# Oracle® User Management Tool

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# **Preface**

This guide provides information about how to use User Management Tool (UMT).

### **Audience**

This guide is intended for InForm, IRT, OLX, and IPMs Sponsor Users.

## **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.

#### **Access to Oracle Support**

Oracle customers 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.

### **Related Documents**

For more information, see the following documents:

- Oracle User Management Tool User's Guide [this document]
- Oracle User Management Tool Release Notes

### **Conventions**

The following text conventions are used in this document:

Convention	Meaning
boldface	Boldface type indicates graphical user interface elements associated with an action, or terms defined in text or the glossary.
italic	Italic type indicates book titles, emphasis, or placeholder variables for which you supply particular values.
monospace	Monospace type indicates commands within a paragraph, URLs, code in examples, text that appears on the screen, or text that you enter.

# Introduction

The Oracle User Management Tool (UMT) is an application for creating and managing user identity and access for Inform trials supported by Oracle. It also lets sponsor personnel enter, update, and confirm user and site details for their trials. It contains the following sections:

- Section 1.1, "Main Functions"
- Section 1.2, "How to Use Help"

#### 1.1 Main Functions

The main functions of this application are:

- Delivers a robust, validated, secure, and intuitive user management environment that can be used across all InForm trials.
  - Lets you import information to the UMT from external source files such as Excel spreadsheet and DAT files.
  - Facilitates global updates to Oracle user information.
- Provides easy-to-use interface and data exchange for the automated transfer of information to the InForm trial, Automated Site Assessment (ASA) used for end-user infrastructure assessments, and InStruct Online (IOL) end-user computer-based training application.
- Provides Dual Control functionality, where two users are required to perform a transaction, such as creating and managing sites, and creating users and configuration related records.
- Provides an integrated training log for updating and reviewing the training status of trial personnel.
- Provides a flexible environment for users to extract information from the UMT in a reportable format.
- Improves the user management experience for users and internal staff.
- Ensures full traceability.
- Ensures auditability.

## 1.2 How to Use Help

The Help system is divided into left and right panes. The left pane of the window is organized in the form of books and topics. Books contain related topics and topics

contain information about performing a specific task. When you click a topic, the content is displayed in the right pane.

### 1.2.1 Navigational and Layout Features

- The and buttons on the navigation bar help you browse through all available topics.
- The X button lets you close the left pane. Click the Contents tab on the main help bar to open the left pane.
- The **Index** tab helps you search for a topic.
- The **Search** tab displays all the topics which contain the search text.

# **Getting Started**

This section helps you use the Oracle User Management Tool (UMT) application. It gives you a description of the interface and its various elements. It contains the following sections:

- Section 2.1, "Getting a New Password"
- Section 2.2, "Changing the Login Password"
- Section 2.3, "Accessing Support Help Desk"
- Section 2.4, "User Management Tool Interface"
- Section 2.5, "Performing a Quick Search"
- Section 2.6, "Saving Details"
- Section 2.7, "Viewing Audit Trails"
- Section 2.8, "Logging out of the Application"

### 2.1 Getting a New Password

If you forget your login password, click the Forgot Your Password? link on the UMT login page to get your new password.

To get a new password:

- 1. On the login page, click the Forgot Your Password? link. The Forgot Your Password? page is displayed.
- Enter your user name in the **Please Enter Your Username** field and click **Submit**.
- You are prompted to enter the answer for your hint question. Enter the answer for the question and click **Send New Password**.
  - Your new password is sent to the email address, specified during user creation and in the UMT settings.
- To view the login page, click **Return**.

# 2.2 Changing the Login Password

Every user is assigned a unique password. This password expires or becomes invalid after the password expiration period or if you exceed the maximum login attempts (specified in the UMT settings). If the password has expired, the system prompts you to change the password. Oracle recommends that you periodically change your password.

**Note:** Contact the UMT system administrator for details on the current setting for maximum number of login attempts.

To change the login password:

- 1. Click the CHANGE PASSWORD link on the top-right corner of the page. The Change Your Password page is displayed.
- **2.** Enter your new password and password hint.
  - When you change your password, the new password is validated based on the settings selected in the UMT Settings page.
- Click **Submit** to submit the changes. To discard the changes, click **Return**.

# 2.3 Accessing Support Help Desk

The Oracle UMT home page has links that let you access the support link and e-mail the customer support team.

To access the Oracle UMT support help desk:

- 1. On the Oracle UMT login page, click the http://www.oracle.com/us/corporate/Acquisitions/phaseforward/support-17 6416.html in the Help Desk Information section. The Support Overview page is displayed. The page has links that have various support information.
- 2. Click the Help Desk E-mail link in the Help Desk Information section to send an email to the customer support team.

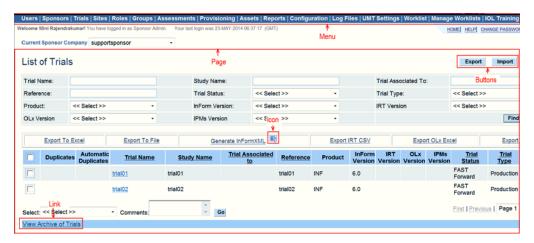
# 2.4 User Management Tool Interface

This section introduces you to the different elements on the UMT interface. It also explains how you can use these elements to navigate and perform tasks.

### 2.4.1 Navigation Elements

The main navigation elements in the UMT application are menus, links, and buttons, which in turn display pages where you can define or modify existing details. The following figure illustrates the navigation elements:

Figure 2-1 Navigation Elements



#### **Viewing Data on List Pages**

Sorting: When viewing records on list pages, click the required column header to sort the list in alphanumeric order.

Filters: The filter criteria at the top of a list page lets you filter the list based on the criteria you select.

#### 2.4.1.1 Menu

UMT is a web-based application that consists of a menu with several submenus. Each menu opens a page enabling you to perform various tasks.

**Note:** The menu items displayed on the menu vary depending upon your access rights.

#### 2.4.1.2 Page

Each menu item takes you to a new page. Each of these pages may contain icons, buttons, and links that may open other pages or perform tasks such as delete or save.

#### 2.4.1.3 Buttons

Buttons let you access a new page where you can define, change, or view details.

#### 2.4.1.4 Links

Most of the pages in this application contain links. Links are used for various purposes. On clicking a link, the view or edit page is displayed. For example, on clicking the Trial Name link on the List of Trials page, the Trial Details page is displayed.

#### 2.4.1.5 Icons

An icon is a small graphic symbol that represents an action. When clicked, the action associated with the icon is executed. For example, on clicking the **1** icon, the corresponding user-role association is displayed.

### 2.4.2 Entry Fields

#### **2.4.2.1 Text Boxes**

Text boxes let you enter or type information specific to a field. Depending on the kind of information that is required, these fields let you enter either alphabetical or numeric values. For example, entering a name in the First Name text box. In specific cases, alphanumeric values may be required.

#### 2.4.2.2 Drop-down Lists

Drop-down lists let you select a value from the list that is displayed on clicking the drop-down arrow beside it. Most of the drop-down lists display all the items defined in the system for that particular field.

The options available in the drop-down list may vary depending upon your access rights.

#### 2.4.2.3 Check Boxes

Check boxes let you select more than one option. Click a blank check box to select it. Click a selected check box to clear or deselect it. Click the top select box in the select box column to select all records.

#### 2.4.2.4 Radio or Option Buttons

Option buttons usually, though not always, appear in pairs and give you an either-or option. One of the options is always selected by default. Selecting one of the other option buttons deselects the default option.

#### 2.4.2.5 **List Boxes**

List boxes usually appear in pairs. The left list box contains a list of all available items. You can select individual items from it and click the >> and > buttons provided between the two list boxes. The items move to the right list box. To remove an item or all items from the selected list, select the item and click the < or << button.

#### 2.4.2.6 Date Boxes

Date boxes are basically text boxes provided with the date picker beside it. Clicking this icon opens up a calendar, letting you select a date.

### 2.5 Performing a Quick Search

The Quick Search feature is available on the List of Countries page (located in the right corner).

Using this feature, you can search for sites and users, and directly access the required

For details on the List of Countries page, see Section 14.6.2.

To perform quick search:

- In the Quick Search section, select the search item (such as sites or users) from the **Find** drop-down list.
- 2. Enter the search keyword in the with name as text box and click **Submit**. Based on your search criteria, the corresponding page is displayed.

### 2.6 Saving Details

The **Submit** button lets you save the changes made to the current page. You are prompted to save the changes made on a page if you are navigating to another page without saving the changes on the current page.

Oracle recommends you not to use the Back button of the browser. The pages are not displayed most of the time or you may lose the changes you have made. To navigate, use the menu or the **Return** button of the application.

Using any of the browser buttons such as, Refresh takes you to the home page of the application.

# 2.7 Viewing Audit Trails

Any changes made to a field item are captured and the reasons for change are tracked and audited. You can view the changes made to a particular field by viewing its corresponding audit trail.

To view audit trails:

- Click the icon corresponding to a field item. On the Audit Trail page that appears, the audit details for corresponding field item are displayed.
- To view the previous screen, click **Return**.

# 2.8 Logging out of the Application

You can log out of the application any time.

Oracle recommends you not to close your browser window to close the application without logging off from the UMT system. The connection with the server is disconnected properly only when you log out of the application.

To log out of the application:

Click the **LOG OUT** link on the top-right corner of this application. You are logged out of the application and the login page is displayed.

**Note:** The UMT system automatically logs you off when your session is inactive. You need to re-login to continue working.

Loaaina	out	of	the	qΑ	plication

# **Managing Users**

This chapter contains the following topics:

- Section 3.1, "User Types"
- Section 3.2, "InForm, IRT, and OLx Users"
- Section 3.3, "UMT Users"
- Section 3.4, "Oracle Users"
- Section 3.5, "Global Users"
- Section 3.6, "Merging Duplicate Users"
- Section 3.7, "Linking Users"

## 3.1 User Types

The following are the types of users:

- InForm, IRT, and OLx Users
- **UMT Users**
- **Oracle Users**
- Global Users

The InForm, Oracle, and Global users can be enabled for single sign-on (SSO), which is a user authentication process. It lets users use single user name and password to access multiple trials and applications within a sponsor or a clinical research organization (CRO). It also lets users to switch from one application or trial to another without re-signing.

## 3.2 InForm, IRT, and OLx Users

This section contains the following topics:

- Section 3.2.1, "Viewing the List of InForm, IRT, or OLx Users"
- Section 3.2.2, "Creating InForm, IRT, or OLx Users"
- Section 3.2.3, "Viewing and Modifying InForm User Details"
- Section 3.2.4, "Viewing Multiple Association"
- Section 3.2.5, "Associating a User with a Site"
- Section 3.2.6, "Terminating InForm Users"

- Section 3.2.7, "Viewing Terminated InForm Users"
- Section 3.2.8, "Unterminating InForm Users"
- Section 3.2.9, "Approving or Rejecting InForm Users"
- Section 3.2.10, "Marking Users for Upload to InForm"
- Section 3.2.11, "Marking Users as Trained"
- Section 3.2.12, "Assigning IOL Classes"
- Section 3.2.13, "Sending InForm Account Details"
- Section 3.2.14, "Exporting InForm Users"
- Section 3.2.15, "Marking Users for Upload to IRT"
- Section 3.2.16, "Marking Users for Load to OLx"
- Section 3.2.17, "Marking Users for Updating User Name in Email Notifications"
- Section 3.2.18, "Updating Assessment Status"
- Section 3.2.19, "Assigning Preferred Study Locale"

#### 3.2.1 Viewing the List of InForm, IRT, or OLx Users

The InForm Users page lets you manage InForm, IRT, and OLx users. You can view the list of InForm users and their details on this page. Additionally, it lets you filter the users based on the filter criteria.

To view the list of InForm users:

- 1. Select **Users** from the menu bar. The InForm Users page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of InForm users for the selected sponsor company and trial is displayed.
- To filter users, enter the filter criteria, and click **Find**. The list of InForm users that satisfy the specified filter criteria is displayed.
  - For more details on how to filter and view InForm, IRT, and OLx users, see Section A.1.
- **4.** To clear the filter criteria, click **Clear**.

While specifying the filter criteria, you can use the full name or part of the name.

**Note:** To navigate through the user list, click the **First**, **Previous**, Next, or Last links.

To view a particular page, select the page from the drop-down list.

To view all the users on a single page, select **All** from the drop-down

Click the column name link to sort users either in the ascending or descending order, based on the column name. On the first click, the users are sorted in the ascending order. To sort them in descending order, click the column name link again.

#### 3.2.2 Creating InForm, IRT, or OLx Users

The Create InForm Details page lets you create three types of InForm users, that is, PF users, sponsor users, and site users. Only PF users (Administrators) can create both PF and sponsor users, and associate with any sponsor. Sponsor users can create only sponsor users within that sponsor. Enter the user details and user association to create a new InForm user.

To create InForm users:

- Select **Users** from the menu bar. The InForm Users page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of InForm users for the selected sponsor company and trial is displayed.
- Click the **Create InForm User** link. The Create InForm User Details page is displayed.
- Enter the user details and user association.

For more details on how to create InForm, IRT, and OLX users, see Section A.1.

**Note:** The **User Association** section, on the Create InForm User Details page, varies depending upon the selected User Type.

Click **Submit** to save the user details.

**Note:** To save the current user details and create another user, click Submit and Add Another.

To discard the changes, click **Return**.

### 3.2.3 Viewing and Modifying InForm User Details

The InForm User Details page lets you view and modify InForm user details. If the user details are modified, the reason for change is captured and the changes are tracked and audited. You can view the changes made to a particular field by viewing its corresponding audit trails.

To view and modify InForm user details:

- Select Users from the menu bar. On the InForm Users page that appears, select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of InForm users for the selected sponsor company and trial is displayed.
- Click the **Username** link. On the InForm User Details page that appears, the user details for the selected user are displayed.
- Modify the user details.

For more details on how to modify InForm, IRT, and OLX user details, see Section A.3.

**Note:** If you modify the current sponsor company or the trial displayed in the Current Sponsor Company and Trial drop-down lists, the InForm Users page is displayed.

**4.** Enter the reason for modifying the user details in the **Reason for Change** text box and click **Submit**.

**Note:** To cancel the changes made to the InForm user details, click Return.

To view the list of audit trails for a particular field, click the corresponding icon.

#### 3.2.4 Viewing Multiple Association

The Multiple Association icon lets you view the sites associated with the user. You can also request equipment assessment for the site or mark the site as assessed or request immediate provisioning.

To view multiple associations:

- 1. Select **Users** from the menu bar. The InForm Users page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and **Trial** drop-down lists. The list of InForm users for the selected sponsor company and trial is displayed.
- Click the icon in the **Site(s)** column. On the page that appears, the list of users and their associated sites are displayed.

**Note:** The icon is active only for non-ZPF users.

4. Select a user from the Select Username list box and click Go. The list of sites to which the user is associated is displayed.

For more details on multiple associations, see Section A.4.

**Note:** To navigate through the user list, click the **First**, **Previous**, Next, or Last links.

To view a particular page, select the page from the drop-down list.

To view all the users on a single page, select **All** from the drop-down

Click the column name to sort the sites either in the ascending or descending order, based on the column name. On the first click, the sites are sorted in the ascending order. To sort the sites in descending order, click the column name again.

To view the list of InForm users, click **Return**.

### 3.2.5 Associating a User with a Site

You can associate a user with all sites located within a country and time zone. Only sponsor users can be associated with sites within a country and/or a time zone.

To automatically associate a user to a site:

1. Select **Users** from the menu bar. The InForm Users page is displayed.

- 2. Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of InForm users for the selected sponsor company and trial is displayed.
- 3. Click the required sponsor user name link in the grid. The Edit InForm User Details page displays the details of the sponsor user.
- Select Country or Country & TimeZone from the Filter By drop-down list.
- Select the required country or country and time zone from the drop-down list.
- Select the **Automatic Association** check box.
- 7. Enter the reason for modifying the user details in the **Reason for change** text box and click **Submit**.

The sponsor user is automatically associated with all the sites of the selected country and time zone.

#### 3.2.6 Terminating InForm Users

The InForm Users page lets you terminate InForm users. You can also view the list of terminated users.

To terminate InForm users:

- Select **Users** from the menu bar. The InForm Users page appears.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of InForm users for the selected sponsor company and trial is displayed.
- Select the check box corresponding to the user you want to terminate.
- Select **Terminate User** from the **Select** drop-down list.
- Enter the details in the **Comments** check box and click **Go**.
- On the confirmation dialog box that appears, click **OK** to terminate the selected InForm user.

**Note:** To cancel termination of the InForm user, click **Cancel**.

7. Click **OK** on the dialog box that appears on successful termination of the InForm user.

### 3.2.7 Viewing Terminated InForm Users

The InForm Terminated User List page displays the list of terminated InForm users. You can view the user name, first name, last name, and country of the terminated users.

To view terminated InForm users:

- Select **Users** from the menu bar. The InForm Users page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of InForm users for the selected sponsor company and trial is displayed.
- Click the **Terminated User List** link. The InForm Terminated User List page is displayed, which shows the list of terminated users.

For more details on InForm terminated user list, see Section A.65.

**Note:** To go back to the previous page, click **Return**.

#### 3.2.8 Unterminating InForm Users

The Terminated User List page lets you revoke the termination of InForm users. You can either revoke the termination of all users or a particular user.

To unterminate InForm users:

- 1. Select **Users** from the menu bar. The InForm Users page is displayed.
- 2. Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of InForm users for the selected sponsor company and trial is displayed.
- **3.** Click the **Terminated User List** link. The InForm Terminated User List page is displayed.
- **4.** Select the check box corresponding to the user whose termination you want to revoke and click **Unterminate**.
- Click **OK** in the dialog box that appears on revoking the termination of the InForm user.

**Note:** To go back to the previous page, click **Back**.

### 3.2.9 Approving or Rejecting InForm Users

The Approve and Reject options available on the InForm Users page let you approve and reject InForm users. You can approve or reject a user, only if the user status is pending. If user details or association are changed, the approved or rejected status is changed to **Pending** or **Approved** based on the approval rights of the user logged in.

To approve or reject InForm users:

- 1. Select **Users** from the menu bar. The InForm Users page is displayed.
- Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists. The list of InForm users for the selected sponsor company and trial is displayed.
- 3. Select the check box corresponding to the user you want to approve or reject.
- Select **Approve** or **Reject** from the **Select** drop-down list.
  - If you select **Reject**, enter the reason for rejecting the user in the **Comments** text box.
  - If you select **Approve**, the Electronic Signature Affidavit page is displayed. Enter your password and click **Submit**. To cancel approval, click **Cancel**.

The **Approval Status** for the selected user changes based on the action performed.

**5.** Click **Go**.

### 3.2.10 Marking Users for Upload to InForm

The InForm user details created in UMT can be uploaded into the InForm system. The **Load to InForm** option on the InForm Users page lets you mark users for upload.

To mark users for upload to InForm:

- 1. Select **Users** from the menu bar. The InForm Users page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of InForm users for the selected sponsor company and trial is displayed.
- **3.** Select the check box corresponding to the user you want to upload to InForm.
- Select **Mark Upload To InForm** from the **Select** drop-down list.
- Enter the reasons in the **Comments** text box and click **Go**.

#### 3.2.11 Marking Users as Trained

The InForm user created may already be trained or may require training. The InForm Users page lets you mark a user as trained. You can also enter this information while creating or modifying the InForm user details.

To mark a user as trained:

- 1. Select **Users** from the menu bar. The InForm Users page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of InForm users for the selected sponsor company and trial is displayed.
- **3.** Select the check box corresponding to the user you want to mark as trained.
- Select **Mark as Trained** from the **Select** drop-down list.

**Note:** You can mark a user as trained only if the user is approved.

**5.** Enter the reason for marking the user as trained in the **Comments** text box and click Go.

The selected user is marked as trained.

### 3.2.12 Assigning IOL Classes

This feature is only usable for trials for which the Switchoff IOL option (on the Configuration Settings page) is not selected, that is, the UMT-IOL integration is enabled for the trials. For more details on configuration settings, see Chapter 14.

To assign an IOL class to a user:

- Select **Users** from the menu bar. The InForm Users page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of InForm users for the selected sponsor company and trial is displayed.
- **3.** Select the check box corresponding to the user you want to assign the IOL class to.
- Select **Assign IOL Class** from the **Select** drop-down list.
- Enter the reason in the **Comments** text box and click **Go**. The Request Training page is displayed.
- Move the appropriate IOL class into the **Selected** window and click **Submit**.

#### 3.2.13 Sending InForm Account Details

The Send InForm Account Details option lets you send the InForm account details to the selected users in the form of an email. This email contains the study URL of a particular trial. Additionally, emails containing the InForm user name and password are sent by the UMT system. However, these actions take place only if the Upload to **InForm** status is complete and the trial is in a **golive** state.

To send InForm account details:

- Select **Users** from the menu bar. The InForm Users page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of InForm users for the selected sponsor company and trial is displayed.
- 3. Select the check box corresponding to the user you want to send the InForm account details.
- Select **Send InForm Account Details** from the **Select** drop-down list and click **Go**.
- Click **Go** on the confirmation dialog box.

### 3.2.14 Exporting InForm Users

The Export to Excel and Export to File links available on the InForm Users page let you export InForm users. You can export the InForm user details either to an Excel spreadsheet or to a flat file.

To export InForm users:

- 1. Select **Users** from the menu bar. The InForm Users page is displayed.
- 2. Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of InForm users for the selected sponsor company and trial is displayed.
- **3.** Select the check box corresponding to the user you want to export.
- Click the **Export to Excel** or **Export to File** link. On the dialog box that appears, click **Open** to open the file or click **Save** to save the file.

### 3.2.15 Marking Users for Upload to IRT

The Load to IRT option on the InForm Users page lets you mark users for upload to IRT.

To mark users for upload to IRT:

- Select **Users** from the menu bar. The InForm Users page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of InForm users for the selected sponsor company and trial is displayed.
- **3.** Select the check box corresponding to the user you want to upload to IRT.
- Select **Mark Upload To IRT** from the Select drop-down list.
- **5.** Enter the reasons in the **Comments** text box and click **Go**.

### 3.2.16 Marking Users for Load to OLx

The Load to OLx option on the InForm Users page lets you mark users for upload to OLx.

To mark users for upload to OLx:

- Select **Users** from the menu bar. The InForm Users page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of InForm users for the selected sponsor company and trial is displayed.
- **3.** Select the check box corresponding to the user you want to upload to OLx.
- Select Mark Upload To OLx from the Select drop-down list.
- Enter the reasons in the **Comments** text box and click **Go**.

### 3.2.17 Marking Users for Updating User Name in Email Notifications

The Update User Name in Email Notifications option on the InForm Users page lets you mark users for updating user name in email notifications.

To mark users for updating user name in email notifications:

- 1. Select **Users** from the menu bar. The InForm Users page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of InForm users for the selected sponsor company and trial is displayed.
- 3. Select the check box corresponding to the user you want to mark for updating the user name in email notifications.
- 4. Select **Update User Name in Email Notifications** from the **Select** drop-down list.
- Select the corresponding option from the User Name Order drop-down list.
- Click **Go**.

### 3.2.18 Updating Assessment Status

The Update Assessment Status option on the InForm Users page lets you update the assessment status of the InForm users.

To update the assessment status of InForm users:

- 1. Select **Users** from the menu bar. The InForm Users page is displayed.
- 2. Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of InForm users for the selected sponsor company and trial is displayed.
- 3. Select the check box corresponding to the user whose assessment status you want to update.
- 4. Select **Update Assessment Status** from the **Select** drop-down list.
- Enter the reasons in the **Comments** text box and click **Go**. The Update Assessment Status page is displayed.
- **6.** Select the check box corresponding to the status you want to update.
- **7.** Enter the reasons in the **Assessment Summary Box** and click **Update**.

**Note:** Click **Return** to go back to the **InForm Users** page.

#### 3.2.19 Assigning Preferred Study Locale

The Edit Oracle User Details page lets you assign a preferred study locale to InForm users.

To assign a preferred study locale to an InForm user:

- Select **Users** from the menu bar. The InForm Users page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of InForm users for the selected sponsor company and trial is displayed.
- 3. Select the check box corresponding to the user whose preferred study locale you want to update.
- Select **Assign Preferred Study Locale** from the **Select** drop-down list.
- Select the preferred language from the **Language** drop-down list.
- Enter the reason in the **Comments** text box and click **Go**.

**Note:** To cancel the changes made to the user details, click **Return**.

#### 3.3 UMT Users

This section contains the following topics:

- Section 3.3.1, "Viewing the List of UMT Users"
- Section 3.3.2, "Creating UMT Users"
- Section 3.3.3, "Viewing and Modifying UMT User Details"
- Section 3.3.4, "Activating UMT Users"
- Section 3.3.5, "Terminating UMT Users"
- Section 3.3.6, "Viewing Terminated UMT Users"
- Section 3.3.7, "Unterminating UMT Users"
- Section 3.3.8, "Resetting the Password for UMT Users"

### 3.3.1 Viewing the List of UMT Users

The UMT Users page lets you view the list of UMT users and their details. It also lets you filter the UMT users based on the filter criteria.

To view the list of UMT users:

- 1. Select **Users** from the menu bar. On the page that appears, click the **UMT Users**
- On the UMT Users page, select the sponsor company from the Current Sponsor Company drop-down list. The list of UMT users for the selected sponsor company is displayed.
- To filter UMT users, enter the filter criteria and click Find. The list of UMT users that satisfy the specified filter criteria is displayed.

While specifying the filter criteria, you can either use the full name or the first few letters of the name.

For more details on how to filter and view UMT users, see Section A.34.

To clear the filter criteria, click **Clear**.

**Note:** To navigate through the user list, click the **First**, **Previous**, **Next**, or **Last** links.

To view a particular page, select the page from the drop-down list.

To view all the users on a single page, select All from the drop-down

Click the column name link to sort the UMT users in the ascending or descending order, based on the column name. On the first click, the UMT users are sorted in the ascending order. To sort the UMT users in descending order, click the column name link again.

### 3.3.2 Creating UMT Users

The Create UMT User Details page lets you create following UMT users:

- PF users Only PF users (Administrators) can create both PF and sponsor users and associate UMT users with any sponsor. PF users have access to all sponsors.
- Sponsor users A sponsor user can create only sponsor users within that sponsor. Sponsor users can access only their own data and cannot view other sponsor details.

To create UMT users:

- Select **Users** from the menu bar. On the page that appears, click the **UMT Users**
- 2. On the UMT Users page, select the sponsor company from the Current Sponsor Company drop-down list. The list of UMT users for the selected sponsor company is displayed.

**Note:** To create a user for all sponsors, select **All** from the drop-down

- 3. Click the Create UMT User link. The Create UMT User Details page is displayed.
- Enter the user details and assign a role for the user.

For more details on how to create UMT users, see Section A.34.

**Note:** To override, click **OK** in the dialog box that appears. Click Cancel to change the email address.

- **5.** Click **Submit** to save the user details.
- To save the current user details and create another UMT user, click **Submit and** Add Another.
- To discard the changes, click **Return**.

On successful creation of the UMT user, the user name and temporary password are sent to the email address specified on the Create UMT User Details page.

### 3.3.3 Viewing and Modifying UMT User Details

The UMT User Details page lets you view and modify UMT user details. If the user details are modified, the reason for change is captured, and the changes are tracked and audited. You can view the changes made to a particular field by viewing its corresponding audit trails.

To view and modify UMT user details:

- Select **Users** from the menu bar. On the page that appears, click the **UMT Users** link.
- On the UMT Users page, select the sponsor company from the Current Sponsor Company drop-down list. The list of UMT users for the selected sponsor company is displayed.
- **3.** Click the user name link. The UMT User Details page is displayed, which shows the details for the selected user.
- **4.** Modify the user details.

For more details on how to modify UMT user details, see Section A.34.

**Note:** If the sponsor company in the **Current Sponsor Company** drop-down list is changed to another sponsor company, the **UMT Users** page is displayed.

- **5.** Enter the reason for modifying the user details in the **Reason for Change** text box and click **Submit**.
- To cancel the changes made to the UMT user details, click **Return**.
- To view the list of audit trails for a particular field, click the corresponding icon.

### 3.3.4 Activating UMT Users

The UMT Users page also lets you activate UMT users.

To activate UMT users:

- Select **Users** from the menu bar. On the page that appears, click the **UMT Users** link.
- On the UMT Users page, select the sponsor company from the **Current Sponsor** Company drop-down list. The list of UMT users for the selected sponsor company is displayed.
- **3.** Select the check box corresponding to the user you want to activate or inactivate.
- Select **Activate** from the **Select** drop-down list and enter the reason for activating the user in the **Comments** text box. Click **Go**.
- 5. Click **OK** on the dialog box that appears on successful activation of the UMT user.

**Note:** The status for the selected user changes based on the action performed.

### 3.3.5 Terminating UMT Users

The UMT Users page lets you terminate UMT users. You can also view the list of terminated users.

To terminate UMT users:

- Select Users from the menu bar. On the page that appears, click the UMT Users link.
- On the UMT Users page, select the sponsor company from the Current Sponsor Company drop-down list. The list of UMT users for the selected sponsor company is displayed.
- Select the check box corresponding to the user you want to terminate.
- Select **Terminate** from the **Select** drop-down list.
- Enter the reason for terminating the user in the **Comments** text box and click **Go**.
- On the confirmation dialog box that appears, click **OK** to terminate the selected UMT user.

**Note:** To cancel termination of the UMT user, click **Cancel**.

Click **OK** on the dialog box that appears on successful termination of the UMT

### 3.3.6 Viewing Terminated UMT Users

The Terminated User List page displays the list of terminated UMT users. You can view the user name, first name, last name, and country of the terminated users.

To view terminated UMT users:

- Select Users from the menu bar. On the page that appears, click the UMT Users
- On the UMT Users page, select the sponsor company from the Current Sponsor Company drop-down list. The list of UMT users for the selected sponsor company is displayed.
- Click the **Terminated User List** link. The list of terminated users is displayed.

**Note:** To go back to the previous page, click **Return**.

### 3.3.7 Unterminating UMT Users

The Terminated User List page lets you revoke the termination of UMT users. You can either revoke the termination of all users or a particular user.

To unterminate UMT users:

- Select **Users** from the menu bar. On the page that appears, click the **UMT Users** link.
- On the UMT Users page, select the sponsor company from the Current Sponsor Company drop-down list. The list of UMT users for the selected sponsor company is displayed.
- **3.** Click the **Terminated User List** link. The Terminated User List page is displayed.

- **4.** Select the check box corresponding to the user you want to revoke the termination and click Unterminate.
- 5. Click **OK** on the dialog box that appears on revoking the termination of the UMT user.

**Note:** To go back to the previous page, click **Return**.

### 3.3.8 Resetting the Password for UMT Users

The login password for an UMT user can be reset in case the password is blocked or expired.

To reset password for UMT users:

- Select **Users** from the menu bar. On the page that appears, click the **UMT Users** link.
- **2.** On the UMT Users page, select the sponsor company from the **Current Sponsor** Company drop-down list. The list of UMT users for the selected sponsor company is displayed.
- **3.** Select the check box corresponding to the user you want to reset the password.
- Select **Reset Password** from the **Select** drop-down list.
- Enter the reason for resetting the password in the **Comments** text box.
- Click **Go**. Click **OK** on the dialog box that appears.

### 3.3.9 Resending UMT Login Details

The UMT Users page also lets you resend UMT login details to a user.

To resend login details of UMT users:

- Select Users from the menu bar. On the page that appears, click the UMT Users link.
- On the UMT Users page, select the sponsor company from the **Current Sponsor** Company drop-down list. The list of UMT users for the selected sponsor company is displayed.
- 3. Select the check box corresponding to the user whose login details you want to resend.
- Select **Resend UMT Login Details** from the **Select** drop-down list.
- Enter the reason for resending the details in the **Comments** text box.
- Click **Go**.
- 7. Click **OK** on the dialog box that appears.

## 3.4 Oracle Users

This section contains the following topics:

- Section 3.4.1, "Viewing the List of Oracle Users"
- Section 3.4.2, "Creating Oracle Users"
- Section 3.4.3, "Viewing and Modifying Oracle User Details"

#### 3.4.1 Viewing the List of Oracle Users

The Oracle Users page lets you view the list of Oracle users and their details. This page also lets you filter Oracle users based on the filter criteria.

To view the list of Oracle users:

- Select **Users** from the menu bar. On the page that appears, click the **Oracle Users**
- Set the Current Sponsor Company and Trial drop-down lists to Select by default. The list of Oracle users is displayed on the Oracle Users page.
- To filter users, enter the filter criteria and click **Find**. The list of Oracle users that satisfy the specified filter criteria is displayed. For more details on how to filter and view Oracle users, see Section A.64.

**Note:** While specifying the filter criteria, you can either use the full name or part of the name.

**4.** To clear the filter criteria, click **Clear**.

**Note:** To navigate through the user list, click the **First**, **Previous**, Next, or Last links.

To view a particular page, select the page from the drop-down list.

To view all the users on a single page, select **All** from the drop-down

Click the column name link to sort the users either in the ascending or descending order, based on the column name. On the first click, the users are sorted in the ascending order. To sort the users in descending order, click the column name link again.

Oracle users having Modify Oracle Rights can approve or reject users on the Oracle Users list page.

Select Mark upload to InForm from the action item drop-down list. The Sponsor and **Trial** drop-down lists are displayed.

- Set sponsor and trial to All for the user to be associated with all sponsors and trials.
- Set trial to All for the user to be associated with all trials of the selected sponsor.
- Select a sponsor and trial for the user to be associated with only that trial and sponsor.

Use the + icon for associating a site with each user record. The site association popup is displayed on the basis of the site selected.

You can download the Excel template.

### 3.4.2 Creating Oracle Users

The Create Oracle User page lets you create an Oracle user. To create an Oracle user, you must have the Create Oracle User rights. You can create only Oracle user type users.

To create Oracle users:

- 1. Select **Users** from the menu bar. On the page that appears, click the **Oracle Users**
- **2.** Set the **Current Sponsor Company** and **Trial** drop-down lists to **Select** by default. The list of Oracle users is displayed on the Oracle Users page.
- **3.** Click the **Create Oracle User** link. The Create Oracle User Details page is displayed.
- **4.** Enter the Oracle user's details.

For more details on how to create Oracle users, see Section A.40.

- **5.** On the Create Oracle User Details page, associate the user with a sponsor and trial.
  - To associate a user with all sponsors and trials, select **All** from the **Select Sponsor** and **Select Trial** drop-down lists.
  - To associate a user with one sponsor and all trials, select the sponsor from the Select Sponsor drop-down list, and select All from the Select Trial drop-down list.
  - To associate a user with all sponsors and one trial, select All from the Select **Sponsor** drop-down list, and select a trial from the **Select Trial** drop-down list.

**Note:** To save the current Oracle user details and create another Oracle user, click Submit and Add Another.

To discard the changes, click **Return**.

### 3.4.3 Viewing and Modifying Oracle User Details

The PF User Edit page lets you view and modify the PF user details. If the user details are modified, the reason for change is captured and the changes are tracked and audited. You can view the changes made to a particular field by viewing its corresponding audit trails.

To view and modify PF user details:

Select **Users** from the menu. On that page, click the **Oracle Users** link. The list of Oracle Users is displayed.

**Note:** The **Sponsor** and **Trial** drop-down lists should be set by default to Select.

- 2. Click the required username link in the grid. The Edit Oracle User Details page appears that displays the user details for the selected user.
- **3.** Modify the user details as required. For more details on how to create Oracle users, see Section A.40.
- **4.** Enter the reason for modifying the user details in the **Reason for change** text box and click Submit.
- **5.** On the Edit Oracle User Details page, associate the user to sponsor and trial.

- If sponsor and trial are set to All, the user is associated with all sponsors and
- If trial is set to All and one sponsor is selected, the user is associated with all trials of the selected sponsor.
- If one sponsor and trial are selected, the user is associated only with that selected trial and sponsor.

**Note:** To cancel the changes made to the user details, click **Return**.

To view the list of audit trails for a particular field, click the corresponding icon.

#### 3.5 Global Users

A Global user is a user managed by Oracle Identity Management suite. You can assign Global user to multiple InForm trials and applications within a sponsor or a CRO. A Global user that has access to applications for multiple sponsors or CROs will have a unique identity per sponsor or CRO. You can update the Global users' details, assign them to trials, or globally de-provision.

This section contains the following topics:

- Section 3.5.1, "Viewing the List of Global Users"
- Section 3.5.2, "Creating Global Users"
- Section 3.5.3, "Assigning a Product"
- Section 3.5.4, "Viewing and Modifying Global User Details"
- Section 3.5.5, "Terminating a Global User"
- Section 3.5.6, "Viewing the Terminated User List"
- Section 3.5.7, "Unterminating Global Users"

**Note:** Global Users feature is enabled only if Switchoff Global User option (on the Configuration Settings page) is not selected.

#### 3.5.1 Viewing the List of Global Users

The Global Users page lets you view the list of Global users and their details. It lets you filter the Global users based on the filter criteria. You can also associate the product to the user here.

To view the list of Global users:

- Select Users from the menu bar. On the page that appears, click the Global Users link.
- On the Global Users page, select the sponsor company from the Current Sponsor **Company** drop-down list. The list of Global users for the selected sponsor company is displayed.
- To filter users, enter the filter criteria and click Find. The list of Global users that satisfy the specified filter criteria is displayed.

For more details on how to filter and view Global Users, see Section A.5.

**Note:** To clear the filter criteria, click **Clear**.

While specifying the filter criteria, you can either use the full name or the first few letters of the name.

To navigate through the user list, click the **First**, **Previous**, **Next**, or Last links.

To view a particular page, select the page from the drop-down list.

