User Guide

Oracle® Health Sciences InForm 6.0

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About this guide

In this preface

Overview of this guide

The *User Guide* provides an overview of the InForm application including details on multilingual studies, how to navigate through the user interface, and how to use the application to accomplish typical tasks you perform while running a clinical study.

Audience

This guide is for everyone who uses the InForm application through the user interface. This includes the site and sponsor users, as well as the InForm administrators who are responsible for configuring the application and performing user and study administration activities.

Related information

Documentation

All documentation is available from the Oracle Software Delivery Cloud (https://edelivery.oracle.com) and the Download Center (https://extranet.phaseforward.com).

Document	Description
Release Notes	The *Release Notes* document describes enhancements introduced and problems fixed in the current release, upgrade considerations, release history, and other late-breaking information.
Known Issues	The *Known Issues* document provides detailed information about the known issues in this release, along with workarounds, if available. **Note:** The most current list of known issues is available on the Extranet. To sign in to the Extranet, go to https://extranet.phaseforward.com.
Upgrade and Migration Guide	The *Upgrade and Migration Guide* provides instructions for upgrading and migrating the InForm software and InForm Portal software to the current InForm release, and for upgrading the Cognos 8 Business Intelligence software for use with the Reporting and Analysis module. The guide also describes any changes and additions made to the database schema, MedML, and resource files.
Secure Configuration Guide	The *Secure Configuration Guide* provides an overview of the security features provided with the Oracle® Health Sciences InForm application, including details about the general principles of application security, and how to install, configure, and use the InForm application securely.
Installation Guide	The *Installation Guide* describes how to install the software and configure the environment for the InForm application and Cognos 8 Business Intelligence software.
Study and Reporting Setup Guide	The *Study and Reporting Setup Guide* describes how to perform the tasks that are required to set up an InForm study and configure the Reporting and Analysis module for the study.
User Guide	The *User Guide* provides an overview of the InForm application including details on multilingual studies, how to navigate through the user interface, and how to use the application to accomplish typical tasks you perform while running a clinical study. This document is also available from the Documentation CD and the InForm user interface.

Document	Description
Reporting and Analysis Guide	The *Reporting and Analysis Guide* provides an overview of the Reporting and Analysis module. It includes a brief overview of the Reporting and Analysis interface, illustrates how to access the Ad Hoc Reporting feature, and describes the study management and clinical data packages available for Reporting and Analysis. It also provides detailed descriptions of each standard report that is included with your installation.
	This document is also available from the Documentation CD.
Reporting Database Schema Guide	The *Reporting Database Schema Guide* describes the Reporting and Analysis database schema, and provides information on creating Reporting Database Extracts (RDEs).
Portal Administration Guide	The *Portal Administration Guide* provides step-by-step instructions for setting up the InForm Portal software, and configuring and managing the InForm Portal application.
	This document is also available from the Documentation CD.
Utilities Guide	The *Utilities Guide* provides information about and step-by-step instructions for using the following utilities:
	• PFConsole utility
	• MedML Installer utility
	• InForm Data Import utility
	• InForm Data Export utility
	• InForm Performance Monitor utility
	• InForm Report Folder Maintenance utility
	This guide also provides reference information for the MedML elements and scripting objects that are used to import and export data to and from the InForm application, as well as sample data import XML.
	This document is also available from the Documentation CD.
MedML Installer utility online Help	The MedML Installer utility online Help provides information about, and step-by-step instructions for using, the MedML Installer utility, which is used to load XML that defines study components into the InForm database.
	This guide also provides reference information for the MedML elements and scripting objects that are used to import and export data to and from the InForm application, as well as sample data import XML.
	This document is also available from the user interface.

Document	Description
InForm Data Export utility online Help	The InForm Data Export utility online Help provides information about and step-by-step instructions for using the InForm Data Export utility, which is used to export data from the InForm application to the following output formats: • Customer-defined database (CDD). • Name value pairs. This document is also available from the user interface.
InForm Data Import utility online Help	The InForm Data Import utility online Help provides information about and step-by-step instructions for using the InForm Data Import utility, which is used to import data into the InForm application. This document is also available from the user interface.

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.

InForm overview

In this chapter

About the InForm software

The InForm software is a data collection and study management application that uses a secure web browser to provide access to clinical study data and management of the clinical study process. Your user profile and rights determine which InForm features you can access.

Use the InForm application to:

- Screen and enroll subjects.

- Enter and manage form, comment, and visit data.

- Issue, answer, and close queries.

- Source verify forms, or a subset of items and itemsets on a form.

- Freeze and lock forms.

- Sign forms and case report books.

- View study specific documentation.

- Perform and view subject transfers.

- Perform administrative tasks.

About the Data Viewer

The Data Viewer is a standard feature in the InForm application that provides Clinical Data Managers (CDMs) and other InForm users with a real-time overview of clinical study data across visits and sites. You can use the Data Viewer to facilitate the cleaning of data, to look for patterns in data, and to identify items that may be anomalies.

Use the Data Viewer to:

- Compare items on the same type of forms.

- Compare two forms side-by-side.

- View data from multiple clinical forms in one custom view.

- Perform InForm actions on one or more forms, such as freezing, locking, and source verifying.

- View and issue queries on clinical data.

- Review form and item comments.

- Export data and comments.

- Use review states for custom review workflows.

The Data Viewer is installed as part of the InForm software installation. To use the features in the Data Viewer, you must have access rights to the Data Viewer as well as rights to perform certain tasks. For details on the XML associated with the Data Viewer rights, see the *Utilities Guide*.

About the Reporting and Analysis module

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

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

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

InForm system configuration

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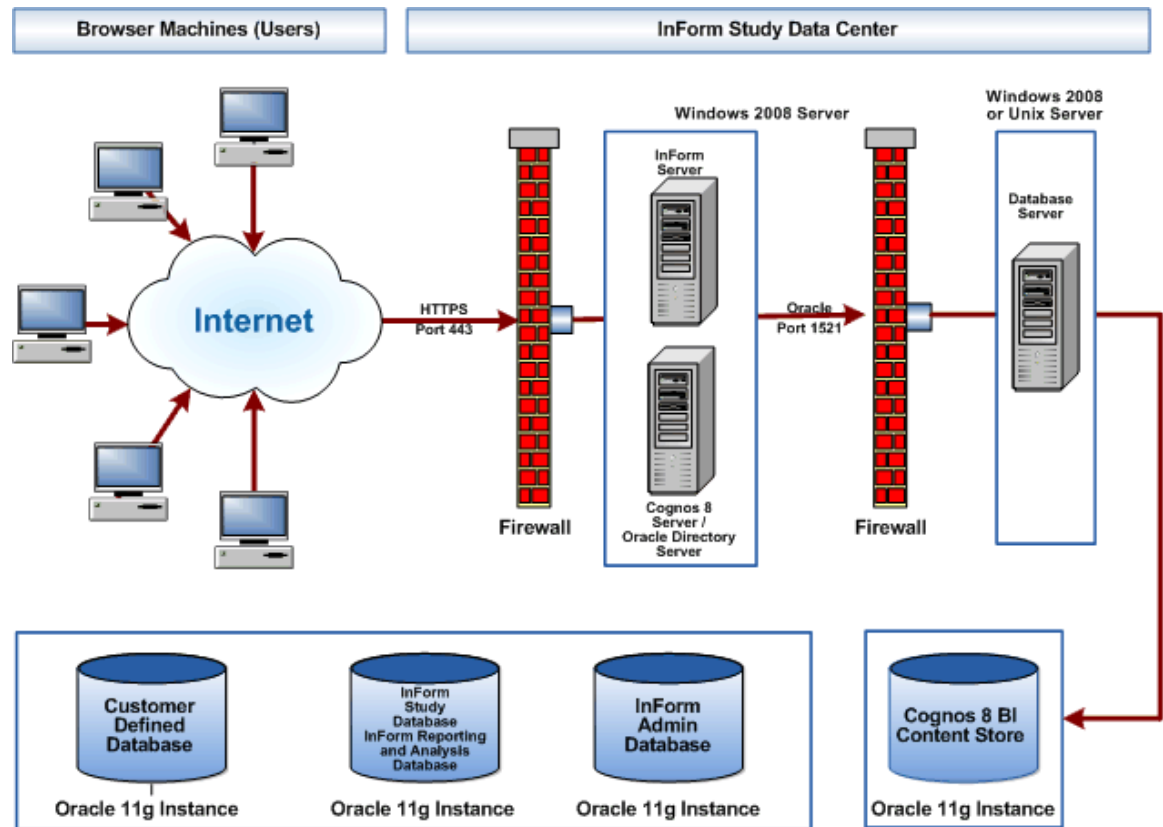
InForm users

User	Description
Clinical data manager (CDM)	A person responsible for preparing and maintaining a study database and reviewing data.
Clinical project manager	A person responsible for all aspects of one or more clinical studies or for the entire clinical plan for a drug, device, or procedure.
Clinical research associate (CRA)	A person who is hired by a sponsor to supervise and monitor the progress of sites that are participating in a study. Also called *monitor, site monitor.*
Clinical research coordinator (CRC)	An assistant to the investigator at a site. Also called *site coordinator, study coordinator.*
Principal investigator (PI)	The clinician who is responsible for treating subjects, executing the protocol of a study at a specific site, and filling out CRFs for subjects. Also called c*linical investigator, investigator, primary investigator.*
Medical monitor	A person who designs the study protocol and reviews data.
Site user	An InForm user, typically a CRC or PI, who performs the following tasks: • Obtains an InForm site user name and password. • Screens and enrolls subjects into a study. • Enters and changes clinical data in electronic case report forms. • Answers queries on clinical data. • Prepares for monitoring visits.
Sponsor user	An InForm user, typically a CRA, CDM, or medical monitor, who performs the following tasks: • Obtains an InForm sponsor user name and password. • Reviews clinical data queries. • Performs source verification. • Transfers subjects from one site to another. • Runs standard reports. • Creates ad hoc (custom) reports.

Case report forms

Case report forms allow you to enter, correct, or update data for a subject visit.

> **Note:** Case report forms are referred to as CRFs or forms throughout the InForm product and documentation. These terms are used interchangeably.

Form types

The InForm application supports the following types of case report forms:

- **Regular form**—A CRF that you use to collect data that is specific to the visit in which the form occurs.

- **Common form**—A CRF containing data that is cumulative from visit to visit.

  Each time the form occurs in a visit, it displays the data that was accumulated from all previous visits, and you can add to the data in the current visit.

  Examples of forms that are often implemented as common forms are Concomitant Medication and Adverse Event forms.

- **Repeating form**—A CRF that can have multiple instances within a visit.

  A regular or common form can be a repeating form.

  Examples of forms that are often implemented as repeating forms are Vital Signs and Physical Examination forms.

- **Associated forms**—Instances of a repeating form that are linked to each other.

Form association

Form association is the ability to establish a relationship between two repeating forms. Associating the information on forms can make it easier to recognize possible relationships between collected data, study drugs, adverse reactions, and concomitant medication.

A form can have zero-to-many associations. Study designers define the ability to link two forms. If your study is set up with this feature, the lower half of the page lists the possible instances of forms that can be associated when you create a new instance of a form.

For example, an instance of an adverse event can be linked to a concomitant medication, and that particular concomitant medication can be linked to one or more adverse events.

Dynamic forms, dynamic visits, and alternate forms

Dynamic forms, dynamic visits, and alternate forms are created in a study only if certain conditions are met.

- **Dynamic forms**—CRFs that appear in a visit based on the clinical data that you enter for a subject. For example:

  - When you indicate that a subject is female, a Pregnancy Result form appears.

  - When a subject comes in for an unscheduled visit, you can indicate which forms should appear in that visit.

- **Dynamic visits**—An extension visit that appears only if a user enters data on an Eligibility form that indicates that the subject is eligible to continue.

  Dynamic visits are automatically added to a subject's Time and Events Schedule based on the clinical data that you enter for that subject. For example, if a subject agrees to extend participation in the study, extension visits are automatically generated.

- **Alternate forms**—A new version of a form that collects additional data on a subject after the visit in which such data would usually be recorded. The alternate form appears in the visit where the data would have been collected originally.

Form views

The form views are:

- **Summary view**—For repeating forms.

  Form data items appear in table format with each form appearing in a row. Each row has an underlined number in the left-most column and a status icon in the column next to it.

  - When you click the number or the status icon, the detailed view of that row appears.

  - You can sort these rows by clicking the column headings. If applicable, a frozen or locked icon also appears in this column.

  - The far-right column displays a comment and audit trail icon that provide access to comments and audit trail activity that apply to a particular instance of the form.

- **Detailed view**—For instances of a form.

  Form data items appear in a table format with a question on the left and the data entry controls for answering the question on the right.

- **Cross-reference view**—For forms that are defined as associated forms.

  The page is divided in half horizontally, so that it displays two associated forms at the same time. The forms behave the same way whether you are in the cross-reference view, summary view, or detailed view.

Item types

Forms can contain items or itemsets.

- **Item**—A non-repeating data point on a CRF.

- **Itemset**—A group of items that repeat on a CRF.

  You use itemsets for submitting multiple rows of data on a form at one time. There are two types of itemsets: Add Entry itemsets and Repeating Data itemsets.

  These itemsets have attributes that are configured during study design. The display and behavior of the itemsets differ in the InForm application depending on the type. Both itemset types can appear on the same form.

  For more information, see *Feature comparison: Add Entry itemsets and Repeating Data itemsets* (on page 8).

An item is composed of multiple controls. Controls on a form are visible or hidden depending on whether their parent controls are selected. For more information, see *Dynamic child controls* (on page 10).

Feature comparison: Add Entry itemsets and Repeating Data itemsets

	Add Entry itemset	Repeating Data itemset
New features		
Variable rows	Yes	No
Fixed rows	No	Yes
Grid display of not started rows.	No	Yes
Predefined items	No	Yes
		Predefined items and values appear in a static display with a light grey background to distinguish them from items that allow data entry.
Display an asterisk (*) in the column header for required items.	Yes	Yes
Enter items from the grid view.	Yes	Yes
	Click the Add Entry button to add a new row to the itemset or to enter items.	Click on or tab through the controls.

	Add Entry itemset	Repeating Data itemset
New features		
Blank items	No	Yes
		Cells for blank items appear with a light grey background. The associated item has no value, and the cell is not editable. Blank items are defined during study design.
Row comments	No	Yes
		Click the Add Item Comment icon to the right of the itemset. Use as a shortcut to apply the same comment to all items in the itemset that are not pre-defined or blank.
Existing features		
Allow new entries/rows	Yes	No
		No Add Entry button on the form.
Column sorting	Yes	No
Row hyperlinks	Yes	Yes
	After the first row submission.	For every row after the form is started.
	Click the underlined number at the beginning of the row to view each item in the Detailed view. In the Detailed view, you can enter comments, queries, and rules for individual items within an itemset row and display audit trail information on an item-by-item basis.	Click the underlined number at the beginning of the row to view each item in the Detailed view. In the Detailed view, you can enter comments, queries, and rules for individual items within an itemset row and display audit trail information on an item-by-item basis.
Row delete/undelete actions	Yes	No

Dynamic child controls

Child controls on a form are visible or hidden depending on whether their parent controls are selected. Study designers specify this behavior by defining a property on a control that is set in the Central Designer application during the study design. For more information, see **Study design considerations** (on page 10).

A parent control may be either a radio button or a checkbox. When you do not select a parent control in the InForm application, this functionality allows the child control to be visible or hidden. For hidden controls, values in the child control are cleared, and the control does not occupy space on the InForm form.

How dynamic controls affect the InForm application

Dynamic controls:

- Can be configured on all InForm forms created in the Central Designer application on which users can enter data.

- Are hidden in the sample case report book if they are set to be hidden (collapsed) on a form.

- Do not affect the Data Viewer.

  Data Viewer columns corresponding to hidden child controls remain visible in the Data Viewer user interface.

- Do not affect the InForm Data Import utility functionality; the utility works the same way as in previous InForm releases.

Study design considerations

When study designers create or edit a form using the Central Designer application, they can specify whether a child control should be visible or hidden in the InForm application when its parent control is not selected. For more information, see the Central Designer *InForm Design Guide*.

InForm workflow

The typical InForm workflow includes the following steps:

1   Clinical research coordinators (CRCs) log in to an InForm study using a web browser.

2   CRCs fill out and submit electronic case report forms (CRFs) over the Internet.

3   The InForm application stores the clinical data entered into the CRFs in the InForm study database.

4   The InForm application evaluates the data and automatically generates queries on any questionable data.

5   CRCs answer the queries generated by the InForm application.

6   Clinical research associates (CRAs) review the clinical study data.

7   CRAs send queries to the CRCs if there are questions on clinical data items.

8   CRAs source verify data and mark the CRFs, or a subset if the items and itemsets on a CRF, as source verified.

9   CRAs may also freeze the CRFs to indicate to the Clinical Data Manager (CDM) that the data is ready for analysis.

10 CDMs prepare data for analysis.

11 CDMs may send queries to the CRCs if there are questions on clinical data items.

12 After data has been verified and analyzed, the CDM locks the CRFs (usually done by visit).

13 Investigators review locked CRFs and sign required CRFs and/or case report books.

Multilingual studies

A multilingual study is one that has CRFs and queries in multiple languages. The language used in various parts of the user interface depends on locales that are defined during the installation and configuration of the InForm application.

Locales

Locales are the language or languages presented to an InForm user in the user interface.

- **Product Locale**—The language(s)—English or Japanese—of the product user interface components: menus, controls, commands, system screen labels, error messages, and so on. Oracle creates product locales.

- **Study Locale**—The language(s) in which study metadata are designed using the Central Designer application. This includes CRFs and related study design labels, such as visit names, CRF (form) names, section labels, CRF questions, item control labels, auto-query text, and so on. A study may contain multiple study locales.

- **Study Data Locale**—The language in which study data, most significantly text, is entered and stored.

- **Review Schema Locale**—The language, set automatically during installation, in which data appears in the Data Viewer. For information on how to change the Review Schema Locale, see the *Installation Guide*.

> **Note:** Messages in the InForm application are generated from a number of sources, including the operating system and the product itself. Because the product locale in the InForm application may be set to a language other than that of the user's operating system, it is possible for the user to see messages generated from the InForm application in mixed languages.

How locales are applied in the InForm user interface

The supported product locales are English (en-US) and Japanese (ja-JP).

The InForm administrator can select a global default Product Locale. In addition:

- All users can select a product locale independent of their site association or associations. When a user makes this selection, it is considered the user's Product Locale.

- Each investigator site is assigned a study locale. All subjects for a site use CRFs in the site's Study Locale. The study locale stays with the subject regardless of the user viewing the CRF.

> **Note:** Studies can still be versioned based on protocol changes, even though each study version may have multiple languages.

User interface page(s)	Locale(s)
Administration	The administration pages, including the user password reset page, are all based on the user's Product Locale.
	The administration pages allow setting of locales and entering the following information in any language:
	• Site names.
	• Country names.
	• Rights groups names.
	• Custom group names.
	Standard group names are provided in English.
Login	Uses the locale that matches the user's browser setting, if available. Otherwise, the page uses the default Product Locale.
Screening Log	Uses the user's Product Locale.
CRFs	Day, month, and year ordering is controlled through configuration settings at the study, site, and user levels. The user's Product Locale controls whether months appear as abbreviations or numbers.
Subject (users) listings	Operational status values such as subject status (Enrolled, Randomized, and so on), form status (Verified, Locked, and so on) and query status (Open, Answered, and so on) display based on the user's Product Locale.
	• Visit names display based on user's Study Locale.
	• All labels other than the visit names display based on the user's Product Locale.
Time and Events Schedule page	Presents visit and CRF names in the user's Study Locale. Other text is in the user's Product Locale.

User interface page(s)	Locale(s)
Source Verification	Displays study elements such as visit and CRF names in the user's Study Locale. This applies to the saved filter dialog box as well. The user's Product Locale is used for all other displayed elements.
Reg Docs and Visit Reports	For other monitor functions, the Reg Doc and Visit Report forms must be translated to each of the study locales, and they appear in the user's Study Locale.
Query Listing	Uses the user's Study Locale for displaying study elements. All other page elements are rendered using the user's Product Locale. • Query actions in the drop-down list on the Query Listings Action View page display based on the user's Product Locale. • The language of the default query reason drop-down list on the Query Listings Action View page displays based on the user's Product Locale.
Queries	• Users can enter manual query text in any language, regardless of locale settings. • Product labels are based on the user's Product Locale. • CRF elements on the Queries page display in the language of the associated CRF instance. • Query actions in a drop-down list display in the user's Product Locale. **Note:** The audit trail may contain a mix of languages describing the query action (Open, Answer, Close) as well as the query text itself.
Data Value(s)	• The reason for change drop-down list defaults to the user's Product Locale. • Other product labels display based on user's Product Locale. • CRF elements display in the language of the associated CRF instance.
Audit Trail	Data in the Audit Trail page is in the language that was captured at the time of an event. Following a subject transfer, codelist labels (such as Male/Female) are translated to the language of a receiving site. • CRF elements in the Audit Trail page display in the language of the associated CRF instance. • Labels on the Audit Trail page display based on the user's Product Locale. The audit trail in the InForm application and CRF Submit application may contain a mix of languages for event labels. In addition, audit trails include dates and times based on the local time of the site user and might be associated with the CRF locale.

User interface page(s)	Locale(s)
Online Help	There are two types of online Help: • InForm system help is available in any of the supported product locales and displays in the user's Product Locale. • CRF Help (if implemented) displays based on the user's Study Locale.
Comment history	• The Comment page and Itemset Row Comment page display the standard Incomplete Reasons based on the user's Product Locale. • Labels are based on user's Product Locale. • CRF elements on the Comment page and Itemset Row Comment page display in the language of the associated CRF instance. • When presented in CRFs, Incomplete Reasons appear in the user's Product Locale for the user that is viewing the page. This means that different users viewing the CRF may see Incomplete Reasons in different languages.
Subject record transfers	When subjects move between sites that have different study locales, the already started CRFs display in the locale of the destination site. The InForm application does not allow subject transfers to sites that are on earlier study versions or which do not have translations for any started CRFs in the study locale of the destination site. • The archival copy of the CRFs for the source site is stored in the Study Locale for that site, with exceptions around audit trail entries that may be in other languages. • Reasons for change/transfer display in the default Product Locale used in the Subject Record Transfer administrative page. • Text data in the audit trail entries in both the archival copy of CRFs and the live CRFs are stored in the language entered and appear in that language. The archival copy is created at the time of the subject transfer using the Study Locale of the source site. This includes codelists (such as race and gender). CRFs viewed at the destination site after the subject transfer are rendered in the locale of the destination site.
Affidavit	The InForm application allows for signature affidavit text to be translated to any Study Locale and displayed to the signer in the language specific to a CRF's Study Locale. The signature print preview functionality is configurable by study. **Note:** Translating the signature affidavit must be done by editing the MedML, not through the Central Designer application. For more information, see the *Utilities Guide*. The InForm application supports a paper-based signature process. You have the option to print a copy of the CRF in order to manually sign the CRF or CRB.

User interface page(s)	Locale(s)
Data Viewer	Uses the same multilingual support as the main InForm application. • All user interactions such as commands, menus, and dialog boxes appear in the user's Product Locale. You set the user's Product Locale on the User details page—Details tab. For more information, see *User details page* (on page 368). • All study metadata such as form names, visit names, and code labels appear in the Review Schema Locale. For information on how to change the Review Schema Locale, see the *Installation Guide*.
Documents	The Documents button displays: • A set of document tabs according to the available study locales. • Study-specific documentation appears with the user's Study Locale. The Central Designer application allows users to create study documentation in each study locale.

Available online Help

The InForm application provides extensive online Help from the user interface to give you easy access to procedural, conceptual, and detailed task-related information that you need while working with the application.

> **Note:** The popup blocker in your browser may prevent the Help pages from opening. If this occurs, either turn off the popup blocker or press the Ctrl key before you click the Help icon.

Online Help	Description	How to access
InForm User Guide	The *User Guide* provides an overview of the InForm application including details on multilingual studies, how to navigate through the user interface, and how to use the application to accomplish typical tasks you perform while running a clinical study. This guide appears in a separate browser window that you can resize and move for easy viewing.	• In the upper-right corner of the main InForm application window, click the **Help** icon ( ) **> InForm User Guide**.
Cognos 8 Business Intelligence documentation	The complete Cognos 8 Business Intelligence documentation set, created by Cognos. This documentation is available only if using the Reporting and Analysis module. These guides appear in separate browser windows that you can resize and move for easy viewing.	• In the upper-right corner of the main InForm application window, click the **Help** icon ( ) **> Reporting User Guide**. An HTML page appears with links to the complete Cognos 8 Business Intelligence documentation set.
Descriptions of InForm standard reports	Detailed descriptions for the fields in the report. This information Is available from within the Reporting and Analysis module, after you output any InForm standard report.	• After you output any InForm standard report in HTML format, click the **Report Help** link. An HTML page appears with detailed page-level Help for the report.
Cognos documentation for Query Studio	The Cognos Query Studio User Guide, created by Cognos. Query Studio is the Cognos tool that provides Ad Hoc Reporting capability. This guide is available from within the reporting user interface only if using the Reporting and Analysis module. This guide appears in a separate browser window that you can resize and move for easy viewing.	• In the Ad Hoc Reporting workspace, select **Ad Hoc Tools Help**.

Online Help	Description	How to access
Hover Help	Provides a brief description of the selected item, button, or icon.	• Hold your mouse pointer over the item and the hover Help text appears in a popup window. When you move your mouse pointer off the item, the hover Help disappears.

C H A P T E R   2
InForm user interface

In this chapter

Overview of the InForm user interface

The InForm user interface appears in a browser window that displays all the features to which you have access, based on your rights and rights groups. As you move through the InForm application, the content of the window varies depending on the study and the activities you are performing, but the purpose of each component stays the same. You can view and edit data in multiple browser windows.

The components in the InForm application are:

- **Main user interface window**—The window that appears when you log in to the InForm application.

- **Case Report Books page**—A summary view of the status of forms and visits for each subject that you use to navigate to specific subjects and visits. Use this page to navigate to the Time and Events Schedule.

- **Time and Events Schedule**—A summary view that groups the CRFs by visit or provides a list of the CRFs.

- **CRF pages**—The forms you use to record clinical data about an enrolled subject.

- **Data Viewer**—Provides Clinical Data Managers (CDMs) and other InForm users with a real-time overview of study data across visits and sites.

- **Icons**—Represent form, visit, query, and signature status.

Main user interface window

The main user interface window appears when you log in to the InForm application. If you have a Home page designed for your study, such as the InForm Portal application, it appears when you log in.

Components—Main user interface window

Component	Description
1 Title bar	Top horizontal line of the main window. Displays:
	• **Study**—Study name.
	• **Location**—Title of the currently selected page.
	• **Subject ID**—Currently selected subject number and initials, if any.
	Note: In all places where both the subject number and initials appear in the user interface, the order is always the Subject Number and then the Subject Initials, separated by a slash.
	The information in the title bar may change as you navigate through the user interface. When you select a new page to navigate to, the Title bar updates with the new page name. Additionally, a highlight appears behind the icon that represents the page you are currently viewing.

Component	Description
2 Navigation toolbar	Horizontal row of icons below the title bar, each representing a different section of the user interface. The icons that appear in the toolbar depend on your role and rights.

- **Home**—Click to navigate to the main user interface window, or, if applicable, to the Home page designed for your study (for example, the InForm Portal application).

- **Enroll**—Click to screen and enroll a candidate.

- **Subjects**—Click to view the Case Report Books page that displays the status of forms and visits for each subject and lets you navigate to specific subjects and visits.

- **Queries**—Click to view and work with queries.

- **Monitor**—Click to source verify data.

- **Signatures**—Click to sign a form or case report book.

- **Review**—Click to open the Data Viewer to view and work with a real-time overview of study data across visits and sites.

- **Reports**—Click to open the Reporting and Analysis module.

- **Documents**—Click to open the study-specific documentation is a separate browser window.

- **Admin**—Click to open the Admin user interface.

Note: The controls in the navigation toolbar allow you to navigate throughout the InForm application. The controls are always visible and do not change, so you can move easily from section to section.

Component	Description
3 Subject control	Use to search for a subject or to navigate through the Time and Events Schedules and CRFs based on an ordered list of subjects within a site. This control is always visible. For more information, see *Subject search and navigation* (on page 23).
4 CRF history icon	Displays a scrollable drop-down list of the 10 most recently viewed CRFs by the logged in user. To navigate to a CRF, click its name in the list. This control is always visible.
5 Help icon	Displays links from which you can open the InForm *User Guide* or the Cognos reporting documentation.
6 Logout icon	Logs you out of the study.
7 Picture or logo	Displays the Change Password page so that you can view or update your password or password recovery information.
8 User name	The name of the currently logged in user.

Component		Description
9	Content pane	The center of the main window displays the screen for the current activity; for example, summary lists, forms, details of queries, comments, audit trails, and reports.
		The bottom of the pane displays contents that vary depending on the information in the content pane.
10	Home page Go controls	Use the Go controls on the study Home page to navigate directly to the CRFs for a specific subject and visit.
		The study Home page is the window that appears when you log in to the InForm application. The Go controls appear at the bottom of the InForm main window in the content pane. For more information, see *Using the Go controls on the study Home page* (on page 112).

Subject search and navigation

The InForm application provides a subject control in the upper-right of the main window that you can use to search for a subject or to navigate through the Time and Event Schedules and CRFs based on an ordered list of subjects within a site.

There are two versions of the subject control; only one version is available at a time.

- **Search mode**—Default. Use to search for a subject and navigate directly to the information for that subject. For more information, see *Subject search mode* (on page 23).

- **Navigation mode**—Use to navigate through the Time and Event Schedules and CRFs based on an ordered list of subjects within a site that you have the rights to access. For more information, see *Subject navigation mode* (on page 24).

  When in the navigation mode, you can manually change the mode back to the search mode in order to search for a particular subject.

Subject search mode

The subject search mode provides a Subject # field in which you can enter the subject number only, and then click the search button to go directly to the Time and Events Schedule for that particular subject.

The subject search mode is the default version of the search control. It is available on all pages except the Time and Events Schedule, CRFs, and forms under source verification.

Subject navigation mode

The subject navigation control replaces the subject search mode on the Time and Events Schedule, CRFs, and forms under source verification, and allows you to navigate through the Time and Events Schedule and forms based on an ordered list of subjects within a site.
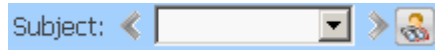
The subject navigation control:

- Displays a drop-down list of all subjects in the current subject's site, with the current subject selected.

- Displays the Subject Number and Initials.

- Orders subjects according to the Subject Order feature, if applicable. For more information, see *Subject order* (on page 24).

You can:

- Click the right or left arrows to navigate to the Time and Events Schedule or CRF for the next or previous subject.

- Click the icon to return to the search mode.

When navigating by subjects, the current form always remains on display. When the form is not available for a particular subject, the form area on the screen displays a statement saying the form is not available.

If the current form is a repeating form, navigating through subjects shows you the summary views.

If the current visit is a dynamic visit, you can only navigate through subjects that have that particular dynamic visit. Subjects without that dynamic visit are skipped.

> **Note:** Because the Data Viewer has its own navigation controls, the subject navigation control is not needed and is hidden when you are using the Data Viewer.

Subject order

The Subject Order feature allows a site's subjects to be placed in a particular order that is used to order subjects in the Case Report Books page when you are viewing subjects for a single site. The order is not used in the Case Report Books page when you are viewing subjects in all sites.

- The ordering applies to all users; there is no per-user ordering.

- You control the subject order within a site with the Allow subject ordering option on the System Configuration page.

For more information, see *Changing the subject order in the Case Report Books page* (on page 104).

Sorting

On the user interface pages with underlined column headings, you can sort the rows on the page by the information in the column.

- To sort the page, click the column heading.

- To reverse the sort, click the column heading again.

- An up arrow indicates the page is sorted by the column data in ascending order.

- A down arrow indicates the page is sorted in descending order.

Email address length

You can enter email addresses on multiple pages in the user interface. In all the places in the user interface where you can enter an email address, the InForm application supports an email address length of 255 characters. On any page where the email address is truncated because it is too long to display, the hover Help displays the entire value.

Case Report Books page

The Case Report Books page summarizes the status of forms and visits for each subject and lets you navigate to specific subjects and visits. The Case Report Books page is a convenient place to view the log of enrolled subjects. The Case Report Books page displays 30 subjects by default.

The icons on the page help you quickly recognize the visit status. Use the hover Help for a description of each icon.

- Each icon provides a combined visit state.

- Frozen or locked states have an extra icon that appears to the right of the main icon. For a form that is both frozen and locked, only the locked icon appears.

- Visit-level frozen, locked, and verified status icons appear only if all the forms in a visit are frozen, locked, or verified.

- When a visit is both frozen and locked, only the locked icon appears; the icons never show both frozen and locked. However, the hover Help shows both frozen and locked.

- Site users do not see Answered or Verified status. Only Sponsor and administrator users see these states.

Components—Case Report Books page
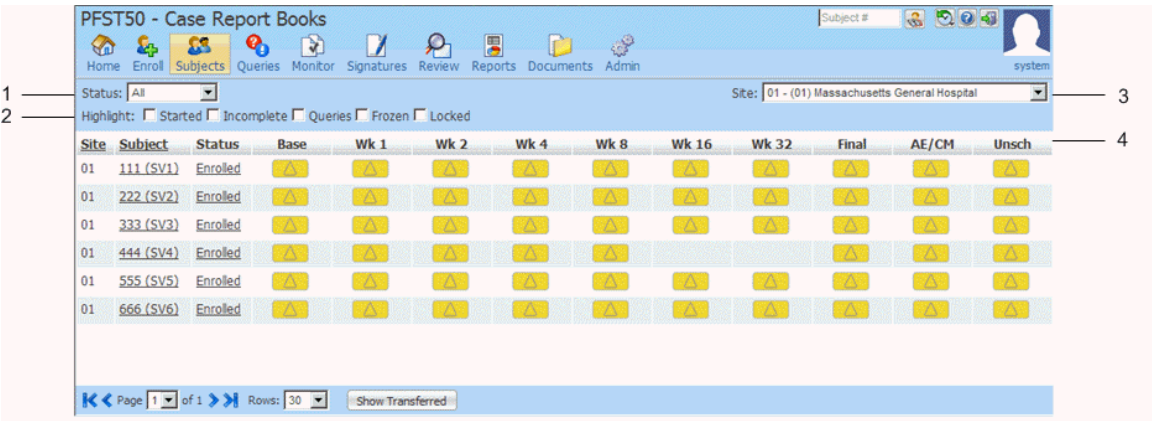
Component		Description
1	Status filter	Filters the page content based on the enrollment status.
		• All
		• Enrolled
		• Randomized
		• Complete
		• Not Complete

	Component	Description
2	Highlight options	Checkboxes to filter the display of status icons for visits that contain forms that are started, incomplete, contain queries, or are frozen or locked. Status icons for visits that contain forms that match all of your selections are highlighted.
3	Site drop-down list	Drop-down list of all the sites you can access.
4	Data columns	
	Site	Site mnemonic.
	Subject	Subject number / subject initials. Click the link to open the Time and Events Schedule.
	Status	Enrollment status. Click the link to open the Time and Events Schedule.
	Visits	Visits for each subject. Each subject has one status icon for each visit. Use the hover Help for a description of each icon. • The color of the status icon shows the state of completion for the forms in the visit. • Each status icon is a link to the subject forms for a visit.

Buttons

Button	Description
Page selector	A multi-part control on the bottom-left of the content pane. By clicking different parts of the control, you can move through the pages of the Case Report Books page when the list of subjects fills more than one page.
Show Transferred	Opens the Transferred Subjects for Site page, from which you can view the list of subjects who have been transferred into or out of the sites to which you have access. Appears only if you have the Transfer Subject right.

Time and Events Schedule

The Time and Events Schedule is a list of forms and visits for a specific subject. Use this page to review the status of the forms and visits, and to navigate to a specific form.

The Time and Events Schedule has two different layouts with a link to switch between them. In each layout, the icons provides a detailed form state for a single form, or a combined state for repeating forms. Use the hover Help for a description of each icon.

* **Visit view**—Groups the CRFs by visit. For more information, see *Time and Events Schedule—Visit view* (on page 28).

* **Form view**—Provides a list of the CRFs. For more information, see *Time and Events Schedule—Form view* (on page 32).

Time and Events Schedule—Visit view

> **Note:** The Visit view is always the first view of the Time and Events Schedule that you see.

The Visit view layout of the Time and Events Schedule groups the CRFs by visit. This layout provides the Time and Events Schedule for a single subject that shows the overall visit status and the percent of complete, verified, frozen, and locked CRFs in that visit. You can expand each visit to show the CRFs associated with the visit. You can click a form status icon to navigate to the selected form.

Use the Visit view to:

* See the status of a visit in the Time and Events Schedule.

    Visit rows display aggregate form state values (visit status information is the same as in the case report book under all conditions).

* Expand and collapse one or all visits to show all CRFs associated with the visit.

    The initial display is with Visits collapsed.

Components—Time and Events Schedule Visit view
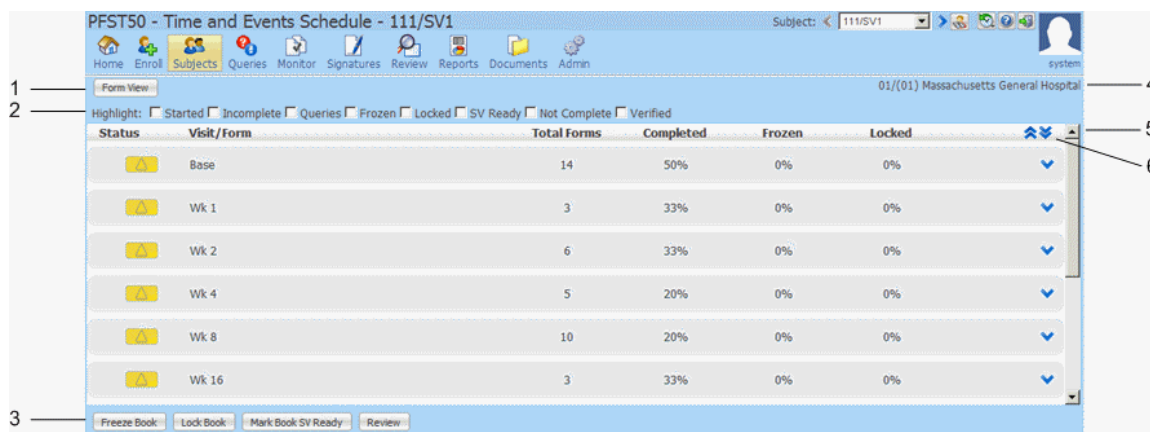
If the Time and Events Schedule page is large enough to require a vertical scroll bar, the header remains locked and visible while scrolling.

The status icons from the Case Report Books page are added to the visit banners and separate Complete, Verified, Frozen, and Locked data into columns. A number in these columns represents the percent of forms that have that particular status. When that number reaches 100%, a checkmark replaces the number.

	Component	Description
1	Form View button	Click to change to the Form view of the Time and Events Schedule.
2	Highlight options	Checkboxes to filter the display of status icons for forms that are started, incomplete, frozen, locked, or contain queries. Status icons for forms that match all of your selections are highlighted.
		If you have the appropriate rights, you can also filter for Source Verification status.
3	Command buttons	Buttons in the content pane to perform activities that affect the entire case report book for that subject.
		For example, as a CRC you might have the right to mark a case report book ready for source verification by clicking the appropriate command button in the Time and Events Schedule.
4	Site	Abbreviation of the site name.
5	Data columns	
	Status	Visit status.
	Visit/Form	Visit name or form name.
	Total Forms	Total number of forms in the visit.

	Component	Description
	Completed	Percentage of forms with complete data.
		When the number reaches 100%, a checkmark replaces the number.
	Verified	Percentage of verified forms.
		When the number reaches 100%, a checkmark replaces the number.
		Note: This column is visible to Sponsor users but not to Site users.
	Frozen	Percentage of frozen forms.
		When the number reaches 100%, a checkmark replaces the number.
	Locked	Percentage of locked forms.
		When the number reaches 100%, a checkmark replaces the number.
6	Expand / Collapse indictor	Expands or collapses all visits to display or hide their forms.

Visit view—Expand and collapse feature

When displaying the Visit view, visits are collapsed when you navigate to the Time and Events Schedule.

You can:

- Expand individual visits by clicking on the visit banner (or the single down arrow at the end of the visit banner).

  or

- You can press the double arrow icon to expand or collapse all forms for all visits.

When you expand a visit, the list of forms associated with that visit appears. For each form, you see the following form columns, from left to right:

- Status (form status, using the detailed icons used in the CRB).

- Form long name.

- Form short name (Mnemonic).

- Blank column where the visit shows the date.

- Completed (meaning data complete).

- Verified (this column is visible to Sponsor users but not to Site users).

- Frozen.

- Locked.

- Expand / Collapse indicator.

The Complete, Verified, Frozen, and Locked columns display a green checkmark if the form has that state, and are blank if it does not.

Clicking the form status icon brings you to the selected form.

Visit view—Repeating forms

Repeating forms are treated as a single form in the Time and Events Schedule. That is, if there are 10 instances of a repeating form, the InForm application calculates the percent complete, locked, frozen, and verified as a single form. The repeating form is considered complete, locked, frozen, or verified only if **all** instances of the repeating form within the visit are complete, locked, frozen, or verified.

Time and Events Schedule—Form view

The Form view of the Time and Events Schedule provides a list of the CRFs. You can click a form status icon to navigate to the selected form.

Components—Time and Events Schedule Form view
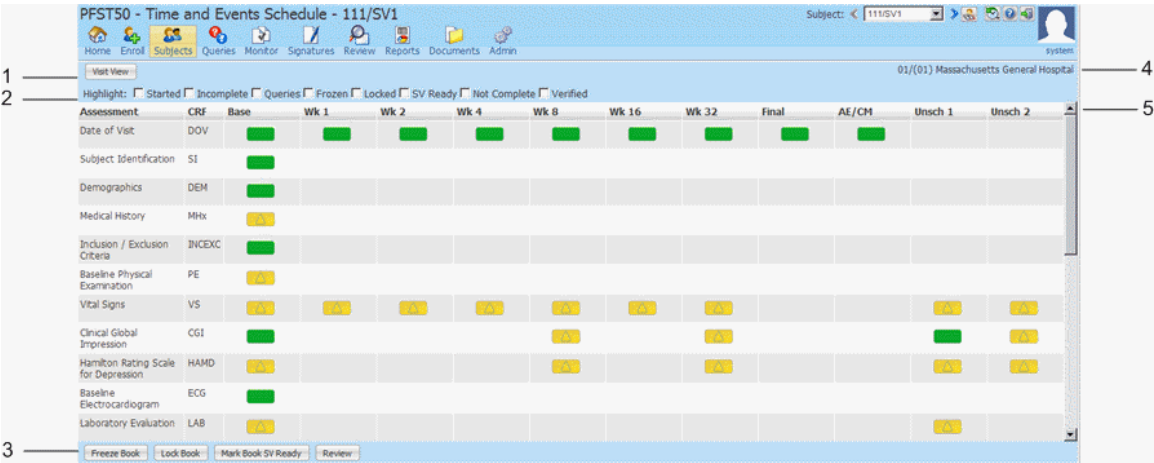
Component		Description
1	Visit View button	Click to change to the Visit view of the Time and Events Schedule.
2	Highlight options	Checkboxes to filter the display of status icons for forms that are started, incomplete, frozen, locked, or contain queries. Status icons for forms that match all of your selections are highlighted.
		If you have the appropriate rights, you can also filter for Source Verification status.
3	Command buttons	Buttons in the content pane to perform activities that affect the entire case report book for that subject.
		For example, as a CRC you might have the right to mark a case report book ready for source verification by clicking the appropriate command button in the Time and Events Schedule.
4	Site	Abbreviation of the site name.
5	Data columns	
	Visits and CRFs	List of visits and forms. A status icon indicates which forms must be completed at each visit.

Component	Description
Form status	Each status icon indicates the state of completion of a form at a specific visit.
Links to CRFs	Each status icon also provides a link to a form. To display the form, click the status icon.

Time and Events Schedule navigation

The Time and Events Schedule provides:

- Maintenance of the view state, for your user session:

  When you expand or collapse a set of visits in the Time and Events Schedule, navigate to a form, and then press the Return button on the CRF, you return to the Time and Events Schedule view, in whichever Time and Events Schedule state it was in (Visit view or Form view).

- If you return to the Visit view:

  - The set of expanded or collapsed visits is the same as when you left the Visit view.

  - The view is scrolled so that you can see the visit or form you are returning from.

- If you return to the Form view:

  - The view is not scrolled to the visit or form you are returning from.

CRF pages

Components—Case report form (CRF) pages

When you view CRFs, additional navigation components appear on the page.
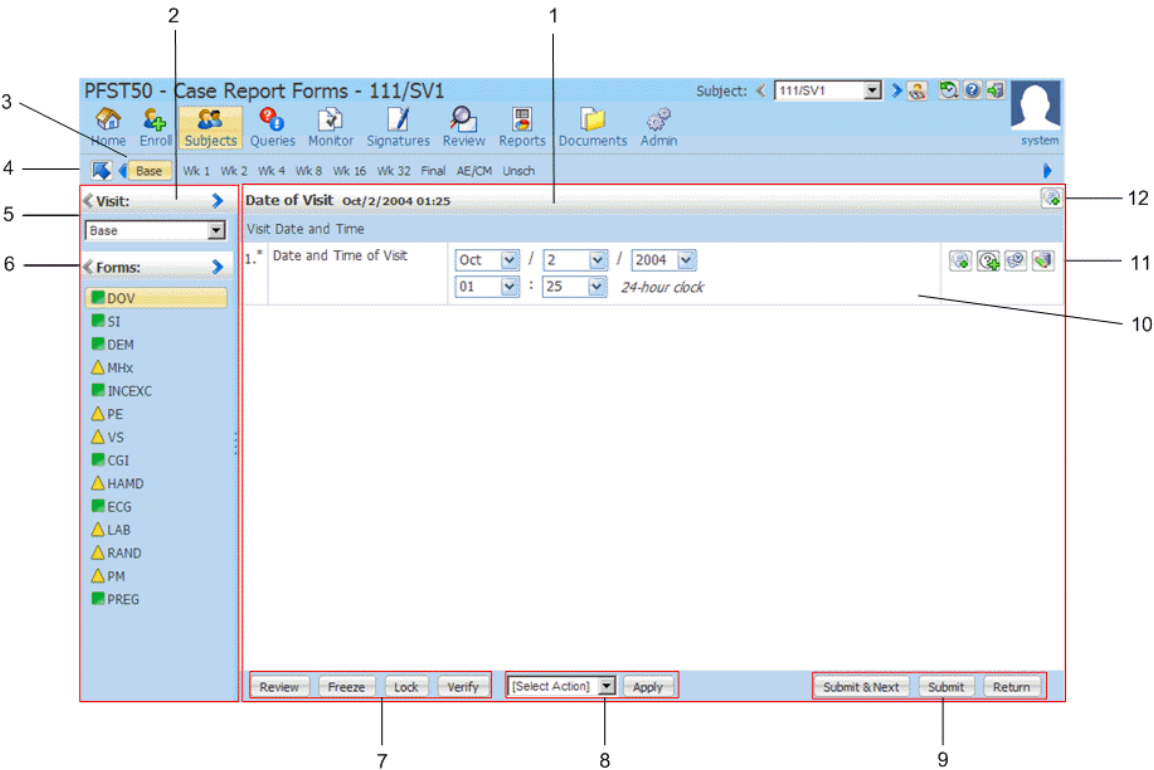
Component	Description
1 Content pane	The center of the main window displays the screen for the current activity; for example, summary lists, forms, details of queries, comments, audit trails, and reports.
	The bottom of the pane displays contents that vary depending on the information in the content pane.
2 Navigation pane	Located to the left of the content pane in a CRF, contains the visit and form selection controls.
3 Visit ruler	The timeline at the top of the form that summarizes the visits in the study. The name of the current visit is selected.
4 Time and Events Schedule navigation arrow	Click to go to the Time and Events Schedule. For more information, see *Visit navigation—Visit drop-down list and visit ruler* (on page 37).
5 Visit selectors	Visit navigation controls. For more information, see *Visit navigation—Visit drop-down list and visit ruler* (on page 37).

	Component	Description
6	Form selectors	Form navigation controls. For more information, see *Form navigation—Form drop-down list and forms selector* (on page 38)
	CRF status icons	Indicate the status of the CRF. Use the hover Help for a description of each icon. For more information, see *CRF status icons* (on page 78).
	Form mnemonics	Each mnemonic represents a form that is used in the visit.
	Links to form help	If your study includes a study document that provides help for form items, and the study document was linked to the forms during study setup, the question text or form name is underlined. Click the underlined question text to display the study document help.
	Form indexer	Use to move through the individual forms of a repeating form. For more information, see *Form indexer* (on page 39).
7	Command buttons	The command buttons at the bottom of the form allow you to perform activities that affect the form. Your rights determine the buttons you can see and the actions you can perform.
8	Select Action drop-down list	Provides a list of tasks that you are most likely to perform. For example, Print Preview, Mark SV Ready, Clear CRF, and Freeze Visit. It contains additional actions such as Print Preview, Mark SV Ready, Clear CRF, and Freeze Visit. Select a command in the list and click the Apply button to perform any of these commands. For more information, see *Select Action list* (on page 39).
9	Navigation buttons	

Component		Description
	Submit & Next button	Click to submit the form and advance to the next form in the visit.
		• When you click the Submit & Next button, you submit the form.
		▪ If the form submits successfully, you navigate to the next form in the visit.
		▪ If there is an error on the form, you do not advance to the next form.
		• If you click the Submit & Next button on a form with unchanged data or on a read-only form, the form data is not stored in the database and the browser advances to the next form in the visit.
		• The next form loads automatically even if it is created dynamically during the submittal of the current form.
		When you click this button on the last form in a visit, a message box appears stating that the current form is the last form in the visit.
		Note: The Enter key provides the same functionality as the Submit & Next button on CRFs.
	Submit button	Click to submit the form data.
	Return button	Click to return to the previous page.
		Note: The Esc key provides the same functionality as the Return button on CRFs.
10	Items	Form data items are listed in table format. Questions appear on the left, and data-entry controls that you use to answer the question appear on the right.
11	CRF item icons	Click to add comments, view the audit trail, clear data, or work with queries. Use the hover Help for a description of each icon. For more information, see *CRF item icons* (on page 79).
		On the detailed view of the form, the far-right column for each form item contains a set of icons that provide status information about the item and allow you to display detailed item information.
		Each icon on the CRF view of a repeating form provides the detailed form state for a single form.
12	Form comment icon	The comment icon is located in the detail view of the form, in the upper-right corner. It provides access to comments about the form as a whole. Click the icon to enter, display or update a comment.

Visit navigation—Visit ruler and visit selectors
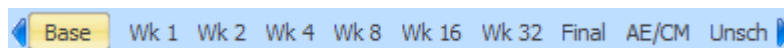
There are multiple ways to navigate visits.

- **Time and Events Schedule navigation arrow:**

  This blue, upward-pointing arrow is located next to the visit ruler. Click the arrow to go to the Time and Events Schedule.
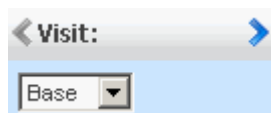
- **Visit ruler:**

  Use to navigate to other visits within a study. The name of the current visit is highlighted.

  When you display the forms for a subject visit, the timeline at the top of each form summarizes the visits in the study. You can navigate to forms within the current visit and throughout the study.

- **Visit selectors:**

  - **Visit arrows**—Use to navigate from one visit to another in the order in which they occur.

  - **Visit drop-down list**—Use to select any visit in the study.

    The visit mnemonic appears in the drop-down list. If the visit mnemonics are truncated, you can expand the size of the navigation pane.

    The drop-down list displays up to 25 visits without the need to scroll.

    Visits are listed in the order in which they occur.

Note: When you select from either the Visit ruler or the Visit selectors, the other is updated to indicate the same visit. If you use either Visit selector, the Visit ruler scrolls so that the selected visit is visible.

Form navigation—Form selectors

There are multiple ways to display the forms in the current visit. The form selectors appear in the navigation pane, below the visit navigation controls.

- **Form selectors:**
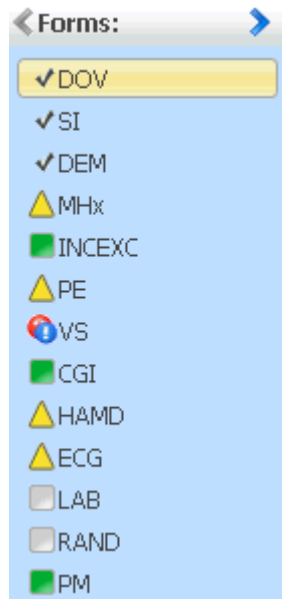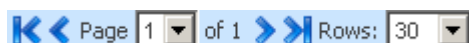
- **Forms arrows**—Use to navigate to the subsequent or preceding form.

> **Note:** If you are viewing one of a set of repeating forms, the Right and Left arrows do not go to the next or previous repeating form instance. Instead, they go to the next or previous form in the Form Selection list.

- **Forms list**—Use to select any form in the study.

  - The list displays up to 20 CRF mnemonics without the need to scroll.

  - To go to a different form, click the corresponding mnemonic.

  - The mnemonic of the current form is highlighted in yellow.

  - Names that do not fit the hover Help are truncated. The long form names appear in the hover Help.

