dose | Standing          |              |

The following illustration shows the fixed repeating section in the form layout.

The screenshot shows the InForm Designer interface for a form named 'form1'. The form is divided into two sections: a fixed section (rows 2-6) and a repeating section (rows 7-10). The fixed section contains predefined values for TimePoint and Position, and a Heart Rate input field. The repeating section contains predefined values for TimePoint and Position, and a Heart Rate input field. The Heart Rate input field in the repeating section is highlighted in grey, indicating it is the item that does not contain predefined values. The fixed section is highlighted in light blue, indicating it contains predefined values. The repeating section is highlighted in light blue, indicating it contains predefined values. The Heart Rate input field in the repeating section is highlighted in grey, indicating it is the item that does not contain predefined values.

| TimePoint            | Position | Heart Rate           |
|----------------------|----------|----------------------|
| Pre-dose             | Sitting  | <input type="text"/> |
| Pre-dose             | Standing | <input type="text"/> |
| 15 minutes post dose | Sitting  | <input type="text"/> |
| 15 minutes post dose | Standing | <input type="text"/> |
| 30 minutes post dose | Sitting  | <input type="text"/> |
| 30 minutes post dose | Standing | <input type="text"/> |
| 45 minutes post dose | Sitting  | <input type="text"/> |
| 45 minutes post dose | Standing | <input type="text"/> |
| 60 minutes post dose | Sitting  | <input type="text"/> |
| 60 minutes post dose | Standing | <input type="text"/> |

1—HeartRate item that does not contain predefined values.

2—Fixed TimePoint and Position items that contain predefined values.

3—TimePoint codelist item for the Pre-dose predefined value. Each TimePoint codelist item contains two rows; each row corresponds to a Position codelist item.

- 4—Position codelist with predefined Sitting and Standing values. These predefined values appear five times in the fixed repeating section layout; each instance corresponds to a TimePoint predefined value
- 5—Blank cell for an item in a non-fixed column.
- 6—Blank cell for an item in a fixed column.

As noted in the form layout screenshot, you can also specify a data point that you do not want data for, but that appears in the fixed repeating section. In addition, in some cases, it might not make sense for you to collect certain data points. To do this, when you create a fixed repeating section, you locate the cell that corresponds to the data point, and set it as blank. In the annotated form preview, a cell that corresponds to data that should not be collected is grayed out. In the target application, data cannot be entered for that data point.

## About writing rules for fixed repeating sections

When you create rules that use the study objects in fixed repeating sections, consider the following:

- For values in fixed columns:
  - You can create a rule that references a value in a fixed column.
  - You can create a rule to check the value in a fixed column.
  - You cannot create a rule with a query, set value, or email action that affects a value in a fixed column.
- For values in non-fixed columns:
  - You can create a rule that references a value in a non-fixed column.
  - You can create a rule to check a value in a non-fixed column.
  - You can create a rule with a query, set value, or email action that affects a value in a non-fixed column.
- For blank cells:
  - You can create a rule that references a blank cell in a fixed or non-fixed column.
  - You cannot create a rule with a query, set value, or email action that affects a blank cell in a fixed or non-fixed column.
- You can create a rule for a fixed repeating section to compare data between the rows of data in the fixed repeating section.

For example, you can compare a subject's seated heart rate before receiving a drug to the subject's seated heart rate 30 minutes after receiving a drug.



## Creating and editing a fixed repeating section

To create a fixed repeating section:

- 1 Create a section.
- 2 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 3 In the **Study Forms** folder, right-click a form, and select **New Section**.

The Object Name dialog box appears.

- 4 Fill in the fields as necessary, and click **OK**.

The section is created and appears in the Project Explorer, and the Design tab of the Section Editor appears in the workspace.

- 5 In upper-right corner of the section editor, select the following checkboxes:
  - a Repeating
  - b Fixed.

- 6 Add one or more items to the section.

- 7 In the Project Explorer, select a form or section, and select the **Design** tab.

- 8 On the toolbar, click **Columns**, and display the columns that you need in the grid, including **Codelist** and **Item Properties**.

- 9 In the grid, create items on the form or section by typing values in each field. Press **Tab** to advance to the next field and, when you have reached the end of a row, to the next item.

Your changes are saved after you move the cursor away from the row.

**Note:** To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add *HTML formatting characters* (on page 244) to a text field to control its appearance when deployed.

- 10 To modify the properties of an item:

- a In the **Item Properties** field, click **Edit**, or, on the toolbar, select **Item Properties**.


The Item Properties dialog box appears.

- b Define the *properties of the item* (on page 379). The fields that appear in the dialog box depend upon the type of item that you select. These properties are also available on the **Design** tab for an item.

- 11 For each item that you want to define as a fixed item:

- *Create a codelist* (on page 124).
- *Create a codelist item* (on page 126).

**To mark one or more items as fixed in a fixed repeating section:**

- 1 In the *<Fixed repeating section name>* editor, do one of the following:
  - In the upper-right corner, click the **Fixed Table** icon ().
  - In the toolbar for the editor, click **Fixed Table**.

**Note:** If there is more than one fixed repeating section on the form, the Fixed Table control in the toolbar for the editor is a drop-down list. If there is one fixed repeating section on the form, the Fixed Table control is a button.

The Edit Fixed Table dialog box appears.

- 2 In the **Define Fixed Columns** section, select the items to mark as fixed.

A fixed item must:

- Be a top level item with no nested items.
- Be a text, integer, or float item.
- Have a control type of radio button or pull-down.
- Have a codelist and at least one codelist item defined.

**Note:** You cannot mark all items in a fixed repeating section as fixed.

- 3 Optionally, to view only fixed items in the fixed repeating section in the grid, deselect **Show non-fixed columns**.
- 4 Click **Add Row**, or right-click any arrow in the grid and select **Add Row** to add a row to the grid.
- 5 Optionally, to indicate that you do not want a user to enter data for a particular cell, right-click the cell and select **Set as Blank**.

The cell is grayed out, and when the study is deployed, the cell is disabled so that a user cannot enter data for that control. You can set a cell as blank for fixed and non-fixed items.

- 6 To modify the rows, use the buttons on the right of the dialog box.

# Items and codelists

## About items

An item is a study object used as a container for the collection of clinical data collected in a study. You can design different types of items, depending on the type of information you want to collect. By default, you can create the following types of items.

Additional item types might be available in your study if a library user has created and published them in a library that your study project uses.

| Item type      | Description   |
|----------------|---|
| Blood pressure | A specialized type of compound item used to collect blood pressure information on a form.   |
| Compound       | An item that has one or more child items that can have different data types.  |
| Date time      | An item used to collect date and time information on a form.  |
| Float          | An item used to collect numerical values with decimal points. You can also use a float item to collect information for a question with a codelist.  |
| Integer        | An item used to collect a numerical value without a decimal point. You can also use an integer item to collect information for a question with a codelist. The value entered in the InForm application must be between -2147483647 and +214483647.  |
| Text           | An item used to collect alphanumeric information. You can also use a text item to collect information for a question with a codelist.   |
| Yes no         | A specialized type of integer item used to collect yes or no answers to questions. A yes no item contains a predefined codelist with Yes and No options.<br><br><b>Note:</b> After you create a yes no item, it is listed as an integer item in the Form Editor and the Study Items Editor. |

## Conditional relationships between items

Conditional relationships between items make it possible to design items in which a user both selects one or more options and provides additional information about the selected option or options. You can use conditional relationships for collecting:

- Nested levels of multiple-choice data.
- User-entered information along with multiple-choice data, when you want to allow user-entered information for more than one choice in a list.

You can use up to five levels of nesting for compound and conditional items.

You design an item that contains nested information by:

- 1 Creating an item for each level of nesting. The parent item must include a codelist.
- 2 Making the nested item conditional on one of the codelist items in the parent item. You specify conditional relationships between items on the Design tab of the Form Editor.

For example, you can design an item that displays as a set of checkboxes nested within a radio group and includes text fields in which a user can type other information not covered by the existing options.

To design this item, you could create three items with codelists:

- An integer item for the Unknown/No/Yes options.
- An integer item for the family member options. The family member item is *conditional on* the Yes option of the Unknown/No/Yes codelist.
- A text item for the Other field. The text item is conditional on the Other option of the family member codelist.

#### Illustration of conditional items

Does any member of the subject's immediate family have a history of depression?

Unknown  
 No  
 Yes, please check as many as apply:
 

- Grandparent
- Parent
- Parent's sibling
- Sibling
- Other, specify:

1—First item contains Unknown/No/Yes codelist.  
 2—Second item contains family members codelist.  
 3—In the family members codelist, the text field is associated with the Other, specify codelist item.

1—First item contains Unknown/No/Yes codelist.

2—Second item contains family members codelist.

3—In the family members codelist, the text field is associated with the Other, specify codelist item.

For more information, see **Design tab of the Form Editor or Section Editor - Option Descriptions** (on page 363).

## About codelists and codelist items

Codelists enable you to design items in which a user selects from multiple choices. A codelist is 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). Each code-label pair makes up a codelist item.

Certain properties of codelists and codelist items must be unique:

- **Code of a codelist item**—Must be unique within a codelist.
- **Label of a codelist item**—Must be unique within a codelist.
- **RefName of a codelist or codelist item**—Must be unique within study object type.
- **Title of a codelist or codelist item**—Must be unique within a codelist.

You can include a codelist in the definition of a float, integer, or text item, and the Yes No item type includes a predefined codelist that contains Yes and No options. When you create a codelist, specify whether a study user must select only one option or can select multiple options.

Codelist data can appear as a drop-down list, as a set of radio buttons, or as a set of checkboxes. You specify the formatting information when you generate the layout of the form or item containing the codelist.

### Codelists and conditional item relationships

If you want to design more complex items in which a user both selects one or more options and provides additional information about the selected option or options, you can make an item conditional on an option in a codelist. You can use conditional relationships for collecting:

- Nested levels of multiple-choice data.
- User-entered information along with multiple-choice data.

## Items and units

When you create integer or float items, you can specify the base unit and one or more conversion units in which users can enter data. The available units and their conversion calculations are stored in the database. To specify additional units and conversion calculations or to provide locale-specific abbreviations, you must export the units file using the Central Designer Administrator application, edit it, and import the file using the Central Designer Administrator application.

For more information, see *Adding units and conversion calculations in the Administrator Guide*.

## Creating and editing an item

You create a study object (study design, study element, study event, form, section, item, codelist, and codelist item) in a study or library. You can create a study object outside the hierarchy of a study or library, but the study object is not deployed until you add it to a parent study object in a study or library. To include a study object in the hierarchy of a study or library, add it to an existing parent in the study or library.

**Note:** You can use an item only one time in any level of a particular study object hierarchy. For example, you can use the same item in different sections of a form but not twice in the same section of the form. In a single section, you can use the same item as a child item in two different compound items. To use identical item definitions multiple times in a single form, section, or compound item, copy the item as many times as you need, and use the copies.

**To add one or more items to a form or section:**

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 In the Forms folder, select a form.
- 3 Select the **Design** tab.
- 4 On the toolbar, click **Columns**, and display the columns that you need in the grid, including **Codelist** and **Item Properties**.

- 5 In the grid, create items on the form or section by typing values in each field. Press **Tab** to advance to the next field and, when you have reached the end of a row, to the next item.  
Your changes are added to the grid after you move the cursor away from the row but are not saved in the database until you explicitly save them.

**Note:** To type extended ASCII characters in text fields, press **ALT** while entering the decimal code for the character. You can also add *HTML formatting characters* (on page 244) to a text field to control its appearance when deployed.

- 6 To modify the properties of an item:
  - a In the **Item Properties** field, click **Edit**, or on the toolbar, select **Item Properties**.  
The Item Properties dialog box appears.
  - b Define the *properties of the item* (on page 379). The fields that appear in the dialog box depend upon the type of item that you select. These properties are also available on the **Design** tab for an item.

**To create an item outside the hierarchy of a study or library:**

- 1 In the Project Explorer, select the **Items** Explorer bar.
- 2 Select the **InForm Items** folder.  
The InForm Items editor appears.
- 3 On the toolbar, click **New**.  
A drop-down list appears with a list of available item types.
- 4 Select the type on which to create the item.
- 5 Type the title, RefName, and description, and click **OK**.  
The new item is added to the grid and to the container in the Project Explorer.

**To add a codelist to an item:**

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 In the **Forms** folder, select the form or section that contains the item, and select the **Design** tab.
- 3 In the grid, select an integer, text, or float item.
- 4 Do one of the following:
  - If the codelist already exists, select it from the drop-down list in the **Codelist** field.
  - *Create a codelist* (on page 124) on the item.

**To make an item conditional on a codelist selection within another item:**

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 In the **Forms** folder, select a form, and select the **Design** tab.
- 3 In the grid, select an item.
- 4 In the **Conditional On** column, select the title of the item with which to create a conditional relationship.

- In the **Conditional Value** column, select the **Code** and **Label** of the codelist item on which to make the current item conditional.

For more information, see *Conditional relationships between items* (on page 113).

#### To mark an item as a special InForm field:

- In the Project Explorer, select the **Items** Explorer bar.
- In the **InForm Items** folder, select an item.
- Open the **Properties Browser**.

**Note:** If the **Properties Browser** is not visible, open the **View** menu and select **Properties**.

- From the **Special Fields** drop-down list, select the type of special field.

#### To mark an item as critical for source verification:

You can indicate that an item is critical for source verification in the InForm application by setting its SDV Critical property.

**Note:** All items that are marked SDV Critical are automatically marked SDV Required.

- In the Project Explorer, select the **Items** Explorer bar.
- In the **InForm Items** folder, select an item.  
The Item Editor appears.
- Select the **Properties Browser**.

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

- From the **SDV Critical** drop-down list, select **True**, and press **Enter**.

#### To mark an item as collapsible:

You can indicate that an item is collapsible, meaning that it does not appear in the InForm application until specified conditions are met, by setting its Collapsible property.

**Note:** The **Collapsible** property is only available for child items that are conditional on parent items.

- In the Project Explorer, select the **Items** Explorer bar.
- In the **InForm Items** folder, select an item.  
The Item Editor appears.
- Select the **Properties Browser**.

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

- From the **Collapsible** drop-down list, select **True**, and press **Enter**.

**To mark an item as containing Personal/Protected Health Information (PHI):**

You can indicate that an item contains Personal/Protected Health Information (PHI) so that, during rule design and validation, the Central Designer application can verify that no PHI is transmitted through email in the InForm application because of a rule with an email action. For more information, see *Item properties* (on page 477).

- 1 In the Project Explorer, select the **Items** Explorer bar.
- 2 In the **InForm Items** folder, select an item.

The Item Editor appears.

- 3 Select the **Properties Browser**.

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

- 4 From the **PHI** drop-down list, select True, and press **Enter**.

**To edit the properties of an item in a form:**

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 In the **Forms** folder, select a form, and select the **Design** tab.
- 3 In the grid, select an item.
- 4 In the **Item Properties** field, click **Edit**, or, on the toolbar, select **Item Properties**.

The Item Properties dialog box appears.

- 5 Define the *properties of the item* (on page 379). The fields that appear in the dialog box depend upon the type of item that you select. These properties are also available on the **Design** tab for an item.

**To edit the properties of an item in the Properties Browser:**

- 1 In the Project Explorer, select the **Items** Explorer bar.
- 2 In the **InForm Items** folder, select an item.
- 3 Select the **Properties Browser**.

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

- 4 Edit the *properties of the item* (on page 477). 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.



**Default maximum input field lengths:**

When you create an item, you specify the length of the input field. The Central Designer application supports the following maximum field lengths as a default.

| Type of input field | Maximum length |
|---------------------|----------------|
| Text item           | 2000           |
| Integer item        | 10             |
| Float item          | 18             |
| Float precision     | 10             |

**Adding a child item to a compound item**

Compound items collect data in two or more data fields. The items that make up a compound item are its child items. The child items of a compound item can be different data types; for example, you can create a compound item with a date time and a text item.

**Note:** A blood pressure item is a specialized type of compound item, collecting a blood pressure measurement in two child items called **Systolic Variable** and **Diastolic Variable**.

**To create and add a child item to a compound item:**

- 1 In the Project Explorer, select the **Items** Explorer bar.
- 2 In the **InForm Items** folder, select a compound item.  
The Design tab of the Item Editor appears in the workspace.
- 3 In the **Child Items** section, complete a row in the **Compound Item** grid for each child item in the compound item:
  - a Type the **Question** and **Title**.
  - b Select the **Type**.
- 4 After you complete each row, and after the final row, press **Enter**, or tab or click in the next row.  
The child item is added to the compound item.

**To add an existing child item to a compound item:**

- 1 In the Project Explorer, select the **Items** Explorer bar.
- 2 In the **InForm Items** folder, select a compound item.  
The Design tab of the Item Editor appears in the workspace.
- 3 Drag an item from the **Project Explorer**, and drop it onto the **Child Items** grid.

## Reordering an item in a form or section

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 In the **Forms** folder, select the form or section containing the item to reorder.

The Design tab of the Form Editor opens.

- 3 In the leftmost column of the grid, drag and drop the button of the item to move onto the button of the item to appear below it.

The items are reordered so that the item you moved appears above the item you dropped it on.

## Specifying column heading text for an item in a repeating form or section

If an item is included in a repeating form or section, you must specify a value to be used as the column heading for the item in the layout of the form or section. Specify this value in the Short Question property of the item.

**Note:** If your InForm installation includes the Reporting and Analysis module, do not use the words **Subject Number** or **Subject Initials** as the value of the Short Question property for an item in a repeating form or section. **Subject Number** and **Subject Initials** are reserved terms in the Reporting and Analysis module. Using the words **Subject Number** or **Subject Initials** as a column heading in a repeating form or itemset definition causes an error when you generate the clinical reporting model. If the Question property of an item in a repeating form or section is **Subject Number** or **Subject Initials**, use a different formulation for the Short Question, (for example, **Subject Num** or **Subject Init**).

- 1 *Create the item* (on page 115).
- 2 Select the **Properties Browser**.

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

- 3 In the **Properties Browser**, type the column heading text in the Short Question property.
- 4 Press **Enter**.

## Reserved words for an item question or short question

The reserved words below cannot be used for the following item properties:

- Short question.
- Default question or Question if a Short question is not provided, or is populated with a reserved word.

If you specify a reserved word for the item Default question or Question you must provide a Short question that is not a reserved word, or the clinical model in the Reporting and Analysis module fails to generate.

To design an item for which a reserved word appears as the question on the form in the InForm application, specify the following:

- **Question**—Reserved word such as Subject Number.
- **Default question or Short question**—A word that is not on the reserved words list, such as Subj Number.

In this example, Subject Number appears as the question on the form, and Subj Number appears in the clinical model in the Reporting and Analysis module and as the itemset column header on the form in the InForm application. In addition, the clinical model is successfully generated.

- Subject Initials
- Subject Number
- Visit Mnemonic
- Form Mnemonic
- Site Mnemonic
- Visit Index
- Visit Order
- DOV
- Deleted Form
- CREATEDBYUSERID
- CREATEDDATETIME
- MODIFIEDBYUSERID
- MODIFIEDDATETIME
- Site Name
- Site Country
- SUBJECTID
- SITEID
- SUBJECTVISITID
- VISITID
- VISITINDEX
- FORMID
- FORMREV
- FORMINDEX
- CD\_COUNT

## About key items in a repeating form or section

In repeating forms and repeating sections, you can identify certain items as key items. In the InForm application, key items are used to:

- Simplify navigation to a specific instance of a repeating form. The values of key items appear in a drop-down list in the summary view of the repeating form, and users can navigate to a specific instance of the form by clicking the key item values for that instance.
- Verify that the values of certain items are unique among instances of a repeating form or an itemset.

### Key items for navigating to an instance of a repeating form

When you identify an item as a key item in a repeating form, regardless of whether it is used to establish data uniqueness, the value of the item appears in a drop-down list in the summary view of the repeating form in the InForm application. When an InForm user selects a specific set of key item values, the instance of the repeating form containing those key item values appears.

**Note:** Key items in a repeating section must always be defined as having individual or group uniqueness and are not used as navigation tools for instances of itemsets in the InForm application.

### Unique keys

Key items can have individual or group uniqueness:

- If key items are defined with *individual* uniqueness, an InForm user cannot add an instance of a repeating form or itemset in which the value of *any* key item is identical to the value of that item in another instance. For example, if the DATE and PROCEDURE items are defined as individually unique keys in a repeating form or section, the following table shows how the DATE and PROCEDURE items are evaluated when a user attempts to add new instances.

| DATE value    | PROCEDURE value | Result when data is submitted |
|---------------|-----------------|-------------------------------|
| May 1, 2009   | Hematocrit      | Instance or row added         |
| May 1, 2009   | Hemoglobin      | Instance or row rejected      |
| June 14, 2009 | Hematocrit      | Instance or row rejected      |
| June 15, 2009 | Platelet count  | Instance or row added         |

**Note:** A set of key items for a repeating form can include both items that are individually unique and items that appear in the drop-down list for navigation but are not used to enforce uniqueness. The key items can come from the repeating form or from a non-repeating section in the form.

- If key items are defined with *group* uniqueness, they make up a composite key. An InForm user cannot add an instance of a repeating form or itemset in which the values of *all* of the items in the composite key are the same as the values of all of the composite key items in another instance. For example, if the DATE and PROCEDURE items are defined as group unique keys

in a repeating form or section, the following table shows how the DATE and PROCEDURE items are evaluated when a user attempts to add new instances.

| DATE value    | PROCEDURE value | Result when data is submitted |
|---------------|-----------------|-------------------------------|
| May 1, 2009   | Hematocrit      | Instance or row added         |
| May 1, 2009   | Hemoglobin      | Instance or row added         |
| June 14, 2009 | Hematocrit      | Instance or row added         |
| May 1, 2009   | Hemoglobin      | Instance or row rejected      |

**Note:** If a group of key items is defined with group uniqueness, no other items in the repeating form or section can be defined as non-unique key items. Only the items that are defined with group uniqueness appear in the drop-down list of a repeating form.

## Key item requirements

A key item must:

- Be in a repeating section, if the key is for an itemset.
- Be in a repeating form or in a non-repeating section of the repeating form, if the key is for a repeating form.

A key item must not:

- Be a hidden item.
- Be a compound item.
- Be formatted as a checkbox.
- Have a caption that is aligned at the top or bottom of the control.
- Be in a nested control structure, unless it is at the top of the hierarchy and conforms to other eligibility requirements.

For example, consider an item called Continuing in an Adverse Events form. The Continuing item has a YesNo codelist formatted as radio buttons, and the No codelist item has a conditional date time item called End Date. In this example, the Continuing item can be a key item, but the End Date item cannot.

## Creating keys in a repeating form or section

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 Select a repeating form or section, and select the **Design** tab.
- 3 Right-click the row of an item, and select **Keys**.

The Keys dialog box appears.

- 4 In the **Data uniqueness for selected keys** section, select one of the following:
  - **None**—Key items appear in a drop-down list in the summary view of a repeating form as navigation aids. The key items are not used to enforce uniqueness of key values across instances of the repeating form.
  - **Individual**—Each key item must be unique across all instances of the repeating form or itemset in the InForm application.
  - **Group**—The combination of all key items evaluated together must be unique across all instances of the repeating form or itemset in the InForm application.
- 5 In the **Key selection** section, move the key items from the **Items available as keys** list to the **Selected keys** list.
- 6 If you are creating keys for a repeating form, and you selected **Individual** in the previous step, select the **Unique** checkbox for each item to designate as a unique key. (In a repeating section, the **Unique** checkbox is selected and disabled for all selected key items.)

**Note:** A set of key items for a repeating form can include both items that are individually unique and items that appear in the drop-down list for navigation but are not used to enforce uniqueness. The key items can come from the repeating form or from a non-repeating section in the form.

- 7 To change the order in which the items appear in the InForm application in the drop-down summary list of a repeating form, select an item and click the **Move Up** or **Move Down** button. Repeat this step for each item you want to move.
- 8 Click **OK**.

## Creating and editing a codelist

You create a study object (study design, study element, study event, form, section, item, codelist, and codelist item) in a study or library. You can create a study object outside the hierarchy of a study or library, but the study object is not deployed until you add it to a parent study object in a study or library. To include a study object in the hierarchy of a study or library, add it to an existing parent in the study or library.

### To add a codelist to an item:

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 In the **Forms** folder, select the form or section that contains the item, and select the **Design** tab.
- 3 In the grid, select an integer, text, or float item.
- 4 Do one of the following:
  - If the codelist already exists, select it from the drop-down list in the **Codelist** field.
  - **Create a codelist** (on page 124) on the item.

**To create a codelist outside the hierarchy of a study or library:**

- 1 In the Project Explorer, select the **Codelists** Explorer bar.
- 2 Select the **Codelists** folder.  
The Codelists Editor appears.
- 3 In the toolbar, click **New**.  
The Object Name dialog box appears.
- 4 Type a title, RefName, and description, and click **OK**.  
The codelist appears in the grid.
- 5 Double-click the codelist.  
The codelist is selected in the Project Explorer, and the Codelist Editor appears.
- 6 To add codelist items:
  - a In the rows and columns of the grid, type information about each codelist item to include in the codelist.
  - b After you complete each row, and after the final row, press **Enter**, or tab to the next row.

**To edit the properties of a codelist in the Properties Browser:**

- 1 In the Project Explorer, select the **Codelists** Explorer bar.
- 2 In the **Codelists** folder, select a codelist.
- 3 Select the **Properties Browser**.

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

- 4 Edit the *properties of the codelist* (on page 472). 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.

## Creating and editing a codelist item

You create a study object (study design, study element, study event, form, section, item, codelist, and codelist item) in a study or library. You can create a study object outside the hierarchy of a study or library, but the study object is not deployed until you add it to a parent study object in a study or library. To include a study object in the hierarchy of a study or library, add it to an existing parent in the study or library.

### To add codelist items to a codelist:

- 1 In the Project Explorer, select the **Codelists** Explorer bar.
- 2 In the **Codelists** folder, select a codelist.  
The Codelist Editor appears in the workspace.
- 3 In the rows and columns of the grid, type information about each codelist item to include in the codelist.
- 4 After you complete each row, and after the final row, press **Enter**, or tab to the next row.

### To edit the properties of a codelist item in the Properties Browser:

- 1 In the Project Explorer, select the **Codelists** Explorer bar.
- 2 In the **Codelist Items** folder, select a codelist item.
- 3 Select the **Properties Browser**.

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

- 4 Edit the *properties of the codelist item* (on page 473). 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.



# CHAPTER 4

## Designing rules

### In this chapter

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## About rules

The two classes of rules are:

- **Data-entry rule**—A rule that checks whether data is valid or that sets the value of an item based on a calculation. You can create a data-entry rule for study designs, study elements, study events, forms, and items.
- **Workflow rules and global conditions**
  - **Workflow rule**—A logical construct that tests data values to determine the study element, study event, or form to which a subject progresses next.  
You can create a workflow rule for a study element, study event, or form only.
  - **Global condition**—A logical construct that, when applied to a study object, determines whether the study object will appear for a particular subject.

## About data-entry rules

| Characteristic | Description   |
|----------------|---|
| Creating       | <p>You create the following rules in the <b>Rules tab</b> (on page 137):</p> <ul style="list-style-type: none"> <li>• <i>An intrinsic rule</i> (on page 150).</li> <li>• <i>A rule without a function</i> (on page 154).</li> <li>• <i>A rule using a function</i> (on page 160).</li> </ul>  |
| About          | <p>A data-entry rule is a rule that checks whether data is valid or that sets the value of an item based on a calculation. Different actions occur as a result of the evaluation of the rule expression. For example, an email can be sent or a query can be created.</p> <p>A data-entry rule is part of a study object and not a separate component that is attached to the study object. Rules can be part of study designs, study elements, study events, forms, and items.</p> <p>Because rules are part of study objects, when you reuse a study object from the library, you reuse the rules that are defined on that study object.</p> <ul style="list-style-type: none"> <li>• When a rule is part of a study object template or type, the rule is automatically part of all study objects created from the template or type.</li> <li>• When a rule is part of a study object and the study object is copied into another project, the rule is copied with the study object.</li> <li>• For valid data-entry rules, if you modify the RefName of a study object referenced by the rule, the data-entry rule is automatically updated with the change.</li> </ul> <p><b>Note:</b> Modifying the RefName of a study object from within the rule expression prevents the study object from being updated in rules that reference the study object.</p> |

| Characteristic             | Description  |
|----------------------------|--|
| Types                      | <p>You can create the following types of rules.</p> <ul style="list-style-type: none"> <li>• <i>Intrinsic rules</i> (on page 130).</li> <li>• <i>Calculation rules</i> (on page 134).</li> <li>• <i>Constraint rules</i> (on page 132).</li> </ul> <p>Depending on the rule, it might be better to use <i>an intrinsic rule, an expression rule, or a function</i> (on page 136).</p>  |
| Structure                  | <p>All data-entry rules consist of three parts.</p> <ul style="list-style-type: none"> <li>• <b>Precondition</b><br/>The event that causes a rule to execute, such as <b>On Demand (Batch Mode)</b> or <b>Form Submission</b>.</li> <li>• <b>Expression</b><br/>The <i>expression</i> (on page 146) that is evaluated.</li> <li>• <b>Action</b><br/>The action or actions to take depending on the result of evaluating the rule expression, such as create a query, store a value, or send an email message.<br/><b>Note:</b> The action clause is similar to an If statement in C++, C#, or Java.</li> </ul> |
| <b>Scope</b> (on page 138) | <p>A rule that is part of a study object can refer only to:</p> <ul style="list-style-type: none"> <li>• The study object and its children.</li> <li>• Properties and values of the study object and its children.</li> </ul> <p>This concept is called scope.</p>   |
| Running order              | <p>You cannot set the order in which data-entry rules are run.</p>   |
| Rule deployment            | <p>Rules created with two or more different actions are deployed to the InForm application as multiple rules. For example, a rule might call for:</p> <ul style="list-style-type: none"> <li>• A query to be sent.</li> <li>• An email message to be sent.</li> <li>• A value to be set.</li> </ul> <p>A different rule is created in the InForm application for each type of action. In the previous example, three rules are created:</p> <ul style="list-style-type: none"> <li>• One rule sends a query.</li> <li>• One rule sends an email message.</li> <li>• One rule sets a value.</li> </ul>          |

| Characteristic   | Description  |
|--|--|
| Deciding among hard-coded values, constants, and data mappings | <p>Oracle recommends that you do not use hard-coded values or hard-coded constants in rules, as the rule might be less reusable. Consider using constants or data mappings instead. A data mapping is another name for an item that has been added to a data series and has a global scope for the purposes of rule creation.</p> <p>If the value of an item is constant for every subject in a study, such as lab normal ranges, use constants. For example, if you expect blood pressure ranges to be uniform for all subjects in a study, you can use a constant for blood pressure.</p> <p>If you want to capture dynamic values, such as gender, which varies from subject to subject, use data mappings. For example, acceptable hemoglobin ranges differ for men and women, so it makes more sense to use data mappings for these values in a rule.</p> |
| Testing rules  | <p>You create test cases in the Rule Test Cases dialog box to test data-entry rules, workflow rules, and global conditions before deploying a study. Depending on the rule, you might create several or many test cases.</p> <p>You can create test cases either after writing each rule or after all rules are finished.</p> <p>To make sure that a rule is written correctly, consider writing and running a single test case for it, so you do not write many test cases for a rule that needs to be modified.</p>  |
| Naming conventions   | <p>You are not required to use a naming convention for rules, but conventions can help you distinguish one type of rule from another and avoid duplicate RefNames. If you want to adopt a naming convention, consider prefixing rules with the following:</p> <ul style="list-style-type: none"> <li>• wr - workflow rule</li> <li>• gc - global conditions</li> <li>• rul - data-entry rules (for example, rulDMConsDtCompare)</li> </ul>   |

## Intrinsic rules

| Characteristic                              | Description   |
|---|---|
| Definition                                  | <p>An intrinsic rule is a constraint rule or calculation rule based on a predefined rule template. Rule templates can be created for constraint rules and calculation rules. If no rule templates have been defined for the selected study object, then you cannot create an intrinsic rule for the study object.</p> |
| Study objects that can have intrinsic rules | <ul style="list-style-type: none"> <li>• Forms.</li> <li>• Form templates.</li> <li>• Items.</li> <li>• Item templates and types.</li> </ul>  |

| Characteristic                   | Description   |
|----------------------------------|---|
| Programming experience necessary | <ul style="list-style-type: none"> <li>• <b>To create intrinsic rules</b>—Programming knowledge is not required.</li> <li>• <b>To create rule templates</b>—Programming knowledge is required.</li> </ul>   |
| What to define                   | <p>The rule expression is defined by the rule template. You must define:</p> <ul style="list-style-type: none"> <li>• <b>When to evaluate the rule.</b></li> <li>• <b>Parameters for the rule template.</b></li> </ul> <p>If the rule template contains parameters, you indicate the source of the values to be substituted in the parameter with:</p> <ul style="list-style-type: none"> <li>▪ Numeric values.</li> <li>▪ Values of study objects and their rule model properties.</li> <li>▪ Constants.</li> <li>▪ Another function.</li> <li>▪ Data mapping study objects and their rule model properties.</li> </ul> <ul style="list-style-type: none"> <li>• <b>The action to take after the rule executes.</b></li> </ul>   |
| Example                          | <p>An intrinsic rule evaluates whether a weight value falls within a range that you specify using parameters.</p> <p>A programmer writes the rule expression in a rule template, and a non-programmer provides the following information to create the rule:</p> <ul style="list-style-type: none"> <li>• <b>When to evaluate the rule</b>—On form submission.</li> <li>• <b>Parameters for the rule template</b>—Provide the range. In this case, it is 45 to 125 kilograms.</li> <li>• <b>The action to take after the rule executes</b>—When the value is false, a query is issued. You can create additional actions to occur under different circumstances, such as an action to take when the value is true.</li> </ul> <p>The following information appears in the Rule Summary section:</p> <pre> evaluate on Form Submission value = Is the item between {MinValue:45} and {MaxValue:125} when value is false   issue query: Out of range </pre> <p>Alternatively, you can use a <i>constraint rule</i> (on page 132) to create this rule.</p> |

## Constraint rules

| Characteristic                                      | Description   |
|---|---|
| <b>Definition</b>                                   | <p>A constraint rule checks whether data is valid.</p> <p><b>Note:</b> There is no real difference between a calculation rule and a constraint rule. Each offers different starting points in the Rule Wizard; the options on the Actions tab change depending on the rule type that you select.</p>  |
| <b>Study objects that can have constraint rules</b> | <ul style="list-style-type: none"> <li>• Study designs</li> <li>• Study elements</li> <li>• Study events</li> <li>• Forms</li> <li>• Items</li> </ul>   |
| <b>Programming experience necessary</b>             | <p>Creating a constraint rule is comparable to writing formulas in the Microsoft Excel spreadsheet software.</p>  |
| <b>What to define</b>                               | <p>You must define:</p> <ul style="list-style-type: none"> <li>• <b>When to evaluate the rule.</b></li> <li>• <b>The rule expression.</b></li> </ul> <p>For calculation and constraint rules, you can use the following to define the rule expression:</p> <ul style="list-style-type: none"> <li>▪ <b>Study objects and their rule model properties.</b></li> <li>▪ <b>Functions.</b> If you use a function, you define values for its parameters using numeric values, values of study objects and their rule model properties, constants, and data mapping study objects and their rule model properties.</li> <li>▪ <b>Constants.</b></li> <li>▪ <b>Data mapping study objects and their rule model properties.</b></li> </ul> <ul style="list-style-type: none"> <li>• <b>The action to take after the rule executes.</b></li> </ul> |

| Characteristic                                 | Description   |
|--|---|
| <p><b>Example</b><br/>(without a function)</p> | <p>A constraint rule determines if a calculated BMI value is below the expected value of 30. You create the rule on the form that contains the weight and height items.</p> <p>You provide the following information to create the rule:</p> <ul style="list-style-type: none"> <li>• <b>When to evaluate the rule</b>—On form submission.</li> <li>• <b>The rule expression</b>—To create the rule expression, which calculates body mass index, either drag the weight and height items from the Data tab to the Expression workspace, or type the expression.</li> <li>• <b>The action to take after the rule executes</b>—You specify the constraint in the action. When the BMI is below 30, an email is sent.</li> </ul> <p>The following information appears in the Rule Summary section:</p> <p><b>evaluate on Form Submission</b></p> <pre>value = this.weight / (this.height)*(this.height) when value &lt; 30   send email: Subject has reached target BMI.</pre> <p>You could create the rule with a function, as described in the next example, or with a <i>rule template</i> (on page 130).</p>  |
| <p><b>Example</b><br/>(with a function)</p>    | <p>A constraint rule uses a function (<code>_CalculateBMI</code>) and determines if a calculated BMI value is below the expected value of 30. You create the rule on the form that contains the weight and height items.</p> <p>A programmer creates the function, and a non-programmer provides the following information to create the rule:</p> <ul style="list-style-type: none"> <li>• <b>When to evaluate the rule</b>—On form submission.</li> <li>• <b>The rule expression</b>—After you drag the function to the Expression workspace, the Invoke Function dialog box appears, and you can provide values for the parameters. In this case, you provide the weight and height items as parameters.</li> <li>• <b>The action to take after the rule executes</b>—When the BMI is below 30, an email is sent.</li> </ul> <p>The following information appears in the Rule Summary section:</p> <p><b>evaluate on Form Submission</b></p> <pre>value = _CalculateBMI(this.height.value, this.weight.value) when value &lt; 30   send email: Subject has reached target BMI.</pre> <p>You could create the rule without a function, as described in the previous example, or with a rule template. For more information, see <i>Intrinsic rules</i> (on page 130).</p> |

## Calculation rules

| Characteristic                                       | Description   |
|--|---|
| <b>Definition</b>                                    | <p>A calculation rule sets the value of an item based on a calculation.</p> <p><b>Note:</b> There is no real difference between a calculation rule and a constraint rule. Each offers different starting points in the Rule Wizard; the options on the Actions tab change depending on the rule type that you select.</p>   |
| <b>Study objects that can have calculation rules</b> | <ul style="list-style-type: none"> <li>• Study designs</li> <li>• Study elements</li> <li>• Study events</li> <li>• Forms</li> <li>• Items</li> </ul>   |
| <b>Programming experience necessary</b>              | <p>Creating a calculation rule is comparable to writing formulas in the Microsoft Excel spreadsheet software.</p>   |
| <b>What to define</b>                                | <p>You must define:</p> <ul style="list-style-type: none"> <li>• <b>When to evaluate the rule.</b></li> <li>• <b>The rule expression.</b></li> </ul> <p>For calculation and constraint rules, you can use the following to define the rule expression:</p> <ul style="list-style-type: none"> <li>▪ <b>Study objects and their rule model properties.</b></li> <li>▪ <b>Functions.</b> If you use a function, you define values for its parameters using numeric values, values of study objects and their rule model properties, constants, and data mapping study objects and their rule model properties.</li> <li>▪ <b>Constants.</b></li> <li>▪ <b>Data mapping study objects and their rule model properties.</b></li> </ul> <ul style="list-style-type: none"> <li>• <b>The action to take after the rule executes.</b></li> </ul> |



| Characteristic                          | Description   |
|---|---|
| <b>Example<br/>(without a function)</b> | <p>A calculation rule calculates BMI using height and weight values with RefNames of HT and WT. You create the rule on the form that contains the items.</p> <p>You provide the following information to create the rule:</p> <ul style="list-style-type: none"> <li>• <b>When to evaluate the rule</b>—On form submission.</li> <li>• <b>The rule expression</b>—The rule expression divides the weight value by the height value squared.</li> <li>• <b>The action to take after the rule executes</b>—The rule calculates BMI and stores the value in the BMI field.</li> </ul> <p>The following information appears in the Rule Summary section:</p> <pre> evaluate on Form Submission value = this.WT.Value / (this.HT.Value * this.HT.Value) always set this.BMI.Value = value </pre> <p>You could create the rule with a function, as described in the next example.</p>   |
| <b>Example<br/>(with a function)</b>    | <p>A calculation rule uses a function (<code>_BMI</code>) to calculate BMI from height and weight values with RefNames of HT and WT. You create the rule on the form that contains the items.</p> <p>A programmer creates the function, and a non-programmer provides the following information to create the rule:</p> <ul style="list-style-type: none"> <li>• <b>When to evaluate the rule</b>—On form submission.</li> <li>• <b>The rule expression</b>—After you drag the function to the Expression workspace, the Invoke Function dialog box appears, and you can provide values for the parameters. In this case, you provide the weight and height items as parameters.</li> <li>• <b>The action to take after the rule executes</b>—The rule calculates BMI and stores the value in the BMI field.</li> </ul> <p>The following information appears in the Rule Summary section:</p> <pre> evaluate on Form Submission value = _BMI(this.HT.Value,this.WT.Value) always set this.BMI.Value = value </pre> <p>You could create the rule without a function, as described in the previous example.</p> |

## When to use intrinsic rules, expression rules, and functions

The following table helps you to decide whether to use an intrinsic rule, expression rule, or a rule with a function. The table also provides guidance about whether rule developer or programming skills are required to create the rule. In many cases, form developers are able to create rules.

| Rule   | When to use it   | Who can create it   |
|--|--|---|
| Intrinsic rule                                   | Intrinsic rules are most helpful for simple functionality that is already defined in a rule template.  | Anyone who can write a logical expression. Typically, form designers are able to create intrinsic rules.                  |
| Expression rule (constraint or calculation rule) | If the functionality of a rule can be created in a rule expression and is not already defined in a rule template, create an expression rule.   | Expression rules are more complex than intrinsic rules. However, many form designers are able to create expression rules. |
| Function   | If the functionality of a rule is too complex for a rule expression and cannot be created using logical operators, the rule requires a function. If the functionality is not available in an existing function, the function must be created. Functions are built outside of the Central Designer application in a .NET environment. | A user with .NET skills.  |

## Rule collaboration

Some tasks for rule creation require programming knowledge, while others require some or no programming knowledge.

| Skill level             | Experience   | Typical tasks   |
|-------------------------|--|---|
| Programmer              | Ability to program in a .NET language (for example, C#) and create .NET assemblies.  | <ul style="list-style-type: none"> <li>Creates functions.</li> <li>Creates complex rule templates.</li> </ul>   |
| Some programming skills | <ul style="list-style-type: none"> <li>Understanding of C# or similar (for example, Java, C, or C++) expression syntax.</li> <li>Ability to incorporate functions in expressions.</li> </ul> | <ul style="list-style-type: none"> <li>Creates calculation and constraint rules and specifies: <ul style="list-style-type: none"> <li>When the rule fires.</li> <li>The action to take.</li> <li>A simple rule expression.</li> </ul> </li> <li>Creates less-complex rule templates, with or without functions.</li> <li>Creates constants.</li> <li>Checks rule syntax.</li> </ul> |

| Skill level               | Experience | Typical tasks   |
|---------------------------|------------|---|
| No programming experience | None.      | <ul style="list-style-type: none"> <li>• Creates intrinsic rules and specifies: <ul style="list-style-type: none"> <li>▪ When the rule fires.</li> <li>▪ What action to take.</li> <li>▪ The parameters of the rule template.</li> </ul> </li> <li>• Checks rule syntax.</li> </ul> |

## Disabled rules

To deploy a study without validating data-entry rules, workflow rules, or global conditions, you can disable the rules in the Central Designer application. Disabled rules are not deployed to the InForm application. This functionality allows you to more easily perform testing for a study during a development process in which forms and rules are being developed collaboratively by different users, by viewing the study in the InForm application, without having to validate rules. Disabling a rule does not prohibit you from performing rule-related tasks, such as editing the rule, and creating and running test cases for the rule. When you run validation, a message appears, listing the disabled rules for the study.

Disabled rules are:

- Not validated.
- Excluded from the deployment package.

**Note:** You can successfully run a test case for a single disabled rule. However, if you run more than one rule at a time, the Central Designer application will not run the test cases for any disabled rules.

**Note:** Oracle recommends that you disable rules and workflows only while developing a study. Use the InForm application to disable a rule on a live study.

## Rules tab

The Rules tab lists all the rules that are part of the selected study object. The tab can also display the rules on each child study object of the selected study object.

When a rule is selected in the Rules tab, the Rule Summary at the bottom of the tab shows a structured specification of the rule.

The Rules tab is part of the editors for study designs, study elements, study events, forms, sections, and items. In the Rules tab, you can view, search, and manage rules at the study object level. As in most grids, you can filter and sort the columns.

For more information, see **Rules tab - Option descriptions** (on page 423).

## Rule design considerations

### Rule scope

#### About scope

A rule that is part of a study object can refer only to:

- The study object and its children.
- Properties and values of the study object and its children.

This concept is called scope.

#### Child items of a compound item

The child items of a compound item are in the scope of the compound item.

#### Study objects that are outside the scope of a rule

If a study object falls outside the scope of a rule, you have the following options:

- Create the rule on a study object that is higher in the hierarchy and that has the necessary study object in its scope.
- Move the necessary study object within the scope of the study object on which you create the rule.
- Add the study object to a data series. Study objects that are part of mappings can be included in any rule in a study.

For more information, see:

- *Mappings for rule creation* (on page 195).
- *Rule mappings* (on page 208).

#### Tips

- To allow for reuse, create data-entry rules on the lowest-level study object that is reasonable based on scope requirements. For example, if an item requires a range check, create the range check on the item, not on the form that contains the item.
- Do not create all rules on the study design. Although all study objects in the study are in scope, you cannot reuse the rules because you cannot reuse study designs.
- If one or more study objects are outside the scope of a study object, Oracle recommends creating the rule on a higher-level study object that has all required study objects in its scope.

If you choose this option, the data-entry rule might be less likely to be reused because it is created on a study object that might not be reused in many other studies, but you are no longer limited by the scope of a particular study object.

- As early as possible, plan the study object on which every rule will be created.

For example, if a study event contains two forms, and you have a rule that requires data from both forms, the scope of the rule will allow you to create the rule on the study event or a higher study object.

## Rules and calculated fields

To write a rule that sets a value and sends an email, program the edit check in two separate rules, one to perform the calculation and another to contain the email action.

For example, consider the scenario where a rule should send an **Initial** email when a Serious Adverse Event has occurred and should also send a **Follow-up** email when subsequent changes are made to the Adverse Event form after the initial email has been sent.

In this scenario, you should create two rules:

- Rule 1: Calculate the value of a hidden item that stores the date the Initial email versus Follow-up email needs to be sent.
- Rule 2: Create an explicit trigger dependency on this hidden item, and specify an action to send email based on its value (Initial or Follow-Up).

## About overriding Screening and Enrollment failures

To design a rule that causes a subject to fail Screening and Enrollment in the InForm application:

- Create a rule on the Screening and Enrollment form or any of its child study objects (such as an item on the form).
- Add a query action to the rule.

When a subject fails Screening and Enrollment, an InForm user with the appropriate rights can override the failure if the study is configured to permit screening and enrollment overrides.

## Rules with multiple actions

You can create a rule with multiple actions, with some exceptions.

For a rule, you can create:

- Multiple calculation actions using the Set Value Action dialog box.
- Multiple query actions, as long as the queries are on the same item.
- A combination of the previous two.

You cannot create multiple query actions if the queries are on different items.

**Note:** Multiple query actions appear as additional lines in the Rules report.

## Rules on repeating study objects

When you create a rule on a repeating study object, and data is entered or updated in the InForm application:

- The rule executes only on the instance of the itemset, repeating form, or repeating visit where the data changes. It does not execute on all instances of the study object.
- The rule action (such as issuing a query) occurs only on the instance of the itemset, repeating form, or repeating visit where the data changes, not on all instances.

However, if the rule has a dependency on another study object, and data is entered or changed on the other study object, the InForm application executes the rule against all instances of the itemset, repeating form, or repeating visit.

## About copying and moving data-entry rules

You can copy and paste a data-entry rule or move a data-entry rule.

- **Copy and paste a data-entry rule.**

When you copy and paste a data-entry rule, a new instance of the data-entry rule is created. The copy of the data-entry rule has:

- A RefName in the following format:
  - **[Original rule RefName]\_[Number to uniquely identify the copied rule]**

For example, if you copy a data-entry rule with the RefName **chkDOV**, the RefName for the copied rule is **chkDOV\_1**. The appended number is incremented with each subsequent copy of the rule so that each rule has a unique RefName.

**Note: For library rules, a data-entry rule RefName must only be unique among sibling rules with the same parent object.**

- New instances of rule test cases associated with the original rule.

On a copied or moved data-entry rule, the Central Designer app deletes the test cases and does not modify the rule expression or action parameters. When you copy or move a rule, you must edit the rule as necessary and create new test cases.

- **Move a data-entry rule to another study object, using the cut and paste functionality.**

When you move a data-entry rule to another study object using the cut and paste functionality, a new instance of the data-entry rule is *not* created. The following occurs:

- In the Rules tab, the data-entry rule is grayed out.
- When you paste the data-entry rule to a new study object, the data-entry rule is moved from the original study object to the target study object. The Central Designer application does not create a new instance of the rule. The RefName and ID for the rule remain unchanged.

**Note: The cut and paste functionality for moving a data-entry rule from the Rules tab is different behavior than using the cut and paste functionality for study objects in the Project Explorer.**

### Notes:

- You cannot copy or move rule templates, workflow rules, or global conditions. You can only copy or move intrinsic rules to study objects for which the rule template (on which the intrinsic rule is based) is defined. However, a rule that is based on a function might not work as expected if you move or copy and paste the rule onto a study object with a rule that is based on a function with the same name and parameters but with a different expression.
- If you copy or cut a data-entry rule with rule test cases, the test cases are not copied with the rule.
- If you move a data-entry rule, rename any type of rule, or rewrite a rule so that its dependencies change, and then install a deployment package over an existing study, you must manually remove old rule attachments from the InForm application. If you do not change the name of the rule and the study contains old attachments, the StudyInstaller.log file lists warnings about them.

## About locking data-entry rules, workflow rules, and global conditions

You lock study objects and rules, including data-entry rules, workflow rules, and global conditions, independently of each other. Only the user who holds the lock can modify a data-entry rule, workflow rule, or global condition. The following types of locks are available:

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

**Note:** A lock icon is red if someone else holds the lock and green if you hold the lock. To view details about the lock, including the person who holds it, point to the lock icon.

## About workflow rules and global conditions

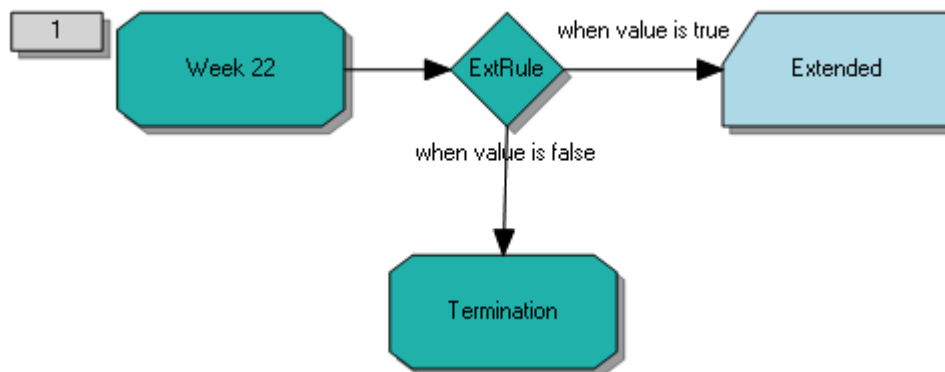
### Workflow rules

#### Definition

A workflow rule is a logical construct that tests data values to determine the study element, study event, or form to which a subject progresses next.

#### Example

For example, a workflow rule on a group of lab values could determine whether a subject branches to a set of extended visits or to a termination visit.



When you deploy a study to the InForm application, both study workflow branches that follow the rule are dynamic; no study objects in the workflow that come after the rule appear in the study until activated by the rule. When the workflow in the previous example is deployed, the Termination study event and all of the study events in the Extended study element do not exist until the ExtRule is executed. If the rule evaluates to true, the visits in the Extended study element appear in the Case Book, and if the rule evaluates to false, the Termination visit appears in the Case Book.

### Workflows and workflow rules

A workflow rule is part of the workflow in which it is created. If you want to use the logic of a workflow rule in multiple workflows, you must create it in each workflow separately.

For valid workflow rules, if you modify the RefName of a study object referenced by the rule, the workflow rule is updated with the change.

**Note:** Modifying a study object RefName from within the workflow rule expression prevents the study object from being updated in rules that reference the study object.

### Where to define

You can define workflow rules in the Workflow Diagram and Workflow Grid tabs.

### Naming conventions

You are not required to use a naming convention for rules, but it can help you distinguish one type of rule from another. If you want to adopt a naming convention, consider prefixing workflow rules with **wr** and global conditions with **gc** to differentiate them from data-entry rules.

### Deployment

Workflow rules and global conditions are deployed to the InForm application as trigger dependencies.

## Global conditions

A global condition is a logical construct that, when applied to a study object, determines whether the study object will appear for a particular subject. You can use a global condition instead of a workflow rule if, for example, multiple workflows depend upon the value of the same observation.

Using a global condition in a study workflow involves two steps:

- 1 **Creating** the global condition and its expression. For more information, see *Creating a global condition* (on page 172).
- 2 **Assigning** the global condition by associating it with a study object and specifying how its outcome affects the workflow. For more information, see *Assigning and removing a global condition* (on page 173).



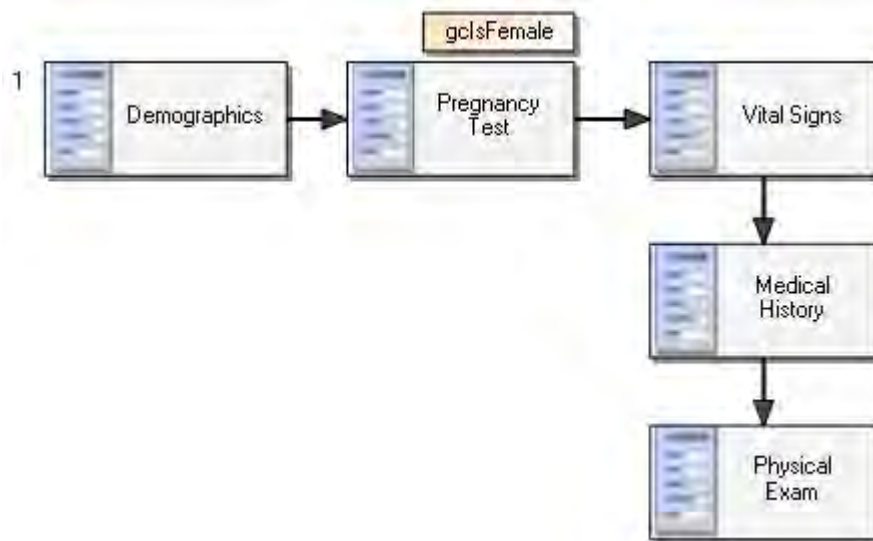
When you create a global condition, you specify the system with which you will use it.

You can assign an InForm global condition to any:

- Study element
- Study event
- Form

### Example

In the following example, a global condition checks whether the subject is female, based on the Gender item in the Demographics form. If the condition is true, the Pregnancy form is presented.



**Global condition: Is subject female?**

**(this.Demographics.Gender.Value == this.Demographics.Gender.GenderCodeList.Female)**

When you deploy a study to the InForm application, only the study object assigned to the global condition is dynamic. Study objects that follow the study object with the global condition in the workflow appear in the study. When the workflow in the example is deployed, the Vital Signs, Medical History, and Physical Exam forms appear in the visit after the Demographics form. The Pregnancy Test form appears in the visit only if the global condition outcome is True.

**Copying study objects with global conditions using the Libraries Browser**

Global conditions appear to be attached to study objects but are actually part of a workflow. They are copied with study objects in the following way:

- If a study event contains a form with a global condition, the global condition is actually part of the study event. When you use the Libraries Browser to copy the study event from a study to a library, the global condition is copied. The global condition is not copied if you copy only the form.
- If you use the Libraries Browser to copy the study event from a study to a library, publish only the form, and copy only the form into a study, the global condition is not copied into the study because the global condition is part of the workflow at the study event level.

**Note:** When a global condition is on a study element or study event that is created directly under the study design in the Project Explorer, the global condition cannot be copied from a study to a library. The global condition is actually on the study design, and you cannot copy a study design from a study to a library.

**Notes**

- You can apply only one global condition per study object, so you must create an expression that evaluates all relevant data points in one global condition. Therefore, you cannot apply the global condition to multiple study objects if the other study objects require other actions. When you need to apply the same action to multiple study objects, Oracle recommends creating a workflow rule instead of applying a single global condition to multiple study objects. A workflow rule is evaluated only once.
- For valid global conditions, if you modify the RefName of a study object referenced by the rule, the global condition is updated with the change.

If you modify a study object RefName in the global condition expression, the study object is not automatically updated in other rules that reference it.

- You are not required to use a naming convention for rules, but it can help you distinguish one type of rule from another. If you want to adopt a naming convention, consider prefixing workflow rules with **wr** and global conditions with **gc** to differentiate them from data-entry rules.
- Workflow rules and global conditions are deployed to the InForm application as trigger dependencies.

## Deciding between a workflow rule and a global condition

### When to use workflow rules

Use a workflow rule to determine the branch of a study workflow that a subject should follow. For example, you can use a workflow rule to determine whether a subject completes a study with the standard termination visit or continues on to a set of extended visits.

When you need to apply the same action to multiple study objects, Oracle recommends creating a workflow rule instead of applying a single global condition to multiple study objects. A workflow rule is evaluated only once.

When a study is deployed, the study objects that follow the workflow rule do not appear in the study book until the rule outcome determines the branch a study subject should follow.

### When to use global conditions

Use a global condition when you want a single study workflow object to be dynamic. For example, you can use a global condition to generate a pregnancy test form for female subjects.

Because you can apply only one global condition per study object, you must create an expression that evaluates all relevant data points in one global condition. Therefore, you cannot apply the global condition to multiple study objects if the other study objects require other actions.

When a study is deployed, the study object to which the global condition is applied does not appear in the study book until the outcome of the global condition determines whether it is needed.

## About the rule expression language

Use the rule expression language to create the expression component of a data-entry rule, workflow rule, or global condition.

You create rule expressions in:

- The Expression tab of the Rule Wizard.
- The Expression workspace of the dialog boxes used to create or edit a workflow rule or global condition.

As you type, a list of the rule model components that you can use in the expression (study objects and their properties, functions, constants, and data mappings) appears in the Expression workspace. When you select a rule model component, a tooltip appears to indicate its usage (for example, the parameters and their data types required for using a function). The list changes dynamically to support the contents of the expression as you create it.

You can also use the following methods for creating a rule expression:

- Drag rule model components into the Expression workspace from the tabs that appear on the right side of the workspace.
- Type an expression directly in the Expression workspace.

A rule expression can include any valid C# expression that can appear on the right side of the equals sign (=), including:

- Operators and literals.
- Study objects and their rule model properties.
- Functions.
- Constants defined for the study.
- Data mapping study objects and their rule model properties.
- Methods. You can use any method, including:
  - Math methods.
  - Data set methods.
  - Methods for repeating study objects.

A rule expression cannot include:

- Complex structures, such as if statements (conditionals are allowed) and looping statements.  
Use functions to build more complex rule expressions. For more information, see ***Functions tab of the Rule Wizard*** (in the *Rules Reference Guide*).
- Multi-line expressions.  
The rule expression does not allow flow-of-control operators, such as *like*, *if*, *then*, *for*, or *while*. You can use parentheses to provide better readability and grouping.

An expression must evaluate to one of the following types:

- Integer
- Float
- Boolean
- Text
- Date time

**Note:** A rule expression is similar to a switch statement in C++, C#, or Java.

## Dynamic prompts in the Expression workspace

When you create an expression, you can type directly in the Expression workspace, and you can drag rule model objects from the tabs at the right side of the windows where you create a data-entry rule, workflow rule, or global condition.

When you type in the Expression workspace, prompts appear dynamically as you type, listing the rule model objects that are available for you to use based on the scope of the rule and the content of the expression. As an alternative to dragging rule model objects from the tabs, you can select the objects from the prompts.

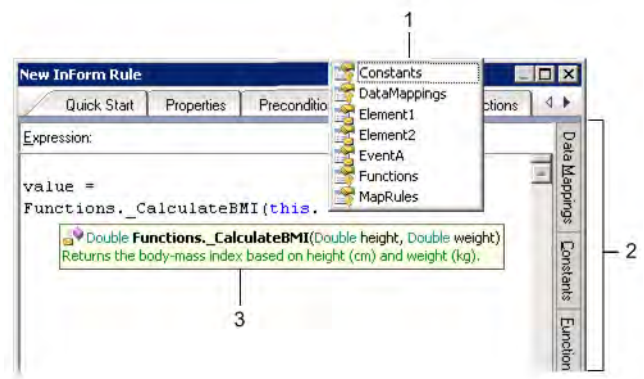
A dynamic expression prompt appears when you type a period. The prompt contains a list of rule model objects that you can select.

- To use the value of a study object or rule model property, type **this.**, and select the study object or property from the dynamic expression prompt.
- To use a function, type **Functions.**, and select the function from the dynamic expression prompt.
- To use a constant, type **Constants.**, and select the constant from the dynamic expression prompt.
- To use a data mapping study object or a rule model property, type **DataMappings.**, and select the study object or rule model property from the dynamic expression prompt.

When you select a rule model object that requires parameter values (for example, a function or method), an open parenthesis mark follows the name of the rule model object, and a tooltip indicates the parameters and their data types. The tooltip also appears when you point to the name of the rule model object.

The following illustration shows a dynamic expression prompt and tooltip that appear when you create a rule expression with a function on a study event that includes several forms. The Rule Wizard tabs containing the same options are visible on the right.

Dynamic expression prompt and tooltip



1—Dynamic expression prompt. Constants, functions, data mappings, and child study objects are available for selection.

2—Standard Rule Wizard tabs.

3—Tooltip showing format and data types of required parameters for the function.

## Selecting a rule model object from a dynamic expression prompt

When a dynamic expression prompt appears:

- Double-click a rule model object.

or

Select a rule model object, and press the **Tab** or **Enter** key.

**Note:** You can navigate the list in the dynamic expression prompt with arrow keys or by typing the first letter of a rule model object.

# Designing data-entry rules

## Creating an intrinsic rule

An intrinsic rule is a constraint rule or calculation rule based on a predefined rule template. Rule templates can be created for constraint rules and calculation rules. If no rule templates have been defined for the selected study object, then you cannot create an intrinsic rule for the study object.

You can create *intrinsic rules* (on page 130) for:

- Forms
- Form templates
- Items
- Item templates
- Item types

**Note:** As you create a rule, the Rule Summary reflects the structure of the rule, including precondition, action, and expression information. Click a link in the Rule Summary to navigate through the Rule Wizard.

### Step 1: Select a study object and open the Rule Wizard

- 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 selected study object appears in the workspace.

- 2 Select the **Rules** tab.
- 3 Click **New Rule**.

The Rule Wizard appears with the Quick Start tab selected.

### Step 2: Select the rule type and templates

- 1 In the **Select a rule type** area, select **Intrinsic Rule**.
- 2 From the list, select a rule template.
- 3 Click **Next**.

The Properties tab appears.

### Step 3: Name the rule

- Type a name and, optionally, a description for the rule, and click **Next**.

The Preconditions tab appears.



**Step 4: Select the preconditions for the rule**

- 1 From the **Evaluate on Event** drop-down list, select one:
  - **Form submission**—(Default selection) Rule executes on form submission. To figure out the form that causes the rule to execute, the InForm application determines rule dependencies by detecting the study objects on which the rule depends.
  - **On demand (batch mode)**—Rule is validated and deployed to the InForm application with a deactivated status, so the rule does not run in the InForm application.
- 2 Click **Next**.  
The Expression tab appears.

**Step 5: Provide values for the parameters**

- 1 Provide values for the parameters.
  - To provide a value, type it in the **Value** field.
  - To use the value of a study object or a rule model property, drag the study object from the **Data** tab to the Expression workspace. To view the rule model properties of all of the study objects, click **Show All**.
  - To use a constant, drag the constant from the **Constants** tab to the Expression workplace.
  - To use a data mapping study object or a rule model property, drag the data mapping study object or rule model property from the **Data Mappings** tab to the Expression workspace.

For more information, see *Rule Wizard—Option descriptions* (on page 419).

- 2 Click **Next**.  
The Actions tab appears.

**Note:** In the Actions tab, you specify a condition and an action to take when the condition occurs.

**Step 6: Define one or more actions for the rule**

- 1 From the **If the value is** section, select one of the following options:
  - **False**—If the rule calculates a False value, the action occurs.
  - **True**—If the rule calculates a True value, the action occurs.
  - **Always**—(Default for calculation rules) The action always occurs.
  - **Only if no other action executes**—The action occurs only if no other action occurs. Select this option only if you define at least two actions.
  - **Values to specify:**
    - **Equals**—If the rule calculates a value that is equal to the provided value, the action occurs.
    - **Not Equals**—If the rule calculates a value that is not equal to the provided value, the action occurs.
    - **Less Than**—If the rule calculates a value that is less than the provided value, the action occurs.

- **Greater Than**—If the rule calculates a value that is greater than the provided value, the action occurs.
- **Between**—If the rule calculates a value that is between the provided values, the action occurs.
- **Inclusive** checkbox—Select this option to make the number comparisons inclusive. For example, **Less Than** becomes **Less Than or Equal To**.

**Note:** You can include string values in the Equals and Not Equals fields. Enclose the string in double quotes. For example, "text".

- 2 In the **Execute these actions** section, choose the action or actions that will occur when the rule executes.

**Note:** Instructions for defining a query, specifying email information, and setting a value follow this procedure.

- **SetValue**—(Default for calculation rules) Set the value of an item.
  - **Email**—Send an email message to a distribution list.
  - **Query**—Issue a query. A query is a text string that appears on a CRF item in the InForm application when a rule on that item fails.
  - **UpdateWorkflow**—Recreate the state of a workflow rule. For more information, see *Updating the state of a workflow rule* (on page 171).
- 3 Optionally, to specify multiple actions, click **Add Action**. For more information, see *Rules with multiple actions* (on page 139).

The condition and action to take appear in the Fire Event grid.

#### Step 6A: Defining a query

- 1 In the **Rule Summary** section, click the **query** link.  
The Query Action dialog box appears.
- 2 From the **Initial Query State** drop-down list, select one:
  - **Open**—The query is visible on the form and available for response.
  - **Candidate**—The query is not visible on the form until someone reviews and explicitly opens it.
- 3 In the **Item** field, type a value or drag an item from the **Data** tab to the field.

**Note:** You can type an expression in the Item field if it satisfies rule expression requirements. For more information, see *About the rule expression language* (on page 146).

You cannot define a query on a fixed item.

- 4 From the **Locale** drop-down list, select a locale.

- 5 In the **Message** field, type the query message. Optionally, to use a parameter in the message, do the following in the **Message Parameters** section:
    - 1 To define a value for a parameter, either type a value or drag information from the **Data**, **Functions**, **Constants**, and **Data Mappings** tabs to the **Value** field.
    - 2 Select the parameter, and drag the parameter to the **Message** field.

or

Double-click the parameter.

The parameter is added to the message. Parameters are enclosed by curled braces.
  - 6 Click **OK**.
- For more information, see *Query Action dialog box—Option descriptions* (on page 415).

### Step 6B: Specifying email information

- 1 In the Rule Summary, click the **email** link, or press **CTRL+M**.  
The Email Action dialog box appears.
- 2 To choose the item that triggers the email action, either type a value or drag an item from the **Data** tab to the **Item** field.

**Note:** You cannot trigger an email action from a fixed item.

- 3 Type the **To** email addresses, separated by semicolons.
- 4 Type a **From** email address.

**Note:** If you do not provide an email address, an address is taken from the registry. If the registry does not contain an email address, `<studyname>@<default_webserver>` is used.

- 5 Select a **Locale**.
- 6 Type an email **Subject** and **Message**. Optionally, to use a parameter, create one or more parameters in the **Message and Subject Parameters** section:
  - a To define a value for a parameter, either type a value or drag information from the **Data**, **Functions**, **Constants**, and **Globals** tabs to the **Value** field.
  - b Select the parameter, and drag the parameter to the **Message** or **Subject** field.  
The parameter is added to the message. Parameters are enclosed by curled braces.
- 7 Click **OK**.

For more information, see *Email Action dialog box—Option descriptions* (on page 412).

### Step 6C: Setting a value

- 1 In the **Rule Summary** section, click the **[select] = value** link.  
The Set Value Action dialog box appears.
- 2 In the **Item** field, type a value or drag an item from the **Data** tab.

**Note:** The value must be set on an item. You cannot set the value of a fixed item.

- 3 In the **Value to set the Item** area, do one of the following:
  - To use the value that is calculated in the expression, leave the default **value** text.
  - To modify the value that is calculated in the expression, type a value or an expression that will return a value for the item. For example, **value + 2** adds two to the value returned by the expression.

**Note:** You can type an expression in the Item field if it satisfies rule expression requirements. For more information, see *About the rule expression language* (on page 146).

- 4 Click **OK**.

**Note:** Set value actions run in the InForm software in the order in which you define them.

For more information, see *Set Value Action dialog box—Option descriptions* (on page 427).

#### Step 6D: Setting the stage of a review state

- 1 In the **Rule Summary** section, click the **SetReviewState** link.  
The Set Review State Action dialog box appears.
- 2 In the **Form** field, type a value or drag a form from the **Data** tab.
- 3 From the **ReviewState** drop-down list, select a review state.
- 4 Do one of the following:
  - Select the **Review Stage** radio button, and select a review stage from the drop-down list.
  - Select the **Review Stage expression** radio button, and in the text box, create a rule expression that evaluates to a valid review stage. You can use the objects and properties in the **References** window.
- 5 Optionally, enter a comment in the **Comment** field.
- 6 Click **OK**.

For more information, see *Set Value Action dialog box—Option descriptions* (on page 427).

#### Step 7: Finish creating the rule

- 1 Click **Finish**.

## Creating a rule without a function

You create rules in the Rule Wizard. The Rule Wizard includes a Quick Start tab containing rule types, including constraint rule and calculation rule, which populate the Actions tab with information. You can override the default information and provide additional information.

**Note:** As you create a rule, the Rule Summary reflects the structure of the rule, including precondition, action, and expression information. Click a link in the Rule Summary to navigate through the Rule Wizard.

**Step 1: Select a study object and open the Rule Wizard**

- 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 selected study object appears in the workspace.

- 2 Select the **Rules** tab.
- 3 Click **New Rule**.

The Rule Wizard appears with the Quick Start tab selected.

