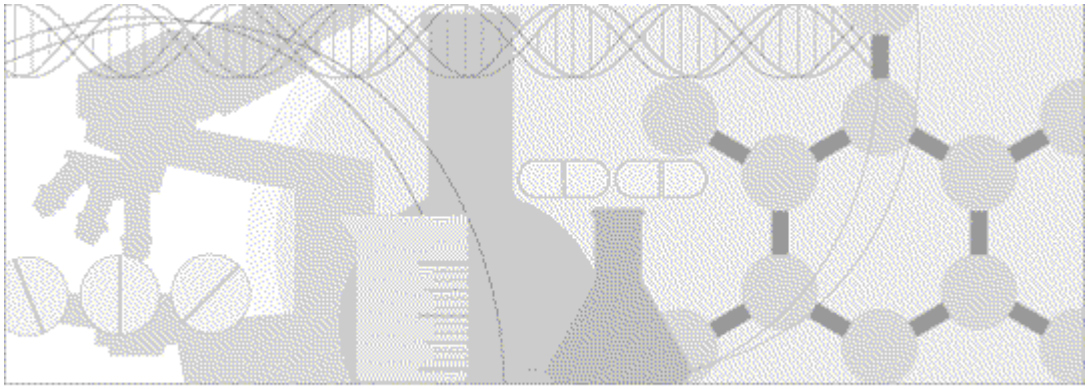
Administration Guide

Oracle® Health Sciences IRT Cloud Service Release 5.5.7



ORACLE

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Contents

About this guide

In this preface

Overview of this guide

The *Administration Guide* provides concepts and step-by-step instructions you use to perform tasks such setting up roles and permissions, configuring corrections to subject information, setting up notifications, adding custom menus to the user interface, managing integrations, and using features for testing and support. The *Administration Guide* is included in the online help in its entirety.

Audience

This guide is for everyone who sets up and configures the IRT application. Often these tasks are performed by Oracle representatives. However, for some studies, this audience can include an IRT administrator, sponsor user, or other persons who are assigned these tasks for your study.

Documentation

The product documentation is available from the following locations:

- My Oracle Support (https://support.oracle.com)—*Release Notes* and *Known Issues*. These are posted for Oracle employees only.
- Oracle Technology Network (http://www.oracle.com/technetwork/documentation)—The most current documentation set, excluding the *Release Notes* and *Known Issues*.

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

Title	Description	Last updated
Release Notes	The *Release Notes* document lists the system requirements for the IRT Designer software, and provides information about new features, enhancements, and updates for the current release.	5.5.7
Known Issues	The *Known Issues* document provides information about known issues for the current release, along with workarounds, if available.	5.5.7
Secure Configuration Guide	The *Secure Configuration Guide* provides an overview of the security features provided with the Oracle® Health Sciences IRT application, including details about the general principles of application security, and how to install, configure, and use the IRT application securely.	5.5.7
Installation Instructions	The *Installation Instructions* provide an overview of the components of the IRT application, a description of a typical IRT environment, and step-by-step instructions for installing the IRT software and deploying study packages.	5.5.7
User Guide	The *User Guide* provides online access to all tasks you can perform with the IRT application, as well as supporting concepts and reference information. You can access the *User Guide* from the Help button in the IRT application.	5.5.7
Administration Guide	The *Administration Guide* provides concepts and step-by-step instructions you use to perform tasks such setting up roles and permissions, configuring corrections to subject information, setting up notifications, adding custom menus to the user interface, managing integrations, and using features for testing and support. The *Administration Guide* is included in the online help in its entirety.	5.5.7
Third Party Licenses and Notices	The *Third Party Licenses and Notices* document includes licenses and notices for third party technology that may be included with the IRT software.	5.5.7

Documentation accessibility

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

If you need assistance

Access to Oracle Support

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

Finding IRT information and patches on My Oracle Support

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

Creating a My Oracle Support account

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

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

2 Click the **Register** link.

3 Follow the instructions on the registration page.

Finding information and articles

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

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

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

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

Finding patches

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

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

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

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

4 Click the patch ID number.

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

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

Finding Oracle documentation

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

Finding Oracle Health Sciences documentation

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

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

Finding other Oracle documentation

1 Do one of the following:

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

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

Finding prerequisite software for Oracle Health Sciences applications

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

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

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

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

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

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

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

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

CHAPTER 1

Getting started

In this chapter

What is the IRT application?

The IRT application is a randomization and trial supply management application that extends the operational capabilities of traditional interactive voice response/interactive web response (IVR/IWR) technologies and gives sponsors better management of complex trial designs and global supply chains.

Key benefits for clinical supply operations

- Reduced need for change orders, since you can edit subject and supply parameters at any time.
- Approval system, which:
  - Gives the sponsor control over study data and subject management while reducing costs and time for change orders.
  - Increases communication between sites and sponsors.
- Increased accuracy in subject records through the ability to correct subject information (field by field or entire record).
- On-demand access to trial information.
- Lower event charges by leveraging the web vs. phone.
- Access to multiple protocols with a single sign-on.
- Support for global multilingual studies.
- (optional) Integration with Oracle Health Sciences InForm GTM for streamlined workflow.

Key benefits for clinical supply management

- Ability to release drug supplies through the Web.
- Improved ability to manage inventory and over labeling activities.
- Ability to create, assign, and manage supply strategies through the Web.
- Reduced excess drug overage and waste—optional integrated clinical supply forecasting module.
- Limited stock-outs due to built-in system intelligence.

Key benefits for investigator site

- Ability to screen, randomize, and dispense drugs through an interactive subject dashboard.
- Simplified drug receipt and inventory management.

Users, roles, and permissions

In the IRT application, job roles and permissions control access to the functions of the application, the tasks you can perform, and the type of subject and drug supply information you can access. As a result, the environment is secure and tailored to the tasks you commonly perform.

Here are some key concepts:

- **User**

  A person who uses the IRT application. A user must be assigned a role to perform tasks with the IRT application.

- **Roles**

  In a study, groups of people have responsibilities in common. These responsibilities define the user's role—for example, study coordinator, field monitor, principal investigator, or drug supply manager. The IRT application provides a standard list of common roles for a study, which can be supplemented with custom roles.

- **Permissions**

  In the IRT application, each role has specific permissions. A permission provides or restricts access to the features of the application. Because a page is designed around particular tasks, assigning a permission to a role determines whether a person who is assigned that role can perform those tasks. The tasks a person can perform in the IRT application should correspond to that role's job responsibilities for the study.

Getting authenticated

The authentication process

Authentication is your first step toward getting access to the IRT application.

Authentication is a required security process for confirming that a person is who he or she claims to be. In the IRT application, the authentication process takes place through email (for a web user) or through fax or email (phone user), and provides you with a user ID and password for accessing the application.

The authentication process includes these steps:

1 Your user information is uploaded into the IRT application.

Unless this task is part of your job responsibilities, you don't need to worry about this step. For more information, if you are responsible for this task, see Adding and managing users.

This step prompts the IRT application to send you the two emails. You need the information in both communications to become authenticated.

2 *Sign the User Authentication Form (UAF)* (on page 6).

Before authentication, you receive the UAF by email or fax.

This fax contains the User Authentication Code (UAC), which you enter during the authentication process the first time you log in to the study.

Note: Do not send the signed UAF to Oracle.

3 *Authenticate your user account* (on page 6).

Before you authenticate your account, you receive an email message that contains the following information:

- User ID.
- Default phone password.
- A link to reset the web password.

This step sets up a new password for the user name provided to you.

For instructions on using the phone, see *Phone access* (on page 139).

4 Log in to the IRT application.

User ID, password, and confidentiality

Confidentiality

It is your responsibility to maintain the confidentiality of your user account.

- Keep your user ID and password confidential at all times.
- Do not share your user ID and password with anyone else.
- If at any time you lose your password or believe that someone else has access to it, contact

Oracle Support right away.

User ID

- You have one user ID for both the Web and phone (if you have access to both).
- **Note:** For details on access through the phone interface, see *Phone Access* (on page 139).

Passwords

- You create your own password during authentication or password reset. The password must be based on *strong password requirements* (on page 5).
- You have separate passwords for the Web and phone.
- You can reset your web password at any time by clicking the **Forgot your password?** link on the logon page.
- You can also reset your password or phone PIN by clicking the links at the top of the *Application page* (on page 10).

IRT strong password requirements

The password must:

- Have at least eight characters.
- Contain at least one uppercase character.
- Contain at least one lowercase character.
- Contain at least one number or special character.

The password must not:

- Contain a space.
- Be the same password that you are currently using.
- Be one of your previous five passwords.
- Be a dictionary word or common character combination (examples: welcome1, guest2, oracle1, password5, 12345678).

Other password rules:

- Passwords expire every 60 days. The IRT application prompts you to create a new password before the current one expires.
- You account is locked if you attempt to reset the password three times in a ten-minute period.
- When you receive an email to reset your password, the link in the email expires after 60 minutes have passed.
- You cannot use these web passwords: 10000, 11111, 20000, 22222, 30000, 33333, 44444, 40000, 50000, 55555, 60000, 66666, 70000, 77777, 80000, 88888, 90000, 99999, 00000, 54321, 78945.

Signing the User Authentication Form (UAF)

Before you receive the email to authenticate your IRT account, you receive a fax or email with an attachment, the User Authentication Form (UAF). This document authenticates your identity, your use of the IRT application, and your understanding that your user ID and password must be kept confidential at all times.

- Sign this document and return it to the sponsor or study coordinator, according to the policies of the study.

Note: Do not send the signed UAF to Oracle.

User activation

If you are a new user of the IRT application, you are asked to provide the UAC the first time you choose a study on the Application page.

You must provide the following information:

- **User Authentication Code (UAC)—**The UAC is on the User Authentication Form that is faxed or emailed to you. If it is sent by email, open the attached PDF to find the UAC.
- **Site ID**—A unique ID for the site to which you are assigned (if you are a site user).
- **Depot ID**—A unique ID for the depot to which you are assigned (if you are a depot user).

Authenticating your user account

The first time you log on to the IRT application, your user account is authenticated. For more information, see *The authentication process* (on page 4). Before you can authenticate your account, you receive an email with instructions on this process.

For instructions on authenticating through the phone, see *Phone access* (on page 139).

When you receive the email, follow these steps:

1 Click the **Reset** link in the email.

You receive an email that notifies you of your user ID and provides a link to a web page where you set up your password.

2 In the **New Web Password** textbox, type a password.

Follow the *password requirements* (on page 5) on the page.

3 In the **Confirm New password** textbox, type the new password again.

This password must be exactly the same as the one you typed in the **New Password** textbox.

4 Click **Update Password**.

A message informs you that your password has been reset.

5 Click **Login**.

If you have not set up a PIN, you are asked to supply this information.

Note: Be sure to remember the pin, which is required to reset your password and authenticate

your identity if you contact IRT Technical Support.

6 In the **Re-enter Web Password** textbox, type your web password.

7 In the **New PIN** textbox, type a 4-digit PIN.

8 In the **Confirm PIN textbox**, type the PIN again.

9 This password must be exactly the same as the one you typed in the **New PIN** textbox.

The User Activation page appears with a series of steps on the left. The steps you perform depend upon your role in the IRT application.

10 For the **UAC** step, in the **Value/Section** textbox, type the 8-digit User Authentication Code from the User Authentication Form (UAF) that was attached to the email.

11 Click **Continue**.

12 If prompted, provide your Site or Depot ID, and click **Continue**.

The Application page appears.

You can now log in to the IRT application.

Accessing the IRT application

Logging in and out

After authentication, you can log in to the IRT application. If you have not yet authenticated your user account, you must complete this process the first time you log in. For more information, see *Authenticating your user account* (on page 6).

For instructions on logging in to the phone, see *Phone access* (on page 139).

Logging in

If you have access to both the IRT and InForm applications, you can log on to both applications at one time.

1 In the web browser, navigate to the path for the IRT application.

The logon page appears.

2 In the **UserID** textbox, type your user ID.

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

The password is case sensitive.

If you forget your password, you can reset it through the **Forgot your password?** link. For more information, see *Changing and resetting your password.* (on page 9)

If you type your password incorrectly too many times, your account is locked out. For more information, see *Unlocking your account* (on page 9).

4 (optional) In the **Language** drop-down list, select your language.

5 Click **Enter**.

If you have access to more than one study, the Application page appears.

6 On the Application page, select the study.

7 If this is the first time you have logged on to this study, you must complete user activation.

Logging out

From the IRT web user interface:

- On the toolbar, click **Log out** ().

From the application page with the list of studies you can access:

- Click **Log out**.

Changing and resetting your password

You might need to change your password if you forget it or if your account becomes locked. To change or reset your password:

1 In the web browser, navigate to the path for the IRT application.

2 Click the **Forgot your password?** link.

3 Follow the instructions on the screen.

Unlocking your account

Your user account might be locked out if you attempt to log in unsuccessfully several times consecutively. If this happens, you cannot unlock your account on your own. Contact the field monitor for the study, who can unlock the account.

A user interface walkthrough

Standard vs. study-specific content

This guide provides instructions on how to use the standard (non-customized) version of the IRT application. However, many sponsors customize some aspects of the application, such as:

- The terminology you use to refer to certain aspects of the interface, such as the options on the main menu.
- The terminology you use to refer to certain concepts, such as drug units, site, or depot.
- The prompts you see when you log subject information during a visit.
- The manner and degree by which the IRT application makes use of the Approvals system.
- The specific policies and procedures of the study or site.

If requested by the sponsor, Oracle develops study-specific guides that are available from the Home page. For more information, see *Opening the study documentation* (on page 19) (see **Help** ).

The study-specific guides contain instructions that describe how the IRT application is set up for your study. The standard documentation provides a broader, more in-depth view of the product than you are likely to find in the brief study guides.

You should use the study guide to get started and to learn how the IRT application has been customized for your study. Use the standard documentation, such as this online help system, for more detailed information.

Application page

If you are working on more than one study that uses the IRT application, the Application page appears whenever you access the IRT application. This page lists all of the studies associated with your user account.

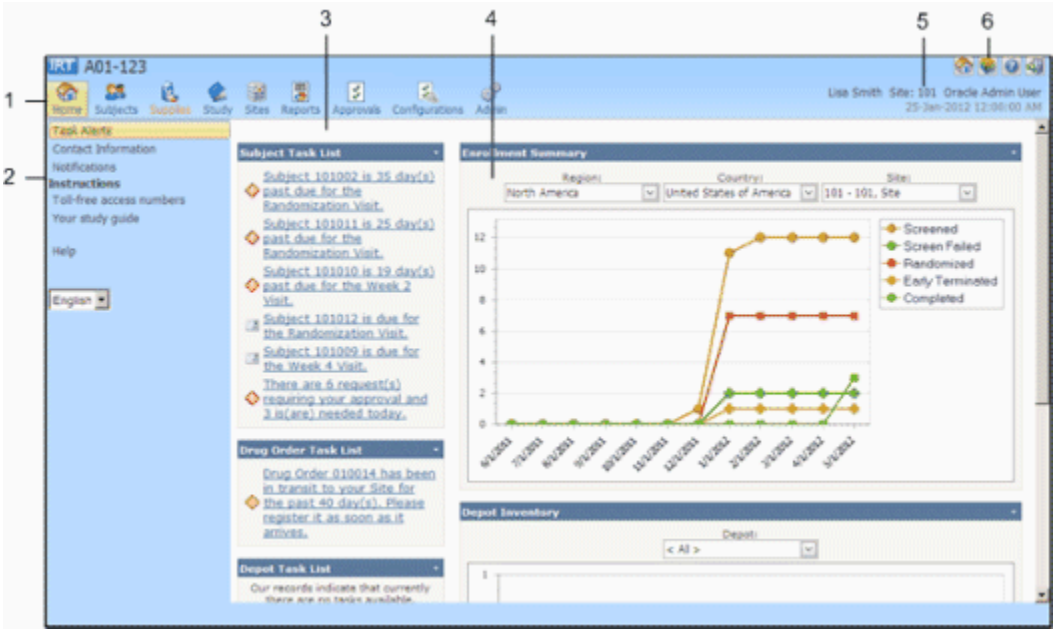
On this page, you can do the following:

- **Application List**—Access all of the IRT studies associated with your user account.
- **Change Phone Password**—Update the password for accessing the phone.
- **Change Web Password**—Reset the password for accessing the web user interface.
- **Change PIN**—Reset the PIN.

For more information on accessing the IRT application with the phone, see *Phone access* (on page 139).

Home dashboard

Through the dashboard on the Home page, you get an at-a-glance view of the status of the study. How much of this view you can see depends on your role and permissions in the IRT application. For more information, see *Users, roles, and permissions* (on page 3).



1	Main menu	The main menu lists the categories of tasks for the IRT application. The picture above shows the full list of menus. You see only those menus that your role allows you to access.
2	Menu pane	When you select from the main menu, the functions associated with that menu are listed in the menu pane. Select a function from the menu pane to open the page where you can perform the task. **Home** —Opens the Home page (dashboard). **Subjects** —Perform all subject transactions on the visit schedule, correct subject information, and unblind subjects (if permitted by your role). **Supplies** —Manage depot inventory, perform order transactions, perform end-of-study reconciliation, and complete similar tasks. **Study** ( )—Monitor study limits, approve randomization and drug schedules, set up email notifications, set up regions and countries, manage users for the study, and complete similar tasks. **Sites** ( )—Upload and manage sites for the study (for example, activate a site). **Reports** ( )—Monitor the study through reports and create custom reports.

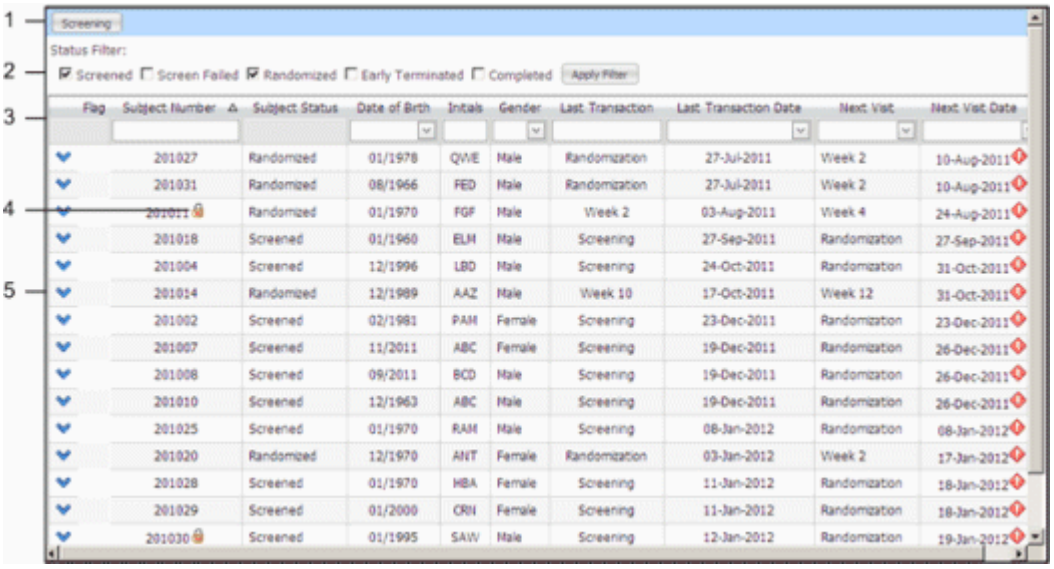
		Approve  —View and approve requests for approval that are assigned to your role. **Configuration**  —Authorize and configure subject data edits and rollbacks for each type of transaction; set up roles and permissions, and set up approvals, out-of-visit windows, and Do Not Dispense (DND) dates for the study. (Typically available only to IRT administrators.) **Admin**  —Perform various testing and support tasks, view the audit history, and manage custom menu items. (Typically available only to IRT administrators.)
3	Task list	The tasks display a list of subject, drug order, and depot tasks that require attention. Pending approvals are listed in the Subject Task List. For more information, see ***Viewing a task alert*** (on page 21).
4	Trend charts	These charts show up-to-the-minute trends for: • **Enrollment:** Total subjects by transactions (screening, screen failed, randomized, early termination, and completed) and by date. You can filter the data to limit the results by region, country, and site. • **Depot inventory:** Inventory levels by drug supply type. You can filter the data to limit the results to a specific depot.
5	User profile	This area shows: • Your name (as set up on the Contact Information page). • The site you are currently associated with, if applicable (for site and depot users). • The role you are assigned in the IRT application.
6	Toolbar	The toolbar, available from any page in the application, provides these options:  —Opens the Home page (dashboard).  —Opens the list of studies to which you have access.  —Opens Help for the current page  —Logs out of the IRT application.