To view all the users on a single page, select **All** from the drop-down

Click the column name link to sort the Global users either in the ascending or descending order, based on the column name. On the first click, the users are sorted in the ascending order. If you want to sort the users in descending order, click the column name link again.

A new link **Import** on **Global User List** page is displayed. On clicking this menu, a new page **Import** is available.

You can download the Excel template and use it to perform bulk import of Global Users.

#### 3.5.2 Creating Global Users

The Create Global User page lets you create a global user. To create a global user, you must have the Manage Global User rights. You can create two types of global users, that is site users and sponsor users.

To create Global users:

- Select **Users** from the menu bar.
- On the Global Users page, select the sponsor company from the Current Sponsor **Company** drop-down list.
- 3. Click the Global Users link. The list of users for the selected sponsor company is displayed.
- **4.** Click the **Create Global User** link. The Create Global User page is displayed.
- Enter the global user details.
  - For more details on how to create Global Users, see Section A.6.
- 6. To save the current Global User details and create another, click Submit and Add Another.

**Note:** To create a Global User, the values entered in the **UserName**, First Name, Last Name, and E-mail ID fields must be unique.

- If you try creating a Global user with duplicate values in the First Name, Last Name, User Name, or Email Address fields, an error message *User already exists* is displayed and the user is not created.
- If you try creating a Global user with duplicate values in the **First** Name, Last Name, and Email ID fields, with a different User Name, an error message First Name, Last Name and Email ID combination already exists in the sponsor is displayed and the user is not created.

To discard the changes, click **Return**.

#### 3.5.3 Assigning a Product

The Assign Product action item on Global Users page lets you assign global users to a product.

To assign global users to a product:

- Select **Users** from the menu bar. On the page that appears, click the Global User link.
- On the Global Users page, select the sponsor company from the Current Sponsor Company drop-down list. The list of Global Users for the selected sponsor company is displayed.
- Select the check boxes corresponding to the user you want to assign a product and click Assign Product.
- Select the product type from the **Product** drop-down list.
- Select the trial version from the **Trial Version** drop-down list that appears.
- Select the trial from the **Trial** drop-down list that appears.

The trial gets populated based on the selected trial version and product. On selecting the trial, the user information associated with that trial is displayed.

**Note:** You can add new users to the selected product and can also edit existing users.

IRT roles are displayed on selecting only the IRT trial.

InForm roles are displayed on selecting only InForm trial.

Both IRT and InForm roles are displayed for joint IRT and InForm trials.

- Select the InForm Role, IRT Role, User name in Email Notification, Preferred study locale, Product Locale, Load To InForm, and Load To IRT details from their respective drop-down lists.
- To associate a site with a user:
  - Click the + icon. The site association list based on the trial selected is displayed.

- **b.** Select the site you want to associate with a user and use the navigational keys to the **Selected** text box.
- **c.** Click **Save** and click **OK** on the confirmation dialog box.
- Enter the reasons in the **Comments** text box and click **Submit**.
- **10.** Click **OK** on the confirmation dialog box that appears.
- **11.** Click **Return** to go back to the Global Users page.

#### 3.5.4 Viewing and Modifying Global User Details

The Global User page lets you view and modify Global user details. If the user details are modified, the reason for change is captured and the changes are tracked and audited. You can view the changes made to a particular field by viewing its corresponding audit trails.

To view and modify Global user details:

- Select **Users** from the menu bar. Select the sponsor company and click the **Global Users** tab. The list of Global users for that selected sponsor company is displayed.
- **2.** Click the **Username** link in the grid. The **Global User Details** page is displayed, which shows the user details for the selected user.
- **3.** Modify the user details.
  - For more details on how to filter and view Global Users, see Section A.7.
  - On changing the current sponsor company in the drop-down list, the users belonging to that sponsor are displayed.
- Enter the reason for modifying the user details in the **Reason for Change** text box and click Submit.

When editing a Global user, ensure the User Name, First Name, Last Name, and E-mail ID are unique.

**Note:** If a user is assigned to trials and the Global User record is modified, the changes are reflected across all trials the user is associated to.

**Note:** If you try to edit a Global user record with already existing First Name, Last Name, Email ID and User Name, an error message **User already exists** is displayed on clicking **Submit**.

If you try to edit a Global user record with an already existing First Name, Last Name, and Email ID, which already exists but with a different User Name, an error message First Name, Last Name and **Email Id combination already exists in the sponsor** is displayed on clicking **Submit**.

If you try to edit a Global user record with a different First Name, Last Name, and Email ID, but with an existing User Name, an error message User Name already Exists is displayed on clicking Submit.

- **5.** To cancel the changes made to the user details, click **Return**.
- To view the list of audit trails for a particular field, click the corresponding icon.

#### 3.5.5 Terminating a Global User

The Global Users page lets you terminate a global user.

**Note:** Terminating a Global User will terminate the user across all products the user is assigned to.

To terminate a global user:

- 1. Select **Users** from the menu bar. On the page that appears, click the **Global User**
- 2. On the Global Users page, select the sponsor company from the Current Sponsor Company drop-down list. The list of Global Users for the selected sponsor company is displayed.
- Select the check boxes corresponding to the user you want to terminate and select **Terminate User** from the **Select** drop-down list.
- Enter the reasons in the **Comments** text box and click **Submit**.
- Click **OK** on the confirmation dialog box that appears.

#### 3.5.6 Viewing the Terminated User List

The Terminated User List page displays the list of terminated global users. You can view the user name, first name, last name, country, and email address of the terminated users.

To view terminated Global users:

- Select **Users** from the menu bar. The Global Users page is displayed.
- Select the sponsor company from the **Current Sponsor Company** drop-down list. The list of Global users for the selected sponsor company is displayed.
- Click the **Terminated User List** link. The Global User Terminated List page is displayed, which shows the list of terminated users.
- To go back to the previous page, click **Return**.

#### 3.5.7 Unterminating Global Users

The Terminated User List page lets you revoke the termination of Global users. You can either revoke the termination of all users or a particular user.

To unterminate Global users:

- 1. Select **Users** from the menu bar. The Global Users page is displayed.
- Select the sponsor company from the Current Sponsor Company drop-down list. The list of Global users for the selected sponsor company is displayed.
- **3.** Click the **Terminated User List** link. The Global User Terminated List page is displayed.
- 4. Select the check box corresponding to the user whose termination you want to revoke and click Unterminate.
- 5. Click **OK** in the dialog box that appears on revoking the termination of the InForm
- To go back to the previous page, click **Back**.

# 3.6 Merging Duplicate Users

You may have the same user registered with a different user name for a different trial under the same sponsor. This results in many duplicate users. The Merge Duplicate Users page lets you merge these duplicate users under one master user. After you select one record as the master user, the others are automatically terminated.

To view and merge duplicate users:

- Select Users from the menu bar. On the page that appears, select the sponsor company from the **Current Sponsor Company** drop-down list.
- Click Merge Duplicate Users.
- To filter duplicate users, enter the filter criteria and click **Find**. The list of users that satisfy the specified filter criteria is displayed.
- 4. Select the check boxes corresponding to the users you want to merge and click Merge.
- **5.** The Merge Duplicate users page is displayed.
- Select the record you want as the Master User.
- 7. Select the check boxes corresponding to the users you want to merge. Select Merge **Selected Users** from the **Select** drop-down list.
- Enter the reasons for change in the **Comments** text box. Click **Save** to merge the changes.
- **9.** Click **OK** on the dialog box that appears on successfully merging the duplicate records.
- **10.** Click **Return** to go back to the Merge Duplicate Users page.

**Note:** Click **Group Duplicate Users** to display possible duplicate users without entering any filter criteria.

# 3.7 Linking Users

The Link Users functionality also lets you manage duplicate users by linking one or more users with similar details. However, after the linking process is complete, the remaining users are not automatically terminated.

To view and link duplicate users:

- Select **Users** from the menu bar. On the page that appears, select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists.
- 2. Click Link Users.
- The list of users that satisfy the specified linking criteria is displayed.
- Click the **Link User** link corresponding to the user you want to link to another user. The Updating Link Users page is displayed.
- 5. Select the check boxes corresponding to the user you want to link the selected user to and enter the reasons for change in the **Comments** text-box.
- **6.** Click **Update** to link the users.
- 7. Click **OK** on the dialog box that appears on successfully linking the duplicate users.

**8.** Click **Return** to go back to the Link Users page.

# **Managing Trials**

This chapter contains the following sections:

- Section 4.1, "Viewing the List of Trials"
- Section 4.2, "Creating Trials"
- Section 4.3, "Viewing and Modifying Trial Details"
- Section 4.4, "Viewing and Resolving Duplicate Items"
- Section 4.5, "Bulk Copying"
- Section 4.6, "Selective Copying"
- Section 4.7, "Archiving Trials"
- Section 4.8, "Viewing Archived Trials"
- Section 4.9, "Exporting Trial Details"
- Section 4.10, "Exporting Trials"
- Section 4.11, "Importing Trials"
- Section 4.12, "Generating InForm XML"

# 4.1 Viewing the List of Trials

The List of Trials page lets you view the list of trials and their details. It also lets you filter the trials based on the filter criteria.

To view the list of trials:

- Select **Trials** from the menu bar. The List of Trials page is displayed.
- Select the sponsor company from the **Current Sponsor Company** drop-down list. The list of trials for the selected sponsor company is displayed.
- To filter trials, enter the filter criteria in the filter section and click Find. The list of trials that satisfy the specified filter criteria is displayed.
  - When you specify the filter criteria, you can use the full name or part of the name.
  - For more details on how to filter and view trials, see Section A.66.
- To clear the filter criteria, click **Clear**.

**Note:** To navigate through the trial list, click the **First**, **Previous**, Next, or Last links.

To view a particular page, select the page from the drop-down list.

To view all the trials on a single page, select **All** from the drop-down

Click the column name link to sort the trials in the ascending or descending order, based on the column name. On the first click, the trials are sorted in the ascending order. To sort the trials in descending order, click the column name link again.

# 4.2 Creating Trials

The Create Trial Details page lets you create a main trial, training trial, and UAT trial. Enter the trial and association details to create a trial. You can also copy the sites, roles, groups, and configuration settings from another trial. You cannot create production trials.

To create trials:

- Select **Trials** from the menu bar. The List of Trials page is displayed.
- Select the sponsor company from the **Current Sponsor Company** drop-down list. The list of trials for the selected sponsor company is displayed.
- Click the **Create Trial** link. The Create Trial Details page is displayed.
- **4.** Enter the trial details.

For more details on how to create trials, see Section A.41.

- To copy the details of an existing trial, click **Copy From**. In the confirmation dialog box that appears, click **OK** to continue. In the pop-up window that appears, select the sites, roles, groups, users, and configuration that you want to copy and click Copy.
- **6.** Click **Submit** to save the trial details.

**Note:** To save the current trial details and create another trial, click Submit and Add Another.

To discard the changes, click **Cancel**.

## 4.3 Viewing and Modifying Trial Details

The Trial Details page lets you view and modify the trial details. If the trial details are modified, the reason for change is captured and the changes are tracked and audited. You can view the changes made to a particular field by viewing its corresponding audit trails.

To view and modify trial details:

- Select **Trials** from the menu bar. The List of Trials page is displayed.
- Select the sponsor company from the Current Sponsor Company drop-down list. The list of trials for the selected sponsor company is displayed.
- 3. Click the trial name link in the grid. The Trial Details page is displayed, which shows the selected trial details.

4. Modify the trial details.

For more details on how to modify trial details, see Section A.41.

**Note:** If you modify the current sponsor company displayed in the Current Sponsor Company drop-down list, the List of Trials page is displayed.

- 5. Enter the reason for modifying the trial details in the **Reason for Change** text box and click Save.
- To cancel the changes made to the trial details, click **Cancel**.
- **7.** To view the list of audit trails for a particular field, click the corresponding icon.

# 4.4 Viewing and Resolving Duplicate Items

When you import trials, records or trial items may be duplicated. The List of Duplicate Items page displays the list of duplicate items and lets you resolve the duplicate trial items.

To view and resolve duplicate items:

- Select **Trials** from the menu bar. The List of Trials page is displayed.
- Select the sponsor company from the **Current Sponsor Company** drop-down list. The list of trials for the selected sponsor company is displayed.
- 3. Click the icon corresponding to a trial.
  - The List of Duplicate Items page is displayed, which shows the list of duplicate trial items.
- Select the check box corresponding to the item you want to resolve and click Resolve.
- On the confirmation dialog box that appears, select **OK**. All unchecked items are deleted.

## 4.5 Bulk Copying

You can copy all or selected modules entirely (such as sites, users, and so on) from a trial to another.

To bulk copy trial details:

- Select **Trials** from the menu bar. The List of Trials page is displayed.
- Select the sponsor company from the Current Sponsor Company drop-down list. The list of trials for the selected sponsor company is displayed.
- 3. Click the icon corresponding to a trial.
- **4.** On the page that appears, click the **Bulk Copy** link. The Bulk Copy page is displayed.

For more details on selective trials copy, see Section A.22.

- **5.** Select the source trial from the **Source Trial** drop-down list.
- **6.** Select the check boxes of the modules you want to copy.
- **7.** Click **Submit** to create a copy of the trial.

# 4.6 Selective Copying

You can selectively copy trial details from a module onto another trial.

To copy selective trial details:

- Select **Trials** from the menu bar. The List of Trials page is displayed.
- Select the sponsor company from the **Current Sponsor Company** drop-down list. The list of trials for the selected sponsor company is displayed.
- Click the icon corresponding to a trial. The Selective Copy page is displayed.
- Select the source trial and type of detail from the **Source Trial** and **Select Type** drop-down lists. The Selective Copy page displays the details according to the selected type in the **Available** text box.

For more details on selective trials copy, see Section A.29.

**Note:** Depending on the details type you select from the **Select Type** drop-down list, the **User Management Tool** gives you an option to copy additional details. For instance, if you select **Roles**, you can copy the details of all associated sponsor users and associated site users, in addition to the regular details of the roles.

**5.** Use >> or > to move all or selected details to the **Selected** field.

**Note:** Press and hold the **Ctrl** key to select multiple choices.

Use the << or < button to move all or selected details back to the Available field.

Click **Submit** to create a copy of the trial.

# 4.7 Archiving Trials

The Archive option available on the List of Trials page lets you archive inactive trials.

To archive trials:

- Select **Trials** from the menu bar. The List of Trials page is displayed.
- Select the sponsor company from the **Current Sponsor Company** drop-down list. The list of trials for the selected sponsor company is displayed.
- Select the check box corresponding to the trial you want to archive.
- Select **Archive** from the **Select** drop-down list.
- Enter the reason for archival in the **Comments** text box and click **Go**.
- To view the archived sponsors, click the **View Archive of Trials** link.

# 4.8 Viewing Archived Trials

The List of Archived Trials page lets you view the archived trials. You can view the trial name, reference, protocol number, therapeutic area, and status. This page also displays the date and time of archival.

To view archived trials:

- 1. Select **Trials** from the menu bar. The List of Trials page is displayed.
- Select the sponsor company from the Current Sponsor Company drop-down list. The list of trials for the selected sponsor company is displayed.
- Click the **Archived Trials** link. The List of Archived Trials page is displayed, which shows the list of archived trials.

For more details on archived trials, see Section A.67.

**Note:** To navigate through the trial list, click the **First**, **Previous**, **Next**, or **Last** links.

To view a particular page, select the page from the drop-down list.

To view all the trials on a single page, select All from the drop-down list.

Click the column name link to sort the trials in the ascending or descending order, based on the column name. On the first click, the trials are sorted in the ascending order. To sort the trials in descending order, click the column name link again.

To go back to the list of trials, click **Back**.

# 4.9 Exporting Trial Details

The Export to Excel and Export to File links available on the List of Trials page let you export trial details. You can export the trial details either to an Excel spreadsheet or to a flat file.

To export trial details:

- Select **Trials** from the menu bar. The List of Trials page is displayed.
- Select the sponsor company from the **Current Sponsor Company** drop-down list. The list of trials for the selected sponsor company is displayed.
- **3.** Select the check box corresponding to the trial you want to export.
- Click the **Export to Excel** or **Export to File** link. On the dialog box that appears, click **Open** to open the file or click **Save** to save the file.

## 4.10 Exporting Trials

Clicking Export on the List of Trials page lets you export trials and their associated sites, site users, sponsor users, roles, and groups.

To export trials:

- 1. Select **Trials** from the menu bar. The List of Trials page is displayed.
- Select the sponsor company from the **Current Sponsor Company** drop-down list. The list of trials for the selected sponsor company is displayed.
- **3.** Click **Export**. The Export page is displayed.
- Select the trial name from the **Trial Name** drop-down list.
- Select the modules to be exported by clicking the corresponding check boxes.

- **6.** Click the **Export to Excel** or **Export to File** links to export the file to an Excel spreadsheet or to a flat file or Export IRT CSV (which exports only the IRT trial in CSV format).
- **7.** To cancel the export, click **Return**.

# 4.11 Importing Trials

Clicking Import on the List of Trials page lets you import trial details and their associated sites, site users, sponsor users, roles, and groups. This facility is available only to users having the Import Data right.

To import trials:

- 1. Select **Trials** from the menu bar. The List of Trials page is displayed.
- Select the sponsor company from the Current Sponsor Company drop-down list. The list of trials for the selected sponsor company is displayed.
- Click **Import**. The Import page is displayed.
- **4.** Enter the path of the file in the **Filename** text box or click **Browse** to select the path of the file.

**Note:** The selected path is copied in the **Filename** text box.

- **5.** Select the trial name from the **Trial Name** drop-down list.
- **6.** Select the modules to be imported by clicking the corresponding check boxes.
- Select the import template from the Excel Template For All Products and Version drop-down list.

**Note:** Composite Template is the default import template.

- 8. Click Validate and Import.
- To cancel import, click **Cancel**.

For Import Error Information and Trouble shooting, see Section A.47.

## 4.12 Generating InForm XML

You can export the details of a trial to an XML file. However, you can export the details of only one trial to an XML file at a time.

To generate InForm XML:

- Select **Trials** from the menu bar. The List of Trials page is displayed.
- 2. Select the sponsor company from the Current Sponsor Company drop-down list. The list of trials for the selected sponsor company is displayed.
- **3.** Select the check box corresponding to the trial you want to generate.
- Click the **Generate InFormXML** link. On the dialog box that appears, click **Open** to open the file or click **Save** to save the file.

# **Managing Sites**

This chapter contains the following topics:

- Section 5.1, "Viewing the List of Sites"
- Section 5.2, "Creating Sites"
- Section 5.3, "Viewing and Modifying Site Details"
- Section 5.4, "Approving or Rejecting Sites"
- Section 5.5, "Marking Sites as Uploaded to InForm"
- Section 5.6, "Marking Sites as Not Participating"
- Section 5.7, "Viewing Not Participating Sites"
- Section 5.8, "Marking a Not Participating Site as Participating"
- Section 5.9, "Assigning or Updating the Study Version"
- Section 5.10, "Exporting Sites"
- Section 5.11, "Marking Upload to IRT"
- Section 5.12, "Updating Assessment Status for a Site"
- Section 5.13, "Sending Assessment Email"
- Section 5.14, "Stopping Assessment Process"
- Section 5.15, "Assigning Preferred Study Locale"

## 5.1 Viewing the List of Sites

The List of Sites page lets you view the list of sites and site details. This page also lets you filter the sites based on the filter criteria.

To view the list of sites:

- Select **Sites** from the menu bar. The List of Sites page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of sites for the selected sponsor company and trial is displayed.
- To filter the sites, enter the filter criteria in the filter section and click **Find**. The list of sites that satisfy the specified filter criteria is displayed.
  - While specifying filter criteria, you can use the full name or part of the name.
  - For more details on how to filter and view sites, see Section A.31.

**4.** To clear the filter criteria, click **Clear**.

Note: To navigate through the site list, click the First, Previous, Next, or Last links.

To view a particular page, select the page from the drop-down list.

To view all the sites on a single page, select All from the drop-down list.

Click the column name link to sort the sites in the ascending or descending order, based on the column name. On the first click, the sites are sorted in the ascending order. To sort the sites in descending order, click the column name link again.

## 5.2 Creating Sites

The Create Site Details page lets you create sites. Enter the site and user association details to create a new site.

To create sites:

- Select **Sites** from the menu bar. The List of Sites page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of sites for the selected sponsor company and trial is displayed.
- **3.** Click the **Create Site** link. The Create Site Details page is displayed.
- **4.** Enter the site and user association details.

For more details on how to create sites, see Section A.45.

- **5.** Click **Submit** to save the details.
- **6.** To save the current site details and create another site, click **Submit and Add** Another.
- **7.** To discard the changes, click **Return**.

## 5.3 Viewing and Modifying Site Details

The Site Details page lets you view and modify site details. When the site details are modified, the reason for change is captured and the changes are tracked and audited. You can view the changes made to a particular field by viewing its corresponding audit trail.

To view and modify site details:

- Select **Sites** from the menu bar. The List of Sites page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of sites for the selected sponsor company and trial is displayed.
- 3. Click the site name link. The Site Details page is displayed, which shows the selected site details.
- **4.** Modify the site details.

For more details on how to modify site details, see Section A.46.

**Note:** If you modify the current sponsor company or the trial displayed in the Current Sponsor Company and Trial drop-down lists, the **List of Sites** page is displayed.

- Enter the reason for modifying the site details in the **Reason for Change** text box and click Submit.
- To cancel the changes made to the site details, click **Return**.
- To view the list of audit trails for a particular field, click the corresponding icon.

# 5.4 Approving or Rejecting Sites

The List of Sites page lets you approve and reject sites. A site must be approved before you carry out any clinical trials. Once you approve a site, you cannot approve it again unless the site details are modified. You can approve or reject sites depending on your access rights.

To approve or reject sites:

- Select **Sites** from the menu bar. The List of Sites page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of sites for the selected sponsor company and trial is displayed.
- Select the check box corresponding to the site you want to approve or reject.
- Select Approve or Reject from the Select drop-down list. If you select Reject, enter the reason for rejection in the **Comments** text box.
- Click **Go**.
- If you select **Approve**, the **Electronic Signature Affidavit** page is displayed. Enter your password and click **Submit**. To cancel approval, click **Cancel**.

The **Status** for the selected site changes based on the action performed.

# 5.5 Marking Sites as Uploaded to InForm

Site information is uploaded to the InForm system if the applicable sites are marked as Uploaded to InForm in UMT.

To mark a site as uploaded to InForm:

- Select **Sites** from the menu bar. The List of Sites page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of sites for the selected sponsor company and trial is displayed.

**Note:** You can also search for the site you want to mark by specifying at least one search criteria.

- Select the check box corresponding to the site you want to mark as uploaded to InForm.
- Select Mark Upload to InForm from the Select drop-down list.

- **5.** Enter the reasons in the **Comments** text box and click **Go**.
- Click **OK** on the confirmation dialog box.

# 5.6 Marking Sites as Not Participating

Sites which no longer participate in a study can be marked as not participating, making them inactive in the study. The site user accounts associated only with the non-participating site are marked as terminated.

To mark sites as non-participating:

- Select **Sites** from the menu bar. The List of Sites page is displayed.
- Select the sponsor company and trial from the **Current Sponsor Company** and Trial drop-down lists. The list of sites for the selected sponsor company and trial is displayed.

**Note:** You can also search for the site you want to mark by specifying at least one search criteria.

- 3. Select the check box corresponding to the site you want to mark as non participating.
- 4. Select Mark as Not Participating from the Select drop-down list and enter your comments in the **Comments** text box.
- **5.** Click **Go**.
- **6.** Click **OK** on the confirmation dialog box.

# 5.7 Viewing Not Participating Sites

You can view the list of not participating sites under the trial of a sponsor company.

To view not participating sites:

- 1. Select **Sites** from the menu bar. The List of Sites page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of sites for the selected sponsor company and trial is displayed.
- 3. Click the View Not Participating Sites link. The List of Not Participating Sites page appears.
- The list of not participating sites for the selected sponsor company and trial is displayed.

**Note:** To view not participating sites from a different trial of the same sponsor company, select the trial from the Trial drop-down list.

To view not participating sites for a different sponsor company, select the sponsor company and the trial from the **Current Sponsor Company** and **Trial** lists.

To view the list of sites again, click **Back**.

## 5.8 Marking a Not Participating Site as Participating

You can mark a not participating site as participating again. Users associated with such sites are no longer considered terminated.

To mark a not participating site as participating:

- **1.** Open the list of not participating sites.
  - The **List of Not Participating Sites** page is displayed.
- 2. Select the check box corresponding to the site you want to mark as participating.
- Click Mark as Participating.
- Click **OK** on the confirmation dialog box.

# 5.9 Assigning or Updating the Study Version

You can assign a study version to a site or update the study version after you have modified a site.

To assign or update study version:

- Select **Sites** from the menu bar. The List of Sites page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of sites for the selected sponsor company and trial is displayed.

**Note:** You can also search for the site whose study version you want to update by specifying at least one search criteria.

- 3. Select the check box corresponding to the site you want to mark as assigned or update study version.
- Select **Assign study version** from the **Select** drop-down list.
- Select the version from the **study version** drop-down list.
- Enter the reasons in the Comments text box and click **Go**.
- Click **OK** on the confirmation dialog box.

# 5.10 Exporting Sites

The Export to Excel and Export to File links available on the List of Sites page let you export site details to an Excel spreadsheet or a flat file.

To export sites:

- Select **Sites** from the menu bar. The List of Sites page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of sites for the selected sponsor company and trial is displayed.
- **3.** Select the check box corresponding to the site you want to export.
- Click the **Export to Excel** or **Export to File** link.
- On the dialog box that appears, click **Open** to open the file or click **Save** to save the file.

# 5.11 Marking Upload to IRT

The List of Sites page lets you mark sites as uploaded to IRT.

To mark a site as uploaded to IRT:

- 1. Select **Sites** from the menu bar. The List of Sites page is displayed.
- Select the sponsor company and trial from the **Current Sponsor Company** and Trial drop-down lists. The list of sites for the selected sponsor company and trial is displayed.

**Note:** You can also search for the site you want to mark by specifying at least one search criteria.

- 3. Select the check box corresponding to the site you want to mark as uploaded to IRT.
- **4.** Select Mark Upload to IRT from the Select drop-down list.
- Click **Go**.
- **6.** Click **OK** on the confirmation dialog box.

## 5.12 Updating Assessment Status for a Site

The List of Sites page also lets you update the assessment status for a site.

To update the assessment status for a site:

- 1. Select **Sites** from the menu bar. The List of Sites page is displayed.
- **2.** Select the sponsor company and trial from the **Current Sponsor Company** and Trial drop-down lists. The list of sites for the selected sponsor company and trial is displayed.

**Note:** You can also search for the site you want to mark by specifying at least one search criteria.

- 3. Select the check box corresponding to the site whose assessment status you want to update.
- **4.** Select **Update Assessment Status** from the **Select** drop-down list.
- Enter the reasons in the **Comments** text box and click **Go**.
- Click **OK** on the confirmation dialog box.

# 5.13 Sending Assessment Email

The List of Sites page lets you send an assessment email for a site.

To send an assessment email for a site:

- 1. Select **Sites** from the menu bar. The List of Sites page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of sites for the selected sponsor company and trial is displayed.

**Note:** You can also search for the site you want to mark by specifying at least one search criteria.

- 3. Select the check box corresponding to the site for which you want to send an assessment email.
- **4.** Select **Send Assessment Email** from the **Select** drop-down list.
- Enter the reasons in the **Comments** text box and click **Go**.
- Click **OK** on the confirmation dialog box.

# **5.14 Stopping Assessment Process**

The List of Sites page lets you stop the assessment process for a site.

To stop the assessment process for a site:

- 1. Select **Sites** from the menu bar. The List of Sites page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and **Trial** drop-down lists. The list of sites for the selected sponsor company and trial is displayed.

**Note:** You can also search for the site you want to mark by specifying at least one search criteria.

- 3. Select the check box corresponding to the site for which you want to stop the assessment process.
- **4.** Select **Stop Assessment Process** from the **Select** drop-down list.
- Enter the reasons in the **Comments** text box and click **Go**.
- Click **OK** on the confirmation dialog box.

# 5.15 Assigning Preferred Study Locale

The List of Sites page lets you assign a preferred study locale for a site.

To assign a preferred study locale for a site:

- 1. Select **Sites** from the menu bar. The List of Sites page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of sites for the selected sponsor company and trial is displayed.

**Note:** You can also search for the site you want to mark by specifying at least one search criteria.

- 3. Select the check box corresponding to the site for which you want to assign a preferred study locale.
- 4. Select Assign Preferred Study Locale from the Select drop-down list.
- Enter the reasons in the **Comments** text box and click **Go**.

 $\textbf{6.} \quad \text{Click } \textbf{OK} \text{ on the confirmation dialog box.}$ 

# **Managing Roles**

This chapter contains the following topics:

- Section 6.1, "Managing InForm Roles"
- Section 6.2, "Managing UMT Roles"
- Section 6.3, "Managing IRT Roles"

# 6.1 Managing InForm Roles

This section describes the following:

- Section 6.1.1, "Viewing the List of InForm Roles"
- Section 6.1.2, "Creating InForm Roles"
- Section 6.1.3, "Viewing and Modifying InForm Role Details"
- Section 6.1.4, "Viewing and Modifying InForm User-Role Associations"
- Section 6.1.5, "Setting the Display Override Option"
- Section 6.1.6, "Approving or Rejecting InForm Roles"
- Section 6.1.7, "Transferring InForm Roles"

#### 6.1.1 Viewing the List of InForm Roles

The InForm Roles page lets you view the list of InForm roles and its details. It also lets you filter roles based on the filter criteria.

To view the list of InForm roles:

- 1. Select **Roles** from the menu bar. The InForm Roles page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of InForm roles for the selected sponsor company and trial is displayed.

**Note:** The trial selected must be an InForm trial else the InForm users tab is not displayed.

3. To filter roles, enter the filter criteria and click Find. The list of InForm roles that satisfy the specified filter criteria is displayed.

To specify the filter criteria, use the full name or the first few letters of the name.

For more details on how to filter and view InForm roles, see Section A.8.

**4.** To clear the filter criteria, click **Clear**.

**Note:** To navigate through the InForm roles list, click the **First**, **Previous**, **Next**, or **Last** links.

To view a particular page, select the page from the drop-down list.

To view all the InForm roles on a single page, select All from the drop-down list.

Click the column name link to sort the InForm roles in the ascending or descending order, based on the column name. On the first click, the InForm roles are sorted in the ascending order. To sort the InForm roles in descending order, click the column name link again.

#### 6.1.2 Creating InForm Roles

The Create InForm Role page lets you create a role and assign rights under various categories such as User administration, CRF rights, Case Book rights, Query rights, Rule rights, and System Administration rights. You can assign the roles to each user, which defines the access level of the account to the system.

To create InForm roles:

- Select **Roles** from the menu bar. The InForm Roles page is displayed.
- Select the sponsor company and trial from the **Current Sponsor Company** and Trial drop-down lists. The list of InForm roles for the selected sponsor company and trial is displayed.
- **3.** Click the **Create InForm Role** link. The Create InForm Role page is displayed.
- Enter the InForm role details. You can select the role type as Site, Sponsor, or both. For more details on how to create InForm roles, see Section A.9.
- Click **Submit** to save the details.

**Note:** To save the current InForm role details and create another InForm role, click Submit and Add Another.

To go back to the List of InForm Roles page, click **Return**.

#### 6.1.3 Viewing and Modifying InForm Role Details

The InForm Role Details page lets you view the rights associated with a role and modify the details, if required. When role details are modified, the reason for change is captured and the changes are tracked and audited. You can view the changes made to a particular field by viewing its corresponding audit trails.

To view and modify InForm role details:

- Select **Roles** from the menu. On the InForm Roles page that appears, select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of InForm roles for the selected sponsor company and trial is displayed.
- 2. Click the role name link within the grid. On the InForm Roles page that appears, the details for the selected InForm role are displayed.
- Modify the InForm role details.

The Associate users icon beside the Roles field displays user-role association. The icon is displayed only when a user is associated to a role.

For more details on how to modify the InForm role details, see Section A.10.

**Note:** If you modify the current sponsor company or the trial displayed in the Current Sponsor Company and Trial drop-down lists, the InForm Roles page is displayed.

- Enter the reason for modifying the details of the InForm role in the **Reason For Change** text box and click **Go**.
- To cancel the changes made to the trial details, click **Cancel**.
- To view the list of audit trails for a particular field, click the corresponding icon.

#### 6.1.4 Viewing and Modifying InForm User-Role Associations

The User-Role Association page lets you view the list of users associated with the selected role. You can also add or remove users for the selected role.

To view and modify InForm user-role association:

- Select **Roles** from the menu bar. The InForm Roles page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of InForm roles for the selected sponsor company and trial is displayed.
- **3.** Click the icon corresponding to a role. The User-Role Association page is displayed, which shows the list of users for the selected role.
- Modify the user-role association.

For more details on how to view and modify user-role association, see Section A.11.

- **5.** Click **Submit** to save the changes.
- To go back to the List of InForm Roles page, click **Return**.

## 6.1.5 Setting the Display Override Option

The Change Display Overrides page lets you set the display override option for an item group.

To set a display override option:

- Select **Roles** from the menu bar. The InForm Roles page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of InForm roles for the selected sponsor company and trial is displayed.
- Click the **\*** icon corresponding to a role.

You can set the display override option for item group as read only, editable, or hidden. Based on the option assigned to the role, a user can view or modify the item group.

The Change Display Overrides page is displayed, which shows the list of available and selected Item groups.

**4.** Modify the details.

For more details on how to view and modify the Display Override option, see Section A.12.

- Click **Submit** to save the changes.
- To go back to the List of InForm Roles page, click **Return**.

#### 6.1.6 Approving or Rejecting InForm Roles

The InForm Roles page lets you approve and reject InForm roles. You can either approve or reject InForm roles depending on your access rights.

You can approve or reject only those roles which are in the Pending status.

To approve or reject InForm roles:

- 1. Select **Roles** from the menu bar. The InForm Roles page is displayed.
- Select the sponsor company and trial from the **Current Sponsor Company** and Trial drop-down lists. The list of InForm roles for the selected sponsor company and trial is displayed.
- Select the check box corresponding to the role you want to approve or reject.
- Select **Approve** or **Reject** from the **Select** drop-down list. If you select Reject, enter the reason for rejection in the **Comments** text box.

**Note:** If you select **Approve**, the Electronic Signature Affidavit page is displayed. Enter your password and click **Submit**. To cancel approval, click **Cancel**.

The Approval Status for the selected InForm role changes based on the action performed.

5. Click Go.

## 6.1.7 Transferring InForm Roles

The InForm Roles page also lets you transfer InForm roles.

To transfer InForm roles:

- Select **Roles** from the menu bar. The InForm Roles page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of InForm roles for the selected sponsor company and trial is displayed.
- Click the icon corresponding to the role you want to transfer.
- Select the user from the User(s) Available (Role Name) text box and transfer to the **Transfer to** text box using the navigational buttons.
- **5.** Select the required role from the drop-down list and click **Submit**.
- **6.** Click **OK** on the dialog box that appears.
- **7.** Click **Return** to go back to the List of InForm roles page.

The change is reflected in the Member Count and on the Users page.

# 6.2 Managing UMT Roles

This section contains the following topics:

- Section 6.2.1, "Viewing the List of UMT Roles"
- Section 6.2.2, "Creating UMT Roles"
- Section 6.2.3, "UMT Roles and Rights"
- Section 6.2.4, "Viewing and Modifying UMT Role Details"
- Section 6.2.5, "Viewing and Modifying UMT User Role Association"
- Section 6.2.6, "Deleting UMT Roles"

#### 6.2.1 Viewing the List of UMT Roles

The UMT Roles page lets you view the list of UMT roles and role details. This page also lets you filter the UMT roles based on the filter criteria.

To view the list of UMT roles:

- Select **Roles** from the menu bar. On the page that appears, click the **UMT Roles** link. The UMT Roles page is displayed.
- **2.** Select the sponsor company from the **Current Sponsor Company** drop-down list. The list of UMT roles for the selected sponsor company is displayed.
- **3.** To filter the role, enter the role name in the **Role Name** text box and click **Find**. The list of UMT roles that satisfy the filter criteria is displayed.

To specify the filter criteria, use the full name or the first few letters of the name.

For more details on how to filter and view roles, see Section A.20.

To clear the filter criteria, click **Clear**.

**Note:** To navigate through the UMT roles list, click the **First**, Previous, Next, or Last links.

To view a particular page, select the page from the drop-down list.

To view all the UMT roles on a single page, select **All** from the drop-down list.

Click the column name link to sort the UMT roles in the ascending or descending order, based on the column name. On the first click, the UMT roles are sorted in the ascending order. To sort the UMT roles in descending order, click the column name link again.

## 6.2.2 Creating UMT Roles

The Create UMT Role page lets you create a role and assign rights under various categories such as UMT Admin, Import, Export, User, Sponsor, Site Details, Log Files, Approval, InForm Rights, and Miscellaneous. You can assign all or some of the rights under each category to a user.

To create UMT roles:

Select **Roles** from the menu bar. On the page that appears, click the **UMT Roles** link.

- **2.** On the UMT Roles page that appears, select the sponsor company from the Current Sponsor Company drop-down list. The list of UMT roles for the selected sponsor company is displayed.
- **3.** Click the **Create UMT Role** link. The Create UMT Role page is displayed.
- **4.** Enter the UMT role details.

For more details on how to create UMT roles, see Section A.35.

- **5.** Click **Submit** to save the details.
- 6. To save the current UMT role details and create another UMT role, click Submit and Add Another.
- **7.** To discard the changes, click **Return**.

#### 6.2.3 UMT Roles and Rights

UMT roles are assigned certain rights and privileges that help them perform different tasks. Table 6–1 provides a list of various rights and privileges that are typically assigned to a UMT role.