**Step 2: Select the type of rule to create**

- 1 In the **Select a rule type** area, select **Constraint Rule** or **Calculation Rule**.

**Note:** Selecting a rule type populates information in the Actions tab. You can override the default information.

- 2 Click **Next**.

The Properties tab appears.

**Step 3: Name the rule**

- Type a name and, optionally, a description for the rule, and click **Next**.

The Preconditions tab appears.

**Step 4: Select the preconditions for the rule**

- 1 From the **Evaluate on Event** drop-down list, select one:
  - **Form submission**—(Default selection) Rule executes on form submission. To figure out the form that causes the rule to execute, the InForm application determines rule dependencies by detecting the study objects on which the rule depends.
  - **On demand (batch mode)**—Rule is validated and deployed to the InForm application with a deactivated status, so the rule does not run in the InForm application.
- 2 Click **Next**.

The Expression tab appears.

**Step 5: Create the rule expression**

1 Create the rule expression in the Expression workspace with the following:

- Operators and literals.

For more information, see *Operators and literals* (in the *Rules Reference Guide*).

- Study objects, rule model properties for study objects, constants, global study objects, or rule model properties for global study objects.

- To use the value of a study object or a rule model property:

Type **this.**, and select the study object from the dynamic expression prompt.

or

Drag the study object from the **Data** tab to the **Expression** workspace. To view the rule model properties of all of the study objects, click **Show All Properties**.

- To use a constant:

Type **Constants.**, and select the constant from the dynamic expression prompt.

or

Drag the constant from the **Constants** tab to the **Expression** workspace.

- To use a data mapping study object or a rule model property:

Type **DataMappings.**, and select the data mapping study object or rule model property from the dynamic expression prompt.

or

Drag the data mapping study object or rule model property from the **Data Mappings** tab to the **Expression** workspace.

For more information, see *Rule Wizard—Option descriptions* (on page 419).

- Methods.

- To use a method for a repeating study object:

Type **this.**, and select the method from the dynamic expression prompt.

or

Drag the method from the **Data** tab to the **Expression** workspace.

- To use a method for a global study object:

Type **DataMappings.**, and select the (from the dynamic expression prompt.

or

Drag the method from the **Data Mappings** tab to the **Expression** workspace.

- To use a math method, type the method in the **Expression** workspace.

For more information, see *Methods* (in the *Rules Reference Guide*).

- 2 Click **Next**.

The Actions tab appears.

**Note:** In the Actions tab, you specify a condition and an action to take when the condition occurs.

#### Step 6: Define one or more actions for the rule

- 1 From the **If the value is** section, select one of the following options:
  - **False**—If the rule calculates a False value, the action occurs.
  - **True**—If the rule calculates a True value, the action occurs.
  - **Always**—(Default for calculation rules) The action always occurs.
  - **Only if no other action executes**—The action occurs only if no other action occurs. Select this option only if you define at least two actions.
  - **Values to specify:**
    - **Equals**—If the rule calculates a value that is equal to the provided value, the action occurs.
    - **Not Equals**—If the rule calculates a value that is not equal to the provided value, the action occurs.
    - **Less Than**—If the rule calculates a value that is less than the provided value, the action occurs.
    - **Greater Than**—If the rule calculates a value that is greater than the provided value, the action occurs.
    - **Between**—If the rule calculates a value that is between the provided values, the action occurs.
    - **Inclusive** checkbox—Select this option to make the number comparisons inclusive. For example, **Less Than** becomes **Less Than or Equal To**.

**Note:** You can include string values in the Equals and Not Equals fields. Enclose the string in double quotes. For example, "text".

- 2 In the **Execute these actions** section, choose the action or actions that will occur when the rule executes.

**Note:** Instructions for defining a query, specifying email information, and setting a value follow this procedure.

- **SetValue**—(Default for calculation rules) Set the value of an item.
- **Email**—Send an email message to a distribution list.
- **Query**—Issue a query. A query is a text string that appears on a CRF item in the InForm application when a rule on that item fails.
- **UpdateWorkflow**—Recreate the state of a workflow rule. For more information, see *Updating the state of a workflow rule* (on page 171).

- 3 Optionally, to specify multiple actions, click **Add Action**. For more information, see *Rules with multiple actions* (on page 139).

The condition and action to take appear in the Fire Event grid.

#### Step 6A: Defining a query

- 1 In the **Rule Summary** section, click the **query** link.  
The Query Action dialog box appears.
- 2 From the **Initial Query State** drop-down list, select one:
  - **Open**—The query is visible on the form and available for response.
  - **Candidate**—The query is not visible on the form until someone reviews and explicitly opens it.
- 3 In the **Item** field, type a value or drag an item from the **Data** tab to the field.

**Note:** You can type an expression in the Item field if it satisfies rule expression requirements. For more information, see *About the rule expression language* (on page 146).

You cannot define a query on a fixed item.

- 4 From the **Locale** drop-down list, select a locale.
- 5 In the **Message** field, type the query message. Optionally, to use a parameter in the message, do the following in the **Message Parameters** section:
  - 1 To define a value for a parameter, either type a value or drag information from the **Data**, **Functions**, **Constants**, and **Data Mappings** tabs to the **Value** field.
  - 2 Select the parameter, and drag the parameter to the **Message** field.

or

Double-click the parameter.

The parameter is added to the message. Parameters are enclosed by curled braces.
- 6 Click **OK**.

For more information, see *Query Action dialog box—Option descriptions* (on page 415).

#### Step 6B: Specifying email information

- 7 In the Rule Summary, click the **email** link, or press **CTRL+M**.  
The Email Action dialog box appears.
- 8 To choose the item that triggers the email action, either type a value or drag an item from the **Data** tab to the **Item** field.

**Note:** You cannot trigger an email action from a fixed item.

- 9 Type the **To** email addresses, separated by semicolons.



- 10 Type a **From** email address.

**Note:** If you do not provide an email address, an address is taken from the registry. If the registry does not contain an email address, <studyname>@<default\_webserver> is used.

- 11 Select a **Locale**.
- 12 Type an email **Subject** and **Message**. Optionally, to use a parameter, create one or more parameters in the **Message and Subject Parameters** section:
- To define a value for a parameter, either type a value or drag information from the **Data, Functions, Constants, and Globals** tabs to the **Value** field.
  - Select the parameter, and drag the parameter to the **Message** or **Subject** field.  
The parameter is added to the message. Parameters are enclosed by curled braces.
- 13 Click **OK**.

For more information, see *Email Action dialog box—Option descriptions* (on page 412).

#### Step 6C: Setting a value

- 14 In the **Rule Summary** section, click the [select] = value link.  
The Set Value Action dialog box appears.
- 15 In the **Item** field, type a value or drag an item from the **Data** tab.

**Note:** The value must be set on an item. You cannot set the value of a fixed item.

- 16 In the **Value to set the Item** area, do one of the following:
- To use the value that is calculated in the expression, leave the default **value** text.
  - To modify the value that is calculated in the expression, type a value or an expression that will return a value for the item. For example, **value + 2** adds two to the value returned by the expression.

**Note:** You can type an expression in the Item field if it satisfies rule expression requirements. For more information, see *About the rule expression language* (on page 146).

- 17 Click **OK**.

**Note:** Set value actions run in the InForm software in the order in which you define them.

For more information, see *Set Value Action dialog box—Option descriptions* (on page 427).

#### Step 6D: Setting the stage of a review state

- 4 In the **Rule Summary** section, click the **SetReviewState** link.  
The Set Review State Action dialog box appears.
- 5 In the **Form** field, type a value or drag a form from the **Data** tab.
- 6 From the **ReviewState** drop-down list, select a review state.

- 7 Do one of the following:
  - Select the **Review Stage** radio button, and select a review stage from the drop-down list.
  - Select the **Review Stage expression** radio button, and in the text box, create a rule expression that evaluates to a valid review stage. You can use the objects and properties in the **References** window.
- 8 Optionally, enter a comment in the **Comment** field.
- 9 Click **OK**.

For more information, see *Set Value Action dialog box—Option descriptions* (on page 427).

### Step 7: Finish creating the rule

- 1 Click **Finish**.

## Creating a rule using a function

You create rules in the Rule Wizard. The Rule Wizard includes a Quick Start tab containing rule types, including constraint rule and calculation rule, which populate the Actions tab with information. You can override the default information and provide additional information.

**Note:** As you create a rule, the Rule Summary reflects the structure of the rule, including precondition, action, and expression information. Click a link in the Rule Summary to navigate through the Rule Wizard.

### Step 1: Select a study object and open the Rule Wizard

- 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 selected study object appears in the workspace.

- 2 Select the **Rules** tab.
- 3 Click **New Rule**.

The Rule Wizard appears with the Quick Start tab selected.

### Step 2: Select the type of rule to create

- 1 In the **Select a rule type** area, select **Constraint Rule** or **Calculation Rule**.

**Note:** Selecting a rule type populates information in the Actions tab. You can override the default information.

- 2 Click **Next**.

The Properties tab appears.

### Step 3: Name the rule

- Type a name and, optionally, a description for the rule, and click **Next**.

The Preconditions tab appears.

**Step 4: Select the preconditions for the rule**

- 1 From the **Evaluate on Event** drop-down list, select one:
  - **Form submission**—(Default selection) Rule executes on form submission. To figure out the form that causes the rule to execute, the InForm application determines rule dependencies by detecting the study objects on which the rule depends.
  - **On demand (batch mode)**—Rule is validated and deployed to the InForm application with a deactivated status, so the rule does not run in the InForm application.
- 2 Click **Next**.  
The Expression tab appears.

**Step 5: Create the rule expression using values from the dynamic expression prompt**

- 1 To use a function, type **Functions.**, and select the function from the dynamic expression prompt.  
The function name appears in the Expression workspace, along with a tooltip showing the syntax of the function.
  - 2 Provide values for the parameters:
    - To provide a value, type it as a parenthetic expression following the function name.
    - To use the value of a study object or rule model property, type **this.**, and select the study object or property from the dynamic expression prompt.
    - To use a constant, type **Constants.**, and select the constant from the dynamic expression prompt.
    - To use a data mapping study object or a rule model property, type **DataMappings.**, and select the study object or rule model property from the dynamic expression prompt.
  - 3 To add other components to the rule expression, use the following:
    - Operators and literals.  
For more information, see *Operators and literals* (in the *Rules Reference Guide*).
    - Study objects, rule model properties for study objects, constants, global study objects, or rule model properties for global study objects.
      - To use the value of a study object or rule model property, type **this.**, and select the study object or property from the dynamic expression prompt.
      - To use a constant, type **Constants.**, and select the constant from the dynamic expression prompt.
      - To use a data mapping study object or a rule model property, type **DataMappings.**, and select the study object or rule model property from the dynamic expression prompt.
- For more information, see *Rule Wizard—Option descriptions* (on page 419).

- Methods.
  - To use a method for a repeating study object, type **this.**, and select the method from the dynamic expression prompt.
  - To use a method for a data mapping study object. type **DataMappings.**, and select the method from the dynamic expression prompt.
  - To use a math method, type the method in the Expression workspace.

For more information, see *Methods* (in the *Rules Reference Guide*).

- 4 Click **Next**.

The Actions tab appears.

**Note:** In the Actions tab, you specify a condition and an action to take when the condition occurs.

or

#### Step 5: Create the rule expression by dragging values from the reference tabs

- 1 Select the **Functions** tab, and drag the function you want to use for the rule expression to the Expression workspace.

The Invoke Function dialog box appears. It contains the parameters that must be defined for the expression.

- 2 Provide values for the parameters.
  - To provide a value, type it in the **Value** field.
  - To use the value of a study object or a rule model property, drag the study object from the **Data** tab to the Expression workspace. To view the rule model properties of all of the study objects, click **Show All**.
  - To use a constant, drag the constant from the **Constants** tab to the Expression workplace.
  - To use a data mapping study object or a rule model property, drag the data mapping study object or rule model property from the **Data Mappings** tab to the Expression workspace.

For more information, see *Rule Wizard—Option descriptions* (on page 419).

- 3 Click **OK**.

You return to the Rule wizard. In the Expression workspace, the function name is preceded by the word **Functions**.

- 4 To add other components to the rule expression, use the following:
  - Operators and literals.

For more information, see *Operators and literals* (in the *Rules Reference Guide*).

- Study objects, rule model properties for study objects, constants, global study objects, or rule model properties for global study objects.
  - To use the value of a study object or a rule model property, drag the study object from the **Data** tab to the Expression workspace. To view the rule model properties of all of the study objects, click **Show All Properties**.
  - To use a constant, drag the constant from the **Constants** tab to the Expression workspace.
  - To use a data mapping study object or a rule model property, drag the data mapping study object or rule model property from the **Data Mappings** tab to the Expression workspace.

For more information, see *Rule Wizard—Option descriptions* (on page 419).

- Methods.
  - To use a method for a repeating study object, drag the method from the **Data** tab to the Expression workspace.
  - To use a method for a data mapping study object, drag the method from the **Data Mappings** tab to the Expression workspace.
  - To use a math method, type the method in the Expression workspace.

For more information, see *Methods* (in the *Rules Reference Guide*).

#### 5 Click **Next**.

The Actions tab appears.

**Note:** In the Actions tab, you specify a condition and an action to take when the condition occurs.

### Step 6: Define one or more actions for the rule

- 1 From the **If the value is** section, select one of the following options:
  - **False**—If the rule calculates a False value, the action occurs.
  - **True**—If the rule calculates a True value, the action occurs.
  - **Always**—(Default for calculation rules) The action always occurs.
  - **Only if no other action executes**—The action occurs only if no other action occurs. Select this option only if you define at least two actions.

- **Values to specify:**
  - **Equals**—If the rule calculates a value that is equal to the provided value, the action occurs.
  - **Not Equals**—If the rule calculates a value that is not equal to the provided value, the action occurs.
  - **Less Than**—If the rule calculates a value that is less than the provided value, the action occurs.
  - **Greater Than**—If the rule calculates a value that is greater than the provided value, the action occurs.
  - **Between**—If the rule calculates a value that is between the provided values, the action occurs.
  - **Inclusive** checkbox—Select this option to make the number comparisons inclusive. For example, **Less Than** becomes **Less Than or Equal To**.

**Note:** You can include string values in the Equals and Not Equals fields. Enclose the string in double quotes. For example, "text".

- 2 In the **Execute these actions** section, choose the action or actions that will occur when the rule executes.

**Note:** Instructions for defining a query, specifying email information, and setting a value follow this procedure.

- **SetValue**—(Default for calculation rules) Set the value of an item.
  - **Email**—Send an email message to a distribution list.
  - **Query**—Issue a query. A query is a text string that appears on a CRF item in the InForm application when a rule on that item fails.
  - **UpdateWorkflow**—Recreate the state of a workflow rule. For more information, see *Updating the state of a workflow rule* (on page 171).
- 3 Optionally, to specify multiple actions, click **Add Action**. For more information, see *Rules with multiple actions* (on page 139).

The condition and action to take appear in the Fire Event grid.

#### Step 6A: Defining a query

- 1 In the **Rule Summary** section, click the **query** link.  
The Query Action dialog box appears.
- 2 From the **Initial Query State** drop-down list, select one:
  - **Open**—The query is visible on the form and available for response.
  - **Candidate**—The query is not visible on the form until someone reviews and explicitly opens it.
- 3 In the **Item** field, type a value or drag an item from the **Data** tab to the field.

**Note:** You can type an expression in the Item field if it satisfies rule expression requirements. For more information, see *About the rule expression language* (on page 146).

You cannot define a query on a fixed item.

- 4 From the **Locale** drop-down list, select a locale.
- 5 In the **Message** field, type the query message. Optionally, to use a parameter in the message, do the following in the **Message Parameters** section:
  - 1 To define a value for a parameter, either type a value or drag information from the **Data**, **Functions**, **Constants**, and **Data Mappings** tabs to the **Value** field.
  - 2 Select the parameter, and drag the parameter to the **Message** field.  
or  
Double-click the parameter.  
The parameter is added to the message. Parameters are enclosed by curled braces.
- 6 Click **OK**.

For more information, see *Query Action dialog box—Option descriptions* (on page 415).

#### Step 6B: Specifying email information

- 1 In the Rule Summary, click the **email** link, or press **CTRL+M**.  
The Email Action dialog box appears.
- 2 To choose the item that triggers the email action, either type a value or drag an item from the **Data** tab to the **Item** field.

**Note:** You cannot trigger an email action from a fixed item.

- 3 Type the **To** email addresses, separated by semicolons.
- 4 Type a **From** email address.

**Note:** If you do not provide an email address, an address is taken from the registry. If the registry does not contain an email address, `<studyname>@<default_webserver>` is used.

- 5 Select a **Locale**.
- 6 Type an email **Subject** and **Message**. Optionally, to use a parameter, create one or more parameters in the **Message and Subject Parameters** section:
  - a To define a value for a parameter, either type a value or drag information from the **Data**, **Functions**, **Constants**, and **Globals** tabs to the **Value** field.
  - b Select the parameter, and drag the parameter to the **Message** or **Subject** field.  
The parameter is added to the message. Parameters are enclosed by curled braces.

- 7 Click **OK**.

For more information, see *Email Action dialog box—Option descriptions* (on page 412).

#### Step 6C: Setting a value

- 1 In the **Rule Summary** section, click the **[select] = value** link.  
The Set Value Action dialog box appears.
- 2 In the **Item** field, type a value or drag an item from the **Data** tab.

**Note:** The value must be set on an item. You cannot set the value of a fixed item.

- 3 In the **Value to set the Item** area, do one of the following:
  - To use the value that is calculated in the expression, leave the default **value** text.
  - To modify the value that is calculated in the expression, type a value or an expression that will return a value for the item. For example, **value + 2** adds two to the value returned by the expression.

**Note:** You can type an expression in the Item field if it satisfies rule expression requirements. For more information, see *About the rule expression language* (on page 146).

- 4 Click **OK**.

**Note:** Set value actions run in the InForm software in the order in which you define them.

For more information, see *Set Value Action dialog box—Option descriptions* (on page 427).

#### Step 6D: Setting the stage of a review state

- 1 In the **Rule Summary** section, click the **SetReviewState** link.  
The Set Review State Action dialog box appears.
- 2 In the **Form** field, type a value or drag a form from the **Data** tab.
- 3 From the **ReviewState** drop-down list, select a review state.
- 4 Do one of the following:
  - Select the **Review Stage** radio button, and select a review stage from the drop-down list.
  - Select the **Review Stage expression** radio button, and in the text box, create a rule expression that evaluates to a valid review stage. You can use the objects and properties in the **References** window.
- 5 Optionally, enter a comment in the **Comment** field.
- 6 Click **OK**.

For more information, see *Set Value Action dialog box—Option descriptions* (on page 427).

#### Step 7: Finish creating the rule

- 1 Click **Finish**.



## Modifying a 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, and click **Edit**.

The Rule Wizard appears without the Quick Start tab.

- 4 Modify the rule as necessary. Navigate by selecting the tabs or clicking the links in the Rule Summary.

For more information about modifying the rule, see:

- *Rule Wizard* (on page 419).
- *Creating an intrinsic rule* (on page 150).
- *Creating a rule without a function* (on page 154).
- *Creating a rule using a function* (on page 160).

- 5 Click **Finish**.

## Translating query and email information for rules

The following rule-related information can be translated:

- Query messages.
- Email messages and subjects.

To translate information, you must have the necessary language skills defined in the Central Designer Administrator application.

- 1 In the **Rules** tab, select a rule.
- 2 Click **Edit**, or double-click the rule.  
The Rule Wizard appears.
- 3 In the **Rule Summary** (located at the bottom of the Rule Wizard), click one of the following links:
  - **issue query**—Translate a query message.  
The Query Action dialog box appears.
  - **send email**—Translate an email subject and message.  
The Email Action dialog box appears.
- 4 From the **Locale** drop-down list, select a locale.
- 5 Type translated text for the fields requiring translation.

**Note:** The field that requires translation is read-only when you do not have the necessary language skills to translate in the locale. You specify language skills in the Central Designer Administrator application.

- 6 Click **OK**.
- 7 In the **Rule Wizard**, click **Finish**.

## Viewing all rules for a study object and its children

In the Rules tab, you view all rules that are part of a study object and, optionally, its children.

- 1 In the Project Explorer, select a study design (in a study only), study element, study event, form, section, or item.
- 2 In the **Rules** tab, select **Show Child Rules**.

All rules that are part of the children of the study object appear in the Rules tab.

## Selecting multiple rules

You can select multiple rules in the Rules Editor and perform actions that affect all selected 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 To select all rules, press **CTRL+A**.

## Deactivating a rule

An alternative to deleting a rule is to deactivate it. This functionality is useful if you do not want a rule to run in the InForm application, but you want it to remain in the Central Designer database, or if you want to suspend execution of the rule on a temporary basis.

Deactivated rules are:

- Validated in the Central Designer application.
- Deployed to the InForm application.
- Run only manually in the InForm application.

To deactivate a 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, and click **Edit**.

The Rule Wizard appears without the Quick Start tab.

- 4 Select the **Preconditions** tab.
- 5 In the **Evaluate on Event** drop-down list, select **On Demand (Batch Mode)**.

- 6 Click **Finish**.

## Disabling 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 **Disable**, or press **CTRL+D**.

If any rules are locked by someone else or on a study object that is protected by someone else, the Central Designer application disables all unlocked and unprotected rules and a dialog box appears, listing the rules that could not be disabled.

A gray X appears in the grid in the first column of the row for the disabled rules, and the row is grayed out.

## Enabling one or more disabled 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 **Enable**, or press **CTRL+E**.

If any rules are locked by someone else or on a study object that is protected by someone else, the Central Designer application enables all unlocked and unprotected rules and a dialog box appears, listing the rules that could not be enabled.

The gray X disappears in the grid in the first column of the row for the rule, and the row text becomes black.

# Designing workflow rules

## Creating a workflow rule in a workflow diagram

You can create a workflow rule for a study element, study event, or form.

**Note:** A study object can include only one workflow rule.

- 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 **Add Rule**.  
The Workflow Expression Editor dialog box appears.
- 4 Type a name and description for the workflow rule.
- 5 Using either or both of the following methods, create an expression in the Expression section:
  - Type directly in the Expression section. As you type, prompts appear dynamically, listing the rule model objects that are available for you to use based on the context.
    - To use the value of a study object or rule model property, type **this.**, and select the study object or property from the dynamic expression prompt.
    - To use a function, type **Functions.**, and select the function from the dynamic expression prompt. The function name appears in the Expression workspace, along with a tooltip showing the syntax of the function.  
Provide values for the parameters.
    - To use a constant, type **Constants.**, and select the constant from the dynamic expression prompt.
    - To use a data mapping study object or a rule model property, type **DataMappings.**, and select the study object or rule model property from the dynamic expression prompt.
  - Drag in components from the **Data**, **Functions**, **Constants**, or **Data Mappings** tabs.

A reference to the study component, function, constant, or data set appears in the Expression section in the appropriate format.

- 6 If you dragged a function into the Expression section, use the Invoke Function dialog box to specify the values of the required parameters, and click **OK**.
- 7 Click **OK**.

A workflow rule object appears in the Workflow Diagram tab, connected to the study object for which you defined the workflow rule.

For information about connecting the workflow rule to workflow objects, see *Connecting and ordering study objects in a workflow diagram* (on page 58).

For more information, see:

**Workflow Expression Editor dialog box - Option descriptions** (on page 428).

**Invoke Function dialog box - Option descriptions** (on page 414).

## Editing a workflow rule 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 the rule in the workflow diagram, and select **Edit Rule**.  
The Workflow Expression Editor dialog box appears.
- 4 Edit the definition of the expression using the options in the **Workflow Expression Editor** dialog box and, if applicable, the **Invoke Function** dialog box.
- 5 Click **OK**.

For more information, see *Components of the rule expression language* (in the *Rules Reference Guide*).

For more information, see:

**Workflow Expression Editor dialog box - Option descriptions** (on page 428).

**Invoke Function dialog box - Option descriptions** (on page 414).

## Updating the state of a workflow rule

The Update Workflow action re-evaluates the workflow for a subject after workflow rules and global conditions have already run.

You need to select the UpdateWorkflow action if you change a study or move a subject after workflow rules and global conditions have run for one or more subjects.

For example, if you change the parameters on a workflow rule that assigns subjects to treatment arms at the beginning of a study, you would need to use the UpdateWorkflow action to retrigger all the rules after that point in the workflow and determine which forms and visits should appear.

To implement this functionality you can add an item with a checkbox to the study, such as on a new form at the beginning of the study, and then create a rule with the UpdateWorkflow action that fires when the checkbox is selected.

# Designing global conditions

## Creating a global condition

- 1 In the Project Explorer, select a study design (in a study only), study element, or study event.
- 2 In the **Workflow Diagram** tab, click **Global Conditions**.  
The Edit Global Conditions dialog box appears.
- 3 To the right of the grid, click **Add**.  
The Add Global Condition dialog box appears.
- 4 Type a name and description (optional), and select the target application with which you will use the global condition.
- 5 Click **OK**.  
The condition appears in the list.
- 6 Using either or both of the following methods, create an expression in the Expression section:
  - Type directly in the Expression section. As you type, prompts appear dynamically, listing the rule model objects that are available for you to use based on the context.
    - To use the value of a study object or rule model property, type **this.**, and select the study object or property from the dynamic expression prompt.
    - To use a function, type **Functions.**, and select the function from the dynamic expression prompt. The function name appears in the Expression workspace, along with a tooltip showing the syntax of the function.  
Provide values for the parameters.
    - To use a constant, type **Constants.**, and select the constant from the dynamic expression prompt.
    - To use a data mapping study object or a rule model property, type **DataMappings.**, and select the study object or rule model property from the dynamic expression prompt.
  - Drag in components from the **Data**, **Functions**, **Constants**, or **Data Mappings** tabs.  
A reference to the study component, function, constant, or data set appears in the Expression section in the appropriate format.
- 7 If you dragged a function into the Expression section, use the Invoke Function dialog box to specify the values of the required parameters, and click **OK**.
- 8 Click **OK**.

After you create a global condition, you can *assign the global condition* (on page 173).

For more information, see:

**Workflow Expression Editor dialog box - Option descriptions** (on page 428).

**Invoke Function dialog box - Option descriptions** (on page 414).

## Assigning and removing a global condition

Before you can assign a global condition, you must *create a global condition* (on page 172).

- 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 study object on which to add or remove a global condition, and select **Assign Conditions**.

The Assign Conditions dialog box appears.

- 4 To assign a global condition:
  - a In the **Global Conditions** list, select the global condition.
  - b Click the add button (>>).

The global condition name moves to the Assigned Conditions list.

  - c Below the **Expression** field, indicate when the rest of the workflow after the global condition will be executed, based on the outcome of the expression. For example, select **False** if you want a subject to progress to the next study object if the expression evaluates to False.
  - d Click **OK**.

In the workflow, the name of the global condition appears in a box above the study object.

- 5 To remove a global condition assignment:
  - a In the **Assigned Conditions** list, select the global condition.
  - b Click the remove button (<<).

The global condition name moves to the Global Conditions list.

- c Click **OK**.

For more information, see **Assign Conditions dialog box - Option descriptions** (on page 404).

## Viewing and editing 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 To edit a global condition:
  - a Select a global condition from the list and click **Edit**.  
The Edit Global Conditions dialog box appears.
  - b Update the global condition as needed. You can change the target application with which you plan to use the global condition only if the global condition is not assigned in a workflow.
  - c Click **OK**.

For more information, see **Edit Global Conditions dialog box - Option descriptions** (on page 408).



# Testing rules

## About test cases

| Characteristic                               | Description  |
|--|--|
| About  | You create test cases in the Rule Test Cases dialog box to test data-entry rules, workflow rules, and global conditions before deploying a study.  |
| How many to create                           | Depending on the rule, you might create several or many test cases.  |
| When to create                               | <p>You can create test cases either after writing each rule or after all rules are finished.</p> <p>To make sure that a rule is written correctly, consider writing and running a single test case for it, so you do not write many test cases for a rule that needs to be modified.</p>   |
| Running test cases                           | You can run test cases on demand in the Rule Test Cases dialog box. Additionally, test cases are run during study validation.  |
| Modifying rules                              | <p>If you modify a rule, make sure that you modify its test cases, as well.</p> <p>You can also filter the tree so that you see only the rules that were modified since you created its test cases. Use the list to check that the test cases are still accurate for the modified rules.</p>   |
| Locking                                      | <p>When you select a test case, the following are locked:</p> <ul style="list-style-type: none"> <li>• All test cases on the rule.</li> <li>• The data-entry rule, workflow rule, or global condition for which the test case was created.</li> </ul> <p>If you save the study object in the study, your changes in the Rule Test Cases dialog box are also saved, and the locks are released.</p> |
| Rules for which you cannot create test cases | <p>You cannot create test cases for a rule if:</p> <ul style="list-style-type: none"> <li>• The rule does not have an action.</li> <li>• The rule has no item paths; for example, if the rule uses a function that finds the current date.</li> </ul> <p>Additionally, you cannot perform unit conversions in the Rule Test Cases dialog box.</p>  |
| Repeating study objects                      | When a rule expression references a repeating study object, such as a repeating form or section, you can provide test values for each instance.  |

| Characteristic                    | Description  |
|-----------------------------------|--|
| Results                           | <ul style="list-style-type: none"> <li>The progress indicator is green if all test cases are valid, red if one or more test cases are not valid, or yellow if one or more test cases have warnings.</li> <li>Red circles (for invalid test cases), green circles (for valid test cases), or yellow triangles (for test cases with warnings) appear next to the name of the test case in the grid.</li> <li>In the Syntax column, either <b>valid</b>, <b>invalid</b>, or <b>incomplete</b> (for rules or global conditions that have valid syntax but are not complete; for example, if the rule has no action defined) appears.</li> </ul>  |
| Saving                            | Saving a study also saves all changes in the Rule Test Cases dialog box, including any changes that you did not save in the Rule Test Cases dialog box before closing.   |
| Troubleshooting failed test cases | <p>A test case fails when the parameters that you enter are run in the rule, and the result that you expected does not occur. To troubleshoot failed test cases, consider the following:</p> <ul style="list-style-type: none"> <li>Does the test case reflect the expected behavior of the rule?</li> <li>Is the rule written correctly?</li> </ul> <p>You can sort the results of test cases by the Status field and use the failed test cases as a checklist of rules or test cases to review.</p> <p>When you close the Rule Test Cases dialog box, test case results are not saved. To view results, you must run the test cases again the next time you open the Rule Test Cases dialog box. The results of the test cases appear in the Jobs Browser after validation is performed.</p> |

## Opening the Rule Test Cases dialog box

- In the Project Explorer, select a study design (in a study only), study element, study event, form, section, or item.
- Perform one of the following steps:
  - In the Workflow Diagram tab (for a study design, study element, or study event only), click **Rule Tests**, or right-click a workflow rule, and select **Rule Tests**.
  - In the Rules tab, click **Rule Tests**, or right-click a data-entry rule, and select **Rule Tests**.

The Rule Test Cases dialog box appears.

- The default *filter* (on page 182) displays the rules that are in the scope of the study object that was selected in the Project Explorer.
- In the Rules tab, if Show Child Rules is selected, child rules appear in the tree of rules.
- If you opened the Rule Test Cases dialog box by right-clicking a rule, the rule is selected in the Rule Test Cases dialog box.

## Viewing rules in the Rule Test Cases dialog box

The Rule Test Cases dialog box lists all data-entry rules, workflow rules, and global conditions in a study, listed in alphabetical order.

- 1 *Open the Rule Test Cases dialog box* (on page 176).  
Rules appear in the left tree, organized by rule type.
- 2 To change your view of rules, click the **Structured** and **Flat** buttons, located to the right above the tree:
  - **Structured icon**—Group rules by type, then study object type, and then study object.
  - **Flat icon**—Group rules by type.

## Opening a rule from the Rule Test Cases dialog box

All edits to rules are reflected immediately in the Rule Test Cases dialog box; you do not need to close and reopen it.




- In the Rule Test Cases dialog box toolbar, click **Go to Rule**, or double-click the rule in the tree. The Rule Test Cases dialog box is minimized, and you are brought to the following location:
  - **Data-entry rules**—The study object on which the rule is created.
  - **Workflow rules**—The Workflow Diagram tab that contains the workflow rule. The workflow rule is selected in the diagram.
  - **Global conditions**—The study object on which the global condition was created (in a study, the study design). The Edit Global Conditions dialog box opens with the global condition selected. All edits to rules are reflected immediately in the Rule Test Cases dialog box; you do not need to close and reopen it.

## Checking rule syntax

Check rule syntax to ensure that the code in the rule expression is written correctly.

- 1 Create a rule. For more information, see:
  - *Creating an intrinsic rule* (on page 150).
  - *Creating a rule without a function* (on page 154).
  - *Creating a rule using a function* (on page 160).
- 2 In the **Rules** tab, click **Check Syntax**.

Syntax is checked for all rules in the grid. One of the following icons appears next to each rule:

-  —Rule syntax is valid.
-  —Rule syntax has one or more warnings associated with it, or the rule could not be compiled.
-  —Rule syntax contains one or more errors and is not valid.

- 3 To view the error or warnings associated with a rule, look in the **Rule Summary** section, located at the bottom of the **Rules** tab.

**Note:** To hide the errors, click **Hide Errors**.

## Viewing the errors for a rule

You can view the errors for a rule only after you have checked the syntax of the rule. The errors are displayed by default. For more information, see *Checking rule syntax* (on page 177).

- In the Rules tab, select **Show Errors**.

The errors appear in the Rule Summary, located at the bottom of the Rules tab.

## Checking syntax for one or more rules or global conditions

In the Rule Test Cases dialog box, you can check the syntax of data-entry rules, workflow rules, and global conditions.

- 1 *Open the Rule Test Cases dialog box* (on page 176).
- 2 Select the **Run** tab.

The rule that is selected in the Design tab and its test cases are selected. Optionally, to expand or collapse the tree, right-click the tree, and select **Expand All** or **Collapse All**.

- 3 Optionally, in the tree to the left, select additional rules.

**Note:** To select or deselect all rules and test cases, right-click the tree and select **Check All** or **Uncheck All**.

- 4 Click **Check Syntax**.

The syntax of the selected rules is checked.

- The progress indicator is green if all rules are valid, red if one or more rules are not valid, or yellow if one or more rules have warnings.
- Red circles (for valid rules), green circles (for invalid rules), or yellow triangles (for rules with warnings) appear next to the name of the test case in the grid.
- In the Validation column, **valid**, **invalid**, or **incomplete** (for rules or global conditions that have valid syntax but are not complete; for example, if the rule has no action defined) appears.

Related errors appear in the Execution Results section at the bottom.

## Writing a test case for a rule or global condition

You can write test cases for data-entry rules, workflow rules, and global conditions.

- 1 *Open the Rule Test Cases dialog box* (on page 176).
- 2 In the list of rules, select a data-entry rule, workflow rule, or global condition.
- 3 In the toolbar, click **Create**.  
A test case is created.
- 4 Optionally, rename the test case.
- 5 Provide test values for the items that are used in the rule:
  - **Item with a single-select codelist**—From the drop-down list, select a codelist item to test. The code and label appear in the drop-down list. To view the RefName, select the Test Properties tab, and then point to the item in the grid.
  - **Item with a multi-select codelist**—Click the box at the end of the field, and select one or more codelist items to test.
  - **Item without a codelist**—Type the value to test. For an integer, float, or text item, you must follow the item's requirements, which appear in the Test Properties tab when you point to an item.
  - **Date time item**—Provide values for the parts of the date time item that are allowed.
    - To test for an empty date, select Empty date, or select Empty for a date time component.
    - To test for an unknown value, select Unknown for a date time component. Unknown is available only if an unknown value is allowed for the date time part and if the date time part is not required.
  - **Item on a repeating section, form, or study event**—Click the box at the end of the field, and provide values in the dialog box that appears.

**Note:** To provide an empty value for an item with a codelist, select the <empty> option. For items without a codelist, do not enter a value in the field. The field changes to <empty>.

**Note:** To enter test cases without using a mouse, use the Tab key to advance to cells. Use the spacebar to open dialog boxes from within cells, such as the date picker dialog box.

- 6 In the **Expected Result** field, do one of the following:

**Note:** For data-entry rules, one Expected Result field appears for each of the rule actions.

**For data-entry rules:** Select the expected result or type the expected value, based upon the values that you provided in the test case. For example:

- Rule issues a query—Select QUERY or NOQUERY.
- Rule sends an email message—Select Sent or Not Sent.
- Rule sets a value—Calculate and type the expected value. For example, for a BMI rule, use the Height and Weight values in the test case to calculate the value.

**For workflow rules:** Select the study object that you expect to appear next in the workflow, based upon the test case.

**For global conditions:** Select **True** or **False**, depending on how you expect the expression to evaluate based on the test case.

- 7 Write additional test cases as necessary. Optionally, use Copy and Paste on the toolbar to create test cases.

**Note:** To run test cases for a rule that references third-party code (for example, ODP.NET), the referenced third-party components must be installed on the client computer.

## Selecting values for an item on a repeating study object

When you write a test case and one of the items in a rule is on a repeating study object, you can provide test values for each instance of the item. For more information about writing test cases, see *Writing a test case for a rule or global condition* (on page 179).

- 1 In the Rule Test Cases dialog box, in the cell that contains <repeating>, click the box at the end of the cell.

The Define Test Values for Repeating Instances dialog box appears.

- 2 To create a test instance for an additional instance of the repeating study object:
  - a Select the study object.
  - b Click either **Add Repeating Instance** or **Copy Repeating Instance**.
    - For example, if a rule refers to an item on a repeating form, you can specify an item path for each instance of the repeating form on which the item exists.

- 3 To mark an instance of the repeating study object as current or deleted:

- Right-click the study object path, and select either **Mark as Current** or **Mark as Deleted**.

The current instance is preceded by a green checkbox icon, and deleted instances are preceded by a red X icon.

**Note:** The first repeating instance is marked as current after you create a test case.

- 4 To remove an instance of a repeating study object:

- Select the instance, and on the toolbar, click **Remove Repeating Instance**.

If you remove the last instance, it becomes grayed out and has an X icon next to it to indicate that you are testing using zero instances.

- 5 Provide test values for the items that are used in the rule:

**Note:** You can select any study object in the tree to provide values. Values of child study objects also appear in the grid for their parents. If the rule contains multiple items that are children of repeating study objects, they are listed in the Repeating Items section; select an item to provide its test values in the grid.

- **Item with a single-select codelist**—From the drop-down list, select a codelist item to test. The code and label appear in the drop-down list. To view the RefName, select the **Test Properties** tab, and then point to the item in the grid.
  - **Item with a multi-select codelist**—Click the box at the end of the field, and select one or more codelist items to test.
  - **Item without a codelist**—Type the value to test. For an integer, float, or text item, you must follow the item's requirements, which appear in the Test Properties tab when you point to an item.
  - **Date time item**—Provide values for the parts of the date time item that are allowed.
    - To test for an empty date, select **Empty date**, or select **Empty** for a date time component.
    - To test for an unknown value, select **Unknown** for a date time component. Unknown is available only if an unknown value is allowed for the date time part and if the date time part is not required.
- 6 Click **OK**.

You return to the Rule Test Cases dialog box. Continue writing the test case.

## Running test cases and viewing the results

When you run test cases, the syntax of the selected rules is checked.

**Note:** To skip a written test case, select the test case, open the Test Properties tab on the Run tab, and set the IgnoreTest property to True.

- 1 *Open the Rule Test Cases dialog box* (on page 176).
- 2 *Write one or more test cases* (on page 179).
- 3 Select the **Run** tab.
 

The rule that is selected in the Design tab and its test cases are selected. Optionally, to expand or collapse the tree, right-click the tree, and select **Expand All** or **Collapse All**.
- 4 In the tree to the left, select test cases to run. Selecting a rule also selects its test cases.

**Note:** To select or deselect all rules and test cases, right-click the tree and select **Check All** or **Uncheck All**.

- 5 Click **Execute Tests**.

The test cases run.

- The progress indicator is green if all test cases are valid, red if one or more test cases are not valid, or yellow if one or more test cases have warnings.
- Red circles (for invalid test cases), green circles (for valid test cases), or yellow triangles (for test cases with warnings) appear next to the name of the test case in the grid.
- In the Validation column, either **valid**, **invalid**, or **incomplete** (for rules or global conditions that have valid syntax but are not complete; for example, if the rule has no action defined) appears.

Related errors and warnings appear in the Execution Results section at the bottom.

**Note:** To run test cases for a rule that references third-party code (for example, ODP.NET), the referenced third-party components must be installed on the client computer.

## Addressing rule compilation errors

When you run a rule test case, the rule is compiled, and you might receive errors even if the syntax is correct. If the syntax check succeeds but the rule compilation fails:

- Attempt to resolve the errors using the error messages generated by the Rule Test Cases dialog box.
- Validate the study, and attempt to resolve the errors using the error messages generated by the validation.
- Make sure that any review states you have defined for the study are complete.

## Filtering the rules that appear in the Rule Test Cases dialog box

Several filters, including a view of all rules and all rules with test cases, are available by default.

- 1 *Open the Rule Test Cases dialog box* (on page 176).

**Note:** Disabled rules appear grayed out with a gray X to the left of the rule name. You can still create and run test cases for the disabled rules.

- 2 Click **Filters**.

The Define Rule Search Filters dialog box appears.

- 3 (Optional) To create a named filter:
  - a From the **Filters** drop-down list, select the **All Rules** filter, and click **Clone**.
  - b Type a name, and click **OK**.



- 4 To filter by study object, in the **Filter on objects** section:
  - a Using the first drop-down list, filter by rules that are created on the type of study object, such as all study objects or the study design.
  - b (Optional) Using the second drop-down list, filter by the following characteristics:
    - Enabled or disabled.
    - Object with children.
    - Contain specified text in the RefName, title, or description.
    - The date range within which the rule was saved.
  - c If you selected a text or date information option from the second drop-down list, type the text or select a date in the blank field.
  - d To add additional filtering rows, select the plus sign (+) button at the end of the row.
- 5 Next to **Filter on rules/conditions**, select one of the following options:
  - **AND Filters**—Search results appear only if they satisfy all filters.
  - **OR Filters**—Search results appear if they satisfy only one filter.

**Note:** These options apply only when you add additional filtering rows to the **Filter on rules/conditions** section.

- 6 To filter by the type of rule, do the following in the **Filter on rules/conditions** section:
  - a Using the first drop-down list, you can filter by the type of rule:
    - All rules and global conditions (data-entry rules, workflow rules, and global conditions).
    - Data-entry rules.
    - Global conditions.
    - Workflow rules.
  - b (Optional) Using the second drop-down list, you can filter by the following characteristics. Depending on the type of rule that you selected, some options might not be available.
    - Enabled or disabled.
    - With or without test cases, or with older tests.
    - Specified text information, such as the rule or condition name.
    - Action information, such as whether a query or set value action is defined for the rule.
    - The date range within which the rule was saved.
  - c If you selected a text or date information option from the second drop-down list, type the text or select a date in the blank field.
  - d To add additional filtering rows, select the plus sign (+) button at the end of the row.
- 7 Click **OK**.

## Finding a rule

- 1 *Open the Rule Test Cases dialog box* (on page 176).
- 2 In the **Find** field, type all or part of the rule name. The field is not case-sensitive. The field finds only exact text matches unless you type an asterisk as a wildcard operator. For example:
  - **\*BMI** finds all rules that end in **BMI**.
  - **Calc\*** finds all rules that begin with **Calc**.
  - **\*End\*** finds all rules that contain **End**.
- 3 Press **Enter**.

The first rule that matches the search value is selected in the tree.
- 4 (Optional) To advance to the next rule that matches the search value, press **F3**.

## Deleting and renaming filters in the Rule Test Cases dialog box

You cannot delete default filters.

- 1 *Open the Rule Test Cases dialog box* (on page 176).
- 2 Click **Filters**.

The Define Rule Search Filters dialog box appears.
- 3 Click **Manage**.

The Manage Search Filters dialog box appears.
- 4 Select a filter, and click one of the following:
  - **Rename**. Type a name, and click **OK**.
  - **Delete**.
- 5 Click **OK**.

## Deleting a test case

- 1 *Open the Rule Test Cases dialog box* (on page 176).
- 2 Make sure the **Design** tab is selected.
- 3 Select a rule.
- 4 In the grid, select a test case, and on the toolbar, click **Delete**.

or

Right-click the beginning of the row, and select **Delete**.

## Saving test cases

You can save test cases in the Rule Test Cases dialog box at any time, but the results of test cases are removed when you close the Rule Test Cases dialog box.

- 1 *Open the Rule Test Cases dialog box* (on page 176).
- 2 *Write one or more test cases* (on page 179).
- 3 Click **Save Tests** (in the lower-right corner).



## CHAPTER 5

# Designing data mappings

### **In this chapter**

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## About data mappings, data sets, and data series

You use data mappings, data sets, and data series to group items into abstract associations. The associations that you create are independent of the way that you collect data values in forms.

- **Data mappings**—A data mapping is a data grouping that provides an alternate data view of a study. For example, you can group data sets to form an SDTM (Study Data Tabulation Model) data mapping.
- **Data sets**—A data set is a grouping of one or more related data series. For example, the Temperature data series and Weight data series might comprise a Vital Signs data set.
- **Data series**—A data series is a grouping of one or more items with the same clinical meaning, such as one or more items that measure weight.

### Example—Data mapping: Vital signs

| Data set: Vital signs initial   | Data set: Vital signs final   |
|---|---|
| <ul style="list-style-type: none"> <li>• Data series: Temperature</li> <li>• Data series: Weight</li> <li>• Data series: Pulse rate</li> <li>• Data series: Blood pressure</li> </ul> | <ul style="list-style-type: none"> <li>• Data series: Temperature</li> <li>• Data series: Weight</li> <li>• Data series: Pulse rate</li> <li>• Data series: Blood pressure</li> </ul> |

## About data mappings

A data mapping is a data grouping that provides an alternate data view of a study. For example, you can group data sets to form an SDTM (Study Data Tabulation Model) mapping.

A data mapping is an independent definition of the data structure. Data mappings are not affected when you move items between forms.

You can create a data mapping before you design your study or as part of the study design process. For example, a study administrator might create a data mapping that study designers use as a checklist to make sure that a study is complete.

You can create one or more mappings in a study or library, but they are not required for any project. You can include an item in one or more mapping definition.

In a data mapping, items are added to a data series. The association remains with the item whenever it is used. You can compare the parts of a data mapping to database concepts with which you are already familiar.

| Compare a mapping to       | Compare a data set to | Compare a data series to |
|----------------------------|-----------------------|--------------------------|
| A database schema          | A database table      | A column in a table      |
| A Microsoft Excel workbook | A worksheet           | A column in a worksheet  |

**Note:** The analogies are to physical objects, whereas data associations are abstract associations with items for which data has not yet been collected.

You can create the following types of data mappings:

- **Rule data mappings** (on page 208).
- **CDD data mappings** (on page 213).
- **CIS data mappings** (on page 218).

## Creating a data mapping

You can create data mappings in both studies and libraries.

- 1 In the Project Explorer, select the **Data Mappings** Explorer bar.
- 2 Right-click one of the mapping containers, and select the appropriate option:

- **Rule Mappings** container > **New Rule Mapping**.

Mappings definitions are not generated or validated.

- **CDD Mappings** container > **New CDD Mapping**.

Mappings are generated and validated for a Customer-Defined Database.

- **CIS Mapping** container > **New CIS Mapping**.

Mappings are generated and validated for synchronizing between the InForm application and the Clintrial application.

The Object Name dialog box appears.

- 3 Fill in the fields in the dialog box.
- 4 Click **OK**.

You can now **create a data set** (on page 196) in the data mapping.

## Persistence of data mappings

After you add an item to a data series in a data mapping, the association between the item and data mapping persists wherever the item and data mappings are used. Therefore, you can create a data mapping between an item and a data series once and never have to recreate it in other studies.

Even when a mapped item and data mapping are not used together in a study, the association still exists. If you use the data mapping in another study and later add the item to the study, the item's mapping to the data mapping is restored. Similarly, the data mapping is restored if a study contains an item and the data mapping is later added to the library.

## Different ways to set up data mappings

Grouping data using data mappings provides flexibility to set up data mappings that are customized to fit your needs. For example, consider a study in which a weight value is collected for every subject. To group all weight information, you have several options:

- If a single Weight item appears on multiple forms, you can add a Weight item to a Weight data series.
- If multiple Weight items appear in the study, you can:
  - Add all Weight items to a Weight data series.
  - Add one or several Weight items to multiple Weight data series.

If you create three data series (one for each value type), you have the ability to map a different value type to each data series. Consider using naming conventions to indicate the data series used for the different value types. For example, for Weight data series, you could create the following data series: Weight\_Normalized, Weight\_Entered, and Weight\_Units.

For more information, see:

- *About adding and mapping items to data series* (on page 190)
- *About mapping data values to data mappings* (on page 192)

### About adding and mapping items to data series

| Characteristic | Add an item to a data series  | Specify when an item is mapped to a data series  |
|----------------|---|--|
| <b>Purpose</b> | The data values for the item can be used when you use the data mapping. | The data value of the item is part of the data series and can be used in several ways: <ul style="list-style-type: none"> <li>• In a rule data mapping, you can use all data values for the item in rules.</li> <li>• In a CDD data mapping, all values of the item appear in the CDD.</li> <li>• In a CIS data mapping, normalized values are mapped to the Clintrial application.</li> </ul> |



| Characteristic      | Add an item to a data series   | Specify when an item is mapped to a data series   |
|---------------------|--|---|
| <b>How to do it</b> | <ul style="list-style-type: none"> <li>• Drag the item from the Project Explorer to the Data Series Editor.</li> </ul> <p>By default, all data values collected for the item are automatically mapped to the data series.</p> <ul style="list-style-type: none"> <li>• Select a form or study event and then select the Data Series Summary tab.</li> </ul> <p>You can add an item to a data series at the same time as you map the item to a data series.</p> | <p>Select a form or study event and then select the Data Series Summary tab.</p> <p>You can add an item to a data series at the same time as you map the item to a data series.</p>   |
| <b>Example</b>      | <p>If an item appears on a form that is used three times in a study, you can add an item to the data series so the data values collected for the item can be used when you use the data mapping.</p>   | <p>If an item appears on a form that is used three times in a study, you can specify that the item is mapped to the data series only when the item appears on the specific form and only when the form appears in a specific study event.</p> |

You have the following options for mapping an item to a data series:

- The item is always mapped to the data series, on every form, in every study, and in the library.
- (Available only when a study event is selected.) The item is mapped to the data series only when it appears on any form in a specific study event. You can select this option for multiple study events.
- The item is mapped to the data series only when the item appears on a specific section (or form, if the form has no sections). You can select this option for multiple sections or forms.
- (Available only when a study event is selected.) The item is mapped to the data series only when it appears on a specific form in a specific study event.
- The item is not added to the data series. For example, an item can be mapped to one data series in a study but not another.

**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.

## About mapping data values to data mappings

When an integer or float item that has data collected in multiple units is added to a data series in a mapping, the **Item has units** dialog box appears, prompting you to choose the data value to map to the data series. You have the following options.

| Option           | Description  |
|------------------|--|
| Normalized Value | Map the normalized value of the item with the data series. Normalization is the process of converting data to a required format. The normalized units appear in parentheses. |
| Entered Value    | Map the entered value of the item with the data series. The entered value can be the same as or different from the normalized value.   |
| Entered Unit     | Map the unit in which a value is entered.  |

For example, a Weight item appears on three forms. Two forms collect the weight value in kilograms, and one form collects the weight value in pounds. The Weight items are normalized to kilograms. You can map different types of values to different data series, as shown in the following example.

| Values collected or mapped                | Source | Values in data series |
|---|--------|-----------------------|
| Values collected for the Weight items     | Form 1 | 75 kg                 |
|   | Form 2 | 155 lb                |
|   | Form 3 | 62 kg                 |
| Normalized values mapped to a data series | Form 1 | 75                    |
|   | Form 2 | 70.45                 |
|   | Form 3 | 62                    |
| Entered values mapped to a data series    | Form 1 | 75                    |
|   | Form 2 | 155                   |
|   | Form 3 | 62                    |
| Entered units mapped to a data series     | Form 1 | kg                    |
|   | Form 2 | lb                    |
|   | Form 3 | kg                    |

## 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 | <p>The new study object is mapped to the data series.</p> <p>If you break the link between the original and the new study object, the new study object is still mapped to the data series.</p> | <p>The study object is copied, but data mappings are not copied.</p> <p><b>Note:</b> 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.</p> |

**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.

## Example—Creating a data mapping to create an SDTM model

The following sample data mapping creates an SDTM model.

| Mapping | Data set | Data series                  | Items   |
|---------|----------|------------------------------|---|
| SDTM    | VS_OBS   | tempEnteredValue             | The temp item is always part of all three data series.          |
|         |          | tempNormalizedValue          |   |
|         |          | tempEnteredUnit              |   |
|         |          | weightEnteredValue           | The weight item is always part of all three data series.        |
|         |          | weightNormalizedValue        |   |
|         |          | weightEnteredUnit            |   |
|         |          | systolicValueEnteredValue    | The systolicValue item is always part of all three data series. |
|         |          | systolicValueNormalizedValue |   |
|         |          | systolicValueEnteredUnit     |   |
| DM      |          | BRTHDT                       | Date of birth   |
|         |          | SEX                          | Sex   |
|         |          | ETHNIC                       | Ethnicity   |

## Data mappings for data extraction

Data mappings in the Central Designer application allow you to collect data parts separately and then group them in a way that makes sense. The ability to create mappings is similar to functionality in the InForm application. Data collected in the InForm application is saved in a database, but you must map data to a customer-defined database (CDD) in order to view the data in an organized way.

When you create a data series, you are prompted to provide a title, RefName, and alias for the data series. If an alias is present, it is used as the column name in the customer-defined database (CDD) or as the Clintrial item name in CIS mappings. If an alias is not present, the RefName is used as the column header. Because RefNames must be unique throughout a study, you must create an alias if the RefName is used by a study object. Data series aliases must be unique within a data set.

Checking for RefName and alias uniqueness is case insensitive; that is, the names BP and bp are considered identical.

### CIS and CDD data mappings

You can create a data mapping when you design your study to define what your data will look like. When you create a deployment package, you choose the data mappings to include in the package, and the selected data mappings are deployed as CDDs in the InForm application.

You can also use mapping definitions to create CIS mappings. CIS mappings are used to transfer data from an InForm study to a Clintrial protocol using the CIS application.

### SDTM data mappings

You cannot create complete SDTM data mappings with a data mapping in the Central Designer application; however, the ability to create SDTM data mappings is available as a Oracle Services offering.

### Rules and data mappings

You can write a rule that references a data mapping, but you cannot use rules to manipulate data mappings.

### Rule creation

Data mappings can also be used for rule creation.

## About using CDD and CIS data mapping definitions

Data mappings created for Customer-Defined Databases (CDDs) or for TDE data mappings are deployed to the InForm application but must be enabled in the InForm application.

Similarly, CIS data mappings must also be enabled. To enable your data mappings in the InForm application, you must create a synchronization connection in the CIS application.

## Data mappings for rule creation

You can create data mappings to classify and query data more easily in rules. Data mappings behave like global variables, allowing rules to access data outside their normal scope. Any rule in a study can refer to any item that is part of a data mapping in the study.

This functionality might make it possible to move rules to lower-level study objects. You can use an item in any rule in a study when you add the item to a data series, which is part of a data mapping.

Using data mappings for rules also simplifies the process of looking at arrays of data, such as data that is collected over time. When a single item is used in multiple forms, you can use the array of data collected for the item in rules. For example, you can check that dates of visits are sequential or calculate aggregate values for the data.

### Useful structure for rule creation

The first data mapping that you create for the purpose of rule creation should contain subject information, as you are most likely to need this information to be available for all rules. Over time, you will probably add and subtract information in the data mapping. The following data sets provide a useful structure:

- **A data set for single-item data series.**

In this data set, include items for which the data does not change in the study, including enrollment-type items, demographics items, and any other items that are static for a subject. Examples of items that you might include in the data set include Initials and Date of Birth.

When a data series contains an item on a single form, and the item is not part of a repeating form or a repeating section, the data series is treated as an alias for the item itself and can be accessed as if it were a single global variable.

- **A data set for ongoing, per-visit information.**

In this data set, include items with values that change for the subject from study event to study event. This type of information is an array of data. For example, you might include items that appear on a Vital Signs form or a Physical Exam Results form, or items that are related to adverse events or concomitant medications.

### **Mappings and data extraction**

Mappings can also be used for data extraction.

## **Data sets**

A data set is a grouping of one or more related data series. For example, the Temperature data series and Weight data series might comprise a Vital Signs data set.

When you create a data set, you can specify standard and custom dimensions.

### **Creating a data set**

The only place to create a data set is in a data mapping.

- 1 In the Project Explorer, select the **Data Mappings** Explorer bar.
- 2 Right-click a data mapping, and select **New Data Set**.

The Data Set Properties dialog box appears.

- 3 Fill in the fields of the dialog box. **Title** and **RefName** are required.
- 4 To specify standard data dimensions, select one or more from the **Standard Data Dimensions** section.
- 5 To specify custom data dimensions for the data set:
  - a In the **Custom Dimensions** section, type a name and description and choose a data type for each custom data dimension.
  - b In the **Codelist Lookup** column, click the ellipsis button.  
The Custom Dimension Labels - Select Codelist dialog box appears.
  - c From the drop-down list, select a codelist, or to create a codelist, click **New**, and type the Code and Label pairs in the grid.
  - d To require users to select only the codelist labels that are in the codelist, select **Use only listed labels**. If you do not select it, a user-defined codelist label can be used.

**Note:** If you select **Use only listed labels**, the codelist must have at least one codelist item.

- e Click **OK**.  
You return to the Data Set Properties dialog box.
- 6 Click **OK**.

- 7 If the data set is in a CDD or CIS data mapping, in the **Properties Browser**, set the values of the appropriate CDD or CIS custom properties.

You can now **create a data series** (on page 199) in the data set.

For more information, see:

**Data Set Properties dialog box - Field descriptions** (on page 388).

**Custom Dimension Labels - Select Codelist dialog box - Option descriptions** (on page 384).

## Standard and custom data dimensions

When you create a data set, you specify standard data dimensions, which indicate the additional information that will be saved when study data is collected. Data dimensions are the keys to the data. The way the keys are defined determines how you can view the data that is collected.

For example, a Vital signs data set contains several data series, including Weight. After data is collected, the Weight data series provides the weight values that were recorded in the study. The data series does not include context information, such as identifying information for the subject and the study event in which weight was recorded. To provide this information, you can specify standard data dimensions for a data set.

**Note:** Clintrial users might find it helpful to compare specifying data dimensions to choosing a panel type. Data dimensions are similar to panel keys.

You can specify the following standard data dimensions when you create a data set.

| Standard data dimension | Information saved                    |
|-------------------------|--------------------------------------|
| Study                   | RefName of the study.                |
| Subject                 | Subject ID.                          |
| Section                 | RefName of the section.              |
| Section Index           | Instance of a repeating section.     |
| Event                   | RefName of the study event.          |
| Event Index             | Instance of a repeating study event. |
| Form                    | RefName of the form.                 |
| Form Index              | Instance of a repeating form.        |
| Item                    | RefName of the item.                 |

You can also specify custom data dimensions. Like standard data dimensions, custom data dimensions specify additional information that is saved when study data is collected. You can provide names and values for custom data dimensions by selecting or creating a codelist, and you can allow a user-defined value. When you add an item to a data series contained by the data set, you are prompted to select a custom dimension label. You can choose a label from the list of codelist items, or, if providing a user-defined value is allowed, you can type a label name.

**Note:** In CIS data mapping definitions, custom dimensions are used to identify a subset key item for pages with multiple sections that contain the same panel items. The value of the subset key item determines the section in which data appears.

## Example—Standard and custom data dimensions

To understand how you might use custom data dimensions, consider the following example, which illustrates how you can use standard and custom data dimensions to look at your data in different ways.

The following sample form collects information about eye cloudiness and color in a glaucoma study.

| Item                 | Options   |
|----------------------|---|
| Left eye cloudiness  | <input type="radio"/> Clear<br><input type="radio"/> Moderately cloudy<br><input type="radio"/> Very cloudy |
| Left eye color       | <input type="radio"/> Brown<br><input type="radio"/> Blue<br><input type="radio"/> Green                    |
| Right eye cloudiness | <input type="radio"/> Clear<br><input type="radio"/> Moderately cloudy<br><input type="radio"/> Very cloudy |
| Right eye color      | <input type="radio"/> Brown<br><input type="radio"/> Blue<br><input type="radio"/> Green                    |

If you select Subject as a standard data dimension, the data collected in the form might be stored in the following manner.

| Subject | Left cloud        | Left color | Right cloud | Right color |
|---------|-------------------|------------|-------------|-------------|
| A       | Moderately cloudy | Blue       | Clear       | Blue        |
| B       | Very cloudy       | Brown      | Very cloudy | Brown       |
| C       | Clear             | Green      | Clear       | Blue        |



Alternately, you might want to pivot your data on a piece of information, such as Eye.

In the following example, Subject is selected as a standard data dimension. In addition, a custom data dimension of Eye has been created with the values of Left and Right. When you add items that collect data for the left eye to the data series, you select the Left value for the custom dimension. When you add items that collect data for the right eye to the data series, you select the Right value for the custom dimension.

| Subject | Eye   | Cloudiness  | Color |
|---------|-------|-------------|-------|
| A       | Left  | Very cloudy | Blue  |
| A       | Right | Clear       | Blue  |
| B       | Left  | Very cloudy | Brown |
| B       | Right | Very cloudy | Brown |
| C       | Left  | Clear       | Green |
| C       | Right | Clear       | Blue  |

## Data series

A data series is a grouping of one or more items with the same clinical meaning, such as one or more items that measure weight. You can add items to a data series, and the items that you add can appear on multiple forms and study events. A data series provides you with a grouping of all study data collected for the item or items.

When you create a data series, you choose a data type for it.

### Creating a data series

The only place to create a data series is in a data set.

**Note:** In CDD and CIS data mappings, the order in which you add data series to a data set determines the order of items in the CDD or Clintrial target table. You cannot change the order after a data series is added to a data set except by modifying the Item Order property in the Clintrial Design module after the data mappings are synchronized to the Clintrial application.

- 1 In the Project Explorer, select the **Data Mappings** Explorer bar.
- 2 Right-click a data set, and select **New Data Series**.  
or  
Select a data set, and in the **Data Set Editor**, right-click the grid, and select **New Data Series**.  
The Data Series Properties dialog box appears.
- 3 Fill in the fields in the dialog box, and click **OK**.

- If the data series is in a CDD or CIS data mapping, in the **Properties Browser**, set the values of the appropriate CDD or CIS custom properties.

You now can *add one or more items to the data series* (on page 200).

For more information, see **Data Series Properties dialog box - Option descriptions** (on page 385).

## Data types for data series

When you create a data series, you choose a data type for it.

The data types of an item and data series must be compatible for you to add the item to the data series. The following table indicates the item types that you can add to each data series type.

| Item type             | Text   | Integer  | Float | Date time |
|-----------------------|--|--|-------|-----------|
| <b>Text item</b>      | Yes  | No   | No    | No        |
| <b>Integer item</b>   | Yes  | Yes  | Yes   | No        |
| <b>Float item</b>     | Yes  | No   | Yes   | No        |
| <b>Date time item</b> | Yes. You are asked if you want to choose part of the date or the whole date. | Yes. You are asked to choose the part of the date. | No    | Yes       |

You can add any item to a data series with a text type, but if the data mapping is for a CDD, the value that is provided for an item (in the InForm application) is saved in the customer-defined database (CDD) as the data type of the data series. Therefore, if you add a float item to a text data series, the float item is saved as a text item in the CDD.

In a rule data mapping, Oracle recommends creating data series with a type that matches the type of the item or items that will be added to the data series.

## Adding an item to a data series

After you add an item to a data series in a data mapping, you can specify the circumstances for which the item is mapped to the data series. For example, an item that appears on several forms in a study can be added to a data series, but you might want to analyze data collected for the item only when it appears on a specific form. In that situation, you can map the item to the data series for the specific form.

You have the following options for adding an item to a data series:


- At the form level, you indicate whether the item is mapped to the data series only when it appears on a specific form.
- At the study event level, you indicate whether the item is mapped to the data series only when it appears on a specific study event or form.

**Note:** The data types of an item and data series determine whether the item can be added to a data series. For more information, see *Data types for data series* (on page 200).

**To add an item to a data series by selecting a data series:**

- 1 In the Project Explorer, select the **Data Mappings** Explorer bar.
- 2 In the Project Explorer, select one of the following:
  - Rule Mappings
  - InForm Mappings > CDD
  - InForm Mappings > CIS
- 3 Select a data series.

The Data Series Editor appears in the workspace, and all items in the data series appear in the grid.

- 4 Select the **Add To** tab to open the Add To browser.
- 5 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.
  - Click **Refresh Results** ().

The item is added to the data series. If custom data dimensions were defined for the data set that contains the data series, the Select Custom Dimension dialog box appears.

- 6 If the **Select Custom Dimension** dialog box appears, select the custom data dimension to use, and from the **Labels** drop-down list, choose a codelist label for the custom data dimension. Optionally, depending on how the custom data dimensions were set up, you might be able to provide a user-defined label in the **Labels** field. Click **OK**.

**Note:** If you type a label or modify an existing label, a new codelist item is created for the codelist.

- 7 Optionally, add more items to the data series.

**To add an item to a data series by selecting a study event or form:**

**Note:** When you add an item to a data series by selecting a study event or form, you can determine when the item is mapped to the study event or form.

- 1 In the Project Explorer, select the form or study event containing the item to be added to a data series.
 

Either the Form Editor or Study Event Editor appears in the workspace.
- 2 Select the **Data Series Summary** tab.
 

If a form is selected, its items appear in the grid.

If a study event is selected, its forms appear in the grid.
- 3 Optionally, to change your view of the grid, use the filters at the top of the grid.

- 4 In the item's row in the grid, click the cell in the column for the data series to which you want to add the item.

A drop-down arrow appears at the end of the cell.

**Note:** If the item cannot be added to the data series—for example, if the data types for the item and data series are not compatible—**None compatible** appears in the cell.

- 5 Click the drop-down arrow, and select one of the following options from the list:
  - **None**—The item is not added to the data series.
  - **Always**—The item is always mapped to the data series, on every form, in every study, and in the library.
  - **Form**—The item is mapped to the data series only when the item appears on a specific section (or form, if the form has no sections). You can select this option for multiple sections or forms.
  - **Study Event**—(Available only when a study event is selected.) The item is mapped to the data series only when it appears on any form in a specific study event. You can select this option for multiple study events.
  - **Study Event & Form**—(Available only when a study event is selected.) The item is mapped to the data series only when it appears on a specific form in a specific study event.

If you select a data series that has custom data dimensions, the Select Custom Dimension dialog box appears. Otherwise, skip the next step.

- 6 Select a value for each custom dimension, or, if providing a user-defined value is allowed, type a value for each custom dimension.

If the item is an integer or float, you are asked if you want to map the normalized value, entered value, or entered unit to the data series.

**Note:** You can create one data series for each type of value, so you can map the item to three data series (one for each representation of the unit).

- 7 For an integer or float item with a selected unit, select the item representation to map to the data series. You have the following options:
  - Normalized value
  - Entered value
  - Entered unit

- 8 Optionally, add the item to more data series, or add other items to data series.

For more information, see:

**Data Series Summary tab - Option descriptions** (on page 386).

**Select Custom Dimension dialog box - Option descriptions** (on page 391).

## Removing an item from a data series

You can remove an item from a data series by selecting a data series, study event, or form. To keep the item in the data series but remove the data mapping for a study, *unmap the item* (on page 203).

### To remove an item from a data series by selecting a data series:

- 1 In the Project Explorer, select a data series.  
The Data Series Editor appears in the workspace.
- 2 Right-click the item with an association to remove, and select **Remove**.  
A confirmation message appears.
- 3 Click **Yes**.

### To remove an item from a data series by selecting a study event or form:

- 1 In the Project Explorer, select the form or study event containing the item to remove.  
The editor for the study object appears in the workspace.
- 2 Select the **Data Series Summary** tab.  
If a form is selected, its items appear in the grid.  
If a study event is selected, its forms appear in the grid.
- 3 Optionally, to change your view of the grid, use the filters at the top of the grid.
- 4 In the grid, follow the row containing the item across until you reach the column of the data series from which you want to remove the item, and point to the cell.  
A drop-down arrow appears at the end of the cell.
- 5 Click the drop-down arrow, and select **None**.

For more information, see **Data Series Summary tab - Option descriptions** (on page 386).

## Unmapping and restoring an item mapping with a data series

When you unmap an item in a study, the item is no longer part of the data series for the study, but it is still part of the data series in the library in which it is saved. You might unmap an item from a data series if you have added both to a study from a library and do not want the item to be part of the data series for the particular study.

You can restore an unmapped item if you want the item to be part of the data series for a study.

### To unmap an item and a data series:

- 1 In the Project Explorer, select a data series.  
The Data Series Editor appears.
- 2 Right-click the item, and select **Unmap the Data Series**.  
The mapping between the item and data series is removed, and the value in the **State** column changes to Unmapped for the item.

**To restore an item data mapping with a data series:**

- 1 In the Project Explorer, select a data series.  
The Data Series Editor appears in the workspace.
- 2 Right-click the item that you want to map, and select **Map the Data Series**.  
A mapping is created between the item and data series, and the value in the **State** column changes to Mapped for the item.

For more information, see **Data Series Editor - Field descriptions** (on page 384).

## Opening an item from the Data Series Editor

- 1 In the Project Explorer, select a data series.  
The Data Series Editor appears.
- 2 In the grid, right-click an item, and select **Go to [item name] item**.  
The Item Editor, with information about the item, appears in the workspace.

## Changing the data value that is associated with a data series

When you add an integer or float item with a selected unit to a data series, you choose if you want to map the normalized value, entered value, or normalized units to the data series. You can change the data value that is mapped at any time.

- 1 In the Project Explorer, select a data series.  
The Data Series Editor appears.
- 2 Right-click an integer or float item, and select **Modify data point value collected**.  
The **Item has units** dialog box appears.
- 3 Select the value to associate with the data series, and click **OK**.

For more information, see **Item has units dialog box - Option descriptions** (on page 389).