  - You can expand or shrink the form selector area.

  - Status icons appear with the form selector.

Page and row selectors

The page selector and row selectors are located on the bottom-left of the content pane on some screens.

- **Page selector**—Click different parts of the control to move through the pages of the screen when the list fills more than one page.

  or

  You can click the appropriate arrow or select a page number from the drop-down list to use the page.

- **Row selector**—Appears on the listing pages (CRB, monitor, query, signature) and sets the number of rows to display.
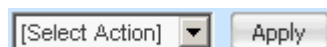
  The pagination control is a drop-down list with entries for 5, 10, 15, 30, 50, and 100. The default is 30. The setting is retained within your current user session.

  Changing the rows per page affects all pages in the InForm user interface that paginate data.

> Note: The repeating forms view does not show this expanded pagination control. However, it uses the value of the control that you set in the current session.

Select Action list

The Select Action list appears, along with an Apply button, on the lower part of the content pane of a CRF. This control appears next to buttons for tasks that you are most likely to perform. It contains additional actions such as Print Preview, Mark SV Ready, Clear CRF, and Freeze Visit.

In the Select Action drop-down list, select an action, and click **Apply**.

Form indexer

The form indexer, which appears in the title bar on some InForm pages, allows you to move through the individual forms of a repeating form.

To use the form indexer, click the appropriate arrow or select a form from the drop-down list.

> Note: If you are in Summary view for a repeating form, the previous and next arrows show you the previous and next 10 instances of the form.

Randomization

Randomization is an optional feature that you use to assign drug kits, devices, or treatments to subjects in a study.

During the study design in the Central Designer application, one form can be set up to provide the Randomization option. When this is designed into your study, a Randomization button appears on one form in the InForm application. You click the button to run the randomization rule, which assigns the drug kits, devices, or treatments to the subjects in the study.

CRF item detail pages

The InForm user interface for CRF item details provides the following options in the navigation pane:

- Data Value(s)

- Queries

- Audit Trail

- Comment

- Rule Dependencies

  Rules are defined in the Central Designer application as part of the study design. For more information, see **Rule dependencies** (on page 338).

Data Value(s) page

The Data Value(s) page allows you to change the value of a specific form data item and requires you to provide a reason for the data value change. The title of the page is based on the form on which the data item appears.

Fields

Field	Description
Current data value	The current value of the data item appears at the top of the page.
Audit Trail	List of changes to the form item. Each entry consists of the date and time of the change and the user name of the user who made the change. The list also includes an item called Enter new value, which allows you to change the data item and enter a reason for the change. Select the change from the list to view the change details.
Change controls	The item and its controls appear on the Data Value(s) page just as they are on the form. Enter the new data item value in these controls to change the value.
Reset item values icon	Clears the value of the data item.

Queries detail page

Use the Queries detail page to create, respond to, change the status, or review the details of queries on a specific form data item, in accordance with your responsibilities and rights in a study. The detail page provides information about the current status and the history of queries on the item.

Audit Trail page

The Audit Trail page allows you to review the history of changes that were made to a specific data item, along with a history of query activity on the item.

> **Note:** Audit trails include dates and times based on the local time of the user entering or changing data. For more information, see *Audit trail date/time conversion* (on page 41).

Fields

Field	Description
Current data value	The current value of the data item appears at the top of the page.
Audit Trail	The history of data value changes and query activity appears in a table that indicates the date and time of activity and the responsible user.
Links to details	Each item in the audit trail is underlined, indicating a link to more detailed information. To view details, click the underlined text.

Audit trail date/time conversion

The time (Date hour:min:sec) at which you enter data into the InForm application is stored in the InForm database in Greenwich Mean Time (GMT). However, the time that displays in the InForm audit trail depends on the time zone you specify for a site. You specify the time zone for a site through processing of the Site MedML, or by selecting a Time Zone on the Sites detail page when creating a site through the InForm Admin interface.

Valid time zone values must match those provided by Microsoft in the registry for your operating system. In addition to the list of time zone names, Microsoft stores each time zone's offset from GMT and details on the start and end date/time of daylight saving time where applicable. The InForm application uses this information to convert the data entry date/time stamp to the time zone for the site.

The InForm application:

1   Reads the audit date/time stamp from the database.

2   Retrieves the site's time zone setting specified in the InForm metadata.

3   Looks up the site time zone in the operating system registry, returns the necessary offset information, and determines whether the date/time in question is within or outside the daylight saving time adjustment.

4   Converts the date/time stamp from the database according to the offset information, and displays the converted information in the audit trail in the user interface.

Comment page

Comments are blocks of text in which you can enter any pertinent additional details about a form item.

> Note: Comments should not contain clinical data.

On the Comment page you can create, update, or view a comment on an individual form data item or on the entire form.

- Form-level comments apply to an entire form.

- Item-level comments apply to items within a form.

The Comment page for a form or data item contains the current version of the comment text. The changes made to the comment text are tracked in the history of the comment.

> Note: To enter comments, you must have the appropriate rights in the study.

You can use the Comment page to:

- Add a new comment, if none currently exists.

- Edit the text of an existing comment.

- Add information to the text of an existing comment.

- Replace an existing comment.

> Note: You can also view comments in the Data Viewer. For more information, see *Comments View* (on page 65), *Reviewing comments across a single form and one or more subjects, visits, or sites* (on page 246), and *Reviewing comments across all forms* (on page 247).

Fields

Field	Description
Current data value	The current value of the data item appears at the top of the page.
Comment History	If more than one addition or update has been made to a comment, the history list allows you to view details about each addition or update.
Selected Comment	Provides details about the comment version that is selected in the Comment History list.
Current Comment	Text box where you can enter a new comment or edit an existing comment.

Buttons

Button	Description
Submit	Submit the comment for the form or item.
Return	Return to the form without applying the comment.

Itemset Row Comment page

Itemset row comments provide a shortcut for applying the same comment to all items in a Repeating Data itemset row that are not pre-defined or blank.

> **Note:** To enter itemset row comments, you must have the appropriate rights in the study.
>
> **Note:** You can also view comments in the Data Viewer. For more information, see *Comments View* (on page 65), *Reviewing comments across a single form and one or more subjects, visits, or sites* (on page 246), and *Reviewing comments across all forms* (on page 247).

Fields

Field	Description
Comment	Text box where you can enter a new comment to be applied to all items in the itemset row.
Reason incomplete	• Not Done • Not Applicable • Unknown

Buttons

Button	Description
Submit	Submit the comment for all items in the Repeating Data itemset row, and return to the form.
Return	Return to the form without applying the comment.

Data Viewer user interface

Types of views in the Data Viewer

There are four views in the Data Viewer.

- **Summary View**—Provides summary data counts across multiple form types, grouped by visits or sites.

- **Record Listing View**—Provides a display of clinical data per form that can span across sites, subjects, and visits, or provides a display of data from multiple clinical forms in one view.

- **Record Comparison View**—Provides a side-by-side comparison of two Record Listing Views.

- **Comments View**—Provides a list of form and item comments for all sites, visits, and forms.

The user interface for each view uses the same toolbar, filter, pagination, and column customization features. For more information, see *Common Data Viewer features* (on page 68).

> **Note:** The Data Viewer supports blinded data and display overrides. Data that is blinded to the user does not appear in any of the Data Viewer views.

Summary View

The Summary View provides summary data counts across multiple form types, grouped by visits or sites.

Use the Summary View to view the status of the studies you have access to by displaying a summarized status of operational data, such as queries, form states, verification states, and custom review states (if defined).

Components—Summary View

The Summary View provides summary status counts of operational data, such as queries, form states, verification states, and custom review states (if defined) across multiple form types, grouped by visits or sites for the sites to which you have access.

Component	Description
1 Toolbar	Provides centralized options in menu format for the actions you can perform on the data in the Summary Data Table. For more information, see *Toolbar—Data Viewer* (on page 68).
	The options that appear in the toolbar vary depending on the current view. Options that are not available for the current view are not visible; options that are not applicable to the current selection(s) are disabled.
2 Filters pane	Provides options to filter the data that appears in the Summary Data Table. For more information, see *Filters pane—Data Viewer* (on page 71).
	This pane collapses to maximize the viewing area for the main data portion of the page.

Component		Description
3	Summary Data Table	Displays summary data counts for queries, form states, source verification states, and custom review states (if defined) grouped by visits or sites, for the data you have the rights to view.
		• The counts of various states for each visit or site appear in a separate row.
		• Each count indicates how many form instances have the specific state.
		For example, the count of open queries is the count of how many individual form instances have open queries. It is not a summary count of the number of open queries for all instances of a form.
		• The states are existing InForm states, such as form completed or locked, as well as any defined custom review states.
		• The header columns show the total counts of each state for the records you have the rights to view across the entire study.
		▪ The counts are limited to the data you have the rights to view.
		For example, if you have the rights to see 5 of 20 sites in the study, the totals in the header are for the 5 sites to which you have access.
		▪ The counts are subjected to the selected filter criteria but are not limited to the current page.
		For more information, see *Summary Data Table—Summary View* (on page 48).
	Site	The site mnemonic.
		The column is locked in place so that it remains visible when you scroll to the right.
	Country	The country in which the site is located.
		The column is locked in place so that it remains visible when you scroll to the right.
	Forms with Queries columns	Number of candidate, opened, answered, and closed queries.
	Form State columns	Number of forms in the following states: Not Complete, Complete, Frozen, Locked, and Not Done.

Component	Description
Source Verify columns	Source verification status. • **Target Rate**—The SV Target Rate for the specific site. This is the percentage at which you want subjects to be selected for source verification after the initial subjects are verified. You enter this value in the **Subject selection rate after initial subjects** field in the **Set SV settings** dialog box. **Note:** This column appears only when viewing summary data that is grouped by sites. • **Not Verified**—The number of forms that have not been verified and are either associated with a subject in the SV Pool or listed in the Critical Forms list. • **Not Complete**—The number of forms that are partially source verified (that is, all items marked SV Required during the study design have *not* been verified) and are either associated with a subject in the SV Pool or listed in the Critical Forms list. • **Verified**—The number of forms that have been verified (that is, all items marked SV Required during the study design have been verified) and are either associated with a subject in the SV Pool or listed in the Critical Forms list. • **% Verified**—The percentage of started forms that have been verified, rounded to 1 decimal point, calculated as: Verified / (Not Complete + Not Verified + Verified). **Note:** This column appears only when viewing summary data that is grouped by sites. • **Selected**—The number of forms selected for source verification by critical subject, form, or item selections.
Custom Review State columns	Status for the custom review states. Up to five custom review states may be defined. For more information, see *Custom review states in the Data Viewer* (on page 256).

Summary Data Table—Summary View

The Summary Data Table displays summary data counts for queries, form states, source verification states, and custom review states (if defined) grouped by visits or sites, for the data you have the rights to view.

Locked columns and headers—Summary Data Table

The header rows are locked in place so that they remain visible when scrolling vertically.

The left-most columns that display contextual information are locked in place so that they remain visible when scrolling to the right.

- When viewing the data by visits, the Visit column is locked.

- When viewing the data by sites, the Site column and Country column are locked.

Column sorting—Summary Data Table

The columns sort when you click a column header. An arrow indicating the direction of sorting appears in the corner of the column header.

- The sort order is the selected column, and then the default sort order.

    - When viewing the data by visits, the default sort order is the visit sequence defined during the study design.

    - When viewing the data by sites, the default sort order is the alphabetical order of the site mnemonic.

- Any sort selections or highlights on rows are not saved after you display data with new sorting.

- When you sort a column, any cell that was marked as Incomplete is treated the same as a cell that contains no data.

Column customization—Summary Data Table

In the Summary Data Table in the Summary View, you can:

- Resize the width of the columns.

    For more information, see **Resizing a column** (on page 236).

- Hide and unhide groups of columns.

    For more information, see **Hiding or unhiding columns** (on page 237).

> **Note:** You can only hide or unhide the column groups in the Summary Data Table. You cannot hide, unhide, or reorder individual columns in the Summary Data Table.

Record Listing View

The Record Listing View is a display of clinical data per form that can span across sites, subjects, and visits.

Use the Record Listing View to:

- View form data for multiple subjects across multiple visits at the same time.

- View data from multiple clinical forms in one custom view.

- Quickly compare items on the same type of CRFs and itemsets.

- View detailed information and the audit history for a selected item.

- Access the Record Listing Single Subject View.

    The Record Listing Single Subject View is a filtered Record Listing View for a single subject across all visits. For more information, see *Record Listing Single Subject View* (on page 56).

Components—Record Listing View

The Record Listing View shows the clinical data for a form that can span across sites, subjects, and visits, or shows data from multiple clinical forms in one view.

	Component	Description
1	Toolbar	Provides centralized options in menu format for the actions you can perform on the data in the Form Data Table.
		The options that appear in the toolbar vary depending on the current view. Options that are not available for the current view are not visible; options that are not applicable to the current selection(s) are disabled.
		For more information, see *Toolbar—Data Viewer* (on page 68).

Component		Description
2	Forms pane	Displays the form mnemonics for started forms, in alphabetical order, and the number of instances of each form. For more information, see *Forms pane—Record Listing View* (on page 54).
		This pane collapses to maximize the viewing area for the main data portion of the page.
3	Filters pane	Provides options to filter the data that appears in the Form Data Table. For more information, see *Filters pane—Data Viewer* (on page 71).
		This pane collapses to maximize the viewing area for the main data portion of the page.
4	Summary Data pane	Provides a counting summary of the states for the available form instances filtered by the criteria set for the current view. For more information, see *Summary Data pane—Record Listing View* (on page 55).
		This pane provides a way to filter the data in the Form Data Table with a single-click. This pane collapses to maximize the viewing area for the main data portion of the page.
5	Form Data Table	Displays all data for the form that is selected in the Forms pane, filtered by the criteria selected in the Filters pane.
		The left-most column shows the InForm state for the form.
		• Locked
		• Frozen
		• Complete
		• Incomplete
		• Not Started
		• Verified
		• Not Verified
		Because there is only one column to show the six states, and because the states can co-exist, the Data Viewer uses the same prioritizing scheme as the icons that appear in other parts of the InForm application. For more information, see *CRF status icons* (on page 78).
		The Query state does not appear in this first column because query states have their own icons that appear in the data cells when appropriate. For more information, see *Data Viewer icons* (on page 82).
		For a data item that is marked Incomplete, the data cell is grayed out and displays the text *Incomplete*.
		If the InForm metadata contains HTML tags, the tags appear in the data columns.

	Component	Description
6	Detail Pane	Provides information on the data item (cell) that was last clicked in the Form Data Table. For more information, see **Detail Pane—Record Listing View** (on page 55).
		If the InForm metadata contains HTML tags, the tags appear in the Detail Pane.
		Note: The Detail Pane does not appear by default when you navigate to a Record Listing View. You must manually expand the pane by clicking the arrow located in the lower-right corner of the page.

Form Data Table—Record Listing View

The Form Data Table shows all data for the form that is selected in the Forms pane, filtered by the criteria selected in the Filters pane.

- Each row in the table represents a single form instance.

  > **Note:** Because the source verification summary counts include only *form* counts and do not consider itemsets, you may see more rows in the Record Listing View than the number specified in the Summary View.

- For a repeating visit, the visit mnemonic is appended with the visit index in parentheses to distinguish between repeating visits.

  > **Note:** Deleted repeating forms and deleted itemsets are not recognized as existing forms in the Data Viewer, and therefore are not counted or displayed anywhere in the Data Viewer.

- There are, by default, three columns to identify the records:

  - Site mnemonic

  - Subject

  - Visit

  These columns are locked so that this data can be used as context as the table scrolls left and right.

- The columns on the right are individual data items representing individual controls in the form.

  For example, a Demographic form has Gender, DOB, Race, Height, and Marital Status as columns.

- Each column represents one control in a form.

- The value of a control is concatenated with its unit, if any.

  - You can use the Show Codes option in the toolbar to toggle between showing the labels (default) or the represented codes of the CRF control. For more information, see **Showing the codes or code labels** (on page 239).

  - You can use the Show Normalized Values option in the toolbar to toggle between showing the entered values (default) or the corresponding normalized values. For more information, see **Showing the entered or normalized values** (on page 239).

- Icons that appear in each row indicate the state of each record.

  If there are open queries or answered queries, different query icons that are specific to the Data Viewer also appear. For more information, see *CRF status icons* (on page 78) and *Data Viewer icons* (on page 82).

Locked columns and headers—Form Data Table

> **Note:** The column names that appear in the Data Viewer are the same names used in the Reporting and Analysis module.

The header rows are locked in place so that they remain visible when scrolling vertically.

The left-most columns that display the states and contextual information (such as site, subject, and visit) are locked in place so that they remain visible when scrolling to the right.

Column sorting—Form Data Table

The columns sort when you click a column header. An arrow indicating the direction of sorting appears in the corner of the column header.

- The sort order is the selected column, and then the default sort order.

  - The default sort order is by site, subject, and then the visit sequence defined during the study design.

- All columns except for the Visit column are sorted based on the column data type.

- Whenever a column with an entered value is selected for sorting, sorting is applied with its normalized value column if a normalized value column exists.

  For more information, see *Showing the entered or normalized values* (on page 239).

- For sorting on a date entered in a CRF, the entered dates are sorted.

- Any sort selections or highlights on rows are not saved after you display data with new sorting.

- When you sort a column, any cell that was marked as Incomplete is treated the same as a cell that contains no data.

Column customization—Form Data Table

In the Form Data Table in the Record Listing View and Record Comparison View, you can:

- Resize the width of the columns.

  For more information, see *Resizing a column* (on page 236).

- Reorder columns by dragging and dropping them to a new position.

  For more information, see *Reordering column positions* (on page 236).

- Hide and unhide individual columns.

  For more information, see *Hiding or unhiding columns* (on page 237).

  - Any customizations for hidden data columns persist, and apply to the current view and current form only.

  - Any customizations for contextual columns (for example, Site and Visit) that you hide for the current view are carried over to all views where those views have the same column (identified by the column name).

> **Note:** You cannot hide the Subject column.

- Set the column names.

  For more information, see *Setting the column names* (on page 238).

Forms pane—Record Listing View

The Forms pane, which appears in the top left corner of the Record Listing View, displays a list of started forms and custom views (if any) in alphabetical order. When you select a form, it is highlighted and its data appears in the Form Data Table.

The list does not include:

- Forms that had been started but then deleted.

- Dynamic forms that have no started instances.

Use the Forms pane to navigate between available forms that already have form instances started and have instances that meet the current filtering criteria.

- The counts of the currently filtered instances appear to the right of each form.

  There are no counts for custom views; a hyphen (-) appears in the count column.

- Instance counts are for forms only; itemsets are not counted individually.

The Forms pane displays forms and itemsets as follows:

- A form that has regular items and itemsets, or has two or more itemsets, appears in the Forms pane with its form name, and an itemset icon () underneath it for each itemset.

  - Clicking on the form name in the Forms pane displays the regular items in the Form Data Table.

  - Clicking on the itemset icon displays the itemset data in the Form Data Table.

- A form that has no regular items and contains only one itemset appears in the Forms pane without the itemset icon. The form is treated as the itemset itself for display purposes.

- If an itemset has a section RefName that is too long for display, it is truncated for display purposes. Use the hover Help to view the full section RefName.

You can also use the Forms pane to initiate the:

- Creation, display, and deletion of custom views.

  Custom views provide a way to view data from multiple forms in one view. Columns from multiple clinical forms can be put together into a single view on which you can create queries, verify items, and export the data to Excel.

  For more information, see *Overview of creating custom views* (on page 249).

Summary Data pane—Record Listing View

The Summary Data pane provides a counting summary of the states for the available form instances filtered with criteria set for the current view.

- The states are the same states that are viewable in the Summary View.

- Each individual state shows the count of forms with that state.

- States are grouped into categories for presentation.

- Each state within the Summary Data pane is clickable.

> **Note:** This pane provides a way to filter the data in the Form Data Table with a single-click. For example, clicking on a state adds that state to the current filtering criteria, which provides the same result as picking that state in the Filters pane, and applies the selection across pages.

Detail Pane—Record Listing View

> **Note:** The Detail Pane does not appear by default when you navigate to a Record Listing View. You must manually expand the pane by clicking the arrow located in the lower-right corner of the page.

The Detail Pane contains information on a data item in the Form Data Table. This information includes:

- Item details.

  Icons in the upper right of the Detail Pane show the current status of the item.

  - Site name.

  - Subject number.

  - Visit name.

  - Form name.

  - Column name heading.

  - Item description or question as it appears on the form.

  - Item comments.

  - Data value.

  - Form states.

- Candidate, open, and answered queries.

- Custom review states assignment history.

- Audit History.

  The audit history contains information on any data changes made to the item, such as the initial value or any changed values, as well as any queries that were on the item.

  The Data Viewer uses the same date format used in all other areas of the InForm application, which is configured for a user on the User details page in the Admin user interface.

> **Note:** The Detail Pane only shows information when a data item in the Form Data Table is selected. If a data cell is not selected, the Detail Pane does not display any information.

Record Listing Single Subject View

The Record Listing Single Subject View is a filtered Record Listing View for a single subject across all visits.

- Any time a subject number appears in the Form Data Table, it appears as a clickable cell.

  You can click on the subject cell to navigate to a Record Listing View for a single subject across visits.

- The Record Listing Single Subject View has the option of displaying expected forms.

  Expected forms are the set of CRFs that should be completed by a specified date, usually based on when the visit for the CRF was scheduled to start. For more information, see *Definition of Expected forms* (on page 60).

- All features available for the standard Record Listing View are available for the Record Listing Single Subject View.

When you select a subject number in the Record Listing View:

- The Subject(s) field in the Filters pane is automatically populated with the subject number that you select.

- The Summary Data pane displays and highlights the word Subject to indicate how the Form Data Table is being filtered.

You can:

- Navigate to another form for the current subject by selecting a different form in the Forms pane.

- Navigate to another subject by typing over the current subject number with another subject number in the Subject(s) field in the Filters pane.

> **Note:** This view displays when you navigate to the Data Viewer from a CRF. For more information, see *Navigating from a CRF to the Data Viewer* (on page 116).

Create custom view dialog box

The Create custom view dialog box allows you to pick columns from different forms and arrange the order of the columns in the target view. You can also drag and drop columns between the fields.

Fields

Field	Description
Forms	Available forms.
Available columns	Available columns for the form selected in the Forms list.
Add	Adds the selected column(s) in the Available columns list to the Selected columns list.
Remove	Removes the selected column(s) in the Selected columns list, and returns them to the Available columns list.
	The columns appear at the bottom of the list.
Selected columns	The columns to appear in the custom view.
Custom view name	A unique name for the custom view.

Buttons

Button	Description
Remove all selected columns icon	Removes all the columns in the Selected columns list.
Create	Creates the custom view.
	The custom view name appears in the Forms pane in the Record Listing View.
	• If the custom view is created with columns from non-repeating forms and no itemsets, the view opens in the Record Listing View.
	• If the custom view is created with columns from regular forms, repeating forms, or itemsets the view opens in the Record Comparison View.
Cancel	Closes the dialog box without saving any selections or changes.

How the Data Viewer displays dates, visits, and form types

Item	Description
Date	The Data Viewer uses the same date format used in all other areas of the InForm application, which is configured for a user on the User details page in the Admin user interface.
Repeating visit	Repeating visit instances appear in the Record Listing View as individual visits identified by their visit mnemonic and its visit index concatenated together throughout the Data Viewer.
Repeating form	Each repeating form instance appears in the Data Viewer as a record in the Record Listing View. For example, if subject A has three AE form instances, when you select the AE form from the form selector, the data table shows three rows for subject A. A form index is not needed because each form instance has data to identify it from the other instances, such as the start date for an AE form instance.
Alternate form	An alternate form appears separately from the original form. Both forms coexist in all views as a form by itself. Data is not populated from the original form to the alternate form or vice versa. Data items added in an alternate form that were not required for past visits appear as empty data cells. They are not specifically identified as *Not in version*.
Common form	Appears as part of a common visit, but not a specific visit.
Itemsets	Each itemset appears as a form in the Form Data Table in the Record Listing View, which provides an easy way to sort on the itemset items. The Forms pane includes an entry for the form if the form contains regular items. The Forms pane also has an entry for each itemset. • When you select the original form, records with all the regular items of all instances of that form appear in the Form Data Table. • When you select a form itemset, all records of instances of that itemset appear in the Form Data Table. • When a form contains only one itemset without a regular item, the form is the itemset itself as it appears in the Forms pane. • Forms and their itemsets appear together in the Forms pane for easy reference. • Itemsets include their section RefName to identify them as an itemset of a form. Because every Record Listing View contains only one row for each instance, and therefore, each itemset appears by itself, the only way to look at an itemset and the regular items of the same form instance at the same time is to use the Record Comparison View, or to create a custom view.

Item	Description
Expected forms	Use the Record Listing Single Subject View to show expected forms. Expected forms are the set of CRFs that should be completed by a specified date, usually based on when the visit for the CRF was scheduled to start.

- CRFs that are in visits that are scheduled to start as of the specified date are not counted as expected.

- For subjects that have completed the study or dropped out of the study, only started forms are considered as expected.

Because there is no single definition of an expected form that meets everyone's needs, the Data Viewer can be customized for your individual requirements. For example, the current date can be replaced with a specified date so that Data Viewer users can specify a date for finding expected forms.

The date a user enters in the Data Viewer is in the local time for the user. The Data Viewer converts the local time to GMT time to find matching expected forms.

For more information, see:

- *Definition of Expected forms* (on page 60).

- *Expected CRFs and common forms* (on page 61).

- *Expected CRFs and study completion* (on page 61).

Dates and times

The Data Viewer uses the same date format used in all other areas of the InForm application, which is configured for a user on the User details page in the Admin user interface.

- All clinical data entered on a CRF appears in the InForm audit trail and in the Data Viewer Detail Pane using the local time zone for the site, which is stored in the database as Greenwich Mean Time (GMT).

- In the Data Viewer, dates recorded in the system other than those entered as clinical data on a CRF appear in the user's local time, even though they were recorded in the study in GMT.

   To determine the user's local time, the Data Viewer converts the GMT date time recorded in the InForm audit trail to the local time of the user's browser.

The conversion to the user's local time affects the date of last change used to filter records, the date recorded and displayed in the audit trail, and the following fields in the Data Viewer Filters pane:

- Updated since date

- Updated since review

- Show expected forms

Definition of Expected forms

> **Note:** The definition of expected forms in the Data Viewer is different from the definition used in the Reporting and Analysis module.

In the Data Viewer, a CRF is counted as Expected if it meets any of the following criteria.

1   A Started CRF is counted as Expected, regardless of whether its visit was supposed to start.

    A dynamic form that is Activated but not Started does not count as Expected. The one case where a Started CRF does not count as Expected is if the subject is not enrolled.

2   An ALT form is counted as Expected if the ALT form appears in the InForm user interface.

    The ALT form appears in the InForm user interface if the form to which it is an alternate has been started. The calculation does not take into account whether the visit in which the ALT form appears was supposed to start yet.

3   Every CRF in the current study version for each subject counts as Expected, unless the following restrictions cause the CRF to NOT be counted as Expected:

    * CRFs are only counted as Expected for Enrolled subjects.

    * CRFs are only counted as Expected for subjects who have started at least one CRF.

    * The date the first CRF is started in the InForm application is the First CRF Date for the subject and is used in some calculations, as follows.

        * This First CRF Date is the Server Date/Time when the CRF was entered electronically into the InForm application, which could be after the real-world subject visit when the paper form was filled in.

        * This First CRF Date is an internal date in the InForm application, and does not appear in the InForm user interface.

    * Only subject visits and the common visit are considered. Other special visits such as screening, enrollment, monitoring and so on, are not considered.

    * Only CRFs are considered. Other kinds of forms are not considered.

    * Dynamic forms that have been deleted (removed) are not counted as Expected.

    * CRFs are only counted as Expected if the visit in which they appear is expected to have started, which is calculated as follows:

        * Dynamic visits are Expected if activated and the specified date is more than the dynamic visit's ProjectedStartHours after the First CRF Date. The ProjectedStartHours is converted to whole days and then truncated before this calculation.

        * Repeating Visits and Unscheduled Visits are Expected if the specified date is greater than the date from the Date-of-Visit CRF.

        * Scheduled Visits are expected if the specified date is more than the visit's StartHours after the First CRF Date. The StartHours value is converted to whole days and then truncated before this calculation.

All the calculations to determine if a visit is expected to have started use several dates with varying time zones:

- The First CRF Date is GMT.

- The Date-of-Visit for repeating and unscheduled visits is the value entered by the user in the Date of Visit form. No time zone is entered, so none can be assumed.

- The date specified in the Data Viewer user interface as input for this expected CRF. No time zone is entered, so none can be assumed.

> Note: The date a user enters in the Data Viewer is in the local time for the user. The Data Viewer converts the local time to GMT time to find matching expected forms.

Expected CRFs and common forms

In the Data Viewer, common forms require some special handling in the calculation of Expected CRFs.

- A common form can appear in multiple non-common visits in the current study version.

- Each non-common visit can be scheduled, unscheduled, dynamic, or repeating.

- In each non-common visit, the common form can be dynamic.

> Note: A common form can be dynamic in multiple visits and not dynamic in other visits. For the visits in which it is dynamic, it might be activated in some, but not others.

- If a common form is started, it is counted as Expected.

- A non-started common form is counted as Expected if the following two conditions are both met in at least one non-common visit in the current study version:

  - The visit is expected to have started.

  - The common form is not dynamic in the visit, or the common form is dynamic in the visit and the common form is activated (and not deleted) in that non-common visit.

Expected CRFs and study completion

In the Data Viewer, for subjects who have completed or dropped out of the study and completed the Study Completion form, only started forms are treated as Expected. All other forms that have been skipped are not treated as Expected forms.

For example, suppose a study has four scheduled visits, Visits 1 through 4. A subject completes Visit 1 and Visit 2, and then drops out of the study. Even when the StartHours on Visit 3 or Visit 4 are reached, those forms in Visit 3 and Visit 4 are not counted as Expected.

Record Comparison View

The Record Comparison View provides a side-by-side comparison of two Record Listing Views. Each data view panel has identical functionality, and each has its own toolbar, Form drop-down list, Filters pane, and Form Data Table.

The components in each data view panel function the same as those in the Record Listing View. For more information, see *Components—Record Listing View* (on page 49).

Use the Record Comparison View to:

- View and filter data on two forms at the same time.

  In each data view panel you can:

  - Select a form and filter it by site, subject, visit, and so on.

  - Change the form that appears.

  - Change the filtering criteria.
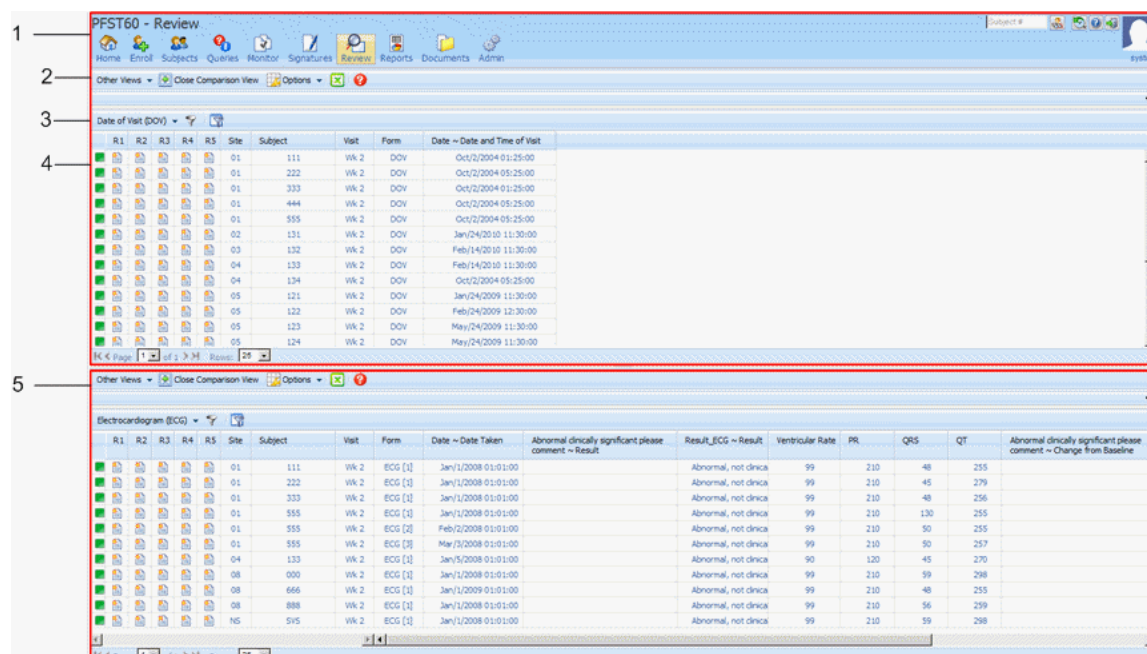
    The two data view panels are independent of each other except that when you click a subject number in the top view, the rows in the bottom view are automatically filtered to display data only for the selected subject.

- Perform InForm actions on one or more data cells in the Form Data Table in either data view panel.

- Export data from the active data view panel to an Excel file.

You can close either panel in the Record Comparison View to return to the Record Listing View you started from.

Components—Record Comparison View

The Record Comparison View allows you to perform a comparison of CRFs and itemsets. It provides a side-by-side comparison of two Record Listing Views.

Component	Description
1 Top data view panel	The top view in the Record Comparison View.
	• The form that you selected in the Record Listing View appears in the top data view panel.
	• The top data view panel inherits all current filtering criteria set for the Record Listing View.
2 Toolbar	Provides centralized options in menu format for the actions you can perform on the data in the Form Data Table. For more information, see *Toolbar—Data Viewer* (on page 68).
	The options that appear in the toolbar vary depending on the current view. Options that are not available for the current view are not visible; options that are not applicable to the current selection(s) are disabled.
3 Data view panel section header	
Form name drop-down list	Lists the available form names that you can choose from to change the form that appears in the data view panel. The name of the currently selected form appears as the label for the drop-down list.
Filter icon	Opens the Filters dialog box, which you can use to filter the data that appears in the data view panel. For more information, see *Filters pane—Data Viewer* (on page 71).

Component	Description
Delete custom view icon	Deletes the custom view that appears in the data panel. A confirmation dialog box does not appear.
Filter column data icon	Opens the Column filter dialog box, which you can use to perform single column filtering on clinical data values. You can filter on any column, except the columns for the review states, site, subject, and visit.
	Column filtering is applied only in the current view. All column filtering selections are lost when you navigate away from the current view.
4 Form Data Table	Displays all data for the form that is selected in the Forms pane, filtered by the criteria selected in the Filters pane. For more information, see *Form Data Table—Record Listing View* (on page 51).
	• The header rows are locked in place so that they remain visible when scrolling vertically.
	• The left-most columns that display the states and contextual information (such as site, subject, and visit) are locked in place so that they remain visible when scrolling to the right.
	• Data items added in a new version that were not required to be filled in for past visits appear as empty data cells. They are not specifically identified as *Not in version*.
	• If the InForm metadata contains HTML tags, the tags appear in the data columns.
	Note: The column names that appear in the Data Viewer are the same names used in the Reporting and Analysis module.
5 Bottom data view panel	The bottom view in the Record Comparison View.
	• The form that you selected from the Open Comparison View drop-down list appears in the bottom data view panel.
	• The bottom data view panel inherits all current filtering criteria except for the form states.

Comments View

The Comments View, which opens in a separate browser window, provides a list of form and item comments for all sites, visits, and forms.

> **Note:** Comments on deleted repeating forms or itemsets do not appear in the Comments View.

Use the Comments View to:

- Open and view the comments and a Data Viewer view simultaneously.

  The comments that initially appear when you open the Comments View depend on the Data Viewer view you navigated from.

  You can choose to view the comments for all forms or for single forms.

  > **Note:** You can only review comments—you cannot add or edit item-level or form-level comments—in the Data Viewer Comments View. To add or edit a comment, you must navigate to a CRF.

- Change the filter and apply new filtering criteria as in other Data Viewer views.

- Sort columns as in other Data Viewer views.

  For more information, see *Column sorting—Comments View* (on page 67).

- Mark comments as reviewed.
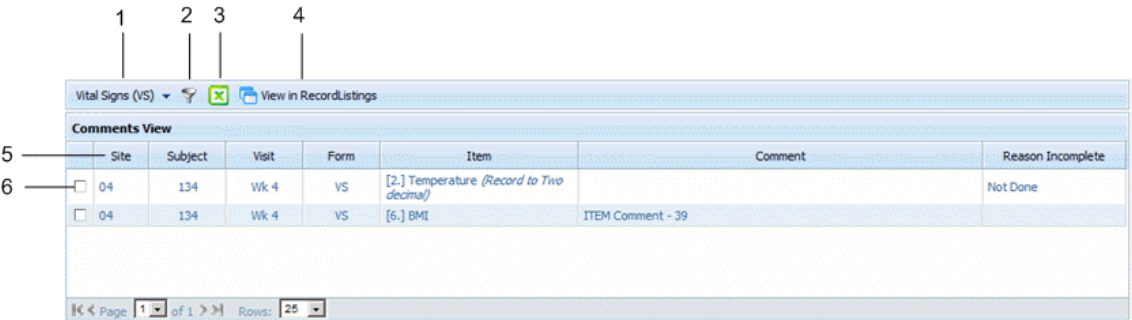
  For more information, see *Marking comments as reviewed* (on page 248).
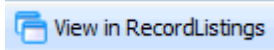
- Export comments in Excel format.

- Access the Record Listing Single Subject View for a form by clicking on a row in the Comments View.

  You can perform InForm actions on the selected record in the Record Listing Single Subject View, or you can navigate to the form to review the whole form.

Components—Comments View

The Comments View provides a list of form and item comments across one or more form types.

Component		Description
1	Form drop-down list	Use to select the forms for which you want to view comments.
2	Filter icon	Opens the Filters pane in a separate window. For more information, see *Filters pane—Data Viewer* (on page 71).
3	Excel icon	Click to save or export the comments in Excel spreadsheet format.
4	View in Record Listings icon	Click to open the Record Listing View.
5	Data columns	
	Site	Abbreviation of the site name.
	Subject	Numerical identifier for the subject; the format is specified during study design.
	Visit	Name of the visit.
		For repeating visits, the visit name is appended with a visit index to differentiate between the repeating visits (for example, Unscheduled 1 and Unscheduled 2). This is the same as how repeating visits appear in the Time and Events Schedule.
	Form	Form mnemonic.
		For repeating forms, the form name is appended with a form index for each repeating form index (for example, AE1 and AE2). This repeating form index is the same as how repeating forms appear in the summary page of that repeating form. For more information, see *Form views* (on page 7).

Component		Description
	Item	Item on the form.
		For itemsets, the form name is appended with an itemset index to differentiate between the itemsets (for example, DOSE 1.a and DOSE 1.b).
		• If text appears in the Item column, the comment is an item-level comment.
		• If text does not appear in the Item column, the comment is a form-level comment.
	Comment	Comment text from the CRF.
	Reason Incomplete	User-entered reason incomplete.
6	Comment reviewed checkbox	Select to mark a comment as reviewed.
	□	

Column sorting—Comments View

The columns sort when you click a column header. An arrow indicating the direction of sorting appears in the corner of the column header.

The default sort order is the selected column, followed by the site, subject, visit sequence, and then form mnemonic.
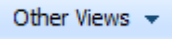
Common Data Viewer features

The same toolbar, filters pane, page controls, and column customization controls appear in the Summary View, Record Listing View, and Record Comparison View in the Data Viewer. The filters and page controls are also available in the Comments View.
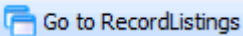
Toolbar—Data Viewer

The Data Viewer toolbar provides centralized options in menu format for the actions you can perform on the data in the Data Viewer. The toolbar is located at the top of the Data Viewer window, and appears in the Summary View, Record Listing View, and Record Comparison View.

> **Note:** The options that appear in the toolbar vary depending on the current view. Options that are not available for the current view are not visible; options that are not applicable to the current selection(s) are disabled.

Control	Description
Sites button Sites or Visits button Visits	The button label changes based on the grouping of the summary data. • **Sites button**—Appears when the summary data is grouped by visits. • **Visits button**—Appears when the summary data is grouped by sites. **Note:** This option is only available in the Summary View.
Other Views drop-down list Other Views ▾	• **Visits**—Navigates to the Summary by Visits view. • **Sites**—Navigates to the Summary by Sites view. • **Time & Events Sch.**—Navigates to the Time and Events Schedule. **Note:** This option is only available in the Record Listing View.
Open Comparison View drop-down list	Provides a list of all started forms so that you can pick a form to view in the Record Comparison View. **Note:** This option is only available in the Record Listing View.
View Comments icon	Opens the Comments View in a separate window. The comments appear with the currently selected filtering criteria.

Control	Description
Options drop-down list	Provides options to customize the current workspace and column displays.
	• **Maximize Workspace**—Minimizes all panels that appear except for the data table to provide maximum viewing area for the data table.
	• **Configure Columns**—Provides a dialog box to allow you to hide and display the available columns for the current views.
	• **Show Codes / Show Code Labels (default)**—Toggles between showing the labels (default) or the represented codes of the CRF control. This option is only available in the Record Listing View.
	Note: Codes are numeric or alphabetical values that represent the clinical data on the CRFs. For example, 0 represents No, 1 represents Yes, F represents Female, and M represents Male. These codes (0, 1, F, and M) are values that are stored in the database as the clinical data for the CRFs. The code labels (for example, No, Yes, Female, and Male) are metadata used in the display to make it easier to understand the entered value.
	• **Show Entered Values (default) / Show Normalized Values**— Toggles between showing the values entered on a CRF (default) or the corresponding normalized values. This option is only available in the Record Listing View.
	Note: Normalized values are values that are converted from the format (or unit) that was entered for a given item on a CRF to a format that is available based on the study design. For example, the value of a data item can be changed (normalized) from one unit to another (inches to cm or kg to lbs).
	• **Set SV Settings**—Opens the **Set SV settings** dialog box, from which you can configure Partial SV.
	Note: This option appears if you have the Change Site SV Settings right or the Monitor right. If you have the just the Monitor right, you can view the SV Settings but you cannot not change them.
Excel icon	Opens a File Download dialog box from which you can open or save the data from the current Data Viewer view in Excel spreadsheet format.
Freeze icon	For the selected rows or cells, prevents site users from entering data, editing existing data, or adding comments. A CRF that is frozen allows queries and signatures.
Unfreeze icon	For the selected rows or cells, returns the ability for site users to enter data, edit existing data, or add comments.
Lock icon	For the selected rows or cells, prevents all tasks, except for electronic signatures, from being performed on a CRF.
Unlock icon	For the selected rows or cells, returns the ability to perform all tasks on a CRF.

Control	Description
Go To Record Listings icon Go to RecordListings	Opens the Record Listing View. **Note:** This option is only available in the Summary View after you select a data cell.
Source Verify drop-down list	For forms: • **Mark Verified**—For the selected rows or cells, indicates that the data has been compared to data on source documents and has been checked for inconsistencies or errors. • **Mark Not Verified**—For the selected rows or cells, indicates that the data does not need to be compared to data on source documents or checked for inconsistencies or errors. For items in custom views: • **Mark item verified**—For the selected item, indicates that the data has been compared to data on source documents and has been checked for inconsistencies or errors. • **Mark item not verified**—For the selected item, indicates that the data does not need to be compared to data on source documents or checked for inconsistencies or errors.
Review drop-down list	For the selected rows or cells, assigns a custom review state. For more information, see *Custom review states in the Data Viewer* (on page 256).
Create Query icon	Opens a dialog box, from which you can create queries for selected items. **Note:** This option is only available in the Record Listing View and the Record Comparison View.
View Queries icon	Navigates to the CRF so that you can view any queries for the selected item. **Note:** This option is only available in the Record Listing View and the Record Comparison View.

Filters pane—Data Viewer

The Filters pane provides options to filter the data that appears in a Data Viewer view.

The filtering criteria appear:

- In a collapsible pane in the left side of the Data Viewer window in the Summary View and Record Listing View.

    - In the Summary View, the filters affect the data in the Summary Data Table.

    - In the Record Listing View, the filters affect the data in the Form Data Table.

- In a separate, modal dialog box from the Record Comparison View and Comments View.

    - In the Record Comparison View, the filters affect the data in the Form Data Table for the associated data view panel.

> **Note:** The filtering criteria you set in the Filters pane are carried across all Data Viewer views in the same session, so that you can navigate through different views using a consistent set of filtering criteria.

Component	Description
Save icon	Saves the current filter selections for the current session. Provide a name for the new filter, or use an existing name to overwrite a filter.
Load filter icon	Does one of the following:
	- Saves the current filter selections for the current session. Provide a name for the new filter, or use an existing name to overwrite a filter.
	- Saves the current filter selections for future use. Opens a folder from which you can choose from previously saved filters.
Delete filter icon	Deletes a saved filter.
Filter column data icon	Opens the Column filter dialog box, which you can use to perform single column filtering on clinical data values. You can filter on any column, except the columns for the review states, site, subject, and visit.
	Column filtering is applied only in the current view. All column filtering selections are lost when you navigate away from the current view.
	Note: This option is only available in the Record Listing View and the Record Comparison View.
Site	Select one or more sites in the study. Displays the site mnemonic and name.
Subject(s)	Enter one or more subject numbers, separated by commas, in the selected site.
Visit(s)	Select one or more visits in the study.

Component	Description
State(s)	Select one or more InForm state. • All • Candidate • Opened • Answered • Closed • Not Complete • Complete • Frozen • Locked • Not Done • SV Ready • Partially Verified • Not Verified • Verified • Data Review custom review states (if defined).
Updated since date	View only forms with clinical data changes and forms with query status changes of Opened or Answered that occurred after the specified date. Changes to other query statuses (such as Candidate, Closed, or Deleted) are not counted as an update. Cells that belong to an item that contains changed data are highlighted. • Click in the field or on the **Calendar** icon ( ) to open the calendar control, and then select a date. • Click the **Eraser** icon ( ) to clear the date entry. **Note:** The audit trail in the Data Viewer Detail Pane displays the time for this field in the time zone of the user's browser. For more information, see *Dates and times* (on page 59).
Updated since review	View only forms with clinical data changes and forms with query status changes of Opened or Answered that occurred after the selected review state was assigned. Changes to other query statuses (such as Candidate, Closed, or Deleted) are not counted as an update. Cells that belong to an item that contains changed data are highlighted. **Note:** The audit trail in the Data Viewer Detail Pane displays the time for this field in the time zone of the user's browser. For more information, see *Dates and times* (on page 59).

Component	Description
Show expected forms	Show expected forms at a certain date.
	• Click in the field or on the **Calendar** icon ( ) to open the calendar control, and then select a date.
	Note: This option is only available when you are viewing the Record Listing Single Subject View.
	Note: The audit trail in the Data Viewer Detail Pane displays the time for this field in the time zone of the user's browser. For more information, see *Dates and times* (on page 59).
Show All link	Clears all filtering criteria. Applies to the current view so that you can view a list of records that are not filtered in any way.
Apply button	Apply the filtering criteria to the current view.

Pagination—Data Viewer

The Summary Data Table in the Summary View, the Form Data Table in the Record Listing View and Record Comparison View, and the Comments View are paginated.

• You can change the pagination using the page controls at the bottom of the page.

• The default number of records per page is 25.

• You can change the number of records per page to 10, 25, 50, or 100.

Configure Columns dialog box

The Configure Columns dialog box allows you to:

- Hide or unhide the available groups of columns in the Summary View, or individual columns in the Record Listing View and Record Comparison View.

  For more information, see *Hiding or unhiding columns* (on page 237).

- Select the column names that you want to display in the Form Data Table in the Record Listing View.

  For more information, see *Setting the column names* (on page 238).

The options that appear in the dialog box depend on the columns that appear in the Data Viewer view.

> **Note:** You cannot hide the Subject column.
>
> **Note:** The names of columns that appear in the Visibility section change to match the selection you make from the Header Names drop-down list.

Field	Description
Header Names	Identifies the type of column names to display in the Form Data Table in the Data Viewer Record Listing View or Record Comparison View.
	This field appears in the User's Product Locale.
	• **Report element**—Default. Select if you want to use Ad Hoc Reporting column names as the column headings.
	The Ad Hoc Reporting column names appear in the Visibility section of the dialog box.
	• **Reporting data extract column**—Select if you want to use RDE column names as the column headings.
	The RDE column names appear in the Visibility section of the dialog box.
	Note: This section appears only when you access the Configure Columns dialog box from the Record Listing View or Record Comparison View.
Visibility	
All columns	Selects or deselects all the checkboxes in the columns list.
	• Contextual columns (for example, Site and Visit) that are hidden for the current view are carried over to all views with the same column (identified by the column name).
	These columns appear in the User's Product Locale.
	• Data columns that are hidden apply to the current view only.
	These columns appear in the Review Schema Product Locale.

Field	Description
Reset All	Resets the Header Names field to Report element, and resets the options in the Visibility section to the default (all selected).
Apply	Click to save and apply the selections.

Column filter dialog box

The Column filter dialog box allows you to perform single column filtering on clinical data values. You can filter on any one column at a time, except the columns for the review states, site, subject, and visit.

- Columns that contain entered values are filtered by the normalized value.

- For each column you filter, you can select up to five filtering criteria that are appropriate for the column type (for example, numeric, case-insensitive alphanumeric, or date).

- Column filtering is applied only in the current view. All column filtering selections are lost when you navigate away from the current view.

Field	Description
Filtering criteria	Displays the column name for the selected data cell, and the filtering conditions that are appropriate for the column type (for example, numeric, case-insensitive alphanumeric, or date).
	You can specify a maximum of five criteria for each column.
Apply	Click to save and apply the selections.
Cancel	Closes the dialog box without saving or applying the selections.

Icons

The icons in the InForm user interface provide a way to easily recognize status and system behavior. Use the hover Help for a description of each icon.

> **Note:** Using Partial SV does not change any of the icons in the user interface to visually differentiate forms that require SV from forms that do not require SV. For more information, see *Overview of source verification* (on page 178).

Icon type	Use to	Appear on these pages
Visit and form status	View a detailed visit or form state.	Multiple pages in the user interface.
CRF status	• View the status of a CRF. • These icons do not show an entire form or visit state.	Individual CRFs.
CRF item	• Add comments. • View the audit trail. • Clear data. • Work with queries.	Next to items on a CRF.
Query status	View the status of a query.	Multiple pages in the user interface.
Signature status	• Review the status of forms and case report books that require signatures. • Navigate to the electronic signature form for a specific form or case report book.	Required Signatures page.
Data Viewer	• View states (standard and custom). • Identify the status of a query on a form.	Record Listing View. Record Comparison View.

Visit and form status icons

The visit and form status icons provide a detailed visit or form state and appear in the following places in the user interface:

- **Case Report Books page**—Each icon provides a detailed rolled-up visit state.

- **Time and Events Schedule page (Visit and Form view)**—Each icon provides a detailed form state for a single form or rolled-up state for repeating forms.

- **CRF View of repeating form**—Each icon provides a detailed form state for a single form.

- **Source Verification Listing page**—Each icon provides a detailed form state for a single form.

- **Required Signatures page**—Each icon gives the detailed form state for a single form.

> Note: You choose whether to use the status icons described here, or a version of the traffic light icons that were used in all versions of the InForm application prior to release 5.0, during the installation. In the user interface, the type of icons being used is indicated on the System Configuration page. You cannot change the icon selection in the user interface; you can only change it through MedML. For more information, see the *Utilities Guide*.

For each form or visit, the InForm application displays a basic icon or a variation of the icon—depending on whether the state is source verified, frozen, locked, has queries, or some combination of those states—by adding one or more of the applicable CRF status icons onto or next to the basic status icon. The hover Help displays a full description for each status icon.

Icon	Description
Basic visit and form icons	
	Not started
	Incomplete
	Complete
	Complete and locked
	Incomplete and locked
CRF status icon additions	
	Frozen
	Verified **Note:** Site users do not see this state.
	Answered query **Note:** Site users do not see this state.
	Open Query
	Open and Answered query

Icon	Description
🔒	Locked

CRF status icons

The CRF status icons indicate the status of the CRF. They do not show an entire form or visit state.

Because some of the CRF statuses can overlap, the InForm application displays the icon(s) based on a priority. When there are multiple statuses, the priority determines the icon that appears. For example, if a form is both frozen and locked, only the locked icon appears.

Icon	Description	Priority
⬜	Not Started	7—Lowest
⚠️	Incomplete	7—Lowest
🟩	Complete	7—Lowest
❄️	Frozen	6
✔️	Verified **Note:** Site users do not see this state.	5
❗	Answered Query **Note:** Site users do not see this state.	4
❓	Open Query	3
🔵	Open and Answered query	2
🔒	Locked	1—Highest

CRF item icons

The CRF item icons appear next to items on a CRF. Use them to add comments, view the audit trail, clear data, or work with queries.

Icon	Description
	Comment(s)—Exist.
	Comment(s)—None exist.
	Query—Open query or queries exist.
	Query—None exist.
	Query—Closed query or queries exist.
	Audit trail—None exists.
	Audit trail—Exists.
	Edit item rules.
	Reset item values.

Query status icons

The query status icons appear in the following places in the user interface:

- **Query Listing page**—Status column.

- **Case Report Forms**—These icons appear next to the Open or Answered queries that may appear under a CRF Item.

  Note: Queries in other states do not appear under an item, and Answered queries appear only for Sponsor users.

- **Case Report Form details—Queries page**—These icons appear next to queries that appear under the item in the Current Value section.

