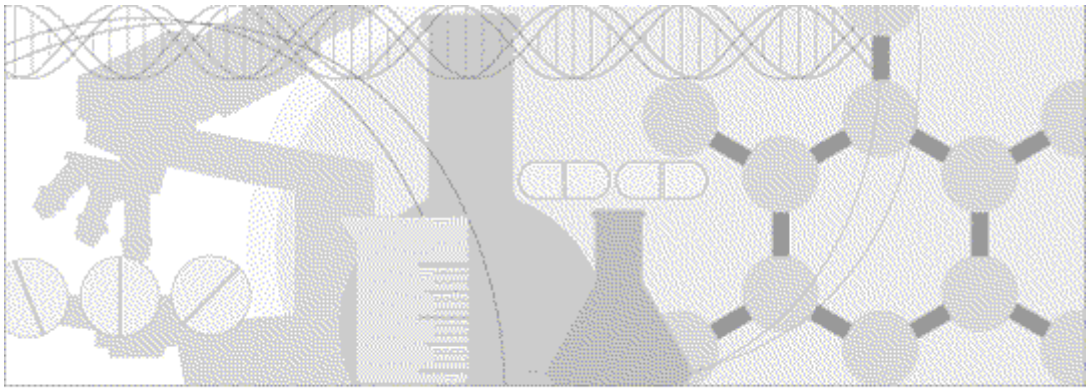
User Guide

Oracle® Health Sciences OutcomeLogix 3.2



ORACLE

Part Number: E40557-01

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About this guide

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Overview of this guide

The *User Guide* provides an overview of the OutcomeLogix application including details on how to navigate through the user interface and how to use the application to accomplish typical tasks you perform while running a late-phase, registry, or observational study.

Audience

This guide is for sponsor and site users of the OutcomeLogix application. These users conduct late-phase, post-marketing, and observational studies through a user interface accessed with an internet browser. Users enter study-specific data into electronic forms. The data is saved in an Oracle database, and is available for data monitoring, reporting, and exporting from the OutcomeLogix application.

Related information

Documentation

All documentation is available from the Oracle Software Delivery Cloud (https://edelivery.oracle.com) and the Oracle Technology Network (http://www.oracle.com/technetwork/documentation).

All documents may not be updated for every OutcomeLogix release. Therefore, the version numbers for the documents in a release may differ. For a complete list of the documents in this OutcomeLogix release, their release version numbers, and part numbers, see the *Release Notes*.

Document	Description	Last updated
Release Notes	The *Release Notes* document describes hardware and software requirements and describes the new features, enhancements, and fixed issues in this release.	3.2
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.	3.2
User Guide	The *User Guide* provides an overview of the OutcomeLogix application including details on how to navigate through the user interface and how to use the application to accomplish typical tasks you perform while running a late-phase, registry, or observational study. This document is also available from the Documentation CD and the OutcomeLogix user interface.	3.2
Secure Configuration Guide	The *Secure Configuration Guide* provides an overview of the security features provided with the OutcomeLogix application, including general principles of application security. Throughout the *Secure Configuration Guide* are references to chapters in the OutcomeLogix *User Guide* covering how to configure and use the OutcomeLogix application securely.	3.2
Standard Data Extracts Guide	The *Standard Data Extracts Guide* contains information about the standard data extract that is available for the OutcomeLogix application, and includes descriptions of the default views for the extract, naming conventions for the views and the columns in the views, and contact information for requesting a standard data extract.	3.2

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.

CHAPTER 1

OutcomeLogix basics

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About the OutcomeLogix application

The OutcomeLogix application is an application for late-phase, post-marketing, and observational studies. The OutcomeLogix application is accessed through an internet browser. Users, such as patients, study sponsors, and site investigators, enter study-specific data into electronic forms. The data is saved in an Oracle database and is available for data monitoring, reporting, and exporting from the OutcomeLogix application. The OutcomeLogix features described below provide flexibility, reliability, and scalability, and comply with regulatory requirements such as documenting changes through audit trails.

Feature	Description
Audit trail	Creates a secure record specifying the user name, the date and time of the action, and the reason for change for all types of data that are entered, modified, and deleted.
Call Center	Enables sponsors to follow up with patients who have missed a data entry window or who require assistance in providing patient-reported data.
Configuration of study attributes	Provides a user interface for configuring studies; for example, changing how long a user account remains locked before it is automatically unlocked.
Custom Homepage	Provides an alternative to the Dashboard as the Homepage. Creation of a custom Homepage is performed outside of the OutcomeLogix application.
Data extract	Extracts a defined set of clinical data, based on the study design, for analysis. • Sponsors can analyze and integrate data from the application into other systems in their own environment. • Extracted data can be delivered as Oracle DMP files, Oracle Data Pump format, comma-delimited ASCII (CSV) files, SAS datasets, SAS CPORT files, or SAS XPORT files. The Oracle Data Pump format is the database extract format using the Oracle Data Pump Export utility that was introduced in Oracle Database 10g.
Database-driven forms	Stores forms in an Oracle database, making customization, maintenance, and reuse easy.
EDC and ePRO forms	Collects data entered at sites or by patients or other parties through the OutcomeLogix application. Permits a combination of Electronic Data Capture (EDC) and Electronic Patient-Reported Outcome (ePRO) forms.
Multilingual functionality	Presents the OutcomeLogix application user interface in multiple languages. Help Desk assistance is also multilingual.
Patient transfer	Transfers a patient and the patient record and forms from an originating site to a destination site.
Reporting	Provides a set of standard operational reports and allows users to create and save ad hoc reports using operational and clinical data.
Security	Keeps Personal/Protected Health Information and study data secure.

Accessing OutcomeLogix functions

Signing in and out

Your OutcomeLogix study is a web application accessed through your internet browser.

To sign in:

1 In the address line of your web browser, type the URL given to you by the sponsor.

2 Press **Enter**.

The Sign In page appears.

- Study-specific information appears at the bottom of the page, if defined for your study. A red exclamation point denotes that an error has occurred. A blue exclamation point denotes information.
- The study name appears above the sign-in fields.

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

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

If this is the first time you are signing in, use the password supplied by Oracle or the study sponsor.

5 From the **Language** drop-down list, select the language for your Sign In page, if you want to change it.

> **Note:** The Sign In page initially appears in the same language as your browser and then appears in the language you select from the **Language** drop-down list. Language selection on the Sign In page does not associate a language to the user profile. Subsequent pages appear in the language specified in your ***user profile*** (on page 6).

6 If you want the OutcomeLogix application to use the selected language for the Sign In page, select the **Remember selected language** checkbox.

7 Click **Sign In**.

8 If you are signing in for the first time, the OutcomeLogix application prompts you to create a new password and select security questions to answer when ***changing your password*** (on page 6).

a Click **Submit**.

b In the **Old Password** field, type the Oracle- or sponsor-supplied password you just used to sign in.

c In the **Password** and **Confirm Password** fields, type a new password that conforms to the password rules for your study.

d From the **First password-reset question** and **Second password-reset question** drop-down lists, select a password-reset question.

e In the **Password-reset Answer** fields, type the answers.

f In the **Memorable Date** fields, enter a month and year that are significant to you.

The Help Desk uses this date to confirm your identity.

g Click **Submit**.

The Dashboard or your custom Homepage appears. When a Call Center staff member signs in, the Call Center List page appears.

Note: Your study allows a defined number of attempts to sign in correctly, and locks you out if you exceed that number. Wait until you can sign in again or contact the Help Desk by clicking the Help link.

To log out:

From any page:

- Click the **Logout icon** () in the upper right of the page.

or

- From the down arrow in the upper right, click **Logout**.

Timing out and reauthenticating

If your session expires after the timeout interval specified for your study, the application prompts you to re-enter your authentication information.

- If the timeout occurs on an EDC or ePRO form, a dialog box appears.
  - Re-enter your password in the dialog box.

    The application returns you to the form you were working on.
- If the timeout occurs on a list or an Administration page, the application returns you to the Sign In page.
  - Sign in again.

    The application returns you to the Dashboard or your custom Homepage.

The Dashboard

The Dashboard provides a high-level overview of key study details. The OutcomeLogix application automatically updates the metrics to reflect changes in patient, query, and form status and to log email notifications.

By default, the Dashboard includes data for all sites to which you are assigned. To limit the metrics to a particular site, click the drop-down list in the page title bar and select the site. To clear site selection, select a different site or **All**.

Depending on the configuration of your study, the Dashboard might appear as your Homepage or be accessed with a Dashboard icon from a custom Homepage. In either case, the Dashboard can include some or all of these metrics:

- **Query Status**—Shows the distribution of Open, Answered, Approved, Closed, Deleted, and Candidate queries in a list or pie chart. Click a count to navigate to the Query List page, which displays the queries for the selected status and sites.
- **Patient Status**—Lists the number of patients in the study by status. Click a count to navigate to the Patient List page, which displays the patients for the selected status and sites.
- **ePRO Status**—Shows the number of ePRO sessions and visits completed and due. Click the **ePRO Sessions Past Due** link to see a list of patients with forms due. This information also appears on the Patient Summary page.
- **Notifications**—Lists the subject and date and time of each email notification you have received. Click the column headings to sort the notifications by subject or when received. Click a subject to display the notification.

Email notifications

The OutcomeLogix application uses email notifications to communicate important information about a study. A summary of your email notifications appears in the Notifications table on the Dashboard. During study development you decide which notifications to send, which email addresses to notify, how to trigger notifications, and the text of the notification email messages.

You cannot create notifications from within the OutcomeLogix application. You can, however, view a list of the email messages sent to specific email addresses on the Email Notifications page, if you have the appropriate administrative right. You can also specify an email address that is not associated with a role.

Note: If the study is designed to contain Personal/Protected Health Information, and designers and sponsors choose to encrypt it, they have the ability to indicate which items on forms contain sensitive information that should be encrypted and also excluded from email messages, data exports, and reports by default.

The following table describes the notifications that might be used in your study.

Notification	Recipient
New Informed Consent Document (ICD) has been uploaded.	Site user
Patient ePRO (online) session is past due.	Patient
Password reset or reminder has been sent.	All users

Notification	Recipient
Patient reported an adverse event.	Investigator, Sponsor
Configuration change was made to the study.	Site administrator
Number of available eCodes has dropped below the specified level. You must add more eCodes.	Sponsor

Note: Users and patients must provide valid email addresses to receive email notifications. The OutcomeLogix application does not confirm that the notification was received; only that it was sent.

Viewing and editing your profile

Your user profile contains contact information, localization parameters, and other preferences. You can edit your profile information at any time.

1 In the upper right of any page, click your user name.

The User Profile page appears.

2 Edit the fields as necessary. For more information, see *User Profile page* (on page 47).

You cannot edit your user name, role type, or assigned sites.

3 Click **Submit**.

Changing your password and password-reset questions

You can change your password and password-reset questions at any time. When your password expires, you must change it the next time you sign in.

1 In the upper right of any page, click your user name.

The User Profile page appears.

2 To change your password:

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

b In the **Password** and **Confirm Password** fields, type your new password.

3 To change your password-reset questions or answers:

a From the **Password-reset Question 1** and **Password-reset Question 2** drop-down lists, select a password-reset question.

b In the **Answer** fields, type the answers.

4 To change the memorable date, in the **Memorable Date** fields, enter a month and year that are significant to you.

The Help Desk uses this date to confirm your identity.

5 Click **Submit**.

Obtaining your forgotten user name or password

If you exceed the number of allowed sign in attempts, which results in a locked user account, you can reset your password and unlock your user account.

1 On the Sign In page, click the **Forgot User Name** or **Forgot Password** link.

The Forgot User Name or Forgot Password page appears.

2 Fill in the fields.

a To obtain your user name, enter your email address.

or

To obtain your password, enter your user name.

b Depending on the requirements of your study, you must answer one or two reset questions.

3 Click **Submit**.

If you answered the question or questions correctly, a notification appears informing you that sign in information has been sent in an email message:

- For a forgotten user name, the email message contains your user name.
- For a forgotten password, the email message contains a link to a webpage that prompts you to type a new password. New passwords must conform to the requirements in the *password rule* (on page 64) to which your role has been assigned.

Getting Help

Type of Help	How to access	Description
Page-level	1 In the upper right of the page, click the down arrow. 2 Click **Help.** 3 Click **OutcomeLogix Help**.	Opens the *User Guide* to the topic associated with the page you are on. The *User Guide* does not include descriptions of study-specific forms.
Field-level	Click a text box on a page.	Displays a field description to the right and indicates whether the information is required.
Tool tips	Hover the mouse over an icon.	Displays a description of the icon.
Help Desk	On the Sign In page, click **Help**. or 1 In the upper right of any page, click the down arrow. 2 Click **Help**. 3 Click **Contact us**.	Help Desk personnel respond by telephone or email.

Note: For protocol-related questions, contact your clinical research associate or other designated study personnel.

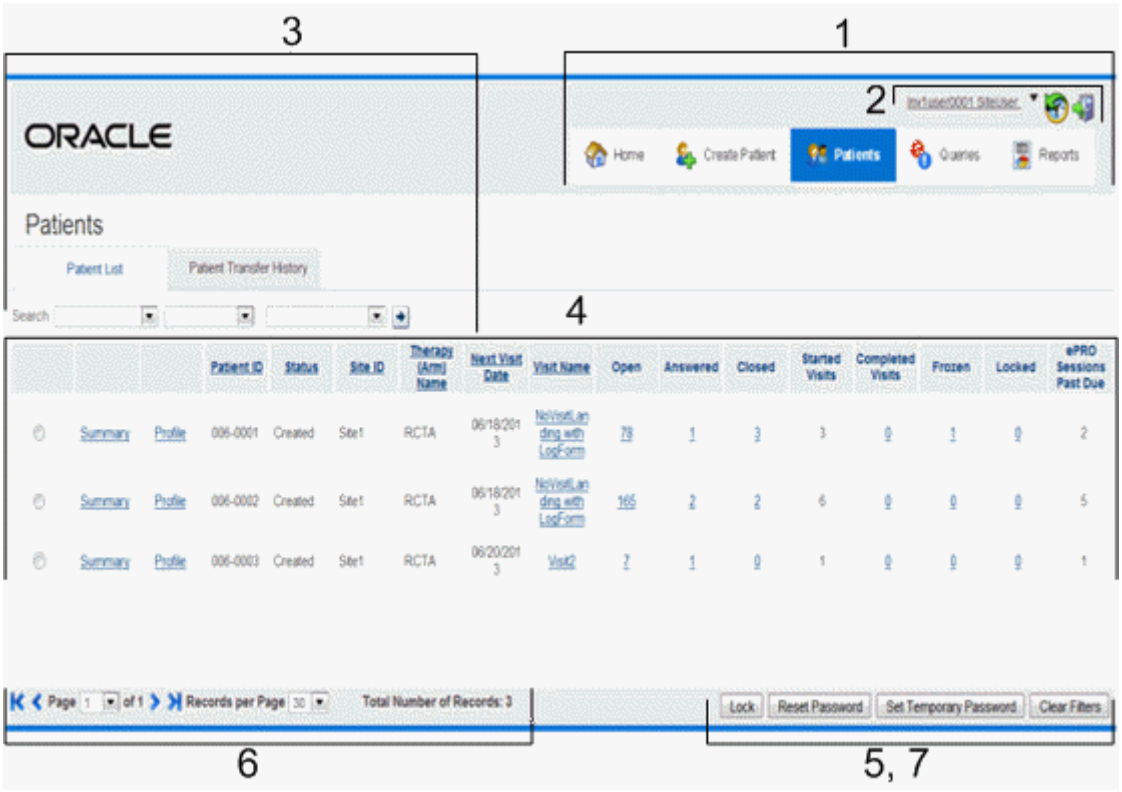
Working with OutcomeLogix pages and forms

OutcomeLogix pages and navigation

The OutcomeLogix application is a web-based application that you work with from an internet browser. All of the application pages have the same layout and parts.

Note: Do not use the navigation controls built into the internet browser. Using the browser Back button might delete the data you have entered on the page. Use the History icon ( ) instead.

Navigation in OutcomeLogix pages



Navigation in OutcomeLogix pages

1—Navigation icons

Always visible, each icon provides access to a different functional area of the OutcomeLogix application. Only icons for functions that you have permission to use appear.

- **Home**—Navigate to the Dashboard or your custom Homepage from any place in the application.
- **Create Patient**—Create and enroll a patient.
- **Patients**—View the Patients List page, which displays the status of forms and visits for each patient, lets you navigate to a specific visit, and provides a link to the Patient Summary and Profile pages of each patient. To view transferred patient, click the Patient Transfer History tab.
- **Queries**—View the Query List page and work with queries. Queries are errors, warnings, or questions related to data that does not meet certain criteria.
- **Reports**—View the standard reports you can run or design a new, ad hoc report.
- **Export Data**—Open the Export Data page. You can export data in any language supported by the study in PDF format or Microsoft Excel spreadsheet software format (XLS).
- **Call Center**—View the Call Center List page.
- **Administration**—View the Administration page to access the administrative functions.

2—Utilities

Always visible in the upper right of the page. These utilities do not appear on pages viewed by patients.

- **User Name/Role**—Click to navigate to your User Profile page.
- **Down arrow**—Click to use these utilities.
  - **History**—Display a list of the last few pages you opened; click a page to reopen it.
  - **Help**—Display the online User Guide or page-level Help; view contact information for the Help Desk; or display the software and database versions.
  - **Status Legend**—Display the status icons and their meanings for forms and queries.
  - **Logout**—Log out of the OutcomeLogix application.
- **History icon**—Display a list of the last few pages you opened; click a page to reopen it.
- **Logout icon**—Log out of the OutcomeLogix application.

3—Page Title bar

The title of the currently selected page. Might also include:

- **Tabs**—Display a closely related page. For example, the Patient Summary page includes a tab for the Patient Diary page.
- **Search and Filter drop-down lists**—Filter the data to include.

Navigation in OutcomeLogix pages

4—Content-specific functionality

Applicable to the content of the page.

- **Column sorting**—Sort the information that appears in columns with underlined headings.
  - When patient IDs are numeric, the application sorts them in ascending order beginning with 0.
  - When patient IDs are alphanumeric, the application sorts them alphabetically. For example: S1, S10, S2.
- **Lists**—List information pertaining to sites, users, and patient visit, such as the queries associated with data.
- **Detail**—Display detailed information about a selected item in a separate pane below the list or as an expansion of the selected record.

5—Action buttons and Status and Review icons

- **Action buttons**—Apply to the page as a whole; for example, the Submit, Add, Back, and Update buttons.
- **Status and Review icons**—Use after selecting a patient, visit, form, or item to change the status or track review. The active icons are determined by the rights assigned to your role.
- **Clear Filters button**—Clear filters or data sorts.

6—Paging and display options

- **View the list page by page**—Use the **next page** (**>**), **previous page** (**<**), **last page** (**>>**), and **first page** (**<<**) buttons.
- **View a specific page**—From the **Page** drop-down list, select a page number.
- **Change the number of displayed rows on the page**—From the **Records per Page** drop-down list, select the number of rows to include.

7—Navigation

- **Cancel button**—Close a dialog box.
- **Esc key**—Close a dialog box.

Accessibility support

The application provides alternative text for icons. In addition, to assist users who are color blind, the OutcomeLogix application conveys information without reliance on the use of color.

When running the OutcomeLogix application in a browser with image loading disabled, all necessary information appears without reliance on images.

- Alternative text appears in lieu of all images.
- The application replaces images used as page backgrounds with a background color.

Data entry and editing guidelines

You enter data using various controls:

- **Text boxes—**Typically, the text box width matches the number of characters you can enter. Validation logic can be associated with a text box to ensure that the entry is in the correct format. For example, an email address must be in the form: name@email.com.
- **Drop-down lists**—When you must choose one value from a list of predefined values, the values appear in a drop-down list. Click the down arrow to view the choices, and then select your choice. For example, you select your birth year from a list of years. If a value is truncated on a form, point to the choice with your mouse to see the entire value.
  - When items are alphabetic, the application sorts them alphabetically from a through z.
  - When items are numeric, the application sorts them in ascending order beginning with 0.
  - When items are alphanumeric, the application sorts them alphabetically. For example: S1, S10, S2.
- **Radio buttons**—When you must choose one value from a set of predefined values, the values appear with round buttons to their left for you to click, to select or deselect. For example, to make a site active, you click the Yes radio button. To deselect a radio button, double-click it.
- **Checkboxes**—The application uses checkboxes to present predefined values for a field and allow you to select one or more value. The values may be Yes or No, or applicable to the specific field or control. Checkboxes also appear to the left of records in lists when you can select multiple values and apply the same status or action to the values. For example, you can issue queries on multiple items on a form by selecting their checkboxes on the Patient Summary page.
- **Dialog boxes**—A dialog box consists of one or more fields in which you select or enter data. You can dismiss a dialog box by clicking the dialog box **Cancel** button or the **Esc** button in the browser. The application uses dialog boxes to display abbreviated versions of the Query List page and Patient Transfer page. The dialog box overlays the page or form that is active and allows you to perform related tasks without leaving the form or page. You can reposition the dialog boxes and display multiple dialog boxes at the same time.
- **Calendar controls**—Calendar controls can be associated with date text boxes to allow you to select dates from a calendar view. You can select Today's date or the day, month, or year. The Year drop-down list defaults to the currently selected year.
- **Partial calendar controls**—When either the day or month is unknown, but you know the year, you can select UNK MONTH or UNK DAY from a calendar view of a known year. For example, when entering medication dosing or adverse event start/stop dates, you usually know the year even if you do not know the month or day.
- **Time controls**—Time controls allow you to specify a time by selecting or entering the hour, minute, and AM or PM.

After you enter and submit data, the application validates the data and accepts it or displays an error message. Typically, a message in green indicates that the operation you performed was successful. Error messages are red. On EDC and ePRO pages that include a **Save Only** button, you can save the data you entered without submitting the form.

Note: Wait until a page loads completely before entering data or clicking any buttons or links.

Date handling

Date display—When dates appear in OutcomeLogix pages, the month is written out and not abbreviated, for example, 23/February/2012.

- The date format used in forms, audit trail pages, standard reports, and data extracts is the format defined in the user's profile and is based on date format configuration at the study, site, and user levels.
- In the audit trail, system dates are displayed in Greenwich Mean Time (GMT), and user-entered dates are displayed in the time zone of the user who entered them.
- Dates on clinical input forms appear exactly as entered. No conversion is made to show the dates in the current user's time zone.
- The Next Visit Date is in GMT and is not converted to the time zone of the current user.

Date storage—In the OutcomeLogix database:

- Clinical date times are stored in ISO 8601 format: YYYY-MM-DDTHH:MM:SS.
- Clinical dates are stored in ISO 8601 format: YYYY-MM-DD.
- No time zone is stored with date time components.

Partial dates—When either the day or month is unknown, but you know the year, you can select UNK MONTH or UNK DAY from a calendar view of a known year. For example, when entering medication dosing or adverse event start/stop dates, you usually know the year even if you do not know the month or day.

- **Reporting**—Standard and ad hoc reports display a hyphen (–) in place of unknown date parts. Ad hoc report writers should allow for the possibility of partial dates when constructing WHERE clauses that use dates.
- **Data extracts**—PDF extracts display a hyphen (–) in place of unknown date parts. Microsoft Excel extracts display dates using the date formats set as defaults or configured in the Microsoft Excel application.

Calendar controls—If the date field is blank, the calendar control displays the current year and month. If the date field contains data, the calendar control displays the values entered.

Note: A change (study patch) may be needed to implement this feature in your study.

OutcomeLogix concepts

Users and patients

Patients and all other users are managed separately. This section discusses how to manage non-patient users. For information about managing patients, see ***Patients*** (on page 71).

Rights and roles control access

Your ability to perform a particular function depends on the role you have been assigned to and the rights associated with that role.

Rights grant permission to perform specific activities in the OutcomeLogix application. Access to each administrative function is granted to a user as a right. For more information, see ***Roles and rights descriptions*** (on page 271).

Roles are labels for typical site and sponsor users. The OutcomeLogix application contains a set of roles typically used in a study; for example: investigator, clinical data manager, and sponsor help desk.

You can modify the set of roles and rights provided as well as add roles. For your convenience, the rights are grouped into several categories.

You modify the rights for a role on the Rights Group page. For more information, see ***Rights Group page*** (on page 61).

OutcomeLogix hierarchy

A hierarchical relationship exists between the major components of the OutcomeLogix application and affects most actions you perform.

- **Study**—The highest level. The study contains everything below it.
- **Arm**—A subgroup of patients. All the patients in a particular study arm are treated in the same manner, and their visits and forms are identical. Branching can occur at the patient level (most common), visit level, and form level. For example, the difference between Arm 1 and Arm 2 might be a visit that is used for Arm 1 but not for Arm 2.
- **Patient**—Participants in the study; people under a physician's care for a particular disease or condition. The arm determines the visits and forms set up for each patient.
- **Visit**—A patient evaluation checkpoint during which a set of forms for the visit must be completed. The study defines the number and sequence of visits for a patient or arm. Patients can visit study sites, complete forms through the Call Center, or sign into the study and complete the visit independently.
- **Form**—One or more forms that must be completed during a visit. These forms might be Electronic Data Capture (EDC), Electronic Patient-Reported Outcome (ePRO), or a combination of forms. The same form can be associated with multiple visits.
- **Item**—Items within forms where you enter patient data. An item may be a question, measurement (such as temperature), or a control, such as a checkbox, radio button, drop-down list, and so on.
- **Repeating section**—A group of items within a form that repeats so that patients can enter

multiple diagnoses, multiple treatments, and so on.

You can perform actions at each hierarchical level. The actions you perform at a higher level impact the lower levels. For example:

- Locking a patient locks all of the visits and forms for the patient, even though you did not lock the visits and forms individually.
- Locking a visit locks all forms within the visit.
- Locking a form locks all the items and repeating sections within a form.

Note: Signatures are not propagated to other levels of the hierarchy; that is, the signatures at different levels are independent of each other. The audit trail reflects this independence. For more information, see ***Signatures and the OutcomeLogix object hierarchy*** (on page 111).

CHAPTER 2

Sites

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Studies contain sites

A site is the location where users collect study-related information. Sponsor users, such as medical monitors and clinical data managers, review the information and issue queries. Site users, such as investigators and clinical research coordinators, answer the queries and sign off on the items, forms, visits, and patients. Sponsor representatives then use the information to generate reports for publication or to fulfill regulatory requirements.

You add sites one site at a time. For more information, see *Adding and editing a site* (on page 21). If you need to add many sites, contact your project manager.

You can add a user to individual sites or all sites, including new sites that are added to the study. Users can work only with patient and visit data collected at their assigned sites. For example, an investigator who works at only one site is assigned to that site and has access to the data for only that site. A medical monitor who has to review data across several sites is assigned to those specific sites and can see only data for those sites.

When a user is assigned to a site, the data that a user can view and edit is determined by the role to which the user is assigned. For more information, see:

- *Assigning rights to a role* (on page 54).
- *Assigning a user to a role* (on page 55).

Roadmap: Managing sites

Step	Action	Procedure
1	Add a site.	1 Select **Administration** (). 2 The Administration page appears. 3 Click **Manage Sites**. The Manage Sites page appears. Click **Add Site**. 4 Fill in the fields as necessary. 5 Click **Submit**.
2	Display the site list.	1 On the Manage Sites page, do one or more of the following: ▪ **View the site list page by page:** Use the **next page** (**>**), **previous page** (**<**), **last page** (**>|**), and **first page** (**|<**) buttons. ▪ **View a specific page:** From the **Page** drop-down list, select a page number. ▪ **Change the number of displayed records:** From the **Records per Page** drop-down list, select the number of records (rows) to include.
3	Search for a site.	1 Display the site list. 2 Enter search criteria: ▪ **To search by site name:** In the **Search** field, type a full or partial site name, and select **By Name** from the drop-down list. ▪ **To search by number of patients:** In the **Search** field, type the number of patients at the site and select **Number of Patients** from the drop-down list. 3 To the right of the search drop-down lists, click **Submit**.

Step	Action	Procedure
4	Assign a user to a site.	1 On the Administration page, click **Manage Users.** 2 Click the **Profile** link for the user. 3 Scroll down to the Available Sites list. 4 Do one of the following: ▪ From the **Available Sites** list, select one or multiple sites and click the **add** (**>**) button to move the sites to the **Selected Sites** list. ▪ To assign a user to all sites, click the **add all** (**>>**) button. ▪ To assign a user to all sites created in the future, in the **All Sites** field, select **Yes**. 5 Click **Submit**.
5	View the users assigned to a site.	1 Display the site list. 2 Click the **Change** link for the site.
6	Edit a site.	1 Display the site list. 2 Click the **Edit** link for the site. 3 Edit the fields as necessary. 4 Click **Submit**. **Note:** Any changes made on the study or site level take effect the next time you sign in.
7	Change the user assignments for a site.	1 Display the site list. 2 Click the **Change** link for the site. 3 Do one of the following: ▪ To add users to the site, in the **Available users** list, select one or multiple users and click the **add** (**>**) button to move the users to the **Users at site** list. ▪ To remove users from the site, in the **Users at site** list, select one or multiple users and click the **remove** (**<**) button to move the users back to the **Available users** list. ▪ To assign all users to or remove all users from the site, click the **add all** (**>>**) or the **remove all** (**<<**) button. 4 Click **Submit**.

Adding and editing a site

Note: Any changes made on the study or site level take effect the next time you sign in.

To add a site:

1 Select **Administration** ().

2 Click **Manage Sites**.

The Manage Sites page appears.

3 Click **Add Site**.

4 Fill in the fields as necessary. For more information, see *Manage Sites page* (on page 30).

5 Click **Submit**.

The site appears in the list at the bottom of the page.

To edit a site:

1 Select **Administration** ().

2 Click **Manage Sites**.

The Manage Sites page appears.

If no sites appear, clear the Search fields and click **Submit**.

3 Click the **Edit** link for the site.

The site information appears.

4 Edit the fields as necessary. For more information, see *Manage Sites page* (on page 30).

5 Click **Submit**.

Viewing study sites and users

The Manage Sites page includes a list of all the study sites. You can change the number of rows that appear on each page, display a specific page, or view the site list page by page.

To display the site list:

1 Select **Administration** ().

2 Click **Manage Sites**.

The Manage Sites page appears.

3 Do one or more of the following:

- **To change the number of records per page:** From the **Records per Page** drop-down list, select the number of records to include.
- **To view a specific page:** From the **Page** drop-down list, select a page number.
- **To view the list page by page:** Use the **next page** (**>**), **previous page** (**<**), **last page** (**>|**), and **first page** (**|<**) buttons.

To view the users assigned to the site:

1 Display the site list.

2 Click the **Change** link for the site.

The Change Users page appears.

The Users at site list shows all the users assigned to the selected site.

3 To change the user assignments for the site, see *Assigning a user to and removing a user from a site* (on page 24).

4 To return to the Manage Sites page, click **Back**.

Note: To change the patient site assignments, see ***Managing patients and sites*** (on page 88). To change user assignments, see ***Assigning a user to and removing a user from a site*** (on page 24).

Searching for a site

1 Select **Administration** ().

2 Click **Manage Sites**.

The Manage Sites page appears.

3 Enter search criteria:

- **To search by site name:** In the **Search** field, type a full or partial site name, and select **By Name** from the drop-down list.
- **To search by number patients:** In the **Search** field, type the number of patients at the site and select **Number of Patients** from the drop-down list.
- **To display all sites:** Leave the **Search** field blank or click **Clear Filters.**

Note: The search is not case-sensitive.

4 To the right of the **By Name** drop-down list or the **Number of Patients** drop-down list, click **Submit**.

Sites that match your search criteria appear.

Note: To search for another site, click **Clear Filters** before entering your search criteria.

Assigning a user to and removing a user from a site

You assign a user to and remove a user from a site on the *User Profile page* (on page 47). You can assign a user to one, multiple, or all sites, or you can select the **All Sites** option. With this option, the user is assigned to all sites that are added in the future.

To select a user and view the available sites:

1 Select **Administration** ().

2 Click **Manage Users**.

The Manage Users page appears.

3 Click the **Profile** link for the user.

The User Profile page appears.

4 Scroll down until the Available Sites list appears.

- The sites to which you can assign a user appear in the Available Sites list.
- The sites to which a user has been assigned appear in the Selected Sites list.

To assign a user to one, multiple, or all sites:

1 Do one of the following:

- From the **Available Sites** list, select one or multiple sites and click the **add** (**>**) button to move the sites to the **Selected Sites** list.
- To assign a user to all sites, click the **add all** (**>>**) button.

2 Click **Submit**.

To remove the user from one, multiple, or all sites:

1 Do one of the following:

- From the **Selected Sites** list, select one or multiple sites and click the **remove** (**<**) button to move the sites back to the **Available Sites** list.
- To remove a user from all sites, click the **remove all** (**<<**) button.

2 Click **Submit**.

To assign users to all sites, including the ones added in the future:

1 If necessary, scroll up or down to see the **All Sites** field.

2 In the **All Sites** field:

a To assign the user to all sites, including the ones added in the future, select **Yes**.

b To retain the current site settings in the future, select **No**.

3 Click **Submit**.

Changing the user assignments for a site

1 Select **Administration** ().

2 Click **Manage Sites**.

The Manage Sites page appears.

3 Click the **Change** link for the site.

4 To add users to the site, in the **Available users** list, select one or multiple users and click the **add** (**>**) button to move the users to the **Users at site** list.

5 To remove users from the site, in the **Users at site** list, select one or multiple users and click the **remove** (**<**) button to move the users back to the **Available users** list.

6 To assign all users to or remove all users from the site, click the **add all** (**>>**) or the **remove all** (**<<**) button.

7 Click **Submit**.

Making a site active or inactive

On the Manage Sites page, you can specify whether a site is active or inactive. You cannot enter data for patients assigned to inactive sites.

This option is useful when you need to assign site staff to a different site. Rather than deleting a site, you make it inactive, allowing you to activate it again at a different time. This is especially useful for studies that are being rolled out through a particular region or longitudinal studies where the site becomes active after a number of years; for example, every five years.

1 Select **Administration** ().

2 Click **Manage Sites**.

The Manage Sites page appears.

3 Click the **Edit** link for the site.

4 Set the **Active** field setting.

a To make the site active, select **Yes**.

b To make the site inactive, select **No**.

5 Click **Submit**.

Viewing the audit trail for a site

Changes to most fields for a site are audited and are viewable on the *Audit Trail page* (on page 28).

1 Select **Administration** ().

2 Click **Manage Sites**.

The Manage Sites page appears.

You can now view the site list.

3 Click the **Edit** link for the site.

4 Click the **Audit Trail** button (**A**).

The Audit Trail page for the site appears.

5 To see the audit trail for changes made to one or more fields, click the plus sign to the left of the item in the Field column.

or

To see the changes to all fields in a grid, click **Show all details** at the top of the page.

For each item, the most recent changes appear first.

6 To filter the Audit Trail, choose a criterion and click **Search**.

For a description of each audit item, see *Audit Trail page* (on page 28).

7 To return to the Manage Sites page, click **Back**.

For information about other audit trails, see:

- *Viewing the audit trail for a user* (on page 43).
- *Viewing the audit trail for a patient* (on page 87).
- *Viewing the audit trail for a visit or form* (on page 131).
- *Viewing the signing history of a visit or form* (on page 136).

Audit Trail page

The following tasks use this page:

- *Viewing the audit trail for a site* (on page 27).
- *Viewing the audit trail for a user* (on page 43).
- *Viewing the audit trail for a patient* (on page 87).
- *Viewing the audit trail for a visit or form* (on page 131).

Field	Description
Field	Name of field containing data that changed.
Date Changed (GMT)	Date and time of the change.
New Value	Current field value.
Old Value	Previous field value.
Reason	Reason the value was changed.
Modified by	User who changed the value.

Change Users page for a site

The following tasks use this page:

- *Viewing study sites and users* (on page 22)
- *Changing the user assignments for a site* (on page 25)

To view a job aid that you can print, see:

- Quick Reference: Administration.

Field	Description
Available users	List of users who can be assigned to the site.
Users at site	Users who have been assigned to the site.

Manage Sites page

The following tasks use this page:

- *Adding and editing a site* (on page 21).
- *Searching for a site* (on page 23).

To view a job aid that you can print, see:

- Quick Reference: Administration.

Field	Description	Note
Site Information		
Site Name	Name of the site.	Required. The application prevents you from specifying a site name that differs from an existing site name only by capitalization.
Organization	Sponsor organization name.	
Number	Identifier assigned for arm management.	Required.
ZIP code (postal code)	Site ZIP code or postal code.	Required.
PO Box	Post office box number.	
Target Number of Patients	Desired number of patients to be assigned to the site.	
Maximum Number of Patients	Maximum number of patients who can be assigned to the site.	Required. Can be larger than the target number.
Limit Patients	Whether to limit the number of patients who can be assigned to the site.	
Active	Whether the site is active.	Required. All sites appear in the Available Sites list, and you can assign patients to them. For more information, see *Making a site active or inactive* (on page 26).
Country	Country where the site is located.	
Time Zone	Time zone in which the site is located.	
State or Province	State or province where the site is located.	

Field	Description	Note
City	City where the site is located.	
Street	Street number and name where the site is located.	
Building	Building name or number where the site is located.	
Room	Room number within the building.	
Address	Street address of the site.	
Phone	Phone number for contacting a site representative.	Required. Up to 20 digits.
Date Format Name Sort Number Format Currency Format	Date format, how names are sorted, number format, and currency type.	You can also specify these settings at the: **Study level**—On the *Manage Localization Settings page* (on page 195). **User level**—On the *Create User* (on page 45) and *User Profile* (on page 47) pages.
List of Available ICDs	Informed Consent documents that may be associated with the site.	
Selected ICDs	Informed Consent documents associated with the site.	
Available Destination Sites	All sites available to be associated with the originating site for patient transfers.	
Selected Destination Sites	All sites associated with the originating site as destination sites for patient transfers.	
List of sites		
Edit link	View and edit information for the selected site.	Appears only if you can edit sites.
Change Users link	Change which users are assigned to the site.	Appears only if you can edit user roles and rights.
Site Name	Name of the site.	
Organization	Sponsor organization name.	
Actual Number of Patients	Number of patients assigned to the site.	

Field	Description	Note
User Count	Number of users assigned to the site.	
Address	Street address of the site.	
Phone	Phone number of a site representative.	
ZIP code (postal code)	Site ZIP code or postal code.	
Country	Country where the site is located.	
Time Zone	Time zone in which the site is located.	You can also specify this setting at the: **User level**—On the *Create User* (on page 45) and *User Profile* (on page 47) pages.

CHAPTER 3

Users

In this chapter

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Roadmap: Managing a user

Step	Action	Description
1	Create a user.	1 Select **Administration** (). 2 Click **Manage Users**. 3 Click **Create User**. 4 On the Create User page, complete the user profile, which includes specifying the user name and email address, assigning the user to a role and to a single site, multiple sites, or all sites. 5 Click **Submit**.
2	Activate the user.	• On the Manage Users page, select the user and click **Activate**.
3	Manage the user.	Perform the following procedures as needed.
	Search for a user.	1 On the Manage Users page, enter search criteria: ▪ **To search by user name:** In the **Search** field, type a full or partial user name, and select **By Name** from the drop-down list. ▪ **To search by role:** In the **Search** field, type a full or partial role, and select **By Role** from the drop-down list. 2 To the right of the drop-down list, click **Submit**.
	View and edit a user profile.	1 On the Manage Users page, click the **Profile** link for the user. 2 Edit the fields as necessary. 3 Click **Submit**.
	Deactivate a user.	• On the Manage Users page, select the user and click **Deactivate**.
	Assign a user to a role.	1 On the User Profile page, from the **Role** drop-down list, select the role. 2 Click **Submit**.
	Assign a user or remove a user from a site.	1 On the User Profile page, do one of the following: ▪ From the **Available Sites** list, select one or multiple sites and click the **add** (**>**) button to move the sites to the **Selected Sites** list. ▪ To assign a user to all sites, click the **add all** (**>>**) button. 2 Click **Submit**.
	Lock or unlock a user.	• On the User Profile page, click **Lock User** or **Unlock User**.
	Reset a user password.	• On the User Profile page, click **Reset Password**.