## Validation for data mappings

The type of data mapping, either CDD, CIS, or rules, determines whether the data mapping definition is validated against criteria for CDD data mappings, CIS data mappings, or no data mappings, respectively.

| Validation area          | Must be true for successful validation   |
|--------------------------|--|
| <b>CDD data mappings</b> |  |
| Data type compatibility  | <ul style="list-style-type: none"> <li>All components of a date time item must be required and must not allow unknowns if the date time item is mapped to a data series with a data type of DateTime.</li> <li>If one or more parts of a date time item are not required or allowed to be unknown, the data series to which the item is mapped must have a type of Text.</li> <li>The length of an item mapped to a data series must not be longer than the value set in the DB Format Length custom property of the data series.</li> <li>The precision of a float item mapped to a float data series must not be greater than the value set in the DB Format Float Precision custom property of the data series.</li> <li>If a float item is mapped to an integer data series, the precision must be 0.</li> </ul> |
| Date part and split date | If any item is mapped to a data series with the split date option, all items mapped to the data series must use the split date option.   |
| Target key types         | <ul style="list-style-type: none"> <li>Data series mapped to items in a repeating section cannot have a pivot target key type. Pivot tables are not supported for itemset data.</li> <li>If the target key type of the data set is a pivot target key type, one (and only one) data series must be identified as the pivot column.</li> </ul>  |
| <b>CIS data mappings</b> |  |
| Block key and page key   | <p>The block key and page key must conform to the specifications of the data series for the block key item or page key item in the context panel:</p> <ul style="list-style-type: none"> <li>The data type must convert to a compatible data type.</li> <li>The length must be within the length specified in the DB Format Length CIS custom property.</li> <li>If the data type of the data series is float, the precision must be within the precision specified in the DB Format Float Precision CIS custom property.</li> </ul>   |

| Validation area          | Must be true for successful validation   |
|--------------------------|--|
| Context panel            | <ul style="list-style-type: none"> <li>• A data mapping can have only one custom context panel.</li> <li>• The data series in a context panel must have data types of Text, Fixed, or Float.</li> <li>• The value of the Context Type property of a data series in a context panel cannot be: <ul style="list-style-type: none"> <li>▪ <b>Other context item</b> if the value of the Is Key property is True.</li> <li>▪ <b>Not a context item.</b></li> </ul> </li> <li>• A context panel can have only one: <ul style="list-style-type: none"> <li>▪ Subject key item.</li> <li>▪ Block key item.</li> <li>▪ Page key item.</li> <li>▪ Block repeat key item.</li> <li>▪ Page repeat key item.</li> </ul> </li> <li>• For a subject key item, if the data type of the data series is Text, the value of the DB Format Length custom property cannot be greater than 80.</li> <li>• Data set aliases used in a context panel cannot be used in data sets for noncontext panels.</li> <li>• If the study contains a data set that is a custom context panel, and the study contains a common form with one or more items that are mapped to any data series, you must specify a value in the Shared Form Block Key custom property on the study design.</li> </ul> |
| Data type compatibility  | <ul style="list-style-type: none"> <li>• All components of a date time item must be required and must not allow unknowns if the date time item is mapped to a data series with a data type of DateTime.</li> <li>• If one or more parts of a date time item are not required or allowed to be unknown, the data series to which the item is mapped must have a type of Text.</li> <li>• The length of an item mapped to a data series must not be longer than the value set in the DB Format Length custom property of the data series.</li> <li>• The precision of a float item mapped to a float data series must not be greater than the value set in the DB Format Float Precision custom property of the data series.</li> <li>• If a float item is mapped to an integer data series, the precision must be 0.</li> </ul>   |
| Date part and split date | If any item is mapped to a data series with the split date option, all items mapped to the data series must use the split date option.   |
| Enrollment panel         | A data mapping can have only one enrollment panel.   |



| Validation area                        | Must be true for successful validation  |
|--|---|
| Non-patient data panel                 | The data series in a non-patient data panel cannot have any mapped items.   |
| Other validation for CIS data mappings | <ul style="list-style-type: none"> <li>• The following CIS custom data series properties must be mutually exclusive: <ul style="list-style-type: none"> <li>▪ Checklist and CIS Codelist.</li> <li>▪ Derived and Item Required.</li> </ul> </li> <li>• RefNames of data sets and data series that are used for: <ul style="list-style-type: none"> <li>▪ CIS data mappings must not be longer than 20 characters.</li> <li>▪ CDD data mappings must not be longer than 25 characters.</li> </ul> </li> <li>• Aliases for data sets and data series must not be longer than 20 characters.</li> <li>• RefNames and aliases for data sets must be unique within a data mapping, and RefNames and aliases for data series must be unique within a data set. Checking for RefName and alias uniqueness is case insensitive; for example, the names BP and bp are considered identical.</li> <li>• The RefName and alias of a custom data dimension that is used as a subset key must not be the same as the RefName or alias of any data series in the data dimension.</li> <li>• If the value of the Is Key custom property of a data series is True, the value of the Item Required custom property must also be True.</li> <li>• If you do not create mappings for a CIS enrollment panel, the Central Designer application creates an enrollment panel from the items in the special screening and enrollment forms. The RefNames of the special screening and enrollment items used to create the enrollment panel must not be longer than 20 characters.</li> <li>• If a data set is marked as an enrollment or non-patient data panel, the value of the Detail Key Item, Detail Panel, Master Item, and Master Panel custom properties of all data series in the data set must not be True.</li> </ul> |

# Rule data mappings

## About rule data mappings

### Deciding when to use a data mapping and when to move a rule to a higher-level study object

If you need to create a rule on a study object, such as a form, but an item that the rule must reference is not in the scope of the study object, you have the following options:

- Add the item to a data series, so you can use the item in any rule in the study.
- Move the rule to a higher-level study object that includes all study objects that are needed for the rule in its scope.

There is no set guideline for which approach is better. The Central Designer application does not require you to use data mappings for rule creation, and you must weigh the benefits and limitations of using data mappings when making this decision.

- **Benefits and limitations of using a data mapping.**

You can create the rule on a lower-level study object, thus improving the likelihood that the rule will be reused.

However, you must include the data mapping in every study that uses the study object on which the rule is created.

- **Benefits and limitations of moving a rule to a higher-level study object.**

You can create the rule on the study object with all study objects in its scope without adding another item to the data mapping.

However, if the rule is created at a higher-level study object, the likelihood that it will be reused might be low. For example, some organizations might be more likely to reuse an item or form rather than an entire study event.

- **Oracle recommendation.**

Oracle recommends that you create a data mapping and use it for rule creation if you use:

- Every instance of a study object in one or more rules. Add the study object to a data mapping.

For example, you should create a data mapping if you have a repeating Adverse Event form and a rule must reference the event description or event ID from every single instance of the form.

- An item frequently in a study. Add the item to a data mapping.
- An item and a rule in many studies. Consider adding the item to a data mapping.

## Data mappings and the rule engine

The Central Designer rule engine handles forms and items that have been mapped to a data mapping the same as study objects that have not been mapped to a data mapping—the rule engine follows the data mappings to access the data in the original items. There is no physical representation of the data mapping in the InForm application.

The Central Designer application determines the data that is in a data mapping and uses the information to analyze rule dependencies. In some situations, more triggers (ATTACHRULESET objects) might be created for rules that use data mappings in comparison to rules that do not use data mappings.

Keep in mind the following when brainstorming different ways to use data mappings:

- The data in the data mapping comes from the standard InForm data model, and the Central Designer rule engine refers to the InForm database for study objects that are in a data mapping.
- The InForm application allows you to work with data for a single subject at a time, and data mappings provide the same functionality. You cannot use data mappings to access site information or information from other subjects.

## Example of data mappings for rule creation

The following sample data mappings can be used for rule creation.

| Data mapping                                    | Data set | Data series | Items  | Sample rule expressions   |
|---|----------|-------------|--|---|
| Rules<br>(Single data point in data mapping)    | BMI      | Weight      | <ul style="list-style-type: none"> <li>• Weight item always part of the data series.</li> <li>• Weight item appears on only one form.</li> </ul>   | $\text{BMI.Weight.Value} / \text{Math.Pow}(\text{BMI.Height.Value}, 2)$   |
|   |          | Height      | <ul style="list-style-type: none"> <li>• Height item always part of the data series.</li> <li>• Height item appears on only one form.</li> </ul>   |   |
| Rules<br>(Multiple data points in data mapping) | BMI      | Weight      | <ul style="list-style-type: none"> <li>• Weight item always part of the data series.</li> <li>• Weight item appears on multiple forms, so you must specify which value to use in the rule expression.</li> </ul> | $\text{BMI.StudyEvent}(\text{StudyEvents.Visit1}).\text{Weight.Values}[0] / \text{Math.Pow}(\text{BMI.Height.Value}, 2)$ $\text{BMI.StudyEvent}(\text{StudyEvents.FinalVisit}).\text{Weight.Values}[0] / \text{Math.Pow}(\text{BMI.Height.Value}, 2)$ |
|   |          | Height      | <ul style="list-style-type: none"> <li>• Height item always part of the data series.</li> <li>• Height item appears on only one form.</li> </ul>   |   |

**Notes:**

- Math.Pow computes the power of a value. You can also define functions for calculating a squared value.
- As with any calculation rule, in data mapping rules you should check for empty values and for division by zero.

**Modifying labels of mapped custom data dimensions**

When you add an item to a data series in a data set with a custom data dimension, you are prompted to select a value for the custom data dimension and the data mapping. You can change the value at any time.

- 1 In the Project Explorer, select a data series.  
The Data Series Editor appears in the workspace.
- 2 Right-click an item, and select **Modify labels**.  
The Select Custom Dimension dialog box appears.
- 3 From the **Labels** drop-down list, choose a codelist label for the custom data dimension. Optionally, depending on how the custom data dimensions were set up, you might be able to provide a user-defined label in the **Labels** field.

**Note:** If you type a label or modify an existing label, a new codelist item is created for the codelist.

- 4 Click **OK**.

**Deleting a custom data dimension**

- 1 In the Project Explorer, select a data mapping.  
The Data Mappings Editor appears in the workspace.
- 2 Right-click a data set, and select **Properties**.  
The Data Set Properties dialog box appears.
- 3 In the **Custom Data Dimensions** section, right-click a custom data dimension, and select **Delete Row**.

**Mappings and the Data Mappings tab**

Data mappings make study objects available to rule expressions on a global level, without regard to the scope of a particular study object. Global study objects defined in a data mapping appear on the Data Mappings tab.

The Data Mappings tab (on the Expression tab of the Rule Wizard) lists:

- RefNames of the *data mappings* (on page 188), *data sets* (on page 196), and *data series* (on page 199) in the study or library.

- Rule model properties for data series.  
A data series has the properties of the item that is mapped to it. If a data series contains an item that collects more than one value, the rule model properties for repeating study objects appear so you can access an array of all of the values of the item.
- Methods for data sets.  
A method appears if you select the corresponding standard data dimension of the data set. You can use data set methods to return a subset of the data in the data set.
- Study events, forms, sections, and items that are mapped to each data set.
- Study objects appear if you select the corresponding standard data dimension of the data set. The properties of the study objects are used as parameters of data set methods.

## Data mapping setup for referencing specific instances of an item

If an item that you will use in a rule appears multiple times in a study, you can use either of the following approaches to setting up a data mapping so that you can reference specific instances of the item:

- When you add an item to a data series in the Data Series Summary tab of the Form or Study Event editor, specify the instances of the item that you want to be mapped to the data series.
- When you create a data set, select standard data dimensions that enable the data set methods you need in the Data Mappings tab.

## Data series mapping options and the Data Mappings tab

When you add an item to a data series in the Data Series Summary tab of the Form or Study Event editor, you can specify the instances of the item that you want to be mapped to the data series:

- **None**—The item is not added to the data series.
- **Always**—The item is always mapped to the data series, on every form, in every study, and in the library.
- **Form**—The item is mapped to the data series only when the item appears on a specific section (or form, if the form has no sections). You can select this option for multiple sections or forms.
- **Study Event**—(Available only when a study event is selected.) The item is mapped to the data series only when it appears on any form in a specific study event. You can select this option for multiple study events.
- **Study Event & Form**—(Available only when a study event is selected.) The item is mapped to the data series only when it appears on a specific form in a specific study event.

This approach is recommended if the specifications for your rules are well known at the time when you are designing your data mappings. For example, if an item occurs in more than one form, and you know that your rules will reference the item in a specific form, you can map the item to a data series in the Form editor with a Form data mapping type.

## Standard data dimensions and data set methods on the Data Mappings tab

When you create a *data set* (on page 196), you can select standard data dimensions that enable the data set methods you need in the Data Mappings tab. Each data set method enables you to reference a particular subset of the instances of an item in a study. For example, the StudyEvent(StudyEvents) data set method returns a data set subset with data from only the specified study event. To enable the StudyEvent(StudyEvents) data set method, you select the Event standard data dimension when creating the data set.

You can use this approach if you design your *data mappings* (on page 188) before the complete specifications for your rules are known. With this approach, you can add an item to a data series without considering all of the forms and study events in which it is used. In your rule expression, you can use data set methods to select specific instances of the item.

**Note:** This approach is less efficient than adding an item to a *data series* (on page 199) with a data mapping type that narrows the selection of instances of the item. When possible, select for specific instances of an item when adding it to a data series.

## Study object nodes in the Data Mappings tab

When you select a standard data dimension for a data set, the study objects included in the standard data dimension appear as nodes in the Data Mappings tab:

- Under the *data set* (on page 196).
- Under each data set method.

For example, if you select the Form standard data dimension, a list of the RefNames of all forms that contain items mapped to the data series in the data set appears in the Data Mappings tab.

Study object nodes enable you to drag RefNames of specific study objects into the expression window, instead of typing them. Additionally, when you drag a *data series* (on page 199) property or data set method into the expression window, the same study object RefNames appear in the References tab of the Invoke Function dialog box and are available for use as parameter values.

# CDD data mappings

## About CDD mappings

### Example—Creating a CDD mapping

The following data mapping could be used to create a customer-defined database (CDD) in the InForm application.

| Data mapping | Data set     | Data series | Items          | Standard data dimensions  |
|--------------|--------------|-------------|----------------|---------------------------|
| Study name   | Vital Signs  | BP          | Blood pressure | Subject<br>Study<br>Event |
|              |              | Temp        | Temperature    |                           |
|              |              | PulseRate   | Pulse Rate     |                           |
|              | Demographics | Gender      | Gender         | Subject<br>Study          |
|              |              | DOB         | Date of Birth  |                           |
|              |              | Race        | Race           |                           |

### How data mappings are deployed to CDD tables

When you create a deployment package and choose one or more data mappings to create CDD data mappings:

- Each data set becomes a target table, and each data series becomes a column in the table.
- The key columns of the target tables are defined by the value of the Target Key Type CDD custom property on the data set.
- Additional attributes of the target tables and columns are defined by the values of CDD custom properties on the item, data set, and data series.
- When you map an item with a unit into a text data series, you must choose whether to map the entered value, normalized value, or entered unit. However, all items are mapped as the entered value regardless of what is specified when the item is mapped. The InForm CDD supports the mapping of the different parts, but there is no option in the InForm application to choose the column names or which parts to include, so the CDD data mapping from data mapping definitions ignores this setting.
- All values in a multi-select codelist are mapped to a single column. It is not possible to define a data series mapping in such a way that each possible value of a multi-select codelist appears in a different CDD table column.
- When you define a data set, you can specify one or more standard data dimensions and custom data dimensions. Standard and custom data dimensions are not used in CDD data mappings.

- You can define CDD data mappings for associations by associating two forms and selecting those forms as the value of the Associated Forms property on a data set.

## Mapping associated forms to a CDD

The target table for an association has a fixed format that consists of ID and index columns to identify the visit instance, form instance, and patient for the data in the two associated forms. Instead of specifying data sets and data series for the data in each form, you specify the association.

- 1 Create two repeating, common forms, and associate them.
- 2 *Create a data set* (on page 196).

**Note:** Do not create any data series in the data set. You can create mappings for associations only in a data set that has no data series.

- 3 In the **Properties Browser**, select the associated forms as the value of the **Associated Forms** property, and press **Enter**.

**Note:** If you change the association between two forms, you must manually update the data mapping by changing the value of the Associated Forms CDD custom property of the data set.

## Target keys in CDD data mappings

When you create a data set to use for CDD data mappings, you specify the target key type. Target key types control how data is grouped in a CDD. Target key types are used for tables that do not pivot and for pivot tables.

- **Target key types for tables that do not pivot**—These target key types enable you to define CDD tables in which data is grouped by a portion of the control path of the data point in the InForm application. For example, to capture all of the data for a single patient in one row, you might define a target table with the Patient Only target key type. To capture the data for each form in a single row, with a new row for each patient and visit, you might define a target table with the Patient to Form target key type.

The primary key of the target table determines how data is inserted into CDD target tables. When you create a CDD target table definition, the primary key of the table is a set of database IDs (DBUIDs) and indexes that correspond to the components of a data point's control path or a subset of the control path. When the InForm application loads data into a CDD table, it creates a new row each time the value of the primary key changes.

- **Target key types for pivot tables**—These target key types enable you to define CDD tables in which you can:
  - Map multiple data points to the same CDD table column.
  - Associate a particular data point with each row in the table.



In pivot tables, insertion of data is organized around a set of rows called a pivot set. The data points that make up a pivot set share the same values in specified parts of their control paths. The target key type of a pivot table determines where each pivot set breaks by defining which parts of the control path are the same within a pivot set. For example, in a table with a target key type of Pivot Section, a pivot set is made up of all data points in which the patient, visit, form, and section components of the control path match.

One of the columns in a pivot table is identified as the pivot column. Each time the InForm application loads one pivot set of data into a pivot table, it creates a new row for each data point mapped to the pivot column, and it duplicates data points mapped to nonpivot columns in each of those rows.

## Target key types for tables that do not pivot

In tables that do not pivot, each target key type specifies the components of the primary key of the target table. For example, the primary key of a table with a target key type of Patient to Form consists of columns containing the PatientID, VisitID, ItemsetIndex, VisitIndex, and FormID.

| Target key type    | Primary key components   | Data grouping in target table   |
|--------------------|--|---|
| Patient Only       | PatientID, FormIndex, ItemsetIndex.  | All data for a patient in one row.  |
| Patient Visit      | PatientID, VisitID, FormIndex, ItemsetIndex, and VisitIndex.   | All data for a visit in one row, with a new row for each patient or visit.  |
| Patient to Form    | PatientID, VisitID, FormIndex, ItemsetIndex, VisitIndex, and FormID.   | All data for a form in one row, with a new row for each patient, visit, or form.                                    |
| Patient to Section | PatientID, VisitID, FormIndex, ItemsetIndex, VisitIndex, FormID, and SectionID.                                    | All data for a section in one row, with a new row for each patient, visit, form, or section.                        |
| Patient to Itemset | PatientID, VisitID, FormIndex, ItemsetIndex, VisitIndex, FormID, SectionID, and ItemsetID.                         | All data for an itemset instance in one row, with a new row for each patient, visit, form, section, or itemset row. |
| Patient to Item    | PatientID, VisitID, FormIndex, ItemsetIndex, VisitIndex, FormID, SectionID, ItemsetID, and ItemID.                 | All data for an item in one row, with a new row for each patient, visit, form, section, itemset, or item.           |
| Patient to Control | PatientID, VisitID, FormIndex, ItemsetIndex, VisitIndex, FormID, SectionID, ItemsetID, ItemID and five ControlIDs. | Each control on a separate row.   |

**Note:** A target table with the Patient to Control key type also contains a data label that can be used for data selection. The data label is specified in the Data Label custom property of the item.

## Target key types for pivot tables

In pivot tables, the target key type determines the composition of a pivot set. Within a pivot set, data points mapped to the columns that are not in the pivot set are repeated in each row. You might choose one of these target key types to be able to select all data values that have some related data value in common, for example, to select all lab values for a specific test that were collected on the same date.

The primary key columns are PatientID, VisitID, ItemsetIndex, VisitIndex, FormID, SectionID, ItemsetID, ItemID, and five ControlIDs. Pivot target tables also contain a data label that can be used for data selection. The data label is specified in the Data Label custom property of the item.

| Target key type | Pivot set components                                  |
|-----------------|---|
| Pivot Patient   | PatientID and VisitIndex.                             |
| Pivot Visit     | PatientID, VisitID, and VisitIndex.                   |
| Pivot Form      | PatientID, VisitID, FormID, and VisitIndex            |
| Pivot Section   | PatientID, VisitID, FormID, SectionID, and VisitIndex |

## Setting up a pivot table with CDD data mappings

- 1 **Create a data set** (on page 196) for the target table.
- 2 In the **Properties Browser**, select a **Target Key Type** value that begins with Pivot, and press **Enter**.
- 3 **Create a data series** (on page 199) for each column in the target table.
- 4 In the **Properties Browser**, select True as the value of the **Pivot Column** property for the data series to use as the pivot column, and press **Enter**.
- 5 For each text data series, in the **Properties Browser**, specify the maximum length of the target column as the value of the **Target Column Max Length** property, and press **Enter**.

For more information, see **CDD mapping properties** (on page 467).

## CDD data mappings for date time items

You can set up CDD data mappings for date time items so that:

- The entire date appears in a single database column in the CDD.
- Each date time part appears in a separate database column in the CDD. The data mappings that the Central Designer application generates include the SPLITDATE attribute of the TARGETCOLUMNTYPE tag.

## Modifying CDD date time part data mappings

- 1 In the Project Explorer, select a data series.  
The Data Series Editor appears.
- 2 Right-click an item, and select **Modify data point date part**.  
The Date-Time Data Point dialog box appears.
- 3 Select one of the following:
  - **All in one column**—Changes the data mapping from multiple columns to one column.
  - **Split columns**—Changes the data mapping from one column to a column for each date time part.
- 4 Click **OK**.

## CDD data mapping setup for date time items

The following table describes how to set up the mappings in a CDD data mapping definition.

| CDD database result  | Data series and mapping setup  |
|--|--|
| Entire date appears in a DATE database column.                     | <ul style="list-style-type: none"> <li>• Map the date time item to a data series with a type of Date Time.</li> </ul>  |
| Entire date appears in a TEXT database column.                     | <ol style="list-style-type: none"> <li>1 Map the date time item to a data series with a type of Text.</li> <li>2 In the <b>Date-Time Data Point</b> dialog box, select <b>All in one column</b>, and click <b>OK</b>.</li> </ol> |
| Each date time part appears in a separate TEXT database column.    | <ol style="list-style-type: none"> <li>1 Map the date time item to a data series with a type of Text.</li> <li>2 In the <b>Date-Time Data Point</b> dialog box, select <b>Split columns</b>, and click <b>OK</b>.</li> </ol>     |
| Each date time part appears in a separate INTEGER database column. | <ul style="list-style-type: none"> <li>• Map the data time item to a data series with a type of Integer.</li> </ul> <p>The Central Designer application creates a separate column mapping for each date time part.</p>           |

# CIS data mappings

## How data mappings are deployed to Clintrial study objects

When you create a deployment package and choose one or more data mappings to use to create CIS data mappings:

- Each data set becomes a panel, and each data series becomes an item in the panel.
- A custom data dimension on a data set is mapped to the Subset Item in the Clintrial application. Only one custom data dimension is supported for each data set.
- The Panel Type is defined by the value of the Panel Type CIS custom property on the data set.
- Other panel and panel item attributes are defined by the values of CIS custom properties on the study event, form, data set, and data series.
- Only normalized values mapped to the Clintrial application.

## CIS data mappings and Clintrial subsets

### About Clintrial subsets

In the Clintrial application, subsets provide a way to group similar items together in a page section. A subset page section can occur multiple times on a study page in a Type 0, Type 2, or Type 4 panel, with each different value of a subset key item representing distinct rows (subsets) of data. Each occurrence of a subset page section constitutes a separate observation.

You might want to set up data mappings for a subset if both of the following are true:

- Your InForm study collects identical data items on multiple forms (for example, lab test results for different body systems).
- You want to store the data in a single panel in the Clintrial application.

For example, in the Medika-Clinical sample study in the Clintrial application, the LABLNG page template has subset page sections for blood chemistry (LABCHEM), hematology (LABHEM), and urinalysis (LABURN). Each of these sections is made up of the same panel items, including the subset key item TEST\_TYPE. The value of TEST\_TYPE distinguishes the type of lab test represented by each subset of lab data.

### Subset keys and subset values in the Central Designer application

When subsets are used in the Clintrial application, one item in a panel is designated as the subset key item. The value of the subset key item determines the record in which to store a set of subset data.

In the CIS data mappings generated by the Central Designer application:

- The panel (CTPanel) data mapping identifies the subset key item. The Central Designer application obtains the name of the subset key item from the name of a custom dimension defined on a data set. An unmapped item with the name of the custom dimension is added to the data mappings for the panel and becomes a column in the panel when synchronized to the Clintrial application.

- The item (CTItem) data mappings hold the subset value (the value of the subset key item). The Central Designer application obtains the subset value from the custom dimension label that you associate with an item when you map it to a data series within the data set.

## Setting up data mappings for a Clintrial subset

- 1 **Create a data set** (on page 196) for the panel that contains the subset, and:
  - a In the **Custom Data Dimensions** section of the **Data Set Properties** dialog box, add a custom data dimension for the subset key item.  
  
The name of the custom data dimension becomes the name of the subset key item in the data mappings and in the Clintrial panel. This name must not be the same as the RefName or alias of any data series in the data set.
  - b In the **Custom Dimension Labels - Select Codelist** dialog box, select or create a codelist that has a codelist item label for each value that the subset key item can have.
- 2 **Create a data series** (on page 199) for each item in the subset.
- 3 **Add the items** (on page 200) that participate in the subset to the appropriate data series.  
The Select Custom Dimension dialog box appears.
- 4 In the **Select Custom Dimension** dialog box for each item:
  - a Select the custom data dimension you created for the subset key item.
  - b In the **Labels** column, select the label that corresponds to the subset key item value with which the item will be stored in the Clintrial application.
  - c Click **OK**.

## Block keys and page keys in CIS data mappings

Block keys are identifiers for Clintrial blocks, which correspond to Central Designer study events and InForm visits. Page keys are identifiers for Clintrial pages, which correspond to Central Designer and InForm forms. All data that is synchronized to the Clintrial application must have a block key and a page key associated with it. The context panel in a Clintrial study contains items that hold the values of the block key and page key. These items are called the block key item and the page key item.

In the Central Designer application, the data series in the data set that marked as the context panel (the value of the Panel Type custom property is Context Panel) identify the block key item and the page key item.

### How block key values are assigned

Any of the following definitions can be used as the value of the block key item:

- By default, the RefName of the study event.
- If the RefName of the study event contains a double underscore (for example, Week2\_\_21), the value that follows the double underscore.
- The Block Key Value custom property for the study event. If a value is specified for the Block Key Value custom property, that value overrides the block key value formed from all or a part of the RefName.

For common visits, the value of the Shared Form Block Key custom property on the study design becomes the value of the block key in data mappings for the internal visit definition (the CommonCRF visit) that the InForm application requires for common forms.

The resulting block key value must conform to the specifications of the data series for the block key item in the context panel:

- The data type must convert to a compatible data type.
- The length must be within the length specified in the DB Format Length CIS custom property.
- If the data type of the data series is float, the precision must be within the precision specified in the DB Format Float Precision CIS custom property.

For example, validation fails if:

- The block key value is First but the block key item has a type of Integer.
- The block key value is 99 but the page key item has a Length of 1.

### How page key values are assigned

Any of the following definitions can be used as the value of the page key item:

- By default, the RefName of the study form.
- If the RefName of the study form contains a double underscore (for example, Hema\_\_21), the value that follows the double underscore.
- The Page Key Value custom property for the study form. If a value is specified for the Page Key Value custom property, that value overrides the page key value formed from all or a part of the RefName.

The resulting page key value must conform to the specifications of the data series for the page key item in the context panel:

- The data type must convert to a compatible data type.
- The length must be within the length specified in the DB Format Length CIS custom property.
- If the data type of the data series is float, the precision must be within the precision specified in the DB Format Float Precision CIS custom property.

For example, validation fails if:

- The page key value is First but the page key item has a type of Integer.
- The page key value is 99 but the page key item has a Length of 1.

## CIS data mappings for specialized Clintrial panels

The setting of the Panel Type CIS customized property for data sets determines how data mappings are generated for specialized Clintrial panels.

| Panel Type value | How panel is used   | What is included in CIS data mappings   |
|------------------|---|---|
| Context          | Contains context items, which are included in every record in a clinical data table. The context items form the primary key of the clinical data record.  | <ul style="list-style-type: none"> <li>• <b>If selected</b>—Custom context panel made up of the items that are mapped to the data series in the data set.</li> <li>• <b>If not selected (default)</b>—Default context panel created during deployment.</li> </ul> <p>For more information, see <i>MedML definition of the default context panel</i> (on page 223).</p> <p><b>Note:</b> A data mapping can have only one data set with a Context panel type.</p>   |
| Enrollment       | Contains screening and enrollment data for each study subject. The Clintrial application does not use separate records for screening and enrollment data. | <ul style="list-style-type: none"> <li>• <b>If selected</b>—Custom enrollment panel made up of the items that are mapped to the data series in the data set. The data mappings for the custom enrollment panel exist only in the data mapping where the data set is defined.</li> <li>• <b>If not selected (default)</b>—Enrollment panel made up of: <ul style="list-style-type: none"> <li>▪ The items in the combined screening and enrollment forms in the study design, if they exist.</li> <li>▪ The items in the combined default screening and enrollment forms generated by the Central Designer application, if the forms are not defined in the study design.</li> </ul> </li> </ul> <p>The data mappings for either version of the default enrollment panel are included in the mappings for all data mappings for a study.</p> |
| Non-Patient Data | Contains data that is not related to a particular subject or visit, such as standard coding thesauruses, view codelists, or laboratory normal ranges.     | <p>If selected, the Central Designer application generates data mappings for a non-patient data panel that has a column for each data series in the data set.</p> <p><b>Note:</b> The data series in a non-patient data set must not have any items mapped to them.</p>   |

## Creating a custom Clintrial context panel

- 1 *Create a data set* (on page 196) for the context panel.
- 2 *Create a data series* (on page 199) for each context item.
- 3 In the **Properties Browser**, set the values of custom properties for the data set and each data series, and press **Enter**.
- 4 Optionally, *map items to the data series* (on page 200).

If you do not map specific items to a data series, the values of the key items are derived from the control path of each InForm transaction as it is processed.

**Note:** The validation process checks the design of a custom context panel for compliance with Clintrial design rules. However, the Central Designer user interface does not enforce similar checking. Therefore, make sure that your definition of a custom Clintrial context panel does not violate *Clintrial design considerations* (on page 223).

## Creating a Clintrial enrollment panel

- 1 *Create a data set* (on page 196) for the enrollment panel.

**Note:** Master-detail relationships are not supported in enrollment panels. If the Detail Key Item, Detail Panel, Master Item, or Master Panel CIS custom properties have values in the data set for an enrollment panel, validation fails.

- 2 In the **Properties Browser**, set the value of the **Panel Type** CIS custom property to Enrollment, and press **Enter**.
- 3 *Create a data series* (on page 199) for each screening or enrollment item to include in the panel. (The Clintrial application does not have a separate panel for screening and enrollment data.)
- 4 *Add items to the data series* (on page 200).

## Creating a non-patient data (Type 0) panel

- 1 *Create a data set* (on page 196) for the non-patient data panel.

**Note:** Master-detail relationships are not supported in non-patient data panels. If the Detail Key Item, Detail Panel, Master Item, or Master Panel CIS custom properties have values in the data set for a non-patient data panel, validation fails.

- 2 In the **Properties Browser**, set the value of the **Panel Type** CIS custom property to Non-Patient Data, and press **Enter**.
- 3 *Create a data series* (on page 199) for each item to include in the panel.

**Note:** Do not map items to any of the data series in the panel.



## MedML definition of the default context panel

If you do not create a data set as a custom context panel definition, the Central Designer application generates the following context panel definition during deployment:

```
<CONTEXTPANEL REFNAME="CISLS2">

  <CTITEM REFNAME="PATNUM" ITEMDATATYPE="TEXT" ISREPEAT="false"
  ISREQUIRED="true"
  DBFORMAT="VARCHAR2(20)" CONTEXTTYPE="1" ISKEY="true" />
  <CTITEM REFNAME="VISITID" ITEMDATATYPE="TEXT" ISREPEAT="false"
  ISREQUIRED="true"
  DBFORMAT="VARCHAR2(20)" CONTEXTTYPE="2" ISKEY="true" />
  <CTITEM REFNAME="FORMID" ITEMDATATYPE="TEXT" ISREPEAT="false"
  ISREQUIRED="true"
  DBFORMAT="VARCHAR2(20)" CONTEXTTYPE="3" ISKEY="true" />
  <CTITEM REFNAME="VISITINDEX" ITEMDATATYPE="FIXED" ISREPEAT="true"
  ISREQUIRED="false"
  DBFORMAT="NUMBER(38)" CONTEXTTYPE="2" ISKEY="true" />
  <CTITEM REFNAME="FORMINDEX" ITEMDATATYPE="FIXED" ISREPEAT="true"
  ISREQUIRED="false"
  DBFORMAT="NUMBER(38)" CONTEXTTYPE="3" ISKEY="true" />

</ CONTEXTPANEL>
```

## Design considerations for a custom context panel

| Design consideration   | Custom property settings   | Design rules   |
|--|--|--|
| Data set   | Panel Type—Context panel.  | A data mapping can have only one data set for which the Panel Type value is Context panel.   |
| Data series for:   |  |  |
| <ul style="list-style-type: none"> <li>Subject key item</li> </ul> | <ul style="list-style-type: none"> <li>Context Type—Subject-related context item.</li> <li>Is Key—True.</li> </ul> | <ul style="list-style-type: none"> <li>A context panel can have only one subject key item.</li> <li>If the data type of the data series is Text, the value of the DB Format Length custom property cannot be greater than 80.</li> </ul> |
| <ul style="list-style-type: none"> <li>Block key item</li> </ul>   | <ul style="list-style-type: none"> <li>Context Type—Visit-related context item.</li> <li>Is Key—True.</li> </ul>   | A context panel can have only one block key item.  |
| <ul style="list-style-type: none"> <li>Page key item</li> </ul>    | <ul style="list-style-type: none"> <li>Context Type—Page-related context item.</li> <li>Is Key—True.</li> </ul>    | A context panel can have only one page key item.   |

| Design consideration  | Custom property settings   | Design rules  |
|---|--|---|
| Data series for the following key items for repeating visits and forms:               |  |   |
| <ul style="list-style-type: none"> <li>Block repeat key (visit index) item</li> </ul> | <ul style="list-style-type: none"> <li>Context Type—Visit-related context item.</li> <li>Is Key—True.</li> <li>Repeated—True.</li> </ul> | A context panel can have only one block repeat key item.  |
| <ul style="list-style-type: none"> <li>Page repeat key (form index) item</li> </ul>   | <ul style="list-style-type: none"> <li>Context Type—Page-related context item.</li> <li>Is Key—True.</li> <li>Repeated—True.</li> </ul>  | A context panel can have only one page repeat key item.   |
| Additional data series  | Context Type—Other context item.   | <p>Use for additional data points to be collected for every record.</p> <p><b>Note:</b> Data series with a Context Type of <b>Other context item</b> are designed to be used in hybrid studies in which users can enter data using either the Clintrial or the InForm application. When you deploy a study that contains a data series with a Context type property of <b>Other context item</b>, the item definition for that data series is created in the Clintrial context panel, but the CIS application does not synchronize data from the InForm application to that context item. To enter data into a context panel item that is defined using the <b>Other context item</b> Context type property, users must use the Clintrial Enter module.</p> |
| Context Type custom property  |  | <ul style="list-style-type: none"> <li>Must not be set to Not a Context Item for any data series in the context panel.</li> <li>Must not be set to Other Context Item if the value of the Is Key property is True.</li> </ul>   |
| Data series data type   |  | <ul style="list-style-type: none"> <li>Must be Text, Fixed, or Float if the value of the Is Key property is True.</li> <li>Must be compatible with the data type of the corresponding item in the Clintrial context panel, if the Clintrial context panel already exists.</li> </ul>  |

## CIS data mappings for date time items

You can set up CIS data mappings for date time items so that:

- The entire data appears in a single database column in the Clintrial database.
- Each date time part appears in a separate database column in the Clintrial database. To split data mappings for a date time item into date part components, you define a separate data series and mapping for each date part. The data mappings that the Central Designer application generates include the DATEPART attribute of the CTTITEM tag.

### CIS data mapping setup for date time items

The following table describes how to set up a CIS data mapping.

| Clintrial database result   | Data series and data mapping setup   |
|---|--|
| Entire date appears in a DATE database column. The DATE data type corresponds to the Oracle DATE database format.               | <ol style="list-style-type: none"> <li>1 In the <b>Item Editor</b> for the date time item, select the <b>Required</b> and <b>Allowed</b> checkboxes for each date part.</li> <li>2 Map the date time item to a data series with a type of Date Time.</li> </ol>  |
| Entire date appears in a DATETIME database column. The DATETIME data type corresponds to the Oracle DATE database format.       | <ol style="list-style-type: none"> <li>1 In the <b>Item Editor</b> for the date time item, select the <b>Required</b> and <b>Allowed</b> checkboxes for each date and time part.</li> <li>2 Map the date time item to a data series with a type of Date Time.</li> </ol>   |
| Entire date appears in a TEXT database column. The TEXT data type corresponds to the Oracle VARCHAR(n) format.                  | <ol style="list-style-type: none"> <li>1 Map the date time item to a data series with a type of Text.</li> <li>2 In the <b>Date-Time Data Point</b> dialog box, select <b>All in one column</b>, and click <b>OK</b>.</li> </ol>   |
| Each date time part appears in a separate TEXT database column. The TEXT data type corresponds to the Oracle VARCHAR(n) format. | <ol style="list-style-type: none"> <li>1 Map the date time item to a data series with a type of Text.</li> <li>2 In the <b>Date-Time Data Point</b> dialog box, select <b>Split columns</b>.</li> <li>3 In the <b>CIS Date Part</b> list, select the date time part to map, and click <b>OK</b>.</li> <li>4 Repeat these steps for each date time part. Place each date time part in a different data series.</li> </ol> |

| Clintrial database result   | Data series and data mapping setup  |
|---|---|
| Each date time part appears in a separate FIXED database column. The FIXED data type corresponds to the Oracle NUMBER(n) database format. | <ol style="list-style-type: none"> <li>1 Map the date time item to a data series with a type of Integer.</li> <li>2 In the <b>Date-Time Data Point</b> dialog box, select <b>Split columns</b>.</li> <li>3 In the <b>CIS Date Part</b> list, select the date time part to map, and click <b>OK</b>.</li> <li>4 Repeat these steps for each date time part. Place each date time part in a different data series.</li> </ol> |

## Modifying CIS date time part data mappings

- 1 In the Project Explorer, select a data series.  
The Data Series Editor appears.
- 2 Right-click an item, and select **Modify data point date part**.  
The Date-Time Data Point dialog box appears.

| Action   | Steps   |
|--|---|
| Change the data mapping from multiple columns to one column.                 | <ul style="list-style-type: none"> <li>• Select <b>All in one column</b>.</li> </ul>  |
| Change the data mapping from one column to a column for each date time part. | <ol style="list-style-type: none"> <li>1 Select <b>Split Columns</b>.</li> <li>2 In the <b>CIS Date Part</b> list, select the date time part to map.</li> </ol> |

- 3 Click **OK**.

## CIS data mappings for unmapped items and no items in a data series

A data series can have mapped items, unmapped items, or no items. When generating CIS data mappings, the Central Designer application processes data series with unmapped items and data series with no items as follows:

- **Unmapped items**—The Central Designer application generates the panel mappings for the data set where the data series is created. The item mappings for the panel have no control path specifications.

- **No items**—The Central Designer application does not generate mappings for the data series. If none of the data series for a data set have any items, the Central Designer application does not generate a panel mapping for the data set. However, note the following exceptions:
  - **Enrollment panel**—The Central Designer application always generates mappings for the Clintrial enrollment panel. If a data set for a custom enrollment panel does not exist, the enrollment panel mappings are made up of:
    - The items in the combined screening and enrollment forms in the study design, if they exist.
    - The items in the combined default screening and enrollment forms generated by the Central Designer application, if the forms are not defined in the study design.
  - **Non-patient data panel**—If a data set has a Panel Type property value of Non-Patient Data, the data series have no items by definition. The Central Designer application generates mappings for a non-patient data panel and does not generate item mappings.
  - **Derived item**—If a data series in the data set has a Derived property value of True, the Central Designer application generates an item mapping with no control path.



## CHAPTER 6

# Formatting layouts

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## About layouts and the Layout tab

| Characteristic          | Description  |
|-------------------------|--|
| Locales and translation | <p>Every layout supports all locales. You do not need to create a unique layout for every form and locale in the study. Use the Locales drop-down list on the toolbar in the Layout tab to switch between locales and provide translations.</p> <p>For more information, see:</p> <ul style="list-style-type: none"> <li>• <i>Translating text in the Layout tab</i> (on page 257).</li> <li>• <i>Previewing a locale</i> (on page 258).</li> </ul>  |
| Styles and inheritance  | <p>Styles specified for the study, individual forms, and individual controls determine the appearance of each layout.</p> <p>For more information, see <i>About styles and inheritance</i> (on page 231).</p>  |
| Creating and deleting   | <p>You can create and delete layouts, and you can reset an existing layout to use the styles of another layout for a form.</p>   |
| Automatic refreshing    | <p>The Layout tab automatically refreshes its display after you change the structure of a form. For example, the layout refreshes after you add or delete an item, codelist, or codelist item; reorder items; or mark an item as conditional or not conditional.</p> <p>If you modify an item layout, the changes are not propagated to the form unless you reset the form layout. Similarly, if a compound item has an item layout and one of its child items also has an item layout, changes to the child item's layout are not propagated to the layout for the compound item unless you reset or create the layout for the compound item.</p> <p><b>Note:</b> If a form contains a compound item with an item layout, and the compound item has a child item with an item layout, the form reads only the item layout from the compound item.</p> |
| Primary layouts         | <p>Every layout requires a primary layout, or validation fails. An icon on the tab that contains the name of the layout (at the bottom of the Layout tab) indicates the primary layout.</p> <p>For more information, see <i>Setting the primary layout for a study</i> (on page 6).</p>  |
| Deployment options      | <p>When you create a deployment package, an additional page appears if the study contains one or more new layouts. The page, called Select Layouts, appears after the Select Locales page. On the page, you choose the layout to deploy. If the layout does not exist for a form, the primary layout for the form is deployed instead.</p> <p>For more information, see <i>Creating a deployment package</i> (on page 286).</p> <p><b>Note:</b> The rendering of content in the Layout tab is not an exact representation of the appearance of content in the InForm application.</p>  |
| Importing               | <p>When you import a study for which study styles have been set, the styles in the imported study overwrite the study styles in the existing study.</p>  |



## About styles and inheritance

Two factors determine the appearance of a layout, the data design of the form and the styles that are defined on the study, form, or controls. Styles are inherited in the following way:

- Study styles apply to all forms and items in the study. For studies created in release 1.3 or later, study styles are created when the study is created. For studies created in release 1.2 or earlier, study styles are created with default values the first time that you create or convert a layout. A change to the study styles is immediately reflected in all forms that inherit the study styles.
- Form styles override study styles and apply to all layouts for a form.
- Control styles override form and study styles for one control only. Keep in mind that some items, such as compound items, contain multiple controls. If you modify a control style, only the selected control is changed.

You set study styles in the Study Styles dialog box, and you set form styles in the Form Styles dialog box. The options in both dialog boxes are identical, except the Form Styles dialog box contains **Inherit** checkboxes for all options. If you select **Inherit** for an option, the value that is set in the study styles is automatically applied in the form styles. This option simplifies the process of overriding study styles because you can leave **Inherit** selected for all options except those that you want to override.

Styles can significantly reduce the time that you spend customizing a layout because you can set a style, such as caption alignment, in the study styles once, and all captions use the alignment. For example:

- To align all captions on a form in the same way, you can provide a value in the form styles.
- To align all captions on a form differently, you can provide a different value for each control in the control styles.

You can set most settings in the study, form, and control styles only, with the following exceptions:

- *Specifying the question width for a specific layout* (on page 249).
- *Specifying the year range for a single date time item* (on page 252).
- *Specifying the display override status of a single item* (on page 252).

## Editing the appearance of layouts using study, form, and control styles

The appearance of a layout is determined by study, form, and control styles. For more information, see *About styles and inheritance* (on page 231).

**To edit study styles:**

- 1 Select **Tools > Edit Study Level Styles**.

**Note:** You can also open the Study Level Styles dialog box from the Form Styles dialog box, using the Edit Study Level Styles button in the lower-left corner.

The Study Level Styles dialog box appears.

- 2 Edit the fields as necessary. For more information, see *Study Level Styles and Form Level Styles dialog boxes—Option descriptions* (on page 396).

**To edit form styles:**

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 Select a form, and select the **Layout** tab.
- 3 On the toolbar, click **Edit Styles**.

The Form Level Styles dialog box appears.

- 4 Edit the fields as necessary. For more information, see *Study Level Styles and Form Level Styles dialog boxes—Option descriptions* (on page 396).

**To edit control styles:**

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.

or

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

- 2 Select a form or item, and select the **Layout** tab.
- 3 Double-click a control. Controls appear in the right column of a layout.

or

Right-click a control, and select **Edit Control Styles**.

The Control Styles dialog box appears.

- 4 Edit the fields as necessary. For more information, see *Control Styles dialog box—Option descriptions* (on page 392).

## Adding and removing names for layouts

A layout name is global for a study, and you can use it once for each form in a study. Layout names are case-insensitive; for example, you cannot have two layout names called **ABC** and **abc**. You can add a name for a layout:

- When you create the layout.
- At any time using the Layout Names dialog box.

You can remove the name of a layout at any time, even if the name of the layout is used in the study or library. However, you can no longer deploy layouts with the name, and you cannot use the name for new layouts that you create

**Note:** You cannot remove the Main layout name. By default, this name is used as the name of the primary layout, though you can change the name of the primary layout.

- 1 Select **Tools > Layout Names Manager**.

The Layout Names Manager appears.

- 2 To add a layout name, click **Add**, type the name of the layout, and click **OK**.

To remove a layout name, from the list of layout names, select a layout, and click **Remove**.

- 3 Click **OK**.

## Restricting the text that an InForm user can type in a text field

You can restrict the text that an InForm user can type for a text item without a codelist.

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.  
or  
In the Project Explorer, select the **Items** Explorer bar.
- 2 Select a form or item, and select the **Layout** tab.
- 3 Do one of the following:
  - To set the option in the study styles—Select **Tools > Edit Study Level Styles**, and on the left, select **Text Item**.
  - To set the option in the form styles—On the toolbar, select **Edit Styles**, and on the left, select **Text Item**.
  - To set the option in the control styles—Right-click a text control without a codelist, and select **Edit Control Styles**, then select the **Advanced** tab.
- 4 Under **Character set restriction**, select one of the following options:
  - **Unrestricted** (Default)—Do not restrict the entry of values in text fields without codelists.
  - **ASCII Only**—In release 5.0 and later of the InForm application, restrict the entry of values in text fields without codelists to the complete ASCII character set (byte range 0 to 127). Items with restricted values are marked with a star (★) in the Annotated Study Book.
- 5 Click **OK**.

## Removing a layout

You can delete any layout, including the primary layout. If you delete all layouts for a form, the Layout tab displays the initial work area with the Create Layout button.

All text strings, including captions, notes, section titles, form titles, and codelist item label overrides, are saved until you delete the last layout for a form, even if you created the text strings on a layout that you then deleted. However, after you delete the last layout for a form, all of the text strings that you created for the form in the Layout tab are deleted. Questions are not deleted, even if you delete the last layout for a form.

**Note:** If someone removes the primary layout, you can recreate it. For more information, see *Creating a layout for a form or item* (on page 237).

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.  
or  
In the Project Explorer, select the **Items** Explorer bar.
- 2 Select a form or item, and select the **Layout** tab.
- 3 If the layout is in the old format, convert it. For more information, see *Converting layouts* (on page 235).

- 4 On the toolbar, select **Layouts > Remove Layout**.  
The Remove Layout dialog box appears.
- 5 From the **Layout name** drop-down list, select the name of the layout to delete, and click **OK**.

## Resetting a layout

When you reset a layout, all control styles that you have set for the controls on the form are discarded. All styles in the Control Styles dialog box are modified to inherit the settings from form styles and study styles.

**Note:** Text strings in the layout, including captions, notes, section titles, form titles, and codelist item label overrides, are not affected when you reset.

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.  
or  
In the Project Explorer, select the **Items** Explorer bar.
- 2 Select a form or item, and select the **Layout** tab.
- 3 On the toolbar, select **Layouts > Reset Layout**.  
The Reset Layout dialog box appears.
- 4 From the **Layout to reset** drop-down list, select the name of a layout.
- 5 Select one of the following options:
  - **Recreate layout using form-level styles and item layouts (if any)**—Recreate the layout using the form styles and existing item layouts.
  - **Replace all control styles with the styles from the following layout**—Recreate the layout using the form styles (which might inherit styles from the study styles) from another layout for the same form. If you select this option, existing item layouts are not used to recreate the layout.  
If you select this option, select a layout from the drop-down list.
- 6 Click **OK**.

## Renaming a layout

When you rename a layout, you can choose from existing layout names or provide a new name. You cannot choose a layout name that is already used for the form. You rename a layout for a single form or item only.

**Note:** If you rename the primary layout, the layout is no longer the primary layout because the name of the layout determines whether it is the primary layout. You must set a primary layout for every layout in the new format, or validation will fail.

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.  
or
- 2 In the Project Explorer, select the **Items** Explorer bar.

- 3 Select a form or item, and select the **Layout** tab.
- 4 On the toolbar, select **Layouts > Rename Layout**.  
The Rename Layout dialog box appears.
- 5 From the **Layout to rename** drop-down list, select a layout.
- 6 From the **New layout name** drop-down list, do one of the following:
  - To use a new layout name, select **New**, and type a name for the layout. The name is added to the list of registered names for the study, and you can select it from the drop-down list.
  - To use an existing name, select it from the drop-down list. The list includes all of the study's registered names that have not been used for the form or item.

## Undoing and redoing an action in a layout

You can undo every action that you perform in the Layout tab. You can redo an action that you have undone.

**Note:** You can undo the conversion of an individual layout. However, you cannot undo the conversion of all layouts in a study or library.

### To undo an action:

- After performing an action in the Layout tab, do one of the following:
  - On the toolbar, click **Undo**.
  - Press **Ctrl+Z**.
  - Select **Edit > Undo**.

### To redo an action:

- After undoing an action in the Layout tab, do one of the following:
  - On the toolbar, click **Redo**.
  - Press **Ctrl+Y**.
  - Select **Edit > Redo**.

## Converting layouts

Optionally, you can convert layouts that were created in release 1.2 and earlier.

**Note:** Before converting all layouts in a study, instruct all other users to exit the application. Converting all layouts locks all forms and items in the study or library.

### To convert all layouts:

- 1 Open a study or library.

- 2 Select **Tools > Convert Layouts**.

The Convert Layouts dialog box appears, allowing you to specify how the layouts should be converted. Select one of the following options, and click **Convert**.

- **Convert the layout for one locale, rename it to [name of primary layout], and set it as the primary layout.**

The names of other layouts are discarded, but the translations are saved. You can view them in the Layout tab by using the **Locale** drop-down list on the toolbar. If you have not explicitly chosen a primary layout, the primary layout is named Main.

The layout that you convert, the primary layout, is renamed to the name of the primary layout for the study.

- **Convert all layouts, and set one layout as the primary layout.**

All translations are saved and viewable from all of the layouts by using the **Locale** drop-down list on the toolbar.

Optionally, to rename the primary layout to the name that is currently selected as the primary layout, select **Rename the primary layout to [name of primary layout]**. If you have not explicitly chosen a primary layout, the primary layout is named Main.

The status of the conversion appears under **Conversion results**.

**Note:** If an item is locked by another user, it does not convert. If an item fails to convert, you can convert the layouts in the study again.

- 3 After the conversion is complete, click **Close**.

#### To convert the layouts for a single form or item:

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.

or

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

- 2 Select a form or item, and select the **Layout** tab.

If the layout was created in release 1.2 or earlier, a note below the toolbar indicates that the layout is read-only and that you must convert it before you can modify it.

- 3 Click **Convert Layout**.
- 4 If the study supports a single locale, the layout is converted and is set as the primary layout.

If the study supports multiple locales, all the layouts are converted, and the following occurs:

- If you have not yet converted any layouts in the study, you are prompted to choose the layout to set as the primary layout.
- If you have converted one or more layouts in the study, the layout with the same name as the primary layout is set as the primary layout.

**Note:** The first layout that you create for a form is given the name of the primary layout.

# About layout design

## Creating a layout for a form or item

Every layout requires a primary layout, or validation fails. An icon on the tab that contains the name of the layout (at the bottom of the Layout tab) indicates the primary layout. A layout name is global for a study, and you can use it once for each form in a study. Layout names are case-insensitive; for example, you cannot have two layout names called **ABC** and **abc**. You can add a name for a layout:

- When you create the layout.
- At any time using the Layout Names dialog box.

### To create a layout for a form or item without any layouts:

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.  
or  
In the Project Explorer, select the **Items** Explorer bar.
- 2 Select a form or item, and select the **Layout** tab.  
If a layout has not been created, the **Create Layout** button appears in the workspace.
- 3 Click **Create Layout**.

### To create a layout for a form or item with one or more or more layouts:

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.  
or  
In the Project Explorer, select the **Items** Explorer bar.
- 2 Select a form or item, and select the **Layout** tab.
- 3 On the toolbar, select **Layouts > Create Layout**.  
The Create Layout dialog box appears.
- 4 Do one of the following:
  - To use an existing layout name, select the name from the **Name of new layout** drop-down list. The list includes all of the study's registered names that have not been used for the form or item. The list includes the primary layout if it does not exist for the form or item.
  - To use a new layout name, select **New**, and type a name for the layout. The name is added to the list of registered names for the study, and you can select it from the drop-down list.

**Note:** Registered names enforce the selection of the correct layout name.

- 5 From the **Initialize styles from the following layout** drop-down list, select a layout. The layout is copied and named according to the name that you provide.
- 6 Click **OK**.

## Ease of use and navigation in the Layout tab

The Layout tab provides several visual cues to help you navigate and modify a layout.

- A toolbar contains many of the most commonly performed actions, including managing controls. Also available from the right-click menu, the actions include the following:
  - Caption alignment.
  - Control orientation.
  - Control type.
- The Layout tab provides visual cues that indicate the caption or control that you are pointing to or have selected. For example, a selectable area becomes highlighted when you point to it. Additionally, when you point to a control, a tooltip appears, identifying the item that is associated with the control. The tooltip includes relevant information for the control, such as RefName, Display Override settings, and control styles. A dotted line around a control indicates that it is hidden.
- You can navigate through the Layout tab using the arrows on the keyboard, and you can perform all actions using the keyboard.
- The Layout tab displays either the titles or RefNames of study objects, depending on your **Display Names Using** selection in the Project Explorer.

## About creating site-specific layouts

A layout supports every locale in a study; however, you can change only the text strings in each layout. If you need different control styles for a specific locale, you must create a new layout. Creating a new layout is necessary if, for example, you cannot ask a question at a particular site. Consider using the following workflow to deploy the correct layouts for your study.

- 1 Set the primary layout for the study, and make sure that a primary layout exists for every form in the study, even the forms for which you have to hide one or more questions for a specific locale.
- 2 For the form that contains the question that you cannot ask at a site, create a new layout. For example, you might call the layout **Hidden Question**. This form still requires a primary layout, even though you will not deploy it.
- 3 In the **Hidden Question** layout, select the locale for the site that does not allow the question, and hide the question.
- 4 Create additional layouts called **Hidden Question** for any other forms that must not ask certain questions for the site.
- 5 When you create a deployment package, choose the **Hidden Question** layout as the layout to deploy.

The **Hidden Question** layout is deployed for all forms that have it. For all other forms, the primary layout is deployed.



## Form previews

You can generate and print a preview of a form, showing how it will appear when deployed to the target application. In a form preview, the layout of questions and controls is different for a regular form and a repeating form or section:

- **Regular form**—Questions and controls are laid out vertically.
- **Repeating form or section**—Short titles for the questions are arranged horizontally across the top of the preview, and the questions and controls are laid out vertically.
- **Fixed repeating section**—The preview for a fixed repeating section contains two views.
  - **Grid landscape view**—Short questions for top-level items are arranged horizontally across the top of the preview, and the labels for codelist items are laid out vertically for each fixed item.  
In the grid landscape view, blank cells have a gray background.
  - **Portrait view**—Short questions for top-level items are laid out vertically, and the labels for codelist items are laid out horizontally for each fixed item.

You can generate a form preview with or without annotations.

### Notes:

- The form preview feature of the Layout tab allows you to view a preview of one form at a time. To view a preview of all forms in a study, you can generate an annotated study book.
- In the Annotated Study Book and Form Preview window, if a row contains many components, the browser that displays the page might wrap text to fit all components onto the page. Consequently, for Asian languages, a wrapped text label might appear to have vertical orientation, with a single character on each line, because the browser wraps text on a word boundary, and a single character can represent a word. To compensate, you can make the question portion of the row smaller so the labels in the control section are wide enough not to wrap.

## Annotated form previews

The options that are selected for an annotated study book determine the information that appears in the annotated preview of a form.

| Annotated Study Book option | What appears in the annotated preview of a form  |
|-----------------------------|--|
| Inline CRF annotations      | <ul style="list-style-type: none"> <li>• <b>If selected</b>—The annotations described below.</li> <li>• <b>If not selected</b>—Titles or RefNames that appear in square brackets.</li> </ul> <p>The annotated forms display RefNames if <b>Show Object RefNames</b> is selected and titles if <b>Show Object RefNames</b> is not selected.</p> |

|   |   |
|---|---|
| Item formats  | <ul style="list-style-type: none"> <li>• <b>Text</b>—<b>A</b> plus maximum character length (for example, A128).</li> <li>• <b>Integer</b>—<b>N</b> plus maximum field length (for example, N3).</li> <li>• <b>Float</b>—Significant digits and decimal places. The decimal point is included as a character in the length of an item. For example, if the length of a float item is 5 and the precision is 0, the annotation appears as <b>xxxx</b>. (the decimal point appears).</li> </ul>   |
| Captions on compound items                          | A caption for the parent item of a compound item appears with the alignment specified on the Layout tab.  |
| Hidden, ReadOnly, or Editable display overrides     | The word <b>hidden</b> , <b>read-only</b> , or <b>editable</b> appears in square brackets below the item question.  |
| Minimums and maximums for integer and float items   | <p>Specifications set in the <b>MinProperty</b>, <b>MinValue</b>, <b>MaxProperty</b>, and <b>MaxValue</b> item properties are represented as values and operators and listed along with the item format. For example, the notation is <b>2.0 &lt;= xx.xx &lt; 100.0</b> if:</p> <ul style="list-style-type: none"> <li>• <b>MinProperty</b>—GREATERTHANEQUAL</li> <li>• <b>MinValue</b>—2.0</li> <li>• <b>Float length</b>—5</li> <li>• <b>Float precision</b>—2</li> <li>• <b>MaxProperty</b>—LESSTHAN</li> <li>• <b>MaxValue</b>—100.0</li> </ul> |
| Date time items                                     | Required and unknown specifications appear in the date and time controls, and year ranges appear in parentheses following the controls.   |
| Required items                                      | An asterisk appears after the item number. In the grid view of fixed repeating sections, an asterisk appears in the column header for each required item.   |
| Items that require source verification              | For an item in a form or non-repeating section, a check mark appears under the item number.   |
| Repeating sections that require source verification | <p>A check mark appears in the following locations:</p> <ul style="list-style-type: none"> <li>• <b>For a repeating section</b>—Under the number in the repeating section header row.</li> <li>• <b>For a fixed repeating section</b>—Under the # symbol in the fixed-item section header.</li> </ul>   |

|   |   |
|---|---|
| Forms and items that are critical for source verification | <p>For an item in a form or non-repeating section, a check mark inside a circle appears under the item number.</p> <p>For a form, a check mark inside a circle appears to the right of the form name.</p> <p>Forms and items that are source-verification critical are also source-verification required, so these forms and items show only the check mark inside the circle and not an additional check mark denoting their source-verification required status.</p> <p>A footnote indicates that settings for critical source verification that are made in the InForm application override settings made in the Central Designer application.</p>   |
| Collapsible items   | <p>A collapsible item icon (☰) appears after the item RefName.</p> <p><b>Note:</b> In the InForm application, a collapsible item is called a dynamic control.</p>   |
| Key items   | <p>A key icon appears under the item number.</p>  |
| Base units  | <p>A superscript b in square brackets appears to the right of the control for the base unit.</p>  |
| Repeating forms and sections                              | <p>A summary item layout containing top-level items appears (for example, the children of compound items and conditional items do not appear), followed by a form layout.</p>   |
| Fixed repeating sections                                  | <p>A fixed item icon (☒) appears after the item number.</p> <p>The following views appear:</p> <ul style="list-style-type: none"> <li>• Grid view containing a column for each top-level item and, for each fixed item, a row for each combination of item and codelist items. Depending on the definitions that exist in the study, column headers show the short question in the specified locale, the long question in the specified locale, or an empty cell. <ul style="list-style-type: none"> <li>▪ For a hidden item, the text in the column header is grayed out.</li> <li>▪ The cell for a blank instance of a fixed or non-fixed item is grayed out and includes a blank icon (☐).</li> </ul> </li> <li>• Data entry preview containing controls for each fixed item.</li> </ul> |
| Associated forms  | <p>The name of the associated form, if it exists, appears at the bottom of the annotated form.</p>  |

|                                 |   |
|---------------------------------|---|
| Codelist Values and Tables      | <p>Annotations on the form for codelist controls that are formatted as radio buttons or checkboxes. The data type and value appears in square brackets and italic font to the left of each option (for example, <i>[N:1]</i> indicates an integer data type and a codelist item value of 1). Data types are:</p> <ul style="list-style-type: none"> <li>• A—Text</li> <li>• F—Float</li> <li>• N—Integer</li> </ul> <p>Additionally, this section includes a table that lists the specifications of each codelist and codelist item along with the title or RefName of the item with which they are associated.</p> <p>The table displays RefNames if <b>Show Object RefNames</b> is selected and titles if <b>Show Object RefNames</b> is not selected.</p> <p><b>Include All Codelist Control Types</b> option:</p> <ul style="list-style-type: none"> <li>• <b>If selected</b>—The codelist table includes all codelist formats.</li> <li>• <b>If not selected</b>—The codelist table includes only codelists that are formatted as a drop-down list.</li> </ul> |
| Study Object Description Tables | <p>A table that lists the type (Form, Section, or Item), title or RefName, and description for the form and any sections or items that the form contains.</p> <p>The table displays RefNames if <b>Show Object RefNames</b> is selected and titles if <b>Show Object RefNames</b> is not selected.</p> <p>If <b>Only Show Properties with Values</b> is selected, the study object description table lists only study objects that have descriptions.</p>   |
| Coding Summary Tables           | <p>A table that lists verbatim, dictionary, coding item, and context item data for each item that is coded.</p> <p>The table displays RefNames if <b>Show Object RefNames</b> is selected and titles if <b>Show Object RefNames</b> is not selected.</p>  |

|                            |  |
|----------------------------|--|
| RDE Analytics Tables       | <p>A table that displays the titles or RefNames, table column names, and data types that are generated in the InForm Reporting Database Extract (RDE) for each data object in a form. The format of each table column name consists of the RefName of the data object, concatenated with a suffix that depends on the data object type.</p> <p>The table displays RefNames if <b>Show Object RefNames</b> is selected and titles if <b>Show Object RefNames</b> is not selected.</p> <p>For more information, see <i>RDE Analytics tables in the Annotated Study Book</i> (on page 333).</p>   |
| Data Series Summary Tables | <p>A table that lists the following information for each data series:</p> <ul style="list-style-type: none"> <li>• Item number, based on the order of the item in the form.</li> <li>• Item title or RefName, depending on whether <b>Show Object RefNames</b> is selected.</li> <li>• Mapping RefName.</li> <li>• Data set alias if available, otherwise RefName.</li> <li>• Data series alias if available, otherwise RefName.</li> <li>• Data series type.</li> </ul>   |
| Show Object RefNames       | <ul style="list-style-type: none"> <li>• Uses study object RefNames, rather than titles, to identify study objects. The following areas are affected: <ul style="list-style-type: none"> <li>• The RefName for a form or section is appended to the form or section title that is displayed in the annotated form header. RefNames are enclosed in square brackets.</li> <li>• Items are identified with RefNames.</li> <li>• Data tables that follow the annotated form use a column header of RefName instead of Title, and the column contains RefNames. However, the Data Series Summary Table always uses RefName to identify mappings and data sets, regardless of whether this option is selected.</li> </ul> </li> </ul> |

## Choosing the default view for a fixed repeating section

- 1 In the main application toolbar, select **Tools > Options**.  
The Options dialog box appears.
- 2 In the **Environment** section, click **Fixed Repeating Section**.
- 3 In the **Default view type** field, select one of the following:
  - **Grid landscape**—Short questions for top-level items are arranged horizontally across the top of the preview, and the labels for codelist items are laid out vertically for each fixed item.  
In the grid landscape view, blank cells have a gray background.
  - **Portrait**—Short questions for top-level items are laid out vertically, and the labels for codelist items are laid out horizontally for each fixed item.

## Supported HTML formatting tags

HTML formatting tags, including but not limited to the following examples, are supported in the InForm application when deployed from a Central Designer study.

| HTML tag                                   | Use  |
|--|--|
| <code>&lt;b &gt;&lt;/b&gt;</code>          | Bold text.   |
| <code>&lt;br&gt;</code>                    | Line break.  |
| <code>&lt;center&gt;&lt;/center&gt;</code> | Centering text.  |
| <code>&lt;i&gt;&lt;/i&gt;</code>           | Italic text.   |
| <code>&lt;li&gt;&lt;/li&gt;</code>         | List items.  |
| <code>&lt;ol&gt;&lt;/ol&gt;</code>         | Numbered list.   |
| <code>&lt;p&gt;&lt;/p&gt;</code>           | Paragraphs.  |
| <code>&lt;pre&gt;&lt;/pre&gt;</code>       | Preformatted plain text, for example, computer output. |
| <code>&lt;s&gt;&lt;/s&gt;</code>           | Strikethrough text.                                    |
| <code>&lt;strike&gt;&lt;/strike&gt;</code> | Strikethrough text.                                    |
| <code>&lt;tt&gt;&lt;/tt&gt;</code>         | Monospace font.  |
| <code>&lt;u&gt;&lt;/u&gt;</code>           | Underlined text.                                       |
| <code>&lt;ul&gt;&lt;/ul&gt;</code>         | Bulleted list.   |

## Generating and printing a preview or annotated preview of a form

**Note:** To print a form preview, you need the Adobe Acrobat PDF Distiller print driver.

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 Select a form, and select the **Layout** tab.  
If the layout is not generated, click **Create Layout**.
- 3 To generate a preview:
  - a Right-click a section header or the area below the layout table, and select **Preview Form**.  
or
  - b On the toolbar, select **Preview > Preview Form**.  
The Preview Form window appears.

- 4 To generate an annotated preview:
  - a Right-click a section header or the area below the layout table, and select **Preview Form**.
  - or
  - b On the toolbar, select **Preview > Preview Form**.  
The Preview Form window appears.
- 5 To print the preview, click **Print**.  
The Microsoft Windows Print dialog box appears.
- 6 Specify the printer and print options, and click **Print**.

# Formatting questions and controls

## Editing and translating a question

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.  
or  
In the Project Explorer, select the **Items** Explorer bar.
- 2 Select a form or item, and select the **Layout** tab.
- 3 From the **Locale** menu on the toolbar, select a locale for which you want to edit or translate text.
- 4 Right-click a question, and select **Edit Question**.  
The text of the question becomes editable.
- 5 Type the question text, and press **Enter**.

## Creating, editing, translating, and removing a section note

You can add section notes to the layouts for forms only.

**Note:** For a form with multiple layouts, if you add or edit a section note or caption for a locale, the text is visible in all of the layouts. For example, if a study supports English and French, and you have two layouts, Layout1 and Layout2, both layouts support both English and French. If you edit a note or caption in Layout1 for the French locale, the note or caption is always visible in Layout2 for the French locale.

### To create a note:

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 Select a form, and select the **Layout** tab.
- 3 Right-click a form or section header, and make sure that **Section Note** is selected.  
An editable note field appears below the header.

### To edit or translate a note:

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 Select a form, and select the **Layout** tab.
- 3 From the **Locale** menu on the toolbar, select a locale for which you want to edit or translate text.
- 4 Double-click within the text field of a note.  
or  
Right-click the note, and select **Edit Note**.  
or  
Select the note, and on the toolbar, click **Edit Text**.  
The note becomes editable.
- 5 Type the note, and press **Enter**.



**To remove a note:**

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 Select a form, and select the **Layout** tab.
- 3 Right-click a form or section header, and make sure that **Section Note** is not selected.

## Showing and hiding a section header

A form can have multiple section headers. The top section header on a form contains the form title. An additional section header appears for each section on the form, and it displays the section title.

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 Select a form, and select the **Layout** tab.
- 3 From the **Locale** menu on the toolbar, select a locale for which you want to edit or translate text.
- 4 Right-click a section header or question, and view the selection of **Section Header**:
  - If **Section Header** is selected, the header is shown.
  - If **Section Header** is not selected, the header is hidden. A dashed line around the header indicates that the header is hidden.

## Editing and translating a form or section title

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 Select a form, and select the **Layout** tab.
- 3 From the **Locale** menu on the toolbar, select a locale for which you want to edit or translate text.
- 4 Right-click a section header or question, and make sure that **Section Header** is selected.
- 5 To edit the section or form title, double-click the section header.  
or  
Right-click the section header, and select **Edit Title**.  
or  
Select the section header, and on the toolbar, select **Edit Text**.  
The text becomes editable.
- 6 Type the new section or form title, and press **Enter**.

## Working with captions

You can add a caption to every control.

**Note:** For a form with multiple layouts, if you add or edit a section note or caption for a locale, the text is visible in all of the layouts. For example, if a study supports English and French, and you have two layouts, **Layout1** and **Layout2**, both layouts support both English and French. If you edit a note or caption in **Layout1** for the French locale, the note or caption is always visible in **Layout2** for the French locale.

**To edit or translate a caption:**

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.  
or  
In the Project Explorer, select the **Items** Explorer bar.
- 2 Select a form or item, and select the **Layout** tab.
- 3 From the **Locale** menu on the toolbar, select a locale for which you want to edit or translate text.
- 4 In the layout, select a control.
- 5 Right-click a control, and select **Edit Caption**.

or

Select a control, and on the toolbar, click **Edit Text**.