- **Case Report Form detail—Data Value(s) page**—These icons appear next to queries that appear under the item in the Current Value section.

Icon	Description
	Candidate
	Open
	Answered
	Closed
	Deleted
	Site Conflict
	Sponsor Conflict

Signature status icons

The signature status icons allow you to review the status of forms and case report books that require signatures, and to navigate to the electronic signature form for a specific form or case report book.

The signature status icons appear in the following place in the user interface:

- **Required Signatures page**—Signature column.

Icon or link	Description
	CRF has been signed by all required signatories.
	This icon is visible only if you have the right to view CRF signing information.
	CRF has not been signed by all required signatories. This can mean that the CRF or case report book has never been signed or that signatures have been invalidated by data updates or query activity.
	This icon is visible only if you have the right to view CRF signing information.
	The form is signed, so the signature is unnecessary.
	This occurs if the form was signed by those groups that were required to sign at the time of the original signatures, but the user is in a group that was later added and required to sign the form.
	Case report book has been signed by all required signatories.
	This icon is visible only if you have the right to view CRF signing information.
	Case report book has not been signed by all required signatories. This can mean that the CRF or case report book has never been signed or that signatures have been invalidated by data updates or query activity.
	This icon is visible only if you have the right to view CRF signing information.
	The case report book is signed, so the signature is unnecessary.
	This occurs if the case report book was signed by those groups that were required to sign at the time of the original signatures, but the user is in a group that was later added and required to sign the case report book.
Sign link	Click to sign the CRF.
Sign Book link	Click to sign the CRB.
View link	Click to view details for the CRF or CRB.

Data Viewer module icons

The Data Viewer icons appear in the data cells in the following places in the Data Viewer:

- **Record Listing View**—Summary Data pane and Form Data Table.

- **Record Comparison View**—Summary Data pane and Form Data Table.

Icon	Description
	Represents the first stage (default) for a custom review state. For example, Needs Review.
	Represents the second stage for a custom review state. For example, Pending.
	Represents the third stage for a custom review state. For example, Reviewed.
	Indicates there is an Open query on the item.
	Indicates there is an Answered query on the item.
	Indicates there is an Open and Answered query on the item.

C H A P T E R 3
Log in and passwords

In this chapter

Overview of logging in and passwords

The InForm application uses your user name, password, and security questions to confirm your identity and provide access to your study.

- **Passwords**—You can change your password at any time after you log in to the InForm application.

   For more information, see *Guidelines for choosing a password* (on page 85) and *Changing your password* (on page 89).

- **Initial log in**—The first time you log in to the InForm application, you must use the temporary password that your study administrator assigned to you.

   To access the InForm application you are required to change the temporary password, provide an email address, and select and provide answers for two different security questions. You can change this information at any time after your initial log in.

   For more information, see *Logging in to the InForm application for the first time* (on page 86).

- **Password recovery information**—The system uses the password recovery information to confirm your identity when you want to reset a forgotten password or change an expired password.

   The password recovery information includes an email address, and two different security questions.

   For more information, see *Setting up your password recovery information* (on page 91).

- **Reset a forgotten password**—If you forget your password, you can use your password recovery information to request a temporary password that you can use to log in to the InForm application.

   Before you can receive a temporary password, you must provide answers for the two security questions you selected in your password recovery information. After the InForm application confirms your identity, an email message with a temporary password and instructions on how to access your account is sent to you.

   After you log in with the temporary password, you should immediately change the password.

   For more information, see *Resetting your password* (on page 92) and *Changing your password* (on page 89).

- **Expired password**—Administrators can require that you reset your password at specified intervals.

   To reset your expired password, you must provide answers for the two security questions you selected in your password recovery information.

   For more information, see *Changing your expired password* (on page 93).

Guidelines for choosing a password

Oracle recommends the following guidelines for choosing a password.

Passwords should contain:

- A minimum of eight characters.

- At least one upper case character, and at least one number or non-alphanumeric character (special character).

Passwords should *not* contain:

- A common word, name, or any part of the user name.

- A word or name that can be easily guessed. For example, do not use the names of family members.

For more information on passwords and security requirements, see the *Secure Configuration Guide*.

Password configuration options

An administrator can set the following password configuration options on the System Configuration page. For more information, see *System Configuration page* (on page 298).

- Password expiration period.

- Minimum password length.

- Require at least one numerical character in password.

- Require at least one uppercase character in password.

- Require at least one non-alphanumeric character in password.

- Allow password reuse.

- Enable password recovery.

Logging in to the InForm application for the first time

The first time you log in to the InForm application, the Change Expired Password page appears, and you must select and provide answers for two different security questions before you can access the application.

1   Open an Internet browser.

2   Type the URL for your assigned site, and press **Enter**.

The Login page appears. For a description of the fields on this page, see *Login page* (on page 95).

3   In the **User Name** field, type your user name.

4   In the **Password** field, type the temporary password provided to you by your study administrator.

5   Click **Log In**.

The Change Expired Password page appears. For a description of the fields on this page, see *Change Expired Password page* (on page 100).

To continue, you must select and provide answers for two different security questions.

6   In the **Current Password** field, type the temporary password provided to you by your study administrator.

7   In the **New Password** field, type your new password.

Passwords should have a minimum of 8 characters. For security reasons, Oracle recommends using a combination of letters, numbers, and non-alphanumeric characters. Passwords are case-sensitive.

For more information, see *Guidelines for choosing a password* (on page 85).

8   In the **Confirm Password** field, type your new password again.

9   In the **E-mail address** field, type your email address.

The email address must be at least three (3) characters long and contain the at (@) character.

If you reset your password, the InForm application sends a message to this address with a temporary password and instructions on how to access your account.

10   In the **Question 1** drop-down list, select a security question.

- What is your mother's maiden name?
- What is the name of your pet?
- What is the city of your birth?
- What is your favorite color?

11   In the **Enter your confirmation response 1** field, type the answer to **Question 1**.

You must provide an answer to the question.

- The answer is case-insensitive.
- Leading and trailing spaces are ignored.

12 In the **Question 2** drop-down list, select a security question.

You cannot select the same question more than one time.

- What is your mother's maiden name?

- What is the name of your pet?

- What is the city of your birth?

- What is your favorite color?

13 In the **Enter your confirmation response 2** field, type the answer to **Question 2**.

You must provide an answer to the question.

- The answer is case-insensitive.

- Leading and trailing spaces are ignored.

14 Click **Submit**.

Logging in to the InForm application

1 Open an Internet browser.

2 Type the URL for your assigned site, and press **Enter**.

The Login page appears. For a description of the fields on this page, see *Login page* (on page 95).

3 In the **User Name**, type your user name.

4 In the **Password** field, type your password.

5 Click **Log In**.

- If this is the first time you are logging in to the InForm application, the Change Expired Password page appears. To continue, you must select and provide answers for two different security questions. For more information, see *Logging in to the InForm application for the first time* (on page 86).

- If your login credentials are accepted:

  The InForm application opens and displays the Home page for the study. The Home page is customized for each study and can include many types of information.

  The InForm application displays all the features to which you have access, based on your rights and rights groups.

Your study allows a specific number of login attempts. If you exceed this number, the system locks you out. If this happens, do one of the following:

- Reset you password using your password recovery information. For more information, see *Resetting your password* (on page 92).

- Contact your administrator to reactivate your account.

Inactive user messages

If the Login page displays a message that you are an inactive user, contact your system administrator to activate your account; then, you can log in again and start using the InForm application.

After the administrator activates your account, change your password and use the new password for subsequent log ins. For more information, see *Changing your password* (on page 89).

If you are automatically logged out

Study administrators can set a maximum inactivity period and a maximum usage period for the study, which require you to provide your log in credentials if either of the following occurs:

- No activity occurs in the application for a specified period of time.

- A session runs longer than a specified period of time, with or without activity.

If your study includes these settings and you are automatically logged out, the Login page appears with a message that explains what has happened.

If you receive an automatic log out message, log in again. Any data that you are in the process of entering when you were logged out is saved until you submit it.

Changing your password

1 Log in to the InForm application.

   For more information, see *Logging in to the InForm application* (on page 88).

2 In the upper-right corner of the main user interface window, click the picture or user name.

   The Change Password page appears. For a description of the fields on this page, see *Change Password page—For InForm users* (on page 96).

3 In the **Change Password** section, provide your password information.

   a In the **Password** field, type your current password.

   b In the **New password** field, type your new password.

      Passwords should have a minimum of 8 characters. For security reasons, Oracle recommends using a combination of letters, numbers, and non-alphanumeric characters. Passwords are case-sensitive.

      For more information, see *Guidelines for choosing a password* (on page 85).

   c In the **Confirm new password** field, type your new password again.

4 In the **Password Recovery Information** section, provide the information the system will use to confirm your identity when you need to change an expired password or if you forgot your password and want to reset it.

   > **Note:** The password recovery feature is available only if your study has been configured to allow it.

   a In the **E-mail address** field, type your email address.

      The email address must be at least three (3) characters long and contain the at (@) character.

      If you reset your password, the InForm application sends a message to this address with a temporary password and instructions on how to access your account.

   b In the **Confirmation question 1** drop-down list, select a security question.

      * What is your mother's maiden name?

      * What is the name of your pet?

      * What is the city of your birth?

      * What is your favorite color?

   c In the **Confirmation question response 1** field, type the answer to **Confirmation question 1**.

      You must provide an answer to the question.

      * The answer is case-insensitive.

      * Leading and trailing spaces are ignored.

    d   In the **Confirmation question 2** drop-down list, select a security question.

        You cannot select the same question more than one time.

- What is your mother's maiden name?

- What is the name of your pet?

- What is the city of your birth?

- What is your favorite color?

    e   In the **Confirmation question response 2** field, type the answer to **Confirmation question 2**.

        You must provide an answer to the question.

- The answer is case-insensitive.

- Leading and trailing spaces are ignored.

5   Click **Submit**.

Setting up your password recovery information

> **Note:** The password recovery feature is available only if your study has been configured to allow it.

Password recovery information is used to confirm your identity if you need to change an expired password or if you forgot your password and want to reset it.

1   In the upper-right corner of the main user interface window, click the picture or user name.

    The Change Password page appears. For a description of the fields on this page, see *Change Password page—For InForm users* (on page 96).

2   In the **Change Password** section, do one of the following:

    - Leave the Change Password section blank to keep your current password.

    - Change your password. For more information, see *Changing your password* (on page 89).

3   In the **Confirmation question 1** drop-down list, select a security question.

    - What is your mother's maiden name?

    - What is the name of your pet?

    - What is the city of your birth?

    - What is your favorite color?

4   In the **Confirmation question response 1** field, type the answer to **Confirmation question 1**.

    You must provide an answer to the question.

    - The answer is case-insensitive.

    - Leading and trailing spaces are ignored.

5   In the **Confirmation question 2** drop-down list, select a security question.

    You cannot select the same question more than one time.

    - What is your mother's maiden name?

    - What is the name of your pet?

    - What is the city of your birth?

    - What is your favorite color?

6   In the **Confirmation question response 2** field, type the answer to **Confirmation question 2**.

    You must provide an answer to the question.

    - The answer is case-insensitive.

    - Leading and trailing spaces are ignored.

7   Click **Submit**.

Resetting your password

If you forget your password, you can use the password recovery information you entered to reset your password. After the InForm application confirms your identity, an email message with a temporary password and instructions on how to activate your account is sent to you.

The security questions that appear on the page are the ones you selected when setting up your password recovery information. For more information, see *Setting up your password recovery information* (on page 91).

1   Open the InForm **Login** page.

2   In the **User Name** field, type your user name.

3   Click the **Forgot Your Password** link.

The Reset Your Password page appears. For a description of the fields on this page, see *Reset Your Password page* (on page 98).

4   In the **Answer 1** field, type the answer to **Question 1**.

You must provide an answer to the question.

- The answer is case-insensitive.

- Leading and trailing spaces are ignored.

5   In the **Answer 2** field, type the answer to **Question 2**.

You must provide an answer to the question.

- The answer is case-insensitive.

- Leading and trailing spaces are ignored.

6   Click **Reset Password**.

If the answers you enter are not correct, they continue to display, and you have to modify them.

If the answers you enter are correct, the InForm application confirms your identity, and the Reset Your Password Confirmation page appears. This page contains a message informing you that a temporary password has been emailed to you.

> **Note:** The email subject is Reset Password Notification. The message text contains your temporary password and instructions on how to access your account.

7   Click **Return to Log-In screen**.

8   Use the temporary password to log in to the InForm application.

For more information, see *Logging in to the InForm application* (on page 88).

> **Note:** The temporary password is case-sensitive.

9   Change the temporary password, and use the new password for subsequent logins.

For more information, see *Changing your password* (on page 89).

Changing your expired password

If your password expires, you can use the password recovery information you entered to reset your password. The security questions that appear on the page are the ones you selected when setting up your password recovery information. For more information, see *Setting up your password recovery information* (on page 91).

1 In the **Current Password** field, type your current password.

2 In the **New Password** field, type your new password.

   Passwords should have a minimum of 8 characters. For security reasons, Oracle recommends using a combination of letters, numbers, and non-alphanumeric characters. Passwords are case-sensitive.

   For more information, see *Guidelines for choosing a password* (on page 85).

3 In the **Confirm Password** field, type your new password again.

4 In the **E-mail address** field, type your email address.

   The email address must be at least three (3) characters long and contain the at (@) character.

   If you reset your password, the InForm application sends a message to this address with a temporary password and instructions on how to access your account.

5 In the **Enter your confirmation response 1** field, type the answer to **Question 1**.

   You must provide an answer to the question.

   • The answer is case-insensitive.

   • Leading and trailing spaces are ignored.

6 In the **Enter your confirmation response 2** field, type the answer to **Question 2**.

   You must provide an answer to the question.

   • The answer is case-insensitive.

   • Leading and trailing spaces are ignored.

7 Click **Submit**.

   • If your answers are correct, the InForm application opens.

   • If the answers are not correct, they continue to display, and you have to modify them.

Logging out of the InForm application

1   In the navigation toolbar, click the **Logout** icon ( ).

A confirmation dialog box appears.

2   Click **OK**.

User interface—Log in and passwords

Login page

Use the Login page to open the InForm application and display the Home page for the study.

The Login page:

- Appears in the language set in your browser.

  If multiple languages are defined, the InForm application uses the first language in the list.

  If a language is not defined for your browser, the Login page appears in the language of the default product locale.

- Displays the name of your study.

- Displays a Forgot your Password link.

- Optionally, provides support and contact information, if defined by your study administrator.

  By default, contact information does not appear on the Login page. For more information, see the *Study and Reporting Setup Guide*.

Fields

Field	Description
User Name	The name you enter to access the InForm application.
Password	Your password. You can change your password at any time. For more information, see *Changing your password* (on page 89).
Forgot Your Password link	Click to open the Reset Your Password page, which you can use to reset your password after providing answers to the two security questions you selected on the Change Password page. For more information, see *Resetting your password* (on page 92) and *Change Password page—For InForm users* (on page 96).

Buttons

Button	Description
Log In	Submits your user name and password for processing. The User Name continues to display if the password you specify is incorrect.

Change Password page—For InForm users

Use the Change Password page to change your password and to specify your password recovery information. The system uses the password recovery information to confirm your identity when you want to reset a forgotten password or change an expired password. The password recovery information includes an email address, and two different security questions.

> **Note:** This page is automatically populated with the information you enter on the Change Expired Password page. For more information, see *Change Expired Password page* (on page 100). You can change the information at any time using this page.

Fields

Field	Description
Change Password	
User name	Name you enter to log in to the InForm application.
Password	Current password.
New password	New password.
Confirm new password	Repeat of new password, for confirmation.
Password Recovery Information	
E-mail address	Your email address.
	The email address must be at least three (3) characters long and contain the at (@) character.
	If you reset your password, the InForm application sends a message to this address with a temporary password and instructions on how to access your account.
Confirmation question 1	Select a security question that will be used to confirm your identity if you need to reset your password.
	• What is your mother's maiden name?
	• What is the name of your pet?
	• What is the city of your birth?
	• What is your favorite color?
Confirmation question response 1	Answer to Confirmation question 1. You must provide an answer to the question.
	• The answer is case-insensitive.
	• Leading and trailing spaces are ignored.

Field	Description
Confirmation question 2	Select a security question that will be used to confirm your identity if you need to reset your password.
	You cannot select the same question more than one time.
	• What is your mother's maiden name?
	• What is the name of your pet?
	• What is the city of your birth?
	• What is your favorite color?
Confirmation question response 2	Answer to Confirmation question 2. You must provide an answer to the question.
	• The answer is case-insensitive.
	• Leading and trailing spaces are ignored.

Buttons

Button	Description
Submit	Submits the password changes to the database.
Return	Returns you to the previous page without submitting any changes to the database.

Reset Your Password page

The Reset Your Password page appears when you click the Forgot Your Password link on the Login page.

This page:

- Displays the two different security questions you selected in the Password Recovery Information section on the Change Password page, in read-only format.

    For more information, see *Setting up your password recovery information* (on page 91) and the *Change Password page—For InForm users* (on page 96).

- Provides a text box for you to enter the answer for each question.

    You must provide answers to both questions. The answers are case-insensitive. Leading and trailing spaces are ignored.

Fields

Field	Description
User Name	The name you use to log in to the InForm application. READ-ONLY.
Question 1	Security question 1. READ-ONLY. • What is your mother's maiden name? • What is the name of your pet? • What is the city of your birth? • What is your favorite color?
Answer 1	Answer to Question 1. You must provide an answer to the question. • The answer is case-insensitive. • Leading and trailing spaces are ignored.
Question 2	Security question 2. READ-ONLY. • What is your mother's maiden name? • What is the name of your pet? • What is the city of your birth? • What is your favorite color?
Answer 2	Answer to Question 2. You must provide an answer to the question. • The answer is case-insensitive. • Leading and trailing spaces are ignored.

Buttons

Button	Description
Reset Password	Resets your password so you can regain access to the application.
	• If the answers you enter are not correct, they continue to display, and you have to modify them.
	• If the answers you enter are correct, the InForm application confirms your identity, and the Reset Your Password Confirmation page appears. This page contains a message informing you that a temporary password has been emailed to you.

Reset Your Password Confirmation page

The Reset Your Password Confirmation page appears after you submit the correct answers to the security questions on the Reset Your Password page.

This page displays a hint to check your spam or junk folder, if after successfully resetting your password, you have not received an email with your new password in a reasonable period of time.

Change Expired Password page

The Change Expired Password page appears the first time you log in to the InForm application, and when your password expires after the time period specified by an administrator.

To reset your expired password, you must select and provide answers for two security questions. Your questions and answers populate the Password Recovery Information section on the Change Password page. For more information, see *Change Password page—For InForm users* (on page 96).

Fields

Field	Description
User Name	Name you enter to log in to the InForm application.
Current Password	Current password.
New Password	New password.
Confirm Password	Repeat of new password, for confirmation.
E-mail Address	Your email address.
	The email address must be at least three (3) characters long and contain the at (@) character.
	If you reset your password, the InForm application sends a message to this address with a temporary password and instructions on how to access your account.
Question 1	Security question 1.
	The first time you log in to the InForm application, this field is active. After your first login, this field is read-only.
	• What is your mother's maiden name?
	• What is the name of your pet?
	• What is the city of your birth?
	• What is your favorite color?
Enter your confirmation response 1	Answer to Question 1. You must provide an answer to the question.
	• The answer is case-insensitive.
	• Leading and trailing spaces are ignored.

Field	Description
Question 2	Security question 2.
	The first time you log in to the InForm application, this field is active. After your first login, this field is read-only.
	You cannot select the same question more than one time.
	• What is your mother's maiden name?
	• What is the name of your pet?
	• What is the city of your birth?
	• What is your favorite color?
Enter your confirmation response 2	Answer to Question 2. You must provide an answer to the question.
	• The answer is case-insensitive.
	• Leading and trailing spaces are ignored.

Buttons

Button	Description
Submit	Submits the reauthentication information you entered on the page.
	The entered data continues to display if the InForm application does not accept the data, and you have to modify it.

C H A P T E R   4
Navigation

In this chapter

Displaying the Case Report Books page

- In the navigation toolbar, click **Subjects**.

  The Case Report Books page appears. For a description of the fields on this page, see *Case Report Books page* (on page 26).

Changing the subject order in the Case Report Books page

You can change the order of subjects in the Case Report Books page to a sequence that most closely matches the order in which you enter or review data.

> **Note:** The Subject order icon (🧑↕) appears in the upper-right corner of the Case Report Books page only if your study has been configured to enable the feature, and you have the rights to use it.
>
> Check with your administrator before you change the order of subjects. If you change the order of subjects, the new order appears to all users of the study.

To change the order of subjects in the Case Report Books page:

1   In the navigation toolbar, click **Subjects**.

   The Case Report Books page appears.

2   In the upper-right corner of the page, click the **Subject order** icon (🧑↕).

   The Order Subjects for Site page appears. By default, the list of subjects is sorted by subject number within each site.

3   Select a subject.

4   Use the navigation buttons to move the subjects to the desired order.

5   Do one of the following:

- To submit the new subject order to the database and navigate back to the Case Report Books page, click **Submit**.

  The new subject order appears to all users of the study.

- To return to the Case Report Books page without making any changes to the subject order, click **Return**.

- To remove any custom ordering of subjects and restore the default alphabetical ordering, click **Reset**.

Displaying the Time and Events Schedule

1   In the navigation toolbar, click **Subjects**.

The Case Report Books page appears.

2   In the **Subject Number** or **Status** column, click the link for the subject whose Time and Events Schedule you want to access.

The Visit view of the Time and Events Schedule appears. For more information, see *Time and Events Schedule* (on page 28).

Working with CRFs

Displaying a single CRF

Use case report forms to enter, correct, or update data for a subject visit.

1   In the navigation toolbar, click **Subjects**.

2   Click the status icon for the subject and visit.

3   Use one of the form selectors to choose a form.

     If the form is defined as a repeating form, the form first displays in summary form. If data has been entered in one or more forms, click the status icon or the number to the left of the form to see details.

Displaying the CRFs for a visit

1   In the navigation toolbar, click **Subjects**.

     The Case Report Books page appears. Each subject has one status icon for each visit.

2   Click a status icon to open the forms for a visit.

Using the summary view

Use the summary view to perform the same action, such as locking, freezing, source verifying, or deleting, on several different form instances at the same time.

1   In the summary view, click the button for the action to perform.

     If the action does not appear in the row of command buttons, find it in the **Select Action** list and click **Apply**. The summary view reappears with a column of checkboxes along the left side.

2   Select the checkbox next to the form instance or instances on which to perform the action that you selected in step 1.

3   Click the action button (for example, **Mark SV Ready**).

Displaying the Data Value(s) page

1   Navigate to a form for a subject.

2   Click anywhere in the darkened area that appears when you move the mouse over an item.

Displaying the Queries page

To display the Queries page for a specific form item do one of the following:

*   From the form, click the underlined query text or the query icon.

*   From the Query Listing, click the underlined query text.

Displaying the Audit Trail page

- Click the **Audit trail** icon ( ) in the far-right column of a form item.

Displaying comments

To display a form item comment:

- From the detailed view of a CRF, click the **Comment** icon ( ) in the farthest right column of a form item.

To display a form comment:

- In the upper-right corner of the form, click the **Comment** icon ( ).

Navigating between the form views

You can move between the three form views to see a list of all visits and detailed information for a single visit.

To move from	To	Select
Summary view	Standard view	The number in the far-left column of the instance that you want to see.
Standard view	Summary view	[Summary] in the drop-down list.
Standard view	Cross-reference view	There is no standard view if the form can be associated with another form. The two forms always appear in cross-reference view.
Summary view	Cross-reference view	The number in the far-left column of the instance that you want to see.
Cross-reference view	Summary view	[Summary] in the drop-down list.

Navigating between detail pages and forms

When you display a detail page for a form item, you can move to other detail screens or you can return to the form.

- In the navigation pane, use one of the form selectors to choose the page you want to move to other detail screens.

- Click **Return** in the content pane at the bottom of the page to go back to the form page.

Finding a subject by subject number

1   In the navigation toolbar, type a subject number in the **Search** field.

> **Note:** Type only the subject number in the field. Do not include the subject initials.

2   Click the **Search subject** icon ( ).

The Time and Events Schedule for the subject appears. The Subject control changes to the Navigation mode and:

- Displays a drop-down list of all subjects in the current subject's site, with the current subject selected.

- Displays the Subject Number and Initials.

- Subjects are ordered according to the Subject Order feature, if applicable. For more information, see *Subject order* (on page 24) and *Changing the subject order in the Case Report Books page* (on page 104).

3   To navigate to the Time and Events Schedule or CRF for the next or previous subject, click the right or left arrows.

4   To return to the Search mode, repeat step 1.

If the InForm application finds more than one subject with the same number, the content pane displays a list of case report books for all sites where a matching subject number exists. You can click the underlined **Subject** or **Status** links to display the Time and Events Schedule for the subject.

Navigating among subjects

Navigating among subjects is generally allowed only when viewing the Time and Events Schedule (Visit or Form view) or a CRF, but not from an item detail page. For example, if you navigate into the audit trail for an item, the subject navigation goes away and the subject number appears as static text.

1   Navigate to the Time and Events Schedule, a CRF, or a form under source verification.

The Subject navigation control:

- Displays a drop-down list of all subjects in the current subject's site, with the current subject selected.

- Displays the Subject Number and Initials.

- Orders subjects according to the Subject Ordering feature, if applicable.

2   In the **Subject navigation** control, click the right or left arrows to navigate to the Time and Events Schedule or CRF for the next or previous subject.

- In the Time and Events view, the navigation goes to the Time and Events of the next or previous subject, while maintaining the current Time and Events mode (Visit view or Form view).

- In a CRF, the navigation goes to the same visit, same form.

- If you are viewing a repeating visit, navigation always goes to the first instance of the repeating visit.

- When displaying a dynamic visit, any subject for whom that dynamic visit is not activated will be skipped.

- When displaying a dynamic or alternate form, if the subject being navigated to does not have that form, the CRF area of the user interface displays **Form does not exist for this subject**.

3   Click the icon to return to the Search mode.

- When navigating by subjects, the current form always remains on display. When the form is not available for a particular subject, the form area on the screen displays a statement saying the form is not available.

- If the current form is a repeating form, navigating through subjects shows you the summary views.

- If the current visit is a dynamic visit, you can only navigate through subjects that have that particular dynamic visit. Subjects without that dynamic visit are skipped.

Navigating through the CRFs in a visit without a mouse

You can use the Enter and Esc keys, instead of your mouse, to perform typical navigation tasks on every regular and associated form in a visit.

> **Note:** This key mapping does not apply to itemset-only forms or repeating forms.

To perform this task	Click this button	Or press this Key	Description
Submit the form.	Submit & Next	Enter	The Submit & Next button: • Appears on all non-ItemSet forms including the last form in a visit, and allows you to submit a form and advance to the next form in the visit. • Does not appear on ItemSet-only or repeating forms. • Is available for Monitor users in the SV mode. • Submits the entered data if a form is partially completed. • If the current form is not changed, it is not submitted and the user interface navigates to the next form in the current visit (if any). Focus: • When a non-ItemSet visit form loads, the focus is set on the first control in the form. • If the form is read-only, the focus is set to the Submit & Next button. • When the focus is in a multi-line text box or in a drop-down list, the Enter key works in the default manner. **Note:** To submit a form and remain on the page, click the Submit button.

To perform this task	Click this button	Or press this Key	Description

Return to the previous page or to the Time and Events Schedule—Visit view.	Return (or Cancel)	Esc	• The Return or Cancel button appears on all visit forms.
			
			   ▪ Returns to the previous page when viewing a non-CRF page in the user interface.
			
			   ▪ Returns to the Time and Events Schedule—Visit view from a CRF.
			
			• If a read-only form has only a Return button, the focus is set on this button.

Using the Go controls on the study Home page

The study Home page is the window that appears when you log in to the InForm application. The Go controls appear at the bottom of the InForm main window in the content pane. Use the Go controls on the study Home page to navigate directly to the CRFs for a specific subject and visit.

1   In the navigation toolbar, click **Home**.

    The study Home page appears.

2   If you have access to more than one site, use the **Site** drop-down list to select the site.

3   From the **Subject** drop-down list, select the subject whose information you want to access.

4   From the **Visit** drop-down list, select the visit in which the subject information is located.

5   Click **Go**.

Working with the Data Viewer

Displaying the Summary View

1   In the navigation toolbar, click **Review**.

The Summary View appears. For a description of the fields on this page, see *Components— Summary View* (on page 45).

- The first time you navigate to the Data Viewer in a new browser session, the Summary View data is grouped by visits.

- When you navigate back to the Summary View in the same browser session, even if you have logged out and back in to the InForm application, the Summary View displays the data grouped by the last view you selected: visits or sites.

2   To change the grouping of the summary data, in the toolbar, click **Sites** or **Visits**.

3   Single-click any data cell to activate it so that you can perform an action on the data using the options in the toolbar.

For more information, see *Overview of performing InForm actions* (on page 253).

Displaying the Record Listing View

Use this procedure to navigate to the Record Listing View in the Data Viewer. The details that appear on the page depend on which Summary View grouping and which data cell you navigate from.

1   In the navigation toolbar, click **Review**.

The Summary View appears.

2   To change the grouping of the summary data, in the toolbar, click **Sites** or **Visits**.

3   Single-click any contextual cell (that is, a visit or site cell), or any cell that contains an operational data count.

4   In the toolbar, click **Go to Record Listings.**

The Record Listing View appears. For a description of the fields on this page, see *Components—Record Listing View* (on page 49).

- If you selected a contextual cell, the visit or site you clicked in the Summary View is selected in the Filters pane.

- If you selected a data cell, the state you clicked and the contextual data (that is, the visit or site) of the clicked row is selected in the Filters pane.

Either action opens the Record Listing View for the first available form. The first available form is the first form in the Forms pane, which is sorted in alphabetical order, that has instances that satisfy the current filter criteria.

The filter criteria from the Summary View page are carried over into the Record Listing View and appear in the Filters pane.

5   In the Record Listing View, single-click:

- A cell in the **Site** column to add it to the filter criteria.

- A cell in the **Subject** column to add it to the filter criteria, and open the single subject view of the form across all visits (also called the *Record Listing Single Subject View*).

  Data for the current form for the selected subject across all visits appears in the Form Data Table. All features available for the standard Record Listing View are available for the Record Listing Single Subject View. For more information, see *Record Listing Single Subject View* (on page 56).

- A cell in the **Visit** column to add it to the filter criteria.

- A cell in the **Form** column to navigate to the CRF.

  For more information, see *Navigating from the Data Viewer to a CRF* (on page 116).

- One or more data cells to activate them, so that you can perform an action on the selected records using the options in the toolbar.

- A single data cell to update the contents of the Detail Pane to show information for the selected cell.

6   From the Record Listing View, click the arrow in the lower-right corner of the page to open the Detail Pane.

For more information, see *Detail Pane—Record Listing View* (on page 55).

Displaying the Record Comparison View

1   Navigate to the Record Listing View in the Data Viewer.

For more information, see *Displaying the Record Listing View* (on page 114).

2   In the **Forms** pane, single-click the name of the clinical form that you want to compare against another form.

3   In the toolbar, from the **Open Comparison View** drop-down list ( ), select the form that you want to compare to the currently selected form.

The Record Comparison View appears. For a description of the fields on this page, see *Components—Record Comparison View* (on page 63).

- The form that you selected in the Record Listing View appears in the top data view panel.

    The top data view panel inherits all current filtering criteria set for the Record Listing View.

- The form that you selected from the Open Comparison View drop-down list appears in the bottom data view panel.

    The bottom data view panel inherits all current filtering criteria except for the form states.

4   Do one of the following:

- To return to the Record Listing View, in the toolbar, click **Close Comparison View**.

- To return to the Summary View with the data grouped by visits, in the toolbar, from the **Other Views** drop-down list, select **Visits**.

- To return to the Summary View with the data grouped by sites, in the toolbar, from the **Other Views** drop-down list, select **Sites**.

Displaying the Comments View

1   Navigate to the Summary View or Record Listing View in the Data Viewer.

For more information, see:

- *Displaying the Summary View* (on page 113).

- *Displaying the Record Listing View* (on page 114).

2   In the toolbar, click the **View Comments** icon ( ).

The Comments View appears in a separate browser window, filtered by the current filtering criteria. For a description of the fields on this page, see *Components—Comments View* (on page 66).

Navigating from the Data Viewer to a CRF

Use this procedure when you are looking at a Record Listing View or Record Comparison view in the Data Viewer and you want to look at a particular data item within the context of a CRF.

1   Navigate to the Record Listing View or Record Comparison View in the Data Viewer.

For more information, see:

*   *Displaying the Record Listing View* (on page 114).

*   *Displaying the Record Comparison View* (on page 115).

2   In the Form Data Table, click the form mnemonic in the **Forms** column for a subject.

The CRF where the data was entered for the selected subject appears.

3   To return to the Data Viewer, click the **Review** button in the lower left corner of the page.

The Record Listing Single Subject View in the Data Viewer containing the data for the CRF for the selected subject appears.

For more information, see *Navigating from a CRF to the Data Viewer* (on page 116).

Navigating from a CRF to the Data Viewer

Use this procedure when you are looking at a CRF for a subject and you want to review the data on the CRF against data on the same CRF for other subjects.

*   From any CRF, click the **Review** button in the lower left corner of the page.

The Record Listing Single Subject View in the Data Viewer containing the data for the CRF for the selected subject appears.

For information on how to return to the CRF, see *Navigating from the Data Viewer to a CRF* (on page 116).

Navigating from the Data Viewer to the Time and Events Schedule

Use this procedure when you are looking at a Record Listing View or Record Comparison View in the Data Viewer and you want to look at a particular data item within the context of the Time and Events Schedule.

1   Navigate to the Record Listing View or Record Comparison View in the Data Viewer.

    For more information, see:

    • *Displaying the Record Listing View* (on page 114).

    • *Displaying the Record Comparison View* (on page 115).

2   In the Form Data Table, click a data cell for a subject, and then in the toolbar, from the **Other Views** drop-down list, select **Time & Event Sch**.

    The Time and Events Schedule for the selected subject appears.

3   To return to the Data Viewer, click the **Review** button in the lower left corner of the page.

    The Record Listing Single Subject View in the Data Viewer containing the records of the first form for the current subject across visits appears.

    For information on how to return to the Data Viewer, see *Navigating from the Time and Events Schedule to the Data Viewer* (on page 117).

Navigating from the Time and Events Schedule to the Data Viewer

Use this procedure when you are looking at the Time and Events Schedule for a subject and you want to review all records of the subject across visits.

• From the Time and Events Schedule, click the **Review** button in the lower left corner of the page.

    The Record Listing Single Subject View in the Data Viewer containing the records of the first form for the current subject across visits appears.

    For information on how to return to the Time and Events Schedule, see *Navigating from the Data Viewer to the Time and Events Schedule* (on page 117).

CHAPTER 5
Screening and enrollment

In this chapter

Overview of screening and enrollment

Subject registration is the process of screening candidates, enrolling them into an InForm study, and creating an electronic case report book (CRB) for them.

Screening and enrollment forms can vary from study to study. The basic registration forms required in all InForm studies include:

- **Screening form**—Use to capture subject initials, record basic candidate information, and indicate whether the candidate is eligible for the study.

  When you submit the Screening form, the candidate is added to the Screening Log.

- **Enrollment form**—Use to capture a subject number, record whether a screened candidate meets the enrollment criteria of the study, and complete the enrollment of the candidate.

> **Note:** If some information is not available when you begin the Enrollment form, you can enter partial enrollment data and submit the incomplete form. Then, at a later time, you can return to the form, complete the data, and submit the form again.

- **Screening Log**—Use to view the list of study subjects.

> **Note:** If your study uses an IVRS system (Interactive Voice Response System) for subject screening and enrollment, the screening and enrollment forms may be automatically populated from that system.

Screening a candidate

1   In the navigation toolbar, click **Enroll**.

    The Screening Log appears. For a description of the fields on this page, see *Screening Log* (on page 128).

2   Click **Add Candidate**.

    The Screening form appears. For a description of the fields on this page, see *Screening form* (on page 129).

3   In the **Subject Initials** field, enter three initials; use a dash if there is no middle initial.

4   Enter all other candidate information required by the study.

5   Click **Submit**.

    The Screening Log appears. The study candidate is added to the bottom of the list. The status of the screening process appears in the **Enrolled** column.

    • If screening was successful, the **Enrolled** column contains an **Enroll** link.

    • If screening failed, the **Enrolled** column contains the **Enrollment failed** icon (), and the **Screening Failure** column contains information about why the screening was unsuccessful.

Enrolling a screened candidate

1   In the navigation toolbar, click **Enroll**.

The Screening Log appears. For a description of the fields on this page, see ***Screening Log*** (on page 128).

> **Note:** New candidates are always added to the end of the Screening Log. To advance quickly to the end of the Screening Log, use the page selector.

2   In the **Enrolled** column, click the **Enroll** link for a candidate.

The Enrollment form appears. For a description of the fields on this page, see ***Enrollment form*** (on page 130).

3   Complete the **Enrollment** form.

4   Click **Submit**.

5   If all data is present on the Enrollment form and the candidate meets all inclusion and exclusion criteria, a message page appears, indicating that the subject can be enrolled.

> **Note:** For information about what to do if the subject cannot be enrolled because of missing data or nonconformance with inclusion and exclusion criteria, see ***Missing enrollment data*** **(on page 124)**.

6   Click **Enroll**.

The InForm application processes the enrollment by:

- **Updating the Screening Log**—The InForm application adds the subject number to the **Screening Number** column and changes the entry in the **Enrolled** column to a checkmark (✔).

- **Changing the Enrollment form to a read-only form**—After enrollment is complete, you can update enrollment data only if your study is set up to include the enrollment data on one or more enrollment forms in a regular subject visit.

- **Creating the case report book for the subject**—After enrollment is complete, you can access subject visits and forms by clicking **Subjects** in the navigation toolbar.

- **Displaying the Visit calculator (Subject schedule) page**.

  The visit calculator appears with the current date for the baseline visit and computes the remaining visit dates based on that initial visit date.

  - To recalculate proposed visit dates, change the **Start Date** by selecting a new date in the month, day, and year drop-down lists.

  - To print the visit calculator so that you can give it to the subject for reference, click the browser **Print** button.

> **Note:** The visit calculator is for informational purposes only and has no affect on the actual visit schedule. After enrollment is complete, you can access the visit calculator through your study-specific documentation. For more information, see ***Viewing the visit calculator (subject schedule)*** (on page 283).

7   Do one of the following:

- Click **Go to First Visit** to go directly to the first form.

- Click **Return** to return to the Screening Log.

Resubmitting a candidate who failed screening

You can resubmit a candidate who has failed screening if you think the candidate should be eligible for the study.

1   In the Screening Log, look in the **Screening Failure** column to determine why screening failed.

2   In the **Screening Number** column, click the link for the candidate.

The Screening form appears.

3   Make the necessary changes according to the table.

Reason for failure	Solution
Some screening data is missing.	Complete the Screening form, then click **Submit**.
The subject is ineligible for the study.	Check the data and make corrections if necessary. To correct a data value: 1 Click the entered value. 2 On the **Data Value(s)** page, type the correct value and select or type a reason for change. 3 Click **Submit**. A confirmation dialog box appears. 4 Click **OK**. 5 Click **Return** to go back to the Screening form.

4   Click **Submit**.

Reasons for an enrollment failure

Either of the following reasons can cause an enrollment failure:

- Subject did not meet eligibility criteria.

- Subject data is incomplete.

To override the failure and complete enrollment, use the procedure described in *Overriding an enrollment failure due to incomplete data* (on page 124).

Missing enrollment data

If all enrollment data is not available when you fill out the Enrollment form, or if you missed any required data items on the form, one of the following occurs:

- If your protocol permits enrollment with incomplete enrollment data, an enrollment override page appears.

  After you obtain approval from an authorized sponsor representative, you can continue with enrollment. For more information, see *Overriding an enrollment failure due to incomplete data* (on page 124).

- If your protocol does not permit enrollment with incomplete enrollment data, the InForm application returns you to the Screening Log after you submit the Enrollment form.

  The **Enrollment Failure** column displays **Enrollment Form Incomplete** as the reason for failure. The **Enrolled** column contains the **Enrollment failed** icon (), which indicates that the candidate has not been enrolled. For more information, see *Providing missing data and completing the enrollment* (on page 125).

Overriding an enrollment failure due to incomplete data

If your study allows enrollment with incomplete data, you must have an approval from a sponsor representative in order to complete the enrollment.

1   Obtain approval from the appropriate sponsor representative to override the enrollment failure.

2   In the navigation toolbar, click **Enroll**.

    The Screening Log appears.

3   Locate the candidate that you want to enroll.

4   In the **Enrolled** column, click the **Enrollment failed** icon ().

    The Enrollment form appears.

5   Click **Submit**.

    The Enrollment Override page appears.

6   Complete the information on the **Enrollment Override** page.

    You must provide information that documents your discussion with the sponsor representative and give the reason for the override.

7   Click **Enroll**.

Providing missing data and completing the enrollment

If your study does not allow enrollment with incomplete data, you must provide the missing data to complete the enrollment.

1   Click **Enroll**.

    The Screening Log appears. The page may already be visible.

2   Locate the candidate that you want to enroll.

3   In the **Enrolled** column, click the **Enrollment failed** icon ( ).

    The Enrollment form appears.

4   Enter the missing data items.

    Items with missing data have a yellow background.

5   Click **Submit**.

    If all data is now present on the Enrollment form and the candidate meets all inclusion and exclusion criteria, a message appears, indicating that the candidate meets all study criteria and can be enrolled.

6   Click **Enroll**.

What to do if a candidate does not meet study criteria

If the candidate does not meet all inclusion criteria and the sponsor elects to use the override feature, the Enrollment Override page appears.

On the Enrollment Override page, you have these options:

* If the candidate is ineligible, you can complete the enrollment process by indicating that enrollment is refused.

* If the candidate is ineligible because of an error in data entry, you can correct the form and attempt again to enroll the candidate.

* If your study protocol permits candidates who are appear to be ineligible to be accepted into the study with approval from an appropriate sponsor representative, you can override the enrollment failure and complete the enrollment.

Refusing enrollment because the candidate does not meet eligibility criteria

1   After you submit the Enrollment form, the Enrollment Override page appears.

2   Click **Do Not Enroll**.

    A message appears, asking you to confirm that you are refusing enrollment.

3   Click **OK**.

    The Screening Log appears. The **Enrollment Failure** column displays the reasons the candidate is ineligible, and the **Enrolled** column contains the **Enrollment failed** icon ( ), indicating that the candidate has not been enrolled.

Correcting a data-entry error

A subject can fail to meet eligibility criteria as a result of a data-entry error.

1   After you submit the Enrollment form, the Enrollment Override page appears.

2   Click **Return**.

The Screening Log appears. The **Enrollment Failure** column displays the reasons the candidate is ineligible, and the **Enrolled** column contains the **Enrollment failed** icon (), indicating that the candidate has not been enrolled.

3   In the **Enrolled** column, click the **Enrollment failed** icon ().

The Enrollment form appears.

4   Review the entries on the form, and correct any data entry errors as follows:

   a   Click the entered value.

   b   On the **Data Value(s)** page, type the correct value, and select or type a reason for change.

   c   Click **Submit**.

      A confirmation dialog box appears.

   d   Click **OK**.

   e   Click **Return**.

      The Enrollment form appears.

5   Click **Submit**.

If the candidate meets all inclusion criteria, a message appears indicating that the subject can be enrolled.

6   Click **Enroll**.

Refusing enrollment

In some cases, even if a subject meets all eligibility criteria, the Principal Investigator for the site can decide not to enroll the subject.

1   Submit the Enrollment form.

A **Patient Meets All Study Criteria** message appears.

2   Click **Do Not Enroll**.

A message appears, asking you to confirm that you are refusing enrollment.

3   Click **OK**.

The Screening Log appears. The **Enroll** link appears in the **Enroll** column, which indicates that the candidate is not enrolled.

Accessing candidate information

The InForm application does not set up a case report book for a subject until the final phase of enrollment is complete. Until the case report book is created, the only way to access candidate information is through the Screening Log.

Both screening and enrollment information are available through links from the Screening Log. For more information, see *Viewing the Screening form for a candidate* (on page 127) and *Viewing the Enrollment form for a candidate* (on page 127).

Viewing the Screening form for a candidate

1 In the navigation toolbar, click **Enroll**.

The Screening Log appears.

2 In the **Screening Number** column, click the link for a candidate.

The Screening form appears. For a description of the fields on this page, see *Screening form* (on page 129).

Viewing the Enrollment form for a candidate

1 In the navigation toolbar, click **Enroll**.

The Screening Log appears.

2 In the **Enrolled** column, click the **Enrolled** icon (), **Enrollment failed** icon (), or the **Enroll** link for a candidate.

The Enrollment form appears. For a description of the fields on this page, see *Enrollment form* (on page 130).

User interface—Screening and enrollment

Screening Log

The Screening Log lists the names and status of all study candidates in table form. For candidates who were successfully enrolled, the list displays the subject number. For candidates you have attempted unsuccessfully to screen or enroll, the list displays messages that indicate why the attempts failed. The Enrollment column indicates enrollment status.

> **Note:** The Screening Log and all the pages you access from it, including the Screening and Enrollment forms, do not display a subject in the Subject control because the InForm application considers subjects *candidates* until the enrollment process is complete.

Fields

Field	Description
Site filter	Drop-down list of all the sites you can access.
Enrolled	Registration status of the subject.
	• ✔—Candidate has been enrolled successfully. Click to open the Enrollment form.
	• ❌—Some screening or enrollment information has been entered for the candidate, but the candidate has not been screened or enrolled successfully. The Screening Failure or Enrollment Failure column indicates the reasons for failure.
	Click the icon to open the Enrollment form to make additions or corrections.
	Click the Screening Number to open the Screening form and to make additions or corrections.
	• **Enroll**—Candidate has been screened successfully and is ready for enrollment. Click to open a blank Enrollment form.
Screening Number	InForm-generated subject number.
	Click the link to display the Screening form. If screening is incomplete or incorrect, you can make changes and resubmit the form.
Subject Number	Numerical identifier for the subject; the format is specified during study design.
Initials	Three initials that represent the subject. Use a dash if there is no middle initial.
Screening Failure	Reason(s) why a subject failed the screening process.
Enrollment Failure	Reason(s) why a subject failed the enrollment process.

Buttons

Button	Description
Add Candidate	Displays a blank Screening form from which you can add a new candidate.
	Appears only if you have the right to add candidates.
Page control	A multi-part control on the bottom-left of the content pane.
	By clicking different parts of the control, you can move through the pages of the Screening Log when the list of study candidates fills more than one page.

Screening form

Use the Screening form to record basic candidate information and indicate whether the candidate is eligible for the study. When you complete the Screening form, the candidate is added to the Screening Log.

The minimum required data to collect on the Screening form is Subject Initials.

All fields on this form are read only after you screen the candidate.

Fields

Field	Description
Subject Initials	Three initials that represent the subject. Use a dash if there is no middle initial.
Edit item rules icon	Navigates away from the page and displays the rule dependencies for the item. This icon appears only when a rule exists and you have the right to edit item rules.
Reset item values icon	Clears the data entry. This icon appears only when you have the right to add and edit candidates.

Buttons

Button	Description
Submit	Submits the screening information to the database.
	This button appears only when screening a new candidate.
Return	Returns you to the Screening Log. If you are screening a new candidate, this button returns you to the Screening Log without submitting the data to the database.

Enrollment form

Use the Enrollment form to record data that indicates whether a screened candidate meets the study enrollment criteria.

The minimum required data to collect on the Enrollment form is Subject Number.

Fields

Field	Description
Subject Num	InForm-generated subject number.
Edit item rules icon	Navigates away from the page and displays the rule dependencies for the item. This icon appears only when a rule exists and you have the right to edit item rules.
Reset item values icon	Clears the data entry. This icon appears only when you have the right to add and edit candidates. Appears before you submit data.
View item audit history icon	Navigates to the audit history for the item. Appears after you submit data.

Buttons

Button	Description
Submit	Submits enrollment data to the database. This button appears only when the candidate has not been enrolled.
Return	Returns you to the Screening Log. If the candidate has not been enrolled, returns you to the Screening Log without submitting the data to the database.

Visit calculator (subject schedule)

The visit calculator provides a quick way to estimate visit dates based on a selected start date. After you enroll a subject, the visit calculator page appears and computes suggested visit dates based on the date of the enrollment visit. After enrollment is complete, you can access the visit calculator through your study-specific documentation. For more information, see *Viewing the visit calculator (subject schedule)* (on page 283).

After calculating visit dates, you can use the browser print functionality to print the visit calculator page and fill in the Scheduled Date and Time column on paper.

Fields

Field	Description
Start Date	
Visit	Start date of the first visit date. Subsequent visit dates are recalculated from the date that you specify.
Subject Schedule	
Visit	Suggested visit dates based on the start date.
Tentative Date	
Scheduled Date and Time	

Buttons

Button	Description
Close	Closes the Visit calculator page.

CHAPTER 6
Forms, comments, and visits

In this chapter

Overview of forms, comments, and visits

Forms are a mechanism that you use to gather study data. You use forms to enter, correct, or update data for a subject visit. For more information, see *Case report forms* (on page 6).

Comments are blocks of text in which you can enter any pertinent additional details about a form item.

Note: Comments should not contain clinical data.

On the Comment page you can create, update, or view a comment on an individual form data item or on the entire form.

- Form-level comments apply to an entire form.
- Item-level comments apply to items within a form.

Visits are subject evaluation checkpoints when you collect data.

Entering form data and comments

Entering form data

1   In the navigation toolbar, click **Subjects**.

The Case Report Books page appears.

2   Click the status icon for a subject and visit.

3   Use one of the form selectors to choose a form.

An empty form appears.

4   Enter data as follows:

- **For a regular item**—Enter data from the source documents into the controls on the form.

- **For an Add Entry itemset**—Click **Add Entry**. Then, in the itemset entry page that appears, enter data from the source documents into the data-entry controls.

- **For a Repeating Data itemset**—Enter data from the source documents into the data-entry controls.

- **For a repeating form**—Click **New**. Then, on the entry page, enter data from the source documents into the data-entry controls.

5   Click **Submit**.

A **Form Submitted Successfully** message appears. Depending on your study design, the message appears in either of the following ways:

- **As a pop-up message box**—If the message **Form Submitted Successfully** appears in a pop-up box, click **OK** to acknowledge the message and continue using the InForm application.

- **As a message in the title bar of the form**—If the message **Form Submitted Successfully** appears in yellow to the right of the title of the form, you do not have to respond to the message. You can continue using the InForm application.

6   Click **Return**.

You return to the main form from an itemset or repeating form entry page.

Complete data is unavailable

If you cannot complete an entire form in one data-entry session, submit the form with data partially entered. The background color of incomplete items changes to yellow so that you can find them easily when you return to the form later and enter the missing data.

What to do if an item is not editable or visible

The rights groups to which you belong determine whether you can see or modify items. For example:

- If you cannot see an item on a form, you might not have rights to view that item.

- If you can see an item, but are not allowed to edit, or enter data for it, you might not have editing rights.

- If the form is blank or empty, the items and itemsets on the form might all be designated as a hidden display override.

What to do if you find a data-entry error after submitting

A data-entry error might automatically generate a query if it is caught by the built-in edit checks on a data-entry item. For information about how to correct a data-entry error and answer a query simultaneously, see *Answering a query by submitting answer text* (on page 164).

To correct an error that does not automatically generate a query:

1   Click the entered value.

The Data Value(s) page appears.

2   Enter the correct value and a reason for change.

3   Click **Submit**.

A confirmation dialog box appears.

4   Click **OK**.

5   Click **Return**.

Marking an item as skipped (an item is not applicable, unknown, or not done)

If your study protocol permits, you can skip form items if they meet any of the following criteria:

- The item on the form does not apply to the subject.

- The data is not available.

- The procedure to collect the data for an item was not done and the data was not collected.

To mark an item as skipped:

1   Instead of entering data in the item, click the **Comment** icon for the item to display the comment page.

2   In the **Reason incomplete** section, select the reason that best describes why you are leaving the item blank.

3   Click **Submit**.

     A confirmation dialog box appears.

4   Click **OK**.

5   Click **Return**.

     The item reflects the reason selection you made, and the background color of the item is gray, indicating that it is considered complete.

Marking a form as skipped (a form is not applicable, unknown, or not done)

In some cases it might be appropriate to skip an entire form. If your study protocol permits, you can skip a form for any of these reasons:

- The form is not applicable.

- The data is not available.

- The procedure to collect the data for an item was not done and the data was not collected.

To mark a form as skipped:

1   Instead of entering data in the form, enter a form comment that describes the reason the form is skipped.

2   In the **If Incomplete, Reason** section of the Comment page, select the reason that best describes why you are leaving the item blank.

3   Click **Submit**.

     A confirmation dialog box appears.

4   Click **OK**.

5   Click **Return**.

     The items on the form reflect the reason selection you made, and the item background color is gray, indicating that the items are considered complete.

Attributes of an automatically-generated query

A data-entry error might automatically generate a query if it is caught by the built-in edit checks on a data-entry item. When an automated query is generated in the Opened state:

- The background color of the item changes to pink.

- The query text is red and begins with the word **Open**.

- The query text appears under the item.

Entering a comment on a form

1   In the navigation toolbar, click **Subjects**.

The Case Report Books page appears.