Forms

Forms are formatted pages that contain:

- Data you can filter to find the exact information you need (for example, all subjects who have been randomized or all drug units within a specific range).
- Fields that you can fill to set up or log details about an item (for example, subject information gathered during a visit, properties of a depot you are setting up).

The IRT application uses the information you enter as parameters for managing the study and to keep track of study trends.



1	Add New or perform transaction	Most forms have a button in this position that you can select to perform a transaction (for example, screen a subject) or add a new item (for example a new depot).
2	Status filters	These filters help you to find items in the list by identifying only those items that have a particular status (for example, all randomized subjects or all drug orders that have been canceled). These filters are only available on forms where status is important, such as a subject or drug order transaction.
3	Column headings or field descriptions	Click the column heading to sort the list of items alphabetically or numerically. In some cases, you can select from a list of properties to filter the list. For example, if you select the arrow below a date column header, you can select a specific date from the calendar. The form then displays all transactions on that date. These column headings correspond to the field labels on the form when you enter information.

4	Icons for special status	Some transactions are marked by icons that indicate a special status. For example, in the above picture, the icon () marks a locked subject. This subject is locked because a user has requested to change the subject's record and the record is being reviewed. When the approver accepts or rejects the request, the subject is unlocked and the icon disappears.
5	Item detail	If you select an item row or click the blue arrow (), the form expands to show details of that item or the fields where you perform a transaction. For example, if you select a subject from the list, the form shows the visit schedule for that subject. Or, if you select a drug order, the form expands to show the drug units in the order. You must expand the form to perform a transaction.

Sorting and filtering data in a form

Filtering data in a form

Often a form contains many entries, but you might only want to see those that have common characteristics, such as status or date of transaction.

Use the filters to limit the information that you might see in the form. Filters are located at the top of the form under each column heading.

To filter the information in the form:

- For filters with a drop-down list:
  - Click the arrow, and select the filter option from the drop-down list.

    or
  - Type the value in the field.

  The information that appears in the form is filtered by the value you selected.
- For the filters that do not have an arrow, type the value in the field.

  The information that appears in the form is filtered by the value you selected.

Applying status filters

Status filters allow you to filter transactions by one or more statuses. For example, on the Subject Transactions page, you might want to filter for subjects who have been both screened and randomized.

On IRT pages that contain status filters, the status filters appear at the top of the form.

To apply a status filter:

1 In the **Status Filter** section, select one or more status filter options.

2 Click **Apply Filter**.

The information that appears in the form is filtered by the value you selected.

To clear a status filter:

If you clear all status filters, the list contains all entries, because each entry has a status associated with it.

1 In the **Status Filter** section, select the status filter.

2 Click **Apply Filter**.

Custom filters

For many pages in the IRT application, you can build custom filters to retrieve information in a form.

Custom filters use logical operators (for example, And or Or) to join conditions or simple equations (for example, Subject Number Equals 201031) to create condition groups.

To create a custom filter, see:

- *Logical operators for custom filters* (on page 15).
- *Conditions for custom filters* (on page 15).
- *Creating a custom filter* (on page 16).

Logical operators for custom filters

Logical Operator	Function
And	Narrows the filter and retrieves information containing *all* specified conditions.
Or	Broadens the filter and retrieves information containing *any* of the specified conditions.
Not And	Narrows the filter and retrieves *everything but* the specified conditions.
Not Or	Narrows the filter and retrieves *nothing* from the specified conditions.

Conditions for custom filters

A condition contains three parts:

- A **column** (which corresponds to a column in an IRT form). Examples-—Subject Number, Randomized, Gender.
- A **criteria operator**. Examples-—Is greater than, Is between, Equals.
- An **operand value**: Examples-—201031, Female, 20-Feb-1970.

Examples of conditions

Column	Criteria operator	Operand value
Subject Number	= Equals	201031
Gender	≠ Does not equal	Female

Column	Criteria operator	Operand value
Date of Birth	Is between	17-Jan-1945 AND 5-Dec-1980

A condition group consists of all the conditions that are combined under one logical operator. For example, the following custom filter (for the Subject Transactions page) contains a condition group with two conditions. This custom filter limits the data that will appear in the data grid to Subject Number 201027 in Week 2 of the next visit:

And

Subject Number Equals 201027

Next Visit Equals Week 2

You can add multiple condition groups under the main logical operator in the filter. For example:

And

Subject Number Equals 201027

Next Visit Equals Week 2

Or

Date of Birth Is greater than 20-Feb-1970

Gender Does not equal Male

Creating a custom filter

Custom filters are found in two places in the IRT user interface:

- A **Create Filter** link at the bottom of a form. The link has an icon of a key in front of it.
- A **Create Filter** button at the top of a Reports form.

You can only create custom filters on these pages.

To create a custom filter:

1 Click **Create Filter**.

A Create Filter (or Filter Builder) dialog box appears. The default logical operator is *And*.

2 To change the logical operator, click **And**, and select the logical operator from the pop-up menu.

3 To add a condition, click the plus sign (**+**) next to the logical operator.

A condition appears below the logical operator.

4 To define the condition, click each part of the condition and select the values from the pop-up menus.

5 (optional) *Build a custom filter* (on page 17).

6 When you finish building the filter, click **OK**.

The information that appears in the form is filtered by the value you selected.

For pages with **Create Filter** at the bottom of the form, the custom filter that you created replaces the Create Filter link.

Note: The custom filter remains saved only while you are on the page. After you leave the page, the custom filter automatically clears.

To unapply the filter

For pages with **Create Filter** at the bottom of the form:

- At the bottom of the form, deselect the checkbox in front of the custom filter link.

  The custom filter is unapplied from the data grid; however, it remains saved at the bottom of the form.

To edit the filter

For pages with **Create Filter** at the bottom of the form:

1. Click the custom filter link.

   The Create Filter (or Filter Builder) dialog box appears.

2. Edit the values as necessary, and click **OK**.

   The changes are applied to the filter.

For reports with **Create Filter** at the top of the data grid:

1. Click **Create Filter**.

   The Create Filter dialog box appears.

2. Click on the logical operator and condition components, and select new values from the pop-up menus.

3. Click **Apply Filter**.

To clear the filter

For pages with **Create Filter** at the bottom of the form:

- Click **Clear**.

For reports with **Create Filter** at the top of the data grid:

1. Click **Create Filter**.

   The Create Filter dialog box appears.

2. Click **Clear Filter**.

Building the custom filter

Task	Steps
Add a condition to a condition group	Click the plus sign (**+**) next to the logical operator. or Click the logical operator, and select **Add Condition** from the pop-up menu.
Start a new condition group	Click the logical operator, and select **Add Group** from the pop-up menu. A new logical operator *And* appears indented under the last condition of the above condition group. A new condition appears under the new logical operator.
Change a logical operator	Click the logical operator and select another logical operator from the pop-up menu.
Edit components of a condition	Click on the parts of the conditions and select new values from the pop-up menus.
Remove a condition	Click the **x** at the end of the condition.
Remove a condition group	Click the logical operator that joins the conditions, and select **Remove** from the pop-up menu.

Accessing documentation

Getting online help

You can display the online help in these ways:

- In the upper right corner, click the **Help** icon.
- Below the list of menu options for a page, click **Help**.

Opening study-specific documentation

Your study might be supported by one or more guides that provides details on how the IRT application has been configured for your study. You can open these guides from the Home page.

1 Click **Home** ().

The dashboard page appears.

2 From the **Home** menu, select the name of the document you want to open.

Getting notifications

Email notifications

A notification is a message you receive from the IRT application that lets you know you have completed an action (a confirmation) or reminds you of an action you must take as soon as possible (an alert).

- Example of a confirmation—a scheduled visit has completed, a subject has been randomized, or a request for approval is received.
- Example of an alert—a drug order has failed, a subject is overdue for a visit, or a drug order is overdue.

Notifications are a normal part of IRT operation. They do not mean you have done something wrong.

Who should care about notifications?

Notifications affect everyone who uses the IRT application. Some people—such as the study manager, drug supply manager, or Oracle administrator—set up how notifications work, but most IRT roles receive notifications that apply to the tasks they perform.

If you log subject visits, you receive email notifications as a record of that visit. You should file these emails according to the policies of the study.

Decisions you must make

Confirmations are informational and do not require action. However, most alerts require you to make decisions about how to act and then to take action. If you receive an alert:

- Decide how to act on the alert.

  The alert often includes a recommended action. If you are not clear on what to do, speak with the site monitor or field monitor.

- Decide when to act on the alert.

  You typically must act on the alert as soon as possible. Some alerts are critical and require immediate action. Other alerts, such as requests for approval of changes to subject information, have deadlines to avoid conflicts in subject visits. Check the ***Subject Approvals page*** (see **Help** ) to see when approvals are due.

- Decide who should act on the alert.

  You receive a notification because you perform a specific role. In most cases, anyone who receives the alert should be able to resolve it. If you are not comfortable dealing with the alert, speak with the site monitor or field monitor.

Viewing and editing your contact information

It is important to keep your contact information up-to-date, because you receive critical notifications through email. Your email address is set up in your contact information.

For descriptions of the fields on this page, see *Notifications page* (on page 86).

1 Click **Home** ().

The dashboard page appears.

2 From the Home menu, select **Contact Information**.

3 (optional) Edit the information on the page.

4 If you changed your contact information, click **Submit**.

Viewing a task alert

The Home dashboard lists alerts to notify you of the status of subject visits and drug orders for the site.

The alerts are organized in Tasks Lists on the Home page.

- **Subject Tasks List** – Lists subjects who are past due for a visit and approval requests for your role.
- **Drug Order Task List** – List drug orders that are in transit or are overdue.

To view an alert:

- Click the alert in the Task List.

  The page associated with the alert appears. If a transaction is associated with the alert, you can click the alert to go to the page where you perform the transaction.

CHAPTER 2

Configuring corrections to subject information

In this chapter

Roadmap: Configuring corrections to subject information

This roadmap describes the typical process of configuring edits to subject information, including the approval cycle set up by the sponsor. The way these systems operate can vary from study to study, so be sure to check with the Field Monitor for your study for exact details.

Step #	Action	Menu to select	What happens?
1	Determine which fields a user should be able to edit.	N/A	This collaborative effort between Oracle and the sponsor is completed during the design phase of the study.
2	*Identify editable fields in AppBlock Designer* (on page 28).	N/A	An Oracle representative must perform this task during study design using an internal tool called the AppBlock Designer.
3	*Configure out-of-age approvals in the Config Tool* (on page 39).	N/A	An Oracle representative must perform this task during study design using an internal tool called the Config Tool.
3	Authorize the type of edits that are permitted: • *Subject data edits* (on page 29). • *Drug reallocation* (on page 34). • *Visit rollbacks* (on page 32).	**Configuration** **General Configurations** **Transaction Configurations**	Each type of change must be: • Authorized–switched on in the IRT application. • Configured–set up to work properly for your study (for example, set the roles that can approve or reject a request.
4	*Enable editing and assign permissions for each editable field* (on page 29).	**Configuration** **Transaction Configurations**	If you subject data edits have been authorized, you can: • Set the roles whose assigned uses should review changes to each field. • Review other functions that might be impacted by editing the data in the field (dependencies). This process can be configured to require up to two levels of approval.

Step #	Action	Menu to select	What happens?
5	***Set up visit windows and approval settings*** (on page 37).	**Configuration** **Manage Visit Schedule**	The initial visit schedule is set during the design phase of the study. You can adjust the following: • Visit windows. • Out-of-window approvals. • Do Not Dispense (DND) days.
6	Edit data during subject transactions.	**Subjects** All transactions	If subject edits are authorized for the study, a user can correct subject information collected during a visit. For more information, see Roadmap: Subject visits and The process of correcting subject information.
7	Approve or reject requests to edit subject information.	**Approve** **Subject approval**	If approval is required, the IRT application sends a notification to the user assigned to the roles that are configured to review the type of correction. For more information, see ***Roadmap: Approvals*** (see **Help**).

Types of corrections you can configure

You can configure settings in the IRT application to allow users to correct subject information after it is saved. Review the ***approval roadmap*** (see **Help** ) before starting the configuration process.

You must have the appropriate permissions in the IRT application to perform these tasks.

The types of subject information you can correct are:

- ***Subject data edits*** (on page 27).

  Subject data edits are corrections to the subject information gathered during a subject visit. These changes can include subject demographics, transaction date, and other study-specific information.

- ***Drug reallocation*** (on page 34).

  Drug reallocations in unblinded studies must be acknowledged by an unblinded role.

  Drugs are reallocated when drug units that have not been assigned by the IRT application are provided to the subject during a visit. During reallocation, you identify the drug units that were provided to the subject, and reallocate the drug units that should have been supplied to the subject.

- ***Visit rollbacks*** (on page 31).

  A rollback restores the information gathered during a visit to a previous state—typically, to the last fully correct version of data for the subject.

- ***Out-of-window approvals*** (on page 36).

  Out-of-window visits occur outside the number of days either before or after the date on the visit schedule that a visit is permitted to happen. An out-of-window visit might require approval.

- ***Out-of-age approvals*** (on page 39).

  An out-of-age approval request is a request for a subject who does not meet the study age requirements to continue in the study.

Configuring subject data edits

Subject data edits described

Subject data edits are corrections to the subject information gathered during a subject visit. These changes can include subject demographics, transaction date, and other study-specific information.

All data entry fields are identified during the design process through a collaborative effort between Oracle and the sponsor.

The process of configuring subject data edits

During configuration, you complete each of these tasks:

1 In the AppBlock Designer, enable each field to be editable.

An Oracle representative must perform this task.

2 In the IRT application, authorize subject data edits for the study.

This procedure switches on the ability to change subject information in a study after a transaction is complete.

3 In the IRT application, identify editable fields and permissions.

This procedure identifies which fields in the study are editable, and the level of approval assigned to each field.

You can enable or disable editing of each field for a transaction. You can also set the approver roles and approval level for each field: no approval, one level of approval, or two levels of approval.

A subject affected by a request for approval is locked () until the request is reviewed and either approved or rejected.

Related tasks:

- *Identifying editable fields in the AppBlock Designer.* (on page 28)
- *Authorizing subject data edits* (on page 29).
- *Identifying editable fields and permissions* (on page 29).

Identifying data entry fields in AppBlock Designer

This procedure identifies the data entry fields in the study so they can be configured for subject data edits in the IRT application.

The IRT application collects the data entry fields for the study from the AppBlock Designer. The AppBlock Designer is an internal Oracle tool for designing clinical studies. The IRT application collects study design configuration properties from the AppBlock Designer and displays it in the user interface, where you can configure, view, and add data to the study.

The IRT application only collects data entry fields. It does not collect calculated fields even if they are based on data entry fields. For example, if BMI is calculated from Height and Weight, the IRT application can only collect Height and Weight as editable fields, but not BMI.

- Identify all data entry fields for the study in the AppBlock Designer so the IRT application collects all possible data entry fields and makes them available for configuration.

  Later, as the needs of the study mature, you can enable or disable each field in the IRT application to set up which fields are editable. This way, if the sponsor decides to later make editable field that was not initially made editable, the field is available from the Configuration page.

An Oracle representative must perform this procedure for each editable field prior to deploying the trial. For more information, see *Configuring subject data edits* (on page 27).

1 Log on to AppBlock Designer.

2 Select the **Sponsor**.

3 Select the **Protocol**.

A list of AppBlock functions appear.

4 Select the AppBlock function for the transaction.

5 Click **Load Workflow**.

The flowchart for the function appears.

6 Double-click the step containing the field you want to make editable.

7 Click the **IRT Developer** tab.

8 Select the button to the right of the **Name AppMessage** field.

The AppMessage Editor dialog box appears.

9 In the **WebMessage** textbox, type a name for the field as it should display in the IRT user interface.

10 Click **OK**.

11 Click **OK** again.

12 Repeat steps 6 - 12 for each field that should be editable in this AppBlock flow.

Common tasks following this procedure:

- *Authorizing subject data edits* (on page 29).
- *Identifying editable fields and permissions* (on page 29).

Authorizing subject data edits

This procedure switches on the ability to change subject information in a study after a transaction is complete. For more information, see *Correcting subject information* (see **Help** ) and *Configuration of subject data edits* (on page 27).

Before you perform this procedure, you must set up the data entry fields during the design phase so they are collected by the IRT application. For more information, see *Identifying the data entry fields in AppBlock Designer* (on page 28).

For descriptions of the fields on this page, see *General Configurations page* (on page 87).

1 Click **Configurations** ().

2 From the **Configurations** menu, select **General Configuration**.

The configuration settings for authorizing subject data edits appear.

3 In the **Allow Data Edits** section, select **Yes**.

4 In the **Allow Data Editable** section, select each type of transaction that can be edited.

5 In the **Approvals Alert Frequency** textbox, type the number of days between the reminders to review an approval or an acknowledgment.

When an approval or acknowledgment is requested, the IRT application sends the first alert immediately. This option sets the number of days between later reminders.

6 Click **Submit**.

After you enable edits to subject transactions, you must *identify the editable fields and set permissions* (on page 29).

Identifying editable fields and permissions

This procedure identifies which fields in the study are editable, and the level of approval assigned to each field. Before you identify editable fields, you must set up the IRT application to permit subject data edits. For more information, see *Authorizing subject data edits* (on page 29) and Levels of approval.

If the study has been configured for an out-of-window hard stop, be sure to require at least one level of approval for transactions that include date changes. The approver should check the date entered in this field to make sure the date does not conflict with the study requirements for out-of-window visits.

For descriptions of the fields on this page, see *Transaction Configurations page* (on page 90).

1 Click **Configurations** ().

2 From the **Configurations** menu, select **Transaction Configuration**.

The settings for configuring screening transactions appear.