The Edit Caption dialog box appears. The name of the dialog box is appended with the name of the layout for which you are editing a caption.

**Note:** You can also edit a caption in the Control Styles dialog box, which appears when you double-click a control.

- 6 Type the caption. You can type up to 1000 characters.
- 7 Click one of the following buttons:
  - **Apply/Next**—Apply the caption, and advance to the next control, so that you can edit its caption. The control for which you are editing a caption is outlined with a dotted black line on the Layout tab.
  - **Apply**—Apply the caption, and close the dialog box.

**To align a caption:**

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.  
or  
In the Project Explorer, select the **Items** Explorer bar.
- 2 Select a form or item, and select the **Layout** tab.
- 3 In the layout, select a control.
- 4 On the toolbar, select **Align Caption**, and select **Top**, **Left**, **Right**, or **Bottom**, depending on where you want the caption to be placed in relation to the control.

**To remove a caption:**

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.  
or  
In the Project Explorer, select the **Items** Explorer bar.
- 2 Select a form or item, and select the **Layout** tab.
- 3 Right-click a control or section header with a caption, and select **Remove Caption**.

## Editing and translating a codelist item label override

You can override the label for a codelist item in a layout.

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.  
or  
In the Project Explorer, select the **Items** Explorer bar.
- 2 Select a form or item, and select the **Layout** tab.
- 3 Right-click the control for codelist items, and select **Edit Label Override**.
- 4 From the **Codelist item** drop-down list, select a codelist item.
- 5 In the **Label override** field, type the new label for the codelist item.
- 6 Click **OK**.

## Editing the size of a text box

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.  
or  
In the Project Explorer, select the **Items** Explorer bar.
- 2 Select a form or item, and select the **Layout** tab.
- 3 Right-click the control for a float, integer, or text control, and select **Edit Textbox Size**.  
The Textbox Size dialog box appears.
- 4 To inherit the settings from the form styles (which might inherit from the study-level styles), select **Inherit size**.  
To override the form and study styles, deselect **Inherit size**, and provide the number of characters in the **Width** field and the number of lines in the **Height** field.
- 5 Click **OK**.

## Editing the width of the question column

The following procedure describes how to edit the width of the question column **for an individual layout only**. Additionally, you can set this information as part of the *form and study styles* (on page 396).

**Note:** If the contents of the control column exceed the specified width, the page might not display in the InForm application as you specify. For example, if you specify a 50 percent column width but an item has many radio buttons that are displayed horizontally, the web browser will adjust the width of the question column so that the entire control column fits on the page.

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 Select a form, and select the **Layout** tab.

- 3 Right-click a question or a section header, and select **Edit Question Column Width**.  
The Question Column Width dialog box appears.
- 4 To use the option set in the Form- or Study-Level styles, select **Inherit**.  
To override the Form- and Study-Level styles, deselect **Inherit**, and specify a percent value for the question column.
- 5 Click **OK**.

## Formatting codelist items and items with units

You have the following formatting options:

- Codelist items.

The codelist settings for an item with a codelist determine the formatting that you can use.

- If **Select Single Value** is selected on the Design tab, you can format the codelist items using radio buttons or a pulldown control only.

**Note:** You cannot format single-select codelist items using checkboxes.

- If **Select Multiple Values** is selected on the Design tab, the codelist items are formatted using checkboxes.

- Integer and float items with units.

You can format the units as radio buttons or pulldown controls.

You can display radio buttons and checkboxes vertically or horizontally.

### To format codelist items:

- 1 In the Project Explorer, select the **Items** Explorer bar.
- 2 Select an item with a codelist, and select the **Design** tab.
- 3 Under **Codelist Settings**, select an option:
  - To format the codelist items using checkboxes, select **Select Multiple Values**.  
The codelist items are automatically formatted as checkboxes in the layout.
  - To format the codelist items using radio buttons or a pulldown control, select **Select Single Value**, and then do the following:
    - 1 In the **Project Explorer**, select a form or item, and select the **Layout** tab.
    - 2 Right-click a control and select **Control Type > Radio Button** or **Pulldown**.  
or  
Select the control in the layout table, and on the toolbar, select **Control Type** and then either **Radio Button** or **Pulldown**.

**To format the units for integer and float items:**

- 1 In the Project Explorer, select the **Items** Explorer bar.
- 2 Select an integer or float item for which a base unit is selected.

**Note:** You select a base unit in the **Design** tab.

- 3 Select the **Layout** tab.
- 4 Select the control for the item.
- 5 Right-click a control and select **Control Type > Radio Button** or **Pulldown**.

or

Select the control in the layout table, and on the toolbar, select **Control Type** and then either **Radio Button** or **Pulldown**.

**To change the orientation (vertical or horizontal) of radio buttons or checkboxes:**

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.  
or  
In the Project Explorer, select the **Items** Explorer bar.
- 2 Select a form or item, and select the **Layout** tab.
- 3 Right-click a codelist that is formatted using radio buttons or checkboxes, and select **Orientation > Horizontal** or **Orientation > Vertical**.

## Changing the orientation of a group control

A group control is the collection of controls for:

- A compound item.
- An item with a codelist.

The child items of a compound item and the items in a codelist can appear either horizontally or vertically in a layout.

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.  
or  
In the Project Explorer, select the **Items** Explorer bar.
- 2 Select a form or item, and select the **Layout** tab.
- 3 Right-click a group control, point to **Orientation**, and select either **Horizontal** or **Vertical**.

or

On the toolbar, select **Orientation**, and then select either **Horizontal** or **Vertical**.

## Specifying the year range for a date time item

The following procedure describes how to specify the year range for an item. This setting overrides the value specified in the form and study styles. You can override this setting using control styles.

For more information, see *Study Level Styles and Form Level Styles dialog boxes—Option descriptions* (on page 396) and *Control Styles dialog box—Option descriptions* (on page 392).

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 Select a form, and select the **Design** tab.
- 3 In the grid, select a date time item.
- 4 On the toolbar, click **Item Properties**.

The Item Properties dialog box appears.

- 5 Under **Year Range**, specify a start and end year.
- 6 Click **OK**.

## Marking an item as hidden or read-only

The following procedure describes how to mark an item as hidden or read-only. This setting overrides the value specified in the form and study styles. You can override this setting using control styles.

For more information, see *Study Level Styles and Form Level Styles dialog boxes—Option descriptions* (on page 396) and *Control Styles dialog box—Option descriptions* (on page 392).

**Note:** Setting this value in a layout affects the layout only and does not change the value of the Display Override setting in the Properties Browser for an item.

- 1 In the Project Explorer, select the **Items** Explorer bar.
- 2 Select a date time item.
- 3 Open the **Properties Browser**.
- 4 Under the **InForm** grouping, expand the drop-down list next to **Display Override** and select either **Hidden** or **ReadOnly**.
- 5 Save your changes.

## Translating text

You can translate the titles, questions, labels, and captions of a study object to the languages associated with the locales defined for a study:

- Through the Central Designer user interface. The type of text (for example, item question or caption) determines whether locale-specific text can be specified in:
  - The definition of the study object.
  - The layout of the study object.
  - Both locations.

With the exception of captions, which are defined only in the layout and do not update the study object definition, the changes you make in either location update the other location.

- By exporting the text strings to a CSV file, translating them, and reimporting the file. The translated text strings are added to the study objects to which they belong. For more information, see *Exporting and importing text for translation* (in the *User Guide*).

## Where to enter translated text

| Type of text  | Where to translate  | Translation saved with study object definition? |
|---|---|---|
| Study event short title                             | General tab of the Study Event Editor.  | Yes   |
| <b>Form or section title (header)</b> (on page 247) | Layout tab of Form Editor.  | No  |
| Form short title                                    | General tab of Form Editor.<br><b>Note:</b> The Short Title does not appear in the layout for a form.                             | Yes   |
| <b>Note</b> (on page 246)                           | Layout tab of Form Editor.  | No  |
| <b>Item Default Question</b> (on page 246)          | <ul style="list-style-type: none"> <li>• Design tab of Item Editor.</li> <li>• Layout tab of Item Editor.</li> </ul>              | Yes   |
| Item Short Question                                 | <ul style="list-style-type: none"> <li>• Design tab of Item Editor.</li> <li>• Layout tab of Item Editor.</li> </ul>              | Yes   |
| <b>Codelist item label</b> (on page 257)            | <ul style="list-style-type: none"> <li>• Design tab of Codelist Item Editor.</li> <li>• Design tab of the Item Editor.</li> </ul> | Yes   |
| <b>Caption</b> (on page 247)                        | Layout tab of Form Editor or Item Editor.   | No  |
| Query text  | Query Action dialog box, which is accessible from the Rule Wizard.  | Yes   |

| Type of text  | Where to translate  | Translation saved with study object definition? |
|---|---|---|
| Email subject and message                                 | Email Action dialog box, which is accessible from the Rule Wizard.                            | Yes   |
| Instructions and Help text                                | Instructions and Help tabs for study designs, study elements, study events, forms, and items. | Yes   |
| InForm review state and review stage labels and mnemonics | Product locale tabs of Review State editor.   | Yes   |

## Examples of data that cannot be translated

The following information is stored in the database for the English (United States) locale and cannot be translated into any other language:

- Custom properties and groupings.
- Categories and keywords.
- Roles.

**Note:** You can translate units in the units file, but not in the Central Designer application. For more information, see *Editing the units file* (in the *Administrator Guide*).

## Creating and translating instructions and Help for a study design

You can create study documents that are specific to a target application or locale for study designs, study elements, study events, forms, sections, and items.

You can provide instructions and Help information if the study or library supports one or more locales, and if you have been given skills to work in the locales (in the Central Designer Administrator application).

### To create and delete instructions and Help:

- 1 In the Project Explorer, select a study object (study design, study element, study event, form, section, item, codelist, or codelist item).  
The editor for the study object appears in the workspace.
- 2 Select the **Instructions & Help** tab.
- 3 To select a locale for the study documents, select the tab for the locale. The tabs are located along the bottom of the workspace.
- 4 To create or edit study documents:
  - a Type in the text area.
  - b Optionally, use the toolbar to format the appearance of the text. Additionally, you can use HTML formatting characters. For more information, see *Supported HTML formatting tags* (on page 244).



- 5 To delete study documents:
  - a On the toolbar, click the **Delete** button.  
or  
Select all of the text, and press **Delete**.  
A dialog box appears.
  - b Choose one of the following options:
    - Delete the study documents for only the selected locale.
    - Delete the study documents for all locales.

**To translate instructions and Help:**

- 1 In the Project Explorer, select a study object (study design, study element, study event, form, section, item, codelist, or codelist item).  
The editor for the study object appears in the workspace.
- 2 Select the **Instructions & Help** tab.
- 3 To select a locale for the study documents, select the tab for the locale. The tabs are located along the bottom of the workspace.
- 4 Optionally, copy and paste study documents from a locale for which the information is already written.
- 5 Select the locale to which you want to translate.
- 6 Translate the study documents.
- 7 Optionally, use the toolbar to format the appearance of the text.

## Entering and translating the title and short title of the Common Visit

In the Common Visit tab, which is part of the editor for the study design, you can enter, edit, and translate the title and short title for a study's common visit. A common visit is created during deployment when a study contains common forms.

Specifying a title and short title is optional. For studies with common forms, if you translate a title or short title for one language, you must translate values for all languages.

- 1 In the Project Explorer, select the **Visit Schedule** Explorer bar.
- 2 Select the study design.  
The Study Design Editor appears.
- 3 Select the **Common Visit** tab.
- 4 Enter title and short title values in the fields at the top.
- 5 Optionally, in the **Languages** column of the **Languages** section, select the drop-down arrow at the end of the cell, and select a language for translation.

**Note:** For studies with common forms, if you translate a title or short title for one language, you must translate values for all languages.

- 6 Type a translated title and short title.

- 7 Press **Enter**, or click the next row.
- 8 Type translations for all languages in the study.

## Translating the short title of a study event

You can translate the short title of a study event into the languages and locales with which you have been associated in your skills profile. An administrator sets up this profile in the Central Designer Administrator application. The short title of a study event is deployed as the visit mnemonic in the InForm application.

- 1 In the Project Explorer, select the **Elements and Events** Explorer bar.
- 2 Select a study event.  
The Study Event Editor appears.
- 3 Select the **General** tab.
- 4 In the **Language** column of the **Short Title Languages** section, click the arrow that appears when you move the cursor over the far-right side of the cell in the first available row, and select the language for translating the short title.
- 5 In the **Short Title** column, type the translated text.
- 6 Press **Enter**, or click the next row.

## Translating the short title of a form

You can translate the short title of a form into the languages and locales with which you have been associated in your skills profile. An administrator user sets up this profile in the Central Designer Administrator application. The short title of a form is deployed as the form mnemonic in the InForm application.

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.
- 2 Select a form.  
The Form Editor appears.
- 3 In the **Language** column of the **Short Title Languages** section, click the arrow that appears when you move the cursor over the far-right side of the cell in the first available row, and select the language into which to translate the short title.
- 4 In the **Short Title** column, type the translated text for the short title.
- 5 Press **Enter**, or click the next row.

## Translating the question text of an item

- 1 In the Project Explorer, select the **Items** Explorer bar.
- 2 Select an item.  
The Design tab of the Item Editor appears.
- 3 In the **Language** column of the **Languages** section, click the arrow that appears when you move the cursor over the far-right side of the cell in the first available row, and select the language into which you want to translate the question text.

- 4 In the **Question** column, type the translated text for the item question.
- 5 In the **Short Question** column, type the translated text for the short version of the item question.
- 6 Press **Enter**, or click the next row.

## Translating a codelist item label

You can translate the text of a codelist item label into the languages and locales with which you have been associated in your skills profile. An administrator sets up this profile in the Central Designer Administrator application.

- 1 In the Project Explorer, select the **Items** Explorer bar.
- 2 Select a codelist item.  
The Codelist Item Editor appears.
- 3 In the **Language** column, click the arrow that appears when you move the cursor over the far-right side of the cell in the first available row, and select the locale for which to translate the codelist item label.
- 4 In the **Label** column, type the translated text for the codelist item label.
- 5 Press **Enter**, or click the next row.

The translated text appears in the Codelist Item Editor and in the Layout tab of the Form or Item Editor for the selected locale.

## Translating text in the Layout tab

Every layout supports all locales. You do not need to create a unique layout for every form and locale in the study. Use the Locales drop-down list on the toolbar in the Layout tab to switch between locales and provide translations.

Translations are not layout-specific. Every layout supports every locale that is supported by the study. For example, if you have two layouts, you can view the translations for every supported locale in each layout.

You can provide translations for the following components in a layout:

- **Captions** (on page 247).
- **Section notes** (on page 246).
- **Form and section titles** (on page 247).
- **Questions** (on page 246).
- **Codelist item label overrides** (on page 249).

**Note:** You can also provide translations for questions in the Design tab of the Item Editor.

You can *translate codelist item labels* (on page 257) in the Codelist Editor.

## Viewing locale-specific translations in a layout

Every layout supports all locales. You do not need to create a unique layout for every form and locale in the study. Use the Locales drop-down list on the toolbar in the Layout tab to switch between locales and provide translations.

**Note:** Layouts that you created in release 1.2 display text in the locale for which the layout was created.

When you select a locale other than the default locale for a study, the locale name appears above the work area, and all captions and questions appear in the language for the locale. If the values are not translated for the locale, the text for the primary locale appears in red.

- 1 In the Project Explorer, select the **Forms and Transactions** Explorer bar.

or

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

- 2 Select a form or item, and select the **Layout** tab.
- 3 On the toolbar, select **Layout**, and then select the locale to view.

The locale appears, along with all locale-specific text strings.

**Note:** Text that you modify is saved for the selected locale only. For example, you can modify captions, notes, and section titles, and the values are saved for the locale.

## CHAPTER 7

# Validating and deploying a study

### **In this chapter**

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| Validating a workflow or study.....               | 262 |
| Deploying a study to the InForm application ..... | 276 |

## About study validation and deployment

Study validation and deployment is the process of:

- 1 Preparing a study to be moved from the design environment to a test or production environment.
- 2 Moving the study into the test or production environment.

### Studies only

You can validate and deploy a study but not a library.

### Deployment packages

You must validate a study before you can create a deployment package. The process of validation checks for conditions that would make it impossible to deploy the study. When you validate a study, the Central Designer application creates a validation baseline.

### Frequency of validation

Validate as often as needed to make sure that the design will be deployable. When deciding how frequently to validate, consider that validation requires you to save the study.

For validation to succeed, a study must contain the following study objects at a minimum:

- One study event.
- One form for each study event.
- One item for each form.
- A label for each codelist item.

## Validation and deployment definitions

Study validation and deployment use the following terms.

| Term              | Definition  |
|-------------------|---|
| Approval          | Consent to deploy a study directly to the InForm application, given by a user with the appropriate rights.  |
| 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.   |
| Deployment        | <p>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.</p> <p>There are two types of deployment:</p> <ul style="list-style-type: none"> <li>• <b>Automated</b>—A study design is moved directly from the Central Designer application to the InForm environment.</li> <li>• <b>Manual</b>—You must deliver and install a deployment package to the InForm environment.</li> </ul> |

| Term                  | Definition   |
|-----------------------|--|
| Deployment instance   | The environment to which you deploy a study.   |
| Deployment request    | <p>A request to deploy a study directly to the InForm application.</p> <ul style="list-style-type: none"> <li>• If your study is configured so that deployment requests require approval, the user who makes the request must have the appropriate rights to deploy the study to the InForm application.</li> <li>• If your study is configured so that deployment requests do not require approval, the user who makes the request does not need to have the appropriate rights to deploy the study to the InForm application.</li> </ul> |
| Jobs Browser          | A browser in which you view the results of asynchronous jobs, such as validation or import.  |
| Pending Approvals tab | A tab on the Home page in which you view, approve, or reject deployment requests that are waiting your approval, and review approval records.  |
| Study 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.   |
| Target application    | The application (for example, the InForm application) on which a completed deployment package runs.  |

## Validation and deployment workflow summary

The process of validating and deploying a study consists of the following steps:

- 1 ***Validate the study, creating a validation baseline*** (on page 264).
- 2 ***Create a deployment package from a validation baseline*** (on page 286).
- 3 ***Deploy the study to the InForm application*** (on page 276).

## Upgrade considerations

- A baseline that is valid in a previous release is not necessarily valid after an upgrade. For example, if you upgrade from a previous release, the study could contain RefNames that you could create in an earlier release but that you cannot create and are not valid in the current release. A study that contains such RefNames does not pass validation.
- Deployment packages created in Central Designer releases prior to 2.1 are not compatible with this release. After you upgrade to this release, create new deployment packages from the baselines created in releases prior to 2.1.
- You cannot download deployment packages that are created in Central Designer release 2.1.

# Validating a workflow or study

## Validating a workflow

You can validate a workflow to make sure that it is valid and that all of the study objects that it references still exist in the study. If you receive an error during validation about an invalid workflow, perform this step to correct the issue.

- 1 In the Project Explorer, select the **Visit Schedule** Explorer bar.
- 2 Select a study design, study element, or study event.
- 3 Select the **Workflow Diagram** tab.
- 4 Right-click the workspace, and select **Refresh Workflow**.
  - The application corrects issues with the workflow. For example, if a workflow arrow is not pointing to anything, it is removed. You receive a message that tells you about any visible changes that have been made.
  - If the application does not detect issues with the workflow, the workflow is not changed.

## Validating a study and creating a baseline

- 1 Do one of the following:
  - Right-click the study, and select **Validate > Study**.
  - In the Project Explorer, select any object in the study and click the **Validate** button in the main toolbar.

A study validation job starts.

**Note:** If the job scheduling service is not running on the server, the job is placed in a queue.

- 2 In the message box that indicates a validation job has started, click **OK**.

A slide-up message appears to indicate when the job starts and finishes.

- 3 After the job finishes, check the status in the **Baselines Browser**, located by default at the bottom of the Central Designer window.



## Saving validation messages to a CSV file

From the Baselines Browser or the Jobs Browser, you can save the processing messages for all validation baselines to a comma-separated value (CSV) file that can be opened in a Microsoft Excel spreadsheet.

This file contains all of the columns that the Baselines Browser or the Jobs Browser can display. This information differs between the Baselines Browser and the Jobs Browser. Additionally:

- A file saved from the Baselines Browser contains messages only from validation jobs.
- A file saved from the Jobs Browser contains messages from all types of jobs that appear in the Jobs Browser. These messages can include information from validation, deployment, and import jobs.

### To save validation baseline messages from the Baselines Browser:

- 1 Open the **Baselines Browser**.

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

- 2 Click **Save As**, or right-click the browser, and select **Save As**.

The Save As dialog box appears.

- 3 Browse to the location in which to save the file.
- 4 Specify a file name, and click **Save**.

### To save validation baseline messages from the Job Log Browser:

- 1 In the row of browser tabs, select the **Jobs Browser**.

The Jobs Browser appears.

- 2 Click **Save As**, or right-click the browser, and select **Save As**.

The Save As dialog box appears.

- 3 Browse to the location in which to save the file.
- 4 Specify a file name, and click **Save**.

For more information, see:

**Baselines Browser - Option descriptions** (on page 444).

**Job Log Browser - Option descriptions** (on page 464).

## Disabling a workflow

To deploy a study without validating data-entry rules, workflow rules, or global conditions, you can disable the rules in the Central Designer application. Disabled rules are not deployed to the InForm application. This functionality allows you to more easily perform testing for a study during a development process in which forms and rules are being developed collaboratively by different users, by viewing the study in the InForm application, without having to validate rules. Disabling a rule does not prohibit you from performing rule-related tasks, such as editing the rule, and creating and running test cases for the rule.

**Note:** You can successfully run a test case for a single disabled rule. However, if you run more than one rule at a time, the Central Designer application will not run the test cases for any disabled rules.

Disabling a workflow disables all workflow rules and global conditions associated with the workflow. You cannot disable an individual workflow rule or global condition. However, this functionality only applies to the current workflow, and does not apply to child workflows. For example, if you disable a workflow at the study design level, the child workflows at the event or form level are not disabled.

Workflow rules and global conditions in a disabled workflow are:

- Not validated.
- Excluded from the deployment package.

When a study with a disabled workflow is deployed, the forms associated with that workflow appear in the InForm application in the order specified by their sequence numbers in the Workflow Diagram.

To disable a workflow:

- 1 In the Project Explorer, select the **Visit Schedule** Explorer bar.
- 2 Select a study design, study element, or study event.
- 3 Select the **Workflow Diagram** tab.
- 4 Click **Disable Workflow**.

The workflow arrows turn gray, and the study event sequence numbers re-appear and turn gray.

**Note:** The Central Designer application only sends a message on validation about disabled rules. You will not receive a message that lists the disabled workflows in your study.

## Baseline

### Validating a study and creating a baseline

When you validate a study, the Central Designer application creates a baseline.

A validation baseline is temporary until you make it public, either explicitly or by using it to create a deployment package. Subsequent validation jobs that you run create a new temporary validation baseline and replace the previous one. Only you can view, edit, or delete a temporary validation baseline that you created, or use that baseline in a deployment package.

## Viewing baseline validation errors and warnings

Validation can produce errors and warnings, as well as informational messages. You can read the errors and warnings to find out if any modifications are necessary for your study to pass validation and be deployed.

You can deploy a study that has received validation warnings, but you must acknowledge the warnings to indicate that you understand them and choose to ignore them in order to proceed with building the deployment package.

A validation baseline can have the following statuses:

- **Invalid**—One or more errors. The validation baseline cannot be used in a deployment package.
- **Invalid with warnings**—One or more warnings. A user must indicate that the warnings can be ignored before using the validation baseline in a deployment package.
- **Pending**—Validation is in process.
- **Valid**—No errors. The validation baseline can be used in a deployment package.
- **Valid with warnings**—One or more warnings. A user has indicated that the warnings can be ignored, and the validation baseline can be used in a deployment package.

### To view validation errors and warnings in the Baselines Browser:

- 1 Open the **Baselines Browser**.

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

- 2 Click **Refresh**.
- 3 Select the baseline validation to view.
- 4 Click **Show Validation**, or right-click in the browser, and select **Show Validation**.

The baseline row shifts to the right, and an expandable node appears to the left of the row.

- 5 Expand the node at the left of the baseline row.

Validation information, warning, and error messages appear below the baseline row.

**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**.

### To view validation errors and warnings in the Jobs Browser:

- 1 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.

- 2 Click **Refresh**.  
The list of jobs is refreshed from the database.
- 3 On the toolbar, click **Show Job Results**, and expand the results for an individual job.

- 4 Scroll to the beginning of messages for the baseline validation. The name Validation baseline and the date and time appear in the Name column for validation baseline jobs.

Validation information, warning, and error messages appear.

**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.

## Ignoring and resolving baseline validation errors and warnings

You can build a deployment package only if validation produces no errors and no warnings, or if you resolve or acknowledge and choose to ignore all warnings. Oracle recommends that you examine and analyze all warnings before deploying a baseline. A warning indicates that the study is valid, but the behavior of the study in the InForm application might not be expected or desired. You ignore all warnings as a group. You cannot select specific warnings to ignore.

### To ignore validation warnings:

- 1 Open the **Baselines Browser**.

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

- 2 In the **Baselines Browser**, select a baseline (with a status of Invalid with Warnings).
- 3 Examine the warning messages.
- 4 If you decide to ignore the warnings, click **Ignore Warnings**, or right-click the browser, and select **Ignore Warnings**.

The status of the validation baseline changes to Valid with Warnings.

**Note:** You ignore all warnings as a group. You cannot select specific warnings to ignore.

### To resolve validation errors and warnings:

- 1 In the **Baselines Browser** or **Jobs Browser**, view the messages for the validation baseline.
- 2 Review the **Description** for each message for which the **Validation Type** is Error or Warning.

**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.

- 3 Double-click the error or warning.

If you can or must correct the issue in multiple locations, a dialog box appears, displaying the locations. Multiple locations appear if you can correct an issue in any of them, even if you have to correct the issue in only one place. Double-click a location. This dialog box remains open so you can navigate to additional locations.

If you can correct the issue in only one location, the application takes you to the location.

**Note:** Double-clicking a validation message does not take you to a location in the application if the job result is from a previous release's validation baseline, the issue is in the library, or you select an information message.

- 4 Update the study definition as necessary to correct each error or warning, and save your changes. For more information, see *Checks performed during validation* (on page 269).

#### To run the study repair tool:

- 1 In the **Baselines Browser**, view the messages for the validation baseline.
- 2 Review the **Description** for each message for which the **Validation Type** is Internal Error.

**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**.

- 3 Right-click the error or warning.
- 4 Select **Repair Study**.  
A confirmation dialog box appears.
- 5 Click **OK**.

**Note:** You cannot undo this action.

- 6 Do one of the following:
  - **Click OK**—To close the dialog box if the Study Repair tool resolves all issues or does not find any issues.
  - **Click Save Log**—To save a copy of the event log if the Study Repair tool cannot resolve all issues. After you save the event log, contact customer support to resolve outstanding issues.

## Editing a validation baseline description

- 1 Open the **Baselines Browser**.

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

- 2 In the **Baselines Browser**, select a baseline.
- 3 Click **Edit**, or right-click the browser, and select **Edit**.  
The Edit Baseline dialog box appears.
- 4 In the **Name** field, type the name of the baseline.
- 5 In the **Description** field, type a description for the baseline.
- 6 Click **OK**.

## Deleting a validation baseline

You can delete a validation baseline only if no deployment packages are associated with it. Baselines associated with a deployment package are retained for auditing.

- 1 Open the **Baselines Browser**.

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

- 2 In the **Baselines Browser**, select a baseline to delete.
- 3 Click **Delete**, or right-click the browser, and select **Delete**.

## Making a validation baseline public

When you create a validation baseline, it is considered temporary. Only you can view and work with a temporary validation baseline that you created, and subsequent validation jobs that you run overwrite it. To enable other users to view and work with a validation baseline, you make it public.

**Note:** When you use a validation baseline to create a deployment package, it is made public.

- 1 Open the **Baselines Browser**.

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

- 2 In the **Baselines Browser**, select a baseline to make public.
- 3 Click **Make Public**, or right-click the browser, and select **Make Public**.

The Edit Baseline dialog box appears.

- 4 In the **Name** field, type the name of the baseline.
- 5 In the **Description** field, type a description for the baseline.
- 6 Click **OK**.

## Checks performed during validation

For a study to be deployed to the InForm application, it must pass a series of validation checks. For more information, see:

- *General validation checks* (on page 269).
- *Validation checks for InForm deployment* (on page 270).
- *Validation for special InForm forms and items* (on page 99).
- *Validation for coding* (on page 274).
- *Validation for monitoring forms* (on page 103).
- *Validation for data mappings* (on page 205).
- *Validation for in-place revisions* (on page 351).

Some information is not validated. For more information, see *Information not validated* (on page 275).

## General validation checks

| Validation area        | Must be true for successful validation   |
|------------------------|--|
| Study objects          | <ul style="list-style-type: none"> <li>• All study object RefNames are valid and unique.</li> <li>• Reserved words are not used as RefNames.</li> <li>• References to study objects are valid (for example, if you delete an item from a form, you make sure that the layout does not continue to refer to the deleted item).</li> <li>• The study does not contain: <ul style="list-style-type: none"> <li>▪ Duplicate references to a study object (for example, if you import an archived study that contains duplicate references).</li> <li>▪ References to study objects that are not included in the study.</li> <li>▪ Empty string resources.</li> </ul> </li> <li>• A study object is not a child of itself.</li> <li>• Parent/child study object relationships are valid.</li> </ul> |
| Locale and translation | <ul style="list-style-type: none"> <li>• At least one locale is selected in the Study Editor as a deployment target.</li> <li>• Translations to all study languages are complete.</li> <li>• Notes on sections are translated for all locales. If you provide a translation and then clear the value, the translation is considered valid.</li> </ul>  |
| Layout                 | <ul style="list-style-type: none"> <li>• The study contains form layout definitions for all deployable locales.</li> <li>• You have provided translations for captions and notes for all supported locales for the study.</li> <li>• An error has not occurred with any layouts.</li> </ul>  |

| Validation area | Must be true for successful validation   |
|-----------------|--|
| Rules           | <ul style="list-style-type: none"> <li>Rules compile successfully, including rule templates and workflow rules, whether or not they are used.</li> <li>Rules do not refer to study objects that have been deleted.</li> <li>Rules reference the current RefNames of study objects. If a RefName is not updated automatically, you must manually update the RefName in the rule.</li> <li>Only one current instance of a repeating form is referenced in a rule.</li> </ul> |

## Validation checks for InForm deployment

| Validation area | Must be true for successful deployment to the InForm application   |
|-----------------|--|
| Study           | The study has at least one study event.  |
| Study design    | A warning occurs if the title or RefName of the study design, when appended with the version and locale of the study design, might exceed 63 characters. If the warning occurs, shorten the title or RefName, or the deployment process truncates the title or RefName in the InForm application.                              |
| Common visit    | For studies with common forms, if you translate a title or short title of the common visit for one language, the title and short title are translated for all languages.   |
| Study event     | <ul style="list-style-type: none"> <li>Each study event has at least one form.</li> <li>A study event is not used on both a study element and a study design.</li> </ul>   |
| Form            | Each form: <ul style="list-style-type: none"> <li>Contains at least one item.</li> <li>Has a layout defined for each locale that is deployed.</li> <li>Does not contain duplicate items.</li> <li>Is included in a study event no more than once.</li> <li>Each Study Completion form has a Completion Status item.</li> </ul> |
| Section         | Each section has a layout defined for each locale that is deployed.  |



| Validation area            | Must be true for successful deployment to the InForm application  |
|----------------------------|---|
| Item                       | <ul style="list-style-type: none"> <li>• Questions for top-level items are not blank.</li> <li>• Year range for date time items is valid (for example, start year cannot be later than end year).</li> <li>• The precision value of a float item is not longer than the specified length of the item.</li> <li>• The nesting of compound and conditional items is not greater than five. If an item holds more than one child control, a group control is created, and each group control counts as one level of nesting.</li> <li>• Each compound item has at least one child item.</li> <li>• An item that is designated as a key item is not: <ul style="list-style-type: none"> <li>▪ Formatted as a checkbox.</li> <li>▪ An item on which other items are conditional.</li> <li>▪ Conditional on another item if the key item is a child of a compound item.</li> </ul> </li> <li>• The study does not contain any items for which <b>NA</b> or <b>UNK</b> is the RefName.</li> <li>• An item that is designated as Personal/Protected Health Information (PHI) is not included in the subject line or body of an email to be sent by a rule.</li> </ul> |
| Codelist and codelist item | <ul style="list-style-type: none"> <li>• Each codelist has codelist items.</li> <li>• Each codelist item has a label for the appropriate locale.</li> <li>• The codes of codelist items are unique within a codelist.</li> <li>• The codes for codelist items on text items do not exceed the length that is specified for the text item.</li> <li>• The codes for codelist items match the type of the codelist. For example, the codes for an integer codelist cannot contain letters.</li> <li>• The code of a codelist item that is conditional on another item has not been modified since the codelist item was made conditional.</li> <li>• Codelist labels do not contain apostrophes.</li> <li>• The Study Completion Status Item custom property is not set for codelist items in multiple items.</li> <li>• Each instance of a copied or linked codelist item has the same codelist type.</li> </ul>   |

| Validation area | Must be true for successful deployment to the InForm application  |
|-----------------|---|
| Review state    | <ul style="list-style-type: none"> <li>• The maximum number of review states is not exceeded, and there are no duplicate State values.</li> <li>• State, Label, and Mnemonic are defined for a review state.</li> <li>• Label and Mnemonic are defined for each review stage.</li> <li>• Label and Mnemonic fields for a review state and each of its review stages have values for each required product locale. Values for an InForm product locale (English [United States] or Japanese [Japan]) are required if the locales specified for the study include a locale with the same language. For example, English translations are required if the study includes en-US or en-GB locales.</li> <li>• Review stage names exist for each review stage and are unique within a review state.</li> <li>• Each review state has three defined review stages.</li> </ul>  |
| Workflow        | <ul style="list-style-type: none"> <li>• A study object does not have multiple global conditions.</li> <li>• A workflow object does not have two outgoing arrows without a rule.</li> <li>• All study objects in a workflow reference study objects that still exist in the study. If validation fails due to an invalid workflow, go to the Workflow Diagram tab for the workflow with the issue, and right-click in the white space of the diagram and select <b>Refresh Workflow</b> to correct the issue.</li> </ul>  |
| Data-entry rule | <ul style="list-style-type: none"> <li>• No rules are created on a linked item that is in multiple compound items.</li> <li>• The query message of a rule has 255 characters or fewer, not including the parameters.</li> <li>• For each data-entry rule, an item that triggers the rule is selected. If an item is not selected, you receive a warning during validation.</li> <li>• Each constant has a value (the length of the value must be greater than 0).</li> <li>• No email rules refer to items designated as Personal/Protected Health Information (PHI) in the subject or body of the email message.</li> </ul> <p><b>Note:</b> If two rules (on different study objects) have the same name, in release 2.1 of the Central Designer application, you receive a warning during validation. Using the same rule name for rules on different study objects is not recommended, and future releases may not support the practice.</p> |

| Validation area   | Must be true for successful deployment to the InForm application   |
|-------------------|--|
| Function          | <ul style="list-style-type: none"> <li>• All functions that are used in rules exist in the DLL file for user-defined functions.</li> <li>• A warning occurs if a study or library contains a user-defined function that uses an incorrect version of the Log4Net application.</li> <li>• A warning occurs if a study or library contains a user-defined function with an assembly that is: <ul style="list-style-type: none"> <li>▪ Unsigned.</li> <li>▪ Not signed with a strong named signature.</li> <li>▪ Signed with an invalid or untrusted signature.</li> </ul> <p><b>Note:</b> If you ignore the warning for a user-defined function with an assembly that requires signing with a strong named, valid, and trusted signature, an error occurs when the rule executes in the InForm application. For more information about user-defined function assemblies that require signing, see the <i>Rules Reference Guide</i>.</p> </li> <li>• A warning occurs if a study or library contains a user-defined function with invalid references to ExternalFunctions.dll.</li> </ul> |
| Unit              | <ul style="list-style-type: none"> <li>• All units that are used in the study are in the units file. The file must have a symbol for each unit in each locale that is deployed, and a conversion map must exist to convert between the base unit and the conversion unit.</li> <li>• All units are translated for all of the supported locales for a study.</li> <li>• In the units file, unit names are 31 characters or fewer.</li> </ul>  |
| In-place revision | <ul style="list-style-type: none"> <li>• The study objects associated with in-place revisions exist.</li> <li>• No more than one in-place revision exists for each study object.</li> <li>• Every in-place revision is associated with an existing deployment instance and a study version.</li> </ul>   |

| Validation area           | Must be true for successful deployment to the InForm application  |
|---------------------------|---|
| Study administration data | <p>General checks:</p> <ul style="list-style-type: none"> <li>Imported study administration CSML does not contain more than one StudyAdministration object, which contains the study administration configuration settings.</li> </ul> <p>Item group checks:</p> <ul style="list-style-type: none"> <li>Each item group contains one or more item.</li> <li>Each item in an item group is a top-level item on at least one form in the study design.</li> <li>Each item in an item group exists on a form in the study design.</li> <li>Each item in an item group exists in only one item group.</li> </ul> <p>Rights group checks:</p> <ul style="list-style-type: none"> <li>Each rights group contains one or more item groups.</li> <li>Each item group in a rights group exists in the study.</li> </ul> <p>Signature group checks:</p> <ul style="list-style-type: none"> <li>Each signature group contains a form.</li> <li>Each form in a signature group exists in the study design.</li> <li>For each signature group, a translation is provided for the Signature Meaning and Signature Text for each locale in the study.</li> </ul> |
| Other                     | Oracle reserved words are not used as RefNames of any study object or Aliases of data sets and data series.   |

## Validation for coding

To be valid, a study must pass the following coding-related checks:

- A form can contain only one copy of an item.
- Items in a coding map must all be either in or not in a repeating section.
- A coding map must include at least one target item.
- A target item must be a top-level item or a child of a top-level compound item. It cannot be a child of a nested compound item and cannot be conditional on another item.
- All query target items must be:
  - Top-level items.
  - Visible and available for editing in the InForm application. Items designated as query targets must not have the Display Override property set to ReadOnly or Hidden in the Central Designer application.
- All items in a coding map, except the query target item, must be text items.
- Each coding map is valid in the dictionary type from which it was created.

- The dictionary metadata in the study CSML must be in the dictionaries that are supported in the Central Designer application.

## Information not validated

| Validation area       | Information not validated   |
|-----------------------|---|
| Layout                | <ul style="list-style-type: none"><li>• Non-EDC layouts.</li><li>• Item layouts.</li><li>• Layouts for a locale that is not supported in a study (for example, if a layout is created for a locale that is later deselected for the study).</li></ul> |
| Instructions and help | Instructions and help information for a locale that is not supported in a study.  |

# Deploying a study to the InForm application

## About deploying to the InForm application

To deploy a study to the InForm application, you do the following:

- 1 Create a deployment instance.  
For more information, see *Setting up deployment instances* (on page 289).
- 2 Create a deployment package and transfer a deployment package to the InForm server.  
For more information, see *About deployment packages* (on page 276).

There are two methods for deploying to the InForm application:

- **Automated deployment**—A study design is moved directly from the Central Designer application to the InForm environment.  
For more information, see *Automated deployment* (on page 288).
- **Manual deployment**—You must deliver and install a deployment package to the InForm environment.  
For more information, see *Manual deployment* (on page 295).

## About deployment packages

### When you can create a deployment package

When a validation baseline is free from errors and warnings, or if you have indicated that warnings can be ignored, you can create a deployment package from it. A deployment package is a ZIP file that contains:

- Metadata that describes the study and the files required to create the MedML for the metadata.
- Deployment options specific to the target application.
- A list of all files in the deployment package.
- InForm rule engine assemblies.
- Rule assembly and user-defined functions.
- Assemblies required to deploy the study.

You install the deployment package on the computer where the InForm server is running.

### Types of deployment packages

Full and incremental deployment packages both contain the definitions for every study object in the study. Consider the following:

- **Full package**—Deployment package that contains everything needed to deploy a complete study, including study administration data.

- **Incremental package**—Deployment package that contains everything needed to deploy a complete study, including study administration data, plus additions and changes to the study, reflected in Alternate forms in the InForm application. Alternate forms are not created when you install an incremental deployment package that contains additions to repeating forms or fixed repeating sections (Repeating Data itemsets in the InForm application).
- **Administration data**—Deployment package that contains only study administration data.

**Note:** If you deactivate a rule in the InForm application, do one of the following in the Central Designer application before creating a new deployment package:

- Remove the rule from the study.
- Disable the rule.
- Change the triggering event to **On Demand (Batch Mode)**.

Rule-related changes that you make in the InForm application are overridden when you install a new deployment package.

**Note:** If you create or modify a coding map, use a full deployment package to deploy the changes. Changes to coding maps are not supported in incremental deployment packages.

Before you can create a deployment package, you must specify deployment options for the study in the Study Editor. Deployment options indicate the target applications, format, and languages or locales for which the study is being designed.

### Naming conventions for baselines and deployment packages

Developing naming conventions for validation baselines and deployment packages is recommended. For example, you might want to name validation baselines that are created while testing the study design differently from validation baselines that are actually deployed.

## Deployment package processing in the InForm application

| Characteristic                              | Description   |
|---|---|
| What the deployment process creates         | <ul style="list-style-type: none"> <li>• For a manual deployment, an InForm server and a study, if they do not already exist. The process of creating the InForm study creates an Oracle user for the study database tables.</li> <li>• MedML definitions for CDD or CIS mappings, if the deployment package includes CDD or CIS mappings.</li> <li>• A log file called StudyInstaller.log in the InForm installation folder. This log file contains information that can be used to debug problems with deployment. Messages from each subsequent deployment are appended to the log.</li> </ul> |
| What the deployment process does not create | The Oracle user and system DSN for a CDD or for a Clintrial protocol that is the target of CIS mappings. You must create the CDD Oracle user and DSN through the InForm Service. The Oracle user and DSN for a Clintrial protocol are created through the Clintrial application or through CIS synchronization.   |

| Characteristic                | Description   |
|-------------------------------|---|
| Deployment package processing | <p>The deployment process for deployment in the InForm application:</p> <ol style="list-style-type: none"><li>1 Creates the InForm application server, if it does not already exist.</li><li>2 Creates the InForm study database, if it does not already exist.</li><li>3 Installs the MedML (InForm-specific metadata XML) definitions for the Base study components, if the deployment package is for a full deployment. The Base study components include system resources, settings, and form definitions common to all InForm studies.</li></ol> <p><b>Note:</b> Do not create the Base study with the dbsetup utility before running the Deployment Wizard. Deployment processing does not succeed if the Base study already exists. If you install a deployment package using command-line options, you can override this restriction. For more information, see <i>Installing a deployment package using command-line options</i> (on page 296).</p> <p>You can follow the progress of the deployment in the message box on the last page of the Deployment Wizard.</p> |

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## Central Designer and InForm study component correspondences

When you deploy a study created in the Central Designer application to the InForm application, the Central Designer study components and workflow are translated to InForm study components. The conversion to InForm study components is based on both the data definition of each study component and the layout specified for each form or item in the Central Designer application.

| Central Designer study component | Corresponding InForm study component   | Notes   |
|----------------------------------|--|---|
| Codelist                         | Radio, checkbox, or pulldown control   | <p>The following codelist specifications determine how codelist items deploy to the InForm application:</p> <ul style="list-style-type: none"> <li>• <b>Single selection</b>—Deploys as a radio or pulldown control.</li> <li>• <b>Multiple selection</b>—Deploys as a checkbox control.</li> <li>• The Layout section of the Central Designer Options dialog box (available from the Tools &gt; Options menu) specifies the following defaults: <ul style="list-style-type: none"> <li>▪ Automatic formatting of codelist-based controls based on the number of codelist items.</li> <li>▪ Default control sizes.</li> </ul> </li> <li>• The layout specification in the Central Designer application determines whether a radio control is displayed vertically or horizontally. You can also use the layout specification to indicate whether a codelist is single selection, single selection with user, or multiple selection, and whether codelist items in a single-selection codelist deploy as a radio control or a pulldown control.</li> </ul> |
| Codelist item                    | Simple control   |   |
| Collaboration note               | No corresponding component   | This type of study object is not deployed to the InForm application.  |
| Data series                      | <ul style="list-style-type: none"> <li>• Table column in CDD mapping definition.</li> <li>• Panel item in CIS mapping definition.</li> </ul> |   |

| Central Designer study component | Corresponding InForm study component   | Notes   |
|----------------------------------|--|---|
| Data set                         | <ul style="list-style-type: none"> <li>Table in CDD mapping definition.</li> <li>Panel in CIS mapping definition.</li> </ul> | The data dimensions of a data set form the key for each row of a CDD table. Data values defined as custom dimensions form pivot columns around which the data in the table is organized.  |
| Description                      | No corresponding component   | Study object descriptions are visible only in a Central Designer annotated study book.  |
| Form                             | Form   | <ul style="list-style-type: none"> <li>In the Central Designer application, a form note is specified in the layout definition.</li> <li>The Short Title specified in the Central Designer application deploys as the form mnemonic in the InForm application.</li> <li>The form RefName is used in Reporting and Analysis and in CDD table columns for which no data series alias exists.</li> </ul>  |
|                                  | Alternate form   | <ul style="list-style-type: none"> <li>In the InForm application, an alternate form is used to collect new or changed information for those subjects who have started the original version of the form.</li> <li>A form containing new or changed items in a subsequent, incremental deployment deploys as an alternate form for those subjects who have started the original version of the form.</li> <li>Alternate forms are not created when you install an incremental deployment package that contains additions to repeating forms or itemsets.</li> </ul> |
|                                  | Associated forms   | Two forms defined as repeating and linked with the AssociatedForm property in the Central Designer application deploy as associated forms in the InForm application.  |
|                                  | Common form  | A form defined as a common form deploys as a common form.   |
|                                  | Date of Visit form   | If you do not include a special Date of Visit item in the study, a default Date of Visit form is deployed to the InForm application.  |
|                                  | Dynamic form   | A form for which the precondition is the outcome of a workflow rule or global condition deploys as a dynamic form in the InForm application.  |
|                                  | Enrollment form  | If you do not include a special Enrollment form in the study, a default Enrollment form is deployed to the InForm application.  |

| Central Designer study component | Corresponding InForm study component           | Notes   |
|----------------------------------|--|---|
|                                  | Regulatory report forms and visit report forms | You can create regulatory report and visit report forms in the NonClinical container in the Project Explorer. If you do not create the forms, default versions are generated and deployed.  |
|                                  | Repeating form                                 | A form defined as repeating in the Central Designer application deploys as a repeating form in the InForm application.  |
|                                  | Screening form                                 | If you do not include a special Screening form, a default Screening form is deployed to the InForm application.   |
| Global condition                 | Rule   | The deployment process treats a global condition as a rule and creates rule attachments, arguments, and dependencies in the InForm application as necessary based on the items referenced in the global condition definition.   |
| Help text                        | CRF Help                                       | Instructions and Help defined for forms or items in the Central Designer application deploy as CRF Help in the InForm application. Instructions and Help defined for other study objects (for example, study events) in the Central Designer application do not deploy to the InForm application. |

| Central Designer study component | Corresponding InForm study component | Notes  |
|----------------------------------|--------------------------------------|--|
| Item                             | Item                                 | <p>Item deployment considerations:</p> <ul style="list-style-type: none"> <li>• The Central Designer application includes the following <i>custom properties</i> (on page 477) for InForm deployment: <ul style="list-style-type: none"> <li>▪ <b>Collapsible</b> (for items)—Defaults to False in the InForm application. Collapsed items in the Central Designer application become dynamic controls in the InForm application.</li> <li>▪ <b>Display Override</b> (for items)—Defaults to False in the InForm application.</li> <li>▪ <b>Required</b> (for items)—Defaults to True in the InForm application.</li> <li>▪ <b>SDV Critical</b> (for forms and items)—Defaults to False in the InForm application.</li> <li>▪ <b>SDV Required</b> (for items)—Defaults to True in the InForm application.</li> <li>▪ <b>Special Fields</b> (for items)—Identifies items that have a special meaning in the InForm application, including special Date of Visit and Randomization items and items that appear on special forms.</li> </ul> </li> <li>• Layout specifications determine how controls appear in the InForm application. For date time items, layout specifications include the specification of year ranges.</li> </ul> |
| Date/time control                |                                      | Date time items in the Central Designer application become date/time controls in the InForm application.   |
| Group control                    |                                      | A compound item defined with child items in the Central Designer application deploys in the InForm application as a group control consisting of the child items.   |
| Nested control                   |                                      | An item in the Central Designer application that is conditional on another item deploys in the InForm application as a nested control within the item on which it is conditional.  |
| Text control                     |                                      | Text, integer, and float items in the Central Designer application become the appropriate text controls in the InForm application.   |

| Central Designer study component | Corresponding InForm study component | Notes   |
|----------------------------------|--------------------------------------|---|
|                                  | Unit                                 | <ul style="list-style-type: none"> <li>A base unit or a base unit and a single conversion unit specified in an integer, float, or yes no item definition in the Central Designer application deploy as units in the InForm application.</li> <li>If more than one conversion unit is selected in the item definition, the conversion units deploy in the InForm application as a radio or pulldown control, depending on the layout option selected.</li> </ul> |
| Library                          | No corresponding component           | This type of study object is not deployed to the InForm application.  |
| Library project                  | No corresponding component           | This type of study object is not deployed to the InForm application.  |
| Mapping                          | CDD or CIS mapping definition object |   |
| Rule                             | Rule                                 | The deployment process creates rule attachments, arguments, and dependencies in the InForm application as necessary based on the items referenced in the rule definition.   |
| Section                          | Section                              | <ul style="list-style-type: none"> <li>In the Central Designer application, a section note is specified in the layout definition.</li> <li>If you do not create a section for a form in the Central Designer application, a section with the same title as the form is automatically generated when the study is deployed to the InForm application.</li> </ul>   |
|                                  | Itemset                              | The items in a section defined as repeating in the Central Designer application are grouped into an itemset in the InForm application.  |
|                                  | Repeating Data itemset               | The items in a section defined as fixed and repeating in the Central Designer application are grouped into a Repeating Data itemset in the InForm application.  |
| Short Question                   | Itemset column header                | <ul style="list-style-type: none"> <li>If a Short Question is specified, the value is used for the column header that appears in the itemset.</li> <li>If a Short Question is not specified, the value of the Default Question is used.</li> </ul>  |

| Central Designer study component | Corresponding InForm study component      | Notes   |
|----------------------------------|---|---|
| Study                            | Study                                     | <p>The study version (VERSIONDESCRIPTION attribute in InForm MedML) is a concatenation of:</p> <ul style="list-style-type: none"> <li>• The Title property of the study object.</li> <li>• The revision number of the validation baseline used to create the deployment package.</li> <li>• An abbreviation for the locale, if the deployment package is created for multiple locales.</li> </ul> |
| Study element                    | No corresponding component                | This type of study object is not deployed to the InForm application.  |
| Study event                      | Visit                                     | The Short Title of a study event is used as the visit mnemonic in the InForm application.   |
|                                  | Dynamic visit                             | A study event for which the precondition is the outcome of a workflow rule or global condition deploys as a dynamic visit in the InForm application.  |
|                                  | Enrollment visit                          | <p>A special InForm visit that must be included in the Central Designer study design.</p> <ul style="list-style-type: none"> <li>• The enrollment form must belong to the enrollment visit.</li> <li>• The enrollment visit must be a standalone visit in the study workflow.</li> <li>• The enrollment visit must be the second visit in the workflow after the screening visit.</li> </ul>      |
|                                  | Regulatory report and visit report visits | The deployment process creates regulatory report and visit report visits.   |
|                                  | Repeating visit                           | A study event defined as repeating in the Central Designer application deploys as a repeating visit in the InForm application.  |
|                                  | Screening visit                           | <p>A special InForm visit that must be included in the Central Designer study design.</p> <ul style="list-style-type: none"> <li>• The screening form must belong to the screening visit.</li> <li>• The screening visit must be a standalone visit in the workflow.</li> </ul> <p>The screening visit must be the first visit in the workflow and the enrollment visit must be second.</p>       |

| Central Designer study component | Corresponding InForm study component | Notes  |
|----------------------------------|--------------------------------------|--|
| Study project                    | No corresponding component           | This type of study object is not deployed to the InForm application.   |
| Task                             | No corresponding component           | This type of study object is not deployed to the InForm application.   |
| Template                         | No corresponding component           | This type of study object is not deployed to the InForm application.   |
| Type                             | No corresponding component           | This type of study object is not deployed to the InForm application.   |
| No corresponding component       | Calculated control                   | You cannot create calculated controls in the Central Designer application. You can create a read-only control that serves the same purpose as a calculated control in that it uses a rule to fill in data. |

**Note:** Components in MedML are named based on the RefNames of study objects in the Central Designer application, with the following two exceptions:

- PFElements. The RefName from the codelist item is concatenated with an underscore and a 40-character identifier that the application creates using the RefName, code, and translations of the codelist label. If you modify the RefName, code, or codelist label, the application creates a new PFElement.
- Group controls are prefaced with "GC\_" only when multiple items are conditional on the same item.

## Saving the job log to a CSV file

You can save contents of the Jobs Browser to a comma-separated value (CSV) file that can be opened in a Microsoft Excel spreadsheet. Saving the job log enables you to review job log messages for validation, deployment, and import jobs.

- 1 In the row of browser tabs, select the **Jobs Browser**.  
The Jobs Browser appears.
- 2 Click **Save As**, or right-click the browser, and select **Save As**.  
The Save As dialog box appears.
- 3 Browse to the location in which to save the file.
- 4 Specify a file name, and click **Save**.

## Creating a deployment package

- 1 In the Project Explorer, select **Study Information**.
- 2 Select a study, and select **Actions > Create Deployment Package**.

or

Right-click a study, and select **Create Deployment Package**.

- 3 In the Deployment Editor, click **New Package**.

The Create Deployment Package Wizard appears.

- 4 Complete the pages of the **Create Deployment Package Wizard**:

- Click **Next** when you complete each page.
- On the **Select a Deployment Package Type** page, specify the type of deployment package to create (full, incremental, or administration data).

Based on your choice on the Select a Deployment Package Type page, the Create Deployment Package Wizard prompts for different information as you progress through the wizard.

- 5 On the final page of the **Create Deployment Package Wizard**, click **Finish**.

A deployment package job starts, and a slide-up message appears to indicate when the job starts and completes.

- 6 When the job completes, check the status in the Jobs Browser.

For more information, see:

*Create Deployment Package Wizard - full deployment package* (on page 446).

*Create Deployment Package Wizard - incremental deployment package* (on page 450).

*Create Deployment Package Wizard - administration data deployment package* (on page 454).



## Deployment Editor

Use the Deployment Editor to create and manage the deployment packages and automated deployments for a study. The Deployment Editor lists all existing deployment packages in a hierarchical display that indicates how incremental deployment packages relate to the full deployment package on which they are based.

Using the Deployment Editor, you can:

- Create a deployment package.
- Save a deployment package to the file system.
- Delete a deployment package and all its children.
- Create an automated deployment request.
- View the status of a deployment request.
- Cancel an automated deployment.
- View a history of automated deployments for a deployment package.

### To open the Deployment Editor:

- In the Project Explorer, select the **Study Information** Explorer bar > **Deployment** folder.

For more information, see *Deployment Editor—Option descriptions* (on page 455).

## Deleting a deployment package

You can delete a deployment package for a LIVE or UAT deployment instance when the following is true:

- The deployment package was not transferred to the InForm environment.

**Note:** If the deployment package was transferred to the InForm environment but the deployment was cancelled you cannot delete the package.

- The deployment package is not associated with a rejected deployment request.
- The deployment package is not associated with a locked deployment request approval.

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

2 Select the **Deployment** folder.

The Deployment Editor appears.

3 In the Deployment Editor, select the deployment package to delete.

4 Click **Delete**, or right-click the row containing the deployment package, and select **Delete**.

A confirmation message prompts you to confirm the deletion.

**Note:** To delete a deployment package with a deployment request to a UAT or LIVE deployment instance, the status of the deployment must be Not Applicable or Unknown.

5 Click **OK**.

When you delete a deployment package, the following are also deleted:

- Any incremental deployment packages associated with the package.
- Any automated deployment data associated with the package, including deployment requests; deployment approvals and rejections; deployment cancelations and deployment request cancelations; and deployment logs.

## Automated deployment

Automated deployment is the process through which a study design is moved directly from the Central Designer application to the InForm environment.

**Note: Automated deployment is supported only in release 6.1 and later of the InForm application.**

The deployment request is the basis of the automated deployment process. To initiate an automated deployment:

- 1 Set up the InForm environment. For example, you must create the InForm server and study before you use the automated deployment feature. For more information, see the *InForm Study and Reporting Setup Guide*.
- 2 Create a deployment instance to define the InForm servers to which to deploy the study. For more information, see *Creating a deployment instance* (on page 289).
- 3 Create a deployment request for a deployment package. In the request, you define where the study is deployed, what the deployment options and schedule are, and who is notified of the deployment. For more information, see *Creating a deployment request* (on page 290).
- 4 If the deployment requires an approval, obtain approval by a user with the appropriate right. For more information, see *Approving or rejecting a deployment request* (on page 292).

If the deployment does not require an approval, skip the next step.

- 5 The Central Designer application transfers the deployment package to the InForm server and installs the package according to the schedule configured in the deployment request.


Before you can perform automated deployments to the InForm application, the following prerequisites must be met:

- In the Central Designer Administrator application, roles must exist with the Create deployment request and Approve deployment request rights, and users must be assigned to these roles. For more information, see the *Administrator Guide*.
- Users assigned to roles with the Create deployment request and Approve deployment requests rights must be on the study team. For more information, see *Setting up study teams* (on page 14).
- The deployment instance to which the deployment will be performed must be set up. For more information, see *Setting up deployment instances* (on page 289).
- In the Central Designer Administrator application, the default deployment options are configured for each type of deployment instance.

## Setting up deployment instances

To perform automated deployments to the InForm application, you must define the InForm servers to which to deploy by creating a deployment instance study object for each server.

### Creating a deployment instance

- 1 In the Project Explorer, select **Study Information**.
- 2 Select a study.
- 3 Select the **Deployment Setup** tab.
- 4 On the toolbar, click **New** .

The New Deployment Instance dialog box appears.

- 5 In the **Name** field, type the RefName of the deployment instance.
- 6 In the **Type** drop-down list, select the type of deployment instance:
  - **UAT**—User acceptance testing
  - **QA**—Quality assurance
  - **DEV**—Development
  - **LIVE**—Production
  - **TRN**—Training
- 7 In the **URL** field, type the URL for the machine on which to deploy the InForm study.
- 8 In the **Port** field, type the port used to query for deployment status. The default port is 14040 for HTTPS, and 80 for HTTP.

**Note:** You can add one deployment instance for each server type.

- 9 To require deployment approval for the deployment instance, select the **Approvals Required** checkbox.

**Note:** This option is available only if you configured the Central Designer application to allow a user to override the default setting for the type of server. For more information, see the *Administrator Guide*.

- 10 In the **Description** field, type a description for the deployment instance.
- 11 Click **OK**.
- 12 Optionally, to test the deployment instance URL:
  - a Select the URL.
  - b Click the **Test URL** button on the toolbar.

A message appears with the test results.

**Note:** To reference a deployment instance in a deployment request, the deployment instance must not have any unsaved changes.

For more information, see *Deployment Setup—Option descriptions* (on page 436).

## Editing or deleting a deployment instance

- 1 In the Project Explorer, select **Study Information**.
- 2 Select a study.
- 3 Select the **Deployment Setup** tab.
- 4 In the grid, select a deployment instance.
  - To remove the instance, on the toolbar, click **Delete** (✖).
  - To edit the instance, on the toolbar, click **Edit** (✎).

### Notes:

- Editing or deleting an instance does not affect deployment requests created before the edit or deletion.
- You cannot delete an instance that is associated with in-place revisions. If you edit an instance with in-place revisions, the changes affect the in-place revisions.

## Creating a deployment request

- 1 In the Project Explorer, select **Study Information**.
- 2 Select the **Deployment** folder.  
The Deployment Editor appears.
- 3 In the Deployment Editor, select the deployment package to deploy.
- 4 On the toolbar, click **Deployment**, and select **Request**.  
The Deployment Request dialog box appears.
- 5 In the **Name** drop-down list, select the target deployment instance.
- 6 Set the deployment schedule. You can select to perform the deployment immediately, or at a specific time based on your local time.

**Note:** For a LIVE deployment, if you configure the study to deploy immediately, the deployment is delayed five minutes.

- 7 In the **Deployment option** drop-down list, select whether you are deploying to a new study, or modifying an existing study.
- 8 In the **Reason for deployment** drop-down list, select the reason for creating the deployment request.
- 9 Optionally, enter additional information about the deployment in the corresponding text box.

**Note:** This information is not included in the email notifications.

- 10 In the **Email distribution list** table, select the users who receive email notifications about the deployment.

If approvals are required for the deployment instance, you must select at least one user with the right to approve deployments.

- 11 Optionally, select the **Advanced** tab to set the deployment start delay option.  
For more information, see *Deployment Request—Option descriptions* (on page 462).
  - 12 Click **OK**.  
The Deployment Request Summary dialog box appears.
  - 13 Do one of the following:
    - If your study requires deployment request approval, click **Request Approval**.  
You must wait for approval before continuing with the deployment request.
    - If your study does not require deployment request approval, click **Deploy**.  
The Deployment Request Summary dialog box appears.
  - 14 Review the deployment information, and click **Deploy**.
- Note: Make sure the schedule of deployments to the LIVE deployment instance does not interfere with the operation of the production environment.**
- 15 If the deployment request does not require an approval, the InForm Login dialog box appears.
  - 16 Type your InForm user name and password, and click **Login**.

### Canceling a deployment

After you create a deployment request, you can cancel the deployment request or deployment in the following two scenarios:

- If the deployment request requires an approval but it has not been approved or rejected yet, and you have the appropriate rights, you can cancel the deployment request.
- If the deployment request has been approved, or it does not require an approval, and you have the appropriate rights, you can cancel the deployment if the status of deployment is either Scheduled or Submitted.


To cancel a deployment or a deployment request:

- 1 In the Project Explorer, select **Study Information**.
- 2 Select the **Deployment** folder.  
The Deployment Editor appears.
- 3 Select a deployment package.
- 4 On the toolbar, click **Deployment** and select **History**.  
The Deployment Package History dialog box appears.
- 5 Select a deployment and do one of the following:
  - To cancel a deployment with the status of Scheduled or Submitted, click **Cancel Deployment**.
  - To cancel a deployment request that has not been approved or rejected yet, click **Cancel Deployment Request**.

- 6 Enter a reason for the cancelation and, optionally, additional information, and click **OK**.  
If you are canceling a deployment with the status of Scheduled or Submitted, the InForm Login dialog box appears.
- 7 Type your InForm user name and password and click **Login**.  
A confirmation message appears.
- 8 Click **Yes**.

## Approving or rejecting a deployment request

If you have the appropriate rights, you can view all the deployment requests that you can approve in the Pending Approvals tab of the Home page. Additionally, if you are a team member for a study, you may receive an email notification when a deployment request is created for that study.

- 1 On the toolbar, click the **Home Page** button ()
- 2 Select the **Pending Approvals** tab.
- 3 In the grid, select a deployment request.
- 4 On the toolbar, click **Approve/Reject**.

The Approve Request dialog box appears.

**Note:** As long as the dialog box is open, the request is locked and cannot be accessed by other users.

- 5 Do one of the following:
  - To approve the request, select **Approve**, sign the approval affidavit by providing your password, and click **Approve**.
  - To reject the request, select **Reject**, select a reason for rejecting, optionally, type additional information in the corresponding text box, and click **Reject**.
- 6 If you selected **Approve**, the InForm Login dialog box appears.
- 7 Type your InForm user name and password, and click **Login**.  
The deployment package will be transferred to the InForm server immediately and installed according to the schedule specified in the deployment request.

For more information, see *Pending Approvals tab—Option descriptions* (on page 457).

## Email notifications

The Central Designer application sends email notifications whenever one of the following events related to automated deployments occurs:

- Deployment request is created.
- Deployment request is canceled.
- Deployment request is approved or rejected.
- Deployment is canceled.
- Deployment starts.
- Deployment completes successfully or with failures.

You select the users who receive email notifications when you create the deployment request. For more information, see *Creating a deployment request* (on page 290).

**Note:** An administrator must configure the Central Designer application to send email notifications. For more information, see the *Installation Guide*.

## Viewing the history of deployments associated with your user account

In the Deployment History dialog box, you view detailed information about the deployment requests that are:

- Created by you.
- Waiting for your approval.
- Approved or rejected by you.

If you are assigned to a role with the View approvals across studies right, the Deployment History dialog box displays a complete record of automated deployments from all studies, including those on which you are not a team member. However, you must be a team member for a study to approve or reject a deployment request for the study.

### To open the Deployment History dialog box:

- Select **Tools > Deployment History**.

Or

- On the Home Page, select the **Pending Approvals** tab, and then click **Deployment History** on the toolbar.

The Deployment History dialog box appears. For more information, see *Deployment History dialog box—Option descriptions* (on page 458).

## Viewing the history of deployments for a package

The Deployment Package History dialog box displays a complete history of all the deployment requests created for a deployment package, and any approvals, rejections, or cancellations associated with the deployment requests.

### To open the Deployment Package History dialog box:

- 1 In the Project Explorer, select **Study Information**.
- 2 Select the **Deployment** folder.  
The Deployment Editor appears.
- 3 In the Deployment Editor, select a deployment package.
- 4 On the toolbar, click **Deployment**, and select **History**.

The Deployment Package History dialog box appears. For more information, see *Deployment Package History dialog box—Option descriptions* (on page 460).

## Viewing and exporting the deployment log

To follow the progress of a deployment after the deployment package has been transferred to the InForm server, you can view the deployment log. The deployment log contains an entry for steps reached in the deployment process. The following information is available for each entry:

- **Deployment Step**—Description of step reached in the deployment process.
- **Timestamp**—Time when the step was reached and the entry was added to the log.

To view and export the deployment log for a deployment:

- 1 In the Project Explorer, select **Study Information**.
- 2 Select the **Deployment** folder.  
The Deployment Editor appears.
- 3 In the Deployment Editor, select a deployment package.
- 4 On the toolbar, click **Deployment** and select **History**.  
The Deployment Package History dialog box appears.
- 5 Select a deployment and click **View Log** on the toolbar.  
The View Deployment Log dialog box appears.
- 6 To export the complete deployment log to a CSV file, click **Export**.



## Manual deployment

You must use manual deployment to deliver and install a deployment package to a study in InForm release 6.0 or earlier. You can also use manual deployment as an alternative to automated deployment for studies in the InForm release 6.1 or later. However, if you do not use automated deployment, you might notice differences in functionality when using the View Differences dialog box and performing in-place revisions.

For more information, see *Viewing the differences between two versions of a form* (on page 345).

### Saving a deployment package to the file system

- 1 In the Project Explorer, select **Study Information**.
- 2 Select the **Deployment** folder.  
The Deployment Editor appears.
- 3 In the Deployment Editor, select the deployment package to deliver.
- 4 Click **Save as**.  
The Save as dialog box appears.
- 5 If you are deploying to InForm release 6.1 or later, do the following:
  - Optionally, in the **Deployment Start Delay** field, specify a time in milliseconds to delay deployment.
  - Optionally, if the deployment package contains in-place revisions, select a deployment instance to which to deploy the in-place revisions.
- 6 Click **Save**, and specify the location in which to save the deployment package ZIP file.

### Installing a deployment package

- 1 To manually install a study in the InForm application:
- 2 If you are deploying to an InForm release prior to 6.1, you must use the PKGInst.exe file from the Central Designer 2.1 product ISO to process the deployment package and install the study to the InForm application.
  - a Copy the PKGInst.exe file in the InstallSupport folder on the product ISO.
  - b Paste the file to the InForm server, and run the deployment from that location.
- 3 Save a deployment package to the file system.
- 4 Save the package in a location from which it can be retrieved (for example, a folder on a shared network).
- 5 Install the deployment package on the computer where the InForm application is running. You must have the following administrative privileges on the InForm computer:
  - Permission to install and register COM objects.
  - Permission to write to the \bin and \Trials folders in the InForm directory structure.

You can install a deployment package:

- *Using the Deployment Wizard* (on page 296).
- *Using command-line options* (on page 296). Using this feature, you can execute a deployment package by running a script that contains command-line deployment options or a reference to a configuration file of deployment options.
- From the Deployment page in the InForm user interface (for InForm release 6.1 and later). For more information, see the InForm documentation.

### Installing a deployment package using the Deployment Wizard

- 1 Log on to the computer where the InForm server software is installed.
- 2 If you are deploying to an InForm release prior to 6.1, you must use the PKGInst.exe file from the Central Designer 2.1 product ISO to process the deployment package and install the study to the InForm application.
  - a Copy the PKGInst.exe file in the InstallSupport folder on the product ISO.
  - b Paste the file to the InForm server, and run the deployment from that location.
- 3 Make sure the Oracle.Designer.DeploymentInstaller executable exists on the computer.
- 4 Open a command prompt and run the following command:  
**Oracle.Designer.DeploymentInstaller [/DeploymentFile *File*]**  
where **File** is the full path to the deployment package ZIP file.  
The welcome page of the Deployment Wizard appears.
- 5 Click **Next** to complete the pages of the Deployment Wizard.
- 6 Click **Finish**.

For more information, see **Deployment Wizard for InForm deployment** (on page 463).

### Installing a deployment package using command-line options

- 1 Log on to the computer where the InForm server software is installed.
- 2 If you are deploying to an InForm release prior to 6.1, you must use the PKGInst.exe file from the Central Designer 2.1 product ISO to process the deployment package and install the study to the InForm application.
  - a Copy the PKGInst.exe file in the InstallSupport folder on the product ISO.
  - b Paste the file to the InForm server, and run the deployment from that location.
- 3 Open a Microsoft Windows command window.
- 4 Do one of the following:
  - In the directory where the deployment package is saved, run the Oracle.Designer.DeploymentInstaller executable, along with the desired deployment options.
  - Execute a script that contains the desired deployment options.
  - Execute a script that refers to an XML configuration file containing the desired deployment options.

For more information, see:

*Deployment command-line options* (on page 297).

*Deployment ConfigFile options* (on page 300).