2   Click the status icon for a subject and visit.

3   Use one of the form selectors to choose a form.

4   Click the **Comment** icon in the upper-right corner of the form.

The hover Help for the Comment icon displays **Enter a comment for the form**.

The Comment page appears. For a description of the fields on this page, see *Comment page* (on page 42).

5   In the **Comment** box, type the comment.

6   Click **Submit**.

A confirmation dialog box appears.

7   Click **OK**.

8   Click **Return**.

Entering a comment on a form item

1 In the navigation toolbar, click **Subjects**.

   The Case Report Books page appears.

2 Click the status icon for a subject and visit.

3 Use one of the form selectors to choose a form.

4 Do one of the following:

   - **For an item in an itemset or repeating form**—Click the row number of the itemset or repeating form instance.

   - **For a regular item**—Proceed to step 5.

5 Click the **Comment** icon in the far-right of the item row.

   The hover Help for the Comment icon displays **Enter item comment**.

   The Comment page appears. For a description of the fields on this page, see *Comment page* (on page 42).

6 In the **Comment** box, type the comment.

7 Click **Submit**.

   A confirmation dialog box appears.

8 Click **OK**.

9 Click **Return**.

Entering row comments in a Repeating Data itemset

Itemset row comments provide a shortcut for applying the same comment to all items in a Repeating Data itemset that are not pre-defined or blank.

1   In the navigation toolbar, click **Subjects**.

The Case Report Books page appears.

2   Click the status icon for a subject and visit.

3   Use one of the form selectors to choose a form that has a Repeating Data itemset.

4   Click the **Comment** icon in the far-right of the item row.

The hover Help for the Comment icon displays **Apply comment to all items on the row**.

The Itemset Row Comment page appears. For a description of the fields on this page, see *Itemset Row Comment page* (on page 43).

5   In the **Comment** box, type the comment.

6   Click **Submit**.

The comment is applied to all the items in the itemset row, and the form page reappears.

7   Optionally, review the comment for each item in the itemset.

a   Click the item link.

The Data Value(s) page for the item appears.

b   Click the **View item comment** icon.

The Column Comment page for the item appears, and displays the comment you entered in step 5.

Creating an association between two forms

1   Make sure that data exists on the two forms that you want to link.

2   Display the summary view of one of the forms.

3   From the summary view, select the number in the far-left column for the form.

The bottom half of the page displays the form instances that can be linked with the form that you selected.

4   Select the checkbox to associate the form instances.

5   Click **Submit**.

After you have created an association between instances of two repeating forms, the summary view of each form includes the associated instance of the other form, and you can navigate from one instance to the other. For more information, see *Navigating between the form views* (on page 107).

Updating form data

About updating form data

Using the Data Value(s) page, you can:

- Clear form data.

- Delete or undelete an itemset.

- Change form data.

All changes are tracked on the Audit Trail page. For more information, see ***Reviewing the Audit trail*** (on page 146).

About updating a form item on the Data Value(s) page

Use the Data Value(s) page to update a form item. This page is linked to each data item. When you click the value that is entered in the form, the Data Value(s) page appears and displays the current value of the item. The page also includes a way to access previous values for the item, a set of data-entry controls for changing the value of the item, and a section where you provide the reason the item is being changed.

Clearing data

Implications of clearing data

Affected area	What happens when you clear an item

Queries on a cleared item	In a regular CRF with no itemsets, the following status changes occur:
	
	• An Automatic query is changed to Closed.
	
	• For manual queries:
	
	  ▪ An Opened query is changed to Answered.
	
	  ▪ A Candidate query is purged.
	
	  ▪ Other queries are unchanged.
	
	In a CRF with itemsets, queries on an itemset are treated as if the itemset were one item, and the same status changes occur as they would for an item.

Itemsets	If an itemset is deleted, the deleted data is cleared. The audit trail records two entries indicating that the data was deleted and then cleared.
Calculated control	The value of the calculated control is cleared if the calculated control depends on the cleared item.
CDD (customer-defined database) mapping for a cleared item	The value mapped to the CDD is cleared along with the value of the cleared item.
Subject number	After you enter a Subject Number, you cannot clear it.
Randomization number	After you calculate a Randomization Number, you cannot clear it.

Clearing data from an item

To clear data before submission:

- Click the **Reset item values** icon () in the far-right column in the item row.

To clear data that has already been submitted:

1 Click the entered value.

2 On the **Data Value(s)** page, click the **Reset item values** icon () and select or enter a reason for the change.

3 Click **Submit**.

A confirmation dialog box appears.

4 Click **OK**.

The item row background color changes from gray to yellow, to indicate that the item is now incomplete.

Clearing data from a form

1 Navigate to the form.

2 From the **Select Action** drop-down list, select **Clear CRF**.

3 Click **Apply**.

The Reason for Clearance page appears.

4 In the **Reason for clearing the form** drop-down list or text box, select or type a reason for clearing.

5 Click **Submit**.

Each item row background color changes from gray to yellow, to indicate that the item is incomplete.

Deleting or undeleting an Add Entry itemset

Deleting an Add Entry itemset before submission

> **Note:** Only Add Entry itemsets can be deleted. You cannot delete Repeating Data itemsets.

To clear an entire row of an itemset, do not use the Reset item values icon (![icon]) located next to each data item. To remove a row from an itemset, you must delete the row. The audit trail for each item indicates that data has been removed by clearing or deleting.

1   On the form where the Add Entry itemset exists, click **Return**.

    A warning appears, informing you that data has not been submitted.

2   Click **OK**.

Deleting an Add Entry itemset after submission

> **Note:** Only Add Entry itemsets can be deleted. You cannot delete Repeating Data itemsets.

To clear an entire row of an itemset, do not use the Reset item values icon (![icon]) located next to each data item. To remove a row from an itemset, you must delete the row. The audit trail for each item indicates that data has been removed by clearing or deleting.

1   On the form where the Add Entry itemset exists, click the underlined row number.

    The Data Value(s) page for the selected itemset row appears.

2   In the **Reason for change** drop-down list or text box, select or type a reason for the deletion.

3   Click **Delete**.

    After you delete a row, the entries in all columns are crossed out and the columns are gray to indicate that all items in the row are complete.

Undeleting an Add Entry itemset

1   On the form where the Add Entry itemset exists, click the underlined row number.

    The Data Value(s) page appears, displaying the itemset row that you selected.

2   In the **Reason for change** drop-down list or text box, select or enter a reason for undeleting the itemset row.

3   Click **Undelete**.

    A confirmation dialog box appears.

4   Click **OK**.

    The InForm application reinstates the entries in all columns of the row, and the color of each column reflects the state of the item before the row was deleted.

Changing form data

1   In the navigation toolbar, click **Subjects**.

    The Case Report Books page appears.

2   Click the status icon for a subject and visit.

3   Use one of the form selectors to choose a form.

4   Do one of the following:

- **To update a regular item**—Click the cell with the control that you want to change.

- **To update a value in an itemset**—Click the itemset row number.

    The Data Value(s) page appears. For a regular item, only the selected item is visible.

    For an itemset, all items in the itemset are visible.

5   In the **Enter New Value** section of the page, select or type the new value of the item.

6   In the **Reason for Change** section of the page, select or type the reason why you are changing the data.

7   Click **Submit**.

    A confirmation dialog box appears.

8   Click **OK**.

9   Click **Return**.

    You return to the form. Note the changes of appearance in the item:

- If the data change answers a query, the background color changes from pink to gray.

- If the data change clears the value from the item, the item is incomplete. The background color changes from gray to yellow.

- If this was the first time the data value was changed since initial data entry, the audit trail icon changes from gray to yellow to indicate the existence of additional events in the audit trail.

    If you deleted an itemset:

- The original itemset values are visible but crossed out.

- If the itemset or item had a query, the query is cleared.

- If the itemset row was part of a rule, the rule is not refreshed.

What to do if a new data item value results in a query

If the value to which you changed a data item fails an edit check, the InForm application generates a query, which you can answer by doing one of the following:

To change the data value again:

1   Check that the value was entered correctly.

2   Check that the value matches your source data.

3   Check the study documents, including CRF Help, if it is available, to find the range of permitted values for the item.

    Change the data if necessary.

4   Click the current item value, and proceed as described in Changing form data.

To enter answer text:

Follow the instructions in *Answering a query by submitting answer text* (on page 164).

Reviewing the audit trail

Each time you change the value of a data item, an audit trail records the date and time of the change, the user name of the person making the change, and the reason for the change. You can review the audit trail of an item in several ways:

- **On the Data Value(s) page**—Select a change date and time from the **Audit Trail** list.

  The change details appear in the Reason for Change section.

- **On the Data Value(s) page**—In the navigation pane, click **Audit Trail**.

- **On the form**—Click the audit trail icon for an item.

Printing a CRF

1   Navigate to the CRF.

2   Optionally, in the **Select Action** drop-down list, select **Print Preview**, and click **Apply**.

     A preview of the CRF appears.

3   Click **Print**.

Adding an unscheduled visit for a subject

If your study has unscheduled visits, the Case Report Books list and Time and Events Schedule include an **Unscheduled** column.

1   Navigate to an unscheduled visit for the subject.

- If the subject does not have any unscheduled visits, in the content pane, click **New** to display a blank visit.

2   In the **Date and Time of Visit** field on the first CRF of the visit, type the visit date and time.

3   Click **Submit**.

If the visit contains more than one form, the additional forms become visible after you submit the date and time. The Time and Events Schedule is updated to show the name of the unscheduled visit.

4   Complete the rest of the visit CRFs.

CHAPTER 7
Queries

In this chapter

Overview of queries

A query is a question that the InForm application automatically generates, or that a CRA or sponsor staff manually creates, when data does not meet certain criteria.

The InForm application provides two main pages for working with queries:

- **Query Listing page**—Displays a summary of all queries and provides links to the form items against which the queries are written.

  For more information, see *Query Listing page* (on page 173) and *Viewing the list of queries* (on page 157).

- **Queries page**—Displays details about a query and allows you to enter an answer.

  For more information, see *About working with queries* (on page 152), *Queries page* (on page 175), and *Viewing the queries for a specific form item* (on page 158).

Query types

The InForm application supports two methods for creating queries:

- **Automatic**—A query that the InForm application generates when a submitted data item does not meet certain criteria that is defined by the study designer.

  An automatic query appears immediately after data submission, and site users can respond to them before data review.

- **Manual**—A query that a sponsor user creates and issues during the review process.

  A manual query is created by Clinical Research Associates (CRAs), Clinical Data Managers (CDMs), or other personnel during source verification or other data review. There are two types of manual queries:

  - **Open query**—The original state of a query that is visible to the site and available for response.

  - **Candidate query**—A preliminary query, issued by a sponsor user, that is visible to sponsor users but not to site users.

Query states

State	Description
Candidate	Queries that are visible only to sponsor personnel; they are not visible to site users. A sponsor representative reviews the query and then either opens or deletes it.
Opened	Queries that are visible to site users and are awaiting response.
Answered	Queries for which a site user submitted a response. • For manual queries, when a site user responds to a query, the query enters the Answered status and is ready for review by the Clinical Data Manager or CRA. • The Clinical Data Manager or CRA reviews Answered queries and either closes or reopens them.
Closed	Queries that have been answered by a site user and then reviewed by a Clinical Data Manager or CRA. If the Clinical Data Manager or CRA is satisfied with the query answer, he or she closes the query.

Your study can be set up to allow you to issue queries in the **Opened** or **Candidate** states.

About working with queries

The Queries page displays details about a query and allows you to enter an answer.

> **Note:** You must be a member of a query group in order to work with any queries generated by a user in the group (for example, to answer or close queries).

The Queries page has several main sections:

- **Current Data Value**—Displays the current value of the data item. For more information, see *Query—Data Value section* (on page 153).

- **Query Action**—Provides a list of options (as buttons) depending on the type of query you selected. For more information, see *Query—Action section* (on page 154).

- **Query History**—Provides access to the query history. To view the query history, select the radio button next to the query of interest in the Current Data Value section.

- **Context buttons**—Appear at the bottom of the content pane.

  - **Create Query**—Available for users who have the right to create a query.

  - **Submit**—Appears if you selected a Query Action button. It submits either a data change or query change, depending on which button you selected in the Query Action section. After the submission, the application leaves the Queries page, and navigates back to the page you came from (the Query Listing page or the CRF).

  - **Return**—Navigates you back to the page you came from (the Query Listing page or the CRF).

You can answer queries by changing the data on the Queries page, or by viewing the query and then navigating to the Data Values page to change the data.

- For manual queries, when you answer a query by changing the data, the Automatically answer manual queries configuration option is ignored and the query is automatically answered by the data change. The Automatically answer manual queries option is used in every other part of the InForm application, including all other data entry and update screens, and PFImport.

- For automatic queries, if an associated rule passes after a data change, the query is closed; otherwise, it remains open.

Query—Data Value section

The Data Value section on the Queries page displays:

- The current value of the data item.

- All the queries you have the rights to see if the Hide Closed Queries option is deselected.

- All the queries you have the rights to see, except for closed queries, if the Hide Closed Queries option is selected.

- Answered, Open, and Candidate queries on a pink background.

- Closed and Deleted queries on a white background.

- Open and Candidate queries in red text.

- Answered queries in black text.

- Closed queries in gray text.

- Queries with radio buttons for selection and an icon representing the query state.

  Selecting the radio button for a query changes the Query selection, which changes the Query Action and Query History areas of the page.

If you navigate from the Query Listing page or from the CRF by clicking directly on a query, the selected query is passed through and preselected.

Query—Action section

The Query Action section provides a list of options (as buttons) depending on your role and the type of query you selected.

When you click a Query Action button, a new section appears, with a section header and the appropriate form so that you can provide additional detail.

User	State	Button options	Section title when selected
Site	Open	• Update Data & Answer • Answer	• Enter New Data • Answer Query
	Site Conflict	Resolve	Resolve Query
Sponsor	Open	Close	Close Query
	Answered	• Close • Reissue as Candidate • Reissue as Open	• Close Query • Reissue Query as Candidate • Reissue Query as Open
	Candidate (never opened)	• Open • Delete	• Open Query • Delete Query
	Candidate (if previously in open state)	Close	Close Query
	Closed	No actions available.	Query Action section does not appear for closed queries.
	Deleted	No actions available.	Query Action section does not appear for deleted queries.
	Sponsor Conflict	Resolve	Resolve Query

Query workflow—For a site user

The site user can arrive at the Queries page either through the Query Listing page or through the CRF. The page that appears has two options:

- **Update Data & Answer**—When you click this button, a pane appears to let you edit the data.

  When you click this button and edit data for the item on which the query appears, the query is always answered.

  > Note: The Update Data & Answer button appears only if you have the right to change data and the right to change the query state from its current state. If you do not have the right to change the current state of the query, you can still navigate to the page that shows the Current Data Value and the Query History.

- **Answer**—When you click this button, a pane appears to let you answer the query by entering a reason.

Query workflow—For a sponsor

Sponsor users do not answer queries. Instead, they either open new queries or decide whether an answered query can be closed.

Query—Update Data and Answer

Option	Line in new section	Detail
Update Data & Answer	New Value Line	CRF item name with editable fields.
	Date Entered	Date will be filled in upon submit.
	Entered By:	Pre-filled with user name.
	Reason for change:	Radio buttons for the preset response drop-down list and Other textbox.
Answer and all other query response	Action:	Static text with the query action chosen when you have the rights to only one query action. The Action is chosen through the Query Action buttons.
	Reason for change:	Radio buttons for the preset response drop-down list and Other textbox.

Query descriptions

By default, the InForm application displays up to 350 characters in a query description that appears on a CRF.

> **Note:** This setting is not the maximum length of a query; it is the maximum number of characters in the query that display on the **Case Report Form**.

Viewing the list of queries

- In the navigation toolbar, click **Queries**.

    The Query Listing page appears. For a description of the fields on this page, see *Query Listing page* (on page 173).

Viewing the queries for a specific form item

- Do one of the following:

    - From the form, click the underlined query text or the query icon.

    - From the **Query Listing** page, click the underlined query text in the **Description** column.

    The Queries page appears. For a description of the fields on this page, see *Queries page* (on page 175).

Navigating between queries and CRFs

Use the following links to navigate between the Query Listings page, the Queries page, and the form on which the query is located.

To navigate from this page	To this page	Use this control
Queries page	The form on which the query was entered.	Time and Events arrow ().
CRF	Queries page	The underlined text of the query.
Query Listing page.	Queries page	The underlined text of the query.
Queries page	Query Listing page.	Return button.

Issuing queries

Issuing a query

> **Note:** You can also create a query in the Data Viewer. For more information, see *Creating a query in the Data Viewer* (on page 257).

1 In the navigation toolbar, click **Subjects**.

   The Case Report Books page appears.

2 Click the status icon for the subject and visit in which to create a query.

3 In the navigation pane, use one of the form selectors to choose a form.

   The form appears.

4 Do one of the following:

   - **For a regular item**—Click the **Create query** icon ( ) in the farthest-right column of the item.

   - **For an item in an itemset or a repeating form instance**—Click the itemset or repeating form instance row number, and click the **Create query** icon ( ) in the farthest-right column of the item.

   The Queries page appears. If the item has no queries, the Queries page is blank. If the item has at least one query, the most recent query appears.

5 Click Create Query.

6 From the **Action** drop-down list, select a state for the query.

   - Create Query in Opened State

   - Create Query in Candidate State

> **Note:** Both options appear if you have the rights to create a query in either the Candidate or Opened state. If you have only one of these access rights, the state is preselected.

7 In the **Reason for change** field, enter the reason for issuing the query.

   - From the **Action** drop-down list, select the appropriate text.

     or

   - Select **Other**, and type the reason in the text box.

8 Click **Submit**.

   The form on which you entered the query appears. For more information, see *Appearance of items with opened queries* (on page 161) and *Appearance of items with candidate queries* (on page 161).

9 Optionally, in the navigation toolbar, click Queries to return to the Query Listing page, and use the Query Status filter to see the status of all queries on this item.

Appearance of items with opened queries

An Opened query on a form item has the following attributes:

- The background color of the item is pink.

- The query text is red and begins with the word **Open**.

- The query text appears under the item.

- The Query icon ( ) appears in the far-right column of the item.

> Note: To open the Queries page to view detailed information, click the query text.

> Note: On the summary page for itemsets, not all items with open queries have query links. Although the cell backgrounds for all items with queries are pink, query links appear only on items that are defined with simple controls. Items with nested controls do not have links. To work around the issue, navigate to the query using the link on an item that does not contain nested controls.

Appearance of items with candidate queries

> Note: A Candidate query is not visible to site users until the query is opened.

A Candidate query has the following attributes:

- The Query icon ( ) appears in the far-right column of the page.

- The background color and query text do not change until the query status is changed to Opened by a user with the rights to make that change.

Changing a candidate query to an opened query

1   In the navigation toolbar, click **Queries**.

The Query Listing page appears.

2   From the **Query Status** drop-down list, select **Candidate**. Optionally, use the drop-down lists to filter the queries by site or subject.

3   In the **Description** column, click a query link.

The Queries page appears.

4   Click **Place Query in Opened State**.

5   In the **Reason for change** field, enter the reason for placing the query in the opened state:

- From the **Action** drop-down list, select the appropriate text.

    or

- Select **Other**, and type the reason in the text box.

6   Click **Submit**.

Deleting a candidate query

1   In the navigation toolbar, click **Queries**.

   The Query Listing page appears.

2   From the **Query Status** drop-down list, select **Candidate**. Optionally, use the drop-down lists to filter the queries by site or subject.

3   In the **Description** column, click a query link.

   The Queries page appears.

4   Click **Delete Query**.

5   In the **Reason for change** field, enter the reason for deleting the candidate query.

   - From the **Action** drop-down list, select the appropriate text.

      or

   - Select **Other**, and type the reason in the text box.

6   Click **Submit**.

Answering queries

Answering a query by changing the data value

1   In the navigation toolbar, click **Queries**.

The Query Listing page appears. If necessary, filter the list of queries by selecting a particular subject, query status, or query issuer from the drop-down lists at the top of the page.

2   In the **Description** column, click a query link.

The Queries page appears.

3   Click **Data Value(s)**.

The Data Value(s) page appears.

4   Enter the new data value and the reason for change.

5   Click **Submit**.

The InForm application:

- Runs all automated edit checks that exist on the item.

- If the new value fails the edit checks, the InForm application generates new queries.

- If the new value passes all edit checks, the InForm application closes the query.

- Closes all manual queries on the item.

- The audit trail for the item shows that the user who edited the item closed the query.

- Updates the appearance of the form item to reflect the new query state.

What to do if the new data value results in another query

If the InForm application generates a new automatic query when you answer a query by changing the item's data value, you can answer the new query by using one of the following methods:

To change the data value again:

1   Check that the value was entered correctly.

2   Check that the value matches your source data.

3   Check the study documents, including CRF Help, if it is available, to find the range of permitted values for the item.

Change the data if necessary.

4   Click the current item value, and proceed as described in *Answering a query by changing the data value* (on page 163).

To enter answer text:

- Follow the instructions in *Answering a query by submitting answer text* (on page 164).

Answering a query by submitting answer text

1. In the navigation toolbar, click **Queries**.

   The Query Listing page appears. If necessary, filter the list of queries by selecting a particular subject, query status, or query issuer from the drop-down lists at the top of the page.

2. In the **Description** column, click a query link.

   The Queries page appears.

3. Do one of the following:

   - To answer the query by changing the data value on the page, click **Update and Answer**.

     The **Enter New Value** section appears on the page; update the data as needed.

   - To answer the query without changing the data value, click **Answer**.

4. In the **Reason for change** field, enter the reason that describes the answer to the query.

   - From the **Action** drop-down list, select the appropriate text.

     or

   - Select **Other**, and type the reason in the text box.

5. Click **Submit**.

   The InForm application:

   - Changes the status of the query to Answered. The query must be closed manually by a data reviewer who has the right to close queries.

   - Updates the appearance of the form item to reflect the new query state.

Reissuing a query

If a response to a query does not resolve the issue (the answer is unacceptable), you can reissue the query.

1. Navigate to the **Queries** page for the item.

2. Select **Reissue as Open** or **Reissue as Candidate**.

3. In the **Reason for change** field, enter the reason for reissuing the query.

   - From the **Action** drop-down list, select the appropriate text.

     or

   - Select **Other**, and type the reason in the text box.

4. Click **Submit**.

Closing queries

The InForm application closes queries in the following ways:

- **Automatic query generated by the failure of an edit check**—When a user enters a new data value that passes the edit check, the InForm application closes the query.

  If the new data value fails the edit check, the InForm application redisplays the query. When an automatic query is answered with explanatory text, the query can only be closed when an authorized sponsor user closes it.

- **Manual query**—When a user submits an answer to a manual query, the InForm application changes the query state to Answered.

  A sponsor user with query closing rights must close answered queries manually.

Appearance of items with answered queries

An Answered query has the following attributes:

- The background color is pink.

- The text of the query is black in color and begins with the word **Ans'd**.

To view query details, click the **Query** icon () to the right of the query text. The query expands to show the following information:

- The date the query was answered.

- The name of the person who answered the query.

- The answer to the query.

Finding answered queries from the Query Listing page

1   In the navigation toolbar, click **Queries**.

    The Query Listing page appears. If necessary, filter the list of queries by selecting a particular subject, query status, or query issuer from the drop-down lists at the top of the page.

2   From the **Query Status** filter, select **Answered**.

    Optionally, use the drop-down lists to filter the list of queries to display queries for a specific site or subject.

3   Locate the query to open.

Finding answered queries from the Case Report Books page

1 In the navigation toolbar, click **Subjects**.

or

Use the **Subject** field to locate a specific subject.

The Case Report Books page appears.

2 Do one of the following:

- Click the **Subject Number** for a subject who has one or more Answered Query icons.

  The Time and Events Schedule appears. Expand the visit and select the form with the query.

- Click an Answered Query icon.

  The visit opens and you can select the form with the query.

Closing an answered query

1 In the navigation toolbar, click **Queries**.

The Query Listing page appears.

2 In the **Description** column, click the link for the query that you want to close.

The Queries page appears.

3 Review the answer.

4 Click **Close Query**.

5 In the **Reason for change** field, enter the reason for closing the query.

- From the **Action** drop-down list, select the appropriate text.

  or

- Select **Other**, and type the reason in the text box.

6 Click **Submit**.

The InForm application updates the status of the query. The Query Listing page and Queries page show the updated status.

Working with multiple queries

There are two modes on the Query Listing page that you can use to view and perform actions on queries:

- **List view**—Use to view the details of all the queries, or a filtered list of queries. (Default.)

- **Action view**—Use to perform one action on a specified set of queries, and apply the same reason for change to all the queries.

> **Note:** The Action View button that puts the Query Listing page into the Action mode is available only when you select Opened, Answered, or Candidate from the Query Status drop-down list.

When you are in action view mode, you can perform the following actions:

Query Status filter on Query Listings page	Available actions on selected queries
Answered	Reissue the query.
	Close the query.
Candidate	Place the query in the opened state
	Delete the query.
Opened	Close the query.

> **Note:** You can change the display mode by clicking the List View button when in the action view, and clicking the Action View button when in the list view.

Closing or reissuing a set of answered queries

1   In the navigation toolbar, click **Queries**.

   The Query Listing page appears. If necessary, filter the list of queries by selecting a particular subject, query status, or query issuer from the drop-down lists at the top of the page.

2   In the **Query Status** filter, select **Answered**.

3   Click **Action View**.

   A checkbox appears to the left of each query and the Action and Reason fields appear at the bottom of the page.

4   Select the checkboxes to the left of the queries with which you want to work.

> **Note:** To select all queries at one time, select the **Select all checkboxes** icon (☑) at the top of the page.

5   In the **Action** drop-down list, select the action to perform.

   Your rights determine which actions appear in the drop-down list.

6   In the **Reason for change** field, enter the reason for closing or reissuing the query:

   •   From the **Action** drop-down list, select the appropriate text.

      or

   •   Select **Other**, and type the reason in the text box.

7   Click **Submit**.

Opening or deleting a set of candidate queries

1   In the navigation toolbar, click **Queries**.

The Query Listing page appears. If necessary, filter the list of queries by selecting a particular subject, query status, or query issuer from the drop-down lists at the top of the page.

2   In the **Query Status** drop-down list, select **Candidate**.

3   Click **Action View**.

A checkbox appears to the left of each query and the Action and Reason fields appear at the bottom of the page.

4   Select the checkboxes to the left of the queries with which you want to work.

> **Note:** To select all queries at one time, select the **Select all checkboxes** icon () at the top of the page.

5   In the **Action** drop-down list, select the action to perform.

Your rights determine which actions appear in the drop-down list.

6   In the **Reason for change** field, enter the reason for opening or deleting the queries:

- From the **Action** drop-down list, select the appropriate text.

  or

- Select **Other**, and type the reason in the text box.

7   Click **Submit**.

Closing a set of opened queries

1   In the navigation toolbar, click **Queries**.

The Query Listing page appears. If necessary, filter the list of queries by selecting a particular subject, query status, or query issuer from the drop-down lists at the top of the page.

2   In the **Query Status** drop-down list, select **Opened**.

3   Click **Action View**.

A checkbox appears to the left of each query and the Action and Reason fields appear at the bottom of the page.

4   Select the checkboxes to the left of the queries with which you want to work.

> **Note:** To select all queries at one time, select the **Select all checkboxes** icon (☑) at the top of the page.

5   In the **Action** drop-down list, select the action to perform.

Your rights determine which actions appear in the drop-down list.

6   In the **Reason for change** field, enter the reason for closing the queries.

- From the **Action** drop-down list, select the appropriate text.

    or

- Select **Other**, and type the reason in the text box.

7   Click **Submit**.

Hidden queries

If you expect to see a query, but it is not there, that item is marked as hidden for your user group. If during study design an individual item is marked as hidden for your user group and a query appears for that item, the query will not be visible to you.

Understanding query conflicts

Query conflicts can occur if multiple users are working on more than one copy of the same study. For example, if one user makes a change, and a second user makes another change before the first change is synchronized to both computers, a query conflict can occur.

User interface—Queries

Query Listing page

The Query Listing page displays a summary of all queries and provides links to the items against which the queries are written.

- One query displays per row.

- Thirty queries appear on the page by default.

Fields

Field	Description
Subject filter	Filters page content based on the subject.
Query Status filter	Filters page content based on the state of the query. The default value depends on your role. • All • Opened—Default for Site users. • Answered—Default for Sponsor users. • Closed
Issuer filter	Filters the page content based on who created the query.
Site filter	Filters the page content based on the site.
Status	Displays an icon representing the query state. Use the hover Help for a description of each icon. • Candidate • Open • Answered • Closed • Deleted • Site Conflict • Sponsor Conflict

Field	Description
Age	Number of days the query has been in the current state.
	• This column shows the number of days since the last change to the query state. This is computed as the number of complete multiples of 24 hours. Anything less than 24 hours shows as "New." For example, a query that has not been modified in 47 hours shows as "1 day", while a query that has not been modified in 49 hours shows as "2 days."
	• For closed queries, the Age column is blank.
	Note: All time calculations are done with Greenwich Mean Time (GMT) so that time zones play no role in the calculations.
Site	Full name of the site.
Subject	Subject name.
Visit	Name of the visit.
CRF	Name of the form.
Issuer	User who created the query.
Description	The query text. The link opens the Queries detail page for the specific query.

Buttons

Button	Description
Page selector	A multi-part control on the bottom-left of the content pane.
	By clicking different parts of the control, you can move through the pages of the Query Listing when the list of queries fills more than one page.

Queries page

The Queries page displays details about a query and allows you to enter an answer.

Fields

Field	Description
Current data value	The current value of the data item appears at the top of the page.
Query History	If more than one query has been issued on an item, the history list allows you to view details about each query.
Query details	Provides details about the query that was selected in the History List. The appearance of this section varies with the type of query activity for which you are responsible, and with the state of the query.
	For example, if you have the right to answer a query, a row called Answer Text includes the controls for answering a query. After you submit an answer, the Answer Text row becomes a read-only section in which your answer is visible, and the query state changes to Answered. If you have the right to issue a query, the Query section includes data-entry controls in the Query Text row.
Command buttons	The command buttons in the content pane allow you to submit a query response or to return to the form.

Buttons

Button	Description
Create Query	Displays fields that you can use to create a new query.
	Available if you have the right to create a query.
Submit	Appears if you selected a Query Action button and submits either a data change or query change, depending on which button you selected in the Query Action section. The Queries page closes and you are returned to the previous page (CRF or Query Listing).
Return	Returns you to the previous page (CRF or Query Listing).

C H A P T E R   8

Source verification

In this chapter

Overview of source verification

Source verification allows you to verify the data entered on forms against source documents, and to mark the data items you have verified to indicate that they are complete. The forms can be marked as verified or not verified from the Source Verification Listing page or from the Data Viewer.

During study design, any item that should be source verified is marked as SV Required by the study designer. You can decide whether all the data marked as SV Required during study design must be source verified, or if the amount of data to be source verified can be reduced using partial source verification (Partial SV). For more information, see *Partial source verification (Partial SV)* (on page 179).

You can perform source verification:

- Online, from the Source Verification Listing page or from the Data Viewer.

  For more information, see *Online source verification* (on page 199) or *Marking records Verified or Not Verified in the Data Viewer* (on page 261).

- Offline, from a printed listing.

  For more information, see *Offline source verification* (on page 207).

> **Note:** Form or data changes invalidate source verification. For more information, see *How a form change affects source verification* (on page 209).

Partial source verification (Partial SV)

Partial source verification (Partial SV) allows you to control, for each site, what data marked as SV Required during the study design must be verified for all subjects in the study. When you use Partial SV, the only data that requires verification is the data that fits the criteria that you provide.

Partial SV provides the flexibility to force the source verification of specific forms all of the time.

> Note: Partial SV is configured at the site level.

Partial SV terminology

Term	Description
SV	Source verification.
SV Pool	A collection of subjects. You can add subjects to this collection either manually or through an auto-selection process.
General Pool	All the subjects in the study at a site.
Auto-select Pool	The automatically selected portion of the SV Pool. The selections are based on the SV Target Rate.
SV Target Rate	The percentage at which you want subjects to be selected for source verification after the initial subjects are verified.
Excluded Subject	A subject that is not in the SV Pool and is not eligible for consideration for automated selection.
Manual Pool	The manually selected portion of the SV Pool.
SV Eligible Pool	The subjects that can be added to the SV Pool through the auto-selection process, based on the SV Target rate.
	For example:
	SV Eligible Pool = [General Pool] – [SV Pool] – [Excluded subjects]
Critical Form	A form that must be source verified even if the corresponding subject is not a member of the SV Pool.
	• Critical forms are those forms, which contain data of critical importance to the sponsor, that must be source verified for all subjects in a site.
	• Examples of such data might be Adverse Event forms and Concomitant Medication forms. Sponsors can assign a set of forms to the critical forms list for a site.

Term	Description
Critical item or itemset	An SV Required item or itemset that is designated as critical in any of three ways: • In the Central Designer application during study design. • Using MedML in the InForm application. • Using the Set SV Settings dialog box in the InForm user interface. Only items or itemsets that are SV Required can be designated as critical. Not all items on a form need to be critical.

Partial SV and items marked as SV Required during study design

During the study design, any item that must be source verified is marked as SV Required by the study designer. If you are using Partial SV, items marked as SV Required must be source verified in the InForm application only if the following selections are made:

- **Partial SV Subject Selection**—SV Required items are on a form associated with a subject that is selected for Partial SV (that is, the subject is in the SV Pool).

  For more information, see *Subjects and the SV Pool* (on page 181).

- **Partial SV Form Selection**—SV Required items are on a form that is identified as a critical form.

  - Every SV Required item on the form is considered critical.

  - Items on the form that are not SV Required are not considered critical.

  For more information, see *Critical forms* (on page 185).

- **Partial SV Item Selection**—SV Required items or itemsets on a form are designated as critical.

  In the InForm application, you can override the criticality defined for an item or itemset in the Central Designer application. Items that are only SV Required, but are not critical (either through the Item SV Critical property or the SV Critical override) are not considered to be critical.

  For more information, see *Critical items* (on page 186).

> **Note:** In cases where there are multiple Partial SV settings in effect, the critical subjects and critical forms selections take priority over the critical item selections. For more information, see *When item-level source verification takes effect* (on page 186).

Subjects and the SV Pool

The Source Verification Pool of Subjects (SV Pool) is a collection of subjects. The subjects identified for source verification at a site are managed in the SV Pool. You can add subjects to this collection either manually or through an auto-selection process.

- Manual subject selection

  - Add subjects one at a time, or import an externally created list of subjects.

    For more information, see *Manually selected subjects* (on page 183) and *Imported subjects* (on page 183).

  - Exclude individual subjects.

    For more information, see *Excluded subjects* (on page 184).

- Automatic subject selection

  Subjects are automatically selected based on an SV Target Rate (% of subjects) that you define and change as needed throughout the study. For more information, see *Configuring Partial SV* (on page 190).

The InForm application manages both the manually selected and automatically selected subjects identically with the exception that the manually selected subjects do not count as part of the SV Target Rate calculation.

> **Note:** All subject pools are managed at the site level.
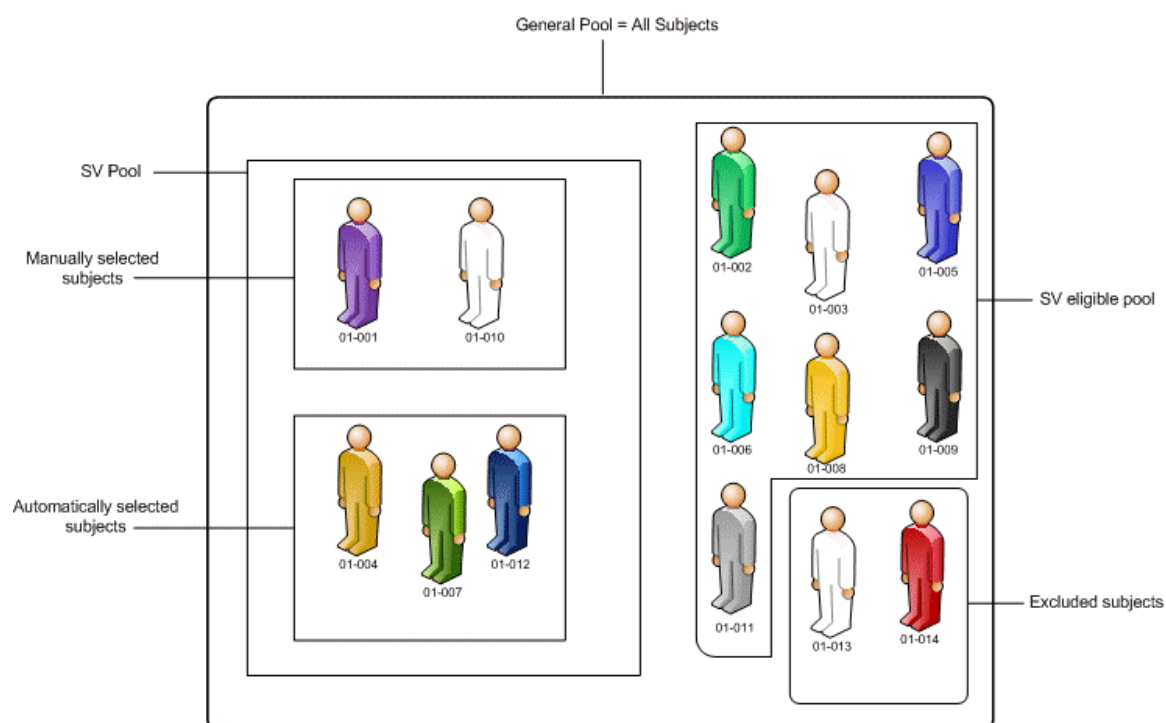
Automatically selected subjects

Automatically selected subjects are those subjects that are added to the SV Pool based on:

- The number of initial subjects enrolled in the site that you want to be source verified. The default is 0.

  These subjects are added automatically to the Manual Pool, but are otherwise the same as other manual subjects.

- A percentage (0 to 100%) target rate at which you want subjects to be selected for source verification after the initial subjects are verified (the SV Target Rate). The default is 100%, which means all subjects are selected.

  - If you increase the target rate, the auto-selection process only considers subjects from the SV Eligible Pool.

  - If you decreases the target rate, the auto-selection process ranks subjects in the Auto-select Pool for return to the SV Eligible Pool based on the current number of forms already source verified.

    For example:

    If subject 01-004 has one form source verified, subject 01-007 has two forms source verified, and subject 01-012 has three forms source verified:

    - The process returns 01-004 to the SV Eligible Pool if the rate reduction called for removing a single subject.

    - If the rate reduction called for removal of two subjects from the Auto-select Pool, then subjects 01-004 and 01-007 would be returned.

      This occurs so that reduction of the Auto-select Pool maintains a preference for retaining subjects with the highest number of SV Complete forms for the study. This ensures that the least amount of additional source verification work is required when the target rate is reduced.

Manually selected subjects

Manually selected subjects are those subjects that you explicitly add to the SV Pool. The Manual Pool is the user-managed portion of the SV Pool.

You can add subjects to the Manual SV Pool from either the Auto-select Pool or the SV Eligible Pool.

> **Note:** Manually-selected subjects are not considered in the SV Target Rate calculation. The auto-select process never considers subjects from the Manual Pool or the Excluded Subjects list. Moving subjects between the Manual Pool and the Excluded Subjects list are the only actions that do not require the Auto-select Pool to be recalculated.

Source pool	Destination pool	Auto-select reprocessing required?
SV Eligible	Manual	Yes
SV Eligible	Excluded Subjects	Yes
Manual	SV Eligible	Yes
Manual	Excluded Subjects	No
Auto-select	Manual Pool	Yes
Auto-select	Excluded Subjects	Yes
Excluded Subjects	Manual	No
Excluded Subjects	SV Eligible	Yes

Imported subjects

Imported subjects are those subjects that you add to the Manual SV Pool by importing an externally created list of subjects. These subjects are not part of the Auto-select Pool, and they do not affect the SV Target Rate for the site.

> **Note:** The SV Target Rate only applies to the automatically selected subjects in the SV Pool. Therefore, none of the subjects introduced into the SV Pool through the import process are affected.

When you import a subject list, the InForm application filters out subjects not present in the site, excluded subjects, and subjects already present in the Manual Pool.

The result is a list of qualified subject IDs to be added to the Manual Pool. For subjects that cannot be added to the Manual Pool, a notification dialog box appears. The dialog box displays a scrollable list of subjects successfully added, along with a list of subjects not meeting the acceptance criteria.

Excluded subjects

Excluded subjects are those subjects that are not in the SV Pool and are not eligible for auto-selection. Subjects that you manually remove from the SV Pool either return to the General Pool as eligible for reconsideration in the auto-selection process, or are designated as Excluded.

Excluded subjects are removed from the SV Eligible Pool, and cannot be added to the SV Pool through auto-selection.

Excluded subjects:

- Are not restricted in any other way from participating in the study events, visits, and so on.

- Still require their Critical Forms to be source verified as any other subject in the SV Eligible Pool.

Subjects removed from the Excluded Subject list are placed in the SV Eligible Pool.

Critical forms

Critical Forms are those forms whose data is determined to be of critical importance to the sponsor and must be source verified for all subjects in a study at a site. Examples of such data might be Adverse Event forms and Concomitant Medication forms.

Critical Forms are specified by site in the InForm application as those forms that always require source verification, for all subjects at that site.

For each site, you can select a subset of forms to include in the Critical Forms list. This list identifies all the forms to be source verified for all subjects in the study (that is, the General Pool). These are forms that must be source verified even if the corresponding subject is not a member of the SV Pool.

You can:

- Choose which forms to verify across all subjects.

    For example, the demographic, adverse events, and concomitant medications for all subjects.

- Force the source verification of specific forms all of the time.

- Change the form selection criteria at any time during the study.

After you define the Critical Forms list, the InForm application processes the list of subjects in the SV Pool to determine which form instances require source verification for the site. You can run this process multiple times during the study to determine the set of form instances that require source verification for the site.

You can specify Critical Forms through the InForm user interface or using MedML. For more information, see *Configuring Partial SV* (on page 190) or the *Utilities Guide*.

Considerations for selecting critical forms

Sponsors can assign a set of forms to the Critical Forms list for a site.

The Critical Forms list needs to take into account forms that could be present in earlier study versions that may no longer be present in the current study version. For any forms that fall under this description, any with data entered for any subject in the study need to be maintained in the Critical Forms list throughout the life of the study. This allows the sponsor to select from all forms that could have been selected in the past as Critical Forms even if they are no longer present in the latest study version.

Forms not selected for SV

The InForm application does not prohibit you from verifying forms that are not currently selected for source verification.

You can enter Verify mode, verify the appropriate items on a form, and submit the changes even if the form is not marked as SV Required. This allows you to verify more forms than were selected by the SV Target Rate.

Critical items

Critical items or itemsets are those designated as both SV Required and critical.

Items or itemsets can be designated as critical in three ways.

- **In the Central Designer application**—The study designer specifies a property of an item or itemset to be SV Required and SV Critical.

    For more information, see the Central Designer *InForm Design Guide.*

- **With MedML in the InForm application**—A system administrator can use MedML to manually override the SV Critical property for an item or itemset that was defined in the Central Designer application. MedML can be used to apply overrides for one site or across all sites.

    For more information, see the *Utilities Guide.*

- **With the Set SV Settings dialog box in the InForm user interface—**If you have the proper rights, you can use the Set SV Settings dialog box to manually override the SV Critical property for an item or itemset that was defined in the Central Designer application. The user interface can be used to apply overrides for one site.

    You can choose one of the following override options.

    - **Study Default**—Use the criticality set for the item during the study design in the Central Designer application.

    - **This Form**—Set the item to critical for only the selected form.

    - **All Forms**—Set the item to critical for all forms. All instances of the item must be verified, not just the items on the form on which you set the override.

    - **Not Critical**—Set the item to not critical for only the selected form.

If an itemset is designated as critical, all items within the itemset are critical. However, because the InForm application verifies itemsets at the row level, and not by individual items, setting an item within an itemset as critical has no effect.

When item-level source verification takes effect

The critical property for an item takes effect in the InForm application only when the form that the item is on will not otherwise be verified, due to the Partial SV settings for subjects and forms.

By default, all subjects are verified. However, if you use the InForm user interface to limit the set of subjects and forms to be verified, all subject and forms no longer need to be verified.

- If a subject or form is selected to be verified, every SV Required item for those subjects and forms must be verified.

- On all other forms that are not selected to be verified, only the items that are designated as critical (not all the SV Required items) must be verified.

Critical items—Effective SV states

The Effective SV state is a status that indicates the criticality of an item based on the study and override settings. This information appears in the Set SV Settings dialog box. For more information, see *Set SV settings dialog box* (on page 212).

Study setting	Override	Effective SV state
Not Critical	No Override	Not SV Critical
Not Critical	Critical This Form	SV Critical
Not Critical	Critical All Forms	SV Critical
Not Critical	Not Critical	Not SV Critical
Critical	No Override	SV Critical
Critical	Critical This Form	SV Critical
Critical	Critical All Forms	SV Critical
Critical	Not Critical	Not SV Critical

About the Critical All Forms Effective SV state

When you set the Critical All Forms override, you are applying the same override to all forms on which the item exists. All instances of the item must be verified, not just the items on the form on which you set the override.

When you change the override from Critical All Forms to something else, the new state is applied to the current form and all other item instances are set to No Override.

For example:

Assume there is an item (Item1) on two forms (Form A and Form B) and the item is not marked as critical in the study design.

- If you set Item1 to Critical All Forms, the item will be considered critical for both Form A and Form B.

- If you change the setting on Item1 from Critical All Forms to Critical This Form:

  - Item1 on Form A will be considered critical.

  - Item1 on Form B becomes not critical because the initial study setting for the item was not critical.

Checklist—Criteria for configuring Partial SV

To use Partial SV, you must set certain criteria for each site that you have access to. All of the items listed in the following table are defined through the InForm user interface in the Set SV settings dialog box, which is available from the Source Verification Listing page and the Data Viewer. For more information, see *Configuring Partial SV* (on page 190).

☑	Step	Description	For more information, see
❏	1 Select a site.	The site for which you want to configure Partial SV.	*Set SV settings dialog box* (on page 212).
❏	2 Specify whether to use Partial SV.	• **Source Verify all Data (default)**—Select to disable partial source verification for the selected site. When you select this option, you are setting the subject selection rate to 100%. All forms with at least one item set as SV Required must be verified. All other options in the Set SV settings dialog box are disabled. • **Partial Source Verification**—Select to enable partial source verification for the selected site. When you select this option, you are choosing to use Partial SV. All options in the Set SV settings dialog box are enabled.	*Partial source verification (Partial SV)* (on page 179).
❏	3 Set up the Subject list.	Identify the subjects to source verify.	
		• Set the **Number of initial subjects**—The number of initial subjects enrolled in the site that you want to be source verified. The default is 0.	*Subjects and the SV Pool* (on page 181).
		• Set the **Subject selection rate after initial subjects** (the SV Target Rate)—The percentage at which you want subjects to be selected for source verification after the initial subjects are verified. This is the percentage of subjects that the automated subject selection algorithm attempts to meet. The default is 100%, which means all subjects are selected.	*Automatically selected subjects* (on page 182).

☑	Step		Description	For more information, see
		• **Enter or import subjects**—You can manually select the subjects for a site that you want to be source verified, or you can have the InForm application automatically select them based on the SV Target Rate that you define. Alternatively, you can import a text file that specifies a set of subjects that you want to source verify.	*Manually selected subjects* (on page 183). *Imported subjects* (on page 183).
		• **Decide whether to exclude subjects**—You can exclude a subject from the SV Pool.	*Excluded subjects* (on page 184).
❑	4	Set Critical Forms List	Identifies the forms to source verify for all subjects. You manually select the forms that you want to always be source verified. These are the forms that you want verified for all subjects in the site. You can change the form selection at any time during the study.	*Critical Forms* (on page 185).
❑	5	Set the criticality overrides for items, as needed.	Identifies whether to manually override the criticality setting for the items or itemsets.	*Critical items* (on page 186).

Configuring Partial SV

1   To configure Partial SV from the Source Verification Listing page:

   a   In the navigation toolbar, click **Monitor**.

      The Source Verification Listing page appears.

   b   Click **Set SV Settings**.

      The Set SV settings dialog box appears. For a description of the fields on this page, see *Set SV settings dialog box* (on page 212).

   c   Proceed to step 3.

2   To configure Partial SV from the Data Viewer:

   a   In the navigation toolbar, click **Review**.

      The Summary View appears.

   b   In the Data Viewer toolbar, select **Options > Set SV settings**.

      The Set SV settings dialog box appears. For a description of the fields on this page, see *Set SV settings dialog box* (on page 212).

3   In the **Site** drop-down list, select the site for which you want to configure Partial SV.

   •   To view the audit history for the site, click the **Audit History** icon (   ) next to the **Site** drop-down list. For more information, see *Set SV settings—Audit History dialog box* (on page 215).

4   Indicate whether you want to disable or enable partial source verification for the selected site.

   •   To disable Partial SV, select **Source Verify all Data**.

      When you select this option, you are setting the subject selection rate to 100%. All forms with at least one item set as SV Required must be verified. All other options in the Set SV settings dialog box are disabled.

      The **Subject selection rate after initial subjects** field is automatically set to 100%, and is then disabled.

   •   To use Partial SV, select **Partial Source Verification**.

      When you select this option, you are choosing to use Partial SV. All options in the Set SV settings dialog box are enabled.

5   Click the **Subject Selection** tab.

6   In the **Number of initial subjects** field, enter the number of initial subjects enrolled in the site that you want to be source verified. The default is 0.

7   In the **Subject selection rate after initial subjects** field, enter the **SV Target Rate**.

This is the percentage at which you want subjects to be selected for source verification after the initial subjects are verified.

This is the percentage of subjects that the automated subject selection algorithm attempts to meet. The default is 100%, which means all subjects are selected.

> **Note:** The default rate of 100% refers to all forms associated with any subject in the site that has at least one item marked as SV Required.

8   Optionally, in the **Enter subject number** drop-down list, type the Subject ID or select a subject number that you want to add to the **Subjects selected for verification** list, and click **Add**.

The subject number appears in the adjacent box.

a   To display all the available, enrolled subjects for the site, clear the **Enter subject number** drop-down list.

b   To exclude a subject, select its number in the **Subjects selected for verification** list box, and click the **Remove** icon (❌) one time.

A grey Exclude icon (⬜) appears next to the subject number in the list box. All excluded subjects appear in the list with the Exclude icon and the Removed label.

The excluded subject is removed from the SV Eligible Pool.

c   To remove a subject from the list, select its number in the **Subjects selected for verification** list box, and click the **Remove** icon (❌) two times.

The removed subject is returned to the SV Eligible Pool.

> **Note:** Manually-selected subjects are not considered in the SV Target Rate calculation.

9   Optionally, to import subjects, click the **Import Subject List** link.

The Import Subject List dialog box appears. For a description of the fields on this page, see *Set SV settings—Import subjects dialog box* (on page 215).

a   Click **Browse**, navigate to the file, and click **Submit**.

When you import a subject list, the InForm application filters out subjects not present in the site, excluded subjects, and subjects already present in the Manual Pool.

The result is a list of qualified subject IDs to be added to the Manual Pool. For subjects that cannot be added to the Manual Pool, a notification dialog box appears. The dialog box displays a scrollable list of subjects successfully added, along with a list of subjects not meeting the acceptance criteria.

b   Click **OK** to close the **Set SV settings—Import subjects** dialog box.

10   Click the **Critical Data** tab.

11 Select the forms that you want to include in the Critical Forms list.

These are the forms that you want verified for all subjects in the site. You can change the form selection at any time during the study.

The InForm application does not prevent you from verifying forms that are not currently selected for source verification. That is, you can enter Verify mode, verify the appropriate items on a form, and submit the changes even if the form was not set as SV Required during study design. This allows you to verify a greater number of forms than what was selected by the SV Target Rate.

a In the **Critical** column, select the checkbox next to every form that you want to select as critical.

- For a form designated as critical (the Critical checkbox is selected), the critical item selection is disabled, and the **CRF has been marked SV Critical** message appears in the item section area of the dialog box.

- For a form designated as not critical, the items and itemsets on the form appear in the item section of the dialog box.

- Hover over the form name to display the FormRefName as a tooltip.

b To remove a form from the Critical Forms list, deselect the checkbox in the **Critical** column next to the form.

12 Override the SV Critical setting for an item or itemset, as needed.

a In the **Forms** column, highlight a form.

The names of all the form items and itemsets appear in the right-hand pane, with the following information:

- **Question**—The question field on the selected form.

  Study Critical items are marked with a superscript asterisk (*) at the beginning of the Item Question. For an itemset where the Item Question is blank (empty), the Item Question is replaced by the text: [ITEMSETREFNAME] is an ITEMSET.

- **Item**—The item or itemset on the selected form.

  The list of items on the form includes all items from current and previous study versions. This allows items started on earlier study versions to be marked critical.

  Only items designated as SV Required are included in the selection list.

  Only itemset parent items appear, and not the child items of the itemset.

- **Effective SV State**—A status that indicates the criticality of an item based on the study and override settings. The options are Not SV Critical and SV Critical. For more information, see *Critical items—Effective SV states* .

- **Override**—A status that indicates the SV Critical override setting for the item or itemset.

13 In the **Override** column, for each item, select one of the following options.

- **Study Default**—The criticality set for the item during the study design.

- **This Form**—Sets the item to critical for only the selected form.