Step	Action	Description
	Set a temporary password for a user.	• On the User Profile page, click **Set Temporary Password**.
	View the audit trail for a user.	• On the User Profile page, click the **Audit Trail** button (**A**).

Creating, activating, and deactivating a user

Creating a user involves two steps: creating and activating. Depending on how a study is configured, a different user might perform each action.

Active users can sign in and use the application. Active users can also receive notifications that communicate important information. Deactivated users cannot sign in and do not receive notifications. Typically, you deactivate users who leave the organization. All users, including deactivated users, remain in the study for audit purposes.

Note: If you create a new role type using the **Manage Roles and Rights** link in the Administration module, that new role type appears in the Roles list and can be selected. When you create a new user using the **Manage Users** link, the new role type is available to assign to the user.

You can also *lock and unlock users* (on page 40).

To create a user:

1 Select **Administration** ().

2 Click **Manage Users**.

The Manage Users page appears.

3 Click **Create User**.

The Create User page appears.

4 Fill in the fields as necessary. For more information, see *Create User page* (on page 45).

Note: For a user to work in the application and receive notifications, you must assign the user to a role and at least one site. You can modify the assignments later by editing the user profile. You must also activate the user.

5 Click **Submit**.

To activate a user:

1 Select **Administration** ().

2 Click **Manage Users**.

The Manage Users page appears.

3 Select the checkbox for the user.

4 Click **Activate**.

The application sends the user an email with a link to a webpage where the user specifies a password.

Note: The application sends an email to a user on every activation. If you activate, deactivate, and subsequently re-activate a user, the user receives two emails, one for each activation.

To deactivate a user:

1 Select **Administration** ().

2 Click **Manage Users**.

The Manage Users page appears.

3 Select the checkbox for the user.

4 Click **Deactivate**.

Searching for a user

1 Select **Administration** ().

2 Click **Manage Users**.

The Manage Users page appears.

3 Enter search criteria:

- **To search by user name:** In the **Search** field, type a full or partial user name, and select **By Name** from the drop-down list.
- **To search by role:** In the **Search** field, type a full or partial role, and select **By Role** from the drop-down list.
- **To display all users:** Leave the **Search** field blank or click **Clear Filters.**

Note: The search is not case-sensitive.

4 To the right of the drop-down list, click **Submit**.

Users that match your search criteria appear.

5 Optionally:

- **To change the number of records per page:** From the **Records per Page** drop-down list, select the number of records to include.
- **To view a specific page:** From the **Page** drop-down list, select a page number.
- **To view the list page by page:** Use the **next page** (**>**), **previous page** (**<**), **last page** (**>|**), and **first page** (**|<**) buttons.

Viewing and editing a user profile

You can edit *active and deactivated users* (on page 36) and *locked and unlocked users* (on page 40). Changes appear in the audit trail. For more information, see *Viewing the audit trail for a user* (on page 43).

1 Select **Administration** ().

2 Click **Manage Users**.

The Manage Users page appears.

3 Click the **Profile** link for the user.

The User Profile page appears.

4 Edit the fields as necessary. For more information, see *User Profile page* (on page 47).

5 Click **Submit**.

Note: If a Study Administrator modifies another user profile, that user has to log out and sign back to see the respective changes.

Locking and unlocking a user

To prevent a user from signing in and using the application, you can lock the user account.

Typically, a member of the Help Desk locks an account when the Help Desk member suspects that an unauthorized user is trying to sign in. After you lock an account, you must manually unlock it before the user can work in the application.

Additionally, the application locks a user after the user exceeds the number of allowed sign-in attempts. The application unlocks the user after a specified interval. For more information, see *Changing default study configuration settings* (on page 183).

1 Select **Administration** ().

2 Click **Manage Users**.

The Manage Users page appears.

3 Click the **Profile** link for the user.

The User Profile page appears.

4 Click **Lock User** or **Unlock User**.

Resetting a user password

When users forget their passwords, a user with the appropriate rights can reset the passwords.

Note: When you reset a password, the new password does not appear in the profile. When you set a temporary password, the new password appears in the profile and the user must change the password immediately. For more information, see ***Setting a temporary password for a user*** (on page 42).

1 Select **Administration** ().

2 Click **Manage Users**.

The Manage Users page appears.

3 Click the **Profile** link for the user.

The User Profile page appears.

4 Click **Reset Password**.

A confirmation dialog box appears.

5 Click **OK**.

The application sends an email to the user with a link to a webpage where the user can reset the password.

Note: If the user did not provide an email address, the **Reset Password** button is disabled.

Setting a temporary password for a user

Typically, a user with the appropriate rights sets a temporary password for a user when:

- The study does not use password-reset questions.
- The study uses password-reset questions, but the user does not remember the answers.

Note: When you reset a password, the new password does not appear in the profile. When you set a temporary password, the new password appears in the profile and the user must change the password immediately. For more information, see ***Resetting a user password*** (on page 41).

1 Select **Administration** ().

2 Click **Manage Users**.

The Manage Users page appears.

3 Click the **Profile** link for the user.

The User Profile page appears.

4 Click **Set Temporary Password**.

The read-only Temporary Password field appears with the password. For most studies, you provide the temporary password over the phone.

Viewing the audit trail for a user

1 Select **Administration** ().

2 Click **Manage Users**.

The Manage Users page appears.

3 Click the **Profile** link for the user.

The User Profile page appears.

4 Click the **Audit Trail** button (**A**).

The Audit Trail page appears.

For each item, the most recent changes appear first.

For more information, see *Audit Trail page* (on page 28).

5 To view details for a field, click the plus sign to the left of an audit item.

6 To view all details, click **Show all details**.

For a description of each audit item, see *User Profile page* (on page 47).

For information about other audit trails, see:

- *Viewing the audit trail for a site* (on page 27).
- *Viewing the audit trail for a patient* (on page 87).
- *Viewing the audit trail for a visit or form* (on page 131).

Manage Users page

The following tasks use this page:

- *Creating, activating, and deactivating a user* (on page 36).
- *Searching for a user* (on page 38).
- Viewing and editing a user profile.

To view a job aid that you can print, see:

- Quick Reference: Administration.

Column	Description
Checkbox	Use to select a user to activate or deactivate.
Profile	Link to the User Profile page for the user.
Name	User name for signing into the application.
Role	Role to which the user is assigned.
Active	Whether the user is active. Active users can sign in and use the application. Active users can also receive notifications that communicate important information.
Locked	Whether the user is locked.

Create User page

The following task uses this page:

- *Creating, activating, and deactivating a user* (on page 36).

To view a job aid that you can print, see:

- Quick Reference: Administration.

Field	Description	Notes
First Name	First name of the user.	Required.
Middle Name	Middle name of the user.	
Last Name	Last name of the user.	Required.
Custom Homepage URL	Domain-specific URL for a custom Dashboard.	If non-applicable, leave blank.
Role	Role to which the user is assigned.	Required. To work in the application and receive notifications, the user must be assigned to at least one role.
Language	Language for all text in the application.	If the selected language is supported, all pages appear in the selected language for the user when you submit the settings on this page.
ZIP code (postal code)	ZIP code or postal code of residence.	Required.
Country	Country of residence.	
Phone	Phone number to contact the user.	Required.
Time Zone	Time zone for all time values in the application.	You can also specify this setting at the: • **Site level**—On the *Manage Sites page* (on page 30).
Receive Email	Whether to send email notifications to the user or patient.	
Email Address	Email address for notifications.	Maximum length: 40 characters. Must be unique. The ending must be standard for an email address, such as **.com**, **.org**, or **.edu**.

Field	Description	Notes
User Name	User name for signing into the application.	Required. The user name cannot be an email address. The user name can contain underscore characters.
Date Format Name Sort Number Format Currency Format	Date format, how names are sorted, number format, and currency type.	You can also specify these settings at the: • **Study level**—On the *Manage Localization Settings page* (on page 195). • **Site level**—On the *Manage Sites page* (on page 30).
All Sites	When **Yes** is selected, the user is assigned to all sites, including sites that you add in the future.	
Available Sites	Sites to which you can assign the user.	To work in the application, the user must be assigned to at least one site.
Selected Sites	Sites to which the user is assigned.	

Note: If you create a new role type using the **Manage Roles and Rights** link in the Administration module, that new role type appears in the Roles list and can be selected. When you create a new user using the **Manage Users** link, the new role type is available to assign to the user.

User Profile page

The following tasks use this page:

- *Viewing and editing your profile* (on page 6).
- *Assigning a user to and removing a user from a site* (on page 24).
- Viewing and editing a user profile.

You can edit *active and deactivated users* (on page 36) and *locked and unlocked users* (on page 40). Changes appear in the audit trail. For more information, see *Viewing the audit trail for a user* (on page 43).

1 Select **Administration** ().

2 Click **Manage Users**.

The Manage Users page appears.

3 Click the **Profile** link for the user.

The User Profile page appears.

4 Edit the fields as necessary. For more information, see *User Profile page* (on page 47).

5 Click **Submit**.

Note: If a Study Administrator modifies another user profile, that user has to log out and sign back to see the respective changes.

- *Assigning a user to a role* (on page 55).

To view a job aid that you can print, see:

- Quick Reference: Administration.

Field	Description	Notes
Active	Yes or No, indicating whether a user is active. Only active users can sign in and work in the application.	Appears only in the profile of another user.
First Name	First name of the user.	Required.
Middle Name	Middle name of the user.	
Last Name	Last name of the user.	Required.
Custom Homepage URL	Domain-specific URL for a custom Dashboard.	If non-applicable, leave blank.
ZIP Code (postal code)	ZIP code or postal code of residence.	

Field	Description	Notes
Role	Role to which the user is assigned.	Read-only in your profile. Required when the profile you are viewing is not your own. To work in the application and receive notifications, the user must be assigned to at least one role.
Language	Language for all text in the application.	Required. If the selected language is supported, all pages appear in the selected language for the user when you submit the settings on this page.
Country	Country of residence.	Required.
Time Zone	Time zone for all time values in the application.	Required. After you submit the settings on this page, time values appear in the selected time zone for the user. You can specify this setting at the: • **Site level**—On the *Manage Sites page* (on page 30).
Phone	Phone number to contact the user.	Required.
Receive Email	Whether to send email notifications to the user or patient.	
Email Address	Email address for notifications.	Maximum length: 40 characters. Must be unique. The ending must be standard for an email address, such as **.com**, **.org**, or **.edu**.
User Name	User name for signing into the application.	Read-only.
Memorable Date	Significant month and year combination for the Help Desk to ask the user.	Editable only in your profile.
Date Format Name Sort Number Format Currency Format	Date format, how names are sorted, number format, and currency type.	You can also specify these settings at the: • **Study level**—On the *Manage Localization Settings page* (on page 195). • **Site level**—On the *Manage Sites page* (on page 30).

Field	Description	Notes
Old Password Password Confirm Password	Type your current and new passwords.	Visible only in your profile. If you do not want to change your password, do not provide values in these fields.
Password-reset Question 1 Answer 1 Password-reset Question 2 Answer 2	Password-reset questions and answers.	Visible only in your profile. If you forget your password, you must provide identical answers to receive an email that lets you reset your password.
All Sites	When **Yes** is selected, the user is assigned to all sites, including sites that you add in the future.	If you are not assigned to all sites, this field is read-only.
Available Sites	Sites to which you can assign the user.	Appears only in the profile of another user. To work in the application, the user must be assigned to at least one site.
Selected Sites	Sites to which the user is assigned.	Appears only in the profile of another user.
Site table	All sites to which the user is assigned.	The table includes the Site Name, Site Number, and Organization to which the site is affiliated.

CHAPTER 4

Roles and rights

In this chapter

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Roles and rights

Rights grant permission to perform specific activities in the application. Rights are assigned to roles, which are assigned to users. You assign users to roles when you create users or when you edit their user profiles.

The OutcomeLogix application comes with a predefined set of roles, which are configurable in the OutcomeLogix user interface, and rights, which are also predefined for the study and not configurable in the OutcomeLogix user interface. You can, however, ***modify the rights*** (on page 54) assigned to the predefined roles.

For more information, see ***Roles and rights descriptions*** (on page 271).

The rights assigned to a role form a rights group, which is assigned to all the users assigned to the role. For example, all the users assigned to the investigator role have the same rights and can only perform the activities specific to their role, such as entering data. Users assigned to the medical monitor role have rights to review data, but not to enter it.

Note: Assign only the appropriate rights and users to each role.

Roadmap: Managing roles and rights

Step	Action	Description
1	Review the available rights and the default roles included in the application.	The application comes with a predefined set of roles, which are configurable, and rights, which are not configurable. • Determine whether the default roles meet the needs of your study. • Add any other roles that are needed. For more information, see *Adding a role* (on page 57).
2	Modify the rights assigned to the predefined roles as necessary.	1 Select **Administration** (). 2 Click **Manage Roles and Rights**. 3 Click the **Edit** link for the role. The Rights Group page appears. 4 In the Rights Group Details section, edit the rights selections for the role. 5 Click **Submit**.
3	Assign reports to roles.	1 On the Administration page, click **Assign Reports to Roles**. 2 Click the **Assign Reports to Roles** link for the role. 3 Do one of the following: ▪ From the **Available Reports** list, select the reports to assign to the role, and click **Add** (**>**). ▪ To assign all available reports to the role, click **Add All** (**>>**). ▪ To remove an assigned report or all reports, click **Remove** (**<**) or **Remove All** (**<<**). 4 Click **Submit**.
4	Assign each user to a role.	1 On the Manage Roles and Rights page, click the **Change Assigned Users** link for the role. 2 Do one of the following: ▪ From the **Available users** list, select the users to assign to the role, and click **Add** (**>**). ▪ To assign all available users to the role, click **Add All** (**>>**). ▪ To remove an assigned user or all users, click **Remove** (**<**) or **Remove All** (**<<**). 3 Click **Submit**.

Assigning rights to a role

Note: Editing the rights assigned to a role changes the rights for all users assigned to the role.

1 Select **Administration** ().

2 Click **Manage Roles and Rights**.

The Manage Roles and Rights page appears.

3 Click the **Edit** link for the role.

The Rights Group page appears.

4 In the **Rights Group Details** section, assign rights to this role and edit the rights selections as necessary. For more information, see *Roles and rights descriptions* (on page 271).

5 Click **Submit**.

Assigning a user to a role

You can assign one or many users to roles. However, a user can be assigned to only one role at a time. If a user is assigned to RoleA and you assign the user to RoleB, the application removes the user from RoleA. To remove a user assignment from a role, you must assign the user to a different role.

You cannot change your own role assignment.

For more information, see *Roles and rights* (on page 52).

Note: Assign only the appropriate rights and users to each role.

1 Select **Administration** ().

2 Click **Manage Users**.

The Manage Users page appears.

3 To search for a user:

a Enter search criteria:

- **To search by user name:** In the **Search** field, type a full or partial user name, and select **By Name** from the drop-down list.
- **To search by role:** In the **Search** field, type a full or partial role, and select **By Role** from the drop-down list.

b To the right of the drop-down list, click **Submit**.

Users that match your search criteria appear.

For more information, see *Searching for a user* (on page 38).

4 Click the **Profile** link for the user.

The User Profile page appears.

5 From the **Role** drop-down list, select the role.

Note: The roles you can assign other users to are configured on the Rights Group page for your role. For more information, see *Rights Group page* (on page 61).

6 Click **Submit**.

Assigning multiple users to a role

1 Select **Administration** ().

2 Click **Manage Roles and Rights**.

The Manage Roles and Rights page appears.

3 Click the **Change Assigned Users** link for the role.

The Change Assigned Users page appears.

For more information, see *Change Assigned Users page* (on page 60).

4 Do one of the following:

- From the **Available users** list, select the users to assign to the role, and click **Add** (**>**).
- To assign all available users to the role, click **Add All** (**>>**).
- To remove an assigned user or all users, click **Remove** (**<**) or **Remove All** (**<<**).

5 Click **Submit**.

Adding a role

1 Select **Administration** ().

The Administration page appears.

2 Click **Manage Roles and Rights**.

The Manage Roles and Rights page appears.

3 Click the **Add Role** button.

The Rights Group page appears.

4 Fill in the fields as necessary. For more information, see *Rights Group page* (on page 61).

5 From the Available Roles list, select the roles that the users you assign to the new role can assign users to.

6 Click **Add**.

7 In the Rights Group Detail section of the page, select the checkboxes of the rights to assign the new role.

8 Click **Submit**.

The OutcomeLogix application adds the new role and makes it available in the Role drop-down list on the Create User page.

Note: You cannot create multiple roles with the same description.

Editing a role

When you edit a role, you provide the following information:

- Name and description of the role.
- Whether the role is active.
- Rights assigned to the role.

Note: Editing the rights assigned to a role changes the rights for all users assigned to the role.

1 Select **Administration** ().

2 Click **Manage Roles and Rights**.

The Manage Roles and Rights page appears.

3 Click the **Edit** link for the role.

The Rights Group page appears.

4 Edit the fields as necessary. For more information, see *Rights Group page* (on page 61).

5 Click **Submit**.

Manage Roles and Rights page

The following tasks use this page:

- *Assigning a user to a role* (on page 55).
- *Assigning rights to a role* (on page 54).
- *Assigning multiple users to a role* (on page 56).
- *Editing a role* (on page 58).

To view a job aid that you can print, see:

- Quick Reference: Administration.

Column	Description
Edit	Link to the Edit Role page for the role.
Assigned users	Link to the Change Assigned Users page for the role.
Role Name	Name of the role.
Role Description	Description of the role.
Active	Whether the role is active. Users can only access the application when their role is active.

Change Assigned Users page for a role

The following tasks use this page:

- *Assigning a user to a role* (on page 55).
- *Assigning multiple users to a role* (on page 56).

To view a job aid that you can print, see:

- Quick Reference: Administration.

Field	Description
Users lists	
Available users	Users you can assign to the role.
Assigned users	Users assigned to the role.
Roles grid	
Name	User name.
Role	Role to which the user is assigned.
Active	Whether the user is active.
Locked	Whether the user account is locked.

Rights Group page

The following tasks use this page:

- *Assigning rights to a role* (on page 54).
- *Editing a role* (on page 58).
- *Adding a role* (on page 57).

To view a job aid that you can print, see:

- Quick Reference: Administration.

Field	Description	Notes
Role Name	Name of the role.	Required.
Role Description	Description of the role.	
Active	Whether the role is active.	Required.
Available Roles	All roles in the study.	
Selected Roles	Roles that users assigned to this role can assign other users to. For example, if you are working on the Study Administrator role, and you select the Help Desk role, Study Administrators can assign other users to the Help Desk role.	
Rights Group Details	Available rights to assign to or remove from the role. For more information, see *Roles and rights descriptions* (on page 52).	

CHAPTER 5

Password rules

In this chapter

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Password rules and password management

A password rule defines the *formatting, entry, and reuse requirements* (on page 69) for passwords. When you assign a password rule to a role, the passwords of all users who are assigned to that role must conform to its requirements. By creating multiple password rules, you can apply different levels of security to different roles. The *default password rule* (on page 68) is applied to all roles without an explicitly assigned password rule. For more information, see *Assigning a password rule to a role* (on page 66).

Creating and editing a password rule

To create a password rule:

1 Select **Administration** ().

2 Click **Manage Password Rules**.

The Manage Password Rules page appears.

3 Click **Create Password Rule**.

The Create Password Rule page appears.

4 Fill in the fields as necessary. For more information, see *Manage Password Rules page* (on page 69).

5 Click **Submit**.

To edit a password rule:

1 Select **Administration** ().

2 Click **Manage Password Rules**.

The Manage Password Rules page appears.

3 Click the **Edit** link for the rule.

The Edit Password Rule page appears.

4 Edit the fields as necessary. For more information, see *Manage Password Rules page* (on page 69).

5 Click **Submit**.

Note: If the password rule assigned to your sign-in changes and your password no longer conforms to the rule, the OutcomeLogix application requires you to change your password to meet the requirements of the new rule.

Assigning a password rule to a role

You can create password rules as necessary. You assign one password rule to each role, and all users and patients assigned to the role must create passwords that conform to the rule.

1 Select **Administration** ().

2 Click **Assign Password Rules to Roles**.

The Assign Password Rules to Roles page appears.

3 Click **Assign Password Rule**.

The Assign Password Rule page appears.

4 From the **Role** drop-down list, select a role.

5 From the **Password Rule** drop-down list, select a password rule.

6 Click **Submit**.

Changing a password rule assignment

To change a password rule assignment, assign a different password rule to a role.

1 Select **Administration** ().

2 Click **Assign Password Rules to Roles**.

The Assign Password Rules to Roles page appears.

3 Click the **Edit** link for the role.

The Edit Password Rule Assignment page appears.

4 From the **Password Rule** drop-down list, select a password rule.

5 Click **Submit**.

Default password rule

For more information on each property, see *Manage Password Rules page* (on page 69).

Property	Value
Password Rule Name	Default
Minimum Length	6
Maximum Length	12
At Least One Numeric Character	N
At Least One Uppercase Character	N
At Least One Nonalphanumeric character	N
Number of Previous Passwords that cannot be Reused	5
Number of Login Attempts Permitted	5
Change Password at First Login	Y
Expires in How Many Days	365
Default Rule	Y

Manage Password Rules page

The Manage Password Rules page lists the password rules defined for your study, including a ***default rule*** (on page 68) and any password rules you created.

The following tasks use this page:

- ***Password rules and password management*** (on page 64).
- ***Creating and editing a password rule*** (on page 65).
- ***Assigning a password rule to a role*** (on page 66).

To view a job aid that you can print, see:

- Quick Reference: Administration.

Field	Description	Note
Edit link	Edit the password rule.	
Password Rule Name	Password rule name.	Required.
Minimum Length	Minimum password length.	Must be an integer greater than 0.
Maximum Length	Maximum password length.	Must be an integer greater than 0.
At Least One Numeric Character	Whether the password must include a number.	
At Least One Uppercase Character	Whether the password must include a capital letter.	
At Least One Nonalphanumeric Character	Whether the password must include a nonalphanumeric character.	
Number of Previous Passwords that cannot be Reused	One of the following: • **A positive number**—Number of previous passwords that cannot be reused. • **0**—No previous passwords can be reused. • **-1**—All passwords can be reused.	
Number of Login Attempts Permitted	One of the following: • **A positive number**—Number of consecutive failed sign-in attempts allowed. • **0**—No limit on sign-in attempts.	
Change Password at First Login	Whether users must change their passwords after signing in the first time.	

Field	Description	Note
Expires in How Many Days	One of the following: • **A positive number**—Number of days before the password expires. • **0**—Password never expires.	
Default Rule	Whether the password rule is applied to all roles without explicitly defined password rules.	

CHAPTER 6

Patients

In this chapter

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Enrolling patients

Roadmap: Adding patients to a study

Typically, only users assigned to a role with the View Protected Health Information right can enroll patients.

You can enroll patients only one at a time. If a patient does not provide all the required information, enrollment cannot proceed. However, if you must stop the enrollment process before it is complete, the information already entered is saved.

Step	Action	Description
1	Create the patient.	The patient reports to a site. 1 Select **Create Patient** (). 2 Click **Yes, Create a new patient**. 3 Fill in the fields as necessary. 4 Click **Submit**. The Patient Status Summary table on the Dashboard tracks the number of patients with each enrollment status.
2	View or view and sign any Informed Consent Documents (ICDs).	1 Create the patient. 2 Select **Patients** (). 3 Click the **Summary** link for the patient. 4 The patient views and signs any ICDs. 5 If required, a site user and an observer also sign the ICD. 6 Click **Sign/Accept**.
3	Complete any required screening forms to determine whether the patient is eligible to participate.	The patient is assigned to a site, visits are scheduled, and visits are populated with the required forms. Site users: • Complete any EDC forms for screening. • If a patient fails screening, a site user with the appropriate rights must ***discontinue*** (on page 74) or ***re-enroll*** (on page 74) the patient. Patients: • Depending on the study configuration, patients who enter data on ePRO forms may be notified through email that they have forms to complete. • Complete any required ePRO forms for screening.

Step	Action	Description
4	Complete any required forms for enrollment.	Typically, a site user completes any required EDC forms for enrollment. The patient completes any required ePRO forms for enrollment. The patient status becomes Enrolled when the EDC forms and ePRO forms required for enrollment are complete.

Creating a patient account

1 Select **Create Patient** ().

A confirmation page appears.

2 Click **Yes, Create a new patient**.

The application checks to see whether the limit on enrollment for the study has been exceeded.

- If enrollment is closed, you are informed that you cannot add the patient.
- If enrollment is open, the Create Patient page appears.

3 Fill in the fields as necessary. For more information, see *Create Patient page* (on page 75).

4 Click **Submit**.

What happens next depends on your study design:

- The application sends the patient an email message with a link to a webpage, where the patient specifies a password.
- The Patient Summary page appears. The patient just added appears at the bottom of the Patient list.
- The application prompts you to view and sign the ICD. For more information, see *Viewing and signing ICDs* (on page 73).

The initial visit page or form for the patient appears. The first page that appears when a patient is created depends on the study design.

Viewing and signing ICDs

1 Select **Patients** ().

The Patient List page appears.

For information on locating patients, see *Searching for a patient* (on page 85).

2 Click the **Summary** link for the patient.

Note: The status of the patient when you begin screening or enrollment depends on the study configuration.

For studies designed to include online consent, the ICD appears.

3 Fill in the fields as necessary. For more information, see *Informed Consent Document (ICD)*

page (on page 77).

4 Optionally, use the Adobe Acrobat options to print the ICD.

5 Click **Sign/Accept**.

The Patient Summary page appears.

Discontinuing a patient

Enrolled patients may choose to stop participating in a study at any time, beginning with the second visit. When a patient decides to stop participating, a user with the appropriate rights can discontinue the patient. You might discontinue a patient for other reasons, such as noncompliance with the study protocol. Discontinued patients are deactivated, cannot sign in, and do not receive notifications. The audit trail reflects the reason for discontinuing the patient. You cannot re-activate a discontinued patient.

1 Select **Patients** ().

The Patient List page appears.

2 Click the **Summary** link for the patient.

The Patient Summary page appears.

3 Click the visit when the patient stopped participating. Typically, this is any visit after Visit 1.

The Visit landing page appears.

4 Click **Discontinue**.

A confirmation dialog box appears.

5 Click **OK**.

6 Complete any required information.

7 Click **Submit**.

Re-enrolling a patient

You can re-enroll patients who fail screening or do not complete the enrollment process. If a site user began screening and enrolling the patient at the site using the OutcomeLogix user interface, the patient information was saved, so you do not have to start over. You can contact the patient to obtain the missing information and complete the enrollment process. For more information, see *Creating a patient account* (on page 73).

Create Patient page

The following task uses this page:

- *Creating a patient account* (on page 73).

To view a job aid that you can print, see:

- Quick Reference: Patients.

Note: The content of the Create Patient page is configurable during the study design and may differ from study to study.

Field	Description	Notes
Parents Name	Parent of the patient.	Whether this needs to be provided is specific to the study and patient. A parent may be an additional observer and/or required to provide information for young children.
First Name	First name of the patient.	Required.
Middle Name	Middle name of the patient.	
Last Name	Last name of the patient.	Required.
Language	Language of the patient. After you make a change and submit, all forms that have been translated to the selected language appear in the selected language.	Required.
Zip (Postal Code)	ZIP code or postal code of residence.	Required.
Country	Country of residence.	Required.
Time Zone	Time zone in which the patient resides. After you make a change and submit, time values use the selected time zone.	Required.
Patient Group	Group attached to a study arm to which the patient is assigned.	Required.
Phone Number	Phone number to contact the patient.	Required.
Email Address	Email address for notifications. This is also the user name/sign in name for the patient.	Required. Maximum length: 40 characters. The ending must be standard for an email address, such as **.com**, **.org**, or **.edu**.

Field	Description	Notes
Site	Site to which the patient is assigned.	Required.

Informed Consent Document (ICD) page

The following task uses this page:

- *Viewing and signing ICDs* (on page 73).

To view a job aid that you can print, see:

- Quick Reference: Patients.

Field	Description	Notes
Sign/Accept	Accept the ICD.	The Visit Landing page or first form in the visit appears.
Do Not Accept	Do not accept the ICD.	If an ICD has been set up for your study, you cannot continue with the selected visit until the ICD is signed.
Patient User Name	User name of the patient.	Appears only when the patient signature is required.
Staff Witnessing Consent	User name of the site user.	Appears only when a site user signature is required.
Patient Password	Password of the patient.	Appears only when the patient signature is required.
Staff Witnessing Consent Password	Password of the site user.	Appears only when a site user signature is required.
Observer User Name	User name of the observer. An observer provides additional observations about the patient.	Appears only when an observer signature is required.
Observer Password	Password of the observer.	Appears only when an observer signature is required.

Depending on the study design, both site users and patients provide electronic signatures on the ICD signature page.

- If the currently signed-in user or patient enters an invalid user name/password combination, after the number of attempts exceeds the configured maximum number of allowed attempts, the application locks the user account and logs the user out, forcing the user to change the password at the next sign in.
- If a user or patient who is not currently signed in enters an invalid user name/password combination, the application clears out the incorrect User Name and Password fields and displays a message for the user to try again.
- If a user or patient who is not currently signed in exceeds the number of permitted attempts, the application:
  - Issues a message asking the user or patient to change the password and try again.
  - Closes the ICD page.
  - Locks the user or patient account, forcing the user or patient to change the password at the

next sign in.

Note: If a user or patient is not signed in and becomes locked out while attempting to co-sign the ICD signature page in the session of the currently signed-in user or patient, the application does not log out the currently signed-in user or patient.

Patient Summary page

Only users with the appropriate rights can view and use certain buttons.

The following tasks use this page:

- *Roadmap: Adding patients to a study* (on page 72).
- *Viewing and signing Informed Consent documents* (on page 73).

To view a job aid that you can print, see:

- Quick Reference: Patients.

Field	Icon	Description	Notes
Tabs			
Patient Summary tab		Displays the Patient Summary page for the patient.	
Patient Diary tab		Displays the Patient Diary page for the patient.	
Patient ICD History tab		Displays the Patient ICD History for the patient.	
Fields			
Checkbox		Use to select the patient, a visit, a form, or an item.	
Patient ID		Unique identifier for the patient.	
Patient Initials		Initials of the patient.	
Status		Visit, form, item, and query status at the patient level.	The application applies the Not Started, In-Progress, Complete, and Open with Queries statuses to repeating sections. A Not Started status icon applied to a repeating section means that the repeating section has not been submitted.
Columns			

Field	Icon	Description	Notes
Visits		• Click the Visit name to link to the Visit landing page for the visit or the first form. • Click the arrow to expand a visit and display the forms within the visit and any repeating sections within a form. • Click the arrow next to a form to display the items on the form.	Repeating sections within forms appear in descending order by creation date. The newest instance appears first.
Actual		Actual visit date.	
Open		Number of open queries on patient forms.	
Answered		Number of answered queries.	
Approved		Number of approved queries.	
Closed		Number of closed queries.	
Query Status		Visit, form, item, and query statuses.	
System Status		Status of automatically issued queries.	
Manual Actions		Status of manually issued queries.	
Status and Review icons	**Icon**		
Create Query		Create a query about the patient, visit, or form.	
Response Query		Respond to a query.	
Modify Query		Modify a query.	
Approve Query		Approve a query.	
Re-issue as Open		Re-issue a query.	
Close Query		Close a query.	
Unlock		Unlock the patient, visit, or form.	
Lock		Lock the patient, visit, or form.	No further modification to the data is permitted.
Unmark DM Reviewed		Unmark the patient, visit, or form as DM Reviewed.	Changing the data automatically activates the Unmark status.

Field	Icon	Description	Notes
Mark DM Reviewed		Mark the patient, visit, or form as DM Reviewed.	A data manager has reviewed the data entries.
Remove Remote Review		Unmark the patient, visit, or form as Remote Review.	Changing the data automatically activates the Unmark status.
Mark for Remote Review		Mark the patient, visit, or form as Remote Review.	The form or visit has been reviewed remotely and found to be complete. The data was not checked against source documents.
Unmark SDV		Unmark as SDV (Source Document Verification) reviewed.	Changing the data automatically activates the Unmark status.
Mark SDV		Mark as SDV (Source Document Verification) reviewed.	The data on the form has been reviewed against the source data.
Unfreeze		Unfreeze the patient, visit, or form.	
Freeze		Freeze the patient, visit, or form.	The data has been reviewed and cannot be modified at this time; however, you can open queries.
Left blank		Intentionally left blank.	The sponsor has chosen to skip this visit, form, or item.
Unsign		Unsign the selected patient, visit, or form.	A site user, typically an investigator or clinical research coordinator, performs this action. Changing the data automatically activates the Unsign status.
Sign		Sign the selected patient, visit, or form.	The OutcomeLogix application automatically requests authentication of the user.
Signed at parent level		An object at a higher level in the object hierarchy has been signed (for example, the visit in which a form appears has been signed).	The design of your study determines whether a visit, form, or item that is signed at a higher level in the object hierarchy can be considered signed itself.

Managing patients

Roadmap: Managing a patient

Step	Action	Procedure
1	Upload the ICDs.	A sponsor user can upload the ICDs for the site. 1 Select **Administration** (). Click **Manage ICDs**. 2 Fill in the fields as necessary. 3 Browse for the ICD file to upload. 4 Click **Add**.
2	Create, screen, and enroll the patient.	1 Select **Create Patient** () to create the patient. 2 Sign any ICDs. 3 From the Visit Landing page, complete any EDC forms required for screening and enrollment. 4 Have the patient complete any ePRO forms required for screening and enrollment.
3	Discontinue or re-enroll the patient if the patient does not complete enrollment.	• To discontinue the patient, from the Visit Landing page, click **Discontinue**. • To re-enroll the patient, obtain the missing information and complete the enrollment process.
4	Track the status of the patient.	1 Select **Patients** (). The Patient List page appears. 2 View the status of the patient in the Status column.
5	Manage the patient.	Perform the following procedures as needed.
	Search for the patient.	1 On the Patient List page, enter search criteria. 2 To the right of the drop-down list, click **Submit** ().
	View and edit the patient profile.	1 On the Patient List page, click the **Profile** link for the patient. The Patient Profile page appears. 2 Edit the fields as necessary. 3 Click **Submit**.
	Reset the patient password.	• On the Patient List page, select the radio button for the patient and click **Reset Password**.

Step	Action	Procedure
	Set a temporary password for the patient.	• On the Patient List page, select the radio button for the patient and click **Set Temporary Password**.
	View the audit trail for the patient.	• On the Patient Profile page, click the **Audit Trail** button (**A**).
	Transfer the patient,	1 On the Patient List page, click the radio button of the patient to transfer. 2 Click the **Transfer** button.
6	Manage the ICDs.	Perform the following procedures as needed.
	Add an ICD.	On the ICD Management page: • Fill in the fields as necessary. For more information, see *ICD Management page* (on page 97).
	Edit or add a new version of an ICD.	1 On the ICD Management page, click the **Details** link for the ICD. The Edit ICD page appears. 2 Edit the fields as necessary. 3 Click **Update**.
	Add new languages for an ICD.	1 On the Edit ICD page, click **Add New Language** (). 2 From the **Language** drop-down list, select the language of the ICD. 3 Specify the ICD to upload. 4 Click **Upload**. 5 Click **Update**.

Patient status

A list of patient statuses appears in the Patient Status section on the Dashboard along with the number of patients with each status. The statuses track the patient through the enrollment process. The Patient Status section also includes the number of Active patients (total number of patients minus patients with a Completed or Discontinued status).

The following statuses are standard with the OutcomeLogix application. Study designers can create additional, study-specific statuses. A patient can have only one status at a time.

Status	Description
Prescreened	Patient has been created but not enrolled.
Created	Patient details were submitted. The first visit with an expected date is created for the patient.
Withdrawn	Patient withdrew from the study or declined the ICD form. The trigger for this status is study-specific.
Consented	Patient signed the ICD.
Screening	Patient completed the EDC and ePRO forms required for screening. The patient met all the inclusion criteria and none of the exclusion criteria.
Screen-Failed	Patient started the screening process and then failed for one or more reasons; for example, the patient selected **No** on the Site Inclusion form and, therefore, cannot be included in the study.
Opt Out	Patient declined to sign the ICD.
Enrolled	Patient completed the EDC and ePRO forms required for enrollment.
Randomized	Patient was randomized in the study.
Discontinued	Patient was enrolled, but was discontinued for one or more reasons.
Lost to follow-up	Patient was enrolled in the study but never returned or cannot be contacted after repeated efforts. The trigger for this status is study-specific.
Completed	Patient completed the last protocol-specified event (visit, web, or telephone contact).

Viewing patient status information

Patient statuses appear on the Dashboard and in the Status column on the Patient List page.

1 Select **Home** ().

A list of patient statuses appears in the Patient Status table on the Dashboard along with the number of patients with each status.

2 To view the Patient List filtered for a status, click the count for the status.

The Patient List page appears and is filtered by the selected status.

For more information, see *Patient List page* (on page 89).

Searching for a patient

You can search for the patient by patient status, the Patient List, Patient ID, Site Name, or ePRO session. Searching by Patient ID is the preferred method of searching.

1 Select **Patients** ().

The Patient List page appears.

2 Enter your search criteria:

a From the first **Search** drop-down list, select a **patient status** or leave blank to include all statuses.

b From the second **Search** drop-down list, select whether to search by Patient List, Site Name, or Patient ID.

c Do one of the following:

- If you chose to search by **Patient List**, from the third **Search** drop-down list, select the patient.
- If you chose to search by **Patient ID**, from the third **Search** drop-down list, type some or all of the Patient ID, with or without leading zeros, or leave the null value to include all patients. The application sorts the records in ascending order by creation date. This choice may result in the retrieval of multiple patient records.
- If you chose to search by **Site Name**, from the third **Search** drop-down list, select a specific site. If you make no selection, the application includes patients for all sites.

d From the fourth **Search** drop-down list, select whether the **number of ePRO sessions** is greater than 0.

3 To the right of the drop-down list, click **Submit** ().

Patients that match your search criteria appear.

4 To clear the search criteria, click **Clear Filters**.

Viewing and editing a patient profile

Edit the fields as necessary. Users with the appropriate rights can edit the following information for any patient:

- Patient details.
- Site assignment.

Before you can edit a patient profile:

- The patient must be active.
- The patient must be assigned to a site to which you are also assigned.

1 Select **Patients** ().

The Patient List page appears.

2 Click the **Profile** link for the patient.

The Patient Profile page appears.

3 Edit the fields as necessary. For more information, see *Patient Profile page* (on page 92). If your administrator has hidden Call Center-related fields, they do not appear on the Patient Profile page.

Note: If you try to remove the only site to which the patient is assigned, the application prevents you from submitting the change.

4 Click **Submit**.

Note: Alternatively, you can access the patient profile from the navigation pane displayed to the left of any form. If you do not have permission to view patient profiles, the link does not appear.

Patients who sign in to the OutcomeLogix website can access their own profile by clicking their user name in the upper right corner of the page.