Table 6-1 UMT Roles and Rights

Rights	Description
UMT Admin	
Create UMT User	Create a UMT user.
Modify UMT User	Edit UMT user details.
View UMT User	View UMT user details.
Manage UMT User	Edit UMT user country details and user association with trials.
Create UMT Role	Create a UMT role.
Modify UMT Role	Sponsor Role Users: Modify sponsor role user details.
	<b>PF Role Users</b> : Update default role settings of PF role.
View UMT Role	View UMT user role details.
Manage UMT Role	Edit the association between a user and a role.
Modify UMT Configurations (PF Only)	Configure and edit UMT settings.
Modify Provisioned by (PF only),	Configure and edit provisioning Settings.
Manage IOL Training	Configure and edit IOL settings.
Import/Export	
Import/Export	Import and export trial details.
Import Form and Items Ref Names	Import XML forms and item ref names.
Manage Auto Import Duplicates	Resolve automatically duplicated trial items.
User/Sponsor/Site Details	
Create Sponsor	Create a sponsor.
Modify Sponsor Details	Edit sponsor details.
View Sponsor Details	View sponsor details.

Table 6–1 (Cont.) UMT Roles and Rights

Rights	Description
Create Trial	Create a trial.
Modify Trial Details	Edit trial details.
Create InForm User	Create InForm user.
Modify InForm User	Edit InForm user details.
View InForm User	View InForm user details.
Manage InForm User	Associate a group and a role.
Create Site	Create a site.
Modify Site	Edit site details.
View Site Details	View site details.
Manage Site Details	Create and modify user and site association.
Load to InForm	Load user and site details to InForm.
Request InStruct account (IOL) (PF Only)	Request IOL training for PF users.
Copy Between Trials	Copy trial.
Manage Mass Associations	Enable mass association.
Lock Trial	Rights to lock trials.
View/Edit Pivotal Fields	Rights to view or edit Pivotal details.
Create/Edit UAT details	Rights to create or edit UAT details.
View Terminated User Details	Rights to view the terminated User Details.
View IRT User Details	Rights to view the IRT user details.
View IRT Site Details	Rights to view the IRT site details.
View IRT Right and Roles	Rights to view the IRT right and roles.
Manage IRT User Details	Rights to edit the IRT user details.
Manage IRT Site Details	Rights to edit the IRT site details.
Manage IRT Right and Roles	Rights to edit the IRT right and roles.
Load to IRT	Load user and site details to IRT.
Create OLx User	To create an OLx user.
View OLx User	To view OLx user.
Modify OLx user	Modify existing OLx user.
Manage OLx user	To manage OLx users.
Load to OLx	Load user and site details to OLx.
Log Files	
View Import/Export Log File	View MUL application log files.
View Data Transfer Log to Pivotal (PF Only)	View Pivotal application log files.

Table 6–1 (Cont.) UMT Roles and Rights

Rights	Description
View Data Transfer Log to InForm (PF Only)	View InForm application log files.
View Data Transfer Log to eCS (PF Only)	View eCS application log files.
View Data Transfer Log to IOL* (PF Only)	View IOL application log files.
View Training Log (PF Only)	Enable the training logs menu.
Approval	
Approve Site Details	Approve or reject site details.
Approve InForm User Details	Approve, reject or terminate InForm user.
Approve InForm Rights and Role	Approve or reject InForm role.
Approve InForm Groups	Approve or reject InForm group.
Approve InForm Configuration	Approve or reject InForm settings.
Approve IRT Rights and Role	Approve or reject IRT role.
InForm Rights	
Edit InForm Config Settings	Edit the InForm configuration settings.
Create InForm Rights and Role	Create InForm rights and roles.
Modify InForm Rights and Role	Edit InForm rights and roles.
Manage InForm Rights and Role	Manage the user-role associations.
Create InForm Groups	Create InForm group details.
Modify InForm Groups	Edit InForm group details.
Manage InForm Groups	To enable user, role association with groups. Associate an InForm group with a user and a group.
View InForm Config	View InForm configuration details.
View InForm Rights and Roles	View InForm rights and roles.
View InForm Groups	View InForm groups.
Create OLx Rights and Role	To create OLx rights and role.
Modify OLx Rights and Role	To modify OLx rights and role.
Manage OLx Rights and Role	To manage OLx roles and rights.

Table 6–1 (Cont.) UMT Roles and Rights

Rights	Description
View OLx Roles and Rights	To view OLx roles and rights.
Miscellaneous	
View Reports	To view billing details report, training report, and assessment detail report.

#### 6.2.4 Viewing and Modifying UMT Role Details

The UMT Role Details page lets you view the rights associated with a role and modify the details, if required. If the role details are modified, the reason for change is captured and the changes are tracked and audited. You can view the changes made to a particular field by viewing its corresponding audit trail.

To view and modify UMT role details:

- Select **Roles** from the menu bar. On the page that appears, click the **UMT Roles** link. The UMT Roles page is displayed.
- Select the sponsor company from the **Current Sponsor Company** drop-down list. The list of UMT roles for the selected sponsor company is displayed.
- Click the role name link in the grid. The UMT Role Details page is displayed, which shows the selected UMT role details.
- Modify the UMT role details.

For more details on how to modify the UMT role details, Section A.33.

**Note:** If the sponsor company in the **Current Sponsor Company** drop-down list is changed to another sponsor company, the UMT Roles page is displayed.

- Enter the reason for modifying the details of the UMT role in the **Reason For** Change text box and click Submit.
- To cancel the changes made to the UMT role details, click **Cancel**.
- To view the list of audit trails for a particular field, click the corresponding icon.

## 6.2.5 Viewing and Modifying UMT User - Role Association

The User - Role Association page lets you view the list of users associated with the selected role. You can also add or remove users for the selected role.

To view and modify UMT user-role association:

- Select **Roles** from the menu bar. On the page that appears, click the **UMT Roles** link. The UMT Roles page is displayed.
- Select the sponsor company from the **Current Sponsor Company** drop-down list. The list of UMT roles for the selected sponsor company is displayed.
- Click the icon corresponding to a role. The User-Role Association page is displayed, which shows the list of users for the selected role.
- Modify the user-role association.

For more details on how to view and modify the user-role associations, see Section A-19.

- **5.** Click **Submit** to save the changes.
- To cancel the changes, click **Return**.

#### 6.2.6 Deleting UMT Roles

The UMT Roles page lets you delete roles. However, you must specify the reason for deleting the UMT role.

To delete UMT roles:

- Select **Roles** from the menu bar. On the page that appears, click the **UMT Roles** link. The UMT Roles page is displayed.
- Select the sponsor company from the Current Sponsor Company drop-down list. The list of UMT roles for the selected sponsor company is displayed.
- Select the check box corresponding to the role you want to delete.
- **4.** Enter the reason for deleting the role in the **Comments** text box and click **Delete**.

# 6.3 Managing IRT Roles

This section contains the following topics:

- Section 6.3.1, "Viewing the List of IRT Roles"
- Section 6.3.2, "Creating IRT Roles"
- Section 6.3.3, "Approving or Rejecting IRT Roles"

## 6.3.1 Viewing the List of IRT Roles

The IRT Roles page lets you view the list of IRT roles and role details. This page also lets you filter the IRT roles based on the filter criteria.

To view the list of IRT roles:

- Select **Roles** from the menu bar. On the page that appears, click the **IRT Roles** link. The IRT Roles page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and **Trial** drop-down lists. The list of IRT roles for the selected sponsor company is displayed.
- To filter the role, enter the role name in the **Role Name** text box and click **Find**. The list of IRT roles that satisfy the filter criteria is displayed.
  - To specify the filter criteria, use the full name or the first few letters of the name.
- To clear the filter criteria, click **Clear**.

**Note:** To navigate through the IRT roles list, click the **First**, **Previous**, Next, or Last links.

To view a particular page, select the page from the drop-down list.

To view all the IRT roles on a single page, select **All** from the drop-down list.

Click the column name link to sort the IRT roles in the ascending or descending order, based on the column name. On the first click, the IRT roles are sorted in the ascending order. To sort the IRT roles in descending order, click the column name link again.

#### 6.3.2 Creating IRT Roles

The Create IRT Role page lets you create a role and assign rights under various categories such as Subject Related, Study Admin Activities, Site Admin Activities, User Related Activities, Drug Related Activities, Reports, Ad-Hoc Reports, and Instructions and Forms. You can assign all or some of the rights under each category to a user.

To create IRT roles:

- Select **Roles** from the menu bar. On the page that appears, click the **IRT Roles** link. The IRT Roles page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and **Trial** drop-down lists. The list of IRT roles for the selected sponsor company is displayed.
- Click the **Create IRT Role** link. The Create IRT Role page is displayed.
- Enter the IRT role details.
- Click **Submit** to save the details.
- To save the current IRT role details and create another IRT role, click **Submit and** Add Another.
- To discard the changes, click **Return**.

# 6.3.3 Approving or Rejecting IRT Roles

The IRT Roles page lets you view approve or reject IRT roles.

To approve or reject IRT roles:

- Select **Roles** from the menu bar. On the page that appears, click the **IRT Roles** link. The IRT Roles page is displayed.
- 2. Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of IRT roles for the selected sponsor company is displayed.
- **3.** Select the check box corresponding to the role you want to approve or reject.
- Enter the reasons in the **Comments** text box and click **Go**.

# **Managing Groups**

This chapter contains the following topics:

- Section 7.1, "Viewing the List of Groups"
- Section 7.2, "Creating Groups"
- Section 7.3, "Viewing and Modifying User and Group Association"
- Section 7.4, "Validating AutoQuery Groups"
- Section 7.5, "Viewing and Modifying Group Details"
- Section 7.6, "Approving or Rejecting Groups"
- Section 7.7, "Creating PF Groups"

# 7.1 Viewing the List of Groups

The List of Groups page lets you view the list of groups and their details. It also lets you filter groups based on the filter criteria.

To view the list of groups:

- Select **Groups** from the menu bar. The List of Groups page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of groups for the selected sponsor company and trial is displayed.
- To filter the groups, enter the filter criteria in the filter section and click **Find**. The list of groups that satisfy the specified filter criteria is displayed.
  - When you specify the filter criteria, you can use either the full group name or the first few letters of the group name.
  - For more details on how to filter and view groups, see Section A.13.
- To clear the filter criteria, click **Clear**.

**Note:** To navigate through the group list, click the **First**, **Previous**, Next, or Last links.

To view a particular page, select the page from the drop-down list.

To view all the groups on a single page, select All from the drop-down

Click the column name link to sort the groups in the ascending or descending order, based on the column name. On the first click, the groups are sorted in the ascending order. To sort the groups in descending order, click the column name link again.

# 7.2 Creating Groups

To create groups:

- 1. Select **Groups** from the menu bar. The **Sponsor** and **Trial** drop-down lists must be set to **Select**. The List of PF Groups page is displayed.
- **2.** Click the **Create PF Group** link. The Create PF Groups page is displayed.
- Enter the group details.

For more details on how to create groups, see Section A.14.

**Note:** The groups created here are not copied to other trials until they are assigned to a user.

- **4.** Click **Submit** to save the group details.
- To save the current group details and create another group, click **Submit and Add** Another.
- **6.** To discard the changes, click **Return**.

## 7.3 Viewing and Modifying User and Group Association

You can view users associated with a group and modify the number of users associated with it.

To view and modify group and user association:

- 1. Select **Groups** from the menu bar. The List of Groups page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of groups for the selected sponsor company and trial is displayed.
- 3. Click the icon corresponding to the group for which you want to view and modify the user and group association. The User-Group Association page displays the users that are associated with the group.
- **4.** Modify the user and group association.

For more details on how to modify user and group association, see Section A.15.

- 5. Click Submit.
- **6.** Click **OK** on the confirmation dialog box.

**7.** To cancel all changes and return to the List of Groups page, click **Return**.

## 7.4 Validating AutoQuery Groups

You can validate approved autoquery groups for the purpose of uploading XML forms into the InForm system.

To validate autoquery groups:

- Select **Groups** from the menu bar. The List of Groups page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of groups for the selected sponsor company and trial is displayed.
- Click the **AutoQuery** or **CTValidation** link. The autoquery dialog box is displayed.
- 4. Select the autoquery user and CT Validation User from the AutoQuery User drop-down lists respectively.
- Click **Submit**.
- Click **OK** on the confirmation dialog box.

## 7.5 Viewing and Modifying Group Details

The Edit Groups page lets you view and modify group details. If the group details are modified, the reason for change is captured and the changes are tracked and audited. You can view the changes made to a particular field by viewing its corresponding audit trails.

To view and modify group details:

- Select **Groups** from the menu bar. The List of Groups page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of groups for the selected sponsor company and trial is displayed.
- 3. Click the group name link in the grid. The Edit Groups page is displayed, which shows the selected group details.
- Modify the group details.

For more details on how to modify group details, see Section A.16.

If you modify the current sponsor company or the trial displayed in the Current Sponsor Company and Trial drop-down lists, the List of Groups page is displayed.

- **5.** Enter the reason for modifying the group details in the **Reason For Change** text box and click **Submit**.
- To go back to the List of Groups page, click **Return**.
- To view the list of audit trails for a particular field, click the corresponding icon.

## 7.6 Approving or Rejecting Groups

The List of Groups page lets you approve and reject groups. You can approve or reject groups depending on your access rights. All changes made to the group must be approved. You must provide your password on the Electronic Signature Affidavit page that appears during the process.

To approve or reject a group:

- 1. Select **Groups** from the menu bar. The List of Groups page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of groups for the selected sponsor company and trial is displayed.
- 3. Select the check box corresponding to the group you want to approve or reject.
- **4.** Select **Approve** or **Reject** from the **Select** drop-down list.

If you select **Reject**, enter the reason in the **Comments** text box.

If you select **Approve**, the Electronic Signature Affidavit page is displayed. Enter your password and click Submit. The Approval Status for the selected group changes based on the action performed.

To cancel approval, click **Cancel**.

Click **Go**.

## 7.7 Creating PF Groups

To create PF groups, see Section 7.2

# **Managing Reports**

This chapter contains the following topics:

- Section 8.1, "Viewing the List of Reports"
- Section 8.2, "Generating the Reports"

## 8.1 Viewing the List of Reports

To view the list of reports:

1. Select **Reports** from the menu bar. The List of Reports page is displayed.

## 8.2 Generating the Reports

The section contains the following topics:

- Section 8.2.1, "Generating Assessment Reports"
- Section 8.2.2, "Generating Master Reports"
- Section 8.2.3, "Generating General Reports"

## 8.2.1 Generating Assessment Reports

You can generate the following assessment reports:

- Assessment Report Sponsor Level: It displays the assessment details for all trials of a sponsor.
- Assessment Summary Report Trial Level: It displays the summary of assessment details for a trial.
- Assessment Detail Report Trial Level: It displays the complete details of the assessment for a trial.
- Assessment Summary Report Site Level: It displays the summary of assessment details for a site.
- Assessment Detail Report Site Level: It displays the complete details of the assessment for a trial.

#### 8.2.1.1 Generating the Assessment Summary Report at Sponsor Level

To generate the Assessment Summary Report at sponsor level:

1. Select **Reports** from the menu bar. The List of Reports page is displayed.

- 2. Click the Assessment Report Sponsor Level link. The Generate Assessment Report - Sponsor Level page is displayed.
- **3.** For more details on how to generate the Assessment Summary Report at Sponsor Level, see Section A.52.
- **4.** Click **Generate**. The Assessment Summary Report at sponsor level is generated. You can export the report to an Excel spreadsheet or print the report.
  - **a.** To export the report to an Excel spreadsheet, click the **Export To Excel** link. On the dialog box that appears, click **Open** to open the file or click **Save** to save the file.
  - **b.** To print the report, click the **Print** link. On the dialog box that appears, click **Print**.
- Click **Return** to go back to the List of Reports page.

#### 8.2.1.2 Generating the Assessment Summary Report at Trial Level

To generate the Assessment Summary Report at trial level:

- Select **Reports** from the menu bar. The List of Reports page is displayed.
- Click the **Assessment Summary Report Trial Level** link. The Generate Assessment Summary Report - Trial Level page is displayed.
- 3. For more details on how to generate the Assessment Summary Report at trial level, see Section A.53.
- **4.** Click **Generate**. The Assessment Summary Report at trial level is generated. You can export the report to an Excel spreadsheet or DAT file, or print the report.
  - **a.** To export the report to an Excel spreadsheet, click the **Export To Excel** link. On the dialog box that appears, click **Open** to open the file or click **Save** to save the file.
  - **b.** To export the report to a DAT file, click the **Export To File** link. On the dialog box that appears, click **Open** to open the file or click **Save** to save the file.
  - **c.** To print the report, click the **Print** link. On the dialog box that appears, click **Print**.
- **5.** Click **Return** to go back to the List of Reports page.

#### 8.2.1.3 Generating the Assessment Detail Report at Trial Level

To generate the Assessment Detail Report at trial level:

- Select **Reports** from the menu bar. The List of Reports page is displayed.
- Click the Assessment Detail Report Trial Level link. The Generate Assessment Detail Report - Trial Level page is displayed.
- **3.** For more details on how to generate the Assessment Detail Report at Trial Level, see Section A.54.
- 4. Click Generate. The Assessment Detail Report at trial level is generated. You can export the report to an Excel spreadsheet or DAT file, or print the report.
  - For more details, see Section 8.2.1.2.

Click **Return** to go back to the List of Reports page.

#### 8.2.1.4 Generating the Assessment Summary Report at Site Level

To generate the Assessment Summary Report at site level:

- Select **Reports** from the menu bar. The List of Reports page is displayed.
- Click the Assessment Summary Report Site Level link. The Generate Assessment Summary Report - Site Level page is displayed.
- **3.** For more details on how to generate the Assessment Summary Report at Site Level, see Section A.55.
- 4. Click Generate. The Assessment Summary Report at site level is generated. You can export the report to an Excel spreadsheet or DAT file, or print the report. For more details, see Section 8.2.1.2.
- Click **Return** to go back to the List of Reports page.

#### 8.2.1.5 Generating the Assessment Detail Report at Site Level

To generate the Assessment Detail Report at site level:

- 1. Select **Reports** from the menu bar. The List of Reports page is displayed.
- Click the Assessment Detail Report Site Level link. The Generate Assessment Detail Report - Site Level page is displayed.
- **3.** For more details on how to generate the Assessment Detail Report at Site Level, see Section A.56.
- 4. Click Generate. The Assessment Summary Report at site level is generated. You can export the report to an Excel spreadsheet or DAT file, or print the report. For more details, see Section 8.2.1.2.
- Click **Return** to go back to the List of Reports page.

## 8.2.2 Generating Master Reports

You can generate the following master reports:

- Master Summary Report Site Level
- Master Detail Report Site Level

#### 8.2.2.1 Generating the Master Summary Report at Site Level

To generate the Master Summary Report at site level:

- 1. Select **Reports** from the menu bar. The List of Reports page is displayed.
- Click Master Reports and then click Master Summary Report Site Level link. The Generate Master Summary Report - Site Level page is displayed.
  - For more details on how to generate the Master Summary Report at Site Level, see Section A.57.
- 3. Click Generate. The Master Summary Report at site level is generated. You can export the report to an Excel spreadsheet or DAT file, or print the report.
  - For more details, see Section 8.2.1.2.
- **4.** Click **Return** to go back to the List of Reports page.

#### 8.2.2.2 Generating the Master Detail Report at Site Level

To generate the Master Detail Report at site level:

- Select **Reports** from the menu bar. The List of Reports page is displayed.
- Click Master Reports and then click Master Detail Report Site Level link. The Generate Master Detail Report - Site Level page is displayed.
  - For more details on how to generate the Master Detail Report at Site Level, see Section A.57.
- Click Generate. The Master Detail Report at site level is generated. You can export the report to an Excel spreadsheet or DAT file, or print the report.
  - For more details, see Section 8.2.1.2.
- Click **Return** to go back to the List of Reports page.

### 8.2.3 Generating General Reports

You can generate the following general reports:

- Billing Report Details
- Training Report
- User Detail Report
- Worklist-Site/User Report
- Trial Archive Package (TAP) Report

#### 8.2.3.1 Generating the Billing Report Details

To generate the Billing Report details:

- 1. Select **Reports** from the menu bar. The List of Reports page is displayed.
- Click **General Reports** and then click **Billing Details Report** link. The Generate Billing Details page is displayed.
  - For more details on how to generate the Billing Details Report, see Section A.59.
- Click Generate. The Billing Details Report is generated. You can export the report to an Excel spreadsheet or DAT file, or print the report.
  - For more details, see Section 8.2.1.2.
- Click **Return** to go back to the List of Reports page.

#### 8.2.3.2 Generating the Training Details Report

To generate the Training Report:

- 1. Select **Reports** from the menu bar. The List of Reports page is displayed.
- 2. Click **General Reports** and then click **Training Report** link. The Training Details Report page is displayed.
  - For more details on how to generate the Training Details Report, see Section A.60.
- 3. Click Generate. The Training Details Report is generated. You can export the report to an Excel spreadsheet or DAT file, or print the report.
  - For more details, see Section 8.2.1.2.
- Click **Return** to go back to the List of Reports page.

#### 8.2.3.3 Generating the User Detail Report

To generate the User Detail Report:

- Select **Reports** from the menu bar. The List of Reports page is displayed.
- 2. Click **General Reports** and then click **User Detail Report** link. The Generate User Detail Report page is displayed.
  - For more details on how to generate the User Detail Report, see Section A.61.
- Click **Generate**. The User Detail Report is generated. You can export the report to an Excel spreadsheet or DAT file, or print the report.
  - For more details, see Section 8.2.1.2.
- **4.** Click **Return** to go back to the List of Reports page.

#### 8.2.3.4 Generating the WorkList-Site/User Report

To generate the WorkList-Site/User Report:

- Select **Reports** from the menu bar. The List of Reports page is displayed.
- Click General Reports and then click WorkList-Site/User Reports link. The Site-User Detail Report page is displayed.
  - For more details on how to generate the Site-User Detail Report, see Section A.62.
- 3. Click Generate. The Site Detail Report is generated. You can export the report to an Excel spreadsheet.
  - To export the report to an Excel spreadsheet, click the **Export To Excel** link.
  - **b.** On the dialog box that appears, click **Open** to open the file or click **Save** to save the file.
- Click **Return** to go back to the List of Reports page.

#### 8.2.3.5 Generating the Trial Archive Package (TAP) Report

To generate the Trial Archive Package (TAP) Report:

- 1. Select **Reports** from the menu bar. The List of Reports page is displayed.
- 2. Click **General Reports** and then click **Trial Archive Package (TAP) Report** link. The Trial Archive Report (TAP) page is displayed.
- **3.** Select the sponsor company and trial.
- 4. Click Generate Report.
- **5.** On the dialog box that appears, click **Open** to open the file or click **Save** to save the file.
  - The Trial Archive Report is generated in the form of an Excel spreadsheet.
- Click **Return** to go back to the List of Reports page.

# **Managing Worklists**

This chapter contains the following topics:

- Section 9.1, "Overview"
- Section 9.2, "Managing Worklist Generation"

#### 9.1 Overview

The Manage Workslists Generation page lets you assign trials to manual worklists or automatic worklists as required. It also lets you set the default worklist type for all the new trials you create. Assignment to automatic worklists must be initiated by a Support ticket. For more details on manual worklists and automated worklists, see Chapter 10.

**Note:** Only Oracle administrator users and third party Tier-I help desk users with required access rights can access the Manage Worklists tab.

## 9.2 Managing Worklist Generation

To manage worklist generation:

- Select Manage Worklists from the menu bar. The Manage Worklists Generation page is displayed.
  - For more details on how to manage worklist generation, see Section A.49.
- Select the sponsor company from the **Sponsor** drop-down list.
- To assign a trial to a manual worklist:
  - Select the required trial from the **Disabled** box and click the right arrow. The selected trial is moved to the Manual Worklists box.
- To assign a trial to an automatic worklist, Oracle support team has to create a support ticket.
- Enter the reason for modification in the **Reason for change** text box.
- Click **Submit** to save the changes. To discard the changes, click **Return**.

# **Worklist**

This chapter contains the following topics:

- Section 10.1, "Overview"
- Section 10.2, "Viewing Manual Worklist"
- Section 10.3, "Viewing Archived Records"

#### 10.1 Overview

The worklist details page lets you track the transactions carried out in UMT for a trial at user, site, role, and group levels, after the trial goes live. There are two types of worklists, such as Manual and Automated.

**Note:** Only UMT users and third party Tier-I help desk users with required access rights can access the Worklists tab.

## 10.2 Viewing Manual Worklist

You can view manual worklist details at user, site, role, group, and configuration levels. You can assign a manual worklist to User Manager (UM), User Approver (UA), and Quality Control (QC), and complete the worklist. The completed worklists are archived.

To view a manual worklist:

1. Select **Worklist** from the menu bar. By default, the manual worklist details page is displayed.

For more details on worklist details, see Section A.48.

Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists. The list of worklists at user level for the selected sponsor company and trial is displayed.

**Note:** To view the worklist details at site, role, group, and configuration levels, click the corresponding links.

**3.** To filter worklists based on user, site, role, group, or configuration levels, enter the filter criteria, and click **Find**. The list of worklists that satisfy the specified filter criteria is displayed.

For more details on how to filter and view worklist details, see Section A.48.

- **4.** Select the required worklist from the list by clicking the corresponding check box.
- Select the user to assign the worklist to, for approval from the **Select** drop-down list.

**Note:** You should assign a worklist to User Manager (UM), User Approver (UA), and Quality Control (QC), in the sequence, for approval.

- **6.** Select **Mark as Pending** or **Archive Records** as required from the Select drop-down list.
- 7. Enter the reasons in the **Comments** text box and click **Go**. The worklist record is updated successfully.

## 10.3 Viewing Archived Records

After a worklist is approved and processed completely, it will be archived in UMT.

To view the archived worklists:

- 1. Select Worklist from the menu bar. By default, the manual worklist details page is displayed.
- 2. Click the **View Archived Records** link. The list of archived worklists is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and **Trial** drop-down lists. The list of archived worklists for the selected sponsor company and trial is displayed.

# **Managing Assessment**

This chapter contains the following sections:

- Section 11.1, "Viewing the List of Assessed Users"
- Section 11.2, "Updating Assessment Status for an Assessed User"
- Section 11.3, "Viewing Assessment Comment History"

## 11.1 Viewing the List of Assessed Users

The List of Assessed Users page lets you view the list of assessed users and their details. Additionally, it lets you filter the users based on the filter criteria.

To view the list of assessed users:

- Select **Assessments** from the menu bar. The List of Assessed Users page is displayed.
- Select the sponsor company, trial, and site from the Current Sponsor Company, Trial and Site drop-down lists. The list of assessed users for the selected sponsor company, trial, and site is displayed.
  - An error message No User Details Found is displayed when there are no assessed users in the selected sponsor company, trial, and site.
- To filter users, enter the filter criteria and click Find. The list of assessed users that satisfy the specified filter criteria is displayed.

#### Note:

Filtering options cannot be used unless you specify a current sponsor company, a trial, and a site.

While specifying the filter criteria, you can use the full name or part of the name.

An error message No Result found for the Selected Criteria is displayed when there are no users who meet the search criteria.

- To navigate through the user list, click the **First**, **Previous**, **Next**, or **Last** links.
- To view a particular page, select the page from the drop-down list.
- To view all the users on a single page, select **All** from the drop-down list.
- Click the column name link to sort the users either in the ascending or descending order, based on the column name. On the first click, the users are

sorted in the ascending order. To sort them in descending order, click the column name link again.

**e.** To clear the filter criteria, click **Clear**.

## 11.2 Updating Assessment Status for an Assessed User

The List of Assessed Users page lets you update the assessment status of assessed

To update the assessment status of an assessed user:

- Select **Assessments** from the menu bar. The List of Assessed Users page is displayed.
- 2. Select the sponsor company, trial, and site from the Current Sponsor Company, Trial, and Site drop-down lists. The list of assessed users for the selected sponsor company, trial, and site is displayed.
- To filter users, enter the filter criteria and click **Find**. The list of assessed users that satisfy the specified filter criteria is displayed.

**Note:** To clear the filter criteria, click **Clear**.

- **4.** Select the check box corresponding to the user whose status you want to update.
- Select **Update Assessment Status** from the **Select** drop-down list.
- Enter the reason for updating in the **Comments** text box and click **Go**. The Update Assessment Status page is displayed.
- **7.** Select the check box corresponding to the status you want to update.
- **8.** Enter a summary of updating in the **Assessment Summary Box** text box and click Update.

The assessment status of the user is updated successfully.

- **9.** Click **OK** on the dialog box that appears.
- **10.** Click **Return** to go back to the List of Assessed Users page.

## 11.3 Viewing Assessment Comment History

The List of Assessed Users page also lets you view the Assessment Comment History for an assessed user.

To view the Assessment Comment History for an assessed user:

- 1. Select **Assessments** from the menu bar. The List of Assessed Users page is displayed.
- **2.** Select the sponsor company, trial, and site from the **Current Sponsor Company**, Trial, and Site drop-down lists. The list of assessed users for the selected sponsor company, trial, and site is displayed.
- To filter users, enter the filter criteria and click Find. The list of assessed users that satisfy the specified filter criteria is displayed.

**Note:** To clear the filter criteria, click **Clear**.

- 5. The Assessments Comment History page displays the comments history of the selected user.

**Note:** Click **Return** to go back to the List of Assessed Users page.

## 11.3.1 Adding New Comments to the Assessment Comments History

The Add New Comments link on the Assessments Comments History Page lets you add new comments to an assessed user's comments history.

To add new comments to an assessed user's comments history:

- Click the **Add New Comments** link on the Assessment Comments History page. The Add Assessment Comments page is displayed.
- 2. Enter your comments in the **Public Comments** and **Private Comments** text boxes and click Submit.

**Note:** You must enter comments in both text boxes.

- Click **OK** on the dialog box that appears.
- Click **Return** to go back to the Assessment Comments History page.
- Click **Clear** to clear the comments entered.

### 11.3.2 Editing Comments

The Edit or Delete link on the Assessment Comments History page lets you edit comments from an assessed user's assessments comments history.

To edit an assessed user's assessments comments history:

- Click the **Edit** or **Delete** link for the corresponding user.
- The **Comments** tab is highlighted and the Comment type radio button displays whether it is a public or private comment.
- **3.** Edit the comments as required and enter the reasons for change in the **Comments** text box. Click **Update**.
- **4.** Click **OK** on the dialog box that appears.
- Click **Return** to go back to the List of Assessed Users page.

### 11.3.3 Deleting Comments

The Edit or Delete link on the Assessment Comments History page lets you delete comments from an assessed user's assessments comments history.

To delete an assessed user's assessments comments history:

- Click the **Edit** or **Delete** link for the corresponding user.
- The Comments tab is highlighted and the Comment type radio button displays whether it is a public or private comment.
- Enter the reasons for deletion in the **Comments** text box and click the delete icon.

**4.** Click OK on the dialog box that appears.

**Note:** Click **Return** to go back to the List of Assessed Users page.

# **Managing Log Files**

This chapter contains the following topics:

- Section 12.1, "Viewing the List of Log Files"
- Section 12.2, "Viewing the List of Transferred Data"
- Section 12.3, "Archiving Log Files"
- Section 12.4, "Viewing Archived Log Files"

## 12.1 Viewing the List of Log Files

The Log Files page displays the list of log files and its details. You can view the details of the import such as application name, batch ID, name of the user who initiated the import, date and time of the import, and status of the import.

To view the list of log files:

- Select Log Files from the menu bar. The Log Files page is displayed. Select the sponsor company from the Current Sponsor Company drop-down list.
- Select the sponsor company and trial from the Current Sponsor Company and **Trial** drop-down lists.
- Enter the filter criteria and click **Find**. The list of log files for the specified filter criteria is displayed.

For more details on viewing log files, see Section A.26.

**Note:** Click the column name link to sort the log files in the ascending or descending order, based on the column name. On the first click, the log files are sorted in the ascending order. To sort the log files in the descending order, click the column name link again.

To view list of transferred data, click the module name link.

## 12.2 Viewing the List of Transferred Data

The Data Transferred page displays the list of transferred data in the corresponding module.

To view the list of transferred data:

- Select **Log Files** from the menu bar. The Log Files page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and **Trial** drop-down lists.

- **3.** Enter the filter criteria and click **Find**. The list of log files for the specified filter criteria is displayed.
- 4. Click the HTML Log View link. The Data Transferred page is displayed, which shows the list of transferred data for the corresponding module.
- To view the previous page, click **Back**.

## 12.3 Archiving Log Files

The Archive option available on the Log Files page lets you archive inactive log files.

To archive log files:

- Select **Log Files** from the menu bar. The Log Files page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and **Trial** drop-down lists.
- Enter the filter criteria and click **Find**. The list of log files for the specified filter criteria is displayed.
- Select the check box corresponding to the log file you want to archive and enter the reason for archival in the **Comments** text box.
- Click **Archive**.
- To view the archived log files, click the **View Archive of Log Files** link.

## 12.4 Viewing Archived Log Files

The List of Archived Log Files page lets you view archived log files. You can view the application name, module name, name of the user who initiated the import, date and time of the import, and status of the import.

To view archived log files:

- Select **Log Files** from the menu bar. The Log Files page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and **Trial** drop-down lists.
- Enter the filter criteria and click **Find**. The list of log files for the specified filter criteria is displayed.
- 4. Click the **View Archive of Log Files** link. The List of Archived Log Files page is displayed, which shows the list of archived log files.
- To view the archived log files of a particular sponsor company, select the sponsor company from the **Current Sponsor Company** drop-down list.
- To view list of transferred data, click the **Batch ID** link.
- To view the previous page, click **Back**.

# **InStruct Online Training**

This chapter contains the following topics:

- Section 13.1, "Overview"
- Section 13.2, "Assigning an IOL Class to a Trial"
- Section 13.3, "Managing Training"

#### 13.1 Overview

InStruct Online (IOL) lets you assign training classes to trials and manage the training classes. You can assign IOL classes for trials for which the Swithchoff IOL option is disabled.

## 13.2 Assigning an IOL Class to a Trial

To assign an IOL class to a trial:

- 1. Select **IOL Training** from the menu bar.
- Select the sponsor company and trial from the Current Sponsor Company and **Trial** drop-down lists. The list of classes available for the selected sponsor company and trial is displayed.
- **3.** Select the classes you want to assign to the trial and specify the number of seats. You can select either Unlimited or enter the required number of seats.
- Click Submit.

## 13.3 Managing Training

The Manage Training page lets you view the list of classes assigned to the users and their statuses. You can reassign the classes to the users and download the class completion certificates.

To manage the training classes:

- Select **IOL Training** from the menu bar.
- 2. Select the sponsor company and trial from the Current Sponsor Company and Trial drop-down lists.
- **3.** Click **Manage Training**. The list of training records is displayed.
- 4. Enter the filter criteria and click Find. The list of training records that satisfy the filter criteria is displayed.

For more details on how to assign, filter, and view training records, see Section A.68.

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

# **Configuring Settings**

## 14.1 Configuring UMT Settings

The Configuration settings page lets you configure UMT settings such as trial configuration, site configuration, and user configuration.

### 14.1.1 Configuring Default Trials, Sites, and User Settings

The Trial Configurations, Site Configurations, and User Configurations sections let you configure settings. New sites and InForm users created under a selected trial reflect these settings.

To configure default trial, site, and user settings:

- Select **Configuration** from the menu bar. The Configuration settings page is displayed.
- 2. Select the current sponsor company and trial from the Current Sponsor Company and Trial drop-down lists.
- 3. Enter the settings in the Trial Configurations, Site Configurations, and User Configurations sections.
  - For more information on how to configure the default trial, site, and user settings, see Section A.17.
- **4.** Enter the reason for modifying the settings in the **Comments** text box and click
- **5.** To discard the changes, click **Return**.

## 14.1.2 Exporting UMT Configuration Settings

The Export to Excel and Export to File links available on the Configuration settings page lets you export UMT configuration settings. You can export the settings to an Excel spreadsheet or to a flat file.

To export UMT configuration settings:

- 1. Select **Configuration** from the menu bar. The Configuration settings page is displayed.
- 2. Select the current sponsor company and trial from the Current Sponsor Company and Trial drop-down lists.
- **3.** Click the **Export to Excel** or **Export to File** link.

**4.** On the dialog box that appears, click **Open** to open the file or click **Save** to save the file.

## 14.2 Configuring InForm Settings

The Configuration settings page lets you configure InForm settings such as editable system configuration and general settings.

### 14.2.1 Configuring Editable System Configuration Options for Trials on Trial Level

The Editable System Config Options section lets you configure editable system configuration options for a selected trial.

To configure editable system configuration options for trials:

- Select Configuration from the menu bar. The Configuration settings page is displayed.
- Select the current sponsor company and trial from the Current Sponsor Company and Trial drop-down lists.
- **3.** Enter the settings required.
  - For more details on how to configure the editable system configuration options for a trial, see Section A.17
- Enter the reason for modifying the settings in the **Comments** text box and click Submit.
- To discard the changes, click **Return**.

## 14.2.2 Configuring Editable System Configuration Options for New and Existing Trials on Sponsor Company Level

You can also configure the editable system configuration options for a new trial and update the settings for all existing trials under the selected sponsor company in the Editable System Config Options section.

To configure editable system configuration options for new and existing trials:

- 1. Select **Configuration** from the menu bar. The Configuration settings page is displayed.
- Select the current sponsor company from the **Current Sponsor Company** drop-down list and All from the Trial drop-down list.
- Enter the settings in the Editable System Configuration Options section. For more details on how to configure the editable system configuration options for new trials, see Section A.17.
- Select the check boxes corresponding to the setting items under Editable System Config Options section. This updates all existing trials and sets the default value for new trials to be created under the selected sponsor company.
- Enter the reason for modifying the settings in the **Comments** text box and click Submit.
- To discard the changes, click **Return**.