3 From the **Transaction** drop-down list, select the type of transaction.

4 In the **Data Edit Settings** section, select the **Allow Edit** checkbox for each field to make editable.

5 From the **Approval Required** drop-down list, select the appropriate level of approval for each field.

Each field can be set to a different level of approval.

6 (optional but recommended) To set the dependencies for the field, click the number in the **Dependencies** column.

Initially, this number is always 0 (no dependencies have been set).

Dependencies are transactions that are impacted by changing the value of the editable field. These dependencies are informational only—that is, you can check these dependencies on the page when you configure the field. Selecting a dependency does not cause any functional changes in the IRT application.

7 If edits to this field require approval:

- Select the role for the first-level approver from the **Data Edit First Approver(s)** list.
- (optional) Select the role for the second-level approver from the **Data Edit Second Approver(s)** list.

  To select multiple approval roles, press the **Ctrl** key and then select each role.

8 Click **Submit**.

Configuring rollbacks

Visit rollbacks described

A rollback restores the information gathered during a visit to a previous state—typically, to the last fully correct version of data for the subject. Typical purposes of a rollback are to:

- Delete a transaction for the wrong subject.
- Re-do a visit with incorrect information that might affect the outcome of the visit.

Note: You cannot roll back a screening visit.

To roll back more than one visit, you must roll back one visit at a time. For example, consider the following scenario:

Visit Schedule	Notes
Screening	
Randomization	
Visit 2	Desired state of data
Visit 4	
Visit 6	Current visit (with incorrect data)

In this situation, you must roll back:

1 Visit 6 to Visit 4

2 Visit 4 to Visit 2

The process of configuring rollbacks

You can roll back a visit to a previous state. For more information, see *Visit rollbacks defined* (on page 31).

Note: If a study threshold fluctuates and drops below theshold values more than once due to a rollback, the alert message is sent the first time the study drops below the threshold values. It is not sent again.

During rollback configuration, you complete each of these tasks:

1 Authorize rollbacks for the study.

This procedure switches on the ability for users of the IRT application for this study to roll back a visit to a previous state. If the visit you want to roll back to occurred several visits ago, you must roll back one visit at a time.

You cannot roll back a screening visit.

2 Identify specific properties and permissions for the rollback.

For example, you can determine whether you want to roll back the drug status.

You can also set the approval level for the rollback: no approval, one level of approval, or two levels of approval.

A subject affected by a request for approval is locked ( ) until the request is reviewed and either approved or rejected.

Related tasks:

- *Authorizing and setting approvals for rollbacks* (on page 32).
- *Requesting a visit rollback* (see **Help**).

Authorizing and setting approvals for rollbacks

Before you identify editable fields in the IRT application, you must set up the IRT application to permit rollbacks. You can configure rollbacks differently for each type of transaction. For more information, see *Visit rollbacks* (see **Help**).

You cannot roll back a screening visit.

For descriptions of the fields on this page, see *Transaction Configuration page* (on page 90).

1 Click **Configurations** ( ).

2 From the **Configurations** menu, select **Transaction Configuration**.

The settings for configuring screening transactions appear.

3 In the **Transaction** drop-down list, select the type of transaction for which you want to authorize rollbacks.

4 In the **Rollback settings** area, select **Allow Rollback**.

5 Identify additional rollback settings that are specific to the transaction.

- For randomization visits, select **Re-use Randomization number** to re-circulate the randomization number that had been applied to the subject prior to the rollback.

  This field appears only if the study is configured for forced randomization. Selecting this field reduces gaps between randomization numbers.

- If the field is available, select **Roll-back drug status** to indicate that the status of the drug was not affected during the visit.

  For example, suppose the site user sees the error immediately after the transaction is completed. In this case, the drug units are never provided to the subject or removed from a temperature controlled environment. Since the status of the drug has not been affected, the approver can roll back the drug status.

6 If a roll back requires approval:

- Select the role for the first-level approver from the **Roll-Back First Approver(s)** list.
- (optional) Select the role for the second-level approver from the **Roll-Back Second Approver(s)** list.

  You can select multiple approval roles by pressing the **Ctrl** key and then select the roles.

7 Repeat steps 3 -6 for each transaction type.

Configuring drug reallocation

Drug reallocation described

Drugs are reallocated when drug units that have not been assigned by the IRT application are provided to the subject during a visit. During reallocation, you identify the drug units that were provided to the subject, and reallocate the drug units that should have been supplied to the subject.

Drugs must be reallocated when:

- The subject is given the wrong drug units.
- The subject is given drug units that were not first identified by the IRT application.

The process of configuring drug reallocation

Drug reallocation occurs after the drug units are improperly dispensed, so these edits are acknowledged rather than approved. However, the process is similar to approval.

Important: Drug reallocations in unblinded studies must be acknowledged by an unblinded role.

During configuration, you complete each of these tasks:

1 Authorize drug reallocation for the study.

This procedure switches on the ability for users of the IRT application for this study to reallocate drugs after a transaction is complete.

2 Identify specific properties and permissions.

You can identify the conditions when acknowledgment is required (never, always, or only during incorrect drug supply transactions).

You can also identify the unblinded role that should acknowledge the request to reallocate drugs.

A subject affected by a request for approval is locked ( ) until the request is reviewed and either approved or rejected.

Related tasks:

- *Authorizing and setting approvals for drug reallocation* (on page 34).
- *Reallocating drugs* (see **Help**).

Authorizing and setting approvals for drug reallocation

This procedure switches on the ability for users of the IRT application for this study to reallocate drugs after a transaction is complete.

Important: Drug reallocations in unblinded studies must be acknowledged by an unblinded role.

For descriptions of the fields on this page, see *General Configuration page* (on page 87).

1 Click **Configurations** ().

2 From the **Configurations** menu, select **General Configuration**.

The configuration settings for authorizing subject data edits appear.

3 In the **Allow Drug Reallocation** section, select **Yes**.

4 In the **Acknowledge** section, select when drug reallocation should be acknowledged:

- **All Reallocation Transactions**–All transactions require acknowledgment.
- **No Reallocation Transactions**–Drug reallocations can be edited without acknowledgment.
- **Incorrect Trial Supply Transaction (Used for Open Label trials only)**–The drug type of the drug units identified by the IRT application is different from the drug type of the drug units provided to the subject.

5 Select each unblinded role that should be responsible for acknowledging drug reallocations.

6 In the **Approvals Alert Frequency** textbox, type the number of days between the reminders to review an approval or an acknowledgment.

When an approval or acknowledgment is requested, the IRT application sends the first alert immediately. This option sets the number of days between later reminders.

7 Click **Submit**.

Configuring visit windows

Visit schedule configuration elements described

During configuration, you set up the following elements of the visit schedule:

- **Visit window**–The visit window is the number of days before and after the date in the visit schedule when a subject can complete a visit.
- **Out-of-window range**–Out-of-window visits occur outside the number of days either before or after the date on the visit schedule that a visit is permitted to happen. An out-of-window visit might require approval.
- **Do Not Dispense (DND) date**–The DND date is the number of days before the expiration date of a drug unit from which the drug unit cannot be dispensed to a subject.

  The DND date is calculated as:

  Dispense Date < = Lot Expiration Date – Days from Expiry (DND)

The process of configuring visit windows

The IRT application shows you certain details about the visit schedule that help you to understand how to configure the visit window, such as the visit all dates are projected from. You can only edit the information that affects the visit window. For more information, see *Visit schedule configuration elements described* (on page 36) and *Manage Visit Schedule page* (on page 95).

During configuration, you complete each of these tasks:

1 Set the approver permissions for out-of-window visits.

  Set these permissions on the Manage Permissions page. You can set these permissions before or after the other steps in this process.

2 Set the number of days in the visit window.

  The window can include the number of days before or after the visit.

3 Authorize an approval for out-of-window visits for each visit.

  Each visit in the visit schedule must be set up individually. The hard stop for each visit must be set to **Yes** to switch on out-of-window approvals for the visit.

  A subject affected by a request for approval is locked ( ) until the request is reviewed and either approved or rejected.

4 (optional) For all visits where drugs are dispensed, adjust the DND date as necessary for each treatment or dosing level.

Related tasks:

- *Setting approver permissions for out-of-window visits* (on page 37).
- *Authorizing and setting approvals for out-of-window requests* (on page 37).
- *Setting the Do Not Dispense (DND) date* (on page 38).

Setting approver permissions for out-of-window visits

Set up the roles that approve out-of-window visits before configuring the visit window.

For descriptions of the fields on this page, see Manage Permissions page.

For details on this page, see the *Roles and permissions matrix* (on page 50).

1 Click **Configurations** ().

2 From the **Configuration** menu, select **Manage Permissions**.

A table of functions (vertical list on the left) and permissions (horizontal list across the top) appears.

3 In the list of functions on the left, in the **Subject Approval** category, find the **Subject Out of Window Approval** function.

The Permission ID for this function is 210.

4 Locate the approver role in the **Function/Role** heading at the top of the page.

5 Select the checkbox below the approver role in the row for the **Subject Out of Window Approval** function.

6 Click **Submit**.

Authorizing and setting approvals for out-of-window requests

For each visit in the visit schedule, you must decide whether to authorize out-of-window requests and whether these requests require approval. If you set up approvals for these visits, you must *identify the approvers* (on page 37).

For descriptions of the fields on this page, see *Manage Visit page* (on page 95).

1 Click **Configurations** ().

2 From the **Configurations** menu, select **Manage Visit Schedule**.

The properties of the current visit schedule appear.

3 In the **Visit Schedule** tab, find the visit whose approval settings you want to change, and click **Edit**.

4 To authorize the out-of-window approvals for the site, in the **Out of Window Hard Stop?** drop-down list, select **Yes**.

5 To set up the study to require approvals for out-of-window visits, in the **Out of Window Approval?** drop-down list, select **Yes**.

Setting the Do Not Dispense (DND) date

You can set the Do Not Dispense (DND) date for any visit in which drug units are dispensed and for all drug units that are dispensed during that visit.

The DND date is calculated as:

Dispense Date < = Lot Expiration Date – Days from Expiry (DND)

On the Manage Visit Schedule page, you set the Days from Expiry (DND) in this calculation.

For descriptions of the fields on this page, see *Manage Visit Schedule page* (on page 95).

1 Click **Configurations** ().

2 From the **Configurations** menu, select **Manage Visit Schedule**.

The properties of the current visit schedule appear.

3 Click the **Drug Assignment** tab.

4 Find the drug whose DND date you want to change, and click **Edit** on the right side of the row.

5 In the **DND** column, select the maximum number of days before the expiration date that subjects can receive the drug units.

6 Click **Save**.

Configuring out-of-age approvals

The process of configuring out-of-age approvals

An out-of-age approval request is a request for a subject who does not meet the study age requirements to continue in the study. If these approvals are authorized for the study, a request for approval is automatically sent to the approval system when an out-of-age subject is screened. The age is calculated from the date of birth.

During configuration, you complete each of these tasks:

1 Authorize and configure out-of-age approvals during study design, if requested by the sponsor.

An Oracle representative must perform this task. This task switches on out-of-age approvals for the study.

2 Set the approver permissions for out-of-age visits.

You can set none or one level of approval for out-of-age visits. Set the approval by assigning a role to the out-of-age approval function on the Manage Permissions page.

A subject affected by a request for approval is locked ( ) until the request is reviewed and either approved or rejected.

Related tasks:

- *Setting approver permissions for out-of-age approvals* (on page 39).

Authorize and configure out-of-age approvals

An Oracle representative configures out-of-age approvals in the Config Tool during study design. The following configuration keys must be configured:

Column	Setting
StudyHasAgeApproval	Yes
StudyHasHardStop	No
StudyMaximumAgeLimit	The maximum age (in years and months) for a subject to be eligible for the enrollment in the study.
StudyMinimumAgeLimit	The minimum age (in years and months) for a subject to be eligible for enrollment in the study.

Setting approver permissions for out-of-age approvals

If approval is required out-of-age visits, you must set up the roles for the approvers.

For descriptions of the fields on this page, see Manage Permissions page.

1 Click **Configurations** ( ).

2 From the **Configurations** menu, select **Manage Visit Schedule**.

The properties of the current visit schedule appear.

3 In the list of functions on the left, in the **Other Permissions** category, find the **Subject_AgeApproval** function.

The Permission ID for this function is 214.

4 Locate the approver role in the **Function/Role** heading at the top of the page.

5 Select the checkbox below the approver role in the row for the **Subject Out of Window Approval** function.

6 Click **Submit**.

Setting the number of days between approval reminders

When a request for approval is initially made, the IRT application sends an email alert to all persons assigned the role that approves the type of request. Later reminders are scheduled by setting up the number of days between emails.

If approvers complain of receiving too many (or too few) reminders to review approval or acknowledgment requests, you can change the number of days between reminders.

For descriptions of the fields on this page, see *General Configuration page* (on page 87).

1 Click **Configurations** ().

2 From the **Configurations** menu, select **General Configuration**.

The configuration settings for authorizing subject data edits appear.

3 In the **Approval Alert Frequency** field, edit the number.

To receive fewer alerts, use a larger number.

4 Click **Submit**.

CHAPTER 3

Setting up roles and permissions

In this chapter

Roadmap: Roles and permissions

Step #	Action	Menu to select	What happens?
1	Determine which roles should be associated with the users of your study, and which tasks each user performs.	N/A	The tasks are mapped to specific functions in the IRT application, and permissions to access these functions are associated with the roles. This process is a collaborative effort between Oracle and the sponsor, which is completed during the design phase of the study.
2	Assign users to a role.	**Study** ( ) **User Upload**	When the user list for the study is uploaded into the IRT application, the role for each user must be defined.
2	*Set up the roles in the IRT application* (on page 48).	**Configuration** **Manage Roles**	Each role in the study is mapped to a role in the IRT application. If necessary, you can create new roles to supplement the standard roles.
3	*Assign permissions to the roles* (on page 50).	**Configuration** **Manage Permissions**	These permissions restrict access to the subject information and functions of the IRT application.
4	Test access to make sure the roles and permissions are set up correctly.	N/A	The sponsor tests access to make sure roles and permissions for each role are set up correctly.

Users, roles, and permissions

In the IRT application, job roles and permissions control access to the functions of the application, the tasks you can perform, and the type of subject and drug supply information you can access. As a result, the environment is secure and tailored to the tasks you commonly perform.

Here are some key concepts:

- **User**

  A person who uses the IRT application. A user must be assigned a role to perform tasks with the IRT application.

- **Roles**

  In a study, groups of people have responsibilities in common. These responsibilities define the user's role—for example, study coordinator, field monitor, principal investigator, or drug supply manager. The IRT application provides a standard list of common roles for a study, which can be supplemented with custom roles.

- **Permissions**

  In the IRT application, each role has specific permissions. A permission provides or restricts access to the features of the application. Because a page is designed around particular tasks, assigning a permission to a role determines whether a person who is assigned that role can perform those tasks. The tasks a person can perform in the IRT application should correspond to that role's job responsibilities for the study.

Setting up roles

Adding a new role

You can add new roles to supplement the standard roles in the IRT application. For more information, see *Users, roles, and permissions described* (on page 3).

For descriptions of the fields on this page, see *Manage Roles page* (on page 93).

1 Click **Configurations** ().

2 From the **Configuration** menu, select **Manage Roles**.

A list of the user roles for the IRT application appears.

3 In the **ID** field, type a unique identifier for the subject.

4 In the **Role Description** field, type a brief description for the role.

Select whether the role is **Site-Specific** or **Depot-Specific**.

A site-specific role accesses functions that are performed at study sites (such as logging subject information). A depot-specific role accesses functions that deal with drug supply management.

If the role is not specific to either sites or depots, select **No** from each drop-down list.

5 Type a number for the **Display Order**.

This number controls the order of the role in the horizontal list on the Manage Permissions page.

Check the other roles to see the display order assigned to them. Do not select a number assigned to another role. You might want to leave some space between roles in case you add another role - for example, if the role should display between 1 and 10, assign 5 to the role.

6 In the **Include on Reports** drop-down list, select **Yes** if information about this role should be included on applicable reports.

For more information, see *Reports* (on page 107).

7 Select the new role from the Roles not managed by this Role list, and click **Add**.

The role is now in the **Roles Managed by this Role** list.

Each role must be able to manage itself, so you must always add a new role to the **Roles managed by this Role** list.

8 If this role manages other roles, select those roles from the **Roles not Managed by this Role** list, and click **Add** to add it to the **Roles Managed by this Role** list.

9 Click **Submit**.

10 If other roles should manage this role, edit those roles to add this role to their **Roles managed by this Role** list.

If you do not do this step, the role does not display on the Manage Permissions page.

Recommendations for roles managed

When you set up a role on the Manage Roles page, you can set up the other roles that are managed by a role.

For detailed descriptions of recommended role assignments by IRT function, see the Roles and permissions matrix.

This table lists the features that are affected by the Roles managed function.

Main menu	Menu selection
Configurations	Manage Roles
	Manage Permissions
Study	Role Notifications
	Edit User
	Link to Site/Depot
	User Upload
	Pending Users

This table provides suggestions for the roles managed list and notes for roles that are unique to the IRT application.

Category	Roles managed	Notes
Oracle user		
Oracle Admin User	All roles	Complete access to all aspects of the system. Typically includes Oracle Program Managers, Study Designers, Second Level Support, and Third Level Support.
First Level Support	All roles except Oracle Admin user.	Initial line of support for questions about the IRT application.
Sponsor users		
Unblinded Approver	Self	Reviews the randomization and drug upload list to ensure the information is accurate. Authorizes the use of the randomization and drug schedules that are uploaded into the IRT application.
Field Monitor	Self	

Category	Roles managed	Notes
Medical Monitor	Self	
Study Manager	Everyone except Oracle Admin and First Level Support.	
Statistician	Self	
Unblinded Clinical Supply Manager	Self Depot User DDF User	
Global Safety user	Self	
Site users		
Investigator	Self	
Study Coordinator	Self	
Site Unblind Once	Self	Unblinds a subject during a serious adverse event (SAE). If a subject experiences a SAE and requires medical attention, the Principal Investigator (or other designated person at the site) must unblind the subject to make sure emergency treatment does not conflict with study meds. This action removes the subject from the trial.
Depot user		
DDF User	Self	
Depot User	Self	

Editing an existing role

The initial roles are set up according to study requirements identified by the sponsor. However, you might need to edit the properties of a role if the role changes. You cannot change the ID of the role.

For descriptions of the fields on this page, see *Manage Roles page* (on page 93).

1 Click **Configurations** ().

2 From the **Configuration** menu, select **Manage Roles**.

A list of the user roles for the IRT application appears.

3 For the role you want to change, click **Edit**.

The fields where you set the property for the role appear.

4 Make the necessary changes, and click **Submit**.

Deleting a role

You cannot a delete a role that has been applied to a function (such as approval) or user.

For descriptions of the fields on this page, see *Manage Roles page* (on page 93).

1 Click **Configurations** ().

2 From the **Configuration** menu, select **Manage Roles**.

A list of the user roles for the IRT application appears.

3 To the left of the role you want to delete, click **Delete**.

The role is deleted.