- **All Forms**—Sets the item to critical for all forms. All instances of the item must be verified, not just the items on the form on which you set the override. For more information, see *About the Critical All Forms Effective SV state* (on page 187).

- **Not Critical**—Sets the item to not critical for only the selected form.

14 Click **OK** to save any changes you made to the Partial SV settings.

The **Reason for Change** dialog box appears.

15 Enter a brief description of the configuration changes you made, and click **OK**.

How Partial SV affects InForm features

SV status icons and Partial SV

Using Partial SV does not change any of the icons in the user interface to visually differentiate forms that require SV from forms that do not require SV.

Only forms that require source verification appear on the Source Verification Listing page. In all other areas of the InForm user interface there is no filtering of forms based on the Requires SV form state. To view any forms not selected for SV, you can navigate to the desired forms through other parts of the user interface, such as the Time and Events Schedule and Case Report Books page.

Subject transfers and Partial SV

The InForm application allows subjects to transfer between sites during a study. All subjects not on the Excluded Subjects list that transfer to a different site are automatically added to the Manual Pool for inclusion in the SV Pool. This simplifies the process of changing the General Pool on the destination site, because manually added subjects have no effect on the SV Target Rate. Subjects on a site's excluded list that transfer to a new site are automatically added to the excluded list on the new site.

Source site pool	Destination site pool	Auto-select required on Source site pool?
SV Eligible	Manual	Yes. The auto-select process is rerun on the Source site.
Manual	Manual	No. The auto-select process is not rerun on the Source site.
Excluded Subjects	Excluded Subjects	No. The auto-select process is not rerun on the Source site.
Auto-select	Manual	Yes. The auto-select process is rerun on the Source site.

Audit trail and Partial SV

The InForm application creates an audit trail entry when you change a Partial SV configuration parameter.

Note: Subjects selected by the auto-select process are not logged in the audit trail.

Event	Audit data	Example audit message
Change SV Target rate	User, Site, Old rate, New rate, Reason for change	SV Target rate for Site A is 5 %.
Change First N subjects selected	User, Site, Old value , New value, Reason for change	Number of initial subjects is 5 for Site A.
Change in Manual Subject list	User, Site, Action (Add/Remove), Subject, Reason for change	Subject XYZ added to the manual subject list for Site A.
		Note: Adding users to the Manual Pool through the file import process produces audit trail messages similar to the "Change in Manual Subject list" example. The import only references subjects that were added successfully. Subjects that fail import due to an error are not logged.
Change in Excluded Subject list	User, Site, Action (Add/Remove), Subject, Reason for change	Subject XYZ added to the excluded subject list for Site A.
Change in Critical Forms	User, Site, Action (Add/Remove), Form, Reason for change	Form 123_1 added to the critical forms list for Site A.
Change in Critical Items	Add critical item, Remove critical item	Item [NAME] on [FORM NAME/ALL FORMS] is added to the critical item list.
		Item [NAME] on [FORM NAME/ALL FORMS] is removed from the critical item list.

Locked forms and Partial SV

The InForm application allows monitors to lock forms that are in a state where the data is not allowed to change. This is typically done when a form has been reviewed (source verified) and is ready to be signed by the signing authority. Throughout the study, forms may be locked for different subjects as they progress through the visits.

Because the locked state has no effect on Partial SV, you can include subjects even if they have forms that are currently in a locked state. A form may be locked before it is designated for source verification, and then selected for Partial SV at a later point in the study. This happens either because the form is for a subject that was newly added to the SV Pool or because the form is in the Critical Forms list.

Source verification states

State	Description
All	All started forms. **Note:** This state is an option only when you are creating a custom filter.
Not Verified	A form marked as SV Required in the study design is not verified.
Not Complete	An item marked as SV Required in the study design is not verified.
Verified	The form has no unverified items. For more information, see *Verified form state* (on page 196). **Note:** If you modify data or add a comment to a form that is Verified, the state of the form reverts to Not Verified.
SV Ready	The form has been marked by a user as ready for source verification.
Not SV Ready	The form has been marked by a user as not ready for source verification.

Verified form state

The Verified form state means that there are no unverified items on the form.

- If a form has items that require verification, the items have been manually verified.

- If a form has no items that require verification, the form state is automatically set to Verified.

  - If the only item on a form that requires verification is an itemset, but no instances (rows) of that itemset have been created, the form has no items that require verification, and it is automatically set to Verified.

    In the InForm application you verify itemset rows, not individual items within the itemset. The SDVREQUIRED attribute of the itemset determines this.

  - If the only item on a form that requires verification is an itemset, and the instances (rows) of that itemset have been started, the form must be manually verified.

If a form has a hidden item that requires verification, the form cannot be verified. Study designers must make verifiable items visible to users who perform verification.

Form instances that are automatically marked Verified because they have no items to be verified are not included in the set of forms selected by the partial source verification feature.

Viewing the source verification listing

The Source Verification Listing page displays information about all subjects at all sites to which you have access. The information appears in a table, with each row representing one form at one visit for a single subject. The Source Verification Listing page displays each instance of a repeating form as a separate row. The number of the instance is added to the name of the form; for example, AE[1], AE[2].

> **Note:** Only forms that require source verification appear on the **Source Verification Listing** page. In all other areas of the InForm user interface there is no filtering of forms based on the **Requires SV** form state. To view any forms not selected for SV, you can navigate to the desired forms through other parts of the user interface, such as the **Time and Events Schedule** and **Case Report Books** page.

* In the navigation toolbar, click **Monitor**.

  The Source Verification Listing page appears. For a description of the fields on this page, see *Source Verification Listing page* (on page 210).

Marking a form SV Ready or Not SV Ready

1   In the navigation toolbar, click **Subjects**.

    The Case Report Books page appears.

2   Click the status icon for the subject and visit.

    The Case Report Forms page appears.

3   In the navigation pane, use one of the form selectors to choose a form.

4   In the **Select Action** list, choose an action:

    • Select **Mark SV Ready** to indicate that the form is ready for source verification.

    • Select **Mark Not SV Ready** to indicate that the form is not ready for source verification.

5   Click **Apply**.

    The form does not change appearance. However, the **Select Action** drop-down list changes to include the opposite SV readiness command. For example, if you marked the form SV Ready, the list updates to include the **Mark Not SV Ready** command. When the monitor views the Source Verification Listing page, the SV status of the form is SV Ready or Not SV Ready, according to the action that you selected.

Online source verification

You can perform the following source verification tasks online:

- **Compare CRF data to source documents**—During source verification, the InForm application displays a specialized view of forms.

- **Issue queries where necessary**—If your review turns up errors or inconsistencies, you can navigate directly from the source verification view of the form to the Queries page, so that you can issue queries.

- **Record the results of your review**—The source verification view of a form contains checkboxes so you can mark the items and forms that you have verified.

About accessing the source verification view of a form

When you perform source verification online, you can access the source verification view of forms from the following locations:

- **The Source Verification Listing page**—Perform an interim analysis.

  - Use standard or custom filters to sort the list of forms by various criteria, such as by query state, visit, or various status indicators.

  - Select a specific form and look at that form for each subject in the list.

  - Filter the list to display only certain kinds of forms, and then perform source verification for that form for each subject.

  For more information, see *Accessing the form from the Source Verification Listing page* (on page 202).

- **The Case Report Books page or Time and Events Schedule**—Perform source verification on all the forms for a single subject.

  For more information, see *Accessing the form from a case report book* (on page 204).

Public and custom source verification status filters

The InForm application supports the following types of source verification status filters, which appear on the Source Verification Listing page:

- **Public filters**—Display records based on the CRF completion status. For example, Not Complete, Not Verified, Ready to Verify. For more information, see *Selecting a public filter* (on page 200).

- **Custom filters**—Specify the exact characteristics of the forms that appear in the Source Verification listing.

  You can create a custom filter by editing an existing public filter and saving it with a new name, or by creating a new filter and specifying all filter criteria.

  Only you can view custom filters in the Filter drop-down list.

Public and custom filters are applied to the list of subject forms that appear on the Source Verification Listing page as a result of your selections in the Site and Subject drop-down lists.

For example, if you select a specific site, then select a subject number 01-003, a list of forms for subject 01-003 appears in the Source Verification Listing. If you then select the Not Verified public filter, the list of forms for subject 01-003 is further narrowed to list only those CRFs that meet the Not Verified criteria.

Selecting a public filter

1   In the navigation toolbar, click **Monitor**.

    The Source Verification Listing page appears.

2   From the **Filter** drop-down list, select a public filter.

    - **Not Complete**—Displays a list of CRFs that have been started.

      On each CRF, one or more required items are not complete.

    - **Not Verified**—Displays a list of CRFs that contain items that are SV Required.

      On each CRF, every item that is SV Required has any status other than SV Complete.

    - **Ready to Verify**—Displays a list of CRFs that have required items.

      On each CRF, all required items are complete.

      Each required item has one of the following states:

      - Not SV Ready

      - SV Ready

      - Not Complete

3   To view details about the filter criteria, click **Edit**.

4   Select or deselect the checkboxes to make changes to the filter criteria.

5   To save the changes as a Custom filter, click **Save**.

Creating a custom filter

1   In the navigation toolbar, click **Monitor**.

The Source Verification Listing page appears.

2   In the **Filter** drop-down list, do one of the following:

- To modify an existing filter, select the filter name from the list.

- To create a new filter, select the blank area from the list (that is, make sure that nothing is selected).

3   To the right of the **Filter** drop-down list, click **Edit**.

The Criteria dialog box appears. By default, all checkboxes are selected.

- To deselect a checkbox, click in the box.

- To select or deselect all checkboxes in a category, select or deselect the **All** checkbox.

4   Select the checkboxes for the criteria that you want the filter to use. You must make at least one selection in each category.

> **Note:** In the Visit category, select CCRF to list all instances of a common form.

5   Expand the Criteria dialog box by clicking the **SV filter criteria** icon ( ) that is located in the lower-right corner, above the **Cancel** button, to view a summary of your selections.

6   Do one of the following:

- Click **Apply** to apply the filter without saving it.

  After you apply the filter, the following occurs:

  - The filter is applied to the list of forms that was displayed at the time you clicked **Apply**.

  - Subject records that match all your selections appear.

  - The Criteria dialog box closes.

  - The **Filter** drop-down list displays one of the following, depending on whether you started with a public filter or a blank filter name:

    If you started with a public filter, the name of the filter appears with the name of the public filter that you edited, followed by the words **Public Filter** in parentheses, and an asterisk. For example:

    Not Complete (Public Filter)*

    If you started with a blank filter name, the word **Custom** appears.

- Click **Save** and provide a name for the filter.

> **Note:** If you started with an existing filter, the name of the filter appears in the dialog box.

Saving an applied custom filter

> **Note:** You must save the filter immediately after you apply it, or your edits will be lost.

To save a custom filter that you applied without saving:

1   In the navigation toolbar, click **Monitor**.

    The Source Verification Listing page appears.

2   The **Filter** drop-down list displays the filter that you applied.

    The name of the filter appears as either of the following:

    - The word **Custom**.

    - The name of the public filter that you edited, followed by the words **Public Filter** in parentheses, and an asterisk. For example:

      Not Verified (Public Filter)*

3   Click **Edit**.

    The Criteria dialog box appears.

4   Click **Save**.

5   Type a name for the filter, and click **Save**.

> **Note:** If you make any changes to the criteria and apply the filter before you save it, the filter appears with the new criteria.

Deleting a custom filter

1   In the navigation toolbar, click **Monitor**.

    The Source Verification Listing page appears.

2   In the **Filter** drop-down list, select the name of the filter to delete.

3   Click **Edit**.

    The Criteria dialog box appears.

4   Click **Delete**.

    A confirmation dialog box appears.

5   Click **OK**.

Accessing the form from the Source Verification Listing page

1   In the navigation toolbar, click **Monitor**.

    The Source Verification Listing page appears. For a description of the fields on this page, see *Source Verification Listing page* (on page 210).

2   Optionally, filter the list of forms. For more information, see *Filtering the Source Verification listing* (on page 203).

3   In the **CRF** column, click the abbreviation for the form whose data you want to source verify.

Filtering the Source Verification listing

1   In the navigation toolbar, click **Monitor**.

    The Source Verification Listing page appears.

2   From the Site drop-down list, do one of the following:

- To display a list of forms from that specific site, select the site name from the list.

  The Source Verification listing displays a list of forms for all subjects that are at the site you selected. The Subject drop-down list changes so that it contains a list of subject numbers from that site.

- To display forms for all sites, select **All**.

  The Source Verification listing displays a list of forms for all subjects at all sites. The Subject drop-down list changes so that it contains a list of subject numbers from all sites.

3   From the Subject drop-down list, do one of the following:

- To display a list of forms for a single subject, select the subject number.

  The Source Verification listing displays a list of forms for the subject.

- To display forms for all subjects, select **All**.

  The Source Verification listing displays a list of forms for all subjects at the site or sites you selected in the Site drop-down list.

4   Optionally, in the Filter drop-down list, select a public filter or a custom filter that you created previously. For more information, see *Selecting a public filter* (on page 200) and *Creating a custom filter* (on page 201).

5   From the **Site** drop-down list, do one of the following:

- Select the site name from the list to display a list of forms from that specific site.

  The Source Verification listing displays a list of forms for all subjects that are at the site you selected. The Subject drop-down list changes so that it contains a list of subject numbers from that site.

- Select **All** to display forms for all sites.

  The Source Verification listing displays a list of forms for all subjects at all sites. The Subject drop-down list changes so that it contains a list of subject numbers from all sites.

6   From the **Subject** drop-down list, do one of the following:

- Select the subject number to display a list of forms for a single subject.

  The Source Verification listing displays a list of forms for the subject.

- Select **All** to display forms for all subjects.

  The Source Verification listing displays a list of forms for all subjects at the site or sites you selected in the **Site** drop-down list.

7   Optionally, in the **Filter** drop-down list, select a public filter or a custom filter that you created previously. For more information, see *Selecting a public filter* (on page 200) and *Creating a custom filter* (on page 201).

Accessing the form from a case report book

1   In the navigation toolbar, click **Subjects**.

The Case Report Books page appears.

2   Display the CRF on which to perform source verification, by doing one of the following:

- Click a status icon that represents the subject visit whose forms you want to source verify.

- Click the subject number to display the Time and Events Schedule for a subject.

  Optionally, filter the display for source verification status. For more information, see *Filtering the Time and Events Schedule for Source Verification status* (on page 205). Then, click the status icon that represents the appropriate visit and form.

3   Click **Verify**.

The source verification view of the form appears. For more information, see *Source verifying data on an online form* (on page 205).

4   Select the items to be source verified.

5   Click **Submit**.

All started forms will be in the source verification mode (with checkboxes for the items) until you click the Stop Verifying button or you log out.

About filtering the Time and Events Schedule for Source Verification status

Sponsor users can filter a subject in the Time and Events Schedule to find forms that have the following source verification status:

- SV Ready

- SV Partial

- SV Complete

These source verification filters can be used in combination with the other filters that appear on both the Case Report Books page and the Time and Events Schedule:

- Started

- Incomplete

- Queries

- Frozen

- Locked

When you select one or more filters, the status icons for the forms that match all your selections are highlighted. For example, if you select the Frozen and the SV Ready checkboxes, only the status icons for forms that are both Frozen and SV Ready are highlighted. The status icons for a form that is SV Ready and not frozen is dimmed.

Your filter selections remain in effect as you navigate to Time and Events Schedules and forms for different subjects, until you log out.

Filtering the Time and Events Schedule for Source Verification status

1 Display the Time and Events Schedule:

a In the navigation toolbar, click **Subjects**.

The Case Report Books page appears.

b Click a **Subject Number** link.

The Time and Events Schedule appears.

2 Select the checkboxes that represent the status of the forms to view.

The status icons that meet the criteria are highlighted.

Source verifying data on an online form

> **Note:** You can also source verify forms in the Data Viewer. For more information, see *Marking records Verified or Not Verified in the Data Viewer* (on page 261).
>
> **Note:** Form or data changes invalidate source verification. For more information, see *How a form change affects source verification* (on page 209).

1 In the source verification view of the form, verify each item for which verification is required.

Items that require source document verification have deselected checkboxes.

> **Note:** When you are verifying data for an itemset, one checkbox is used to mark an entire itemset row as source verified.

2 Handle each item as required.

Action	Do this
Indicate that an item is source verified	• **For a data item:** Select the checkbox in the left column of the row that contains the item.
	▪ Click the checkmark in the upper-left corner of the form to select all checkboxes at one time.
	or
	▪ Click the checkmark to select or deselect a checkbox.
	Note: If only a few items still require verification when you finish with this form, you can select all boxes and then deselect the checkboxes for those items that still require verification.
	• **For an itemset:** Select the itemset checkbox. One checkbox marks the entire itemset row as source verified.
	When a subset of the items or itemsets on a form are marked as critical, an asterisk (*) appears next to the SV checkbox for the items and itemsets.
	When a form is marked as critical (by the Subject or Form selection process in partial source verification), an asterisk (*) appears next to every SVRequired item or itemset.

Action	Do this
Enter a query	• **Against an item:** Click the query icon in the far-right column of the row. • **Against an itemset:** Click the itemset row number, and then click the query icon for the item.
Review a comment	• **On an item:** Click the comment icon in the far-right column of the row. • **On an itemset:** Click the itemset row number, and then click the comment icon for the item.
Review a comment on the form as a whole	Click the form-level comment icon at the upper-right corner of the page.
Review the audit trail	• **Of an item:** Click the audit trail icon in the far-right column of the row. • **Of a itemset:** Click the itemset row number, and then click the audit trail icon for the item.

3   Click **Submit**.

In the Source Verification Listing page, the SV Status entry changes for each form whose source verification state has changed.

If a form becomes SV Complete, a checkmark appears next to the status icon of the form, in the following places:

• Source Verification Listing page.

• Case Report Books page.

• Time and Events Schedule.

This checkmark is visible if you are in a rights group with the right to monitor CRFs.

Offline source verification

Source verifying data from a printed listing

To verify data without logging in to the InForm application, you can print copies of CRFs and review the data offline, and then make necessary changes online by doing the following:

- Log in to the InForm application.

- Issue queries where necessary.

- Record the results of your review. Use the source verification view of the CRFs that you checked.

Printing an SV Report for offline verification

To print a copy of the forms for a subject and perform source verification offline:

1   In the navigation toolbar, click **Monitor**.

The Source Verification Listing page appears.

2   Click **SV Report**.

The Source Verification Reports page appears.

3   Optionally, to change the sort order, click the column heading of the **Site**, **Subject Number**, or **Subject Initials** columns.

If the report occupies more than one page, use the page selector to navigate to the page that contains data for the subject for whom you want to print CRFs.

4   Optionally, in the **Print Preview** column for the subject for whom you want to print CRFs, click the link.

The InForm application displays a ready-to-print view of the first form in the first visit for the subject.

5   Do one of the following to display the form or forms that you want to print:

- Click **All** to generate a report consisting of all forms.

- Use the right and left arrows to navigate to a specific form.

6   Click **Print**.

7   Click **Return**.

The Source Verification Reports page appears.

Displaying the Site Visit Report

The Site Visit Report is a form that allows you to prepare a site visit report. The format of this page, which is an optional feature of the InForm application, is customizable for each study and is created when your study is set up.

Do one of the following:

1   Select an existing site visit report.

    a   In the navigation toolbar, click **Monitor**.

    b   Click **Visit Reports**.

       The Site Visit Report page appears; it lists any existing reports.

    c   Click the report site name or date.

2   Create a new visit report.

    a   In the navigation toolbar, click **Monitor**.

    b   Click **Visit Reports**.

    c   In the content pane, select the site for which to create the report.

    d   Click **New**.

       The Visit Report for Site page appears.

    e   Complete the form, and click **Submit**.

How a form change affects source verification

After source verification is complete, some updates cause a form or item to be un-verified.

- The value of a data item on a form changes.
- A form or item comment is entered.
    - Form comments un-verify every item on the form.
    - An item comment un-verifies just that item.
- Repeating forms or itemset rows are deleted or undeleted.
    - The form or the itemset row is un-verified.

When the verification status changes, the InForm application highlights the form or item so that you can re-verify it.

- The source verification status of the form changes to a status that indicates that source verification is incomplete.
- You can see this change in the Source Verification Listing page.

User interface—Source verification

Source Verification Listing page

The Source Verification Listing page displays information about all subjects at all sites to which you have access. The information appears in a table, with each row representing one form at one visit for a single subject. The Source Verification Listing page displays each instance of a repeating form as a separate row. The number of the instance is added to the name of the form; for example, AE[1], AE[2].

> **Note:** Only forms that require source verification, and forms that contain critical items that require source verification appear on the **Source Verification Listing** page. In all other areas of the InForm user interface there is no filtering of forms based on the Requires SV form state. To view any forms not selected for SV, you can navigate to the desired forms through other parts of the user interface, such as the Time and Events Schedule and Case Report Books page.

To make it easier to find specific forms, the Source Verification Listing includes drop-down lists from which you can choose to display a list of forms for a specific site and subject. You can also filter the list by source verification state, CRF completion state, and additional content and status criteria. You can create and save custom filters.

The Source Verification Listing page displays a summary of the CRFs for each subject. Each icon provides a detailed form state for a single form. Use the hover Help for a description of each icon.

Use the Source Verification Listing page to:

- Determine the source verification status and data entry status of forms.

- Display the source verification view of a particular form.

- Filter the list of forms.

- Freeze or lock selected forms.

- Access the dialog box to configure partial source verification (Partial SV).

Fields

Field	Description
Subject filter	Filters the information on the page based on the subject.
Filter filter	Provides additional filters for the subject records that are listed as a result of your selections from the Site and Subject filters. You can choose any of the following actions: • Leave the Filter drop-down list blank to display all records. • Select a public filter to display records based on CRF completion status. For example, Not Complete, Not Verified, Ready to Verify. • Click Edit to modify a public filter or create a custom filter.
Edit	View details on the filter criteria.

Field	Description
Set SV Settings button	Opens the Set SV settings dialog box, from which you can configure partial source verification.
	Note: This button appears if you have the Change Site SV Settings right or the Monitor right. If you have the just the Monitor right, you can view the SV Settings but you cannot not change them.
Site filter	Drop-down list of all the sites you have access to.
X	A column of checkboxes allows you to select one or more forms and perform a group freeze, unfreeze, lock, or unlock on them by clicking the appropriate button in the lower right corner of the page.
CRF Status	CRF completion status. The status icons are the same as in the case report book.
Site	Drop-down list of all the sites you can access.
Subject	Subject number and initials for all subjects based on your selection in the Sites filter.
	• Select All to display all records from the site(s).
	• Select the Subject Number to display records for a specific subject.
Visit	Visit name.
CRF	Form abbreviation (mnemonic). Click the link to display a source verification view of the form.
SV Status	Source verification status.
Comments	Icon to indicate that form or item-level comments exist. Click the icon to view the comments.

Buttons

Button	Description
Page selector	A multi-part control that is located on the bottom-left of the content pane. Click different parts of the control to move through the pages of forms in the Source Verification Listing.
Freeze / Unfreeze	The buttons in the lower right corner of the page allow you to freeze or unfreeze the selected forms.
Lock / Unlock	The buttons in the lower right corner of the page allow you to lock or unlock the selected forms.

Set SV settings dialog box

Use the Set SV settings dialog box to configure Partial SV.

- Use the Subject Selection tab to select the subjects at a site to be source verified.

- Use the Critical Data tab to identify the forms and items for all subjects to be source verified.

- The list of forms and items appears in the user's study locale.

Fields

Field	Description
Site drop-down list	The site for which you want to configure Partial SV.
	• The drop-down list displays the mnemonics and names of all sites to which you have access, in alphabetical order.
	• If you access this dialog box from the Source Verification Listing page, the Site selected on that page appears in this field.
Audit Trail icon	Click to open the Set SV settings—Audit History dialog box, from which you can view the audit history for the selected site.
Source Verify all Data	Select to disable partial source verification for the selected site. Default.
	When you select this option, you are setting the subject selection rate to 100%. All forms with at least one item set as SV Required must be verified. All other options in the Set SV settings dialog box are disabled.
Partial Source Verification	Select to enable partial source verification for the selected site.
	When you select this option, you are choosing to use Partial SV. All options in the Set SV settings dialog box are enabled.
Subject Selection	
Import Subject List link	Click to open the Set SV settings—Import subjects dialog box, from which you can enter a file name or browse to a text file of enrolled subject data.
	• Click Browse to navigate to the file you want to import.
	• Click Submit to start the import.
Number of initial subjects	The number of initial subjects enrolled in the site that you want to be source verified. The default is 0.
Subject selection rate after initial subjects	The SV Target Rate. The percentage at which you want subjects to be selected for source verification after the initial subjects are verified.
	This is the percentage of subjects that the automated subject selection algorithm attempts to meet. The default is 100%, which means all subjects are selected.
Enter subject number drop-down list	The subjects available to add to the Subjects selected for verification list.

Field	Description
Add link	Click to add the entered or selected subject number to the adjacent Subjects selected for verification list box.
Subjects selected for source verification list box	The list of subjects selected for source verification, and the method of selection.
	• **Initial Subject**—Subject was selected as an initial subject to source verify.
	• **Auto**—Subject was added by the auto-select process.
	• **Manual**—Subject was entered manually or selected from the Enter subject number drop-down list.
	• **Imported**—Subject was imported.
	• **Excluded**—Subject was excluded.
Exclude icon ✖	Click one time to exclude a subject from the SV Pool. The excluded subject is removed from the SV Eligible Pool.
Remove icon ✖	Click two times to remove a subject from the Subject List. The removed subject is returned to the SV Eligible Pool.
Critical Data: Forms and items	
Critical checkbox	Select to designate the adjacent form as critical.
Form	The list of forms in your study that you can include in the Critical Forms list.
	• For a form designated as critical (the Critical checkbox is selected), the critical item selection is disabled, and the **CRF has been marked SV Critical** message appears in the item section area of the dialog box.
	• For a form designated as not critical, the items and itemsets on the form appear in the item section of the dialog box.
	• Hover over the form name to display the FormRefName as a tooltip.
Question	The question field on the selected form.
	Study Critical items are marked with a superscript asterisk (*) at the beginning of the Item Question. For an itemset where the Item Question is blank (empty), the Item Question is replaced by the text: [ITEMSETREFNAME] is an ITEMSET.

Field	Description
Item	The item or itemset on the selected form.
	• The list of items on the form includes all items from current and previous study versions. This allows items started on earlier study versions to be marked critical.
	• Only items designated as SV Required are included in the selection list.
	• Only itemset parent items appear, and not the child items of the itemset.
Effective SV State	A status that indicates the criticality of an item based on the study and override settings. For more information, see **Critical items—Effective SV states** (on page 187).
	• Not SV Critical
	• SV Critical
Override	A status that indicates the SV Critical override setting for the item or itemset.
	• **Study Default**—The criticality set for the item during the study design.
	• **This Form**—Sets the item to critical for only the selected form.
	• **All Forms**—Sets the item to critical for all forms. All instances of the item must be verified, not just the items on the form on which you set the override. For more information, see **About the Critical All Forms Effective SV state** (on page 187).
	• **Not Critical**—Sets the item to not critical for only the selected form.
OK	Click to save changes. The Reason for Change dialog box appears.
Cancel	Click to close the dialog box without saving changes.

Set SV settings—Audit History dialog box

Use the Set SV settings—Audit History dialog box to view the audit history for the selected site.

Fields

Field	Description
User	The user who made the change to the Partial SV configuration setting.
Date Time	The date and time that the change to the Partial SV configuration setting was performed.
Server	The server where the InForm application is installed.
Message	The system-generated text that describes the Partial SV configuration change.
Reason	The user-entered Reason for Change text.

Buttons

Button	Description
OK	Click to close the Set SV settings—Audit History dialog box and return to the Set SV settings dialog box.

Set SV settings—Import subjects dialog box

Use the Set SV settings—Import subjects dialog box to navigate to the file with the subject data that you want to import to make available to add to the Manual Pool for use in Partial SV.

Fields

Field	Description
File name	The name of the file with the list of subject numbers that you want to import for use in Partial SV.
Browse button	Click to navigate to the file.
Submit button	Click to start the import.

Source Verification Reports page

The SV Reports (Source Verification Report) page is a formatted listing of one or all forms that exist for a subject. When you print the SV Report, you can obtain a complete printed copy of the forms so that you can perform source verification offline. The SV Report consists of two pages: a list of subjects for whom you can generate reports and a list of forms that you can print.

> Note: The SV Report shows only forms that are marked for SV.

Fields

Field	Description
Site	Site associated with the subject.
Subject Number	Subject number.
Subject Initials	Subject initials.
Print Preview	Displays a page on which you can select the form to print or specify that you want to print all forms.

Buttons

Button	Description
Page selector	A multi-part control that is located on the bottom-left of the content pane. Click different parts of the control to move through the pages of the SV Report.

SV Report Print Preview page

Use the SV Report Print Preview page to display a view of a form in a format suitable for printing. From this page, you can print the form, or you can print all forms in the case report book.

Buttons

Button	Description
Navigation arrows	Navigate to the page that you want to print. Forms are in the same order in which they occur in the study.
All	Displays a version of the SV Report that includes the entire case report book.
Print	Prints the SV Report.
Return	Returns you to the Source Verification Reports page

Site Visit Reports page

The Site Visit Report page is a form that allows you to prepare a site visit report. The format of this page, which is an optional feature of the InForm application, is customizable for each study and is created when your study is set up.

Fields

Field	Description
Site	Site associated with the subject. Click the link to open the report.
Date	Date of the report.
Site filter	Drop-down list of all the sites you can access.

Buttons

Button	Description
New	Opens the Visit Report for Site page.

Visit Report for Site page

The Site Visit Report is a form that allows you to prepare a site visit report. The format of this page, which is an optional feature of the InForm application, is customizable for each study and is created when your study is set up.

Regulatory Document Checklists page—Site list

The Regulatory Documentation Checklist allows you to select a site to complete a checklist that describes regulatory documentation for a site. The format of this page, which is an optional feature of the InForm application, is customizable for each study and is created when your study is set up.

Fields

Field	Description
Site	List of sites to which you have access. Click any link to view the Regulatory Documentation Checklist for the site.

Regulatory Documentation Checklist for a Site page

The Regulatory Documentation Checklist allows you to fill in a checklist that describes regulatory documentation for a site. The format of this page, which is an optional feature of the InForm application, is customizable for each study and is created when your study is set up.

CHAPTER 9

Freezing and locking

In this chapter

Overview of freezing and locking

Freezing and locking data allows you to prevent changes in forms, either temporarily during a study or permanently at the end of a study.

You can freeze and lock:

- Forms

- Visits

- Case report books

Note: You can only freeze or lock a form in which a user has entered at least one data item or comment. If you freeze or lock a case report book, freeze or lock icons appear only on started forms; however, all forms in the case report book are frozen or locked. The activities that are allowed, or not allowed, pertain to all forms. For more information, see *Rules for freezing and locking* (on page 220).

Rules for freezing and locking

When you freeze or lock a form or case report book, the following rules are in place:

Activity allowed?	Frozen CRF	Frozen case report book	Locked CRF	Locked case report book
Add/update subject data	No unless allowed.*	No unless allowed.*	No	No
Add/update comments	No unless allowed.*	No unless allowed.*	No	No
Open queries	No unless allowed.*	No unless allowed.*	No	No
Answer queries	Yes, but can change data value only if allowed.*	Yes, but can change data value only if allowed.*	No	No
Close queries	No unless allowed.*	No unless allowed.*	No	No
Mark SV ready	Yes	Yes	No	No
Source verify	No unless allowed.*	No unless allowed.*	No	No
Sign CRF	Yes	Yes	Yes	Yes
Sign case report book	Yes	Yes	Yes	Yes

* Sponsor users can perform this activity only if the study has been configured to allow sponsor users to update forms after they are frozen.

The freezing and locking icons

The InForm application combines the following multiple states into a single state for the icon:

- Individual form states into a state for the visit.

- Individual repeating form instance states into one state for the repeating form as a whole.

  For example, if visit Week1 has a repeating Vital Signs form with 10 instances, those ten instances are combined into a single state to show in the Time and Events Schedule and in the form selection list.

When you freeze or lock a form or case report book, a snowflake icon (*) or a padlock icon (🔒) appears next to the CRF or case report book status icons on the Case Report Books page, Time and Events Schedule, Source Verification Listing, and Required Signatures page.

- If a form or case report book is both frozen and locked, only the locked icon appears. However, the hover Help describes both the frozen and locked status.

The InForm application applies this behavior whether your study uses the status icons or the traffic light icons, and whether you are viewing the Visit or Forms view on the Time and Events Schedule page.

- The visit-level frozen, locked, and verified status appear only if all the forms in a visit are frozen, locked, or verified.

- When a visit is both frozen and locked, only the locked icon appears. However, the hover Help shows both frozen and locked.

- A combined state is Locked only if every individual state being combined is Locked.

- A combined state is Frozen only if every individual state being combined is Frozen.

- A combined state is Verified only if every individual state being combined is Verified.

Freezing or locking a form

> **Note:** You can also freeze and unfreeze forms in the Data Viewer. For more information, see *Freezing and unfreezing records in the Data Viewer* (on page 259).

1   Navigate to the form you want to freeze, unfreeze, lock, or unlock.

   The buttons you see at the bottom of the form depend on your rights and the state of the form. For example, if you have the right to freeze a form but not to lock it, only the **Freeze** button is present.

   The **Freeze** and **Unfreeze** buttons, and the **Lock** and **Unlock** buttons are toggles. Only one of each pair is present, depending on the state of the form.

2   Click one of the following:

   - **Freeze**

   - **Unfreeze**

   - **Lock**

   - **Unlock**

> **Note:** When you freeze, unfreeze, lock, or unlock a common form, the InForm application updates the status icon that represents the form in the Time and Events Schedule in all visits where the form occurs. However, the status icon for a common form in an unscheduled visit is not updated until you create at least one unscheduled visit.

Freezing or locking several forms at one time

> **Note:** You can also freeze and unfreeze forms in the Data Viewer. For more information, see *Freezing and unfreezing records in the Data Viewer* (on page 259).
>
> **Note:** You can also lock and unlock forms in the Data Viewer. For more information, see *Locking and unlocking records in the Data Viewer* (on page 260).

You can freeze, unfreeze, lock, or unlock several forms at one time:

To freeze, unfreeze, lock, or unlock	Use the buttons on
All forms in a visit.	Any view of the form.
Selected repeating form instances.	The summary view of the form.
Any selected forms.	The Source Verification Listing page.

Freezing or locking all forms in a visit

To freeze, unfreeze, lock, or unlock all forms in a visit:

1   Navigate to any form within the visit.

2   In the **Select Action** drop-down list, click one of the following:

- **Freeze Visit**—Freeze all forms in the visit.

- **Unfreeze Visit**—Unfreeze all forms in the visit.

- **Lock Visit**—Lock all forms in the visit.

- **Unlock Visit**—Unlock all forms in the visit.

> **Note:** The selections that you see in the Select Action drop-down list depend on your rights.
> For example, if you have the right to freeze a visit but not to lock it, only the Freeze Visit and
> Unfreeze Visit selections are present.

3   Click **Apply**.

A message appears, indicating the number of forms that were affected. Additionally, freeze or
lock icons are added or removed as follows.

Action	Changes to the display of icons
Freeze Visit	In the Time and Events Schedule, the freeze icon appears next to the status icon for each non-common, started CRF in the visit. The freeze icon also appears next to the status icon for the visit in the Case Report Books page.
Unfreeze Visit	The InForm application removes the freeze icons from the non-common forms in the Time and Events Schedule. The InForm application also removes the freeze icon from the visit in the Case Report Books page.
Lock Visit	In the Time and Events Schedule, the lock icon appears next to the status icon for each non-common, started CRF in the visit. The lock icon also appears next to the status icon for the visit in the Case Report Books page.
Unlock Visit	The InForm application removes the lock icons from non-common forms in the Time and Events Schedule. The InForm application also removes the lock icon from the visit in the Case Report Books page.

> **Note:** When you freeze, unfreeze, lock, or unlock a visit, the status of any common form in the
> visit does not change. You can freeze, unfreeze, lock, or unlock a common form at the form or
> case report book level.

Performing one freezing or locking action on several instances of a form

You can use the summary view of a repeating form to select multiple instances of the form and freeze, unfreeze, lock, or unlock them. For more information, see *Form views* (on page 7).

1   Navigate to the summary view of a repeating form.

2   While in summary view, click one of the following buttons:

   - **Freeze Visit**—Freeze form instances.

   - **Unfreeze Visit**—Unfreeze form instances.

   - **Lock Visit**—Lock form instances.

   - **Unlock Visit**—Unlock form instances.

   The summary view reappears with a column of checkboxes along the left side.

3   Select the checkbox for each form instance on which to perform the action that you selected in step 2.

4   Click the button for the action that you selected:

   - **Freeze Visit**—Freeze the selected form instances.

   - **Unfreeze Visit**—Unfreeze the selected form instances.

   - **Lock Visit**—Lock the selected form instances.

   - **Unlock Visit**—Unlock the selected form instances.

   The InForm application adds or removes freeze or lock icons next to the status icon for each form instance that you selected. It also adds or removes icons on the Time and Events Schedule page and the Case Report Books page to reflect the actions you performed.

Freezing or locking while monitoring

You can freeze or lock multiple forms in one action from the Source Verification Listing page. Similarly, you can unfreeze or unlock a form that previously was frozen or locked.

1   In the navigation toolbar, click **Monitor**.

   The Source Verification Listing page appears.

2   Optionally, filter the list of subject forms.

   For more information, see *Filtering the Source Verification listing* (on page 203).

3   Select the checkbox for each form to freeze or lock.

4   Do one of the following:

   - To freeze or lock the forms, click **Freeze** or **Lock**.

   - To unfreeze or unlock the forms, click **Unfreeze** or **Unlock**.

Freezing or locking a case report book

To freeze, unfreeze, lock, or unlock a case report book:

1   Navigate to the Time and Events Schedule for a subject.

2   Click one of the following:

- **Freeze Book**

- **Unfreeze Book**

- **Lock Book**

- **Unlock Book**

Note: You can freeze a case report book that includes forms that were frozen previously. When you unfreeze or unlock a case report book, the InForm application unfreezes or unlocks all previously frozen or locked forms.

Data changes after freezing or locking

If you need to add or change data on a frozen or locked form, contact a sponsor representative who is authorized to unfreeze or unlock the form. Make your changes, and then ask the sponsor to re-freeze or lock the form.

Data Viewer tasks

In this chapter

Customizing the Data Viewer workspace

Overview of customizing the Data Viewer workspace

You can customize the Data Viewer user interface to fit your viewing preferences. You can:

- Filter and sort data in all views.

- Resize columns in all views.

- Reorder the column positions in the Record Listing View and Record Comparison View.

- Hide and unhide groups of columns in the Summary View, and individual columns in the Record Listing View and Record Comparison View.

- Specify whether the column names in the Form Data Table in the Data Viewer Record Listing View use the Report element name (default) or the RDE (Reporting Data Extract) column name.

- Maximize the viewing area for the data in the Summary View and Record Listing View.

- Display the labels (default) or the represented codes of the CRF control in the Record Listing View and Record Comparison View.

- Display the values entered in a CRF (default) or the corresponding normalized values in the Record Listing View and Record Comparison View.

User Guide

Filtering data for all views in the Data Viewer

All filtering criteria (that is, all criteria that can be set in the Filters pane) that you set for a session must be saved manually in order to be available for use in subsequent sessions.

The Filters pane provides options to save, load, and delete filter settings using icons at the top of the pane. For more information, see *Filters pane—Data Viewer* (on page 71).

- When you navigate to the Data Viewer module for the first time, no filtering criteria is loaded (the default is Show All).

- After you save any filters, the next time you log in to the InForm application and navigate to the Data Viewer, the system automatically loads the saved filter used in the last session.

  Saved filters are for an individual user and are not shared with other users.

- Any unsaved filtering criteria persist only in the current session and are lost when the current session ends.

- Filtering criteria set in the Filters pane apply across all Data Viewer views in the same session; by setting it one time you can navigate through different views under a consistent set of filtering criteria.

> **Note:** You can also perform single column filtering on clinical data values that are applied in the current view only. For more information, see *Filtering on clinical data* (on page 234).

To filter data in the Data Viewer:

1   Navigate to any view in the Data Viewer.

    For more information, see:

    - *Displaying the Summary View* (on page 113).

    - *Displaying the Record Listing View* (on page 114).

    - *Displaying the Record Comparison View* (on page 115).

    - *Displaying the Comments View* (on page 115).

2   In the **Filters** pane, select the filtering criteria, and click **Apply**.

    The filtering criteria you select apply to all Data Viewer views. For more information, see *Filters pane—Data Viewer* (on page 71).

    The filters are preserved when navigating between forms. For example, if you narrow the view down to Site A and Visit 1 data, these filters are preserved when switching to another form.

3   Optionally, save the filtering criteria for use in subsequent sessions.

> **Note:** If you do not save your filter selections, the filtering criteria last only for the current session.

Saving a filter

1   Navigate to any view in the Data Viewer.

For more information, see:

- *Displaying the Summary View* (on page 113).

- *Displaying the Record Listing View* (on page 114).

- *Displaying the Record Comparison View* (on page 115).

- *Displaying the Comments View* (on page 115).

2   In the **Filters** pane, select the filtering criteria, and click **Apply**.

For more information, see *Filters pane—Data Viewer* (on page 71).

3   Click the **Save filter** icon ( ).

A text box appears.

4   Type a name for the filter, or select a name to overwrite an existing filter, and click **Save**.

The filter you save is for personal use only. It is not shared with other users.

The next time you log in to the InForm application and navigate to the Data Viewer module, the saved filter used in the last session is automatically loaded for the session.

Modifying a saved filter

Use this procedure to change the filtering criteria saved in a previous session.

1   Navigate to any view in the Data Viewer.

For more information, see:

- *Displaying the Summary View* (on page 113).

- *Displaying the Record Listing View* (on page 114).

- *Displaying the Record Comparison View* (on page 115).

- *Displaying the Comments View* (on page 115).

2   In the **Filters** pane, click the **Load filter** drop-down list ( ), and select a saved filter.

The current view refreshes with the criteria from the filter you select. For more information, see *Filters pane—Data Viewer* (on page 71).

3   Change the filtering criteria as needed, and click **Apply**.

4   Click the **Save filter** icon ( ).

A text box appears.

5   Type a name to create a new filter, or save the filter using the original filter name, and click **Save**.

The filter you save is for personal use only. It is not shared with other users.

Loading a saved filter

Use this procedure to use the filtering criteria saved in a previous session.

1. Navigate to any view in the Data Viewer.

    For more information, see:

    - *Displaying the Summary View* (on page 113).

    - *Displaying the Record Listing View* (on page 114).

    - *Displaying the Record Comparison View* (on page 115).

    - *Displaying the Comments View* (on page 115).

2. In the **Filters** pane, click the **Load filter** drop-down list (   ), and select a saved filter.

    The current view refreshes with the criteria from the filter you select.

Deleting a saved filter

1. Navigate to any view in the Data Viewer.

    For more information, see:

    - *Displaying the Summary View* (on page 113).

    - *Displaying the Record Listing View* (on page 114).

    - *Displaying the Record Comparison View* (on page 115).

    - *Displaying the Comments View* (on page 115).

2. In the **Filters** pane, click the **Delete filter** drop-down list (   ), and select a filter to delete.

    A confirmation dialog box appears.

3. Click **OK**.

    - You cannot retrieve a deleted filter.

    - If the filter you delete is the currently loaded filter, the next session starts without any filter criteria being pre-loaded.

Filtering data on clinical values for the current view

Use this procedure to perform single column filtering on clinical data values. You can filter on any one column at a time, except for the columns for the review states, site, subject, and visit.

- Columns that contain entered values are filtered by the normalized value.

- For each column you filter, you can select up to five filtering criteria that are appropriate for the column type (for example, numeric, case-insensitive alphanumeric, or date).

- Column filtering is applied only in the current view. All column filtering selections are lost when you navigate away from the current view.

To filter on clinical data:

1   Navigate to the Record Listing View or Record Comparison View in the Data Viewer.

For more information, see:

- *Displaying the Record Listing View* (on page 114).

- *Displaying the Record Comparison View* (on page 115).

2   In the Form Data table, click a data cell.

3   In the **Filters** pane, click the **Filter column data** icon ( ).

The Column filter dialog box appears. For a description of the fields on this page, see *Column filter dialog box* (on page 75).

The Column filter dialog box is populated with the column name for the cell you selected, and the filtering conditions that are appropriate for the column type (for example, numeric, case-insensitive alphanumeric, or date).

4   Enter the filtering criteria for the selected column.

For example:

- For a numeric column, such as a height column, enter a value for the height.

- For a alphanumeric column, such as a gender item on a Demographics form, enter the value (male or female).

- For a date column, enter the date in the appropriate format.

5   Optionally, click the plus sign (**+)** to add another row of criteria for the selected column.

You can specify a maximum of five criteria for each column.

6   When you are done entering all the filtering criteria, click **Apply**.

The view refreshes, and shows the data filtered with the specified criteria. The results for the column filter are combined with other selected filtering criteria, such as the site, subject, and form states.

When column filtering is applied, the column name with the applied column filtering criteria appears in the view as follows:

- **Record Listing View**—Title bar in the Summary Data Pane displays.

- **Record Comparison View**—Title bar in the data view panel where you set the column filtering.

7   To clear the filtering criteria, delete the values in the **Column filter** dialog box, and click **Apply**.

The column filtering conditions are cleared, and the view refreshes with no column filtering.

Sorting data in the Data Viewer

> **Note:** Column sorting applies to the current session only. Sorting criteria are not saved, and do not persist within the session.

1   Navigate to any view in the Data Viewer.

For more information, see:

- *Displaying the Summary View* (on page 113).

- *Displaying the Record Listing View* (on page 114).

- *Displaying the Record Comparison View* (on page 115).

- *Displaying the Comments View* (on page 115).

2   Click the column heading that represents the data by which you want to sort the information on the page.

> **Note:** You can select only one column; you cannot sort on multiple columns.

- To sort the page, click the column heading.

- To reverse the sort, click the column heading again.

- An up arrow indicates the page is sorted by the column data in ascending order.

- A down arrow indicates the page is sorted in descending order.

For more information, see:

- *Column sorting—Summary Data Table* (on page 48).

- *Column sorting—Form Data Table* (on page 52).

- *Column sorting—Comments View* (on page 67).

Customizing the columns in the Data Viewer

In the Data Viewer, all column customizations are saved automatically for the current user, and are reloaded automatically for subsequent sessions.

Resizing a column

1 Navigate to any view in the Data Viewer.

For more information, see:

- *Displaying the Summary View* (on page 113).

- *Displaying the Record Listing View* (on page 114).

- *Displaying the Record Comparison View* (on page 115).

- *Displaying the Comments View* (on page 115).

2 Click on the separator between any two columns, and drag the column to the desired width.

Reordering column positions

1 Navigate to the Record Listing View or Record Comparison View in the Data Viewer.

For more information, see:

- *Displaying the Record Listing View* (on page 114).

- *Displaying the Record Comparison View* (on page 115).

2 In the Form Data Table, click on any data column heading and drag it to reposition it within the current view.

The view shows the re-ordered position for the columns. The changes are saved automatically in the InForm database for the current user, and are applied in subsequent sessions automatically. The changes are not shared with other users.

Hiding or unhiding columns

Use this procedure to specify the groups of columns that you want to display in the Summary Data Table in the Summary View, and the individual columns that you want to display in the Form Data Table in the Record Listing View and Record Comparison View.

> **Note:** Any contextual columns (for example, Site or Visit) that you mark as hidden are hidden in all Data Viewer views.

1   Navigate to the Summary View, Record Listing View, or Record Comparison View in the Data Viewer.

    For more information, see:

    • *Displaying the Summary View* (on page 113).

    • *Displaying the Record Listing View* (on page 114).

    • *Displaying the Record Comparison View* (on page 115).

2   In the toolbar, select **Options > Configure Columns**.

    The Configure Columns dialog box appears. For a description of the fields on this page, see *Configure Columns dialog box* (on page 74).

3   Select the checkboxes for the groups of columns in the Summary View, or individual columns in the Record Listing View or Record Comparison View that you want to display, and click **Apply**.

    The options that appear in the dialog box depend on the columns that appear in the Data Viewer view.

> **Note:** You cannot hide the Subject column.

    • Select the **All columns** checkbox to select or deselect all the checkboxes in the columns list.

        • Contextual columns (for example, Site and Visit) that are hidden for the current view are carried over to all views with the same column (identified by the column name).

        • Data columns that are hidden apply to the current view only.

    • Click **Reset All** to reset the options to the default (all selected).

    The view refreshes and shows only the selected groups and columns. The changes are saved automatically in the InForm database for the current user, and are applied in subsequent sessions automatically. The changes are not shared with other users.

Setting the column names

Use this procedure to specify whether the column names in the Form Data Table in the Data Viewer Record Listing View or Record Comparison View use the Report element name (default) or the RDE (Reporting Data Extract) column name.

1   Navigate to the Record Listing View or Record Comparison View in the Data Viewer.

For more information, see:

- *Displaying the Record Listing View* (on page 114).

- *Displaying the Record Comparison View* (on page 115).

2   In the toolbar, select **Options > Configure Columns**.

The Configure Columns dialog box appears.

3   In the **Header Names** drop-down list, select the type of column names that you want to appear in the Forms Data Table in the Record Listing View or Record Comparison View.

- **Report element**—Default. Select if you want to use InForm Ad Hoc Reporting column names as the column headings.

- **Reporting data extract column**—Select if you want to use RDE column names as the column headings.

The column names that appear in the Visibility section in the Configure Columns dialog box update based on your selection.

4   Click **Apply**.

The dialog box closes, the Record Listing View or Record Comparison View refreshes, and the Form Data Table displays the column names based on your selection.

Maximizing the Data Viewer workspace

Use this procedure to hide any open panes in the Data Viewer window, except for the Summary Data Table in the Summary View or the Form Data Table in the Record Listing View to provide maximum viewing area for the data table.

1   Navigate to the Summary View or Record Listing View in the Data Viewer.

For more information, see:

- *Displaying the Summary View* (on page 113).

- *Displaying the Record Listing View* (on page 114).

2   In the toolbar, select **Options > Maximize Workspace**.

The data table area is maximized, and all other panes in the Data Viewer window are minimized (hidden).

3   To redisplay the hidden panes, in the toolbar, select **Options > Reset Workspace**.

Showing the codes or code labels

Use this procedure to toggle between showing the labels (default) or the represented codes of the CRF control in the data table.

Codes are numeric or alphabetical values that represent the clinical data on the CRFs. For example, 0 represents No, 1 represents Yes, F represents Female, and M represents Male. These codes (0, 1, F, and M) are values that are stored in the database as the clinical data for the CRFs. The code labels (for example, No, Yes, Female, and Male) are metadata used in the display to make it easier to understand the entered value.

1   Navigate to the Record Listing View or Record Comparison View in the Data Viewer.

   For more information, see:

   * *Displaying the Record Listing View* (on page 114).

   * *Displaying the Record Comparison View* (on page 115).

2   To show the code values, in the toolbar, select **Options > Show Codes**.

3   To show the code labels, in the toolbar, select **Options > Show Code Labels**.

Showing the entered or normalized values

Use this procedure to toggle between showing the values entered in a CRF (default) or the corresponding normalized values in the data table.

Normalized values are values that are converted from the format (or unit) that was entered for a given item on a CRF to a format that is available based on the study design. For example, the value of a data item can be changed (normalized) from one unit to another (inches to cm or kg to lbs).

1   Navigate to the Record Listing View or Record Comparison View in the Data Viewer.

   For more information, see:

   * *Displaying the Record Listing View* (on page 114).

   * *Displaying the Record Comparison View* (on page 115).

2   To display the values that were entered on the CRF, in the toolbar, select **Options > Show Entered Values**.

3   To display normalized values, in the toolbar, select **Options > Show Normalized Values**.

Reviewing summary data for started and expected forms

Reviewing summary data for a set of visits

Use this procedure to review the summary counts of all operational data by visits to ensure that started visits are completed and cleaned.

> **Note:** Some values of summary information that appear for a user may be larger than the sum of individual records that are viewable by a user. This occurs because the Data Viewer summarizes state counts for all users, and does not consider the rights that a particular user has to view certain data.

1   In the navigation toolbar, click **Review**.

The Summary View appears. For a description of the fields on this page, see *Components— Summary View* (on page 45).

2   If necessary, to display the summary data by visits, in the toolbar, click **Visits**.

3   Do any or all of the following:

- Filter the data.

  For more information, see *Filtering data for all views in the Data Viewer* (on page 231).

- Sort the columns in the Summary Data Table.

  For more information, see *Sorting data in the Data Viewer* (on page 235).

- Customize the columns in the Summary Data Table.

  For more information, see *Customizing the columns in the Data Viewer* (on page 236).

- Review the form and item comments.

  For more information, see *Reviewing comments across a single form and one or more subjects, visits, or sites* (on page 246) or *Reviewing comments across all forms* (on page 247).

- Export data from the current Summary View.

  For more information, see *Exporting data to Excel* (on page 264).

4   Optionally, display the list of forms available for a visit.

a   In the **Visit** column, click a specific visit.

b   In the toolbar, click **Go to Record Listings**.

The Record Listing View appears. For a description of the fields on this page, see *Components—Record Listing View* (on page 49).

Reviewing summary data for a set of sites

Use this procedure to look at operational data summaries for sites focusing on cleaning data site by site to detect if there are data collection issues such as high query rates or incomplete forms.