## Executing the deployment package

### Deployment command-line options

The usage for the deployment command-line feature is as follows:

```
/help |
/testconversion | /testc |
/silent [/ConfigFile filename] |
[[/LogFileName filename][/UnpackDirectory directoryname][/ForceBASEInstall
(TRUE | FALSE)][/CheckInFormVersion (TRUE | FALSE)][/DontExitIfUnsuccessful
(TRUE | FALSE)][/Server ServerName][/Trial TrialName][/User UserName
][/Password UserPassword]
[/Strict (TRUE | FALSE)][/TrialCreateModeValue DB [/Connect
DatabaseConnectString] | DSN [/TRIDSN DSNString]]]
```

For example, the following statement installs the ASM916S deployment package located in the C:\ directory, without prompting for user input, to a study called ASM916 on an InForm server called INF916:

```
Oracle.Designer.DeploymentInstaller /DeploymentFile C:\ASM916S.zip/silent
/LogFileName ASM916S.log /ForceBASEInstall TRUE /Server INF916 /Trial ASM916
/User ASM916guid /Password ASM916pid /Strict TRUE /TrialCreateModeValue DB
/Connect APPSRV_dev1
```

| Option                | Description  |
|-----------------------|--|
| /help                 | Display a dialog box summarizing the command-line usage and options.   |
| /CsmfToMedml          | Convert the study to MedML.  |
| or                    | <b>Note:</b> Optionally, you can specify a file name. If you do not specify a file name, an XML file is saved in the directory that holds the deployment package.  |
| /medml [filename]     |  |
| /FullCsmf [filename]  | Extract the CSML from the deployment package.  |
|                       | <b>Note:</b> Optionally, you can specify a file name. If you do not specify a file name, a CSML file is saved in the directory that holds the deployment package.  |
| /InFormCsmf           | Extract the CSML that was deployed to InForm.  |
| /RuleAssembly         | Extract the rule assembly and all function DLL files.  |
| or                    | <b>Note:</b> Optionally, you can specify a directory in which to store the files. If you do not specify a directory, a rule directory is created in the directory that holds the deployment package, and all extracted files are saved in the directory. |
| /rule [directoryname] |  |
| /DesignerUnit         | Export the units file.   |
| or                    | <b>Note:</b> Optionally, you can specify a directory in which to store the file. If you do not specify a directory, the file is saved in the directory that holds the deployment package.  |
| /unit [directoryname] |  |

| Option                                   | Description   |
|--|---|
| /CustomProperties                        | Extract the custom properties.  |
| or                                       |   |
| /CP                                      |   |
| /Target targetid<br>[foldername]         | Extract the CSML to the specified folder.   |
| /TargetList                              | Target applications for the deployment package.   |
| /Version                                 | Obtain the release number of the Central Designer application from which the deployment package was created.  |
| or                                       |   |
| /ver                                     |   |
| /silent                                  | Run in silent mode (without prompting for user input), using the options specified either on the command line or in the configuration file named in the /ConfigFile option.   |
| /ConfigFile <i>filename</i>              | Use the specified configuration file to obtain deployment options.  |
| /LogFileName <i>filename</i>             | Create a log file in the specified location. By default, a log file called StudyInstaller.log is created in the InForm installation folder.   |
| /UnpackDirectory<br><i>directoryname</i> | <p>Unzip the deployment package in the specified local directory. Deployment files include:</p> <ul style="list-style-type: none"> <li>• Deployment package.</li> <li>• Deployment DLLs.</li> <li>• MedML.xml file containing the MedML generated by the deployment process if the deployment is unsuccessful.</li> </ul> <p>If you do not specify this option, the files are unzipped to a temporary system directory. The StudyInstaller.log file includes the location of the deployment files.</p>  |
| /ForceBASEInstall<br>(TRUE   FALSE)      | <ul style="list-style-type: none"> <li>• <b>TRUE</b>—Clear the study database, if the study exists, and install the Base study.</li> <li>• <b>FALSE</b>—(Default) Do not force the Base study to be installed.</li> </ul>   |
| /CheckInFormVersion<br>(TRUE   FALSE)    | <ul style="list-style-type: none"> <li>• <b>TRUE</b>—(Default) Check the InForm version to make sure that it is compatible with the current version of the Central Designer application. If the software versions are not compatible, deployment does not continue.</li> <li>• <b>FALSE</b>—Do not check the InForm version to make sure that it is compatible with the current version of the Central Designer application. You might select this option if you are running deployment with the /testconversion option, which does not install the study MedML.</li> </ul> |

| Option                                    | Description   |
|---|---|
| /DontExitIfUnsuccessful<br>(TRUE   FALSE) | <ul style="list-style-type: none"> <li>• <b>TRUE</b>—Keep the Deployment Wizard open if the deployment is unsuccessful.</li> <li>• <b>FALSE</b>—(Default) Close the Deployment Wizard if the deployment is unsuccessful.</li> </ul>   |
|   | The following values are required if you run deployment in silent mode; otherwise, they are optional. If you specify any of the following command-line options and do not run in silent mode, the corresponding fields in the Deployment Wizard are populated with the values you specify.  |
| /Server <i>ServerName</i>                 | Name of the InForm application server.  |
| /Trial <i>TrialName</i>                   | Name of the InForm study.   |
| /User <i>UserName</i>                     | Oracle user name for the study database.  |
| /Password <i>UserPassword</i>             | Oracle password for the study database.   |
| /Strict (TRUE   FALSE)                    | <ul style="list-style-type: none"> <li>• <b>TRUE</b>—Only complete MedML definitions of study components can be loaded into the study; an incomplete definition causes the installation to fail.</li> <li>• <b>FALSE</b>—Incomplete study component definitions are permitted.</li> </ul>   |
| /TrialCreateModeValue<br>(DB   DSN)       | <ul style="list-style-type: none"> <li>• <b>DB</b>—The deployment process creates an ODBC connection for the study to the specified database instance. When you specify this option, include the connection string to the database instance in the /Connect option.</li> <li>• <b>DSN</b>—The study uses an existing ODBC connection. When you specify this option, include the name of the study DSN in the /TRIDSN option.</li> </ul> |
| /Connect<br><i>DatabaseConnectString</i>  | Connection string for the Oracle instance.  |
| /TRIDSN <i>DSNString</i>                  | ODBC System DSN for the InForm study.   |
| /ServerAutoStartup                        | The InForm server starts automatically when the InForm Service starts. If you do not include the /ServerAutoStartup option, the InForm server must be started manually.   |
| /TrialAutoStartup                         | The InForm study starts automatically when the InForm Service starts. If you do not include the /TrialAutoStartup option, the InForm study must be started manually.  |
| /DeploymentStartDelay                     | Time to wait (in milliseconds) for the InForm caches to initialize before deploying.  |
| /IPRServer <i>ServerName</i>              | Name of the InForm server to which to apply in-place revisions.   |

## Deployment ConfigFile options

As an alternative to entering deployment options at the command line or in a script, you can include the options for executing a deployment package in a configuration file referenced by the /ConfigFile command-line option. The configuration file is in XML format.

| Option                           | Description   |
|----------------------------------|---|
| <DeploymentData>                 | xmlns:xsd="http://www.w3.org/2001/XMLSchema"<br>xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"<br>xmlns="http://www.phaseforward.com/DeploymentData/2006-04-25"  |
| <HostName />                     | Reserved for future use.  |
| <HostUserName />                 |   |
| <HostUserPassword />             |   |
| <HostSharedDirectory />          |   |
| <HostSharedDirectoryLocalPath /> |   |
| <TargetType/>                    | INFORM  |
| <ServerName/>                    | Name of the InForm application server.  |
| <TrialName/>                     | Name of the InForm study.   |
| <UserName/>                      | Oracle user name for the study database.  |
| <UserPassword/>                  | Oracle password for the study database.   |
| <StrictMode/>                    | <ul style="list-style-type: none"> <li>• <b>TRUE</b>—Only complete MedML definitions of study components can be loaded into the study; an incomplete definition causes the installation to fail.</li> <li>• <b>FALSE</b>—Incomplete study component definitions are permitted.</li> </ul>   |
| <TrialMode/>                     | <ul style="list-style-type: none"> <li>• <b>DB</b>—The deployment process creates an ODBC connection for the study to the specified database instance. When you specify this option, include the connection string to the database instance in the &lt;DatabaseConnectionString/&gt; option.</li> <li>• <b>DSN</b>—The study uses an existing ODBC connection. When you specify this option, include the name of the trial DSN in the &lt;TRIDSN /&gt; option.</li> </ul> |
| <TRIDSN />                       | ODBC System DSN for the InForm study.   |
| <DatabaseConnectionString/>      | Connection string for the Oracle instance.  |
| <TrialStartupMode/>              | <ul style="list-style-type: none"> <li>• <b>Automatic</b>—The InForm study starts automatically when the InForm Service starts.</li> <li>• <b>Manual</b>—The InForm study must be started manually.</li> </ul>  |

| Option                   | Description   |
|--------------------------|---|
| <ServerStartupMode/>     | <ul style="list-style-type: none"> <li>• <b>Automatic</b>—The InForm server starts automatically when the InForm Service starts.</li> <li>• <b>Manual</b>—The InForm server must be started manually.</li> </ul>  |
| <ForceBASEInstall/>      | <ul style="list-style-type: none"> <li>• <b>TRUE</b>—Clear the study database, if the study exists, and install the Base study.</li> <li>• <b>FALSE</b>—(Default) Do not force the Base study to be installed.</li> </ul>   |
| <CheckInFormVersion/>    | <ul style="list-style-type: none"> <li>• <b>TRUE</b>—(Default) Check the InForm version to make sure that it is compatible with the current version of the Central Designer application. If the software versions are not compatible, deployment does not continue.</li> <li>• <b>FALSE</b>—Do not check the InForm version to make sure that it is compatible with the current version of the Central Designer application. You might select this option if you are running deployment with the /testconversion option, which does not install the study MedML.</li> </ul> |
| <ProtocolName />         | Reserved for future use.  |
| <ProtocolUserName />     |   |
| <ProtocolUserPassword /> |   |
| <DBAdminUser />          |   |
| <DBAdminUserPassword />  |   |
| <DataSpace />            |   |
| <TableSpace />           |   |
| <UNCHelpDirectory />     |   |
| <VirtualHelpDirectory /> |   |
| <WebPath />              |   |
| <SSL/>                   |   |

## Sample deployment configuration file

```
<DeploymentData xmlns:xsd="http://www.w3.org/2001/XMLSchema"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns="http://www.phaseforward.com/DeploymentData/2006-04-25">
  <HostName />
  <HostUserName />
  <HostUserPassword />
  <HostSharedDirectory />
  <HostSharedDirectoryLocalPath />
  <TargetType>INFORM</TargetType>
  <ServerName>INF916</ServerName>
  <TrialName>ASM916</TrialName>
  <UserName>ASM916uid</UserName>
  <UserPassword>ASM916pid</UserPassword>
  <StrictMode>>false</StrictMode>
  <TrialMode>DB</TrialMode>
  <TRIDSN />
  <DatabaseConnectionString>APPSRV_dev1</DatabaseConnectionString>
  <TrialStartupMode>Manual</TrialStartupMode>
  <ServerStartupMode>Manual</ServerStartupMode>
  <ForceBASEInstall>>false</ForceBASEInstall>
  <CheckInFormVersion>>true</CheckInFormVersion>
  <ProtocolName />
  <ProtocolUserName />
  <ProtocolUserPassword />
  <DBAdminUser />
  <DBAdminUserPassword />
  <DataSpace />
  <TableSpace />
  <UNCHelpDirectory />
  <VirtualHelpDirectory />
  <WebPath />
  <SSL>>false</SSL>
</DeploymentData>
```



## CHAPTER 8

# Performing post-design activities

### In this chapter

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| Archiving and decommissioning a study.....      | 308 |
| Generating reports.....                         | 316 |
| Generating an Annotated Study Book .....        | 326 |

# Protecting and unprotecting study objects

## About protecting study objects

When a study or library is protected, changes cannot be made to study objects or to the structure of the study or library.

| In a protected study, you cannot do the following  | In a protected study, you can do the following   |
|--|--|
| <ul style="list-style-type: none"> <li>• Update a protected study object.</li> <li>• Explicitly or implicitly lock a protected study object.</li> <li>• Drag and drop a study object onto a protected study object.</li> <li>• Paste a study object onto a protected study object.</li> <li>• Delete a study object that is the direct child of a protected study object.</li> </ul> | <ul style="list-style-type: none"> <li>• Validate, create, and delete baselines.</li> <li>• Create and delete deployment packages.</li> <li>• Add or copy and paste a study object into a container in the flat view.</li> <li>• Copy and paste a protected study object onto an unprotected study object. The protected study object remains protected.</li> <li>• Delete a study object that is not the direct child of a protected study object.</li> </ul> |

**Note:** If a protected rule references a study object for which the RefName is modified, the rule is updated with the new RefName.

When a study object is protected, its icon changes to reflect its protected state.

For each study object, you can:

- **Protect**—Protect the selected study object and all its children regardless of their origin, including study objects that you copied into the study or library from another project.

**Note:** You cannot delete study objects that are the direct children of a protected study object.

**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.

- **Unprotect**—Unprotect only the selected study object. You can unprotect a study object that came from a library only if you have the **Unprotect study objects from libraries** right.
- **Unprotect with children**—Unprotect the selected study object and all of its children.

The way that children are unprotected depends upon the location in which you are working.

- **In a study:**
  - If the study object that you are unprotecting with children was copied from a library, the study object and all of its children are unprotected as long as you have the **Unprotect study objects from libraries** right.

- If the study object that you are unprotecting with children was created in the study and you copied one or more of its children from a library, the study object is unprotected, but any children copied from the library are not unprotected. You can unprotect them individually if you have the **Unprotect study objects from libraries** right.
- **In a library:**
  - The study object and all of its children are unprotected, regardless of whether or not any of the children were copied from a library or study as long as you have the **Unprotect study objects in libraries** right. If you do not have this right, the parent and children remain protected.

**Note:** You are not prompted or required to save after you protect or unprotect a study object. Protecting and unprotecting does not change the study object.

You cannot protect the following areas:

- The Study and Library Editors.
- The Jobs Browser.
- The Baselines Browser.

**Note:** After you protect a study object, you cannot select undo, but you can select unprotect.

## Protecting and unprotecting a study or study object

You are not prompted or required to save after you protect or unprotect a study object. Protecting and unprotecting does not change the study object.

### To protect a study or study object:

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

If the study object or any of its children are shared within the current study, the Protect dialog box appears. The Protect dialog box displays the shared objects, parent study objects, and the type of study object.

**Note:** The Protect dialog box does not appear if you protect an entire study.

- 2 Click **Yes** to proceed.

The selected study or study object and all of its children are protected.

The icons to the left of the study or study object and all of its children change to reflect a protected state.

Study objects that came from a library are also protected.

**Note:** After you protect a study object, you cannot undo, but you can unprotect the study object.

**To unprotect a study or study object:**

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

If the study object is shared within the current study, the Unprotect dialog box appears. The Unprotect dialog box displays the shared object, parent study objects, and the type of study object.

- 2 Click **Yes** to proceed.

The selected study or study object is unprotected, and all of its children remain protected.

The icon to the left of the study or study object changes to reflect an unprotected state.

**To unprotect a study or study object with children:**

- 1 In the Project Explorer, right-click a study or study object and select **Unprotect with Children**.

**Note: Unprotect with Children is available only if the selected study object has children.**

If the study object or any of its children are shared within the current study, the Unprotect dialog box appears. The Unprotect dialog box displays the shared objects, parent study objects, and the type of study object.

**Note: The Unprotect dialog box does not appear if you unprotect an entire study with children.**

- 2 Click **Yes** to proceed.

The way that children are unprotected depends upon the location in which you are working.

- **In a study:**

- If the study object that you are unprotecting with children was copied from a library, the study object and all of its children are unprotected as long as you have the **Unprotect study objects from libraries** right.
- If the study object that you are unprotecting with children was created in the study and you copied one or more of its children from a library, the study object is unprotected, but any children copied from the library are not unprotected. You can unprotect them individually if you have the **Unprotect study objects from libraries** right.

- **In a library:**

- The study object and all of its children are unprotected, regardless of whether or not any of the children were copied from a library or study as long as you have the **Unprotect study objects in libraries** right. If you do not have this right, the parent and children remain protected.

The icons to the left of the study or study object and all of its children change to reflect an unprotected state.

## 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.

# Archiving and decommissioning a study

## About decommissioning studies and projects

### Workflow for decommissioning studies and projects

Decommissioning is the process of archiving and deleting a study, study project, or library project.

| Workflow step   | More information  |
|---|---|
| 1 <i>Archive the study or project</i> (on page 313).  | <ul style="list-style-type: none"> <li>• <i>Information that is archived</i> (on page 309).</li> <li>• <i>About archiving</i> (on page 308).</li> </ul>   |
| 2 (Optional but highly recommended)<br>Make a full database backup.   |   |
| 3 <i>Delete the study or project</i> (on page 12, on page 313).   | <ul style="list-style-type: none"> <li>• <i>Information that is deleted when you delete a study or project</i> (on page 310).</li> <li>• <i>About deleting a study or project</i> (on page 309).</li> </ul> |
| 4 (If you need to modify a decommissioned study, study project, or library project)<br><i>Download and import an archived study or project</i> (on page 314). | <ul style="list-style-type: none"> <li>• <i>Information that is imported from an archive</i> (on page 311).</li> <li>• <i>About downloading and importing an archive</i> (on page 309).</li> </ul>          |
| 5 (Optional)<br><i>Delete an archived study or project from the database</i> (on page 315).   |   |

**Note:** You also can archive without deleting and delete without archiving.

### About archiving

Archiving and deleting allow you to decommission an entire study, study project, or library project, including all of its study objects. The archiving functionality is not intended to be your only backup mechanism. You should also schedule regular database backups.

An archive contains the components that reconstruct a study, study project, or library project. All archives are saved on the database server, and you can copy them to another location and delete them from the database.

The archive process locks the study or project, but not the study objects in it. Therefore, Oracle recommends that you schedule archive processes for a time when no one is using the application.

**Note:** You cannot delete or archive the System Library or its project.

## About deleting a study or project

Deleting an archive file decreases the size of the database by removing unwanted studies, study projects, and library projects.

Before you delete a study, study project, or library project, Oracle recommends that you perform a full database backup. You can also *archive the study or project* (on page 313).

When you download an archive file, you have the option of permanently deleting it from the database.

**Note:** You cannot delete or archive the System Library or its project.

## About downloading and importing an archive

You have the following options for importing an archive:

- Import an archived study into a study project.
- Import an archived study project or library project and create a new project.

You can import an archive into the database in which it was created or into another database. You cannot import an archived study, study project, or library project if it still exists in the target database—first you must *delete the existing study, study project, or library project* (on page 12, on page 313).

Before you can import an archived study or project, you must download it from the database. Optionally, you can delete the file from the database after downloading it.

## Information that is archived

| Component                     | Information that is saved in an archive  |
|-------------------------------|--|
| Attachments                   | Attachments on: <ul style="list-style-type: none"> <li>• The study or library.</li> <li>• The study project or library project.</li> </ul>   |
| Baselines                     | <ul style="list-style-type: none"> <li>• All baselines.</li> <li>• Most recent revision of any study objects that the most recent baseline does not contain.</li> </ul>  |
| Categorizations               | <ul style="list-style-type: none"> <li>• System and user keywords.</li> <li>• Automatically generated and manually generated categories.</li> <li>• The mappings that connect keywords and categories to study objects.</li> </ul> |
| Collaboration notes and tasks | All collaboration notes and tasks in the study, study project, or library project.   |
| Custom properties             | <ul style="list-style-type: none"> <li>• Custom properties and their corresponding keywords and categories.</li> <li>• Values of the custom properties.</li> </ul>   |

| Component   | Information that is saved in an archive   |
|---|---|
| Functions   | All functions in the study, study project, or library project.  |
| Study objects   | <ul style="list-style-type: none"> <li>All study objects, including their revisions and ancestry information that connects a study object to its parent and children.</li> <li>Information about whether a study object is a copy of another study object, as well as the study object from which it was copied.</li> <li>Information about whether a study object is published, including the revisions that were published.</li> </ul>                                |
| Teams   | <ul style="list-style-type: none"> <li>Teams in the study or library.</li> <li>Information about users in the team, such as user name, first name, and last name, but not the roles for the users.</li> </ul>   |
| Units   | The units file.   |
| Validation results (Studies only)   | Validation results for the most recent baseline only.   |
| Direct deployment records (for UAT and LIVE deployment type instances only) | <ul style="list-style-type: none"> <li>Information about deployment requests and approvals.</li> <li>Deployment packages.</li> <li>Information about users associated with the request, including the user who created the deployment package, the user who created the deployment request, the user who approved or rejected the request, and the users in the email distribution list for the request</li> <li>Deployment logs created for the deployment.</li> </ul> |

### Information that is deleted when you delete a study or project

| Component                     | Information that is deleted   |
|-------------------------------|---|
| Attachments                   | <p>Attachments on:</p> <ul style="list-style-type: none"> <li>The study or library.</li> <li>The study project or library project.</li> </ul> <p><b>Note:</b> Attachments are not deleted if they are referenced by study objects that are not deleted. For example, study objects are not deleted if they are shared with another library.</p> |
| Baselines                     | All baselines.  |
| Categorizations               | <p>The mappings that connect keywords and categories to study objects.</p> <p><b>Note:</b> The actual keywords and categories are not deleted.</p>  |
| Collaboration notes and tasks | All collaboration notes and tasks in the study, study project, or library project.  |



| Component                         | Information that is deleted  |
|-----------------------------------|--|
| Custom Properties                 | The mappings that connect custom properties and their hierarchy to study objects.<br><br><b>Note:</b> The actual custom properties are not deleted.  |
| Study objects                     | <ul style="list-style-type: none"> <li>All study objects, including their revisions.</li> </ul> <p><b>Note:</b> When the repository contains children or a parent of a deleted study object, the children and parent are connected.</p> <ul style="list-style-type: none"> <li>Information about whether a study object is a copy of another study object, as well as the study object from which it was copied.</li> <li>Information about whether a study object is published, including the revisions that were published.</li> </ul> |
| Teams                             | The teams in the study or library.<br><br><b>Note:</b> Users are not deleted from the Central Designer application, and their corresponding roles are not deleted from the Central Designer Administrator application.   |
| Validation results (Studies only) | All validation results.  |

## Information that is imported from an archive

| Component                     | Information that is imported   |
|-------------------------------|--|
| Attachments                   | Attachments on: <ul style="list-style-type: none"> <li>The study or library.</li> <li>The study project or library project.</li> </ul> Files with the same name are overwritten.   |
| Baselines                     | All baselines.   |
| Categorizations               | <ul style="list-style-type: none"> <li>System and user keywords.</li> <li>Automatically generated and manually generated categories.</li> <li>The mappings that connect keywords and categories to study objects.</li> </ul> <p><b>Note:</b> If categories or keywords already exist in the target database, they are not overwritten.</p> |
| Collaboration notes and tasks | All collaboration notes and tasks in the study, study project, or library project.   |
| Custom properties             | <ul style="list-style-type: none"> <li>Custom properties and their corresponding keywords and categories.</li> <li>Values of the custom properties.</li> </ul> <p><b>Note:</b> If custom properties with the same name and on the same study object already exist in the target database, they are not overwritten.</p>                    |

| Component                            | Information that is imported  |
|--------------------------------------|---|
| Functions                            | All functions in the study, study project, or library project.<br><b>Note:</b> Functions with the same file name in the target database are overwritten.  |
| Study objects                        | <ul style="list-style-type: none"> <li>All study objects are imported with their original identifiers. Archived study objects are re-inserted so the family tree is restored.</li> <li>Information about whether a study object is a copy of another study object, as well as the study object from which it was copied.</li> <li>Information about whether a study object is published, including the revisions that were published.</li> </ul> <p><b>Note:</b> The identifiers for study objects are maintained after an import. Linked study objects are overwritten in the target database only if the archive contains a newer revision of the study object.</p> |
| Validation results<br>(Studies only) | All validation results.   |

**Notes:**

- The units file is not imported. If you need to recover this file from an archive, contact Oracle Services.
- Users and teams are not imported. When study objects in the archive refer to a user that does not exist in the target database, **archiveimporter** is inserted for the user's name. For example, if the user JohnSmith modified a study object in the archive but does not exist in the database, the History Viewer lists **archiveimporter** in place of JohnSmith after the archive is imported.

## Decommissioning

Decommissioning is the process of archiving and deleting a study, study project, or library project.

Archiving and deleting allow you to decommission an entire study, study project, or library project, including all of its study objects.

**Note:** The archiving functionality is not intended to be your only backup mechanism. You should also schedule regular database backups.

## Archiving a study or project

You must save before archiving.

**Note:** You cannot delete or archive the System Library or its project.

**Note:** You cannot archive a study project if it contains hidden studies (studies for which you are not a team member).

- 1 Do one of the following:
  - For a study project, in the **Project Explorer**, select the **Study Information Explorer** bar.
  - For a library project, in the **Project Explorer**, select the **Library Information Explorer** bar.
- 2 Right-click the study project or library project, and select **Archive > Create Archive**.

**Note:** If a deployment to a LIVE or UAT deployment instance is scheduled or in progress, you must wait to archive until the deployment process is complete.

- 3 If you selected a study, specify whether you want to archive the study or the entire study project. Slide-up messages appear, indicating when the job begins and finishes.

## Viewing archived studies and projects

- 1 Open a study, study project, or library project.
- 2 In the Project Explorer, right-click a study, study project, or library project, and select **Archive > View Archives**.

The View Archives dialog box appears.

## Deleting a study or project

When you delete a study, study project, or library project, the contents are permanently removed from the database.

**Note:** You cannot delete or archive the System Library or its project.

**Note:** To delete a study deployed to a LIVE or UAT deployment instance, you must first archive the study. Do not delete the archive.

- 1 (Optional but highly recommended) Perform a full database backup.
- 2 (Optional) *Archive the study or project* (on page 313).
- 3 In the Project Explorer, right-click a study, study project, library, or library project, and select **Delete**.

A confirmation message appears.

The message indicates if the latest version of the selected study, or any of the studies or libraries in the selected project, has not been archived.

**Note:** You cannot delete a study project if it contains hidden studies (studies for which you are not a team member).

- 4 Click **Yes**.

You receive a message that recommends performing a full database backup before deleting.

- 5 Click **Yes**.

## Downloading and importing an archived study or project

You can import an archive into the database in which it was created or into another database. You cannot import an archived study, study project, or library project if it still exists in the target database—first you must *delete the existing study, study project, or library project* (on page 12, on page 313).

Before you can import an archived study or project, you must download it from the database. Optionally, you can delete the file from the database after downloading it.

### To download an archived study or project:

- 1 (Optional) Perform a full database backup.
- 2 In the Project Explorer, right-click a study, study project, or library project, and select **Archive > View Archives**.

The View Archives dialog box appears.

- 3 Select an archive, and click **Download**.

You are asked if you want to delete the archive after it is downloaded.

If you choose Yes, the archive file is permanently deleted from the database and cannot be recovered.

- 4 Click **Yes** to delete the archive from the database, or click **No** to leave the archive in the database.

The Save As dialog box appears.

- 5 Navigate to a location for saving the archive, modify the file name as necessary, and click **Save**.

If you chose to delete the file after downloading it, the file is removed from the list.

- 6 Click **Close**.

### To import an archived study or project:

- 1 Download the archive file from the database.
- 2 To import a study, open a study project. To import a study project or library project, close the project in which you are working.

- 3 Do one of the following:

- Right-click a study or study project, and select **Archive > Import Archive**.
- Right-click the library project, and select **Archive > Import Archive**.

The Import from Archive wizard appears.

- 4 Click **Next**.

The **File Location** page appears.

- 5 Click **Browse**, and navigate to and select the file to import.

The Archive Contents page appears.

- 6 Click **Next**.
- 7 Click **Finish**.

If you imported a study, the project is reloaded. If you imported a project, you can open it by selecting **File > Open**.

## Deleting an archived study or project from the database

Archives are stored on the database server until you delete them. Optionally, you can delete an archive when you download it. For more information, see *Downloading and importing an archived study or project* (on page 314).

**Note:** You cannot undo the deletion of an archived study or project from the database.

- 1 In the Project Explorer, right-click a study, study project, or library project, and select **Archive > View Archives**.

The View Archives dialog box appears.

- 2 Select one or more archives
- 3 Click **Delete**.

A confirmation dialog box appears.

- 4 Click **Yes**.

## Viewing errors associated with an archive

If errors occur during the creation of an archive, you can view the errors in the project's Jobs Browser.

If a project or study fails to import, you can view the errors in a study project that is created to show error messages.

- 1 Select **File > Open**.

The Open dialog box appears.

- 2 Select the **Import Archive Project Placeholder**, and click **Open**.

The project opens.

- 3 Open the **Jobs Browser**, where you can view the errors associated with the archive.

# Generating reports

## About reports

You can generate reports to check the progress of work for the following study objects:

- Studies.
- Libraries.
- All study objects in a library.

Reports provide information about study objects, such as:

- Study objects that have been copied from a library to a study and then modified and saved in either the study or library.
- Number of times a study object was copied to a study or library.
- Data-entry rule action/locale combinations in a study.
- RefName paths for all deployed items (InForm controls) in a study.

**Note:** You can open the Reports dialog box for all study objects. If no reports are available for the study object, *There are no reports for the selected object* appears in the drop-down list.

| Study object               | Report  | InForm-specific |
|----------------------------|---|-----------------|
| Studies                    | Data Entry Rule Actions Report.               | Yes             |
|                            | InForm RefName Report.                        | Yes             |
|                            | Library Objects Modified in the Study.        | No              |
|                            | Library Objects Modified in the Library.      | No              |
| Libraries                  | Number of Studies Containing Library Objects. | No              |
|                            | Library Objects Modified in Studies.          | No              |
| Study objects in a library | Studies Containing Selected Library Object.   | No              |

## Generating, saving, and printing a report

The View System that you select determines the reports that you can run.

For more information, see *About reports* (on page 316).

- 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 Select **Actions > Reports**.

or

Right-click the study object, and select **Reports**.

If the study contains unsaved objects, a dialog box appears, asking if you want to save the changes to you made to your study.

- 3 Click **Yes**.

The Reports dialog box appears.

- 4 From the **Reports** drop-down list, select a report, and click **Run Report**.

**Note:** You can open the Reports dialog box for all study objects. If no reports are available for the study object, *There are no reports for the selected object* appears in the drop-down list.

- 5 To save the report:

- a Click **Save As**.

The Save As dialog box appears.

- b Navigate to the location in which to save the report.

- c In the **File name** field, type the name of the report, and click **Save**.

The report is saved as a CSV file.

**Note:** The saved CSV file is UTF-8 encoded to accommodate international characters. You can open the saved file by double-clicking the file or selecting File > Open in the Microsoft Excel spreadsheet software.

- 6 To print the report, click **Print**.

**Note:** When you generate a report for a study that contains an invalid workflow, an error occurs, and the report cannot be run.

For more information, see *Invalid workflows* (on page 76).

## Data Entry Rule Actions report

The Data Entry Rule Actions report runs at the study level. The report lists each data-entry rule action/locale combination in a study. Each row in the report corresponds to a supported locale for a unique rule action. For example, if a data-entry rule has two actions and two supported locales, the report would display four rows for that rule. This report does not include data for workflow rules or global conditions. The selected study must have at least one defined locale in order for this report to run.

The report displays each rule only once, regardless of the number of times that the study object on which it exists is used in a study. For example, a rule that is defined on an item that appears on more than one form appears once in the report.

**Note:** This report contains InForm-specific study objects and is not available for studies that do not have InForm selected as one of the Deployment Systems or contain only non-InForm study objects. When you generate a report for a study that contains an invalid workflow, an error occurs, and the report cannot be run.

Running this report should not be considered a substitute for validation. Errors (or lack thereof) encountered while generating this report are not necessarily a reflection of study validity.

**Note:** This report runs against data in the database. Oracle recommends that you save the study before running the report.

| Field             | Description  |   |
|-------------------|--|---|
| Action Expression | For SetValue expressions: The expression that you create in the SetValue Action box.<br><br>For Update Workflow actions: UpdateWorkflow(). |   |
| Action Type       | Type of action, such as Query or SetValue, that occurs upon evaluation of the rule expression.   |   |
| Email Sender      | (Applicable for Email actions only.)   |   |
| Email Recipient   | The following information about the email that is sent upon evaluation of the rule expression:   |   |
| Email Subject     |  |   |
| Email Body        |  | <ul style="list-style-type: none"> <li>• Sender's email address</li> <li>• Recipient's email address</li> <li>• Subject</li> <li>• Body text</li> </ul> |
| Error Message(s)  |  | Description of the error(s) encountered while gathering data for the data-entry rule action/locale combination represented in this row.                 |



| Field                 | Description   |
|-----------------------|---|
| Error status icon     | Indicates whether an error was encountered while gathering data for the data-entry rule action/locale combination represented in this row. <ul style="list-style-type: none"> <li>• A red circle with an X indicates that an error occurred.</li> <li>• A green circle with a checkmark indicates that no error occurred.</li> </ul>      |
| Locale                | Locale in which translated text appears for the action.<br>Translated text appears in the following fields: <ul style="list-style-type: none"> <li>• Email Subject (if applicable)</li> <li>• Email Body (if applicable)</li> <li>• Query Text (if applicable)</li> <li>• Target Form Mnemonic</li> <li>• Target Item Question</li> </ul> |
| Query Status          | (Applicable for Query actions only.)  |
| Query Text            | Status and text of the query that is created upon evaluation of the rule expression.  |
| Rule Description      | Description for the data-entry rule.  |
| Rule Last Update User | Name of the user who most recently updated the data-entry rule.   |
| Rule Match            | Selection in the Rule Wizard > Actions > If the value is section. For example, Always.  |
| Rule Name             | Name of the data-entry rule.  |
| Rule Revision         | Revision number of the data-entry rule.   |
| Rule Status           | Status of the data-entry rule; either Enabled or Disabled.  |
| Rule Switch           | Expression for the data-entry rule.   |
| Rule Timestamp        | Date and time when the data-entry rule was most recently updated.   |
| Rule Trigger          | Event that causes the rule to run; either FormSubmission or OnDemand.   |
| Rule Type             | Type of rule; either Intrinsic (for a rule created based on a rule template) or Expression (for a calculation or constraint rule).  |
| Study Object RefName  | The following information about the study object on which the data-entry rule exists:   |
| Study Object Title    |   |
| Study Object Type     | <ul style="list-style-type: none"> <li>• RefName.</li> <li>• Title.</li> <li>• Type.</li> </ul>   |
| Target Form Mnemonic  | Short title and RefName of the form on which the item that is the target of the rule action exists.   |
| Target Form RefName   | <p><b>Note:</b> If the item is used on multiple forms in the study, the mnemonics and RefNames for the forms are listed and separated by semicolons.</p>  |

| Field                | Description  |
|----------------------|--|
| Target Item Number   | Number, question, RefName, and title of the item that is the target of the rule action. For example:   |
| Target Item Question |  |
| Target Item RefName  | <ul style="list-style-type: none"> <li>For Query actions, the item on which the query appears.</li> </ul>  |
| Target Item Title    | <ul style="list-style-type: none"> <li>For Email actions, the item to which the email action is attached. You select this item in the Email Action dialog box, in the Item field.</li> <li>For SetValue actions, the item for which a value is set.</li> </ul> <p>This information does not apply to UpdateWorkflow actions.</p> <p><b>Note:</b> If the item is used on multiple forms in the study, the item numbers for the forms are listed and separated by semicolons.</p> <p><b>Note:</b> When an item appears on only one form and is in a repeating section, therefore ending in zero, such as <b>2.10</b>, the number in the Target Item Number column is enclosed in single brackets, such as <b>'2.10'</b>.</p> |

## InForm RefName report

The InForm RefName report runs at the study level. The report lists the full InForm RefName paths of all items (InForm controls) for a study. The selected study must have at least one defined locale in order for this report to run.

The InForm RefName Report includes:

- One item per row.
- Items in the study design.
- Items that hold data. For example, the RefName for a compound item without child controls does not appear in the report.
- Up to five levels of nested items.

**Note:** This report contains InForm-specific study objects and is not available for studies that do not have InForm selected as one of the Deployment Systems or contain only non-InForm study objects. When you generate a report for a study that contains an invalid workflow, an error occurs, and the report cannot be run.

The report does not process items on non-clinical forms, such as Regulatory Document and Visit Report forms.

**Note:** This report runs against data in the database. Oracle recommends that you save the study before running the report.

| Field               | Description  |
|---------------------|--|
| Control 1 RefName   | RefName of the item.   |
| Control 2-5 RefName | <p>RefNames of the items that are conditional on the item or that are children of the compound item.</p> <p>For a codelist item that contains multiple conditional items, a control is created to contain the conditional items. The control name includes the RefName of the codelist item, which is:</p> <ul style="list-style-type: none"> <li>• Prefixed with GC_.</li> <li>• Appended with the numerical position of the codelist item in the codelist.</li> </ul> <p>For example, if the Medication item has three codelist items with two items that are conditional on the third codelist item, the following control is created to contain the items that are conditional on the third codelist item:</p> <p>GC_Medication3</p> |
| Error Message(s)    | The error that occurred while the report processed the data for the item.  |
| Error status icon   | <p>Indicates whether an error occurred while the report processed the data for the item.</p> <ul style="list-style-type: none"> <li>• A red circle with an X indicates that an error occurred.</li> <li>• A green circle with a checkmark indicates that no error occurred.</li> </ul>   |
| Form RefName        | RefName of the form on which the item exists.  |
| Item RefName        | RefName of the item.   |
| Itemset RefName     | <p>RefName of the repeating section on which the item exists.</p> <p>If the item is not on a repeating section, this field is blank.</p>   |
| Section RefName     | <p>RefName of the section in which the item exists.</p> <p>If a section is not defined, the Form RefName for the item appears in this field.</p>   |
| Visit RefName       | <p>RefName of the study event in which the item exists.</p> <p>If the form on which the item study object is located is a common form, CommonCRF appears in this field.</p>  |

## Library Objects Modified in the Study report

### Level at which the report runs

The report runs at the study level.

### Description

The report lists study objects (when they exist) that were copied from a library to the study and then modified and saved in the study. For a copied study object to appear in the report, it must be saved before it was modified. Similarly, if you copy the study object, modify it without saving it, and then save it, the study object does not appear in the report.

### Purpose

If all study objects in the library have been fully tested, use the report to identify study objects that might require further testing as part of the test plan.

Additionally, you can use the report to monitor whether designers are adhering to library standards for a particular study.

### Fields

| Field                  | Description                                 |
|------------------------|---|
| Study Object Title     | Title of the study object in the study.     |
| Study Object RefName   | RefName of the study object in the study.   |
| Library Object Title   | Title of the study object in the library.   |
| Library Object RefName | RefName of the study object in the library. |

## Library Objects Modified in the Library report

### Level at which the report runs

The report runs at the study level.

### Description

The report lists study objects (when they exist) that were copied from a library to the study and then modified and saved in the library.

### Purpose

Use the report to identify the study objects that were modified in the library after being copied to a study, so you can determine if an update to the study object in the study is required, as well.

**Fields**

| Field                  | Description                                 |
|------------------------|---|
| Study Object Title     | Title of the study object in the study.     |
| Study Object RefName   | RefName of the study object in the study.   |
| Library Object Title   | Title of the study object in the library.   |
| Library Object RefName | RefName of the study object in the library. |

**Note:** It is possible for a study object to appear in the report if it has not been modified and saved in the study. For example, if a study object is linked in multiple libraries, copied to a study, and subsequently modified and saved in one of the libraries, the study object appears in the report.

**Number of Studies Containing Library Objects report****Level at which the report runs**

The report runs at the library level.

**Description**

The report lists:

- Study objects (when they exist) that were created in the library and copied into a study.
- The number of studies to which each study object was copied.

**Note:** Study objects that are marked as templates or types do not appear in the report.

**Purpose**

Use the report to determine the number of studies to which a study object has been copied from the library.

**Fields**

| Field                  | Description  |
|------------------------|--|
| Library Object Title   | Title of the study object in the library.            |
| Library Object RefName | RefName of the study object in the library.          |
| Number of Studies      | Number of studies in which the study object is used. |

**Note:** A study object copied into a single library two or more times is counted only once.

## Library Objects Modified in Studies report

### Level at which the report runs

The report runs at the library level.

### Description

The report lists:

- Study objects (when they exist) that were created in the library and copied into a study.
- The study to which each study object was copied.

**Note:** Study objects that are marked as templates or types do not appear in the report.

### Purpose

Use the report to identify how frequently a study object was modified after it was copied from a library to a study. Many updates to a study object might indicate that the study object needs to be updated in the library.

### Fields

| Field                  | Description  |
|------------------------|--|
| Library Object Title   | Title of the study object in the library.  |
| Library Object RefName | RefName of the study object in the library.  |
| Study Copied To        | Name of the study to which the study object was copied. A study object has a row for each study to which it is copied. |

## Studies Containing Selected Library Object report

### Level at which the report runs

The report runs in a library only for study elements, study events, forms, sections, items, codelists, codelist items, mappings, data sets, and data series.

### Description

The report lists the studies to which the study object has been copied from a library.

**Note:** Study objects that are marked as templates or types do not appear in the report.

**Purpose**

Use the report to identify the number of studies to which a study object has been copied. The usage of a study object might influence a decision to maintain a study object or remove it from the library.

Additionally, when you are considering changing a study object and propagating the change to the studies in which the study object is used, the report can help you determine the impact of the change.

**Fields**

| Field       | Description   |
|-------------|---|
| Study Title | Title of the study to which the selected study object was copied. |

# Generating an Annotated Study Book

## About Annotated Study Books

An Annotated Study Book is 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. Optionally, it includes a schedule of events, a preview of each form, and selected annotations that list design details. You can print an Annotated Study Book or save it to a PDF file and use it as a tool for reviewing the study design.

For details about how design information is displayed in an Annotated Study Book, see:

- *Annotated Study Book Options dialog box* (on page 327).
- *Schedule of Events table in the Annotated Study Book* (on page 336).
- *RDE Analytics tables in the Annotated Study Book* (on page 333).

## Annotated study books, locales, and layouts

When you generate an annotated study book for a study that supports multiple locales, you specify the layout and locale to use. When you generate a deployment package, you specify the default layout locale for the deployment package. These settings are independent of each other.

- **Annotated Study Book**—When you specify a layout and generate an annotated study book, the annotated study book reflects the layout customizations that you have made for the layout.
- **Deployment package**—In InForm release 4.7 and later, a single study version contains the layout information for all locales in the study, and you specify a default layout locale, from which all layouts, regardless of locale, inherit customizations in the InForm application.

The site locale language in the InForm application determines the language in which forms appear.

For example, a study contains layouts for the French (France) and the English (United Kingdom) locales. Radio buttons are horizontal in the French (France) layout but are vertical in the England (United Kingdom) layout. If French (France) is the default layout locale, then all layout customizations for the France (French) layout, including the alignment of radio buttons, are deployed to the InForm application and appear for all users, regardless of their site locale. Therefore, if your site locale in the InForm application is English (United Kingdom), the forms appear in English but with the customizations that were made in the French (France) layout in the Central Designer application.





## Annotated Study Book Options dialog box

**Note:** Items with restricted values are marked with a star (★) in the Annotated Study Book.

| Option  | What appears in the annotated study book when you select the option   |
|---|---|
| Select Display Options section                  | <ul style="list-style-type: none"> <li>• <b>No Annotated Information</b>—Form previews without annotations.</li> <li>• <b>Selected Annotated Information</b>—Only the selected annotation information. If you choose <b>Selected Annotated Information</b>, select the specific information to include in the checkboxes that appear under that radio button.</li> <li>• <b>All Annotated Information</b>—All annotated information.</li> </ul>   |
| Time and Events Schedule                        | A listing of the Schedule of Events table.  |
| Forms   | Selected information about each form in the study.  |
| Inline CRF annotations                          | <ul style="list-style-type: none"> <li>• <b>If selected</b>—The annotations described below.</li> <li>• <b>If not selected</b>—Titles or RefNames that appear in square brackets.</li> </ul> <p>The annotated forms display RefNames if <b>Show Object RefNames</b> is selected and titles if <b>Show Object RefNames</b> is not selected.</p>  |
| Item formats                                    | <ul style="list-style-type: none"> <li>• <b>Text</b>—<b>A</b> plus maximum character length (for example, A128).</li> <li>• <b>Integer</b>—<b>N</b> plus maximum field length (for example, N3).</li> <li>• <b>Float</b>—Significant digits and decimal places. The decimal point is included as a character in the length of an item. For example, if the length of a float item is 5 and the precision is 0, the annotation appears as <b>xxxx</b>. (the decimal point appears).</li> </ul> |
| Captions on compound items                      | A caption for the parent item of a compound item appears with the alignment specified on the Layout tab.  |
| Hidden, ReadOnly, or Editable display overrides | The word <b>hidden</b> , <b>read-only</b> , or <b>editable</b> appears in square brackets below the item question.  |

| Option  | What appears in the annotated study book when you select the option   |
|---|---|
| Minimums and maximums for integer and float items         | <p>Specifications set in the <code>MinProperty</code>, <code>MinValue</code>, <code>MaxProperty</code>, and <code>MaxValue</code> item properties are represented as values and operators and listed along with the item format. For example, the notation is <code>2.0 &lt;= xx.xx &lt; 100.0</code> if:</p> <ul style="list-style-type: none"> <li>• <b>MinProperty</b>—<code>GREATERTHANEQUAL</code></li> <li>• <b>MinValue</b>—<code>2.0</code></li> <li>• <b>Float length</b>—<code>5</code></li> <li>• <b>Float precision</b>—<code>2</code></li> <li>• <b>MaxProperty</b>—<code>LESSTHAN</code></li> <li>• <b>MaxValue</b>—<code>100.0</code></li> </ul> |
| Date time items   | Required and unknown specifications appear in the date and time controls, and year ranges appear in parentheses following the controls.   |
| Required items  | An asterisk appears after the item number. In the grid view of fixed repeating sections, an asterisk appears in the column header for each required item.   |
| Items that require source verification                    | For an item in a form or non-repeating section, a check mark appears under the item number.   |
| Repeating sections that require source verification       | <p>A check mark appears in the following locations:</p> <ul style="list-style-type: none"> <li>• <b>For a repeating section</b>—Under the number in the repeating section header row.</li> <li>• <b>For a fixed repeating section</b>—Under the <code>#</code> symbol in the fixed-item section header.</li> </ul>  |
| Forms and items that are critical for source verification | <p>For an item in a form or non-repeating section, a check mark inside a circle appears under the item number.</p> <p>For a form, a check mark inside a circle appears to the right of the form name.</p> <p>Forms and items that are source-verification critical are also source-verification required, so these forms and items show only the check mark inside the circle and not an additional check mark denoting their source-verification required status.</p> <p>A footnote indicates that settings for critical source verification that are made in the InForm application override settings made in the Central Designer application.</p>           |
| Collapsible items   | <p>A collapsible item icon (☐) appears after the item <code>RefName</code>.</p> <p><b>Note:</b> In the InForm application, a collapsible item is called a dynamic control.</p>  |
| Key items   | A key icon appears under the item number.   |

| Option                             | What appears in the annotated study book when you select the option  |
|------------------------------------|--|
| Base units                         | A superscript b in square brackets appears to the right of the control for the base unit.  |
| Repeating forms and sections       | A summary item layout containing top-level items appears (for example, the children of compound items and conditional items do not appear), followed by a form layout.   |
| Fixed repeating sections           | <p>A fixed item icon () appears after the item number.</p> <p>The following views appear:</p> <ul style="list-style-type: none"> <li>• Grid view containing a column for each top-level item and, for each fixed item, a row for each combination of item and codelist items. Depending on the definitions that exist in the study, column headers show the short question in the specified locale, the long question in the specified locale, or an empty cell. <ul style="list-style-type: none"> <li>▪ For a hidden item, the text in the column header is grayed out.</li> <li>▪ The cell for a blank instance of a fixed or non-fixed item is grayed out and includes a blank icon (.</li> </ul> </li> <li>• Data entry preview containing controls for each fixed item.</li> </ul> |
| Associated forms                   | The name of the associated form, if it exists, appears at the bottom of the annotated form.  |
| Codelist Values and Tables         | <p>Annotations on forms for codelists that are formatted as radio or checkbox groups. The data type and value appears in square brackets and italic font to the left of each option (for example, <i>[N:1]</i> indicates an integer data type and a codelist item value of 1). Data types are:</p> <ul style="list-style-type: none"> <li>• A—Text</li> <li>• F—Float</li> <li>• N—Integer</li> </ul> <p>Additionally, the annotated study book includes tables that list the specifications of each codelist and codelist item along with the title or RefName of the item with which they are associated.</p> <p>The tables display RefNames if <b>Show Object RefNames</b> is selected and titles if <b>Show Object RefNames</b> is not selected.</p>   |
| Include All Codelist Control Types | <p>Available if Codelist Values and Tables is selected:</p> <ul style="list-style-type: none"> <li>• <b>If selected</b>—The codelist tables include all formats of codelists.</li> <li>• <b>If not selected</b>—The codelist tables include only codelists that are formatted as a drop-down list.</li> </ul>  |
| Study Object Description Tables    | <p>Tables that list the type (Form, Section, or Item), title or RefName, and description for each form, section, and item.</p> <p>The tables display RefNames if <b>Show Object RefNames</b> is selected and titles if <b>Show Object RefNames</b> is not selected.</p>  |

| Option                                    | What appears in the annotated study book when you select the option   |
|---|---|
| Only Show Properties With Values          | <p>Available if <b>Study Object Description Tables</b> is selected. If selected, the study object description tables list only study objects that have descriptions.</p> <p><b>Note:</b> If you select All Annotated Information, <b>Only Show Properties With Values</b> is not available.</p>   |
| Key Items Tables                          | <p>Tables that list the following information for items in a repeating form or section that are defined as key items for navigation assistance (repeating forms only) or to enforce data uniqueness:</p> <ul style="list-style-type: none"> <li>• Item name.</li> <li>• Uniqueness (None, Individual, or Group).</li> <li>• Order in which the items appear in the drop-down summary list of a repeating form.</li> </ul> <p>The tables display RefNames if <b>Show Object RefNames</b> is selected and titles if <b>Show Object RefNames</b> is not selected.</p>  |
| Coding Summary Tables                     | <p>Tables that list verbatim, dictionary, coding item, and context item data for each item on a form that is coded.</p> <p>The tables display RefNames if <b>Show Object RefNames</b> is selected and titles if <b>Show Object RefNames</b> is not selected.</p>  |
| <b>RDE Analytics Tables</b> (on page 333) | <p>Tables that display the titles or RefNames, database table column names, and database types that are generated in the InForm Reporting Database Extract (RDE) Analytics offering for each data entry object in a form. The format of each table column name consists of the RefName of the item or the RefName plus a suffix that depends on the type of item and the format of the data entry control.</p> <p>The Data Variable column of the RDE Analytics tables displays RefNames if <b>Show Object RefNames</b> is selected and displays titles if <b>Show Object RefNames</b> is not selected.</p> |
| Data Series Summary Tables                | <p>Tables that list the following information for each data series that has mappings for items contained in the form:</p> <ul style="list-style-type: none"> <li>• Item number, based on the order of the item in the form.</li> <li>• Item title or RefName, depending on whether <b>Show Object RefNames</b> is selected.</li> <li>• Mapping RefName.</li> <li>• Data set alias if available, otherwise RefName.</li> <li>• Data series alias if available, otherwise RefName.</li> <li>• Data series type.</li> </ul>  |

| Option                                      | What appears in the annotated study book when you select the option   |
|---|---|
| Display Forms in Workflow Order             | <ul style="list-style-type: none"> <li>• <b>If selected</b>—Forms appear in study workflow order, except that: <ul style="list-style-type: none"> <li>▪ Forms that occur in more than one study event are not duplicated.</li> <li>▪ Nonclinical forms (Regulatory Documents and Visit Reports) appear at the end of the listing.</li> </ul> </li> <li>• <b>If not selected</b>—Forms appear in alphabetical order.</li> </ul> <p><b>Note:</b> In the Time and Events Table, forms always appear in workflow order, regardless of the setting of the <b>Display Forms in Workflow Order</b> option.</p> |
| Display Hidden Items                        | <ul style="list-style-type: none"> <li>• <b>If selected</b>—Hidden items are included.</li> <li>• <b>If not selected</b>—Hidden items are not included. If a form contains one or more hidden items, the footer of the table indicates that hidden items on the table are not displayed.</li> </ul>   |
| InForm Special Properties Table             | <p>A table that lists the values of the InForm Special Visit, Special Form, and Special Item properties, along with the property type and the study objects to which the properties are assigned.</p> <p>If a special property has not been assigned to a study object, the table shows the value as Unassigned.</p>  |
| Personal/Protected Health Information Table | <p>A table that lists each item in the study for which the PHI custom property is set to True, along with the section (if the item exists in a section) and form on which the item exists.</p>  |
| Unit Conversions Table                      | <p>A table that lists the unit type and unit conversion formulas for items that have units and appear in one or more forms.</p>   |
| Review States Table                         | <p>A table that lists information about the review states defined for the study, along with information about the review stages defined for each review state. If a review state is not activated, only the review state header appears.</p> <p>If translations are missing for one of the product locales but present for the other, the locale for which translations have been defined appears in the table in the place of the other locale. An asterisk and footnote appear for translations that have been replaced in this manner.</p>   |
| In-place Revisions Summary Table            | <p>A table that lists the following information about the in-place revisions associated with a deployment instance:</p> <ul style="list-style-type: none"> <li>• Deployment instance to which the in-place revision applies.</li> <li>• RefName of the in-place revision study object.</li> <li>• Type of the revised study object.</li> <li>• Description of the change.</li> <li>• Study version to which the revision applies.</li> <li>• Path in the study hierarchy where the revised study object appears.</li> </ul>   |

| Option                                   | What appears in the annotated study book when you select the option   |
|--|---|
| Show Object RefNames                     | <ul style="list-style-type: none"> <li>• The annotated study book uses study object RefNames, rather than titles, to identify study objects. The following areas are affected:</li> <li>• The RefName for a form or section is appended to the form or section title that is displayed in the annotated form header. RefNames are enclosed in square brackets.</li> <li>• In annotated forms, items are identified with RefNames.</li> <li>• With the following exceptions, data tables that follow the annotated form use a column header of RefName instead of Title, and the column contains RefNames. <ul style="list-style-type: none"> <li>▪ The Time and Events table is not affected by this option.</li> <li>▪ The Data Series Summary Table always uses RefName to identify mappings and data sets, regardless of whether this option is selected.</li> </ul> </li> </ul> |
| <b>Select Cover Page Options section</b> | <p><b>Include Cover Page</b>—Cover page with the study design properties selected from the <b>Display the following in addition to the study title</b> list, along with the study design title.</p> <p>If you select a user-defined custom property, the property must have a value and be visible, or it does not appear on the cover page.</p> <p><b>Do Not Include Cover Page</b>—No cover page.</p> <p><b>Note:</b> The values of cover page options are set in the Properties Browser for the study design.</p>  |
| <b>Select Date Variable Format</b>       | Format of date time items in the annotated forms.   |

## RDE Analytics tables in the Annotated Study Book

RDE Analytics tables are listings of the column names that are generated when study data is extracted to the InForm reporting database.

| Field            | Description  |
|------------------|--|
| Data Variable    | Title of the item for which the column names are generated, or RefName if <b>Show Object RefNames</b> is selected in the Annotated Study Book Options dialog box.  |
| RD Column Name   | <p>Name of the column in the reporting database where the data will be inserted.</p> <ul style="list-style-type: none"> <li>Column names consist of the item RefName or the RefName concatenated with a suffix.</li> <li>All types of top-level items have a column with the suffix <code>_ND</code> to hold the reason that an item is not done or incomplete. The format of the other column names generated for an item depends on the type of item.</li> <li>For child items of compound items, the RefName of the parent and child items are concatenated before the suffix.</li> <li>If the RefName part of the generated column name exceeds 25 characters, an asterisk appears in front of the column name to indicate that it will not match the actual RDE output. A footnote explains the asterisk.</li> <li>If an item is used multiple times on a form, an asterisk appears in front of the column name to indicate that it might not match the actual RDE output. A footnote explains the asterisk.</li> </ul> <p>For more information, see <i>RD Column Name in RDE Analytics tables</i> (on page 334).</p> |
| Column Data Type | <p>Data type of the column.</p> <p><b>Note:</b> For each form, items that are outside of a section on a form and items that are in a nonrepeating section are included in a table. If a form contains a repeating section, each repeating section has its own table and the items in the repeating section are listed in the corresponding table for the repeating section.</p>  |

## RD Column Name in RDE Analytics tables

| RD Column Name   | Source of data   | Column data type  |
|--|--|---|
| <b>Text, integer, or float item without units:</b>                 |  |   |
| • <i>Item_RefName</i>  | Entered value  | VARCHAR2, NUMBER, or FLOAT, depending on the data type of the item. |
| • <i>Item_RefName_ND</i>   | Reason why an item is incomplete (Not Done, Not Applicable, or Unknown). | VARCHAR2  |
| <b>Integer or float item with units:</b>                           |  |   |
| • <i>Item_RefName</i>  | Entered value  | NUMBER or FLOAT   |
| • <i>Item_RefName_N</i>  | Normalized value   | NUMBER or FLOAT   |
| • <i>Item_RefName_U</i>  | Entered unit symbol  | VARCHAR2  |
| • <i>Item_RefName_NU</i>   | Normalized unit symbol   | VARCHAR2  |
| • <i>Item_RefName_ND</i>   | Reason why an item is incomplete (Not Done, Not Applicable, or Unknown). | VARCHAR2  |
| <b>Radio buttons or drop-down lists:</b>                           |  |   |
| • <i>Item_RefName</i>  | Label  | VARCHAR2  |
| • <i>Item_RefName_C</i>  | Coded value  | VARCHAR2, NUMBER, or FLOAT, depending on the data type of the item. |
| • <i>Item_RefName_ND</i>   | Reason why an item is incomplete (Not Done, Not Applicable, or Unknown). | VARCHAR2  |
| <b>Checkboxes</b>  |  |   |
| Two columns for each checkbox:                                     |  |   |
| • <i>RefName_of_parent_item - RefName_of_child_item_or_control</i> | Label of codelist item control in child item.                            | VARCHAR2  |
| • <i>RefName_of_parent_item - RefName_of_child_control_C</i>       | Coded value of codelist item control in child item.                      | VARCHAR2, NUMBER, or FLOAT, depending on the data type of the item. |



| RD Column Name   | Source of data  | Column data type                                |
|--|---|---|
| <b>Dates and times:</b>  |   |   |
| <ul style="list-style-type: none"> <li><i>Item_RefName</i></li> </ul>  | Valid, complete date time or complete date plus hours and minutes (A complete date time can include UNK or ND entries).   | DATE  |
| <ul style="list-style-type: none"> <li><i>Item_RefName_DTS</i></li> </ul>  | Date string   | VARCHAR2  |
| <ul style="list-style-type: none"> <li><i>Item_RefName_DTR</i></li> </ul>  | Appears when: <ul style="list-style-type: none"> <li>The <i>Item_RefName_DTS</i> column name appears for an item.</li> <li>and</li> <li>The value of any date part that appears is not required, or an unknown value is allowed for the date part.</li> </ul> | VARCHAR2  |
| <ul style="list-style-type: none"> <li><i>Item_RefName_TMS</i></li> </ul>  | Time string   | VARCHAR2  |
| <ul style="list-style-type: none"> <li><i>Item_RefName_TMR</i></li> </ul>  | Appears when: <ul style="list-style-type: none"> <li>The <i>Item_RefName_TMS</i> column appears for an item.</li> <li>and</li> <li>The value of any date part that appears is not required, or an unknown value is allowed for the date part.</li> </ul>      | VARCHAR2  |
| <ul style="list-style-type: none"> <li><i>Item_RefName_ND</i></li> </ul>   | Reason why an item is incomplete (Not Done, Not Applicable, or Unknown).  | VARCHAR2  |
| <b>Compound items (parent item):</b>   |   |   |
| <ul style="list-style-type: none"> <li><i>RefName_of_parent_item_ND</i></li> </ul>   | Reason why an item is incomplete (Not Done, Not Applicable, or Unknown).  | VARCHAR2  |
| <b>Compound items (child item):</b>  |   |   |
| <ul style="list-style-type: none"> <li><i>RefName_of_parent_item - RefName_of_child_item_Suffix</i></li> </ul> <p>One or more columns for each child item, based on the item type. The value of <i>Suffix</i> is based on the type of the child item or control, as described in this table.</p> | Based on the type of the child item or control.   | Based on the type of the child item or control. |

## Schedule of Events table in the Annotated Study Book

| Field             | Description  |
|-------------------|--|
| Element           | <p>If the study design uses study elements, they appear in the first row, and the study events in each study element are grouped under the study element columns.</p> <p><b>Note:</b> The study element name for the special Screening and Enrollment visits is System.</p>  |
| Assessment        | <p>Study events are listed in study workflow order, as they appear in the workflow editor for the study design or study element.</p> <p>The heading of each visit column shows the study event title, short title (in parentheses), and visit type (in square brackets).</p> <p>Visit types:</p> <ul style="list-style-type: none"> <li>• S—Scheduled</li> <li>• D—Dynamic</li> <li>• U—Unscheduled</li> <li>• R—Repeating</li> </ul>  |
| CRF               | Short title of each form, or blank if the ShortTitle property is not defined.  |
| Visit Start Hours | <p>The visit start hour appears for study events. The visit start hour is a calculated value based on the scheduling specified for the study workflow.</p> <p>The start hour for the special Screening and Enrollment visits is zero. If the first visit after the Screening and Enrollment visits is not scheduled in the study workflow, its start hour is also zero.</p>  |
| Forms             | <ul style="list-style-type: none"> <li>• Identified with their translated names in the language in which the annotated study book is generated. If the translated name is not specified, the form title appears. This form identifier also appears on each annotated form in the annotated study book.</li> <li>• Forms are listed in study workflow order, except that: <ul style="list-style-type: none"> <li>▪ Forms that occur in more than one visit are not duplicated.</li> <li>▪ If a study design includes a Regulatory Documents or Visit Report form, those forms appear in the form listing but do not appear in the Time and Events table.</li> </ul> </li> </ul> <p>A number in each visit column where the form appears indicates the order in which the form occurs in the visit.</p> <p>Special form types are indicated by a code that follows the form order number:</p> <ul style="list-style-type: none"> <li>• C—Common</li> <li>• DF—Dynamic</li> <li>• RF—Repeating</li> </ul> |
| Key               | Codes used for special types of forms and visits.  |

## Generating an Annotated Study Book

**Note:** In the Annotated Study Book and Form Preview window, if a row contains many components, the browser that displays the page might wrap text to fit all components onto the page. Consequently, for Asian languages, a wrapped text label might appear to have vertical orientation, with a single character on each line, because the browser wraps text on a word boundary, and a single character can represent a word. To compensate, you can make the question portion of the row smaller so the labels in the control section are wide enough not to wrap.

- 1 In the Project Explorer, select **Study Information**.
- 2 Select the study.
- 3 Select **File > Annotated Study Book Options**.  
The Annotated Study Book Options dialog box appears.
- 4 Select display and cover page options.
- 5 Click **OK**.
- 6 Select **File > View Annotated Study Book**.

If the deployment properties of the study include more than one locale or layout format, or the Annotated Study Book includes an In-place Revisions Summary Table and the study contains in-place revision objects with IPR configurations for one or more deployment instances, the View Annotated Study Book dialog box appears.

- 7 In the **Layout** and **Language** fields, select the name of the layout and a locale.

**Note:** The language setting that you specify when generating an Annotated Study Book and the locale setting that you specify when generating a deployment package for the InForm application are independent and can produce different results.

- 8 In the **Deployment instance** field, select the deployment instance for which to display the IPR Summary table.
- 9 Click **OK**.

When you generate an Annotated Study Book with a Schedule of Events table, and the study contains an invalid workflow, an error message appears in a dialog box and in the Schedule of Events table, and forms are listed in the Annotated Study Book in alphabetical order regardless of the selected order. When this occurs, the option to save the Schedule of Events table as a CSV file is disabled.

For more information, see:

- *Invalid workflows* (on page 76).
- *Annotated Study Book Options dialog box* (on page 327).

## Printing an annotated study book

- 1 *Generate an annotated study book* (on page 337).
- 2 In the Annotated Study Book window, click **Print**.  
The Print dialog box appears.
- 3 Specify printer options.
- 4 Click **Print**.

## Creating a PDF file for an annotated study book

**Note:** To generate a PDF file for an annotated study book, you need a PDF print driver such as Adobe Acrobat PDF Distiller or PDFcamp from verypdf.com, Inc.

- 1 *Generate an annotated study book* (on page 337).
- 2 In the Annotated Study Book window, click **Print**.  
The Print dialog box appears.
- 3 Select a print queue that is backed by a PDF print driver.
- 4 Optionally, to set preferences for PDF generation, select **Preferences**.  
The dialog box for the PDF print driver appears.
- 5 Specify preferences for PDF generation, and click **OK**.  
The Print to File dialog box appears.
- 6 Specify a file location, and click **OK**.

## Tips for printing an annotated study book or creating a PDF file

| Tip   | Steps  |
|---|--|
| In Microsoft Internet Explorer, activate printing of background images and colors. This ensures that background images used for some controls appear in the output. | <ol style="list-style-type: none"> <li>1 Open Microsoft Internet Explorer.</li> <li>2 Select <b>Tools &gt; Internet Options</b>.</li> <li>3 Select the <b>Advanced</b> tab, and scroll to the <b>Printing</b> options.</li> <li>4 Select <b>Print background colors and images</b>.</li> <li>5 Click <b>OK</b>.</li> </ol> |
| Do not print to file.   | <ol style="list-style-type: none"> <li>1 In an annotated study book, click <b>Print</b>.</li> <li>2 In the <b>Print</b> dialog box, do not select <b>Print to file</b>.</li> </ol>   |
| Do not download fonts.  | <ol style="list-style-type: none"> <li>1 In an annotated study book, click <b>Print</b>.</li> <li>2 In the <b>Print</b> dialog box, select a printer and click <b>Preferences</b>.</li> <li>3 Select <b>Do not send fonts to Adobe PDF</b>.</li> </ol>   |
| Print in Landscape mode.  | <ol style="list-style-type: none"> <li>1 In an annotated study book, click <b>Print</b>.</li> <li>2 In the <b>Print</b> dialog box, select a printer and click <b>Preferences</b>.</li> <li>3 In the Orientation section of the <b>Layout</b> tab, select <b>Landscape</b>.</li> </ol>                                     |

## Formatting dates on the Annotated Study Book for the Japanese locale

For studies developed in the Japanese locale, the long date format is used to format the dates (Generated Date and Sponsor Date) that appear on the cover page of the Annotated Study Book.

Optionally, you can customize the long date format in the following way:

- 1 Open the **Control Panel > Regional and Language Options**.
- 2 Click **Region and Language**.
- 3 In the **Format** drop-down list, select Japanese (Japan).
- 4 Click **Additional Settings**.

The Customize Format dialog box appears.

- 5 On the **Formulas** tab, in the **Long date format** drop-down list, select a formatting option.
- 6 Select the **Time** tab, and select a **Time format**.
- 7 Close the **Control Panel**.
- 8 Generate the Annotated Study Book for the Japanese locale.

The dates on the cover page match the configuration that you specified in the Control Panel.

## Exporting the Schedule of Events table to a CSV file

- 1 *Generate an Annotated Study Book* (on page 337).

When you generate an Annotated Study Book with a Schedule of Events table, and the study contains an invalid workflow, an error message appears in a dialog box and in the Schedule of Events table, and forms are listed in the Annotated Study Book in alphabetical order regardless of the selected order. When this occurs, the option to save the Schedule of Events table as a CSV file is disabled.

- 2 In the lower-left corner of the dialog box, click **Save Time & Events as**.

**Note:** This option appears only when Schedule of Events Table is selected in the Annotated Study Book Options dialog box.

The Save As dialog box appears.

- 3 Type a file name, and click **Save**.

The CSV file is different from the Schedule of Events table in the Annotated Study Book in the following ways:

- The titles of forms might contain HTML tags, such as `<b >` and `</b>`.
- The row for the study event appears in three rows instead of one.

## CHAPTER 9

# Making in-place study design revisions

### In this chapter

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## About in-place revisions

An in-place revision (IPR) allows you to make a study design change and apply it to existing study versions that were previously deployed to the InForm application. When you update a study by deploying a new study version, you can only modify forms that have not been started in the InForm application. However, the in-place revision feature allows you to modify an item on a form and deploy the changes to all instances of the form in a specified study version, including forms that were started or completed in that study version.

You create an in-place revision on a top-level item or a section by navigating to the layout view of a form that you select in the Visit Schedule Explorer bar. The annotated study book for a study optionally includes a listing of the in-place revisions created for a study.

**Note:** You must navigate to the form on which to make an in-place revision by selecting the Visit Schedule Explorer bar. You cannot perform an in-place revision if you access the form by selecting the Forms and Transactions Explorer bar.

Before you can make an in-place revision to a study, you must:

- Be assigned to a role with the Apply in-place revisions right. For more information, see the *Administrator Guide*.
- Be assigned to the study team for the study on which you are performing an in-place revision. For more information, see *Setting up study teams* (on page 14).
- Set up a deployment instance for the study. For more information, see *Setting up deployment instances* (on page 289).



## Overview of the in-place revision process

**Note:** You can only perform an in-place revision for a study that you deploy to InForm release 6.1 or later.

- 1 Edit the design of a top-level item or a section.
- 2 Mark the change as an in-place revision, and create an IPR configuration for the change. For more information, see *Marking a change as in-place revision* (on page 344).
- 3 Validate the study. A validation baseline is created. For more information, see *Validating a study and creating a baseline* (on page 264).
- 4 Create a deployment package from the validation baseline. For more information, see *Creating a deployment package* (on page 286).
- 5 Install the deployment package in the InForm study. For more information, see *Delivering a deployment package* (on page 276).

## Marking a change as an in-place revision

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

**Note:** You must navigate to the form on which to make an in-place revision by selecting the **Visit Schedule Explorer** bar. You cannot perform an in-place revision if you access the form by selecting the **Forms and Transactions Explorer** bar.

- 2 Select a form.
- 3 Select the **Layout** tab.
- 4 Select an item question or section header on which to apply the in-place revision.
  - To make an in-place revision change to an existing item in a non-repeating section, select the item question.
  - To make an in-place revision change to an existing item in a repeating section, select the section header.
  - To make an in-place revision change to add an item to a repeating or non-repeating section, select the section header.

- 5 Click the **IPR Configuration** button.

The IPR Configuration dialog box appears.