Setting up permissions

Assigning a permission to a role

Permissions control whether a role can access a page in the IRT application. Since access to tasks and subject information is provided through the pages of the application, these permissions also control what you can do in the IRT application.

Unblinded functions are controlled by role, not by permissions. These permissions are provided on the Manage Permissions page so you can see which roles control unblinding functions. Unblinded functions are highlighted in red. A red box (), which cannot be deselected, restricts access to these functions.

1 Click **Configurations** ().

2 From the **Configuration** menu, select **Manage Permissions**.

A table of functions (vertical list on the left) and permissions (horizontal list across the top) appears.

3 Scan the list of functions to find the first function the role should be able to access.

The functions are organized by menu on the left side of the page.

4 Locate the role in the **Function/Role** heading at the top of the page.

5 In the row for the function, do one of the following:

- To allow the role to access this function—Select the checkbox below the role.
- To remove the permission from the role—Deselect the checkbox below the role.

6 Repeat the previous step for each function the role should be permitted to access.

Roles and permission matrix

This tables provides details about each permission on the Manage Permissions page, and suggested roles for each permission.

Role	Internal ID	Mode of access	Allows Access to:	Recommended roles
Home				
Task Alerts	150	W	Home page	Site Users Sponsor Users
Contact Information	501	W	Contact Information page	Site Users Sponsor Users
Notifications	301	W	Notifications page	Site Users Sponsor Users

Role	Internal ID	Mode of access	Allows Access to:	Recommended roles
Subjects				
Subject Transactions	200	P/W	Subject Transactions page	Site Users Sponsor Users
Subject Transfer	213	W	Subject Transfer page	Sponsor Users
Screening				
Screening	201	P/W	Screening tasks on the Subject Transactions page	Site Users
Subject Approval				
Subject Out of Window Approval	210	W	Out-of-window approval tasks on the Subject Transactions page	Sponsor Users
Subject Transactions				
Screen Fail	202	P/W	Screen failure tasks on the Subject Transactions page	Site Users
Randomization	203	P/W	Randomization tasks on the Subject Transactions page	Site Users
Scheduled Visit	204	P/W	Scheduled Visit tasks on the Subject Transactions page	Site Users
Drug Replacement	205	P/W	Drug Replacement tasks on the Subject Transactions page	Site Users
Early Termination	206	P/W	Early Terminations tasks on the Subject Transactions page	Site Users
Completion	211	P/W	Subject Completion tasks on the Subject Transactions page	Site Users
Unblind Treatment	207	P/W	UNBLINDING tasks on the Subject Transactions page	Investigator, Safety or Medical Monitor ONLY

Role	Internal ID	Mode of access	Allows Access to:	Recommended roles
Flag Subject	291	W	Flag a subject as misrandomized or off-treatment on the Subject Transactions page	
Set-Up (Supplies)				
Depots	620	W	Depots page	Sponsor Users
Depot Association	623	W	Depot Association page	UNBLINDED USERS ONLY Sponsor Users (Drug Supply Manager)
Lots & Expiry	606	W	Lots & Expiry page	UNBLINDED USERS ONLY (Unblinded Drug Supplies Manager)
Manufacturing Lot	619	W	Manufacturing Lot page	UNBLINDED USERS ONLY (Unblinded Drug Supplies Manager)
Lot Association	624	W	Lot Association page	UNBLINDED USERS ONLY (Unblinded Drug Supplies Manager)
Label Groups	618	W	Label Groups page	UNBLINDED USERS ONLY (Unblinded Drug Supplies Manager)
Label Group Association	625	W	Label Group Association page	UNBLINDED USERS ONLY (Unblinded Drug Supplies Manager)
Inventory (Supplies)				
Resupply Setting	605	W	Resupply Setting page	UNBLINDED USERS ONLY (Unblinded Drug Supplies Manager)
Smart System	627	W	Smart System page	UNBLINDED USERS ONLY (Unblinded Drug Supplies Manager)
Inventory Management	611	W	Inventory Management page	UNBLINDED USERS ONLY (Unblinded Drug Supplies Manager)
Update Site Inventory	602	P/W	Update Site Inventory page	Site User (cannot undamage drugs)
Update Depot Inventory	604	P/W	Update Depot Inventory page	Depot User (cannot undamage drugs)
Drug Order (Supplies)				

Role	Internal ID	Mode of access	Allows Access to:	Recommended roles
Order Transactions	600	W	Order Transactions	Site User and Sponsor User
Request Manual	609	W	Request Manual page	UNBLINDED USERS ONLY (Unblinded Drug Supplies Manager)
Trial Supply Orders (Supplies, Drug Orders)				
Ship Information	614	W	Shipment details on the Order Transactions page	Depot User or Drug Supply Manager
Register Site Drug Order Receipt	601	P/W	Drug orders receipts on the Order Transactions page	Site User
Register Depot Drug Order Receipt	603	P/W	Drug orders receipts on the Depot page	Depot User
Cancel	610	W	Drug order cancelation tasks on the Order Transactions page	UNBLINDED USERS ONLY (Unblinded Drug Supplies Manager)
Initiate Cancel	638	W	Drug order cancelation tasks on the Order Transactions page	UNBLINDED USERS ONLY (Unblinded Drug Supplies Manager)
Complete Cancel	639	W	Drug order cancelation tasks on the Order Transactions page	UNBLINDED USERS ONLY (Unblinded Drug Supplies Manager)
Drug Accountability				
Reconciliation by Site and Monitor	615	W	Reconciliation by Site and Monitor page	Site User and Field Monitor
Ready for Shipment or Destruction	616	W	Ready for Shipment or Destruction page	Site User and Field Monitor
Reconciliation by Return Depot	617	W	Reconciliation by Return Depot (DDF) page	DDF User
Study Set-Up				
Study Limits	304	W	Study Limits page	Sponsor Users (Study Manager)
Randomization Schedule	302	W	Randomization Schedule page	UNBLINDED USERS ONLY (Statistician)

Role	Internal ID	Mode of access	Allows Access to:	Recommended roles
Drug Schedule	303	W	Drug Schedule page	UNBLINDED USERS ONLY (Statistician)
Role Notifications	504	W	Role Notifications page	Sponsor Users (Study Manager)
Manage Countries	307	W	Manage Countries page	Sponsor Users (Study Manager)
Manage Regions	308	W	Manage Regions page	Sponsor Users (Study Manager)
Users				
Edit User	502	W	Edit User page	Sponsor Users
Link to Site/Depot	503	W	Link to Site/Depot page	Sponsor Users
User Upload	505	W	User Upload page	Sponsor Users
Pending Users	510	W	Pending Users page	Sponsor Users
Edit User				
Edit Role	511	W	Edit role on Edit User page	Sponsor Users
Edit Site/Depot	512	W	Edit site/depot on Edit User page	Sponsor Users
Reset Password	513	W	Reset password on Edit User page	Sponsor Users
Lock/Unlock User	514	W	Lock user on Edit User page	Sponsor Users
Activate/Reactivate User	515	W	Deactivate user on Edit User page	Sponsor Users
Sites				
Manage Sites	401	W	Can view Sites tab Manage Sites page	Sponsor Users
Site Upload	405	W	Site Upload page	Sponsor Users
Manage Sites				
Manage Site Information	402	W	Manage Sites page (site information)	Sponsor Users

Role	Internal ID	Mode of access	Allows Access to:	Recommended roles
Manage Site Activity	403	W	Manage Sites page Activate/deactivate site Manage site limits Open and close the screening and randomization for site	Sponsor Users (Study Manager)
Manage Site Trial Supply Order Settings	404	W	Manage Sites page Supply Type, Drug Ordering status	Sponsor Users (Drug Supply Manager)
Suspend Trial Supply Ordering	406	W	Manage Sites page Drug Order Suspension tab	Sponsor Users (Drug Supply Manager)
Subject (Reports)				
Subject Details	705	W	Subject Details report	Site Users Sponsor Users
Subject Details Sponsor	720	W		
Visit Summary	706	W	Visit Summary report	Site Users Sponsor Users
Randomization Report Unblinded	717	W	Randomization Report UNBLINDED report	UNBLINDED USERS ONLY (Unblinded Drug Supplies Manager)
Edit Subject Data Report	713	W	Edit Subject Data report	Sponsor Users
Drug Reallocation	716	W	Drug Reallocation report	Sponsor Users
Visit Rollback Report	714	W	Visit Rollback report	Sponsor Users
Drug Reallocation Unblinded	722	W	Drug Reallocation UNBLINDED report	UNBLINDED users only
Study (Reports)				
Enrollment Summary	701	W	Enrollment Summary report	Sponsor Users
Overall Summaries	702	W	Overall Summaries report	Sponsor Users

Role	Internal ID	Mode of access	Allows Access to:	Recommended roles
Site Overall & Monthly	704	W	Site Overall & Monthly report	Site Users Sponsor Users
Site Statistics	703	W	Site Statistics	Site Users Sponsor Users
Audit Site Reports	729	W	Audit Site report	Sponsor Users
Supplies (Reports)				
Order Summary	707	W	Order Summary report	Site Users and Sponsor Users (such as Drug Supply Manager)
Site Inventory	708	W	Site Inventory report	Site Users and Sponsor Users (such as Drug Supply Manager)
Site Inventory Unblinded	718	W	Site Inventory UNBLINDED report	UNBLINDED users only (Unblinded Drug Supplies Manager)
Depot Inventory	709	W	Depot Inventory report	Depot User and Drug Supplies Manager
Depot Inventory Unblinded	719	W	Depot Inventory UNBLINDED report	UNBLINDED USERS ONLY (Unblinded Drug Supplies Manager)
Depot Inventory by Unit Unblinded	721	W	Depot Inventory by Unit UNBLINDED report	UNBLINDED USERS ONLY (Unblinded Drug Supplies Manager)
Site Inventory by Unit Unblinded	728	W	Site Inventory by Unit UNBLINDED report	UNBLINDED USERS ONLY (Unblinded Drug Supplies Manager)
Drug Accountability Overview	710	W	Drug Accountability Overview report	Sponsor Users
Detailed Drug Reconciliation	715	W	Detailed Drug Reconciliation report	Sponsor Users
Projected Supply Usage	723	W	Projected Supply Usage report	UNBLINDED USERS ONLY (Unblinded Drug Supplies Manager)
Users				
User Contact Information	711	W	User Contact Information report	Site Users Sponsor Users
System Access	712	W	System Access report	Sponsor Users

Role	Internal ID	Mode of access	Allows Access to:	Recommended roles
Ad Hoc				
Create Custom Report	798	W	Create Custom Report reports	Depends on report
View/Manage Custom Reports	799	W	View/Manage Custom reports	Depends on report
Approvals				
Subject Approvals	309	W	Subject Approvals report	Oracle Administrator Sponsor users
Configurations				
General Configuration	801	W	General Configuration page	Oracle Administrator Sponsor users
Transaction Configuration	802	W	Transaction Configuration page	Oracle Administrator Sponsor users
Manage Permissions	803	W	Manage Permissions page	Oracle Administrator Sponsor users
Manage Roles	804	W	Manage Roles page	Oracle Administrator Sponsor users
Manage Visit Schedule	805	W	Manage Visit Schedule page	Oracle Administrator Sponsor users
Admin				
View AppBlock Logs	901	W	View AppBlock Logs page	Oracle Administrator
View Diagnostic Logs	914	W	View Diagnostic Logs page	Oracle Administrator
Notification Subscriptions	909	W	Notification Subscriptions page	Oracle Administrator
Manage Inform Setup	918	W	Manage Inform Setup page	Oracle Administrator
Verify Configuration	911	W	Verify Configuration page	Oracle Administrator
Run Scheduled Task	912	W	Run Scheduled Task page	Oracle Administrator
AppBlock Validation	950	W	AppBlock Validation page	Oracle Administrator

Role	Internal ID	Mode of access	Allows Access to:	Recommended roles
Audit History View	915	W	Audit History View page	Oracle Administrator
Manage Custom Page Menus	913	W	Manage Custom Page Menus page	Oracle Administrator
Instructions				
Toll-free Access Numbers	N/A	W	Toll-free phone numbers list	Site Users Sponsor Users
Study Team User Manual (One per role)	N/A	W	Study manual for the assigned role	Site Users Sponsor Users
Other Permissions				
Subject_EditSubjectData	208	W	Edit Subject Data on Transactions Configurations page	Sponsor Users
Subject Age Approval	214	W	Out-of-age approval tasks on the Subject Approvals page	Sponsor Users
Subject Out of Window Approval	210	W	Out-of-window approval tasks on the Subject Approvals page	Sponsor Users
Subject_ViewFlag	290	W	Flag a subject as misrandomized or off-treatment on the Subject Transactions page	Sponsor Users
Drug_ManageDrugSupplyTypes_ ResupplySetting	651	W	Resupply Settings page	
Drug_ManageDrugSupplyTypes_Edit	652	W	Edit the supply type on the Resupply Settings page	
Reports_Home	700	W	Reports tab	Site Users Sponsor Users
Reports_SubjectSummarySponsor	720	W		
Ad Hoc Base Report - Dispensed Units	724	W	Dispensed Units on the Ad Hoc Report page	

Role	Internal ID	Mode of access	Allows Access to:	Recommended roles
Ad Hoc Base Report - Subject Details	725	W	UNBLINDED subject details on the Ad Hoc Report page	
Ad Hoc Base Report - Site Details	726	W	Site Details on the Ad Hoc Report page	
Ad Hoc Base Report - Depot Details	727	W	Depot Details on the Ad Hoc Report page	
Dashboard - Subject Task List	1300	W	Subject Task List on Home page	Site Users Sponsor Users
Dashboard - Drug Order Task List	1301	W	Drug Order Task List on Home page	Site Users Sponsor Users
Dashboard - Depot Task List	1302	W	Depot Task List on Home page	UNBLINDED users only
Dashboard - Enrollment Summary	1303	W	Enrollment Summary graph on Home page	Site Users Sponsor Users
Dashboard - Depot Inventory	1304	W	Depot Inventory graph on Home page	UNBLINDED users only
Site User Manual	N/A	W	Study manual for the assigned role	Site Users Sponsor Users

CHAPTER 4

Managing email notifications

In this chapter

Subscribing a notification type by role

When a role is subscribed to a notification type, users assigned to that role receive these notifications.

For descriptions of the fields on this page, see *Notifications Subscriptions page* (on page 101).

1 Click **Admin** ().

2 From the **Admin** menu, select **Notification Subscriptions**.

The Subscriptions Notification page appears.

3 From the **Select Notification** drop-down list, select the notification type.

4 To add roles, in the **Roles NOT subscribed** list, select the roles, and click **Add>>**.

The roles appear in the Roles Subscribed list.

5 To remove roles from the list, in the **Roles NOT subscribed** list, select the roles, and click **<<Remove**.

The roles are removed from the Roles Subscribed list.

6 Click **Submit**.

Setting up a distribution list for subscriptions

A distribution list allows you to send a notification type to multiple email addresses when:

- People do not have access to the IRT application.
- You want to send a message to specific users rather than everyone in a particular role.

Caution: This method does not allow identify if a recipient is blinded or unblinded. Do not subscribe a blinded user to an unblinded notification.

For descriptions of the fields on this page, see *Notification Subscriptions page* (on page 101).

1 Click **Admin** ().

2 From the **Admin** menu, select **Notification Subscriptions**.

The Subscriptions Notification page appears.

3 From the **Select Notification** drop-down list, select the notification type.

4 To add a user to the distribution list, in the **Add Email address** field, type the email address of the user to add to the distribution list, and click **Add Email**.

The email address appears in the distribution list.

5 To remove an email from the distribution list, in the distribution list, click an email address, and click **Remove Email(s)**.

The email address is removed from the distribution list.

6 Click **Submit**.

Subscribing a notification type by user

Creating a user list allows you to send a notification type to multiple IRT users who might not be assigned a role that usually receives those notification types.

Caution: This method does not allow identify if a recipient is blinded or unblinded. Do not subscribe a blinded user to an unblinded notification.

For descriptions of the fields on this page, see *Notification Subscriptions page* (on page 101).

1 Click **Admin** ().

2 From the **Admin** menu, select **Notification Subscriptions**.

The Subscriptions Notification page appears.

3 From the **Select Notification** drop-down list, select the notification type.

4 To add a user, from the **Users NOT subscribed** list, select a user, and click **Add>>**.

The user appears in the Users subscribed list.

5 To remove a user from the list, from the **Users NOT subscribed** list, select a user, and click **<<Remove**.

The user is removed from the Users subscribed list.

6 Click **Submit**.

Resending a notification

You might need to resend a notification or notification type to a user (for example, if the user's email address changed, or the user was assigned to a different role).

1 Click **Home** ().

2 From the **Home** menu, select **Notifications**.

A Retransmission Type field appears.

3 From the **Retransmission Type** drop-down list, select how to resend the notification.

4 Provide the necessary information, and click **Retransmit**.

Field descriptions for this page

If you selected	Field	Description	Notes
By Notification Number			
	Notification Number	The ID number of the notification type.	
By Subject			
	Subject	The subject number.	
	Notification	The notification type. For example, Screening Confirmation or Age Approval Request Alert.	
	Notification message	The notification message.	READ-ONLY
	Retransmit To	The user name and ID number to whom the notification type is retransmitted.	
By Notification Type			
	Notification Type	The notification type. For example, Screening Confirmation or Age Approval Request Alert.	
	Notification	The notification.	
	Notification message	The notification message.	READ-ONLY

CHAPTER 5

Managing customizations and integrations

In this chapter

Managing the InForm setup

InForm integration with the IRT application

IRT studies can be configured to share information with the InForm application. These integrations provide a one-way flow of data from the IRT application to the InForm application and eliminate duplicate data entry. For example, if a potential subject is screened in the IRT application, a subject file is created and sent to the InForm application. The subject information does not have to be re-entered in the InForm application.

Setting up the InForm application to receive data

You must identify whether the InForm application is ready to receive data from the IRT application. Ensure that the InForm application is fully configured, online, and ready to receive data from the IRT application before you set **Inform Is Up** to Yes.

For descriptions of the fields on this page, see *Manage Inform Setup page* (on page 102).

1 Click **Admin** ().

2 From the **Admin** menu, select **Manage Inform Setup**.

The Manage InForm Setup page appears.

3 Do one of the following:

- If the InForm application is ready to receive data from the IRT application, from the **Inform Is Up** drop-down list, select **Yes**, and click **Submit**.

  IRT files will be sent to the InForm application.

- If the InForm application is not ready to receive data from the IRT application, from the **Inform Is Up** drop-down list, select **No**, and click **Submit**.

  Files will not be sent to the InForm application.

Note: If the InForm application is not available for an extended period of time, you must reset the **Inform Is Up** option to No. When the InForm application is available again, set the option back to Yes. The files that are created while InForm is not available are sent to the InForm application at scheduled intervals (typically, 15-minute increments).

Managing custom menu items

Adding a new menu section to the Home menu

Menu sections are headings you can create to group related menu items. For example, you can create a menu section called Important Links and then add links to useful websites under the section.

For descriptions of the fields on this page, see *Manage Custom Menu Items page* (on page 104).

1 Click **Admin** ( ).

2 From the **Admin** menu, select **Manage Custom Menu Items**.

The Manage Custom Menu Items page appears.