### 14.2.3 Configuring General Settings

Only PF users can modify the general settings available in the Settings section of the Configuration settings page. You can update the settings for existing trials and also set the default settings for new trials.

To configure general settings:

- Select Configuration from the menu bar. The Configuration settings page is displayed.
- Select the current sponsor company from the Current Sponsor Company drop-down list and All from the Trial drop-down list.
- Enter the settings.
  - For more details on how to configure the general settings, see Section A.17.
- Select the check boxes corresponding to the settings item to update the settings for all existing trials and set the default settings for new trials.
- Enter the reason for modifying the settings in the **Comments** text box and click Submit.
- To discard the changes, click **Return**.

### 14.2.4 Exporting InForm Configuration Settings

The Export to Excel and Export to File links available on the Configuration settings page lets you export configuration settings. You can export the settings to an Excel spreadsheet or to a flat file.

To export UMT configuration settings:

- Select **Configuration** from the menu bar. The Configuration settings page is displayed.
- 2. Select the current sponsor company and trial from the Current Sponsor Company and **Trial** drop-down lists.
- **3.** Click the **Export to Excel** or **Export to File** link.
- On the dialog box that appears, click **Open** to open the file or click **Save** to save the file.

## 14.3 Configuring Custom Review State

The Custom Review settings page lets you configure custom review states and custom review stages for InForm 5.5 trials only.

To add a review state and a review stage:

- Select **Configurations** from the menu bar. The Configuration settings page is displayed.
- Click the **Custom Review State Config** link. The Custom Review settings page is
- **3.** Select the current sponsor company and trial from the **Current Sponsor Company** and Trial drop-down lists.

**Note:** You should select an InForm 5.5 trial.

- **4.** Enter the settings.
  - For more details on Custom Review State configuration settings, see Section A.69.
- Enter the comments for modifying the configurations in the **Comments** text box.
- Click **Submit** to save the changes.
- 7. Click **Remove Review Stage** to delete the custom review stages.

## 14.4 Configuring Assessment

The Assessment Configuration Settings page lets you configure the assessment settings at sponsor level and trial level.

To configure the assessment settings:

- Select **Configurations** from the menu bar. The Configuration settings page is displayed.
- Click the **Assessment Config** link. The Assessment Configuration Settings page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and **Trial** drop-down lists.
  - For more details on Assessment Configuration Settings, see Section A.50.
- Enter the comments for modifying the configurations in the **Comments** text box.
- Click **Submit** to save the changes. To discard the changes, click **Return**.

## 14.5 Configuring Assessment Benchmark

The Assessment Benchmark Settings page lets you configure the benchmark settings for assessment.

To configure the assessment benchmark:

- Select **Configuration** from the menu bar. The Configuration Settings page is displayed.
- Click the **Assessment Benchmark** link. The Assessment Benchmark Settings page is displayed.
- Select the sponsor company and trial from the Current Sponsor Company and **Trial** drop-down lists.

**Note:** You can configure the benchmark settings for assessment on sponsor company level by not selecting a trial.

For more details on Assessment Benchmark Settings, see Section A.51.

- Enter the comments for modifying the configurations in the **Comments** text box.
- Click **Submit** to save the changes. To discard the changes, click **Return**.

## 14.6 UMT Settings

### 14.6.1 Configuring UMT Settings

The UMT Settings page lets you view and configure the password and login settings, worklist schedule and staging schedule settings. The password assigned to the UMT users during creation is based on the settings configured on the UMT Settings page.

To configure UMT settings:

- Select **UMT Settings** from the menu bar. The UMT Settings page appears.
- Modify the UMT configuration settings.
  - For more information on how to configure the UMT settings, see Section A.18.
- Enter the reason for modification in the **Reason for change** text box and click **Submit** to save the changes.
- To discard the changes, click **Return**.

### 14.6.2 Managing ISD Codes and Time Zones for Countries

The List of Countries page lets you manage ISD codes and time zones for countries. You can view list of countries and corresponding ISD codes.

To view list of countries:

- Select **UMT Settings** from the menu bar. The UMT Settings page is displayed.
- Click the Manage Countries List link. The List of Countries page is displayed that displays the list of countries and the corresponding ISD codes.
- To filter the countries, enter the country name in the **Country Name** text box and click **Find**.

While specifying the filter criteria, you can use the full name or use the first few letters of the name.

You can use the **Quick Search** feature to search for sites and users and directly access the required page. For more details on the Quick Search feature, see Section 2.5.

**Note:** To navigate through the country list, click the **First**, **Previous**, **Next**, or **Last** links.

To view a particular page, select the page from the drop-down list.

To view all the countries on a single page, select All from the drop-down list.

To view the country details, click the country name link.

To view the UMT Settings page, click **Cancel**.

## 14.6.3 Viewing and Modifying Country Details

The Country Details page lets you view and modify the country details and the Time Zone Association.

To view and modify the country details:

- Select **UMT Settings** from the menu bar. The UMT Settings page is displayed.
- Click the **Manage Countries List** link. The List of Countries page is displayed.

- **3.** Click the country name link. The Country Details page is displayed, which shows the selected country details.
- **4.** Modify the country details. For more details on how to modify the country details, see Section A.19.
- Enter the reason for modifying the sponsor details in the Reason for change text box and click **Submit**.
- To discard the changes, click **Return**.

# **UMT Field Information**

**Note:** All fields marked with \* are mandatory.

# A.1 InForm, IRT, and OLx Users Field Information

Table A-1 InForm, IRT Users, and OLx - Field Information

Field Name	Description	Field Size (In Character)
Username	Enter the name of the user.	32
First Name	Enter the first name of the user.	127
Last Name	Enter the last name of the user.	127
User Status	Select the status of the user from the drop-down list.	NA
User Type	Select the user type from the drop-down list.	NA
Role	Select the role from the drop-down list.	NA
Approval Status	Select the approval status from the drop-down list.	NA
Training Status	Select the training status from the drop-down list.	NA
Site(s)	Enter the site number.	255
Assessment Status	Select the assessment status from the drop-down list.	NA
Uploaded to InForm	Select the option from the drop-down list.	NA
Country	Select the country from the drop down.	NA
User ID	Enter the user ID.	NA
InForm/IRT User Details:	-	-
	Displays the icon:	NA
	if the user is marked Upload to InForm.	
	$oxedsymbol{\Xi}$ if the user is marked Upload to IRT.	
	if the user is marked Upload to InForm/IRT.	
Username	Displays the user name. Click the hyperlink to view the corresponding user details.	NA
First Name	Displays the first name of the user.	NA
Last Name	Displays the last name of the user.	NA
User Status	Displays the status of the user.	NA

Table A-1 (Cont.) InForm, IRT Users, and OLx - Field Information

Field Name	Description	Field Size (In Character)
User Type	Displays the user type.	NA
Role	Displays the role of the user.	NA
Approval Status	Displays the approval status. The approval status can be Approved, Rejected, or Pending.	NA
Training Status	Displays the training status. The training status can be Trained or Not Trained.	NA
Site(s)	Displays the sites associated with the user. If the user is associated	NA
	to multiple sites, the icon is displayed. Click the icon to view the association details. The icon is disabled for the user type Sponsor.	
Assessment Status	Displays the assessment status of the latest site assessment performed by the user. Click the icon to view the list of provisioning details.	NA
User ID	Displays the user ID of the IRT user.	NA
IRT Roles	Displays the IRT roles.	NA
Trained Date	Displays the trained date of the user.	NA
Country	Displays the country name of the user.	NA
Pass/Fail	Displays the pass or fail status of the user.	NA
Provisioning Status	Displays the provisioning status of the user.	NA

Table A-2 InForm Users - Error Information

Field Name/ Action	Scenario	Error Message
Role	When you click the role drop- down list without selecting the User Type.	Select User Type to load Role.
Check Box	When you click Go without selecting a user.	Select a User.
Check Box	When you click <b>Go</b> without checking a user.	Please check at least one User and then proceed.
Select Drop-down LIst	When you click $\mathbf{Go}$ without selecting any option in Select drop down list.	Select an action.
Pending User	When the pending user is assigned to Request for Equipment Assessment.	Pending User(s) cannot be requested for Equipment Assessment.
Request For Equipment Assessment	When the PF user is assigned to Request for Equipment Assessment.	PF users are not allowed for Assessment.
Request For Equipment Assessment	When the user who do not have site or multiple sites assigned to Request for Equipment Assessment.	Users associated to no sites or multiple sites cannot be requested for Equipment Assessment on this page.
Request For Equipment Assessment	Error occurs when the user status is not approved and the user is assigned to Request Equipment Assessment.	One or more of the site(s) are not approved. Please approve to Request Equipment Assessment.
Immediate Provisioning	Error occurs when the user is already marked for Immediate Provisioning.	One or more of the selected users is already marked for Immediate Provisioning - Equipment Assessment is not available.
Immediate Provisioning	Error occurs when the user is already marked for Immediate Provisioning.	One or more of the selected users is already marked for Equipment Assessment.
Active user	Error occurs when you try to change the user status to Active who is locked for QC.	User is locked for QC.

Table A-2 (Cont.) InForm Users - Error Information

Field Name/ Action	Scenario	Error Message
Active user	Error occurs when you try to change the user status to Active whose status is already in the Active status.	You have selected active users.
Inactivate User	Error occurs when you try to change the status of an inactive user.	You have selected inactive users.
Reject	Error occurs when you reject the user whose status is not pending.	You have selected users whose approval status is not pending.
Comment	Error occurs when you click <b>Go</b> button without entering a comment.	Enter a comment.
Comment	Error occurs when the character limit of the comments text exceed 255 characters.	Comments text should not exceed 255 characters.
Approve	Error occurs when you change the status of the user who is already approved.	You have selected users whose approval status is not pending.
Requires IOL Training	Error occurs when an enrolled user is requested for Requires for IOL.	You have selected enrolled users.
Mark as Assessed	Error occurs when you mark the PF user as Assessed.	PF users are not allowed for Assessment.
Pending Users	Error occurs when you mark the pending user as site Assessed.	Pending Users cannot be marked as Site Assessed.
User Site Association	Error occurs when you mark the user as Assessed who have association with no sites or multiple sites.	Users associated to no sites or multiple sites cannot be marked as site Assessed on this page.
Marked as Assessed	Error occurs when you mark the user as Assessed who is already marked as assessed.	One or more of the selected users is already marked as Assessed.
Mark as Trained	Error occurs when you change the training status of the user as Trained whose status is already trained.	You have selected Users whose Training status is Completed/Trained.
Terminate User	Error occurs when you try to terminate the user who is locked for QC.	User is locked for QC.
Mark Upload To InForm	Error occurs when you mark pending user as Upload to InForm.	Pending User(s) cannot be Marked Upload to InForm.
Mark Upload To InForm	Error occurs when you mark Upload the User who do not have a Role association.	Selected Users do not have a Role association.
Send Welcome Pack	Error occurs when you send welcome pack to the user who are not uploaded to InForm.	You have selected users who are not uploaded to InForm (second column icon).
Request Immediate Provisioning	Error occurs when you request immediate provisioning to the user whose status is pending.	Pending Users cannot be requested for Immediate Provisioning.
Request Immediate Provisioning	Error occurs when you request immediate provisioning to PF user.	PF users are not allowed for Provisioning.
Request Immediate Provisioning	Error occurs when you request immediate provisioning to the user who have no association or multiple association with the sites.	Users associated to no sites or multiple sites cannot be marked as Immediate provisioning started on this page.
Request Immediate Provisioning	Error occurs when you request immediate provisioning to the user who is already marked for the same.	One or more of the selected users is already marked for Immediate Provisioning.
Request Immediate Provisioning	Error occurs when you request immediate provisioning to the user who is already marked as Assessed.	One or more of the selected users is already assessed/currently being assessed - immediate provisioning is not available.
Request Immediate Provisioning	Error occurs when you request immediate provisioning to the user who already marked as Assessed.	One or more of the selected users is currently being Assessed - immediate provisioning is not available.

Table A-2 (Cont.) InForm Users - Error Information

Field Name/ Action	Scenario	Error Message
Request Immediate Provisioning	Error occurs when request immediate provisioning to the user whose Request Assessment column is pending.	Users requested for Equipment Assessment cannot be requested for Immediate provisioning. One or more users selected have been requested for Equipment Assessment.
Stop Assessment Process	Error occurs when you stop the assessment process for the user whose status is Provisioning Recommended - Requires Customer Approval.	Cannot stop Assessment process for User(s) with status as "Provisioning Recommended - Requires Customer Approval".
Stop Assessment Process	Error occurs when you stop the assessment process for the user whose status is Requires Customer Assistance.	Cannot stop Assessment process for User(s) with status as "Requires Customer Assistance".
Stop Assessment Process	Error occurs when you stop the assessment process for the user whose status is Provisioning - Started.	Cannot stop Assessment process for User(s) with status as "Provisioning - Started".
Stop Assessment Process	Error occurs when you stop the assessment process for the user who is associate with no site or more than one site.	One or more selected User(s) associated to multiple Sites. Please click on + symbol to perform the action.
Stop Assessment Process	Error occurs when you stop the assessment process for the user whose assessment is already stopped	Assessment is already stopped for selected user(s).
Stop Assessment Process	Error occurs when you stop assessment process for the user whose status is Provisioning Recommended/Requires Customer Approval.	Cannot stop Assessment process for User(s) with status as "Provisioning Recommended - Requires Customer Approval".
Stop Assessment Process	Error occurs when you stop assessment process for the user whose status is No Provisioning Recommended/Requires Customer Approval.	Cannot stop Assessment process for User(s) with status as "No Provisioning Recommended / Requires Customer Approval".
Stop Assessment Process	Error occurs when you stop assessment process for the user whose status is Provisioning - Started.	Cannot stop Assessment process for User(s) with status as "Provisioning - Started".
Stop Assessment Process	Error occurs when you stop assessment process for the PF user.	One or more selected users is (are) PF users.
Stop Assessment Process	Error occurs when you stop assessment process for the user whose assessment process is already completed.	Assessment process completed already for the selected User(s).
Stop Assessment Process	Error occurs when you stop assessment process for the user whose is already approved.	One or more users is already approved.
Stop Assessment Process	Error occurs when you stop assessment process for the user who do not have the assessment process started.	One or more selected users does not have the Assessment process started.
Stop Assessment Process	Error occurs when you stop assessment process for the user who has immediate provisioning started.	Assessment cannot be stopped for user(s) who has immediate provisioning started.
Stop Assessment Process	Error occurs when you stop assessment process for the user whose is already assessed.	Assessment cannot be stopped for user(s) who is already Assessed.
User ID	Error occurs when you enter the alphabets or special character.	Enter a valid User id. Only Numerics (0-9) are allowed.

# A.2 Create InForm, IRT, and OLX User Details

Table A-3 Create InForm, IRT, and OLX User Details – Field Information

Field Name	Description	Length
Basic User Info		
User Type*	Displays the user type.	NA
Username*	Displays/Modify the name of the user.	32 Characters
First Name*	Displays/Modify the first name of the user.	127 Characters
Last Name*	Displays/Modify the last name of the user.	127 Characters
Title	Displays/Modify the title for the user.	NA
Description	Displays/Modify the description.	NA
Display Name*	Displays/Modify the display name of the user.	255 Characters
Contact Details		
Address1* Address2:	Displays/Modify the communication address of the user.	255 Characters
Town/City*	Displays/Modify the town or city name to which the user belongs.	255 Characters
State/Province	Displays/Modify the state or province name to which the user belongs.	255 Characters
Country*	Displays/Modify the country to which the user belongs.	NA
Postal Code	Displays/Modify the postal code of the user.	16 Characters
Phone Number*	Displays/Modify the phone number of the user.	25 Characters
Alternate Phone Number	Displays/Modify the alternate phone number of the user.	25 Characters
Beeper Number:	Displays/Modify the beeper number of the user.	255 Characters
Fax Number:	Displays/Modify the fax number of the user.	25 Characters
E-Mail Address*	Displays/Modify the email address of the user.	255 Characters
Confirm User E-mail Address*	Displays/Modify the email address of the user for confirmation.	255 Characters
User Misc		
InForm Home Page Path	Displays/Modify the path of the InForm home page.	255 Characters
Change Password on Next Login	Displays the selected option. Select <b>Yes</b> to change the password at next log on. Otherwise, select <b>No</b> .	NA
Date Format	Displays/Modify the date format.	NA
Load to InForm	Select the check box to load the user's information into the InForm system.	NA
Require IOL Training in	Displays/Select the areas in which the user requires training. Press and hold the Ctrl key to select multiple choices.	NA
Already Trained	Displays/Select the areas in which the user has already been trained.	NA
Email Trigger	Displays the selected email trigger option. This information refers to the email trigger of Registration and Certificate emails by eCS.	NA
Status:	Displays/Select the status of the user.	NA
Training Status:	Displays/Modify the training status of the user.	NA
Image Status:	Displays/Modify the image URL.	255 Characters
IOL Email ID	Displays/Modify the IOL Email ID of the user.	NA
Preferred Study Locale	Displays/Modify the preferred study locale of the user.	NA

Table A-3 (Cont.) Create InForm, IRT, and OLX User Details – Field Information

Field Name	Description	Length
Product Locale	Displays/Modify the product locale of the user.	NA
User Name in Email Notifications	Displays/Modify the user name order for the user service mail.	NA
IRT Related		
Userid	Enter the IRT user ID.	NA
Middle Initial	Enter the middle initial of the user.	NA
Institution	Enter the institution of the user.	NA
Time Zone	Select the time zone from the drop-down list.	NA
Depot	Enter the depot of the user.	NA
IRT Role	Select the IRT role for the IRT user from the drop-down list.	NA
Load to IRT	Select the check box to load the user's information into the IRT system.	NA
OLX Related		
View Patient Identifiable Data:*	Enter the data to identify the patient.	255 Characters
Load to OLX	Select the check box to load the user's information into the OLX system.	NA
User Association		
Filter By	Displays/Select the filter criteria.	NA
Select Sites		
Available	Displays the list of available sites. Use the >> or > button to move all or the selected sites respectively to the Selected field.	-
Selected	Displays the list of selected sites. Use the << or < button to move all or the selected sites respectively to the Available field.	-
Rights Group*/OLX Role Group*	Displays/Modify the Rights group of the user and OLX role group displays the roles of OLX user.	-
Signature Group	Displays/Modify the Signature group of the user.	-
Query Group	Displays/Modify the Query group of the user.	-
Manager Group	Displays/Modify the Manager group of the user.	-
Site Association Description	Provide the description about the site association.	NA
Active Date	Enter the active date.	NA
Pivotal Added Date	Enter the pivotal added date.	NA
Activation Date	Enter the activation date.	NA
Termination Date	Enter the termination date.	NA

Table A-4 Scenarios and Error Messages

Field Name	Scenario	Error Message
Current Sponsor Company	Error occurs when you click <b>Submit</b> without selecting a Sponsor Company	Select a Sponsor Company.
Trial	Error occurs when you click <b>Submit</b> without selecting a trial.	Select a Trial.
User Type	Error occurs when you click <b>Submit</b> without selecting user type.	Select User Type.

Table A-4 (Cont.) Scenarios and Error Messages

Field Name	Scenario	Error Message
Username	Error occurs when you enter the character other than alphanumeric and underscore.	Enter a valid Username. Only Alphanumeric (A-Z, 0-9), underscores(_), and at sign (@) are allowed.
UserName	Error occurs when you click <b>Submit</b> without entering an username.	Error occurs when the user submit without enter Username.
FirstName	Error occurs when you click <b>Submit</b> without entering First Name.	Enter First Name.
First Name	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid First Name. Only Letters (A-Z), Hyphens (-) and Blank Spaces are allowed.
Last Name	Error occurs when you click <b>Submit</b> without entering the last name.	Enter Last Name.
Last Name	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid Last Name. Only Letters (A-Z), Hyphens (-) and Blank Spaces are allowed.
Title	NA	NA
Description	Error occurs when you enter an invalid character in the description.	Enter a valid Description. Only Alphanumerics (A-Z, 0-9), Hyphens(-), underscores(_), and Blank Spaces are allowed.
Display name	Error occurs when you click <b>Submit</b> without entering the display name.	Enter Display Name.
Address1	Error occurs when you enter an invalid character in Address1.	Enter a valid Address1. Only Alphanumerics (A-Z, 0-9), Period (.), Comma(,), Hyphens (-),underscores (_), and Blank Spaces are allowed.
Address2	Error occurs when you enter an invalid character in Address2.	Enter a valid Address2. Only Alphanumerics (A-Z, 0-9), Period (.), Comma(,), Hyphens(-), underscores(_), and Blank Spaces are allowed.
Town/City	Error occurs when you enter the character other than alphabet, integer, and blank space.	Enter a valid Town/City. Only Alphanumeric (A-Z,0-9) and Blank Spaces are allowed.
State/Province	Error occurs when you enter the character other than alphabet and blank space.	Enter a valid State/Province. Only Letters (A-Z) and Blank Spaces are allowed.
Uploaded to InForm	NA	Select the check box to view the list of InForm uploaded user details.
Country	NA	NA
Postal Code	Error occurs when you enter the character other than alphabet, integer, and blank space.	Enter a valid Postal Code. Only Alphanumeric (A-Z, 0-9) and Blank Spaces are allowed.
Phone Number	Error occurs when you click <b>Submit</b> without entering the phone number.	Enter Phone Number.
Phone Number	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid Phone Number. Only Numbers (0-9), Hyphens (-) and Blank spaces are allowed.
Alternate Phone Number	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid Alternate Phone Number. Only Numbers (0-9), Hyphens (-) and Blank spaces are allowed.

Table A-4 (Cont.) Scenarios and Error Messages

than alphabet, hypfien, and blank space.  E-mail Address  Error occurs when you click Submit without entering the crnail address.  E-mail Address  E-mail Address  Error occurs when you enter the wrong email ID or when you enter wrong mail format.  E-mail Address does not end with @phaseforward.com. Select OK in sensage is displayed at the time of creating a FT user. Description of the pour copy and paste your email address. How you come to provide paste your email address. How you come to provide paste your email address. In the word paste was a sensage is displayed when the email address do not match. (This message is displayed when the email address do not match.)  Error occurs when you enter the wrong email ID or when you enter wrong mail format.  Confirm User E-mail Address  Error occurs when you enter the wrong email ID or when you enter wrong mail format.  E-mail address does not end with @phaseforward.com. Select OK @phasef	Field Name	Scenario	Error Message
E-mail Address	Beeper Number		Only Numbers (0-9), Hyphens (-)
E-mail Address  Ernor occurs when you enter the wrong email ID or when you enter wrong mail format.  Ernor occurs when you click Submit without confirm email address on the on the you copy and pasts your email address. (This message is displayed when the you copy and pasts the email address and the Confirm email address and the confirm email address and the confirm user E-mail Address  Confirm User E-mail Address  Error occurs when you click Submit without confirm user E-mail Address  Error occurs when the email address and confirm email address and the confirm email address and the confirm user E-mail Address  Error occurs when you enter the wrong email ID or when you enter wrong mail format.  Enter Confirm User E-mail Address  Error occurs when you enter the wrong email ID or when you enter wrong mail format.  Ernal address does not end with (Phaseforward.com. Select OK (Phase on the power message is displayed at the time of continue, Clins error message is displayed when the email address. Please note: Do not copy and pasts your email enders. Please roonfirm your email address. Please note: Do not copy and pasts your email address. Please note: Do not copy and pasts your email address. Please note: Do not copy and pasts your email address do not match. This message is displayed when the email address do not match. This message is displayed when the email address do not match. This message is displayed when the email address do not match. This message is displayed when the email address. Please note: Do not copy and pasts your email enders. Please reconfirm your email enders. Please note: Do not copy and pasts your email address do not match. This message is displayed when the email address do not match. This message is displayed when the email address do not match. This message is displayed when the email address do not match. This message is displayed when the email	Fax Number		Numbers (0-9), Hyphens (-) and
or when you enter wrong mail format.  ### Splayed at the time of creating a PT to continue. (This error message is displayed at the time of creating a PT to entot pour email address. Please note: Do not copy and paste the email address. Please note: Do not copy and paste the email address and the confirm the email address and the confirm the email address and the confirm user E-mail Address  Confirm User E-mail Address  Error occurs when you enter the wrong email ID or when you enter wrong mail format.  Confirm User E-mail Address  Error occurs when you enter the wrong email ID or when you enter wrong mail format.  Confirm User E-mail Address  Error occurs when you enter the wrong email ID or when you enter wrong mail format.  Error occurs when you enter the wrong email ID or when you enter wrong mail format.  E-mail address does not end with @phaseforward.com. Select OK to confirm. (If his error message is displayed at the time of creating a PT buser).  Please re-confirm your email address. (If his error message is displayed at the time of creating a PT buser).  Please re-confirm your email address. (If his error message is displayed when the email address.) (If his error message is displayed when the email address.) (If his error message is displayed when the email address.) (If his error message is displayed when the email address.)  InForm Home Page Path  Error occurs when you enter an invalid home page path. (If his message is displayed when the email address.) (If his error mail address.) (	E-mail Address		Enter E-Mail Address.
address. Please note: Do not copy and paste your email address. (This message is displayed when the vou company and paste the email address). The email address and the confirm memail address and the confirm memail address and the confirm to match.  Confirm User E-mail Address  Confirm User E-mail Address  Error occurs when you click Submit without confirming the user email address and confirming the user email address.  Confirm User E-mail Address  Error occurs when you enter the wrong email ID or when you enter wrong email ID or when you to copy paste the email address do not exact the time of creating a PF user).  Please re-confirm your email address of the email address do not expect OK to continue. (This error message is displayed when the email address do not expect to the email address of the email address of the email address of the email address of the email address do not expect to the email address	E-mail Address		@phaseforward.com. Select OK to continue. (This error message is displayed at the time of
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or when you enter wrong mail format.  @phaseforward.com. Select OK to continue. (This error message is displayed at the time of creating a PF user).  Please re-confirm your email address. Please note: Do not copy and paste your email address. (This message is displayed when you to copy pand paste your email address.)  The email address and the Confirm email address do not match. (This message is displayed when the email address and the confirm email address on the email address and the confirm email address and the confirm email address on the email address and the confirm email address on the email address and the confirm email address do not match.)  Chapter Password on Next Login NA	Confirm User E-mail Address		
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Confirm email address do not match. (This message is displayed when the email address and the confirm email address do not match.)  InForm Home Page Path  Error occurs when you enter an invalid home page Enter a valid Home Page path. Only Alphanumeric (A-Z, 0-9), Colon (:), Forward slash (/), Period (.), Hyphen (-) and Underscore (_) are allowed.  Change Password on Next Login  NA  NA  NA  NA  NA  Status  NA  NA  NA  NA  Training Status  NA  NA  NA  NA  NA  NA  NA  NA  NA  N			address. Please note: Do not copy and paste your email address. (This message is displayed when you to copy paste the email
path.  Only Alphanumeric (A-Z, 0-9), Colon (:), Forward slash (/), Period (.), Hyphen (-) and Underscore (_) are allowed.  Change Password on Next Login  NA  NA  Date Format  NA  NA  Load to InForm  NA  NA  E-mail Trigger  NA  NA  NA  NA  NA  Training Status  NA  NA  NA  NA  NA  NA  NA  NA  NA  N			Confirm email address do not match. (This message is displayed when the email address and the confirm email
Date Format NA NA Load to InForm NA NA E-mail Trigger NA NA Status NA NA Training Status NA NA	InForm Home Page Path	, ,	Only Alphanumeric (A-Z, 0-9), Colon (:), Forward slash (/), Period (.), Hyphen (-) and
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E-mail Trigger NA NA NA Status NA NA NA Training Status NA NA NA	Date Format	NA	NA
Status NA NA Training Status NA NA	Load to InForm	NA	NA
Training Status NA NA	E-mail Trigger	NA	NA
	Status	NA	NA
Image URL NA NA	Training Status	NA	NA
	Image URL	NA	NA

Table A-4 (Cont.) Scenarios and Error Messages

Field Name	Scenario	Error Message
Filter By	NA	NA
Right Group	NA	NA
Signature Group	NA	NA
Query Group	NA	NA
Manager Group	NA	NA
Automatic Association	NA	NA
Validation for all fields	Error occurs when you click <b>Submit</b> without	
validation for all fields	entering an appropriate data.	Select UserType. Please Enter User Name.
		Enter First Name.
		Please Enter Last Name.
		Please Enter Display name.
		Please Enter Phone Number.
		Please Enter E-mail Address.
		Please Confirm User E-mail Address. (This message is displayed before selecting User Type).
		Please Enter User Name.
		Enter First Name.
		Please Enter Last Name.
		Please Enter Display name.
		Please Enter Phone Number.
		Please Enter E-mail Address.
		Please Confirm User E-mail Address.
		Select Rights Group. (This message is Displayed after selecting User Type and clicking on submit button.
Submit Button	NA	User Cannot be saved without 'InForm Settings' for the selected Sponsor and trial.
On Paste	NA	Please re-confirm your Email address. Please note: Do not copy and paste your Email address.
Automatic Association	NA	NA
User ID	Error occurs you enter the non-numeric values.	Enter a valid IRT userid. Only Numeric values are allowed.
Active Date	Error occurs when you enter an invalid date format.	Invalid Date Format in Active Date.
Pivotal Added Date	Error occurs when you enter an invalid date format.	Invalid Date Format in Pivotal Added Date.
Activation Date	Error occurs when you enter an invalid date format.	Invalid Date Format in Activation Date.
Termination Date	Error occurs when you enter an invalid date format.	Invalid Date Format in Termination Date.
Edit Page		

Table A-4 (Cont.) Scenarios and Error Messages

Field Name	Scenario	Error Message
Display name	Error occurs when you the display name is not entered.	Please Enter Display Name.
Reason For Change	Error occurs when you did not enter reason for change.	Please Enter The Reason For Change.
Clicking the Return button without saving the changes	Error occurs when you click <b>Return</b> without saving the changes.	You have made changes to this form. Press OK to ignore the changes and leave the form; Press Return to return to the form.

# A.3 Modify InForm and IRT User Details

All fields marked with \* are mandatory.

Table A-5 Modify InForm and IRT User Details – Field Information

Field Name	Description	Length
Basic User Info		
User Type*	Displays the user type.	NA
Username*	Displays/Modify the name of the user.	25 Characters
First Name*	Displays/Modify the first name of the user.	127Characters
Last Name*	Displays/Modify the last name of the user.	127Characters
Title	Displays/Modify the title for the user.	NA
Description	Displays/Modify the description.	NA
Display Name*	Displays/Modify the display name of the user.	255 Characters
Contact Details		
Address1* Address2:	Displays/Modify the communication address of the user.	255 Characters
Town/City*	Displays/Modify the town or city name to which the user belongs.	255 Characters
State/Province	Displays/Modify the state or province name to which the user belongs.	255 Characters
Country*	Displays/Modify the country to which the user belongs.	NA
Postal Code	Displays/Modify the postal code of the user.	16 Characters
Phone Number*	Displays/Modify the phone number of the user.	25 Characters
Alternate Phone Number	Displays/Modify the alternate phone number of the user.	25 Characters
Beeper Number:	Displays/Modify the beeper number of the user.	255 Characters
Fax Number:	Displays/Modify the fax number of the user.	25 Characters
E-Mail Address*	Displays/Modify the email address of the user.	255 Characters
Confirm User E-mail Address*	Displays/Modify the email address of the user for confirmation.	255 Characters
User Misc		
InForm Home Page Path	Displays/Modify the path of the InForm home page.	255 Characters
Change Password on Next Login	Displays the selected option. Select <b>Yes</b> to change the password at next log on. Otherwise, select <b>No</b> .	NA
Date Format	Displays/Modify the date format.	NA
Load to InForm	Select the check box to load the user's information into the InForm system.	NA

Table A–5 (Cont.) Modify InForm and IRT User Details – Field Information

Field Name	Description	Length
Require IOL Training in	Displays/Select the areas in which the user requires training. Press and hold the <b>Ctrl</b> key to select multiple choices.	NA
Already Trained	Displays/Select the areas in which the user is already trained.	NA
Email Trigger	Displays the selected email trigger option. This information refers to the email trigger of Registration and Certificate emails by eCS.	NA
Status:	Displays/Select the status of the user.	NA
Training Status:	Displays/Modify the training status of the user	NA
Image Status:	Displays/Modify the image URL.	255 Characters
IOL Email ID	Displays/Modify the IOL email ID of the user	NA
Preferred Study Locale	Displays/Modify the preferred study locale of the user.	NA
Product Locale	Displays/Modify the product locale of the user.	NA
User Name in Email Notifications	Displays/Modify the user name order for the user service mail.	NA
IRT Related		
Userid	Enter the IRT user ID.	NA
Middle Initial	Enter the middle initial of the user.	NA
Institution	Enter the institution of the user.	NA
Time Zone	Select the time zone from the drop-down list.	NA
Depot	Enter the depot of the user.	NA
IRT Role	Select the IRT role for the IRT user from the drop-down list.	NA
Load to IRT	Select the check box to load the user's information into the IRT system.	NA
OLX Related		
View Patient Identifiable Data:*	Enter the data to identify the patient.	255 Characters
Load to OLX	Select the check box to load the user's information into the OLX system.	NA
User Association		
Filter By	Displays/Select the filter criteria.	NA
Select Sites		
- Available	Displays the list of available sites. Use the >> or > button to move all or the selected sites respectively to the Selected field.	-
- Selected	Displays the list of selected sites. Use the << or < button to move all or the selected sites respectively to the Available field.	-
Rights Group*/OLX Role Group*	Displays/Modify the Rights group of the user and OLX role group displays the roles of OLX user.	-
Signature Group	Displays/Modify the Signature group of the user.	-
Query Group	Displays/Modify the Query group of the user.	-
Manager Group	Displays/Modify the Manager group of the user.	-
Site Association Description	Provide the description about the site association.	NA
Active Date	Enter the active date.	NA

Table A-5 (Cont.) Modify InForm and IRT User Details - Field Information

Field Name	Description	Length
Pivotal Added Date	Enter the pivotal added date.	NA
Activation Date	Enter the activation date.	NA
Termination Date	Enter the termination date.	NA

Table A-6 Scenarios and Error Messages

Field Name	Scenario	Error Message
Current Sponsor Company	Error occurs when you click <b>Submit</b> without selecting a Sponsor Company.	Select a Sponsor Company.
Trial	Error occurs when you click <b>Submit</b> without selecting a trial.	Select a Trial.
User Type	Error occurs when you click <b>Submit</b> without selecting a user type.	Select User Type.
Username	Error occurs when you enter the character other than alphanumeric and underscore.	Enter a valid Username. Only Alphanumeric (A-Z,0-9) and underscores(_) are allowed.
UserName	Error occurs when you click <b>Submit</b> without entering the user name.	Error occurs when the user submit without enter Username.
FirstName	Error occurs when you click <b>Submit</b> without entering the first name.	Enter First Name.
First Name	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid First Name. Only Letters (A-Z), Hyphens (-) and Blank Spaces are allowed.
Last Name	Error occurs when you click <b>Submit</b> without entering the last name.	Enter Last Name.
Last Name	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid Last Name. Only Letters (A-Z), Hyphens (-) and Blank Spaces are allowed.
Title	NA	NA
Description	Error occurs when you enter an invalid character in the description.	Enter a valid Description. Only Alphanumerics (A-Z, 0-9), Hyphens(-), underscores(_), and Blank Spaces are allowed.
Display name	Error occurs when you click <b>Submit</b> without entering the display name.	Enter Display Name.
Address1	Error occurs when you enter an invalid character in Address1.	Enter a valid Address1. Only Alphanumerics (A-Z, 0-9), Period (.), Comma(,), Hyphens(-), underscores(_), and Blank Spaces are allowed.
Address2	Error occurs when you enter an invalid character in Address2.	Enter a valid Address2. Only Alphanumerics (A-Z, 0-9), Period (.),Comma(,), Hyphens(-), underscores (_), and Blank Spaces are allowed.
Town/City	Error occurs when you enter the character other than alphabet, integer, and blank space.	Enter a valid Town/City. Only Alphanumeric (A-Z, 0-9) and Blank Spaces are allowed.
State/Province	Error occurs when you enter the character other than alphabet and blank space.	Enter a valid State/Province. Only Letters (A-Z) and Blank Spaces are allowed.
Uploaded to InForm	NA	Select the check box to view the list of InForm uploaded user details.
Country	NA	NA

Table A-6 (Cont.) Scenarios and Error Messages

Field Name	Scenario	Error Message
Postal Code	Error occurs when you enter the character other than alphabet, integer, and blank space.	Enter a valid Postal Code. Only Alphanumeric (A-Z, 0-9) and Blank Spaces are allowed.
Phone Number	Error occurs when you click <b>Submit</b> without entering the phone number.	Enter Phone Number.
Phone Number	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid Phone Number. Only Numbers (0-9), Hyphens (-) and Blank spaces are allowed.
Alternate Phone Number	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid Alternate Phone Number. Only Numbers (0-9), Hyphens (-) and Blank spaces are allowed.
Beeper Number	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid Beeper Number. Only Numbers (0-9), Hyphens (-) and Blank spaces are allowed.
Fax Number	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid Fax Number. Only Numbers (0-9), Hyphens (-) and Blank spaces are allowed.
E-mail Address	Error occurs when you click <b>Submit</b> without entering the email address.	Enter E-Mail Address.
E-mail Address	Error occurs when you enter the wrong email ID or wrong mail format.	E-mail address does not end with @phaseforward.com. Select OK to continue. (This error message is displayed at the time of creating a PF user).
		Please re-confirm your email address. Please note: Do not copy and paste your email address. (This message is displayed when the you copy and paste the email address).
		The email address and the Confirm email address do not match. (This message is displayed when the email address and the confirm email address do not match).
Confirm User E-mail Address	Error occurs when you click <b>Submit</b> without entering the confirm user email address.	Enter Confirm User E-mail Address.
Confirm User E-mail Address	Error occurs when the email address and confirm email address mismatch.	Confirm E-mail Address does not match.
Confirm User E-mail Address	Error occurs when you enter the wrong email ID or wrong mail format.	E-mail address does not end with @phaseforward.com. Select OK to continue. (This error message is displayed at the time of creating a PF user).
		Please re-confirm your email address. Please note: Do not copy and paste your email address. (This message is displayed when you to copy paste the email address).
		The email address and the Confirm email address do not match. (This message is displayed when the email address and the confirm email address do not match).