- 6 In the IPR Configuration dialog box, provide details about the in-place revision:
  - a Optionally, in the **Description of the change** field, type a description of the change.
  - b Click **Add**.

The Add Deployment Instance dialog box appears.


- c Select the deployment instance to associate with the in-place revision.

For more information, see *Setting up deployment instances* (on page 289).

- d Select the study version or versions to which to apply the change.
  - To retrieve the latest study version information from the InForm server, click **Refresh Versions**.

**Note:** Refreshing version information overwrites the current study version association.

- Optionally, to compare the form containing the revised study object with the same form from an existing InForm study version, click **View Differences**. For more information, see *Viewing the differences between two versions of a form* (on page 345).
- e Click **OK**.

An in-place revision study object is created. In the layout tab, the in-place revision icon  appears for the study object associated with the in-place revision.

For more information, see *IPR Configuration dialog box—Option descriptions* (on page 400).

## Viewing the differences between two versions of a form

When you create an in-place revision for a study object, the View Differences dialog box allows you to compare the latest version of the form containing the revised study object with the same form from an existing InForm study version.

If you do not use automated deployment to deploy your study, you are unable to use the View Differences dialog box without a successfully deployed baseline. In addition, if a successfully deployed baseline exists, if you perform an in-place revision change and apply the change manually, the differences that appear in the View Differences dialog box are not correct.

**Note:** If in-place revision changes are made to a study that was created in a Central Designer release prior to 2.1, you must continue to review the Annotated Study Book PDFs to see differences.

- 1 In the **IPR Configuration** dialog box, select a study version, and click **View Differences**.

The View Differences dialog box appears, and displays data for the first form and study version that appear in the Form and Preexisting version drop-down lists.

- 2 To view the differences between other form versions, enter the following:
  - In the **Form** drop-down list, select a form.
  - In the **Preexisting version** drop-down list, select a study version with which to compare the form.
  - If your study uses more than one locale, in the **Locale** drop-down list, select a locale.
- 3 Click **Show Differences**.

The two versions of the form appear in layout view at the top of the dialog box.

- New study objects are highlighted in green on the latest version of the form.
  - Deleted study objects are highlighted in red on the existing version of the form.
  - Modified study objects are highlighted in yellow on both versions of the form.
- 4 To view details about the differences, at the bottom of the dialog box, select a study object.
  - 5 To preview or print each version of the form individually, click the **Preview Form** button, and select an action from the drop-down list.

## Deploying an in-place revision

You apply an in-place revision by deploying a package that contains the revision into the InForm application. In the Create deployment package wizard, you can review the changes and you must confirm you understand the implications of making in-place revisions before you can create a deployment package that contains in-place revisions.

For more information, see:

- *Creating a deployment package* (on page 286).
- *Delivering a deployment package* (on page 276).

**Note:** After you deploy a study that contains an in-place revision change to a LIVE deployment instance, Oracle recommends that you remove all IPR configurations for the study. You can delete the IPR configurations manually using the IPR Summary Editor, or you can configure the Central Designer application to do so automatically. For more information, see the *Administrator Guide*.

# Managing in-place revisions

Use the IPR Summary Editor to manage in-place revisions for a study.

## To view in-place revision changes for a study:

**Note:** The annotated study book for a study optionally includes a listing of the in-place revisions created for a study.

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.

The In-place revision Summary editor appears. For more information, see *In Place Revision Summary Editor—Option descriptions* (on page 401).


## To delete the IPR configuration for an in-place revision:

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 Select an in-place revision, and click **Delete** .

## To edit the IPR configuration for an in-place revision:

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 Select an in-place revision, and click **Edit** .

The IPR Configuration dialog box appears.

5 Make the necessary changes, and click **OK**.

For more information, see *IPR Configuration dialog box—Option descriptions* (on page 400).

## To remove the association between a deployment instance and an in-place revision:

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 Select one or more in-place revision study objects for which to remove a deployment instance association.

- 5 Click **IPR Configurations**, and select **Remove**.  
The Remove IPR Configurations dialog box appears.
- 6 Select one or more deployment instances, and click **OK**.

**Note:** If you delete a deployment instance that is associated with an IPR configuration, and that IPR configuration is not associated with any other deployment instances, the Central Designer application deletes the IPR configuration from the study.

**To copy an IPR configuration from one deployment instance to another:**

You can copy an IPR Configuration from one deployment instance to another if the source and target deployment instances use the same study version number and contain the same path information for the study object on which you made an in-place revision change.

**Note:** You must manually ensure that this criteria is met, as the Central Designer application does not validate this information before you copy the IPR Configuration.

- 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 Select one or more in-place revision study objects for which to copy an IPR configuration.
- 5 Click **IPR Configurations**, and select **Copy**.  
The Copy IPR Configurations dialog box appears.
- 6 At the top of the dialog box, select the deployment instance from which to copy IPR configurations.
- 7 At the bottom of the dialog box, select one or more instances to which to copy the configurations.
- 8 Click **OK**.

**Note:** The Central Designer application overwrites IPR configurations that already exist for the deployment instance.

**To view a history of in-place revisions for a LIVE deployment instance:**

- 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 Click **History**.  
The IPR History dialog box appears.

- 5 At the top of the dialog box, select a baseline with successful deployments to a LIVE deployment instance, and click **Show IPRs**.

The in-place revision summary for the selected baseline appears at the bottom of the dialog box.

**Note:** IPR history appears only for in-place revisions applied through automated deployments.

- 6 To view the IPR configuration for an in-place revision, select the in-place revision and click **View Configuration**.

For more information, see the following:

- *IPR Summary Editor—Option descriptions* (on page 401).
- *View Differences dialog box—Option descriptions* (on page 402).
- *IPR History dialog box—Option descriptions* (on page 403).

## Copying and deleting study objects associated with in-place revisions

When you copy a study object, any in-place revision study objects associated with it are not copied. This rule also applies to child objects: when you copy a study object with children, the in-place revision study objects associated with the children are not copied.

However, when you delete a study object from a study, any in-place revision study objects associated with it are deleted. This rule also applies to child objects: when you delete a study object and choose to remove its children, if the operation removes the children from the study, the in-place revision study objects associated with the children are removed. A confirmation dialog box appears when you delete a study object associated with an in-place revision.

**Note:** When you delete an item, you can no longer apply an in-place revision change to it.



## Validation for in-place revisions

The following in-place revision changes cause validation warnings. If you make these changes using in-place revision, you must ensure that the changes do not result in data loss, do not compromise data integrity, and do not have regulatory impact.

- Reduce the length of an alphanumeric, numeric, or float study object.
- Reduce the minimum or maximum limit for a numeric or float study object.
- Remove an item for which data was entered in the InForm application.

**Note:** The Central Designer application does not check whether data has been entered for a study in the InForm application. Oracle recommends creating or using an existing manual process to determine whether data loss, data integrity or regulatory impact occurs.

- Modify the precision for a numeric or float study object.
- Modify a codelist label.
- Decrease the date range for a date control.
- Remove a date part such as hours or minutes from a date control.
- Modify item text to correct spelling or punctuation errors.
- Add an item to an existing section.

The following in-place revision changes cause validation errors. You cannot deploy your study successfully if you make these changes by performing an in-place revision.

- Remove a unit selection for an item.
- Modify a codelist selection value.
- Modify a fixed repeating section by doing the following:
  - Add an additional row.
  - Change a predefined value.
  - Remove a row.
  - Rearrange rows.
  - Change an existing item cell from non-blank to blank.
  - Change an existing item cell from blank to non-blank.
  - Add new items that have blank cells.
- Modify the structure of a control by adding a level of nesting or changing a radio control to a pulldown control.
- Remove a special item.



# APPENDIX A

## Option and property descriptions

### In this appendix

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
# Annotated Study Book

## Annotated Study Book Options dialog box

**Note:** Items with restricted values are marked with a star (★) in the Annotated Study Book.

| Option  | What appears in the annotated study book when you select the option   |
|---|---|
| Select Display Options section                  | <ul style="list-style-type: none"> <li>• <b>No Annotated Information</b>—Form previews without annotations.</li> <li>• <b>Selected Annotated Information</b>—Only the selected annotation information. If you choose <b>Selected Annotated Information</b>, select the specific information to include in the checkboxes that appear under that radio button.</li> <li>• <b>All Annotated Information</b>—All annotated information.</li> </ul>   |
| Time and Events Schedule                        | A listing of the Schedule of Events table.  |
| Forms   | Selected information about each form in the study.  |
| Inline CRF annotations                          | <ul style="list-style-type: none"> <li>• <b>If selected</b>—The annotations described below.</li> <li>• <b>If not selected</b>—Titles or RefNames that appear in square brackets.</li> </ul> <p>The annotated forms display RefNames if <b>Show Object RefNames</b> is selected and titles if <b>Show Object RefNames</b> is not selected.</p>  |
| Item formats                                    | <ul style="list-style-type: none"> <li>• <b>Text</b>—<b>A</b> plus maximum character length (for example, A128).</li> <li>• <b>Integer</b>—<b>N</b> plus maximum field length (for example, N3).</li> <li>• <b>Float</b>—Significant digits and decimal places. The decimal point is included as a character in the length of an item. For example, if the length of a float item is 5 and the precision is 0, the annotation appears as <b>xxxx.</b> (the decimal point appears).</li> </ul> |
| Captions on compound items                      | A caption for the parent item of a compound item appears with the alignment specified on the Layout tab.  |
| Hidden, ReadOnly, or Editable display overrides | The word <b>hidden</b> , <b>read-only</b> , or <b>editable</b> appears in square brackets below the item question.  |

| Option  | What appears in the annotated study book when you select the option   |
|---|---|
| Minimums and maximums for integer and float items         | <p>Specifications set in the <code>MinProperty</code>, <code>MinValue</code>, <code>MaxProperty</code>, and <code>MaxValue</code> item properties are represented as values and operators and listed along with the item format. For example, the notation is <code>2.0 &lt;= xx.xx &lt; 100.0</code> if:</p> <ul style="list-style-type: none"> <li>• <b>MinProperty</b>—<code>GREATERTHANEQUAL</code></li> <li>• <b>MinValue</b>—<code>2.0</code></li> <li>• <b>Float length</b>—<code>5</code></li> <li>• <b>Float precision</b>—<code>2</code></li> <li>• <b>MaxProperty</b>—<code>LESSTHAN</code></li> <li>• <b>MaxValue</b>—<code>100.0</code></li> </ul> |
| Date time items   | Required and unknown specifications appear in the date and time controls, and year ranges appear in parentheses following the controls.   |
| Required items  | An asterisk appears after the item number. In the grid view of fixed repeating sections, an asterisk appears in the column header for each required item.   |
| Items that require source verification                    | For an item in a form or non-repeating section, a check mark appears under the item number.   |
| Repeating sections that require source verification       | <p>A check mark appears in the following locations:</p> <ul style="list-style-type: none"> <li>• <b>For a repeating section</b>—Under the number in the repeating section header row.</li> <li>• <b>For a fixed repeating section</b>—Under the <code>#</code> symbol in the fixed-item section header.</li> </ul>  |
| Forms and items that are critical for source verification | <p>For an item in a form or non-repeating section, a check mark inside a circle appears under the item number.</p> <p>For a form, a check mark inside a circle appears to the right of the form name.</p> <p>Forms and items that are source-verification critical are also source-verification required, so these forms and items show only the check mark inside the circle and not an additional check mark denoting their source-verification required status.</p> <p>A footnote indicates that settings for critical source verification that are made in the InForm application override settings made in the Central Designer application.</p>           |
| Collapsible items   | <p>A collapsible item icon (☐) appears after the item <code>RefName</code>.</p> <p><b>Note:</b> In the InForm application, a collapsible item is called a dynamic control.</p>  |
| Key items   | A key icon appears under the item number.   |

| Option                             | What appears in the annotated study book when you select the option  |
|------------------------------------|--|
| Base units                         | A superscript b in square brackets appears to the right of the control for the base unit.  |
| Repeating forms and sections       | A summary item layout containing top-level items appears (for example, the children of compound items and conditional items do not appear), followed by a form layout.   |
| Fixed repeating sections           | <p>A fixed item icon () appears after the item number.</p> <p>The following views appear:</p> <ul style="list-style-type: none"> <li>• Grid view containing a column for each top-level item and, for each fixed item, a row for each combination of item and codelist items. Depending on the definitions that exist in the study, column headers show the short question in the specified locale, the long question in the specified locale, or an empty cell. <ul style="list-style-type: none"> <li>▪ For a hidden item, the text in the column header is grayed out.</li> <li>▪ The cell for a blank instance of a fixed or non-fixed item is grayed out and includes a blank icon (.</li> </ul> </li> <li>• Data entry preview containing controls for each fixed item.</li> </ul> |
| Associated forms                   | The name of the associated form, if it exists, appears at the bottom of the annotated form.  |
| Codelist Values and Tables         | <p>Annotations on forms for codelists that are formatted as radio or checkbox groups. The data type and value appears in square brackets and italic font to the left of each option (for example, <i>[N:1]</i> indicates an integer data type and a codelist item value of 1). Data types are:</p> <ul style="list-style-type: none"> <li>• A—Text</li> <li>• F—Float</li> <li>• N—Integer</li> </ul> <p>Additionally, the annotated study book includes tables that list the specifications of each codelist and codelist item along with the title or RefName of the item with which they are associated.</p> <p>The tables display RefNames if <b>Show Object RefNames</b> is selected and titles if <b>Show Object RefNames</b> is not selected.</p>   |
| Include All Codelist Control Types | <p>Available if Codelist Values and Tables is selected:</p> <ul style="list-style-type: none"> <li>• <b>If selected</b>—The codelist tables include all formats of codelists.</li> <li>• <b>If not selected</b>—The codelist tables include only codelists that are formatted as a drop-down list.</li> </ul>  |
| Study Object Description Tables    | <p>Tables that list the type (Form, Section, or Item), title or RefName, and description for each form, section, and item.</p> <p>The tables display RefNames if <b>Show Object RefNames</b> is selected and titles if <b>Show Object RefNames</b> is not selected.</p>  |

| Option                                    | What appears in the annotated study book when you select the option   |
|---|---|
| Only Show Properties With Values          | <p>Available if <b>Study Object Description Tables</b> is selected. If selected, the study object description tables list only study objects that have descriptions.</p> <p><b>Note:</b> If you select All Annotated Information, <b>Only Show Properties With Values</b> is not available.</p>   |
| Key Items Tables                          | <p>Tables that list the following information for items in a repeating form or section that are defined as key items for navigation assistance (repeating forms only) or to enforce data uniqueness:</p> <ul style="list-style-type: none"> <li>• Item name.</li> <li>• Uniqueness (None, Individual, or Group).</li> <li>• Order in which the items appear in the drop-down summary list of a repeating form.</li> </ul> <p>The tables display RefNames if <b>Show Object RefNames</b> is selected and titles if <b>Show Object RefNames</b> is not selected.</p>  |
| Coding Summary Tables                     | <p>Tables that list verbatim, dictionary, coding item, and context item data for each item on a form that is coded.</p> <p>The tables display RefNames if <b>Show Object RefNames</b> is selected and titles if <b>Show Object RefNames</b> is not selected.</p>  |
| <i>RDE Analytics Tables</i> (on page 333) | <p>Tables that display the titles or RefNames, database table column names, and database types that are generated in the InForm Reporting Database Extract (RDE) Analytics offering for each data entry object in a form. The format of each table column name consists of the RefName of the item or the RefName plus a suffix that depends on the type of item and the format of the data entry control.</p> <p>The Data Variable column of the RDE Analytics tables displays RefNames if <b>Show Object RefNames</b> is selected and displays titles if <b>Show Object RefNames</b> is not selected.</p> |
| Data Series Summary Tables                | <p>Tables that list the following information for each data series that has mappings for items contained in the form:</p> <ul style="list-style-type: none"> <li>• Item number, based on the order of the item in the form.</li> <li>• Item title or RefName, depending on whether <b>Show Object RefNames</b> is selected.</li> <li>• Mapping RefName.</li> <li>• Data set alias if available, otherwise RefName.</li> <li>• Data series alias if available, otherwise RefName.</li> <li>• Data series type.</li> </ul>  |

| Option                                      | What appears in the annotated study book when you select the option   |
|---|---|
| Display Forms in Workflow Order             | <ul style="list-style-type: none"> <li>• <b>If selected</b>—Forms appear in study workflow order, except that: <ul style="list-style-type: none"> <li>▪ Forms that occur in more than one study event are not duplicated.</li> <li>▪ Nonclinical forms (Regulatory Documents and Visit Reports) appear at the end of the listing.</li> </ul> </li> <li>• <b>If not selected</b>—Forms appear in alphabetical order.</li> </ul> <p><b>Note:</b> In the Time and Events Table, forms always appear in workflow order, regardless of the setting of the <b>Display Forms in Workflow Order</b> option.</p> |
| Display Hidden Items                        | <ul style="list-style-type: none"> <li>• <b>If selected</b>—Hidden items are included.</li> <li>• <b>If not selected</b>—Hidden items are not included. If a form contains one or more hidden items, the footer of the table indicates that hidden items on the table are not displayed.</li> </ul>   |
| InForm Special Properties Table             | <p>A table that lists the values of the InForm Special Visit, Special Form, and Special Item properties, along with the property type and the study objects to which the properties are assigned.</p> <p>If a special property has not been assigned to a study object, the table shows the value as Unassigned.</p>  |
| Personal/Protected Health Information Table | <p>A table that lists each item in the study for which the PHI custom property is set to True, along with the section (if the item exists in a section) and form on which the item exists.</p>  |
| Unit Conversions Table                      | <p>A table that lists the unit type and unit conversion formulas for items that have units and appear in one or more forms.</p>   |
| Review States Table                         | <p>A table that lists information about the review states defined for the study, along with information about the review stages defined for each review state. If a review state is not activated, only the review state header appears.</p> <p>If translations are missing for one of the product locales but present for the other, the locale for which translations have been defined appears in the table in the place of the other locale. An asterisk and footnote appear for translations that have been replaced in this manner.</p>   |
| In-place Revisions Summary Table            | <p>A table that lists the following information about the in-place revisions associated with a deployment instance:</p> <ul style="list-style-type: none"> <li>• Deployment instance to which the in-place revision applies.</li> <li>• RefName of the in-place revision study object.</li> <li>• Type of the revised study object.</li> <li>• Description of the change.</li> <li>• Study version to which the revision applies.</li> <li>• Path in the study hierarchy where the revised study object appears.</li> </ul>   |



| Option                                   | What appears in the annotated study book when you select the option   |
|--|---|
| Show Object RefNames                     | <ul style="list-style-type: none"> <li>• The annotated study book uses study object RefNames, rather than titles, to identify study objects. The following areas are affected:</li> <li>• The RefName for a form or section is appended to the form or section title that is displayed in the annotated form header. RefNames are enclosed in square brackets.</li> <li>• In annotated forms, items are identified with RefNames.</li> <li>• With the following exceptions, data tables that follow the annotated form use a column header of RefName instead of Title, and the column contains RefNames. <ul style="list-style-type: none"> <li>▪ The Time and Events table is not affected by this option.</li> <li>▪ The Data Series Summary Table always uses RefName to identify mappings and data sets, regardless of whether this option is selected.</li> </ul> </li> </ul> |
| <b>Select Cover Page Options section</b> | <p><b>Include Cover Page</b>—Cover page with the study design properties selected from the <b>Display the following in addition to the study title</b> list, along with the study design title.</p> <p>If you select a user-defined custom property, the property must have a value and be visible, or it does not appear on the cover page.</p> <p><b>Do Not Include Cover Page</b>—No cover page.</p> <p><b>Note:</b> The values of cover page options are set in the Properties Browser for the study design.</p>  |
| <b>Select Date Variable Format</b>       | Format of date time items in the annotated forms.   |




# Forms, items, codelists, and codelist items

## Codelists Editor—Option descriptions

### Columns common to all study object editors

All study object editors have the following columns.

**Note:** Not all fields appear in the default view. Optionally, you can *add the other fields and rearrange the browser view* (in the *User Guide*).

| Property                      | Description   |
|-------------------------------|---|
| Icon (first column)           | Status of the study object: <ul style="list-style-type: none"> <li>• —New.</li> <li>• —Locked.</li> <li>• —Protected. When a study object is protected, you cannot :               <ul style="list-style-type: none"> <li>▪ Update or lock it.</li> <li>▪ Add child study objects to it by pasting or dragging and dropping.</li> <li>▪ Delete its child study objects.</li> </ul> </li> </ul> |
| Description                   | Description of the study object. The description can have 0-255 characters.   |
| Identifier                    | Unique internal identifier of the study object.   |
| Published (only in libraries) | Indicates that the study object has been published.   |
| RefName                       | RefName of the study object. The RefName can have 1-63 characters.  |
| Revision                      | Revision number of the study object. The revision number is incremented each time the study object is changed and saved.  |
| Title                         | Title of the study object. The title can have 1-63 characters.  |
| Version                       | Version number of the study object. The version number is incremented only when a user explicitly updates it.   |

**Note:** Not all fields appear in the default view. Optionally, you can *add the other fields and rearrange the browser view* (in the *User Guide*).

| Option       | Description  |
|--------------|--|
| CodeListType | Data type of the codelist. The data type of a codelist must be compatible with the data type of any items in which it is included. |




**Note:** To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add *HTML formatting characters* (on page 244) to a text field to control its appearance when deployed.

## Codelist Items Editor—Option descriptions

### Columns common to all study object editors

All study object editors have the following columns.

**Note:** Not all fields appear in the default view. Optionally, you can *add the other fields and rearrange the browser view* (in the User Guide).

| Property                      | Description  |
|-------------------------------|--|
| Icon (first column)           | Status of the study object: <ul style="list-style-type: none"> <li>•  —New.</li> <li>•  —Locked.</li> <li>•  —Protected. When a study object is protected, you cannot : <ul style="list-style-type: none"> <li>▪ Update or lock it.</li> <li>▪ Add child study objects to it by pasting or dragging and dropping.</li> <li>▪ Delete its child study objects.</li> </ul> </li> </ul> |
| Description                   | Description of the study object. The description can have 0-255 characters.  |
| Identifier                    | Unique internal identifier of the study object.  |
| Published (only in libraries) | Indicates that the study object has been published.  |
| RefName                       | RefName of the study object. The RefName can have 1-63 characters.   |
| Revision                      | Revision number of the study object. The revision number is incremented each time the study object is changed and saved.   |
| Title                         | Title of the study object. The title can have 1-63 characters.   |
| Version                       | Version number of the study object. The version number is incremented only when a user explicitly updates it.  |

**Note:** Not all fields appear in the default view. Optionally, you can *add the other fields and rearrange the browser view* (in the User Guide).

| Option                       | Description  |
|------------------------------|--|
| Code                         | Code of the codelist item.   |
| CodeListType                 | Data type of the codelists in which the codelist item is included.   |
| Label                        | Label of the codelist item. The label can have 1-255 characters.   |
| Study Completion Status Item | Function of the codelist item in the codelist that is used in the special Completion status item of the Study Completion form: <ul style="list-style-type: none"> <li>• None—The codelist item is not part of the codelist in the Completion status item.</li> <li>• Complete Study (Study Completion).</li> <li>• Incomplete Study (Study Completion).</li> </ul> |

**Note:** To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add *HTML formatting characters* (on page 244) to a text field to control its appearance when deployed.

## Design tab of the Codelist Editor—Option descriptions

| Option                | Description   |
|-----------------------|---|
| Title (codelist)      | Title of the codelist. The title can have 1-63 characters.  |
| Description           | Description of the codelist.  |
| Data type             | Data type of the codelist; must be compatible with the values specified for codelist item codes: <ul style="list-style-type: none"> <li>• Float</li> <li>• Integer</li> <li>• String</li> </ul> |
| <b>Fields</b>         |   |
| Title (codelist item) | Title of the codelist item. The title can have 1-63 characters.   |
| Code                  | Value stored in the repository for the codelist item. The value can have 1-2000 characters.   |
| Label                 | Default label that appears on the form for the codelist item. The label can have 1-255 characters.  |
| Description           | Description of the codelist item. The description can have 0-255 characters.  |

**Note:** To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add *HTML formatting characters* (on page 244) to a text field to control its appearance when deployed.

## Design tab of the Form Editor or Section Editor—Option descriptions

| Option   | Description   |
|--|---|
| Repeating  | Indicates that the form or section is repeating. Multiple instances of the same set of data appear in the form or section.  |
| Common (forms only)  | Indicates that the form is common. The same data is visible in all study events that contain the form.  |
| Fixed (sections only)  | Indicates that the section is a fixed repeating section containing static text that repeats for each instance of the item.  |
| Keys (toolbar button and icon for repeating forms and sections only) | <ul style="list-style-type: none"> <li>For a repeating form with no sections, opens the Keys dialog box, in which you can define key items.</li> <li>For a form with one or more repeating sections, displays a drop-down list of repeating sections. Selecting a section opens the Keys dialog box, in which you can define key items.</li> </ul>  |
| <b>Fields</b>  |   |
| Codelist   | <p>Applies to text, float, and integer items only.</p> <p>Drop-down list with available codelists for the item. Available codelists are all of the codelists in the study or library with the same type as the item.</p>  |
| Conditional On   | Title of the item on which the current item is conditional. The drop-down list in this column contains items that contain a codelist. If the current item is conditional on one of the items in this column, the current item provides additional data about one of the options in the codelist. For more information, see <i>Conditional relationships between items</i> (on page 113).  |
| Conditional Value  | Code and label of the codelist item on which the current item is conditional.   |
| Data Label   |   |
| Description  | Description of the item. The description can have 0-255 characters.   |
| Display Override   |   |
| Item Properties  | Contains an <b>Edit</b> link, which you can click to open the Item Properties dialog box. If you navigate to the field using the Tab button, you can open the dialog box by pressing the spacebar.  |
| Item Required  | Indicates that the item is required.  |
| Key  | <p>For key items, displays icons and numbers that indicate:</p> <ul style="list-style-type: none"> <li>Type of key item uniqueness (None, Individual, or Group).</li> <li>Order of the items in the drop-down navigation list that appears in the summary view of a repeating form in the InForm application.</li> </ul> <p>In the InForm application, key items are used to make it easier to navigate among the instances of a repeating form and to enforce data uniqueness in specific items.</p> |

| Option        | Description  |
|---------------|--|
| Length        | Applies to text, float, and integer items only.<br>Length of the item.<br>Allowed values: <ul style="list-style-type: none"> <li>• Text items—1 to 2000.</li> <li>• Float items—1 to 18.</li> <li>• Integer items—1 to 10.</li> </ul>  |
| Locked        | Indicates that the item is locked.   |
| MaxProperty   | If a MaxValue is specified for the item, indicates whether the value can be less than or less than or equal to the MaxValue.   |
| MaxValue      | Maximum value that the InForm application will allow to be typed for the item.   |
| MinProperty   | If a MinValue is specified for the item, indicates whether the value can be greater than or greater than or equal to the MinValue.   |
| MinValue      | Minimum value that the InForm application will allow to be typed for the item.   |
| Modified      | Indicates that the item has been modified and has not yet been saved.  |
| New           | Indicates that the item is new and has not yet been saved.   |
| Protected     | Indicates that the item is protected.  |
| Question      | Default question for the item. This question appears on the form if no customized label or translation is defined for the item. The question can have 0-1000 characters. Certain words may be reserved for this field. For more information, see <i>Reserved words for an item question or short question</i> (on page 120).   |
| RefName       | RefName of the item.   |
| Revision      | Revision number of the study object.   |
| SDV Critical  | Indicates that the study object is considered critical for source verification. If you select SDV Critical, SDV Required becomes selected as well.   |
| SDV Required  | Indicates that the study object must be source verified in the InForm application.   |
| ShortQuestion | Text of a short version of the item question. In the InForm application, the short question appears as a column heading in a repeating form, an itemset, and in reports generated by the Reporting and Analysis application. The short question can have 0-255 characters. Certain words may be reserved for this field. For more information, see <i>Reserved words for an item question or short question</i> (on page 120). |

| Option         | Description  |
|----------------|--|
| Special Fields | <p>Type of special InForm field, or None, indicating that the item is not a special InForm field. Available special fields, along with the forms in which they appear, are:</p> <ul style="list-style-type: none"> <li>• Initials (Screening).</li> <li>• DOB (Screening).</li> <li>• Screening date (Screening).</li> <li>• Patient No. (Enrollment).</li> <li>• Initials (Patient Identification).</li> <li>• Completion status (Study Completion).</li> <li>• Drop-out reason (Study Completion).</li> <li>• DOV (Date of Visit).</li> <li>• Randomization field (Randomization).</li> </ul> <p>For more information, see <i>About special InForm forms</i> (on page 86).</p> |
| Title          | Title of the item. The title can have 1-63 characters.   |
| Type           | <p>Item type; one of the following, or a custom item type defined in a library to which the study has access:</p> <ul style="list-style-type: none"> <li>• Blood pressure</li> <li>• Compound</li> <li>• Date time</li> <li>• Float</li> <li>• Integer</li> <li>• Text</li> <li>• Yes No</li> </ul>  |
| Version        | Version number of the study object. The version number is incremented only when a user explicitly updates it.  |

**Note:** To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add *HTML formatting characters* (on page 244) to a text field to control its appearance when deployed.

## Design tab of the Item Editor—Option descriptions

### Compound or blood pressure item options

| Option                             | Description  |
|------------------------------------|--|
| <b>Compound Properties section</b> |  |
| Default question                   | Default question for the item. This question appears on the form if no customized label or translation is defined for the item. The question can have 0-1000 characters. Certain words may be reserved for this field. For more information, see <i>Reserved words for an item question or short question</i> (on page 120).   |
| Title                              | Title of the item. The title can have 1-63 characters.   |
| <b>Child Items section</b>         |  |
| Child Items section                | List the items that make up the compound item. For a blood pressure item, the predefined child items Systolic Variable and Diastolic Variable appear in this list.   |
| Type                               | Item type. For a blood pressure item, the item type of the two child items is Integer.   |
| Title                              | Title of the child item. The title can have 1-63 characters.   |
| RefName                            | RefName of the child item.   |
| Question                           | Caption that appears with the child item on the form.  |
| <b>Languages section</b>           |  |
| Languages section                  | Translate item questions. This section is active if: <ul style="list-style-type: none"> <li>• More than one language and locale have been selected for the study in the Study Editor.</li> <li>• You have been associated with one of the languages for the study in your user skills profile. An administrator user sets up this profile in the Central Designer Administrator application.</li> </ul>                        |
| Language                           | Language in which the question appears.  |
| Question                           | Text of the question in the specified language. The question can have 0-1000 characters.   |
| Short Question                     | Text of a short version of the item question. In the InForm application, the short question appears as a column heading in a repeating form, an itemset, and in reports generated by the Reporting and Analysis application. The short question can have 0-255 characters. Certain words may be reserved for this field. For more information, see <i>Reserved words for an item question or short question</i> (on page 120). |



**Note:** To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add *HTML formatting characters* (on page 244) to a text field to control its appearance when deployed.

## Date time item options

| Option                              | Description   |
|-------------------------------------|---|
| <b>Date Time Properties section</b> |   |
| Default question                    | Default question for the item. This question appears on the form if no customized label or translation is defined for the item. The question can have 0-1000 characters. Certain words may be reserved for this field. For more information, see <i>Reserved words for an item question or short question</i> (on page 120).  |
| Title                               | Title of the item. The title can have 1-63 characters. The title can have 1-63 characters.  |
| Year                                | When selected, this part of the date time item (Year, Month, Day, Hour, Minute, or Second) can be made visible on the form if it is marked as visible in the Layout tab.  |
| Month                               |   |
| Day                                 |   |
| Hour                                |   |
| Minute                              |   |
| Second                              |   |
| <b>Languages section</b>            |   |
| Languages section                   | Translate item questions. This section is active if: <ul style="list-style-type: none"> <li>• More than one language and locale have been selected for the study in the Study Editor.</li> <li>• You have been associated with one of the languages for the study in your user skills profile. An administrator user sets up this profile in the Central Designer Administrator application.</li> </ul> |
| Language                            | Language in which the question appears.   |
| Question                            | Text of the question in the specified language. The question can have 0-1000 characters. Certain words may be reserved for this field. For more information, see <i>Reserved words for an item question or short question</i> (on page 120).  |

| Option         | Description   |
|----------------|---|
| Short Question | Text of a short version of the item question. In the InForm application, the short question appears as a column heading in a repeating form, an itemset, and in reports generated by the Reporting and Analysis application. The short question can have 0-255 characters. Certain words may be reserved for this field. For more information, see <b><i>Reserved words for an item question or short question</i></b> (on page 120). |

**Notes:**

- To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add ***HTML formatting characters*** (on page 244) to a text field to control its appearance when deployed.
- The Required and Allow unknown fields are not available until you select the corresponding Allow fields.

**Float item options**

| Option                          | Description   |
|---------------------------------|---|
| <b>Float Properties section</b> |   |
| Default question                | Default question for the item. This question appears on the form if no customized label or translation is defined for the item. The question can have 0-1000 characters. Certain words may be reserved for this field. For more information, see <b><i>Reserved words for an item question or short question</i></b> (on page 120).   |
| Title                           | Title of the item. The title can have 1-63 characters.  |
| Base Unit                       | The unit for which a measurement is stored in the repository.   |
| Conversion Units                | One or more optional units in which a user can enter a measurement. A conversion unit value is converted to the base unit when stored in the study database.  |
| Length                          | Maximum length of the data that a user can enter into the item, including the values before and after the decimal point.<br><br><b>Note:</b> When a float item is deployed to an InForm study, the decimal point counts in the length, and you must account for the decimal point when designing the float item. For example, in the InForm application, the largest number that can be entered in a field that has a length of 4 and a precision of 1 is 99.9. |
| Precision                       | Number of required characters following the decimal point.  |
| Codelist Settings               | <ul style="list-style-type: none"> <li>• <b>Select Single Value</b>—A user must select only one codelist item.</li> <li>• <b>Select Multiple Values</b>—A user can select multiple codelist items.</li> </ul>   |

| Option                   | Description  |
|--------------------------|--|
| <b>Codelist section</b>  |  |
| Codelist section         | Select or define a codelist for the item. A codelist consists of a group of codelist items, each containing a code and a label.  |
| Codelist                 | List of existing codelists or the name of a new codelist that you type.  |
| New                      | Create a codelist in the repository, using the name entered in the Codelist field.   |
| Code                     | Value stored in the repository for the codelist item. The value can have 1-2000 characters.  |
| Label                    | Default label that appears on the form for the codelist item. The label can have 1-255 characters.   |
| <b>Languages section</b> |  |
| Languages section        | Translate item questions. This section is active if: <ul style="list-style-type: none"> <li>• More than one language and locale have been selected for the study in the Study Editor.</li> <li>• You have been associated with one of the languages for the study in your user skills profile. An administrator user sets up this profile in the Central Designer Administrator application.</li> </ul>                        |
| Language                 | Language in which the question appears.  |
| Question                 | Text of the question in the specified language. The question can have 0-1000 characters. Certain words may be reserved for this field. For more information, see <i>Reserved words for an item question or short question</i> (on page 120).   |
| Short Question           | Text of a short version of the item question. In the InForm application, the short question appears as a column heading in a repeating form, an itemset, and in reports generated by the Reporting and Analysis application. The short question can have 0-255 characters. Certain words may be reserved for this field. For more information, see <i>Reserved words for an item question or short question</i> (on page 120). |

**Note:** To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add *HTML formatting characters* (on page 244) to a text field to control its appearance when deployed.

## Integer or yes no item options

| Option                            | Description   |
|-----------------------------------|---|
| <b>Integer Properties section</b> |   |
| Default question                  | Default question for the item. This question appears on the form if no customized label or translation is defined for the item. The question can have 0-1000 characters. Certain words may be reserved for this field. For more information, see <i>Reserved words for an item question or short question</i> (on page 120).  |
| Title                             | Title of the item. The title can have 1-63 characters.  |
| Base Unit                         | The unit for which a measurement is stored in the repository.   |
| Conversion Units                  | One or more optional units in which a user can enter a measurement. A conversion unit value is converted to the base unit when stored in the study database.  |
| Length                            | Maximum length of the data that a user can enter into the item, including the values before and after the decimal point.  |
| Signed Value                      | Reserved for future use.  |
| Codelist settings                 | <ul style="list-style-type: none"> <li>• <b>Select Single Value</b>—A user must select only one codelist item.</li> <li>• <b>Select Multiple Values</b>—A user can select multiple codelist items.</li> </ul>   |
| <b>Codelist section</b>           |   |
| Codelist section                  | Select or define a codelist for the item. A codelist consists of a group of codelist items, each containing a code and a label.<br><br><b>Note:</b> A yes no item includes a predefined codelist named YesNo Codelist. This codelist has the values 0 (No) and 1 (Yes).   |
| Codelist                          | List of existing codelists or the name of a new codelist that you type.   |
| New                               | Create a codelist in the repository, using the name entered in the Codelist field.  |
| Code                              | Value stored in the repository for the codelist item. The value can have 1-2000 characters.   |
| Label                             | Default label that appears on the form for the codelist item. The label can have 1-255 characters.  |
| <b>Languages section</b>          |   |
| Languages section                 | Translate item questions. This section is active if: <ul style="list-style-type: none"> <li>• More than one language and locale have been selected for the study in the Study Editor.</li> <li>• You have been associated with one of the languages for the study in your user skills profile. An administrator user sets up this profile in the Central Designer Administrator application.</li> </ul> |

| Option         | Description  |
|----------------|--|
| Language       | Language in which the question appears.  |
| Question       | Text of the question in the specified language. The question can have 0-1000 characters. Certain words may be reserved for this field. For more information, see <i>Reserved words for an item question or short question</i> (on page 120).   |
| Short Question | Text of a short version of the item question. In the InForm application, the short question appears as a column heading in a repeating form, an itemset, and in reports generated by the Reporting and Analysis application. The short question can have 0-255 characters. Certain words may be reserved for this field. For more information, see <i>Reserved words for an item question or short question</i> (on page 120). |

**Note:** To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add *HTML formatting characters* (on page 244) to a text field to control its appearance when deployed.

### Text item options

| Option                  | Description  |
|-------------------------|--|
| <b>Text Properties</b>  | Specify text item properties.  |
| Default question        | Default question for the item. This question appears on the form if no customized label or translation is defined for the item. The question can have 0-1000 characters. Certain words may be reserved for this field. For more information, see <i>Reserved words for an item question or short question</i> (on page 120). |
| Title                   | Title of the item. The title can have 1-63 characters.   |
| Length                  | Maximum length of the data that a user can enter into the item, including the values before and after the decimal point.   |
| Codelist Settings       | <ul style="list-style-type: none"> <li>• <b>Select Single Value</b>—A user must select only one codelist item.</li> <li>• <b>Select Multiple Values</b>—A user can select multiple codelist items.</li> </ul>  |
| <b>Codelist section</b> | Select or define a codelist for the item. A codelist consists of a group of codelist items, each containing a code and a label.  |
| Codelist                | List of existing codelists or the name of a new codelist that you type.  |
| New                     | Create a codelist in the repository, using the name entered in the Codelist field.   |
| Code                    | Value stored in the repository for the codelist item. The value can have 1-2000 characters.  |
| Label                   | Default label that appears on the form for the codelist item. The label can have 1-255 characters.   |

| Option                   | Description  |
|--------------------------|--|
| <b>Languages section</b> | Translate item questions. This section is active if: <ul style="list-style-type: none"> <li>• More than one language and locale have been selected for the study in the Study Editor.</li> <li>• You have been associated with one of the languages for the study in your user skills profile. An administrator user sets up this profile in the Central Designer Administrator application.</li> </ul>                        |
| Language                 | Language in which the question appears.  |
| Question                 | Text of the question in the specified language. The question can have 0-1000 characters. Certain words may be reserved for this field. For more information, see <i>Reserved words for an item question or short question</i> (on page 120).   |
| Short Question           | Text of a short version of the item question. In the InForm application, the short question appears as a column heading in a repeating form, an itemset, and in reports generated by the Reporting and Analysis application. The short question can have 0-255 characters. Certain words may be reserved for this field. For more information, see <i>Reserved words for an item question or short question</i> (on page 120). |

**Note:** To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add *HTML formatting characters* (on page 244) to a text field to control its appearance when deployed.

### Default maximum input field lengths

When you create an item, you specify the length of the input field. The Central Designer application supports the following maximum field lengths as a default.




| Type of input field | Maximum length |
|---------------------|----------------|
| Text item           | 2000           |
| Integer item        | 10             |
| Float item          | 18             |
| Float precision     | 10             |

## Forms and sections editor—Option descriptions

### Columns common to all study object editors

All study object editors have the following columns.

**Note:** Not all fields appear in the default view. Optionally, you can *add the other fields and rearrange the browser view* (in the User Guide).

| Property                      | Description  |
|-------------------------------|--|
| Icon (first column)           | Status of the study object: <ul style="list-style-type: none"> <li>•  —New.</li> <li>•  —Locked.</li> <li>•  —Protected. When a study object is protected, you cannot :               <ul style="list-style-type: none"> <li>▪ Update or lock it.</li> <li>▪ Add child study objects to it by pasting or dragging and dropping.</li> <li>▪ Delete its child study objects.</li> </ul> </li> </ul> |
| Description                   | Description of the study object. The description can have 0-255 characters.  |
| Identifier                    | Unique internal identifier of the study object.  |
| Published (only in libraries) | Indicates that the study object has been published.  |
| RefName                       | RefName of the study object. The RefName can have 1-63 characters.   |
| Revision                      | Revision number of the study object. The revision number is incremented each time the study object is changed and saved.   |
| Title                         | Title of the study object. The title can have 1-63 characters.   |
| Version                       | Version number of the study object. The version number is incremented only when a user explicitly updates it.  |

| Field                 | Description   |
|-----------------------|---|
| AssociatedForm        | Title of the associated form, or None, if the form is not associated with another form. For more information, see <i>About forms</i> (on page 80).  |
| Common                | Indicates that the form is common. The same data is visible in all study events that contain the form.  |
| Fixed (sections only) | Indicates that the section is a repeating section containing items for which the text is fixed and repeated in each instance of the item.   |
| Item Required         | Indicates that a value must be entered for the item for the form to be considered complete.   |
| Page Key Value        | Value of the Clintrial page key, used for transferring data to the Clintrial application through CIS mappings. If you specify the Page Key Value, it overrides the form RefName as the page key.  |
| Repeating             | Indicates that the form or section is repeating. Multiple instances of the same set of data appear in the form or section.  |
| SDV Critical          | Indicates that the study object is considered critical for source verification. If you select SDV Critical, SDV Required becomes selected as well.  |
| SDV Required          | Indicates that the study object must be source verified in the InForm application.  |
| Short Title           | Short title of the form. The short title is deployed to the InForm application as the form mnemonic. The short title can have 1-63 characters.  |
| Special Forms         | Type of special InForm form, or None, indicating that the form is not a special InForm form. Available special forms are: <ul style="list-style-type: none"> <li>• Screening</li> <li>• Enrollment</li> <li>• Patient Identification</li> <li>• Study Completion</li> </ul> For more information, see <i>About special InForm forms</i> (on page 86). |

**Note:** To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add *HTML formatting characters* (on page 244) to a text field to control its appearance when deployed.



## General tab of the Form Editor or Section Editor—Option descriptions

| Option  | Description  |
|---|--|
| <b>Settings section</b>                                 |  |
| Title   | Title of the form or section. The title can have 1-63 characters.  |
| Short Title (Form Editor only)                          | Short title of the form. The short title is deployed to the InForm application as the form mnemonic. The short title can have 1-63 characters. |
| RefName   | RefName of the form or section. The RefName can have 1-63 characters.  |
| Description   | Description of the form or section. The description can have 0-255 characters.   |
| <b>Behavior section</b>                                 |  |
| Repeating   | Indicates that the form or section is repeating. Multiple instances of the same set of data appear in the form or section.                     |
| Common (Form Editor only)                               | Indicates that the form is common. The same data is visible in all study events that contain the form.   |
| <b>Short Title Languages section (Form Editor only)</b> |  |
| Language  | Language and locale to which the short title is translated.  |
| Short Title   | Translated text of the short title. The short title can have 1-63 characters.  |




**Note:** To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add *HTML formatting characters* (on page 244) to a text field to control its appearance when deployed.

## InForm Items Editor—Option descriptions

### Columns common to all study object editors

All study object editors have the following columns.

**Note:** Not all fields appear in the default view. Optionally, you can *add the other fields and rearrange the browser view* (in the *User Guide*).

| Property                      | Description  |
|-------------------------------|--|
| Icon (first column)           | Status of the study object: <ul style="list-style-type: none"> <li>•  —New.</li> <li>•  —Locked.</li> <li>•  —Protected. When a study object is protected, you cannot :               <ul style="list-style-type: none"> <li>▪ Update or lock it.</li> <li>▪ Add child study objects to it by pasting or dragging and dropping.</li> <li>▪ Delete its child study objects.</li> </ul> </li> </ul> |
| Description                   | Description of the study object. The description can have 0-255 characters.  |
| Identifier                    | Unique internal identifier of the study object.  |
| Published (only in libraries) | Indicates that the study object has been published.  |
| RefName                       | RefName of the study object. The RefName can have 1-63 characters.   |
| Revision                      | Revision number of the study object. The revision number is incremented each time the study object is changed and saved.   |
| Title                         | Title of the study object. The title can have 1-63 characters.   |
| Version                       | Version number of the study object. The version number is incremented only when a user explicitly updates it.  |

**Note:** Not all fields appear in the default view. Optionally, you can *add the other fields and rearrange the browser view* (in the *User Guide*).

| Option           | Description  |
|------------------|--|
| Data Label       | Text label for the item, enabling access to the item in a target table with the Patient To Control key type or any of the pivot key types.   |
| Display Override | <p>Determines the default behavior of an item when a layout is generated.</p> <ul style="list-style-type: none"> <li>• <b>ReadOnly</b>—The item is visible but not editable.</li> <li>• <b>Editable</b>—The item is visible and editable by any user, regardless of the rights assigned to the user.</li> <li>• <b>Hidden</b>—The item is not visible.</li> <li>• <b>None</b>—The item is visible to all users, and visible and editable by any user who has the rights to view and/or edit the item.</li> </ul> <p>This is a custom property for items deployed in a study in the InForm application.</p> |
| Item Required    | <p><b>True</b> (default) or <b>False</b>, indicating whether the item is required for data entry on the form to be complete.</p> <p>This is a custom property for items deployed in a study in the InForm application.</p>   |
| MaxProperty      | If a MaxValue is specified for the item, indicates whether the value can be less than or less than or equal to the MaxValue.   |
| MaxValue         | Maximum value that the InForm application will allow to be typed for the item.   |
| MinProperty      | If a MinValue is specified for the item, indicates whether the value can be greater than or greater than or equal to the MinValue.   |
| MinValue         | Minimum value that the InForm application will allow to be typed for the item.   |
| PHI              | <b>True</b> or <b>False</b> (default), indicating whether an InForm user might enter Personal/Protected Health Information (PHI) for the item.   |
| Question         | Default question for the item. This question appears on the form if no customized label or translation is defined for the item. The question can have 0-1000 characters. Certain words may be reserved for this field. For more information, see <i>Reserved words for an item question or short question</i> (on page 120).   |
| SDV Critical     | <b>True</b> or <b>False</b> (default), indicating whether the item is considered critical for source verification. If you select True, SDV Required changes to True.   |
| SDV Required     | <p><b>True</b> (default) or <b>False</b>, indicating whether the item requires source document verification.</p> <p>This is a custom property for items deployed in a study in the InForm application.</p>   |

| Option         | Description  |
|----------------|--|
| ShortQuestion  | Text of a short version of the item question. In the InForm application, the short question appears as a column heading in a repeating form, an itemset, and in reports generated by the Reporting and Analysis application. The short question can have 0-255 characters. Certain words may be reserved for this field. For more information, see <i>Reserved words for an item question or short question</i> (on page 120).   |
| Special Fields | <p>Type of special InForm field, or None, indicating that the item is not a special InForm field. Available special fields, along with the forms in which they appear, are:</p> <ul style="list-style-type: none"> <li>• Initials (Screening).</li> <li>• DOB (Screening).</li> <li>• Screening date (Screening).</li> <li>• Patient No. (Enrollment).</li> <li>• Initials (Patient Identification).</li> <li>• Completion status (Study Completion).</li> <li>• Drop-out reason (Study Completion).</li> <li>• DOV (Date of Visit).</li> <li>• Randomization field (Randomization).</li> </ul> <p>For more information, see <i>About special InForm forms</i> (on page 86).</p> |
| Type           | <p>Item type; one of the following, or a custom item type defined in a library to which the study has access:</p> <ul style="list-style-type: none"> <li>• Blood pressure</li> <li>• Compound</li> <li>• Date time</li> <li>• Float</li> <li>• Integer</li> <li>• Text</li> <li>• Yes No</li> </ul>  |

**Note:** To type extended ASCII characters in text fields, press ALT while entering the decimal code for the character. You can also add *HTML formatting characters* (on page 244) to a text field to control its appearance when deployed.

## Item Properties dialog box—Option descriptions

### Options for the compound or blood pressure item type

| Option           | Description   |
|------------------|---|
| Title            | Title of the item. The title can have 1-63 characters.  |
| RefName          | RefName of the study object. The RefName can have 1-63 characters.  |
| Default Question | Default question for the item. This question appears on the form if no customized label or translation is defined for the item. The question can have 0-1000 characters. Certain words may be reserved for this field. For more information, see <b><i>Reserved words for an item question or short question</i></b> (on page 120). |

### Options for the float item type

| Option                   | Description   |
|--------------------------|---|
| Title                    | Title of the item. The title can have 1-63 characters.  |
| RefName                  | RefName of the study object. The RefName can have 1-63 characters.  |
| Default Question         | Default question for the item. This question appears on the form if no customized label or translation is defined for the item. The question can have 0-1000 characters. Certain words may be reserved for this field. For more information, see <b><i>Reserved words for an item question or short question</i></b> (on page 120).   |
| Base Unit                | The unit for which a measurement is stored in the repository.   |
| Conversion Units         | One or more optional units in which a user can enter a measurement. A conversion unit value is converted to the base unit when stored in the study database.  |
| Length                   | Maximum length of the data that a user can enter into the item, including the values before and after the decimal point.<br><br><b>Note:</b> When a float item is deployed to an InForm study, the decimal point counts in the length, and you must account for the decimal point when designing the float item. For example, in the InForm application, the largest number that can be entered in a field that has a length of 4 and a precision of 1 is 99.9. |
| Precision                | Number of required characters following the decimal point.  |
| <b>Codelist Settings</b> |   |
| Codelist                 | List of existing codelists or the name of a new codelist that you type.   |
| New                      | Create a new codelist on the item.  |

| Option            | Description   |
|-------------------|---|
| Edit              | Edit the codelist on the item. If the item does not have a codelist, this option is not available.  |
| Codelist Settings | <ul style="list-style-type: none"> <li>• <b>Select Single Value</b>—A user must select only one codelist item.</li> <li>• <b>Select Multiple Values</b>—A user can select multiple codelist items.</li> </ul> |

### Options for the date time item type

| Option                             | Description   |
|------------------------------------|---|
| Title                              | Title of the item. The title can have 1-63 characters.  |
| RefName                            | RefName of the study object. The RefName can have 1-63 characters.  |
| Question                           | Text of the question in the specified language. The question can have 0-1000 characters. Certain words may be reserved for this field. For more information, see <i>Reserved words for an item question or short question</i> (on page 120).  |
| <b>Date Time Component Setting</b> |   |
| Year                               | <p>When selected, this part of the date time item (Year, Month, Day, Hour, Minute, or Second) can be made visible on the form if it is marked as visible in the Layout tab.</p> <ul style="list-style-type: none"> <li>• <b>Required</b>—(Selected by default for Year, Month, and Day) When selected, this part of the date time item (Year, Month, Day, Hour, Minute, or Second) is required.</li> <li>• <b>Allow unknown</b>—A data-entry user can mark this part of the date time item (Year, Month, Day, Hour, Minute, or Second) unknown. An entry marked unknown is considered completed.</li> </ul> |
| Month                              |   |
| Day                                |   |
| Hour                               |   |
| Minute                             |   |
| Second                             |   |
| <b>Year Range</b>                  |   |
| Start Year                         | First and last year in the drop-down list for the year range for the item. The year range is available only when the <b>Year</b> component is selected.   |
| End Year                           |   |

## Options for the integer or yes no item type

| Option                   | Description   |
|--------------------------|---|
| Title                    | Title of the item. The title can have 1-63 characters.  |
| RefName                  | RefName of the study object. The RefName can have 1-63 characters.  |
| Default Question         | Default question for the item. This question appears on the form if no customized label or translation is defined for the item. The question can have 0-1000 characters. Certain words may be reserved for this field. For more information, see <b><i>Reserved words for an item question or short question</i></b> (on page 120). |
| Base Unit                | The unit for which a measurement is stored in the repository.   |
| Conversion Units         | One or more optional units in which a user can enter a measurement. A conversion unit value is converted to the base unit when stored in the study database.  |
| Length                   | Maximum length of the data that a user can enter into the item, including the values before and after the decimal point.  |
| Signed Value             | Reserved for future use.  |
| <b>Codelist Settings</b> |   |
| Codelist                 | List of existing codelists or the name of a new codelist that you type.   |
| New                      | Create a new codelist on the item.  |
| Edit                     | Edit the codelist on the item. If the item does not have a codelist, this option is not available.  |
| Codelist Settings        | <ul style="list-style-type: none"> <li>• <b>Select Single Value</b>—A user must select only one codelist item.</li> <li>• <b>Select Multiple Values</b>—A user can select multiple codelist items.</li> </ul>   |

## Options for the text item type

| Option           | Description   |
|------------------|---|
| Title            | Title of the item. The title can have 1-63 characters.  |
| RefName          | RefName of the study object. The RefName can have 1-63 characters.  |
| Default Question | Default question for the item. This question appears on the form if no customized label or translation is defined for the item. The question can have 0-1000 characters. Certain words may be reserved for this field. For more information, see <b><i>Reserved words for an item question or short question</i></b> (on page 120). |

| Option                   | Description   |
|--------------------------|---|
| Length                   | Maximum length of the data that a user can enter into the item, including the values before and after the decimal point.  |
| <b>Codelist Settings</b> |   |
| Codelist                 | List of existing codelists or the name of a new codelist that you type.   |
| New                      | Create a new codelist on the item.  |
| Edit                     | Edit the codelist on the item. If the item does not have a codelist, this option is not available.  |
| Codelist Settings        | <ul style="list-style-type: none"> <li>• <b>Select Single Value</b>—A user must select only one codelist item.</li> <li>• <b>Select Multiple Values</b>—A user can select multiple codelist items.</li> </ul> |

## Keys dialog box

| Field                                    | Description   |
|--|---|
| <b>Data uniqueness for selected keys</b> |   |
| None                                     | Key items appear in a drop-down list in the summary view of a repeating form as navigation aids. The key items are not used to enforce uniqueness of key values across instances of the repeating form. |
| Individual                               | Each key item must be unique across all instances of the repeating form or itemset in the InForm application.   |
| Group                                    | The combination of all key items evaluated together must be unique across all instances of the repeating form or itemset in the InForm application.   |
| <b>Key selection</b>                     |   |
| Items available as keys                  | The list of items in the repeating form or section that have not been selected as keys.   |
| Section                                  | Name of the section in which an available item occurs; blank for repeating forms.   |
| Item                                     | Title of the available item.  |
| Selected keys                            | The list of items in the repeating form or section that have been selected as keys.   |
| Section                                  | Name of the section in which the key item occurs; blank for repeating forms.  |
| Item                                     | Title of the key item.  |
| Unique                                   | Selected if the item is an individually or group unique key.  |



| Field              | Description   |
|--------------------|---|
| <b>Button</b>      |   |
| >, <               | Moves one or more selected items between the Items available as keys list and the Selected keys list.   |
| >>, <<             | Moves all items between the Items available as keys list and the Selected keys list.  |
| Move Up, Move Down | Moves the selected key item up or down in the Selected keys list. The resulting order determines the order in which key items appear in a drop-down list on a repeating form in the InForm application. |

## Languages tab of the Codelist Item Editor—Option descriptions

| Option   | Description  |
|----------|--|
| Language | Language and locale into which the codelist item label is translated. The default language appears in the first row. |
| Label    | Label of the codelist item. The label can have 1-255 characters.   |

## Data mappings

### Custom Dimension Labels - Select Codelist dialog box—Option descriptions

In the Custom Dimension Labels - Select Codelist dialog box, you select or create a codelist for the labels for custom data dimensions created with a data set.

**Note:** The dialog box appears when you define a custom data dimension and then click the button in the Codelist Lookup column.

| Option                          | Description   |
|---------------------------------|---|
| [Codelist drop-down list]       | List of available codelists.  |
| New                             | Create a codelist.  |
| Code                            | List of codes for the selected codelist.  |
| Label                           | List of labels for the selected codelist.   |
| Use only listed labels checkbox | <p>Indicates whether users are required to choose from the custom dimension labels that you provide, or if they can provide their own values.</p> <ul style="list-style-type: none"> <li>Selected—When defining the value of the custom data dimension, users are required to choose from the codelist items you type in the Custom Dimension Labels section.</li> <li>Not selected—When defining the value of the custom data dimension, user can choose from the values you type or provide a value.</li> </ul> <p><b>Note:</b> If you select <b>Use only listed labels</b>, the codelist must have at least one codelist item.</p> |

### Data Series Editor—Field descriptions

| Field | Description  |
|-------|--|
| Item  | Name of the item that has been added to the selected data series.  |
| Form  | <p>Indicates the forms that are included in the mapping of the item to the data series.</p> <ul style="list-style-type: none"> <li><b>{All}</b>—The item is always mapped to the data series, on every form, in every study, and in the library.</li> <li><b>[Form names]</b>—The item is mapped to the data series only when the item appears on the listed forms.</li> <li><b>[blank]</b>—The item is not added to the data series.</li> </ul> |

| Field       | Description  |
|-------------|--|
| Study Event | <p>Indicates which study events are included in the mapping of the item to the data series.</p> <ul style="list-style-type: none"> <li>• <b>{All}</b>—The item is always mapped to the data series, on every form, in every study, and in the library.</li> <li>• <b>[Study event names]</b>—The item is mapped to the data series only when the item appears on the listed study events.</li> <li>• <b>[blank]</b>—The item is not added to the data series.</li> </ul> |
| State       | <p>Indicates if the association between the item and data series is currently mapped.</p> <ul style="list-style-type: none"> <li>• <b>Mapped</b>—The item is mapped to the data series.</li> <li>• <b>Unmapped</b>—The item is part of the data series but is not mapped to the data series for the study. You might add an item to a data series but not want the mapping to exist in a particular study.</li> </ul>  |
| Labels      | All specified values for custom data dimensions.   |

## Data Series Properties dialog box—Option descriptions

| Option      | Description   |
|-------------|---|
| Title       | Name of the data series in the data set.  |
| RefName     | RefName of the data series in the data set.   |
| Description | Description of the data series in the data set.   |
| Alias       | <p>Alias for the data series. If an alias is present, it is used as the column name in the customer-defined database (CDD) or as the Clintrial item name in CIS mappings. If an alias is not present, the RefName is used as the column header. Because RefNames must be unique throughout a study, you must create an alias if the RefName is used by a study object. Data series aliases must be unique within a data set.</p> <p>Checking for RefName and alias uniqueness is case insensitive; for example, the names BP and bp are considered identical.</p> |
| Type        | Data type of the data series.   |

The data types of an item and data series must be compatible for you to add the item to the data series. The following table indicates the item types that you can add to each data series type.

| Item type             | Text   | Integer  | Float | Date time |
|-----------------------|--|--|-------|-----------|
| <b>Text item</b>      | Yes  | No   | No    | No        |
| <b>Integer item</b>   | Yes  | Yes  | Yes   | No        |
| <b>Float item</b>     | Yes  | No   | Yes   | No        |
| <b>Date time item</b> | Yes. You are asked if you want to choose part of the date or the whole date. | Yes. You are asked to choose the part of the date. | No    | Yes       |

## Data Series Summary tab—Option descriptions

The Data Series Summary tab appears in the editors for study events and forms.

| Option                  | Description  |
|-------------------------|--|
| <b>Filtering bar</b>    |  |
| Mapping                 | View data series in the selected mapping.  |
| Data Set                | View data series in the selected data set.   |
| Filter                  | <ul style="list-style-type: none"> <li>• <b>Show All</b>—View all items</li> <li>• <b>Associated</b>—View items that are part of a data series.</li> <li>• <b>Not Associated</b>—View items that are NOT part of a data series.</li> </ul> |
| Compatible types only   | When selected, items that cannot be added to any data series are hidden.   |
| CardView                | View each item grouped individually.   |
| <b>Fields</b>           |  |
| Forms and Items columns | Forms and items appear as the left-most column headers. The Forms column appears only when a study event is selected.<br><br>The columns list all forms and items in the study.  |

| Option                      | Description   |
|-----------------------------|---|
| [Data series names] columns | <p>Data series appear as column headers in the grid beneath column headers of their data sets.</p> <p>The cells where an item meets with the data series have one of the following background colors:</p> <ul style="list-style-type: none"> <li>• <b>Gray</b>—You cannot map the item to the data series.</li> <li>• <b>White</b>—You can map the item to the data series. The following mapping types are available: <ul style="list-style-type: none"> <li>▪ <b>[No value]</b>—The item is not in the data series. Selecting [No value] for an item that previously was mapped to the data series removes the item from the data series.</li> <li>▪ <b>Always</b>—The item is always mapped to the data series, on every form, in every study, and in the library.</li> <li>▪ <b>Form</b>—The item is mapped to the data series only when the item appears on a specific section (or form, if the form has no sections). You can select this option for multiple sections or forms.</li> <li>▪ <b>Study event</b>—(Available only when a study event is selected.) The item is mapped to the data series only when it appears on any form in a specific study event. You can select this option for multiple study events.</li> <li>▪ <b>Study event &amp; Form</b>—(Available only when a study event is selected.) The item is mapped to the data series only when it appears on a specific form in a specific study event.</li> </ul> </li> </ul> |

## Data Set Editor—Field descriptions

| Field       | Description   |
|-------------|---|
| Title       | Title of the data series in the data set.   |
| Description | Description of the data series in the data set.   |
| Type        | Data type of the data series.   |
| Alias       | <p>Alias for the data series. If an alias is present, it is used as the column name in the customer-defined database (CDD) or as the Clintrial item name in CIS mappings. If an alias is not present, the RefName is used as the column header. Because RefNames must be unique throughout a study, you must create an alias if the RefName is used by a study object. Data series aliases must be unique within a data set.</p> <p>Checking for RefName and alias uniqueness is case insensitive; for example, the names BP and bp are considered identical.</p> |

## Data Set Properties dialog box—Field descriptions

In the Data Set Properties dialog box, you can define the name and description of a data set and choose the standard dimensions that you want to create for the data set. You have the option of defining custom dimensions for the data set, as well.

| Field                              | Description  |
|------------------------------------|--|
| Title                              | Title of the data set.   |
| RefName                            | RefName of the data set.   |
| Description                        | Description of the data set.   |
| Alias                              | <p>Alias for the data set. If an alias is present, it is used as the column name in the customer-defined database (CDD) or as the Clintrial item name in CIS mappings. If an alias is not present, the RefName is used as the column header. Because RefNames must be unique throughout a study, you must create an alias if the RefName is used by a study object. Data series aliases must be unique within a data set.</p> <p>Checking for RefName and alias uniqueness is case insensitive; for example, the names BP and bp are considered identical.</p> |
| <b>Standard Dimensions section</b> | In this section, you view the standard data dimensions that were selected when the data set was created.   |
| Study                              | RefName of the study.  |
| Subject                            | Subject ID.  |
| Section                            | RefName of the section.  |
| Section Index                      | Instance of a repeating section.   |
| Event                              | RefName of the study event.  |
| Event Index                        | Instance of a repeating study event.   |
| Form                               | RefName of the form.   |
| Form Index                         | Instance of a repeating form.  |
| Item                               | RefName of the item.   |
| <b>Custom Dimensions section</b>   | In this section, you view the custom data dimensions, if any, for the data set.  |
| Name                               | Name of the custom dimension for the selected data set.  |
| Description                        | Description of the custom dimension created with the selected data set.  |

| Field           | Description  |
|-----------------|--|
| Data Type       | Data type of the custom dimension created with the selected data set.<br>The following types are available: <ul style="list-style-type: none"> <li>• <b>Text</b>—Contains alphanumeric characters.</li> <li>• <b>Integer</b>—Contains only numbers.</li> </ul> |
| Codelist Lookup | Click the button to choose or create a codelist to use for the custom data dimension labels.   |

## Date-Time Data Point dialog box—Option descriptions

Use the Date-Time Data Point dialog box to specify custom mappings for date time items. The dialog box appears when you map a date to a data series that has a type of Integer or Text or when you modify the date part of a mapped date time item.

**Note:** When you map a date time item to an integer data series in a CDD mapping, the item is mapped as a split date, with a separate column for each date time part.

| Option            | Description  |
|-------------------|--|
| All in one column | Map the date to a single database column. This option is available only if the date item is mapped to a data series with a type of Text.   |
| Split columns     | Split the date parts into multiple database columns. If the mapping is for: <ul style="list-style-type: none"> <li>• <b>CDD</b>—The Central Designer application splits the date parts into multiple database columns.</li> <li>• <b>CIS</b>—You must create a different mapping for each date part that you want to map to a different panel item.</li> </ul> |
| CIS Date Part     | Date part to map. This option is available for rule and CIS mappings but not for CDD mappings.   |

## Item has units dialog box—Option descriptions

| Option           | Description  |
|------------------|--|
| Normalized Value | Map the normalized value of the item with the data series. Normalization is the process of converting data to a required format. The normalized units appear in parentheses. |
| Entered Value    | Map the entered value of the item with the data series. The entered value can be the same as or different from the normalized value.   |
| Entered Unit     | Map the unit in which a value is entered.  |

## Mapping Editor—Field descriptions

| Field                              | Description   |
|------------------------------------|---|
| <b>Grid section</b>                |   |
| Title                              | Name of the data set.   |
| Description                        | Description of the data set.  |
| Alias                              | <p>Alias for the data set. If an alias is present, it is used as the CDD table name in CDD mappings and as the Clintrial panel name in CIS mappings. If an alias is not present, the RefName is used as the column header. Because RefNames must be unique throughout a study, you must create an alias if the RefName is used by another study object. Data set aliases must be unique within a mapping.</p> <p><b>Note:</b> Checking for RefName and alias uniqueness is case insensitive; for example, the names BP and bp are considered identical.</p> |
| <b>Standard Dimensions section</b> |   |
|                                    | In this section, you view the standard data dimensions that were selected when the data set was created.  |
| Study                              | RefName of the study.   |
| Subject                            | Subject ID.   |
| Section                            | RefName of the section.   |
| Section Index                      | Instance of a repeating section.  |
| Event                              | RefName of the study event.   |
| Event Index                        | Instance of a repeating study event.  |
| Form                               | RefName of the form.  |
| Form Index                         | Instance of a repeating form.   |
| Item                               | RefName of the item.  |
| <b>Custom Dimensions section</b>   |   |
|                                    | In this section, you view the custom data dimensions, if any, for the data set.   |
| Name                               | Name of the custom dimension for the selected data set.   |
| Description                        | Description of the custom dimension created with the selected data set.   |
| Data Type                          | <p>Data type of the custom dimension created with the selected data set.</p> <p>The following types are available:</p> <ul style="list-style-type: none"> <li>• <b>Text</b>—Contains alphanumeric characters.</li> <li>• <b>Integer</b>—Contains only numbers.</li> </ul>   |
| Codelist Lookup                    | Click the button to choose or create a codelist to use for the custom data dimension labels.  |



**Note:** The Standard Dimensions and Custom Dimensions sections are read-only.

## Select Custom Dimension dialog box—Option descriptions

The Select Custom Dimension dialog box appears when you add an item to a data series, and the item is in a data series that is in a data set with one or more custom data dimensions defined.

| Option                                   | Description   |
|--|---|
| X  | When checkbox is selected, custom data dimension is selected.   |
| Dimension Name,<br>Dimension Description | Name and description of the custom data dimension.  |
| Data Type                                | Data type of the custom data dimension  |
| Labels                                   | Drop-down list containing the codelist item labels for the custom data dimension.<br><br><b>Note:</b> If you type a label or modify an existing label, a new codelist item is created for the codelist. |

# Layouts

## Control Styles dialog box—Option descriptions

### General tab

| Option             | Description  |
|--------------------|--|
| Item name          | Display name (either the title or RefName) of the item that is associated with the control.<br><br>READ-ONLY   |
| Caption            | Caption for the control.<br><br>Limit: 4000 characters.  |
| Inherit all styles | When selected, all control styles are inherited from the study-level styles or the form-level styles, if they are defined.<br><br>This setting does not affect the caption. The caption that you specify appears, regardless of whether you selected <b>Inherit all styles</b> . |

**Note:** Click Apply to save your changes and close the dialog box. Click Apply/Next to apply your changes (if you made any) and advance to the next control.

### Basic Styles tab

The options that are available depend on the type of control that is selected in the Layout tab.

| Option              | Description   |
|---------------------|---|
| Caption alignment   | (Available for all controls.)<br><br>Align the caption to the left, top, right, or bottom of the control.   |
| Textbox size        | (Available for controls on text, float, and integer items.) <ul style="list-style-type: none"> <li>• <b>Width</b>—Width of the text box, in characters.</li> <li>• <b>Height</b> (Available for text items only)—Height of the text box, in lines.</li> </ul> |
| Control orientation | (Available for compound items.)<br><br>Align the controls of the compound item either horizontally or vertically.   |

**Note:** The Inherit checkbox is available for each option. When Inherit is selected, the value for the option is inherited from the study-level styles or, if it is used, the form-level styles. To override the study-level or form-level styles, deselect Inherit, and provide a different value.

**Note:** Click Apply to save your changes and close the dialog box. Click Apply/Next to apply your changes (if you made any) and advance to the next control.

## Date Time Settings tab

The following options are available when you select a Date Time item in the Layout tab.

| Option         | Description   |
|----------------|---|
| Visible fields | Select the fields to set as visible for the date time item. |
| Year range     | Select the year range for the date time item.               |

**Note:** The Inherit checkbox is available for each option. When Inherit is selected, the value for the option is inherited from the study-level styles or, if it is used, the form-level styles. To override the study-level or form-level styles, deselect Inherit, and provide a different value.

**Note:** Click Apply to save your changes and close the dialog box. Click Apply/Next to apply your changes (if you made any) and advance to the next control.

## Control Type tab

The Control Type tab appears when a control is:

- A float, integer, or text item with a codelist.
- A float or integer item with units.