3 Click **++Add New Section++**.

The Add New Section form appears.

4 In the **Menu Type** section, click **Section Title**.

5 In the **Title** field, type the name of the new section.

6 Click **Submit**.

The new menu section appears in the Home menu.

Adding a new menu item to the Home menu

Menu items are links to URLs or files that you can add to a menu section in the Home menu.

You must first add a menu section before you add a menu item to the section.

If your study requires role-based user guides or translations of user guides, you can add those documents as menu items.

1 Click **Admin** ( ).

2 From the **Admin** menu, select **Manage Custom Menu Items**.

The Manage Custom Menu Items page appears.

3 Click **++Add New Item++**.

The Add New Item form appears.

4 Provide the necessary information, and click **Submit**.

The new menu item appears under the selected menu section in the Home menu.

Fields descriptions for the Add New Item form

Field	Description	Notes
Menu Type	The type of menu item: • Section Title • Upload File • Use Existing URL You can select either **Upload File** or **Use Existing URL**.	Default: Upload File.
Title	The title of the menu item.	
File	Uploads a file to add as a menu item. This field appears if you selected **Upload File** from the **Menu Type** section.	
URL	The URL to add as the menu item. This field appears if you selected **Use existing URL** from the **Menu Type** section.	
Common URLs	Opens a **Select common URL** drop-down list. This field appears if you selected **Use existing URL** from the **Menu Type** section.	
Display for roles	A list of user roles. Select the roles whose users can view the new menu item.	Default: All roles are deselected.
Submit	Creates your new section, which appears in the Home menu.	
Delete	Removes the menu option from the Home menu. This button is enabled after you create a section.	Default: Disabled.
Move Up	Moves the menu option up one position in the Home menu. This button is enabled after you create a section.	Default: Disabled.
Move Down	Moves the menu option down one position in the Home menu. This button is enabled after you create a section.	Default: Disabled.

Field	Description	Notes
Close	Terminates the process and returns you to the Manage Custom Menu Items page.	

Editing menu section details

You can edit the details of menu sections and change their position in the Home menu.

1 Click **Admin** ( ).

2 From the **Admin** menu, select **Manage Custom Menu Items**.

The Manage Custom Menu Items page appears.

3 Select the menu section to edit.

The Menu Section form appears

4 Edit the fields as necessary, and click **Submit**.

Field descriptions for the Menu Section form

Field	Description	Notes
Menu Type	The type of menu: • Section Title • Upload File • Use Existing URL You cannot select **Upload File** and **Use Existing URL** until you create the section and provide a title.	Default: Section Title.
Title	The title of the section that appears in the Home menu.	
Submit	Creates your new section, which appears in the Home menu.	
Delete	Removes the menu option from the Home menu. This button is enabled after you create a section.	Default: Disabled.
Move Up	Moves the menu option up one position in the Home menu. This button is enabled after you create a section.	Default: Disabled.

Field	Description	Notes
Move Down	Moves the menu option down one position in the Home menu. This button is enabled after you create a section.	Default: Disabled.
Close	Terminates the Add New Section process and returns you to the Manage Custom Menu Items page.	

Editing menu item details

You can edit the details of menu items and change their position in the Home menu.

1 Click **Admin** ().

2 From the **Admin** menu, select **Manage Custom Menu Items**.

The Manage Custom Menu Items page appears.

3 Select the menu item to edit.

The Menu Item form appears.

4 Edit the fields as necessary, and click **Submit**.

Field descriptions for the Menu Item form

Field	Description	Notes
Menu Type	The type of menu item: • Section Title • Upload File • Use Existing URL You can select either **Upload File** or **Use Existing URL**.	Default: Upload File.
Title	The title of the menu item.	
File	Uploads a file to add as a menu item. This field appears if you selected **Upload File** from the **Menu Type** section.	
URL	The URL to add as the menu item. This field appears if you selected **Use existing URL** from the **Menu Type** section.	

Field	Description	Notes
Common URLs	Opens a **Select common URL** drop-down list. This field appears if you selected **Use existing URL** from the **Menu Type** section.	
Display for roles	A list of user roles. Select the roles whose users can view the new menu item.	Default: All roles are deselected.
Submit	Creates your new section, which appears in the Home menu.	
Delete	Removes the menu option from the Home menu. This button is enabled after you create a section.	Default: Disabled.
Move Up	Moves the menu option up one position in the Home menu. This button is enabled after you create a section.	Default: Disabled.
Move Down	Moves the menu option down one position in the Home menu. This button is enabled after you create a section.	Default: Disabled.
Close	Terminates the process and returns you to the Manage Custom Menu Items page.	

CHAPTER 6

Testing and support

In this chapter

Monitoring logs and system records

AppBlock logs

An AppBlock log is a detailed record of an AppBlock transaction that occurs on either phone or web platforms. For example, when a user randomizes a subject, the AppBlock log of that randomization provides the steps in the randomization.

Viewing an AppBlock log

The View AppBlock Logs page displays a list of all AppBlock logs. Reviewing an AppBlock log can help you diagnose problems with transactions that occur on both the phone and the Web.

For descriptions of the fields on this page, see *View AppBlock Logs page* (on page 98).

Because each study usually contains many AppBlock logs, filter the entries to help find the log you are looking for. Before applying a filter, it is important to know the type of transaction, the name of the user who performed the transaction, and the date of the transaction.

1 Click **Admin** ().

2 From the **Admin** menu, select **View AppBlock Logs**.

A list of AppBlock logs appears.

3 Click a page number or the arrow icons to navigate through the pages.

4 Find the AppBlock log you want to open, and click **View**.

The AppBlock log opens in a new window. This window displays all information about the transaction.

Exporting an AppBlock log

You can export an AppBlock log and save it as a TXT file. You might want to export an AppBlock log so that you not only have evidence of the transaction, but so that you can also attach the file to a support ticket.

For descriptions of the fields on this page, see *View AppBLock Logs page* (on page 98).

1 Click **Admin** ().

2 From the **Admin** menu, select **View AppBlock Logs**.

A list of AppBlock logs appears.

3 Find the AppBlock log to export, and do one of the following:

- Click **Download**.

or

a Click **View**.

The AppBlock log opens in a new window. This window displays all information about the

transaction.

b Click **Download**.

Diagnostic log

The diagnostic log is a record of diagnostic information, error messages, and running background services and applications that support the IRT application. This log provides details on scheduled and automated transactions such as data transfers and dug ordering. Each time one of these transactions occurs, a record of the transaction is added to the diagnostic log.

Viewing the Diagnostic Log

Viewing the diagnostic log can help you diagnose problems that might result from errors in background service processes, such as data transfers or automatic drug ordering.

For descriptions of the fields on this page, see *View Diagnostic Logs page* (on page 99).

1 Click **Admin** ().

2 From the **Admin** menu, select **View Diagnostic Logs**.

The diagnostic log appears.

3 Click a page number or the arrow icons to navigate through the pages.

You might find it useful to *filter the log* (on page 15) to find specific entries.

Audit History

The audit history provides a view into the database for an IRT study. Each time data is changed in the IRT application, the change is recorded in the database, and can therefore be viewed in the audit history.

Viewing the audit history

To view a record of all IRT transactions, view the audit history.

For descriptions of the fields on this page, see *Audit History View page* (on page 103).

1 Click **Admin** ().

2 From the **Admin** menu, select **Audit History View**.

The audit history appears.

3 Click a page number or the arrow icons to navigate through the pages.

You might find it useful to *filter the log* (on page 15) to find specific entries.

Exporting the audit history

You can export the audit history to save it as a file on your computer.

Audit history reports can get quite large. You might find it useful to *filter the log* (on page 15) to find specific entries.

For descriptions of the fields on this page, see *Audit History View page* (on page 103).

1 Click **Admin** ( ).

2 From the **Admin** menu, select **Audit History View**.

The audit history appears.

3 Click **Export/Save**.

4 Select the file type.

5 Click **Submit**.

Verifying system configuration

Verifying the system configuration

Before a study goes into production, you can verify that the system is properly configured.

For descriptions of the fields on this page, see *Verify Configuration page* (on page 103).

1 Click **Admin** ().

2 From the **Admin** menu, select **Verify Configuration**.

A message appears to verify the system configuration and, if necessary, *update your contact information* (on page 79).

3 Click **Submit**.

One of the following results occurs:

- If a problem with the configuration is detected, an alert appears on the page:
  - Warnings appear in orange.
  - Errors appear in red.
- If no problems with the system configuration are detected:
  - A verification message appears on the page.
  - You receive a Verify System Configuration email message.

Updating your contact information

To ensure you receive notifications about system configuration, your contact information must be correct. If necessary, you can update it from the *Verify Configuration page* (on page 103)

1 Click **Admin** ().

2 From the **Admin** menu, select **Verify Configuration**.

A message appears to verify the system configuration and, if necessary, *update your contact information* (on page 79).

3 Click **Contact Information**.

The Contact Information page appears.

4 Edit the fields as necessary, and click **Submit**.

Field descriptions for the Contact Information page

This table describes the default fields for this page. Your study might require different fields, and those fields could have different names.

Field	Description	Notes
First Name	Your first name.	
Middle Initial	Your middle initial.	

Field	Description	Notes
Last Name	Your last name.	
Title	Your title.	
Company	The company that you work for.	
Email	Your email address.	REQUIRED. For: • Resetting your password. • Receiving approval notifications. • Receiving other email notifications. Must be a valid email address.
Phone Number	Your phone number.	Must be a valid phone number: • Numeric. • If international, the initial characters must be 01 or 11.
Fax Number	Your fax number.	Must be a valid fax number: • Numeric. • If international, the initial characters must be 01 or 11.
Address	Your address: Street number.	
City	Your address: City.	
State	Your address: State.	
Zip	Your address: Zip code.	
Country	Your address: Country.	
Language	Your preferred language.	
Time Zone	The time zone where you are located.	
Phone Date Format	The format for entering the date.	

Running scheduled tasks

Scheduled Tasks

Scheduled tasks can be configured to run automatically at designated dates and times. Scheduled tasks include:

- Run Manual Drug Ordering.
- Run Resupply Drug Ordering.
- Audit History PDF generation.
- Any type of data transfer.

Before a study goes into production, a programmer sets up scheduled tasks in the database.

Running a scheduled task

During the initial IRT application setup, scheduled tasks are configured to run automatically. However, you might need to run one of those tasks on demand. For example, if Run Manual Drug Ordering is scheduled to run each hour, but a depot is going to close in 15 minutes and needs to receive the shipment, you can immediately run that normally scheduled task.

For descriptions of the fields on this page, see *Run Scheduled Task page* (on page 103).

1 Click **Admin** ().

2 From the **Admin** menu, select **Run Scheduled Task**.

The Run Scheduled Task page appears.

3 From the **Select Task** drop-down list, select a task, and click **Submit**.

CHAPTER 7

Page descriptions

In this chapter

Home: Page descriptions

Home tab

Home  controls functions for alerts and notifications, contact information, and custom menu options.

See Also: *Getting Started* (on page 1)

Menu page	Tasks performed / notes
Task Alerts	Displays the Home dashboard with any Task Lists (alerts) and summary graphs you have permissions to view.
Contact Information	Displays your contact information, such as your name and email address.
Notifications	Resend a notification by number, subject, or type.
Instructions	
Toll-free access numbers	Displays a document that lists, by country, the toll-free numbers for the IRT application phone interface.
Custom menu options	Displays any custom menu options for the study (example: study user guide).
Help	Displays the online help for the active page.

Contact Information page

On this page, you set up your contact information. This form should already be filled in with the contact information provided to the sponsor during the design phase of the study. Check the information on this page to make sure it is accurate.

Tasks performed from this page

- *Viewing and editing your contact information* (on page 21).

Fields on this page

This table describes the default fields for this page. Your study might require different fields, and those fields could have different names.

Field	Description	Notes
First Name	Your first name.	
Middle Initial	Your middle initial.	
Last Name	Your last name.	
Title	Your title.	

Field	Description	Notes
Company	The company that you work for.	
Email	Your email address.	REQUIRED. For: • Resetting your password. • Receiving approval notifications. • Receiving other email notifications. Must be a valid email address.
Phone Number	Your phone number.	Must be a valid phone number: • Numeric. • If international, the initial characters must be 01 or 11.
Fax Number	Your fax number.	Must be a valid fax number: • Numeric. • If international, the initial characters must be 01 or 11.
Address	Your address: Street number.	
City	Your address: City.	
State	Your address: State.	
Zip	Your address: Zip code.	
Country	Your address: Country.	
Language	Your preferred language.	
Time Zone	The time zone where you are located.	
Phone Date Format	The format for entering the date.	

Notifications page

From this page, you can resend a notification by type of transmission:

- Notification number
- Subject
- Notification type

Tasks performed from this page

- *Resending a notification* (on page 65)

Field descriptions for this page

If you selected	Field	Description	Notes
By Notification Number			
	Notification Number	The ID number of the notification type.	
By Subject			
	Subject	The subject number.	
	Notification	The notification type. For example, Screening Confirmation or Age Approval Request Alert.	
	Notification message	The notification message.	READ-ONLY
	Retransmit To	The user name and ID number to whom the notification type is retransmitted.	
By Notification Type			
	Notification Type	The notification type. For example, Screening Confirmation or Age Approval Request Alert.	
	Notification	The notification.	
	Notification message	The notification message.	READ-ONLY

Configurations menu: Page descriptions

Configurations menu

Configuration controls functions for setting up corrections to subject information, including approvals, managing roles and permissions, and setting up the visit schedule.

See Also: *Roadmap: Configuring corrections to subject information* (on page 24).

Types of corrections you can configure (on page 26).

This table describes the default fields for this page. Your study might require different fields, and those fields could have different names.

Menu page	Tasks performed
General Configuration	Authorize subject data edits and drug reallocation. Set up roles that can acknowledge a drug reallocation. Set the number of days between reminders.
Transaction Configuration	Authorize rollbacks and rollback approvers for each type of subject transaction. Set up the individual fields that can be edited during a subject transaction. Set up approvers and dependencies for subject data edits.
Manage Roles	Set up the user roles who perform tasks in the IRT application
Manage Permissions	Assign specific permissions to the user roles in the IRT application
Manage Visit Schedule	Adjust the visit window that was set up during study design

General Configuration page

On this page, you set up:

- Authorization for subject data edits - that is, correcting information entered during a subject transaction.
- Authorization for reallocating drugs.
- The roles that can acknowledge a drug reallocation.
- The number of days (after the initial email) when reminders are sent for a subject edit or drug reallocation.

Important: The role(s) you select to acknowledge a drug reallocation must be unblinded.

Tasks performed from this page

Task	Supporting information
Authorizing subject data edits (on page 29)	*Roadmap: Approvals* (see **Help**) *The process of correction subject information* (see **Help**)
Authorizing drug reallocation (on page 34)	*Drug reallocation* (see **Help**) *Reallocating drugs* (see **Help**)
Changing the number of days between approval reminders (on page 41)	

Fields on this page

Field	Description	Notes
Data Edits		
Allow Data Edits (selections on the left))	The information from a subject transaction can (**Yes**) or cannot (**No**) be edited for this study.	
Allow Data Edits (column heading on the right)	The types of subject transactions that can be edited. Select each transaction that you want users to be able to edit, and deselect those that should not be editable. Select the transaction type to open the *Transaction Configurations page* (on page 90), where you can set up the permissions for each transaction.	
Data Reallocation		

Field	Description	Notes
Allow Data Reallocation	Identifies whether drugs can be reallocated in this study. • **Yes–**Drugs can be reallocated when editing subject transactions. • **No–**Drugs cannot be reallocated when editing subject transactions. All other options for drug reallocation are disabled.	
Acknowledge	The level of acknowledgment required for drug reallocation: • **All Reallocation Transactions**–All transactions require acknowledgment. • **No Reallocation Transactions**–Drug reallocations can be edited without acknowledgment. • **Incorrect Trial Supply Transaction (Used for Open Label trials only)**–The drug type of the drug units identified by the IRT application is different from the drug type of the drug units provided to the subject.	
Acknowledger(s)	A list of the unblinded roles that can acknowledge a drug reallocation. All active roles from the *Manage Permissions page* (on page 95) are listed. **Important:** The role(s) you select to acknowledge a drug reallocation must be unblinded.	Default role: UNBLINDED Clinical Supplies Manager (or equivalent role for the study)
Alerts Frequency		

Field	Description	Notes
Approvals Alerts Frequency	When an approval or acknowledgment is requested, the IRT application sends the first alert immediately. This option sets the number of days between later reminders. This setting is not for specific alerts. All alerts are sent at this frequency.	Must be an integer. Range: 0 -99.

Transaction Configuration page

On this page, you can set up:

- Authorization for rollbacks for each type of subject transaction.
- The roles that can approve a rollback.
- The individual fields that can be edited during a subject transaction.
- The roles that can approve subject data edits.

You can also view functions that are dependent on each editable field.

Tasks performed from this page

Task	Supporting information
Authorizing roll-backs (on page 32)	*Visit rollbacks* (see **Help** ) *Authorizing subject data edits* (on page 29)
Identifying editable fields and permissions (on page 29)	The process of correcting subject information *Authorizing subject data edits* (on page 29)

Fields on this page

This table describes the default fields for this page. Your study might require different fields, and those fields could have different names.

Field	Description	Notes
Transaction		
Transaction	The type of transaction. When you select the transaction, the configuration settings for that type of transaction appear.	
Roll-back settings		

Field	Description	Notes
Allow Roll-back	When selected, rollbacks can be performed for this study.	You cannot roll back a screening visit.
Re-use Randomization number	When this field is selected, the randomization number assigned during the visit can be reassigned. As a result, gaps in randomization numbers are reduced. This field appears only if the study is configured for forced randomization.	
Roll-back drug status	Indicates the status of the drug was not affected during the visit. This option is available for these transactions: randomization, scheduled visit, drug replacement, and dose change.	
Roll-Back First Approver(s)	A list of the roles that can approve a rollback. All active roles from the ***Manage Permissions page*** (on page 95) are listed. The first-level role approves the request first. After this role acts on the request, the second-level approver is notified. For more information, see Levels of approval. You can select multiple roles for each transaction.	
Roll-Back Second Approver(s)	A list of the roles that can approve a rollback. All active roles from the ***Manage Permissions page*** (on page 95) are listed. This approver has the final say on requests approved by the first-level approver. For more information, see Levels of approval. You can select multiple roles for each transaction.	

Field	Description	Notes
Data Edit Settings		
Field Description	A list of all fields that editable for this transaction.	READ-ONLY
Allow Edit	When this checkbox is selected, this field is editable in this study.	
Approval Required	The level of approval required.	Default: Level 1
Dependencies	The number of functions that are dependent on this field. The number is linked to a window that shows a list of transactions. You can select a transaction as a dependency if the data affects a result in that transaction. Example: The field is a weight field that determines dose or strata, which affects the randomization visit. You select Randomization as a dependency. Example: Gender could affect randomization if males are given one dose and females another.	Default: 0
Data Edit First Approver(s)	A list of the roles that can approve an edit to subject information. All active roles from the ***Manage Permissions page*** (on page 95) are listed. The first-level role approves the request first. After this role acts on the request, the second-level approver is notified. For more information, see Levels of approval. You can select multiple roles for each transaction.	