Table A-6 (Cont.) Scenarios and Error Messages

Field Name	Scenario	Error Message
InForm Home Page Path	Error occurs when you enter an invalid home page path.	Enter a valid Home Page path. Only Alphanumeric (A-Z, 0-9), Colon (:), Forward slash (/), Period (.), Hyphen (-) and Underscore (_) are allowed.
Change Password on Next Login	NA	NA
Date Format	NA	NA
Load to InForm	NA	NA
E-mail Trigger	NA	NA
Status	NA	NA
Training Status	NA	NA
Image URL	NA	NA
Filter By	NA	NA
Right Group	NA	NA
Signature Group	NA	NA
Query Group	NA	NA
Manager Group	NA	NA
Automatic Association	NA	NA
Validation for all fields	Error occurs when you click <b>Submit</b> without	Select UserType.
	entering an appropriate data.	Please Enter User Name.
		Enter First Name.
		Please Enter Last Name.
		Please Enter Display name.
		Please Enter Phone Number.
		Please Enter E-mail Address.
		Please Confirm User E-mail Address. (This message is displayed before selecting User Type).
		Please Enter User Name.
		Enter First Name.
		Please Enter Last Name.
		Please Enter Display name.
		Please Enter Phone Number.
		Please Enter E-mail Address
		Please Confirm User E-mail Address.
		Select Rights Group. (This message is Displayed after selecting User Type and clicking on submit button.
Submit Button	NA	User Cannot be saved without 'InForm Settings' for the selected Sponsor and trial.
On Paste	NA	Please re-confirm your Email address.\n Please note: Do not copy and paste your Email address.
Automatic Association	NA	NA
User ID	Error occurs when you enter the non-numeric values.	Enter a valid IRT userid. Only Numeric values are allowed.

Table A-6 (Cont.) Scenarios and Error Messages

Field Name	Scenario	Error Message
Active Date	Error occurs when you enter an invalid date format.	Invalid Date Format in Active Date.
Pivotal Added Date	Error occurs when you enter an invalid date format.	Invalid Date Format in Pivotal Added Date.
Activation Date	Error occurs when you enter an invalid date format.	Invalid Date Format in Activation Date.
Termination Date	Error occurs when you enter an invalid date format.	Invalid Date Format in Termination Date.
Edit Page		
Display name	Error occurs when the display name is not entered.	Please Enter Display Name.
Reason For Change	Error occurs when the reason for change is not entered.	Please Enter The Reason For Change.
Clicking the Return button without saving the changes	Error occurs when you click <b>Return</b> without saving the changes.	You have made changes to this form. Press OK to ignore the changes and leave the form; Press Return to return to the form.

# A.4 Multiple Association

Table A-7 Multiple Association – Field Information

Field Name	Description	
Select User	Select a user for whom you want to view site association details.	
User	Displays the name of the selected user.	
Site No.	Displays the number of sites that are associated with the selected user.	
Provisioning Recommendation	Displays whether provisioning recommendation has begun.	
Assessment Status	Displays the assessment status of the site. This column is displayed only if the Switch off Site Assessment facility check box is not selected in the InForm Config page.	
P/F	Display the pass or fail details for the site.	

Table A–8 Multiple Association – Error Information

Field Name/Action	Scenario	Error Message
Site	Error occurs when you click <b>Go</b> without selecting any site.	Select a site.
Go Button	Error occurs when you click <b>Go</b> without selecting any action in drop-down list.	Select an action.
Associate user	Error occurs when the not approved sites are associated to user.	One or more site(s) are not approved. Approve to Request Equipment Assessment.
Associate user	Error occurs when the assessed sites are associated to the user.	One or more of the selected sites is already assessed/currently being Assessed.
Immediate Provisioning	Error occurs when the sites already marked for immediate provisioning are again marked for the same.	One or more of the selected sites is already marked for Immediate Provisioning - Equipment Assessment is not available.
Equipment Assessment	Error occurs when you mark the site for equipment assessment where the user is already marked for Equipment Assessment.	User is already marked for Equipment Assessment at this site.

Table A-8 (Cont.) Multiple Association – Error Information

Field Name/Action	Scenario	Error Message
Mark Sites as Assessed	Error occurs when you mark the sites as assessed which is already marked as Assessed.	One or more of the selected sites is already marked as Assessed.
Mark Sites as Assessed	Error occurs when you give assessment for the site of the user whose assessment process is completed.	Assessment is completed for one or more selected user(s).
Immediate Provisioning	Error occurs when you mark the site for immediate provisioning to the sites which is already marked for immediate provisioning.	One or more of the selected sites is already marked for Immediate Provisioning.
Immediate Provisioning	Error occurs when you mark the assessed sites to immediate provisioning.	One or more of the selected sites is already assessed/currently being Assessed - immediate provisioning is not available.
Immediate Provisioning	Error occurs when the user already requested for equipment assessment is requesting for immediate provisioning.	Users requested for Equipment Assessment cannot be requested for Immediate provisioning. One or more users selected have been requested for Equipment Assessment (If pending user given Immediate provisioning).
Stop Assessment	Error occurs when you stop assessment for the sites associated with the user who status is Provisioning Recommended - Requires Customer Approval.	Cannot stop Assessment process for User(s) with status as "Provisioning Recommended - Requires Customer Approval".
Stop Assessment	Error occurs when you stop assessment for the sites associate with the user who status is Requires Customer Assistance.	Cannot stop Assessment process for User(s) with status as "Requires Customer Assistance".
Stop Assessment	Error occurs when you stop assessment for the sites associate with the user who status is Provisioning - Started.	Cannot stop Assessment process for User(s) with status as "Provisioning - Started".
Stop Assessment	Error occurs when you stop assessment for the sites associate with the user who have immediate provisioning started.	Assessment cannot be stopped for user(s) who has immediate provisioning started.
Stop Assessment	Error occurs when you assessment for the sites associated with the user who is already assessed.	Assessment cannot be stopped for user(s) who is already Assessed.
Stop Assessment	Error occurs when stop the assessment process for the site when the user of the site do not have the assessment process started.	One or more selected users does not have the Assessment process started.
Stop Assessment	Error occurs when you stop the assessment process for the site when the user of the site has stopped the assessment process already.	One or more selected users Assessment process has already stopped.
Go Button	Error occurs when you click <b>Go</b> without selecting an action.	Select an action.
Comments	Error occurs when you enter more than 255 character in a comment text-box.	Comments text should not exceed 255 characters.

# A.5 Global User List Page

Table A-9 Global User List Page - Field Information

Field Name	Description	Field Size
Basic User Info		
User Name	User name is displayed for all users.	32 Characters
First Name	The first name is displayed for all users	255 Characters

Table A-9 (Cont.) Global User List Page – Field Information

Field Name	Description	Field Size
Last Name	The Last Name is displayed for all users.	127 Characters
Email	The email id is displayed for all users	127 Characters
Display Name	This field is displayed for all product	255 Characters
Country	This field is displayed for all products after selecting the trial.	NA
User Type:	This field is available for both InForm and IRT products.	NA
Phone Number	This field is available for all products.	16 Characters
InForm Role	This field is available for both InForm and joint InForm IRT products.	NA
IRT Role	This field is available for both IRT and joint InForm IRT products.	NA
UMT Role	This field is available only for UMT products.	NA
Username in Email notification	This field is available for both InForm and IRT products with trial version above $4.5.$	NA
Preferred study locale	This field is available for both InForm and IRT products with trial version above $4.5.$	NA
Product Locale	This field is available for both InForm and IRT products with trial version above 4.5.	NA
Load To InForm	This field is available for InForm and Joint InForm IRT products with trial version above 4.5.	NA
Load To IRT	This field is available for IRT and Joint InForm IRT products with trial version above 4.5.	NA
Sites	This field is available for InForm products to let you assign sites.	NA
Export To Excel Link	Select an user and click this to export the user details to an Excel spreadsheet.	NA
Import	This field lets you import the user details.	NA

### A.6 Create Global User

Table A-10 Create Global User - Field Information

Field Name/	Description	Field Size (In Character)
Basic User Info:		
User Type	You need to select the type of user, either sponsor user or site user.	NA
User Name *	The user name format must follow the specifications in the UMT settings.	255 Characters
First Name*	Enter the first name of the user.	127 Characters
Last Name*	Enter the last name of the user.	127 Characters
Title	Select a title for the user from the drop-down list.	NA
Description	Enter the description for the user.	255 Characters
Display Name	Enter the display name for the user.	255 Characters
Contact Details		
Address1	Enter the communication address1 of the user.	255 Characters
Address2	Enter the communication address2 of the user.	255 Characters
Town/City	Enter the town or city to which the user belongs.	255 Characters

Table A-10 (Cont.) Create Global User - Field Information

Field Name/	Description	Field Size (In Character)
State/Province	Enter the state or province to which the user belongs.	255 Characters
Country	Select the country to which the user belongs from the drop-down list.	NA
Postal Code	Enter the postal code of the user.	16 Characters
Phone Number	Enter the phone number of the user.	25 Characters
Alternate Phone Number	Enter the alternate phone number of the user.	25 Characters
Beeper Number	Enter the beeper number of the user.	25 Characters
Fax Number	Enter the fax number of the user.	25 Characters
E-mail Address*	Enter the email address of the user.	255 Characters
Confirm User E-mail Address*	Enter the email address of the user for confirmation.	255 Characters
User Misc		
Assessment mail	Select whether to enable or disable assessment mail.	NA
Image URL	Enter the URL of the image.	255 characters
Change password in next login	Select Yes or No.	NA
Date Format	Select the format for the date to be displayed.	NA
Training Status	Select the training status from the options given.	NA
Load to InForm	Select if you want to load the user to InForm.	NA
IRT Related		
User Id	Enter the user ID.	255 Characters
Depot	Enter the depot.	255 Characters
Middle Initials	Enter the middle initials.	255 Characters
Institution	Enter the institution.	255 Characters
Load to IRT	Select if you want to upload the user to IRT.	NA

Table A-11 Create Global User - Error Information

Field Name	Scenario	Error Message
Filter Section:		
Basic User Info		
User Type	You need to select the type of user, either sponsor user or site user.	NA
User Name*	Error occurs when you enter the character other than alphanumeric and underscore.	Enter a valid Username. Only Alphanumeric (A-Z, 0-9) and underscores (_) are allowed.
First Name*	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid First Name. Only Letters (A-Z), Hyphens (-), and Blank Spaces are allowed.
Last Name*	Error occur when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid Last Name. Only Letters (A-Z), Hyphens (-), and Blank Spaces are allowed.
Title	NA	NA
Description:	Enter the description for the user.	255 Characters
Display Name:	Enter the display name for the user.	255 Characters
Change Password on Next Login	NA	NA
Contact Details		
Address1	Enter the communication address1 of the user.	255 Characters

Table A-11 (Cont.) Create Global User - Error Information

Field Name	Scenario	Error Message
Address2	Enter the communication address2 of the user.	255 Characters
Town/City	Enter the town or city to which the user belongs.	255 Characters
State/Province	Enter the state or province to which the user belongs.	255 Characters
Country	Select the country to which the user belongs from the drop-down list.	NA
Postal Code	Enter the postal code of the user.	16 Characters
Phone Number	Enter the phone number of the user.	25 Characters
Alternate Phone Number	Enter the alternate phone number of the user.	25 Characters
Beeper Number	Enter the beeper number of the user.	25 Characters
Fax Number	Enter the fax number of the user.	25 Characters
E-mail Address*	Error occurs when you click <b>Submit</b> without entering a valid email ID.	Enter a valid email ID.
Confirm User E-mail Address*	Error occurs when you do not enter the confirm email address.	Confirm the email address.

#### A.7 Edit Global User

Table A-12 Edit Global User - Field Information

Field Name/	Description	Field Size (In Character)
Basic User Info:		
User Type	You need to select the type of user, either sponsor user or site user.	NA
User Name *	The user name format must follow the specifications in the UMT settings.	255 Characters
First Name*	Enter the first name of the user.	127 Characters
Last Name*	Enter the last name of the user.	127 Characters
Title	Select a title for the user from the drop-down list.	NA
Description	Enter the description for the user.	255 Characters
Display Name	Enter the display name for the user.	255 Characters
Contact Details		
Address1	Enter the communication address1 of the user.	255 Characters
Address2	Enter the communication address2 of the user.	255 Characters
Town/City	Enter the town or city to which the user belongs.	255 Characters
State/Province	Enter the state or province to which the user belongs.	255 Characters
Country	Select the country to which the user belongs from the drop-down list.	NA
Postal Code	Enter the postal code of the user.	16 Characters
Phone Number	Enter the phone number of the user.	25 Characters
Alternate Phone Number	Enter the alternate phone number of the user.	25 Characters
Beeper Number	Enter the beeper number of the user.	25 Characters
Fax Number	Enter the fax number of the user.	25 Characters
E-mail Address*	Enter the email address of the user.	255 Characters
Confirm User E-mail Address*	Enter the email address of the user for confirmation.	255 Characters

Table A-12 (Cont.) Edit Global User - Field Information

Field Name/	Description	Field Size (In Character)
User Misc		
Assessment mail	Select whether to enable or disable assessment mail.	NA
Image URL	Enter the URL of the image.	255 characters
Change password in next login	Select Yes or No.	NA
Date Format	Select the format for the date to be displayed.	NA
Training Status	Select the training status from the options given.	NA
Load to InForm	Select if you want to load the user to InForm.	NA
IRT Related		
User Id	Enter the user ID.	255 Characters
Depot	Enter the depot.	255 Characters
Middle Initials	Enter the middle initials.	255 Characters
Institution	Enter the institution.	255 Characters
Load to IRT	Select if you want to load the user to IRT.	NA

Table A-13 Edit Global User - Error Information

Field Name	Scenario	Error Message
Filter Section:		
Basic User Info		
User Type	You need to select the type of user, either sponsor user or site user.	NA
User Name*	Error occurs when you enter the character other than alphanumeric and underscore.	Enter a valid Username. Only Alphanumeric (A-Z, 0-9) and underscores (_) are allowed.
First Name*	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid First Name. Only Letters (A-Z), Hyphens (-), and Blank Spaces are allowed.
Last Name*	Error occur when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid Last Name. Only Letters (A-Z), Hyphens (-), and Blank Spaces are allowed.
Title	NA	NA
Description	Enter the description for the user.	255 Characters
Display Name	Enter the display name for the user.	255 Characters
Change Password on Next Login	NA	NA
Contact Details		
Address1	Enter the communication address1 of the user.	255 Characters
Address2	Enter the communication address2 of the user.	255 Characters
Town/City	Enter the town or city to which the user belongs.	255 Characters
State/Province	Enter the state or province to which the user belongs.	255 Characters
Country	Select the country to which the user belongs from the drop-down list.	NA
Postal Code	Enter the postal code of the user.	16 Characters
Phone Number	Enter the phone number of the user.	25 Characters
Alternate Phone Number	Enter the alternate phone number of the user.	25 Characters
Beeper Number	Enter the beeper number of the user.	25 Characters

Table A-13 (Cont.) Edit Global User - Error Information

Field Name	Scenario	Error Message
Fax Number	Enter the fax number of the user.	25 Characters
E-mail Address*	Error occurs when you click <b>Submit</b> without entering an valid email ID.	Enter a valid email ID.
Confirm User E-mail Address*	Error occurs when you do not enter the confirm email address.	Confirm email address.

#### A.8 InForm Roles

Table A-14 InForm Roles - Field Information

Field Name	Description	Field Size
Filter Section		
Role Name	Enter the name of the role.	63 Characters
Approval Status	Select the approval status from the drop-down list.	NA
InForm Role Details		
Role Name	Displays the name of the role. Click the hyperlink to view the role details.	NA
Approved/Pending	Displays the approval status of the role.	NA
Member Count	Displays the number of members in the role.	NA
User Association	Click the icon to view the user-role associations.	NA
Display OverRide	Click the icon to set the display override option for selected Item group.	NA
Transfer Role	Click the icon to transfer role for selected users from one role to another.	NA

#### A.9 Create InForm Role

Table A-15 Create InForm Role - Field Information

Field Name	Description	Field Size
Role*	Enter the name of the role.	63 character
Role Type*	Select a role type by clicking the corresponding check box.	NA
User Admin	Displays the list of user administration rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
User Misc	Displays the list of user miscellaneous rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
CRF Rights	Displays the list of CRF rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
Case Book Rights	Displays the list of case book rights.	NA
	To assign a privilege (rights), select the corresponding check box.	

Table A-15 (Cont.) Create InForm Role - Field Information

Field Name	Description	Field Size
Query Rights	Displays the list of query rights.	NA
	To select the rights, click the corresponding check boxes.	
Rule Rights	Displays the list of user rule rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
Synchronization	Displays the list of synchronization rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
Navigation	Displays the list of navigation rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
System Admin Rights	Displays the list of system administration rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
Select Classes	Select the class from the drop-down list.	NA
Available	Displays the list of available IOL classes.	NA
	Click >> or > to move all or the selected classes, respectively, to the Selected field.	
Selected	Displays the list of selected IOL classes.	NA
	Click << or < to move all or the selected classes, respectively, to the Available field.	

Table A-16 Create InForm Role - Error Information

Field Name/Action	Scenario	Error Message
Role*	Error occurs when you click <b>Submit</b> without entering a role name.	Enter a valid Role Name. Only Alphanumerics. (A-Z, 0-9), Hyphens(-), underscores(_), and blank spaces are allowed.
Role Type*	Error occurs when you click <b>Submit</b> without selecting a role type.	Select a Role Type.
Submit Button	Error occurs when the Patient Transfer Right is selected for the trial running in the InForm 4.5 version.	Patient Transfer Right can be selected only for Trials running in InForm 4.5 Version.
Submit Button	Error occurs when the Custom Reports and Admin Reports Rights are selected for the trial running in the InForm 4.5 version.	InForm 4.5 Version cannot have Custom Reports and Admin Reports Right.
Submit Button	Error occurs when the Custom Reports Right is selected for the trial running in the InForm 4.5 version.	InForm 4.5 Version cannot have Custom Reports Right.
Submit Button	Error occurs when the Patient Transfer Right is selected for the trial running in the InForm 4.5 version.	InForm 4.5 Version cannot have Admin Reports Right.
Submit Button	Error occurs when no rights are associated to the Role.	Associate at least one Right for the Role.
Submit Button	Error occurs when you click <b>Submit</b> without entering all mandatory fields.	Complete all mandatory fields before saving.
Role Name	Error occurs when you enter invalid character other than alphanumerics and hyphens.	Enter a valid Role Name. Only Alphanumerics (A-Z, 0-9), Hyphens(-), underscores (_), and blank spaces are allowed.

#### A.10 InForm Role Details

Table A-17 InForm Role Details - Field Information

Field Name	Description	Field Size
Role*	Enter the name of the role.	63 character
Role Type*	Select a role type by clicking the corresponding check box.	NA
User Admin	Displays the list of user administration rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
User Misc	Displays the list of user miscellaneous rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
CRF Rights	Displays the list of CRF rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
Case Book Rights	Displays the list of case book rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
Query Rights	Displays the list of query rights.	NA
	To select the right, click the corresponding check boxes.	
Rule Rights	Displays the list of user rule rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
Synchronization	Displays the list of synchronization rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
Navigation	Displays the list of navigation rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
System Admin Rights	Displays the list of system administration rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
Select Classes	Select the class from the drop-down list.	NA
Available	Displays the list of available IOL classes.	NA
	Click >> or > to move all or the selected classes, respectively, to the Selected field.	
Selected	Displays the list of selected IOL classes.	NA
	Click << or < to move all or the selected classes, respectively, to the Available field.	

Table A-18 InForm Role Details - Error Information

Field Name/Action	Scenario	Error Message
Role	Error occurs when you click <b>Submit</b> without entering a role name.	Enter a valid Role Name. Only Alphanumerics. (A-Z, 0-9), Hyphens(-), underscores(_), and blank spaces are allowed.
Role Type	Error occurs when you click <b>Submit</b> without selecting a role type.	Select a Role Type.
Submit Button	Error occurs when Patient Transfer Right is selected for the trial running in the InForm 4.5 version.	Patient Transfer Right can be selected only for Trials running in InForm 4.5 Version.
Submit Button	Error occurs when Custom Reports and Admin Reports Rights are selected for the trial running in the InForm 4.5 version.	InForm 4.5 Version cannot have Custom Reports and Admin Reports Right.
Submit Button	Error occurs when Custom Reports Right is selected for the trial running in the InForm 4.5 version.	InForm 4.5 Version cannot have Custom Reports Right.
Submit Button	Error occurs when Patient Transfer Right is select for the trial running in the InForm 4.5 version.	InForm 4.5 Version cannot have Admin Reports Right.
Submit Button	Error occurs when no rights are associated to the Role.	Associate at least one Right for the Role.
Submit Button	Error occurs when you click <b>Submit</b> without entering all mandatory fields.	Complete all mandatory fields, before Saving.
Role Name	Error occurs when you enter an invalid character other than alphanumerics and hyphens.	Enter a valid Role Name. Only Alphanumerics (A-Z, 0-9), Hyphens(-), underscores (_), and blank spaces are allowed
Reason for Change	Error occurs when you submit the form without entering any reason for the change.	Enter a reason for the change.

### A.11 User, Role Association

Table A-19 User, Role Association - Field Information

Field Name	Description
Select Users	
- Available	Displays the list of available users.
	Click >> or > to move all or the selected users, respectively, to the Selected field.
- Selected	Displays the list of selected users. Use the << or < button to move all or the selected users, respectively, to the Available field.
Already Associated	Displays the name of users that are already associated with the role.

Table A-20 User - Role Association - Error Information

Field Name/Action	Scenario	Error Message
Submit Form	Error errors when you click <b>Submit</b> without making any change in the form.	Form not Changed.

# A.12 Display and Change Override

Table A-21 Display Override - Field Information

Field Name	Description
Select Item Groups	
- Available	Displays the list of available time zones.
	Click >> or > to move all or the selected time zones, respectively, to the Selected field.
- Selected	Displays the list of selected time zones.
	Click << or < to move all or the selected time zones, respectively, to the Available field.
Select Display Override	Select the corresponding radio button to set the display override option as read-only, editable, or hidden.

Table A-22 Change Display Override - Field Information

Field Name	Description
Select Item Groups	
- Available	Displays the list of available time zones.
	Click >> or > to move all or the selected time zones, respectively, to the Selected field.
- Selected	Displays the list of selected time zones.
	Click << or < to move all or the selected time zones, respectively, to the Available field.
Select Display Override	Select the corresponding radio button to set the display override option as read-only, editable, or hidden.

Table A-23 Change Display Override - Error Information

Field Name/Action	Scenario	Error Message
Submit Form	Error occurs when you click <b>Submit</b> without making any change in the form.	Form not Changed.

### A.13 List of Groups

Table A-24 List of Groups - Field Information

Field Name	Description	Field Size
Filter Section		
Group Name	Enter the name of the group.	63 Characters
Group Type	Select the group type from the drop-down list.	NA
Approval Status	Select the approval status from the drop-down list.	NA
<b>Group Details</b>		NA
Group Name:	Displays the name of the group. Click the hyperlink to view the group details.	NA
Group Type	Displays the type of the group.	NA
	The group type can be ItemGroup, ManagerUser, Query, ReportGroup, and Signature.	

Table A-24 (Cont.) List of Groups - Field Information

Field Name	Description	Field Size
Approval Status	Displays the approval status of the group.	NA
	The approval status can be Approved, Rejected, or Pending.	
Member Count	Displays the number of members in the group.	NA
User Association	Click the icon to view the user-role associations.	NA

Table A-25 List of Groups - Error Information

Field Name/Action	Scenario	Error Message
Approve Group	Error occurs when you click <b>Go</b> without selecting a group.	Select a Group to Approve.
Go Button	Error occurs when you click <b>Go</b> without selecting a group.	Select any one of the check boxes and then proceed.
Go Button	Error occurs when you click <b>Go</b> without selecting any item in the Select drop-down list.	Choose an action.
Rejection	Error occurs when you click <b>Go</b> without entering reason for rejection in the Comments text box.	Enter Reason for Rejection.
Approve/Reject	Error occurs when you approve or reject a group which is already approved or rejected.	Only Pending groups can be Approved / Rejected.
User Association	Error occurs when you click the user association icon of Item Group.	Item group cannot have user associations.
Find Button	Error occurs when you click <b>Find</b> without selecting a trial.	Select a trial.
Find Button	Error occurs when you click <b>Find</b> without selecting a sponsor.	Select a Sponsor Company.

# A.14 Create Groups

Table A-26 Create Groups - Field Information

Field Name/	Description	Field Size (In Character)
Group Details		
Group Name*	Enter the name of the group.	63 Characters
Group Type*	Select the type of the group from the drop-down list.	NA
Group Description	Enter a description about the group.	255 Characters
Fields for Item Group		
Item Association		
Select Items-		
Group Description	Enter a description of the group.	255 Characters
Available	Displays the list of available items.	NA
	Click >> or > to move all or the selected items, respectively, to the Selected field.	
Selected	Displays the list of selected items.	NA
	Click << or < to move all or the selected items, respectively, to the Available field.	
Fields for Manager User Group		
Manager of*	Select the users that reports to the manager from the drop-down list.	NA

Table A-26 (Cont.) Create Groups - Field Information

Field Name/	Description	Field Size (In Character)
Group Description	Enter a description of the manager user group.	255 Characters
Role Association		
Select Roles		
Available	Displays the list of available users.	NA
	Click >> or > to move all or the selected users, respectively, to the Selected field.	
Selected	Displays the list of selected users.	NA
	Click << or < to move all or the selected users, respectively, to the Available field.	
Fields for Query Group		
Group Description	Enter a description of the query group.	255 Characters
Select Roles		
Available	Displays the list of available users.	NA
	Click >> or > to move all or the selected users, respectively, to the Selected field.	
Selected	Displays the list of selected users.	NA
	Click << or < to move all or the selected users, respectively, to the Available field.	
Fields for Report Group		
Group Description	Enter a description of the report group.	255 Characters
Select Roles		
Available	Displays the list of available users.	NA
	Click >> or > to move all or the selected users, respectively, to the Selected field.	
Selected	Displays the list of selected users.	NA
	Click << or < to move all or the selected users, respectively, to the Available field.	
Fields for Signature Group		
Select Form	Select a form from the list box.	NA
Final CRF True	Select the check box, if required.	NA
False	Select the check box, if required.	NA
Added Forms	Displays the selected form.	NA
Signature Meaning (CRF)	Select a signature meaning from the drop-down list.	NA
Default	Select the check box, if required.	NA
Customized	Select the check box, if required.	NA
Signature Meaning (CRB)	Select a signature meaning from the drop-down list.	NA
Default	Select the check box, if required.	NA
Customized	Select the check box, if required.	NA
Group Description	Enter a description of the signature group.	NA
Group Details		
Available	Displays the list of available users.	NA
	Click >> or > to move all or the selected users, respectively, to the Selected field.	
Selected	Displays the list of selected users.  Click << or < to move all or the selected users, respectively, to the Available field.	NA

Table A-27 Create Group - Error Information

Field Name	Scenario	Error Message
Group Details		
Group Name*	Error occurs when you click <b>Submit</b> without entering the group name.	Please Enter a Group Name.
Group Type*	Error occurs when you click <b>Submit</b> without selecting the group type.	Select a Group Type.
Group Description	Error occurs when you enter more than 255 characters in the description.	Enter a group description not more than 255 characters.
Fields for Item Group		
Item Association		
Select Items-		
Group Description	Error occurs when you enter more than 255 characters in the description.	Enter a group description not more than 255 characters.
Available	NA	NA
Selected	NA	NA
Fields for Manager User Group		
Manager of*	Error occurs when you click <b>Submit</b> without selecting manager of the field.	Manager should be chosen.
Group Description	Error occurs when you enter more than 255 characters in the description.	Enter a group description not more than 255 characters.
Role Association		
Select Roles		
Available	NA	NA
Selected	NA	NA
Fields for Query Group		
Group Description	Error occurs when you enter more than 255 characters in the description.	Enter a group description not more than 255 characters.
Select Roles		
Available	NA	NA
Selected	NA	NA
Fields for Report Group		
Group Description	Error occurs when you enter more than 255 characters in the description.	Enter a group description not more than 255 characters.
Select Roles		
Available	NA	NA
Selected	NA	NA
Fields for Signature Group		
Select Form	Error occurs when you click <b>Submit</b> without selecting a form.	Select a Form.
Final CRF True	Error occurs when you turn more than one form true.	Only one form with True is allowed.
False	NA	NA
Added Forms	NA	NA
Signature Meaning (CRF)	Error occurs when you click <b>Submit</b> without selecting the CRF Signature.	Enter CRF Signature Meaning
Default	Error occurs when you click <b>Submit</b> without selecting the CRF type.	Select CRF Default/Customized Affidavi type.

Table A-27 (Cont.) Create Group - Error Information

Field Name	Scenario	Error Message
Customized	Error occurs when you click <b>Submit</b> without selecting the CRF type.	Select CRF Default/Customized Affidavit type.
Signature Meaning (CRB)	Error occurs when you click <b>Submit</b> without selecting the CRB signature.	Enter CRB Signature Meaning.
Default	Error occurs when you click <b>Submit</b> without selecting the CRB type.	Select CRB Default/Customized Affidavit type.
Customized	Error occurs when you click <b>Submit</b> without selecting the CRB type.	Select CRB Default/Customized Affidavit type.
Group Description	Error occurs when you enter more than 255 characters in the description.	Enter a group description not more than 255 characters.
<b>Group Details</b>		
Available	NA	NA
Selected	NA	NA

### A.15 View and Modify User and Group Association

Table A-28 View and Modify User and Group Association

Field Name	Description
Select Users	
Available	Displays the list of available items.  Click >> or > to move all or the selected items, respectively, to the Selected field.
Selected	Displays the list of selected items.  Click << or < to move all or the selected items, respectively, to the Available field.

### A.16 Edit Groups

Table A-29 Edit Groups - Field Information

Field Name/	Description	Field Size (In Character)
Group Details		
Group Type*	Select the type of the group from the drop-down list.	NA
Group Description	Enter a description about the group.	255 Characters
Fields for Item Group		
Item Association		
Select Items-		
Group Description	Enter a description of the group.	255 Characters
Available	Displays the list of available items.	NA
	Click >> or > to move all or the selected items, respectively, to the Selected field.	
Selected	Displays the list of selected items.	NA
	Click << or < to move all or the selected items, respectively, to the Available field.	
Fields for Manager User Group		

Table A-29 (Cont.) Edit Groups - Field Information

Field Name/	Description	Field Size (In Character)
Manager of*	Select the users that reports to the manager from the drop-down list.	NA
Group Description	Enter a description of the manager user group.	255 Characters
Role Association		
Select Roles		
Available	Displays the list of available users.	NA
	Click >> or > to move all or the selected users, respectively, to the Selected field.	
Selected	Displays the list of selected users.	NA
	Click << or < to move all or the selected users, respectively, to the Available field.	
Fields for Query Group		
Group Description	Enter a description of the query group.	255 Characters
Select Roles		
Available	Displays the list of available users.	NA
	Click >> or > to move all or the selected users, respectively, to the Selected field.	
Selected	Displays the list of selected users.	NA
	Click << or < to move all or the selected users, respectively, to the Available field.	
Fields for Report Group		
Group Description	Enter a description of the report group.	255 Characters
Select Roles		
Available	Displays the list of available users.	NA
	Click >> or > to move all or the selected users, respectively, to the Selected field.	
Selected	Displays the list of selected users.	NA
	Click << or < to move all or the selected users, respectively, to the Available field.	
Fields for Signature Group		
Select Form	Select a form from the list box.	NA
Final CRF True	Select the check box, if required.	NA
False	Select the check box, if required.	NA
Added Forms	Displays the selected form.	NA
Signature Meaning (CRF)	Select a signature meaning from the drop-down list.	NA
Default	Select the check box, if required.	NA
Customized	Select the check box, if required.	NA
Signature Meaning (CRB)	Select a signature meaning from the drop-down list.	NA
Default	Select the check box, if required.	NA
Customized	Select the check box, if required.	NA
Group Description	Enter a description of the signature group.	NA

Table A-29 (Cont.) Edit Groups - Field Information

Field Name/	Description	Field Size (In Character)
<b>Group Details</b>		
Available	Displays the list of available users.	NA
	Click >> or > to move all or the selected users, respectively, to the Selected field.	
Selected	Displays the list of selected users.	NA
	Click << or < to move all or the selected users, respectively, to the Available field.	

Table A-30 Edit Group - Error Information

Field Name	Scenario	Error Message
Group Details		
Group Name*	Error occurs when you click <b>Submit</b> without entering the group name.	Please Enter a Group Name.
Group Type*	Error occurs when you click <b>Submit</b> without selecting the group type.	Select a Group Type.
Group Description	Error occurs when you enter more than 255 characters in the description.	Enter a group description not more than 255 characters.
Fields for Item Group		
Item Association		
Select Items-		
Group Description	Error occurs when you enter more than 255 characters in the description.	Enter a group description not more than 255 characters.
Available	NA	NA
Selected	NA	NA
Fields for Manager User Group		
Manager of*	Error occurs when you click <b>Submit</b> without selecting the manager of field.	Manager should be chosen.
Group Description	Error occurs when you enter more than 255 characters in the description.	Enter a group description not more than 255 characters.
Role Association		
Select Roles		
Available	NA	NA
Selected	NA	NA
Fields for Query Group		
Group Description	Error occurs when you enter more than 255 characters in the description.	Enter a group description not more than 255 characters.
Select Roles		
Available	NA	NA
Selected	NA	NA
Fields for Report Group		
Group Description	Error occurs when you enter more than 255 characters in the description.	Enter a group description not more than 255 characters.
Select Roles		
Available	NA	NA
Selected	NA	NA
Fields for Signature Group		

Table A-30 (Cont.) Edit Group - Error Information

Field Name	Scenario	Error Message
Select Form	Error occurs when you click <b>Submit</b> without selecting a form.	Select a Form.
Final CRF True	Error occurs when you turn more than one form true.	Only one form with True is allowed.
False	NA	NA
Added Forms	NA	NA
Signature Meaning (CRF)	Error occurs when you click <b>Submit</b> without selecting the CRF Signature.	Enter CRF Signature Meaning.
Default	Error occurs when click <b>Submit</b> without selecting the CRF type.	Select CRF Default/Customized Affidavit type.
Customized	Error occurs when you click <b>Submit</b> without selecting the CRF type.	Select CRF Default/Customized Affidavit type.
Signature Meaning (CRB)	Error occurs when you click <b>Submit</b> without selecting the CRB Signature.	Enter CRB Signature Meaning.
Default	Error occurs when you click <b>Submit</b> without selecting the CRB type.	Select CRB Default/Customized Affidavit type.
Customized	Error occurs when you click <b>Submit</b> without selecting the CRB type.	Select CRB Default/Customized Affidavit type.
Group Description	Error occurs when you enter more than 255 characters in the description.	Enter a group description not more than 255 characters.
Group Details		
Available	NA	NA
Selected	NA	NA

# A.17 Configuration Settings

Configuration Settings - Field Information Table A-31

Field Name/	Description	Field Size (In Character)
Outbound Integration and SSO Config	urations	
Vanity URL	Enter the vanity URL for customer.	NA
Reset Passoword URL	Enter the URL to reset the password.	NA
Short Org ID	Enter the customer URL prefix for SSO-enabled customers.	NA
Trial Configurations		
Trial Level Duplicate	Select $Y\!e\!s$ to duplicate a trial level. Otherwise, select $No.$	NA
Enable Duplicate Merging	Select the check box to enable duplicate merging.	NA
Send E-mails for Failed Uploads	Select <b>Yes</b> to send emails for failed uploads. Otherwise, select <b>No</b> .	NA
	If you select <b>Yes</b> , enter the email address in the E-mail Address text box.	
Switchoff IOL	Select the check box to disable the IOL feature.	NA
Switchoff Global User	Select the check box to disable Global User.	NA

Table A-31 (Cont.) Configuration Settings - Field Information

the required option to use the sponsor name MT mails. The available options are: Append Sponsor name with Sponsor Customer Name - Select this option to append sponsor name with sponsor customer name. Replace Sponsor name with Sponsor Customer name - Select this option to replace sponsor	NA
Name - Select this option to append sponsor lame with sponsor customer name.  Replace Sponsor name with Sponsor Customer	
name with sponsor customer name.	
	NA
-	NA
ime Zones Dec 2012	
ime Zones Dec 2011	
	NA
	NA
Browse to select the import path.	NA
	NA
f	
*	NA
ption is for SFTP file upload.	
*	NA
ption is for SFTP file upload.	
	NA
ption is for SFTP file upload.	
	NA
select <b>Yes</b> , enter the email address in the text	
	NA
	NA
	NA
<u>*</u>	
• •	
	Yes to enforce UM/UA approval process. wise, select No.  the required default time zone. The available is are:  Time Zones Dec 2012  Time Zones Dec 2011  Yes if the trials are PF-Japan Managed trials. wise, select No.  the email address to send the worklist ration.  Browse to select the import path.  Import Enable to enable schedule import data er to the InForm system.  Potion is for Secure File Transfer Protocol  Import Disable to disable schedule import ransfer to the InForm system.  Potion is for SFTP file upload.  Export Enable to enable schedule export data er to the InForm system.  Potion is for SFTP file upload.  Export Disable to disable schedule export ransfer to the InForm system.  Potion is for SFTP file upload.  Export Disable to disable schedule export ransfer to the InForm system.  Potion is for SFTP file upload.  Yes to send emails for duplicated imports.  Wise, select No.  select Yes, enter the email address in the text  Success to send emails for successful import.  Fail to send emails for failed import.  the email address in the text box to send emails coessful or failed import based on the selection.  the check box if training is required to send maccount details.  the required free phone number URL. The ble options are:  Phaseforward Helpdesk  Sponsor Specific  select Sponsor Specific, enter the URL in the sor Specific URL text box.