Locking and unlocking a patient

To prevent patients from signing in and using the application, you can lock their accounts.

Before you can lock or unlock a patient, the patient must be assigned to a site to which you are also assigned. After you lock an account, you must manually unlock it before the patient can work in the application.

1 Select **Patients** ().

The Patient List page appears.

2 Select the radio button for the patient.

3 Click either **Lock** or **Unlock**.

Resetting a patient password

If patients forget their passwords, a user with the appropriate rights can reset the passwords.

Note: When you reset a password, the new password does not appear in the profile. When you set a temporary password, the new password appears in the profile and the password must be changed immediately. For more information, see ***Setting a temporary password for a patient*** (on page 87).

Before you can reset a patient password:

- The patient must be active.
- The patient must be assigned to a site to which you are also assigned.

1 Select **Patients** ().

The Patient List page appears.

2 Select the radio button for the patient.

3 Click **Reset Password**.

A confirmation dialog box appears.

4 Click **OK**.

The next time the patient signs in, the application requires the patient to change the password.

Setting a temporary password for a patient

Typically, you set a temporary password for a patient when:

- The study does not use password-reset questions.
- The study uses password-reset questions, but the patient does not remember the answers.

Note: When you reset a password, the new password does not appear in the profile. When you set a temporary password, the new password appears in the profile and the password must be changed immediately. For more information, see *Resetting a patient password* (on page 86).

Before you can set a temporary password for a patient:

- The patient must be active.
- The patient must be assigned to a site to which you are also assigned.

1 Select **Patients** ().

The Patient List page appears.

2 Select the radio button for the patient.

3 Click **Set Temporary Password**.

A dialog box appears, showing the Memorable Date for the patient.

4 Confirm the **Memorable Date** for the patient.

5 Click **Set Temporary Password** in the dialog box.

The read-only Temporary Password field appears with the password. For most studies, you provide the temporary password over the phone.

Viewing the audit trail for a patient

Changes to most fields in a patient profile are audited.

1 Select **Patients** ().

The Patient List page appears.

2 Click the **Profile** link for the patient.

The Patient Profile page appears.

3 Click the **Audit Trail** button (**A**).

The Audit Trail page appears.

For more information, see *Audit Trail page* (on page 28).

4 To see the audit trail for changes made to patient information, click the plus sign to the left of the audit item.

For each item, the most recent changes appear first.

To see a description of each audit item, see *Patient Profile page* (on page 92).

For information about other audit trails, see:

- *Viewing the audit trail for a site* (on page 27).
- *Viewing the audit trail for a user* (on page 43).
- *Viewing the audit trail for a visit or form* (on page 131).

Managing patients and sites

To enroll a patient in a site, you must have access to the site. Only the studies and sites you have access to are visible. Additionally, you cannot enroll patients in a site that has reached maximum enrollment.

After enrollment, however, you can change the sites to which the patient is assigned using the Patient Transfer function. For more information, see *Initiating a patient transfer* (on page 264).

Patient List page

The following tasks use this page:

- *Viewing the Patient List* (on page 112).
- *Selecting a patient* (on page 112).
- *Selecting a visit or form* (on page 113).
- *Starting a visit from the Visit Landing page* (on page 114).
- *Tracking missed visits* (on page 116).

To view a job aid that you can print, see:

- Quick Reference: Patients.

By clicking the column headers, you can sort the Patient List based on the information in the column; for example, by status or arm.

Field	Description	Note
Filters		
Search • by Patient Status • by Patient List • by Site Name • by Patient ID • by ePRO sessions	Filter the patient list by patient status by selecting the drop-down list. Filter by patient by selecting Patient List from the second Search drop-down list. Then select the patient from the third Search drop-down list. Filter by site by selecting Site Name from the second Search drop-down list. Then select the site from the third Search drop-down list. Filter by patient ID by selecting Patient ID from the second Search drop-down list. Then select the patient from the third Search drop-down list. Filter by ePRO session by selecting the session from the fourth Search drop-down list.	To apply the filter, you must click **Submit** (). To apply a different filter, you must first click **Clear Filters**. To filter by Patient ID, type a specific Patient ID, with or without leading zeros, or a set of contiguous digits. The application sorts the records in ascending order by creation date. This choice may result in the retrieval of multiple patient records. Select the Filter by ePRO session filter to include patients who are due to complete, or have completed, patient diaries or other forms.
Clear Filters button	Removes search criteria and displays the entire patient list.	You must clear the search criteria before defining new search criteria.
Links		
Summary	Link to the *Patient Summary* (on page 79) page for the selected patient.	

Field	Description	Note
Profile	Link to the ***Patient Profile*** (on page 92) page for the selected patient.	
Columns		
Patient ID	Unique identifier for the patient.	
Status	***Patient status*** (on page 84) assigned by the application.	Only those statuses selected for your study appear in the Status drop-down list.
Site ID	The site to which the patient has been assigned.	
Therapy (Arm) Name	The study arm to which the patient has been assigned.	
Next Visit Date	Date of the next scheduled visit.	
Visit Name	Name of the next scheduled visit and link to the Visit Landing page for the selected patient visit.	
Open	Number of open queries on patient forms and link to the Query List page for the selected patient.	Lists all open queries.
Answered	Number of answered queries and link to the Query List page for the selected patient.	Lists only the answered queries.
Closed	Number of closed queries and link to the Query List page for the selected patient.	Lists only the closed queries.
Started Visits	Number of visits that are started, but not completed.	At least one form within the visit is started, but not all forms are completed.
Completed Visits	Number of complete visits.	
Frozen	Number of frozen visits.	If frozen: • Data cannot be modified. • Visit can be signed.
Locked	Number of locked visits.	If locked: • Data cannot be modified. • Visit cannot be signed.
ePRO Sessions Past Due	Number of ePRO Sessions that are past due.	
Controls		

Field	Description	Note
Page controls	• **Page n of n drop-down list**—Displays the specific page. • **Records per Page drop-down list**—Select the number of records to display. • **|<**—View the first page. • **<**—view the previous page. • **>**—View the next page. • **>|–**View the last page. • **Total Number of Records**—The number of records that appear on each page.	
Buttons		
Lock/Unlock	Lock or unlock the selected user.	A locked user cannot log in to the application.
Reset Password	Reset the password of the selected user.	
Set Temporary Password	Set a temporary password for the selected user.	
Clear Filters	Reset the search drop-down lists to blank.	

Patient Profile page

The Patient Profile page contains both standard and study-specific information about a patient. The fields in the following table are examples of standard information usually included in the patient profile if the Call Center is enabled. The Patient Profile page for your study might contain all or none of these fields as well as additional study-specific fields.

If the study is designed to blind Personal/Protected Health Information to specific users, and your user account is not permitted to view Personal/Protected Health Information, you cannot view the Patient Profile page.

The following tasks use this page:

- *Viewing and editing a patient profile* (on page 85).
- *Locking and unlocking a patient* (on page 86).
- *Viewing the audit trail for a patient* (on page 87).
- *Managing patients and sites* (on page 88).

Field	Description	Note
Call Center fields		
Preferred Method of Contact	Survey completion mode: Web, Phone, or Paper.	Required.
First Name	First name of the patient.	Required.
Middle Name	Middle name of the patient.	
Last Name	Last name of the patient.	Required.
Language	Language of the patient. After you make a change and submit, all forms that have been translated to the selected language appear in the selected language.	Required.
Email	Email address for notifications. This is also the user name for the patient.	Required if the Preferred Method of Contact is Web. Maximum length: 40 characters. The ending must be standard for an email address, such as **.com**, **.org**, or **.edu**.
Phone	Phone number to contact the patient.	Required if the Preferred Method of Contact is Web or Phone.
Confirm Phone	Confirmation of phone number to contact the patient.	Required if the Preferred Method of Contact is Web or Phone.

Field	Description	Note
Time Zone	Time zone in which the patient resides. After you make a change and submit, time values use the selected time zone.	Required if the Preferred Method of Contact is Web or Phone.
Preferred Time of Contact	Set a contact range by moving the sliding controls to the start and end times of the preferred range.	Required if the Preferred Method of Contact is Web or Phone.
Address1	Mailing address of the patient.	
Address2	Mailing address of the patient.	
City	City where the patient is located.	
Zip Code	ZIP code where the patient is located.	
State	State where the patient is located.	
Country	Country of residence.	
Patient Profile Core Data fields These fields appear if ShowPatientProfileCoreData is set to Y. For more information, see *Configure Study Settings page* (on page 189).		
Site ID	Unique identifier of the site to which the patient is assigned.	
Patient ID	Unique identifier assigned to the patient.	
Last 4 of the SSN	The last four digits of the patient Social Security Number.	
Legally Authorized Representative (optional)	Name of an individual legally responsible for the patient.	
Legally Authorized Representative telephone number (optional)	Telephone number of the representative.	
Email Address	Email address for notifications. This is also the user name.	
User Name	Email address of the patient.	Read-only.
Memorable Date	Month and year of significance to the patient. Used to authenticate patient identity by Help Desk personnel.	
Site Name Site Number Organization	The name of the site, its number, and the name of the organization of which the site is a part.	Read-only.

Informed Consent Documents (ICDs)

About ICDs

During the enrollment process, a patient may be required to view or view and sign an ICD. Typically, a sponsor loads an ICD file into the application from the ICD Management page.

Depending on the study configuration, the ICD may require:

- No signature, because it is informational only.
- Patient signature only.
- Patient and site user signatures.
- Patient, site user, and observer signatures.

If your study protocol encompasses online informed consent, after a patient is created, the ICD appears. You certify that the required signatures have been collected by entering the user names and passwords for the required patients and users. The signatures are captured with a date and time stamp. Before you click the Sign button on an ICD, you have the option to print a copy of the form. When the ICD is complete, the Patient Summary page appears.

Uploading an ICD

1 Select **Administration** ().

2 Click **Manage ICDs**.

The ICD Management page appears.

3 Fill in the fields as necessary. For more information, see *ICD Management page* (on page 97).

4 Browse for the ICD file to upload.

5 Click **Add**.

ICD versions

When a new version of an ICD is approved, you can upload the new version on the ICD Management page. After a new version is uploaded, the version number changes. If you load an updated ICD into the application, all the patients must sign the new ICD at their next logins. For more information, see *Viewing and printing an ICD* (on page 95).

When a patient logs in, the application checks to see if the ICD version that he or she signed has changed. If so, the latest version of the ICD appears and the patient must provide his or her signature under the following circumstances:

- ICD is not informational only.
- Visit is an ePRO visit.
- Study requires only the patient to sign the ICD.

The latest version of the ICD is time stamped to prove that the patient viewed the new ICD when

the ICD is informational only.

All required signatures must be provided under the following circumstances:

- ICD is not informational only.
- Visit is an EDC visit.
- Study requires the site user or the observer to sign the ICD.

Uploading a new version of an ICD

1 Select **Administration** ().

2 Click **Manage ICDs**.

The ICD Management page appears.

3 Click the **Details** link for the ICD.

The Edit ICD page appears.

4 Click the **Check to add new version** checkbox.

5 Specify the **Active Date** for the new version. For more information, see *Edit ICD page* (on page 99).

6 From the **Language** drop-down list, select the language of the ICD.

7 Specify the ICD to upload.

8 Click **Upload**.

Viewing and printing an ICD

Only users with the appropriate rights can view and print ICDs.

To view and print an ICD:

1 Select **Administration** ().

2 Click **Manage ICDs**.

The ICD Management page appears.

3 Click the **Details** link for the ICD.

The Edit ICD page appears.

4 Click the **View ICD** icon () for the ICD.

5 Optionally, print the ICD.

To view and print an ICD for a patient:

1 Select **Patients** ().

The Patient List page appears.

2 Click the **Summary** link for the patient.

The Patient Summary page appears.

3 Click the **Patient ICD History** tab.

> **Note:** This tab is available only if you have the appropriate rights.

The Patient ICD History page appears.

4 Click the ICD Name link.

The application displays the ICD in a window.

5 To print the ICD, click **Print View**.

The application displays a printable version of the ICD.

6 From the browser File menu, select **Print**.

Adding a new language for an ICD

1 Select **Administration** ().

2 Click **Manage ICDs**.

The ICD Management page appears.

3 Click the **Details** link for the ICD.

The Edit ICD page appears.

4 Click **Add New Language** ().

> **Note:** This icon appears only when an additional language for the ICD is available.

The Add New Language dialog box appears.

5 From the **Language** drop-down list, select the language of the ICD.

6 Specify the ICD to upload.

7 Click **Upload**.

The new ICD appears in the Language column.

ICD Management page

The following tasks use this page:

- *Uploading an ICD* (on page 94).
- *Viewing and printing an ICD* (on page 95).

Field	Description	Notes
Fields		
ICD Name	Descriptive identifier for the ICD.	Required. You cannot reuse the name of an existing ICD, even with different capitalization. Also appears as a column in the grid.
ICD Type	Type of ICD.	You can upload ICDs for each type: • EDC • ePRO • Observer Also appears as a column in the grid.
Active Date	Date the ICD goes into effect.	Required. Also appears as a column in the grid.
Language	Language of the text in the ICD.	
Load ICD	Browse for the ICD file to upload.	Required.
Columns		
Details link	Edit ICDs already uploaded to the OLX application.	
Name	Descriptive identifier for the ICD.	
ICD Type	Type of ICD.	You can upload ICDs for each type: • EDC • ePRO • Observer
Latest Version	Latest version of the ICD.	
Active Date	Date the ICD goes into effect.	

Field	Description	Notes
Is Active	Whether the ICD is active.	

Edit ICD page

The following task uses this page:

- *Viewing and printing an ICD* (on page 95).

Field	Description	Notes
Fields		
ICD Name	Descriptive identifier for the ICD.	
ICD Type	Type of ICD.	Read-only.
Check to add new version	Whether to add a new version of the ICD.	
Active Date	Date the ICD goes into effect.	Only appears when **Check to add new version** is selected. Also appears as a column in the grid. Can be a future date.
Language	Language of the text in the ICD.	Only appears when **Check to add new version** is selected. Also appears as a column in the grid.
Load ICD	Browse for the ICD file to upload.	Only appears when **Check to add new version** is selected.
Columns		
Version	Version of the ICD.	
Active Date	Date the ICD goes into effect.	
Add New Language ()	Upload the document in another language.	Only appears when another language is available.
Language	Language of the text in the ICD.	
View ICD ()	View the ICD PDF.	

ICD History page

The following task uses this page:

- *Viewing and printing an ICD* (on page 95).

Column	Description
ICD Name	Descriptive identifier for the ICD.
Version	Version of the ICD.
Date Signed	Date the ICD was signed.

CHAPTER 7

Visits and forms

In this chapter

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Working with visits and forms

The *hierarchical relationship* (on page 14) of patients, visits, forms, and items affects the actions you perform during visits and when working with forms.

- A study consists of a set of visits, each involving completion of one or more study-specific forms. Patients in a particular arm of the study have the same visits and forms. The forms appear as a list below their associated visit on the *Patient Summary page* (on page 79).
- A visit is a clinic or hospital visit with a patient at the site for evaluation or dosing during the study. A visit can be:
  - Scheduled on a fixed interval (for example, Follow-up Visit Month 1, Month 3, Month 6, Month 9). A scheduled visit can occur one time or can be a repeating visit that occurs multiple times on demand.

    Each instance of a repeating visit contains the same set of forms. By default, the name of each instance of a repeating visit consists of the name of the previous instance incremented by a number that is specified during study design.

    For example, if the base name of the repeating visit is Visit2, the default name of the first follow-up visit is Follow-up. If the visit is scheduled to occur every three months, the increment value is 3. The sequence of repeating visit instances would then be:
    - RV 1 = Follow-up
    - RV 2 = Follow-up 3
    - RV 3 = Follow-up 6
    - RV 4 = Follow-up 9, and so on.
  - Unscheduled to record adverse events, medication record updates, pregnancies, or study discontinuation.
- A form is a page that contains a grouping of items. Electronic Data Capture (EDC) forms are completed based on patient visit data. Patients complete Electronic Patient-Reported Outcome (ePRO) forms themselves on a study website.
  - After you submit a completed form, you progress to the next form or select the next form, depending on how your study was set up.
  - As you complete forms, the OutcomeLogix application tracks your progress and displays *status icons* (on page 106).

As described in *OutcomeLogix hierarchy* (on page 14), the actions you perform at a higher level of the hierarchy impact the lower levels.

- Patient level applies to all of a patient's visits, forms, and items.
- Visit level applies to all forms and items within a visit.
- Form level applies to all items within a form.

For example, this means that:

- Freezing a patient freezes all visits, forms, and items.
- Freezing a visit freezes all forms and items within the visit.
- Freezing a form freezes all items within a form.
- Freezing an item freezes only that item.

Note: By default, eSignatures are not propagated to other levels of the hierarchy; that is, the signatures at different levels are completely independent of each other. The audit trail reflects this independence.

Roadmap: Starting a visit and entering data

Your study design contains protocols to ensure that you collect data consistently and completely throughout the study.

Step	Action	Description
1	Select the patient.	1 Select **Patients** (). 2 Search by Status, a list of patient IDs, Site Name, Patient ID, or ePRO session.
2	Select the visit.	• For the next scheduled visit: ▪ In the **Visit Name** column, select the **Visit Name** link. • For a specific previous or future visit: ▪ Click the **Summary** link for the patient. ▪ Click a **Visit** link.
3	Record the date and time of the visit.	On the Visit Landing page, in the **Actual Visit Date** field, enter the date and time. You must complete the Visit Landing page if it is included in your study.
4	Select the form.	Your study might be set up to display the first form for the visit automatically upon submission of the Visit Landing page. You can also select the form from the navigation pane on the left.
5	Enter the data.	As you enter the data, the OutcomeLogix application identifies any required fields and might provide additional information about the expected entry.
6	Submit the form. or Click **Save Only** to save the data you have entered without submitting the form. You can return to the form later, complete it, and submit it.	When you submit the form, the OutcomeLogix application validates your entries and does not accept the form until all entries are complete or the OutcomeLogix application has issued queries for missing or unexpected entries. The application displays a Query Status icon next to each Answered, Closed, or Approved query. When you click **Save Only**, the application saves the patient data entered without executing server-side validations and changing the form status to Completed.
7	Complete the rest of the forms.	Your study might be set up to display the next form automatically, or you can select it from the navigation pane on the left.

Step	Action	Description
8	Edit the forms as necessary.	When you submit a revised form, the OutcomeLogix application prompts you to enter a reason for the changes and tracks the revisions in the Audit Trail for the form. 1 Select the form. 2 Edit the fields as necessary. 3 Click **Submit**.
9	Complete the Reason for Change window.	1 For each item, select the reason you changed the field value from the **Reason** drop-down list. If you selected **Other**, type the reason in the **Response** text box. or Apply the same reason to all items changed: ▪ From the **Group RFC** drop-down list, select the reason for change. If you selected **Other,** type the reason in the **Response** text box. ▪ Click the **Apply All** link. 2 Click **Submit**.
10	Sign the patient, visit, form, or item.	Signatures at the patient, visit, form, and item levels are independent of each other. You must sign at each level. 1 Select **Patients** (). 2 Click the **Summary** link for the patient. 3 Select the checkbox to the left of the patient, visit, form, or item. 4 Click the **Sign** icon (). 5 From the **Reason** drop-down list, select the reason for your signature. If you selected **Other** as the reason, type an explanation in the **Reason** text box. 6 Type your **User Name**. 7 Type your **Password**. 8 Click **Submit**. The application displays the Signed status icon in the Manual Actions column for the form. The Signed status icon also appears on the Patient Summary page.

System-applied form and query statuses

As you enter visits and complete forms, the OutcomeLogix application tracks your progress and displays corresponding status icons on the Patient Summary page at the patient, visit, form, and item levels, including repeating sections within forms. For forms with repeating sections, a summary grid contains a Form Status column showing the status of each instance of the repeating section.

At any time, you can see this list of forms and query statuses by clicking the down arrow in the upper right corner of the page and clicking Status Legend.

Status	Icon	Description
Form Status		
Not started (Blank)		Data entry has not begun.
In-Progress		Data entry is incomplete.
Incomplete with open queries		Awaiting a response from a site user; typically an investigator or clinical research coordinator.
Source Verified		A reviewer has checked the data against the source data.
DM Reviewed		A clinical data manager has reviewed the data entries.
Remotely Removed		A data manager or monitor has checked the data for completeness away from the site. Data was not checked against source documents.
Intentionally Left Blank		A site user has left the form blank and will complete it later.
Complete		Upon submission, a form moves to the Complete status if all required fields are complete and no outstanding open queries remain on the form.
Signed		A site user, typically an investigator, has signed off on the patient, visit, form, or item.
Frozen		The patient, visit, form, or item has been frozen and cannot be modified. Queries can be opened, answered, or closed.
Locked		The patient, visit, form, or item has been locked and cannot be modified.
Signed at parent level		An object at a higher level in the object hierarchy has been signed (for example, the visit in which a form appears has been signed). The design of your study determines whether a visit, form, or item that is signed at a higher level in the object hierarchy can be considered signed itself.
Query Status		
Open Query		Awaiting a response from a site user; typically an investigator or clinical research coordinator.

Status	Icon	Description
Approved Query		Query response was approved by a sponsor user. A site user entered the expected response to the automatic query (considered closed).
Candidate Query		A sponsor user issued a manual query visible only to sponsor users. May be reissued as an Open query.
Deleted Query		A sponsor user deleted a manual query.
Answered Query		Received a response from a site user. Awaiting review by a sponsor user.
Closed Query		The query has been manually closed.

User-applied query, review, and status icons

After selecting a patient, visit, form, or item, use the icons in the lower right corner to work with queries, track reviews, or change the status. You can also access these icons from the navigation pane on forms.

Note: These actions may be applied to any object with any status except Locked.

Applying an icon to a higher-level component changes the status of the components below it, including repeating sections. For example, if you freeze a visit, all the forms within the visit are also frozen.

Note: eSignatures are not propagated to other levels of the hierarchy; that is, the signatures at different levels are completely independent of each other. The audit trail reflects this independence. Additionally, if you make a change to a repeating section of a signed form, the status of the form changes to Unsigned.

Action	Icon	Description
Query-related		
Create a query		Issue a manual or candidate query about the patient, visit, form, or item.
Respond to a query		Display the selected queries on the Query List page and answer the queries on the Answer tab.
Modify a query		Open the selected query in the Detail section of the Query List and change the status. If you apply the status at the form level and there are multiple queries associated with the form, the Query List page appears.
Approve a query		Review an answered query and change the status to Approved.
Reissue a query		Reject the answer to a query and reopen the query.
Close a query		Mark a query as closed.
Delete a Candidate query		Visible only to sponsor users, use this icon to delete a candidate query.
Review-related		
Unmark DM Reviewed, Mark DM Reviewed		Unmark or mark a visit, form, or item DM Reviewed. DM Reviewed indicates that the data entries have been reviewed by a clinical data manager. Changing the data automatically activates the Unmark status.

Action	Icon	Description
Unmark SDV , Mark SDV		Unmark or mark a visit, form, or item SDV (Source Document Verification) Reviewed. SDV review indicates that the data has been reviewed against the source data. Changing the data automatically activates the Unmark status.
Remove Remote Review, Mark for Remote Review		Mark a visit, form, or item reviewed remotely, or remove the remove review mark. In a remote review, the data manager or monitor checks the data for completeness away from the site. Data is not checked against source documents. Changing the data automatically activates the Unmark status.
Unsign, Sign		Unsign or sign the selected patient, visit, form, or item. The OutcomeLogix application automatically requests authentication of the user. Changing the data automatically activates the Unsign status.
Status-related		
Unfreeze, Freeze		Unfreeze or freeze the patient, visit, form, or item. Frozen data has been reviewed and cannot be modified at this time; however, queries can be opened, answered, or closed while the data is frozen. Depending on the result of the data change from a query, the automatic system form statuses update accordingly. In addition, manual form statuses can be applied while in a frozen status. You can modify the data only through the Queries List page or the Query Detail dialog box.
Unlock, Lock		Unlock or lock the patient, visit, or form. No further modification to the data is permitted.

About electronic signatures

According to 21 CFR Part 11, which regulates electronic records and electronic signatures, each electronic signature must be unique to one individual and cannot be reused by, or reassigned to, anyone else. The OutcomeLogix application authenticates each user and patient signature, comprising a user name and password, to ensure that each is unique and associated with a valid account.

Password rules (on page 64) define the number of invalid attempts at entering a user name/password combination before the application locks the account, logs out the user, and forces the user to change the password at the next sign-in.

Depending on the study design, both site users and patients provide electronic signatures on the ICD page.

- If the currently signed-in user or patient enters an invalid user name/password combination, after the number of attempts exceeds the configured maximum number of allowed attempts, the application locks the user account and logs the user out, forcing the user to change the password at the next sign-in.
- If a user or patient who is not currently signed in enters an invalid user name/password combination, the application clears out the incorrect User Name and Password fields and displays a message for the user to try again.
- If a user or patient who is not currently signed in exceeds the number of permitted attempts, the application:
  - Issues a message asking the user or patient to change the password and try again.
  - Closes the ICD page.
  - Locks the user or patient account, forcing the user or patient to change the password at the next sign-in.

Note: If a user or patient is not signed in and becomes locked out while attempting to co-sign the ICD signature page in the session of the currently signed-in user or patient, the application does not log out the currently signed-in user or patient.

Signatures and the OutcomeLogix object hierarchy

- **Signing**—When you sign a patient, visit, form, or item, only that object becomes signed. For example, when you sign a visit, the status of the visit becomes **Signed**, but the status of the forms in the visit does not. Instead, the objects receive the status **Signed at parent level**.

  The design of your study determines whether objects with signed parent objects can be considered signed themselves.

  - If the study allows implicit signing of child objects by signing the parent object, any objects with the **Signed at parent level** status are considered signed.
  - If the study requires explicit signatures on all levels, any objects with the **Signed at parent level** status still need to be signed explicitly.

- **Unsigning**—When you unsign a visit, form, or item, any parent objects are unsigned as well. For example, if a visit and form are both signed and you unsign the form, the visit becomes unsigned.

  Unsigning does not affect objects on the same level. For example, if a visit and two of its forms are signed, unsigning one of the forms unsigns the visit but does not affect the status of the other form.

- **Signature invalidation**—A signature is invalidated if any data is changed in the signed object, and the status of the object becomes **Unsigned**. Any parent objects become **Unsigned** as well. For example, if the value of a signed item changes in a signed form and visit, the status of the item, form, and visit becomes **Unsigned**.

Starting and managing visits

Viewing the Patient List

The Patient List displays the status of forms and visits for each patient, provides navigation to a specific patient visit, and provides links to the Patient Transfer History page, Patient Summary page, and Patient Profile page.

1 Select **Patients** ().

The Patient List page appears.

Because the OutcomeLogix application retains the search filters you set previously, the patient list might appear incomplete.

2 To clear the search criteria, click **Clear Filters**.

All patients appear.

For more information, see *Patient List page* (on page 89).

Selecting a patient

There are several ways to find and select a patient from the *Patient List page* (on page 89).

- **Scroll the list**—Use the page controls:
  - To display a specific page, select it from the **Page** drop-down list.
  - To change the number of rows displayed, select a different number from the **Records per Page** drop-down list.
  - To move between pages, use the **First Page** (**|<**), **Last Page** (**>|**), **Previous Page** (**<**), and **Next Page** (**>**) buttons.
- **Search drop-down lists**—Create your search as follows:
  1 From the first **Search** drop-down list, select a **patient status** or leave blank to include all statuses.
  2 From the second **Search** drop-down list, select whether to search by Patient List, Site Name, or Patient ID.
  3 Do one of the following:
    - To search by **Patient List**, from the third **Search** drop-down list, select the patient.
    - To search by **Patient ID**, from the third **Search** drop-down list, type some or all of the Patient ID, with or without leading zeros, or leave the null value to include all patients. The application sorts the records in ascending order by creation date. This choice may result in the retrieval of multiple patient records.
    - To search by **Site Name**, from the third **Search** drop-down list, select a specific site. If you make no selection, the application includes patients for all sites.
  4 From the fourth **Search** drop-down list, select whether the **number of ePRO sessions** is greater than 0 to include patients with ePRO sessions (patient diaries).

5 To the right of the drop-down list, click **Submit** ( ).

- **Identify the patients with visits scheduled today**—Sort the **Next Visit Date** column in descending order (click the column heading).

After you have displayed the patient record:

- To select a visit or form, click **Summary**.
- To view the patient profile, click **Profile**.
- To open the next scheduled visit, click the value in the **Visit Name** column.
- To view another patient record, from the **Patient ID** drop-down list select the **previous link** (**<<**) or the **next link** (**>>**) to view the previous or next patient.

Selecting a visit or form

You can navigate to visits and forms from the Patient List page, Patient Summary page, and navigation pane from an open visit or form.

To display the next scheduled visit:

1 Select **Patients** ( ).

The Patient List page appears.

2 *Locate the patient* (on page 112).

3 In the **Visit Name** column, select the **Visit Name** link.

Depending on the design of your study, the OutcomeLogix application displays the first form for the visit or the Visit Landing page appears. If the Visit Landing page appears, you must *complete the page* (on page 117) or you are not allowed to enter patient data. The forms are read-only.

Note: The selected visit is highlighted in the navigation pane at the left and has been expanded to list the forms that comprise the visit.

To navigate to a specific visit or form:

1 Select **Patients** ( ).

The Patient List page appears.

2 Click the **Summary** link for the patient.

The Patient Summary page appears.

3 To navigate to a specific visit, click a **Visit** link.

or

To navigate to a specific form:

a Expand a visit by clicking the **arrow** to the left of the visit.

b Click the form name.

To display other visits or forms from an open visit or form:

After opening a visit or form, you can:

- Select another form within the visit from the navigation pane.
- Select another visit from the navigation pane to expand it and select a form.

Starting a visit from the Visit Landing page

If your study has been designed to display the Visit Landing page at the start of each visit, the Visit Landing page appears when you select a visit from the Patient List page or a visit or a form from the Patient Summary page. The Visit Landing page might also appear during patient enrollment after you and the patient sign the Informed Consent Document. You record the date and time of the visit on the Visit Landing page.

1 Select **Patients** ().

The Patient List page appears.

2 *Locate the patient* (on page 112).

3 Click the **Summary** link for the patient.

The Patient Summary page appears.

4 *Select a visit or form* (on page 113).

5 If a Visit Landing page has been designed for your study, you must complete the Visit Landing page before you can enter patient data. The forms are read-only until you complete the Visit Landing page.

a Fill in the fields as necessary. You must enter the date and time of the actual visit. For more information, see *Visit Landing page* (on page 117).

b Click **Submit**.

The first form in the visit appears for entry. To display a different form, click the form name in the navigation pane on the left.

Viewing the patient profile from a form

From any EDC form, you can display the Patient Profile page for the selected patient, if you are allowed to view patient profiles.

- On the navigation pane, click the **Patient Profile** link.

The Patient Profile page appears.

Note: If you do not have permission to view patient profiles, the button does not appear.

Adding an unscheduled visit

If an additional visit needs to take place, for example, to perform repeat assessments, then you can create an unscheduled visit to collect this information. You cannot delete unscheduled visits.

1 Select **Patients** ().

The Patient List page appears.

2 In the Visit Name column, click the **Visit** link for the patient.

The Visit Landing page or the first form within the selected visit appears.

3 In the navigation pane, click **Create Unscheduled Visit**.

The Unscheduled Visit page appears.

4 Fill in the fields as necessary. For more information, see *Unscheduled Visit page* (on page 119).

5 Click **Submit**.

The unscheduled visit is added to the patient visit list displayed in the navigation pane and on the Patient Summary page.

Adding a repeating visit

A repeating visit is a scheduled visit that occurs multiple times.

1 Select **Patients** ().

The Patient List page appears.

2 In the Visit Name column, click the **Visit** link for the patient.

The Visit Landing page or the first form within the selected visit appears.

3 In the navigation pane, click **Create Repeating Visit**.

The Repeating Visit page appears.

4 From the **Repeating Visit** drop-down list, select the repeating visit.

5 Optionally, if your study permits it, in the **Visit Name** field, update the name of the repeating visit instance.

6 Click **Submit**.

The repeating visit is added to the patient visit list displayed in the navigation pane and on the Patient Summary page, following the original visit.

Selecting a different patient during a visit

When you have a visit open, you can open a visit for another patient without returning to the Patient List page.

1 On the navigation pane, select the patient from the **Patient ID** drop-down list.

2 If prompted, confirm that you want to open a new page by clicking **OK**.

If the requested patient's visit has the form that form appears. Navigation involving repeating

forms or visits is more complicated.

- If you navigate from a repeating form, the application navigates to the base repeating form, rather than to a specific form.
- If you navigate from a repeating visit, the application navigates to the matching instance; for example, if the form is part of the third instance of the visit, the application opens the third instance of the form for the selected patient.
- If it is an unscheduled visit, the application navigates between unscheduled visits if the user-assigned names for the visits are identical.
- If the application cannot find a matching form, because there is no matching visit, the visit is inactive, or the form is unavailable, the application navigates to the Visit 1 Visit Landing page or the first form in Visit 1.

Tracking missed visits

If your study has been designed to track missed visits, you mark a visit as Missed on the Visit Landing page. Missed visits appear with an (M) to their right on the Patient Summary page and in visit lists.

To mark a visit as missed:

1 Select **Patients** ().

The Patient List page appears.

2 In the Visit Name column, click the **Visit** link for the patient.

The Visit Landing page or the first form within the selected visit appears.

Notice that the visit displayed is the next scheduled visit. You can select a different visit to mark as Missed by clicking it in the navigation pane. Typically, you would not mark Visit 1 as missed.

3 Select the **Missed Visited** checkbox.

4 Click **Submit**.

In the navigation pane, missed visits appear with an (M) to their right.

To view missed patient visits:

1 Select **Patients** ().

The Patient List page appears.

2 Click the **Summary** link for the patient.

The Patient Summary page appears.

In the Visits column, missed visits appear with an (M) to their right.

To reschedule a missed visit, see *Adding an unscheduled visit* (on page 115).

Visit Landing page

The following tasks use this page:

- *Selecting a visit or form* (on page 113)
- *Starting a visit from the Visit Landing page* (on page 114)
- *Viewing the patient profile from a form* (on page 114)
- *Adding an unscheduled visit* (on page 115)
- *Adding a repeating visit* (on page 115)
- *Selecting a different patient during a visit* (on page 115)
- *Tracking missed visits* (on page 116)
- *Viewing the audit trail for a visit or form* (on page 131)

To view a job aid that you can print, see:

- Quick Reference: Working with patient data.

Note: If a Visit Landing page has been designed for your study, you must complete the Visit Landing page before you can enter patient data. The forms are read-only until you complete the Visit Landing page.

Field	Description	Note
Missed Visit checkbox	Marks a visit as Missed (M).	Marks all forms for the missed visit as inactive. Appears post-Visit 1.
Expected Visit Date	Date scheduled for the visit when a new patient is enrolled.	Read-only. Appears post-Visit 1.
Scheduled Visit Date	Date that was originally scheduled for the visit.	After a visit is completed, the OutcomeLogix application calculates the next visit date, which then appears as the Scheduled Visit Date. Appears post-Visit 1.
Actual Visit Date	Date and time you started the current visit.	Typically, this is today's date and time.
Discontinue button	Ends the visit and removes the patient from the study.	The patient becomes inactive but is not removed from the site. Available starting with the second visit.
Audit Trail button ()	Displays changes made to the fields on the Visit Landing page and the audit trail for signatures on forms.	

Field	Description	Note
Action buttons and Status and Review icons	Action buttons appear in the lower right corner of the page and perform the selected action on the page. Status and Review icons appear in the page title bar and the lower left corner of the page and show any *system- or user-applied statuses* (on page 106) applied to the visit.	

Unscheduled Visit page

The following task uses this page:

- *Adding an unscheduled visit* (on page 115)

Field	Description	Note
Visit Name	Name for the unscheduled visit.	Required. Name cannot contain punctuation or special characters.
Actual Visit Date	The date of the unscheduled visit.	Required.
EDC tab	If you are scheduling an onsite visit, click to display the EDC Forms Library.	
ePRO tab	If you are scheduling an ePRO session, click to display the ePRO Forms Library.	
Available Forms	Forms you can select for the unscheduled visit.	
Selected Forms	Forms you have selected for the unscheduled visit.	Depending on how your study was set up, forms may appear in the Selected Forms list automatically.
Buttons		
Add>	Adds the selected forms to the Selected Forms list.	
Add All >>	Adds all the available forms to the Selected Forms list.	
<Remove	Removes the selected forms from the Selected Forms list.	
<<Remove All	Removes all the forms from the Selected forms list.	

Working with forms

Who can enter data into a form?

Federal regulations and data protection laws in different countries require that access to personal information be restricted. Access to patient confidential information is also restricted. Therefore, your study is set up so that only specific users, such as investigators, clinical research coordinators, and patients, can enter patient data.

- **Site users**—A site user enters information into the OutcomeLogix application based on data obtained from patient visits to a clinical site. Site users could be investigators, nurses, Clinical Research Coordinators, or clinical technicians.
- **Patients**—A patient logs in to the study website and answers questions. The answers are entered into the OutcomeLogix application as patient diaries, which can be viewed by site users with the appropriate rights.

Form types

You use forms to enter, correct, and update data for patient visits. These forms are all electronic and can be entered onsite by site users, who complete Electronic Data Capture (EDC) forms, or over the Internet by patients completing Electronic Patient-Reported Outcome (ePRO) forms.

When you edit EDC forms, the changes appear in the *audit trail for the form* (on page 131). Because patient responses to ePRO forms are entered only once and cannot be edited by site users, there is no audit trail for ePRO forms.

Your study might contain several different form types.

Form type	Description
Flat	Most OutcomeLogix forms are flat forms. Each completed flat form becomes one record in a database file.
Dynamic	Used to customize the items in the form based on a particular field entry. For example, questions regarding pregnancy might appear only on forms administered to female patients. When the patient enters the gender, the form refreshes with the dynamically generated questions.
Patient diaries	Patient-entered ePRO forms viewable by users with appropriate permissions. See *Reviewing patient diaries* (on page 136).
Repeating	Used to collect the same data at each visit or complete multiple instances of the same form. Also known as a log form.
Adverse Event	Specific repeating form that tracks adverse reactions.

Form type	Description
Repeating sections	When a patient response can include multiple entries; for example, symptom reported, a form has repeating sections. Depending on the study design, the user adds the sections as needed or the study has predefined a set number of repeating sections. When opened, repeating sections appear in EDC and ePRO forms with a border around the section.