Field	Description	Notes
Data Edit Second Approver(s)	A list of the roles that can approve an edit to subject information. All active roles from the ***Manage Permissions page*** (on page 95) are listed. This approver has the final say on requests approved by the first-level approver. For more information, see Levels of approval. You can select multiple roles for each transaction.	
Submit	Saves the transaction and sends the message to the appropriate function in the IRT application.	

Manage Roles page

On this page, you set up the user roles who perform tasks in the IRT application. These roles are mapped to specific pages in the IRT application to control access to functions and subject information.

The roles in the IRT application include unblinded roles, sponsor roles, site roles, and Oracle roles.

Tasks performed from this page

Task	Supporting information
Editing an existing role (on page 48)	***Roadmap: roles and permissions*** (on page 44) ***The roles and permissions process*** (on page 3)
Adding a new role (on page 46)	***Recommendations for roles managed*** (on page 47) ***Roles and permissions matrix*** (on page 50).
Deleting a role (on page 49)	

Fields on this page

This table describes the default fields for this page. Your study might require different fields, and those fields could have different names.

Field	Description	Notes
Add New Role	The details of a new role.	
Edit	Update the properties of an existing role.	
Delete	Remove an existing role, if that role is not associated with a user or function.	
ID	The unique identifier for the role.	REQUIRED. Must be unique. Field length: 50
Role Description	A brief description of the role. This description is displayed on the Manage Roles and Manage Permissions page to identify each role.	REQUIRED. Must be unique. Field length: 50
Site-specific	If **Yes** is selected, the role is a site role.	
Depot-Specific	If **Yes** is selected, the role is a depot role.	
Unblinded	The role is unblinded. The default unblinded role is Unblinded Clinical Supply.	
Include on Reports	The role is included on applicable reports.	
Display Order	The order the role is displayed on the Manage Permissions page.	
Roles Managed	Other roles managed by this role. A role can manage itself and other roles.	

Manage Permissions page

On this page, you can assign specific permissions to the user roles in the IRT application. These permissions are assigned to specific pages in the IRT application to control access to functions and subject information.

Tasks performed from this page

Task	Supporting information
Assigning a permission to a role (on page 50)	
Setting approver permissions for out-of-window visits (on page 37)	*The process of configuring visit windows* (on page 36) *Manage Visit Window page* (on page 95)
Setting approver permissions for out-of-age requests (on page 39)	*The process of configuring out-of-age approvals* (on page 39)

Fields on this page

For details on this page, see the *Roles and permissions matrix* (on page 50).

Manage Visit Schedule page

On this page, you can adjust the visit window that was set up during study design. You might make this change if you see a repeated pattern of out-of-window requests, an indicator that the visit window might be too small.

When you update the visit window for a visit, the IRT application automatically adjusts the visit schedule for any subject who has not yet completed that visit.

You can adjust the visit window, authorize out-of-window approvals, and set the Do Not Dispense (DND) date for each visit.

Tasks performed from this page

Task	Supporting information
Authorizing and setting approvals for out-of-window visits (on page 37)	*Visit schedule configuration elements described* (on page 36) *The process of configuring visit windows* (on page 36)
Setting approver permissions for out-of-window visits (on page 37)	*Manage Permissions page* (on page 95)
Setting the Do Not Dispense (DND) date (on page 38)	

Fields on this page

This table describes the default fields for this page. Your study might require different fields, and

those fields could have different names.

Field	Description	Notes
Visit Schedule tab		
Visit ID	The unique identifier for the visit.	READ-ONLY
Visit Name	The name of the visit.	READ-ONLY
Projected From	The baseline visit for the study - typically, the randomization visit - which is set up during study design. In most cases, the dates of all visits are calculated (projected) from the date of this visit. Visits can also be projected from the previous visit, but it is most common to project from a specific visit such as the randomization visit.	READ-ONLY
Visit Window - days (Inclusive)	The number of days before the scheduled visit date that the subject can complete the visit and still be in the visit window.	
Expected Days from Projected	The number of days after the Projected From visit that this visit occurs. For example, if the visit is scheduled 28 days after randomization, the **Expected Dates from Projected** is set to 28. This number is used to calculate the randomization notification schedule, the visit schedule on the Subject Transactions page, and other pages of this sort.	READ-ONLY
Visit Window + Days (Inclusive)	The number of days after the scheduled visit date that the subject can complete the visit and still be in the visit window.	

Field	Description	Notes
Out of Window Approval?	Identifies whether out-of-window approval is required for this study. • **Yes**–approval is required • **No**–approval is not required.	
Out of Window Hard Stop?	• **Yes**–the study requires out-of-window approvals. If this field is set to **Yes**, **Out of Window Approval** should also be set to **Yes**. • **No**–Confirm an out-of-window visit with no approval requirement. • If this field is set to **No**, **Out of Window Approval** should also be set to **No.**	
Save	Saves all changes on the page.	
Cancel	Discards changes made to the page.	
Drug Assignment tab		
Treatment/Dosing Level	The treatment assigned to the subject during randomization.	READ-ONLY
Treatment/Dosing Description	A brief description of the treatment.	READ-ONLY
Drug Unit	The type of drug dispensed.	READ-ONLY
Drug Unit Description	A brief description of the drug unit.	READ-ONLY
Quantity	The number of drug units dispensed.	READ-ONLY
DND	The number of days before expiration when you cannot dispense the drug (for example, to make sure the drug does not expire before the next visit).	Maximum: 9999
Action	Edit, save, or cancel changes to the fields on this tab.	

Admin menu: Page descriptions

Admin tab

Admin  controls functions for testing and support the IRT application, managing Inform integrations, and setting up custom menu items.

Pages	Tasks performed
View AppBlock Logs (on page 98)	View a list of AppBlock logs to diagnose problems with AppBlock transactions.
View Diagnostic Logs (on page 99)	View the log of the background services and applications that support the IRT application.
Notification Subscriptions (on page 101)	Subscribe notification types to both IRT users and non-users.
Manage InForm Setup (on page 102)	Select whether or not the InForm application is ready to receive data from the IRT application.
Verify Configuration (on page 103)	Verify that your system is properly configured and in working order.
Run Scheduled Task (on page 103)	Manually run a task that is typically configured to be run on a schedule.
Audit History View (on page 103)	View the record of changes to the IRT database.
Manage Custom Menu Items (on page 104)	Create menu sections and items that appear in the Home menu.

View AppBlock Logs page

On this page, you view a list of AppBlock logs. Each AppBlock log provides details of an AppBlock transaction, a transaction that can occur on both phone and web platforms. Reviewing AppBlock logs can help you diagnose problems with AppBlock transactions.

Tasks performed from this page

- *Viewing an AppBlock log* (on page 76).
- *Exporting an AppBlock log* (on page 76).

Fields on this page

This table describes the default fields for this page. Your study might require different fields, and those fields could have different names.

Column	Description	Notes
Log #	The number assigned to the individual AppBlock log.	READ-ONLY
User	The ID number and name of the user who performed the transaction.	READ-ONLY
Platform	The platform on which the transaction was performed: Phone or Web.	READ-ONLY
Module	The type of AppBlock function. For example, Screening, Randomization, Scheduled Visit.	READ-ONLY
Log Date/Time (GMT)	The date and time of the transaction.	READ-ONLY
View	Opens a window that displays the selected AppBlock log.	
Download	Saves the AppBlock log as a TXT file.	

View Diagnostic Logs page

On this page, you view the log of the background services and applications that support the IRT application. This log can help you diagnose problems that are related to automated or scheduled functions, such as data transfers and drug ordering.

Tasks performed from this page

- *Viewing the diagnostic log* (on page 77).

Fields on this page

This table describes the default fields for this page. Your study might require different fields, and those fields could have different names.

Field	Description	Notes
Report functions		
Interactive Grid	Changes the grid display of the page.	
Layout for Print Mode	Displays the log in a print-friendly format.	
Create Filter	Specifies conditions for filtering information.	
Save Current Report	Saves the current page layout after filters have been applied.	

Field	Description	Notes
Export/Save	Saves and exports the diagnostic log.	
View Diagnostic Logs		
ID	The ID number of the group of functions.	READ-ONLY
Date/Time (GMT)	The date and time when the group of functions occurred.	READ-ONLY
Group	The group of functions that was written in the diagnostic log at the same time.	READ-ONLY
Severity	The severity of the group of functions: • DEBUG • INFO • WARNING • ERROR • FATAL	READ-ONLY
Source	The background application that wrote the line in the diagnostic log.	READ-ONLY
User ID	The ID number of the user who performed the transaction. If the system performed the transaction (for example, if the system ran a scheduled task), the User ID is **(null)**.	READ-ONLY
Message	A message that describes the running task.	READ-ONLY
Exception	A line of code that contains an error. For example, if a C# exception causes an error, the Exception field displays the code that contains the error.	READ-ONLY

Notification Subscriptions page

On this page, you subscribe IRT users and non-users to notification types. This page is useful for subscribing notification types to specific people rather than to everyone in a particular role.

Tasks performed on this page

- *Subscribing a notification type by role* (on page 62).
- *Setting up a distribution list for subscriptions* (on page 63).
- *Subscribing a notification type by user* (on page 64).

Related tasks:

- *Resending a notification* (on page 65).

For more information, see:

- *Role Notifications page* (see **Help** ).
- *Subscribing notifications to a role* (see **Help** )

Fields on this page

This table describes the default fields for this page. Your study might require different fields, and those fields could have different names.

Field	Description	Notes
Select Notification	The list of notification types. After you select a notification type, the following fields appear.	Default: <Select>
Subscription By Role		
Roles NOT subscribed	The list of roles that are not subscribed to the notification type.	
Roles subscribed	The list of roles that are subscribed to the notification type.	
Add >>	Adds the selected roles in the **Roles NOT subscribed** list to the **Roles subscribed** list.	
<<Remove	Removes the selected roles from the **Roles subscribed** list.	
Distribution List Subscription		
Distribution list	The list of user email addresses where notifications are sent.	
Add Email address	A field for typing an email address that you want to add to the list.	

Field	Description	Notes
Add Email	Adds the email address to the distribution list.	
Remove Email(s)	Removes the email address from the distribution list.	
Subscription By User		
Users NOT subscribed	The list of users who are not subscribed to the notification type.	
Users subscribed	The list of users who are subscribed to the notification type.	
Add>>	Adds users to the **Users subscribed** list.	
<<Remove	Removes users from the **Users subscribed** list.	

Manage InForm Setup page

On this page, you select whether or not the InForm application is ready to receive data from the IRT application. This page acts like an on/off switch for sending files from the IRT application to the InForm application.

Tasks performed from this page

- *Specifying whether the InForm application is ready to receive data* (on page 68).

Fields on this page

Field	Description	Notes
Inform Is Up	• **No—**The InForm application is not ready to receive data from the IRT application. • **Yes—**The InForm application is ready to receive data from the IRT application.	Default: No.

Verify Configuration page

On this page, you verify that your system is properly configured and in working order.

Tasks performed from this page

- *Verifying the system configuration* (on page 79).
- *Updating your contact information* (on page 79).

Fields on this page

Field	Description	Notes
Notice about system verification	A message that explains verification.	READ-ONLY
Contact information	A link for updating your contact information.	

Run Scheduled Task page

On this page, you manually run a task that is typically configured to be run on a schedule. Any time you run a scheduled task, the transaction is recorded in the *diagnostic log* (on page 77).

Tasks performed from this page

- *Running a scheduled task* (on page 81).

Fields on this page

Field	Description	Notes
Select Task	A list of available tasks.	

Audit History View page

On this page, you view the record of changes to the IRT database.

Tasks performed from this page

- *Viewing the audit history* (on page 77).
- *Exporting the audit history* (on page 78).

Fields on this page

This table describes the default fields for this page. Your study might require different fields, and those fields could have different names.

Field	Description	Notes
Table Name	The name of the table in the database.	READ-ONLY

Field	Description	Notes
ColumnName	The name of the column in the table.	READ-ONLY
RowKey	The primary key of table.	READ-ONLY
OldValue	The value before the transaction occurred.	READ-ONLY
NewValue	The value after the transaction occurred.	READ-ONLY
Event	The type of event: • Insert • Update • Delete	READ-ONLY
Posted Date Time	The date and time of the transaction (in GMT/UTC).	READ-ONLY
User ID	The ID of the user or service that performed the transaction.	READ-ONLY
User Name	The name of the user who performed the transaction or blank if the transaction was performed by a service.	READ-ONLY
HostName	The host computer that performed the update.	READ-ONLY
TransactionID	The ID of the database transaction.	READ-ONLY
InFormUserID	The ID of the InForm user, if an InForm user performed the transaction.	READ-ONLY
Platform	The platform on which the transaction occurred: Phone or Web.	READ-ONLY

Manage Custom Menu Items page

On this page, you create menu sections and items that appear in the Home menu.

Tasks performed from this page

- *Adding a new menu section to the Home menu* (on page 69).
- *Adding a new menu item to the Home menu* (on page 69).
- *Editing menu section details* (on page 71).
- *Editing menu item details* (on page 72).

Fields on this page

++Add New Section++

Field	Description	Notes
Menu Type	The type of menu: • Section Title • Upload File • Use Existing URL You cannot select **Upload File** and **Use Existing URL** until you create the section and provide a title.	Default: Section Title.
Title	The title of the section that appears in the Home menu.	
Submit	Creates your new section, which appears in the Home menu.	
Delete	Removes the menu option from the Home menu. This button is enabled after you create a section.	Default: Disabled.
Move Up	Moves the menu option up one position in the Home menu. This button is enabled after you create a section.	Default: Disabled.
Move Down	Moves the menu option down one position in the Home menu. This button is enabled after you create a section.	Default: Disabled.
Close	Terminates the Add New Section process and returns you to the Manage Custom Menu Items page.	

++Add New Item++

Field	Description	Notes
Menu Type	The type of menu item: • Section Title • Upload File • Use Existing URL You can select either **Upload File** or **Use Existing URL**.	Default: Upload File.

Field	Description	Notes
Title	The title of the menu item.	
File	Uploads a file to add as a menu item. This field appears if you selected **Upload File** from the **Menu Type** section.	
URL	The URL to add as the menu item. This field appears if you selected **Use existing URL** from the **Menu Type** section.	
Common URLs	Opens a **Select common URL** drop-down list. This field appears if you selected **Use existing URL** from the **Menu Type** section.	
Display for roles	A list of user roles. Select the roles whose users can view the new menu item.	Default: All roles are deselected.
Submit	Creates your new section, which appears in the Home menu.	
Delete	Removes the menu option from the Home menu. This button is enabled after you create a section.	Default: Disabled.
Move Up	Moves the menu option up one position in the Home menu. This button is enabled after you create a section.	Default: Disabled.
Move Down	Moves the menu option down one position in the Home menu. This button is enabled after you create a section.	Default: Disabled.
Close	Terminates the process and returns you to the Manage Custom Menu Items page.	

APPENDIX A

Working with reports

In this appendix

Working with standard reports

The IRT application includes a set of standard reports that provide study information, such as subject details, site statistics, drug supply inventories, and user contact information.

You can select and view reports as an interactive grid or a layout for printing. You can also ***filter*** (on page 14), ***export*** (on page 108), and ***save*** (on page 136) reports.

Note: You must have the appropriate permissions to view specific reports. If you are associated with or linked to a site or sites in the IRT application, you can view only data associated with that site in these reports.

There are four categories of standard reports:

- ***Subject reports*** (on page 113) provide information about the subjects in a study including subject, visit, randomization, initial drug allocation, and drug reallocation information.
- ***Study reports*** (on page 119) provide information about the study including enrollment information, site statistics, and audit histories.
- ***Supplies reports*** (on page 123) provide information about the supplies at sites and depots including drug order information, site and depot inventories, drug reconciliations, and projected supply usage.
- ***Users reports*** (on page 133) provide information about users including contact and system access information.

All standard reports can be customized. For more information, see ***Working with ad hoc reports*** (on page 136).

Viewing a standard report

1 Click **Reports** ( ).

2 From the Reports menu, select the report to view.

The report appears.

Exporting a standard report

1 Click **Reports** ( ).

2 From the Reports menu, select the report to view.

The report appears.

3 Click **Export/Save**.

The Export/Save dialog box appears.

4 Select a format for the export:

- **CSV**
- **PDF**

- **RTF**
- **XLS**
- **XLSX**

5 Click **Submit**.

The File Download dialog box appears.

6 Select whether to open or save the report in the exported format.

Drug unit statuses

User-applied drug unit statuses

Only one status can be applied to a drug unit at a time.

Status	Available for dispensing?	Available in site inventory for drug ordering?	Description
Available	Yes	Yes	• The drug unit is available for either supply order by the depot or dispensing to subjects at a site. • The drug unit is counted in current inventory for re-supply calculation. • The drug unit can be dispensed at the site or returned to the DDF. • The drug units can be over-labeled when a new expiration date is applied.
Damaged	No	No	• The drug unit experienced damage during shipment, at the depot or site, or as the result of a temperature excursion. • The drug unit is not counted in inventory for re-supply calculation. • The drug unit is not available for either shipment order by depot or dispensing by site. • The drug unit can be selected at site for return to DDF.
Destroyed	No	No	• The drug unit has been destroyed at the site or received by the DDF. • The drug unit is not counted in inventory for re-supply calculation. • The drug unit cannot be dispensed to a subject.

Status	Available for dispensing?	Available in site inventory for drug ordering?	Description
Mis-Assigned	No	No	• The drug unit has been selected as mis-assigned during visit rollback or drug reallocation. • Drug unit is not counted in inventory for re-supply calculation.
Missing	No	No	• The drug unit has not been received at the site or cannot be found at the site or depot. • The drug unit is not counted in inventory for re-supply calculation. • The drug unit is not available for either shipment order by the depot or dispensing by the site. • The drug unit cannot be selected at site for return to DDF.
Post-Quarantined	No	No	• The GSP has determined the drug unit cannot be used. • The drug unit is not counted in inventory for re-supply calculation. • The Drug unit is not available for either shipment order by the depot or dispensing by the site. • The drug unit cannot be selected at site for return to the DDF.
Pre-Quarantined	No	Yes	• The drug unit has been exposed to a temperature excursion but has not been examined by the GSP. • The drug unit is counted in inventory for re-supply calculation. • The drug unit is not available for either shipment order by the depot or dispensing by the site. • The drug unit cannot be selected at the site for returned to the DDF. • The drug units can be over-labeled when a new expiration date is applied.