Site Configuration

Table A-31 (Cont.) Configuration Settings - Field Information

Field Name/	Description	Field Size (In Character)
Default Study Version	Select the default study version. The available options are:	NA
	<ul> <li>Latest: Select this option to set the latest study version as default.</li> </ul>	
	<ul> <li>Multiple: Select this option to set multiple study versions as default.</li> </ul>	
	<b>Note</b> : To add a new study version, select <b>Multiple</b> .	
Update All Sites to Latest	Click the button to update all sites to the latest study version.	NA
Switch off Site Assessment facility	Select the check box to disable site assessment facility.	NA
User Configuration		
InForm Home Page Path	Enter the path for the InForm home page.	255 Characters
Overwrite?	Select the check box if you want to overwrite the home page.	NA
Image URL	Enter the image URL.	255 Characters
Overwrite?	Select the check box if you want to overwrite the image URL.	NA
Sponsor Username Format	Select the radio button corresponding to the format, which must be used for the sponsor's user name.	NA
	The available options are:	
	First Letter of Forename and Full Surname.	
	<ul> <li>First Letter of Forename and Full Surname and 3 digit number suffixed.</li> </ul>	
	■ User Entered.	
Site Username Format	Select the radio button corresponding to the format, which must be used for the site's user name.	NA
	The available options are:	
	First Letter of Forename and Full Surname.	
	<ul> <li>First Letter of Forename and Full Surname and 3 digit number suffixed.</li> </ul>	
	<ul><li>User Entered.</li></ul>	
User Status	Select <b>Active</b> to enable the user status active. Otherwise, select <b>Inactive</b> .	NA
Overwrite?	Select the check box if you want to overwrite the user status.	NA
Change Password	Select $Y\!es$ to change password. Otherwise, select $No.$	NA
Overwrite?	Select the check box if you want to overwrite the password change.	NA
Copy Terminate Users	Select $\mathbf{Yes}$ to copy terminated users. Otherwise, select $\mathbf{No}$ .	NA
<b>Editable System Config Options</b>		
Enrol patient with incomplete form	Select <b>Yes</b> to enable enrollment of patients with incomplete forms. Otherwise, select <b>No</b> . The standard option is Yes.	NA
Require a comment when entering N/A, Unknown, or Not Done	Select <b>Yes</b> to set the comment as mandatory when the patient enters values such as $N/A$ , Unknown or Not Done. Otherwise, select <b>No</b> .	NA
Auto close manual queries	Select <b>Yes</b> to enable auto close manual queries. Otherwise, select <b>No</b> . The standard option is Yes.	NA

Table A-31 (Cont.) Configuration Settings - Field Information

Field Name/	Description	Field Size (In Character)
Query maximum length	Enter the maximum length for the query. The standard value is 80 characters.	NA
Require unique patient initials and date of birth	Select <b>Study</b> or <b>Site</b> if unique patient initials and date of birth are required. Otherwise, select <b>None</b> . The standard option is None.	4 Characters
Require unique patient ID	Select <b>Study</b> or <b>Site</b> if unique patient ID is required. Otherwise, select <b>None</b> . The standard option is None.	NA
Allow sponsor users to edit frozen forms	Select <b>Yes</b> to allow sponsor users to edit frozen forms. Otherwise, select <b>No</b> . The standard option is No.	NA
Date Format	Select the date format from the drop-down list. The standard option is Month/Day/Year.	NA
Navigation mode	Select <b>Enable</b> to enable navigation. Otherwise, select <b>Disable</b> . The standard option is Disable.	NA
Re-authentication inactivity period	Enter the re-authentication inactivity duration in minutes. The standard value is 5 minutes.	3 Characters
Re-authentication Password expiration period	Enter the re-authentication password expiration duration in days. The standard value is 30 days.	3 Characters
Re-identification period	Enter the re-identification duration in minutes. The standard value is 120 minutes.	3 Characters
Minimum password length	Enter the minimum password length. The standard value is 8 characters.	2 Characters
Inactivate account after number of failed logon attempts	Enter the maximum attempts allowed for failed logon. If the failed logon attempt exceeds the maximum attempt, the account is made inactive. The standard value is 3 attempts.	2 Characters
Require at least one numerical character in password	Select <b>Yes</b> if at least one numerical character is required in the password. Otherwise, select <b>No</b> . The standard option is Yes.	NA
Require at least one uppercase character in password	Select <b>Yes</b> if at least one uppercase character is required in the password. Otherwise, select <b>No</b> . The standard option is Yes.	NA
Require at least one non alpha-numeric character in password	Select <b>Yes</b> if at least one non-alphanumeric character is required in the password. Otherwise, select <b>No</b> . The standard option is Yes.	NA
Allow password reuse	Select <b>Yes</b> to enable reuse password. Otherwise, select <b>No</b> . The standard option is Yes.	NA
Enable forgot password	Select <b>Yes</b> to enable forgot password help. Otherwise, select <b>No</b> . The standard option is Yes.	NA
Email address for forgot password notification	Enter the email address for receiving the forgot password notification.	255 Characters
Email address for new site and user notification	Enter the email address for receiving new site and user notifications.	255 Characters
Enforce visit date entry (before other date can be entered)	Enter the value for enforcing visit date entry. The standard option is 2.	NA
View CRF Signature List	Enter the value for viewing the CRF Signature list. The standard option is 1.	NA
Post a Query for Conflict Resolution	Select the check box to post a query for conflict resolution.	NA
Enable SSL	Select the check box to enable SSL.	NA
Let user minimize left button panel and picture	Select the check box to let the user minimize left button panel and picture.	NA
Setting		

Table A-31 (Cont.) Configuration Settings - Field Information

Field Name/	Description	Field Size (In Character)
Reporting Service Full URL	Enter the reporting service full URL.	255 Characters
Reporting Authentication namespace ID	Enter the reporting authentication namespace ID.	255 Characters
Reporting user root	Enter the reporting user root.	255 Characters
LDAP Server	Enter the LDAP server.	255 Characters
LDAP base distinguished name	Enter the LDAP base distinguished name.	255 Characters
Number of execution plan listener threads	Enter the number of execution plan listener threads.	255 Characters
Number of execution plan re-submits	Enter the number of execution plan re-submits.	255 Characters
Execution Plan Server	Enter the execution plan server.	255 Characters
MedML Installer Server	Enter the name of the MedML installer server.	255 Characters
Server Friendly Name	Enter the server friendly name.	255 Characters
Number of characters for CRF length (Phase Forward Internal)	Enter the number of characters for the CRF length.	255 Characters
Control panel is maximized by default (Phase Forward Internal)	Select the check box to set the default size of the Control panel to maximized.	NA
Screening number sequence format (Phase Forward Internal)	Enter the screening number sequence format.	255 Characters
Patient number sequence format (Phase Forward Internal)	Enter the patient number sequence format.	255 Characters
Default randomization source manager (Phase Forward Internal)	Enter the default randomization source manager.	255 Characters
Randomization format for simple site (Phase Forward Internal)	Enter the randomization format for simple site.	255 Characters
Randomization source manager for simple site (Phase Forward Internal)	Enter the randomization source manager for simple site.	255 Characters
Randomization format for simple central (Phase Forward Internal)	Enter the randomization format for simple central.	255 Characters
Randomization source manager for simple central (Phase Forward Internal)	Enter the randomization source manager for simple central.	255 Characters
Randomization for central stratified by site (Phase Forward Internal)	Enter the randomization for central stratified by site.	255 Characters
Randomization for source manager for central stratified by site (Phase Forward Internal)	Enter the randomization for source manager for central stratified by site.	255 Characters
Randomization format for central stratified (Phase Forward Internal)	Enter the randomization format for central stratified.	255 Characters
UNC download directory (Phase Forward Internal) (only used in legacy systems)	Enter the UNC download directory.	255 Characters
Virtual download directory (Phase Forward Internal) (only used in legacy systems)	Enter the virtual download directory.	255 Characters

Table A-32 Configuration Settings - Error Information

Field Name	Scenario	Error Message
Send E-mails for Failed Uploads	Error occurs when you click <b>Submit</b> without entering the email address or entering an invalid email address.	Enter email address for Duplicated Imports notification. Enter valid email address
Send E-mails on Failed/Successful Import	Error occurs you click <b>Submit</b> without entering the email address or entering an invalid user address.	Enter valid email address. Enter email address for Failed/Successful Imports notification.
Email Address to send Worklist	Error occurs when the text box for the worklist is blank or when you enter an invalid user address.	NA
Query maximum length	Error occurs when you enter character other than	Enter a valid Number.
	number or enter the value greater than and lesser than the threshold level.	The value must be greater than or equal to constant value and less than or equal to constant value.
Re-authentication inactivity period	Error occurs when you enter character other than number.	Enter a valid Number.
Re-authentication Password expiration period	Error occurs when you enter character other than number.	Enter a valid Number.
Re-identification period	Error occurs when you enter character other than number.	Enter a valid Number.
Minimum password length	Error occurs when you enter character other than number.	Enter a valid Number.
Inactivate account after number of failed logon attempts	Error occurs when you enter character other than number.	Enter a valid Number.
Email address for forgot password notification	Error occurs when you enter an invalid email address.	Enter valid email address.
Email address for new site and user notification	Error occurs when you enter an invalid email address.	Enter a valid Number.
Number of execution plan listener threads	Error occurs when you enter character other than number.	Enter a valid Number.
Number of execution plan re-submits	Error occurs when you enter character other than number.	Enter a valid Number.
Number of characters for CRF length (Phase Forward Internal)	Error occurs when you enter character other than number.	Enter a valid Number.
Default Password	Error occurs when the password field is empty while submitting the form.	Enter the default password.
Comment	Error occurs when you submit the form without entering comment.	The form has not been changed.
Reporting Service Full URL	Error occurs when the URL is invalid.	Enter valid URL.
InForm Home Page Path	Error occurs when the entered home path is invalid.	Enter valid Home Path.

# A.18 UMT Settings

Table A-33 UMT Settings - Field Information

Field Name	Description	Field Size (In Character)
Re-authentication inactivity period	Displays/Modify the re-authentication inactivity duration.	2 Characters
Minimum password length	Displays/Modify the minimum password length.	2 Characters
Password expiration period	Displays/Modify the password expiration duration.	3 Characters

Table A-33 (Cont.) UMT Settings - Field Information

Field Name	Description	Field Size (In Character)
Re-identification period	Displays/Modify the re-identification period.	3 Characters
Inactivate account after number of failed logon attempts	Displays/Modify the maximum attempts allowed for failed logon. If the failed logon attempt exceeds the maximum attempt, the account is made inactive.	1 Character
Email Address for forgot password notification	Displays/Modify the email address to which the forgotten password notification is sent.	255 Characters
Enable forgot password	Select the check box to enable forgot password help.	NA
Export schedule Interval	Displays/Modify export schedule interval.	NA
Import Schedule Interval	Displays/Modify import schedule interval.	NA
Enable Staging Schedule	Select the option to enable staging schedule.	NA
	If you select the <b>Enable Staging Schedule</b> option, enter the scheduled time in the Hours and Minutes text boxes of the Staging Schedule Interval field.	
Staging Schedule Interval	Displays/Modify the staging schedule interval.	2 Characters
Disable Staging Schedule	Select the option to disable staging schedule.	NA
Enable Worklist Schedule	Select the option to enable worklist schedule.	NA
	If you select the <b>Enable Staging Schedule</b> option, enter the scheduled time in the Hours and Minutes text boxes of the Worklist Schedule Interval field.	
Worklist Schedule Interval	Displays/Modify the worklist schedule interval.	2 Characters
Disable Worklist Schedule	Select the option to disable worklist schedule.	NA
Mail Service Interval	Displays/Modify the mail service interval time in minutes.	20 Characters

Table A-34 UMT Settings - Error Information

Field Name/ Action	Scenario	Error Message
Re-authentication inactivity period	Error occurs when you click <b>Submit</b> without entering data or exceeding the maximum value.	Fill the re-authentication inactivity period. The minimum and maximum value that are allowed for this filed are 5 and 30 respectively.
Minimum password length	Error occurs when you click <b>Submit</b> without entering data or exceeding the maximum value.	Fill Minimum password length. The minimum password length value must be greater than or equal to 6 and less than or equal to 12.
Password expiration period	Error occurs when you click <b>Submit</b> without entering data or exceeding the maximum value.	Fill the password expiration period. The minimum and maximum value that are allowed for this filed are 30 and 180 respectively.
Inactivate account after number of failed logon attempts	Error occurs when you click <b>Submit</b> without entering data or exceeding the maximum value.	Fill the number of failed logon attempts. The minimum and maximum value that are allowed for this filed are 2 and 5 respectively.
Email Address for forgot password notification	Error occurs when you click <b>Submit</b> without entering data or entering an invalid email address.	Enter valid email address(es). Fill the email address for forgot password notification
Error occurs when the user click submit button without giving data	Error occurs when you enter invalid characters.	Enter valid Export Schedule Hours.
Import Schedule Interval	Error occurs when you enter invalid characters.	Enter valid Import Schedule Hours.

Table A-34 (Cont.) UMT Settings - Error Information

Field Name/ Action	Scenario	Error Message
Staging Schedule Interval	Error occurs when you enter invalid characters.	Enter valid Staging Schedule Interval
Worklist Schedule Interval	Error occurs when you enter invalid characters.	Enter valid Worklist Schedule Interval.
Email Address for Forgot password Notification	Error occurs when you enter an invalid email address.	Enter valid email address(es).
Inactivate account after number of failed logon attempts:	Error occurs when the maximum and minimum value exceeds.	The number of failed logon attempts value must be greater than or equal to 2 and less than or equal to 5.
Re-authentication inactivity period	Error occurs when the maximum and minimum value exceeds.	The Re-authentication inactivity period value must be greater than or equal to 5 and less than or equal to 30.
Password expiration period:	Error occurs when the maximum and minimum value exceeds.	The password expiration period must be greater than or equal to 30 and less than or equal to 180.
Re-identification period:	Error occurs when the maximum and minimum value exceeds.	The Re-identification period value must be greater than or equal to 15 and less than or equal to 180.
Minimum password length	Error occurs when the maximum and minimum value exceeds.	The minimum password length value must be greater than or equal to 6 and less than or equal to 12.
Worklist Schedule Interval	Error occurs when invalid hours or minutes are entered.	Enter valid Worklist Schedule hours. Enter valid Worklist Schedule minutes.
Export Schedule Interval	Error occurs when invalid hours are entered. Error occurs when invalid minutes are entered.	Enter valid Export Schedule hours. Enter valid Export Schedule minutes.
Import Schedule Interval	Error occurs when invalid hours are entered. Error occurs when invalid minutes are entered.	Enter valid Import Schedule hours. Enter valid Import Schedule minutes.
Staging Schedule Interval	Error occurs when invalid hours are entered. Error occurs when invalid minutes are entered.	Enter valid Staging Schedule hours. Enter valid Staging Schedule minutes.
Re-authentication inactivity period	Error occurs when the field is blank.	Fill the re-authentication inactivity period.
Password expiration period	Error occurs when the field is blank.	Fill the password expiration period.
Inactivate account after number of failed logon attempts	Error occurs when the field is blank.	Fill the number of failed logon attempts.
Re-identification period	Error occurs when the field is blank.	Fill the re-identification period.

### A.19 Country Details

Table A-35 Country Details - Field Information

Field Name	Description
Country Name:	Displays/Modify the name of the country.
ISD Code	Displays/Modify the ISD code of the country.

Time Zone Association

Table A-35 (Cont.) Country Details - Field Information

Field Name	Description
Select Time Zone	
- Available	Displays the list of available time zones.
	Click >> or > to move all or the selected time zones, respectively, to the Selected field.
- Selected	Displays the list of selected time zones.
	Click << or < to move all or the selected time zones, respectively, to the Available field.

#### A.20 UMT Roles

Table A-36 UMT Roles - Field Information

Field Name	Description
Filter Section	
Role Name	Enter the name of the role.
InForm Role Details	
Role Name	Displays the name of the role. Click the hyperlink to view the role details.
Role Type	Displays the type of the role.
Member Count	Displays the number of members in the role.
User Association	Click the 🔟 icon to view the user-role associations.

#### A.21 PF Roles

Table A-37 PF Roles - Field Information

Field Name	Description	Field Size
Filter Section		
Role Name:	Enter the name of the role.	63 Characters
Approval Status	Select the approval status from the drop-down list.	NA
PF Role Details		
Role Name	Displays the name of the role. Click the hyperlink to view the role details.	NA
Approved Status	Displays the approval status of the role.	NA
Member Count	Displays the number of members in the role.	NA
User Association	Click the $\[ \]$ icon to view the user-role associations.	NA

# A.22 Bulk Copy

Table A-38 Bulk Copy - Field Information

Field Name	Description
Source Trial	Select the source trial from the drop-down list.
Destination Trial	Displays the destination trial name.
Choose Items to be Copied	Select the check box to copy the trials from the corresponding items. The items include users, sites, roles, groups, and configuration settings.

Table A-39 Bulk Copy - Error Information

Field Name/Action	Scenario	Error Message
Select Source Trial drop-down list	Error occurs when you click <b>Submit</b> without selecting a source trial.	Select a trial.
Submit Button	Error occurs when you click <b>Submit</b> without selecting a trial.	Choose an option.

#### **A.23 Create Sponsor Company**

All fields marked with \* are mandatory.

Table A-40 Create Sponsor Company - Field Information

Field Name	Description
Sponsor Company*	Enter the name of the sponsor.
Address1	Enter the communication address of the sponsor.
Address2	
City	Enter the city to which the sponsor belongs.
Region	Enter the region to which the sponsor belongs.
State	Enter the state to which the sponsor belongs.
Province	Enter the province to which the sponsor belongs.
Postal Code	Enter the postal code of the sponsor.
Country	Select the country to which the sponsor belongs from the drop-down list.
Phone Number	Enter the phone number of the sponsor.
Alternate Phone Number	Enter the alternate phone number of the sponsor.
Logo File	Select the logo file of the sponsor.
Fax Number	Enter the fax number of the sponsor.
Is Duplicate Validation Trial Specific?	Select the check box if you want all the unique validations to occur at trail level only.
Zip Code	Enter the zip code of the sponsor.

#### A.24 Sponsor Company Details

All fields marked with \* are mandatory.

Table A-41 Sponsor Company Details - Field Information

Field Name	Description	
Sponsor Company*	Displays/Modify the name of the sponsor.	
Address1	Displays/Modify the communication address of the sponsor.	
Address2		
City	Displays/Modify the city to which the sponsor belongs.	
Region	Displays/Modify the region to which the sponsor belongs.	

Table A-41 (Cont.) Sponsor Company Details - Field Information

Field Name	Description	
State	Displays/Modify the state to which the sponsor belongs.	
Province	Displays/Modify the province to which the sponsor belongs.	
Postal Code	Displays/Modify the postal code of the sponsor.	
Country	Select the country to which the sponsor belongs from the drop-down list.	
Phone Number	Displays/Modify the phone number of the sponsor.	
Alternate Phone Number	Displays/Modify the alternate phone number of the sponsor.	
Logo File	Enter the name of the sponsor logo file.	
Fax Number	Displays/Modify the fax number of the sponsor.	
Is Duplicate Validation Trial Specific?	Select the check box if you do not want UMT to check for user duplication across sponsor trials.	
Zip Code	Displays/Modify the zip code of the sponsor.	

### A.25 List of Sponsor Companies

Table A-42 List of Sponsor Companies - Field Information

Field Name	Description	Field Size
Filter Section		
Sponsor Company	Enter the name of the sponsor.	255 Characters
City	Enter the city to which the sponsor belongs.	255 Characters
Postal Code	Enter the postal code of the sponsor.	16 Characters
Phone Number	Enter the phone number of the sponsor.	25 characters
Country	Select the country to which the sponsor belongs from the drop-down list.	255 Characters
Sponsor Details:		
Sponsor Company	Displays the name of the sponsor. Click the hyperlink to view the role details.	NA
City	Displays the city to which the sponsor belongs.	NA
Postal Code	Displays the postal code of the sponsor.	NA
Country	Displays the country to which the sponsor belongs.	NA
Phone Number	Displays the phone number of the sponsor.	NA

# A.26 Log Files

Table A-43 Log Files - Field Information

Field Name	Description
Current Sponsor Company	Select the current sponsor company name from the drop-down list.
Trial	Select the trial from the drop-down list.
Filter Section	
Application Name	Select the name of the application from the drop-down list.
Status	Select the status from the drop-down list.

Table A-43 (Cont.) Log Files - Field Information

Field Name	Description	
From	Select the starting date from the calendar available at the side of the text box.	
То	Select the ending date from the calendar available at the side of the text box.	
Log File Details:		
Application Name	Displays the name of the application.	
Trial Name	Displays the name of the trial.	
Batch	Displays the batch ID. Click the hyper link to view the list of transferred data.	
User Name	Displays the user name.	
Date & Time	Displays the date and time of creation of the log file.	
Status	Displays the status of the log file.	

# A.27 User, Role Association

Table A-44 User, Role Association - Field Information

Field Name	Description
Current Sponsor Company	Displays the selected sponsor company.
Trial	Displays the selected trial.
Select Users	
Available	Displays the list of available users.
	Click >> or > to move all or the selected users, respectively, to the Selected field.
Selected	Displays the list of selected users.
	Click << or < to move all or the selected users, respectively, to the Available field.
Already Associated	Displays the name of users that are already associated with the role.

Table A-45 User, Role Association – Error Information

Field Name/Action	Scenario	Error Message
Submit Form	Error occurs when you click <b>Submit</b> without making any change in the form.	Form not Changed.

### A.28 Study Variables

Table A-46 Study Variable - Field Information

Field Name	Description	Field Size
Study Name	Displays the trial name.	NA
Study Variables		
Browser Version (Minimum)	Displays/Modify the minimum version for Internet Explorer (IE) and Netscape Navigator.	5 Characters

Table A-46 (Cont.) Study Variable - Field Information

Field Name	Description	Field Size
Operating System	Displays the list of operating systems. Select the check boxes corresponding to the available operating systems.	NA
WAN Speed Boundary	Displays/Modify the wide area network speed.	5 Characters
URL for the eWP	Displays/Modify the URL for the eWP.	NA

Table A-47 Study Variables - Error Information

Field Name/Action	Scenario	Error Message	
Submit Button	Error occurs when you click <b>Submit</b> without making any change.	The form has not been changed.	
IE Textbox	Error occurs when you enter an invalid IE version.	Enter a Valid Browser Version for IE.	
Netscape Textbox	Error occurs when you enter an invalid Netscafe version.	Enter a Valid Browser Version for Netscape.	
WAN Speed Boundary	Error occurs when you enter an invalid WAP speed boundary.	Enter a Valid WAP Speed Boundary.	

# A.29 Selective Copy

Table A-48 Selective Copy - Field Information

Field Name	Description
Source Trial	Select the source trial from the drop-down list.
Destination Trial	Displays the destination trial name.
Select Type	Select the source trial item that needs to be copied from the drop-down list.
Available	Displays the list of source trial items.
	Click >> or > to move all or the selected trial items, respectively, to the Selected field.
Selected	Displays the list of selected trial items.
	Click << or < to move all or the selected trial, respectively, to the Available field.
Associated Sponsor Users	Select the check box if you want to copy the associated sponsor users details. This option is displayed depending on the type of copy item you select.
Associated Site Users	Select the check box if you want to copy the associated site users details. This option is displayed depending on the type of copy item you select.
Associated Sites	Select the check box if you want to copy the associated sites details. This option is displayed depending on the type of copy item you select.
Associated Roles	Select the check box if you want to copy the associated roles details. This option is displayed depending on the type of copy item you select.
Associated Groups	Select the check box if you want to copy the associated groups details. This option is displayed depending on the type of copy item you select.

# A.30 PF User List Page

Table A-49 PF User List Page - Field Information

Field Name	Description	Field Size
Basic User Info		
User Name	User name is displayed for all users.	255 Characters
First Name	The first name is displayed for all users.	255 Characters
Last Name	The last name is displayed for all users.	127 Characters
User Type:	This field is available for both InForm and IRT products.	NA
Role	This fields displays the PF role for which the user is assigned.	NA
Approval Status	This fields displays the approval status.	NA
Training Status	This fields displays the training status.	NA
Trained Date	This fields displays the training date.	NA
Sites(s)	This fields displays the list of sites the user is associated.	NA
Product Locale	This field is available for both InForm and IRT products with trial version above $4.5$ .	NA
Country	This fields displays the country to which the user belongs.	NA
Provisional Status	This fields displays the provisional status.	NA
Export To Excel Link	Select a user and on clicking this the user details gets exported to an Excel file.	NA
Export To File Link	Select a user and on clicking this the user details gets exported to a file.	NA

#### A.31 List of Sites

List of Sites - Field Information Table A-50

Field Name	Description	Field Size (In Character)
Filter Section		
Site No	Enter the number of the site.	20 Characters
Site Name	Enter the name of the site.	255 Characters
Approval Status	Select the status of the site from the drop-down list.	NA
City	Enter the city where the site is located.	127 Characters
Country	Select the country where the site is located from the drop-down list.	255 Characters
Study Version	Select the study version of the site from the drop-down list.	NA
Assessment Status	Select the assessment status of the site from the drop-down list.	NA
Provisioning Status	Select the provisioning status of the site from the drop-down list.	NA
Uploaded to IRT	Select whether you want to view sites that are uploaded to the IRT system.	NA
Uploaded to OLx	Select whether you want to view sites that are uploaded to the OLx system.	NA
Uploaded to IPMs	Select whether you want to view sites that are uploaded to the IPMs system.	NA
Uploaded to InForm	Select whether you want to view sites that are uploaded to the InForm system.	NA
Site Details		

Table A-50 (Cont.) List of Sites - Field Information

Field Name	Description	Field Size (In Character)
	Displays the icon,	NA
	$oxedsymbol{\sqsubseteq}$ if the site is Upload to InForm.	
	if the site is Upload to IRT.	
	if the site is Upload to InForm/IRT.	
Site No	Displays the site number.	NA
Site Name	Displays the name of the site. Click the hyperlink to view the site details.	NA
Approval Status	Displays the status of the site. The status of the site can be Approved, Pending, or Rejected.	NA
City	Displays the city where the site is located.	NA
Country	Displays the country where the site is located.	NA
Study Version	Displays the study version.	NA
Assessment Mail	Displays the icon,	NA
	if the mail is sent to the members of that site. if the first reminder mail is sent to the members of that site. if the second reminder mail is sent to the members of that site.	
Daga /Eail		NA
Pass/Fail	Displays the corresponding icons, if the site passed the assessment process.	NA
	if the site is in the border line of the assessment process.	
	if the site failed the assessment process.	
Assessment Status	Displays the status of the assessment process.	NA
Provisioning Status	Displays the status of the provisioned items.	NA

# A.32 Selective Copy

Table A-51 Selective Copy – Field Information

Field Name	Description
Source Trial	Select the source trial from the drop-down list.
Destination Trial	Displays the destination trial name.
Select Type	Select the source trial item that needs to be copied from the drop-down list.
Available	Displays the list of source trial items.
	Click >> or > to move all or the selected trial items, respectively, to the Selected field.
Selected	Displays the list of selected trial items.
	Click << or < to move all or the selected trial, respectively, to the Available field.
Associated Sponsor Users	Select the check box if you want to copy the associated sponsor users details. This option is displayed depending on the type of copy item you select.
Associated Site Users	Select the check box if you want to copy the associated site users details. This option is displayed depending on the type of copy item you select.
Associated Sites	Select the check box if you want to copy the associated sites details. This option is displayed depending on the type of copy item you select.

Table A-51 (Cont.) Selective Copy - Field Information

Field Name	Description
Associated Roles	Select the check box if you want to copy the associated roles details. This option is displayed depending on the type of copy item you select.
Associated Groups	Select the check box if you want to copy the associated groups details. This option is displayed depending on the type of copy item you select.
Already Copied	Displays the list of selected trial items which is already copied to the destination trial.

Table A-52 Selective Copy – Error Information

Field Name/Action	Scenario	Error Message
Trial Drop-down List	Error occurs when you click <b>Submit</b> without selecting a trial.	Select a trial.
Trial Drop-down List	Error occurs when you click <b>Submit</b> without selecting a type from the Type drop-down list.	Select a Type.
Submit Button	Error occurs when you click <b>Submit</b> without selecting a site.	Select a Site.
Submit Button	Error occurs when you click <b>Submit</b> without selecting a role.	Select a Role.
Submit Button	Error occurs when you click <b>Submit</b> without selecting a group.	Select a Group.
Submit Button	Error occurs when you click <b>Submit</b> without selecting a user.	Select a User.

### A.33 UMT Role Details

Table A-53 UMT Role Details - Field Information

Field Name	Description	Field Size
Role*	Enter the name of the role.	63 Characters
Role Type	Select the type of the role from the drop-down list.	NA
UMT Admin	Displays the list of UMT administration rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
Import/Export	Displays the list of import or export rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
User/Sponsor/Site Details	Displays the list of rights for managing user, sponsor, or site details.	NA
	To assign a privilege (rights), select the corresponding check box.	
Log Files	Displays the list of rights for managing log files.	NA
	To assign a privilege (rights), select the corresponding check box.	
Approval	Displays the list of rights for approval.	NA
	To assign a privilege (rights), select the corresponding check box.	
InForm Rights	Displays the list of InForm rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
Miscellaneous	Displays the list of miscellaneous rights.	NA
	To assign a privilege (rights), select the corresponding check box.	

Table A-54 UMT Role Details - Error Information

Field Name/Action	Scenario	Error Message
Role	Error occurs when you enter characters other than alphanumeric, hyphen, underscore, and blank space.	Enter a valid Role Name. Only Alphanumerics (A-Z, 0-9), Hyphens(-), underscores(_) and blank spaces are allowed.
Role Type	Error occurs when you click <b>Submit</b> without selecting a role type.	Select a Role Type.
Submit Button	Error occurs when you click <b>Submit</b> without selecting at least one role.	Associate at least one Right for the Role.
Sponsor Drop-down List	Error occurs when you click <b>Submit</b> without selecting a sponsor company.	Select Sponsor Company.
Submit Button	Error occurs when you click <b>Submit</b> without entering all mandatory fields.	Complete all mandatory fields before saving.

### A.34 UMT Users

Table A-55 UMT Users - Field Information

Field Name	Description	Field Size
Filter Section		
Username	Enter the user name.	25 characters
First Name	Enter the first name of the user.	127 Characters
Last Name	Enter the last name of the user.	127 Characters
User Type	Select the user type from the drop-down list.	NA
Status	Select the status of the user from the drop-down list.	NA
City	Enter the city to which the user belongs.	255 Characters
State /Province	Enter the state or province to which the user belongs.	255 Characters
Country	Select the country to which the user belongs from the drop-down list.	NA
Role	Select the role to which the user belongs from the drop-down list.	NA
Username	Displays the user name. Click the hyperlink to view the corresponding user details.	NA
First Name	Displays the first name of the user.	NA
Last Name	Displays the last name of the user.	NA
User Type	Displays the user type.	NA
Status	Displays the status of the user.	NA
City	Displays the city to which the user belongs.	NA
State/Province	Displays the state or province to which the user belongs.	NA
Country	Displays the country to which the user belongs.	NA
Role	Displays the role to which the user belongs.	NA
UMT USer Details:		
Username	Displays the user name. Click the hyperlink to view the corresponding user details.	NA
First Name	Displays the first name of the user.	NA
Last Name	Displays the last name of the user.	NA
User Type	Displays the user type.	NA
Status	Displays the status of the user.	NA

Table A-55 (Cont.) UMT Users - Field Information

Field Name	Description	Field Size
Role	Displays the role to which the user belongs.	NA
City	Displays the city to which the user belongs.	NA
State/Province	Displays the state or province to which the user belongs.	NA
Country	Displays the country to which the user belongs.	NA

Table A-56 UMT Users - Error Information

Field Name/Action	Scenario	Error Message
Action Drop-down list	Error occurs when you click <b>Go</b> without selecting any action in the drop-down list.	Select an option.
Go Button	Error occurs when you click <b>Go</b> without selecting any user.	Select a user.
Active User	Error occurs when you activate the user whose status is already Active.	You have selected active users.
InActive User	Error occurs when you inactivate the user whose status is already Inactive.	You have selected inactive users.

#### A.35 Create UMT Role

Table A-57 Create UMT Role - Field Information

Field Name	Description	Field Size
Role*	Enter the name of the role.	63 Characters
Role Type	Select the type of the role from the drop-down list.	NA
UMT Admin	Displays the list of UMT administration rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
Import/Export	Displays the list of import or export rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
User/Sponsor/Site Details	Displays the list of rights for managing user, sponsor, or site details.	NA
	To assign a privilege (rights), select the corresponding check box.	
Log Files	Displays the list of rights for managing log files.	NA
	To assign a privilege (rights), select the corresponding check box.	
Approval	Displays the list of rights for approval.	NA
	To assign a privilege (rights), select the corresponding check box.	
InForm Rights	Displays the list of InForm rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
Assessment	Displays the list of Assessment rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
Provisioning	Displays the list of Provisioning rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
Asset	Displays the list of Asset rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
Worklist	Displays the list of Worklist rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
Miscellaneous	Displays the list of miscellaneous rights.	NA
	To assign a privilege (rights), select the corresponding check box.	

Table A-58 Create UMT Role - Error Information

Field Name/Action	Scenario	Error Message
Role	Error occurs when you enter characters other than alphanumeric, hyphen, underscore, and blank space.	Enter a valid Role Name. Only Alphanumerics (A-Z, 0-9), Hyphens(-), underscores(_), and blank spaces are allowed.
Role Type	Error occurs when you click <b>Submit</b> without selecting a role type.	Select a Role Type.
Submit Button	Error occurs when you click <b>Submit</b> without selecting at least one role.	Associate at least one Right for the Role.
Sponsor Drop-down List	Error occurs when you click <b>Submit</b> without selecting a sponsor company.	Select Sponsor Company.
Submit Button	Error occurs when you click <b>Submit</b> without completing all mandatory fields.	Complete all mandatory fields before saving.

### A.36 Create PF Role

Table A-59 Create PF Role - Field Information

Field Name	Description	Field Size
Role*	Enter the name of the role.	63 character
User Admin	Displays the list of user administration rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
User Misc	Displays the list of user miscellaneous rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
CRF Rights	Displays the list of CRF rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
Case Book Rights	Displays the list of case book rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
Query Rights	Displays the list of query rights.	NA
	To select the right, click the corresponding check boxes.	
Rule Rights	Displays the list of user rule rights. To assign a privilege (rights), select the corresponding check box.	NA
Synchronization	Displays the list of synchronization rights. To assign a privilege (rights), select the corresponding check box.	NA
Navigation	Displays the list of navigation rights.	NA
	To assign a privilege (rights), select the corresponding check box.	
System Admin Rights	Displays the list of system administration rights.	NA
	To assign a privilege (rights), select the corresponding check box.	

Table A-60 Create PF Role - Error Information

Field Name/Action	Scenario	Error Message
Role*	Error occurs when click <b>Submit</b> without entering a role name.	Please Enter a valid Role Name. Only Alphanumerics (A-Z, 0-9), Hyphens(-), underscores(_), and blank spaces are allowed.
Submit Button	Error occurs when the Patient Transfer Right is selected for the trial running in the PF 4.5 version.	Patient Transfer Right can be selected only for Trials running in PF 4.5 Version.
Submit Button	Error occurs when the Custom Reports and Admin Reports Rights is selected for the trial running in the PF 4.5 version.	PF 4.5 Version cannot have Custom Reports and Admin Reports Right.
Submit Button	Error occurs when the Custom Reports Right is selected for the trial running in the PF 4.5 version.	PF 4.5 Version cannot have Custom Reports Right.
Submit Button	Error occurs when the Patient Transfer Right is selected for the trial running in the PF 4.5 version.	PF 4.5 Version cannot have Admin Reports Right.
Submit Button	Error occurs when no rights are associated to the role.	Associate at least one Right for the Role.
Submit Button	Error occurs when you click <b>Submit</b> without entering all mandatory fields.	Complete all mandatory fields, before Saving.
Role Name	Error occurs when you enter an invalid character other than alphanumeric characters and hyphens.	Enter a valid Role Name. Only Alphanumerics (A-Z, 0-9), Hyphens(-), underscores (_), and blank spaces are allowed.