Form navigation

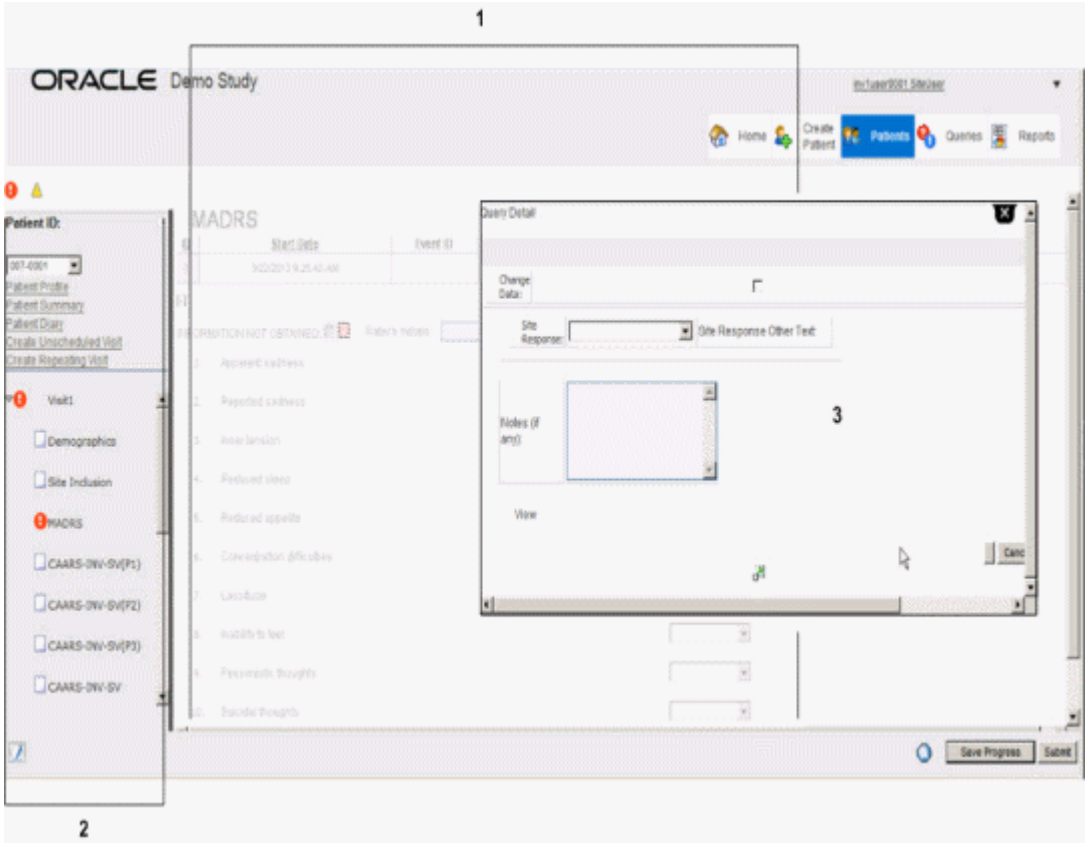
The OutcomeLogix application captures patient data in forms designed by the sponsor organization and completed by site users, Call Center staff, and patients. Pages displaying forms within the OutcomeLogix application contain the following areas:

1 Form

2 Navigation pane

3 Query Detail dialog box

OutcomeLogix form navigation



1 Form

Each form appears in the main section of the page.

OutcomeLogix form navigation

2 **Navigation pane**

When viewing a form, to the left of a form is the navigation pane consisting of a Patient ID drop-down list, links to other OutcomeLogix functions, and a visit tree.

- To expand a visit to view the forms within the visit, click the down-arrow to the left of the visit.
- To select visits and forms for a different patient, select the patient from the **Patient ID** drop-down list.
- To display information about the selected patient, click the **Patient Profile** link.
- To return to the Patient Summary page, click the **Patient Summary** link.
- To display ePRO forms completed by the patient, click the **Patient Diary** link.
- To create a visit, click the **Create Unscheduled Visit** link.
- To create a repeating visit, click the **Create Repeating Visit** link.

3 **Query Detail dialog box**

To act on a query while reviewing a form, click the **Query status** icon. The Query Detail dialog box appears.

Note: If you do not have the appropriate permissions, links do not appear. For example, if you do not have permission to create unscheduled visits, the Create Unscheduled Visit link does not appear.

Entering and editing data on a form

If you have the rights to enter data, you can also edit data that has been entered into a form. However, you cannot edit an ePRO form; that is, a form completed by a patient. When you change entries on a form, you are prompted to provide a reason for changing the data. The change and the reason are documented in the audit trail.

To exit a form or log out of the OutcomeLogix application, leaving a form partially completed, click **Save Only** to save the data. If you submit a form without making changes, the application confirms that no changes were made.

To view the form:

1 Select **Patients** ().

The Patient List page appears.

2 Click the **Summary** link for the patient.

The Patient Summary page appears.

3 Expand a visit by clicking the **arrow** to the left of the visit.

4 Click the form name.

The form appears.

To enter data on a form:

1 *Select the form* (on page 113).

2 Fill in the fields as necessary.

3 Click **Submit**.

or

Click **Save Only** to save the data you have entered without submitting the form. You can return to the form later, complete it, and submit it.

To add another instance of a form:

You can add any number of instances.

1 *Select the log form* (on page 113).

2 Click **Add Form**.

The Add Form button appears only for log forms.

3 Fill in the fields as necessary.

4 Click **Submit**.

The application adds the form to the visit, as shown in the grid at the top of the page. The added form also appears on the Patient Summary page within the visit to which you added it.

To edit data on a form:

1 *Select the form* (on page 113).

2 Edit the fields as necessary.

3 Click **Submit**.

The Reason for Change dialog box appears, displaying each form item changed.

4 For each item, select the reason you changed the field value from the **Reason** drop-down list. If you select **Other** from the **Reason** drop-down list, type the reason in the **Response** text box.

or

Apply the same reason to all items changed:

a From the **Group RFC** drop-down list, select the reason for change.

b If you selected **Other** from the **Reason** drop-down list, type the reason in the **Response** text box.

c Click the **Apply All** link.

5 Click **Submit**.

Your changes are made to the form and added to the audit trail for the form. For more information, see *Viewing the audit trail for a visit or form* (on page 131).

Note: This procedure applies only to EDC forms. You cannot edit ePRO forms.

Saving your changes without submitting the form

The **Save Only** button, which appears next to the **Submit** button on forms, allows users entering data on an EDC or ePRO form to save their changes to the form without executing any validations on the form. It appears on a form when the following are true:

1 The study design has enabled the **Save Only** button.

2 The user has the ability to submit patient data.

3 The form has never been submitted.

A user may use the **Save Only** button an unlimited number of times prior to submitting the form as complete. A form in the Save Only state is still eligible for all operations performed on a blank or completed form, including manual status changes and manual queries. Additionally, the application includes the saved data in reports and data exports.

Once a form has entered the Complete status, by being submitted (even if queries apply to the form), the **Save Only** button is disabled.

Entering multiple responses to an item

Some items in forms include the option to enter multiple responses; for example, if the patient has multiple diagnoses or has completed multiple procedures. If a form has been set up to allow multiple responses, an **Add** button appears opposite the title of the repeating section, which is outlined in green on the form.

1 Select **Patients** ().

The Patient List page appears.

2 Click the **Summary** link for the patient.

The Patient Summary page appears.

3 Expand a visit by clicking the **arrow** to the left of the visit.

4 Expand a form to show its items by clicking the **arrow** to the left of the form.

Instances of repeating sections in the form appear in descending order by creation date.

5 Click the form name.

The form appears.

6 Select the **Add** button to the right of the repeating section title.

The part of the form containing the repeating section refreshes, the repeated section appears below the first section, and the form scrolls to the top of the new repeating section.

7 Enter data into the repeating section.

8 Click **Submit**.

The status icon in the Form Status column of the repeating section grid changes to reflect the status of the repeating section. Data export includes the status of the repeating sections. For more information, see *form and query statuses* (on page 106) and *query, review, and status icons* (on page 108).

All repeating sections remain open unless you specifically collapse them.

Note: Depending on your study design, the number of times you can add a repeating section may be limited.

Uploading an image to a form

If a form is designed to allow it, you can upload an image to the form. The maximum file size is 20 MB, and the following file formats are supported:

- BMP
- GIF
- JPEG
- JPG
- PNG

1 Select **Patients** ().

The Patient List page appears.

2 Click the **Summary** link for the patient.

The Patient Summary page appears.

3 Expand a visit by clicking the **arrow** to the left of the visit.

4 Click the form name.

5 In the field that supports uploading an image, click **Upload**.

6 Browse to the image file.

7 Select the image file and click **Open**.

The picture appears in the form.

Reporting a Major Medical Event

Serious or Major Medical Events can be reported in different ways, depending on the study requirements. For example, sites may enter data into EDC forms, or patients or call centers complete specific Major Medical Event forms set up in the study.

As a Call Center staff member, you can help a patient to report a Major Medical Event by accessing the Call Center. For more information, see *Reporting a Major Medical Event in the Call Center* (on page 253).

As a patient in a study that collects patient-entered data, you can report a Major Medical Event by logging in to your ePRO account. A Submit Major Medical Event button appears on every ePRO form and the Dashboard.

Data validation

During data entry, the OutcomeLogix application validates the information entered and might require you to change your entries before you can navigate to another form. The following scenarios are possible:

1 The validation check identifies errors that must be corrected before the submitted form can be accepted; for example, incorrect formats for an email address or phone number, or passwords that do not match. You cannot continue to another form unless you correct these errors.

2 The validation check identifies errors that must be corrected but allows you to override the error and submit the form. If the application issues a query about the entry, you can correct it later.

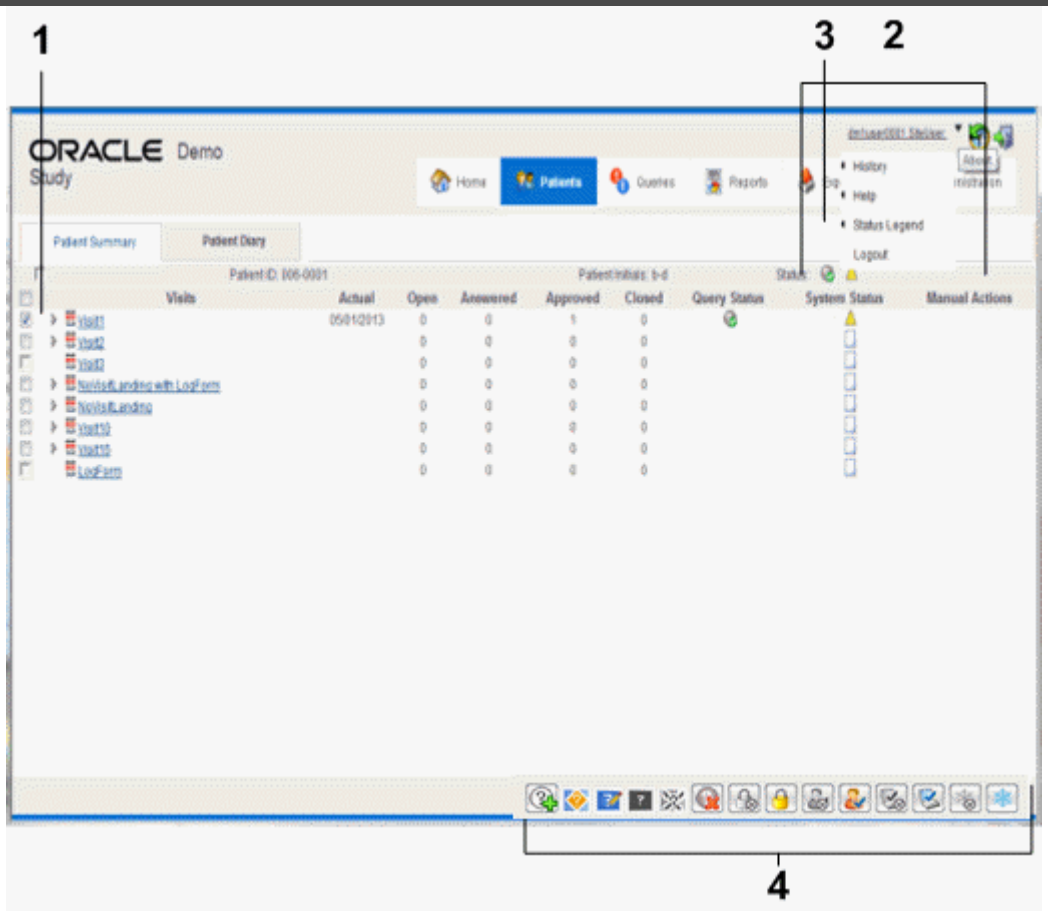
3 The validation check issues queries for items when you submit the form and displays an Open Query status icon ( ) next to the items. These automatic queries usually occur when an entered value falls outside the expected range. The presence of these queries does not prohibit you from moving forward to the next form.

- To reveal the issue, point to the query.
- To display the query in the Query Detail window and make changes without leaving the form, click the Open Query status icon ( ).
- To see how many open, answered, and closed queries have been issued for a patient, click the **Patient Summary** link in the navigation pane. For more information, see *Patient Summary page* (on page 79).
- To answer, approve, and close queries, click the **Queries** navigation icon ( ) to open the *Query List page* (on page 146).

Working with patient, visit, form, and item statuses

On the *Patient Summary page* (on page 79), you can see the status of each patient, visit, form, and item within a form.

Patient, visit, form, and item statuses



1 Arrows

Appear on the visit and form levels. Use to expand a visit and view a list of the forms within the visit and the items within the forms.

2 Status icons

Appear at the patient, visit, form, and item levels and include system and manual status icons. When a status icon appears at the top of a form, it applies to the whole visit, not just the form displayed.

3 Status Legend

To view the status icons and their meanings for forms and queries, click the down arrow in the upper right corner, and then click **Status Legend**.

4 Status and Review icons

Use after selecting a patient, visit, form, or item to change the status or track review. The active icons are determined by the rights assigned to your role.

Applying a status to a patient, visit, or form

1 Select **Patients** ().

The Patient List page appears.

2 Click the **Summary** link for the patient.

The Patient Summary page appears.

The statuses you can apply to patients, visits, forms, and items appear as icons at the bottom right of the page. Your role and rights determine the actions you can perform and the icons you see.

3 Select the checkbox to the left of the patient, visit, form, or item.

4 Click the icon corresponding to the status to apply.

The status icon appears in the Manual Actions column opposite the visit, form, or item to which it was applied.

For a description of each icon and status, see *Query, review, and status icons* (on page 108).

Freezing and unfreezing data on the patient, visit, form, or item level

A user with the appropriate rights can freeze or unfreeze patients, visits, forms, and items with any status except Locked. Freezing prevents changes in data—either temporarily, during a study, or permanently, at the end of a study. Updates can occur, however, via automatic or manual queries.

- Freezing a patient freezes all visits, forms, and items for that patient.
- Freezing a visit freezes all forms and items within the visit.
- Freezing a form freezes all items on a form.

After a patient, visit, form, or item is frozen, you cannot update the data, but you can issue manual queries for data items and respond to queries. If a repeating form is frozen, no new forms can be added to a visit. You can unfreeze any patient, visit, form, or item with a frozen status.

If you freeze all the repeating sections and freeze the form, you are prevented from adding new repeating sections. If you freeze the repeating sections, but do not freeze the form, you can still add repeating sections but cannot change anything in the frozen sections.

Note: A response to a manual query on a frozen item does not remove the frozen status of the item. The frozen status remains intact to prevent additional updates to the item without query generation.

To freeze data on the patient, visit, form, or item level:

1 Select **Patients** ().

The Patient List page appears.

2 Click the **Summary** link for the patient.

The Patient Summary page appears.

3 Select the checkbox to the left of the patient, visit, form, or item.

4 Click the **Freeze** icon ( ).

To unfreeze data on the patient, visit, form, or item level:

1 Select **Patients** ( ).

The Patient List page appears.

2 Click the **Summary** link for the patient.

The Patient Summary page appears.

3 Select the checkbox to the left of the frozen patient, visit, form, or item.

4 Click the **Unfreeze** icon ( ).

Locking and unlocking data on the patient, visit, form, or item level

A user with the appropriate rights can lock or unlock patients, visits, forms, and items. Locking, like freezing, prevents changes in data—either temporarily, during a study, or permanently, at the end of a study. Locked patients, visits, and forms cannot be signed.

- Locking a patient locks all visits, forms, and items for that patient.
- Locking a visit locks all forms and items within the visit.
- Locking a form locks all items on a form.

After a patient, visit, form, or item is locked, you cannot change the data or issue a query on the data. If a repeating form is locked, no new forms can be added to a visit.

If you lock all the repeating sections and lock the form, you are prevented from adding new repeating sections. If you lock the repeating sections, but do not lock the form, you can still add repeating sections but cannot change anything in the locked sections.

To lock data on the patient, visit, form, or item level:

1 Select **Patients** ( ).

The Patient List page appears.

2 Click the **Summary** link for the patient.

The Patient Summary page appears.

3 Select the checkbox to the left of the patient, visit, form, or item.

4 Click the **Lock** icon ( ).

To unlock data on the patient, visit, form, or item level:

1 Select **Patients** ( ).

The Patient List page appears.

2 Click the **Summary** link for the patient.

The Patient Summary page appears.

3 Select the checkbox to the left of the locked patient, visit, form, or item.

4 Click the **Unlock** icon ().

Signing and unsigning at the patient, visit, form, and item levels

A user with the appropriate rights—typically, an investigator or clinical research coordinator—signs each item and form after all corrections have been made, signs each visit after all the forms in the visit have been signed, and signs a patient after the visits have been signed.

Note: By default, signatures at each level are independent of each other. For more information, see *Signatures and the OutcomeLogix object hierarchy* (on page 111). However, when you sign a patient, visit, or form, the status Signed as Parent is assigned to repeating sections.

Unsigning a visit, form, or item indicates that the data entry is no longer considered complete. You can sign frozen forms, but you cannot sign locked forms. If you change data when you respond to a query or update the form, you must re-sign the visit, form, or item.

A signing history also appears on the *Audit Trail page* (on page 28).

To sign a patient, visit, form, or item:

1 Select **Patients** ().

The Patient List page appears.

2 Click the **Summary** link for the patient.

The Patient Summary page appears.

3 Select the checkbox to the left of the patient, visit, form, or item.

4 Click the **Sign** icon ().

A window opens for you to attest to the accuracy and completeness of the data.

5 From the **Reason** drop-down list, select the reason for your signature. If you selected **Other** as the reason, type an explanation in the **Reason** text box.

6 Type your **User Name**.

7 Type your **Password**.

8 Click **Submit**.

The OutcomeLogix application displays the Signed status icon in the Status column for the signed patient, visit, form, or item.

Note: Alternatively, you can sign a form after you enter the data into the form by selecting the Sign () icon and following steps 5 – 8.

To unsign a patient, visit, form, or item:

1 Select **Patients** ().

The Patient List page appears.

2 Click the **Summary** link for the patient.

The Patient Summary page appears.

Signed items have a Signed icon in the Status column.

3 Click the **checkbox** to the left of the signed patient, visit, form, or item.

4 Click the **Unsign** icon ( ).

The OutcomeLogix application removes the Signed status icon from the selected patient, visit, form, or item.

Note: Oracle recommends that you do not sign a form, visit, or patient until all data is complete, source verification is performed, and all queries are resolved.

Viewing the audit trail for a visit or form

The audit trails for visits and forms are accessible to users at all times. The Audit Trail button appears on every page. You can also view the audit trail covering changes to the visit and form data from the selected form.

1 Select **Patients** ( ).

The Patient List page appears.

2 Click the **Summary** link for the patient.

The Patient Summary page appears.

To view the audit trail for a visit:

1 Click a visit.

Note: A visit that has not been started; that is, has the icon in the Status section, has no values in the audit trail.

2 On the Visit Landing page or the form, click the **Audit Trail** button ( ).

The Audit Trail page for a visit appears.

3 To see the changes made to visit information, click the plus sign to the left of the item in the Field column.

or

To see all changes, click the **Show all details** link at the top of the page.

For each item the most recent change appears first.

For more information, see *Audit Trail page* (on page 28).

4 Click **Back**.

To view the audit trail for a form:

1 Expand a visit to view the forms within the visit.

2 Click a form.

The OutcomeLogix application displays the selected form.

3 Click the **Audit Trail** button ().

The Audit Trail page for a form appears.

4 To see the changes made to form information, click the plus sign to the left of the item in the Field column.

or

To see all changes, click the **Show all details** link at the top of the page.

For each item the most recent change appears first.

For more information, see *Audit Trail page* (on page 28).

5 Click **Back**.

Reviewing visits and forms

Roadmap: Reviewing at the patient, visit, form, and item level

Performing a review at the patient, visit, form, or item level is a manual process tracked on the Patient Summary page by *manually applying statuses to visits and forms* (on page 128). A sponsor user, typically the clinical data manager or medical monitor, performs this action.

Note: A reviewer can review any patient, visit, form, or item at any time, even if it is not complete.

Step	Action	Description
1	Review the data.	Data review is a manual task. *Status icons* (on page 108) appear at the patient, visit, form, and item levels to guide reviewers through the review process. 1 Select **Patients** (). 2 Click the **Summary** link for the patient. 3 In the Visits navigation tree, select the patient, visit, form, or item to review. You can select multiple checkboxes. 4 Select the status icon corresponding to the status to apply. 5 Click **Submit**.
2	Issue queries.	1 Select **Patients** (). 2 Click the **Summary** link for the patient. 3 Select the checkbox for the patient, visit, form, or item. You can select multiple checkboxes. 4 Click the **Create Query** icon (). 5 From the **Query Selection** drop-down list, select the query to issue. 6 To write your own query, select **Other** from the **Query Selection** drop-down list and type the query in the **Other Text** box. 7 Click **Submit**. **Note:** You cannot issue a query on any object in the Locked status.

Step	Action	Description
3	Mark the patient, visit, form, or item as reviewed.	1 Select **Patients** (). 2 Click the **Summary** link for the patient. 3 In the Visits navigation tree, select the patient, visit, form, or item to review. You can select multiple checkboxes. 4 Click the **Mark Reviewed** icon corresponding to the type of review.

Note: If changes are made to a form after the review is completed, the OutcomeLogix application applies the Unmarked status.

Reviewing a patient, visit, form, or item

Status icons appear at the patient, visit, form, and item levels to guide reviewers through the review process.

1 Select **Patients** ().

The Patient List page appears.

2 Click the **Summary** link for the patient.

The Patient Summary page appears.

3 In the navigation tree, select the patient, visit, form, or item to review. You can select multiple checkboxes.

4 Select the status icon corresponding to the status to apply. For more information, see *User-applied query, review, and status icons* (on page 108).

5 Click **Submit**.

- When a reviewer applies a status to a form (for example, marks a form as reviewed), the application applies the status to the repeating sections on the form even if they have not been reviewed individually.
- When a reviewer marks a form and all of the repeating sections with a certain status, the application applies the status to the entire form. If the reviewer applies the status only to the repeating sections, the overall status of the form does not change.

Marking and unmarking a patient, visit, form, or item as reviewed

Sponsor users, typically clinical data managers and medical monitors, manually review the visits, forms, and items; issue queries; and record that the visits, forms, and items have been reviewed. This approach applies to the various types of reviews supported; for example, remote review and source verification. Only patients, visits, forms, and items that have no open queries or that were left blank intentionally can be marked as reviewed.

If there is a change to the data, the reviewer can change the status to Unmarked, negating the completed review of the patient, visit, form, or item.

Because of the hierarchical nature of the OutcomeLogix application:

- If all items within a form are marked as reviewed, the form is marked as reviewed.
- If all forms within a visit have been marked as reviewed, the visit is marked as reviewed.
- If all visits are marked as reviewed, the patient is marked as reviewed.

The hierarchy works top-down as well. If you mark a patient as reviewed, the patient visits, forms, and items are marked as reviewed.

1 Select **Patients** ().

The Patient List page appears.

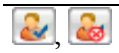
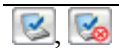
2 Click the **Summary** link for the patient.

The Patient Summary page appears.

3 Select the checkbox to the left of the patient, visit, form, or item.

4 Click the **Mark Reviewed** or **Unmark Reviewed** icon corresponding to the type of review.

The form status changes. In the case of repeating forms, the form refreshes and remains open.

Icons	Review Type
	SDV: Source Document Verification.
	DM: Reviewed by a data manager.
	Remote: Reviewed away from the site.

Reviewing patient diaries

Patient diaries are ePRO forms completed and submitted by patients and appear as diary visits that can be viewed separately. Each diary visit provides links to the forms included in that session. Repeating forms and sections are included.

For site users with viewing permissions, only diary visit sessions that have been completed are displayed, in date order, and can be filtered for viewing by week, month, or year. Site users cannot edit the ePRO forms. ePRO forms typically are not signed, frozen, or reviewed, because they contain source information entered directly by patients.

1 Select **Patients** ().

The Patient List page appears.

2 Click the **Summary** link for the patient.

The Patient Summary page appears.

3 Click the **Patient Diary** tab.

The Patient Diary page appears.

4 View the patient diaries.

a To view the forms within a visit, click the **View** link associated with the visit.

b To view the diaries for a year, month, or week, click the **Year**, **Month**, or **Week** button.

Each view provides a calendar control for browsing the diaries. For more information, see *Patient Diary page* (on page 137).

5 To view the completed form, click the form name.

Note: All forms are read-only. You cannot edit a patient diary form.

6 To return to the Patient Diary page, click **Back**.

or

To return to the Patient Summary page, click the **Patient Summary** tab.

Viewing the signing history of a visit or form

The Audit Trail page for a visit or form includes the signing history of that visit or form.

1 Display the Audit Trail page for a visit or form. For more information, see *Audit Trail page* (on page 28).

2 To see the signing history, click the plus sign to the left of **Sign Form** or **Unsign Form** in the Field column.

The most recent signature appears first.

For more information, see *Audit Trail page* (on page 28).

3 Click **Back**.

Patient Diary page

The following task uses this page:

- *Reviewing patient diaries* (on page 136)

Field	Description
Patient Diary Review	
Patient ID	Unique identifier for the patient assigned by the OutcomeLogix application.
Year button	Displays the patient forms for the current year, month by month. Months are column headings, and each column contains the forms completed that month. Click a **form** link to display the completed form. You cannot edit the form. Use the **Year** drop-down list to navigate to a different year.
Month button	Displays the calendar for the current month. The forms completed appear in the boxes for each day. Click a **form** link to display the completed form. You cannot edit the form. Use the **Year** and **Month** drop-down lists to navigate to another month.
Week button	Displays the patient forms completed day by day for the current week. Click a **form** link to display the completed form. You cannot edit the form. Use the **Year** and **Month** drop-down lists to navigate to another month. Use the **<<** and **>>** arrows to navigate to a different week.
Visit	The visits for which there are forms to review.
View link	Click the link to display the forms within a visit, the date entered, and the status of the form.
Back button	Return to the Patient Diary page.
Patient Summary tab	Return to the Patient Summary page.

CHAPTER 8

Queries

In this chapter

Working with queries 140
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Candidate queries 163

Working with queries

Managing queries

You work with and manage queries from several pages in the OutcomeLogix application:

- **Dashboard**—Displays a high-level view of key study details. The Query Status section shows the number of queries in each status (Open, Answered, Approved, Closed, Candidate, and Deleted). Click a status count to open the Query List page to view the queries that are assigned the status for the site selected. Filter the Dashboard to restrict queries to a particular site.
- **Query List page**—Displays a summary of all queries. Accessed by selecting the Queries icon () on the navigation bar, the Query List page shows the details about each query. Users tasked with answering queries or reviewing responses to queries can use the Query List page as a to-do list and can selectively view queries by ***filtering the list*** (on page 142) first or searching for a specific Query ID or Patient ID.
- **Query Detail page**—Displays details about a specific query selected in the Query List page. The Query Detail page includes an Answer tab, for responding to an open query, and a History tab, to view the history of the query.
  - Site users can answer open queries and view query history.
  - Sponsor users can view query history, review responses to queries, and change the status of queries.
- **Patient Summary page**—Displays query status icons next to patients, visits, forms, and items and provides links to answer queries and icons to update the status of the queries. You access the Patient Summary page by selecting the Patients icon () on the navigation bar and clicking the Summary link for a patient.
- **Navigation pane**—Displays the Open Query icon () to the left of the visit and form names with open queries. Any time you open a visit or form, the navigation pane appears on the left side of the page.
- **Forms**—Displays a Query Status icon to the right of every item with an answered, closed, or approved query associated with it. You can click the item to display the Query Detail window for that query. The grid summarizing the data in repeating sections with forms includes a Form Status column, which displays query status icons that apply to the repeating sections.
- **Query Detail dialog box**—Displays an abbreviated version of the Query Detail page to the right of the form, enabling you to answer the query and view the query history without leaving the form.

Query types

Queries are errors, warnings, or questions related to data that does not meet certain criteria. The OutcomeLogix application might automatically issue a query during data validation or a sponsor user, such as a clinical data manager or medical monitor, might manually create a query when reviewing a visit or form.

- **Automatic (system) query**—Issued for an item by the OutcomeLogix application when a user skips an item or submits data that does not meet certain criteria. The query appears immediately

after data submission and the user can respond to it before data review.

Data entries that trigger automatic queries are configured outside the OutcomeLogix application during study development.

For more information, see *Roadmap: Working with automatic queries* (on page 148).

- **Manual query**—Issued by a reviewer on a patient, visit, form, or item. Queries can be issued during all types of reviews; for example, remote review, source verification review, and so on. There are two types of manual queries:
  - **Open query—**Visible to all users and requires a response. For more information, see *Roadmap: Working with manual queries* (on page 149).
  - **Candidate query**—Preliminary query, issued by a sponsor user, which is visible only to other sponsor users. A sponsor user reviews the query and then reissues it as an open query or deletes it. For more information, see *Roadmap: Working with candidate queries* (on page 163).

Note: The presence of queries does not prevent you from filling in the rest of a form, but a query prevents the form, visit, or patient from being marked Complete until all queries have been answered.

Query statuses

When you issue a query for an item, the Open query status is applied to the item, the form in which the item resides, the visit containing the form, and the patient record. On the Patient Summary page, query status icons appear in the Status column, along with the visit and form statuses described in *System-applied visit and form statuses* (on page 106) and *User-applied query, review, and status icons* (on page 108). The query statuses show you at a glance the patients, visits, forms, and items with queries that must be answered or that were approved or closed automatically. You can answer queries by creating a response on the *Query Detail page* (on page 159).

On forms, query status icons for answered, closed, deleted, and approved queries appear next to the queried items. Click the query icon to open a corresponding Query Detail dialog box. For repeating sections, the query status icons appear in the Form Status column of the summary grid. Click **View** to display the form, and then click the query icon.

Status	Icon	Description	Available actions
		Open and automatic queries	
Open		Visible to all users who have the right to view queries. Awaiting a response from a site user, typically an investigator or clinical research coordinator.	*Respond to the query* (on page 153).

Status	Icon	Description	Available actions
Answered		Received a response from a site user, typically an investigator or clinical research coordinator. If the query was manually created, or the user answered an automatic query without making a change to the data, a sponsor user, typically a clinical data manager or medical monitor, must approve the response before the OutcomeLogix application will close the query.	*Approve the query* (on page 156). *Reissue the query as an open query* (on page 156). *Reissue the query as a candidate query* (on page 165).
Approved		Query response was approved by a sponsor user. or Data changes made in response to an automatic query satisfied validation checks.	None.
Closed		Query was closed manually by a sponsor user. This status is used to cancel queries that no longer need to be addressed by the site.	None.
		Candidate queries	
Candidate		Visible only to sponsor users, typically clinical data managers and medical monitors. Available for review by a sponsor user with the appropriate rights.	*Delete the query* (on page 164). *Change the query to an open query* (on page 165).
Deleted		Visible only to sponsor users, typically clinical data managers and medical monitors. Reviewed and deleted by a sponsor user with the appropriate rights.	None.

Filtering and sorting the Query List

You can search for a specific query or the queries associated with a specific patient. You can also filter the list by a number of selection criteria.

- Once the selected queries have appeared, you can sort the list based on an underlined column header.
- To clear the sort or filter, click **Clear Filters**.

For more information, see *Query List page* (on page 146).

To search for a specific query:

1 Select **Queries** ( ).

The Query List page appears.

2 In the **Query ID** text box, type the query identifier.

3 Click **Submit** ( ).

To search for queries associated with a specific patient:

1 Select **Queries** ( ).

The Query List page appears.

2 In the **Patient ID** text box, type the patient identifier.

3 Click **Submit** ( ).

To filter the queries:

1 Select **Queries** ( ).

The Query List page appears.

2 To filter the list, select a value from one or more of the drop-down lists below the associated column headers.

3 To sort the list based on a column, click an underlined column header.

Viewing queries by status or site

From the Dashboard:

1 Select **Home** ( ).

On the Dashboard, the number of queries for each status appears in the Query Status section. By default, the count includes all sites.

2 From the **Dashboard** drop-down list, select a site or **All**.

3 To clear the filter, click **Clear Filters**.

4 In the **Query Status** section, click a query status.

The Query List page appears, displaying all queries with the selected status. For more information, see *Query List page* (on page 146).

5 To clear the filter, click **Clear Filters**.

From the Query List page:

See *Filtering and sorting the Query List* (on page 142).

Note: If the number of queries for the selected status is 0, no queries appear.

Viewing queries by patient, visit, form, or item

To view queries for one or all patients at your sites:

1 Select **Patients** ().

The Patient List page appears.

The Open, Answered, and Closed columns display the number of queries with each status for each patient. These values are links.

2 To view the queries associated with a specific patient, click the **Open**, **Answered**, or **Closed** link.

The Query List page appears displaying the queries of the selected type for the selected patient.

or

To view all of the queries associated with a specific patient, click the **Summary** link.

The Patient Summary page appears. Query status icons appear on the patient, visit, form, and item levels.

To view queries on a visit, form, or item:

1 Select **Patients** ().

The Patient List page appears.

2 Click the **Summary** link for the patient.

The Patient Summary page appears.

- If queries have been made on any level, one or more query status icons, reflecting the statuses of the queries, appear in the Status field on the Patient ID line as well as in the Status column for the individual items.
- For each visit, a count appears in the Open, Answered, Approved, and Closed columns. The statuses of the queries appear in the Status columns.

3 To view the statuses of the queries associated with each form in a visit, click the arrow to the left of the visit.

The statuses appear in the Status columns.

or

To view the queries associated with the visit, click the Visit checkbox and click a query-related icon.

The Query List page appears displaying all queries associated with the visit.

4 To view the statuses of the queries associated with each item on a form, click the arrow to the left of the form.

The statuses appear in the Status columns.

5 To view the query itself, click the arrow to the left of the item.

The query text appears below the item.

Viewing the current filter for query details

When you are viewing the Query Detail page for a specific query, you can display a dialog box that lists the current filter settings that were applied on the Query List page.

1 On the Query List page, click the query.

The Query Detail page appears.

2 Click **Show Filter**.

A window appears, listing:

- Site ID
- Patient ID
- Type
- Form Name
- Visit Name
- Query Status

3 To close the window, click **OK**.

Query List page

On this page, you view queries at your sites, respond to queries, and view the history of queries.

The following tasks use this page:

- *Filtering and sorting the Query List* (on page 142)
- *Viewing queries by status or site* (on page 143)
- *Viewing queries by patient, visit, form, or item* (on page 144)
- *Issuing a manual query* (on page 150)
- *Modifying a query* (on page 152)
- *Answering a query* (on page 153)
- *Approving an answered query* (on page 156)
- *Closing a query* (on page 152)
- *Issuing a candidate query* (on page 164)
- *Deleting a candidate query* (on page 164)
- *Changing a candidate query to an open query* (on page 165)
- *Reissuing an answered query as an open query* (on page 156)
- *Reissuing an answered query as a candidate query* (on page 165)
- *Viewing the history of a query* (on page 157)
- *Viewing the notes about a query* (on page 158)

To view a job aid that you can print, see:

- Quick Reference: Working with patient data.

Field	Description
Query List > Filters	
Query ID	In the text box, type the query ID and click **Submit** ().
Patient ID	In the text box, type the patient ID and click **Submit** ().
Site Name	From the drop-down list, select from sites you have access to or **All**.
Type	From the drop-down list, select the level of the query within the hierarchy: • Item • Form • Visit • Patient • All

Field	Description
Visit Name	From the drop-down list, select a specific visit or **All**.
Form Name	From the drop-down list, select a specific form or **All**.
Status	From the drop-down list, select a query status. Can include: • Open • Answered • Approved • Closed • Candidate • Deleted • All
Query List > Columns	
Site Name	Name of the site to which the patient belongs.
Query ID	Unique identifier for the query.
Patient ID	Identifier for the patient associated with the query. The application sorts the Patient ID in ascending order by creation date.
Type	Level on which the query was created: visit, form, or item.
Visit Name	Name of the visit.
Form Name	Name of the form.
Item Text	The text of the queried question.
Query Text	Text of the query.
Status	*Status of the query* (on page 141).
Issued by	User who created the query. The author is System if the query was automatically issued.
Date	Date the query was created.

Automatic and manual queries

Roadmap: Working with automatic queries

Based on the validation rules defined for items within forms, the OutcomeLogix application automatically issues queries as you submit forms. A site user, typically an investigator or clinical research coordinator, answers automatic queries.

Step	Action	Procedure
1	The OutcomeLogix application issues an automatic query.	1 Enter data into a form. As you enter data into a form, you skip a field that requires an entry or type a value that does not conform to certain criteria. 2 Click **Submit**. The OutcomeLogix application displays an Open query status icon () next to the item and in the Status field at the top of the form.
2	Answer the query while the form is still open.	1 Enter or change the value that was queried. 2 Click **Submit**. The Reason for Change dialog box appears, displaying each form item changed. 3 For each item, select the reason you changed the field value from the **Reason** drop-down list. If you select **Other**, type the reason in the **Response** text box. or ▪ Apply the same reason to all items changed: ▪ From the **Group RFC** drop-down list, select the reason for change. If you selected **Other**, type the reason in the **Response** text box. ▪ Click the **Apply All** link. 4 Click **Submit**. The Open query status icon changes to the Approved query status icon if the response satisfies the query reason ().

Step	Action	Procedure
3	Answer automatic queries from the Query List page.	1 Select **Queries** (). The Query List page appears. 2 Select an open query that was automatically generated by clicking a field that is not underlined. ▪ The value in the Issued by column is System. The query information appears on the Query Detail page on the Answer tab. 3 On the Answer tab in the **Change Data** field, change or leave the value. 4 From the **Site Response** drop-down list, select the reason for the changed answer. 5 If you select **Other**, type the reason in the **Site Response Other Text** box. 6 Click **Submit**.

Roadmap: Working with manual queries

Users with the appropriate rights, typically clinical data managers and medical monitors, issue manual queries while reviewing visits and forms. As with automatic queries, manual queries must be answered before the visit or form can be completed.

Step	Action	Procedure
1	While reviewing a visit or form, you question a value.	1 Select **Patients** (). 2 Click the **Summary** link for the patient. 3 Expand a visit by clicking the arrow to the left of the visit name. 4 Expand a form by clicking the arrow to the left of the form name.
2	You issue a query at the patient, visit, form, or item level.	1 Select the checkbox for the patient, visit, form, or item. You can select multiple checkboxes. 2 Click the **Create Query** icon ().
3	In the dialog box, you provide a reason for the query.	1 From the **Query Selection** drop-down list, select the query to issue. 2 To write your own query, select **Other** from the **Query Selection** drop-down list and type the query in the **Other Text** box. The OutcomeLogix application displays an Open query status icon () next to the patient, visit, form, and item.

Step	Action	Procedure
4	A site user, typically an investigator or clinical research coordinator, responds to the query. The status changes to Answered.	1 Select **Queries** ( ). The Query List page appears. 2 Select an open query by clicking a field that is not underlined. The query information appears on the Query Detail page on the Answer tab. 3 In the **Change Data** field, change or leave the value. 4 From the **Site Response** drop-down list, select the reason for the changed answer. 5 If you select **Other**, type the reason in the **Site Response Other Text** box. 6 Click **Submit**.
5	You review the answer. • If satisfied, change the status to Approved. • If dissatisfied, re-issue the query. • Add a note to the query, if desired.	1 On the Query List page, select a query with Answered in the Status column. The query information appears on the Query Detail page on the Answer tab. 2 In the **Change Status** field, click **Approve** or **Re-issued as Open**. 3 If desired, add a note in the Notes text box. 4 Click **Submit**.