System-applied drug unit statuses

Status	Available for dispensing?	Available in site inventory for drug ordering?	Description
Dispensed	No	No	• The drug unit has been dispensed to a subject. • Drug unit can be selected at site for return to DDF. • The drug unit is not counted in inventory for re-supply calculation. • The drug unit can be updated to be either damaged or missing.
Do Not Count	Yes	No	The DNC days are the minimum number of days before the expiration date from which drug unit can be counted as available by the system at either the depot or site. The DNC date is calculated as: Current Date < Lot Expiration Date – DNC days The DNC is a lot status set at the lot level. • The drug unit is not counted in inventory for re-supply calculation. • The drug unit is available for shipment order by the depot. • The drug unit is available to be dispensed at the site.
Do Not Dispense	No	No	Do Not Dispense (to subject based on visit window). The DND days are the number of days prior to the Expiration Date from which study trial supply cannot be dispensed to a subject. The DND date is calculated as: Current Date < Lot Expiration Date – Days from Expiry (DND) For drug replacement, the DND is calculated as: DND = DND from Visit Schedule of the last visit – days elapsed from last visit • The drug unit is not counted in inventory for re-supply calculation. • The drug unit is not available for shipment order by the depot. • The drug unit is not available to be dispensed at the site.

Status	Available for dispensing?	Available in site inventory for drug ordering?	Description
Do Not Ship	Yes	Yes (site only)	Do Not Ship (at site or depot). The DNS days are the minimum number of days prior to the Expiration Date from which a study trial supply shipment order can be requested from a depot. The DNS date is calculated as: Current Date < Lot Expiration Date – DNS days • The drug unit is counted in inventory at the site but not the depot for re-supply calculation. • The drug unit is available for shipment order by the depot. • The drug unit is available for shipment order by the site.
Expired	No	No	• The drug order has expired. • The drug unit is not counted in inventory for re-supply calculation. • The drug unit is not available for either shipment order by depot or dispensing by site. • The drug unit can be selected at site for return to DDF. • The drug units can be over-labeled when a new expiration date is applied.
In Transit	No	Yes	• The drug unit has been ordered, shipped by the depot, but has not yet been registered at the depot or site. • The drug unit is not counted at depot in inventory, but is counted in inventory for re-supply calculation at site. • The drug unit is raised in a shipment order and shipped by depot. • The drug unit has not yet been received by site or depot. • The drug units can be over-labeled when a new expiration date is applied.
Not in Use	No	No	• This status is applied at the lot level. • The drug unit is not counted in inventory for re-supply calculation. • The drug unit is not available for shipment order by the depot or dispensing by the site.

Status	Available for dispensing?	Available in site inventory for drug ordering?	Description
Processed for Destruction	No	No	• The drug unit has been selected at site to begin destruction process (a Reconcile Date has been captured). • Drug unit is not counted in inventory for re-supply calculation. • The drug unit cannot be dispensed to subject.
Temporarily Unavailable	No	Yes	• This status is applied to drug units that do not meet the other conditions. • The drug unit is counted in inventory for re-supply calculation. • The drug unit is not available for either shipment order by depot or dispensing by site. • The drug unit cannot be selected at site for return to DDF. • The drug units can be over-labeled when a new expiration date is applied.

Subject reports

The following subject reports are available in the IRT application. Each subject report includes a table that displays the report data in a grid.

- *Subject Details* (on page 114).
- *Visit Summary* (on page 115).
- *Randomization Report Unblinded* (on page 116).
- *Edit Subject Data Report* (on page 116).
- *Drug Reallocation* (on page 117).
- *Drug Reallocation Unblinded* (on page 118).
- *Visit Rollback Report* (on page 118).

Subject Details

This report displays the following information about the subjects in the study.

This table describes all possible fields for the report. Data in the report appears only in fields applicable to the study. Some fields might not appear in your report, and some fields could have different names.

Column	Description
Region	Area defined by the study team where the site is located (example: South America).
Country	Country where the site located (example: Brazil).
Investigator ID	Unique identification number for the investigator.
Site	Unique identification number for the site.
Name	Last name and first name of the Principal Investigator as entered at the site level.
Subject Number	Unique identification number for the subject.
Screening Number	Unique identification number assigned at screening. Typically, this is the same as the Subject Number.
Gender	Gender of the subject.
DOB	Date the subject was born.
Initials	Initials of the subject.
Screened	Date the subject was screened.
Screen Failed	Date the subject failed screening.
Screen Failed reason	Reason the subject failed screening.
Randomized	Date the subject was randomized.
Early Terminated	Date the subject was terminated early.
Early Terminated Reason	Reason the subject was terminated early.
Completed	Date the subject was marked completed.
Flag	Flags set for the subject (example: Mis-Randomized, or Off-Treatment).

Visit Summary

This report displays the following information about the visits in a study.

This table describes all possible fields for the report. Data in the report appears only in fields applicable to the study. Some fields might not appear in your report, and some fields could have different names.

Column	Description
Region	Area defined by the study team where the site is located (example: South America).
Country	Country where the site located (example: Brazil).
Investigator ID	Unique identification number for the investigator.
Site	Unique identification number for the site.
Name	Last name and first name of the Principal Investigator as entered at the site level.
Subject Number	Unique identification number for the subject.
Screening Number	Unique identification number assigned at screening. Typically, this is the same as the Subject Number.
Active	Whether the subject is active. • **Yes**—Subject has a status of Screened or Randomized. • **No**—Subject has a status of Screen Failed, Early Terminated, or Completed.
Visit Name	Description of the visit or transaction that affects the subject. Unblinding is excluded. Dynamic visits such as Drug Replacement, Edit Subject Data, and Subject Transfer visits appear on this report as they occur.
Scheduled	Expected visit date based on the randomization date and the visit schedule.
Actual	Date the visit occurred.
Dispensed	Drug unit number(s) dispensed at the visit.
Replaced	Drug unit number(s) replaced and the status of each replaced unit (example: Missing or Damaged).

Randomization Report Unblinded

This report displays the following unblinded information about randomization. Typically, unblinded statisticians use this report for the necessary data.

This table describes all possible fields for the report. Data in the report appears only in fields applicable to the study. Some fields might not appear in your report, and some fields could have different names.

Column	Description
Region	Area defined by the study team where the site is located (example: South America).
Country	Country where the site located (example: Brazil).
Investigator ID	Unique identification number for the investigator.
Site	Unique identification number for the site.
Name	Last name and first name of the Principal Investigator as entered at the site level.
Subject Number	Unique identification number for the subject.
Screening Number	Unique identification number assigned at screening. Typically, this is the same as the Subject Number.
Randomized	Date the subject was randomized.
Rand Number	Number assigned by the randomization schedule.
Treatment	Description of the treatment arm assigned during randomization.
Units	Number indicating the type of unit dispensed with the unit label in parenthesis (example: 1234 (A), 3456 (A)).
Forced	Whether randomization numbers were forced and assigned differently than the initial study design intended, based on which drug was available at the time of randomization.

Edit Subject Data Report

This report displays the following information about edits to subject data.

This table describes all possible fields for the report. Data in the report appears only in fields applicable to the study. Some fields might not appear in your report, and some fields could have different names.

Column	Description
Site	Unique identification number for the site.
Name	Last name and first name of the Principal Investigator as entered at the site level.
Investigator ID	Unique identification number for the investigator.

Column	Description
Subject Number	Unique identification number for the subject.
Screening Number	Unique identification number assigned at screening. Typically, this is the same as the Subject Number.
Transaction Name	Name of the transaction.
Request Date	Date the edit was requested.
Field	Edited field (example: Screen Fail Reason).
Original Value	Value of the field before the edit.
Request User	User requesting the change.
New Value	Value of the field after the edit.
Reason For Change	Reason the edit was requested.
Request Status	Status of the request.
Dependencies	Transactions that are affected by changing the value of the editable field.

Drug Reallocation

This report displays the following information about drug reallocation.

This table describes all possible fields for the report. Data in the report appears only in fields applicable to the study. Some fields might not appear in your report, and some fields could have different names.

Column	Description
Site	Unique identification number for the site.
Site Name	Last name of the Principal Investigator.
Subject Number	Unique identification number for the subject.
Transaction Name	Name of the transaction.
Transaction Date	Date of the transaction.
Reallocation Date	Date the reallocation was submitted.
Drug Allocated	Drug unit ID of the drug allocated, the lot, the expiration date, and the quantity allocated.
Drug Dispensed	Drug unit ID of the drug dispensed, the lot, the expiration date, and the quantity dispensed.
Site User ID	Unique identification number for the site user who completed the transaction.

Drug Reallocation Unblinded

This report displays the following unblinded information about drug reallocation.

This table describes all possible fields for the report. Data in the report appears only in fields applicable to the study. Some fields might not appear in your report, and some fields could have different names.

Column	Description
Site	Unique identification number for the site.
Site Name	Last name of the Principal Investigator.
Subject Number	Unique identification number for the subject.
Transaction Name	Name of the transaction.
Transaction Date	Date of the transaction.
Reallocation Date	Date the reallocation was submitted.
Drug Allocated	Drug unit ID of the drug allocated, the lot, the expiration date, and the quantity allocated.
Drug Type	Type of drug allocated.
Drug Dispensed	Drug unit ID of the drug dispensed, the lot, the expiration date, and the quantity dispensed.
Drug Type	Type of drug dispensed.
Site User ID	Unique identification number for the site user who completed the transaction.

Visit Rollback Report

Visits are sometimes registered and then rolled back due to data entry errors. This report displays the following information about visit rollbacks. Typically, data managers and study managers use this report for the necessary data.

This table describes all possible fields for the report. Data in the report appears only in fields applicable to the study. Some fields might not appear in your report, and some fields could have different names.

Column	Description
Site ID	Unique identification number for the site.
Subject Number	Unique identification number for the subject.
PI Last Name	Last name of the Principal Investigator.
Requested By	Unique identification number of the user who requested the visit rollback.
Visit Name	Name of the visit rolled back.
Transaction Date	Date of the transaction.

Column	Description
Date of Rollback Request	Date the visit rollback was requested.
Reason for Rollback	Reason the rollback was requested.
Drug Status Rolled Back	Whether the drug status was rolled back.
Drugs Impacted	Drug units that are affected by the rollback.

Study reports

The following study reports are available in the IRT application. A study report might include a graph, which visually depicts the report data, and a table that displays the report data in a grid. Typically, statisticians, study managers, and data managers use these reports for the necessary data.

- *Enrollment Summary* (on page 119).
- *Overall Summaries* (on page 120).
- *Site Overall & Monthly* (on page 121).
- *Site Statistics* (on page 121).
- *Audit Site Reports* (on page 122).

Enrollment Summary

This report contains a historical line graph that displays study totals in intervals based on the start date of the study.

For example:

- **Weekly**—0 to 4 months.
- **Monthly**—4 to 12 months.
- **Quarterly**—Greater than 12 months.

The report table displays the following information about enrollment. This report displays data only for the sites with which you are associated or linked.

This table describes all possible fields for the report. Data in the report appears only in fields applicable to the study. Some fields might not appear in your report, and some fields could have different names.

Row	Description
Study Totals	Total counts for the entire column.
Region	Total counts for the region.
Country	Total counts for the country.
Site	Total counts for the site.

Row	Description
Column	**Description**
Site	Number of sites per region or country.
Screened	Number of screened subjects.
Screen Failed	Number of screen failed subjects.
Randomized	Number of randomized subjects.
Early Terminated	Number of early terminated subjects.
Completed	Number of completed subjects.

Overall Summaries

This report displays the following overall information about enrollment. The report data is study-wide.

This table describes all possible fields for the report. Data in the report appears only in fields applicable to the study. Some fields might not appear in your report, and some fields could have different names.

Row	Description
Regions	Number of regions.
Regions - Active	Number of regions with active sites.
Countries	Number of countries.
Country - Active	Number of countries with active sites.
Sites	Number of sites.
Sites - Approved	Number of sites initially approved for a given month.
Sites - Active	Number of active sites initially approved for a given month.
Screened	Number of screened subjects.
Screen Failed	Number of screen failed subjects.
Randomized	Number of randomized subjects.
Reallocated	Number of reallocated drugs units.
Rollbacks	Number of rolled back visits.
Edit Subject Data	Number of subject data edits.
Columns	**Description**
Title	Description of the row.
Cumulative Total	Total.
Monthly Totals	Total for a given month.

Site Overall & Monthly report

This report displays the following enrollment information per site.

This table describes all possible fields for the report. Data in the report appears only in fields applicable to the study. Some fields might not appear in your report, and some fields could have different names.

Columns	Description
Region	Area defined by the study team where the site is located (example: South America).
Country	Country where the site located (example: Brazil).
Investigator	Unique identification number for the investigator.
Site	Unique identification number for the site.
Name	Last name and first name of the Principal Investigator as entered at the site level.
Title	Subject status or drug order.
Cumulative Total	Total.
Monthly Totals	Total for a given month.

Site Statistics

This report displays the following site statistics.

This table describes all possible fields for the report. Data in the report appears only in fields applicable to the study. Some fields might not appear in your report, and some fields could have different names.

Column	Description
Region	Area defined by the study team where the site is located (example: South America).
Country	Country where the site located (example: Brazil).
Investigator ID	Unique identification number for the investigator.
Site	Unique identification number for the site.
Name	Last name and first name of the Principal Investigator as entered at the site level.
First Screened	Date of first screened subject.
First Randomized	Date of first randomized subject.
Status	Whether the site is active.
Activated	Date of first activation.
Deactivated	Date of current deactivation.

Column	Description
Reactivated	Date of current reactivation.
Resupply	Resupply description (example: High or Low).
Ordering	Whether ordering is open or closed.

Audit Site Reports

These reports are generated as PDFs per site. The name of the report, site, investigator, and time zone appear at the top of the report. The screening number and subject ID appear at the top of each table.

Each table displays the following audit information.

This table describes all possible fields for the report. Data in the report appears only in fields applicable to the study. Some fields might not appear in your report, and some fields could have different names.

Column	Description
Visit / Transaction	Visit or transaction where the change occurred.
Data Point	Data that was changed.
Action	Action that caused the change (example: insert, update, or delete).
Old Value	Value before the change was made.
GMT / Local Time	Time the change was made in GMT and local time of the site.
User ID	Unique identification number for the user who made the change.
User Name	User name of the user who made the change.
Reason for Change	Reason the change was made.

A *Detailed Drug Reconciliation report* (on page 131) appears at the end of each Audit Site report.

Supplies reports

The following supplies reports are available in the IRT application. Each supplies report includes a table that displays the report data in a grid. Typically, drug supply managers use these reports for the necessary data.

- *Order Summary* (on page 123).
- *Site Inventory* (on page 124).
- *Site Inventory Unblinded* (on page 125).
- *Depot Inventory* (on page 126).
- Depot Inventory Unblinded.
- *Depot Inventory by Unit* (on page 128).
- *Site Inventory by Unit* (on page 129).
- *Drug Accountability Overview* (on page 130).
- *Detailed Drug Reconciliation* (on page 131).
- *Projected Supply Usage* (on page 132).

Order Summary

This report displays the following information for orders that were generated by the IRT application.

This table describes all possible fields for the report. Data in the report appears only in fields applicable to the study. Some fields might not appear in your report, and some fields could have different names.

Column	Description
Region	Area where the site or depot is located (example: Asia).
Country	Country where the site or depot is located (example: Japan).
Type	Whether the data is for a depot or site.
Location ID	Unique identification number for the depot or site.
Name	Name of the depot, or the last name and first name of the Principal Investigator.
Drug Order Number	Unique identification number generated for the drug order.
Total	Total supply units in the order.
Status	Description of the current status based on the study design.
Days Outstanding	Difference in the number of days since the order was raised to the current date or shipped date. This number appears until the order is received or canceled.
Raised (GMT)	GMT date and time when the IRT application generated the order.
Raised (Local)	Local date and time (depot time zone) when the IRT application generated the order.

Column	Description
Received (GMT)	GMT date and time when the order registered as received in the IRT application.
Received (Local)	Local date and time (destination time zone) when the order registered as received in the IRT application.
Shipped (GMT)	GMT date and time when the depot sent the order.
Shipped (Local)	Local date and time (depot time zone) when the depot sent the order.
Courier	Name of the courier.
Tracking Number	Courier tracking number.
Canceled (GMT)	GMT date and time when the order was canceled.
Canceled (Local)	Local date and time (depot time zone) when the order was canceled.
Cancel Initiated (GMT)	GMT date and time when the order cancelation was initiated.
Cancel Initiated (Local)	Local date and time (depot time zone) when the order was initiated.
Supply Listing	List of supply units by number.

Site Inventory

This report displays the following information about the inventory at each site.

This table describes all possible fields for the report. Data in the report appears only in fields applicable to the study. Some fields might not appear in your report, and some fields could have different names.

Column	Description
Region	Area defined by the study team where the site is located (example: South America).
Country	Country where the site located (example: Brazil).
Investigator ID	Unique identification number for the investigator.
Site	Unique identification number for the site.
Name	Last name and first name of the Principal Investigator as entered at the site level.
Lot	Unique identification number for the lot.
Available	Number of available units including units marked as Do Not Count. A negative value might be displayed as zero (configured during study design).
Dispensed	Number of units that the IRT application has assigned to subjects.
Damaged	Number of damaged units.
Missing	Number of missing units.
Pre-Quarantined	Number of pre-quarantined units.

Column	Description
Post-Quarantined	Number of post-quarantined units.
Temporarily Unavailable	Number of units temporarily unavailable(for relabeling).
Total Inventory	Total units received.
Not In Use	Units designated as Not In Use, which means they are unavailable.
Misallocated	Number of misallocated units.
Expired	Number of expired units.
Total Dispensed	Total units assigned.
Do Not Count	Number of units marked Do Not Count. This column calculates the quantity of drug units that cannot be counted towards available inventory but which has not yet expired.
In Transit	Number of units that have been ordered or shipped, but not yet received.
Total Processed for Destruction	Total units processed for destruction. **Note:** This field is present if drug reconciliation is set up during study design.
Total Destroyed	Total units destroyed. **Note:** This field is present if drug reconciliation is set up during study design.

Site Inventory Unblinded

This report displays the following unblinded information about the inventory at each site.

This table describes all possible fields for the report. Data in the report appears only in fields applicable to the study. Some fields might not appear in your report, and some fields could have different names.

Column	Description
Region	Area defined by the study team where the site is located (example: South America).
Country	Country where the site located (example: Brazil).
Investigator ID	Unique identification number for the investigator.
Site	Unique identification number for the site.
Name	Last name and first name of the Principal Investigator as entered at the site level.
Run Number	Run number provided.
Lot	Unique identification number for the lot.
Drug Unit Code	Code for the unit type (example: A, B, or C).

Column	Description
Unblinded Lot Number	Identifier for a lot that may contain unblinding information.
Drug Unit Type	Description of the unit type (example: Placebo).
Available	Number of available units including units marked as Do Not Count. A negative value might be displayed as zero (configured during study design).
Dispensed	Number of units that the IRT application has assigned to subjects.
Damaged	Number of damaged units.
Missing	Number of missing units.
Pre-Quarantined	Number of pre-quarantined units.
Post-Quarantined	Number of post-quarantined units.
Temporarily Unavailable	Number of units temporarily unavailable(for relabeling).
Not In Use	Units designated as Not In Use, which means they are unavailable.
Misallocated	Number of misallocated units.
Expired	Number of expired units.
In Transit	Number of units that have been ordered or shipped, but not yet received.
Total Inventory	Total units received.
DoNotCount	Number of units marked Do Not Count. This column calculates the quantity of drug units that cannot be counted towards available inventory but which has not yet expired.
Total Dispensed	Total units assigned.
Expiry Date	Lot number expiration date.
Total Processed for Destruction	Total units processed for destruction.
Total Destroyed	Total units destroyed.