For other controls, this tab is hidden.

| Option            | Description  |
|-------------------|--|
| Unit control type | <ul style="list-style-type: none"> <li>• <b>For a float or integer item with units</b>—Format the units as either radio buttons or pulldowns.</li> <li>• <b>For a float, integer, or text item with a codelist</b>—Format the controls for the codelist items as either radio buttons or pulldowns.</li> </ul> |

**Note:** The Inherit checkbox is available for each option. When Inherit is selected, the value for the option is inherited from the study-level styles or, if it is used, the form-level styles. To override the study-level or form-level styles, deselect Inherit, and provide a different value.

**Note:** Click Apply to save your changes and close the dialog box. Click Apply/Next to apply your changes (if you made any) and advance to the next control.

## Advanced tab

| Option                    | Description  |
|---------------------------|--|
| Display Override          | <p>You can override the item's Display Override value for the control only.</p> <ul style="list-style-type: none"> <li>• <b>Inherit</b>—Use the item's Display Override value.</li> <li>• <b>Read only</b>—Make the control read only. (In the InForm software, corresponds to the Hidden value of the Display Override property of an item.)</li> <li>• <b>Hidden</b>—Make the control hidden. (In the InForm software, corresponds to the Read-Only value of the Display Override property of an item.)</li> </ul> |
| Character set restriction | <p>(Available for text items without codelists.)</p> <ul style="list-style-type: none"> <li>• <b>Unrestricted (Default)</b>—Do not restrict the entry of values in text fields without codelists.</li> <li>• <b>ASCII Only</b>—In release 5.0 and later of the InForm application, restrict the entry of values in text fields without codelists to the complete ASCII character set (byte range 0 to 127). Items with restricted values are marked with a star (★) in the Annotated Study Book.</li> </ul>          |

**Note:** Click Apply to save your changes and close the dialog box. Click Apply/Next to apply your changes (if you made any) and advance to the next control.

## Layout tab options and deployment to the InForm application

The following table lists the options that are available in the right-click menus, toolbar, and form and control styles for the Layout tab. The table describes the effect of each option when the study objects are deployed in the InForm application.

| Option         | Sub-option   | Deployment in the InForm application  |
|----------------|--|---|
| Align Caption  | Left, Right, Top, or Bottom  | Specifies the position of the caption relative to the control. Corresponds to the Caption Alignment property. |
| Align Question | <ul style="list-style-type: none"> <li>• Left, Center, or Right</li> <li>• Top, Middle, or Bottom</li> </ul> | N/A   |

| Option                     | Sub-option   | Deployment in the InForm application  |
|----------------------------|--|---|
| Control Type               | <ul style="list-style-type: none"> <li>• Radio Button</li> <li>• Pulldown</li> </ul> | <p>For codelist items:</p> <ul style="list-style-type: none"> <li>• Radio control</li> <li>• Pulldown control</li> </ul> <p>For units:</p> <ul style="list-style-type: none"> <li>• Specifies how unit selections are displayed. Corresponds to the Unit Display Type property. If an item definition has only one unit with no conversion units, the Unit Display Type property has a value of <b>Element</b>.</li> </ul>  |
| Edit Caption               |  | Specifies the text of the caption that appears with the control. Corresponds to the Caption property.   |
| Edit Textbox Size          |  | <p>For text controls:</p> <ul style="list-style-type: none"> <li>• <b>Width</b>—Specifies the number of characters that can be entered into a text box with the data type of Text. Corresponds to the Length property of a text box control.</li> <li>• <b>Height</b>—Specifies the number of lines displayed in a text box. Corresponds to the Height property of a text box control.</li> </ul> <p>For integer controls:</p> <ul style="list-style-type: none"> <li>• Number of characters that can be entered into a text box with a data type of Integer. Corresponds to the Length property of an integer text control.</li> </ul> <p>For float controls:</p> <ul style="list-style-type: none"> <li>• Number of characters that can be entered into a text box with a data type of Float. Corresponds to the Length plus the Precision properties of a float text control, plus the decimal point.</li> </ul> |
| Edit Question              |  | Question text. Corresponds to the Question property of an item.   |
| Edit Question Column Width |  | Width of the question column. Corresponds to the Question Width property.   |
| Orientation                | <ul style="list-style-type: none"> <li>• Horizontal</li> <li>• Vertical</li> </ul>   | Specifies how the controls included as children of the grouped control are oriented. Corresponds to the Layout property.  |
| Section Header             |  | Form or section title. Corresponds to the Title property of a form or section.  |
| Section Note               |  | Specifies the text of a note that appears immediately below a form or section heading. Corresponds to the Note property of a form or section.   |

| Option                 | Sub-option | Deployment in the InForm application  |
|------------------------|------------|---|
| Preview Annotated Form |            | N/A   |
| Preview Form           |            | N/A   |
| Reset                  |            | N/A   |
| Remove Caption         |            | N/A   |
| IPR Configuration      |            | <p>Opens the IPR Configuration dialog box so that you can specify a change as an in-place revision.</p> <p><b>Note:</b> This button only appears when you access the Layout tab for a form through the Visit Schedule Explorer bar.</p> |

## Study Level Styles and Form Level Styles dialog boxes—Option descriptions

### Form Styles page

| Option                | Description  |
|-----------------------|--|
| Question column width | <p>The percentage of the width of the layout table to use for the question column.</p> <p><b>Default</b>—50 percent.</p> |

**Note:** The Inherit checkbox is not available for the options on the Study Level Styles dialog box. When Inherit is selected, all values for the set of options are inherited from the study styles. To override the study styles, deselect Inherit, and provide different values.

### Codelist Control Styles page

| Option                    | Description   |
|---------------------------|---|
| Control orientation       | <p>Display codelist items either horizontally or vertically.</p> <p><b>Default</b>—Horizontal.</p>  |
| Single selection settings | <p><b>Note:</b> The settings in this section apply only to items that require a single selection (set on the Design tab for an item, when <b>Select Single Value</b> is selected). Multiple-selection codelists are always formatted as checkboxes.</p> |

| Option  | Description   |
|---|---|
| <ul style="list-style-type: none"> <li>Radio buttons</li> </ul> | <p>(Default)</p> <p>Format single-selection codelists as radio buttons.</p> <ul style="list-style-type: none"> <li><b>Use pulldown when item count exceeds</b>—Format single-selection codelists as radio buttons, except when the number of codelist items exceeds the specified number, and then format as pulldowns. <ul style="list-style-type: none"> <li><b>Default</b>—5.</li> </ul> </li> <li><b>Display vertically when item count exceeds</b>—When the number of codelist items exceeds the specified number, display the codelist items as vertical radio buttons. <ul style="list-style-type: none"> <li><b>Default</b>—5.</li> </ul> </li> </ul> |
| <ul style="list-style-type: none"> <li>Pulldown</li> </ul>      | Format single-selection codelists as pulldowns.   |

**Note:** The Inherit checkbox is not available for the options on the Study Level Styles dialog box. When Inherit is selected, all values for the set of options are inherited from the study styles. To override the study styles, deselect Inherit, and provide different values.

#### Compound Items Control Styles page

| Option              | Description  |
|---------------------|--|
| Caption alignment   | <p>Align the caption to the left, top, right, or bottom of an item's controls.</p> <p><b>Default</b>—Left.</p> |
| Control orientation | <p>Display nested controls either horizontally or vertically.</p> <p><b>Default</b>—Vertically.</p>            |

**Note:** The Inherit checkbox is not available for the options on the Study Level Styles dialog box. When Inherit is selected, all values for the set of options are inherited from the study styles. To override the study styles, deselect Inherit, and provide different values.

## Date Time Item Control Styles page

| Description       | Description  |
|-------------------|--|
| Year range        | The default year range for all date time items.<br><b>Default</b> —Current year for both fields.     |
| Caption alignment | Align the caption to the left, top, right, or bottom of an item's controls.<br><b>Default</b> —Left. |

**Note:** The Inherit checkbox is not available for the options on the Study Level Styles dialog box. When Inherit is selected, all values for the set of options are inherited from the study styles. To override the study styles, deselect Inherit, and provide different values.

## Float Item and Integer Item Control Styles pages

| Option            | Description   |
|-------------------|---|
| Caption alignment | Align the caption to the left, top, right, or bottom of an item's controls.<br><b>Default</b> —Left.  |
| Textbox width     | Specify the width of the text boxes. <ul style="list-style-type: none"> <li>• <b>Use the item variable's length as the width</b> (Default)—Use each item's length as the width of the text box.</li> <li>• <b>Use this width</b>—Use a specified width for the text box.</li> </ul> |
| Unit control type | Display the controls for the units for a float or integer item as either radio buttons or pulldowns.<br><b>Default</b> —Radio buttons.  |

**Note:** The Inherit checkbox is not available for the options on the Study Level Styles dialog box. When Inherit is selected, all values for the set of options are inherited from the study styles. To override the study styles, deselect Inherit, and provide different values.



## Text Item Control Styles page

| Option                    | Description  |
|---------------------------|--|
| Caption alignment         | Align the caption to the left, top, right, or bottom of an item's controls.  |
| Textbox size              | <p>Specify the width and height of the text boxes.</p> <ul style="list-style-type: none"> <li>• <b>Use the item variable's length as the width</b> (Default)—Use each item's length as the width of the text box. <ul style="list-style-type: none"> <li>▪ <b>Increase the height by one line for every __ chars</b>—Increment the height of the text box by one line for every 50 characters. For example, the height for 1-50 characters is 1; the height for 51-100 characters is 2; and so on.<br/><b>Default</b>—50.</li> </ul> </li> <li>• <b>Use the following width and height</b>—Use a specified width and height for the textbox. Specify the width using the number of characters and the height using the number of lines.</li> </ul> |
| Character set restriction | <ul style="list-style-type: none"> <li>• <b>Unrestricted</b> (Default)—Do not restrict the entry of values in text fields without codelists.</li> <li>• <b>ASCII Only</b>—In release 5.0 and later of the InForm application, restrict the entry of values in text fields without codelists to the complete ASCII character set (byte range 0 to 127). Items with restricted values are marked with a star (★) in the Annotated Study Book.</li> </ul>   |

**Note:** The Inherit checkbox is not available for the options on the Study Level Styles dialog box. When Inherit is selected, all values for the set of options are inherited from the study styles. To override the study styles, deselect Inherit, and provide different values.

# In-place revisions

## IPR Configuration dialog box

Use the IPR Configuration dialog box to configure the settings of an in-place revision.

The dialog box is read-only if you do not have the right to make in-place revisions, or if the object or in-place revision is locked or protected.

| Option   | Description   |
|--|---|
| Description of the change  | Description of the change. Optional.  |
| Add  | Open the Add Deployment Instance dialog box to add a deployment instance.   |
| Remove   | Remove the selected deployment instance.  |
| Refresh Versions   | Retrieve the latest study version information for the selected deployment instance.   |
| Apply to All   | Apply a change to all study versions.   |
| Copy Association   | Open the Copy IPR Configurations dialog box to copy the in-place revision association from the selected deployment instance to another deployment instance.   |
| View Differences   | Open the View Differences dialog box to compare the latest version of the object with the object from a selected study version.   |
| <b>Columns</b> (Study version association section, at the top of the dialog box) |   |
| Deployment Instance  | RefName of the deployment instance.   |
| Type   | Server type for the deployment instance: <ul style="list-style-type: none"> <li>• <b>UAT</b>—User acceptance testing</li> <li>• <b>QA</b>—Quality assurance</li> <li>• <b>DEV</b>—Development</li> <li>• <b>LIVE</b>—Production</li> <li>• <b>TRN</b>—Training</li> </ul> |
| Description  | Description of the deployment instance.   |
| URL  | URL address of the deployment instance.   |
| <b>Columns</b> (Select study version section, at the bottom of the dialog box)   |   |
| Checkbox   | When selected, associates the change to the study version on that row.  |

| Option        | Description                         |
|---------------|-------------------------------------|
| Study Version | InForm study version.               |
| Form          | Form that contains the revision.    |
| Section       | Section that contains the revision. |
| Item          | Item that contains the revision.    |

## In-Place Revision Summary Editor—Option descriptions

| Option              | Description  |
|---------------------|--|
| <b>Buttons</b>      |  |
| Edit                | Edit the IPR configuration for the selected in-place revision.   |
| Delete              | Delete the selected in-place revision.   |
| IPR Configurations  | Copy IPR configurations from one deployment instance to another, or remove IPR configurations from selected deployment instances.  |
| Select All          | Select all in-place revisions.   |
| Lock and Protect    | Lock or protect the selected in-place revision objects.  |
| History             | Open the IPR History dialog box to view a history of in-place revisions for all baselines with in-place revisions that were successfully deployed to LIVE deployment instances.<br><br><b>Note:</b> The IPR History dialog box only contains information about IPRs applied through automated deployments. |
| <b>Columns</b>      |  |
| RefName             | RefName of the in-place revision study object.   |
| Type                | Type of revised study object.  |
| Deployment Instance | Deployment instance to which to deploy the in-place revision.  |
| Description         | Description of the change.   |

## View Differences dialog box—Option descriptions

| Option              | Description   |
|---------------------|---|
| <b>Buttons</b>      |   |
| Show Differences    | View the differences between the selected versions of the form.   |
| Root                | Select the study object at the top-level in the Modified Objects tree.  |
| Back                | Select the previously-selected study object in the Modified Objects tree.   |
| Preview Form        | View the current and previous layouts for the selected form.  |
| <b>Fields</b>       |   |
| Form                | Form for which to view differences.   |
| Preexisting version | Deployed study version in which the form exists. Select the study version to view the design of the form that you selected in the Form drop-down list that existed in that study version. |
| Locale              | Locale for which to view form data.   |
| Modified Objects    | Explorer tree that displays a list of study objects that were modified in the most current version of the study.  |
| Difference          | Modification that was made to the study object selected in the Modified Objects tree in the most current version of the study.  |
| Source              | Study object that was modified.   |
| Target              | New study object that was created by the in-place revision change.  |

## IPR History dialog box—Option descriptions

| Option  | Description  |
|---|--|
| <b>Buttons</b>                                |  |
| Show IPRs                                     | View a list of in-place revision changes for the selected baseline.<br><br><b>Note:</b> You can only view the in-place revision changes for a baseline for a study that was deployed to the InForm application using automated deployment. |
| View Configuration                            | View the in-place revision configuration for the study object that you select in the bottom of the dialog box.   |
| <b>Fields at the top of the dialog box</b>    |  |
| Baseline                                      | Baseline for a study that was deployed to a LIVE deployment instance with in-place revision changes.   |
| Package Name                                  | Deployment package name.   |
| Deployment Date                               | Date when the study was deployed.  |
| <b>Fields at the bottom of the dialog box</b> |  |
| RefName                                       | RefName of the study object that was modified using an in-place revision change.   |
| Type  | Study object type.   |
| Deployment Instance                           | Type of deployment instance to which the study was deployed.   |
| Description                                   | Description of the in-place revision change that was made to the study object.   |

# Rules

## Assign Conditions dialog box—Option descriptions

Use the Assign Conditions dialog box to add a global condition to or remove a global condition from a study object in a workflow. In this dialog box, you specify the terms under which the next object in a workflow appears in a study, when the next object in a workflow depends on the outcome of a global condition.

| Option              | Description  |
|---------------------|--|
| Global Conditions   | Available global conditions.   |
| Assigned Conditions | Global condition that has been added to the selected study object.                         |
| Add (>>)            | Assign the global condition to the study object, and remove the assigned global condition. |
| Remove (<<)         |  |
| Expression box      | Text of the global condition expression.   |

| Option          | Description  |
|-----------------|--|
| If the value is | <p data-bbox="597 205 1455 268">Specify how the result of the selected global condition determines the study workflow.</p> <p data-bbox="597 289 1347 321">Indicates when the next object in the workflow appears in a study:</p> <ul data-bbox="597 342 1477 1304" style="list-style-type: none"> <li data-bbox="597 342 1258 373">• <b>False</b>—Only if the global condition evaluates to false.</li> <li data-bbox="597 394 1247 426">• <b>True</b>—Only if the global condition evaluates to true.</li> <li data-bbox="597 447 1466 510">• <b>Always</b>—Regardless of the result of the global condition. This option is disabled for a workflow rule.</li> <li data-bbox="597 531 1471 594">• <b>Only if no other action executes</b>—Only if no other workflow object is in effect. This option is disabled for a workflow rule.</li> <li data-bbox="597 615 1477 1304"> <ul style="list-style-type: none"> <li data-bbox="597 615 1455 758">• <b>Relational statement</b>—Only if the value returned by the global condition satisfies the condition specified in the drop-down list and the text fields for this option. The following additional information is required for this selection:               <ul style="list-style-type: none"> <li data-bbox="646 779 1471 842">▪ <b>Drop-down list</b>—Specifies how the value returned by the workflow rule is compared with the values in the two text fields.</li> <li data-bbox="646 863 1477 1031">▪ <b>First text field</b>—Specifies the value to compare with the value returned by the global condition. If Between is selected in the drop-down list, the first text field specifies the first of two values that delineate a range. The global condition result is checked to determine if it is between the two values.</li> <li data-bbox="646 1052 1442 1178">▪ <b>Second text field</b>—Available if Between is selected in the drop-down list. The second text field specifies the second of two values that delineate a range. The global condition result is checked to determine whether it is between the two values.</li> <li data-bbox="646 1199 1466 1304">▪ <b>Inclusive</b>—Available if Between is selected in the drop-down list. If selected, indicates that the range of values delineated in the two text fields includes the values entered in those fields.</li> </ul> </li> </ul> </li> </ul> <p data-bbox="646 1325 1438 1386"><b>Note:</b> Do not use the relational statement fields for string values, or a validation error occurs.</p> |

## Define Test Values for Repeating Instances dialog box—Option descriptions

When an item is on a repeating section, form, or study event, you must provide test values for all of the instances of the item.

| Option                    | Description  |
|---------------------------|--|
| <b>Buttons</b>            |  |
| Add Repeating Instance    | Add an instance of the selected repeating study object to create test cases for each instance.   |
| Copy Repeating Instance   | Adds an instance with the value of the selected instance.  |
| Remove Repeating Instance | Delete the selected instance.  |
|                           | <b>Note:</b> When you add, copy, or delete instances, the indexing of the repeating instances is reordered. For example, if you delete the second of four instances, the third instance becomes the second and the fourth becomes the third. Adding an instance increases all subsequent instance numbers. |
| <b>Sections</b>           |  |
| Selected Item tree        | Tree that contains the study objects in the rule. Use the buttons to create or remove instances.<br><br><b>Note:</b> You can create instances only for repeating study objects, which appear in the Repeating Items list.  |
| Grid                      | Path and value of items that are on repeating study objects. Provide a testing value in the Item Value field.  |
| Repeating Items list      | List of all items in the rule that are children of repeating study objects. Select an item to provide its test values in the grid.   |
| Rule Details tab          | Text representation and description of the rule.   |
| Item Properties tab       | Properties for the test name, item, or expected result that you point to in the grid.<br><br>For more information, see <i>Properties in the Rule Test Cases dialog box</i> (on page 484).  |
| Form Preview tab          | Preview of the form on which the repeating item exists.  |



## Design tab of the Rule Test Cases dialog box—Option descriptions

In the Design tab, you write, modify, and delete test cases for rules.

| Field                           | Description  |
|---------------------------------|--|
| <b>Grid</b>                     |  |
| Test Name                       | Name of the test case. By default, test cases are named <b>Test</b> < <i>incrementing number</i> >, where < <i>incrementing number</i> > is a number that starts with 1 and counts upward.   |
| < <i>item name</i> >            | Each item that is used in the rule expression appears as a field. You can provide test values for each item.<br><br>For more information, see <i>Writing a test case for a rule or global condition</i> (on page 179).   |
| Expected Result                 | The expected result of the test case. Multiple fields appear for data-entry rules with multiple actions. <ul style="list-style-type: none"> <li>For data-entry rules: <ul style="list-style-type: none"> <li><b>Rule issues a query</b>—Select <b>QUERY</b> or <b>NOQUERY</b>.</li> <li><b>Rule sends an email message</b>—Select <b>Sent</b> or <b>Not Sent</b>.</li> <li><b>Rule sets a value</b>—Calculate and type the expected value. For example, for a BMI rule, use the Height and Weight values in the test case to calculate the value.</li> </ul> </li> <li>For workflow rules, you select the study object that you expect to appear next in the workflow, based upon the test case.</li> <li>For global conditions, you select True or False, depending on whether the specified condition is true or false.</li> </ul> |
| <b>Rule Details tab</b>         | Text representation and description of the rule.   |
| <b>Site Info tab</b>            | Information appears in this tab when a locale is defined for a study.  |
| Site name (or mnemonic)         | Name of the site. This information is returned when you use the GetSiteMnemonic() function.  |
| Site locale                     | Drop-down list of supported locales for a study. The selected locale is returned when you use the GetSiteLocale() function.  |
| Site locale date and time       | Drop-down list for selecting a date and time. The selected date and time is returned when you use the GetSiteTime() function.  |
| <b>Form Associations tab</b>    | Information appears in this tab if an item path contains an associated form.   |
| Associated Data View item paths | If you used data from associated forms in the rule, select the item paths that you used so that the Rule Test Cases dialog box can use the information when running the test cases.  |

| Field                       | Description   |
|-----------------------------|---|
| <b>Test Properties tab</b>  | Properties for the test name, item, or expected result that you point to in the grid.<br><br>For more information, see <i>Properties in the Rule Test Cases dialog box</i> (on page 484). |
| <b>Test Description tab</b> | Optionally, type a description of the test case.  |

## Edit Global Conditions dialog box—Option descriptions

Use the Edit Global Conditions dialog box to:

- Create, edit, and delete a global condition.
- View the locations in which a global condition is used.

| Option                        | Description  |
|-------------------------------|--|
| <b>Global Conditions list</b> |  |
| Name                          | Name of the global condition.  |
| Description                   | Description of the global condition. This field is not deployed.<br><br>Maximum characters: 2000.  |
| Target                        | Target application specified for the global condition. The target application determines the study objects that are visible in the References section.   |
| Add, Edit, Delete             | Create a new global condition, or edit or delete the selected global condition.  |
| <b>Expression tab</b>         | Used for developing the expression for the global condition by typing or by dragging in components displayed in the tabs of the References section. When you drag in a component, the reference to the component is converted to the standard Central Designer expression syntax.<br><br>Typically an expression might contain a combination of typed values (such as operators) and dragged-in components (such as functions or references to study objects). |
| <b>Assignments tab</b>        | View the locations in the study in which the selected global condition is used.  |
| Workflow Name                 | Name of the study object with the workflow that contains the global condition.   |
| Workflow Type                 | Type (such as study design) of study object with the workflow that contains the global condition.  |
| Object Name                   | Name of the study object to which the global condition is assigned.  |

| Option                                     | Description  |
|--|--|
| Object Type                                | Type (such as study event) of the study object to which the global condition is assigned.  |
| Rule Action                                | Action for the global condition assignment, such as <b>when value is true</b> .  |
| <b>Reference tabs—Available components</b> | <p>List of the components that are available for use in the global condition being defined.</p> <p>By default, these tabs appear on the right side of the dialog box. When you select a tab, the Reference section appears, with tabs along the bottom edge.</p> |
| Data tab                                   | The available study objects appear in a tree structure similar to the Project Explorer.  |
| Functions tab                              | <p>The available functions appear in a tree structure organized by class.</p> <p><b>Note:</b> Functions are defined in the Study Editor or Library Editor.</p>   |
| Constants tab                              | <p>The available constants appear in a tree structure organized by class.</p> <p><b>Note:</b> Constants are defined in the Study Editor or Library Editor.</p>   |
| Data Mappings tab                          | The components of the available mappings appear in a tree structure similar to the Project Explorer.   |
| Show All checkbox                          | When selected, all available study objects as well as their properties appear. When not selected, only the available study objects appear.   |

## Edit Rule Action dialog box—Option descriptions

Use the Edit Rule Action dialog box to specify the conditions under which the next object in a workflow appears in a study, when the next study object in a workflow depends on the outcome of a workflow rule. This dialog box appears when you:

- Connect a rule to a form in the Workflow Diagram tab.
- Double-click an outgoing connector from a rule in the Workflow Diagram tab.
- Specify a workflow rule outcome as a precondition in the Workflow Diagram tab

The dialog box allows you to define a workflow action only.

| Option          | Description   |
|-----------------|---|
| If the value is | <p data-bbox="646 674 1398 705">Indicates when the next object in the workflow appears in a study:</p> <ul style="list-style-type: none"> <li data-bbox="646 726 1166 758">• <b>False</b>—Only if the rule evaluates to false.</li> <li data-bbox="646 779 1154 810">• <b>True</b>—Only if the rule evaluates to true.</li> <li data-bbox="646 831 1471 894">• <b>Always</b>—Regardless of the result of the rule. This option is disabled for a workflow rule.</li> <li data-bbox="646 915 1414 978">• <b>Only if no other action executes</b>—Only if no other workflow object is in effect. This option is disabled for a workflow rule.</li> <li data-bbox="646 999 1479 1682"> <ul style="list-style-type: none"> <li data-bbox="646 999 1438 1136">• <b>Relational statement</b>—Only if the value returned by the rule satisfies the condition specified in the drop-down list and the text fields for this option. The following additional information is required for this selection:               <ul style="list-style-type: none"> <li data-bbox="691 1157 1471 1220">▪ <b>Drop-down list</b>—Specifies how the value returned by the workflow rule is compared with the values in the two text fields.</li> <li data-bbox="691 1241 1479 1409">▪ <b>First text field</b>—Specifies the value to compare with the value returned by the rule. If Between is selected in the drop-down list, the first text field specifies the first of two values that delineate a range. The rule result is checked to determine if it is between the two values.</li> <li data-bbox="691 1430 1471 1566">▪ <b>Second text field</b>—Available if Between is selected in the drop-down list. The second text field specifies the second of two values that delineate a range. The rule result is checked to determine whether it is between the two values.</li> <li data-bbox="691 1587 1479 1682">▪ <b>Inclusive</b>—Available if Between is selected in the drop-down list. If selected, indicates that the range of values delineated in the two text fields includes the values entered in those fields.</li> </ul> </li> </ul> </li> </ul> <p data-bbox="646 1703 1438 1766"><b>Note:</b> Do not use the relational statement fields for string values, or a validation error occurs.</p> |

## Edit Schedule dialog box—Option descriptions

Use the Edit Schedule dialog box to specify the interval before the next study event in a study workflow. This dialog box appears when you:

- Connect a study element or study event to a study element or study event in the Workflow Diagram tab.
- Double-click an outgoing connector from a study element or study event to a study element or study event in the Workflow Diagram tab.

| Option                | Description  |
|-----------------------|--|
| Target event interval | Amount of time to elapse between the connected study object and study event. This amount is specified as the number of weeks, days, and hours. |
| After event           | Indicates the study event that the current study event follows.  |
| Clear Schedule        | Resets the target event interval to zero.  |

## Edit Schedule and Rule Action dialog box—Option descriptions

Use the Edit Schedule and Rule Action dialog box to specify the conditions under which the next object in a workflow appears in a study, when the next study object in a workflow depends on the outcome of a workflow rule. This dialog box appears when you:

- Connect a rule to a study event in the Workflow Diagram tab.
- Double-click an outgoing connector from a rule in the Workflow Diagram tab.
- Specify a workflow rule outcome as a precondition in the Workflow Diagram tab.

The Edit Schedule and Rule Action dialog box appears when you connect a workflow rule and a study object. The dialog box allows you to define a schedule at the same time that you define a workflow action.

| Option                    | Description  |
|---------------------------|--|
| <b>Event Schedule tab</b> |  |
| Target event interval     | Amount of time to elapse between the connected study object and study event. This amount is specified as the number of weeks, days, and hours. |
| After event               | Indicates the study event that the current study event follows.  |
| Clear Schedule            | Resets the target event interval to zero.  |
| <b>Rule Action tab</b>    |  |

| Option          | Description   |
|-----------------|---|
| If the value is | <p>Indicates when the next object in the workflow appears in a study:</p> <ul style="list-style-type: none"> <li>• <b>False</b>—Only if the rule or global condition evaluates to false.</li> <li>• <b>True</b>—Only if the rule or global condition evaluates to true.</li> <li>• <b>Always</b>—Regardless of the result of the rule or global condition. This option is disabled for a workflow rule.</li> <li>• <b>Only if no other action executes</b>—Only if no other workflow object is in effect. This option is disabled for a workflow rule.</li> <li>• <b>Relational statement</b>—Only if the value returned by the rule or global condition satisfies the condition specified in the drop-down list and the text fields for this option. The following additional information is required for this selection: <ul style="list-style-type: none"> <li>▪ <b>Drop-down list</b>—Specifies how the value returned by the workflow rule is compared with the values in the two text fields.</li> <li>▪ <b>First text field</b>—Specifies the value to compare with the value returned by the rule or global condition. If Between is selected in the drop-down list, the first text field specifies the first of two values that delineate a range. The rule or global condition result is checked to determine if it is between the two values.</li> <li>▪ <b>Second text field</b>—Available if Between is selected in the drop-down list. The second text field specifies the second of two values that delineate a range. The rule or global condition result is checked to determine whether it is between the two values.</li> <li>▪ <b>Inclusive</b>—Available if Between is selected in the drop-down list. If selected, indicates that the range of values delineated in the two text fields includes the values entered in those fields.</li> </ul> </li> </ul> <p><b>Note:</b> Do not use the relational statement fields for string values, or a validation error occurs.</p> |

## Email Action dialog box—Option descriptions

| Option | Description   |
|--------|---|
| Item   | Item that triggers the email action. Optionally, drag an item from the Data tab.  |
| To     | <p>(Required)</p> <p>Email address of the person to receive the email. Separate multiple email addresses with a semicolon. The email address must be in a valid format, such as name@address.value.</p> |

| Option                                     | Description  |
|--|--|
| From                                       | <p>Email address of the person to send the email. The email address must be in a valid format, such as name@address.value.</p> <p>If you do not provide an email address, an address is taken from the registry. If the registry does not contain an email address, &lt;studyname&gt;@&lt;default_webserver&gt; is used.</p>   |
| Locale                                     | <p>Locale for the email subject and message.</p> <p><b>Note:</b> To translate information, you must have the necessary language skills defined in the Central Designer Administrator application.</p>  |
| Subject                                    | <p>Subject of the email message.</p> <p>You can type a value or drag information from the Data, Functions, Constants, and Globals tabs.</p> <p><b>Note:</b> Do not add an item for which the PHI item property is set to True.</p>   |
| Message                                    | <p>Email message.</p> <p>You can type a value or drag information from the Data, Functions, Constants, and Globals tabs.</p> <p><b>Notes:</b></p> <p>Do not add an item for which the PHI item property is set to True.</p> <p>A parameterized string in an email message or query that is generated in the InForm application follows the formatting that is specified for the site in the InForm application. Not allowed and unknown components of a date time value appear as asterisks (*). Leading and following underscores in the value are removed automatically.</p> |
| Message and Subject Parameters             | <p>Optional parameters that you can create and use in the Subject field, Message field, and Parameter Value field.</p> <p>Type a value or drag information from the Data, Functions, Constants, and Globals tabs.</p>  |
| <b>Reference tabs—Available components</b> | <p>List of the components that are available for use in the rule being defined.</p> <p>By default, these tabs appear on the right side of the dialog box. When you select a tab, the Reference section appears, with tabs along the bottom edge.</p>   |
| Data tab                                   | <p>The available study objects appear in a tree structure similar to the Project Explorer.</p>   |
| Functions tab                              | <p>The available functions appear in a tree structure organized by class.</p> <p><b>Note:</b> Functions are defined in the Study Editor or Library Editor.</p>   |
| Constants tab                              | <p>The available constants appear in a tree structure organized by class.</p> <p><b>Note:</b> Constants are defined in the Study Editor or Library Editor.</p>   |

| Option            | Description  |
|-------------------|--|
| Data Mappings tab | The components of the available mappings appear in a tree structure similar to the Project Explorer.                                       |
| Show All checkbox | When selected, all available study objects as well as their properties appear. When not selected, only the available study objects appear. |

## Invoke Function dialog box—Option descriptions

Use the Invoke Function dialog box to assign values to the parameters named in a function that you are invoking in a rule or global condition definition.

| Option                                     | Description   |
|--|---|
| Function                                   | Name and description of the function being invoked.   |
| Return Type                                | Data type of the value returned by the function.  |
| <b>Reference tabs—Available components</b> | List of the components that are available for use in the rule being defined.<br><br>By default, these tabs appear on the right side of the dialog box. When you select a tab, the Reference section appears, with tabs along the bottom edge. |
| Data tab                                   | The available study objects appear in a tree structure similar to the Project Explorer.   |
| Functions tab                              | The available functions appear in a tree structure organized by class.<br><b>Note:</b> Functions are defined in the Study Editor or Library Editor.   |
| Constants tab                              | The available constants appear in a tree structure organized by class.<br><b>Note:</b> Constants are defined in the Study Editor or Library Editor.   |
| Data Mappings tab                          | The components of the available mappings appear in a tree structure similar to the Project Explorer.  |
| Show All checkbox                          | When selected, all available study objects as well as their properties appear. When not selected, only the available study objects appear.  |
| <b>Parameter description section</b>       | Lists the parameters that have been defined for the function, along with spaces in which to specify their values in the rule or global condition expression.  |
| Parameter                                  | Name of the parameter.  |
| Data Type                                  | Data type of the parameter.   |



| Option | Description   |
|--------|---|
| Value  | <p>Value the parameter takes in the rule or global condition expression:</p> <ul style="list-style-type: none"> <li>• An explicit number or string.</li> <li>• A study object, constant, or data series dragged from the Data, Constants, or Data Mappings tab of the References section.</li> <li>• A function that returns a value of the required data type (for example, the GetValue() function).</li> </ul> |

## Query Action dialog box—Option descriptions

| Option              | Description  |
|---------------------|--|
| Initial Query State | <p>Initial state of the query.</p> <ul style="list-style-type: none"> <li>• <b>Open</b>—The query is visible on the form and available for response.</li> <li>• <b>Candidate</b>—The query is not visible on the form until someone reviews and explicitly opens it.</li> </ul>  |
| Item                | <p>Item on which the query will be issued. You can:</p> <ul style="list-style-type: none"> <li>• Type the name of the item.</li> <li>• Drag an item from the Data tab to the field.</li> <li>• Type an expression that satisfies the requirements of the rule expression language. For more information, see <i>About the rule expression language</i> (on page 146).</li> </ul> |
| Locale              | <p>Locale of the query message.</p> <p><b>Note:</b> To translate information, you must have the necessary language skills defined in the Central Designer Administrator application.</p>   |

| Option                                     | Description   |
|--|---|
| Message                                    | <p>Query message that appears. The query message must be 255 characters or fewer. The following errors occur for query messages that have 256 characters or more:</p> <ul style="list-style-type: none"> <li>• If the query message has parameters and the message is 255 characters or fewer without the parameters, you receive a warning during validation, and the query is truncated to 255 characters in the InForm application.</li> <li>• If the query message does not have parameters, you receive an error during validation.</li> </ul> <p><b>Note:</b> A parameterized string in an email message or query that is generated in the InForm application follows the formatting that is specified for the site in the InForm application. Not allowed and unknown components of a date time value appear as asterisks (*). Leading and following underscores in the value are removed automatically.</p> |
| Message Parameters                         | <p>Optional parameters that you can create and use in the query message.</p> <p>Type a value or drag information from the Data, Functions, Constants, and Globals tabs.</p>   |
| <b>Reference tabs—Available components</b> | <p>List of the components that are available for use in the rule being defined.</p> <p>By default, these tabs appear on the right side of the dialog box. When you select a tab, the Reference section appears, with tabs along the bottom edge.</p>  |
| Data tab                                   | <p>The available study objects appear in a tree structure similar to the Project Explorer.</p>  |
| Functions tab                              | <p>The available functions appear in a tree structure organized by class.</p> <p><b>Note:</b> Functions are defined in the Study Editor or Library Editor.</p>  |
| Constants tab                              | <p>The available constants appear in a tree structure organized by class.</p> <p><b>Note:</b> Constants are defined in the Study Editor or Library Editor.</p>  |
| Data Mappings tab                          | <p>The components of the available mappings appear in a tree structure similar to the Project Explorer.</p>   |
| Show All checkbox                          | <p>When selected, all available study objects as well as their properties appear. When not selected, only the available study objects appear.</p>   |

## New Rule Template dialog box—Option descriptions

| Option                       | Description   |
|------------------------------|---|
| <b>Properties tab</b>        |   |
| Name                         | Name of the rule template.  |
| Classification               | User-defined term used to organize rule templates.  |
| Description                  | Description of the rule template.   |
| Display Text                 | Text that appears in the Rule Summary section of the Rule wizard after the <b>When Value Is</b> information.<br><br>If this field is blank, the contents of the Expression workspace are used. If the expression contains parameters, the name of the parameter and the value of the parameter appear. For example, if the expression is <b>value must be between {a} and {b}</b> , and the value of <b>a</b> is 10 and the value of <b>b</b> is 100, the parameters appear as <b>a:10</b> and <b>b:100</b> . |
| <b>Definition tab</b>        |   |
| Return Type drop-down list   | Return type of the rule template; one of the following: Integer, Float, String, Boolean, Date/Time, or Array (A list of values, all of the same type).  |
| Expression                   | Expression of the rule. For more information, see <i>About the rule expression language</i> (on page 146).  |
| <b>Parameters (Optional)</b> |   |
| Parameter                    | Name of the parameter.  |
| Data Type                    | Return type of the parameter; one of the following: Integer, Float, String, Boolean, Date/Time, or Array (A list of values, all of the same type).  |
| Default Value                | Specified value of the parameter.   |
| <b>References</b>            |   |
| Data tab                     | Lists study objects in the scope of the rule. Optionally, to view the rule model properties of all of the study objects, select <b>Show all</b> .   |
| Functions tab                | Lists functions registered in a study and the libraries that appear in the Libraries List in the Study Editor. Any rule in the study can reference a function.  |
| Constants tab                | Lists constants created in the study and the libraries that appear in the Libraries List in the Study Editor. Any rule in the study can reference a constant.   |

| Option            | Description   |
|-------------------|---|
| Data Mappings tab | <p>Lists:</p> <ul style="list-style-type: none"> <li>• RefNames of the <i>data mappings</i> (on page 188), <i>data sets</i> (on page 196), and <i>data series</i> (on page 199) in the study or library.</li> <li>• Rule model properties for data series. <p>A data series has the properties of the item that is mapped to it. If a data series contains an item that collects more than one value, the rule model properties for repeating study objects appear so you can access an array of all of the values of the item.</p> </li> <li>• Methods for data sets. <p>A method appears if you select the corresponding standard data dimension of the data set. You can use data set methods to return a subset of the data in the data set.</p> </li> <li>• Study events, forms, sections, and items that are mapped to each data set.</li> <li>• Study objects appear if you select the corresponding standard data dimension of the data set. The properties of the study objects are used as parameters of data set methods.</li> </ul> |

## Rule Templates tab—Option descriptions

The grid displays rule templates created on the study object selected in the Project Explorer.

| Option                     | Description  |
|----------------------------|--|
| <b>Rule templates grid</b> |  |
| Data Type                  | Return type of the rule template.  |
| Description                | Description of the rule template.  |
| Display Text               | Text that appears in the Rule Summary section of the Rule wizard after the <b>When Value Is</b> information. |
| Id                         | Identification information for the rule.   |
| Expression                 | Rule expression of the rule template.  |
| Parameters                 | Specified parameters of the rule template, separated by semicolons.  |
| Template Name              | Name of the rule template.   |
| Type                       | Indicates that the rule was created using the Central Designer rule expression language.                     |

## Rule Wizard—Option descriptions

The Rule Wizard provides a simple interface for creating data-entry rules, including specifying the type of rule, preconditions, expression, and actions.

Navigate through the wizard using:

- The tabs at the top of the wizard.
- The Next button.
- The links in the Rule Summary section.

The Rule Wizard has the following tabs.

### Quick Start tab

In the Quick Start tab, you choose the type of rule to create.

**Note:** The tab appears when you create a rule but not when you view an existing rule.

| Option           | Description  |
|------------------|--|
| Intrinsic Rule   | An intrinsic rule is a constraint rule or calculation rule based on a predefined rule template. Rule templates can be created for constraint rules and calculation rules. If no rule templates have been defined for the selected study object, then you cannot create an intrinsic rule for the study object. |
| Constraint Rule  | A constraint rule checks whether data is valid.  |
| Calculation Rule | A calculation rule sets the value of an item based on a calculation.   |

### Properties tab

In the Properties tab, you provide a name and a brief description for the rule.

| Option      | Description  |
|-------------|--|
| Name        | <p>The name of the rule:</p> <ul style="list-style-type: none"> <li>• Cannot contain spaces.</li> <li>• Must begin with a letter and can contain letters, numbers, and underscores ( _ ) but no other special characters.</li> <li>• Must be no longer than 63 characters.</li> <li>• Must be unique for the study object. For example, you can create a rule called rulCalcBMI on a form and an item, but you cannot create two rulCalcBMI rules on two different forms.</li> </ul> |
| Description | Description of the rule. The Description field can contain a description of the rule or the formal specification that is used by the actual rule developer. The limit is 2000 characters.  |

**Preconditions tab**

In the Preconditions tab, you select from the options in the Evaluate on Event drop-down list to specify when the rule will be evaluated.

| Option   | Description   |
|--|---|
| Evaluate on Event  | Event that causes the rule to execute: <ul style="list-style-type: none"> <li>• <b>On demand (batch mode)</b>—Rule is validated and deployed to the InForm application with a deactivated status, so the rule does not run in the InForm application.</li> <li>• <b>Form submission</b>—Rule runs on form submission. The InForm application uses the study objects on which the rule depends to determine rule dependencies and the form that causes the rule to run.</li> </ul> |
| Select the rules which should execute before this rule     | Reserved for future use.  |
| Execute this rule only if the following expression is true | Reserved for future use.  |

## Expression tab

The Expression tab has two views, one for creating an intrinsic rule and another for creating a calculation or constraint rule.

For detailed information about creating rule expressions, see Components of a rule expression.

| Option               | Description   |
|----------------------|---|
| Expression workspace | (Read-only for intrinsic rules) Provide the expression of the rule.   |
| Parameters section   | (Visible only for intrinsic rules) Provide the parameters for the function.   |
| Data Mappings tab    | <p>Lists:</p> <ul style="list-style-type: none"> <li>• RefNames of the <i>data mappings</i> (on page 188), <i>data sets</i> (on page 196), and <i>data series</i> (on page 199) in the study or library.</li> <li>• Rule model properties for data series. <p>A data series has the properties of the item that is mapped to it. If a data series contains an item that collects more than one value, the rule model properties for repeating study objects appear so you can access an array of all of the values of the item.</p> </li> <li>• Methods for data sets. <p>A method appears if you select the corresponding standard data dimension of the data set. You can use data set methods to return a subset of the data in the data set.</p> </li> <li>• Study events, forms, sections, and items that are mapped to each data set.</li> <li>• Study objects appear if you select the corresponding standard data dimension of the data set. The properties of the study objects are used as parameters of data set methods.</li> </ul> |
| Constants tab        | Lists constants created in the study and the libraries that appear in the Libraries List in the Study Editor. Any rule in the study can reference a constant.   |
| Functions tab        | Lists functions registered in a study and the libraries that appear in the Libraries List in the Study Editor. Any rule in the study can reference a function. <p><b>Note:</b> This tab does not appear for intrinsic rules.</p>  |
| Data tab             | Lists study objects in the scope of the rule. Optionally, to view the rule model properties of all of the study objects, select <b>Show all</b> .   |

**Actions tab**

In the Actions tab, you specify the action, or actions, that occur as a result of executing the rule.

| Option                            | Description  |
|-----------------------------------|--|
| Add Action button                 | Add an action to the rule.<br><br><b>Note:</b> Click the Add Action button after defining an action only if you need to add another action.  |
| Delete Action button              | Delete the action selected in the Actions grid.  |
| <b>Grid</b>                       |  |
| Fire Event                        | Event that causes the action to occur. You select the event in the If The Value Is section.  |
| Actions                           | Action that occurs.  |
| <b>If the value is section</b>    |  |
| False                             | If the rule calculates a False value, the action occurs.   |
| Always                            | (Default for calculation rules) The action always occurs.  |
| True                              | If the rule calculates a True value, the action occurs.  |
| Only if no other action executes  | The action occurs only if no other action occurs. Select this option only if you define at least two actions.  |
| Values to specify                 | <ul style="list-style-type: none"> <li>• <b>Equals</b>—If the rule calculates a value that is equal to the provided value, the action occurs.</li> <li>• <b>Not Equals</b>—If the rule calculates a value that is not equal to the provided value, the action occurs.</li> <li>• <b>Less Than</b>—If the rule calculates a value that is less than the provided value, the action occurs.</li> <li>• <b>Greater Than</b>—If the rule calculates a value that is greater than the provided value, the action occurs.</li> <li>• <b>Between</b>—If the rule calculates a value that is between the provided values, the action occurs.</li> </ul> <p><b>Note:</b> You can include string values in the Equals and Not Equals fields. Enclose the string in double quotes. For example, "text".</p> |
| (Inclusive) checkbox              | Select this option to make the number comparisons inclusive. For example, <b>Less Than</b> becomes <b>Less Than or Equal To</b> .  |
| <b>Execute these actions grid</b> |  |
| Action                            | Available actions.<br><br><b>Note:</b> Actions appear after you select the event that causes the rule to execute.  |



## Rule Summary section

As you create a rule, the Rule Summary reflects the structure of the rule, including precondition, action, and expression information. Click a link in the Rule Summary to navigate through the Rule Wizard.

## Rules tab—Option descriptions

| Option                    | Description   |
|---------------------------|---|
| <b>Toolbar buttons</b>    |   |
| New Rule                  | Create, edit, or delete a data-entry rule.  |
| Edit                      |   |
| Delete                    |   |
| Check Syntax              | Check the syntax of a rule.   |
| Cut                       | Cut, copy, or paste a data-entry rule.  |
| Copy                      |   |
| Paste                     |   |
| Enable                    | Enable all disabled rules or disable all enabled rules for a study object.  |
| Disable                   | To enable or disable only parent rules for a study object, deselect the Show Child Rules checkbox before clicking the button. |
| Show Errors/Hide Errors   | View the errors associated with the rule. You must check syntax before you can view errors.                                   |
| Rule Tests                | Open the Rule Test Cases dialog box and create rule test cases.   |
| <b>Top section</b>        |   |
| Show Child Rules checkbox | When selected, all data-entry rules on the selected study object and its children appear in the grid.                         |
| <b>Summary grid</b>       |   |
| Description               | Description of the rule.  |
| Expression                | Expression of the rule.   |
| Id                        | Identification information for the rule.  |
| Lock icon                 | Appears if the rule is locked.  |
| Parameters                | Parameters for the rule template.   |
| Parent                    | Title of the study object to which the rule is attached.  |
| Parent RefName            | RefName of the study object to which the rule is attached.  |
| Parent Type               | Type of study object (such as a form) to which the rule is attached.  |
| RefName                   | RefName of the rule.  |

| Option                      | Description   |
|-----------------------------|---|
| Syntax icon                 | Indicates the validity of the rule syntax. <ul style="list-style-type: none"> <li>✓ —Rule syntax is valid.</li> <li>⚠ —Rule syntax has one or more warnings associated with it, or the rule could not be compiled.</li> <li>✗ —Rule syntax contains one or more errors and is not valid.</li> </ul> |
| Target                      | Target application to which the rule is deployed.   |
| When                        | Event that triggers the rule (you select this option from the Evaluate on Event drop-down list in the Rule Wizard).   |
| <b>Rule Summary section</b> | A structured specification of the rule appears, with links that open the Rule Wizard.   |

## Run tab of the Rule Test Cases dialog box—Option descriptions

In the Run tab, you run validate rules, run test cases, and view the results.

| Field                       | Description   |
|-----------------------------|---|
| <b>Top section</b>          |   |
| Check Syntax                | Check syntax for the selected rules.  |
| Execute Tests               | Run the selected test cases and check syntax for the selected rules.  |
| Stop                        | Stop the action.  |
| Go to Rule                  | You are brought to the following location: <ul style="list-style-type: none"> <li><b>Data-entry rules</b>—The study object on which the rule is created.</li> <li><b>Workflow rules</b>—The Workflow Diagram tab that contains the workflow rule. The workflow rule is selected in the diagram.</li> <li><b>Global conditions</b>—The study object on which the global condition was created (in a study, the study design). The Edit Global Conditions dialog box opens with the global condition selected.</li> </ul> |
| Progress indicator          | If the action is successful, the indicator is green. If one or more rules or test cases is invalid, the indicator is red.   |
| Passed<br>Failed<br>Skipped | Metrics for the test cases that you ran.<br><b>Note:</b> If the IgnoreTest property for a test case (set in the Test Properties tab) is set to True, the test case is skipped.  |
| <b>Grid</b>                 |   |

| Field                            | Description  |
|----------------------------------|--|
| Status                           | <ul style="list-style-type: none"> <li>• <b>Red circle</b>—Test case or rule is not valid.</li> <li>• <b>Green circle</b>—Test case or rule is valid.</li> <li>• <b>Yellow circle</b>—(Can appear only after you run test cases) Test case was skipped.</li> </ul> |
| Object Name                      | Study object on which the rule was created.  |
| Rule Name                        | Name of the rule.  |
| Validation                       | Indicates whether the rule is <b>valid</b> , <b>invalid</b> , or <b>incomplete</b> (for rules or global conditions that have valid syntax but are not complete; for example, if the rule has no action defined).   |
| Test Name                        | <ul style="list-style-type: none"> <li>• <b>Run test cases</b>—Name of the test case.</li> <li>• <b>Check syntax</b>—n/a appears</li> </ul>  |
| Results                          | <ul style="list-style-type: none"> <li>• <b>Run test cases</b>—Passed or Failed.</li> <li>• <b>Check syntax</b>—n/a appears.</li> </ul>  |
| Expected                         | <ul style="list-style-type: none"> <li>• <b>Run test cases</b>—Expected result of the test case.</li> <li>• <b>Check syntax</b>—n/a appears.</li> </ul>  |
| Actual                           | <ul style="list-style-type: none"> <li>• <b>Run test cases</b>—Actual result of the test case. If the test case fails, <b>error</b> appears.</li> <li>• <b>Check syntax</b>—n/a appears.</li> </ul>  |
| Time                             | <ul style="list-style-type: none"> <li>• <b>Run test cases</b>—Time (in milliseconds)</li> <li>• <b>Check syntax</b>—n/a appears.</li> </ul>   |
| <b>Execution Results section</b> | Select a result in the grid to view additional information.  |

## Set Review State Action dialog box

Use the Set Value Action dialog box to set the review stage of a form based on the outcome of a rule.

| Option                                     | Description  |
|--|--|
| Form                                       | Form for which the review state is set. You can type a name or drag a form from the Data tab.  |
| ReviewState                                | Review state to set.   |
| Review Stage                               | Review stage to set in the review state.   |
| Review Stage expression                    | Expression for the review stage to set in the review state.  |
| Comment (optional)                         | Optional text describing the action.   |
| <b>Reference tabs—Available components</b> | <p>List of the components that are available for use in the rule being defined.</p> <p>By default, these tabs appear on the right side of the dialog box. When you select a tab, the Reference section appears, with tabs along the bottom edge.</p> |
| Data tab                                   | The available study objects appear in a tree structure similar to the Project Explorer.  |
| Functions tab                              | <p>The available functions appear in a tree structure organized by class.</p> <p><b>Note:</b> Functions are defined in the Study Editor or Library Editor.</p>   |
| Constants tab                              | <p>The available constants appear in a tree structure organized by class.</p> <p><b>Note:</b> Constants are defined in the Study Editor or Library Editor.</p>   |
| Data Mappings tab                          | The components of the available mappings appear in a tree structure similar to the Project Explorer.   |
| Show All checkbox                          | When selected, all available study objects as well as their properties appear. When not selected, only the available study objects appear.   |

## Set Value Action dialog box—Option descriptions

Use the Set Value Action dialog box to set the value of an item based on the outcome of a rule.

| Option                                     | Description  |
|--|--|
| Item                                       | Item for which the value is set. You can type a name or drag an item from the Data tab.  |
| Value to set the Item                      | Value for the item. You can type a value or drag information from any of the tabs.   |
| <b>Reference tabs—Available components</b> | <p>List of the components that are available for use in the rule being defined.</p> <p>By default, these tabs appear on the right side of the dialog box. When you select a tab, the Reference section appears, with tabs along the bottom edge.</p> |
| Data tab                                   | The available study objects appear in a tree structure similar to the Project Explorer.  |
| Functions tab                              | <p>The available functions appear in a tree structure organized by class.</p> <p><b>Note:</b> Functions are defined in the Study Editor or Library Editor.</p>   |
| Constants tab                              | <p>The available constants appear in a tree structure organized by class.</p> <p><b>Note:</b> Constants are defined in the Study Editor or Library Editor.</p>   |
| Data Mappings tab                          | The components of the available mappings appear in a tree structure similar to the Project Explorer.   |
| Show All checkbox                          | When selected, all available study objects as well as their properties appear. When not selected, only the available study objects appear.   |

## Workflow Expression Editor dialog box—Option descriptions

Use the Workflow Expression Editor dialog box to create the expression for a workflow rule in a Workflow Diagram tab.

| Option                                     | Description  |
|--|--|
| Rule Name                                  | Name of the workflow rule.   |
| Rule Description                           | Description of the workflow rule. This field is not deployed.<br>Maximum characters: 2000.   |
| <b>Expression section</b>                  | Used for developing the expression for the rule by typing or by dragging in components displayed in the tabs of the References section. When you drag in a component, the reference to the component is converted to the standard Central Designer expression syntax.<br><br>Typically an expression might contain a combination of typed values (such as operators) and dragged-in components (such as functions or references to study objects). |
| <b>Reference tabs—Available components</b> | List of the components that are available for use in the rule being defined.<br><br>By default, these tabs appear on the right side of the dialog box. When you select a tab, the Reference section appears, with tabs along the bottom edge.  |
| Data tab                                   | The available study objects appear in a tree structure similar to the Project Explorer.  |
| Functions tab                              | The available functions appear in a tree structure organized by class.<br><b>Note:</b> Functions are defined in the Study Editor or Library Editor.  |
| Constants tab                              | The available constants appear in a tree structure organized by class.<br><b>Note:</b> Constants are defined in the Study Editor or Library Editor.  |
| Data Mappings tab                          | The components of the available mappings appear in a tree structure similar to the Project Explorer.   |
| Show All checkbox                          | When selected, all available study objects as well as their properties appear. When not selected, only the available study objects appear.   |

## Setting up and administering a study

### Coding tab—Option descriptions

**Note:** This tab appears only after you have defined context information for a coding map and when the coding map is selected in the top panel. Not all dictionaries allow you to define context information.

| Field                                       | Description  |
|---|--|
| <b>Top panel</b>                            |  |
| Assign queries to Item                      | Title of the item to which to assign queries for the verbatim in the InForm application.   |
| Assign queries to Question                  | (Optional.) Question associated with the item to which to assign queries for the verbatim in the InForm application.   |
| Assign queries to RefName                   | (Optional). RefName of the item to which to assign queries for the verbatim in the InForm application.   |
| Coding Map RefName                          | RefName of the coding map.   |
| Dictionary Type                             | Name of the dictionary type for which the coding map is created.   |
| Form Name                                   | Form on which the verbatim item exists.  |
| Verbatim Item                               | Title of the verbatim item for which a coding map is created.  |
| Verbatim Type                               | Verbatim type that was specified for the coding map.   |
| Verbatim Question                           | Default question of the verbatim item.   |
| Verbatim RefName                            | RefName of the item.   |
| <b>Bottom panel—<br/>Coding Results tab</b> |  |
| Dictionary Level                            | Dictionary level for which the coding map is defined.  |
| Level Type                                  | Information that indicates whether the target item is for: <ul style="list-style-type: none"> <li>• Code</li> <li>• Term</li> <li>• Additional information, which appears as <b>Additional Info for [Level Name]</b>, where [Level Name] is the name of the dictionary level (available only for the WHO-DD dictionary type and in custom dictionary types in which additional information is defined).</li> </ul> |
| Target Item                                 | Title of the item that is specified for the dictionary level in the coding map.  |
| Target Question                             | Default question of the item that is specified for the dictionary level in the coding map.   |
| Target RefName                              | RefName of the target item.  |

| Field  | Description   |
|--|---|
| <b>Bottom panel—<br/>Context<br/>Information tab</b> |   |
| Context Meaning                                      | Descriptive text for the context information. This information is displayed exactly as it is defined in the dictionary. |
| Context Item   | Title of the context item.  |
| Context Question                                     | Default question of the context item.   |
| Context RefName                                      | RefName of the context item.  |



## Coding Map dialog boxes—Option descriptions

| Option                           | Description   |
|----------------------------------|---|
| Dictionary type                  | <p>List of all dictionary types (including custom dictionary types, if any) that have been installed, enabled, and selected for the given study or library.</p> <p>For more information, see:</p> <ul style="list-style-type: none"> <li>• <i>Importing and overwriting a dictionary type</i> (in the <i>Administrator Guide</i>).</li> <li>• <i>Enabling and disabling a dictionary type</i> (in the <i>Administrator Guide</i>).</li> <li>• <i>Selecting and removing dictionary types for a study or library</i> (on page 39).</li> </ul> <p>After you select a dictionary type, additional fields in the dialog box (including Verbatim Type and the information in the grids) are populated with data from the dictionary.</p> |
| Item to code                     | <p>List of titles for all text items that can be coded.</p> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>• If you are creating a coding map, you can change the selected item but you cannot clear it.</li> <li>• If you are modifying a coding map, this field is read-only.</li> </ul>  |
| Verbatim type                    | <p>List of verbatim types that are enabled for the selected dictionary type.</p> <p>The field is enabled after you select a dictionary type.</p>  |
| Assign queries to                | <p>List of items that are eligible for query assignment, including the verbatim item. Each item in the list is:</p> <ul style="list-style-type: none"> <li>• A top-level item.</li> <li>• Visible and available for editing in the InForm application. Items designated as query targets must not have the Display Override property set to ReadOnly or Hidden in the Central Designer application.</li> </ul> <p><b>Note:</b> You can select &lt;use verbatim&gt; in the <b>Assign queries to</b> drop-down list to select the verbatim item as the query target if the verbatim satisfies the requirements for a query target item.</p>   |
| <p><b>Coding Results tab</b></p> |   |
| Dictionary Level                 | <p>Dictionary level for which the coding map is defined.</p>  |

| Option                         | Description  |
|--------------------------------|--|
| Level Type                     | Information that indicates whether the target item is for: <ul style="list-style-type: none"> <li>• Code</li> <li>• Term</li> <li>• Additional information, which appears as <b>Additional Info for [Level Name]</b>, where [Level Name] is the name of the dictionary level (available only for the WHO-DD dictionary type and in custom dictionary types in which additional information is defined).</li> </ul>   |
| Target Item                    | List of titles for all text items that can be selected as target items for a dictionary level in the coding map. If you select an item, the Target Question field is populated with its question.<br><br>The list does <b>not</b> contain items that are already a verbatim, text item, or context item for the specified dictionary type, unless you are modifying a coding map. In that situation, the list includes the item that is currently assigned to the row, so you can review the list of options and reselect the item if you decide not to change the assignment.   |
| Target Question                | List of default questions for all text items that can be selected as target items for a dictionary level in the coding map. If you select a question, the Target Item field is populated with the item name.   |
| <b>Context Information tab</b> |  |
| Context Meaning                | Descriptive text for the context information. This information is displayed exactly as it is defined in the dictionary.  |
| Context Item                   | List of titles for all text items that can be selected as context items for a dictionary level in the coding map. If you select an item, the Context Question field is populated with its question.<br><br>The list does <b>not</b> contain items that are already a verbatim, text item, or context item for the specified dictionary type, unless you are modifying a coding map. In that situation, the list includes the item that is currently assigned to the row, so you can review the list of options and reselect the item if you decide not to change the assignment. |
| Context Question               | List of default questions for all text items that can be selected as context items for a dictionary level in the coding map. If you select a question, the Target Item field is populated with the item name.  |

**Note:** For more information about requirements for verbatims, target items, and context items, see *Verbatims, context items, target items, and query target items* (on page 44).

## Libraries tab—Section descriptions

| Section                        | Description  | For more information, see...  |
|--------------------------------|--|---|
| Library List (In Search Order) | Libraries with study objects that can be copied to the study. The order of the libraries indicates the order in which search results are displayed in the Libraries Browser (results from the first library appear first, followed by results from the second library, and so on). | <ul style="list-style-type: none"> <li>• <i>Choosing the libraries to use for a study</i> (on page 13).</li> <li>• <i>Setting the order of libraries in the Libraries List</i> (on page 13).</li> </ul> |

## Libraries tab—Button descriptions

| Button | Description  | For more information, see...  |
|--------|--|---|
| Add    | Add an existing library to the Libraries list. When users in the study search for study objects in libraries, only the libraries in the Libraries list are searched. | <i>Choosing the libraries to use for a study</i> (on page 13).                      |
| Remove | Remove a library from the Libraries list.  |   |
| Up     | Move a library up in the Libraries list.<br><b>Note:</b> Libraries are searched in the order in which they are listed.   | <i>Setting the order of libraries in the Library list for a study</i> (on page 13). |
| Down   | Move a library down in the Libraries list.   |   |

## References tab—Option descriptions

| Option                 | Description   |
|------------------------|---|
| <b>Top section</b>     |   |
| 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).   |
| <b>Details section</b> |   |
| Description            | Description of the attachment.  |
| Attachments            | All file and URL attachments.<br><b>Note:</b> The default maximum file size is 10 MB. This value can be configured. For more information, see <i>Maximum attachment size</i> (in the <i>User Guide</i> ). |

## Review State editor—Option descriptions

| Field                                     | Description   |
|---|---|
| RefName, Title, Description               | RefName, title, and description of the review state.<br><br>In a study, review state RefNames must be unique. In a library, duplicate RefNames are allowed.   |
| Activated                                 | If selected, indicates that the review state is visible in the InForm application.  |
| State                                     | Number of the review state, indicating the order in which the review state is displayed in the InForm user interface. You can define a maximum of five review states for a study. In a library, the number of review states is unlimited.   |
| English (United States), Japanese (Japan) | InForm product locales. Each tab contains the locale-specific names for the review state and each of its three stages.<br><br>The Label and Mnemonic fields for the review state and each review stage are required for each InForm product locale (English and Japanese). If a required value is missing in a product locale tab, the value from the other locale (if it is defined) appears in the field in red, and an icon appears in the tab to indicate that translation is required. Study validation also checks for missing translated values. Because both English and Japanese locales are always required for review states, the study definition does not need to have the Japanese locale selected, and you do not need the Japanese language skill to translate the review state fields. |
| Label                                     | Name for the review state, which appears in hover Help and drop-down lists in the InForm application.   |
| Mnemonic                                  | Abbreviated name for the review state, which appears in column headings in the Data Viewer of the InForm application.   |
| Stage 1, Stage 2, Stage 3                 | Indicates the stage for which to specify the name, label, and mnemonic. You must create three review stages for each review state.  |
| Name                                      | RefName of the review stage. Each RefName must be unique within its review state.   |
| Label                                     | Name for the review stage, which appears in hover Help and drop-down lists in the InForm application.   |
| Mnemonic                                  | Abbreviated name for the review stage, which appears in column headings in the Data Viewer of the InForm application.   |

## Review States editor—Option descriptions

| Field                      | Description   |
|----------------------------|---|
| Activated                  | If selected, indicates that the review state is visible in the InForm application.  |
| Description                | Description of the review state.  |
| Identifier                 | Internal identifier of the review state.  |
| Published (libraries only) | If True, indicates that the review state is published.  |
| RefName                    | RefName of the review state.  |
| State                      | Number of the review state, indicating the order in which the review state is displayed in the InForm user interface. You can define a maximum of five review states for a study. In a library, the number of review states is unlimited.<br><br>READ-ONLY. |
| Title                      | Title of the review state.  |

## Study General tab—Option descriptions




| Field      | Description   |
|------------|---|
| Study Name | Name of the study.                                      |
| Targets    | Target applications to which you will deploy the study. |
| Phase      | Phase of the study.                                     |
| Sponsor    | Sponsor associated with the study.                      |
| Protocol   | Name of the protocol associated with the study.         |

## Teams tab—Field descriptions

When you select a user in the left section or double-click a user in the right section of the Teams tab, the right section has the following fields.

| Field        | Description  |
|--------------|--|
| Team Name    | The study team to which the selected user is assigned <i>for the selected study only</i> . |
| Must Approve | Reserved for future use.   |

## Deployment Setup tab—Option descriptions

| Option              | Description  |
|---------------------|--|
| <b>Buttons</b>      |  |
| Test URL            | <p>Test the URL of the selected deployment instance.</p> <p>If the test fails, automated deployment fails. The test is successful when:</p> <ul style="list-style-type: none"> <li>• The URL and port are valid for the InForm web service that is associated with the deployment instance.</li> <li>• The Central Designer deployment certificate is installed on the InForm server.</li> <li>• The Central Designer application can connect with the InForm web service.</li> <li>• The type of the deployment instance matches the type selected for the InForm web service.</li> <li>• The Approval Required setting for the deployment instance matches the setting for the InForm web service.</li> <li>• The rule engine that is installed on the Central Designer server is also installed on the InForm server.</li> </ul> <p>For more information, see the InForm <i>Installation Guide</i>.</p> |
| Audit History       | Display all the revisions of the selected deployment instance study object.  |
| Columns             | Select the columns to display.   |
| Lock and Protect    | Lock or protect the selected study object.   |
| <b>Columns</b>      |  |
| Icon (first column) | <p>Status of the study object:</p> <ul style="list-style-type: none"> <li>• —New.</li> <li>• —Locked.</li> <li>• —Protected. When a study object is protected, you cannot : <ul style="list-style-type: none"> <li>▪ Update or lock it.</li> <li>▪ Add child study objects to it by pasting or dragging and dropping.</li> </ul> </li> <li>• Delete its child study objects.</li> </ul>   |
| Description         | Description of the deployment instance.  |

| Option            | Description   |
|-------------------|---|
| Type              | Type of deployment instance: <ul style="list-style-type: none"><li>• <b>UAT</b>—User acceptance testing</li><li>• <b>QA</b>—Quality assurance</li><li>• <b>DEV</b>—Development</li><li>• <b>LIVE</b>—Production</li><li>• <b>TRN</b>—Training</li></ul> |
| URL               | URL address of the deployment instance.   |
| Port              | Port number of the web service used to query deployment status.   |
| Approval Required | Indicates whether deployments to the server must be approved by a user with the appropriate right, as configured in the Central Designer Administrator application.   |




## Study elements and study events

### Study Elements editor—Option descriptions

#### Common columns to all study object editors

All study object editors have the following columns.

**Note:** Not all fields appear in the default view. Optionally, you can *add the other fields and rearrange the browser view* (in the User Guide).

| Property                      | Description   |
|-------------------------------|---|
| Icon (first column)           | Status of the study object: <ul style="list-style-type: none"> <li>• —New.</li> <li>• —Locked.</li> <li>• —Protected. When a study object is protected, you cannot :               <ul style="list-style-type: none"> <li>▪ Update or lock it.</li> <li>▪ Add child study objects to it by pasting or dragging and dropping.</li> <li>▪ Delete its child study objects.</li> </ul> </li> </ul> |
| Description                   | Description of the study object. The description can have 0-255 characters.   |
| Identifier                    | Unique internal identifier of the study object.   |
| Published (only in libraries) | Indicates that the study object has been published.   |
| RefName                       | RefName of the study object. The RefName can have 1-63 characters.  |
| Revision                      | Revision number of the study object. The revision number is incremented each time the study object is changed and saved.  |
| Title                         | Title of the study object. The title can have 1-63 characters.  |
| Version                       | Version number of the study object. The version number is incremented only when a user explicitly updates it.   |

**Note:** Not all fields appear in the default view. Optionally, you can *add the other fields and rearrange the browser view* (in the User Guide).

| Option     | Description  |
|------------|--|
| Drop point | Data type of the codelist. The data type of a codelist must be compatible with the data type of any items in which it is included. |






## Study Events Editor

### Columns common to all study object editors

All study object editors have the following columns.

**Note:** Not all fields appear in the default view. Optionally, you can *add the other fields and rearrange the browser view* (in the *User Guide*).

| Property                      | Description   |
|-------------------------------|---|
| Icon (first column)           | Status of the study object: <ul style="list-style-type: none"> <li>• —New.</li> <li>• —Locked.</li> <li>• —Protected. When a study object is protected, you cannot :               <ul style="list-style-type: none"> <li>▪ Update or lock it.</li> <li>▪ Add child study objects to it by pasting or dragging and dropping.</li> <li>▪ Delete its child study objects.</li> </ul> </li> </ul> |
| Description                   | Description of the study object. The description can have 0-255 characters.   |
| Identifier                    | Unique internal identifier of the study object.   |
| Published (only in libraries) | Indicates that the study object has been published.   |
| RefName                       | RefName of the study object. The RefName can have 1-63 characters.  |
| Revision                      | Revision number of the study object. The revision number is incremented each time the study object is changed and saved.  |
| Title                         | Title of the study object. The title can have 1-63 characters.  |
| Version                       | Version number of the study object. The version number is incremented only when a user explicitly updates it.   |

**Note:** Not all fields appear in the default view. Optionally, you can *add the other fields and rearrange the browser view* (in the *User Guide*).

| Option          | Description   |
|-----------------|---|
| Block key value | Value of the Clintrial block key, used for data transfer to the Clintrial application through CIS mappings. If you specify this value, it overrides the visit RefName as the block key. |
| Drop Point      |   |
| Optional        | Indicates whether the study event is optional or required.  |
| Repeating       | Indicates whether the study event is repeating.   |
| Short Title     | Short title for the study event.  |
| Special Visits  | Indicates whether the study event is an InForm special visit.   |

## Study workflow

### Common Visit tab of the Study Design Editor—Option descriptions

You must have the appropriate language skills to edit the fields, including the skill for the primary locale of the study. Changes are not sorted automatically.

| Option                       | Description  |
|------------------------------|--|
| <b>Common Visit settings</b> |  |
| Title                        | Title of the common visit in the language of the primary locale.<br>If you do not provide a value and the study contains common forms, <b>Common CRF</b> is used.<br>Limit: 63 characters.   |
| Short Title                  | Short title of the common visit in the language of the primary locale.<br>If you do not provide a value and the study contains common forms, <b>Common</b> is used.<br>Limit: 63 characters. |
| <b>Languages grid</b>        |  |
| Language                     | Language and locale to which information is translated.  |
| Title                        | Translated text of the title of the common visit.  |
| Short Title                  | Translated text of the short title of the common visit.  |

#### Notes:

- If you do not specify localized values, the title and short title are used during deployment.
- If you specify localized values, you must specify values for all of the study's supported locales, or validation fails.