# A.37 Sponsor Company Details

Table A-61 Sponsor Company Details - Field Information

Field Name	Description	Field Size
Sponsor Company*	Enter the name of the sponsor company.	255 Characters
Address1	Enter the communication address of the sponsor company.	255 Characters
Address2		
City	Enter the city to which the sponsor company belongs.	255 Characters
Region	Enter the region to which the sponsor company belongs.	255 Characters
Postal Code	Enter the postal code of the sponsor company.	16 Characters
Country	Select the country to which the sponsor company belongs from the drop-down list.	255 Characters
Fax Number	Enter the fax number of the sponsor company.	25 Characters
Phone Number	Enter the phone number of the sponsor company.	25 Characters
Alternate Phone Number	Enter the alternate phone number of the sponsor company.	25 Characters
Is Duplicate Validation Trial Specific?	Select the check box if you do not want UMT to check for user duplication across sponsor trials.	NA
Enter a character*	Enter a character to distinguish similar data that are imported into UMT. This prevents data overwrite.	1 Character
Logo File	Enter the name of the sponsor logo file.	255 Characters
Zip Code	Enter the zip code.	16 Characters

# A.38 Create Sponsor Company

Table A-62 Create Sponsor Company - Field Information

Field Name	Description	Field Size
Sponsor Company*	Enter the name of the sponsor company.	255 Characters
Address1	Enter the communication address of the sponsor company.	255 Characters
Address2		
City	Enter the city to which the sponsor company belongs.	255 Characters
Region	Enter the region to which the sponsor company belongs.	255 Characters
Postal Code	Enter the postal code of the sponsor company.	16 Characters
Country	Select the country to which the sponsor company belongs from the drop-down list.	255 Characters
Fax Number	Enter the fax number of the sponsor company.	25 Characters
Phone Number	Enter the phone number of the sponsor company.	25 Characters
Alternate Phone Number	Enter the alternate phone number of the sponsor company.	25 Characters
Is Duplicate Validation Trial Specific?	Select the check box if you do not want UMT to check for user duplication across sponsor trials.	NA
Logo File	Enter the name of the sponsor logo file.	255 Characters
Zip Code	Enter the zip code.	16 Characters

Table A-63 Create Sponsor Company - Error Information

Field Name/Action	Scenario	Error Message
Current Sponsor Company	Error occurs when you enter the character other than alphanumeric, ampersand, underscore, and blank space.	Enter Sponsor company.
Address1 Address2	Error occurs when you enter character other than alphanumeric.	Enter a character.
City	Error occurs when you enter character other than alphanumeric, and blank space.	Enter a valid City. Only alphanumerics, underscores, and hyphens are allowed.
Region	Error occurs when you enter character other than alphabet and blank space.	Enter a valid Region. Only alphanumerics, underscores, and hyphens are allowed.
State	Error occurs when you enter character other than alphanumeric and blank space.	Enter a valid State. Only Alphanumerics (A-Z, 0-9) and Blank Spaces are allowed.
Province	Error occurs when you enter character other than alphanumeric and blank space.	Enter a valid Province. Only Alphanumerics (A-Z, 0-9) and Blank Spaces are allowed.
Postal Code	Error occurs when you enter character other than alphanumeric, hyphen, and blank space.	Enter a valid Postal Code. Only Alphanumerics (A-Z, 0-9), Hyphens(-), and Blank Spaces are allowed.
Country	NA	NA
Fax Number	Error occurs when you enter character other than number, hyphen, and blank space.	Enter a valid Fax Number. Only numbers, hyphens, and blank spaces are allowed.
Phone Number	Error occurs when you enter character other than number, hyphen, and blank space.	Enter a valid Phone number. Only numbers, hyphens, and blank spaces are allowed.
Alternate Phone Number	Error occurs when you enter character other than number, hyphen, and blank space.	Enter a valid Alternate Phone number. Only numbers, hyphens and blank spaces are allowed/
Is Duplicate Validation Trial Specific?	NA	NA

Table A-63 (Cont.) Create Sponsor Company - Error Information

Field Name/Action	Scenario	Error Message
Enter a character*	Error occurs when you enter a character other than alphanumeric.	Enter a character
Zip Code	Error occurs when you enter a character other than alphanumeric.	Enter a valid Postal code. Only numbers, hyphens, and blank spaces are allowed.
Logo File	Error occurs when you enter space in logo file text box.	Spaces not allowed while specifying file name. Enter a valid file name.
Logo File	Error occurs when enter the file other than jpg, gif, and txt.	Logo file should be only jpg/gif/ txt files.

### A.39 Create Trial Details

Table A-64 Create Trial Details - Field Information

Field Name	Description	Field Size
Trial Details		
Trial Name*	Enter the name of the trial.	255 Characters
Reference*	Enter the reference name.	20 Characters
Protocol Number*	Enter the number of the protocol.	255 Characters
Duration in Months	Enter the duration of the trial in months.	5 Characters
Contracted No of Sites	Enter the number of sites contracted for performing the trial.	5 Characters
Contracted No of Countries	Enter the number of countries contracted for performing the trial.	5 Characters
Contracted No of Patients	Enter the number of patients contracted for performing the trial.	5 Characters
Contracted No of Users	Enter the number of users contracted for performing the trial.	5 Characters
Contracted No of IOL Accounts	Enter the number of IOL accounts contracted for performing the trial.	5 Characters
Contracted No of Site Assessments	Enter the number of contracted site assessments.	5 Characters
Study URL	Enter the study URL.	100 Characters
Therapeutic Area	Enter the therapeutic area.	100 Characters
Trial Phase	Select the phase of the trial from the drop-down list.	NA
Status	Select the status of the trial from the drop-down list.	NA
Compound/Drug/Device Name	Enter the compound, drug, and device name used in the trial.	255 Characters
E-mail Trigger	Select <b>Enable</b> to enable eCS email functionality. Otherwise, select <b>Disable</b> .	1 Character
	This information refers to the email trigger of registration and certificate emails by eCS.	
Notes	Enter your notes on the trial you are creating.	255 Characters
Select Trial Type	Select the trial type from the drop-down list.	NA
Select Trial Version*	Select the trial version from the drop-down list.	NA
Trial, Country Association	-	-

Table A-64 (Cont.) Create Trial Details - Field Information

Field Name	Description	Field Size
Select Country*	-	-
- Available	Displays the list of available countries.	NA
	Click >> or > to move all or the selected country, respective the Selected field.	ely, to
- Selected	Displays the list of selected countries.	NA
	Click << or < to move all or the selected country, respective the Available field.	ly, to

Table A-65 Create Trial Details - Error Information

Field Name/Action	Scenario	Error Message
Trial Details		
Trial Name	Error occurs when you submit without entering the trial name. Another error may occur if you enter the character other than alphanumeric, hyphen, and underscores.	Enter Trial Name. Enter a valid Trial Name. Only Alphanumerics (A-Z, 0-9), Hyphens, and underscores(_) are allowed.
Reference	Error occurs when you enter the character other than alphanumeric.	Enter Reference.
Protocol Number	Error occurs when you enter the character other than alphanumeric.	Enter Protocol Number.
Duration in Months	Enter the duration of the trial in months.	Enter a valid Duration in Months. Only Numbers (0-9) are allowed.
Contracted No of Sites	Error occurs when you enter the character other than number.	Enter a valid Contracted No of sites. Only Numbers (0-9) are allowed.
Contracted No of Countries	Error occurs when you enter the character other than number.	Enter the number of countries contracted for performing the trial.
Contracted No of Patients	Error occurs when you enter the character other than number.	Enter a valid Contracted No of Patients. Only Numbers (0-9) are allowed.
Contracted No of Users	Enter the number of users contracted for performing the trial.	Enter a valid Contracted No of Users. Only Numbers (0-9) are allowed.
Contracted No of IOL Accounts	Enter the number of IOL accounts contracted for performing the trial.	Enter a valid Contracted No of IOL Accounts. Only Numbers (0-9) are allowed.
Contracted No of Site Assessments	Enter the number of contracted site Assessments.	Enter a valid Contracted No of Site Assessments. Only Numbers (0-9) are allowed.
Study URL	Enter the study URL.	NA
Therapeutic Area	Enter the therapeutic area.	NA
Trial Phase	Select the phase of the trial from the drop-down list.	NA
Status	Select the status of the trial from the drop-down list.	Select Trial Status.
Compound/Drug/Device Name	Enter the compound, drug, and device name used in the trial.	NA
E-mail Trigger	Select <b>Enable</b> to enable eCS email functionality. Otherwise, select <b>Disable</b> .	NA
	This information refers to the email trigger of registration and certificate emails by eCS.	
Notes	Error occurs when you enter more than 255 characters.	Note text should not exceed 255 characters.
Import path	Error occurs when you click <b>Submit</b> without selecting the FTP path.	Enter FTP path.

Table A-65 (Cont.) Create Trial Details - Error Information

Field Name/Action	Scenario	Error Message
Select Trial Version	Error occurs when you click <b>Submit</b> without selecting any trial version.	Select the trial version.
Trial, Country Association	-	-
Select Country	Error occurs when you click <b>Submit</b> without selecting any country.	Select a country.
- Available	NA	NA
- Selected	NA	NA

### A.40 Create Oracle User

Table A-66 Create Oracle User - Field Information

Field Name	Description	Field Size
Basic User Info		
User Type *	Select <b>PF user</b> from the drop-down list.	NA
User Name *	The user name format must follow the specifications in the UMT settings.	255 Characters
First Name*	Enter the first name of the user.	127 Characters
Last Name*	Enter the last name of the user.	127 Characters
Title	Select a title for the user from the drop-down list.	NA
Description	Enter the description for the user.	255 Characters
Display Name	Enter the display name for the user.	255 Characters
Contact Details		
Address1	Enter the communication address1 of the user.	255 Characters
Address2	Enter the communication address2 of the user.	255 Characters
Town/City	Enter the town or city to which the user belongs.	255 Characters
State/Province	Enter the state or province to which the user belongs.	255 Characters
Country*	Select the country to which the user belongs from the drop-down list.	NA
Postal Code	Enter the postal code of the user.	16 Characters
Phone Number	Enter the phone number of the user.	25 Characters
Alternate Phone Number	Enter the alternate phone number of the user.	25 Characters
Beeper Number	Enter the beeper number of the user.	25 Characters
Fax Number	Enter the fax number of the user.	25 Characters
E-mail Address*	Enter the email address of the user. By default, the UMT application accepts only email addresses that belong to the Oracle domain (for example, username@oracle.com).	255 Characters
Confirm User E-mail Address*	Enter the email address of the user for confirmation.	255 Characters
User Misc		
Date Format	Select the required date format from the drop-down list.	NA
Load to InForm	Select check box to load the user to InForm.	NA
Overwrite	Select check box to overwrite.	NA
Assessment Mail	Select whether to enable or disable the assessment mail.	NA
Image URL	Enter the URL of the image.	255 characters

Table A-66 (Cont.) Create Oracle User - Field Information

Field Name	Description	Field Size
Trial Association		
Select Sponsor	Select the sponsor to associate the user.	NA
Select Trial	Select the trial to associate the user.	NA

Table A-67 Create PF User - Error Information

Field Name/Action	Scenario	Error Message
Basic User Info		
User Type *	You have to select the type of user, either sponsor user or site user.	NA
User Name*	Error occurs when you enter the character other than alphanumeric and underscore.	Enter a valid Username. Only alphanumeric (A-Z, 0-9) and underscores (_) are allowed.
First Name*	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid First Name. Only alphanumeric (A-Z), hyphens (-), and blank spaces are allowed.
Last Name*	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid Last Name. Only Letters (A-Z), Hyphens (-) and Blank Spaces are allowed.
Title	NA	NA
Description	Enter the description for the user.	255 Characters
Display Name	Enter the display name for the user.	255 Characters
Change Password on Next Login	NA	NA
Contact Details		
Address1	Enter the communication address1 of the user.	255 Characters
Address2	Enter the communication address2 of the user.	255 Characters
Town/City	Enter the town or city to which the user belongs.	255 Characters
State/Province	Enter the state or province to which the user belongs.	255 Characters
Country *	Select the country to which the user belongs from the drop-down list.	NA
Postal Code	Enter the postal code of the user.	16 Characters
Phone Number	Enter the phone number of the user.	25 Characters
Alternate Phone Number	Enter the alternate phone number of the user.	25 Characters
Beeper Number	Enter the beeper number of the user.	25 Characters
Fax Number	Enter the fax number of the user.	25 Characters
E-mail Address*	Error occurs when you click <b>Submit</b> without entering an valid email ID.	Enter a valid email ID.
Confirm User E-mail Address*	Error occurs when you do not enter confirm email address.	Confirm email address.

### **A.41 Create Trial Details**

Table A-68 Create Trial Details - Field Information

Field Name	Description	Field Size
Trial Details		
Study Name*	Enter the study name of the trial.	255 Characters
Trial Name*	Enter the name of the trial.	255 Characters
SOW/Contract Number*	Enter the reference name.	20 Characters
Protocol Number*	Enter the number of the protocol.	255 Characters
Duration in Months	Enter the duration of the trial in months.	5 Characters
Contracted No of Sites	Enter the number of sites contracted for performing the trial.	5 Characters
Contracted No of Countries	Enter the number of countries contracted for performing the trial.	5 Characters
Contracted No of Patients	Enter the number of patients contracted for performing the trial.	5 Characters
Contracted No of Users	Enter the number of users contracted for performing the trial.	5 Characters
Contracted No of IOL Accounts	Enter the number of IOL accounts contracted for performing the trial.	5 Characters
Contracted No of Site Assessments	Enter the number of contracted site assessments.	5 Characters
Study URL	Enter the study URL.	100 Characters
Therapeutic Area	Enter the therapeutic area.	100 Characters
Trial Phase	Select the phase of the trial from the drop-down list.	NA
Status	Select the status of the trial from the drop-down list.	NA
Is Pivotal Trial	Check the Yes or No option from the radio button for Is Pivotal?.	NA
Sponsor Customer	Enter the Sponsor Customer Name.  Use this field when the Sponsor company is a CRO to show the name of the Sponsors Customer.	255
Is OLX Trial	Check the Yes or No options from the radio button for Is OLX?.	NA
Is IRT Trial	Check the Yes or No options from the radio button for Is IRT?.	NA
Is InForm Trial	Check the Yes or No options from the radio button for Is InForm?.	NA
Compound/Drug/Device Name	Enter the compound, drug, and device name used in the trial.	255 Characters
E-mail Trigger	Select <b>Enable</b> to enable eCS email functionality. Otherwise, select <b>Disable</b> .	1 Character
	This information refers to the email trigger of registration and certificate emails by eCS.	
Notes	Enter your notes on the trial you are creating.	255 Characters
Select Trial Type	Select the trial type from the drop-down list.	NA
Select Trial Version*	Select the trial version from the drop-down list.	NA
Trial, Country Association		
Select Country*		
- Available	Displays the list of available countries.  Click >> or > to move all or the selected country, respectively, to the Selected field.	NA
- Selected	Displays the list of selected countries.	NA
	Click << or < to move all or the selected country, respectively, to the Available field.	
Display Name:	Enter the display name for the user.	255 Characters
Change Password on Next Login	NA	NA
Contact Details	-	-
Address1	Enter the communication address1 of the user.	255 Characters
Address2	Enter the communication address2 of the user.	255 Characters

Table A-68 (Cont.) Create Trial Details - Field Information

Field Name	Description	Field Size
Town/City	Enter the town or city to which the user belongs.	255 Characters
State/Province	Enter the state or province to which the user belongs.	255 Characters
Country *	Select the country to which the user belongs from the drop-down list.	NA
Postal Code	Enter the postal code of the user.	16 Characters
Phone Number	Enter the phone number of the user.	25 Characters
Alternate Phone Number	Enter the alternate phone number of the user.	25 Characters
Beeper Number	Enter the beeper number of the user.	25 Characters
Fax Number	Enter the fax number of the user.	25 Characters
E-mail Address*	Error occur when you click <b>Submit</b> without entering an valid email ID.	Enter a valid email id.
Confirm User E-mail Address*	Error occurs when you do not enter confirm email address.	Confirm email address.

Table A-69 Create Trial Details - Error Information

Field Name/Action	Scenario	Error Message
Trial Details		
Study Name	Error occurs when you click <b>Submit</b> without entering the study name or if you enter the character other than alphanumeric, hyphen, and underscores.	Enter a valid Study Name. Only Alphanumerics (A-Z, 0-9), Hyphens, and underscores(_) are allowed.
Trial Name	Error occurs when you click <b>Submit</b> without entering the trial name or if you enter the character other than alphanumeric, hyphen, and underscores.	Enter a valid Trial Name. Only Alphanumerics (A-Z, 0-9), Hyphens, and underscores(_) are allowed.
SOW/Contract Number	Error occurs when you enter the character other than alphanumeric.	Enter Reference.
Protocol Number	Error occurs when you enter the character other than alphanumeric.	Enter Protocol Number.
Duration in Months	Enter the duration of the trial in months.	Enter a valid Duration in Months. Only Numbers (0-9) are allowed.
Contracted No of Sites	Error occurs when you enter the character other than number.	Enter a valid Contracted No of sites. Only Numbers (0-9) are allowed.
Contracted No of Countries	Error occurs when you enter the character other than number.	Enter the number of countries contracted for performing the trial.
Contracted No of Patients	Error occurs when you enter the character other than number.	Enter a valid Contracted No of Patients. Only Numbers (0-9) are allowed.
Contracted No of Users	Enter the number of users contracted for performing the trial.	Enter a valid Contracted No of Users. Only Numbers (0-9) are allowed.
Contracted No of IOL Accounts	Enter the number of IOL accounts contracted for performing the trial.	Enter a valid Contracted No of IOL Accounts. Only Numbers (0-9) are allowed
Contracted No of Site Assessments	Enter the number of contracted site assessments.	Enter a valid Contracted No of Site Assessments. Only Numbers (0-9) are allowed.
Study URL	Enter the study URL.	NA
Therapeutic Area	Enter the therapeutic area.	NA
Trial Phase	Select the phase of the trial from the drop-down list.	NA

Table A-69 (Cont.) Create Trial Details - Error Information

Field Name/Action	Scenario	Error Message
Status	Select the status of the trial from the drop-down list.	Please select Trial Status
Is IRT/ InForm	Select at least any one type of trial IRT or InForm.	Trial should be either InForm or IRT.
Compound/Drug/Device Name	Enter the compound, drug, and device name used in the trial.	NA
E-mail Trigger	Select <b>Enable</b> to enable eCS email functionality. Otherwise, select <b>Disable</b> .	NA
	This information refers to the email trigger of registration and certificate emails by eCS.	
Notes	Error occurs when the entered character exceed 255 characters.	Note text should not exceed 255 characters.
Import path	Error occurs when you click <b>Submit</b> without select FTP path.	Enter FTP path.
Select Trial Version*	Error occurs when the you click <b>Submit</b> without selecting any trial version.	Select Trial Version.
Trial, Country Association		
Select Country*	Error occurs when you click <b>Submit</b> without selecting any country.	Select a country.
- Available	NA	NA
- Selected	NA	NA

### A.42 Edit PF User

Table A-70 Edit PF User - Field Information

Field Name	Description	Field Size
Basic User Info		
User Type *	You have to select the type of user, either sponsor user or site user.	NA
User Name *	The user name format must follow the specifications in the UMT settings.	255 Characters
First Name*	Enter the first name of the user.	127 Characters
Last Name*	Enter the last name of the user.	127 Characters
Title	Select a title for the user from the drop-down list.	NA
Description:	Enter the description for the user.	255 Characters
Display Name:	Enter the display name for the user.	255 Characters
<b>Contact Details</b>		
Address1	Enter the communication address1 of the user.	255 Characters
Address2	Enter the communication address2 of the user.	255 Characters
Town/City	Enter the town or city to which the user belongs.	255 Characters
State/Province	Enter the state or province to which the user belongs.	255 Characters
Country *	Select the country to which the user belongs from the drop-down list.	NA
Postal Code	Enter the postal code of the user.	16 Characters
Phone Number	Enter the phone number of the user.	25 Characters
Alternate Phone Number	Enter the alternate phone number of the user.	25 Characters
Beeper Number	Enter the beeper number of the user.	25 Characters

Table A-70 (Cont.) Edit PF User - Field Information

Field Name	Description	Field Size
Fax Number	Enter the fax number of the user.	25 Characters
E-mail Address*	Enter the email address of the user.	255 Characters
Confirm User E-mail Address*	Enter the email address of the user for confirmation.	255 Characters
User Misc		
Assessment mail	Select whether to enable or disable assessment mail.	NA
InForm Home page path	Select the InForm home page path.	255 characters
Image URL	Enter the URL of the image.	255 characters
Change password in next login	Select Yes or No.	NA
Overwrite	Select to overwrite.	NA
Date Format	Select the format for the date to be displayed.	NA
Training Status	Select the training status from the options given.	NA
Load to InForm	Used to load to InForm.	NA
Rights Association		
Right Group *	Select the Right Group for the user.	NA
Query Group	Select the Query Group for the user.	NA
Trial Association		
Select Sponsor	Select the sponsor to associate the user.	NA
Select Trial	Select the trial to associate the user.	NA
Reason For Change	Enter the reason for change or edit.	NA

Table A-71 Edit PF User - Error Information

Field Name/Action	Scenario	Error Message
Basic User Info		
User Type *	You have to select the type of user, either sponsor user or site user.	NA
User Name*	Error occurs when you enter the character other than alphanumeric and underscore.	Enter a valid Username. Only Alphanumeric (A-Z, 0-9) and underscores (_) are allowed.
First Name*	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid First Name. Only Letters (A-Z), Hyphens (-), and Blank Spaces are allowed.
Last Name*	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid Last Name. Only Letters (A-Z), Hyphens (-), and Blank Spaces are allowed.
Title	NA	NA
Description:	Enter the description for the user.	255 Characters
Display Name:	Enter the display name for the user.	255 Characters
Change Password on Next Login	NA	NA
Contact Details		
Address1	Enter the communication address1 of the user.	255 Characters
Address2	Enter the communication address2 of the user.	255 Characters
Town/City	Enter the town or city to which the user belongs.	255 Characters

Table A-71 (Cont.) Edit PF User - Error Information

Field Name/Action	Scenario	Error Message
State/Province	Enter the state or province to which the user belongs.	255 Characters
Country *	Select the country to which the user belongs from the drop-down list.	NA
Postal Code	Enter the postal code of the user.	16 Characters
Phone Number	Enter the phone number of the user.	25 Characters
Alternate Phone Number	Enter the alternate phone number of the user.	25 Characters
Beeper Number	Enter the beeper number of the user.	25 Characters
Fax Number	Enter the fax number of the user.	25 Characters
E-mail Address*	Error occur when you click <b>Submit</b> without entering an valid email ID.	Enter a valid email id.
Confirm User E-mail Address*	Error occurs when you do not enter confirm email address.	Confirm email address.
Right Group	Error occurs you do not select the right group.	Select the Right Group.
Reason For Change	Error occurs when you do not enter the reason for change.	Enter Reason For Change.

### A.43 Create UMT User Details

Table A-72 Create UMT User Details - Field Information

Field Name	Description	Field Size
User Details		
Username*	Enter the user name.	25 Characters
	The user name format must follow the specifications in the UMT settings.	
User Type*	Select the user type from the drop-down list.	NA
	Select <b>PF User</b> to create a PF user and <b>Sponsor User</b> to create a sponsor user.	
First Name*	Enter the first name of the user.	127 Characters
Last Name*	Enter the last name of the user.	127 Characters
Title	Select a title for the user from the drop-down list.	NA
Status	Select <b>Active</b> to set the user as active. Otherwise, select <b>Inactive</b> .	NA
Change Password on Next Login	Select $\boldsymbol{Yes}$ to change the password at next log on. Otherwise, select $\boldsymbol{No}.$	NA
Address1	Enter the communication address of the user.	255 Characters
Address2		
Town/City	Enter the town or city to which the user belongs.	255 Characters
State/Province	Enter the state or province to which the user belongs.	255 Characters
Country*	Select the country to which the user belongs from the drop-down list.	NA
Postal Code	Enter the postal code of the user.	16 Characters
Phone Number	Enter the phone number of the user.	25 Characters
Alternate Phone Number	Enter the alternate phone number of the user.	25 Characters
Mobile Number	Enter the mobile number of the user.	25 Characters

Table A-72 (Cont.) Create UMT User Details - Field Information

Field Name	Description	Field Size
Fax Number	Enter the fax number of the user.	25 Characters
E-mail Address*	Enter the email address of the user.	255 Characters
Confirm User E-mail Address*	Enter the email address of the user for confirmation.	255 Characters
Select Role*	Based on the user type, select a role for the user from the drop-down list.	NA

Table A-73 Create UMT User Details - Error Information

Field Name/Action	Scenario	Error Message
User Details		
Username	Error occurs when you enter the character other than alphanumeric and underscore.	Enter a valid Username. Only Alphanumeric (A-Z, 0-9) and underscores(_) are allowed.
User Type	Error occurs when the user type is not selected before submit.	Select User Type.
First Name	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid First Name. Only Letters (A-Z), Hyphens (-), and Blank Spaces are allowed.
Last Name	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid Last Name. Only Letters (A-Z), Hyphens (-), and Blank Spaces are allowed.
Title	NA	NA
Status	NA	NA
Change Password on Next Login	NA	NA
Address1 Address2	NA	NA
Town/City	Error occurs when you enter the character other than alphabet, integer, and blank space.	Enter a valid Town/City. Only Alphanumeric (A-Z, 0-9) and Blank Spaces are allowed.
State/Province	Error occurs when you enter the character other than alphabet and blank space.	Enter a valid State/Province. Only Letters (A-Z) and Blank Spaces are allowed.
Country*	Error occurs when you click <b>Submit</b> without selecting the country.	Select a country.
Postal Code	Error occurs when you enter the character other than alphabet, integer and blank space.	Enter a valid Postal Code. Only Alphanumeric (A-Z, 0-9) and Blank Spaces are allowed.
Phone Number	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid Phone Number. Only Numbers (0-9), Hyphens (-), and Blank spaces are allowed.
Alternate Phone Number	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid Alternate Phone Number. Only Numbers (0-9), Hyphens (-), and Blank spaces are allowed.
Mobile Number	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid Mobile Number. Only Numbers (0-9), Hyphens (-) and Blank spaces are allowed.
Fax Number	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid Fax Number. Only Numbers (0-9), Hyphens (-), and Blank spaces are allowed.
E-mail Address*	Error occurs when you click <b>Submit</b> without entering the email address or entering a wrong email address.	<ol> <li>Enter E-mail Address.</li> <li>Enter a valid E-mail Address.</li> </ol>

Table A-73 (Cont.) Create UMT User Details - Error Information

Field Name/Action	Scenario	Error Message
Confirm User E-mail Address*	Error occurs for either of the following reasons:	1. Confirm User E-mail Address.
	<ul> <li>When you click Submit without entering</li> </ul>	2. Confirm a valid E-mail Address.
	the confirm user address.	3. Confirm E-mail Address does not
	<ul> <li>When you enter a wrong email format.</li> </ul>	match
	<ul> <li>When the email address and confirm email address mismatch.</li> </ul>	
Select Role*	Error occurs when you click <b>Submit</b> without selecting a role.	Select a Role.
Common Error		
Copy/Paste	Error occurs when you copy and paste to any text box.	Type using your Keyboard.
Copy/Paste	Error occurs when you copy and paste the Conform Email Address.	Re-confirm your Email address. Note: Do not copy and paste your Email address.
Copy/Paste	Error occurs when you copy and paste the email address.	Enter your Email address. Note: Do not copy and paste your Email address.

### A.44 UMT User Details

Table A-74 UMT User Details - Field Information

Field Name	Description	Field Size
User Details		
Username*	Enter the user name.	25 Characters
	The user name format must follow the specifications in the UMT settings.	
User Type*	Select the user type from the drop-down list.	NA
	Select <b>PF User</b> to create a PF user and <b>Sponsor User</b> to create a sponsor user.	
First Name*	Enter the first name of the user.	127 Characters
Last Name*	Enter the last name of the user.	127 Characters
Title	Select a title for the user from the drop-down list.	NA
Status	Select <b>Active</b> to set the user as active. Otherwise, select <b>Inactive</b> .	NA
Change Password on Next Login	Select $Y\!e\!s$ to change the password at next log on. Otherwise, select $No.$	NA
Address1	Enter the communication address of the user.	255 Characters
Address2		
Town/City	Enter the town or city to which the user belongs.	255 Characters
State/Province	Enter the state or province to which the user belongs.	255 Characters
Country*	Select the country to which the user belongs from the drop-down list.	NA
Postal Code	Enter the postal code of the user.	16 Characters
Phone Number	Enter the phone number of the user.	25 Characters
Alternate Phone Number	Enter the alternate phone number of the user.	25 Characters
Mobile Number	Enter the mobile number of the user.	25 Characters
Fax Number	Enter the fax number of the user.	25 Characters
E-mail Address*	Enter the email address of the user.	255 Characters

Table A-74 (Cont.) UMT User Details - Field Information

Field Name	Description	Field Size
Confirm User E-mail Address*	Enter the email address of the user for confirmation.	255 Characters
Select Role*	Based on the user type, select a role for the user from the drop-down list.	NA
Select Country*		
- Available	Displays the list of available countries.	NA
	Click >> or > to move all or the selected country, respectively, to the Selected field.	
- Selected	Displays the list of selected countries.	NA
	Click << or < to move all or the selected country, respectively, to the Available field.	
Select Trial*		
- Available	Displays the list of available trials.	NA
	Click >> or > to move all or the selected trial, respectively, to the Selected field.	
- Selected	Displays the list of selected trials.	NA
	Click << or < to move all or the selected trials, respectively, to the Available field.	

Table A-75 UMT User Details - Error Information

Field Name/Action	Scenario	Error Message
User Details		
Username	Error occurs when you enter the character other than alphanumeric and underscore.	Enter a valid Username. Only Alphanumeric (A-Z,0 -9) and underscores(_) are allowed.
User Type	Error occur when the user type is not selected before submit.	Select User Type.
First Name	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid First Name. Only Letters (A-Z), Hyphens (-), and Blank Spaces are allowed.
Last Name	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid Last Name. Only Letters (A-Z), Hyphens (-), and Blank Spaces are allowed.
Title	NA	NA
Status	NA	NA
Change Password on Next Login	NA	NA
Address1	NA	NA
Address2		
Town/City	Error occurs when you enter the character other than alphabet, integer, and blank space.	Enter a valid Town/City. Only Alphanumeric (A-Z, 0-9) and Blank Spaces are allowed.
State/Province	Error occurs when you enter the character other than alphabet and blank space.	Enter a valid State/Province. Only Letters (A-Z) and Blank Spaces are allowed.
Country*	Error occurs when you click <b>Submit</b> without selecting the country.	Select a country.
Postal Code	Error occurs when you enter the character other than alphabet, integer, and blank space.	Enter a valid Postal Code. Only Alphanumeric (A-Z, 0-9) and Blank Spaces are allowed.

Table A-75 (Cont.) UMT User Details - Error Information

Field Name/Action	Scenario	Error Message
Phone Number	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid Phone Number. Only Numbers (0-9), Hyphens (-), and Blank spaces are allowed.
Alternate Phone Number	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid Alternate Phone Number. Only Numbers (0-9), Hyphens (-), and Blank spaces are allowed.
Mobile Number	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid Mobile Number. Only Numbers (0-9), Hyphens (-), and Blank spaces are allowed.
Fax Number	Error occurs when you enter the character other than alphabet, hyphen, and blank space.	Enter a valid Fax Number. Only Numbers (0-9), Hyphens (-), and Blank spaces are allowed.
E-mail Address*	Error occurs when you click <b>Submit</b> without entering the email address or if you enter a wrong email address.	1. Enter E-mail Address.
		2. Enter a valid E-mail Address.
Confirm User E-mail Address*	Error occurs for either of the following reasons:	1. Confirm User E-mail Address.
	<ul> <li>When you click Submit without entering the</li> </ul>	2. Confirm a valid E-mail Address.
	confirm user address.	3. Confirm E-mail Address does not
	<ul> <li>When you enter a wrong email format.</li> </ul>	match.
	<ul> <li>When the email address and confirm email address mismatch.</li> </ul>	
Select Role*	Error occurs when you click <b>Submit</b> without selecting a Role.	Select a Role.
Common Error		
Copy/Paste	Error occurs when you copy and paste to any text box.	Type using your Keyboard.
Copy/Paste	Error occurs when you copy and paste the confirm email address.	Re-confirm your Email address. Note: Do not copy and paste your Email address.
Copy/Paste	Error occurs when you copy and paste the email address.	Enter your Email address. Note: Do not copy and paste your Email address.

### A.45 Create Site Details

Table A-76 Create Site Details - Field Information

Field Name	Description	Field Size
Site Details		
Site Number*	Enter the number of the site.	20 Characters
Site Name*	Enter the name of the site.	255 Characters
Site Address1*	Enter the address of the site.	255 Characters
Site Address2		
Town/City*	Enter the city where the site is located.	127 Characters
State/Province	Enter the state or province where the site is located.	255 Characters
Country*	Select the country where the site is located from the drop-down list.	NA
Postal Code	Enter the postal code of the site.	16 Characters
Phone Number*	Enter the phone number of the site.	25 Characters
Alternate Phone Number	Enter the alternate phone number of the site.	25 Characters

Table A-76 (Cont.) Create Site Details - Field Information

Field Name	Description	Field Size
Fax Number	Enter the fax number of the site.	25 Characters
E-mail	Enter the e-mail address of the site.	255 Characters
Date Format	Displays the date format.	NA
TimeZone*	Select the time zone from the drop-down list.	NA
Study Version	Displays the selected study version.	NA
Load to InForm	Select the check box to upload site details to InForm system	NA
Site Study Locale*	Select the site study locale from the drop-down available	NA
Order of Username in Signature	Select the order of username from the drop-down available for signature.	NA
IRT Related		
Site Id	Enter the IRT Site ID.	255
Ship Name	Enter the ship name of the site.	255
Ship Address	Enter the ship address.	255
First Name	Enter the last name.	255
Last Name	Enter the last name.	255
Investigator ID	Enter the investigator ID.	255
Ship Note	Enter the ship note.	255
DEA Registration No	Enter the DEA registration number.	255
DEA Expiration	Enter the DEA expiration.	255
Load to IRT	Select the check box to load the user's information into the IRT system.	NA
Ship City	Enter the ship city.	255
Ship State	Enter the ship state.	255
Ship Zip	Enter the ship zip.	255
Ship Country	Select the ship country.	NA
Ship Phone	Enter the ship phone.	255
Ship Fax	Enter the ship fax.	255
OLX Related		
Project Site Enrolment*	Enter the project site enrollment details.	255
Active Site?	Select the check box.	NA
Load to OLX	Select the check box to load the user's information into the OLX system.	NA
<b>User Association Details</b>		
Filter By	Select the filter criteria from the drop-down lists.	NA
	If you select <b>City</b> , enter the name of the city in the text box that appears and click <b>Go</b> . You can also use wild cards to search for a city.	
	If you select <b>Country</b> and <b>TimeZone</b> , select the country and time zone from the drop-down list that appears.	
Select User		

Table A-76 (Cont.) Create Site Details - Field Information

Field Name	Description	Field Size
- Available	Displays the list of available users.	NA
	Click >> or > to move all or the selected users, respectively, to the Selected field.	
- Selected	Displays the list of selected users. N	
	Click << or < to move all or the selected users, respectively, to the Available field.	
Automatic Association	Select the check box to automatically associate the site to the users created in the selected country and time zone.	NA

Table A-77 Create Site Details - Error Information

Field Name/Action	Scenario	Error Message
Site Details		
Site Number*	Error occurs when the you click <b>Submit</b> without entering the site number or when you enter the characters other than alphanumeric, hyphen, and underscore.	Enter Site Number.  Enter a valid Site number. Only Numbers (0-9), Letters (A-Z), Hyphens(-), and Underscores(_) are
Site Name*	Error occurs when the you click <b>Submit</b> without entering the site name or when you enter the characters other than alphanumeric, hyphen, underscore, and blank space	allowed.  Enter Site Name. Enter a valid Site name. Only Alphanumerics (A-Z,0-9), Hyphens(-), Underscores(_), and Blank Spaces are allowed.
Site Address1*	Error occurs when the you click <b>Submit</b> without	Enter Site Address.
Site Address2	entering the site address or when you enter the characters other than alphanumeric, hyphen, underscore, blank space, period, and comma.	Enter a valid Address. Only Alphanumerics (A-Z,0-9), Period (.), Comma (,), Hyphens(-), Underscores(_ ), and Blank Spaces are allowed.
Town/City*	Error occurs when the you enter the characters other than alphanumeric and blank space.	Enter a valid Town/City. Only Alphanumerics (A-Z, 0-9) and Blank Spaces are allowed.
State/Province	Error occurs when the you enter the characters other than alphabet and blank space.	Enter a valid State/Province. Only Letters (A-Z) and Blank Spaces are allowed.
Country*	Error occurs when you click <b>Submit</b> without selecting the country or when no time zone found for the country.	Select a Country. No TimeZone found.
Postal Code	Error occurs when you enter invalid character in the postal code.	Enter a valid Postal Code. Only Alphanumerics (A-Z, 0-9), and Blank Spaces are allowed
Phone Number*	Error occurs when you click <b>Submit</b> without	Enter Phone Number.
	entering the phone number or when you enter character other than number, hyphen, and blank space.	Enter a valid Phone number. Only Numbers (0-9), Hyphens(-) and Blank Spaces are allowed.
Alternate Phone Number	Error occurs when you click Submit without	Enter Alternate Phone Number.
	entering the alternate phone number or when you enter character other than number, hyphen, and blank space.	Enter a valid Alternate Phone number. Only Numbers (0-9), Hyphens(-), and Blank Spaces are allowed.
Fax Number	Error occurs when you enter the character other than number, hyphen, and blank space.	Enter a valid Fax number. Only Numbers (0-9), Hyphens(-), and Blank Spaces are allowed.
E-mail	Error occurs when the you enter the email ID other than the standard format.	Enter valid E-mail.
Date Format	NA	NA
TimeZone*	Error occurs when you click <b>Submit</b> without selecting the time zone.	Select TimeZone