Depot Inventory

This report displays the following information about the inventory at each depot.

This table describes all possible fields for the report. Data in the report appears only in fields applicable to the study. Some fields might not appear in your report, and some fields could have different names.

Column	Description
Region	Area where the depot is located (example: Europe).
Country	Country where the depot is located (example: United Kingdom).
Depot	Unique identification number for the depot.

Column	Description
Name	Name of the depot.
Label Group	Name of the label group.
Lot	Unique identification number for the lot.
Total Inventory	Total units shipped from the depot to a site or depot.
Total Shipped	Total units ordered or shipped for the depot, but not yet received.
In Transit	Number of units that have been ordered or shipped, but not yet received.
Available	Number of available units including units marked as Do Not Count. A negative value might be displayed as zero (configured during study design).
DNS	Number of units at a depot marked as Do Not Ship.
Damaged	Number of damaged units.
Missing	Number of missing units.
Temporarily Unavailable	Number of units temporarily unavailable(for relabeling).
Not In Use	Units designated as Not In Use, which means they are unavailable.
Pre-Quarantined	Number of pre-quarantined units.
Post-Quarantined	Number of post-quarantined units.
Expired	Number of expired units.

Depot Inventory Unblinded

This report displays the following unblinded information about the inventory at each depot.

This table describes all possible fields for the report. Data in the report appears only in fields applicable to the study. Some fields might not appear in your report, and some fields could have different names.

Column	Description
Region	Area where the depot is located (example: Europe).
Country	Country where the depot is located (example: United Kingdom).
Depot	Unique identification number for the depot.
Name	Name of the depot.
Label Group	Name of the label group.
Run Number	Run number provided.
Lot	Unique identification number for the lot.
Drug Unit Code	Code for the unit type (example: A, B, or C).
Drug Unit Type	Description of the unit type (example: Placebo).

Column	Description
Total Inventory	Total units shipped from the depot to a site or depot.
Total Shipped	Total units ordered or shipped for the depot, but not yet received.
In Transit	Number of units that have been ordered or shipped, but not yet received.
Available	Number of available units including units marked as Do Not Count. A negative value might be displayed as zero (configured during study design).
Damaged	Number of damaged units.
DNS	Number of units at a depot marked as Do Not Ship.
Missing	Number of missing units.
Temporarily Unavailable	Number of units temporarily unavailable(for relabeling).
Not In Use	Units designated as Not In Use, which means they are unavailable.
Pre-Quarantined	Number of pre-quarantined units.
Post-Quarantined	Number of post-quarantined units.
Expired	Number of expired units.
Expiry Date	Lot number expiration date.

Depot Inventory by Unit

This report displays the following information about units initially associated with a depot. This report offers more granularity than the other Depot Inventory reports and provides information by drug unit.

This table describes all possible fields for the report. Data in the report appears only in fields applicable to the study. Some fields might not appear in your report, and some fields could have different names.

Column	Description
Region	Area where the depot is located (example: Europe).
Country	Country where the depot is located (example: United Kingdom).
Depot	Unique identification number for the depot.
Name	Name of the depot.
Label Group	Name of the label group.
Run Number	Run number provided.
Lot	Unique identification number for the lot.
Expiry Date	Lot number expiration date.
Drug Unit Number	Unique identification number for the drug unit.

Column	Description
Drug Unit Code	Code for the unit type (example: A, B, or C).
Drug Unit Type	Description of the unit type (example: Placebo).
Status	Description of the current status based on the study design.
Drug Order Number	Unique identification number for the order.

Site Inventory by Unit

This report displays the following information about units at each site. This report offers more granularity than the other Site Inventory reports and provides information by drug unit.

This table describes all possible fields for the report. Data in the report appears only in fields applicable to the study. Some fields might not appear in your report, and some fields could have different names.

Column	Description
Region	Area defined by the study team where the site is located (example: South America).
Country	Country where the site located (example: Brazil).
Investigator ID	Unique identification number for the investigator.
Site	Unique identification number for the site.
Name	Last name and first name of the Principal Investigator as entered at the site level.
Label Group	Name of the label group.
Run Number	Run number provided.
Lot	Unique identification number for the lot.
Expiry Date	Lot number expiration date.
Drug Unit Number	Unique identification number for the drug unit.
Drug Unit Code	Code for the unit type (example: A, B, or C).
Drug Unit Type	Description of the unit type (example: Placebo).
Status	Description of the current status based on the study design.
Do Not Count	Number of units marked Do Not Count. This column calculates the quantity of drug units that cannot be counted towards available inventory but which has not yet expired.
Drug Order Number	Unique identification number for the order.

Drug Accountability Overview

This report displays the following information about drug accountability. This is report is available when drug reconciliation is done through the IRT application.

This table describes all possible fields for the report. Data in the report appears only in fields applicable to the study. Some fields might not appear in your report, and some fields could have different names.

Column	Description
Region	Area where the site or depot is located (example: Asia).
Country	Country where the site or depot is located (example: Japan).
Type	Whether the data is for a depot or site.
Investigator ID	Unique identification number for the investigator.
Location ID	Unique identification number for the depot or site.
Name	Name of the depot, or the last name and first name of the Principal Investigator.
Total Inventory	Total units received at the site, or associated with the depot, and not at the Drug Destruction Facility.
Total Shipped to Site	Number of units shipped to the site including orders raised or received and not canceled.
In Transit	Number of ordered units raised to the site or depot that have not been received or canceled.
Available	Number of units at the site marked with a status of Available.
Total Processed for Destruction	Total units processed for destruction and reconciled.
Total Destroyed at Site	Total units confirmed as destroyed at the site or depot.
Total Shipped to DDF	Total units sent to the Drug Destruction Facility.
Received by DDF	Number of units received by the Drug Destruction Facility depot.
Total Destroyed at DDF	Total units confirmed as destroyed at the Drug Destruction Facility depot.

Detailed Drug Reconciliation

This report displays the following information about drug reconciliation. This is report is available when drug reconciliation is done through the IRT application.

This table describes all possible fields for the report. Data in the report appears only in fields applicable to the study. Some fields might not appear in your report, and some fields could have different names.

Column	Description
Region	Area defined by the study team where the site is located (example: South America).
Country	Country where the site located (example: Brazil).
Investigator ID	Unique identification number for the investigator.
Site	Unique identification number for the site.
Name	Last name and first name of the Principal Investigator as entered at the site level.
Drug Unit Number	Unique identification number for the drug unit.
Drug Order Number	Unique identification number for the order.
Dispensed	Date the drug unit was dispensed at the visit.
Subject Number	Unique identification number for the subject.
Visit Name	Name of the visit.
Reconcile Type	Unit type or name (example: Bottle or Blister Pack).
Quantity per Type	Total units associated to the unit type.
Quantity Dosed	Amount of the unit dosed by the site.
Quantity Processed	Amount of the unit considered processed for destruction.
Quantity Not Processed	Amount of the unit not processed for destruction.
Reconciled by Site	Date the site reconciled the unit.
Reconciled by Monitor	Date the monitor reconciled the unit.
Destruction Method	Whether the unit was destroyed by the site or the Drug Destruction Facility.
Quantity Shipped to DDF / Destroyed at Site	Amount that the monitor entered or the date the site user signed the destruction form.
Courier	Name of the courier who delivered the lot to the depot or site.
Tracking Number / Destruction ID	Tracking number entered or the destruction ID generated.

Column	Description
Shipped to DDF / Monitor Date	Date the IP form was generated or the date the monitor signed the destruction form.
Received by DDF	Date the Drug Destruction Facility received the unit.
Count at DDF	Number of units the Drug Destruction Facility entered.
Destroyed	Date the site or Drug Destruction Facility confirmed the unit was destroyed.
Difference	Amount that the Drug Destruction Facility entered minus the amount the Monitor entered.
100% Verification?	Whether the verification was performed.
Comments	Additional comments. Maximum length is 250 characters with text wrapping. Name and user ID are listed before each comment.

Projected Supply Usage

To view this report:

1 Filter by region, country, type, or location ID.

2 Select the number of days for the projection.

3 Select whether to display only deficiencies.

4 Click **Recalculate Projection**.

This report displays the following information about the projected supply usage.

This table describes all possible fields for the report. Data in the report appears only in fields applicable to the study. Some fields might not appear in your report, and some fields could have different names.

Column	Description
Region	Area where the site or depot is located (example: Asia).
Country	Country where the site or depot is located (example: Japan).
Type	Whether the data is for a depot or site.
Location ID	Unique identification number for the depot or site.
Name	Name of the depot, or the last name and first name of the Principal Investigator.
Unit Code	Code for the unit type (example: A, B, or C).
Unit Name	Description of the unit.
Projected Days	Number of days projected from the current date.
Required	Number of units required based on the project days. For depots, this quantity accounts for all sites that the depot supplies. Required quantities are calculated for active subjects who are randomized in the study.

Column	Description
Available	Number of available drug units excluding units in transit.
Difference	Number of units required minus available units and units in transit.
In Transit	Number of units in transit to the site or depot.
Resupply Type	Name of the resupply type.
Min Buffer	Minimum buffer per drug unit type.
Max Buffer	Maximum buffer per drug unit type.
Screened	Number of subjects screened and considered active. For depots, this number accounts for subjects screened at all sites that the depot supplies.
Randomized	Number of subjects who have been randomized and are considered to be active. For depots, this number accounts for subjects screened at all sites that the depot supplies.

Users reports

The following users reports are available in the IRT application. Users reports include a table that displays the report data in a grid.

- *User Contact Information* (on page 133).
- *System Access* (on page 134).

User Contact Information

This report displays the following user contact information. This report includes only users with activated accounts who have logged into the IRT application.

This table describes all possible fields for the report. Data in the report appears only in fields applicable to the study. Some fields might not appear in your report, and some fields could have different names.

Column	Description
User ID	Unique identification number for the user.
User Name	First name, middle initial, and last name associated with the user ID.
Role	Role associated with the user ID.
Site	Unique identification number for the site.
Depot	Unique identification number for the depot.
Institution	Institution entered in association with the user ID.
Address	Address where the user is located.
City	City where the user is located
State	State where the user is located.

Column	Description
Zip	Zip code where the user is located.
Phone	Phone number of the user.
Fax	Fax number of the user.
Email	Email address of the user.
Date Format	Date format for the user.
Time Zone	Time zone where the user is located.

System Access

This report displays the following system access information. This report includes information about all users with access to the IRT application. Users included in this report might not have activated accounts.

This table describes all possible fields for the report. Data in the report appears only in fields applicable to the study. Some fields might not appear in your report, and some fields could have different names.

Column	Description
User ID	Unique identification number for the user. Appears in this report only for authenticated users.
Role	Role associated with the user ID.
Role Status	Whether the role has blinded or unblinded access to the IRT application.
Site	Unique identification number for the site.
Depot	Unique identification number for the depot.
Name	First name, middle initial, and last name associated with the user ID.
Email	Email address of the user.
Fax	Fax number of the user.
Entered Date (GMT)	GMT date and time when the user data was entered with a batch user upload.
Entered Date (Local)	Local time (user time zone) when the user date was entered with a batch user upload.
Authenticated Date (GMT)	GMT date and time when the user was authenticated with its user ID.
Authenticated Date (Local)	Local date and time (user time zone) when the user was authenticated with his or her user ID.
Removed Date (GMT)	GMT date and time when user ID role was removed or the user ID was deactivated.
Removed Date (Local)	Local date and time (user time zone) when the user ID role was removed or the user iD was deactivated.

Column	Description
User ID Status	If the user is authenticated, the status of the user.

Working with ad hoc reports

The IRT application provides ad hoc reporting capability. The data that is available for ad hoc reports comes from the base set of IRT standard reports. However, some ad hoc reports are not visible as standard reports.

If you have the appropriate permissions, you can:

- *Create a custom report* (on page 136).
- *Edit a custom report* (on page 136).
- *View a custom report* (on page 136).
- *Save a custom report* (on page 137).

Typically, data managers create custom reports from standard reports that they filter on a regular basis. They can create a custom report that is pre-filtered to meet their needs.

Custom reports can be shared with certain roles or specific users.

Creating a custom report

1 Click **Reports** ( ).

2 From the **Reports** menu, in the **Ad Hoc** section, select **Create Custom Report**.

3 From the **Select base report** drop-down list, select a base report.

4 Select the columns to include in the custom report.

5 Add, select, or remove filters.

For more information, see *Sorting and filtering data in a form* (on page 14).

6 Click **Preview report**.

Editing a custom report

1 Click **Reports** ( ).

2 From the **Reports** menu, in the **Ad Hoc** section, select **Manage/View Custom Reports**.

3 To the left of the report you want to edit, click **Edit**.

4 Edit the report as necessary.

5 Click **Submit**.

Viewing a custom report

1 Click **Reports** ( ).

2 From the **Reports** menu, in the **Ad Hoc** section, select **Manage/View Custom Reports**.

3 To the left of the report you want to view, click **View**.

Saving a custom report

1 *Create* (on page 136) or *view* (on page 136) a report.

2 Click **Save Current Report**.

The Save Current Report dialog box appears.

3 Enter a title.

4 Enter a description.

5 Add, select, or remove filters.

For more information, see *Sorting and filtering data in a form* (on page 14).

6 In the **Shared With Roles** field, select the roles to share the report with.

7 In the **Share With Users** field, select specific users to share the report with.

8 Click **Submit**.

Save Current Report dialog box

Field	Description
Please specify a title	Title for the report.
Please specify a description	Description of the report.
Selected columns	List of columns selected for the report.
Selected filter	Filters for the report.
Shared With Roles	Roles to share the report with.
Shared With Users	Users to share the report with.

APPENDIX B

Phone access

In this appendix

Logging in using the phone

The first time you log on, you are required to know the following:

- Study Code
- User ID
- Default Password
- User Authentication Code

Some users are required to know the following:

- Site ID
- Depot ID

Note: If your study has multilingual capabilities over the phone, you are asked to select your preferred language each time you access the system.

1 Dial the toll-free access number for your country.

A welcome message plays.

2 Enter the 3-digit study number provided in the email.

3 Enter your User ID.

4 Enter your password. If it is the initial logon, use the default password.

The steps below that begin with (Initial log-on) only apply for your first login. The first time you log in, you are prompted to change your password from the provided default to a new 5-digit password.

You are required to change your password every time your password expires. After it is changed, the password is the same for both the phone and the Web.

Note: After three invalid entries, the phone call is disconnected.

5 If this is the first time you have logged on, follow these steps:

1 Enter new password and confirm.

2 Create your PIN and confirm.

3 Enter your User Authentication Code (UAC).

You are required to authenticate your User ID for each study to which you are given access. You receive an email message or fax containing an User Authentication Form (UAF) when you are first entered into a study by the sponsor. The UAC is on this form. When you log into the study for the first time, you need the UAC to proceed to the main menu.

4 Enter your site or depot number, if applicable.

You hear a welcome message announcing the name of the study you have successfully accessed.

When using the telephone for an IRT transaction, study information is recorded if the call is disconnected or if you hang up before the call is completed. Unless otherwise specified, the IRT system confirms the completion of each transaction, and a confirmation is sent to you by email or

fax. If you need to resend a confirmation, use the ***retransmit notifications*** (on page 65) function on the web.

Processing transactions over the phone

After you log in using the phone, the IRT system reads the welcome message and all applicable menu options for your user role.

You might have access to one or more of the following transactions on the phone:

Subject Menu

- Screening
- Screen Fail
- Randomization
- Scheduled Visit
- Drug Replacement
- Early Termination
- Completion
- Unblind Treatment

Trial Supply Menu

- Register Site Drug Order Receipt
- Register Depot Drug Order Receipt
- Update Site Inventory
- Update Depot Inventory

To process the above transactions

- Follow the directions read to you over the phone. Use the following letter codes to enter alpha characters:

A	B	C	D	E	F
01	02	03	04	05	06
G	H	I	J		L
07	08	09	10	11	12
M	N	O	P	Q	R
13	14	15	16	17	18
S	T	U	V	W	X
19	20	21	22	23	24
Y	Z	Dash			
25	26	27			

- To return to the main menu, press **pound** (**#**).
- To exit the application, from the main menu, press **0**, or hang up.
- To input special characters:
  - Press **star** (*****) to input a decimal.
  - Enter **27** to insert a dash.

For example, if a subject does not have a middle initial, the output would be A-B, entered as 012703.

Setting up the phone menu in the IRT web application

Phone menus are required for every IRT study. Because different users require different menus, you can configure phone menus for relevant roles and functions in the IRT web application.

Note: You must have administrator permissions to perform this task.

1 Access the IRT web application.

2 Click **Configurations** ().

3 From the **Configuration** menu, select **Manage Permissions**.

A table of functions (vertical list on the left) and permissions (horizontal list across the top) appears. You can assign functions to roles by selecting the checkboxes. There are text boxes under the checkboxes for the functions that can be accessed in the phone.

Field descriptions for phone-related functions and permissions

This table describes the functions that can be accessed through the IRT phone platform.

Role	Internal ID	Function Description	Recommended roles
Subjects Tab			
Subject Transactions Grants role view permission for Subjects tab	200	Allows user to view the subject transactions landing page.	Site Users and Sponsor Users
Screening	201	Allows user to perform transactions related to screening of the subject.	Site Users and Sponsor Users
Screen Fail	202	Allows user to perform transactions related to screen failing the subject.	Site Users and Sponsor Users
Randomization/Enrollment	203	Allows user to perform transactions towards Randomization/Enrollment.	Site Users and Sponsor Users
Scheduled Visit	204	Allows user to perform transactions towards Scheduled Visit.	Site Users and Sponsor Users
Drug Replacement	205	Allows user to perform replacement of the missing or damaged kit.	Site Users and Sponsor Users
Early Termination	206	Allows user to perform transactions towards Early Termination of the subject.	Site Users and Sponsor Users

Role	Internal ID	Function Description	Recommended roles
Completion	211	Allows user to perform transactions towards Completion of the subject for the study.	Site Users and Sponsor Users
Unblind Treatment	207	Allows user to perform transactions towards UNBLINDING of the Treatment.	Investigator, Safety or Medical Monitor ONLY
Supplies Tab			
Register Site Drug Order Receipt	601	Allows user to register received drug order at the site.	Site User and Drug Supply Manager
Register Depot Drug Order Receipt	603	Allows user to register received drug order at the depot.	Depot User and Drug Supply Manager
Update Site Inventory	602	Allows user to manage site inventory.	Site User (cannot undamage drugs) and Drug Supply Manager
Update Depot Inventory	604	Allows user to manage depot inventory.	Depot User (cannot undamage drugs) and Drug Supply Manager

4 Locate the role in the **Function/Role** heading at the top of the page.

5 Scan the list of functions to find the first the phone function the role should be able to access.

The functions are organized by menu on the left side of the page.

6 Select the checkbox in the row for the function below the role to allow the role to access this function, or deselect it to remove access.

7 To assign a phone menu number to a user role and function, type the number in the text box under the checkbox for the phone function.

This number must be unique within the menu (example: all numbers in Subjects).

8 Repeat steps 4 - 7 for each function the role should be permitted to access.

9 Click **Submit**.

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