> **Note:** Some values of summary information that appear for a user may be larger than the sum of individual records that are viewable by a user. This occurs because the Data Viewer summarizes state counts for all users, and does not consider the rights that a particular user has to view certain data.

1   In the navigation toolbar, click **Review**.

The Summary View appears. For a description of the fields on this page, see *Components— Summary View* (on page 45).

2   If necessary, to display the summary data by sites, in the toolbar, click **Sites**.

3   Do any or all of the following:

* Filter the data.

   For more information, see *Filtering data for all views in the Data Viewer* (on page 231).

* Sort the columns in the Summary Data Table.

   For more information, see *Sorting data in the Data Viewer* (on page 235).

* Customize the columns in the Summary Data Table.

   For more information, see *Customizing the columns in the Data Viewer* (on page 236).

* Review the form and item comments.

   For more information, see *Reviewing comments across a single form and one or more subjects, visits, or sites* (on page 246) or *Reviewing comments across all forms* (on page 247).

* Export data from the current Summary View.

   For more information, see *Exporting data to Excel* (on page 264).

4   Optionally, display the list of subjects for a site.

   a   In the **Site** column, click a specific site.

   b   In the toolbar, click **Go to Record Listings**.

The Record Listing View appears. For a description of the fields on this page, see *Components—Record Listing View* (on page 49).

Reviewing form data for started and expected forms

Reviewing a single form for a single subject

Use this procedure to focus on the clinical data on a particular form for a single subject across visits to see if there are any abnormalities or patterns.

1 Navigate to the Record Listing View in the Data Viewer.

For more information, see *Displaying the Record Listing View* (on page 114).

2 In the Form Data Table, click a cell in the **Subject** column to navigate to the first available form for the subject.

The Record Listing Single Subject View appears. For more information, see *Record Listing Single Subject View* (on page 56).

The Record Listing Single Subject View displays expected forms. Expected forms are the set of CRFs that should be completed by a specified date, usually based on when the visit for the CRF was scheduled to start. For more information, see *Definition of Expected forms* (on page 60).

3 Optionally, select different forms in the **Forms** pane, and continue reviewing form-level data for a single form and single subject.

4 Do any or all of the following:

- Apply filters, sort columns, or re-arrange columns.

  For more information, see *Overview of customizing the Data Viewer workspace* (on page 230).

- Perform InForm actions (such as freezing, locking, and source verifying) after reviewing the form data.

  For more information, see *Performing InForm actions* (on page 253).

- Compare form data between different forms, different subjects, different visits, or different sites, or any combinations of these.

  For more information, see *Comparing data* (on page 244).

- View all comments for the current form across the filtered set of data.

  For more information, see *Reviewing comments* (on page 246).

- Navigate to the CRF for the currently viewed data item.

  For more information, see *Navigating from the Data Viewer to a CRF* (on page 116).

- Export data from the current view.

  For more information, see *Exporting data to Excel* (on page 264).

Reviewing a single form across subjects, visits, or sites

Use this procedure to review the clinical data for a particular form across subjects, sites, or visits to see if there are any abnormalities or patterns.

1   Navigate to the Summary View in the Data Viewer.

For more information, see *Displaying the Summary View* (on page 113).

2   If necessary, to display the summary data by visits, in the toolbar, click **Visits**.

or

If necessary, to display the summary data by sites, in the toolbar, click **Sites**.

3   In the **Form Data Table**, click a data cell.

4   In the toolbar, click **Go to Record Listings**.

The Record Listing View appears. For a description of the fields on this page, see *Components—Record Listing View* (on page 49).

5   In the **Forms** pane, single-click the name of the form whose clinical data you want to view.

In the Form Data Table, one row appears for each site, subject, and visit for the selected form.

6   Do any or all of the following:

●   Filter the data.

For more information, see *Filtering data for all views in the Data Viewer* (on page 231).

●   Sort the columns in the Form Data Table.

For more information, see *Sorting data in the Data Viewer* (on page 235).

Viewing the details for a form

Use this procedure to view the items details and audit history for a form.

1   Navigate to the Record Listing View in the Data Viewer.

For more information, see *Displaying the Record Listing View* (on page 114).

2   In the lower right corner of the page, click the up arrow (**^**).

The Detail Pane appears. For a description of the fields on this page, see *Detail Pane—Record Listing View* (on page 55).

3   To close the Detail Pane, click the down arrow (**V**) in the right-side of the section header.

Comparing data

Comparing two clinical forms

Use this procedure to compare the clinical data for a particular form against a second (same or different) form to see if there are any misalignments or gaps in the data. You can choose to filter the data on either form so that you are viewing only the data for a single subject, site, or visit.

1   Navigate to the Record Listing View in the Data Viewer.

    For more information, see *Displaying the Record Listing View* (on page 114).

2   In the **Forms** pane, single-click the name of the form that you want to compare against another form.

    The data for the selected form appears in the Form Data Table.

3   In the toolbar, from the **Open Comparison View** drop-down list (), select the form that you want to compare to the currently selected form.

    The Record Comparison View appears. For a description of the fields on this page, see *Components—Record Comparison View* (on page 63).

    - The form that you selected in the Record Listing View appears in the top data view panel.

        The top data view panel inherits all current filtering criteria set for the Record Listing View.

    - The form that you selected from the Open Comparison View drop-down list appears in the bottom data view panel.

        The bottom data view panel inherits all current filtering criteria except for the form states.

4   To change the form that appears in either view, use the form name drop-down list in the section header.

    The name of the currently selected form appears as the label for the drop-down list.

5   To filter the data that appears in either view, click the **Filter** icon () in the section header.

    The Filters dialog box appears. For a description of the fields on this page, see *Filters pane—Data Viewer* (on page 71).

> **Note:** The two data view panels are independent of each other except that when you click a subject number in the top view, the rows in the bottom view are automatically filtered to display data only for the selected subject.

6   To filter the data that appears in either view using clinical data values, click the **Filter column data** icon () in the section header.

    The Column filter dialog box appears. For more information, see *Filtering on clinical data* (on page 234).

7   Do any or all of the following to the data in the top or bottom data view panel:

- Customize the columns.

    For more information, see *Customizing the columns in the Data Viewer* (on page 236).

- Perform InForm actions (such as freezing, locking, and source verifying) after reviewing the form data.

    For more information, see *Overview of performing InForm actions* (on page 253).

- Export data.

    For more information, see *Exporting data to Excel* (on page 264).

- Navigate to the CRF for the currently viewed data item, by single-clicking the form mnemonic in the **Form** column.

    For more information, see *Navigating from the Data Viewer to a CRF* (on page 116).

8   To close the Record Comparison View and return to the Record Listing View, from the toolbar for either view, click **Close Comparison View**.

The Record Listing View appears. The data from the form that appeared in the top data view panel appears.

Reviewing comments

Reviewing comments across a single form and one or more subjects, visits, or sites

Use this procedure to review form-level and item-level comments for a single form to make sure that clinical data has not been entered as comments that are not reflected in the form data.

> **Note:** Comments on deleted repeating forms or itemsets do not appear in the Comments View.

1   Navigate to the Record Listing View in the Data Viewer.

For more information, see *Displaying the Record Listing View* (on page 114).

2   Filter the data.

For more information, see *Filtering data for all views in the Data Viewer* (on page 231).

3   In the toolbar, click the **View Comments** icon ( ).

The Comments View appears in a separate browser window. For a description of the fields on this page, see *Components—Comments View* (on page 66).

Because the Comments View appears in a separate window, you can reference the current Data Viewer view side-by-side with the Comments View.

The Comments View displays the form-level and item-level comments for the current form, which are filtered using the existing filtering criteria.

- If text appears in the Item column, the comment is an item-level comment.

- If text does not appear in the Item column, the comment is a form-level comment.

4   To sort the data, click on any column heading.

The default sort order is the selected column, followed by the site, subject, visit sequence, and then form mnemonic. For more information, see *Sorting data in the Data Viewer* (on page 235).

5   To filter the comments data, click the **Filter** icon ( ) at the top of the **Comments View** window.

The Filters dialog box appears. For a description of the fields on this page, see *Filters pane— Data Viewer* (on page 71).

6   To find the form where a comment was entered, click on a row in the Comments View, and click **Go to Record Listings**.

The Record Listing View Single Subject view appears, and highlights the form where the comment was entered.

You can perform InForm actions on the selected record in the Record Listing Single Subject View, or you can navigate to the form to review the whole form.

> **Note:** The Comments View remains open until you close it, or until you log out of the InForm application. Only one Comments View window can be open at a time. If a Comments View is open, and you select the View Comments option again, the same Comments View window is reused.

Reviewing comments across all forms

Use this procedure to review form-level and item-level comments of all forms to make sure that clinical data has not been entered as comments that are not reflected in the form data.

> **Note:** Comments on deleted repeating forms or itemsets do not appear in the Comments View.

1   Navigate to the Summary View in the Data Viewer.

    For more information, see *Displaying the Summary View* (on page 113).

2   Filter the data.

    For more information, see *Filtering data for all views in the Data Viewer* (on page 231).

3   In the toolbar, click the **View Comments** icon ( ).

    The Comments View appears in a separate browser window. For a description of the fields on this page, see *Components—Comments View* (on page 66).

    Because the Comments View appears in a separate window, you can reference the current Data Viewer view side-by-side with the Comments View.

    The Comments View displays the form-level and item-level comments for all forms, which are filtered using the existing filtering criteria.

    • If text appears in the Item column, the comment is an item-level comment.

    • If text does not appear in the Item column, the comment is a form-level comment.

4   To sort the data, click on any column heading.

    The default sort order is the selected column, followed by the site, subject, visit sequence, and then form mnemonic. For more information, see *Sorting data in the Data Viewer* (on page 235).

5   To filter the comments data, click the **Filter** icon ( ) at the top of the **Comments View** window.

    The Filters dialog box appears. For a description of the fields on this page, see *Filters pane—Data Viewer* (on page 71).

6   To find the form where a comment was entered, click on a row in the Comments View, and click **Go to Record Listings**.

    The Record Listing View Single Subject view appears, and highlights the form where the comment was entered.

    You can perform InForm actions on the selected record in the Record Listing Single Subject View, or you can navigate to the form to review the whole form.

> **Note:** The Comments View remains open until you close it, or until you log out of the InForm application. Only one Comments View window can be open at a time. If a Comments View is open, and you select the View Comments option again, the same Comments View window is reused.

Marking comments as reviewed

Use this procedure to mark comments as reviewed. Marking a comment as reviewed is not considered to be a clinical data change.

> **Note:** Comments on deleted repeating forms or itemsets do not appear in the Comments View.

1   Navigate to the Comments View in the Data Viewer.

    For more information, see *Displaying the Comments View* (on page 115).

2   Select the checkbox next to a comment to mark it as reviewed.

    • The Data Viewer saves the user name and date and time that the comment was marked as reviewed to the database immediately.

    • After you mark a comment as reviewed, the comment and its review status are shown to all reviewers.

    • Any update to a comment in the InForm application unmarks the comment within the Data Viewer.

The Data Viewer displays the user name and date of review as a tooltip when you hover over the checkbox within the Comments View dialog box.

• The date and time is the local date and time.

• The date format is determined for each user by the setting in the Date Format field on the User details page in the Admin user interface.

Working with custom Data Viewer views

Overview of creating custom views

In the Data Viewer, custom views provide a way to view data from multiple forms in one view. Columns from multiple clinical forms can be put together into a single view on which you can create queries, verify items, and export the data to Excel.

You can create custom views using columns from non-repeating forms, regular forms, repeating forms, or itemsets.

- If the custom view is created with columns from non-repeating forms and no itemsets, the view opens in the Record Listing View.

- If the custom view is created with columns from regular forms, repeating forms, or itemsets the view opens in the Record Comparison View.

Custom views have the same look and feel as clinical forms. However, they are available only in the Data Viewer; they do not appear with other forms in the InForm application. Form states and review states are not available for custom views because they represent multiple forms, and are not actual clinical forms.

- Only activated clinical forms are available for use in creating a custom view.

- You can select any displayable column from any available clinical form.

- Columns that do not appear in the Record Listing View because of user rights or a blinding restriction are not available as selectable columns.

- Columns from different forms are paired to each other based on site, subject, and visit.

- Columns that have no data or are from a form that has not been activated appear as blank.

- Current filtering criteria in the Record Listings View is applied to the custom view.

- Locales used for the current Record Listing View are used for generating the custom view.

Repeating visits and custom views

For repeating visits, *only* forms that belong to the same repeating visit (that is, the same visit and same visit index) can be paired together and presented as a custom view record (that is, in one single row). The visit sequence appears in the Form Data Table in the Record Listing View to identify the particular visit.

Repeating forms and custom views

Custom views that contain one or more repeating forms (for example, an Adverse Event form) in addition to one or more non-repeating forms) appear in the Record Comparison View instead of the Record Listing View because there can be multiple instances of the same form for a particular visit.

In the Record Comparison View.

- All of the columns you select for the custom view from non-repeating forms appear in the top data view panel.

- The first repeating form you select for the custom view appears in the bottom data view panel.

- All other repeating forms you select for the custom view are available from the Form name drop-down list in either data view panel.

Itemsets and custom views

Custom views that contain itemsets (for example, from a Dose form) in addition to one or more non-repeating forms appear in the Data Viewer Record Comparison View instead of the Record Listing View.

In the Record Comparison View:

- All of the items you select for the custom view from a non-repeating form appear in the top data view panel.

- The itemsets you select for the custom view appear in the bottom data view panel.

- All the itemsets you select for the custom view are available from the Form name drop-down list in either data view panel.

Creating a custom view

1   Navigate to the Record Listing View in the Data Viewer.

    For more information, see *Displaying the Record Listing View* (on page 114).

2   In the **Forms** pane, select a form or itemset, and click the **Create Custom View** icon ( ).

    The Create Custom View dialog box appears. For a description of the fields on this page, see *Create Custom View dialog box* (on page 57).

    The columns that are available in the form or itemset you selected automatically populate the Selected columns list.

    • To clear the list, click the **Remove all selected columns** icon ( ).

        The available columns appear in the Available columns list.

3   In the **Forms** list, select a form or itemset that you want to choose a column from.

    All available columns in the form or itemset you select appear in the Available columns list.

4   In the **Available columns** list, select one or more columns, and click **Add**.

    You can also drag and drop columns between the fields.

    The columns you select appear in the Selected columns list.

    • For non-repeating forms, you can select:

        • Columns from a maximum of five forms.

        • A maximum of 15 columns across the five forms.

    • For repeating forms or itemsets, there are no form and column restrictions because the custom view displays them in primary and secondary views in the Record Comparison View.

5   Repeat steps 3 and 4 as needed until all the columns you want in a single view appear in the **Selected columns** list.

6   In the **Custom view name** field, type a unique name for the custom form.

7   Click **Create**.

    • If the custom view is created with columns from non-repeating forms and no itemsets, the view opens in the Record Listing View.

    • If the custom view is created with columns from regular forms, repeating forms, or itemsets the view opens in the Record Comparison View.

    The custom view name appears in the Forms pane in the Record Listing View.

Displaying a custom view

1   Navigate to the Record Listing View in the Data Viewer.

For more information, see *Displaying the Record Listing View* (on page 114).

2   In the **Forms** pane, select a custom view.

- If the custom view is created with columns from non-repeating forms and no itemsets, the view opens in the Record Listing View.

- If the custom view is created with columns from regular forms, repeating forms, or itemsets the view opens in the Record Comparison View.

Deleting a custom view created with non-repeating forms and no itemsets

1   Navigate to the Record Listing View in the Data Viewer.

For more information, see *Displaying the Record Listing View* (on page 114).

2   In the **Forms** pane, select a custom view.

The Delete Custom View icon ( ) appears in the title bar of the Forms pane.

3   Click the **Delete Custom View** icon ( ).

The custom view is deleted. A confirmation box does not appear.

Deleting a custom view created with regular forms, repeating forms, or itemsets

1   Navigate to the Record Listing View in the Data Viewer.

For more information, see *Displaying the Record Listing View* (on page 114).

2   In the **Forms** pane, select a custom view.

The Record Comparison View appears, and the Delete Custom View icon ( ) appears in the section header in both the top and bottom data panels.

3   In either the top or bottom data panel, click the **Delete Custom View** icon ( ).

The custom view is deleted. A confirmation box does not appear.

Performing InForm actions

Overview of performing InForm actions

In the Data Viewer, you can perform some standard InForm actions, such as freezing, locking, and source verifying. For more information, see *InForm actions available in the Data Viewer* (on page 254). You can perform these InForm actions, if you have the rights to do so, in all Data Viewer views except the Comments View.

> **Note:** Because custom views are created from multiple clinical forms, form-level actions such as freezing, locking, and assigning custom review states are not available for custom views. You can, however, perform item-level actions such as source verifying items in custom views.

You can perform the available actions on a single record, or multiple records at one time. If you select multiple records and any of them have a condition that make the request invalid, an appropriate warning or error message appears, but it does not prevent the whole request from being completed. Records that process successfully are updated and saved to the database. If an action is not successful (for example, you perform a lock action on a record that is already locked), a notification message appears and the record is not changed.

You can also:

- View the InForm states that are applied to items that appear in the Data Viewer.

  For more information, see *InForm states used in the Data Viewer* (on page 255). The Data Viewer summarizes the form counts of individual states and presents them as summaries.

  > **Note:** The InForm states that the Data Viewer displays follow the same computations currently used in the **Reporting and Analysis** module.

- Assign up to five custom review states, if defined.

  For more information, see *Custom review states in the Data Viewer* (on page 256).

InForm actions available in the Data Viewer

You can use the Data Viewer to perform the following InForm actions while reviewing data.

- Create a query on an item.

- Freeze or unfreeze a form or visit.

- Lock or unlock a form or visit.

- Mark a form or visit verified or not verified.

> **Note:** You can perform these InForm actions, if you have the rights to do so, in all Data Viewer views except the Comments View.

Level	InForm action
Item-level	Create query • Open • Candidate
Form and visit levels	• Freeze • Unfreeze • Lock • Unlock **Note:** The Freeze, Unfreeze, Lock, and Unlock actions are not available for custom views. • Mark Verified / Mark item verified • Mark Not Verified / Mark item not verified **Note:** Because a custom view is created from multiple clinical forms, you can apply verification only on the selected items in the Record Listing View or Record Comparison View.

InForm states used in the Data Viewer

The InForm states appear as column headings in the Summary View, labels in the Record Listing View—Summary Data pane, and in the State(s) list in the Filters pane.

Level	InForm state
Form-level	Completeness of Form—Refers to data completeness. The form is considered complete when all required data has been entered. It does not matter if there are open or answered queries. • Not Started (only available in the Record Listing View for a Single Subject.) • Incomplete • Complete
	Verification: • Not Verified • Ready to verify • Partially Verified • Verified
	Frozen
Item-level	Queries on a data item: • Candidate • Opened • Answered • Closed
Item and form levels	• Incomplete • Mark incomplete
Form and visit levels	Locked

Custom review states in the Data Viewer

Up to five form-level customizable states, called Review States, are available in the Data Viewer in addition to the standard InForm states.

These states are defined during study design in the Central Designer application, or by a system administrator using MedML in the InForm application. For more information, see ***Defining the Data Viewer custom review states*** (on page 385).

If defined, the customized review states can provide you with greater flexibility in tracking the review progress.

> **Note:** The custom review states can be assigned and used only in the Data Viewer. You cannot assign custom review states to custom views.

Each custom review state has three customizable stages. For example, an administrator can add two custom review states, labeled Medical Review and Data Management Review, each with three stages of Needs Review, Pending, and Reviewed.

- Review state: Medical Review

  - Stage 1: Needs Review (Default)

  - Stage 2: Pending

  - Stage 3: Reviewed

- Review state: Data Management Review

  - Stage 1: Needs Review (Default)

  - Stage 2: Pending

  - Stage 3: 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 that is applied before any reviewer's assignment of other review stages.

The custom review states and stages are installed with available product locales and they appear in the Data Viewer in the user's Product Locale.

Custom review states and the audit trail

The Data Viewer records the assignments of custom review states so that an audit trail of all assignments is available. The audit trail information is available in the Detail Pane in the Record Listing View. For more information, see ***Detail Pane—Record Listing View*** (on page 55).

All custom review states are available for use by the InForm rule package so that rules can be designed to set or retrieve the custom review states. In the audit trail, any changes made by the rule package on the custom review states are marked as user Autoquery. For more information, see the *Utilities Guide*.

Creating a query in the Data Viewer

1   Navigate to the Record Listing View or Record Comparison View in the Data Viewer.

   For more information, see:

   • *Displaying the Record Listing View* (on page 114).

   • *Displaying the Record Comparison View* (on page 115).

2   Click in one or more data cells in the data table to highlight the records.

3   In the toolbar, click the **Create Query** icon ( ).

   The Create Query dialog box appears.

   > **Note:** You cannot create a query on a calculated item. If you select only one cell, and that cell is for a calculated item, the Create Query icon does not appear. However, if you select more than one cell and some of the selected cells are not calculated items, the Create Query icon does appear. When you submit the data to create the query, a progress indication appears, and any calculated items are returned as unsuccessful with an error message specifying which records failed for the action.

4   From the **Action** drop-down list, select a state for the query.

   • Create Query in Opened State

   • Create Query in Candidate State

   > **Note:** Both options appear if you have the rights to create a query in either the Candidate or Opened state. If you have only one of these access rights, the state is preselected.

5   In the **Reason for change** field, enter the reason for issuing the query.

   • From the **Action** drop-down list, select the appropriate text.

     or

   • Select **Other**, and type the reason in the text box.

6   Click **Submit**.

Answering a query in the Data Viewer

You cannot answer queries in the Data Viewer. To answer a query, you must navigate to the CRF.

For more information, see *Navigating from the Data Viewer to a CRF* (on page 116) and *Answering queries* (on page 163).

Closing a query in the Data Viewer

You cannot close queries in the Data Viewer. To close a query, you must navigate to the CRF.

For more information, see *Navigating from the Data Viewer to a CRF* (on page 116) and *Closing queries* (on page 165).

Freezing and unfreezing records in the Data Viewer

> **Note:** You can also freeze and unfreeze forms from a CRF. For more information, see *Freezing or locking a form* (on page 222) or *Freezing or locking several forms at one time* (on page 223).
>
> **Note:** The Freeze and Unfreeze actions are not available for custom views.

1 Navigate to the Summary View, Record Listing View, or Record Comparison View in the Data Viewer.

For more information, see:

- *Displaying the Summary View* (on page 113).

- *Displaying the Record Listing View* (on page 114).

- *Displaying the Record Comparison View* (on page 115).

2 Click in one or more data cells in the data table to highlight the records.

The level of records (visit or form) that are available for freezing and unfreezing depend on the view you select.

- **Summary View**—Visit or site level.

  Assigning InForm states to records in the Summary View requires that you select one or more cells that contain summary counts, and then click the appropriate icon in the Data Viewer toolbar.

  - The InForm state is applied to all the records represented by the counts in the selected cell(s).

  - You can use the Filters pane to apply the subject filter in the Summary View, or to assign states to a single subject or to multiple subjects across CRF types.

- **Record Listing View**—Visit and form level.

- **Record Comparison View**—Visit and form level.

In the Record Listing View or Record Comparison View, you can click on one or more rows to highlight the rows, and then click the appropriate icon in the Data Viewer toolbar. The InForm state is applied to all selected records.

For example, when you are viewing data in the Record Listing View, you can freeze or unfreeze selected forms, or all forms under selected visits.

3 In the toolbar, click the **Freeze** icon (❄) or **Unfreeze** icon (❄).

> **Note:** A progress indication appears. An error message appears if there are any failed actions.

Locking and unlocking records in the Data Viewer

> **Note:** You can also lock and unlock forms from a CRF. For more information, see *Freezing or locking a form* (on page 222) or *Freezing or locking several forms at one time* (on page 223).
>
> **Note:** The Lock and Unlock actions are not available for custom views.

1   Navigate to the Summary View, Record Listing View, or Record Comparison View in the Data Viewer.

For more information, see:

- *Displaying the Summary View* (on page 113).

- *Displaying the Record Listing View* (on page 114).

- *Displaying the Record Comparison View* (on page 115).

2   Click in one or more data cells in the data table to highlight the records.

The level of records (visit or form) that are available for locking or unlocking depend on the view you select.

- **Summary View**—Visit or site level.

- **Record Listing View**—Visit and form level.

- **Record Comparison View**—Visit and form level.

You can lock records at a higher level than the current view. For example, when you are viewing data in the Record Listing View, you can lock or unlock a selected form, or all forms under selected visits.

3   In the toolbar, click the **Lock** icon ( ) or **Unlock** icon ( ).

> **Note:** A progress indication appears. An error message appears if there are any failed actions.

Marking records Verified or Not Verified in the Data Viewer

> **Note:** You can also mark forms as Verified or Not Verified from a CRF. For more information, see *Source verifying data on an online form* (on page 205).

1   Navigate to the Summary View, Record Listing View, or Record Comparison View in the Data Viewer.

For more information, see:

- *Displaying the Summary View* (on page 113).

- *Displaying the Record Listing View* (on page 114).

- *Displaying the Record Comparison View* (on page 115).

2   Click in one or more data cells in the data table to highlight the records.

The level of records (visit or form) that are available to be marked as verified or not verified depends on the view you select.

- **Summary View**—Visit or site level.

- **Record Listing View**—Visit and form level.

- **Record Comparison View**—Visit and form level.

For example, when you are viewing data in the Record Listing View, you can mark as Verified or Not Verified selected forms, or all forms under selected visits.

3   For a form or forms, in the toolbar, from the **Source Verification** drop-down list (✔), select **Mark Verified** or **Mark Not Verified**.

A progress indication appears. An error message appears if there are any failed actions.

or

For a custom view, in the toolbar, from the **Source Verification** drop-down list (✔), select **Mark item verified** or **Mark item not verified**.

Because a custom view is created from multiple clinical forms, you can apply verification only on the selected items in the Record Listing View or Record Comparison View.

Assigning a custom review state

> **Note:** You cannot assign custom review states to custom views.

1   Navigate to the Summary View, Record Listing View, or Record Comparison View in the Data Viewer.

For more information, see:

- *Displaying the Summary View* (on page 113).

- *Displaying the Record Listing View* (on page 114).

- *Displaying the Record Comparison View* (on page 115).

2   Click in one or more data cells in the data table to highlight the records.

The level of records (visit or form) that are available to be assigned a custom review state depends on the view you select.

- **Summary View**—Visit or site level.

  Assigning InForm states to records in the Summary View requires that you select one or more cells that contain summary counts, and then click the appropriate icon in the Data Viewer toolbar.

  - The InForm state is applied to all the records represented by the counts in the selected cell(s).

  - You can use the Filters pane to apply the subject filter in the Summary View, or to assign states to a single subject or to multiple subjects across CRF types.

- **Record Listing View**—Visit and form level.

- **Record Comparison View**—Visit and form level.

In the Record Listing View or the Record Comparison View, you can click on one or more rows to highlight the rows, and then select the appropriate custom review state from the Review drop-down list in the Data Viewer toolbar.

For example, when you are reviewing data in the Record Listing View, you can assign a custom review state to a selected form, or all forms under selected visits.

3   In the toolbar, from the **Review** drop-down list ( ), select a custom review state.

The Assign review state dialog box appears.

4   Optionally, enter a comment (20 characters maximum) that describes the custom review state assignment, and click **OK**.

The custom review state comments, which are different from other form or item comments on a CRF, appear in a column in the Record Listing View and the Record Comparison View.

> **Note:** A progress indication appears. An error message appears if there are any failed actions.

Adding item or form comments in the Data Viewer

You can only review comments—you cannot add or edit item-level or form-level comments—in the Data Viewer Comments View. To add or edit a comment, you must navigate to a CRF.

For more information, see:

- *Navigating from the Data Viewer to a CRF* (on page 116).

- *Entering a comment on a form* (on page 138).

- *Entering a comment on a form item* (on page 139).

- *Entering row comments in a Repeating Data itemset* (on page 140).

Exporting data to Excel

Overview of exporting data to Excel

All views in the Data Viewer provide an option to export and save data in Excel format.

You export or save the data in the current view, with the selected sorting and filtering criteria, and the product and study locale settings defined for the current view.

Exporting data to Excel

1   Navigate to the Summary View, Record Listing View, or Record Comparison View in the Data Viewer.

For more information, see:

- *Displaying the Summary View* (on page 113).

- *Displaying the Record Listing View* (on page 114).

- *Displaying the Record Comparison View* (on page 115).

2   Customize the data view as needed.

For more information, see *Overview of customizing the Data Viewer workspace* (on page 230).

3   In the toolbar, click the **Excel** icon ( ).

The File Download dialog box appears.

4   Do one of the following:

- To view the data in an Excel spreadsheet, click **Open**.

- To save the data in Excel spreadsheet format, click **Save**.

> **Note:** Any item that has queries in any state except for the Closed state are italicized in Excel.
>
> **Note:** If the current view is a Record Comparison View, only the active view is exported.

You can print the data from Excel; you cannot print the data directly from the Data Viewer.

Exporting comments to Excel

1   Navigate to the Comments View in the Data Viewer.

For more information, see *Displaying the Comments View* (on page 115).

2   Customize the data view as needed.

For more information, see *Overview of customizing the Data Viewer workspace* (on page 230).

3   Click the **Excel** icon ( ) at the top of the Comments View.

The File Download dialog box appears.

4   Do one of the following:

- To view the comments in an Excel spreadsheet, click **Open**.

- To save the comments in Excel spreadsheet format, click **Save**.

> **Note:** Any item that has queries in any state except for the Closed state are italicized in Excel.

You can print the data from Excel; you cannot print the data directly from the Data Viewer.

When you log out of the InForm application, the Comments View closes automatically.

CHAPTER 11
Signatures

In this chapter

Overview of signatures

When a form or case report book is signed, it is expected that data entry is complete, source verification has been performed, and all queries are resolved and closed. The exact significance of a signature can vary from study to study. For example, a Principal Investigator (PI) can sign a form to indicate responsibility for the accuracy and completeness of the data, and a Clinical Research Associate (CRA) can sign the same form to indicate that the review is complete. Signatures can also mean form authorship or approval.

The language of the affidavit page on which a signer enters signature information indicates what the signature is intended to convey. Optionally, you can configure a brief definition or summary of the affidavit to appear in the **Meaning** column of the signature section on all forms that require signatures.

Form and case report book signatures

The InForm application allows you to configure studies so that your signature is attached to a single form, several forms, or an entire case report book. For example, a study can be configured to require a signature on certain key forms for each subject and also to require a signature on the case report book for each subject.

When a study is set up, specific forms are designated as signing CRFs. Additionally, if signing is required for a complete case report book, a single form is designated as the signing CRF for the case report book.

List of required signatures

A list of required and applied signatures appears on the electronic, printed, and PDF versions of a form. For a signed case report book, the list of signatures appears on the CRF that is designated as the case report book signing CRF.

Signature groups

During study setup, users who have rights to sign forms or case report books are assigned to signature groups. A signing form requires a member of one or more signature groups to sign it. The meaning of a signature is included in the definition of the signature group. The InForm application displays a list of required and applied signatures at the bottom of each signing form.

> **Note:** When a form is associated with one signature group, it must be signed by one member of that signature group to be considered signed. When a form is associated with more than one signature group, it must be signed by one member of each signature group to be considered signed.

The Signature Status Details page provides details about signature status, the meaning of the signature, and the date when the form was signed. The **Machine Name** column displays the computer that the user was using when the form was signed.

> **Note:** In order to be able to sign a form or case report book, a user must have signing rights *and* must be in the required signature group.

Invalidation of signature by data update

If a user updates a signed form, the InForm application invalidates the previous signature or signatures and updates the signature listings and each form to indicate that the form or case report book must be signed again.

Data that has been coded and imported to the InForm application has special invalidation considerations. Coded data is often designed to be hidden on a form. If the import of coded data invalidates a signature, it might not be possible to see which item caused the invalidation. Therefore, study designers can specify whether imported data invalidates a signature.

Before you sign a CRF or case report book

Before you can sign a CRF, the following conditions must be true:

- The CRF is set up as a signing form.
- You have the right to sign CRFs.
- You are in the same signature group as the CRF.
- No other user in the signature group has already signed the CRF.
- The CRF has at least one entered data item.

Before you can sign a case report book, the following conditions must be true:

- A CRF has been set up as the form used to sign the case report book.
- You have the right to sign a case report book.
- You are in the same signature group as the case report book.
- No other user in the signature group has already signed the case report book.
- At least one data item is entered in the final CRF of the case report book.

Signing a CRF or case report book

The procedures for signing a CRF or a case report book are the same, with the following exceptions:

- You access the form signature page from a **Sign** button or link.

- You access the case report book signature page from a **Sign Book** button or link.

- To sign a case report book, you sign the designated form on which the signature applies to the entire case report book.

> **Note:** When a form is associated with one signature group, it must be signed by one member of that signature group to be considered signed. When a form is associated with more than one signature group, it must be signed by one member of each signature group to be considered signed.

To sign a CRF or case report book:

1 In the navigation toolbar, click **Signatures**.

The Required Signatures page appears. For a description of the fields on this page, see *Required Signatures page* (on page 276).

2 Optionally, use the drop-down lists to filter the list of documents that require signatures.

You can select **All** to display all forms or case report books in the category.

Use the page selector to navigate through multiple pages of the Required Signatures page.

3 In the **Signature** column, click **Sign** for the form that you want to sign.

The print preview and the signing affidavit appear.

4 Read the affidavit.

5 In the **User Name** and **Password** fields, type your InForm username and password.

> **Note:** You need to type both your user name and password only the first time you sign the form during an InForm session. If you need to re-sign a form, only type your password.

6 Click **Submit**.

The InForm application updates the signing status on the Required Signatures page, on the Signature Status Details page, and on the CRF.

- Alternatively, to access the signing affidavit for a signing CRF without going through the Required Signatures page, click Sign CRF on the signing CRF.

- Alternatively, to access the signing affidavit for the CRF designated for signing a case report book, click Sign Book on the Time and Events Schedule or on the form.

When a form changes after signature

The InForm application automatically invalidates signatures and resets the signing status if it is necessary to issue a query or update data after a form is signed.

Single signed CRF

- The InForm application sets the signing status to **Unsigned**.

- The form must be re-signed by all required signatories, often after the appropriate source verification and query resolution activities.

Signed CRF in a signed case report book

- The InForm application sets the signing status of the CRF to **Unsigned**.

- The form must be re-signed by all required signatories, after the appropriate source verification and query resolution activities.

- The InForm application sets the signing status of the case report book to **Unsigned**, and the case report book must be signed again.

Unsigned CRF in a signed case report book

- The InForm application sets the signing status of the case report book to **Unsigned**.

- The case report book must be re-signed by all required signatories, after the appropriate source verification and query resolution activities.

> **Note:** If the case report book contains individually signed forms, those forms are not considered unsigned and do not need to be re-signed.

The **Sign** or **Sign Book** link for the form reappears in the **Signature** column of the Required Signatures page. The Signature Status Details page maintains an audit trail of the previous signatures, and the message at the top of the page indicates the signature groups from which a member must re-sign the form.

If a signature is invalidated and must be obtained again, follow the steps in *Signing a CRF or case report book* (on page 271) to repeat the signing process.

When your signature fails processing

If you enter an incorrect user name or password while signing, try to re-enter your user name and password, just as you would when logging in to the InForm application. You have the same number of tries as you would when you log in (this number is configured for each study).

If you fail to enter the correct user name and password after the configured number of tries, the InForm application logs you out and inactivates your user account. To reinstate your account, you must contact your system administrator.

Viewing signature status

To review signature status, use the Required Signatures page. Two versions of this page are available:

- My signatures
- All signatures

Viewing the signatures status for your signatures

This version of the Required Signatures page displays the signature status for CRFs and case report books that require a signature by a member of your signature group. This version is available and is the default view if you have the right to sign CRFs or case report books and you are a member of a signature group. In this version, the **Signature** column indicates the signing status of the CRFs or case report books for which your signature group is responsible.

To review signatures using this version of the Required Signatures page:

1 In the navigation pane, click **Signatures**.

   The Required Signatures—My Signatures page appears.

2 Optionally, use the drop-down lists to filter the list of documents that require signatures.

   For more information, see *Required Signatures page* (on page 276).

3 Review the **Signature** column.

   The icon or signing link indicates the signing status of the document.

Viewing the signature status for all signatures

This version of the Required Signatures page displays the signature status of CRFs and case report books by site, regardless of the signature group whose member must sign them. This version is available if you have the right to view CRF or case report book signature information. You can display this version of the page if you have both signing and viewing rights. In this version, the **All Signatures** column in the required signatures table indicates the signing status of all CRFs and case report books for the site.

To review signatures using this version of the Required Signatures page:

1 In the navigation pane, click **Signatures**.

   The Required Signatures—My Signatures page appears.

2 Click **View All Signatures**.

   The Required Signatures—All Signatures page appears.

3 Optionally, use the drop-down lists to filter the list of documents that require signatures.

4 Review the **Signature** column.

   The icon or signing link indicates the signing status of the document.

Viewing signature details

1   In the navigation toolbar, click **Signatures**.

    The Required Signatures—My Signatures page appears.

2   Optionally, click **View All Signatures**.

    The Required Signatures—All Signatures page appears.

3   Optionally, use the drop-down lists to filter the list of documents that require signatures.

4   In the **Details** column, click **View** for the subject and CRF or case report book for which to review the signature history.

    The Signature Status Details page appears.

Viewing a print preview for a CRF or case report book

The InForm application provides the ability to print and manually sign forms and case report books before submitting study data to regulatory authorities.

1   In the navigation toolbar, click **Signatures**.

The Required Signatures page appears.

2   In the **Print** column, click **Preview**.

The following information appears.

Document	Displays
Signed CRF	• CRF and the affidavit in read-only mode. • The Printed Name field, where a PI can manually sign the printed affidavit. **Note:** If the CRF is unsigned, the preview displays the CRF without the affidavit.
Signed CRB	• All visits within the CRB, except the Final Visit, in the order in which they are defined (includes unscheduled and dynamic visits). • All common forms, in the order in which they are defined (started and unstarted). The affidavits and the signature date and time appear for all signed forms. **Note:** Each instance of a repeating form appears. If the form is signed, the accompanying affidavit also appears. Deleted repeating form instances appear with a line through them. • The Final Visit (the visit that includes the Study Completion form).

Note: The user name in a signature appears in the order that is specified at the study level (or at the site level if this setting is not specified at the study level) at the time of the signature.

The Final Visit (the visit with the Study Completion form, which has space for a handwritten signature) appears at the end of the print version and print preview of a signed case report book. Common forms and unscheduled visits appear in the locations in which they occur in the study.

User interface—Signatures

Required Signatures page

The Required Signatures page allows you to review the status of forms and case report books that require signatures, and to navigate to the electronic signature form for a specific form or case report book. Each icon provides a detailed form state for a single form. Use the hover Help for a description of each icon.

Two versions of this page are available: My signatures and All signatures.

Several filters are available; by making selections in the filters, you can specify which forms or case report books you see in the list. For each form or case report book in the list, the Required Signatures page includes the site, subject number and initials, signature date (if signed), signature status, and a status icon indicating form or case report book completion status. Form rows also include the visit name and form abbreviation.

> **Note:** The information on the Required Signatures page varies according to whether you have rights to sign forms or case report books or to view signature information about forms or case report books.

Fields

Field	Description
Site	Drop-down list of all the sites you can access.
Subject filter	Filters the list of documents based on the subject.
Type filter	Filters the list of documents based on the item to be signed. • All • Book • CRF
Status filter	Filters the list of documents based on the signature status. • All • Signed • Unsigned

Field	Description
CRF/CRB Status filter	Filters the list of documents based on the form or case report book status. • All • All Signatures Complete • Not All Signatures Complete • With Queries • With Missing Values • Missing & Queries • Frozen • Locked • Ready For SV • Completed SV • SVd and Complete • Complete • Not Done • Deleted **Note:** The InForm application ignores filters that do not apply to the selected Type. For example, if you select Book from the Type filter and select Ready for SV in the CRF/CRB status filter, the InForm application ignores the Ready for SV filter, because SV readiness applies only at the CRF level.
Status	The form or case report book completion status. Click the icon to navigate to the corresponding form in the corresponding visit. Use the hover Help for a description of each icon.
Signature	The signature status. If a form or case report book requires signature and a user has rights to sign forms or case report books, this column contains an icon that displays the appropriate signature affidavits and enables the user to sign. Use the hover Help for a description of each icon. For more information, see *Signature status icons* (on page 81).
Site	Site mnemonic.
Subject	Subject number and Subject initials.
Visit	Visit name.
CRF	Form abbreviation.
Group	Signature group.
Signed	Signature date, if signed.
Details	Click the View link to display the Signature Status Details page to view the signing history of a form or case report book.

Field	Description

Print	Click the Preview link to do either of the following:
	
	 • Display a print preview of a form and affidavit. The affidavit has a space for the Principal Investigator to manually sign.
	
	     ▪ If the CRF has a status of Signed, the form and affidavit display in read-only mode.
	
	     ▪ If the CRF has a status of Unsigned, the form appears without the affidavit.
	
	 • Display a print preview of all the CRFs in a case report book with the study completion form and the completed affidavits. The affidavit has a space for the Principal Investigator to manually sign.
	
	     ▪ If the case report book has a status of Signed, the case report book signature date and time appear.

Buttons

Button	Description
Page selector	A multi-part control that is located on the bottom-left of the content pane. Click different parts of the control to move through the pages of CRFs or case report books in the Required Signatures list.
View All Signatures	Opens the Required Signature—All Signatures page. Appears only when viewing the Required Signatures—My Signatures page.
View My Signatures	Opens the Required Signature—My Signatures page. Appears only when viewing the Required Signatures—All Signatures page.

C H A P T E R   1 2
Study-specific documentation

In this chapter

Overview of study-specific documentation

Online study documentation is an optional feature of the InForm application. Depending on the way your study is set up, you might have access to one or more of the following types of study documentation:

- **Protocol**—A copy of the sponsor's study protocol, formatted for online viewing, that describes in detail how the study is to be conducted.

- **CRF Help**—A set of instructions and other details about specific CRF data items or about an entire CRF.

  CRF Help is an optional feature that allows you to display study documentation that describes a particular item or form. If your study is set up with this feature, you can navigate directly from the item or form to the study documentation.

  CRF Help can also include information about the edit checks on CRF items.

  You can also link directly to CRF Help on a CRF or CRF item, if your study is set up to provide those links. If these links are set up, the CRF name and the item descriptions in a CRF are underlined.

  If certain forms or items are particularly confusing, or generate many queries, ask your study administrator to create additional form help for the forms or items.

- **Visit calculator (Subject schedule)**—A copy of the Visit Calculator page that appears at the end of the enrollment process.

  The Visit Calculator page computes suggested visit dates based on the date of the enrollment visit. You can edit the start date to determine suggested visit dates that conform to the visit timing that is specified in the study protocol.

- **Sample study case report book**—A complete set of read-only blank CRFs that you can use to familiarize yourself with the layout of the forms and visits.

Viewing study-specific documentation

1   In the navigation toolbar, click **Documents**.

     The Document window appears in a second browser window that you can resize and move for easy viewing. The window displays the following panes:

- **Document selection**—Contains a tab for each document that you can display.

- **Table of contents (TOC)**—Displays the table of contents for the study documents.

- **Document text**—Displays the text of the open document.

- **Navigation**—Contains buttons that let you navigate through the study documents, and close the document window.

2   Select the tab for the type of document to display.

3   Click the appropriate link to navigate to a specific topic within the document.

Displaying study-specific help for a form

> **Note:** If your study supports this type of navigation to form help, the text of the CRF name and item descriptions are underlined.

To navigate from a form to the applicable part of CRF Help:

1 In the navigation toolbar, click **Subjects**.

The Case Report Books page appears.

2 Click the status icon for a subject and visit.

The Case Report Forms page appears.

3 In the navigation pane, use one of the form selectors to choose the form whose help you want to display.

The selected CRF appears.

4 Select the type of help that you want to view.

- To view help for the entire form, click the underlined form name at the top of the page.

- To view help on a specific form item, click the underlined item description.

Viewing the visit calculator (subject schedule)

1   In the navigation toolbar, click **Documents**.

The Document window appears in a second browser window that you can resize and move for easy viewing.

2   Click **Visit Calculator**.

The Visit calculator (Subject schedule) appears. For more information, see *Visit calculator* (on page 131).

Viewing the sample case report book

The sample case report book includes a read-only blank copy of each form in the study, organized by visit. The sample forms are for display only; you can use them to familiarize yourself with the layout of the forms and visits in your study.

1   In the navigation toolbar, click **Documents**.

The Document window appears in a second browser window that you can resize and move for easy viewing.

2   Click **Sample Book**.

CHAPTER 13
Subject transfer data

In this chapter

Overview of subject transfer data

After an administrator transfers a subject to a new site, the InForm application generates an archive of the subject's case report book at the originating site. For more information, see *Audit history and subject record transfer archive* (on page 374).

Users with access to the Case Report Books page can view a list of the subjects who have been moved to or from the current site, and can view the archives.

Viewing the list of transferred subjects

1   In the navigation toolbar, click **Subjects**.

The Case Report Books page appears. If you have access to more than one site, the **Site** drop-down list shows the sites to which you have access. The Case Report Books page displays only the subjects who are currently enrolled in the site or sites to which you have access.

> **Note:** Use the Site drop-down list to filter the display to show subjects that were transferred to and from a particular site.

2   Click **Show Transferred**.

The Transferred Subjects for Site page appears. For a description of the fields on this page, see *Transferred Subjects for Site page* (on page 289).

> **Note:** If you filtered the Case Report Books page, the same filter is applied to the Transferred Subjects for Site page. If you have access to more than one site, you can filter the data again on the Transferred Subjects for Site page.

Viewing a subject transfer archive

1   Display the list of transferred subjects. For more information, see *Viewing the list of transferred subjects* (on page 287).

The Transferred Subjects for Site page appears.

2   In the **Archive** column, click **View**.

A new browser window opens, displaying the initials and subject number of the transferred subject, along with links to each form in the case report book, organized by visit. Common forms appear at the end of the list of links.

3   Click the form link to display the archive for a particular form.

An image of the form appears, along with links to the available detailed information.

4   Click the corresponding link to display details about a form or item.

5   In your browser window, click **Back** to navigate to the previous location in the archive.

User interface—Subject transfer data

Transferred Subjects for Site page

Use the Transferred Subjects for Site page in the Case Report Books to view the list of subjects who have been transferred to or from the site or sites to which you have access.

Fields

Field	Description
Transferred Subjects for Site filter	Drop-down list of the sites you have access to.
Subject	Subject number at the current site.
From Site	The current, or originating, site for the subject before the subject transfer. If you had to change the subject number because of a conflict at the destination site, the new subject number appears enclosed in square brackets.
To Site	The destination site.
Date (GMT)	The date on which the subject transfer occurred. This date is in Greenwich Mean Time (GMT).
Archive	A link to the subject case report book archive. The archive shows the data that was entered before the transfer.

C H A P T E R   1 4
InForm administration

In this chapter

Overview of InForm administration

Administrative data specifies configuration parameters for a study, who is running a study, and how the InForm application distributes the workload. You can configure most of the InForm administration features through the user interface or by editing XML files and installing them using the MedML Installer utility.

To set up an InForm study, you:

- Configure the InForm administrative features using the InForm user interface or XML.

  This guide provides instructions for configuring the administrative features through the user interface.

  For information on configuring the administrative features using XML, see the *Utilities Guide*.

- Configuring additional study features.

  These tasks are not available through the InForm user interface. For more information, see the *Study and Reporting Setup Guide*.

The administration pages in the InForm user interface are all based on the default product locale that is defined during the installation (or by using pfadmin commands). The only exception is the Reset Your Password page, which uses the user's product locale. The administration pages allow setting of locales and entering the following information in any language:

- Site names.

- Country names.

- Rights groups names.

- Custom group names.

  Standard group names are provided in English.

InForm administration tasks

The following administrative tasks are required when setting up and administering a study. For lists of the rights associated with performing all study tasks, see *Rights required for typical study activities* (on page 306).

Task	Description	Required rights for UI access
Manage global system settings	Set options that specify how the InForm application behaves globally. The system configuration settings control the behavior of the study for all users. Configuration options include: • Intervals at which user re-authentication and password changes are required. • Whether users can enroll a subject with incomplete enrollment information. • Whether users must enter a comment when responding N/A, Unknown, or Not Done to a query. • Maximum lengths of CRF data entry controls and query text. • Whether Secure Socket Layer is enabled. • Whether Candidate queries close automatically. • Whether a customer-defined database (CDD) is enabled. • Whether unique subject identifiers are required across studies, sites, or not at all. • Whether sponsor users are allowed to edit frozen forms.	• Modify System Configuration
Manage rights and rights group	Create and maintain groups of rights that give users permission to perform InForm tasks.	• Manage Rights Groups **Note:** You cannot make changes to the rights group in which you are a member.
Manage groups and item groups	Create and maintain groups that allow you to associate users who have similar roles in a study and allow them access to specific areas of InForm functionality.	• Manage Other Groups

Task	Description	Required rights for UI access
Manage display overrides	A display override is a property that is applied to a specific item, which overrides default display properties for all users. The display properties can be set to Hidden, Editable (default), or Read-Only. This additional level of security allows you to give users with the same set of rights different access to specific items.	• Manage Rights Groups • Manage Other Groups
Maintain rules	Maintain rules that specify how data items are calculated or validated, and define automatic queries that are generated when a data item does not pass validation criteria. Rules are created with the Central Designer application and the MedML Installer utility.	At least one rule administration right: • Deactivate a Rule • Run a Rule • Modify a Rule
Maintain events	Maintain the study components that specify the action to take when a rule fails. Events are created with the Central Designer application and/or the MedML Installer utility.	At least one rule administration right: • Deactivate a Rule • Run a Rule • Modify a Rule
Manage sites	Site definitions specify address and contact information about a study location. Sites are associated with specific users, and this association determines the data to which users have access.	Manage Sites
Manage users	A user, or user account, identifies who can access an InForm study. Users are associated with sites, rights groups, and other groups (query, signature, and reporting). Each user can be associated to multiple sites and reporting groups, but to only one rights group, one query group, and one signature group.	• Create User • Modify User Information • Activate Site User • Deactivate Site User • Activate Sponsor user • Deactivate Sponsor User • Terminate User • Un-Terminate User

Task	Description	Required rights for UI access
Transfer subjects	The InForm subject record transfer feature allows you to transfer subject information from one site to another. You can transfer subjects one at a time using the InForm user interface, or you can transfer subjects in bulk using the InForm Data Import utility tool. For more information, see the *Utilities Guide*.	• Subject Transfer
Define custom review states for the Data Viewer	The system administrator for the study must install MedML that contains the definitions for the states. Custom review states cannot be defined using the InForm user interface.	To assign and view the custom review states in the Data Viewer: • Access Data Viewer / Data Export Listings • One or more of the following: ▪ Assign Review State 1 ▪ Assign Review State 2 ▪ Assign Review State 3 ▪ Assign Review State 4 ▪ Assign Review State 5 • View Review States
Configure partial source verification	You can decide whether all the data marked as SV Required during study design must be source verified, or if the amount of data to be source verified can be reduced using partial source verification (Partial SV).	• Mark and Unmark a CRF as SVed • Change Site SV Settings • View CRF

InForm administration and the MedML Installer utility

The administration module of the InForm application includes pages that enable you to administer study elements such as users, groups, and rules one at a time. When you initially set up a study, you may find it more efficient to use MedML and the MedML Installer utility.

- **MedML—**The Oracle XML for representing and exchanging clinical data definitions created in the InForm application.

- **MedML Installer utility**—A utility that parses the XML files you generate with MedML tags, validates them against the MedML schema and the constraints enforced by the database schema, and loads the study components they define into the database.

MedML and the MedML Installer utility enable you to create the definitions of multiple study elements and load them into the database in batch mode. For more information, see the *Utilities Guide*.

To create or edit an XML file and install it:

- Open Notepad, WordPad, or another text editor.

- Create or modify the XML.

- Use the MedML Installer utility to install the file into your study.

System settings

Overview of system settings

System configuration options are global settings that govern certain aspects of how the InForm application handles a study. The settings of configuration parameters specify customizable, system-wide InForm behaviors.

Setting the system configuration options

Changing some options requires that you stop and restart the study. For more information, see *Stopping and restarting an InForm study* (on page 297).

1   In the navigation toolbar, click **Admin**.

2   Click **Configuration**.

The System Configuration page appears.

3   Complete the information on the page using the descriptions in *System Configuration page* (on page 298).

4   Click **Update**.

Stopping and restarting an InForm study

1   Open a Command Prompt window.

2   Use the following **pfadmin** utility commands, as needed:

- To stop a study, use:

    pfadmin stop trial *study name*

- To restart a study, use:

    pfadmin start trial *study name*

For more information about pfadmin commands, see the *Study and Reporting Setup Guide.*

Viewing system information

1   In the navigation toolbar, click **Admin**.

2   Click **System**.

The System Information page appears. For a description of the fields on this page, see *System Information page* (on page 304).

User interface—System settings

System Configuration page

The System Configuration page enables you to set or modify system configuration options. The System Configuration page displays the following information for each editable system configuration option:

- Description.

- Current setting.

- Link to the Audit Trail page, which tracks any changes made to the setting.

Note: You can set most system configuration options using the System Configuration page or by installing their MedML definitions. Exceptions are noted in the following tables. For information about the MedML definitions of system configuration options, see the *Utilities Guide*.