Issuing a manual query

You can issue a manual query on the patient, visit, form, or item level as long as the patient, visit, form, or item is unlocked. You cannot issue queries on ePRO forms.

A sponsor user, typically the clinical data manager or medical monitor, performs this action. For more information, see Query types.

Issuing a query from the Patient Summary page:

1 Select **Patients** ( ).

The Patient List page appears.

2 Click the **Summary** link for the patient.

The Patient Summary page appears.

3 Expand a visit by clicking the arrow next to the visit name.

The forms in the visit appear.

4 Expand a form by clicking the arrow next to the form name.

The items on the form appear.

5 Select the checkbox for one or more items.

6 Click the **Create Query** icon ().

7 In the dialog box, select the reason for the query from the **Query Selection** drop-down list.

If you select **Other** from the drop-down list, you must enter the reason in the **Other Text** box.

8 To create a candidate query, select the **Issue as a Candidate Query?** checkbox.

The query is visible to sponsor personnel only.

9 Click **Submit**.

An Open query status icon () appears in the Status column next to the items, the form, the visit, and the patient. If you created a candidate query, sponsor users see a Candidate query status icon ().

Issuing a query from a form:

1 Open the form. For more information, see *Entering and editing data on a form* (on page 122).

Note: The application displays a message that you have read-only privileges. This does not affect your ability to issue queries on the form or item.

2 Click the **Create Query** icon ().

A dialog box appears.

3 To create a candidate query, click the **Issue as a candidate query?** checkbox.

4 To issue a query on the form as a whole, leave the **Issue as an Item query?** checkbox unchecked.

or

To issue a query on an item within the form:

a Click the **Issue as an Item query?** checkbox.

b From the **Item Name** drop-down list, select the item.

5 Select the reason for the query from the **Query Selection** drop-down list.

If you select **Other** from the drop-down list, you must enter the reason in the **Other Text** field.

6 Click **Submit**.

If you created a query for the form, an Open query status icon appears after the **Status** field at the top of the form and next to the form name.

If you created a query for a particular item, an Open query status icon appears after the **Status** field and to the right of the item.

Note: You must have the Create Manual Query right to perform this function. For more information, see ***Roles and rights*** (on page 52).

Modifying a query

1 Select **Patients** ().

The Patient List page appears.

2 Click the **Summary** link for the patient.

The Patient Summary page appears.

3 Select the checkbox for a visit, form, or item with a query status icon associated with it.

- Expand a visit by clicking the arrow next to the visit name.

  The forms in the visit appear.

- Expand a form by clicking the arrow next to the form name.

  The items on the form appear.

4 Click **Modify Query** ().

The Query List page appears displaying the selected queries.

5 Select a manual query.

The query information appears on the Query Detail page on the Answer tab.

6 In the **Change Status** field, click an active status. Your rights determine the active statuses.

7 Click **Submit**.

The application displays a confirmation message in green type in the middle of the page.

8 To return to the Query List page, click **Back to Query List**.

or

Click **<< Previous** or **Next >>** to modify another query.

Closing a query

You can close an open or candidate query. You cannot close an automatic (system) query.

1 Select **Queries** ().

The Query List page appears.

2 Filter the queries as described in *Filtering and sorting the Query List* (on page 142).

3 Select an open or candidate query.

The query information appears on the Query Detail page on the Answer tab.

4 Click **Close**.

5 Click **Submit**.

- The application displays a confirmation message in green type in the middle of the page.
- The query status changes to Closed. For more information, see *Roadmap: Working with manual queries* (on page 149).

- The visit status and patient status revert to their statuses before the query was opened.

Answering a query

You answer queries on the Query List page or in the Query Detail dialog box. You can go directly to the Query List page and work through the list of queries, or you can start at the Patient Summary page and view the patient queries in relation to visits and forms.

- On the Patient Summary page, select the item with the query and click the **Query Response (**) icon. The Query List page appears.
- If you have a form open, you can click a query status icon to open the Query Detail dialog box and answer the query without leaving the form.

An answer to a query might involve updating the data entered or responding without changing the data because the data is correct. Site users, typically investigators and clinical research coordinators, answer queries.

The site response you select when you answer the query for the item appears on the Audit Trail page.

Answering a query from the Query List page:

1 Select **Queries** ( ).

The Query List page appears.

2 Filter the queries as described in *Filtering and sorting the Query List* (on page 142).

3 Select an open query.

The query information appears on the Query Detail page on the Answer tab.

4 In the **Change Data** field, change or leave the value.

5 From the **Site Response** drop-down list, select the reason for the changed answer.

6 If you select **Other**, type the reason in the **Site Response Other Text** box.

7 To add a note about the query, enter it in the **Notes** text box.

8 Click **Submit**.

The application displays a confirmation message in green type in the middle of the page.

If the answered query is an automatic query, its status changes to Approved, and the OutcomeLogix application removes the query from the Query List page. If the answered query is a manual query, its status changes to Answered. The reason for change appears in the Reason column of the Audit Trail page.

Note: After you answer a manual query, someone must ***approve the query*** (on page 156) or ***reissue the query*** (on page 156). A sponsor user, typically the clinical data manager or medical monitor, performs this action.

Answering a query from the Patient Summary page:

1 Select **Patients** ( ).

The Patient List page appears.

2 Click the **Summary** link for the patient.

The Patient Summary page appears.

3 Select a visit, form, or item with an open query.

a Expand a visit by clicking the **arrow** next to the visit name.

The forms in the visit appear.

b Expand a form by clicking the **arrow** next to the form name.

The items on the form appear.

c View the query associated with an item by clicking the **arrow** next to the item name.

4 Select the query by selecting the **checkbox** to the left of the item.

5 Click the **Response Query icon** ().

- If you selected a visit with an open query, the Query List page appears listing all the forms with queries within the visit.
- If you selected a form with an open query, the Query List page appears listing the queried items within the form.
- If you selected an item with an open query, the Query List page appears listing the queried item.

6 Select the query.

The query information appears on the Query Detail page on the Answer tab.

7 In the **Change Data** field, change or leave the value.

8 From the **Site Response** drop-down list, select the reason for the changed answer.

9 If you select **Other**, type the reason in the **Site Response Other Text** box.

10 To add a note about the query, enter it in the **Notes** text box.

11 Click **Submit**.

The application displays a confirmation message in green type in the middle of the page.

Answering a query from the Query Detail dialog box:

1 Open the form. For more information, see *Entering and editing data on a form* (on page 122).

2 Click an **Open query status icon (****)**. To see the query text, hover over the Open query status icon.

The Query Detail dialog box opens.

3 In the **Change Data** field, change or leave the value.

4 From the **Site Response** drop-down list, select the reason for the changed answer.

a If you select **Other**, type the reason in the **Site Response Other Text** box.

b To add a note about the query, enter it in the **Notes** text box.

5 Click **Save**.

The application updates the **Status** field at the top of the form.

6 To view the history of the query, click the **View** down arrow and click **History**. For more information, see *Viewing the history of a query* (on page 157).

7 To view the notes attached to the query, click the **View** down arrow and click **Note**.

Modifying your answer to a query

Users who have the right to answer queries can modify their answers without reissuing the query. The query must have the status Answered.

Modifying a query answer from the Query List page:

1 Select **Queries** ( ).

The Query List page appears.

2 Filter the queries as described in *Filtering and sorting the Query List* (on page 142).

3 Select a query with the status **Answered**.

The query information appears on the Query Detail page on the Answer tab.

4 On the Query Detail page, click the **Edit** button.

5 Change the query response as necessary. For more information, see *Answering a query* (on page 153).

6 Click **Submit**.

The application records the change on the Query History page and in the Audit Trail.

Modifying a query answer from a form:

1 Open the form. For more information, see *Entering and editing data on a form* (on page 122).

2 Click an **Answered query status icon** ( ). To see the query text, hover over the Answered query status icon.

The Query Detail dialog box opens.

3 Click **Edit**.

4 In the **Change Data** field, change the value.

5 From the **Site Response** drop-down list, select the reason for the changed answer.

a If you select **Other**, type the reason in the **Site Response Other Text** box.

b To add a note about the query, enter it in the **Notes** text box.

6 Click **Save**.

The application updates the **Status** field at the top of the form.

Reissuing an answered query as an open query

If you are not satisfied with the response to a query, you can reissue the answered query as an open query. You can also *reissue an answered query as a candidate query* (on page 165).

Note: You cannot reissue a query for which author is System (automatic query).

1 Select **Queries** ( ).

The Query List page appears.

2 Filter the queries as described in *Filtering and sorting the Query List* (on page 142).

3 Select an answered query.

The query information appears on the Query Detail page on the Answer tab.

4 In the **Change Status** field, click **Re-issue**.

5 Optionally, in the **Notes** text box, type an explanation of why you are reissuing the query or other information.

6 Click **Submit**.

The application displays a confirmation message in green type in the middle of the page.

The status of the query changes from Answered to Open.

Approving an answered query

After an investigator or clinical research coordinator answers a query, a sponsor user, typically the data manager or monitor, must approve it.

Approving an answered query from Query List page:

1 Select **Queries** ( ).

The Query List page appears.

2 Filter the queries as described in *Filtering and sorting the Query List* (on page 142).

3 Select an answered query.

The query information appears on the Query Detail page on the Answer tab.

4 Click **Approve**.

5 Click **Submit**.

The status changes to Approved and the OutcomeLogix application removes the query from the Query List page.

Note: You can also *reissue the answered query as an open query* (on page 156).

Approving an answered query from a form:

1 Open the form. For more information, see *Entering and editing data on a form* (on page 122).

2 Click an **Answered query status icon (**). To see the query text, hover over the Answered query status icon.

The Query Detail dialog box opens.

3 Click **Edit**.

4 In the **Change Status** field, select the **Approve** radio button.

5 To add a note about the query, enter it in the **Notes** text box.

6 Click **Save**.

The application displays a confirmation message in green type near the top of the page.

Answering or managing a query while on a form

You can answer and manage queries directly from a form. The Query Detail dialog box displays an abbreviated version of the Query Detail page to the right of a form, enabling you to answer the query and view the query history without leaving the form.

1 Display the form. For more information, see *Entering and editing data on a form* (on page 122).

2 Click the query status icon.

The Query Detail dialog box appears.

3 If you are a site user with the appropriate rights, you can answer the query or change an answer. For more information, see *Answering a query* (on page 153) and *Modifying your answer to a query* (on page 155).

or

If you are a sponsor user with the appropriate rights, you can change the status of the query by selecting **Change Status** radio button. Your role and rights assigned determine the active statuses.

4 To view the history of the query, click the **View** down arrow and click **History**. For more information, see *Viewing the history of a query* (on page 157).

5 To view the notes attached to the query, click the **View** down arrow and click **Note**.

6 Click **Save**.

Viewing the history of a query

Viewing query history from the Query List page:

1 Select **Queries** ( ).

The Query List page appears.

2 Filter the queries as described in *Filtering and sorting the Query List* (on page 142).

3 Select a query.

The query information appears on the Query Detail page on the Answer tab.

4 Select the **History** tab.

All changes to the selected item appear below the text of the query. For more information, see

Query Detail page (on page 159).

Viewing query history from a form:

1 Open the form. For more information, see *Entering and editing data on a form* (on page 122).

2 Click a query status icon. To see the query text, hover over the query status icon.

The Query Detail dialog box opens.

3 Click **View**.

4 Click **History**.

The Query History dialog box opens.

For more information, see *Query History dialog box* (on page 162).

Viewing the notes about a query

Viewing notes history from the Query List page:

1 Select **Queries** ( ).

The Query List page appears.

2 Filter the queries as described in *Filtering and sorting the Query List* (on page 142).

3 Select a query.

4 The query information appears on the Query Detail page on the Answer tab.

5 View the notes history for the query by scrolling through the **Notes History** table. You can sort by ascending and descending date.

Viewing notes history from a form:

1 Open the form. For more information, see *Entering and editing data on a form* (on page 122).

2 Click a query status icon. To see the query text, hover over the query status icon.

The Query Detail dialog box opens.

3 Click **View**.

4 Click **Note**.

The Query Notes dialog box opens.

For more information, see *Query Notes dialog box* (on page 162).

Query Detail page

On this page, you view details about a specific query, answer a query, respond to an answered query, and change the status of a query.

The following tasks use this page:

- *Issuing a manual query* (on page 150)
- *Modifying a query* (on page 152)
- *Answering a query* (on page 153)
- *Approving an answered query* (on page 156)
- *Closing a query* (on page 152)
- *Issuing a candidate query* (on page 164)
- *Deleting a candidate query* (on page 164)
- *Changing a candidate query to an open query* (on page 165)
- *Reissuing an answered query as an open query* (on page 156)
- *Reissuing an answered query as a candidate query* (on page 165)
- *Viewing the history of a query* (on page 157)
- *Viewing the notes about a query* (on page 158)

To view a job aid that you can print, see:

- Quick Reference: Working with patient data.

Field	Description
Answer tab	
Patient ID	Identifier for the patient associated with the query. Links to the Patient Summary page.
Visit Name	Name of the visit associated with the query. • The Visit Name link opens the visit.
Form Name	Name of the form associated with the query. • The Form Name link opens the form.
Query Status	Status of the query.
New Value	Current value of the item.
Old Value	Previously entered value of the item. This field is blank when the query is raised because no data was entered for the item.
Question Text	Text of the item question on the form.
Query ID	ID of the query.
Query Text	Text of the query.

Field	Description
Back to Query List **<< Previous, Next >>**	Returns to the Query List or navigates to the previous or next query that matches the filters specified on the Query List page.
Show Filter link	Displays a dialog box that lists the current filter selections on the Query List page.
Query section	
Change Data	Question label and data entry fields.
Site Response	Text of the site response to the query.
Site Response Other Text	The Site Response Other Text field contains text if the Site Response value is Other.
Notes History	• Information on each note attached to the query, including: ▪ **Date**—The Date the note was entered. ▪ **Notes**—The text of the note. ▪ **Issued By**—The user who entered the note. • Navigation controls for viewing the notes history. • Notes text box to add a note.
Change status	Actions you can select that occur after you click Submit. In the sponsor view, the radio control selections depend on your rights and the current status of the query. In the site view, only the Submit button is active.
History tab	
Query ID	ID of the query.
Date (GMT)	Date that the change action on the query occurred, in GMT.
Issued By	User who initiated the change to the query.
Change Event	Type of change action.
Notes	Text of the query, query response, or comment.
Show Filter button	Displays a dialog box that lists the current filter selections on the Query List page.

Query Detail dialog box

You can answer and manage queries directly from a form. The Query Detail dialog box displays an abbreviated version of the Query Detail page to the right of a form, enabling you to answer the query and view the query history without leaving the form.

The following tasks use this page:

- *Issuing a manual query* (on page 150)
- *Answering a query* (on page 153)
- *Modifying your answer to a query* (on page 155)
- *Approving an answered query* (on page 156)
- *Closing a query* (on page 152)
- *Viewing the history of a query* (on page 157)
- *Viewing the notes about a query* (on page 158)

To view a job aid that you can print, see:

- Quick Reference: Working with patient data.

Field	Description
Query Text section	
Change Data	Question label and data entry fields.
Site Response	Text of the site response to the query.
Site Response Other Text	Contains text if the Site Response value is Other.
Notes (if any)	Text box to enter notes.
Change status	Actions you can select that occur after you click **Submit**. In the sponsor view, the radio control selections depend on your rights and the current status of the query. In the site view, only the Submit button is active.
View down arrow	Displays **History** link to display Query History dialog box and **Note** link to display Notes History dialog box.
Navigation Controls	
Edit button	Allows users with appropriate rights to edit the query answer, enter a note, or change the query status.
Save button	Saves the changes made to the query.
Cancel button	Closes the Query Detail dialog box without saving the change.
Click Here to Drag! link	Click the link and hold down the mouse button to reposition the Query Detail dialog box.

Query History dialog box

This dialog box, opened from the *Query Detail* (on page 161) dialog box, shows the history of a specific query.

The following tasks use this page:

- *Answering or managing a query while on a form* (on page 157)
- *Viewing the history of a query* (on page 157)

To view a job aid that you can print, see:

- Quick Reference: Working with patient data.

Field	Description
Query ID	ID of the query.
Issued By	User who initiated the change to the query.
Date (GMT)	Date that the change action on the query occurred, in GMT.
Change Event	Type of change action.
Notes	Text of the query, query response, or comment.

Query Notes dialog box

This dialog box, opened from the *Query Detail dialog box* (on page 161), shows the notes attached to a specific query.

The following tasks use this page:

- *Answering or managing a query while on a form* (on page 157)
- *Viewing the notes about a query* (on page 158)

To view a job aid that you can print, see:

- Quick Reference: Working with patient data.

Field	Description
Answer tab	
Date	Date the note was entered.
Notes	Text of the note.
Issued By	User who entered the note.

Candidate queries

Roadmap: Working with candidate queries

A candidate query is a manual query issued by and visible only to a sponsor user who has the appropriate rights, typically the clinical data manager or medical monitor.

Step	Action	Procedure
1	While reviewing a visit or form, a data reviewer might want input from other data managers or monitors before issuing a query.	1 Select **Patients** (). 2 Click the **Summary** link for the patient. 3 Expand a visit by clicking the arrow to the left of the visit name. 4 Expand a form by clicking the arrow to the left of the form name.
2	You issue a query at the patient, visit, form, or item level.	1 Select the checkbox for the patient, visit, form, or item. You can select multiple checkboxes. 2 Click the **Create Query** icon ().
3	In the dialog box, you identify the query as a candidate query and choose the reason for the query.	1 Select the **Issue as a Candidate Query?** checkbox. 2 From the **Query Selection** drop-down list, select the query to issue. 3 To write your own query, select **Other** from the **Query Selection** drop-down list and type the query in the **Other Text** box. 4 Click **Submit**. The OutcomeLogix application displays the Candidate query Status icon () next to the queried patient, visit, form, or item only if the user has candidate query rights. On the Query List page, the candidate query is visible only to users with candidate query rights.
4	Another sponsor user reviews the candidate query and either reissues it as an open query or deletes it.	1 Select **Queries** (). 2 Select a query with Candidate in the Status column. The query information appears on the Query Detail page on the Answer tab. 3 In the **Change Status** field, click **Open** or **Delete**. 4 Click **Submit**.

Note: If an open query is answered, you can reissue it as a candidate query if additional review is required to approve it or identify if another query is required.

Issuing a candidate query

A sponsor user, typically the clinical data manager or medical monitor, performs this action.

1 Select **Patients** ().

The Patient List page appears.

2 Click the **Summary** link for the patient.

The Patient Summary page appears.

3 At the patient, visit, form, or item level, select the checkbox.

4 Select the **Create Query** icon ().

A dialog box appears.

5 Select the **Issue as a Candidate Query?** checkbox.

6 From the **Query Selection** drop-down list, select the query to issue.

To write your own query, select **Other** from the **Query Selection** drop-down list and type the query in the **Other Text** box.

7 Click **Submit**.

The OutcomeLogix application displays the Candidate query Status icon () next to the queried patient, visit, or form, or item only if the user has candidate query rights. On the Query List page, the candidate query appears for users with candidate query rights.

Deleting a candidate query

If a candidate query is no longer needed, you can delete it. A deleted candidate query remains in the application with a Deleted status.

1 Select **Queries** ().

The Query List page appears.

2 Filter the queries as described in *Filtering and sorting the Query List* (on page 142).

3 Select a candidate query.

The query information appears on the Query Detail page on the Answer tab.

4 In the **Change Status** field, select **Delete**.

5 Click **Submit**.

The Deleted Candidate Query status icon () appears next to the query on the Query List page and on the form itself.

Changing a candidate query to an open query

1 Select **Queries** ( ).

The Query List page appears.

2 Filter the queries as described in *Filtering and sorting the Query List* (on page 142).

3 Select a candidate query.

The query information appears on the Query Detail page on the Answer tab.

4 In the **Change Status** field, select **Open**.

5 Click **Submit**.

The status of the query changes from Candidate to Open. All users can now see the query.

Reissuing an answered query as a candidate query

Note: You cannot reissue a query whose author is System.

1 Select **Queries** ( ).

The Query List page appears.

2 Filter the queries as described in *Filtering and sorting the Query List* (on page 142).

3 Select an answered query.

The query information appears on the Query Detail page on the Answer tab.

4 In the **Change Status** field, select **Reissue as Candidate**.

5 Click **Submit**.

The status of the query changes from Answered to Candidate. Only sponsor users, such as data managers and monitors, can see the query.

CHAPTER 9

eCodes

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eCodes

In some studies, sponsors reimburse patients and other study participants for their time spent completing questionnaires and diaries. Reimbursement is in the form of an electronic gift card, redeemed using an eCode sent to the recipient by email. During study design, the sponsor defines the triggers for eCode distribution.

The OutcomeLogix application assigns eCodes as patients or other study participants complete sessions, forms, or reach a designated study milestone. You can issue eCodes in multiple currencies, based on the localization parameters set for your site.

The OutcomeLogix application stores information about assigned eCodes, including the code, the person to whom it was sent, and the email address. If the eCode supply falls below a limit or is depleted, the OutcomeLogix application notifies the sponsor so that additional eCodes can be loaded. When the new eCode supply has been loaded, the OutcomeLogix application sends eCodes to the missed patients. If patients lose their assigned eCodes, the Help Desk can resend the eCodes by email.

Roadmap: Distributing eCodes

Step	Action	Description
1	The sponsor establishes a policy for distributing eCodes.	This task takes place outside of the OutcomeLogix application.
2	The sponsor loads the supply of eCodes into the OutcomeLogix application.	This task takes place outside of the OutcomeLogix application.
3	The OutcomeLogix application distributes eCodes to patients and other people who have earned them.	This step occurs automatically, triggered by the criteria set up in Step 1. For example, a patient might earn an eCode by completing an ePRO visit. The OutcomeLogix application stores information about eCodes, including the code, the person to whom it was assigned, and the email address. Call Center users can read the eCode to the patient when conducting the interview by telephone if the patient profile does not include an email address.
4	When all the eCodes are distributed, or a limited supply remains, the OutcomeLogix application notifies the sponsor to load more eCodes.	Notification is by email and occurs automatically. Loading the eCodes takes place outside of the OutcomeLogix application.
5	A sponsor user selects the people who did not receive their earned eCodes or clicks the checkbox next to the column headers on the Send eCodes page to *send missed eCodes* (on page 170) to everyone listed.	Depending on how your study has been set up, the OutcomeLogix application might automatically send eCodes to the list of people who missed eCodes.
6	If necessary, or if a patient loses an eCode and calls the Help Desk, the Help Desk can resend eCodes that have already been assigned.	Resending eCodes is done by email.

Manually distributing eCodes

1 Select **Administration** ().

2 Click **Send eCodes**.

The Send eCodes page appears.

3 To view people who earned but did not receive eCodes, from the **Search** drop-down list, select **Missed.**

or

To view people who have earned eCodes, select **Assigned**.

4 To find a specific person, in the **Person ID** field, type the identification number of a patient or person.

5 Click **Submit**.

6 To go back to the list of persons with assigned or missed eCodes, clear the **Person ID** field and click **Submit**.

A list of people matching your search criteria appears.

7 Select the people to receive eCodes.

8 Click **Send eCodes**.

The OutcomeLogix application sends eCodes to the selected people.

Note: Only ePRO and phone patients can be sent an eCode.

Resending eCodes

The OutcomeLogix application stores information about assigned eCodes, including the code, the person, and the email address to which it was sent.

When a patient reports not receiving an eCode, instead of sending an additional eCode, the Help Desk can look up the patient and resend the previously assigned eCode.

1 Select **Administration** ().

2 Click **Send eCodes**.

The Send eCodes page appears.

3 In the **Person ID** field, type the identification number of a patient or person.

4 Click **Submit**.

If the person has earned an eCode, that person appears.

5 Select the checkbox next to the person.

6 Click **Send eCodes**.

The OutcomeLogix application resends eCodes to the selected people.

Send eCodes page

The following task uses this page:

- *Manually distributing eCodes* (on page 170).

To view a job aid that you can print, see:

- Quick Reference: Administration.

Field	Description	Note
Patient ID	Patient number of the person who earned the eCode.	
Visit Name	Name of the visit for which the person earned the eCode.	
eCode	The eCode identifier.	
Amount	Value of the eCode.	
Currency	Currency type of the amount.	
Expire Date	Date the eCode expires.	

CHAPTER 10

Study configuration and preferences

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Study configuration levels

The OutcomeLogix application is highly configurable. Configuration options are available:

- **During study design**—Sponsors can work with their Oracle project managers to configure many settings. For example, the columns to include on the Patient List page or when a new patient is required to sign the Informed Consent Document are configurable settings.
- **After study deployment**—Sponsors can work with their Oracle project managers to further refine study settings.
- **After study deployment with built-in administrative functions**—Built-in administrative functions cover the most frequently used configuration changes; for example, the number of password-reset questions and how many minutes before the session times out. You perform these changes in real time; no coding is required.

Note: This *User Guide* describes only the built-in administrative functions for changing study configuration.

Configuration changes through the Administration page

The table below describes some of the configuration changes you can make through the Administration page as well as the impact of those changes on the study. Details of some of these settings appear in other chapters.

Note: Any changes made on the study or site level take effect the next time you sign in.

Configuration change	Page Performed On	Description	Notes
Auto unlock interval	*Configure Study Settings page* (on page 189)	Changes the number of minutes that must pass before the OutcomeLogix application automatically unlocks a locked user or patient.	
Enable Repeat Visit Name	*Configure Study Settings page* (on page 189)	Indicates whether users can change the name that the application calculates for a repeating visit instance.	
Initial password assigned to users	*Configure Study Settings page* (on page 189)	Changes the password that the application sends to users and patients to enable them to sign in for the first time.	If study designers specify a default initial password, all new users and patients automatically receive that password on creation. For security reasons, it is recommended that study designers leave the Initial password assigned to users field blank. That way, upon user creation, the new user receives a unique temporary password by email.
Password string	*Configure Study Settings page* (on page 189)	Changes the masking characters displayed in the Password fields.	Used for user and patient passwords. Length of the masking string does not match password length defined on the Password Rules page.

Configuration change	Page Performed On	Description	Notes
URL for accessing the study	***Configure Study Settings page*** (on page 189)	Changes the internet address of the study.	You can specify only one URL.
Study-specific message on the Sign In page	***Configure Study Settings page*** (on page 189)	Displays study-specific information, notes, or reminders on the Sign In page.	Not translated; appears in the language in which it was entered.
ePRO due counts	***Configure Study Settings page*** (on page 189)	Changes the number of days that must pass before an ePRO form is considered due and appears in the ePRO Status section of the Dashboard.	The ePRO forms included in the Dashboard count have reached or exceeded the number of days specified.
Session timeout	***Configure Study Settings page*** (on page 189)	Changes the number of idle-time minutes before a user session times out.	
Force session timeout	***Configure Study Settings page*** (on page 189)	Changes whether a session can be forced to time out even if the user is active.	
Second password reset question	***Configure Study Settings page*** (on page 189)	Changes the number of reset questions on the Reset Password page so that users need to answer two questions before the password is reset.	
Link expiration day	***Configure Study Settings page*** (on page 189)	Changes the length of time a new user has to sign into the OutcomeLogix application for the first time after receiving a user name and password.	

Configuration change	Page Performed On	Description	Notes
Whether to support sending emails	***Configure Study Settings page*** (on page 189)	Changes whether the User Profile page includes the option of the user receiving email notifications.	Without this function, users do not receive notifications of password changes, site reassignments, and so on.
Help contact support email	***Configure Study Settings page*** (on page 189)	Changes the email address of the Help Desk.	
Showing patient profile core data	***Configure Study Settings page*** (on page 189)	Indicates whether to show the core fields from the patient profile, such as email address, memorable date, reset password, and user name.	The study design determines the fields included on the Patient Profile page.
Study Name	***Manage Study Description page*** (on page 196)	Changes the study name at the top of the navigation bar on every page.	Might cause confusion if changed during an active study.
Sponsor Name	***Manage Study Description page*** (on page 196)	Replaces every occurrence of the sponsor name.	Might cause confusion if changed during an active study.
Therapeutic area	***Manage Study Description page*** (on page 196)	Provides additional information about the study protocol, such as Oncology, if set up for the study.	
Expected number of sites	***Manage Study Description page*** (on page 196)	Number of sites that are expected to be part of the study.	

Configuration change	Page Performed On	Description	Notes
Hide, mask, or make a form, or items within a form, read-only for selected roles	***Edit Display Overrides page*** (on page 191)	Hidden items do not appear on the Audit Trail page and are not included in reports. Masked items make Protected Health Information unreadable. Read-only items may not be edited.	
Assign access to standard reports to roles	***Assign Reports to Roles page*** (on page 228)	Allows users to access specific standard reports.	
Password rules	***Manage Password Rules page*** (on page 69) and ***Assign Password Rules to Roles page*** (on page 66)	Sets password parameters for selected roles, including time before expiration and the password default rule.	Might end up with many variations that are difficult to support.
Rights groups	***Manage Roles and Rights page*** (on page 59) and ***Rights Group page*** (on page 61)	Creates a role and an associated rights group consisting of selected management and user functions.	Might end up with many variations that are difficult to support.
Localization settings	***Manage Localization Settings page*** (on page 195)	Changes the date formats, name sort options, number formats, and currency formats offered on the User Profile and Site Management pages.	
Upload Informed Consent documents in multiple languages and of different types	***Manage ICDs page*** (on page 97)	Changes the list of available ICDs on the Site Management page. Determines which ICDs are active.	When a new version or different ICD is made active, all patients related to that ICD must re-sign it.

Configuration change	Page Performed On	Description	Notes
Destination sites associated with the study site	***Manage Sites page*** (on page 30)	Associates destination sites with an originating site as required for patient transfers.	
Site enrollment target numbers and limitations	***Manage Sites page*** (on page 30)	Determines the maximum number of patients that can be enrolled, as well as target enrollment and limits.	The enrollment limit can exceed the target enrollment.
Activate or deactivate a site	***Manage Sites page*** (on page 30)	Changes the status of the site.	
Report server information	***Edit Report Server Configuration page*** (on page 227)	Specifies the location of the report server and allows the developer and viewer users to enter or change their passwords.	

Viewing and editing administrative study information

Administrative information for a study includes the study and sponsor names, a study ID, and the therapeutic area of the study.

1 Select **Administration** ().

2 Click **Manage Study Description**.

The Manage Study Description page appears.

3 View or edit the fields as necessary. For more information, see Manage Study Description page.

> **Note:** You cannot change the Study ID.

4 Click **Submit**.

Adding, editing, or deleting a display override

You can restrict access to items for users in a specific role by using study display overrides. The display overrides are hidden, read-only, and masked (displayed, but blocked out). When a user within the restricted role signs in, the OutcomeLogix application hides or masks the item or makes the item read-only, depending on the setting.

- If an item is assigned as both read-only and hidden, the item is hidden.
- If an item is assigned as both read-only and masked, the item is masked.
- Read-only items appear on the Audit Trail page; hidden and masked items do not appear.
- Display overrides on a repeating form apply to each instance of the form unless overridden by validation rules.

To add a display override:

1 Select **Administration** ().

2 Click **Manage Display Overrides**.

The Manage Display Overrides page appears.

3 Click **Add**.

The Edit Display Override page appears.

4 Specify the path to the control to be marked hidden, read-only, or masked.

a From the **Arm** drop-down list, select a study arm.

b From the **Visit** drop-down list, select a visit or type of visit.

c From the **Form** drop-down list, select a form.

d From the **Control** drop-down list, select an item.

5 Specify the following:

a To mark the control as Hidden for users in one or more roles, in the **Hidden Roles Available Roles** list, select the roles and click the **add** (**>**) button to move the roles to the Selected Roles list.

b To mark the control as Read Only for users in one or more roles, in the **Read-only Roles Available Roles** list, select the roles and click the **add** (**>**) button to move the roles to the Selected Roles list.

c To mark the control as Masked for users in one or more roles, in the **Masked Roles Available Roles** list, select the roles and click the **add** (**>**) button to move the roles to the Selected Roles list.

6 Click **Submit**.

The study attribute is added to the Manage Display Overrides page.

To edit a display override:

1 Select **Administration** ().

2 Click **Manage Display Overrides**.

The Manage Display Overrides page appears.

3 Click the **Edit** link for the control.

The Edit Display Override page appears.

4 Edit the fields as necessary. For more information, see *Edit Display Override page* (on page 191).

5 Click **Submit**.

To delete a display override:

1 Select **Administration** ().

2 Click **Manage Display Overrides**.

The Manage Display Overrides page appears.

3 Select the checkbox for the display override to delete. You can select multiple display overrides.

4 Click **Delete**.

Note: The change to the control is made for the selected visit only. Other uses of the form are not affected.

Changing default study configuration settings

The OutcomeLogix application contains a set of default values governing basic system configuration issues; for example, how many minutes before a session times out and the initial password assigned to users.

Changes you make to the default values can impact the study. For more information, see *Configuration changes through the Administration menu* (on page 175).

1 Select **Administration** ().

2 Click **Configure Study Settings**.

The Configure Study Settings page appears.

3 Click **Edit** for the parameter to edit.

The Configure Study Settings page appears.

4 Fill in the fields as necessary. For more information, see *Configure Study Settings page* (on page 189).

5 Click **Submit**.

Specifying date, number, and currency formats and name sorting order

You can localize how dates and numbers are formatted through the OutcomeLogix application, the currency used at your site, and how to sort user and patient names—by first or last name. You can make these changes at three levels:

- **User level**—The formatting settings from your user profile are the default.
- **Site level**—If values are not specified in your profile, the settings for the site in which you are working are used.
- **Study level**—If values are not specified for the site, the settings on the Localization Parameter Settings page are used.

To specify localization parameters at the user level:

1 On the Navigation bar, click your user name.

The User Profile page appears.

2 Select values from the **Date Format**, **Name Sort, Number Format**, and **Currency Format** drop-down lists. For more information, see *Viewing and editing your profile* (on page 6).

3 Click **Submit**.

To specify localization parameters at the site level:

1 Select **Administration** ().

2 Click **Manage Sites**.

The Manage Sites page appears.

3 On the site list, click the **Edit** link for the site.

4 Select values from the **Date Format**, **Name Sort, Number Format**, and **Currency Format** drop-down lists. For more information, see *Manage Sites page* (on page 30).

5 Click **Submit**.

To specify localization parameters at the study level:

1 Select **Administration** ().

2 Click **Manage Localization Settings**.

The Manage Localization Settings page appears.

3 Fill in the fields as necessary. For more information, see *Manage Localization Settings page* (on page 195).

4 Click **Submit**.

Viewing email notifications

1 Select **Administration** ().

2 Click **Email Notifications**.

The Email Notifications page appears, listing the email address, the subject of the notification, and the date for which the notification is scheduled.

> **Note:** The OutcomeLogix application does not confirm that the notification was received; only that it was sent.

3 You can filter the notifications by making selections from the Email Address, Subject, and Date Scheduled drop-down lists.

4 To clear the filters, click **Clear Filters**.

Viewing version information

1 Select **Administration** ().

2 Click **Show Versions**.

The Show Versions page appears, listing the version number and update date and time for each component of the OutcomeLogix application.

3 To see the information on the previous versions of the database or application, click **History**.

4 To return to the Show Versions page, click **Back**.

Administration page

The Administration page is the gateway to using configuration options, managing user information and roles, and maintaining your sites.

Note: Any changes made on the study or site level take effect the next time you sign in.

Function	Tasks
Manage Users	*Create, activate, and deactivate a user* (on page 36). *Search for a user* (on page 38). View and edit a user profile.
Manage Sites	*Add and edit a site* (on page 21). *Search for a site* (on page 23). *Change the user assignments for a site* (on page 25).
Manage Study Description	*View and edit administrative information for a study* (on page 180).
Manage Display Overrides	*Add, edit, or delete display overrides* (on page 181), such as hiding and masking controls on forms or designating them as read-only.
Send eCodes	*Manually distribute eCodes* (on page 170).
Assign Reports to Roles	*Assign reports to roles* (on page 226).
Show Versions	View the core database, study database, and application versions on the *Product Version page* (on page 186).
Configure Study Settings	*Change default configuration values* (on page 183).
Manage Password Rules	*Create and edit a password rule* (on page 65). *Assign a password rule to a role* (on page 66).
Assign Password Rules to Roles	*Assign a password rule to a role* (on page 66).
Manage Roles and Rights	*Create and edit a role* (on page 58). *Assign rights to a role* (on page 54). *Assign a user to a role* (on page 55).
Manage Localization Settings	*Specify data, number, and currency formats and how to sort names* (on page 184).
Configure Reports	*Configure the report server settings* (on page 225).
Manage ICDs	*Upload an ICD* (on page 94). *View and print an ICD* (on page 95). *Add a new language for an ICD* (on page 96).

Function	Tasks
Call Center Profile Setting	*Update a Call Center profile* (on page 255).
Call Center Script Setting	*Enter and edit a Call Center script* (on page 257).
Email Notifications	*View email notifications* (on page 185).

Configure Study Settings page

The following task uses this page:

- *Changing default study configuration settings* (on page 183).

Note: You can change only the default parameter values.

Parameter Setting	Description	Default Parameter Value
AutoUnlockInterval	Changes the number of minutes that must pass before the OutcomeLogix application automatically unlocks a locked user or patient.	30
EnableRepeatVisitName	Indicates whether users can change the name that the application calculates for a repeating visit instance.	Y
ePRODueCounts	Changes the number of days that must pass before an ePRO form is considered due and appears in the ePRO Status section of the Dashboard.	6
ForceSessionTimeoutEvenActive	Changes whether a session can be forced to time out even if the user is active.	Off
HelpContactSupportEmail	Changes the email address of the Help Desk.	
InitialPassword	Changes the password that the application sends to users and patients to enable them to sign on for the first time.	changeme1
LinkExpirationDay	Changes the length of time a new user has to sign into the OutcomeLogix application for the first time after receiving a user name and password.	2

Parameter Setting	Description	Default Parameter Value
LoginPageMessage	Displays study-specific information, notes, or reminders on the Sign In page. Appears in the language used to enter the parameter value.	Blank (no message appears on the Sign In page).
PasswordString	Changes the masking characters displayed in the Password fields.	******
SessionTimeout	Changes the number of idle-time minutes before a user session times out.	20
ShowPatientProfileCoreData	Indicates whether to show the core fields from the patient profile, such as email address, memorable date, reset password, and user name.	N
StudyUrl	Changes the internet address of the study.	http://www.46032-Us-01study.com
UsersNeedSecondPasswordResetQuestion	Changes the number of reset questions on the Reset Password page so that users need to answer two questions before the password is reset.	Y
Whethertosupportsendingemails	Changes whether the User Profile page includes the option of the user receiving email notifications.	On

Edit Display Override page

The following task uses this page:

- *Adding, editing, or deleting a display override* (on page 181).

Field	Description	Note
Arm	Study arm to which the display override applies.	Required. The drop-down list includes all study arms defined for the study.
Visit	Visit or type of visit to which the display override applies.	Required. The drop-down list includes all visits within the selected study arm.
Form	Form to which the display override applies.	Required. The drop-down list includes all forms within the selected visit.
Control	The control within the form to which the display override applies; for example, a question number or text field.	Required. The drop-down list includes all controls that can be configured within the selected form.
Hidden Roles	Roles for which the control can be hidden.	
Read Only Roles	Roles for which the control can be read-only.	
Masked Roles	Roles for which the control can be masked.	
Available Roles	Roles that can be selected.	
Selected Roles	Roles that have been selected.	