### General tab of the Study Event Editor—Option descriptions

| Option          | Description  |
|-----------------|--|
| <b>Settings</b> |  |
| Title           | Title of the study event. The title can have 1-63 characters.  |
| Short Title     | Short title of the study event. The short title is deployed to the InForm application as the visit mnemonic. |
| RefName         | RefName of the study event. The RefName can have 1-63 characters.  |
| Description     | Description of the study event. The description can have 0-255 characters.                                   |
| <b>Behavior</b> |  |

| Option                 | Description  |
|------------------------|--|
| Repeating              | Indicates that the study event is repeating.   |
| <b>Title Languages</b> |  |
| Language               | Language and locale to which information is translated.  |
| Short Title            | Translated text of the short title. The short title can have 1-63 characters.  |
| Title                  | <p>Translated text of the title.</p> <p>The Title field (in the Settings section) is not localizable and does not change, regardless of what you enter in the Title column in the Title Languages grid. To enter a localized value for a study object's title, use the Title column. Providing a value in the Title column is optional:</p> <ul style="list-style-type: none"> <li>• If you do not specify a localized value, the title of the study object is used during deployment.</li> <li>• If you specify a localized title, you must specify a localized value for all of the study's supported locales, or validation fails.</li> </ul> |

## Schedule of Events tab—Option descriptions

| Field                | Description   |
|----------------------|---|
| Activity/Observation | <p>Title of each form in the study. Each form creates one row of the table, in the order in which it was added to the study.</p> <p>A selected checkbox at the intersection of a Form row and an Event column indicates that the form is included in that study event.</p>                  |
| Short Title          | Short title (mnemonic) of the form.   |
| Event columns        | <p>Title of each study event in the study. Each study event creates one column in the table, in the order in which it was added to the study.</p> <p>A selected checkbox at the intersection of a Form row and an Event column indicates that the form is included in that study event.</p> |

## Workflow Diagram tab—Option descriptions

| Option   | Description                 |
|--|-----------------------------|
| New Element (Study Editor and Study Design Editor only)  | Create a new study element. |
| New Event (Study Design Editor and Study Element Editor) | Create a new study event.   |

| Option                        | Description  |
|-------------------------------|--|
| New (Study Event Editor only) | Create a new form.   |
| Global Conditions             | Create a global condition.   |
| Rule Tests                    | Create test cases for a workflow rule.   |
| Select All                    | Select all study objects in the workspace.   |
| Layout                        | <p>Arrange the layout of the workflow diagram by using the following options:</p> <ul style="list-style-type: none"> <li>• <b>Grid Layout</b>—Align all study objects along a grid.</li> <li>• <b>Horizontal Layout</b>—Align all connected study objects horizontally.</li> <li>• <b>Spring Layout</b>—Place all connected study objects so that the connecting lines do not need to bend.</li> <li>• <b>Tree Layout</b>—Align all connected study objects in a tree format.</li> <li>• <b>Vertical Layout</b>—Align all connected study objects vertically.</li> </ul> |
| Zoom                          | <p>Adjust the size of the workflow diagram by using the following options:</p> <ul style="list-style-type: none"> <li>• <b>Zoom In</b>—Increase the diagram size.</li> <li>• <b>Zoom Out</b>—Reduce the diagram size.</li> <li>• <b>Fit to Page</b>—Adjust the diagram size to fill the workspace.</li> </ul>  |
| Enable/Disable Workflow       | Enable or disable the workflow. The text on the button changes depending on the workflow state.  |

## Workflow Grid tab—Option descriptions

| Option | Description   |
|--------|---|
| Status | Icon indicating the status of a study object, including Locked, Protected, and so on.   |
| Type   | Study object type. On a study design, where you can create either study elements or study events, the available types appear in a drop-down list. |
| Title  | Title of the study object.  |

# Validation and deployment

## Baselines Browser—Option descriptions

| Option                          | Description  |
|---------------------------------|--|
| <b>Buttons</b>                  |  |
| Edit                            | Edit the name and description of the selected baseline.  |
| Delete                          | Delete the selected baseline. You can only delete a baseline that does not have a deployment package associated with it.   |
| Ignore Warnings                 | View warning messages and either update the study to correct them or indicate that you will ignore the warnings.   |
| Make Public                     | Mark a baseline as public so that other users can view and work with it.   |
| Show Validation/Hide Validation | <ul style="list-style-type: none"> <li>• <b>Show Validation</b>—Change from a grid to a tree structure that you can expand to view the validation messages generated during baseline creation.</li> <li>• <b>Hide Validation</b>—Change from a tree structure back to a grid that lists only baselines without validation messages.</li> </ul> |
| Refresh                         | Refresh the display of baselines from the Central Designer database. Job results for baselines that are expanded are also refreshed from the database.   |
| Save As                         | Save the contents of the Baselines Browser to a comma-separated value (CSV) file that can be opened in a Microsoft Excel spreadsheet.  |
| <b>Columns</b>                  | <b>Note:</b> Not all fields appear in the default view. Optionally, you can <i><b>add the other fields and rearrange the browser view</b></i> (in the <i>User Guide</i> ).   |
| Baseline ID                     | Unique identifier of the baseline.   |
| Date Created                    | Date and time that the baseline was created.   |
| Deployed                        | Yes or No, indicating whether the baseline has been processed for deployment.  |
| Description                     | Description of the baseline, updated if you edit the baseline.   |
| Job ID                          | Unique identifier of the job in which the baseline was created.  |
| Name                            | Name of the baseline. By default, the name consists of the string <b>Validation baseline</b> , along with the date and time it was created.  |
| Public                          | Yes or No, indicating whether the validation baseline has been made public.  |

| Option             | Description   |
|--------------------|---|
| Revision           | <p>Revision number of the baseline. The revision consists of three numbers: "Major.Minor.Revision," such as 1.0.2.</p> <ul style="list-style-type: none"> <li>• <b>Major and minor number</b>—The version number of the study design study object. If the study design does not have a version number, the first two numbers are 0.0, such as 0.0.4.</li> <li>• <b>Revision number</b>—The number of revisions made to the study since the most recent version label (either major or minor) was created.</li> </ul>  |
| Status             | <p>Status of the baseline:</p> <ul style="list-style-type: none"> <li>• <b>Valid</b>—No warnings and no errors. A baseline with this status can be processed for deployment.</li> <li>• <b>Valid with Warnings</b>—One or more warnings exist, but a user has updated them with the Ignore Warnings menu command. A baseline with this status can be processed for deployment.</li> <li>• <b>Pending</b>—Validation is in process.</li> <li>• <b>Invalid with Warnings</b>—One or more warnings exist and have not been updated with the Ignore Warnings menu command. A baseline with this status cannot be processed for deployment.</li> <li>• <b>Invalid</b>—One or more errors exist. A baseline with this status cannot be processed for deployment.</li> </ul> |
| Status Icon        | Icon that corresponds to the status of the baseline.  |
| Study ID           | Unique identifier of the study for which the baseline is generated.   |
| Targets            | The target application(s) for which you validated the study and to which you deploy the study.  |
| <b>Sub-columns</b> | The following columns are in the grid that appears when you click Show Job Results and expand the results for a job.  |
| Code               | Unique identifier for the validation error or warning. You can provide the code when submitting issues to Oracle Support.   |
| Description        | Description of the baseline message.  |
| Date Created       | Date and time the validation message was created.   |
| Issue Name         | Type of issue for which the job result is reporting. This field contains a value only if the job result is a validation error on a rule. Options include Rule Name and sometimes Function Name.   |
| Job Id             | Unique identifier of the job in which the baseline was created.   |
| Job Result Id      | Unique identifier of the baseline message.  |
| Object RefName     | RefName of the study object that is reported in the validation message. This field contains a value only if the job result is a validation error on a rule.   |
| Object Title       | Title of the study object that is reported in the validation message. This field contains a value only if the job result is a validation error on a rule.   |

| Option          | Description  |
|-----------------|--|
| Path            | Path of the study object that is reported in the validation message. This field contains a value only if the job result is a validation error on a rule.   |
| Target          | Target application for which you validate the study and to which you deploy the study.   |
| Type Icon       | Icon that corresponds to the status of the validation type.  |
| Validation Type | Type of message: <ul style="list-style-type: none"> <li>• <b>Information</b>—Description of the processing step being performed during validation.</li> <li>• <b>Warning</b>—Irregularity that should be investigated. Further processing (for example, creation of a deployment package) can be performed if you explicitly choose to ignore warnings.</li> <li>• <b>Error</b>—Fatal problem. No further processing (for example, creation of a deployment package) can be performed until all errors are corrected.</li> </ul> |
| Warning Ignored | Indicates if you have chosen to ignore a warning.  |

## Create Deployment Package Wizard—Full deployment package

| Page                             | Option        | Description  |
|----------------------------------|---------------|--|
| Welcome                          |               | Introduction page.   |
| Select a Deployment Package Type |               | <p>Specify whether to create a full or incremental deployment package.</p> <p><b>Note:</b> To deactivate a rule in the InForm application, do one of the following in the Central Designer application before creating a new deployment package:</p> <ul style="list-style-type: none"> <li>• Remove the rule from the study.</li> <li>• Disable the rule.</li> <li>• Change the triggering event to <b>On Demand (Batch Mode)</b>.</li> </ul> <p>Rule-related changes that you make in the InForm application are overridden when you install a new deployment package.</p> <p><b>Note:</b> If you create or modify a coding map, use a full deployment package to deploy the changes. Changes to coding maps are not supported in incremental deployment packages.</p> |
|                                  | Full package. | Deployment package that contains everything needed to deploy a complete study, including study administration data.  |



| Page               | Option                    | Description   |
|--------------------|---------------------------|---|
|                    | Incremental package.      | Deployment package that contains everything needed to deploy a complete study, including study administration data, plus additions and changes to the study, reflected in Alternate forms in the InForm application. Alternate forms are not created when you install an incremental deployment package that contains additions to repeating forms or fixed repeating sections (Repeating Data itemsets in the InForm application). |
|                    | Administration data       | Deployment package that contains only study administration data.  |
| Select a Baseline  |                           | Specify the baseline to use for creating the deployment package. Validation baselines with a status of Valid or Valid with Warnings are eligible.<br><br><b>Note:</b> If you select an unpublished validation baseline, the baseline is made public during deployment package creation.   |
|                    | Please select a baseline. | Drop-down list of validated baselines available for creating a deployment package.  |
| In-Place Revisions |                           | If the specified baseline contains in-place revisions, review the changes and confirm you understand the risks of deploying before proceeding.  |
|                    | View IPR Summary          | Open the IPR Summary dialog box to review the revisions included in the baseline.   |
|                    | Confirmation text         | Select the checkbox to confirm that you understand the risks involved in deploying to the InForm application.<br><br>Select the checkbox to confirm that you understand the risks involved in deploying to the InForm application.  |

| Page           | Option                             | Description   |
|----------------|------------------------------------|---|
| Select Locales |                                    | <p>Specify the locale or locales for which to create the deployment package. You must select at least one locale.</p> <p><b>Note:</b> Each option is applicable for different releases of the InForm application, and only one option is used for each release. However, you must select values for both options.</p>   |
|                | Please select one or more locales. | <p>List of locales available to be supported by the deployment package.</p> <p><b>Note:</b> This option is used when you deploy to InForm release 4.6.</p>  |
|                | Apply layout from                  | <p>Specify the default layout locale for the deployment package.</p> <p>In InForm release 4.7 and later, a single study version contains the layout information for all locales in the study, and you specify a default layout locale, from which all layouts, regardless of locale, inherit customizations in the InForm application.</p> <p>The site locale language in the InForm application determines the language in which forms appear.</p> <p>For example, a study contains layouts for the French (France) and the English (United Kingdom) locales. Radio buttons are horizontal in the French (France) layout but are vertical in the England (United Kingdom) layout. If French (France) is the default layout locale, then all layout customizations for the France (French) layout, including the alignment of radio buttons, are deployed to the InForm application and appear for all users, regardless of their site locale. Therefore, if your site locale in the InForm application is English (United Kingdom), the forms appear in English but with the customizations that were made in the French (France) layout in the Central Designer application.</p> <p><b>Note:</b> This option is used when you deploy to InForm release 4.7 and later.</p> |

| Page  | Option   | Description   |
|---|--|---|
| Select Layouts  |  | Choose the layout to deploy. If the layout does not exist for a form, the primary layout for the form is deployed instead.<br><br>The list contains only the registered layout names in the study, which appear in the Tools > Layout Names Manager dialog box. |
| Select Customer Defined Database (CDD) Mappings (optional)      |  | Specify the mappings used to generate mappings for a CDD. This page appears only if at least one CDD mapping is defined for the study. Only CDD mappings appear in the list.  |
|   | Optionally, select one or more mappings for CDD mapping. | List of CDD mappings.   |
|   | Select All.  | Select all mappings in the list.  |
|   | Unselect All.  | Deselect all mappings in the list.  |
| Select Clintrial Integration Solution (CIS) Mappings (optional) |  | Specify the mappings used to generate mappings for the CIS application. This page appears only if at least one CIS mapping is defined for the study. Only CIS mappings appear in the list.  |
|   | Optionally, select one or more mappings for CIS mapping. | List of CIS mappings.   |
|   | Select All.  | Select all mappings in the list.  |
|   | Unselect All.  | Deselect all mappings in the list.  |
| Specify a Name and Description                                  |  | Specify a name and description for the deployment package.  |
|   | Please specify a name for your deployment package.       | Name of the deployment package.   |
|   | Package description.                                     | Description of the deployment package.  |
|   | Apply new study version to all sites                     | Select to apply the study to all sites. Deselect to not apply the study to any site.  |
| MedML Files (optional)  |  | Attach MedML files to the deployment package. The order in which the files are deployed is determined by their order in the grid.<br><br><b>Note.</b> The MedML files are validated by the InForm application prior to execution.                               |

| Page                                  | Option           | Description  |
|---------------------------------------|------------------|--|
|                                       | Add              | Add a MedML file to the grid.                                    |
|                                       | Remove           | Remove selected MedML file from the grid.                        |
|                                       | Move Up          | Move selected file higher in the grid.                           |
|                                       | Move Down        | Move selected file lower in the grid.                            |
|                                       | Select All       | Select all files in the grid.                                    |
| Ready to Create<br>Deployment Package |                  | View a summary of the deployment options selected in the wizard. |
|                                       | Options summary. | Summary of options selected for the deployment package.          |

## Create Deployment Package Wizard—Incremental deployment package

| Page                                | Option        | Description  |
|-------------------------------------|---------------|--|
| Welcome                             |               | Introduction page.   |
| Select a Deployment<br>Package Type |               | <p>Specify whether to create a full or incremental deployment package.</p> <p><b>Note:</b> To deactivate a rule in the InForm application, do one of the following in the Central Designer application before creating a new deployment package:</p> <ul style="list-style-type: none"> <li>Remove the rule from the study.</li> <li>Disable the rule.</li> <li>Change the triggering event to <b>On Demand (Batch Mode)</b>.</li> </ul> <p>Rule-related changes that you make in the InForm application are overridden when you install a new deployment package.</p> <p><b>Note:</b> If you create or modify a coding map, use a full deployment package to deploy the changes. Changes to coding maps are not supported in incremental deployment packages.</p> |
|                                     | Full package. | .Deployment package that contains everything needed to deploy a complete study, including study administration data  |

| Page   | Option  | Description   |
|--|---|---|
|  | Incremental package.                                  | Deployment package that contains everything needed to deploy a complete study, including study administration data, plus additions and changes to the study, reflected in Alternate forms in the InForm application. Alternate forms are not created when you install an incremental deployment package that contains additions to repeating forms or fixed repeating sections (Repeating Data itemsets in the InForm application). |
|  | Administration data                                   | Deployment package that contains only study administration data.  |
| Select a Previously Created Deployment Package |   | Specify the previously created deployment package for which this is an incremental package.   |
|  | Please select a deployment package.                   | Drop-down list of previously created deployment packages.   |
| Select a Baseline                              |   | Specify the validation baseline to use for creating the incremental deployment package. This baseline must have a date and time that is later than the validation baseline used to create the deployment package selected on the previous page.   |
|  | Deployment Package.                                   | Name of the deployment package selected on the previous page.   |
|  | Package Baseline.                                     | Validation baseline used to create the selected deployment package.   |
|  | Please select a baseline for the incremental package. | Drop-down list of validated baselines available for creating the incremental deployment package.  |
| In-Place Revisions                             |   | If the specified baseline contains in-place revisions, review the changes and confirm you understand the risks of deploying before proceeding.  |
|  | View IPR Summary                                      | Open the IPR Summary dialog box to review the revisions included in the baseline.   |
|  | Confirmation text                                     | Select the checkbox to confirm that you understand the risks involved in deploying to the InForm application.   |

| Page   | Option                                       | Description   |
|--|--|---|
| Add Locales (Optional)                                       |  | Specify the additional locale or locales for which to create the incremental deployment package. This page appears only if you have added new locales to the validation baseline.   |
|  | Optionally, select one or more locales.      | List of locales available to be supported by the deployment package.  |
|  | Select All.                                  | Select all locales in the list.   |
|  | Unselect All.                                | Deselect all locales in the list.   |
| Add Customer Defined Database (CDD) Mappings (Optional)      |  | Specify the additional mapping or mappings, if any, to use in the incremental package for generation of CDD mappings. This page appears only if you have added new CDD mappings to the validation baseline.<br><br>If you have made changes to existing CDD mappings, those mappings are used in the deployment package to update the CDD mappings. |
|  | Optionally, select one or more CDD mappings. | List of CDD mappings.   |
|  | Select All.                                  | Select all mappings in the list.  |
|  | Unselect All.                                | Deselect all mappings in the list.  |
| Add Clintrial Integration Solution (CIS) Mappings (Optional) |  | Specify the additional mapping or mappings, if any, to use in the incremental package for generation of CIS mappings. This page appears only if you have added new CIS mappings to the validation baseline.<br><br>If you have made changes to existing CIS mappings, those mappings are used in the deployment package to update the CIS mappings. |
|  | Optionally, select one or more CIS mappings. | List of CIS mappings.   |
|  | Select All.                                  | Select all mappings in the list.  |
|  | Unselect All.                                | Deselect all mappings in the list.  |

| Page                               | Option   | Description   |
|------------------------------------|--|---|
| Specify a Name and Description     |  | Specify a name and description for the incremental deployment package.  |
|                                    | Please specify a name for your deployment package. | Name of the incremental deployment package.   |
|                                    | Package description.                               | Description of the incremental deployment package.  |
|                                    | Apply new study version to all sites.              | Select to apply the study to all sites. Deselect to not apply the study to any site.  |
| MedML Files (optional)             |  | Attach MedML files to the deployment package. The order in which the files are deployed is determined by their order in the grid.<br><br><b>Note.</b> The MedML files are validated by the InForm application prior to execution. |
|                                    | Add  | Add a MedML file to the grid.   |
|                                    | Remove   | Remove selected MedML file from the grid.   |
|                                    | Move Up  | Move selected file higher in the grid.  |
|                                    | Move Down  | Move selected file lower in the grid.   |
|                                    | Select All   | Select all files in the grid.   |
| Ready to Create Deployment Package |  | View a summary of the deployment options selected in the wizard.  |
|                                    | Options summary.                                   | Summary of options selected for the incremental deployment package.   |

## Create Deployment Package Wizard—Administration data deployment package

| Page                             | Option               | Description  |
|----------------------------------|----------------------|--|
| Welcome                          |                      | Introduction page.   |
| Select a Deployment Package Type |                      | <p>Specify whether to create a full or incremental deployment package.</p> <p><b>Note:</b> To deactivate a rule in the InForm application, do one of the following in the Central Designer application before creating a new deployment package:</p> <ul style="list-style-type: none"> <li>• Remove the rule from the study.</li> <li>• Disable the rule.</li> <li>• Change the triggering event to <b>On Demand (Batch Mode)</b>.</li> </ul> <p>Rule-related changes that you make in the InForm application are overridden when you install a new deployment package.</p> <p><b>Note:</b> If you create or modify a coding map, use a full deployment package to deploy the changes. Changes to coding maps are not supported in incremental deployment packages.</p> |
|                                  | Full package.        | Deployment package that contains everything needed to deploy a complete study, including study administration data.  |
|                                  | Incremental package. | Deployment package that contains everything needed to deploy a complete study, including study administration data, plus additions and changes to the study, reflected in Alternate forms in the InForm application. Alternate forms are not created when you install an incremental deployment package that contains additions to repeating forms or fixed repeating sections (Repeating Data itemsets in the InForm application).  |
|                                  | Administration data  | Deployment package that contains only study administration data.   |



| Page                               | Option   | Description   |
|------------------------------------|--|---|
| Select a Baseline                  |  | Specify the baseline to use for creating the deployment package. Validation baselines with a status of Valid or Valid with Warnings are eligible.<br><br><b>Note:</b> If you select an unpublished validation baseline, the baseline is made public during deployment package creation. |
|                                    | Please select a baseline.                          | Drop-down list of validated baselines available for creating a deployment package.  |
| Specify a Name and Description     |  | Specify a name and description for the deployment package.  |
|                                    | Please specify a name for your deployment package. | Name of the deployment package.   |
|                                    | Package description.                               | Description of the deployment package.  |
| Ready to Create Deployment Package |  | View a summary of the deployment options selected in the wizard.  |
|                                    | Options summary.                                   | Summary of options selected for the deployment package.   |

## Deployment Editor—Option descriptions

**Note:** Not all fields appear in the default view. Optionally, you can *add the other fields and rearrange the browser view* (in the *User Guide*).

| Option         | Description   |
|----------------|---|
| <b>Buttons</b> |   |
| New Package    | Create a deployment package from a validation baseline by using the Create Deployment Package Wizard.   |
| Save as        | Deliver a deployment package to a location from which it can be deployed. Available for deployment packages created in Central Designer release 2.1 and later.  |
| Delete         | Delete a deployment package.  |
| Deployment     | <ul style="list-style-type: none"> <li>• <b>Request</b>—Create a deployment request for the selected deployment package.</li> <li>• <b>History</b>—Open the Deployment History dialog box to view a history of deployment requests for the selected package.</li> </ul> |
| Columns        | Select the columns to display in the Deployment Editor.   |

| Option                | Description  |
|-----------------------|--|
| Refresh               | Refresh the display of deployment packages.  |
| <b>Columns</b>        |  |
| Name                  | Name of the deployment package.  |
| Type                  | Type of deployment package: either full, incremental, or administration data.  |
| Baseline              | Name of the validation baseline on which the deployment package is based.  |
| Targets               | The target application(s) for which you validated the study and to which you deploy the study.   |
| Package Created By    | User name of the user who created the deployment package.  |
| Package Creation Date | Date and time when the deployment package was created.   |
| Description           | Description of the deployment package.   |
| Version               | Version of the study that you are deploying.   |
| Base Layout           | Layout that was created in the Central Designer 1.3 release or earlier and is used with a multilingual study that was deployed to the InForm 4.7 release or later. |
| Main Layout           | Primary layout that appears if a layout is not specified.  |
| Study Type            | Type of InForm study to which to deploy.   |
| Deployment Counts     | Number of deployments performed for the deployment package.  |
| Apply to All Sites    | Apply the study version to all sites that use the study.   |
| Contains IPR          | Indicate that the study contains in-place revision changes.  |

## Approvals Tab on the Home Page—Option descriptions

| Option                 | Description   |
|------------------------|---|
| <b>Buttons</b>         |   |
| Approve Request        | Open the Approve Deployment Request dialog box to view detailed information about the selected deployment request, and approve or reject the request.   |
| Deployment History     | Open the Deployment History dialog box to view a detailed list of deployment data that includes: <ul style="list-style-type: none"> <li>• deployment requests waiting for your approval and deployment requests for studies on which you are a team member.</li> <li>• all deployment requests from all studies, if you are assigned to a role with the View deployments across studies right.</li> </ul> |
| Columns                | Select the columns to display in the Approvals tab.   |
| <b>Columns</b>         |   |
| Project                | Name of the project containing the study.   |
| Study                  | Name of the study.  |
| Deployment Option Type |   |
| Deployment Instance    | Deployment instance to which to deploy.   |
| Deployment Type        | Type of InForm study to which to deploy.  |
| Deployment URL         | URL address of the deployment instance.   |
| Port Number            | Port used to query for deployment status.   |
| Package Name           | Name of the deployment package.   |
| Package Type           | Type of deployment package.   |
| Additional Information | Additional information specified in the deployment request.   |
| Deployment Id          | Unique identifier of the deployment   |
| Reason                 | Reason for deployment provided when the deployment request was created.   |
| Schedule               | Time when deployment is scheduled.  |
| Requested By           | User name of the user who created the deployment request.   |
| Date Requested         | Time when the deployment request was created.   |

## Deployment History dialog box—Option descriptions

| Option                | Description   |
|-----------------------|---|
| <b>Buttons</b>        |   |
| Package History       | Open the Deployment History dialog box for the selected deployment package.   |
| View Log              | Open the Deployment Log dialog box.   |
| Export                | Save approval history information to a comma-separated value (CSV) file that can be opened in a Microsoft Excel spreadsheet.  |
| Columns               | Select the columns to display. Not all columns appear in the default view.  |
| <b>Columns</b>        |   |
| Project               | Name of the project containing the study for which the deployment package was created.  |
| Study                 | Name of the study for which the deployment package was created.   |
| Package Name          | Name of the deployment package.   |
| Deployment Instance   | RefName of the deployment instance to which the deployment package was deployed.  |
| Deployment Type       | Type of study server to which the deployment package was deployed. One of the following: <ul style="list-style-type: none"> <li>• <b>UAT</b>—User acceptance testing</li> <li>• <b>QA</b>—Quality assurance</li> <li>• <b>DEV</b>—Development</li> <li>• <b>LIVE</b>—Production</li> <li>• <b>TRN</b>—Training</li> </ul> |
| Deployment URL        | URL address of the deployment instance.   |
| Port Number           | Port number of the web service used to query deployment status.   |
| Deployment Id         | Unique identifier of the deployment.  |
| Reason for deployment | Reason for deployment selected when the deployment request was created.   |
| Package Type          | Type of deployment package. Either Full, Incremental, or Administration data.   |
| Schedule              | Date and time when to perform package deployment. Configured when the deployment request was created.   |
| Date Started          | Date and time when the deployment process started.  |
| Date Performed        | Date and time when the deployment process started.  |
| Date Completed        | Date and time when the deployment process completed.  |
| Performed By          | User name of the user who performed the action.   |

| Option                 | Description   |
|------------------------|---|
| Creation Date          | Date and time when the approval status changed.   |
| Approval Required      | Whether the deployment request requires approval for deployment.  |
| Approval Status        | Approval status for the deployment request. One of the following: <ul style="list-style-type: none"> <li>• <b>Not Required</b>—Request does not require an approval.</li> <li>• <b>Requested</b>—Request has been created, and it has not been approved or rejected yet.</li> <li>• <b>Approved</b>—Request has been approved.</li> <li>• <b>Rejected</b>—Request has been rejected.</li> </ul>   |
| Deployment Status      | Deployment status for the deployment request. One of the following: <ul style="list-style-type: none"> <li>• <b>Not Applicable</b>—Deployment has not been initiated.</li> <li>• <b>Unknown</b>—Deployment has been initiated, but the InForm application has either not detected the deployment package, or has not located it.</li> <li>• <b>Submitted</b>—Deployment has been initiated, the package has been transferred to the InForm server, but the InForm application has not detected it yet.</li> <li>• <b>Scheduled</b>—Deployment has been initiated, the package has been transferred to the InForm server, and the InForm application has scheduled it for installation.</li> <li>• <b>In Progress</b>—Deployment is currently being executed.</li> <li>• <b>Succeeded</b>—Deployment has completed successfully.</li> <li>• <b>Failed</b>—Deployment has failed.</li> <li>• <b>Canceled</b>—Deployment has been canceled.</li> </ul> |
| Is Immediate           | Whether the deployment schedule option selected in the deployment request was Immediate.  |
| Additional Information | Additional information provided in the deployment request.  |
| Archived               | Whether the deployment package has been archived.   |

## Deployment Package History dialog box—Option descriptions

| Option                        | Description   |
|-------------------------------|---|
| <b>Buttons</b>                |   |
| Cancel Request                | Cancel the selected deployment request. Available only if the deployment request has not been approved or rejected yet. You cannot cancel a request if the deployment does not require an approval.<br><br><b>Note:</b> Cancelled deployment requests are not archived.   |
| Cancel Deployment             | Cancel the selected deployment. Available only if the deployment status is Scheduled or Submitted.  |
| View Log                      | Open the deployment log for the selected deployment. Available if the deployment status is either Succeeded, Failed, or Canceled.   |
| Save as                       | Open the Save as dialog box to save the deployment package as a zip file. Available only for deployment packages created in Central Designer release 2.1 and later.   |
| Export                        | Save the deployment package history to a comma-separated value (CSV) file that can be opened in a Microsoft Excel spreadsheet.  |
| Columns                       | Select the columns to display. Not all columns appear in the default view.  |
| Filter by Deployment Id field | Enter a Deployment Id to display information only for that deployment.  |
| <b>Columns</b>                |   |
| Deployment Instance           | Deployment instance to which the deployment package was deployed.   |
| Study                         | Name of the study for which the deployment package was created.   |
| Deployment Instance           | RefName of the deployment instance.   |
| Deployment URL                | URL address of the deployment instance.   |
| Schedule                      | Date and time at which to perform package deployment.   |
| Approval Status               | Approval status for the deployment request. One of the following: <ul style="list-style-type: none"> <li>• <b>Not Required</b>—Request does not require an approval.</li> <li>• <b>Requested</b>—Request has been created, and it has not been approved or rejected yet.</li> <li>• <b>Approved</b>—Request has been approved.</li> <li>• <b>Rejected</b>—Request has been rejected.</li> </ul> |

| Option                 | Description  |
|------------------------|--|
| Deployment Status      | <p>Deployment status for the deployment request. One of the following:</p> <ul style="list-style-type: none"> <li>• <b>Not Applicable</b>—Deployment has not been initiated.</li> <li>• <b>Unknown</b>—Deployment has been initiated, but the InForm application has either not detected the deployment package, or has not located it.</li> <li>• <b>Submitted</b>—Deployment has been initiated, the package has been transferred to the InForm server, but the InForm application has not detected it yet.</li> <li>• <b>Scheduled</b>—Deployment has been initiated, the package has been transferred to the InForm server, and the InForm application has scheduled it for installation.</li> <li>• <b>In Progress</b>—Deployment is currently being executed.</li> <li>• <b>Succeeded</b>—Deployment has completed successfully.</li> <li>• <b>Failed</b>—Deployment has failed.</li> <li>• <b>Canceled</b>—Deployment has been canceled.</li> </ul> |
| Reason                 | Reason for deployment selected when the deployment request was created.  |
| Performed By           | <p>If the approval status is Not Required or Requested, user name of the user who created the deployment request.</p> <p>If the approval status is Approved or Rejected, user name of the user who approved or rejected the deployment request.</p>  |
| Date Performed         | <p>If the approval status is Not Required or Requested, date and time when the deployment request was created.</p> <p>If the approval status is Approved or Rejected, date and time when the request was approved or rejected.</p>   |
| Approval Required      | Whether the deployment of the package requires approval.   |
| Port Number            | Port used to query for deployment status.  |
| Deployment Id          | Unique identifier of the deployment.   |
| Project                | Name of the project that contains the study.   |
| Archived               | Whether the deployment package is archived.  |
| Additional Information | Additional information provided in the deployment request.   |

## Deployment Request dialog box—Option descriptions

Use the Deployment Request dialog box to initiate the automated deployment of a package.

### Settings tab

| Option                  | Description   |
|-------------------------|---|
| Deployment instance     | Select a deployment instance from the Name drop-down list. The following information will be displayed for the selected instance: type, URL, and whether approvals are required.  |
| Deployment schedule     | Select when to perform the deployment: <ul style="list-style-type: none"> <li>• <b>Time</b>—Select the time when to deploy the package (local time of the client).</li> <li>• <b>Immediate (after approval)</b>—Deploy the package immediately after the deployment request is approved.</li> </ul> |
| Deployment option       | Select whether this is a new deployment, or a deployment that modifies an existing deployment.  |
| Reason for deployment   | Select a reason for the deployment. The reason is included in the email notification sent to the deployment approvers.  |
| Additional information  | Optionally, provide more information about the deployment request. The information is not included in the email notification sent to the deployment approvers.  |
| Email distribution list | Users who receive email notifications when the deployment request is created, approved or rejected, and when the deployment is completed. <p><b>Note:</b> The user who requests the deployment and all the users who have the right to approve the request are automatically added to the list.</p> |

### Advanced tab

You can configure advanced options if overriding the settings is allowed for the server type in the Central Designer Administrator application. For more information, see the *Administrator Guide*.

| Option                 | Description   |
|------------------------|---|
| Deployment start delay | Time to wait (in milliseconds) for the InForm caches to initialize. |



## Deployment Wizard for InForm deployment

| Page                       | Option   | Description   |
|----------------------------|--|---|
| Welcome                    |  | Introduction page.  |
| Connecting to InForm       | Connect to the InForm application and requests server and study information. |   |
|                            | Message section  | Informational and error messages.   |
|                            | Reconnect  | Reconnect to the InForm application after correcting any error conditions.  |
| InForm Trial Parameters    |  | Specify information about the InForm application server and study to which to deploy the package. If either the server or the study does not already exist, subsequent pages collect additional information needed to create them.                                  |
|                            | Server Name  | Name of the InForm application server.  |
|                            | Trial Name   | Name of the InForm study.   |
|                            | Strict Mode  | <p><b>If selected</b> (default)—Only complete MedML definitions of study components can be loaded into the study; an incomplete definition causes the installation to fail.</p> <p><b>If not selected</b>—Incomplete study component definitions are permitted.</p> |
| Create a New InForm Server |  | Specify whether the InForm server should start automatically when the InForm Service starts. This page appears if the specified InForm server does not yet exist.   |
|                            | Startup Server Automatically on InForm Startup                               | <p><b>If selected</b>—The InForm server starts automatically when the InForm Service starts.</p> <p><b>If not selected</b>—The InForm server must be started manually.</p>  |
| Create a New InForm Trial  |  | Specify information needed to create the study. This page appears if the specified InForm study does not yet exist.   |
|                            | User Name  | Oracle user name for the study database.  |
|                            | User Password  | Oracle password for the study database.   |
|                            | Please specify a database for creating a new InForm study                    | <p>One of the following:</p> <ul style="list-style-type: none"> <li>• <b>Connect String</b>—Connection string for the Oracle instance.</li> <li>• <b>TriDSN</b>—ODBC System DSN for the InForm study.</li> </ul>  |

| Page                 | Option  | Description  |
|----------------------|---|--|
|                      | Startup Trial Automatically on InForm Startup | <p><b>If selected</b>—The InForm study starts automatically when the InForm Service starts.</p> <p><b>If not selected</b>—The InForm study must be started manually.</p>                                       |
| Ready for Deployment |   | View a summary of the parameters that will be used for deployment.   |
| Deployment Results   |   | View messages generated during deployment processing, along with the elapsed time. These messages are also collected in the StudyInstaller.log file in the directory where you execute the deployment package. |

## Jobs Browser—Option descriptions

**Note:** Not all fields appear in the default view. Optionally, you can *add the other fields and rearrange the browser view* (in the User Guide).

| Option                                | Description   |
|---------------------------------------|---|
| <b>Buttons</b>                        |   |
| Hide Job Results/<br>Show Job Results | <ul style="list-style-type: none"> <li>• <b>Show Job Results</b>—Change from a grid to a tree structure that you can expand to view the job results for each job.</li> <li>• <b>Hide Job Results</b>—Change from a tree structure back to a grid that lists only jobs without job results.</li> </ul> |
| Refresh                               | Refresh the display of jobs from the Central Designer database. When you refresh, the job results for expanded jobs are also refreshed.   |
| Save As                               | Save the contents of the Jobs Browser to a comma-separated value (CSV) file that can be opened in a Microsoft Excel spreadsheet.  |
| Jobs Since                            | Drop-down list specifying how far back the display of job results goes.   |
| <b>Columns</b>                        |   |
| Finish Time                           | Date and time at which the job ended.   |
| Job State                             | Run status of the job, either Started or Finished.  |
| Job Id                                | Unique identifier of the job that generated the listing.  |
| Job Result                            | <p>Indicates whether the job scheduler ran successfully for the specified job. This field is <b>not</b> an indication of the status of the job.</p> <ul style="list-style-type: none"> <li>• Succeeded</li> <li>• Failed</li> </ul>   |

| Option             | Description  |
|--------------------|--|
| Name               | Name of the job: <ul style="list-style-type: none"> <li>• <b>For deployment package jobs</b>—Name of the deployment package.</li> <li>• <b>For library import jobs</b>—[Import to], plus the name of the target library.</li> <li>• <b>For validation jobs</b>—[Validation baseline], plus the date and time of job submission.</li> </ul>   |
| Start Time         | Date and time when the job started.  |
| Status             | Overall status of the job results for the selected job. <ul style="list-style-type: none"> <li>• <b>Information</b>—Job results contain only informational messages. This status also appears if the job has started but no job results have been reported yet.</li> <li>• <b>Warning</b>—Job results contain at least one warning (but no errors).</li> <li>• <b>Error</b>—Job results contain at least one error.</li> </ul> |
| Status Icon        | Icon that corresponds to the status of the job.  |
| Study Id           | Unique identifier of the study for which the job was run.  |
| Type               | Type of job, either Import, Validation, or BuildDeploymentPackage.   |
| <b>Sub-columns</b> | The following columns are in the grid that appears when you click Show Job Results and expand the results for a job.   |
| Code               | Unique identifier for the validation error or warning. You can provide the code when submitting issues to Oracle Support.  |
| Date Created       | Date and time the message was generated.   |
| Description        | Text of the message.   |
| Issue Name         | Type of issue for which the job result is reporting. This field contains a value only if the job result is a validation error on a rule. Options include Rule Name and sometimes Function Name.  |
| Job Id             | Unique identifier of the job that generated the listing.   |
| Job Result Id      | Unique identifier of the job result.   |
| Object RefName     | RefName of the study object that is reported in the job result. This field contains a value only if the job result is a validation error on a rule.  |
| Object Title       | Title of the study object that is reported in the job result. This field contains a value only if the job result is a validation error on a rule.  |
| Path               | Path of the study object that is reported in the job result. This field contains a value only if the job result is a validation error on a rule.   |
| Target             | Target application for which you validate the study and to which you deploy the study.   |

| Option          | Description   |
|-----------------|---|
| Type            | Type of message: <ul style="list-style-type: none"><li>• <b>Information</b>—Description of the processing step being performed in the job.</li><li>• <b>Warning</b>—Irregularity that should be investigated. Further processing (for example, creation of a deployment package) can be performed if you explicitly choose to ignore warnings.</li><li>• <b>Error</b>—Fatal problem. No further processing (for example, creation of a deployment package) can be performed until all errors are corrected.</li></ul> |
| Type Icon       | Icon that corresponds to the type of message.   |
| Warning Ignored | True or False, indicating whether you have chosen to ignore the warning message for the purpose of performing additional processing.  |

# Properties

## CDD data mapping properties

| Study object | Option           | Description   |
|--------------|------------------|---|
| Item         | Data Label       | User-defined string to use for searching on data in the column. Maximum length is 30 characters. This label is included in the CDD data mapping control path definition in the InForm database. For CDD data mappings, it also appears in target CDD data mapping tables that have any of the following key types: Patient to Control, Pivot Patient, Pivot Visit, Pivot Form, and Pivot Section. |
| Data set     | Associated Forms | Names of pairs of forms for which associations have been created. Selecting a pair of associated forms results in the generation of CDD data mappings for that association.   |

| Study object | Option                   | Description  |
|--------------|--------------------------|--|
|              | Target Key Type          | <p>For the following key types, the target key type specifies the composition of the primary key columns of the target table. Each time a component of the primary key changes from the previous primary key submitted, the InForm application inserts a new row in the target table. Primary keys consist of the following DBUIDs and indexes:</p> <ul style="list-style-type: none"> <li>• <b>Patient Only</b>—PatientID, FormIndex, ItemsetIndex.</li> <li>• <b>Patient Visit (default)</b>—PatientID, VisitID, FormIndex, ItemsetIndex, and VisitIndex.</li> <li>• <b>Patient to Form</b>—PatientID, VisitID, FormIndex, ItemsetIndex, VisitIndex, and FormID.</li> <li>• <b>Patient to Section</b>—PatientID, VisitID, FormIndex, ItemsetIndex, VisitIndex, FormID, and SectionID.</li> <li>• <b>Patient to Itemset</b>—PatientID, VisitID, FormIndex, ItemsetIndex, VisitIndex, FormID, SectionID, and ItemsetID.</li> <li>• <b>Patient to Item</b>—PatientID, VisitID, FormIndex, ItemsetIndex, VisitIndex, FormID, SectionID, ItemsetID, and ItemID.</li> <li>• <b>Patient to Control</b>—PatientID, VisitID, FormIndex, ItemsetIndex, VisitIndex, FormID, SectionID, ItemsetID, ItemID and five ControlIDs. A target table with this key type also contains a data label that can be used for data selection.</li> </ul> <p>For the following key types, the primary key columns are PatientID, VisitID, ItemsetIndex, VisitIndex, FormID, SectionID, ItemsetID, ItemID and five ControlIDs. The key type selection determines the composition of a pivot set. Within a pivot set, data points mapped to non-pivot columns are repeated in each row. Target tables with these key types also contain a data label that can be used for data selection. Pivot set keys consist of the following DBUIDs and indexes:</p> <ul style="list-style-type: none"> <li>• <b>Pivot Patient</b>—PatientID and VisitIndex</li> <li>• <b>Pivot Visit</b>—PatientID, VisitID, and VisitIndex</li> <li>• <b>Pivot Form</b>—PatientID, VisitID, FormID, and VisitIndex</li> <li>• <b>Pivot Section</b>—PatientID, VisitID, FormID, SectionID, and VisitIndex</li> </ul> |
| Data series  | Pivot Column             | <p>Identifies the column to use as the pivot column, if the key type is Pivot Form, Pivot Patient, Pivot Section, or Pivot Visit.</p> <p><b>Note:</b> Only one column can be the pivot column, and it must be the first column in the table.</p>   |
|              | Target Column Max Length | Maximum length of a column, in the range 1-255. This property is applicable for columns with a type of STRING.   |

## CIS data mapping properties

Use the following custom properties for CIS data mappings to specify how the data that is passed from the InForm application should be used in the Clintrial application. The custom properties have default values or are required only when you want to support specific Clintrial features, such as master-detail panel relationships.

| Study object | Option          | Description   |
|--------------|-----------------|---|
| Study event  | Block Key Value | Value of the Clintrial block key. If you specify this value, it overrides the study event RefName as the block key.   |
| Form         | Page Key Value  | Value of the Clintrial page key. If you specify this value, it overrides the form RefName as the page key.  |
| Data set     | Detail Key Item | Name of the item identified as the detail key item, if the panel definition is part of a detail page section.   |
|              | Detail Panel    | True or False (default), indicating whether the panel definition participates in a detail page section in a master-detail relationship. A master-detail relationship is a relationship between two page sections on a study page, in which each record in one page section (the master page section) can have one or more associated records in the other section (the detail page section). During data entry the displayed records in the detail page section are associated with the selected record in the master page section. |
|              | Master Item     | Name of the item on the master panel that corresponds to the detail key item specified in the Detail Key Item property.<br><br>This property applies only if the value of the Detail Panel property is True.  |
|              | Master Panel    | Name of the master panel with which this panel definition participates in a master-detail relationship.<br><br>This property applies only if the value of the Detail Panel property is True.  |

| Study object | Option     | Description  |
|--------------|------------|--|
|              | Panel Type | <p>A specification of how the database tables associated with the panel are structured:</p> <ul style="list-style-type: none"> <li>• <b>Panel Type 1</b>—One record per subject, collected once during the study.</li> <li>• <b>Panel Type 2</b>—Multiple records for each subject, collected once during the study.</li> <li>• <b>Panel Type 3</b>—One record per subject, collected at multiple visits.</li> <li>• <b>Panel Type 4 (default)</b>—Multiple records for each subject, collected at multiple visits.</li> <li>• <b>Context Panel</b>—One record containing custom context items that are associated with each record in a clinical data table. Use this type to specify a custom context panel.</li> <li>• <b>Enrollment Panel</b>—One record of enrollment data for each enrolled subject.</li> <li>• <b>Non-Patient Data</b>—Data not related to a study subject, for example, lab normals or standard coding thesauruses.</li> </ul> |
|              | Protected  | True or False (default), indicating whether access rights to the panel are limited in the Clintrial application.   |
|              | SAS Name   | <p>Name of the panel when data is sent to SAS through the Clintrial SAS interface.</p> <p>OPTIONAL; if entered, the name must be 8 characters or fewer and conform to SAS naming requirements.</p> <p><b>Note:</b> Panel SAS names must be unique within a protocol.</p>   |
|              | Verifiable | True or False (default), indicating whether double-entry of data in panel items is required for verification.  |



| Study object | Option                       | Description   |
|--------------|------------------------------|---|
| Data series  | Checklist                    | <p>Name of a Clintrial checklist associated with the item. A checklist is a type of codelist used to view suggested entries for a field.</p> <p>The checklist name must be 20 characters or fewer.</p> <p>Checklist and CIS Codelist are mutually exclusive properties.</p>   |
|              | CIS Codelist                 | <p>Name of a Clintrial codelist associated with the item. A codelist encodes entered values.</p> <p>The codelist name must be 20 characters or fewer.</p> <p>Checklist and CIS Codelist are mutually exclusive properties.</p> <p><b>Note:</b> When CIS synchronization processes data mappings and autogenerates codelists, it does <i>not</i> autogenerate codelists for items that have a value in the Code List property. The CIS Codelist property refers to an existing codelist. Therefore, if you want CIS to autogenerate a codelist for an item, leave the Code List property blank.</p>  |
|              | Context Type                 | <p>Specifies the usage of a user-defined context item:</p> <ul style="list-style-type: none"> <li>• Not a context item (default).</li> <li>• Subject-related context item.</li> <li>• Visit-related context item.</li> <li>• Page-related context item.</li> <li>• Other context item.</li> </ul> <p><b>Note:</b> Data series with a Context Type of <b>Other context item</b> are designed to be used in hybrid studies in which users can enter data using either the Clintrial or the InForm application. When you deploy a study that contains a data series with a Context type property of <b>Other context item</b>, the item definition for that data series is created in the Clintrial context panel, but the CIS application does not synchronize data from the InForm application to that context item. To enter data into a context panel item that is defined using the <b>Other context item</b> Context type property, users must use the Clintrial Enter module.</p> |
|              | Copy With Panel              | True (default) or False, indicating whether the item should be included with the panel if the panel is copied.  |
|              | DB Format<br>Float Precision | Number of characters that can be added after the decimal place in an item with a type of FLOAT. This value can be a number between 1 and 15. The default is 10.   |
|              | DB Format<br>Length          | Number of characters that can be entered in this item. The default is 2000 for text items, 18 for numeric items.  |
|              | Derived                      | True or False (default), indicating whether the value of the item is determined from a derivation associated with the panel.  |

| Study object | Option        | Description   |
|--------------|---------------|---|
|              | Is Key        | True or False (default), indicating whether the item mapped to the data series is a subject key, block key, block repeat key, page key, or page repeat key item in the context panel.   |
|              | Item Required | True or False (default), indicating whether the item is required.   |
|              | Key Order     | The order in which the item appears in the concatenation of key items, if the item is part of the panel's key. 0 (not a key item) is the default.   |
|              | Max           | Maximum value that can be entered for the value of the item.  |
|              | Min           | Minimum value that can be entered for the value of the item.  |
|              | Repeated      | True or False (default), indicating whether an item is one for which multiple values can be entered within a page section.  |
|              | SAS Name      | (Optional) Name of the item when data is sent to SAS through the Clintrial SAS interface.<br><br>If entered, the name must be eight characters or fewer and conform to SAS naming requirements.<br><br><b>Note:</b> Item SAS names must be unique within a panel. |

## Codelist properties

### Properties common to all study objects

All study objects have the following properties.

| Property    | Description  |
|-------------|--|
| Description | Description of the study object. The description can have 0-255 characters.  |
| Identifier  | Unique internal identifier of the study object.  |
| Locked      | When True, the study object is locked.   |
| Modified    | When True, the study object has not been saved since the last modification.  |
| New         | When True, the study object has not been saved yet. When False, the study object has been saved at least one time.   |
| Protected   | When true, the study object is protected. When a study object is protected, you cannot : <ul style="list-style-type: none"> <li>• Update or lock it.</li> <li>• Add child study objects to it by pasting or dragging and dropping.</li> <li>• Delete its child study objects.</li> </ul> |
| RefName     | RefName of the study object. The RefName can have 1-63 characters.   |

| Property | Description   |
|----------|---|
| Revision | Revision number of the study object.  |
| Title    | Title of the study object. The title can have 1-63 characters.  |
| Version  | Version number of the study object. The version number is incremented only when a user explicitly updates it. |

| Property     | Description                                |
|--------------|--|
| CodeListType | Type of codelist; integer, float, or text. |

## Codelist item properties

### Properties common to all study objects

All study objects have the following properties.

| Property    | Description  |
|-------------|--|
| Description | Description of the study object. The description can have 0-255 characters.  |
| Identifier  | Unique internal identifier of the study object.  |
| Locked      | When True, the study object is locked.   |
| Modified    | When True, the study object has not been saved since the last modification.  |
| New         | When True, the study object has not been saved yet. When False, the study object has been saved at least one time.   |
| Protected   | When true, the study object is protected. When a study object is protected, you cannot : <ul style="list-style-type: none"> <li>• Update or lock it.</li> <li>• Add child study objects to it by pasting or dragging and dropping.</li> <li>• Delete its child study objects.</li> </ul> |
| RefName     | RefName of the study object. The RefName can have 1-63 characters.   |
| Revision    | Revision number of the study object.   |
| Title       | Title of the study object. The title can have 1-63 characters.   |
| Version     | Version number of the study object. The version number is incremented only when a user explicitly updates it.  |

| Property                      | Description   |
|-------------------------------|---|
| <b>InForm properties</b>      |   |
| Study Completion Status Items | <p>Codelist items in the codelist for the Completion Status item on the Study Completion form, which is used in reporting in the InForm application to determine whether a subject dropped out of a study. Options include:</p> <ul style="list-style-type: none"> <li>• <b>None</b>—(default) The codelist item is not part of the codelist for the Completion Status item.</li> <li>• <b>Complete Study (Study Completion)</b>—Indicates that the subject has completed the study.</li> <li>• <b>Incomplete Study (Study Completion)</b>—Indicates that the subject has not completed the study.</li> </ul> |
| <b>Standard properties</b>    |   |
| Code                          | Code of the codelist item.  |
| CodeListType                  | <p>Type of codelist; integer, float, or text. The value of this property is populated with the value for the CodeListType property of the codelist parent of the codelist item.</p> <p>READ-ONLY</p>  |
| Label                         | Label of the codelist item.   |

## Data mapping properties

| Property                   | Description  |
|----------------------------|--|
| <b>Standard properties</b> |  |
| Description                | Description of the study object. The description can have 0-255 characters.  |
| Identifier                 | Unique internal identifier of the study object.  |
| Locked                     | When True, the study object is locked.   |
| Modified                   | When True, the study object has not been saved since the last modification.  |
| New                        | When True, the study object has not been saved yet. When False, the study object has been saved at least one time. |
| RefName                    | RefName of the study object. The RefName can have 1-63 characters.   |
| Revision                   | Version or revision number of the study object.  |
| Title                      | Title of the study object. The title can have 1-63 characters.   |

## Data series standard properties

| Property                   | Description  |
|----------------------------|--|
| <b>Standard properties</b> |  |
| Alias                      | Alias for the data series.   |
| Classification             | Type of the data series: <ul style="list-style-type: none"> <li>• Integer</li> <li>• Float</li> <li>• Boolean</li> <li>• Text</li> <li>• DateTime</li> </ul> |
| Description                | Description of the study object. The description can have 0-255 characters.  |
| Identifier                 | Unique internal identifier of the study object.  |
| Locked                     | When True, the study object is locked.   |
| Modified                   | When True, the study object has not been saved since the last modification.  |
| New                        | When True, the study object has not been saved yet. When False, the study object has been saved at least one time.   |
| RefName                    | RefName of the study object. The RefName can have 1-63 characters.   |
| Revision                   | Version or revision number of the study object.  |
| Title                      | Title of the study object. The title can have 1-63 characters.   |

## Data set properties

| Property                   | Description  |
|----------------------------|--|
| <b>Standard properties</b> |  |
| Description                | Description of the study object. The description can have 0-255 characters.  |
| Identifier                 | Unique internal identifier of the study object.  |
| Locked                     | When True, the study object is locked.   |
| Modified                   | When True, the study object has not been saved since the last modification.  |
| New                        | When True, the study object has not been saved yet. When False, the study object has been saved at least one time. |
| RefName                    | RefName of the study object. The RefName can have 1-63 characters.   |

| Property | Description  |
|----------|--|
| Revision | Version or revision number of the study object.                |
| Title    | Title of the study object. The title can have 1-63 characters. |

## Form and section properties

### Properties common to all study objects

All study objects have the following properties.

| Property    | Description  |
|-------------|--|
| Description | Description of the study object. The description can have 0-255 characters.  |
| Identifier  | Unique internal identifier of the study object.  |
| Locked      | When True, the study object is locked.   |
| Modified    | When True, the study object has not been saved since the last modification.  |
| New         | When True, the study object has not been saved yet. When False, the study object has been saved at least one time.   |
| Protected   | When true, the study object is protected. When a study object is protected, you cannot : <ul style="list-style-type: none"> <li>• Update or lock it.</li> <li>• Add child study objects to it by pasting or dragging and dropping.</li> <li>• Delete its child study objects.</li> </ul> |
| RefName     | RefName of the study object. The RefName can have 1-63 characters.   |
| Revision    | Revision number of the study object.   |
| Title       | Title of the study object. The title can have 1-63 characters.   |
| Version     | Version number of the study object. The version number is incremented only when a user explicitly updates it.  |

| Property                 | Description  |
|--------------------------|--|
| <b>CIS properties</b>    |  |
| Page Key Value           | Value of the Clintrial page key, used for transferring data to the Clintrial application through CIS mappings. If you specify the Page Key Value, it overrides the form RefName as the page key. |
| <b>InForm properties</b> |  |
| Item Required            | True (default) or False, indicating whether the item is required.  |

| Property                   | Description   |
|----------------------------|---|
| SDV Required               | <b>True</b> (default) or <b>False</b> , indicating whether the item requires source document verification.  |
| SDV Critical               | <b>True</b> or <b>False</b> (default), indicating whether the item is considered critical for source verification. If you select True, SDV Required changes to True.  |
| Special Forms              | Type of special InForm field, or None, indicating that the item is not a special InForm field. Available special fields, along with the forms in which they appear, are: <ul style="list-style-type: none"> <li>• Initials (Screening).</li> <li>• DOB (Screening).</li> <li>• Screening date (Screening).</li> <li>• Patient No. (Enrollment).</li> <li>• Initials (Patient Identification).</li> <li>• Completion status (Study Completion).</li> <li>• Drop-out reason (Study Completion).</li> <li>• DOV (Date of Visit).</li> <li>• Randomization field (Randomization).</li> </ul> <p>For more information, see <i>About special InForm forms</i> (on page 86).</p> |
| <b>Standard properties</b> |   |
| AssociatedForm             | Indicates whether the form is an associated form. <ul style="list-style-type: none"> <li>• <b>None</b>—Form is not an associated form.</li> <li>• <b>[Form name]</b>—Name of the form with which the form is associated.</li> </ul>   |
| Common                     | When True, the form is a common form.   |
| Fixed                      | For sections only. When True (used for repeating sections), the section contains items that are deployed as a Repeating Data itemset.   |
| Repeating                  | When True, the study object is repeating.   |
| Short Title                | Short title of the form, used as a mnemonic when deployed.  |

## Item properties

### Properties common to all study objects

All study objects have the following properties.

| Property    | Description   |
|-------------|---|
| Description | Description of the study object. The description can have 0-255 characters. |
| Identifier  | Unique internal identifier of the study object.                             |

| Property  | Description  |
|-----------|--|
| Locked    | When True, the study object is locked.   |
| Modified  | When True, the study object has not been saved since the last modification.  |
| New       | When True, the study object has not been saved yet. When False, the study object has been saved at least one time.   |
| Protected | When true, the study object is protected. When a study object is protected, you cannot : <ul style="list-style-type: none"> <li>• Update or lock it.</li> <li>• Add child study objects to it by pasting or dragging and dropping.</li> <li>• Delete its child study objects.</li> </ul> |
| RefName   | RefName of the study object. The RefName can have 1-63 characters.   |
| Revision  | Revision number of the study object.   |
| Title     | Title of the study object. The title can have 1-63 characters.   |
| Version   | Version number of the study object. The version number is incremented only when a user explicitly updates it.  |

| Property  | Description   |
|---|---|
| <b>CDD properties</b>   |   |
| Data Label  | Text label for the item, enabling access to the item in a target table with the Patient To Control key type or any of the pivot key types.      |
| <b>Component Settings</b> (The following settings are used only for date time items.)   |   |
| DayAllow,<br>HourAllow,<br>MinuteAllow,<br>MonthAllow,<br>SecondAllow,<br>YearAllow   | When True, indicates that the date time item includes a control for the component of the date time.   |
| DayAllowUnknown,<br>HourAllowUnknown,<br>MinuteAllowUnknown,<br>MonthAllowUnknown,<br>SecondAllowUnknown,<br>YearAllowUnknown | When True, indicates that the date time item includes a control for the component of the date time and allows a user to mark the value unknown. |
| DayRequired,<br>HourRequired,<br>MinuteRequired,<br>MonthRequired,<br>SecondRequired,<br>YearRequired                         | When true, indicates that the component of the date time item is required.  |



| Property                 | Description   |
|--------------------------|---|
| <b>InForm properties</b> |   |
| Collapsible              | <b>True</b> or <b>False</b> (default), indicating whether the item is always visible on the form in the InForm application, or is collapsed and not visible until a condition is met.   |
| Display Override         | Determines the default behavior of an item when a layout is generated. <ul style="list-style-type: none"> <li>• <b>ReadOnly</b>—The item is visible but not editable.</li> <li>• <b>Editable</b>—The item is visible and editable by any user, regardless of the rights assigned to the user.</li> <li>• <b>Hidden</b>—The item is not visible.</li> <li>• <b>None</b>—The item is visible to all users, and visible and editable by any user who has the rights to view and/or edit the item.</li> </ul>   |
| Item Required            | <b>True</b> (default) or <b>False</b> , indicating whether the item is required for data entry on the form to be complete.  |
| MaxProperty              | If a MaxValue is specified for the item, indicates whether the value can be less than or less than or equal to the MaxValue.  |
| MaxValue                 | Maximum value that the InForm application will allow to be typed for the item.  |
| MinProperty              | If a MinValue is specified for the item, indicates whether the value can be greater than or greater than or equal to the MinValue.  |
| MinValue                 | Minimum value that the InForm application will allow to be typed for the item.  |
| PHI                      | <b>True</b> or <b>False</b> (default), indicating whether an InForm user might enter Personal/Protected Health Information (PHI) for the item. If you select True: <ul style="list-style-type: none"> <li>• A warning appears when you close the Rule Wizard if you create a rule with an email action and you add the item to the subject or body of the email.</li> <li>• A validation error occurs if a rule with an email action contains the item in the subject line or body of the email.</li> </ul> |
| SDV Critical             | <b>True</b> or <b>False</b> (default), indicating whether the item is considered critical for source verification. If you select True, SDV Required changes to True. <p><b>Note:</b> The SDV Critical setting for an item can be overridden in the InForm application.</p>  |
| SDV Required             | <b>True</b> (default) or <b>False</b> , indicating whether the item requires source document verification.  |

| Property                   | Description  |
|----------------------------|--|
| Special Fields             | Fields used on the special forms for the InForm application. <ul style="list-style-type: none"> <li>• <b>None</b>—Field is not a special InForm field.</li> <li>• <b>Screening form:</b> <ul style="list-style-type: none"> <li>▪ Initials</li> <li>▪ DOB</li> <li>▪ Screening date</li> </ul> </li> <li>• <b>Enrollment form:</b> Patient No.</li> <li>• <b>Patient Identification form:</b> Initials</li> <li>• <b>Study Completion form:</b> <ul style="list-style-type: none"> <li>▪ Completion status</li> <li>▪ Drop out reason</li> </ul> </li> <li>• <b>Date of Visit form:</b> DOV</li> <li>• <b>Randomization form:</b> Randomization field</li> </ul> |
| <b>Standard properties</b> |  |
| Question                   | Question for the item. The question can have 0-1000 characters.  |
| ShortQuestion              | Short question for the item. The short question can have 0-255 characters.   |

## Study and library standard properties

| Property    | Description  |
|-------------|--|
| Enabled     | For libraries only. Indicates whether the library is enabled or disabled.  |
| Description | Description of the study object. The description can have 0-255 characters.  |
| Identifier  | Unique internal identifier of the study object.  |
| Locked      | When True, the study object is locked.   |
| Modified    | When True, the study object has not been saved since the last modification.  |
| New         | When True, the study object has not been saved yet. When False, the study object has been saved at least one time. |
| Protected   | True or False, indicating whether the study or library is protected.   |
| Title       | Title of the study object. The title can have 1-63 characters.   |
| Version     | Study or library version.  |

## Study design properties

### Properties common to all study objects

All study objects have the following properties.

| Property    | Description  |
|-------------|--|
| Description | Description of the study object. The description can have 0-255 characters.  |
| Identifier  | Unique internal identifier of the study object.  |
| Locked      | When True, the study object is locked.   |
| Modified    | When True, the study object has not been saved since the last modification.  |
| New         | When True, the study object has not been saved yet. When False, the study object has been saved at least one time.   |
| Protected   | When true, the study object is protected. When a study object is protected, you cannot : <ul style="list-style-type: none"> <li>• Update or lock it.</li> <li>• Add child study objects to it by pasting or dragging and dropping.</li> <li>• Delete its child study objects.</li> </ul> |
| RefName     | RefName of the study object. The RefName can have 1-63 characters.   |
| Revision    | Revision number of the study object.   |
| Title       | Title of the study object. The title can have 1-63 characters.   |
| Version     | Version number of the study object. The version number is incremented only when a user explicitly updates it.  |

| Property                 | Description  |
|--------------------------|--|
| <b>InForm properties</b> |  |
| Shared Form Block Key    | Block key to use for a shared form; used for data transfers to the Clintrial application through CIS mappings. You must use this property if the block key in the Clintrial application is defined as a numeric field. The block key that you specify overrides the internal text block key (CommonCRF) that the Central Designer application creates during deployment from the system RefName of the special visit for shared forms. |

| Property                   | Description                                 |
|----------------------------|---|
| <b>Standard properties</b> |   |
| Generic Drug Name          | Generic name for a drug.                    |
| Protocol                   | Name of the study protocol.                 |
| Sponsor                    | Name of the sponsor of the study.           |
| Sponsor Date               | Date specified by the sponsor of the study. |
| Sponsor Drug Name          | Code name given to a drug by a sponsor.     |
| Study Name                 | Name of the study.                          |
| Trade Drug Name            | Commercial name of a drug.                  |

## Study element properties

All study objects have the following properties.

| Property    | Description  |
|-------------|--|
| Description | Description of the study object. The description can have 0-255 characters.  |
| Identifier  | Unique internal identifier of the study object.  |
| Locked      | When True, the study object is locked.   |
| Modified    | When True, the study object has not been saved since the last modification.  |
| New         | When True, the study object has not been saved yet. When False, the study object has been saved at least one time.   |
| Protected   | When true, the study object is protected. When a study object is protected, you cannot : <ul style="list-style-type: none"> <li>• Update or lock it.</li> <li>• Add child study objects to it by pasting or dragging and dropping.</li> <li>• Delete its child study objects.</li> </ul> |
| RefName     | RefName of the study object. The RefName can have 1-63 characters.   |
| Revision    | Revision number of the study object.   |
| Title       | Title of the study object. The title can have 1-63 characters.   |
| Version     | Version number of the study object. The version number is incremented only when a user explicitly updates it.  |

## Study event properties

### Properties common to all study objects

All study objects have the following properties.

| Property    | Description  |
|-------------|--|
| Description | Description of the study object. The description can have 0-255 characters.  |
| Identifier  | Unique internal identifier of the study object.  |
| Locked      | When True, the study object is locked.   |
| Modified    | When True, the study object has not been saved since the last modification.  |
| New         | When True, the study object has not been saved yet. When False, the study object has been saved at least one time.   |
| Protected   | When true, the study object is protected. When a study object is protected, you cannot : <ul style="list-style-type: none"> <li>• Update or lock it.</li> <li>• Add child study objects to it by pasting or dragging and dropping.</li> <li>• Delete its child study objects.</li> </ul> |
| RefName     | RefName of the study object. The RefName can have 1-63 characters.   |
| Revision    | Revision number of the study object.   |
| Title       | Title of the study object. The title can have 1-63 characters.   |
| Version     | Version number of the study object. The version number is incremented only when a user explicitly updates it.  |

| Property        | Description   |
|-----------------|---|
| <b>CIS</b>      |   |
| Block Key Value | Value of the Clintrial block key, used for data transfer to the Clintrial application through CIS mappings. If you specify this value, it overrides the visit RefName as the block key. |
| <b>InForm</b>   |   |
| Optional        | True or False (default), indicating whether the formset (visit) is optional or required.  |
| Special Visits  | When a special visit type is selected, the study event is deployed as a special InForm visit.   |

| Property                   | Description  |
|----------------------------|--|
| <b>Standard properties</b> |  |
| Repeating                  | When True, the study object is repeating.  |
| Short Title                | Short title of the study event. The short title deploys to the InForm application as the visit mnemonic. The short title can have 1-63 characters. |

## Study project and library project properties

| Property                   | Description  |
|----------------------------|--|
| <b>Standard properties</b> |  |
| Description                | Description of the study object. The description can have 0-255 characters.  |
| Locked                     | When True, the study object is locked.   |
| Modified                   | When True, the study object has not been saved since the most recent modification.                                 |
| Name                       | Name of the study object.  |
| New                        | When True, the study object has not been saved yet. When False, the study object has been saved at least one time. |
| Title                      | Title of the study object. The title can have 1-63 characters.   |

## Properties in the Rule Test Cases dialog box

The following properties appear in the Test Properties tab, which you can select in the Design tab of the Rule Test Cases dialog box.

When you point to a component of a test case, its properties appear.

| Property   | Description  |
|--|--|
| <b>Properties for test names</b>                             |  |
| Ignore test  | When False, the test case is run. When True, the test case is not run.   |
| Rule name  | Name of the rule or global condition.  |
| Rule type  | Type of rule (data-entry rule, global condition, or workflow rule).  |
| <b>Properties for item names—<br/>Item Settings grouping</b> | <b>Notes:</b><br>If the item is repeating, the grouping is called Repeating Item Settings.<br><br>Not all properties are available for all types of items. |

| Property   | Description   |
|--|---|
| Codelist choices   | Indicates the type of the codelist. Expand the property to view the code and label for each codelist item in the right column.<br><br><b>Note:</b> The numbers in the left column are for ordering purposes only and do not necessarily correspond to the codes for the codelist items. |
| Codelist type  | The type of codelist on the item, such as float or integer.   |
| Float length   | Length of the float item.   |
| Float precision  | Precision of the float item.  |
| Item object path   | Path of the item in the context of the rule scope.  |
| Object RefName   | RefName of the item.  |
| Object Title   | Title of the item.  |
| Repeating objects  | List of repeating study objects that are in the item's path, including the type of study object (such as form or section).  |
| <b>Properties for item names—Test Settings grouping</b>                  |   |
| Ignore test  | When False, the test case is run. When True, the test case is not run.  |
| <b>Properties for expected results—Repeating Objects grouping</b>        |   |
| Repeating Form Index<br>Repeating Section Index<br>Repeating Event Index | Properties appear in this section when an item path contains a repeating study object. For example, if the only repeating study object in the item path is a section, only Repeating Section Index appears.<br><br>The number of the repeating instance that you are testing.           |
| <b>Properties for expected results—Test Settings grouping</b>            |   |
| Ignore test  | When False, the test case is run. When True, the test case is not run.<br><br>Default: False.   |
| Item object path   | Path of the item in the context of the rule scope.  |
| Rule action type   | <ul style="list-style-type: none"> <li>• Data-entry rules—Value, Query, or Email.</li> <li>• Global conditions—Condition.</li> <li>• Workflow rules—NextStep.</li> </ul>  |
| Rule name  | Name of the rule or global condition.   |
| Rule type  | Type of rule (data-entry rule, global condition, or workflow rule).   |





# 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 494).

### application role

A role associated with administrative activities.

### arm

See *study arm* (on page 494).

### 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 494).

## 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 494).

**clinical protocol**

See *protocol* (on page 492).

**clinical study**

See *study* (on page 493).

**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 488).

**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 488).

**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 495).

**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 492).

## custom data dimension

See *data dimension* (on page 489).

## 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 489), *mapping* (on page 491).

### data set

A grouping of one or more related data series.

See also *data series* (on page 489), *mapping* (on page 491).

### 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 496).

### 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 489).

**element**

See *study element* (on page 494).

**event**

See *study event* (on page 494).

**explicit lock**

A lock that you request and that does not expire.

See also *implicit lock* (on page 490).

**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 496).

**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 490).

**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 493).

**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 490), *explicit lock* (on page 490).

**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 489), *data set* (on

page 489).

## 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 489).

## 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 494).

## 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 491) and *study project* (on page 494).

## 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 495).

## 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 493).

### 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 491), *study role* (on page 494), and *user role* (on page 495).

### 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 489), *workflow rule* (on page 496).

### 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 487), *constraint rule* (on page 488), and *intrinsic rule* (on page 491).

## 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 488).

### 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 489).

### 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 491), *query group* (on page 492), *rights group* (on page 493), *signature group* (on page 493), *sponsor* (on page 493), *study configuration* (on page 494).

**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 487).

**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 488) and *study administration object* (on page 494).

**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 496).

**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 494), *library team* (on page 491).

### 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 492).

### 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 494).

**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 489), *global condition* (on page 490).

**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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