Fields—Optional System Configuration

	Field	Description
1	Enroll subject with incomplete form	Yes or No (default). Indicates whether the InForm application permits a subject to be enrolled with incomplete screening or enrollment information, after override authorization.
2	Require a comment when entering N/A, Unknown, or Not Done	Yes or No (default). Indicates whether the InForm application requires a user to enter a comment when selecting N/A, Unknown, or Not Done on the Comment page instead of filling in a question on a CRF.
3	Post a query for conflict resolution	Yes or No (default). Indicates whether to create a query when, during communication with the Central Coding application, data is found to be entered into a data item by the two different servers.
4	Number of execution plan listener threads	Number of threads running in the background to process pending execution plans. The default is 4; at least 1 is required for any execution plans to run.
5	Number of execution plan re-submits	Maximum number of times to retry submission of a failed execution plan before it is logged as an error in the event log and removed from the queue of execution plans to be run. The default is 2.
6	Enable SSL	On or Off (default). Indicates whether Secure Sockets Layer should be enabled to provide encryption of data. Secure Sockets Layer is an encryption protocol that is provided with the browser software used to run the InForm application. **Note:** Before this option can take effect, you must stop and restart the study.

Field		Description
7	Automatically answer manual queries	On (default) or Off. Indicates whether the InForm application automatically changes a manual query state to Answered when a data item is updated.

Note: Regardless of this setting, the query workflow always performs an auto-answer when the Update Data and Answer option is used. |
| 8 | Maximum length of query text | Maximum number of characters of query text displayed below an item on a CRF. The default is 350 characters. |
| 9 | Require unique subject initials and date of birth | Study, Site, or None (default). Indicates whether the InForm application requires a unique combination of subject initials and date of birth for a study, a site, or not at all.

Note: If you specify that unique initials and date of birth are not required, and subjects with duplicate initials and date of birth are entered, and later you specify that unique IDs are required, the duplicate information that was entered previously will not be reported.

Subject record transfer consideration: If you plan to allow the transfer of subjects from one site to another, set the UniqueIntIDOBSwitch attribute to require unique initials and DOB across the study. This prevents the following situation:

• If a study does not require unique initials and date of birth, or only requires site uniqueness, and a user transfers a subject to a site where another subject exists who has the same initials and date of birth, the subject transfer fails.

• To transfer the subject, the user must change the subject initials to make the combination unique. |

Field		Description
10	Require unique subject ID	Study (default), Site, or None. Indicates whether the InForm application requires a unique subject number for a study, a site, or not at all.
		Note: If you specify that a unique subject number is not required and subjects with identical numbers are entered, and later you specify that unique subject numbers are required, the duplicate information that was previously entered will not be reported.
		Subject record transfer consideration: If you plan to allow the transfer of a subject from one site to another, set this option to require subject numbers to be unique across the entire study. The InForm application does not allow a subject to be transferred to another site in which a subject exists with the same subject number. If a conflict arises, the InForm application rejects the transfer, and you must manually change the subject number of the transferring subject to a value that is not duplicated at the target site.
		Partial SV consideration: If you plan to use partial source verification, set this option to Study or Site.
11	Allow sponsor users to edit frozen forms	Yes or No (default). Indicates whether sponsors will be able to edit a CRF after it has been marked as frozen.
		Batch run calculation rule consideration: If you plan to run calculation batch rules on case report books that are unfrozen and unlocked, but that have individually frozen forms, set this option to Yes to prevent errors. For more information, see *Frozen and locked forms and batch run calculation rules* (on page 340).
12	Order of UserName in Signature	Order of the names in the signature.
		• FirstName,LastName (default)
		• LastName,FirstName
13	Execution plan server	Name of the server(s) on which execution plans run.
14	MedML installation server/reporting administration server	Name of the server that is defined as the server on which all MedML, including changes to a study, is installed.
15	Reporting service full url	URL for the Cognos 8 BI Web service.
16	Reporting Internal URI	Cognos parameter that is set when running the CRNConfig installer. It is an internal URI that the InForm server uses to communicate to the Cognos server. The information can be found in cogstartup.xml. Example: http://appsru02.north.pf.com:9300/p2pd/servlet/dispatch.
17	Reporting authentication namespace ID	LDAP namespace that is used to authenticate InForm users on the reporting server.

Field		Description
18	Reporting user root	The top-level reporting folder for the company. Use this field only if you are hosting several companies on one reporting server and have set up reporting folders for each company.
		Leave this field blank if you are not hosting studies for different companies, or if you have not set up separate reporting folders for each company.
19	Date format	The format in which you want the date to appear in the study.
		• Month / Day / Year
		• Day / Month / Year
		• Year / Month / Day
20	Allow subject ordering	Enabled or Disabled (default). Indicates whether to allow use of the subject ordering feature.
21	Server friendly name	User-friendly server name to display on the Queries details and Signature Status Details pages.
		Note: You can set this option only through the Admin user interface; there is no equivalent MedML tag.
22	Trial Center Url	Not supported.

Fields—Workflow Options

Field		Description
23	Form submit notification style	The location and format of the Form submitted successfully message.
		• **Inline** (default)—Message displays in the header of the form.
		• **Pop-up**—Message displays as a pop-up. User must click OK in order to proceed. Default.
		This setting is global to all users.
24	Inline notification visible duration	Used when Form submit notification style is Inline.
		Specifies the number of seconds that the **Form submitted successfully** message remains visible in the header of the form before it fades.
		Specify a value from 0 to 9 seconds. The default is 3 seconds.
		A value of 0 (zero) causes the message to remain visible until the user performs an action on the form, such as changing a value or entering focus to a control.

	Field	Description
25	QuerySelection	Specifies whether queries are created in the Opened or Candidate state.
		• Create Query in Opened State
		• Create Query in Candidate State

Fields—System Security Configuration

	Field	Description
26	Re-authentication inactivity period	Number of minutes of inactivity that can pass before the InForm application requires a user to log in again.
27	Password expiration period	Number of days that can pass before the InForm application requires users to change their passwords. Recommended setting is 90 days.
28	Re-identification period	Number of minutes that a session can be active before the InForm application requires a user to log in again.
29	Minimum password length	Number of characters that must be in the password. Recommended setting is 8 characters.
30	Inactivate account after number of failed log-on attempts	Number of times a user can attempt to log in with an incorrect user name and password combination before the account is inactivated and an execution plan is run, if defined, to send an email notification. Recommended setting is 3. If an account is inactivated, an administrator must reactivate the account.
31	Require at least one numerical character in password	Yes (recommended) or No. Indicates whether users are required to use at least one numerical character in their passwords.
32	Require at least one uppercase character in password	Yes (recommended) or No. Indicates whether users are required to use at least one uppercase character in their passwords.
33	Require at least one non-alpha-numeric character in password	Yes (recommended) or No. Indicates whether users are required to use at least one non-alphanumeric character in their passwords.
34	Allow password reuse	Yes or No (recommended). Indicates whether to allow users to reuse previous passwords.
35	Enable password recovery	Yes (recommended) or No. Indicates whether to allow users to request a password reset if they have forgotten their password.
36	Email address for password recovery notification	The email address of an administrator who receives notification when a user requests a password reset.

Field		Description
37	Email address for new site and user notification	The email address of an administrator who receives notification when a new site or new user is added.

Fields—Read-Only system Configuration

> **Note:** The read-only system configuration options are for reference only. All of these settings are defined by the initial installation of the study MedML. You can modify these settings only by modifying and reinstalling system configuration MedML. For more information, see the *Utilities Guide*.

Field	
40	Enforce visit date entry *(Required before other data can be entered.)*
41	Screening number sequence format
42	Subject number sequence format
43	Default randomization source manager
44	Randomization format for simple site
45	Randomization source manager for simple site
46	Randomization format for simple central
47	Randomization source manager for simple central
48	Randomization for central stratified by site
49	Randomization source manager for central stratified by site
50	Randomization format for central stratified
51	UNC download directory *(Used only in legacy systems.)*
52	Virtual download directory *(Used only in legacy systems.)*
53	View CRF signature list
54	Display form status with traffic light icons
55	Reporting Database
57	Reporting CAP Admin Database
58	Reporting CAP Admin Database User
59	Reporting User Name

Buttons

Button	Description
Audit Trail icon	Navigates to the audit history for the item.
Update	Updates system configuration changes to the database.

System Information page

The System Information page provides information about the current installation of the InForm software.

Fields

Field	Description
InForm	Displays the version numbers of the InForm software and the InForm software database schema, and the product installed language.
Database	Displays the database name and version number, and the name of the database and ODBC drivers.
Web Server	Displays the version numbers of the Microsoft Windows operating system (NT Version) and of the Microsoft Internet Information Server running on the server (IIS Version).
Components	Lists the InForm software DLLs.
Legal Notice	Lists copyright information for the InForm software and for the software products used with the InForm software.

MedML—System settings

For details on the MedML for setting up the system configuration options, see the *Utilities Guide*.

Rights and rights groups

Overview of rights and rights groups

A right is the permission to perform a specific activity. A rights group is a collection of rights.

The InForm application comes with a predefined set of rights and rights groups covering the activities that are typically restricted to specific roles in a study. When a new user is created in the InForm application, an administrator with the right to modify user information assigns the user to a rights group, providing the user permissions to perform specific study activities.

A user can be a member of only one rights group.

> **Note:** You cannot make changes to the rights group in which you are a member.

Rights required for typical study activities

Users need certain rights to perform typical study activities in the InForm application. The rights are categorized and are available on the Rights Group detail page. For information on all of the available rights and on assigning these rights, see *Rights Groups detail page* (on page 316) and *Creating a rights group and assigning its rights* (on page 313).

System administration rights

To perform this activity	A user must have these rights (Category > Right)
Change system configuration settings	• User Admin > Modify System Configuration
Create a user	• User Admin > Create User
Change user passwords	• User Admin > Modify User Information
Change user name, address, and contact information	• User Admin > Modify User Information
Assign a user to rights, query, and signature groups and to one or more sites	• User Admin > Modify User Information
Activate an Inactive user designated as a Site user	• User Admin > Activate Site User
Deactivate an Active user designated as a Site user	• User Admin > Deactivate Site User
Activate an Inactive user designated as a Sponsor user	• User Admin > Activate Sponsor User
Deactivate an Active user designated as a Sponsor user	• User Admin > Deactivate Sponsor User
Terminate a user	• User Admin > Terminate User
Change the status of a Terminated user to Inactive	• User Admin > Un-Terminate User (change to Inactive Status)
Create, modify the definition, and manage the membership of rights groups	• User Admin > Manage Rights Groups
Create, modify the definition, and manage the membership of query groups and signature groups	• User Admin > Manage Other Groups
Create, modify the definition, and manage the authorization of users to sites	• User Admin > Manage Sites
Configure partial source verification	• CRF Rights > Mark and Unmark a CRF as SVed • CRF Rights > Change Site SV Settings • User Misc > View CRF

CRF rights

To perform this activity	A user must have these rights (Category > Right)
Enter CRF data	• CRF Rights > Enter Data into a CRF
	• User Misc > View CRF
Edit CRF data	• CRF Rights > Edit Data on a CRF
	• User Misc > View CRF
Enter comments on a CRF item or on a whole CRF	• CRF Rights > Enter Comments into a CRF
	• User Misc > View CRF
Freeze a CRF	• CRF Rights > Freeze a CRF
	• User Misc > View CRF
Unfreeze a CRF	• CRF Rights > Unfreeze a CRF
	• User Misc > View CRF
Lock a CRF	• CRF Rights > Lock a CRF
	• User Misc > View CRF
Unlock a CRF	• CRF Rights > Unlock a CRF
	• User Misc > View CRF
Indicate a CRF is ready for source verification, or indicate that a CRF that was ready for source verification is no longer ready	• CRF Rights > Mark a CRF as Ready for SV • User Misc > View CRF
Perform source verification on CRF data	• CRF Rights > Mark and Unmark a CRF as SVed User Misc > View CRF To view the Source Verification Listing, the Monitor right is also required.
Sign a CRF	• CRF Rights > Sign a CRF • User Misc > View CRF Additionally, the user must be in the same signature group as the CRF to sign.
Configure Partial SV	• CRF Rights > Mark and Unmark a CRF as SVed • CRF Rights > Change Site SV Settings • User Misc > View CRF

Case report book rights

To perform this activity	A user must have these rights (Category > Right)
Sign a case report book	• Case Book Rights > Sign a Case Book • User Misc > View CRF Additionally, the user must be in the same signature group as the CRF designated as the signing CRF for the Case Book.
Indicate a case report book is ready for source verification, or indicate that a case report book that was ready for source verification is no longer ready	• Case Book Rights > Mark and Unmark a Case Book as Ready for SV • User Misc > View CRF
Freeze a case report book	• Case Book Rights > Freeze a Case Book • User Misc > View CRF
Unfreeze a case report book	• Case Book Rights > Unfreeze a Case Book • User Misc > View CRF
Lock a case report book	• Case Book Rights > Lock a Case Book • User Misc > View CRF
Unlock a case report book	• Case Book Rights > Unlock a Case Book • User Misc > View CRF

Query rights

To perform this activity	A user must have these rights
Open a Candidate query so that it becomes visible to the site	• Query Rights > Change Query State from Candidate to Open • User Misc > View CRF Additionally, the user must be defined as a Sponsor user.
Delete a Candidate query	• Query Rights > Change Query State from Candidate to Deleted • User Misc > View CRF Additionally, the user must be defined as a Sponsor user and must be a member of the same query group as the user who created the Candidate query.
Close an answered query	• Query Rights > Change Query State from Answered to Closed • User Misc > View CRF Additionally, the user must be a member of a query group.
Close a query in the Opened state	• Query Rights > Change Query State from Open to Closed • User Misc > View CRF Additionally, the user must be defined as a Sponsor user and be a member of the same query group as the user who opened the query
Close a query that has been reissued in the Candidate state	• Query Rights > Change Query State from Reissued Candidate to Closed • User Misc > View CRF Additionally, the user must be defined as a Sponsor user and be a member of the same query group as the user who reissued the query
Answer a query	• Query Rights > Answer Query • User Misc > View CRF
Enter a query in the Candidate state so that it is not visible to the site	• Query Rights > Enter Query in Candidate State • User Misc > View CRF Additionally, the user must be defined as a Sponsor user

To perform this activity	A user must have these rights
Enter a query in the Opened state so that it is visible to the site	• Query Rights > Enter Query in Open State • User Misc > View CRF
Reissue an answered query in the Candidate state so that it is not visible to the site	• Query Rights > Re-issue Query in Candidate State • Query Rights > Enter Query in Candidate State • User Misc > View CRF Additionally, the user must be defined as a Sponsor user and must be a member of the same query group as the user who created the query.
Reissue an answered query in the Opened state so that it is visible to the site	• Query Rights > Re-issue Query in Open State • Query Rights > Enter Query in Open State • User Misc > View CRF Additionally, the user must be a member of the same query group as the user who originally created the query.
Resolve a query that is in a conflict state because multiple users using different copies of a study acted on it before synchronizing	• Query Rights > Resolve Query in Conflict • User Misc > View CRF Additionally, to resolve a Site Conflict, a user must be defined as a Site user. To resolve a Sponsor Conflict, a user must be defined as a Sponsor user.

Rule rights

To perform this activity	A user must have these rights (Category > Right)
Cancel an active rule	• Rule Rights > Deactivate a Rule
Run an existing rule	• Rule Rights > Run a Rule
Edit an existing rule	• Rule Rights > Modify a Rule

Navigation rights

To perform this activity	A user must have these rights (Category > Right)
Place subjects (at a site) in a particular order for more efficient data entry.	• Navigation > Reordering Of Subjects • User Misc > View CRF

Miscellaneous user rights

To perform this activity	A user must have these rights (Category > Right)
Print a CRF	• User Misc > Print
Create Visit Reports	• User Misc > Monitor
Create records of regulatory document reviews	• User Misc > Monitor
Run reports with the InForm Reporting and Analysis module	• User Misc > Reports
Screen and enroll study candidates	• User Misc > Enroll Subjects • CRF Rights > Enter Data into a CRF • User Misc > View CRF
View Screening Log (read-only)	• User Misc > Enroll Subjects or • User Misc > Monitor, with no CRF rights
Display Required Signatures page and see CRF signing status for all signature groups (read-only)	• User Misc > View CRF Signature Information
Display Required Signatures page and see case report book signing status for all signature groups (read-only)	• User Misc > View Case Book Signature Information
Export listings of CRF data to an external data source	• Data Viewer Rights > Access Data Viewer / Data Export Listing
Transfer subject records from one site to another	• User Admin > Subject Transfer

Data Viewer rights

To use the features that the Data Viewer provides, you must have one or more of the Data Viewer rights in addition to any required InForm rights. All existing InForm rights are used and enforced throughout the entire InForm application, including the Data Viewer. For example:

- Site users using the Data Viewer will not be able to see source verification states except for SV Ready, regardless of what rights they have been assigned.

- If a user should not see the verification states, all verification states will not appear in the Summary View, Record Listing View, or Record Comparison View in the Data Viewer.

- The answered query state will not be shown to site users in the Data Viewer even though they can view the query states in the item query display.

The Data Viewer rights are:

- **Access Data Viewer / Data Export Listings**—Allows you to access the Data Viewer.

  This right does not replace other existing, defined InForm rights. You still need existing InForm rights to view or perform actions against records in the Data Viewer.

  For example, users who have the right to access the Data Viewer still need appropriate rights in order to be able to carry out any InForm actions in the Data Viewer, such as freezing or locking forms.

- **Assign Review State (1 to 5)**—Allow you to assign the custom review states in the Data Viewer.

  If you have any of these rights, you automatically have the right to view the custom review states.

- **View Review States**—Allows you to view the custom review states assigned to records.

  If you can access the Data Viewer but do not have this right, you can see all records that you are allowed to see, but you cannot see any custom review states that are assigned to the records that appear.

> Note: For details on the MedML associated with the Data Viewer rights, see the *Utilities Guide*.

To perform this activity	A user must have these rights (Category > Right)
Access the Data Viewer	• Data Viewer Rights> Access Data Viewer / Data Export Listing right
View custom review states assigned to records	• Data Viewer Rights > View Review States
Assign custom review states in the Data Viewer	One or more of the following: • Data Viewer Rights > Assign Review State 1 • Data Viewer Rights > Assign Review State 2 • Data Viewer Rights > Assign Review State 3 • Data Viewer Rights > Assign Review State 4 • Data Viewer Rights > Assign Review State 5

Viewing the list of rights groups

1 In the navigation toolbar, click **Admin**.

2 Click **Rights**.

   The Rights Groups page appears. For a description of the fields on this page, see *Rights Groups page* (on page 315).

Creating a rights group and assigning its rights

1 In the navigation toolbar, click **Admin**.

2 Click **Rights**.

   The Rights Groups page appears.

3 Click **Add Rights Group**.

   The Rights Groups detail page appears. For a description of the fields on this page, see *Rights Groups detail page* (on page 316).

4 In the **Rights Group Name** field, type a name for the rights group.

5 Select the rights that you want to associate with the rights group.

6 Click **Submit**.

Viewing or modifying the rights in a rights group

> **Note:** You cannot make changes to the rights group in which you are a member.

1 In the navigation toolbar, click **Admin**.

2 Click **Rights**.

   The Rights Groups page appears.

3 In the **Rights Group** column, click the link for the rights group that you want to view or modify.

   The Rights Groups detail page appears. For a description of the fields on this page, see *Rights Groups detail page* (on page 316).

4 Select or deselect any rights, as needed.

5 If you made any changes, click **Submit**.

Viewing or modifying the users in a rights group

1   In the navigation toolbar, click **Admin**.

2   Click **Rights**.

The Rights Groups page appears.

3   In the **List Users** column, click **Change Users** for the group for which you want to view or modify the membership.

The Change Members in Rights Group page appears. For a description of the fields on this page, see *Change Members in Rights Group page* (on page 319).

4   Add or remove users as needed.

- To add a user to the rights group, select the user's name in the **Available users** list, and click **Add**.

  - To select more than one user at a time, hold down the **Ctrl** key while selecting each name.

  - To deselect a user while preserving the selection of other users, hold down the **Ctrl** key while clicking the name again.

- To remove a user from the rights group, select the user's name in the **Users in: [Rights Group Name]** list, and click **Remove**.

  - To select more than one user at a time, hold down the **Ctrl** key while selecting each name.

  - To deselect a user while preserving the selection of other users, hold down the **Ctrl** key while clicking the name again.

5   If you made any changes, click **Submit**.

> **Note:** Alternatively, you can change the rights group membership by updating the rights group membership of a specific user. For more information, see *Assigning or modifying a user association to a rights group, site, and other groups* (on page 364).

User interface—Rights and right groups

Rights Groups page

The Rights Groups page summarizes information about rights groups and enables you to navigate to detailed information about a specific rights group, add or modify a rights group, or update rights group membership.

Fields

Field	Description
Rights Group	Name of the rights group.
	Click the link to open the Rights Groups detail page.
Member Count	Number of users assigned to the rights group.
Display Overrides	**Change Overrides** link that opens the Change Display Override in Rights Group page, from which you can define a display override to a selected rights group by adding or removing item groups. For more information, see *Change Display Override in Rights Group page* (on page 332).
List Users	**Change Users** link that opens the Change Members in Rights Group page, from which you can add users to, or remove users from, the rights group.

Buttons

Button	Description
Add Rights Group	Displays the Rights Groups detail page so that you can create a new rights group definition.

Rights Groups detail page

The Rights Groups detail page enables you to add, modify, or view the rights included in a selected rights group. The name of each right that you can assign is preceded by a checkbox. When you select a checkbox, the rights group includes the right. Users who are assigned to the rights group are granted each selected right.

For information on the rights that a user needs to perform typical study activities, see *Rights required for typical study activities* (on page 306).

Fields

Field		Description
1	Rights Group Name	Name of the rights group.
2	User Admin	Rights that govern user creation, activation, deactivation, and modification. - Modify System Configuration - Create User - Modify User Information - Manage Rights Groups - Manage Other Groups - Activate Site User - Deactivate Site User - Activate Sponsor User - Deactivate Sponsor User - Un-Terminate User (change to Inactive Status) - Terminate User - Manage Sites - Subject Transfer
3	User Misc	Rights that govern miscellaneous user activities such as printing, generating reports, enrolling subjects, and monitoring. - Print - Monitor - Reports - Enroll Subjects - View CRF - View CRF Signature Information - View Case Book Signature Information

Field	Description
4 Data Viewer Rights	• Access Data Viewer / Data Export Listings
	• Assign Review State 1
	• Assign Review State 2
	• Assign Review State 3
	• Assign Review State 4
	• Assign Review State 5
	• View Review States
	For more information, see ***Data Viewer rights*** (on page 312).
5 CRF Rights	Rights that govern activities that involve CRFs, including data entry and edit, comment entry and edit, CRF freezing, unfreezing, locking, and unlocking, signing, and source verification.
	• Enter Data into a CRF
	• Edit Data on a CRF
	• Enter Comments into a CRF
	• Freeze a CRF
	• Unfreeze a CRF
	• Lock a CRF
	• Unlock a CRF
	• Mark and Unmark a CRF as SVed
	• Mark a CRF as Ready for SV
	• Sign a CRF
	• Change Site SV Settings
6 Case Book Rights	Rights that govern activities that involve Case Books, including signing, freezing, unfreezing, locking, unlocking, and source verification.
	• Sign a Case Book
	• Mark and Unmark a Case Book as Ready for SV
	• Freeze a Case Book
	• Unfreeze a Case Book
	• Lock a Case Book
	• Unlock a Case Book

Field		Description
7	Query Rights	Rights that govern query creation, answering, closing, reissuing, and state changes.
		• Change Query State from Candidate to Open
		• Change Query State from Candidate to Deleted
		• Change Query State from Answered to Closed
		• Change Query State from Open to Closed
		• Change Query State from Reissued Candidate to Closed
		• Answer Query
		• Enter Query in Candidate State
		• Enter Query in Open State
		• Re-issue Query in Candidate State
		• Re-issue Query in Open State
		• Resolve Query in Conflict
8	Rule Rights	Rights that govern rule creation, activation, modification, and running.
		• Deactivate a Rule
		• Run a Rule
		• Modify a Rule
9	Navigation	Right that governs the navigation of study data.
		• Reordering Of Subjects
10	Portal	• InForm Portal Config Admin
11	Web Service	• ODM Submit

Buttons

Button	Description
Submit	Submits changes to the list of rights included in the rights group.
Return	Returns you to the Rights Group page without submitting the rights group definition to the database.

Change Members in Rights Group page

The Change Members in Rights Group page enables you to assign users to, or remove users from, a selected rights group.

Fields

Field	Description
Available users	Names of users who are available for assignment to the rights group.
Users in: [Rights group name]	Names of users who are assigned to the rights group.

Buttons

Button	Description
Add	Adds the users selected in the Available users list to the rights group.
Remove	Removes the users selected in the Users in: [Rights group name] list from the rights group.
CTRL+Click	Selects multiple entries.
SHIFT+Click	Selects contiguous entries.
Submit	Submits the changed rights group membership to the database.
Return	Returns you to the Rights Groups page.

MedML—Rights and right groups

For details on the MedML for setting up rights and rights groups, see the *Utilities Guide*.

Groups and item groups

Overview of groups and item groups

Groups allow you to associate users who have similar roles in a study and allow them access to specific areas of InForm functionality. Groups provide an advanced level of authorization. In order to perform certain activities, a user must both have rights to perform the activities and be in a group for which the activities are authorized.

The InForm application allows you to define and maintain different types of groups. For more information, see *Group types* (on page 321).

When you add a new group to an InForm study, you must specify the group type, group name, and optionally a group description. After you add a new group, you must add users to the group. You can add users to a group:

- While editing an XML file to create a group.

- Using pages in the Users or Groups sections in the Admin InForm user interface.

The only way to remove a user from a group is through the Admin function in the InForm application. You cannot remove a user from a group using XML.

Group types

Type	Description
Query	Allows any user who is in the same query group as the user who opened a query to change its status (for example, to close it). A user can be a member of only one query group.
Signature	Allows any member of the same signature group to sign forms, if the user has the Sign form right, or to sign case report books if the user has the Sign a Case Book right.
	A user can be a member of only one signature group. When it is defined in the database, a form that requires a signature can be associated with zero, one, or more signature groups.
	• When a form is associated with one signature group, it must be signed by one member of that signature group to be considered signed.
	• When a form is associated with more than one signature group, it must be signed by one member of each signature group to be considered signed.
	For example, to ensure that a form is assigned by both a sponsor and a site representative, create a signature group for the sponsor and a signature group for the site, and associate the form with both signature groups. Assign sponsor users who have signature rights to the sponsor signature group, and assign site users who have signature rights to the site signature group.
ManagerUser	Not supported.
ItemGroup	Identifies a list of items appearing on forms for which display override characteristics can be changed through a rights group.
Reporting	Defines the reporting functionality and type of access available to users with reporting rights. Some Reporting groups allow members to access only standard reports; others allow members access to ad hoc reporting.

Item groups

Item groups are sets of items that you group together so that you can assign a display override to them. Display overrides allow you to specify that, for a particular rights group, the group of items that makes up an item group is Hidden, Editable, or Read-Only. This designation overrides the rights conveyed by membership in the rights group and also overrides the display properties of the items in the group. For more information, see *Overview of display overrides* (on page 329).

Viewing the list of groups

1 In the navigation toolbar, click **Admin**.

2 Click **Groups**.

The Groups page appears. For a description of the fields on this page, see *Groups page* (on page 325).

Creating a group or item group

1 In the navigation toolbar, click **Admin**.

2 Click **Groups**.

The Groups page appears.

3 Click **Add Group**.

The Edit Group Properties page appears.

4 Complete the information on the page using the descriptions in *Edit Group Properties page* (on page 326).

    a In the **Group Type** field, select the group type (Query, Signature, ItemGroup, or Reporting).

    b In the **Group Name** field, type a name for the group or item group.

    c In the **Group Description** field, type a description for the group or item group.

5 Click **Submit**.

Viewing or modifying the users in a group

1   In the navigation toolbar, click **Admin**.

2   Click **Groups**.

The Groups page appears.

3   In the **Members** column, click **Change** for the group for which you want to update membership.

The Change Membership of Group page appears.

4   Edit the information on the page using the descriptions in Change Membership of Group page.

- To add a user to the group, select the user's name in the **Available users** list, and click **Add**.

  - To select more than one user at a time, hold down the **Ctrl** key while selecting each name.

  - To deselect a user while preserving the selection of other users, hold down the **Ctrl** key while clicking the name again.

- To remove a user from the group, select the user's name in the **Users in: [Group name]** list, and click **Remove**.

  - To select more than one user at a time, hold down the **Ctrl** key while selecting each name.

  - To deselect a user while preserving the selection of other users, hold down the **Ctrl** key while clicking the name again.

5   If you made any changes, click **Submit**.

> **Note:** Alternatively, you can change group membership by updating the group membership of a specific user. For more information, see *Assigning or modifying a user association to a rights group, site, and other groups* (on page 364).

Viewing or modifying the items in an item group

> **Note:** An item can belong to only one item group.

1   In the navigation toolbar, click **Admin**.

2   Click **Groups**.

The Groups page appears.

3   In the **Members** column, click **Change** for the item group for which you want to update membership.

The Change Membership of Item Group page appears.

4   Edit the information on the page using the descriptions in Change Membership of Item Group page.

- To add an item to the item group, select a name in the **Available items** list, and click **Add**.

    - To select more than one item at a time, hold down the **Ctrl** key while selecting each name.

    - To deselect an item while preserving the selection of other items, hold down the **Ctrl** key while clicking the name again.

- To remove an item from the item group, select names in the **Items in Item Group: [Item Group Name]** list, and click **Remove**.

    - To select more than one item at a time, hold down the **Ctrl** key while selecting each name.

    - To deselect an item while preserving the selection of other items, hold down the **Ctrl** key while clicking the name again.

5   Click **Submit**.

Viewing or modifying the details for a group or item group

1   In the navigation toolbar, click **Admin**.

2   Click **Groups**.

The Groups page appears.

3   Click the **Group Name**, **Group Type**, or **Description** link.

The Edit Group Properties page appears.

4   View or edit the information on the page using the descriptions in *Edit Group Properties page* (on page 326).

You can change the group name and description.

5   If you made any changes, click **Submit**.

User interface—Groups

Groups page

The Groups page summarizes information about groups and enables you to navigate to detailed information about a specific group or to add or modify a group.

Fields

Field	Description
Group Name	Name of the group. Click the link to open the Edit Group Properties page.
Group Type	Type of group. For more information, see *Group types* (on page 321). Click the link to open the Edit Group Properties page.
Member Count	Number of users who are assigned to the group.
Description	Description of the group. Click the link to open the Edit Group Properties page.
Members	**Change** link that opens the Change Membership of Group page, from which you can add or remove users in the group.

Buttons

Button	Description
Add Group	Displays the Edit Group Properties page, which enables you to add a new group definition.

Edit Group Properties page

The Edit Group Properties page enables you to add, modify, or view details about a specific group.

Fields

Field	Description
Group Type	Type of group. For more information, see **_Group types_** (on page 321).
	• When you add a new group, the Group Type field is a drop-down list from which you can select the type of group.
	• When you view details about an existing group, the Group Type field is read only.
Group Name	Name of the group.
Group Description	Description of the group.

Buttons

Button	Description
Submit	Submits the group addition or modifications to the database.
Return	Returns you to the Groups page without submitting the group definition to the database.

Change Membership of Group page

The Change Membership of Group page enables you to assign users to, or remove users from, a selected group.

Fields

Field	Description
Available users	Displays the user names of users who are available for assignment to the group.
Users in: [Group name]	Displays the user names of users who have been assigned to the group.

Buttons

Button	Description
Add	Adds the users selected in the Available users list to the group.
Remove	Removes the users selected in the Users in: [Group name] list from the group.
CTRL+Click	Selects multiple entries.
SHIFT+Click	Selects contiguous entries.
Submit	Submits the changed group membership to the database.
Return	Returns you to the Groups page.

Change Membership of Item Group page

The Change Membership of Item Group page enables you to add items to, or remove items from, a selected item group. For more information, see **Overview of display overrides** (on page 329).

Fields

Field	Description
Available items	Displays the RefNames of items that are available for assignment to the item group.
Items in Item Group: [Item group name]	Displays the RefNames of items that have been assigned to the item group.

Buttons

Button	Description
Add	Adds the items selected in the Available items list to the item group.
Remove	Removes the items selected in the Items in Item Group: [Item group name] list from the item group.
CTRL+Click	Selects multiple entries.
SHIFT+Click	Selects contiguous entries.
Submit	Submits the changed item group membership to the database.
Return	Returns you to the Groups page.

MedML—Group and item groups

For details on the MedML for setting up groups and item groups, see the *Utilities Guide*.

Display overrides

Overview of display overrides

Display overrides allow you to refine user access to individual data items on forms. For a particular rights group, you can specify whether the group of items that make up an item group is Hidden, Editable, or Read-Only. This designation overrides the rights conveyed by membership in the rights group and also overrides the display properties of the items in the group. This additional level of security allows you to give users with the same set of rights different access to specific items.

An item group can be in only one display override per rights group. For example, if you move an item group into the Read-Only override list and click Submit, that item group is not available for selection in the current rights group for the Editable override.

- **Read-Only**—Users can view but not update the items.

- **Editable**—Users can view and update the items.

- **Hidden**—Users cannot see the items.

You can control data item access:

- Through the InForm user interface with user rights or by defining rights group display overrides.

- With item definition display overrides that are defined in the Central Designer application.

User rights for display overrides

Each of the rights applies to all data items on all forms.

To perform this activity	A user must have these rights (Category > Right)
View all items in all forms.	• User Misc > View CRF
Add data to items that have not had data entered previously.	• CRF Rights > Enter Data into a CRF • User Misc > View CRF **Note:** These rights are commonly assigned to users in a CRC role. Both the **Enter Data into a CRF** right and the **View CRF** right must be assigned to enable this access.
Update data in items in which data has been entered previously.	• CRF Rights > Edit Data on a CRF • User Misc > View CRF **Note:** These rights are commonly assigned to users in a CRC role. Both the **Edit Data on a CRF** right and the **View CRF** right must be assigned to enable this access.

Defining rights group display overrides

After you create an item group, you can assign it to a rights group as a Read-Only, Editable, or Hidden display override. Each of these specifications overrides for all items in the item group the access conferred by membership in a rights group and the access conferred by the definition of an item-level display override. This additional level of security allows you to give users with the same set of rights different access to specific items.

When a rights group has a display override assigned to it, a user who is a member of the rights group has the type of access defined by the display override to the items in the item group. Display overrides overrule the access rights in the rights group and the access rights determined by item definitions.

For example, if an item group contains an item called dose_missed_rsn, and that item group is assigned to the CDMGrp with a hidden override, a member of the CDMGrp rights group cannot see the dose_missed_rsn item even if the rights in the rights group would allow the user to see the item.

To set up rights group overrides:

1   Create an item group that specifies the items for which to apply display overrides.

    For more information, see *Creating a group or item group* (on page 322).

2   Add items for which to apply display overrides to the item group.

    For more information, see *Viewing or modifying items in an item group* (on page 324).

3   Assign or modify the display overrides associated with a rights group.

    For more information, *Assigning display overrides to rights groups* (on page 331).

Item definition display overrides from the Central Designer application

The definition of an item includes a Display Override property that allows you to specify whether the item is Hidden, Editable, or Read-Only. Each of these definitions overrides for a single item the access conferred by the View CRF, Enter Data into a CRF, and Edit Data on a CRF rights.

Therefore, a user in a rights group with the View CRF and Enter Data into a CRF rights is unable to see an item defined with the Hidden Display Override property and is unable to enter data in an item defined with the Read-Only Display Override property.

To create item definition display overrides, use the Central Designer application.

Assigning display overrides to rights groups

1   In the navigation toolbar, click **Admin**.

2   Click **Rights**.

    The Rights Groups page appears.

3   In the **Display Overrides** column, click **Change Overrides** for the rights group that you want to update.

    The Change Display Override in Rights Group: [Name] page appears. For a description of the fields on this page, see Change Display Override in Rights Group page.

4   Click **Read-Only**, **Editable**, or **Hidden** to specify the type of display override that you want to set.

    - **Read-Only**—Users can view but not update the items.

    - **Editable**—Users can view and update the items.

    - **Hidden**—Users cannot see the items.

5   Add to or modify the list of item groups that make up the display override, as needed.

    - To add item groups to the rights group display override, select the item group names in the **Available item groups** list, and click **Add**.

        - To select more than one item group at a time, hold down the **Ctrl** key while selecting each name.

        - To deselect an item group while preserving the selection of other item groups, hold down the **Ctrl** key while clicking the name again.

    - To remove item groups from the rights group display override, select the item group names in the **Item groups overridden in: [Rights Group name]** list, and click **Remove**.

        - To select more than one item group at a time, hold down the **Ctrl** key while selecting each name.

        - To deselect an item group while preserving the selection of other item groups, hold down the **Ctrl** key while clicking the name again.

6   Click **Submit**.

> **Note:** An item group can be in only one display override per rights group. For example, if you move an item group into the Read-Only override list and click Submit, that item group is not available for selection in the current rights group for the Editable override.

User interface—Display overrides

Change Display Override in Rights Group page

The Change *[Override_Type]* Display Override in Rights Group page enables you to define a display override to a selected rights group by adding or removing item groups. When you define a display override to a rights group, users who are members of the rights group are able to assign the following states to the items contained in the item groups that make up the display override:

- **Read-Only**—Users can view but not update the items.

- **Editable**—Users can view and update the items.

- **Hidden**—Users cannot see the items.

> Note: An item group can be in only one display override per rights group. For example, if you move an item group into the Read-Only override list and click Submit, that item group is not available for selection in the current rights group for the Editable override.

Fields

Field	Description
Available item groups	Displays the item groups that are available to assign to the display override.
Item groups overridden in: [Rights Group name]	Displays the item groups that make up the display override.

Buttons

Button	Description
Add	Adds the item groups selected in the Available item groups list to the display override.
Remove	Removes the item groups selected in the Item groups overridden in: [Rights Group name] list from the display override.
CTRL+Click	Selects multiple entries.
SHIFT+Click	Selects contiguous entries.
Read-Only	Sets the display override type to Read-Only.
Editable	Sets the display override type to Editable.
Hidden	Sets the display override type to Hidden.
Submit	Submits the display override to the database.
Return	Returns you to the Rights Groups page.

Rules

Overview of rules

> **Note:** Rules are defined in the Central Designer application as part of the study design. You can view, modify, and run the rules using the InForm user interface. Oracle recommends that all rule design and modifications be performed using the Central Designer application.

A rule is a script that runs in the context of one or more specific items on a form, that checks whether data is valid, or that sets the value of an item based on a calculation, when data in the item is added or updated.

The InForm application uses rules to:

- Provide validation checks on entered data.

- Perform calculations that automatically determine the value of data items based on the value of related data items.

- Convert data from the units in which it is entered to normalized units that other rules can reference.

- Randomize subjects in order to assign drug kits to them.

Rules and events

A rule is associated with one or more specific items on a form. When a user submits new or updated data in an item that has a rule attached, and data is present in the additional data items to which the rule refers, the rule runs.

Each rule can be associated with an event that runs based on the outcome of the rule:

- The event can generate a new query or close an answered query.

- The event can run one or more execution plans that:

  - Send e-mail.

  - Send an entry to the Windows log file.

Types of InForm rules

Rule type	Description
Calculation	Enable you to set the value of a data item by performing a calculation that uses the value entered in one or more related items.
	The data item to which the calculation is applied is a calculated control in an item on a form. When the values in all dependent items are submitted or one or more values is updated, the InForm application runs the calculation rule and places the result in the calculated control.
Form rule (edit check)	Perform a wide range of edit checks on items entered or updated on a form. For example:
	• You can check for conformity with a specified range of values.
	• You can make sure that two items are in an appropriate relationship with each other; for example, that the date of the second visit is between ten days and two weeks later than the date of the first visit.
	• You can make sure that all parts of a multiple-part control are filled in; for example, you make sure that users select a unit value on an item where units are specified, or that all parts of a required date and time control are specified.
	• You can pass a message to an execution plan that logs an event in the Windows event log or sends email.
	Form rules run when both of the following are true:
	• All items that the rule needs for processing have data values.
	• The value of at least one of the items on which the rule depends is entered or updated.
	Each form rule is associated with an event. Depending on the result to which the rule evaluates and on the definition of the event, the following can occur:
	• The event can generate a query or clear an existing query.
	• The event can run execution plans that:
	▪ Send e-mail.
	▪ Send an entry to the Windows event log.

Rule type	Description
Conversion	Convert values from one unit to another.
	You can define unit form components with reference to other units, so that data can be displayed online as one unit and stored in the database, after conversion, as the other.
	For example, you can design a form so that a CRC can choose whether to enter a weight in kilograms or pounds and specify that the weight is always stored in the database in kilograms. The unit in which data is stored in the database after conversion is called the base unit, and the data value, after conversion to the base unit, is called the normalized value.
	To perform conversions between the entered and base unit values, you create conversion rules and associate them with unit definitions.
Randomization rule	A specialized form of calculation that returns the number of a drug kit to assign to a randomized subject.
	In a randomization rule you test the criteria for subject stratification, if any, set the properties of the Randomization object, and call a function that generates the drug kit number. This rule is attached to a special drug kit calculated control in a randomization item and section. The rule runs when a user clicks the Randomization button in the form window.
	Note: A randomization rule can be attached to only one control; that is, it can have only one context.

Browser and server rules

The InForm application supports rules that run on the browser before a user has submitted data, and rules that run on the server upon submission of new or updated data.

- **Browser rules**—These rules are primarily for data type checks; for example, to make sure that a float item is entered with the proper number of digits after the decimal place.

- **Server rules**—These rules can be used for many types of edit checks; for example, to check data ranges, or to calculate or check the value of one item based on the value of another.

Rules contexts

Rules are said to run in the context of the item they are evaluating or calculating and all items on whose values the rule script depends. A rule context answers the questions:

- What item does the rule run against?

- What values are substituted in the rule when it runs against this item?

- What other values does the rule need to run, and what items are those values found in?

By separating the definition of a rule from the specification of the item it runs against, contexts give you the flexibility to associate the same rule with many different items.

A rule context consists of:

- The **key item**—in its section, form, and visit—to which the rule is applied.

- All **arguments** passed to the rule script.

- **Dependencies**—Additional items or associations used in the processing of the rule script.

A single rule can have many contexts; for example, a rule that tests for range limits can be applied to different items on multiple forms, passing arguments that are specific to the context each time it is applied. Therefore, a rule that checks for valid ranges on a height item can use arguments that specify minimum and maximum number of inches in the height context; when the same rule is applied to a pulse rate item, it can use a different set of arguments that specify a minimum and maximum number of heartbeats.

> **Note:** Only form rules, calculations, and randomization rules have contexts; conversion rules, which are applied to unit definitions, do not.

Types of InForm rule contexts

Rule context	Description
Generic Visit Context	Associates the rule with a form and runs the rule in every instance of the form in the study. Use this context when you want the same rule to run on every instance of an item on a particular form throughout a study. For example, you can associate a rule with the body temperature item on the Vital Signs form using the Generic Visit Context. Each time that item is encountered on the Vital Signs form, the rule is run, regardless of the visit. If the body temperature item is used on a form other than Vital Signs, the rule will not be attached to it.
Generic Item Context	Associates the rule with a particular item and runs the rule with every instance of the item in the study. Use this context when you want the rule to run on every instance of an item throughout the study. For example, you can associate a rule with the gender item on the Demographics form using the Generic Item Context. Each time that the Gender item is encountered, regardless of form, the rule is run.
Specific Visit Context	Associates the rule with one item in one or more specific visits. Use this context if you want to attach a rule that you want to run only on specific forms, not all the forms in which the item appears. For example, if you want to run a rule on the blood pressure item on the Vital Signs form for the first visit only, use the Specific Visit Context. The rule will not run on other instances of the blood pressure item in other forms.

Rule dependencies

In addition to the key item, a rule may reference one or more additional items that contain information the rule needs in order to perform its evaluation or calculation. These items—each in its section, form, and visit—are called dependencies. The context item is also a rule dependency; therefore, every rule has at least one dependency representing the context item.

> **Note:** All dependencies associated with a context must have the same scope as the context. For example, if a context is defined as a generic visit context, its dependencies must also be defined with generic visits.

When you associate a rule with the items it runs against, you specify the type of dependency each item represents in its context: applied, dependency, or trigger. Rule processing begins when an item designated as any of these types of dependencies receives an initial entry of data or is updated:

- **Applied**—The rule script applies the outcome of the rule to the item with the applied dependency.

  - If a form rule fails, the item designated as the applied dependency receives a query.

  - If the rule performs a calculation or assigns a randomization drug kit, the item designated as the applied dependency receives the result of the calculation or randomization. For a form rule to run, this item and all items classified as dependencies must have an entered value; for a calculation rule to run, this item does not need an entered value.

- **Dependency**—The rule script uses the value entered for this item in performing its calculations or edit checks.

  For the rule to run, this item and any items classified as applied dependencies must have an entered value.

- **Trigger**—The rule script can use the value entered for this item in performing its calculations or edit checks; however, the rule does not require a value to be in this item in order to run.

Planning considerations—Rule dependencies

Consider the following when planning and defining additional dependencies:

- A Generic Item context cannot have additional dependencies.

- All dependencies associated with a context must have the same scope as the context.

  For example, if a context is defined as a Generic Form context, its dependencies must also be defined with Generic Forms.

- In a Generic Form context, additional dependencies can only be defined in the form specified in the key context.

- An association between two repeating forms can be a dependency of a rule context.

  When you define an association as a context dependency, the rule runs when a user selects or deselects the checkbox control that creates or dissolves an association between a specific instance of a repeating form and the other form in the association.

  A dependency defined for an association must be:

  - Attached to a Specific Visit context.

  - Defined as a Trigger dependency.

Rule implementation tools

When you set up a study, your implementation team designs and codes the rules that are attached to data items on study forms. The following methods are available for implementing rules in a study database.

- **The Central Designer application**—The Central Designer application enables study designers and developers to create rule and rule context definitions, along with definitions of the CRFs used in a study.

- Oracle provides tools that enable you or the Oracle team that sets up your study to administer rules in batch mode:

  - **MedML**—The Oracle XML for representing and exchanging clinical data definitions created in the InForm application. The Forms Definition Language is a set of Extensible Markup Language (XML) tags that conform to a data definition schema created for defining study elements, including rules. By using these tags, you can define the administrative elements and rules for a study in a format that the MedML Installer utility can process and load into the study database.

  - **MedML Installer utility**—A utility that parses the XML files you generate with MedML tags, validates them against the MedML schema and the constraints enforced by the database schema, and loads the study components they define into the database.

- The system administration module of the InForm application includes pages that enable you to perform some rule administration tasks and to review the definitions of rules and the contexts in which they run.

For most rule definition activities, Oracle recommends using the Central Designer application. After using the Central Designer application to define rules, execute a Central Designer deployment package to load the definitions into the study database. After a study is in progress, you can use the InForm application rule administration pages to review or update the definitions of specific rules.

> **Note:** For information about the Central Designer application, the MedML language, and the MedML Installer utility, see the Central Designer documentation and the MedML online Help.

Batch run rules

You can run calculation and form rules manually in batch mode, which may be helpful when you are testing rules under development. Selected rules are run on all subjects in the study.

You can run one rule type (calculation or form rule) at a time.

For more information, see *Running rules in batch mode* (on page 342).

> **Note:** Oracle recommends running calculation rules prior to form rules because calculation rules can alter clinical data values.

Frozen and locked case report books and batch run rules

When you run batch rules on case report books that are frozen or locked:

* Batch run calculation rules skip frozen or locked case report books.
* Batch run form rules skip locked case report books.

    New queries can be opened in frozen case report books.

Frozen and locked forms and batch run calculation rules

When you run calculation batch rules on case report books that are unfrozen and unlocked, but that have individually frozen or locked forms, errors can occur.

* **Frozen forms**—An error occurs when setting calculation values on frozen forms, unless the:

    * **Allow sponsor users to edit frozen forms** option on the System Configuration page is set to Yes. For more information, see *System Configuration page* (on page 298).

        and

    * The user running the batch run calculation rules is a Sponsor.

* **Locked forms**—An error occurs when setting calculation values on locked forms.

Any errors appear on the Batch Run Rules Status page. For more information, see *Batch Run Rules Status page* (on page 345).

The audit trail and batch run rules

When you run batch run rules, the audit trail for modified item values records the name of the user who runs the batch rule; it does not record the name of the user who submitted the original data values.

Implementing and deploying a rule

Use the Central Designer application to implement and deploy a rule. For more information, see the Central Designer documentation.

Viewing the list of rules

1   In the navigation toolbar, click **Admin**.

2   Click **Rules**.

The Rules page appears. For a description of the fields on this page, see *Rules page* (on page 344).

Viewing or modifying a rule

After you implement and deploy a rule by using the Central Designer application or using MedML and the MedML Installer utility, you can use the InForm Admin user interface to modify some of its properties and to display its properties, contexts, dependencies, and arguments.

1   In the navigation toolbar, click **Admin**.

2   Click **Rules**.

The Rules page appears.

3   Click the **Reference Name**, **Description**, **Type**, or **Status** link for a rule.

The Rules detail page appears.

4   View or edit the information on the page using the descriptions in Rules detail page.

You can modify the status, description, help text, rule script text, or the event triggered.

You cannot modify rule reference names, contexts, dependencies, or arguments.

5   If you made any changes, click **Submit**.

Running rules in batch mode

> **Note:** Oracle recommends running calculation rules prior to form rules because calculation rules can alter clinical data values.

1   In the navigation toolbar, click **Admin**.

2   Click **Rules**.

   The Rules page appears.

3   Click **Select Rules to Run**.

   The Select Rules to Run page appears. For a description of the fields on this page, see *Select Rules to Run page* (on page 349).

4   In the **Rule Type** filter, select the type of rules you want to run in batch mode.

   • Select **Calculation** to run calculation rules.

   • Select **Form Rule** to run form rules.

   When you select a filter option, the rule list refreshes to display the selected rule type (Calculation or Form Rule).

5   Select each rule that you want to run.

6   Click **Run Calculations** or **Run Rules**.

   The Rules Selected for Running page appears. For a description of the fields on this page, see *Rules Selected for Running page* (on page 350).

7   Verify your rule selection.

8   Click **Start Running Rules**.

   Running the rules may take a long time. When the rules finish running, you can check the applicable items of subject data to ensure that the rules produced the expected results.

> **Note:** The audit trail for modified item values records the name of the user who runs the batch rule; it does not record the name of the user who submitted the original data values.

Viewing the status of batch run rules

1   In the navigation toolbar, click **Admin**.

2   Click **Rules**.

The Rules page appears.

3   Click **Batch Run Status**.

This button appears only after one or more batch rule selections are created.

The Batch Run Rules Status page appears. For a description of the fields on this page, see *Batch Run Rules Status page* (on page 345).

Viewing the details of batch run rules

1   In the navigation toolbar, click **Admin**.

2   Click **Rules**.

The Rules page appears.

3   Click **Batch Run Status**.

This button appears only after one or more batch rule selections are created.

The Batch Run Rules Status page appears. For a description of the fields on this page, see *Batch Run Rules Status page* (on page 345).

4   Click the **Rules** link.

The Subject-Rules Status page appears. For a description of the fields on this page, see *Subject-Rules Status page* (on page 346).

User interface—Rules

Rules page

The Rules page summarizes information about rules, enables you to navigate to detailed information about a specific rule, and to run selected rules.

Fields

Field	Description
Reference Name	Name by which the rule is defined in the database. READ-ONLY.
	Click the link to open the Rules detail page.
Description	Descriptive rule name.
	Click the link to open the Rules detail page.
Type	• **Calculation**—Calculation used to determine the value of a data item based on the value of another data item.
	• **Form rule**—Edit check on a form data item.
	• **Conversion**—Rule that converts data from the units in which it is entered to normalized units that other rules can reference.
	• **Randomization**—Rule that randomizes subjects in order to assign drug kits to them.
	Click the link to open the Rules detail page.
Status	Status of the rule: Active or Inactive. Only rules in the Active status run when the form is submitted.
	Click the link to open the Rules detail page.

Buttons

Button	Description
Select Rules to Run	Opens the Select Rules to Run page so that you can select rules to run against the data for all subjects in the study.
Batch Run Status	Opens the Batch Run Rules Status page so that you can view the status of the batch rule runs.
	Note: This button appears only after one or more batch rule selections are created.

Batch Run Rules Status page

The Batch Run Rules Status page provides the status of the batch run rules.

Fields

Field	Description
Rules	List of selected Rule RefNames.
	Click the link to open the Subjects-Rules Status page.
Type	The rule type:
	• Calculation
	• Form Rule
Timestamp	Timestamp of latest status change.
Status	Status of the batch rules processing:
	• Queued
	• Running
	• Error
	• Completed
Details	Detailed error messages, if any.

Buttons

Button	Description
Start Running Rules	Opens the Select Rules to Run page so that you can select rules to run against the data for all subjects in the study.
Return	Returns you to the Rules page.

Subject-Rules Status page

The Subject-Rules Status page provides the list of rules run for each subject, and the list of rule contexts run for each rule.