Edit Study Settings page

The following task uses this page:

- *Changing default study configuration settings* (on page 183).

Option	Description	Notes
Category	Configuration option type.	Read-only.
Parameter Description	Description of the parameter viewed by users.	Read-only.
Parameter Setting	Internal name for the parameter.	Read-only.
Parameter Value	Value of the parameter.	

Email Notifications page

The following task uses this page:

- *Viewing email notifications* (on page 185).

To view a job aid that you can print, see:

- Quick Reference: Administration.

Field	Description	Note
Email Address	Patient email address.	
Subject	Subject of the email notification.	Your study design includes predefined email subjects.
Date Scheduled	Date for which the notification is scheduled.	

Manage Display Overrides page

The following task uses this page:

- *Adding, editing, or deleting a display override* (on page 181).

Field	Description	Note
Edit	Link to Edit Display Override page for the selected study attribute.	
Control	Item on form to be hidden, read-only, or masked.	
Hidden	Number of users for whom the control is hidden.	The item is invisible to users within all selected roles and there is no indication that information has been hidden. Hidden items do not appear on reports.
Read Only	Number of users for whom the control is read-only.	The users within the selected roles can view, but not update, the item.
Masked	Number of users for whom the control is masked.	The data is visible, but masked (########), on a form for users within the selected roles.
Checkbox	Control for selecting one or more display overrides.	
Add	Add a display override.	
Delete	Delete one or more selected display overrides.	
Back	Return to the Administration page.	

Manage Localization Settings page

The following task uses this page:

- *Specifying date, number, and currency formats and name sorting order* (on page 184).

Field	Description
Date Format	Format in which to display dates and times.
Name Sort	Order in which names are sorted: by First Name or Last Name.
Number Format	Thousands separator to use in displaying numbers: none, comma or period.
Currency Format	Currency type of monetary displays.

Note: You can specify these values in the following locations:

- The default settings are in a user profile, which you create on the *Create User page* (on page 45) and edit on the *User Profile page* (on page 47).
- If values are not specified for a user, the application uses settings on the *Manage Sites page* (on page 30).
- If values are not specified for the site, the application uses settings on the Manage Localization Settings page.

Manage Study Description page

The following task uses this page:

- *Viewing and editing administrative study information* (on page 180).

To view a job aid that you can print, see:

- Quick Reference: Administration.

Field	Description	Note
Study Name	Name of the study, as assigned by the sponsor.	Required.
Study ID	Unique identifier for the study.	Read-only.
Sponsor Name	Name of the study sponsor.	Required.
Therapeutic Area	Clinical area covered by the study.	Required.
Expected Number of Sites	Number of sites anticipated.	

CHAPTER 11

Reports

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OutcomeLogix reporting

OutcomeLogix reporting provides a library of standard reports and the ability to design ad hoc reports through the Oracle Business Intelligence Publisher tool (BI Publisher).

Note: For information regarding browser support, refer to the User's Guide for Oracle Business Intelligence Publisher.

- **Standard reports**—The library of standard reports satisfies the common reporting needs of sponsor users. Most standard reports show operational data about a study. For example, you can use standard reports to report on the number of visits that are complete, the number of forms that are frozen or locked, patient enrollment statistics, eCodes distribution, or, if your study includes a call center, the number of calls made by each staff member every day. Additionally, the Audit Trail History report provides audit data from clinical tables.
- **Ad hoc reports**—Users with additional reporting rights can pull clinical and operational data items from multiple datasets in the BI Publisher tool to create ad hoc reports. For example, you can compile information on adverse events, vital signs information, and dosing records. You can create ad hoc reports and assign them to different roles at the site or sponsor level.

Note: You can view data only for the sites to which you are assigned.

Standard reports

About standard reports

Standard reports summarize operational and transactional data, such as query metrics, patient statuses, audit trail history, and eCode statuses, for a study. If your study includes a call center, you can also report on the number of calls made by each staff member every day. Standard reports do not include clinical data. The following reports include audit data:

- Audit Trail History report
- Login History report

If you have the right to view reports, you can select the standard reports on the Reporting page, and you can view and export reports using features in the BI Publisher tool.

Note: If the study is designed to contain Personal/Protected Health Information, and designers and sponsors choose to encrypt it, they have the ability to indicate which items on forms contain sensitive information that should be encrypted and also excluded from email messages, data exports, and reports by default.

You can also interact directly with the report. For more information, see *Sorting and filtering report data* (on page 201).

Roadmap: Working with standard reports

OutcomeLogix reporting provides a library of standard reports through the Oracle Business Intelligence Publisher tool (BI Publisher). These standard reports satisfy the reporting needs of most site users. For example, you can use standard reports to report on the number of visits that are complete for a study, the number of forms that are frozen or locked, patient enrollment statistics, eCodes distribution, or, if your study includes a call center, the number of calls made by each staff member every day.

Step	Action	Description
1	View a standard report.	1 Select **Reports** (). 2 Click the link for the report to view.
2	Work with a standard report.	Using options in the BI Publisher tool, perform the following procedures as needed.
	Change the sort order of data in the columns.	• From the **View** drop-down list, select the desired format. In the column to sort, click the arrow in the column heading, and select the sorting option.

Step	Action	Description
	Filter the data in the report.	• Graphs and report listing—Right-click the report sub-heading area above the graphical view, and select a filtering option. The charts or graphs and the report listing reflect the filter selection. • Report listing only—Right-click a column, and select a filtering option. Only the report listing reflects the filter selection.
	View the report in various formats.	• From the **View** drop-down list, select the desired format in which to view the report (for example, RTF, PDF, Microsoft Excel spreadsheet software).
	Export a standard report.	1 From the **Actions** drop-down list, select **Export**. 2 From the **Export** drop-down list, select the output format in which to export the report.

Viewing and exporting a standard report

1 Select **Reports** ().

The Reporting page appears and lists the standard reports to which you have access.

2 Click the link for the report to view.

The BI Publisher tool opens, and the selected report appears in a viewer window.

3 Optionally, to view the report in another format, from the **View Report** drop-down list, select the desired format.

The BI Publisher tool displays the report in the selected format.

4 Optionally, to export a standard report, do the following:

a From the **Actions** drop-down list, select **Export**.

b From the **Export** drop-down list, select the output format in which to export the report.

Sorting and filtering report data

To sort report data:

- Click the arrow button ( ) in the column header and select a sorting option.

  or

  Right-click the column header and select a sorting option.

To filter report data:

- **Interactively**—Right-click the report sub-heading area above the graphical view, and select a filtering option.

  Both the charts or graphs and the table reflect the filter selection.

- **By selecting column data**—Right-click a column, and select a filtering option.

  Only the table reflects the filter selection.

Audit Trail History report

Report:	Audit Trail History
Summary	This report displays the changes that are made to each form item associated with a site.
Charts and graphs	A bar graph displays the count of items changed on each form.
Data groupings in table	• Site • Patient ID • Visit Name

Report:	Audit Trail History
Column	Description
Site Number	Identification number assigned to the site.
Site Name	Full name of the site.
Patient ID	Unique identifier for the patient.
Visit Name	Name of the visit in which the item exists.
Visit Index	Visit index for the visit in which the item exists.
Form Name	Name of the form on which the item exists.
Form Index	Form index for the form on which the item exists.
Item Name	Variable name for the item.
Initial Entry	Yes or No: Indicating whether the original value for the item was the first value entered for the item, or whether it was a modified version of the first value entered.

Report:	Audit Trail History
Previous Value	Previous value for the item.
Current Value	Current value for the item.
Change Date (GMT)	Date and time when the item value was changed.
Reason For Change	Reason for changing the item value, as entered by the user who modified the item.
Role	Role assigned to the user who modified the item.
Username	User name of the user who modified the item.

Call Center by Staff by Day

Report:	Call Center by Staff by Day
Summary	This report displays the number of calls patients made to the Call Center, and records the reason of the call, as well as user notes about the call.
Charts and graphs	A bar graph displays the number of calls taken by each staff member.
Data groupings in table	• Site number • Patient

Report:	Call Center by Staff by Day
Column	Description
Date Called	Date when the patient called into the Call Center, in the format defined in the user profile.
Staff Member	Name of the staff member who attended the patient at the time of the call.
Patient ID	Unique identifier for the patient.
Attempt Number	Attempt number of the call.
Time Called (GMT)	Exact time when the patient made the call.
Visit Name	Name of the visit as displayed in the user interface.
Reason	Reason for the call.
Notes	User comments about the call.

Patient Survey

Report:	Patient Survey
Summary	This report displays the number of missed visits and completed visits, as well as other patient survey information.
Data groupings in table	• Site number • Patient

Report:	Patient Survey
Column	Description
Site number	Identification number assigned to the site.
Site name	Full name of the site.
Patient ID	Unique identifier for the patient.
Preferred Method	Preferred method of contact: • Paper • Phone • Web
Missed Visits	Number of missed visits.
Completed Visits	Number of completed visits.
Visit Name	Name of the visit as displayed in the user interface.
Expected Visit Date	Expected date of the visit.
Latest Visit Updated Date	Updated date of the visit.

CRF Status by Form report

Report:	CRF Status by Form
Summary	For each patient, this report displays the system and manual form statuses of each form. A subtotal appears for each visit. A total row appears at the bottom of the table.
Charts and graphs	For each of the following statuses, a pie chart displays the percentage of all forms in that status represented by each form in the study: • Not Started • Open Query • Complete
Data groupings in table	• Site • Patient ID • Visit Name

Report:	CRF Status by Form
Column	Description
Site Number	Identification number assigned to the site.
Site Name	Full name of the site.
Patient ID	Unique identifier for the patient.
Visit Name	Name of the visit as displayed in the user interface.
Form Name	Name of the form.
Not Started	Yes or blank, indicating whether the form status is Not Started. The report shows subtotal counts of forms in this status by visit, patient, and site and a total count of forms in this status for the study.
In-Progress	Yes or blank, indicating whether the form status is In-Progress. The report shows subtotal counts of forms in this status by visit, patient, and site and a total count of forms in this status for the study.
Open Query	Yes or blank, indicating whether the form status is Open Query. The report shows subtotal counts of forms in this status by visit, patient, and site and a total count of forms in this status for the study.
Complete	Yes or blank, indicating whether the form status is Complete. The report shows subtotal counts of forms in this status by visit, patient, and site and a total count of forms in this status for the study.

Report:	CRF Status by Form
Remote Reviewed	Yes or blank, indicating whether the form status is Remote Reviewed. The report shows subtotal counts of forms in this status by visit, patient, and site and a total count of forms in this status for the study.
DM Reviewed	Yes or blank, indicating whether the form status is DM Reviewed. The report shows subtotal counts of forms in this status by visit, patient, and site and a total count of forms in this status for the study.
Source Verified	Yes or blank, indicating whether the form status is Source Verified. The report shows subtotal counts of forms in this status by visit, patient, and site and a total count of forms in this status for the study.
Signed	Yes or blank, indicating whether the form status is Signed. The report shows subtotal counts of forms in this status by visit, patient, and site and a total count of forms in this status for the study.
Frozen	Yes or blank, indicating whether the form status is Frozen. The report shows subtotal counts of forms in this status by visit, patient, and site and a total count of forms in this status for the study.
Locked	Yes or blank, indicating whether the form status is Locked. The report shows subtotal counts of forms in this status by visit, patient, and site and a total count of forms in this status for the study.

CRF Status by Patient report

Report:	CRF Status by Patient
Summary	For each patient, this report displays the total number of forms that are assigned each form status. A subtotal appears for each site. A total row appears at the bottom of the table.
Charts and graphs	For each site, a pie chart displays: • Percentage of forms with the status Not Started. • Percentage of forms with the status In-Progress. • Percentage of forms with the status Open Query. • Percentage of forms with the status Complete.
Data groupings	• Site • Patient ID

Report:	CRF Status by Patient
Column	Description
Site Number	Identification number assigned to the site.
Site Name	Full name of the site.
Patient ID	Unique identifier for the patient.
Total Visits	Total number of generated visits.
Total Forms	Total number of forms in the Not Started, Incomplete, Incomplete with Queries, and Complete states.
Not Started	Total number of forms with the status Not Started.
In-Progress	Total number of forms with the status In-Progress.
Open Query	Total number of forms with the status Open Query.
Complete	Total number of forms with the status Complete.
Remote Reviewed	Total number of forms with the status Remote Reviewed.
DM Reviewed	Total number of forms with the status DM Reviewed.
Source Verified	Total number of forms with the status Source Verified.
Signed	Total number of forms with the status Signed.
Frozen	Total number of forms with the status Frozen.
Locked	Total number of forms with the status Locked.

CRF Status by Visit report

Report:	CRF Status by Visit
Summary	For each patient visit, this report displays the total number of system and manual form statuses. A subtotal appears for each patient. A total row appears at the bottom of the table.
Charts and graphs	• **Bar graph**—Displays the number of forms in the following form statuses for each visit: ▪ Not Started ▪ In-Progress ▪ Open Query ▪ Complete • **Pie charts**—Display the following data for each patient: ▪ Percentage of forms with the status Not Started. ▪ Percentage of forms with the status In-Progress. ▪ Percentage of forms with the status Open Query. ▪ Percentage of forms with the status Complete.
Data groupings	• Site • Patient ID • Visit Name

Report:	CRF Status by Visit
Column	Description
Site Number	Identification number assigned to the site.
Site Name	Full name of the site.
Patient ID	Unique identifier for the patient.
Visit Name	Name of the visit as displayed in the user interface.
Total Forms	Total number of forms in the Not Started, Incomplete, Incomplete with Queries, and Complete statuses.
Not Started	Total number of forms in the visit with the status Not Started.
In-Progress	Total number of forms with the status In-Progress.
Open Query	Total number of forms with the status Open Query.
Complete	Total number of forms in the visit with the status Complete.
Remote Reviewed	Total number of forms in the visit with the status Remote Reviewed.

Report:	CRF Status by Visit
DM Reviewed	Total number of forms in the visit with the status DM Reviewed.
Source Verified	Total number of forms in the visit with the status Source Verified.
Signed	Total number of forms in the visit with the status Signed.
Frozen	Total number of forms in the visit with the status Frozen.
Locked	Total number of forms in the visit with the status Locked.

eCode by Currency report

Report:	eCode by Currency
Summary	This report displays the total number of assigned and unassigned eCodes for each type of currency. A total row appears at the bottom of the table.
Charts and graphs	• **Bar graph**—Displays the total number of eCodes and the number of assigned and unassigned eCodes for each type of currency. • **Pie chart**—Displays, for each type of currency, the percentage of eCodes that are assigned and unassigned.
Data groupings	Currency

Report:	eCode by Currency
Column	Description
Currency	Currency for the eCode.
eCodes Assigned	For the specified currency, the total number of eCodes that are assigned.
eCodes Unassigned	For the specified currency, the total number of eCodes that are unassigned.
Total eCodes	For the specified currency, the total number of eCodes that exist.

eCode by Patient report

Report:	eCode by Patient
Summary	This report displays the number of eCodes assigned by currency to each patient. A total row appears at the bottom of the table.
Charts and graphs	A bar graph displays the count of eCodes with the Assigned status for each site.
Data groupings	Site

Report:	eCode by Patient
Column	Description
Site Number	Identification number assigned to the site.
Site Name	Full name of the site.
Patient ID	Unique identifier for the patient.
eCode Currency	Currency in which the eCodes were issued.
eCodes Assigned	For the specified currency, the total number of eCodes that are assigned.

ePRO Completion report

Report:	ePRO Completion
Summary	This report displays statuses and completion dates for all ePRO visits.
Charts and graphs	A bar graph displays the number of complete ePRO visits for each site.
Data groupings	• Site • Patient ID

Report:	ePRO Completion
Column	Description
Site Number	Identification number assigned to the site.
Site Name	Full name of the site.
Patient ID	Unique identifier for the patient.
Visit Name	Name of the visit as displayed in the user interface.

Report:	ePRO Completion
Visit Status	• **Complete**—All ePRO items have been submitted successfully. • **Incomplete**—Not all ePRO items have been submitted successfully, and the survey window has expired. • **In Window**—Not all ePRO items have been submitted successfully, but the survey window is still open. • **<null> or Not Started**—The survey window for the visit is not yet open.
Visit Completion Date (GMT)	Date when the visit was completed, if status is Complete.

Informed Consent report

Report:	Informed Consent
Summary	This report displays the site number and patient ID for each patient at a site who has signed the Informed Consent Document (IDC) form.
Charts and graphs	A bar graph displays the number of signed forms from each site.

Report:	Informed Consent
Column	Description
Site Name	Full name of the site.
Patient	Unique identifier for the patient.
Agreed to Consent	Yes or No, indicating whether the patient agreed to sign the Informed Consent form. The table cell is blank if the patient has not yet decided whether to sign the form.
Date Consent Signed (GMT)	Date when the patient signed the ICD form. The table cell is blank if a user did not agree to sign the ICD.

Login History report

Report:	Login History
Summary	This report displays the dates and times when each user at a site signed into the application.
Charts and graphs	Bar graphs display the following information: • The number of sign-ins for each user. • The number of sign-ins for each user role.

Report:	Login History
Column	Description
Login Time (GMT)	Date and time when the user signed into the application.
Username	User name of the user who signed into the application.
First Name	First name of the user who signed into the application.
Last Name	Last name of the user who signed into the application.
Country	Country in which the user who signed into the application is located.
Role	Role assigned to the user who signed into the application.

Open Query Aging report

Report:	Open Query Aging
Summary	For each site, this report displays the number of queries that are open for each time range. A total row appears at the bottom of the table.
Charts and graphs	For each site, a bar graph displays the percentage of queries that are open for each time range in the report.

Report:	Open Query Aging
Column	Description
Site Number	Identification number assigned to the site.
Site Name	Full name of the site.
<7 Days	Number of queries that are less than 7 days old.
7 - 14 Days	Number of queries between 7 and 14 days old.
15 - 30 Days	Number of queries between 15 and 30 days old.
31 - 60 Days	Number of queries between 31 and 60 days old.

Report:	Open Query Aging
>60 Days	Number of queries that are more than 60 days old.

Patient Status report

Report:	Patient Status
Summary	This report displays the status of each patient. Subtotals appear for each site. A total row appears at the bottom of the table. **Note:** The report shows only the statuses that are available in the study; for example, not every study includes a Randomized status.
Charts and graphs	A bar graph displays the count of patients at each site in the following statuses: • Created • Enrolled • Discontinued • Completed
Data groupings	• Site • Patient ID

Report:	Patient Status
Column	Description
Site Number	Identification number assigned to the site.
Site Name	Full name of the site.
Patient ID	Unique identifier for the patient.
Pre-Screened	Yes or No, indicating whether the patient is assigned the Pre-screened status.
Created	Yes or No, indicating whether the patient is assigned the Created status.
Enrolled	Yes or No, indicating whether the patient is assigned the Enrolled status.
Discontinued	Yes or No, indicating whether the patient is assigned the Discontinued status.
Screening	Yes or No, indicating whether the patient is assigned the Screening status.
Completed	Yes or No, indicating whether the patient is assigned the Completed status.
Randomized	Yes or No, indicating whether the patient is assigned the Randomized status.
Screen Failed	Yes or No, indicating whether the patient is assigned the Screen-Failed status.

Report:	Patient Status
Opt Out	Yes or No, indicating whether the patient is assigned the Opt Out status.
Consented	Yes or No, indicating whether the patient is assigned the Consented status.
Lost To Follow Up	Yes or No, indicating whether the patient is assigned the Lost To Follow Up status.
Withdrawn	Yes or No, indicating whether the patient is assigned the Withdrawn status.

Query List Details report

Report:	Query List Details
Summary	For each query at a site, this report displays data about patients, query types, visits, forms, and issuers.
Charts and graphs	Gauge graphs display the number of queries in each form.

Report:	Query List Details
Column	Description
Site Name	Full name of the site.
Patient ID	Unique identifier for the patient.
Query ID	Identification number assigned to the query.
Type	• Automatic queries—System. • Manual queries—Manual.
Visit Name	Name of the visit associated with the query.
Form Name	Name of the form associated with the query.
Item Text	Item text for the item on which the query exists. **Note:** This column is populated only if the query exists at the item level.
Query Text	Query text.
Status	Query status.
Issued By	User name of the user who issued the query. If the query is an automatic query, **System** appears in this column.
Date (GMT)	Date and time when the query was issued.
Response	Query response.
Respondent	Person who answered the query.
Elapsed Days	Number of days since the query was opened. Appears only for open queries.

Query Metrics by Group report

Report:	Query Metrics by Group
Summary	This report displays the total number of queries entered by each role and the System user. A total row appears at the bottom of the table.
Charts and graphs	• **Bar graph**—Displays, for each role, the number of queries in each status that were issued by users in the role. • **Pie charts**—Display, for each role, the percentage of total queries that is made up of queries in each query status.
Data groupings	Issuer.

Report:	Query Metrics by Group
Column	Description
Site ID	Identification number assigned to the site.
Issuer	User name of the user who entered the query. For automatic queries, the issuer is System.
Total Queries	Total number of queries entered by the issuer.
Count of Open Queries	Total number of open queries entered by the issuer.
Count of Answered Queries	Total number of answered queries entered by the issuer.
Count of Approved Queries	Total number of approved queries entered by the issuer.
Count of Closed Queries	Total number of closed queries entered by the issuer.

Query Performance report

Report:	Query Performance
Summary	This report displays query resolution data for each site. The report separates manual and system query data.
Charts and graphs	A bar graph displays data from each site, grouped by the following averages: • Opened to Answered—Average number of days needed to answer an opened query. • Answered to Approved—Average number of days needed to approve an answered query. • Opened to Approved—Average number of days needed to approve an opened query.
Data groupings	Site.

Report:	Query Performance
Column	**Description**
Site Number	Identification number assigned to the site.
Site Name	Full name of the site.
Query Type	Type of query (System Query or Manual Query). This column contains two rows for each site: one to display the total number of automatic queries and one to display the total number of manual queries.
Days Opened to Answered (Average)	For each site, the average number of days between the date when a query was opened and the date when the query was answered.
Days Answered to Approved (Average)	For each site, the average number of days between the date when a query was answered and the date when the query was approved.
Days Opened to Approved (Average)	For each site, the average number of days between the date when a query was opened and the date when the query was approved.

Query Total by Form report

Report:	Query Total by Form
Summary	This report displays the total number of queries that are associated with each form in the study, differentiating candidate queries from automatic and other manual queries.
Charts and graphs	• **Bar graph**—For each site, displays the number of queries that have been raised on each form. • **Pie chart**—For each site, displays the percentage of total queries raised on each form.
Data groupings	Site.

Report:	Query Total by Form
Column	Description
Site Number	Site number.
Site Name	Full name of the site.
Form Name	Name of the form.
# of Candidate Query	Number of candidate queries associated with the form.
# of Real Query	Number of queries that are in the Open, Approved, Answered, Closed, or Deleted query status and are associated with the form.
Query Total	Total number of queries associated with the form.

Site Visit Completion report

Report:	Site Visit Completion
Summary	For each site, this report displays the visits that each patient has completed. Subtotals appear for each patient, showing the number of visits completed by that patient. The report also shows the total number of completed visits for all patients.
Charts and graphs	A bar graph displays the total number of patients whose visits are complete for each site.
Data groupings	• Site • Patient ID

Report:	Site Visit Completion
Column	Description
Site Number	Identification number assigned to the site.
Site Name	Full name of the site.
Patient ID	Unique identifier for the patient.
Visit Name	Name of the visit as displayed in the user interface.
Visit Completion Date (GMT)	Date and time when the visit was completed, if the status is Complete.

Ad hoc reports

Working with ad hoc reports

Ad hoc reports can display operational and clinical data from the forms in your study. If you have the appropriate rights, you can access the ad hoc reporting workspace in the BI Publisher tool and create and save ad hoc reports. For more information about reporting rights, see *Roles and rights for reports* (on page 224).

The OutcomeLogix application includes a data model that is used to create ad hoc reports. The data model is composed of datasets, each of which provides access to a set of related columns from the OutcomeLogix database.

For more information about the datasets supplied for OutcomeLogix reporting, see Reporting views overview.

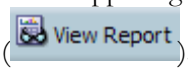
Note: In order to be viewed, every ad hoc report that is created must be assigned to one or more roles.

Roadmap: Creating and saving an ad hoc report

Ad hoc reports can display operational and clinical data from the forms in your study. If you have the appropriate rights, you can access the ad hoc reporting workspace in the BI Publisher tool and create and save ad hoc reports.

Before creating and saving your first ad hoc report, you should create a new folder in the BI Publisher tool in which to store all of your ad hoc reports.

Step	Action	Description
1	Create an ad hoc report.	Using the BI Publisher tool, select the layout and choose the components of the report.
	Access the ad hoc reporting function.	1 Select **Reports** (). 2 Click the **Design a New Report** link. 3 From the **Create** section, select **Report**.
	Choose the OLX Data Model.	1 From the **Catalog** section, select the folder that contains the data model (OLXAdHocDataModel). 2 Highlight the data model, and click **Open**. The Create Layout page appears.
	Select the layout.	• Select from the predefined layouts, or upload an existing layout.
	Add the report components.	1 At the top of the page, select the **Insert** tab. 2 In the **Components** section of the **Insert** tab, select the components as needed, and drag them into the workspace.

Step	Action	Description
	Drag in the report columns from the datasets.	1 From the **Data Source** tree, navigate to a dataset. 2 Select a data item to add to the report, and drag it to the report component where it should be used. Repeat until all the columns have been added to the report layout.
	Save the report layout.	1 In the upper-right corner of the page, click **Save** (). The Save Layout dialog box appears. 2 Specify a Layout Name and Locale for the layout. 3 Click **Save**. 4 Click **Return**. The report layout appears on the page.
2	Save the report.	1 In the upper-right corner of the page, click **Save Report** (). The Save As dialog box appears. 2 Specify a location in which to save the report, the report name, and a description of the report. You can save the report to any folder so that when you later view it in the list on the Reporting page, it appears under its folder heading, making it easier to differentiate between standard reports and ad hoc reports. You can create subfolders to organize your reports. 3 Click **Save**.
3	View the report	• In the upper-right corner of the page, click **View Report** (). The report appears in a BI Publisher window.
4	Assign the report to OutcomeLogix roles.	1 Select **Administration** (). 2 Click **Assign Reports to Roles**. 3 Click the **Assign Reports to Roles** link for the role. 4 From the **Available Reports** list, select the ad hoc report to assign to the role, and click the **add** (**>**) button. 5 Click **Submit**. **Note:** You must assign every report you create to one or more roles.

Creating and saving an ad hoc report

Before creating and saving your first ad hoc report, you should create a new folder in the BI Publisher tool in which to store all of your ad hoc reports. For more information on creating folders, see the *BI Publisher online help* (on page 222).

1 Select **Reports** ().

The reporting page appears.

2 Click the **Design a New Report** link.

The BI Publisher window appears.

3 From the **Create** section, select **Report**.

The Choose Existing Data Model window appears. The Catalog section contains a tree menu with a selection of folders.

Choose the OutcomeLogix Data Model:

1 From the **Catalog** section, select the folder that contains the data model (OLXAdhocDataModel).

The data model appears on the right side of the window.

2 Select the data model, and click **Open**.

The Create Layout page appears.

Select the layout:

- Select from the predefined layouts, or upload an existing layout. For more information, see the BI Publisher online help.

The Layout Editor workspace appears.

Add the report components:

1 At the top of the page, select the **Insert** tab.

2 In the **Components** section of the **Insert** tab, select the following components as needed, and drag them into the workspace:

- **Layout Grid**—Inserts a grid with a specified number of rows and columns into which you can add components such as graphs, charts, and data item columns.
- **Repeating Section**—Inserts a section to display data items based on the number of times they appear in the report.
- **Data Table**—Inserts a table that contains rows and columns, column headers, and a row that automatically calculates column totals.
- **Text Item**—Inserts a text box in which you can type custom text.
- **Chart**—Inserts a customizable chart.
- **Gauge**—Inserts a gauge graph, which allows you to view the status or quantity of a single data item. For example, a gauge graph can display the number of queries at a site at the time the report is generated.
- **Pivot Table**—Inserts a customizable pivot table.

- **Image**—Inserts an image, such as a company logo or a photograph.

Drag in the report columns:

1 From the **Data Source** tree, navigate to a dataset.

2 Select a data item to add to the report, and drag it to the report component where it should be used. Repeat until all the columns have been added to the report layout.

Save the layout:

1 To save the report layout, in the upper-right corner of the page, click **Save** ().

The Save Layout dialog box appears.

2 Specify a Layout Name and Locale for the layout.

3 Click **Save**.

4 Click **Return**.

The report layout appears on the page.

Save the report:

1 To save the report, in the upper-right corner of the page, click **Save Report** ().

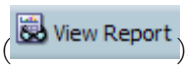
The Save As dialog box appears.

2 Specify a location in which to save the report, the report name, and a description of the report.

You can save the report to your Ad Hoc Reports folder so that when you later view it in the list on the Reporting page, it appears under the Ad Hoc Reports heading, making it easier to differentiate between standard reports and ad hoc reports.

3 Click **Save**.

View the report:

- To view the report, in the upper-right corner of the page, click **View Report** (

).

The report appears in a BI Publisher window.

Assign the report to OutcomeLogix roles:

1 Select **Administration** ().

The Administration page appears.

2 Click **Assign Reports to Roles**.

The Assign Reports to Roles page appears.

3 Click the **Assign Reports to Roles** link for the role.

The Assign Reports to Roles page appears for the role.

4 From the **Available Reports** list, select the ad hoc report to assign to the role, and click the **add** (**>**) button.

5 Click **Submit**.

Note: You must assign every report you create to one or more roles.

Viewing an existing ad hoc report

Before you can view an ad hoc report, the report must be assigned to your role. For more information, see *Creating and saving an ad hoc report* (on page 220).

1 Select **Reports** ().

The reporting page appears.

2 Click the **Design a New Report** link.

The BI Publisher window appears.

3 In the **Browse/Manage** section, select **Catalog Folders**.

The Catalog page appears.

4 From the **Folders** tree, select the folder that contains the ad hoc report to view.

The ad hoc reports that are saved in the folder appear.

5 Click the name of the ad hoc report to view.

The report appears in a new BI Publisher window.

Getting help for ad hoc reporting

The BI Publisher documentation is available from the user interface of the BI Publisher tool.

- Click the **Help** link.
  - To view the BI Publisher online help in a new window, select **Help Contents**.
  - To access the BI Publisher online help from the Oracle Documentation site, go to www.oracle.com.

Reporting page

The following tasks use this page:

- *Viewing and exporting a standard report* (on page 200)
- *Creating and saving an ad hoc report* (on page 220)

To view a job aid that you can print, see:

- Quick Reference: Reports.

Field	Description	Notes
Design a New Report link	For users with the appropriate rights, opens the BI Publisher tool, from which you can design ad hoc reports.	You must have the Design Report right to use this link.
Standard report links	Click to view the report.	Standard report links appear only for the reports to which you have access.

Managing reports

Roles and rights for reports

You can add the default reporting rights in the OutcomeLogix application to one or more roles.

- **Design Report**—Allows users assigned to the role to create ad hoc reports. This right is added to the following roles by default:
  - CRC
  - Investigator
  - Sponsor
  - CRA
  - CDM
  - Medical Monitor
  - OLX Read Only
  - OLX Help Desk
  - Study Administrator
- **View Report**—Allows users assigned to the role to view selected standard reports and saved ad hoc reports. This right is added to the following roles by default:
  - CRC
  - Investigator
  - Sponsor
  - CRA
  - CDM
  - Medical Monitor
  - Call Center Staff
  - Call Center Manager
  - Sponsor Help Desk
  - OLX Read Only
  - OLX Help Desk
  - Study Administrator

Note: You must assign every report you create to one or more roles.

Roadmap: Assigning report rights

Rights control your ability to view reports and create ad hoc reports.

Step	Action	Description
1	Configure the report server.	Configure the server settings for the server on which the BI Publisher software is installed.
2	Assign reporting rights to roles.	Assign one or both of the following rights to one or more roles: • **Design Report**—Allows users in a role to create and modify ad hoc reports. • **View Report**—Allows users in a role to view assigned standard and ad hoc reports.
3	Assign reports to roles.	Associate each report to one or more roles. The reporting rights associated with the role determine whether users assigned to the role can view or modify the report. **Note:** When you create and save ad hoc reports, you must perform this step for each new report to allow users to view the report.

Configuring the report server settings

1 Select **Administration** ().

2 The Administration page appears.

3 Click **Configure Reports**.

The Edit Report Server Configuration page appears.

4 Fill in the fields as necessary. For more information, see *Edit Report Server Configuration page* (on page 227).

5 Click **Submit**.

Assigning reporting rights to roles

1 Select **Administration** ().

2 Click **Manage Roles and Rights**.

The Manage Roles and Rights page appears.

3 Click the **Edit** link for the role.

The Rights Group page appears.

4 In the **Rights Group Details** section, assign rights as necessary.

- To allow users in the role to view reports, in the **Dashboard** section, select the **View Report**

checkbox.

- To allow users in the role to create ad hoc reports, in the **User Operation** section, select the **Design Report** checkbox.

Note: By default, all roles can view a report.

Assigning reports to roles

Users can view only the reports assigned to their roles. You can assign a report to multiple roles, or multiple reports to one role. When you assign a report to a role, a user who is assigned to the role can view the report.

Note: You must assign every report you create to one or more roles.

To view the reports assigned to a role:

1 Select **Administration** ().

The Administration page appears.

2 Click **Assign Reports to Roles**.

The Assign Reports to Roles page appears.

3 Click the **Assign Reports to Roles** link for the role.

The Assign Reports to Roles page appears for the role.

Reports assigned to the role appear in the list on the right.

To assign a report to a role:

1 Select **Administration** ().

The Administration page appears.

2 Click **Assign Reports to Roles**.

The Assign Reports to Roles page appears.

3 Click the **Assign Reports to Roles** link for the role.

The Assign Reports to Roles page appears for the role.

4 Do one of the following:

- From the **Available Reports** list, select the report to assign to the role, and click the **add** (**>**) button.
- To assign all available reports to the role, click the **add all** (**>>**) button.

5 Click **Submit**.

To remove a report assignment from a role:

1 Select **Administration** ().

The Administration page appears.

2 Click **Assign Reports to Roles**.

The Assign Reports to Roles page appears.

3 Click the **Assign Reports to Roles** link for the role.

The Assign Reports to Roles page appears for the role.

4 Do one of the following:

- Select the assigned reports to remove from the role, and click the **remove** (**<**) button.
- To remove all reports from the role, click the **remove all** (**<<**) button.

5 Click **Submit**.

Note: When you modify report role assignments, users assigned to the role must log out and sign in again to see any changes to report assignments.

Edit Report Server Configuration page

The following task uses this page:

- *Configuring the report server settings* (on page 225).

Field	Description	Notes
Server Address	Address for the server on which you installed the Oracle BI Publisher software.	Required.
Catalog Folder	The location in which all reports for a study exist. This is the folder where the StandardReports and DataModel subfolders have been copied.	Required.
Developer Username	Shared user name for all users who are assigned the Design Report right.	Required.
Viewer Username	Shared user name of all users who are assigned the View Report right.	Required.
Select to change the developer password	Allows you to change the Developer password. After selecting this checkbox, the following fields appear: • Old Password • Password • Confirm Password	The OutcomeLogix application uses this password to connect to the BI Publisher tool. It affects all users in roles that are assigned the Design Report right.

Field	Description	Notes
Old Password	Old password for the user specified in the Developer Username field.	
Password	New password for the user specified in the Developer Username field.	
Confirm Password	New password for the user specified in the Developer Username field.	
Select to change the viewer password	Allows you to change the Viewer password. After selecting this checkbox, the following fields appear: • Old Password • Password • Confirm Password	The OutcomeLogix application uses this password to connect to the BI Publisher tool. It affects all users in roles that are assigned the View Report right.
Old Password	Old password for the user specified in the Viewer Username field.	
Password	New password for the user specified in the Viewer Username field.	
Confirm Password	New password for the user specified in the Viewer Username field.	

Assign Reports to Roles page

The following task uses this page:

- *Assigning reports to roles* (on page 226).

To view a job aid that you can print, see:

- Quick Reference: Reports.

Column	Description
Assign Reports to Roles	Displays the Available Reports list, from which you can select reports to make available to users with the selected role.
Role	Role to which the reports are assigned.
Role Description	Description of the role.

CHAPTER 12

Data exports

In this chapter

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Data exports

You can export data in any language that is supported in the study. Typically, you create a data export file at the end of a study. You can export study data to the following formats:

- PDF file, which may contain:
  - Title page identifying the client server, study name, PDF Type selected, and the date of the export.
  - Configuration selections made on the Export Data page.
  - If PDF Type is Patient: Patient ID, initials, and arm.
  - Patient Status history.
  - Table of Contents with links to the data included.
  - Each visit, including a Visit Status History and Form Status History for each form within the visit, including completed, incomplete, and forms with queries and the forms themselves.
  - Images of completed forms for all or some sites. Each form begins on a new page.
  - A complete audit trail for each data element following each form and including the actual value, when it was recorded, who recorded it, and (if the functionality is implemented for the study) the reason for each change.
  - An audit trail of patient transfers that includes the date and time of the transfer.
  - All of the repeating sections or instances of forms.
  - All queries associated with each data element and the full history for each query.
  - The patient ID, visit, and form names in the header of each page.
  - The date the PDF was generated and the page number in the footer of each page.
- Microsoft Excel spreadsheet software file, which may contain:
  - A complete audit trail for each data element, including the actual value, when it was recorded, who recorded it, and (if the functionality is implemented for the study) the reason for each change.
  - All of the repeating sections or instances of forms.
  - All queries associated with each data element and the full history for each query.
  - The subject ID, visit, and form names.
  - The date the file was generated in the automatically generated filename.

Note: If the study is designed to contain Personal/Protected Health Information, and designers and sponsors choose to encrypt it, they have the ability to indicate which items on forms contain sensitive information that should be encrypted and also excluded from email messages, data exports, and reports by default.

Exporting study data

To export study data to a PDF file:

1 Select **Export Data** ().

The Export Data page appears.

2 Select **PDF Format**.

3 Fill in the fields as necessary. For more information, see *Export Data page* (on page 232).

4 Click **Create File**.

A link to download the file appears in the Adobe PDF History Files section.

To export study data to a Microsoft Excel spreadsheet software file:

1 Select **Export Data** ().

The Export Data page appears.

2 Select **XLS format**.

3 Fill in the fields as necessary. For more information, see *Export Data page* (on page 232).

4 Click **Create File**.

A link to download the file appears in the Microsoft Excel History Files section.

To download a file:

1 Select **Export Data** ().

The Export Data page appears.

2 At the bottom of the page, click the link for the file.

Note: If the study is designed to contain Personal/Protected Health Information, and designers and sponsors choose to encrypt it, they have the ability to indicate which items on forms contain sensitive information that should be encrypted and also excluded from email messages, data exports, and reports by default.

Data Export page

The following task uses this page:

- *Exporting study data* (on page 231).

Note: If the study is designed to contain Personal/Protected Health Information, and designers and sponsors choose to encrypt it, they have the ability to indicate which items on forms contain sensitive information that should be encrypted and also excluded from email messages, data exports, and reports by default.

Field	Description	Notes
Choose an export type	Format in which to export data: PDF or XLS.	
Language	Language for the export.	
Adobe PDF exports		
Client	OutcomeLogix client server to connect to.	Required.
PDF Type	Type of PDF to generate: • **Unannotated**—Export forms only. • **Annotated**—Export forms with annotations; for example, tables listing controls used in the form, their type, data type, maximum length, and name displayed on the page. • **Patient**—Export data for specific patients, including status histories and audit trails.	

Field	Description	Notes
Include	Base the export on: • **All Patients**—Export all patients. • **Specific Site**—Export a specific site. ▪ **Site ID**—Select the specific site to export from the drop-down list. • **Specific Patient**—Export a specific patient. ▪ **Patient ID—**Select the patient to export from the drop-down list, which appears in ascending order by creation date.	When Patient is selected from the PDF Type drop-down list, these options appear.
Include EDC Forms	Whether to include EDC forms.	Includes forms completed by site users.
Include ePRO Forms	Whether to include ePRO forms.	Includes forms completed by patients (patient diaries).
Include Observer Forms	Whether to include observer forms.	Includes forms completed by observers (patient diaries).
Study Arm	Arm of the study to export.	Select the arm from the Study Arm drop-down list.
Include Audit Trail	Whether to include the audit trail.	Appears only when Patient is selected from the PDF Type drop-down list.
Include Query List	Whether to include the query list.	Appears only when Patient is selected from the PDF Type drop-down list.
Include Status Histories	Whether to include form, visit, and patient status histories, including patient transfers.	Appears only when Patient is selected from the PDF Type drop-down list.
Microsoft Excel spreadsheet software exports		

Field	Description	Notes
Form Type	Type of forms to export: • **All**—Export all forms. • **EDC**—Export EDC forms only (includes Visit Landing page). • **EPRO**—Export ePRO forms only. • **Observer**—Export observer forms only.	
Form Name	Forms to export. You can export all forms of the specified form type, or a specific form.	
Site	Site(s) to export. You can export all sites, or a specific site.	
Patient	Patient(s) to export. You can export all patients, or a specific patient.	

CHAPTER 13

Call Center

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Call Center basics

What is the Call Center?

The OutcomeLogix application includes an optional Call Center module to assist in managing ePRO patients who complete forms remotely by phone, on a study website, or on paper. All interactions with patients are tracked through an audit trail, and call scheduling is study-specific and configurable through the OutcomeLogix application.

Users with appropriate rights, typically Call Center managers and Call Center staff, have access to the Call Center List page, which displays patients who have not completed their ePRO forms within the required time frame, and patients who want to complete forms over the phone with the assistance of Call Center staff.

Using personalized scripts in the patients' preferred language, Call Center staff complete surveys for patients or assist web-based or paper-based patients in completing their ePRO forms. Call Center staff can log the details of all patient calls.

On the Patient Diary page, site and sponsor users can review ePRO forms, including those completed with the assistance of the Call Center.

Call Center roles

Users with appropriate rights have access to the Call Center. Call Center managers see the Call Center List icon () on their homepage. The Call Center List page is the homepage for Call Center staff. Study administrators perform Call Center configuration functions, such as adding users to the Call Center, through the Administration page.

- **Call Center staff** members are responsible for interacting with patients enrolled in a study. They manage the call queue and help patients to complete surveys. They log patient calls, report Major Medical Events, fill in ePRO forms on behalf of patients, and manage patient contact information.

  The Call Center staff can include site and sponsor personnel, contract research organizations, and other third-party employees who have been assigned the required rights.
- **Call Center managers** perform administrative tasks, assign patients to Call Center staff, and have all of the rights of the Call Center staff.
- **Study administrators** configure Call Center settings and customize Call Center scripts.

The other participants in the Call Center are patients who complete ePRO forms or report major medical events with Call Center assistance.

Preferred method of contact

The preferred method of contact determines how patients complete ePRO forms, how you contact them, and how reimbursement is provided. During patient enrollment, ePRO patients select a preferred method of contact: on the study website, by phone, or on paper. You record this selection and a preferred contact time on the *Patient Profile page* (on page 92).

Based on the preferred method of contact, patients interact with the Call Center in different ways to

complete an ePRO survey.

- **Web-based patient**—After email notification, the patient signs in and fills out the survey on the study website. If a web-based patient fails to complete the survey within the web completion window, the patient appears on the Call Center List page and Call Center staff contact the patient, assisting the patient in completing the survey, if necessary. After the patient completes a survey, if the study is designed to award eCodes, the patient receives an eCode by email.
- **Phone-based patient**—The application prompts the Call Center user to call the patient and help the patient complete the survey. If the Call Center reaches the maximum number of notification attempts, the application removes the patient from the call queue until the next survey completion window opens. After a survey is completed, if the study is designed to award eCodes, the patient receives an eCode by email, or if the patient's email address is not in the system, the Call Center user reads the eCode to the patient.
- **Paper-based patient**—The patient fills out paper surveys sent by the site and mails or faxes them to the site. The patient does not sign into the OutcomeLogix application, and the Call Center does not contact the patient directly. Windows for completion of surveys do not apply to a paper-based patient, and you cannot assign eCodes to a paper-based patient.

  Paper-based patients, however, can contact the Call Center for assistance in filling out their surveys, or to report a Major Medical Event. Using an override option, a Call Center staff member completes the survey with the patient or helps the patient enter a Major Medical Event.

At any time during the study, a patient can change to a different preferred method of contact. For more information, see *Call Center Patient Details page* (on page 246).

How the call queue works

The application adds patients to the call queue during a scheduled time frame, also called a window. Patients in the call queue appear on the Call Center List page. Depending on the design of your study, the call queue can consist of phone-based patients, web-based patients who are delinquent in completing their patient surveys within a specific time frame, or both. Paper-based patients are not in the call queue but can appear on the Call Center List page if you use the search filters to find them.

The Call Center List page serves as the homepage for Call Center staff as well as a task list.

- Call Center staff notifies patients that appear on the Call Center List page that their surveys are due.
- When the maximum number of notification by phone attempts has been reached, the application removes the patient from the call queue until the next scheduled survey completion window.

Working in the Call Center

Roadmaps

Roadmap: Working with web-based patients

Web-based patients complete survey forms directly through the study website.

Step	Action	Description
1	Add a web-based patient.	1 Complete the Patient Profile page. 2 Select Web as the Preferred Method of Contact. 3 You must also enter: ▪ Patient First Name and Last Name. ▪ Language. ▪ Patient email address. ▪ Phone and Confirm Phone. ▪ Time zone. ▪ Preferred time of contact.
2	The patient receives an email notification that a survey is due, as well as reminder notifications to complete the survey.	The patient must complete the survey on the website within a defined number of days (the web completion window). This window is established in the study design and can be edited in the Administration section of the OutcomeLogix application.
3	The patient completes the survey within the web completion window.	If the study is configured to issue eCodes, and if the patient completes the survey within the web completion window, the Call Center emails an eCode to the patient.
4	If the patient does not complete the survey within the web completion window, use the Call Center List to contact the patient by telephone and complete the survey.	1 Select **Call Center List** (). 2 Click the **Patient ID** link of a patient. 3 Call the patient. 4 Click **Interview**.

Step	Action	Description
5	The patient completes the survey with Call Center assistance. or The Call Center is unable to contact the patient and complete the survey.	• If the patient completes the survey with Call Center assistance, and if the study is configured to issue eCodes, the OutcomeLogix application emails an eCode to the patient. • If the patient does not complete the survey within the specified window, or if the Call Center staff members have unsuccessfully attempted to contact the patient the maximum number of times defined for the Call Center, the survey remains blank and no eCode is provided.

Note: A patient can contact the Call Center to complete a survey outside the scheduled window (if permitted by the study design) or to report a Major Medical Event. No eCode is associated with the reporting of a Major Medical Event.

Roadmap: Working with phone-based patients

The Call Center List page prompts staff to call phone-based patients and help them complete their surveys.

Step	Action	Description
1	Add a phone-based patient.	1 Complete the Patient Profile page. 2 Select Phone as the Preferred Method of Contact. 3 You must also enter: ▪ Patient First Name and Last Name. ▪ Language. ▪ Phone. ▪ Time zone. ▪ Preferred time of contact.
2	The application adds the patient to the call queue for contact during the survey window defined for each visit.	When due for a call, the patient appears on the Call Center List page.
3	The Call Center staff member contacts the patient by telephone to complete the survey.	1 Select **Call Center List** (). 2 Click the **Patient ID** link of a patient. 3 Call the patient. 4 Click **Interview**.

Step	Action	Description
4	The Call Center staff member assists the patient to:	Do the following:
	• Complete the currently scheduled survey.	• Click the **Override** button and perform the interview.
	• Complete all previously and currently scheduled surveys, if permitted by the study design.	• Click the **Override** button and perform the interview.
	• Report a Major Medical Event.	• Click the **Report Major Medical Event** button and help the patient to fill out the form for reporting the Major Medical Event.
5	If the study is configured to issue eCodes, and the patient completes the survey with Call Center assistance within the Call Center window, the Call Center staff member emails or reads the eCode to the patient.	If the patient does not complete the survey within the specified window, or if the Call Center staff has unsuccessfully attempted to contact the patient the maximum number of times defined for the Call Center, the survey remains blank and no reimbursement is provided.
6	If the Call Center staff member cannot reach the patient or contacts the patient but cannot perform the interview, the Call Center staff member logs the call.	• Click **Log Call.** The OutcomeLogix application logs the call and increments the call attempt count.

Note: A patient can contact the Call Center to complete a survey outside the scheduled window (if permitted by the study design) or to report a Major Medical Event. No eCode is associated with the reporting of a Major Medical Event.

Roadmap: Working with paper-based patients

Typically, the Call Center does not interact with paper-based patients. You can, however, report major medical events for paper-based patients and assist them in completing a survey, if requested.

Step	Action	Description
1	Add a paper-based patient.	1 Complete the Patient Profile page. 2 Select Paper as the Preferred Method of Contact. 3 You must also enter: ▪ Patient First Name and Last Name. ▪ Language.
2	A patient contacts the Call Center to ask for help completing a survey or to report a Major Medical Event.	The preferred method of contact of the patient determines whether or not the patient appears on the Call Center List page.

Step	Action	Description
3	If necessary, on the Call Center List page, search for the patient.	• To view an individual paper-based patient, search for the specific patient by patient name or ID. • To view all paper-based patients, select **Type** and **Paper**, and click the **Search** button. • To view all patients, including paper-based patients, select **All** and click the **Search** button.
4	If requested, assist the patient to: • Complete the currently scheduled survey. • Complete all previously and currently scheduled surveys, if permitted by the study design. • Report a Major Medical Event.	Do the following: • Click the **Override** button and perform the interview. • Click the **Override** button and perform the interview. • Click the **Report Major Medical Event** button and help the patient to fill out the form for reporting the Major Medical Event.

Note: The OutcomeLogix application does not assign eCodes to paper-based patients.

Adding a patient to the Call Center

You can add a patient to the Call Center when you create a patient account or after a patient has been enrolled. In both instances, after creating the patient account, you add the patient to the Call Center by entering the patient's preferred method of contact, time of contact, and contact information on the Patient Profile page.

Note: You must have permission to enroll patients to perform this task.

1 Create a patient account.

For more information, see *Creating a patient* (on page 73).

2 Select **Patients** ().

The Patient List page appears.

3 Click the **Profile** link for the patient.

The Patient Profile page appears.

4 Edit the fields as necessary.

For more information, see *Patient Profile page* (on page 92).

Viewing a list of Call Center patients

The Call Center List page shows the patients added to the call queue and due for phone calls. Depending on the design of your study, the call queue can consist of phone-based patients, web-based patients who are delinquent in completing their patient surveys within a specific time frame, or both. Paper-based patients are not in the call queue but can appear on the Call Center List page if you use the search filters to find them.

1 Select the **Call Center List** icon ().

2 Filter the Call Center list.

   a From the first **Search** drop-down list, select the search filter to apply. To see only the patients who are in the call queue, select the **Patients Due** search filter.

   b If a second **Search** drop-down list appears, select the value for the filter.

3 Click **Submit**.

For more information, see *Call Center List page* (on page 243).

Searching for a patient

1 Select the **Call Center List** icon ().

   The Call Center List page appears.

2 From the first **Search** drop-down list, select the search filter to apply.

3 If the second **Search** drop-down list appears, select the value for the selected filter.

4 Click **Submit**.

Note: If you select **All** in the first Search drop-down list or click **Clear Filters**, and then click **Submit**, all patients appear in the Call Center List, including paper-based patients.

Viewing Call Center details for a patient

1 Select **Call Center List** ().

   The Call Center List page appears.

2 Click the **Patient ID** link of a patient. If the patient is not listed, use the search options to locate the patient. To see only the patients who are in the call queue, select the **Patients Due** search filter.

   The Call Center Patient Details page appears. For more information, see *Call Center Patient Details page* (on page 246).

Note: Paper-based patients do not appear on the Call Center List page. However, you can search for paper-based patients by selecting **Type** from the first **Search** drop-down list and **Paper** from the second **Search** drop-down list.

Updating patient information

1 Select **Call Center List** ().

The Call Center List page appears.

2 Click the **Patient ID** link of a patient. If the patient is not listed, use the search options to locate the patient. To see only the patients who are in the call queue, select the **Patients Due** search filter.

The Call Center Patient Details page appears. For more information, see *Call Center Patient Details page* (on page 246).

Note: Paper-based patients do not appear on the Call Center List page. However, you can search for paper-based patients by selecting **Type** from the first **Search** drop-down list and **Paper** from the second **Search** drop-down list.

3 Click **Edit**.

4 Edit the fields as necessary.

5 Click **Update**.

Note: You can also update patient information on the Patient Profile page if you have the appropriate permissions. For more information, see *Patient Profile page* (on page 92).

Considerations for changing the preferred method of contact

If you change the preferred method of contact, consider the following:

- If a patient changes from paper- to web- or phone-based, only surveys left to be completed appear on the Call Center List page. After changing to web- or phone-based status, a patient is not eligible for any eCodes for forms completed while the patient was paper-based, even if eCodes would have been assigned for those forms if the patient had been web- or phone-based when completing the forms.
- If a patient changes from web- or phone-based to paper-based, the OutcomeLogix application does not re-send missed eCodes and no longer sends eCodes via email.
- If a patient changes from paper- to phone-based in the middle of a survey window, the OutcomeLogix application does not allow form completion outside of the survey window (including forms completed as a paper-based patient). The application does not keep a history of all these updates. Call Center users can use the Override function to make the required updates.

Call Center List page

The Call Center List summarizes the status of each patient enrolled in the Call Center. You have access to patient contact information and a history of previous calls for only the patients assigned to you. The Call Center List page is the homepage for Call Center staff.

Each row of the Call Center List summarizes the status of a patient based on the visit in which the patient has ePRO forms to complete. If the patient has forms to complete in multiple visits:

- The Call Center List shows data based on the first visit that the patient started.
- If the number of attempts made to contact the patient about the first visit reaches the configured maximum for the Call Center, the Call Center List shows data based on the next-started visit in

which the patient has forms to complete. This logic applies to each visit in the sequence of visits that the patient has started.

- If the number of attempts made to contact the patient about the last-started visit reaches the configured maximum for the Call Center, the Call Center List shows data based on that visit, with the number of remaining contact attempts set to zero.

The following tasks use this page:

- *Adding a patient to the Call Center* (on page 241).
- *Viewing a list of Call Center patients* (on page 242).
- *Searching for a patient* (on page 242).
- *Viewing Call Center details for a patient* (on page 242).

To view a job aid that you can print, see:

- Quick Reference: Call Center.

Option	Description	Note
Column		
Search drop-down lists and Submit button	Selections that enable you to locate particular patients in or out of the Call Center queue.	If you select **All** in the first **Search** drop-down list or click **Clear Filters** and then click **Submit**, all patients appear in the Call Center List, including paper-based patients. The Patients Due selection displays only patients in the queue. You can also search specifically for paper-based patients.
Patient ID	Unique identifier for the patient.	The Patient ID is a link to the Patient Detail page. By default, patients appear in ascending Patient ID order by creation date.
Name	Patient name, in the format <*firstname lastname*>.	
Language	Language selected on the Patient Profile page.	
Type	Survey completion mode for the patient: • Web-based • Phone-based • Paper-based	For more information, see *Preferred method of contact* (on page 236).
Queue Start Date	Date that the patient entered the call queue.	This field is empty if the patient has no forms to complete.

Option	Description	Note
Target Completion Date	Date that the Call Center survey window closes.	This field is empty if the patient has no forms to complete.
Next Call Date	Date that the next call to the patient is due.	This field is empty if the patient has no forms to complete.
Patient Contact Time	Preferred calling time in the time zone where the patient resides.	The time appears as the time in the patient's time zone, followed by the time zone.
User Contact Time	Preferred calling time in the time zone of the Call Center user.	
Attempts Made	Number of actual phone calls made to the patient.	Calculated from the Patient Detail page by counting the number of times that a call has been logged. This field is empty if the patient has no forms to complete.
Remaining Attempts	Number of notifications remaining before the patient is removed from the call queue.	Notification is by phone. This field is empty if the patient has no forms to complete.
Last Call Outcome	Reason that the Call Center was unable to reach the patient.	The action taken at the last call; for example, Left Message Home.
Assigned To	Staff member or manager assigned to the patient (displays only for managers).	Call Center managers can view all assignments. Call Center staff can view only the patients assigned to them.
Buttons		
Assign Staff	Assign Call Center staff to patients.	Visible only to Call Center managers.
Clear Filters	Reset the Search feature to the default.	
Reset Assignments	Discard current changes to the Assigned To drop-down list.	Visible only to Call Center managers. You can use this feature only if you have not submitted the new staff assignment by clicking Assign Staff.

Call Center Patient Details page

The Call Center Patient Details page has the following sections:

- **Patient Information**—Patient details drawn from the Patient Profile page.
- **Call Script**—A personalized script to follow when contacting the patient.
- **Quick Links**—Links to additional scripts to support you while on the phone with a patient.

Note: Changes made to the Patient Information pane update the Patient Profile page.

The following tasks use this page:

- *Viewing Call Center details for a patient* (on page 242).
- *Starting an interview* (on page 249).
- *Logging a call* (on page 249).
- *Performing an interview outside of the survey window* (on page 250).
- *Viewing the Call Center history of a patient* (on page 250).
- *Reporting a Major Medical Event in the Call Center* (on page 253).

To view a job aid that you can print, see:

- Quick Reference: Call Center.

Field	Description	Note
Patient Information pane		
Edit link	Enables fields in the Patient Information pane for editing.	When you click Edit, the Update and Cancel links appear. To update, you must have the right to update patient information.
Preferred Method of Contact	Survey completion mode: Web, Phone, or Paper.	Before changing the preferred method of contact, see *Considerations for changing the preferred method of contact* (on page 243).
First Name Middle Name Last Name	Primary Contact: first, middle (optional), and last name of the primary contact.	This could be someone other than the patient, for example, if the patient is a minor.
Language	Language of the patient.	
Email	Email address for the patient.	Required for web-based patients.
Phone Confirm Phone	Phone number and confirmation of phone number for the patient.	

Field	Description	Note
Time Zone	Time zone where the patient is located.	
Preferred Time of Contact	Set a contact range by moving the sliding controls to the start and end times of the preferred range.	
Address1	Mailing address of the patient.	
Address2	Mailing address of the patient.	Second line of address.
City	City where the patient is located.	
Zip Code	ZIP code where the patient is located.	
State	State where the patient is located.	
Country	Country of residence.	
Call Script pane		
Call script	Personalized script to follow when contacting a patient.	Appears only if the patient has diary entries to complete. Appears in the language specified in the patient profile and can be personalized with variables such as the patient name. For paper-based patients, a message appears indicating that paper-based patients do not have call scripts.
Quick Links pane		
Quick Links	Links to Call Center scripts that cover various scenarios of patient interaction. This link is hidden for paper-based patients.	The selected script appears in the Call Script pane. Scripts may differ depending on whether the patient is web-based or phone-based.
Buttons		
Back	Return to the Call Center List page.	
Call History	Click to display the call history for the patient.	
Log Call	Save information about the contact or attempted contact with the patient.	

Field	Description	Note
Interview	Appears if the patient is within the survey window.	1 To view a list of surveys that can be completed, click Interview. 2 To view the first survey form, click Continue. The form appears in the preferred language of the patient.
Override	When the patient is outside of the survey window, you can click Override to display all incomplete forms and select a form to complete.	
Report Major Medical Event	Enter details about a Major Medical Event reported by the patient.	

Conducting a survey

Starting an interview

1 If the Call Center List page is not your homepage, select **Call Center List** ().

The Call Center List page appears.

2 Click the **Patient ID** link of a patient. If the patient is not listed, use the search options to locate the patient. To see only the patients who are in the call queue, select the **Patients Due** search filter.

The Call Center Patient Details page appears. For more information, see *Call Center Patient Details page* (on page 246).

3 Call the patient.

4 In the **Quick Links** pane, select the call script appropriate to your contact with the patient or the person who answers the call.

The call script appears in the **Call Script** pane, customized to show prompts that are specific to the patient (for example, the name of the patient).

5 If the patient or informant agrees to complete the survey, click **Interview**.

If the patient is within the survey window, a list of the current forms to be completed appears.

Note: If the patient is outside the survey window, you can conduct an interview by clicking **Override** or report a Major Medical Event by clicking **Report Major Medical Event**.

6 Click **Continue**.

The first form in the survey appears.

7 Fill out the form with the patient, and click **Submit**.

The next form in the survey appears.

8 Repeat for each form in the survey.

When the last form is complete:

- An acknowledgment page appears and displays information about eCode compensation, if appropriate.
- The OutcomeLogix application generates an entry in the call log indicating that the interview is completed.

Note: At any time during the course of a study, you can click the **Interview** button to complete a scheduled survey.

Logging a call

You log a call when you cannot reach the patient or you contacted the patient and you cannot perform the interview. If the patient has been contacted the maximum number of times configured for the Call Center, a message appears and indicates that you cannot log the call attempt.

1 On the Call Center Patient Details page, click **Log Call**.

The Log Call form appears below the script.

2 Fill in the fields as necessary. For more information, see Log Call form.

3 Click **Submit**.

The OutcomeLogix application logs the call and increments the call attempt count.

Note: If the study has multiple arms with overlapping visit windows, the application records the call against the visit you opened first.

Performing an interview outside of the survey window

You can assist a patient with a survey outside of the survey window if you have the right to override incomplete forms.

1 Select **Call Center List** ().

The Call Center List page appears.

2 Click the **Patient ID** link of a patient. If the patient is not listed, use the search options to locate the patient. To see only the patients who are in the call queue, select the **Patients Due** search filter.

The Call Center Patient Details page appears. For more information, see *Call Center Patient Details page* (on page 246).

If the patient contact is outside the scheduled window:

- The Next Call Date is not the current date.
- A message appears at the top of the patient profile indicating that the patient has no diaries to complete.

3 Click **Override**.

A list of incomplete surveys appears.

4 Click the survey to complete with the patient.

5 Proceed with the survey. For more information, see *Starting an interview* (on page 249).

Viewing the Call Center history of a patient

1 Select **Call Center List** ().

The Call Center List page appears.

2 Click the **Patient ID** link of a patient. If the patient is not listed, use the search options to locate the patient. To see only the patients who are in the call queue, select the **Patients Due** search filter.

The Call Center Patient Details page appears. For more information, see *Call Center Patient Details page* (on page 246).

3 Click **Call History**.

The Call History page appears. For more information, see *Call History page* (on page 251).

Call History page

The following tasks use this page:

- *Viewing the Call Center history of a patient* (on page 250).

To view a job aid that you can print, see:

- Quick Reference: Call Center.

Field	Description	Note
Date Called (GMT)	Date and time of contact in the format selected on the User Profile page.	Dates appear in descending order.
Visit Name	Name of the visit with which the survey is associated.	
Call Attempt	Number of attempts made to contact the patient.	Includes only contact attempts made by phone. The patient survey form status must be Submitted.
Call Outcome	The reason for the log entry, selected from the Reason drop-down list.	
Notes	User comments about the contact.	Maximum number of characters is 400.
User	Name of Call Center staff assigned to the patient.	The role must be Call Center Manager or Call Center Staff.

Log Call form

The following tasks use this page:

- *Logging a call* (on page 249).

To view a job aid that you can print, see:

- Quick Reference: Call Center.

Field	Description	Note
Reason	Select a choice from the drop-down list.	Required.
Additional Reason	Provide a reason not included in the drop-down list.	
Call Back Date	Select a date from the calendar.	The OutcomeLogix application validates the date to ensure that it is within the survey window.

Field	Description	Note
Call Back Time	Select Morning, Afternoon, or Evening.	

Reporting a Major Medical Event in the Call Center

Serious or Major Medical Events can be reported in different ways, depending on the study requirements. For example, sites may enter data into EDC forms, or patients or call centers complete specific Major Medical Event forms set up in the study. For more information, see *Reporting a Major Medical Event* (on page 125).

As a Call Center staff member, you can help a patient to report a Major Medical Event by accessing the Call Center.

1 Select **Call Center List** ().

The Call Center List page appears.

2 Click the **Patient ID** link of a patient. If the patient is not listed, use the search options to locate the patient. To see only the patients who are in the call queue, select the **Patients Due** search filter.

The Call Center Patient Details page appears. For more information, see *Call Center Patient Details page* (on page 246).

If the patient is not in the call queue, a message appears at the top of the patient profile indicating that the patient has no diaries to complete.

3 Click the **Report Major Medical Event** button.

The Major Medical Events form appears.

4 Fill in the fields as necessary.

5 Click **Submit**.

- The application associates the major medical event reported with the visit, regardless of whether it is reported inside or outside of a survey window.
- The submitted Major Medical Events form is visible on the Patient Diary page.

Note: At any time during the course of a study, you can click the **Report Major Medical Event** button to log a medical event.

Managing the Call Center

Roadmap: Configuring the Call Center

Step	Action	Description
1	Create the Call Center profile.	The Call Center profile is enabled during study design and can be updated, if allowed in the study, in the Administration user interface. 1 Select **Administration** (). 2 Click **Call Center Profile Setting**. 3 Enter details about the Call Center and the web completion windows for each visit. 4 Click **Submit**.
2	Customize the call scripts.	The call scripts are configured during study design and can be updated, if allowed in the study, in the Administration user interface. 1 Select **Administration** (). 2 Click **Call Center Script Setting**. 3 Customize each Call Center script. 4 Click **Update**.
3	Add the Call Center staff.	You assign staff to a Call Center by assigning users to the Call Center Manager or Call Center Staff role. Use the Manage Users option on the Administrative menu.
4	Assign patients to Call Center staff.	For each patient on the Call Center List page, select a Call Center staff member from the Assign Staff drop-down list. 1 Select **Call Center List** (). 2 From the **Assign Staff** drop-down list, select the Call Center staff member to assign to the patient. 3 Click **Assign Staff**.

Updating a Call Center profile

1 Select **Administration** ().

2 Select **Call Center Profile Setting**.

The Call Center Profile Setting page appears.

3 Edit the fields as necessary. For more information, see *Call Center Profile Setting page* (on page 256).

4 Click **Submit**.

Assigning staff to the Call Center

You assign staff to the Call Center by adding the user to a Call Center Staff role within the Administration function.

Note: You must have the right to create users to assign staff to a Call Center.

1 If necessary, create the user. For more information, see *Creating, activating, and deactivating a user* (on page 36).

2 Assign the user to the Call Center Manager or Call Center Staff role. For more information, see *Assigning a user to a role* (on page 55).

Assigning patients to Call Center staff

1 Select **Call Center List** ().

The Call Center List page appears.

2 From the **Assign Staff** drop-down list, select the Call Center staff member to assign to the patient.

3 Click **Assign Staff**.

If you have not clicked **Assign Staff**, you can cancel the assignment by clicking **Reset Assignments**.

Viewing the patients assigned to a Call Center staff member

1 Select the **Call Center List** icon ().

The Call Center List page appears.

2 From the first **Search** drop-down list, select **Assigned To**.

3 From the second **Search** drop-down list, select a Call Center staff member.

4 Click **Submit**.

The patients assigned to the selected staff member appear.

Note: Call Center managers see all assignments. Call Center staff members see only their own assignments.

Call Center Profile Setting page

The following tasks use this page:

- *Updating a Call Center profile* (on page 255).

To view a job aid that you can print, see:

- Quick Reference: Administration.

Field	Description	Note
Call Center Name	Descriptive name for the Call Center.	Required.
Call Center Phone Number	Telephone number of the Call Center.	Number where patients can contact the Call Center. You can use this number in a Call Center Script so that Call Center staff personnel can inform patients of the number.
Max Phone Attempts	The maximum number of attempts to reach a patient allowed during a Call Center window.	Includes only phone attempts. If no total is specified, there is no limit on the number of contact attempts.
Web Completion Window	For each regular visit in the study, the number of days and hours a survey window is open for a web-based patient.	Permanent visits, which hold forms that are cumulative throughout the study (for example, Major Medical Events) are not associated with a Web Completion Window and do not appear in the list of visits. If the value for a visit is blank, patients are added to the Call Center queue immediately on starting the visit.

Customizing Call Center scripts

About customizing a Call Center script

You can customize the text and formatting of a script on the Call Center Script Setting page. Call Center scripts are created using HTML tags. When editing a Call Center script:

- You can copy and paste the raw HTML text of a script into an HTML editor for easier editing and syntax checking and then paste it back into the Call Center Script Setting page.
- Do not change any variable text between curly braces ({ }), for example, {User.UserName}. The application populates these name variables when displaying the script. The variables that you can use appear on the Call Center Script Setting page under the Supported Name Codes heading.
- You can use standard HTML formatting tags to create paragraphs and emphasis.
- Do not insert HTML links with <a href> tags.
- Do not insert external scripts into a Call Center script using the <script> </script> tags.

Entering and editing a Call Center script

1 Select **Administration** ().

2 Select **Call Center Script Setting**.

The Call Center Script Setting page appears.

3 Select the script section from the **Script Name** drop-down list.

4 Select the language from the **Language** drop-down list.

5 Modify the script sections as necessary. For more information, see *About customizing a Call Center script* (on page 257).

6 Click **Update**.

The OutcomeLogix application validates the script to ensure that:

- The text between angle brackets (< >) has not been changed.
- HTML markup has not been inserted in the areas where text cannot to be entered.

If the script is correctly entered and saved, the application generates the HTML for the script.

7 Repeat steps 3 – 6 for each script section and language supported by the Call Center.

Note: The audit trail includes the changes you make in the script.

Call Center Script Setting page

The following task uses this page:

- *Entering and editing a Call Center script* (on page 257).

To view a job aid that you can print, see:

- Quick Reference: Administration.

Field	Description	Note
Script Name drop-down list	The selected script section.	
Script Assignment	Based on the Script Name selection, displays the contact method and script type.	
Language drop-down list	The language in which you are entering the script section.	You create a separate script for each language and enter the sections in the selected language.
Script Text	Displays selected script for you to edit.	
Start Instructions	Lists supported name codes and HTML tags.	

CHAPTER 14

Transferring patients between sites

In this chapter

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About transferring patients

In a long-running study, patients will relocate, change physicians, or be reassigned to a different investigator or site. When these scenarios occur, the OutcomeLogix application supports patient transfer from one site to another.

All records and forms, whether or not they are completed, move with the transferred patient and become the responsibility of the destination site.

After the patient is transferred, investigators at the originating site retain access to pre-transfer data. However, the transferred patient is no longer associated with the originating site for purposes of total patient count, reports, listings, and so on. Investigators at the originating site cannot update visits in the originating site or view data entered at the destination site after the transfer. The users at the destination site can edit forms in incomplete visits after the patient transfer.

A user can only perform a transfer if the user:

- Has access to both the originating and destination sites.
- Belongs to the role with the right to perform a patient transfer.

Patients must have at least a Pre-screened status to be eligible for transfer.

Assigning the Patient Transfer right to a role

Note: Editing the rights assigned to a role changes the rights for all users assigned to the role.

1 Select **Administration** ().

2 Click **Manage Roles and Rights**.

The Manage Roles and Rights page appears.

3 Click the **Edit** link for the role.

The Rights Group page appears.

4 In the Patient rights group, check **Transfer Patient** and **Show Patient Transfer History**.

For more information, see *Roles and rights descriptions* (on page 272).

5 Click **Submit**.

Associating a destination site with an originating site

The destination site is the site to which the patient is transferred. The originating site, your site, and destination site must be associated. However, when sites are added, by default they are not associated with any destination sites. You must select the destination sites and associate them with the originating site.

1 Select **Administration** ().

2 Click **Manage Sites**.

The Manage Sites page appears.

3 Select the originating site and click the **Edit** link.

The profile page for the selected site appears.

4 Do one of the following:

- From the **Available Destination Sites** list, select one or multiple sites and click **Add** (**>**) to move the sites to the Selected Destination Sites list.
- To select all sites, click **Add All** (**>>**).

5 Click **Submit**.

Roadmap: Transferring a patient from one site to another

When a patient requires a transfer to a new site, a user with the right to transfer patients from the originating site begins the process by selecting the patient in the Patient List and clicking the **Transfer** button.

Step	Action	Description
1	Select the patient.	1 Select **Patients** (). 2 Search by Status, Patient List, Site Name, or patient ID.
2	Start the transfer.	1 Click the radio button of the patient to transfer. 2 Click the **Transfer** button.
3	Review the Patient Transfer affidavit and statuses.	Observe the color associated with Signature Status, Query Status, and Source Verification Status. • If the status is black, no action is required. • If red, attention is required. Incomplete statuses of these items do not prevent the patient transfer, but you may want to cancel the transfer, complete these activities, and reinitiate the transfer.
4	Select the destination site.	1 From the **Destination Site** drop-down list, select the site to which to transfer the patient. 2 From the **Reason For Transfer** drop-down list, select the reason for the transfer.
5	Conclude the transfer and create the archive.	• Click **Submit**. Because the archive contains the entire patient record generated to a PDF file, archive creation can take time. During that time, do not update the patient record.
6	View the PDF archive.	1 On the Patient List page, click the **Patient Transfer History** tab. 2 Click the **View** link for the patient.

Initiating a patient transfer

1 Select **Patients** ().

The Patient List page appears.

2 Select the patient you want to transfer by clicking the radio button to the left of the patient record.

3 Click the **Transfer** button.

The Patient Transfer dialog box appears. Notice that the Patient Transfer dialog box shows the Current Site and Patient ID.

4 Review the Patient Transfer affidavit.

Observe the color associated with Signature Status, Query Status, and Source Verification Status.

- If the status is black, no action is required.
- If the status is red, attention is required.

Incomplete statuses of these items do not prevent the patient transfer, but you may want to cancel the transfer, complete these activities, and reinitiate the transfer.

5 From the **Destination Site** drop-down list, select the site to which to transfer the patient.

6 From the **Reason For Transfer** drop-down list, select the reason for transferring this patient.

or

Select **Other** and type the reason in the text box.

7 Click **Submit**.

If this transfer does not cause the destination site to exceed the maximum enrollment count, the transfer occurs. If site enrollment is closed, the application displays an error message. Contact someone at the destination site who can increase the patient enrollment limit.

The application creates the transfer archive. Because the archive contains the entire patient record generated to a PDF file, archive creation can take time. During that time, do not update the patient record.

The OutcomeLogix application displays a confirmation message that the patient was transferred successfully.

8 Click **OK**.

Viewing patient transfer history

The OutcomeLogix application stores the details of each transfer in the audit trail, including Patient ID, the originating site where the patient was transferred from, the destination site where the patient was transferred to, the reason for the transfer, who performed the transfer, and the date and time of the transfer.

1 On the Patient List page, click the **Patient Transfer History** tab.

The Patient Transfer History page appears. For more information, see the *Patient Transfer History page* (on page 269).

2 To view a patient archive, click **View**.

The archive appears in a separate window.

Searching for a transferred patient

1 On the Patient List page, click the **Patient Transfer History** tab.

2 The Patient Transfer History page appears. For more information, see the *Patient Transfer History page* (on page 269).

3 From the **Search** drop-down list, select your search criteria:

- **Patient List**—To select from a list of patients who were transferred.
- **Transferred From**—To select from a list of sites from which patients were transferred.
- **Patient ID**—To search for a specific patient.
- **Transferred To**—To select from a list of sites to which patients were transferred.

4 To the right of the drop-down list, click **Submit** ().

The application displays the patients that match the search criteria.

Viewing the archive of a transferred patient

The OutcomeLogix application generates an archive of the work completed for the patient at the originating site. The archive does not include patient-identifiable data. A table of contents provides links to the various sections of the archive and to specific visits and forms.

The archive is a snapshot of the patient record at the time of the transfer. It is a cumulative record of the patient-related activities, visits, and forms associated with the originating site. After a transfer, the originating site can see the archive only as it existed at the time of transfer.

1 Select **Patients** ().

The Patient List page appears.

2 Click the **Patient Transfer History** tab.

The Patient Transfer History page appears.

3 From the **Search** drop-down list, select your search criteria:

- **Patient List**—To select from a list of patients who were transferred.
- **Transferred From**—To select from a list of sites from which patients were transferred.
- **Patient ID**—To search for a specific patient.
- **Transferred To**—To select from a list of sites to which patients were transferred.

4 To the right of the drop-down list, click **Submit** ().

The application displays the patients that match the search criteria.

5 In the **Archive** column of the patient whose archive you wish to view, click the **View** link.

The application opens the Patient Transfer Archive Document in the Adobe Acrobat Reader application.

You can use the navigation and viewing functions built into the version of the Acrobat Reader application you are running.

6 Close the archive by clicking the **X** button in the upper-right of the Acrobat Reader window.

Patient Transfer dialog box

The following task uses this page:

- *Initiating a patient transfer* (on page 264).

To view a job aid that you can print, see:

- Quick Reference: Patients.

Field	Description	Note
Affidavit	Study-specific guidance on the responsibility of the user regarding moving a patient from one site to another.	No acknowledgment is required.
Patient Status		
Signature Status	Whether or not all forms have been signed.	Red text indicates attention is required.
Query Status	Whether or not open queries exist.	Red text indicates attention is required.
Source Verification Status	Whether or not source verification is complete.	Red text indicates attention is required.
Patient Information		
Current Site	The site where the patient is currently enrolled.	
Patient ID	Unique identifier for the patient.	
Patient Record Transfer Information		
Destination Site	The site to which the patient is transferred.	
Reason For Transfer	Select a reason from the drop-down list, or Other to enter a reason not in the list.	
Buttons		
Submit	Initiate the transfer.	
Cancel	Close the Patient Transfer dialog box without transferring the patient.	

Patient Transfer History page

The following tasks use this page:

- *Viewing patient transfer history* (on page 265).
- *Searching for a transferred patient* (on page 266).
- *Viewing the archive of a transferred patient* (on page 267).

To view a job aid that you can print, see:

- Quick Reference: Patients.

By clicking the column headers, you can sort the Patient Transfer History list.

Field	Description	Note
Filters		
Search by: • Patient List • Transferred From • Patient ID • Transferred To	Filter the patient transfer history list by selecting one of the following from the Search drop-down list: • Patient List—To select from a list of patients who have been transferred. • Transferred From—To select from a list of sites from which patients have been transferred. • Patient ID—To search for a specific patient. • Transferred To—To select from a list of sites to which patients have been transferred.	To apply the filter, you must click **Submit** (). To apply a different filter, you must first click **Clear Filters**. To filter by Patient ID, type a specific Patient ID, with or without leading zeros, or a set of contiguous digits. The application sorts the records in ascending order by creation date. This choice may result in the retrieval of multiple patient records.
Links		
View	Click to view the patient archive.	
Columns		
Patient ID	Unique identifier for the patient.	
Transferred From	The originating site.	
Transferred To	The destination site.	
Reason For Transfer	Justification for transferring the patient.	
Transferred By	User name of person who initiated the transfer.	