Fields

Field	Description
Rule Contexts	Provides information on the list of subjects the rule is run for, the rule, and the rule contexts.
Subjects	The subject(s) the rule is run for.
	Expand each Subject row to show the list of rules that are run for the subject.
Rule	The rule run for the subject.
	Expand each Rule row to show list of Rule Contexts that are run for each rule.
Rule Context	The rule context.
Timestamp	Timestamp of the latest status change.
Status	Status of the batch rules processing: • Queued • Running • Error • Completed
Details	Detailed error messages, if any.
Filter	Filters the subjects and rules. • Show All • Queued • Running • Error • Completed

Buttons

Button	Description
Return	Returns you to the Rules page.

Rules detail page

The Rules detail page enables you to view or modify the details of a selected rule. This page is divided into two panes.

- The upper pane contains items that describe the properties of the rule definition. In this pane, you can modify all items except the Type of Rule.

- The lower pane provides a view of the contexts, dependencies, and arguments associated with the rule. In this pane, all information is read-only.

Fields

	Field	Description
	Upper pane	
1	Reference Name	Name by which the rule is defined in the database. READ-ONLY.
2	Rule Description	Descriptive rule name.
3	Type of Rule	• **Calculation**—Calculation used to determine the value of a data item based on the value of another data item.
		• **Form rule**—Edit check on a form data item.
		• **Conversion**—Rule that converts data from the units in which it is entered to normalized units that other rules can reference.
		• **Randomization**—Rule that randomizes subjects in order to assign drug kits to them.
4	Status	Status of the rule: Active or Inactive. Only rules in the Active status run when the form is submitted.
5	Help Text	User-friendly description of the edit check, calculation, conversion, or randomization performed by the rule. This text appears along with the study-specific help for the data items with which the rule is associated.
6	Rule Script Text	Text of the script that runs when the rule executes.
7	Event Triggered (Only if Rule Type is Form Rule)	Event triggered when the rule fails on execution. This item applies only to Form rules.
	Lower pane	

Field	Description
Rule Context	List of contexts with which the rule is associated.
	• **Default Arguments**—When this item is visible, the Default Arguments button appears, and if any default arguments are defined for the rule, they appear in the pane.
	When Default Arguments is selected in the Rule Context list, the following information appears:
	▪ **Name**—Argument name.
	▪ **Type**—Argument type: STRING, NUMERIC (integer), FLOAT, or DATE.
	▪ **Value**—Argument value.
	• **Specific context**— When a specific context is selected, the Dependencies button and Arguments button appear, and the pane displays dependency or argument values according to the button you select.
	When a specific context is selected in the Rule Context list, the arguments defined for the context, along with the following information appears in the table in the lower pane of the page:
	▪ **Name**—Argument name.
	▪ **Type**—Argument type: STRING, NUMERIC (integer), FLOAT, or DATE.
	▪ **Value**—Argument value.
	The table lists the RefName path of the dependency and the type: Applied, Dependency, or Trigger.

Buttons

Button	Description
Submit	Submits the rule definition to the database.
Return	Returns you to the Rules page without submitting the rule definition to the database.

Select Rules to Run page

The Select Rules to Run page lists, for the rule type you select, all the rules that have been defined for the study. Use the page to select one or more rules to manually run in batch mode against the data for all subjects in the study.

> **Note:** Only calculation and form rules can be run manually in batch mode.

Fields

Field	Description
X	Checkbox used to select a rule to run.
Reference Name	Name by which the rule is defined in the database. READ-ONLY.
Description	Descriptive rule name.
Type	• **Calculation**—Calculation used to determine the value of a data item based on the value of another data item. • **Form Rule**—Edit check on a form data item.
Status	Status of the rule: Active or Inactive. Only rules in the Active status run when the form is submitted.

Rule Type filter	Filters the rules based on type:
	
	• **Calculation (default)**—Calculation used to determine the value of a data item based on the value of another data item.
	
	   ▪ Unlike regular form submissions, data changes introduced by Batch Run Calculations do not automatically trigger running rules that have dependencies on the data.
	
	   ▪ Oracle recommends running Calculations prior to Form Rules because Calculation rules can alter clinical data values.
	
	• **Form Rule**— Select to run an edit check on a form data item.
	
	When you select a filter option, the rule list refreshes to display the selected Rule Type (Calculation or Form Rule).

Buttons

Button	Description
Run Rules/Run Calculations	Opens the Rules Selected for Running page so that you can confirm the list of selected rules and run them. The button text changes depending on the rule type you select in the Rule Type filter.
Return	Returns you to the Rules page that lists all the rules that are defined for the study.

Rules Selected for Running page

The Rules Selected for Running page lists the rules that you have selected for running and enables you to run them.

Fields

Field	Description
Reference Name	Name by which the rule is defined in the database. READ-ONLY.
Description	Descriptive rule name.
Type	• **Calculation**—Calculation used to determine the value of a data item based on the value of another data item.
	• **Form Rule**—Edit check on a form data item.
Status	Status of the rule: Active or Inactive. Only rules in the Active status run when the form is submitted.

Buttons

Button	Description
Start Running Rules	Runs the selected rules against the study database.
Return	Returns you to the Rules page that lists all the rules that are defined for the study.

Events

Overview of events

> **Note:** Events (known as *Rule Actions* in the Central Designer application) are defined in the Central Designer application as part of the study design. You can view and modify the events using the InForm user interface.

An event is a study component that specifies the action to take when a rule fails.

A rule is associated with one or more specific items on a form. When a user submits new or updated data in an item that has a rule attached, and data is present in the additional data items to which the rule refers, the rule runs.

Each rule can be associated with an event that runs based on the outcome of the rule:

- The event can generate a new query or close an answered query.

- The event can run one or more execution plans that:

  - Send e-mail.

  - Send an entry to the Windows log file.

> **Note:** You can view and modify events through the InForm Admin user interface. To perform either task, you must have at least one rule administration right: Deactivate a Rule, Run a Rule, or Modify a Rule.
>
> **Note:** You create events using the Central Designer application or using MedML and the MedML Installer utility.

Viewing the list of events

1 In the navigation toolbar, click **Admin**.

2 Click **Events**.

   The Events page appears. For a description of the fields on this page, see *Events page* (on page 353).

Viewing or modifying the details for an event

1   In the navigation toolbar, click **Admin**.

2   Click **Events**.

   The Events page appears.

3   Click the **Reference Name**, **Query Text**, or **Query Initial State** link for an event.

   The Events detail page appears.

4   View or edit the information on the page using the descriptions in *Events detail page* (on page 353).

   You can modify the query text and the initial status of the query. You cannot modify the event name.

5   If you made any changes, click **Submit**.

User interface—Events

Events page

The Events page summarizes information about events and enables you to navigate to detailed information about a specific event.

Fields

Field	Description
Reference Name	Name by which the event is known when it is included by reference in the definition of a rule.
	Click the link to open the Events detail page.
Query Text	Text of the query that the InForm application generates when the event executes as a result of the failure of the rule with which it is associated.
	Click the link to open the Events detail page.
Query Initial State	Initial query state: Candidate or Open.
	Click the link to open the Events detail page.

Events detail page

The Events detail page enables you to view or modify the details for a specific event.

Fields

Field	Description
Event Reference Name	Name by which the event is known when it is included by reference in the definition of a rule. READ-ONLY.
Enter the text of the query	Text of the query that the InForm application generates when the event executes as a result of the failure of the rule with which it is associated.
Select the initial status of the query	Initial query state: Candidate or Open.

Buttons

Button	Description
Submit	Submits the event definition to the database.
Return	Returns you to the Events page without submitting the event definition to the database.

Sites

Overview of sites

Site definitions specify address and contact information about a study location. Sites are associated with specific users, and this association determines the data to which users have access. For example, a CRC who works at only one site obtains access to the data for that site by being associated with the site definition. A CRA who travels to multiple sites might be associated with multiple site definitions, and therefore obtains access to data for all of those sites.

Viewing the list of sites

1   In the navigation toolbar, click **Admin**.

2   Click **Sites**.

The Sites page appears. For a description of the fields on this page, see *Sites page* (on page 356).

Creating a site

1   In the navigation toolbar, click **Admin**.

2   Click **Sites**.

The Sites page appears.

3   Click **Add Site**.

The Sites detail page appears.

4   Complete the information on the page using the descriptions in *Sites detail page* (on page 357).

The Site Name, Site Mnemonic, and Study Locale fields are required.

5   Click **Submit**.

Viewing or modifying the members in a site (Changing site associations)

1 In the navigation toolbar, click **Admin**.

2 Click **Sites**.

   The Sites page appears.

3 In the **Users** column, click **Change** for the site whose members you want to view or modify.

   The Change Members in Site page appears.

4 View or edit the information on the page using the descriptions in Change Members in Site page.

   - To add a user to the site, select the user's name in the **Available users** list, and click **Add**.

     - To select more than one user at a time, hold down the **Ctrl** key while selecting each name.

     - To deselect a user while preserving the selection of other users, hold down the **Ctrl** key while clicking the name again.

   - To remove a user from the group, select the user's name in the **Users at site: [Site name]** list, and click the **Remove**.

     - To select more than one user at a time, hold down the **Ctrl** key while selecting each name.

     - To deselect a user while preserving the selection of other users, hold down the **Ctrl** key while clicking the name again.

5 If you made any changes, click **Submit**.

Viewing the list of subjects at a site

1 In the navigation toolbar, click **Admin**.

2 Click **Sites**.

   The Sites page appears.

3 Locate the site where the subject is currently enrolled, and in the **Subjects** column, click **List** or **Transfer**.

   The name of the link depends on your rights; Transfer appears only when you have the Subject Transfer right.

   The Subject List for Site page appears. For a description of the fields on this page, see *Subject List for Site page* (on page 381).

   For more information on transferring subjects, see *Transferring a subject to a different site* (on page 377).

4 Optionally, in the **Audit Trail** column, click the **Audit trail** icon ( ) to view the audit trail for the subject.

   The Site Audit Trail By Subject page appears. For a description of the fields on this page, see *Site Audit Trail By Subject page* (on page 384).

Viewing or modifying site information

1   In the navigation toolbar, click **Admin**.

2   Click **Sites**.

The Sites page appears.

3   Click the **Site Name** or **Site Abbrv** link.

The Sites detail page appears.

4   View or edit the information on the page using the descriptions in *Sites detail page* (on page 357).

User interface—Sites

Sites page

The Sites page summarizes information about sites and enables you to navigate to detailed information about a specific site and to add a site.

Fields

Field	Description
Site Name	Full name of the site.
	Click the link to open the Sites detail page.
Site Abbrv	Abbreviation for the site, used for display in site filtering lists.
	Click the link to open the Sites detail page.
Email Address	Email address for the site representative.
User Count	Number of users who are assigned to the site.
Users	**Change** link that opens the Change Members in Site page, from which you can add or remove users from an association with the site.
Subjects	• For users who do not have rights to transfer subjects, a **List** link that opens the Subject List for Site page, from which you can view the subjects enrolled at the site.
	• For users who have the Subject Transfer right, a **Transfer** link that opens the Subject List for Site page, from which you can view the subjects enrolled at the site and initiate a transfer.

Button

Button	Description
Add Site	Displays the Sites detail page so that you can enter a new site.

Sites detail page

The Sites detail page enables you to add, modify, or view information for a selected site.

Fields

	Field	Description
	Site Information	
1	Site Name	Full name of the site. REQUIRED. You can enter the site name in any language.
2	Site Mnemonic	Abbreviation for the site, used for display in site filtering lists. REQUIRED.
3	Address1	First line of the site address.
4	Address2	Second line of the site address.
5	City	City in which the site is located.
6	State/Province	State or province in which the site is located.
7	Country	Country in which the site is located.
8	Postal Code	Site postal code.
9	Day Phone Number	Phone number for contacting a site representative during business hours.
10	Alternate Phone Number	Alternate phone number for contacting a site representative.
11	Fax Number	Fax number for a site representative
12	Email	Email address for the site representative.
13	Time Zone	Time zone where the site is located. This value is used to make conversions between internal system time and the time that displays for transactions that occur at the site. For more information, see *Audit trail date/time conversion* (on page 41).
14	Date Format	Format you want to use for all references to dates for this particular site.
15	Study Version	Title of the study version associated with the site. The study version determines which version of the forms, study protocol, and study documents for a study appear to users at the site.
16	Site Server	Name of the server designated to be the site server. The site server is dedicated for doing specific activities such as randomization, screening and enrollment, and generating subject numbers.

	Field	Description
17	Study Locale	The language(s) in which study metadata are designed using the Central Designer application. This includes CRFs and related study design labels, such as visit names, CRF (form) names, section labels, CRF questions, item control labels, auto-query text, and so on. REQUIRED.
		• A study may contain multiple study locales.
		• The site study locale governs the language presented for CRFs filled in for subjects at that site, regardless of user study locale settings.
		Note: After a subject has been added to the site, this field becomes read only and you cannot change the language.
18	Order of UserName in Signature	Order of the names in the signature.
		• FirstName,LastName (default)
		• LastName,FirstName

Buttons

Button	Description
Submit	Submits the site definition to the database.
Return	Returns you to the Sites page without submitting the site definition to the database.

Change Members in Site page

The Change Members in Site page allows you to assign users to, or remove users from, a selected site. Site members are users authorized to handle site data.

Fields

Field	Description
Available users	Names of users available for assignment to the site.
Users at site: [Site name]	Names of users assigned to the site.

Buttons

Button	Description
Add	Adds the users selected in the Available users list to the site.
Remove	Removes the users selected in the Users at site: [Site name] list from the site.
CTRL+Click	Selects multiple entries.
SHIFT+Click	Selects contiguous entries.
Submit	Submits the changed site membership to the database.
Return	Returns you to the Sites page.

MedML—Sites

For details on the MedML for setting up sites, see the *Utilities Guide*.

Users

Overview of users

A user, or user account, identifies who can access an InForm study. Users are associated with sites, rights groups, and other groups (query, signature, and reporting). To enable a user to use the InForm application, an administrative user must perform the following tasks.

	Task	Rights required	See this topic
1	Create the user.	Create User	*Creating a user* (on page 361).
2	Assign the user an initial password.	Modify User Information	*Assigning a password to a user* (on page 362).
3	Activate the user.	Activate Site User or Activate Sponsor User	*Activating or deactivating a user* (on page 363).
4	Assign the user to: • One rights group. • One or more sites. • If applicable, one signature group, one query group, and one or more reporting groups.	Modify User Information	*Assigning a user to a rights group, site, and other groups* (on page 364).

Viewing the list of users

1   In the navigation toolbar, click **Admin**.

2   Click **Users**.

The Users page appears. For a description of the fields on this page, see *Users page* (on page 366).

Creating a user

User definitions specify name, address, and contact information for an InForm user, as well as:

- The name of an image file that displays a picture when the user logs in to the InForm application.

> **Note:** You must use XML to associate an image with a user.

- The default Home page URL.

- The initial status, Active or Inactive.

To create a user:

1   In the navigation toolbar, click **Admin**.

2   Click **Users**.

The Users page appears.

3   Click **Add User**.

The User details page appears. The Details tab is selected.

4   Complete the information on the page using the descriptions in *User details page* (on page 368).

- The User Name, Product Locale, and Preferred Study Locale fields are required.

- The User Type field is set to Site User, by default. You must change this to Sponsor User, if applicable.

- The User must change password field at next logon field is set to Yes, by default. You must change this to No, if applicable.

5   Click **Submit**.

- The InForm application creates the user.

- The user is in the Inactive state, by default.

- The User Active checkbox becomes active.

- The Change Password button appears at the bottom of the page.

> **Note:** If you intend to assign a password to the user immediately, leave the status Inactive; you can only create a password for an inactive user. For more information, see *Assigning a password to a user* (on page 362).

6   To make the user active, select the **User Active** checkbox.

The Change Password button no longer appears on the page.

> **Note:** To activate a user you need the Activate Site User or Activate Sponsor User right. To keep the user inactive, leave the User Active checkbox deselected.

7   Click **Submit**.

Assigning a password to a user

After a user is created, the **Change Password** button is available on the User page, and you can assign the user an initial password. After the user logs in for the first time, the user is required to change this initial password.

1   In the navigation toolbar, click **Admin**.

2   Click **Users**.

The Users page appears.

3   Click the **Last Name**, **First Name**, or **Account Name** link for a user.

The User details page appears.

4   Make sure that the **User Active** checkbox is not selected (the user is in an inactive state).

The Change Password button appears at the bottom of the page.

5   Click **Change Password**.

The Change Password page appears. For a description of the fields on this page, see *Change Password page—For administrators* (on page 371).

6   In the **New password** field, type a password for the user.

Passwords should have a minimum of 8 characters. For security reasons, Oracle recommends using a combination of letters, numbers, and non-alphanumeric characters. Passwords are case-sensitive.

For more information, see *Guidelines for choosing a password* (on page 85).

7   In the **Confirm new password** field, retype the password.

8   Click **Submit**.

Activating or deactivating a user

For a user to perform any InForm activities, the user must be in the active state. When an Inactive user attempts to log in to the InForm application, the system displays a message indicating that the user is not active and blocks access to the study.

You can activate or deactivate a user from the:

- List of users.

  For more information, see *Activating or deactivating a user—From the Users page* (on page 363).

- User details page for a specific user.

  For more information, see *Activating or deactivating a user—From the Users details page* (on page 363).

Activating or deactivating a user—From the Users page

1 In the navigation toolbar, click **Admin**.

2 Click **Users**.

   The Users page appears.

3 Select the checkbox next to each user you want to activate or deactivate.

4 Do one of the following:

   - To activate the selected user(s), click **Activate**.

   - To deactivate the selected user(s), click **Deactivate**.

     > **Note:** Inactive users are not deleted from the database.

Activating or deactivating a user—From the User details page

1 In the navigation toolbar, click **Admin**.

2 Click **Users**.

3 Click the **Last Name**, **First Name**, or **Account Name** link for a user.

   The User details page appears.

4 Do one of the following:

   - To activate an inactive user, select **User Active**.

   - To deactivate an active user, deselect **User Active**.

     > **Note:** Inactive users are not deleted from the database.

5 Click **Submit**.

Assigning or modifying a user association to a rights group, site, and other groups

After a user is created, you can assign rights to the user by associating the user with a rights group. You can also assign the user to sites and other groups (signature, query, and reporting groups). Before you start, make sure that the groups and sites are set up. For more information, see *Creating a rights group and assigning its rights* (on page 313), *Creating a group or item group* (on page 322), and *Creating a site* (on page 354).

1   In the navigation toolbar, click **Admin**.

2   Click **Users**.

The Users page appears.

3   Click the **Last Name**, **First Name**, or **Account Name** link for a user.

The User details page appears. The Details tab is selected. For a description of the fields on this page, see *User details page* (on page 368).

4   Click the **Group** tab.

5   In the **Rights Group** field, select the rights group to which you want to assign the user.

A user can be a member of only one rights group.

Alternatively, to remove a user from a rights group, you can modify the users in a rights group. For more information, see *Viewing or modifying the users in a rights group* (on page 314).

6   In the **User Site Association** field, select the sites to which you want the user to have access.

A user can be associated with multiple sites; users have access only to the data for the sites with which they are associated.

To select more than one site, hold down the **Ctrl** key while selecting each site.

7   Assign the user to other groups, if applicable.

a   In the **Signature Group Association** field, select a signature group.

b   In the **Query Group Association** field, select a query group.

c   In the **Reporting** field, select a reporting group.

8   Click **Submit**.

Viewing or modifying the details for a user

1   In the navigation toolbar, click **Admin**.

2   Click **Users**.

    The Users page appears.

3   Click the **Last Name**, **First Name**, or **Account Name** link for a user.

    The User details page appears.

4   View or edit the information on the page using the descriptions in *User details page* (on page 368).

5   If you made any changes, click **Submit**.

Terminating or reinstating a user

Terminating users is similar to deleting them, except that terminated users remain in the database and can be reinstated to inactive status, from which they can subsequently be reactivated. For a user to perform any InForm application activities, the user must be in the active state.

When a terminated user attempts to log in to the InForm application, the system displays a message indicating that the user is not active and blocks access to the study. Additionally, users in the terminated state do not appear on the Users page unless the administrator has the right to reinstate terminated users.

1   In the navigation toolbar, click **Admin**.

2   Click **Users**.

    The Users page appears.

3   Select one or more users.

4   Do one of the following:

    a   To terminate the selected user(s), click **Terminate**.

    b   To reinstate selected terminated user(s), click **Reinstate**.

User interface—Users

Users page

The Users page summarizes information about the InForm users and enables you to navigate to detailed information about a specific user, and provides access to user administration activities such as adding or modifying a user or assigning the user to a rights group, site, or group.

Fields

Field	Description
Filter user(s)	Filter that identifies the items that you want to view, based on user information.
	• Type any part of a user name, country, first name, or last name, and press Enter.
	The user listing returns a list of matching users and the **Clear Search Results** icon (✖)appears next to the box. Click the icon to clear the filter.
	• This filter is case-insensitive.
	Note: To sort by Status or Personnel type, you must type the entire field value. For example, you must type "Site" or "Sponsor" (the whole word).
X	Checkbox that allows you to select users. When you select the checkbox for one or more users and then click one of the buttons at the bottom of the page, the InForm application processes the request for all selected users.
	For example, if you select one or more checkboxes and then click the Inactivate button, all selected users change to the Inactive state.
	Caution: If you make all users inactive, you will be unable to re-enter the InForm application to perform any administration activities, including the set up of users. Oracle recommends that you keep one user with administration rights active at all times.
Last Name	Last name of the user.
First Name	First name of the user.
Account Name	Name the user enters to log in to the InForm application.
Status	User status: Active, Inactive, or Terminated.
	• Inactive users remain in the database, are visible on the Users page, and can be reactivated.
	• Terminated users remain in the database, are visible on the Users page only to administrators who have the right to reinstate users, and cannot be reactivated.

Field	Description
Personnel Type	Type of user. Certain features are available only to sponsor users.
	• **Site**—User who performs site functions. Queries in the Candidate state are not visible to Site users.
	• **Sponsor**—User who performs sponsor functions such as monitoring and data management. Queries in the Candidate state are visible to sponsor users.
	• **System**—Internally defined user who performs automated functions; for example, the autoquery user is designated as the originator of automatic queries.
Country	Country where the user is located.
	Caution: Make sure that you always enter the country in the same way so that the field is used correctly in the InForm reports. For example, UA and United States are recognized as two different countries in the reports.

Buttons

Button	Description
Add User	Displays the User details page so that you can add a new user.
Deactivate	Changes the status of the selected users to Inactive.
	Inactive users remain in the database, are visible on the Users page, and can be reactivated.
	Caution: Oracle recommends that you keep one user with administration rights active at all times.
Activate	Changes the status of the selected users to Active.
Terminate	Changes the status of the selected users to Terminated.
	Terminated users remain in the database, are visible on the Users page only to administrators who have the right to reinstate users, and cannot be reactivated.
Reinstate	Changes the status of the selected users from Terminated to Inactive.

User details page

The User details page allows you to add, modify, or review details about a specific InForm user.

Fields—Details tab

Field	Description
Basic User Info	
User Name	Name the user enters to log in to the InForm application. REQUIRED.
	Note: The User Name can contain alphabetic characters, numeric characters, and underscores; it cannot contain spaces.
First Name	First name of the user.
Last Name	Last name of the user.
User Type	Type of user. Certain features are available only to sponsor users.
	• **Site User (default)**—User who performs site functions. Queries in the Candidate state are not visible to Site users.
	• **Sponsor User**—User who performs sponsor functions such as monitoring and data management. Queries in the Candidate state are visible to sponsor users.
	Note: This field does not appear for system users.
User Active	Indicates whether the user is active.
	Note: Only users in the Active state have access to the InForm application features.
Title	Job title for the user.
Description	Description of the job.
User must change password at next logon	Yes (default) or No. Indicates whether the user must change their password at next log in.
	Note: When changing the password for the first time, the user is required to provide an email address, a confirmation question, and confirmation answer. If the user subsequently forgets the password, this information is used to provide the user with a temporary password.
User Address	
Street	Address of the user.
Street2	Address of the user.
City	City where the user is located.
State/Province	State or province where the user is located.
Country	Country where the user is located.
Postal Code	Postal code where the user is located.

Field	Description
User Contact	
Day Phone Number	Daytime telephone number for the user.
Alternate Phone Number	Alternate telephone number for the user.
Beeper Number	Beeper number for the user.
Fax Number	Fax number for the user.
Email address	Email address for the user.
User Misc	
Display Name	User name as it appears under the picture in the upper-right corner of the main window.
Home Page	URL of the page that appears when the user logs in to the InForm application. This URL can be any valid URL that points to an internal or external site that is identified by an IP address or host name.
Date Format	The date format the user wants to use as the default. • Month / Day / Year • Day / Month / Year • Year / Month / Day
Product Locale	The language(s)—English or Japanese—of the product user interface components: menus, controls, commands, system screen labels, error messages, and so on. Oracle creates product locales. REQUIRED.
Preferred Study Locale	The preferred language for CRFs. REQUIRED. The available options are based on the languages specified during the study design. This setting: • Is used for pages that can span multiple sites. • Controls some study locale information presented outside of the CRFs, such as headings on the Time and Events Schedule page or choices in the Source Verification page filter control.

Fields—Group tab

Field	Description
User Group Selection	
UserName	Name of the user for whom to maintain group and site associations.
Rights Group	Name of the rights group with which the user is associated.
	Note: A user can be a member of only one rights group.
User Site Association	Name or names of the sites with which the user is associated.
	Note: A user can be associated with multiple sites; users have access only to the data for the sites with which they are associated.
Signature Group Association	Name of the signature group with which the user is associated.
	Note: A user can be a member of only one signature group.
Query Group Association	Name of the query group with which the user is associated.
	Note: A user can be a member of only one query group.
Reporting	Name of the reporting groups with which the user is associated.
	Note: A user can be a member of more than one reporting group.

Buttons

Button	Description
Change Password	Displays the Change Password page so that you can assign an initial user password or update the existing password.
	Note: This button is visible only on the Details tab for Inactive users, and if you have the Modify User Information right.
	Be sure to check your study protocol for password requirements. There may be restrictions such as minimum length, at least one numeric, uppercase, or non-alphanumeric character.
Submit	Submits the added or updated user definition to the database.
Return	Returns you to the Users page without submitting the user definition to the database.

Change Password page—For administrators

The Change Password page enables you to create or change the password for an InForm user. An administrator must create a password for a new user. Users can change their passwords at any time, and must change their passwords when the password expiration period, if enabled, is reached.

> **Note:** The information in the Password Recovery Information section is populated with the information a user enters on the Change Expired Password page or on the user version of the Change Password page. The section is active only when a user changes their own password. For more information, see *Change Expired Password page* (on page 100) and *Change Password page—For InForm users* (on page 96).

Fields

Field	Description
Change Password	
User name	Name the user enters to log in to the InForm application.
Password	Current password, if any.
New password	New password to assign.
Confirm new password	Repeat of new password, for confirmation.
Password Recovery Information	
E-mail address	User's email address.
	The email address must be at least three (3) characters long and contain the at (@) character.
	If a user resets their password, the InForm application sends a message to this address with a temporary password with instructions on how to access their account.
Confirmation question 1	Security question 1.
	• What is your mother's maiden name?
	• What is the name of your pet?
	• What is the city of your birth?
	• What is your favorite color?
Confirmation question response 1	Answer to Confirmation question 1. The user must provide an answer to the question.
	• The answers are case-insensitive.
	• Leading and trailing spaces are ignored.

Field	Description
Confirmation question 2	Security question 2. The user cannot select the same question more than one time.
	• What is your mother's maiden name?
	• What is the name of your pet?
	• What is the city of your birth?
	• What is your favorite color?
Confirmation question response 2	Answer to Confirmation question 2. The user must provide an answer to the question.
	• The answers are case-insensitive.
	• Leading and trailing spaces are ignored.

Buttons

Button	Description
Submit	Submits the information on the page for processing.
Return	Returns you to the Users page.

MedML—Users

For details on the MedML for setting up users, see the *Utilities Guide*.

Subject transfers

Overview of subject transfers

The InForm subject record transfer feature allows you to transfer subject information from one site to another.

You can transfer subjects one at a time using the InForm user interface, or you can transfer subjects in bulk using the InForm Data Import utility. For more information, see the *Utilities Guide*.

Use the InForm user interface to transfer subjects who meet any of the following criteria:

- Change permanent address before completing the study.

- Have multiple residences throughout the course of the study.

- Were initially assigned to the wrong site or to an investigator who is no longer with the study.

Use the InForm Data Import utility to transfer several subjects from one site to another. For example, you might need to do a bulk transfer if a site is closed down within the course of a study.

Whether you transfer subjects individually, or in bulk, keep in mind that:

- The InForm application allows you to transfer subjects from one site to another only if the study version at the destination site is the same or greater than the study version at the current site.

> **Note:** To see what study version is in effect for a site, display its detail page. For more information, see *Viewing or modifying site information* (on page 356).

- You can transfer only subjects who are fully enrolled; you cannot transfer a subject who is screened but not enrolled, or a subject who has failed enrollment.

Who can transfer subjects?

To be able to transfer subjects from one site to another, users must be:

- Assigned to an InForm rights group with the right to transfer subject records.

- Associated with both the originating and destination sites.

Audit history and subject record transfer archive

When you initiate a subject record transfer, the InForm application automatically creates a:

- **Subject transfer audit history**—Shows the date and time of the transfer, the originating and destination site, the destination site time zone, the user who performed the transfer, and the reason for the transfer.

  Users who are authorized to transfer subjects or to manage site information can view the audit trail for transferred subjects. For more information, see *Viewing the audit trail for a transferred subject* (on page 380).

- **Subject transfer archive**—An XML archive of the subject history up to and including the subject record transfer. You can use the subject archive for submission to regulatory authorities or for a site audit.

  Users with access to the Case Report Books page can view a list of the subjects who have been moved to or from the current site, and can view the archives. For more information, see *Viewing a subject transfer archive* (on page 288).

Contents of a subject transfer archive

Each CRF page in a subject archive can contain the following data:

- Form and item comments.
- Signature history.
- Item audit trail.

The CRF page includes links to the following types of detailed information:

Link	Link location	Description
Association Summary	Right column of repeating form instance	Displays the summary of repeating form instances that are associated with the instance where the link appears. From the association summary table, you can navigate to either association audit history or each of the individual associated pages.
Audit Trail	Right column of item	Displays the audit trail of data changes and query activity for the item.
Comments	Right column of item	Displays the audit trail of comments on the item.
CRF Audit Trail history	Top of form	Displays the audit summary for the entire form. Shows data changes and query activity for each item in the form.
Form Comments	Top of form	Displays the audit trail of comments on the form.
Initial Entry	Right column of item	Displays the record of the initial entry of data on the item. This link is visible only if no activity has occurred since the initial entry. If the item data has changed or includes query activity, the initial entry is included in the item audit trail.

Link	Link location	Description
Repeating Pages	Right column of repeating form instance	Displays a snapshot of current data values in the repeating form instance.

Deleted items

Within the InForm application, deleted items appear crossed out. If you create an archive for a form that contains a deleted item, the item appears with the word **DELETED** in bold above it.

Repeating forms

The InForm application displays repeating forms individually and in summary form. The summary page shows only the data for the first key items in a single table. The details for each form appear in subsequent tables. For example, for the Adverse Events section, a summarized version of the form appears first, with a list of all the adverse events. The details for each instance follow the list.

Subject record transfer flow

The following table shows the transfer of subject XYZ from:

- Site A to Site B

- Site B to Site C

- Site C back to site A

Site A	Site B	Site C
Step 1: Enroll subject XYZ.		
Step 2: Add data for subject XYZ.		
Step 3: Initiate transfer for subject XYZ to Site B. The InForm application creates an archive that includes all forms for the subject as well as the audit history up to and including the subject transfer. Site A can no longer edit the subject data.	**Step 4:** The InForm application transfers subject XYZ to Site B. Site B has edit access and control over all data for subject XYZ.	
	Step 5: Add more data for subject.	

Site A	Site B	Site C
	Step 6: Initiate transfer for subject XYZ to Site C. The InForm application creates an archive that includes all subject data from both Site A and Site B, up to and including the most recent subject transfer. Site B can no longer edit the data of the subject.	**Step 7:** The InForm application transfers subject XYZ to Site C. Site C has edit access and control over all data for subject XYZ.
		Step 8: Add more data for subject.
		Step 9: Initiate transfer for subject XYZ back to site A. The InForm application creates an archive that includes all subject data from Site A, Site B, and Site C, up to and including the most recent subject transfer. Site C can no longer edit the data of the subject.
Step 10: Data for subject XYZ successfully transferred to Site A. Site A regains edit access and control over all data for subject XYZ.		

Subject status and record transfer

Study sponsors develop and maintain their own practices regarding subject status and subject record transfer. When you use the InForm user interface to transfer subjects, the InForm application displays the following subject status information that sponsors can view before they execute the transfer:

- **Signature status**—The number of required signatures that are missing for the subject.

- **Query status**—The number of queries that are open for the subject.

- **Source verification status**—The number of forms that have yet to be source verified for the subject.

> **Note:** While it might be good practice to make sure that all forms for a subject are signed and source verified, and that all queries are resolved before transferring a subject, Oracle acknowledges that each study has different processes and procedures. The InForm application does not prevent transferring a subject with outstanding queries, outstanding required signatures, or forms that are not source verified.

Transferring a subject

1   Click **Sites**.

    The Sites page appears.

2   Identify the current site for the subject that you want to transfer.

3   In the **Subjects** column for that site, click **Transfer**.

    The Subject List for Site page appears.

4   In the **Action** column for the subject you want to move, click **Transfer**.

    The Subject Record Transfer page appears.

5   Read and understand the information in the following sections of the page:

    - **Subject Record Transfer Affidavit**—This section is customized for your study. It provides guidance on the responsibility of the administrative user regarding moving a subject from one site to another.

    - **Subject Status**—This section makes you aware of any of the following: missing required signatures, queries that are not closed, or forms that require source verification.

    After reading these sections of the page, you can choose to continue with the subject transfer, or to cancel. If you choose to continue, you are assuming responsibility for the subject transfer as described in the affidavit.

6   Complete the fields in the **Enter Subject Record Transfer Information** section of the page using the descriptions in *Subject Record Transfer page* (on page 382).

7   Click **Submit**, and then click **OK** to confirm the transfer.

    - The InForm application checks the study versions at the current and destination sites:

        - **If the current site is at a lower study version than the destination site**—The InForm application prompts you to confirm the transfer by resubmitting it.

        - **If the current site is at a higher study version than the destination site**—You cannot complete the transfer.

    - The InForm application checks to ensure there is no conflict with the subject number at the destination site:

        - **If the InForm application finds no conflict at the destination site**—The transfer completes.

        - **If the InForm application finds a duplicate subject number at the destination site**—The transfer stops until you resolve the subject number conflict, as duplicate subject numbers at a site are not permitted in subject record transfers. The Subject Record Transfer page displays again, allowing you to edit the subject number and resubmit the transaction.

    The Subject Transfer Status page appears. For a description of the fields on this page, see *Subject Transfer Status page* (on page 383). The Subject Transfer Status page provides the status of the subject transfer archive process. The page displays until the transfer completes.

Subject initials and DOB conflicts

Study designers can configure a study to require that the combination of subject initials and date of birth be unique within a site or throughout the study. If your study requires unique initials and date of birth only within a site, it is possible to have subjects at different sites with the same combination of initials and date of birth.

If you transfer a subject to a site where another subject exists with the same initials and date of birth, and your study requires unique initials and date of birth at the site, the subject transfer fails. You must change the subject initials to make the combination unique.

Subject number conflicts

The subject number is an identifier that is assigned to each subject at enrollment. If your study is configured to require unique subject numbers at a site, the subject record transfer feature prevents you from creating duplicate subject numbers at the destination site.

> **Note:** Subject screening numbers do not change when a subject transfers to another site.

Number conflicts when transferring subjects with the InForm user interface

When you begin transferring a subject, the InForm application assumes that there is no subject number conflict at the destination site and retains the current number of the subject for the transfer.

When you submit the transaction, the InForm application checks for any subject number conflict at the destination site.

- If no conflict is found at the destination site, the InForm application completes the transfer and the subject retains his or her original subject number after moving to the destination site.

- If a conflict is found at the destination site, the InForm application allows you to change the subject number and resubmit the transaction.

Number conflicts when transferring subjects with the InForm Data Import utility

To transfer subjects in bulk using the InForm Data Import utility, you load a MedML file that specifies details of the subject transfer. During the load process, the InForm application checks for subject number conflicts at the destination site. If a conflict is found, processing stops for that subject, and an error message appears.

Processing continues with the next subject in the file.

Changing a subject number

1   If the InForm application finds a subject number conflict, an error message appears.

2   Click **OK**.

The Subject Record Transfer page appears.

> **Note:** The Subject Number field is now editable.

3   Change the **Subject Number** field to a number that is not currently used at the destination site.

4   Click **Submit**.

The subject transfer transaction is complete.

Subject transfer and study version

The InForm application allows you to transfer subjects to only those sites running a study version that is the same or greater than the one run at the current site. When you transfer a subject to a site at a different study version:

• If the study version at the destination site includes a new item on a form, the new item appears only for subjects who had not started the form in the source site.

• If the study version at the destination includes a new form, the new form appears only for subjects who were added after the new version was implemented.

Study version considerations when transferring subjects with the InForm user interface

The InForm application filters the list of destination sites and displays only those who meet the study version criteria. You cannot choose a site that has an unacceptable study version.

> **Note:** To see what study version is in effect for a site, display its detail page. For more information, see *Sites detail page* (on page 357).

Study version considerations when transferring subjects with the InForm Data Import utility

If the subject transfer MedML file specifies a destination site with an unacceptable study version, processing stops for that subject, and an error message appears.

The subject transfer process continues with the next subject in the file.

Resubmitting a subject transfer

If the destination site for a subject transfer is at a higher study version than the current site, the InForm application displays a message prompting you to confirm the transfer by resubmitting it.

1 Click **OK** to clear the message.

2 Click **Submit**.

3 In the confirmation message, click **OK**.

Viewing the audit trail for a transferred subject

Users who are authorized to transfer subjects or to manage site information can view the audit trail for transferred subjects.

To view the audit trail for a transferred subject:

1 In the navigation toolbar, click **Admin**.

2 Click **Sites**.

The Sites page appears.

3 Locate the site where the subject is currently enrolled, and in the **Subjects** column, click **List** or **Transfer**.

The name of the link depends on your rights; Transfer appears only when you have the Subject Transfer right. The Subject List for Site page appears. For a description of the fields on this page, see *Subject List for Site page* (on page 381).

4 In the **Audit Trail** column, click the **Audit trail** icon ( ) for the subject.

The Site Audit Trail By Subject page appears. For a description of the fields on this page, see *Site Audit Trail By Subject page* (on page 384).

User interface—Subject transfers

Subject List for Site page

The Subject List for Site page displays a list of subjects currently enrolled in the selected site.

Fields

Field	Description
Site	Abbreviation of the site.
Subject	Subject number and name.
Action	Transfer link that opens the Subject Record Transfer page, from which you can complete a subject transfer. **Note:** This column appears only if you have the Subject Transfer right.
Audit Trail	Link to the Site Audit Trail By Subject page, where you can view the record of a subject's enrollment and any transfers to another site. For more information, see *Site Audit Trail By Subject page* (on page 384).

Buttons

Button	Description
Return	Returns you to the Sites page.

Subject Record Transfer page

The Subject Record Transfer page provides the transfer affidavit and details for completing a subject transfer.

Fields

Field	Description
Subject Record Transfer Affidavit	This section is customized for your study. It provides guidance on the responsibility of the administrative user regarding moving a subject from one site to another.
Subject Status	
Signature status Query Status Source Verification Status	Information that makes you aware if any of the following are outstanding for the subject: • Missing required signatures. • Queries that are not closed. • Forms that require source verification.
Enter Subject Record Transfer Information	
Current Site	Read only. The current site to which the subject belongs.
Destination Site	List of destination sites. Includes only those sites that you have access to and that are running study versions that are the same as or greater than the study version at the current site.
Subject Number	The subject number. This read-only field defaults to the subject number used at the current site. If the InForm application finds no subject number conflict at the destination site, the subject retains his or her subject number when the transfer is complete. However, if the InForm application finds a conflict after you submit the transaction, this screen appears again, allowing you to edit the Subject Number field.
Reason for Change	Reason for the subject transfer. • Select the top radio button and select a reason for the transfer. • Select the **Other** radio button. In the text box, type a description of the reason for the transfer.

Buttons

Button	Description
Submit	Submits the subject transfer to the database.
Return	Returns you to the Subject List for Site page without submitting the subject transfer to the database.

Subject Transfer Status page

The Subject Transfer Status page provides the status of the subject transfer archive process. The page displays until the transfer completes.

Fields

Field	Description
Subject Number	The subject being transferred.
From	The Site the subject is being transferred from.
To	The Site the subject is being transferred to.
Timestamp	The date and time of the last status change.
Status	The status of the subject transfer. • Processing • Error • Completed
Details	If the status is Processing, refreshes the count of processed CRFs every 30 seconds. For example, displays: Archiving Subjects CRFs (3/43). If the Status is Error, provides error messages. When the status is Completed, the page closes.

Buttons

Button	Description
Return	Returns you to the Subject Record Transfer page.

Site Audit Trail By Subject page

The Site Audit Trail By Subject page displays an audit trail showing a record of subject enrollment and any transfers to another site.

Fields

Field	Description
Subject Number	The subject number at the destination site.
	• The subject number might be the same for every transfer a subject undergoes.
	• However, the subject number can vary if, for instance, the subject number had to be changed due to a conflict at the destination site.
Site	The site at which the subject is enrolled after the audited action.
Date	The date of the subject transfer. This date reflects the destination site local time and time zone.
User	The InForm user who initiated the subject transfer transaction.
Reason	The reason, in text form, for the subject transfer.

Buttons

Button	Description
Return	Returns you to the Subject List for Site page.

Data Viewer review states

Defining the Data Viewer custom review states

Custom review states for the Data Viewer can be defined in two ways:

- **During study design in the Central Designer application**—For more information, see the Central Designer *InForm Design Guide*.

- **With MedML in the InForm application**—The system administrator can install MedML that contains the definitions for up to five custom review states. For more information, see the *Utilities Guide*.

Custom review states:

- Can be defined at different times, but each state (including its three stages) must be completely defined at one time. An administrator cannot partially define custom review states.

- Must be fully defined before they are available for use by any reviewer.

- If defined in the Central Designer application, can be updated (added, modified, or deleted) using MedML in the InForm application.

> **Note:** Custom review states cannot be defined using the InForm user interface.

Glossary

A

Ad Hoc Reporting

The Reporting and Analysis module that allows you to create, run, and save customized reports on clinical and study-management data.

adverse event (AE)

An undesirable symptom or occurrence that a subject experiences during or after a study.

Also called *adverse experience*, *adverse drug reaction*, *side effect*. See also **serious adverse event** (on page 391).

alternate form

A new version of a form that collects additional data on a subject after the visit in which such data would usually be recorded. The alternate form appears in the visit where the data would have been collected originally.

answered query

The state of a query after a site user has responded to it, and before it has been verified by a sponsor representative.

associated forms

Instances of a repeating form that are linked to each other.

association

The many-to-many relationship that can exist between two repeating forms.

audit trail

A complete record of changes made to study data.

automatic query

A query that the InForm application generates when a submitted data item does not meet certain criteria

that is defined by the study designer.

C

candidate

A person considered for, but not yet accepted into, a study.

candidate query

A preliminary query, issued by a sponsor user, that is visible to sponsor users but not to site users.

case report book (CRB)

The collection of all case report forms (CRFs) for a single study participant.

Also called *case book*.

case report form (CRF)

A form that is used to record clinical data about an enrolled subject.

Also called *case record form*. See also **form** (on page 389).

CDD mapping

A set of mapping definitions, specifying the data source and target, that enable the transfer of data from a study database to a customer-defined database. Mapping definitions are generated by the Central Designer application.

See also **customer-defined database (CDD)** (on page 388).

clinical data

The data entered on a CRF or imported into the database that records the interventions and assessments performed on study subjects according to the study's protocol.

clinical data manager (CDM)

A person responsible for preparing and maintaining a study database and reviewing data.

clinical project manager

A person responsible for all aspects of one or more clinical studies or for the entire clinical plan for a drug, device, or procedure.

clinical reporting package

An Ad Hoc Reporting package that provides access to both clinical and study-management data for reporting.

clinical research associate (CRA)

A person who is hired by a sponsor to supervise and monitor the progress of sites that are participating in a study.

Also called *monitor*, *site monitor*.

clinical research coordinator (CRC)

An assistant to the investigator at a site.

Also called *site coordinator, study coordinator*.

closed query

The state of a query after a site user changes an invalid data value to a valid data value, or a sponsor user manually changes the status to closed.

common form

A CRF containing data that is cumulative from visit to visit.

Also called *common CRF*.

complete form

An expected form that meets the following criteria: it is started and all required items contain data.

complete visit

A visit for which all the expected forms have a current status of complete.

control path

A sequence of IDs that define the physical location of a data point in the InForm database.

customer-defined database (CDD)

An extract of the study database that can be collected as the data is entered.

See also *CDD mapping* (on page 387).

D

data model

A logical representation of the data in the InForm database that describes data objects, structure, grouping, data relationships, and security. Data models are used to create ad hoc reports.

Data Viewer

A standard feature that provides Clinical Data Managers (CDMs) and other InForm users with a real-time overview of clinical study data across visits and sites. The Data Viewer can include custom workflows for tracking the review process.

display override

A property that is applied to a specific item, which overrides default display properties for all users. The display properties can be set to Hidden, Editable (default), or Read-Only.

See also *item blinding* (on page 389).

dynamic control

A control that is visible or hidden depending on whether the parent control is selected.

dynamic form

A form that is generated in a study as a direct result of data that you enter. For example, a Pregnancy Result form can be a dynamic form that is generated if the value of a Gender item is Female.

dynamic visit

A visit that is generated in a study as a direct result of clinical data that you enter. For example, if a subject agrees to extend participation in the study,

extension visits are automatically generated.

E

enrollment override

An optional feature you can use to register candidates into a study when they do not meet study criteria.

event

A study component that specifies the action to take when a rule fails.

exclusion criteria

A list of admission criteria, any one of which excludes a candidate from participation in a study.

expected form

A form that meets any of the following criteria: it appears within a scheduled visit (regardless of whether the form is started), it appears within a started unscheduled visit, or it is a dynamic form that has been activated.

F

form

The data collection mechanism that is used in a study to gather data. The term "form" by itself can be any type of form in the user interface, which includes case report forms, but also several system forms.

See also *case report form (CRF)* (on page 387).

freezing

An action you perform on a CRF or case report book that prevents site users from entering data, editing existing data, or adding comments. A CRF or case report book that is frozen allows queries and signatures.

See also *locking* (on page 390).

H

Home page

The page that appears when you log in to the InForm application. The Home page can be an HTML or ASP page, or a portal created with the InForm Portal application. You can set the Home page at the study, site, or user level.

I

inclusion criteria

A list of admission criteria that candidates must meet to be eligible for participation in a study.

InForm Reporting and Analysis module

An optional part of the InForm application that provides a library of configurable reports, predefined reports, and ad hoc reporting and charting tools.

InForm Trial Management package

An Ad Hoc Reporting package that provides access to study management data for reporting and allows users to share the reports across studies.

instance

One set of repeating data in an itemset, repeating form, or repeating visit.

item

A non-repeating data point on a CRF.

item blinding

The process of refining user access, which is defined in the Central Designer application, to individual data items on forms by specifying, for a particular rights group, whether the group of items that make up an item group is Hidden, Editable, or Read-Only. The user access is implemented using the display override feature.

See also *display override* (on page 388).

item group

A set of items that you group together so that you can assign a display override to it.

See also *display override* (on page 388).

itemset

A group of items that repeat on a CRF. You use itemsets for submitting multiple rows of data on a form at one time.

There are two types of itemsets: Add Entry itemsets and Repeating Data itemsets.

L

locking

An action you perform on a CRF or case report book that prevents all tasks, except for electronic signatures, from being performed.

See also *freezing* (on page 389).

M

manual query

A query that a sponsor user creates and issues during the review process.

medical monitor

A person who designs the study protocol and reviews data.

MedML

The Oracle XML for representing and exchanging clinical data definitions created in the InForm application.

O

opened query

The original state of a query that is visible to the site and available for response.

P

package

A grouping of data from one or more data models in the InForm reporting database.

See also *data model* (on page 388), *InForm Trial Management package* (on page 389), *study-specific clinical model* (on page 392).

partial SV

Partial source verification. A standard feature that allows you to control, for each site, the data marked as SV Required during the study design that must be verified for all subjects in the study. Subjects, forms, and items can be configured for partial source verification.

principal investigator (PI)

The clinician who is responsible for treating subjects, executing the protocol of a study at a specific site, and filling out CRFs for subjects.

Also called c*linical investigator*, *investigator*, *primary investigator*.

product locale

The language(s)—English or Japanese—of the product user interface components: menus, controls, commands, system screen labels, error messages, and so on. Oracle creates product locales.

See also *review schema locale* (on page 391), *study data locale* (on page 392), *study locale* (on page 392).

protocol

The detailed plan for a study.

Q

query

A question that the InForm application automatically generates, or that a CRA or sponsor staff manually creates, when data does not meet certain criteria.

query group

Allows any user who is in the same query group as the user who opened a query to change its status (for example, to close it). A user can be a member of only one query group.

R

randomization

An optional feature that you use to assign drug kits, devices, or treatments to subjects in a study.

RefName

A unique identifier for a study object definition.

regular form

A CRF that you use to collect data that is specific to the visit in which the form occurs.

repeating form

A CRF that can have multiple instances within a visit. A regular or common form can be a repeating form.

repeating visit

A visit for which you can have multiple instances.

reporting group

Defines the reporting functionality and type of access available to users with reporting rights. Some reporting groups allow members to access only standard reports; others allow members access to ad hoc reporting. A user can be a member of multiple reporting groups.

review schema locale

The language, set automatically during installation, in which data appears in the Data Viewer.

See also *product locale* (on page 390), *study data locale* (on page 392), *study locale* (on page 392).

review stage

A status or phase within a Data Viewer review state. For example, Needs Review, Pending, or Reviewed.

review state

A step in a Data Viewer custom review workflow. For example, Medical Review and Data Management Review.

right

A privilege that identifies a feature to which a user has access through a rights group.

rights group

A collection of rights, the users who have those rights, and a set of item groups to which those users have special access. A user can a member of only one rights group.

rule

A script that runs in the context of one or more specific items on a form that checks whether data is valid, or that sets the value of an item based on a calculation, when data in the item is added or updated.

S

screening log

A page in the InForm user interface that lists candidates who have been evaluated for participation in a study.

serious adverse event

An adverse medical occurrence that results in death; is life-threatening; requires inpatient hospitalization or lengthens a hospital stay; results in persistent or significant disability or incapacity; involves the development of cancer, a congenital anomaly, or a birth defect; or involves an overdose.

See also *adverse event (AE)* (on page 387).

signature

The process of attesting to the accuracy and completeness of the data captured on a CRF or in a case report book.

signature group

A group of users who are authorized to sign a specific set of CRFs. A user can be a member of only one signature group.

site user

An InForm user, typically a CRC or PI, who performs the following tasks: obtains an InForm site user name and password, registers subjects into a study, enters and changes clinical data in electronic case report forms, answers queries on clinical data, and prepares for monitoring visits.

source verification

The process of comparing data, which can be online

or on printed forms, to data on source documents to check for inconsistencies or errors, and to record the results of the review.

sponsor user

An InForm user, typically a CRA, CDM, or medical monitor, who performs the following tasks: obtains an InForm sponsor user name and password, reviews clinical data queries, performs source verification, signs electronic case report forms, transfers subjects from one site to another, runs standard reports, and creates ad hoc (custom) reports.

standard report

A report that is included with all Reporting and Analysis installations.

started form

A form that contains data, a query, or a comment.

started visit

A visit in which at least one non-common expected form has been started.

study

The systematic investigation of a test article (such as a treatment, drug, or device) in human subjects.

study data locale

The language in which study data, most significantly text, is entered and stored.

Also called *data locale*. See also ***product locale*** (on page 390), ***review schema locale*** (on page 391), ***study locale*** (on page 392).

study locale

The language(s) in which study metadata are designed using the Central Designer application. This includes CRFs and related study design labels, such as visit names, CRF (form) names, section labels, CRF questions, item control labels, auto-query text, and so on. A study may contain multiple study locales.

See also ***product locale*** (on page 390), ***review schema locale*** (on page 391), ***study data locale***

(on page 392)

study-specific clinical model

An Ad Hoc Reporting data model that is specific to a study, which contains references to subject data that site users enter on forms.

study-specific documentation

A study document that contains details about how to complete the items on a form.

subject

A candidate accepted into a study.

subject registration

The process of screening and enrolling subjects into an InForm study and creating case report books for them.

SV Report

A printed version of one or more CRFs that CRAs use to perform offline source verification.

See also ***source verification*** (on page 391).

T

Time and Events schedule

A list of CRFs and visits for a specific subject that you use to review the status of CRFs and visits, and to navigate to specific CRFs.

U

unscheduled visit

A visit that occurs in addition to the visits required by the study protocol.

user name

The name the user enters to log in to the InForm application.

V

verified

A form state that indicates that there are no unverified items on the form. If a form has items that require verification, the items have been

manually verified. If a form has no items that require verification, the form state is automatically set to Verified.

visit

A subject evaluation checkpoint when data is collected.

visit calculator

An optional scheduling aid that enables you to compute and print suggested visit dates based on the subject start date.

Also called *subject schedule*.

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