Field	Description	Note
Transfer Date (In GMT)	Date and time of transfer.	The time is in GMT and is the time the server made the transfer.
Archive	The patient history up to and including the patient record transfer. In PDF format.	
Controls		
Page controls	• **Page n of n drop-down list**—Displays the specific page. • **Records per Page drop-down list**—Select the number of records to display. • |<—View the first page. • <—view the previous page. • >—View the next page. • >|—View the last page.	
Buttons		
Clear Filters	Reset the search drop-down lists to blank.	

APPENDIX A

Default roles and their rights

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Default roles

As well as being associated with specific studies and sites, each user is assigned to a role. Activities in the OutcomeLogix application are restricted to users who are assigned to specific roles. The OutcomeLogix application ships with the following default roles.

User Types	Role	Description
Site Users	Clinical Research Coordinator (CRC)	An assistant to the investigator at a site.
	Investigator	The clinician who is responsible for treating subjects, executing the protocol of a study at a specific site, and filling out forms for subjects.
Sponsor	Sponsor	The organization that has commissioned the study or a contract research organization (CRO) conducting a study for a sponsor.
	Clinical Research Associate (CRA)	A person hired by a sponsor to supervise and monitor the progress of sites that are participating in a study.
	Clinical Data Manager (CDM)	A person responsible for preparing and maintaining a study database and reviewing data. The CDM can view all patient data but cannot see patient-identifying information.
	Medical Monitor	A person who designs the study protocol and reviews data. The medical monitor can view all patient data but cannot see patient-identifying information.
	Sponsor Help Desk	Support personnel provided by Oracle or the sponsor. Typical OutcomeLogix operations performed include adding sites and users and resetting passwords.
	Call Center Manager	The Call Center manager performs administrative tasks, assigns patients to Call Center staff, and has all of the rights of Call Center staff.
	Call Center Staff	Call Center staff are responsible for interacting with patients enrolled in the study. They manage the call queue and help patients complete surveys, log patient calls, report major medical events, fill in ePRO forms on behalf of patients, and manage patient contact information.
Patient	Patient	A study participant.
	Observer	A person who assists a study participant during the study, typically a parent or guardian.
Oracle or System Users	OLX Read Only	This role provides Oracle staff with access to view a study in read-only mode. Users can view all patient data but cannot see patient-identifying information.

User Types	Role	Description
	OLX Help Desk	The Oracle Tier 1 Support users. Typical OutcomeLogix operations performed include adding sites and users and resetting passwords. Users can view all patient data but cannot see patient-identifying information.
	Study Administrator	This superuser initially sets up Help Desk users (so that the Help Desk users can set up the other users in the study). This role terminates when the study goes live.

Administration rights

Right	Description
User Management	User can create, activate, and deactivate users; edit user profiles; and manage user site assignments using the Manage Users selection on the Administration page. For more information, see *Manage Users page* (on page 44).
Site Management	User can add, edit, activate, and deactivate sites and specify enrollment information using the Manage Sites selection on the Administration page. For more information, see *Manage Sites page* (on page 30).
Study Management	User can view and edit administrative study information using the Manage Study Description selection on the Administration page. For more information, see *Viewing and editing administrative study information* (on page 180).
Study Attribute Management	User can restrict access to items for users in a specified role using the Manage Display Overrides selection on the Administration page. For more information, see *Adding, editing, or deleting a display override* (on page 181).
Manage ICDs	User can upload and activate/deactivate Informed Consent documents using the Manage ICDs selection on the Administration page. For more information, see *Uploading an ICD* (on page 94).
Missed eCodes	User can send eCodes to patients who have earned but not received eCodes using the Send eCodes selection on the Administration page. For more information, see *Manually distributing eCodes* (on page 170).
Report Privilege Management	User can assign access to standard reports to selected roles. For more information, see *Assigning reports to roles* (on page 226).
Configure Reports	User can configure the settings that enable users to connect to the Oracle BI Publisher server and develop ad hoc reports. For more information, see *Configuring the report server settings* (on page 225).
View Product Version	User can view the version number and update date and time for each component of the OutcomeLogix application, as well as the previous versions installed. For more information, see *Viewing version information* (on page 186).
Configuration Management	User can change the default settings governing basic system configuration issues using the Configure Study Settings selection on the Administration page. For more information, see *Changing default study configuration settings* (on page 183).

Right	Description
Password Rules	User can create and edit rules governing password parameters and use using the Manage Password Rules selection on the Administration page. For more information, see *Creating and editing a password rule* (on page 65).
Assign Password Rules to Roles	User can assign password rules to selected roles using the Assign Password Rules selection on the Administration page. For more information, see *Assigning a password rule to a role* (on page 66).
Role Right Management	User can create a role and an associated rights group using the Manage Roles and Rights selection on the Administration page. For more information, see *Manage Roles and Rights page* (on page 59).
Manage Localization Settings	User can change the date formats, name sort options, number formats and currency formats. For more information, see *Manage Localization Settings page* (on page 195).
Call Center Profile Setting	User can set up a Call Center and configure the maximum number of phone attempts and the completion windows for web-based patients. For more information, see *Updating a Call Center profile* (on page 255).
Call Center Script Setting	User can customize the scripts used when calling a patient from the Call Center. For more information, see *Customizing and editing a Call Center script* (on page 257).
Email Notifications	User can view a list of the email messages sent to specific email addresses on the Email Notifications page. For more information, see *Email Notifications page* (on page 193).

User Operation

Right	Description
Enter/Edit EDC Data	User can enter data on forms. For more information, see *Who can enter data into a form?* (on page 120).
View Protected Health Information	User can view protected health information, required of roles tasked with entering or viewing clinical patient information. For more information, see *Assigning rights to a role* (on page 54).
Lock/Unlock Users	User can lock or unlock a user account to prevent the user from using the OutcomeLogix application. For more information, see *Locking and unlocking a user* (on page 40).
Reset Password	User can reset another user's password on the User Profile page, accessed using the Manage Users selection on the Administration page. For more information, see *Resetting a user password* (on page 41).
Set Temporary Password	User can create a temporary password for a user or patient on the User Profile page, accessed using the Manage Users selection on the Administration page. For more information, see *Setting a temporary password for a user* (on page 42).
Edit Your Own Profile	User can view and edit the information on the User Profile page. For more information, see *Viewing and editing your profile* (on page 6).
Sign ICD	User can sign Informed Consent documents as a site user or witness. For more information, see *Informed Consent Document (ICD) page* (on page 77).
Design Report	User can create custom, ad hoc reports using the Oracle BI Publisher tool. For more information, see *Working with ad hoc reports* (on page 218).
Create Users	User can perform the first step of the user creation process by completing the Create User page, accessed using the Manage Users selection on the Administration page. For more information, see *Creating, activating, and deactivating a user* (on page 36).
Activate/Deactivate Users	User can perform the second step of the user creation process, activation, by activating the user on the Manage Users page, accessed using the Manage Users selection on the Administration page. User can also deactivate a user. For more information, see *Creating, activating, and deactivating a user* (on page 36).

Dashboard (Navigation bar)

Right	Description
Show Dashboard	User's Homepage is the Dashboard. For more information, see *About the OutcomeLogix application* (on page 2).
Show Prescreened	The Prescreened icon appears on the navigation bar, and grants the user the right to view self-enrolled patients, screen these patients, and add contact history. For more information, see *Creating a patient account* (on page 73).
Add Patient	The Create Patient icon appears on the navigation bar, and grants the user the right to create and enroll patients. For more information, see *Creating a patient account* (on page 73).
View Patient List	The Patient List icon appears on the navigation bar, and grants the user the right to view the Patient List page. For more information, see *Viewing the Patient List* (on page 112).
View Call Center List	The Call Center List icon appears on the navigation bar, and grants the user the right to view the list of patients in the call queue. For more information, see *Viewing a list of Call Center patients* (on page 242).
Export Data	The Export Data icon appears on the navigation bar, and grants the user the right to open the data export function and export study data as a PDF file or a Microsoft Excel spreadsheet in SAS format. For more information, see *Exporting study data* (on page 231).
Administration	The Administration icon appears on the navigation bar, and grants the user the right to access the Administration page and use the *administrative functions* (on page 274) the user has been granted rights to use. For more information, see *Administration page* (on page 187).
View Query List	The Queries icon appears on the navigation bar, and grants the user the right to view the Query List page. For more information, see *Query List page* (on page 146).
View Report	The Report icon appears on the navigation bar, and grants the user the right to view standard and ad hoc reports. For more information, see *Roadmap: Assigning report rights* (on page 225).

Dashboard Summary Table

Right	Description
Query Status Summary Table	User can view a list or pie chart that shows the distribution of Open, Answered, Approved, Closed, Candidate, and Deleted queries, and can click a count to display the queries on the Query List page. For more information, see *Managing queries* (on page 140).
Patient Status Summary Table	User can view the number of patients in the study by status and click a count to navigate to the Patient List page, which displays the patients for the selected status and sites. For more information, see *Viewing the Patient List* (on page 112).
ePRO Status Summary Table	User can view the number of ePRO sessions and visits completed and past due and click the Past Due link to display the Patient List page filtered to show patients with past-due ePRO sessions. For more information, see *Reviewing patient diaries* (on page 136).
Dashboard Notification	User can view the subject and the date and time of each email notification received and can display the notification by clicking the Subject link. For more information, see *Email notifications* (on page 5).

Form Status

Right	Description
Source Document Reviewed (SDV)	User can mark a patient, visit, form, or item as reviewed against a source document by selecting the Mark SDV icon on the Patient Summary page. For more information, see *Marking and unmarking a patient, visit, form, or item as reviewed* (on page 135).
Remove Source Document Reviewed (SDV)	User can unmark a patient, visit, form, or item as reviewed against a source document by selecting the Unmark SDV icon on the Patient Summary page. For more information, see *Marking and unmarking a patient, visit, form, or item as reviewed* (on page 135).
Freeze	User can freeze a patient, visit, form, or item by selecting the Freeze icon on the Patient Summary page. Users can still issue queries for frozen patients, visits, and forms. For more information, see *Freezing and unfreezing data on the patient, visit, form or item level* (on page 128).
Unfreeze	User can unfreeze a patient, visit, form, or item by selecting the Unfreeze icon on the Patient Summary page. For more information, see *Freezing and unfreezing data on the patient, visit, form or item level* (on page 128).
Mark DM Reviewed	User can mark a patient, visit, form, or item as reviewed by a data manager by selecting the Mark DM Reviewed icon on the Patient Summary page. For more information, see *Marking and unmarking a patient, visit, form, or item as reviewed* (on page 135).
Unmark DM Reviewed	User can unmark a patient, visit, form, or item as reviewed by a data manager by selecting the Unmark DM Reviewed icon on the Patient Summary page. For more information, see *Marking and unmarking a patient, visit, form, or item as reviewed* (on page 135).
Mark for Remote Review	User can mark a patient, visit, form, or item as reviewed remotely by selecting the Mark for Remote Review icon on the Patient Summary page. For more information, see *Marking and unmarking a patient, visit, form, or item as reviewed* (on page 135).
Remove Remote Review	User can unmark a patient, visit, form, or item as reviewed remotely by selecting the Remove Remote Review icon on the Patient Summary page. For more information, see *Marking and unmarking a patient, visit, form, or item as reviewed* (on page 135).

Right	Description
Lock Status	User can lock a patient, visit, form, or item by selecting the Lock icon on the Patient Summary page. Locked objects cannot be modified or signed. For more information, see *Locking and unlocking data on the patient, visit, form, or item level* (on page 129).
Unlock Status	User can unlock a patient, visit, form, or item by selecting the Unlock icon on the Patient Summary page. For more information, see *Locking and unlocking data on the patient, visit, form, or item level* (on page 129).
Sign Object	User can sign the selected patient, visit, form, or item by selecting the Sign icon on the Patient Summary page. For more information, see *Signing and unsigning at the patient, visit, form, and item levels* (on page 130).
Unsign Object	User can unsign the selected patient, visit, form, or item by selecting the Unsign icon on the Patient Summary page. For more information, see *Signing and unsigning at the patient, visit, form, and item levels* (on page 130).
Create Manual Query	User can create a manual query by selecting the Create Query icon on a form. For more information, see *Issuing a manual query* (on page 150).
Intentionally Left Blank	User can skip a visit, form, or item and revisit it later.

Query

Right	Description
Create Query	User can issue a manual query at the patient, visit, form, or item level by selecting the Create Query icon on the Patient Summary page. For more information, see *Issuing a manual query* (on page 150).
Response Query	User can answer an automatic or manual query at the patient, visit, form, or item level on the Query List page or by selecting the Query Response icon on the Patient Summary page. For more information, see *Answering a query* (on page 153).
Response/Edit Query	User can modify the response to an answered query by selecting the Edit button on the Query Details page: For more information, see *Answering a query* (on page 153).
Approve Query	User can approve an answered query on the Query List page or by selecting the Approve Query icon on the Patient Summary page. For more information, see *Approving an answered query* (on page 156).
Re-issue Open Query	User can reissue an answered query as an open query on the Query List page or by selecting the Create Query icon on the Patient Summary page. For more information, see *Reissuing an answered query as an open query* (on page 156).
Close Query	User can close an open, answered, approved, or candidate query on the Query List page or by selecting the Close Query icon on the Patient Summary page. For more information, see *Closing a query* (on page 152).
Issue Candidate Query	User can issue a candidate query at the patient, visit, form, or item level from the Query List page or by selecting the Create Query icon on the Patient Summary page. For more information, see *Issuing a candidate query* (on page 164).
Open Candidate Query	User can issue a candidate query at the patient, visit, form, or item level from the Query List page or by selecting the Create Query icon on the Patient Summary page. For more information, see *Issuing a candidate query* (on page 164).
Delete Candidate Query	User can delete a candidate query from the Query List page or by selecting the Close Query icon on the Patient Summary page. For more information, see *Deleting a candidate query* (on page 164).
View Candidate Query	User can view candidate queries but cannot create or delete candidate queries. For more information, see *Roadmap: Working with candidate queries* (on page 163).

Right	Description
Re-issue Candidate Query	User can reissue an answered query as a candidate query on the Query List page or by selecting the Create Query icon on the Patient Summary page. For more information, see ***Reissuing an answered query as a candidate query*** (on page 165).
Query History	User can view the history of a query by selecting the History tab on the Query List page. Users without this right do not see the History tab. For more information, see ***Viewing the history of a query*** (on page 157).

Patient

Right	Description
View Patient Diary	User can view Electronic Patient-Reported Outcome (ePRO) forms by selecting the Patient Diary link on the Patient Summary page. For more information, see *Patient Diary page* (on page 137).
Show ICD History Link	User can view the signed Informed Consent Documents for the selected patient by selecting the ICD History link on the Patient Summary page. For more information, see *Viewing and printing an ICD* (on page 95).
Transfer Patient	User can initiate a patient transfer from the originating site by selecting the patient in the Patient List and clicking the Transfer button. For more information, see *Roadmap: Transferring a patient from one site to another* (on page 263).
Show Patient Transfer History	User can view the details of patient transfers by clicking the Patient Transfer History tab on the Patient List page. For more information, see *Patient Transfer History page* (on page 269).

Call Center

Right	Description
Interview Patient	User can log and conduct Call Center interviews. For more information, see *Starting an interview* (on page 249).
Edit Patient Profile	User can add a patient to the Call Center by editing the patient profile. For more information, see *Adding a patient to the Call Center* (on page 241).
Assign Call Center Staff	User can assign patients to a user with the Call Center Staff role. For more information, see *Assigning staff to the Call Center* (on page 255).
Override Incomplete Forms	User can perform an interview with a patient outside of the scheduled Survey window. For more information, see *Performing an interview outside of the survey window* (on page 250).
Get eCodes	User can view the eCodes for a phone-based patient if the patient email address is not in the system. For more information, see *Conducting a survey* (on page 249).

APPENDIX B

Reporting views

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Reporting views overview

The OutcomeLogix application contains a number of built-in, or standard, operational reports for you to use. You can also use the ad hoc reporting capabilities of the Oracle Business Intelligence Publisher to produce custom reports.

The reporting views contain operational data that you can use to produce custom reports. Each reporting view is named with the prefix AD_.

Note: Data in the reporting views is not sorted and any sorting needs to be done from the reports user interface.

Audit trail views

AD_AuditTrail

This view contains each change made to an item, including who made the change and when it was made, the original value, and the modified value.

Column	Description
SITEID	Site where the change occurred.
SITE_NUMBER	Number of the site as displayed in the user interface.
SITE_NAME	Name of the site as displayed in the user interface.
PATIENT_ID	Identifier of the patient for whom the change was made.
USER_ID	User name of the user who modified the item.
OBJECTID	Name of the item that changed.
VISIT_NAME	Visit during which the change was made.
VISIT_INDEX	Index indicating the order in which the visit occurs in the study.
FORM_NAME	Name of the form on which the item exists.
FORM_INDEX	Index indicating the order in which the form occurs in the visit.
ITEM_NAME	Name of the item that changed as displayed in the user interface.
INITIAL_ENTRY	Yes or No, indicating whether this record the first entry for the item.
CURRENT_VALUE	Changed value of the item.
PREVIOUS_VALUE	Value of the item before it was changed.
CHANGE_DATE	Date and time when the item value was changed. (In GMT offset format.)
REASON_FOR_CHANGE	Reason for changing the item value, as entered by the user who modified the item.
ROLE	Role of the user who made the change.
CHANGE_USER_NAME	User name of the user who made the change.
LANGUAGE_ID	Identifier of the language, enabling you to filter the view by language.

eCode views

AD_eCodes

This view contains the number of available eCodes, last load date, pending payments, and monthly usage.

Column	Description
CURRENCY_CODE	Code of the currency used for the eCodes.
ECODEASSIGNED	Number of eCodes that have been assigned to a patient.
ECODEAVAILABLE	Number of eCodes loaded into the system that have not been assigned to a patient.
ECODEPENDINGPAYMENT	Number of patients who are due eCodes but for whom eCodes are not available.
LASTECODELOADDATE	Date when the latest eCodes were loaded.
LASTECODELOADTOTALVALUE	Sum of the values of the eCodes that were last loaded, by currency.

AD_eCodesEarned

This view contains number of eCodes that have been assigned to a patient, along with the currency in which the eCodes are issued.

Column	Description
SITE_NUMBER	Number of the site as displayed in the user interface.
SITEID	Database identifier of the site.
SITE_NAME	Name of the site as displayed in the user interface.
LAN_ID	Identifier of the language, enabling you to filter the view by language.
PATIENT_ID	Identifier of the patient to whom eCodes are assigned.
ECODE_CURRENCY	Text label for the currency used for the eCodes.
ECODES_ASSIGNED	Number of eCodes that have been assigned to a patient.

Form status views

AD_FormStatus

This view contains the system status (not started, incomplete, complete) and manual statuses (for example, locked, frozen, signed) of each form.

Column	Description
SITENAME	Name of the site as displayed in the user interface.
SITENUMBER	Number of the site as displayed in the user interface.
PATIENTID	Unique identifier for the patient. (Can be NULL.)
VISITNAME	Name of the visit as displayed in the user interface.
VISIT_ID	Database identifier of the visit.
VISITINDEX	Index indicating the order in which the visit occurs in the study.
VISITTYPE	Type of visit: • System • Unscheduled
FORMNAME	Name of the form.
FORMINDEX	Index indicating the order in which the form occurs in the visit.
REPEATINGFORM	Repeating form: Yes or No.
DYANMICFORM	Dynamic form: Yes or No.
FORMSYSTEMSTATUS	System status of the form: • Not Started. • Incomplete with queries. • Complete.
FORMFROZEN	Yes or blank, indicating whether the form status is Frozen.
FORMLOCKED	Yes or blank, indicating whether the form status is Locked.
FORMDMREVIEWED	Yes or blank, indicating whether the form status is DM Reviewed.
FORMSDV	Yes or blank, indicating whether the form status is Source Verified.
FORMSIGNED	Yes or blank, indicating whether the form status is Signed.
FORMREMOTEREVIEW	Yes or blank, indicating whether the form status is Remote Reviewed.
FORMHASOPENQUERIES	Form has open queries: Yes or No.
FORMFIRSTUPDATEDATE	Date and time when the form was first updated.
FORMLASTUPDATEDATE	Date and time when the form was last updated.

Column	Description
SITEID	Database identifier of the site. (Can be NULL.)
LAN_ID	Identifier of the language, enabling you to filter the view by language.

Patient status and patient lifecycle views

AD_PatientLifeCycle

This view contains the data about the status of the patient as the patient enters and exits the study.

Column	Description
SITENUMBER	Number of the site as displayed in the user interface.
SITE_NAME	Name of the site as displayed in the user interface.
LAN_ID	Identifier of the language, enabling you to filter the view by language.
PATIENT_ID	Unique identifier for the patient. (Can be NULL.)
STATE_DATE	The time the patient's data was modified last (DateTime Type)
PRE_SCREENED	Code indicating whether the patient was pre-screened: • 0—No • 1—Yes
CREATED	Code indicating whether the patient was created: • 0—No • 1—Yes
ENROLLED	Code indicating whether the patient was enrolled: • 0—No • 1—Yes
DISCONTINUED	Code indicating whether the patient was discontinued: • 0—No • 1—Yes
SCREENING	Code indicating whether the patient was screened: • 0—No • 1—Yes • 2 – Unknown (not yet screened)
COMPLETED	Code indicating whether the patient completed the study: • 0—No • 1—Yes
RANDOMIZED	Code indicating whether the patient was randomized: • 0—No • 1—Yes

Column	Description
SCREEN_FAILED	Code indicating whether the patient failed the screen: • 0—No • 1—Yes
OPT_OUT	Code indicating whether the patient opted out of the study: • 0—No • 1—Yes
CONSENTED	Code indicating whether the patient signed an informed consent: • 0—No • 1—Yes
LOST_TO_FOLLOW_UP	Code indicating whether the patient was lost to follow-up: • 0—No • 1—Yes
WITHDRAWN	Code indicating whether the patient withdrew from the study: • 0—No • 1—Yes
SITEID	Database identifier of the site. (Can be NULL.)
PATIENTWEBSCREENED	Code indicating whether the patient came through the Web Screener process: • 0—No • 1—Yes

Patient Profile

This view contains language and location details about each patient. No Personally Identifiable Information is included.

Column	Description
PATIENTID	Unique identifier for the patient. (Can be NULL.)
PATIENTSITEID	Name of the site as displayed in the user interface.
PATIENTENROLLDATE	Patient Enrollment Date.
PATIENTINITIALS	Patient Initials, limited to 3 characters.
PATIENTLANGUAGECODE	Identifier of the patient's language.

Column	Description
PATIENTLANGUAGETEXT	Text label of the patient's language: • English • Japanese • Chinese
PATIENTCOUNTRYCODE	Identifier of the patient's country.
PATIENTCOUNTRYTEXT	Text label of the patient's country.
PATIENTTIMEZONECODE	Abbreviation of the patient's time zone: • EST • CST • PST • CET • EET • GMT • MST • CST • JST
PATIENTTIMEZONETEXT	Text label of the patient's time zone: • Eastern Standard Time. • Central Standard Time. • Pacific Standard Time. • Central European Standard Time. • E. European Standard Time. • GMT Standard Time. • Mountain Standard Time. • China Standard Time. • Tokyo Standard Time.
LANID	Identifier of the language, enabling you to filter the view by language.

AD_PatientStatus

This view contains data about the manually applied statuses a patient can have. A patient acquires a manually applied status when all of the patient's visits have that status.

Column	Description
SITEID	Name of the site as displayed in the user interface.
SITENUMBER	Database identifier of the site. (Can be NULL.)
PATIENTID	Unique identifier for the patient. (Can be NULL.)
DESCRIPTION	System status of the patient.
PATIENTFROZEN	Code indicating whether the patient is frozen: • 0—No • 1—Yes
PATIENTLOCKED	Code indicating whether the patient is locked: • 0—No • 1—Yes
PATIENTDMREVIEWED	Code indicating whether all of the patient's visits have been reviewed by a Data Manager: • 0—No • 1—Yes
PATIENTSDV	Code indicating whether all of the patient's visits have been source verified: • 0—No • 1—Yes
PATIENTSIGNED	Code indicating whether all of the patient's visits have been signed: • 0—No • 1—Yes
PATIENTREMOTEREVIEW	Code indicating whether all of the patient's visits have been reviewed remotely: • 0—No • 1—Yes
LAN_ID	Identifier of the language, enabling you to filter the view by language.

Query views

AD_QueryHistory_All

This view contains information about actions that have created or updated queries, along with the current status of the queries.

Column	Description
SITE_ID	Database identifier of the site. (Can be NULL.)
ID	Database identifier of the query.
QUERY_ID	Identifier of the query as it appears in the user interface.
QUERY_CATEGORY	Type of query: • System • Manual
TIMESTAMPS	Date and time that the query was updated.
CHANGE_USER	User who updated the query.
AUTHOR	User who created the query. The author is System if the query was automatically issued.
EVENT_NAME	Name of the event associated with the query status change: • Created • Re-issued • Approved • Closed
QUERYSTATUS_ID	Database identifier of the current query status.
QUERYSTATUS	Query status: • Open • Answered • Approved • Closed • Candidate • Deleted
NOTES	Text of the query.
LAN_ID	Identifier of the language, enabling you to filter the view by language.

AD_QueryList

This view contains each query and identifies which entity (patient, visit, form, or item) the query applies to, whether the query is system-generated or manual, query status, and who issued the query and when it was issued.

Column	Description
ID	Database identifier of the query.
QUERY_ID	Identifier of the query as it appears in the user interface.
PATIENT_ID	Unique identifier for the patient.
PATIENT_DISPLAY_ID	Identifier of the patient as displayed in the user interface.
OBJECTID	Visit name.
OBJECT_LEVEL	Identifier of the object level.
QUERYELEMENT	Element type on which query has been issued: • Patient • Visit • Form • Item
VISIT_NAME	Name of the visit as displayed in the user interface. Visit name associated with the query. (Could be NULL if manual query is raised against visit or patient.)
FORM_NAME	Form that the query was issued against. (Could be NULL if manual query is raised against visit or patient.)
ITEM_TEXT	Label of the item on which the query was issued.
DATAVALUE	Data value of the item on which the query was issued.
QUERY_TEXT	Text that appears in the query.
QUERY_STATE_ID	Identifier of the query state.
QUERYSTATE	Query status: • Open • Answered • Approved • Closed • Candidate • Deleted

Column	Description
AUTHOR	Account name of the user who issued the query. If the query is an autoquery, this column is populated with **System**.
ORIGINATOR	Account name of the user who first created the query.
QUERYTYPE	Type of query: • System • Manual
FTIMESTAMP	For system-issued queries, the date and time that the query was issued.
CREATE_TIME	Date and time when the query was issued.
MODIFY_TIME	Date and time the query was last updated.
SITE_DISPLAYID	ID of the site as displayed in the user interface.
SITE_NAME	Name of the site as displayed in the user interface.
STAFF_ID	Staff ID.
LISTVALUEVALUE_ID	List value ID.
VISIT_ID	Database identifier of the visit.
FORM_ID	Database identifier of the form.
TRANSLATETEXT	Translation of the query text, if the study is translated into multiple languages.
VALIDATIONACTION_ID	Validation action identifier associated with the query.
RESPONSE	Query response text.
RESPONDENT	First and last name of the user responding to the query.
SITEID	Database identifier of the site. (Can be NULL.)
LAN_ID	Identifier of the language, enabling you to filter the view by language.

Site views

AD_Sites

This view contains details about each site.

Column	Description
SITENUMBER	Number of the site as displayed in the user interface.
ISACTIVE	Is the site active? Yes or No.
DISPLAYNAME	Name of the site as displayed in the user interface. (Can be NULL.)
ORGANIZATION	Sponsor organization that the site belongs to.
ADDRESS	Additional site address information. (Can be NULL.)
ZIP	ZIP Code or postal code of the site.
SITEGROUP_ID	Identifier of the site group.
INV_NUMBER	Identifier of the site.
PATIENTID_MIN	Minimum number of patients who must be assigned to the site.
PATIENTID_MAX	Maximum number of patients who can be assigned to the site. Can be larger than the target.
PATIENTID_TARGET	Desired number of patients to be assigned to the site.
NEXTPATIENTID	Sequential Patient ID to be assigned to the next patient added to the site.
COUNTRY	Text name of the country where the site is located.
COUNTRYID	Identifier of the country where the site is located.
STATE	State or province where the site is located.
CITY	City where the site is located.
STREET	Street on which the site is located.
BUILDING	Building number of the site. (Can be NULL.)
ROOM	Room or suite number of the site.
PO_BOX	Post office box of the site.
PHONE	Phone number of the site.

Column	Description
TIMEZONE	Time zone of the site: • Eastern Standard Time. • Central Standard Time. • Pacific Standard Time. • Central European Standard Time. • E. European Standard Time. • GMT Standard Time. • Mountain Standard Time. • China Standard Time. • Tokyo Standard Time.
SITECURRENCYFORMAT	Type of currency: • U.S. dollar • Japanese yen • Chinese renminbi (RMB)
SITENUMBERFORMAT	Preferred number format: • Normal (12345) • Thousands Separator (12,345)
SITENAMESORTFORMAT	Order of first and last user and patient names: • Firstname-Lastname • Lastname-Firstname
DONEDATEFORMAT	Preferred date format: • 1—Day/Month/Year:Hour:Minute:Second • 2—Month/Day/Year Hour:Minute:Second • 3—Year/Month/Day Hour:Minute:Second
INVESTIGATORS	Primary investigator associated with the site.
ENROLLED	Number of patients currently enrolled at the site.
SITEID	Database identifier of the site. (Can be NULL.)
LAN_ID	Identifier of the language, enabling you to filter the view by language.

AD_SiteUserRole

This view contains IDs and names that link sites to the users assigned to them and to the roles that are assigned to the users.

Column	Description
USERID	Identifier of a user who is associated with the site.
USERNAME	Login name of a user who is associated with the site.
ROLEID	Identifier of the role assigned to the user at the site.
ROLENAME	Text name of the role assigned to the user at the site.
SITE_NAME	Name of the site as displayed in the user interface.
SITENUMBER	Number of the site as displayed in the user interface.
SITEID	Database identifier of the site.
LAN_ID	Identifier of the language, enabling you to filter the view by language.

User views

AD_User_Patient_Acct_Mgmt

This view contains user or patient account information, including whether the account is locked and when the user or patient last logged in.

Column	Description
LASTLOGIN	Date and time when the user or patient last logged in.
USERID	Unique identifier for the user.
ACCOUNTNAME	Login name of the user or patient.
LOCKED	Is the account locked? Yes or No.
LANID	Identifier of the language, enabling you to filter the view by language.

AD_UsersICD

This view contains a record of patient agreement to the Informed Consent Document (ICD) for a study site.

Column	Description
SITE_NUMBER	Number of the site as displayed in the user interface.
SITEID	Database identifier of the site.
SITE_NAME	Name of the site as displayed in the user interface.
LANGUAGE_ID	Identifier of the language, enabling you to filter the view by language.
PATIENT	Unique identifier for the patient.
AGREED_TO_CONSENT	Did the patient sign the ICD? Yes or No.
DATE_CONSENT_SIGNED	Date that the ICD was signed.

AD_Users

This view contains details about each non-patient user.

Column	Description
USERID	Unique identifier for the user.

Column	Description
USERACTIVE	Has the user been activated? Yes or No.
LASTNAME	Last name of the user.
FIRSTNAME	First name of the user.
MIDDLENAME	Middle name of the user.
CUSTOMURL	URL of the Custom Homepage. (Can be NULL.)
ROLEID	Unique identifier of the role.
ROLENAME	Name of the role.
RECEIVEEMAIL	Has the user chosen to receive emails? Yes or No.
USERCOUNTRYCODE	Code of the country where the user is located.
USERCOUNTRYTEXT	Text name of the country where the user is located.
USERTIMEZONE	Time zone of the user: • Eastern Standard Time. • Central Standard Time. • Pacific Standard Time. • Central European Standard Time. • E. European Standard Time. • GMT Standard Time. • Mountain Standard Time. • China Standard Time. • Tokyo Standard Time.
USERPHONE	The phone number of the user (max=20; alphanumeric)
USERDATEFORMAT	Preferred date format: • 1—Day/Month/Year:Hour:Minute:Second • 2—Month/Day/Year Hour:Minute:Second • 3—Year/Month/Day Hour:Minute:Second
USERNAMESORT	Order of first and last user and patient names: • Firstname-Lastname • Lastname-Firstname
USERNUMBERFORMAT	Preferred number format: • Normal (12345) • Thousands Separator (12,345)

Column	Description
USERCURRENCYFORMAT	Type of currency: • U.S. dollar • Japanese yen • Chinese renminbi (RMB)
USEREMAIL	Email address of the user.
MEMORABLEQUESTION	Memorable question that helps to identify the user when the user recalls or changes a password.
MEMORABLEANSWER	Answer to the memorable question that helps to identify the user when the user recalls or changes a password.
LANID	Identifier of the language, enabling you to filter the view by language.

Visit views

AD_AllVisitStatus

This view contains the system status and manually applied statuses for each patient visit. The view reflects both eCRFs and ePRO forms.

Column	Description
PATIENTID	Unique identifier for the patient. (Can be NULL.)
SITEID	Database identifier of the site. (Can be NULL.)
SITENUMBER	Number of the site as displayed in the user interface.
VISITNAME	Name of the visit as displayed in the user interface.
VISIT_ID	Database identifier of the visit.
VISITSYSTEMSTATUS	System status of the visit: • Not Started • Incomplete • Complete
VISITCOMPLETIONDATE	Date that the visit was completed.
VISITFROZEN	Code indicating whether the visit is frozen: • 0—No • 1—Yes
VISITLOCKED	Code indicating whether the visit is locked: • 0—No • 1—Yes
VISITDMREVIEWED	Code indicating whether the visit has been reviewed by a Data Manager: • 0—No • 1—Yes
VISITSDV	Code indicating whether the visit has been source verified: • 0—No • 1—Yes
VISITSIGNED	Code indicating whether the visit has been signed: • 0—No • 1—Yes

Column	Description
VISITREMOTEREVIEW	Code indicating whether the visit has been reviewed remotely: • 0—No • 1—Yes
VISITHASOPENQUERY	Code indicating whether the visit has open queries: • 0—No • 1—Yes
SITENAME	Name of the site as displayed in the user interface.
LAN_ID	Identifier of the language, enabling you to filter the view by language.

AD_eCRFVisits

This view contains the system status and manually applied statuses for each patient visit. The view reflects the eCRF forms in each visit.

Column	Description
PATIENTID	Unique identifier for the patient. (Can be NULL.)
SITEID	Database identifier of the site. (Can be NULL.)
SITENUMBER	Number of the site as displayed in the user interface.
VISITNAME	Name of the visit as displayed in the user interface.
VISIT_ID	Database identifier of the visit.
VISITSYSTEMSTATUS	System status of the visit: • Not Started • Incomplete • Complete
VISITFROZEN	Code indicating whether the visit is frozen: • 0—No • 1—Yes
VISITLOCKED	Code indicating whether the visit is locked: • 0—No • 1—Yes
VISITDMREVIEWED	Code indicating whether the visit has been reviewed by a Data Manager: • 0—No • 1—Yes

Column	Description
VISITSDV	Code indicating whether the visit has been source verified: • 0—No • 1—Yes
VISITSIGNED	Code indicating whether the visit has been signed: • 0—No • 1—Yes
VISITREMOTEREVIEW	Code indicating whether the visit has been reviewed remotely: • 0—No • 1—Yes
VISITHASOPENQUERY	Code indicating whether the visit has open queries: • 0—No • 1—Yes
LAN_ID	Identifier of the language, enabling you to filter the view by language.

AD_eProVisits

This view contains the system status and manually applied statuses for each patient visit. The view reflects the ePRO forms in each visit.

Column	Description
PATIENTID	Unique identifier for the patient. (Can be NULL.)
SITEID	Database identifier of the site. (Can be NULL.)
SITENUMBER	Number of the site as displayed in the user interface.
VISITNAME	Name of the visit as displayed in the user interface.
VISIT_ID	Database identifier of the visit.
VISITSYSTEMSTATUS	System status of the visit: • Not Started • Incomplete • Complete
VISITFROZEN	Code indicating whether the visit is frozen: • 0—No • 1—Yes

Column	Description
VISITLOCKED	Code indicating whether the visit is locked: • 0—No • 1—Yes
VISITDMREVIEWED	Code indicating whether the visit has been reviewed by a Data Manager: • 0—No • 1—Yes
VISITSDV	Code indicating whether the visit has been source verified: • 0—No • 1—Yes
VISITSIGNED	Code indicating whether the visit has been signed: • 0—No • 1—Yes
VISITREMOTEREVIEW	Code indicating whether the visit has been reviewed remotely: • 0—No • 1—Yes
VISITHASOPENQUERY	Code indicating whether the visit has open queries: • 0—No • 1—Yes
LAN_ID	Identifier of the language, enabling you to filter the view by language.

Other views

AD_Arms

This view contains the patient id and patient group (cohort) that identifies the arm to which the patient belongs.

Column	Description
PATIENTGROUP	Group the patient belongs to.
PATIENTID	Unique identifier for the patient. (Can be NULL.)

AD_CC_Calls_By_Staff

This view contains information about calls taken by each Call Center staff member by day.

Column	Description
ATTEMPTCOUNT	Number of the call attempt.
DATECALLED	Date when the patient called into the Call Center.
ID	Database identifier of the call.
ISCOMPLETE	Indicator specifying if the call is complete: • 0—No • 1—Yes
LAN_ID	Identifier of the language, enabling you to filter the view by language.
NOTES	User comments about the call.
PATIENTID	Unique identifier for the patient.
REASON	Reason for the call.
SITEID	Database identifier of the site.
STAFFMEMBER	Name of the staff member who took the call.
TIMECALLED	Time when the staff member took the call.
VISITNAME	Name of the visit as displayed in the user interface.

AD_Mail

This view contains information about system-generated email messages.

Column	Description
ID	Unique identifier of the email message.
MAILTYPE	Identifier of the type of email message.
NAME	Name of the type of email message.
SUBJECT	Subject of the email message.
BODY	Body of the email message.
SENDRESULT	Result of sending the email message.
SENDTIME	Date and time that the email message was sent.
RECORDTIME	Date and time that the email message was recorded in the database.
LAN_ID	Identifier of the language, enabling you to filter the view by language.

AD_Patient Survey

This view contains information such as the number of missed visits and completed visits for a patient, as well as other patient survey information.

Column	Description
COMPLETED_VISITS	Number of completed visits.
LAN_ID	Identifier of the language, enabling you to filter the view by language.
MISSED_VISITS	Number of missed visits.
PATIENT_ID	Unique identifier for the patient.
PREFERRED_METHOD	Preferred method of contact: • Paper • Phone • Web
SITE_ID	Database identifier of the site.
SITE_NAME	Full name of the site.
STATUS_CHANGE_DATE	Date of status change.
VISIT_EXPECTED_DATE	Expected date of the visit.
VISIT_ID	Database identifier of the visit.

Column	Description
VISIT_NAME	Name of the visit as displayed in the user interface.

AD_RightsRoles

This view contains each role with its associated rights.

Column	Description
ROLEID	Unique identifier of the role.
ROLENAME	Name of the role.
RIGHT	Name of the right.

AD_RoleReport

This view contains the roles associated with each report.

Column	Description
REPORTNAME	Name of the report.
ROLEID	Unique identifier of the role.
ISDELETED	Code indicating whether the report has been deleted: • 0—No • 1—Yes
REPORTPATH	Report path.
ROLENAME	Name of the role.

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