Table A-77 (Cont.) Create Site Details - Error Information

Field Name/Action	Scenario	Error Message
Study Version	NA	NA
Load to InForm	NA	NA
Site Study Locale*	Error occurs when you click <b>Submit</b> without selecting the site study locale.	Select the site study locale.
IRT Related Details		
Site ID	Error occurs when the you click Submit without entering the site ID.	Enter Site ID,
Ship Name	Error occurs when you click Submit without entering the ship name.	Enter Ship Name.
First Name	Error occurs when you click Submit without entering the first name.	Enter First Name.
Last Name	Error occurs when the you click Submit without entering the last name.	Enter Last Name.
Ship Address	Error occurs when you click Submit without entering the ship address.	Enter Ship Address.
Ship City	Error occurs when the you click Submit without entering the ship city.	Enter Ship City.
Ship Zip	Error occurs when the you click <b>Submit</b> without entering the ship zip.	Enter Ship Zip.
Ship Country	Error occurs when the you click <b>Submit</b> without selecting the ship country.	Select Ship Country.
OLX Related		
Project Site Enrollment	Error occurs when the you click <b>Submit</b> without entering the project site enrollment.	Enter project site enrollment.
<b>User Association Details</b>		
Filter By	NA	NA
Select User		
- Available	NA	NA
- Selected	NA	NA
Automatic Association	NA	NA

### A.46 Site Details

Table A-78 Site Details - Field Information

Field Name	Description	Field Size
Site Details		
Site Number*	Enter the number of the site.	20 Characters
Site Name*	Enter the name of the site.	255 Characters
Site Address1*	Enter the address of the site.	255 Characters
Site Address2		
Town/City*	Enter the city where the site is located.	127 Characters
State/Province	Enter the state or province where the site is located.	255 Characters
Country*	Select the country where the site is located from the drop-down lis	t. NA
Postal Code	Enter the postal code of the site.	16 Characters
Phone Number*	Enter the phone number of the site.	25 Characters

Table A-78 (Cont.) Site Details - Field Information

Enter the fax number of the site. 25 Characters mail Enter the e-mail address of the site. 255 Characters ate Format Displays the date format. NA mezone* Select the time zone from the drop-down list. NA and to InForm Select the time zone from the drop-down list. NA and to InForm Select the check box to upload site details to InForm system. NA CT Related to the InForm Select the ship name of the site. 255 List and the InForm Select the ship name of the site. 255 List and Select the last name. 255 List and Select the last name. 255 List and Select the last name. 255 List and Select the ship note. 255 List and	Field Name	Description	Field Size
mail Enter the e-mail address of the site. 255 Characters atte Format Displays the date format. NA mcZone* Select the time zone from the drop-down list. NA udy Version Displays the selected study version. NA value Version Select the check box to upload site details to InForm system. NA  IT Related  The table Enter the IRT Site ID. 255  Inply Alarme Enter the ship address. 255  Inst Name Enter the ship address. 255  Inst Name Enter the last name. 255  Inst Name Enter the last name. 255  Inst Name Enter the last name. 255  Inst Name Enter the heship note. 255  EA Registration ID Enter the ship note. 255  EA Registration No Enter the DEA registration number. 255  EA Expiration Enter the DEA expiration. 255  Inst Vity Enter the ship city. 255  Inst State Enter the ship state. 255  Inst City Enter the ship state. 255  Inst City Enter the ship state. 255  Inst City Enter the ship phone. 255  Inst City Select the eship fax. 255  IX Related Topic Country Select the ship fax. 255  IX Related Topic Enter The Ship fax. 255  IX Relat	Alternate Phone Number	Enter the alternate phone number of the site.	25 Characters
Displays the date format.  Displays the date format.  MA  meZone*  Select the time zone from the drop-down list.  NA  Displays the selected study version.  NA  TRelated  TRelated  TRelated  Enter the IRT Site ID.  255  Displays mame  Enter the ship name of the site.  255  Displays mame  Enter the ship address.  Enter the slap address.  Enter the last name.  255  Select the investigator ID.  255  Displays note  Enter the last name.  255  Displays mame  Enter the last name.  255  Displays mame  Enter the last name.  255  Displays the list of available user's information into the IRT system.  NA  TRELATED  NA  Displays the list of available users.  Click >> or > to move all or the selected users, respectively, to the Available field.  NA  NA  NA  NA  NA  NA  NA  Displays the list of available sociate the slite to the user's not must call y associate the slite to the user's not must call y associate the slite to the user's not must call y associate the slite to the selected users, respectively, to the Available field.  NA  NA  NA  NA  NA  NA  NA  Displays the list of available users.  Click < or < to move all or the selected users, respectively, to the Available field.  Select the check box to automatically associate the slite to the user's list to the user's not must call y associate the slite to the user's not must call y associate the slite to the user's not must call y as one of the city in the text box that appears and click Co. You can also use wild cards to search for a clty.  If you select Country and TimeZone, select the country and time zone from the drop-down list hat appears.  NA  NA  NA  Selected  Displays the list of available users.  Click < or < to move all or the selected users, respectively, to the Selected field.  Select the check box to automatically associate the site to the users in the user should be	Fax Number	Enter the fax number of the site.	25 Characters
meZone* Select the time zone from the drop-down list.  NA  udy Version Displays the selected study version. NA  NA  Tr Related  te Id Enter the IRT Site ID 255 pip Name Enter the ship address. 255 set Name Enter the ship address. 255 set Name Enter the last name. 255 site Name Enter the last name. 255 pip Note Enter the last name. 255 EA Registration No Enter the DEA registration number. 255 EA Registration No Enter the DEA registration number. 255 EA State Enter the Ship city. 255 pip Country Select the check box to load the user's information into the IRT system. 255 pip Country Select the ship country. NA  NA  NA  Last Related  The Select the ship fax. 255  Last Related  The Select the ship fax. 255  Last Related  The Select the check box to load the user's information into the OLX Select the check box to load the user's information into the OLX Select the ship fax. 255  Last Related  The Select the check box to load the user's information into the OLX Select the check box. NA  Select the ship fax.  NA  Select the check box. NA  Select the check box. NA  Select the ship fax. NA  If you select City, enter the name of the city in the text box that appears and click Go. You can also use wild cards to search for a city.  If you select City, enter the name of the city in the text box that appears and click Go. You can also use wild cards to search for a city.  If you select Country and TimeZone, select the country and time zone from the drop-down list that appears.  Select User  Wailable Displays the list of available users. Click < or < to move all or the selected users, respectively, to the Selected field.  Unumatic Association Select the check box to automatically associate the site to the users in the users. Click < or < to move all or the selected users, respectively, to the Selected users. Click < or < to move all or the selected use	E-mail	Enter the e-mail address of the site.	255 Characters
udy Version  Displays the selected study version.  NA  And to InForm  Select the check box to upload site details to InForm system.  NA  IT Related  te Id Enter the IRT Site ID.  zip Name Enter the ship name of the site.  zip Address Enter the ship address.  zip Address Enter the last name.  zip Address Enter the last name.  zip Name Enter the last name.  zip Name Enter the last name.  zip Name Enter the Int Site ID.  zip Note Enter the beat part of the site of the sit	Date Format	Displays the date format.	NA
Select the check box to upload site details to InForm system.  NA  IT Related  te ld Enter the IRT Site ID. 255  tip Andre Enter the ship name of the site. 255  tip Address Enter the ship address. 255  rst Name Enter the last name. 255  rst Name Enter the ship note. 255  Ea Registration ID Enter the DEA registration number. 255  EA Registration No Enter the DEA registration number. 255  EA Registration No Enter the DEA systemion. 255  and to IRT Select the check box to load the user's information into the IRT system. 255  rip City Enter the ship city. 255  rip State Enter the ship state. 255  rip Zip Enter the ship state. 255  rip Zip Enter the ship pane. 255  rip Fax Enter the ship pane. 255  rip Fax Enter the ship fax. 255  LX Related  roject Site Enrolment* Enter the project site enrollment details. 255  LX Related  roject Site Enrolment* Enter the project site enrollment details. 255  LX Related  roject Site Enrolment* Enter the check box. 100 and the user's information into the OLX system. 100 and to OLX Select the check box. 100 and the user's information into the OLX system. 100 and to OLX Select the check box. 100 and the user's information into the OLX system. 100 and 100 an	ΓimeZone*	Select the time zone from the drop-down list.	NA
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created in the selected country and time zone.	Automatic Association	Select the check box to automatically associate the site to the users created in the selected country and time zone.	NA

Table A-78 (Cont.) Site Details - Field Information

Field Name	Description	Field Size
Submit button	Click to submit the form.	NA
Cancel button	Click to cancel the changes and return to the previous page.	NA
Reason For change Textbox	Enter the reason for change.	255 characters

Table A-79 Site Details - Error Information

Field Name/Action	Scenario	Error Message
Site Details		
Site Number*	Error occurs when you click Submit without	Enter Site Number.
	entering the site number or when you enter the characters other than alphanumeric, hyphen, and underscore.	Enter a valid Site number. Only Numbers (0-9), Letters (A-Z), Hyphens(-), and Underscores(_) are allowed.
Site Name*	Error occurs when you click <b>Submit</b> without entering the site Name or when you enter the characters other than alphanumeric, hyphen, underscore, and blank space.	Enter Site Name. Enter a valid Site name. Only Alphanumerics (A-Z,0-9), Hyphens(-), Underscores(_), and Blank Spaces are allowed.
Site Address1*	Error occurs when the you click <b>Submit</b> without	Enter Site Address.
Site Address2	entering the site address or when the user enter the characters other than alphanumeric, hyphen, underscore, blanks pace, period, and comma.	Enter a valid Address. Only Alphanumerics (A-Z, 0-9), Period (.), Comma (,), Hyphens(-), Underscores(_ ), and Blank Spaces are allowed.
Town/City*	Error occurs when the you enter the characters other than alphanumeric and blank space.	Enter a valid Town/City. Only Alphanumerics (A-Z, 0-9) and Blank Spaces are allowed.
State/Province	Error occurs when the you enter the characters other than alphabet and blank space.	Enter a valid State/Province. Only Letters (A-Z) and Blank Spaces are allowed.
Country*	Error occurs when you click Submit without selecting the country or when no time zone is found for the country.	Select a Country. No TimeZone found.
Postal Code	Error occurs when you enter an invalid character in the postal code.	Enter a valid Postal Code. Only Alphanumerics (A-Z,0-9) and Blank Spaces are allowed
Phone Number*	Error occurs when you click <b>Submit</b> without	Enter Phone Number.
	entering the phone number or when you enter character other than number, hyphen, and blank space.	Enter a valid Phone number. Only Numbers (0-9), Hyphens(-), and Blank Spaces are allowed.
Alternate Phone Number	Error occurs when you click Submit without	Enter Alternate Phone Number.
	entering the alternate phone number or when you enter character other than number, hyphen, and blank space.	Enter a valid Alternate Phone number. Only Numbers (0-9), Hyphens(-), and Blank Spaces are allowed.
Fax Number	Error occurs when the you enter the character other than number, hyphen, and blank space	Enter a valid Fax number. Only Numbers (0-9), Hyphens(-), and Blank Spaces are allowed
E-mail	Error occurs when the you enter the email ID other than the standard format.	Enter valid E-mail.
Date Format	NA	NA
TimeZone*	Error occurs when the you click <b>Submit</b> without selecting the time zone.	Select TimeZone.
Study Version	NA	NA
Load to InForm	NA	NA
IRT Related Details		

Table A-79 (Cont.) Site Details - Error Information

Field Name/Action	Scenario	Error Message
Site ID	Error occurs when the you click <b>Submit</b> without entering the site ID.	Enter Site ID.
Ship Name	Error occurs when the you click <b>Submit</b> without entering the ship name.	Enter Ship Name.
First Name	Error occurs when the you click <b>Submit</b> without entering the first name.	Enter First Name.
Last Name	Error occurs when the you click <b>Submit</b> without entering the last name.	Enter Last Name.
Ship Address	Error occurs when the you click <b>Submit</b> without entering the ship address.	Enter Ship Address.
Ship City	Error occurs when the you click <b>Submit</b> without entering the ship city.	Enter Ship City.
Ship Zip	Error occurs when the you click <b>Submit</b> without entering the ship zip.	Enter Ship Zip.
Ship Country	Error occurs when the you click <b>Submit</b> without selecting the ship country.	Select Ship Country.
OLX Related		
Project Site Enrollment	Error occurs when the you click <b>Submit</b> without entering the project site enrollment.	Enter project site enrollment.
<b>User Association Details</b>		
Filter By	NA	NA
Select User		
- Available	NA	NA
- Selected	NA	NA
Automatic Association	NA	NA
Submit Button	Error occurs when you click <b>Submit</b> without any change.	The form has not changed.
Submit Button	Error occurs when you click <b>Submit</b> without entering reason for change.	Enter a reason for change.
Submit Button	Error occurs when you enter more than 255 characters.	Reason text should not exceed 255 characters.

# A.47 MUL Import - Error and Corrective Action Information

Table A-80 MUL Import - Error and Corrective Action Information

Error Message	Scenario	<b>Corrective Action</b>
XML Import:		
Number of characters allowed for ItemRefname is 63	Error occurs when the character limit of ItemRefname exceeds 63.	Enter ItemRefname Less than or equal to 63 character.
Maximum Number of characters allowed for ItemQuestion is 255	Error occurs when the character limit of ItemQuestion exceeds 255.	Enter ItemQuestion Less than or equal to 255 character.
Maximum Number of characters allowed for Form Title is 255	Error occurs when the character limit of title exceeds 255.	Enter Title Less than or equal to 255 character.
Maximum Number of characters allowed for Form RefName is 32	Error occurs when the character limit of RefName exceeds 32.	Enter RefName Less than or equal to 32 character.

Table A-80 (Cont.) MUL Import - Error and Corrective Action Information

Error Message	Scenario	Corrective Action
Group Insert:		
Invalid Characters found in Group Name	Error occurs when group name contains characters other than alphanumeric, hyphen, underscore, and blank space.	Remove the character other than Alphanumeric, hyphen, underscore and blank space.
Group Name exceeds maximum limit 63	Error occurs when the group name exceeds 63 characters.	Enter the Group Name Less than or equal to 63 characters.
Group Type not found	Error occurs when the you do not check any group type.	Check at least one group type.
User Insert:		
Site number not found	Error occurs when you enter an invalid site number.	Enter the site number of the existing site.
Rights Group not found	Error occurs when you enter an invalid right group.	Enter the site number of the existing Right Group.
First name not found	Error occurs when the first name column is left blank.	Enter the First name.
Last name not found	Error occurs when the last name column is left blank.	Enter the Last name.
Phone number not found	Error occurs when the phone number column is left blank.	Enter the Phone number.
Display name not found	Error occurs when the display name column is left blank.	Enter the Display name.
Email ID not found	Error occurs when the email ID column is left blank.	Enter the Email ID.
User is Mark Upload to InForm and Trial is Locked	Error occurs when you update the user information when the user is Mark Upload to InForm and the Trial is locked.	User cannot be import with the status Mark Upload to InForm when the Trial is locked for QC.
Cannot create user even by appending the character to UserName, as already exist under the sponsor.	Error occurs when the user already created by appending the character.	User need to enter different username.
RoleType is not matched with User Type	Error occurs when the role type is mismatched with the user type.	Choose a Role type that match with the User Type.
Invalid Characters found in User Name	Error occurs when the user name contains characters other than alphanumeric, hyphen, underscore, and blank space.	Remove the character other than Alphanumeric, Hyphen, Underscore and Blank space.
Invalid Characters found in First Name	Error occurs when the first name contains characters other than alphanumeric, hyphen, underscore, and blank space.	Remove the character other than Alphanumeric, Hyphen, underscore and blank space.
Invalid Characters found in Last Name	Error occurs when the last name contains characters other than alphabet, hyphen, underscore, and blank space.	Remove the character other than Alphabet, Hyphen, underscore and blank space.

Table A-80 (Cont.) MUL Import - Error and Corrective Action Information

Error Message	Scenario	Corrective Action
Invalid Characters found in Phone Number	Error occurs when the phone number contains characters other than number, hyphen, and blank space.	Remove the character other than Alphabet, Hyphen and blank space.
Invalid Characters found in Fax Number	Error occurs when the fax number contains characters other than alphanumeric, underscore, and blank space.	Remove the character other than Alphanumeric, underscore and blank space.
Invalid Characters found in Display Name	Error occurs when the display name contains characters other than alphabet, hyphen, and blank space.	Remove the character other than Alphabet, Hyphen and blank space
Invalid Characters found in Title	Error occurs when the title contains characters other than alphabet, underscore, period, comma, and blank space.	Remove the character other than Alphabet, underscore, period, comma and blank space.
Invalid Characters found in Alternate Phone number	Error occurs when the alternate phone contains characters other than number, underscore, and blank space.	Remove the character other than Number, underscore, and blank space.
Email ID is Invalid	Error occurs when you enter the email ID other than the standard format of email.	Enter the E mail ID in a valid format.
Invalid Characters found in Address1	Error occurs when address1 contains characters other than alphanumeric, underscore, hyphen, period, comma, and blank space.	Remove the character other than Alphanumeric, underscore, hyphen, period, comma and blank space.
Invalid Characters found in Address2	Error occurs when address2 contains characters other than alphanumeric, underscore, hyphen, period, comma, and blank space.	Remove the character other than Alphanumeric, underscore, hyphen, period, comma and blank space.
Invalid Characters found in City/Town name	Error occurs when city or town contains characters other than alphanumeric and blank space.	Remove the character other than Alphanumeric and blank space.
Invalid Characters found in Region/Province/State name	Error occurs when region, province, or state contains characters other than alphabet and blank space.	Remove the character other than Alphabet and blank space.
Phone number not found	Error occurs when the phone number column is left blank.	Enter the Phone number.
Invalid Characters found in Postal Code	Error occurs when postal code contains characters other than alphanumeric and blank space.	Remove the character other than Alphanumeric and blank space.
Invalid Characters found in Beeper	Error occurs when beeper contains characters other than alphanumeric, hyphen, and blank space.	Remove the character other than Alphanumeric, hyphen and blank space.
User name exceeds maximum limit 25 characters	Error occurs when the character limit of the user name exceeds 25.	Enter User name Less than or equal to 25 character.

Table A-80 (Cont.) MUL Import - Error and Corrective Action Information

Error Message	Scenario	<b>Corrective Action</b>
First name exceeds maximum limit 127 characters	Error occurs when the character limit of the user name exceeds 25.	Enter User name Less than or equal to 25 character.
Last name exceeds maximum limit 25 characters	Error occurs when the character limit of the last name exceeds 25.	Enter Last name Less than or equal to 25 character.
Phone number exceeds maximum limit 25 characters	Error occurs when the character limit of the phone number exceeds 25.	Enter Phone number Less than or equal to 25 character.
Fax number exceeds maximum limit 25 characters	Error occurs when the character limit of the fax number exceeds 25.	Enter Fax number Less than or equal to 25 character
Display name exceeds maximum limit 255 characters	Error occurs when the character limit of the display name exceeds 255.	Enter Display name Less than or equal to 255 character.
Alternate phone number exceeds maximum limit 255 characters	Error occurs when the character limit of the phone number exceeds 255.	Enter phone number Less than or equal to 255 character.
Email ID exceeds maximum limit 255 characters	Error occurs when the character limit of the email ID exceeds 255.	Enter Email ID Less than or equal to 255 character.
Address1 exceeds maximum limit 255 characters	Error occurs when the character limit of address1 exceeds 255.	Enter Address1 Less than or equal to 255 character.
Address2 exceeds maximum limit 255 characters	Error occurs when the character limit of address2 exceeds 255.	Enter Address2Less than or equal to 255 character.
Town/City name exceeds maximum limit 255 characters	Error occurs when the character limit of town or city exceeds 255.	Enter Town/City Less than or equal to 255 character.
Region/state name exceeds maximum limit 255 characters	Error occurs when the character limit of region or state exceeds 255.	Enter Region/state Less than or equal to 255 character.
Postal code exceeds maximum limit 16 characters	Error occurs when the character limit of postal code exceeds 16.	Enter Postal code Less than or equal to 16 character.
Beeper exceeds maximum limit 255 characters	Error occurs when the character limit of beeper exceeds 255.	Enter Beeper Less than or equal to 255 character.
Description exceeds maximum limit 255 characters	Error occurs when the character limit of description exceeds 255.	Enter Description Less than or equal to 255 character.
Role Insert:		
The following roles are not imported as only 20 roles will be imported at a time	Error occurs when you import more than 20 records at time.	Import only 20 records at a time.
Invalid characters found in RoleName	Error occurs when the postal code contains characters other than alphanumeric, hyphen, underscore, and blank space.	Remove the character other than Alphanumeric, hyphen, underscore and blank space.
RoleName exceeds maximum limit	Error occurs when the role name exceeds the maximum limit of 63 characters.	Enter RoleName Less than or equal to 63 character.
RoleType not found	Error occurs when enter the role type other than available role type.	Enter only available roletype.
Site Insert:		

Table A–80 (Cont.) MUL Import - Error and Corrective Action Information

Error Message	Scenario	Corrective Action
Site number not found	Error occurs when the site number column is left blank.	Enter the Site number.
Site name not found	Error occurs when the site name column is left blank.	Enter the Site name.
Site Address1 not found	Error occurs when the site address1 column is left blank.	Enter the Site Address1.
Town/city name not found	Error occurs when the site address1 column is left blank.	Enter the Site Address1.
Postal code not found	Error occurs when the postal code column is left blank.	Enter the Postal code.
Country name not found	Error occurs when the country name column is left blank.	Enter the Country name.
Phone number not found	Error occurs when the phone number column is left blank.	Enter the Phone number.
Site GMT conversion time not found	Error occurs when the site GMT conversion time column is left blank.	Enter the Site GMT conversion time.
Site is Mark Upload to InForm and Trial is Locked	Error occurs if you insert a site which is mark upload to InForm when the trial is locked.	If only the trial is unlocked the site could be inserted. And site which is not mark upload to InForm can be Import.
Invalid Characters found in Site number	Error occurs when the site number contains characters other than alphanumeric and hyphen.	Remove the character other than Alphanumeric and Hyphen.
Site number Should have at least one number	Error occurs when the site number does not contain at least one number.	Enter at least one number in the site number.
Invalid Characters found in Site name	Error occurs when the site name contains characters other than alphanumeric, hyphen, underscore, and blank space.	Remove the character other than Alphanumeric, hyphen, underscore and blank space.
Invalid Characters found in Address1	Error occurs when address1 contains characters other than alphanumeric, underscore, hyphen, period, comma, and blank space.	Remove the character other than Alphanumeric, underscore, hyphen, period, comma and blank space.
Invalid Characters found in Address2	Error occurs when address2 contains characters other than alphanumeric, underscore, hyphen, period, comma, and blank space.	Remove the character other than Alphanumeric, underscore, hyphen, period, comma and blank space.
Invalid Characters found in City/Town name	Error occurs when the city or town contains characters other than alphanumeric and blank space.	Remove the character other than Alphanumeric and blank space.
Invalid Characters found in Region/State name	Error occurs when the region, province, or state contains characters other than Alphabet and blank space.	Remove the character other than Alphabet and blank space.
Invalid Characters found in Postal/Zip Code	Error occurs when the postal code contains characters other than alphanumeric and blank space.	Remove the character other than Alphanumeric and blank space.

Table A-80 (Cont.) MUL Import - Error and Corrective Action Information

Error Message	Scenario	<b>Corrective Action</b>
Invalid Characters found in Phone number	Error occurs when the phone number contains characters other than number, hyphen, and blank space.	Remove the character other than Alphabet, Hyphen and blank space.
Invalid Characters found in Fax number	Error occurs when the fax number contains characters other than alphanumeric, underscore, and blank space.	Remove the character other than Alphanumeric, underscore and blank space.
Invalid Characters found in Alternate phone number	Error occurs when the alternate phone number contains characters other than number, hyphen, and blank space.	Remove the character other than Alphabet, Hyphen and blank space.
Email ID is Invalid	Error occurs when the email ID is not in the standard format.	Enter the E mail ID in a valid format.
Time zone is Invalid	Error occurs when the time zone is invalid.	Enter the valid Time zone.
Country Name is Invalid	Error occurs when the entered time zone is invalid.	Enter the valid Country Name.
Site number exceeds maximum limit 20 characters	Error occurs when the character limit of the site number exceeds 20.	Enter Site number Less than or equal to 20 character.
Site name exceeds maximum limit 255 characters	Error occurs when the character limit of the site name exceeds 255.	Enter Site name Less than or equal to 255 character.
City/Town name exceeds maximum limit 127 characters	Error occurs when the character limit of city or town name exceeds 127.	Enter City/Town name Less than or equal to 127 character.
Region/State name exceeds maximum limit 255 characters	Error occurs when the character limit of region or state name exceeds 255.	Enter Region/State Less than or equal to 255 character.
Postal Code exceeds maximum limit 16 characters	Error occurs when the character limit of the postal code exceeds 16.	Enter Postal Code Less than or equal to 16 character.
Phone number exceeds maximum limit 25 characters	Error occurs when the character limit of the phone number exceeds 25.	Enter Phone number Less than or equal to 25 character.
Fax number exceeds maximum limit 25 characters	Error occurs when the character limit of the fax number exceeds 25.	Enter Fax number Less than or equal to 25 character.
Alternate Phone Number exceeds maximum limit 25 characters	Error occurs when the character limit of the alternate phone number exceeds 25.	Enter Alternate Phone Number Less than or equal to 25 character.
Email ID exceeds maximum limit 255 characters	Error occurs when the character limit of the email ID exceeds 25.	Enter Email ID Less than or equal to 25 character.
Address1 exceeds maximum limit 255 characters	Error occurs when the character limit of address1 exceeds 25.	Enter Address1 Less than or equal to 25 characters.
Address2 exceeds maximum limit 255 characters	Error occurs when the character limit of address2 exceeds 25.	Enter Address2 Less than or equal to 25 characters.
Ship Name not found	Error occurs when the ship name column is left blank.	Enter the Ship Name.
Ship Address not found	Error occurs when the ship address column is left blank.	Enter the Ship Address.

Table A-80 (Cont.) MUL Import - Error and Corrective Action Information

Error Message	Scenario	Corrective Action
Ship City not found	Error occurs when the ship city column is left blank.	Enter the Ship City.
Ship Zip not found	Error occurs when the ship zip column is left blank.	Enter the Ship Zip.
Ship Country not found	Error occurs when the ship country column is left blank.	Enter the Ship Country.
File:		
Invalid Dat file. Check the delimeters(Pipe) in the file.	Error occurs when the DAT file is invalid.	Provide a valid DAT File.
Please choose an Excel file or a dat file	Error occurs when the input file is other than Excel or Dat file.	Select Excel or Dat file as input.
Please select only one module for dat file import.	Error occurs when you select more than one module for import from a DAT file.	Select one module at a time for import record from DAT file.
Please select a file to import	Error occurs when you click <b>Import</b> without selecting a file to import.	Select a file for import.
File Uploaded Failed. Invalid DAT File	Error occurs when select an invalid DAT file for import.	Select a valid DAT file to import.
Invalid MUL File	Error occurs when select an invalid MUL (Excel) File for import.	Select a valid MUL (Excel) File for import.

# A.48 Worklist Details

Table A-81 Worklist Details - Field Information

Field Name	Description
Current Sponsor Company	Select the sponsor company from the drop-down list.
Trial	Select the trial from the drop-down list.
Route Type	Select the type of the worklist. The available options are:
	■ Manual
	<ul> <li>Automated</li> </ul>
Manual Worklist	
Trial Type	Select the trial type from the drop-down list.
User	Displays the worklist details of the selected sponsor company and trial at user
Site	level.
Role	Displays the worklist details of the selected sponsor company and trial at site level.
Group	Displays the worklist details of the selected sponsor company and trial at role level.
Config	Displays the worklist details of the selected sponsor company and trial at group level.
	Displays the worklist details of the selected sponsor company and trial at configuration level.
Filter Criteria	
UserName	Enter the user name.
Site No	Enter the site number.
RoleName	Enter the role name.
GroupName	Enter the group name.

Table A-81 (Cont.) Worklist Details - Field Information

Field Name	Description
Status	Select the status from the drop-down list. The available options are:
	<ul><li>New</li></ul>
	<ul><li>Change</li></ul>
	<ul><li>Delete</li></ul>
	<ul><li>Reinstate</li></ul>
Process Status	Select the status of the process from the drop-down list. The available options are:
	<ul><li>Process Started</li></ul>
	<ul> <li>Data Entry Completed</li> </ul>
	<ul> <li>QC Rejected</li> </ul>
	<ul><li>Pending</li></ul>
	<ul> <li>UM Task Completed</li> </ul>
	■ UA Task Completed
	<ul> <li>Records Assigned To QC</li> </ul>
Requested	Select the time (in hours) within which the worklist is requested. The available options are:
	■ +24 hours ago
	■ 12-24 hours ago
	■ 6-12 hours ago
	■ 6 hours ago
Find	Click to view the list of worklist details that satisfy the filter criteria.
Clear	Click to clear the filter criteria.
Result of specified filter criteria	
Sponsor	Displays the name of the sponsor company.
Trial	Displays the name of the trial.
Username	Displays the user name.
Site No	Displays the site number.
RoleName	Displays the role name.
GroupName	Displays the group name.
	Click the link corresponding to user name, site no, role name, or group name for more details.
Modified Date	Displays the date on which the worklist is modified.
Status	Displays the status of the worklist.
Assigned To	Displays the name of the user to whom the worklist is assigned to, for further process.
Assigned UM	Displays the name of the User Manager (UM) to whom the worklist is assigned to for further process.
Assigned UA	Displays the name of the User Approver (UA) to whom the worklist is assigned to for further process.
Assigned QC	Displays the name of the Quality Control (QC) user to whom the worklist is assigned to for further process.
Process status	Displays the status of the worklist process.
Completion Time	Displays the time of completion of the worklist process.
•	1

Table A-81 (Cont.) Worklist Details - Field Information

Field Name	Description
Select	Select the required action from the drop-down list. The available options are:
	■ Assigned to UM
	<ul> <li>Assigned to UA</li> </ul>
	<ul> <li>Assigned to QC</li> </ul>
	■ Mark as Pending
	■ Archive Records
Push Worklist to Automated Queue	Select the required worklist and click this button to push a manual worklist to the automated worklist queue.
Comments	Enter the reason for modifying the worklist.
Go	Click to save the changes.
Automated Worklist	
User Site	Displays the worklist details of the selected sponsor company and trial at user level.
Role	Displays the worklist details of the selected sponsor company and trial at site level.
Group	Displays the worklist details of the selected sponsor company and trial at role level.
1	Displays the worklist details of the selected sponsor company and trial at group level.
Filter Criteria	
Username	Enter the user name.
Site No	Enter the site number.
RoleName	Enter the role name.
Group Name	Enter the group name.
Result of specified filter criteria	
Sponsor	Displays the sponsor company name.
Trial	Displays the trial name.
Username	Displays the user name.
Site No	Displays the site number.
RoleName	Displays the role name.
GroupName	Displays the group name.
	Click the link corresponding to username, site no, role name, or group name for more details.
Modified Date	Displays the date on which the worklist is modified.
Transaction Type	Displays the transaction type of the worklist.
Process Status	Displays the process status of the worklist.
Completion Time	Displays the time of completion of the worklist.
Push Worklist to Manual Queue	Select the required worklist and click this button to push the automated worklist to manual worklist queue.
Comments	Enter the comments for modifying the worklist details.

# A.49 Manage Worklists Generation

Manage Worklists Generation - Field Information Table A-82

Field Name	Description
Sponsor Specific Worklists Setting	
Sponsor	Select the sponsor company from the drop-down list.
Default Worklists Setting for Future Trials	The default setting for worklist type for all the future trials that is created for the selected sponsor company. The available options are:
	<ul><li>Disable</li></ul>
	<ul> <li>Manual Worklists</li> </ul>
	<ul> <li>Automatic Worklists</li> </ul>
Existing Trial(s) Worklists Setting	
Select Trials	
Disabled	Displays the list of trials with no worklist type associated. Use the button to move all or the selected trials, respectively, to the Manual Worklists field.
Manual Worklists	Displays the list of trials associated with the manual worklist type.
	Use the or who button to move all or the selected trials, respectively, to the
	Disabled field. Use the v button to move the selected trials to the Automatic Worklists field.
Automatic Worklists	Displays the list of trials associated with the automatic worklist type.
	Use the button to move the selected trials to the Manual Worklists field.
Reason for change	Enter the reason for modifying the worklist details.

# A.50 Assessment Configuration Settings

Assessment Configuration Settings - Field Information

Field Name	Description
Current Sponsor Company	Displays/Modify the sponsor company.
Trial	Displays/Modify the trial.
Number of Reminder Mails	Displays/Modify the number of reminder mails to be sent to the users.
Reminder Mails Interval (in Hrs)	Displays/Modify the time interval to send the reminder mails to the users.
Enable InForm Question	
Minimum no. of users to Pass Assessment	Displays/Modify the minimum number of users to pass the assessment.
Minimum no. of users to attend to stop reminder mails	Displays/Modify the minimum number of users to attend the assessment to stop sending the reminder mails.
User defined Assessment status	Displays/Modify the user-defined assessment status.
Loginname	Enter the login name of the user.
Manage Assessment Accounts	
Password	Enter the password of the user.
Default Email	Enter the default email ID for sending the assessment result.
Roles	
Included For Assessment	Displays the roles that are included for the assessment.
	Click >> or > to move all or the selected roles to the list of excluded roles for assessment.
Excluded For Assessment	Displays the roles that are excluded for the assessment.
	Click $<<$ or $<$ to move all or the selected roles to move to the list of included roles for assessment.

Table A-83 (Cont.) Assessment Configuration Settings - Field Information

Field Name	Description
E-Mail Templates	
Registration	Displays/Modify the email template to be sent to the users for registering for the assessment.
Reminder	Displays/Modify the email template to be sent to the users to remind to attend the assessment.

# A.51 Assessment Benchmark Settings

Table A-84 Assessment Benchmark Settings - Field Information

Field Name	Description
Current Sponsor Company	Displays/Modify the sponsor company.
Trial	Displays/Modify the trial.
Supported Browser(s)	
Browser Type *	Displays/Modify the browser type.
Browser Version *	Displays/Modify the minimum browser version to be configured.
Minimum	Displays/Modify the maximum browser version to be configured.
Maximum	
Browser Service Pack Minimum	Displays/Modify the browser service pack for the minimum and maximum browser versions that are configured.
Maximum	Displays/Modify the minimum browser service pack to be configured for the selected browser version.
	Displays/Modify the maximum browser service pack to be configured for the selected browser version.
Add Additional Browser	Click to add additional browser.
Second Browser Settings	Displays/Modify the browser type for the second browser from the drop-down
Second Browser Type	list.
Second Browser Version *	Displays/Modify the minimum browser version for the second browser.
Minimum	Displays/Modify the maximum browser version for the second browser.
Maximum	
Cancel	Click to cancel the settings for the second browser.
Operating System	Displays/Modify the list of operating systems to be configured.
Check for Operating System * Yes	Lets you check if the configured operating system is available on the user's system during assessment.
No	Select <b>Yes</b> to always check for the configured operating system. Otherwise, select <b>No</b> .
Browser Version Message *	Displays/Modify the message that is to be displayed regarding the compatibility of the browser version.
LAN Speed Benchmark *	Displays/Modify the benchmark speed (in seconds) for LAN.

# A.52 Generate Assessment Summary Report - Sponsor Level

Table A-85 Generate Assessment Summary Report at Sponsor Level – Field Information

Field Name	Description
Sponsor Company	Select the sponsor company from the drop-down list.
Trial	Select the trial from the drop-down list.
From	Select the starting date from the calender available at the side of the text box.
То	Select the ending date from the calender available at the side of the text box.
Generate	Click to generate the report.
Report Details	
Logon Name	Logon name of the user.
First Name	First name of the user.
Last Name	Last name of the user.
Sponsor	Name of the sponsor company.
Site Number	Number of the site.
Site Name	Name of the site.
Dept. Name	Name of the department.
City	Name of the city.
Country	Name of the country.
Study Name	Name of the study.
Computer	Name of the computer.
Test Date	Date on which the test carried.
Browser Type	Type of the browser.
Browser Version	Version of the browser.
Browser SP	Service pack of the browser.
OS	Name of the operating system.
Internet Access	Type of the internet access used.
Slowest Rating	The slowest rating of the network speed.
Fastest Rating	The fastest rating of the network speed.
Average Rating	The average rating of the network speed.
Status	The status of the assessment.
Email	Email ID of the user.

# A.53 Generate Assessment Summary Report - Trial Level

Generate Assessment Summary Report at Trial Level – Field Information Table A-86

Field Name	Description
Sponsor Company	Select the sponsor company from the drop-down list.
Trial	Select the trial from the drop-down list.
Assessment Status	Select the assessment status from the drop-down list. The available options are:  All Pass Border Line Fail
From	Select the starting date from the calender available at the side of the text box.

Table A-86 (Cont.) Generate Assessment Summary Report at Trial Level – Field Information

Field Name	Description
То	Select the ending date from the calender available at the side of the text box.
Generate	Click to generate the report.
Report Details	
Assessment Result	The assessment result such as pass, borderline, or fail.
Number	The number of assessments based on the assessment result.
Percentage	The percentage of the assessments based on the assessment result.
Total	The total number of assessments and percentage for the specified trial, sponsor, and time.

## A.54 Generate Assessment Detail Report - Trial Level

Table A-87 Generate Assessment Detail Report at Trial Level - Field Information

Field Name	Description
Sponsor Company	Select the sponsor company from the drop-down list.
Trial	Select the trial from the drop-down list.
Assessment Status	Select the assessment status from the drop-down list. The available options are:
	<ul><li>All</li></ul>
	<ul><li>Pass</li></ul>
	■ Border Line
T.	■ Fail
From	Select the starting date from the calender available at the side of the text box.
To	Select the ending date from the calender available at the side of the text box.
Generate	Click to generate the report.
Report Details	
Sl No	Serial number.
Sponsor	Name of the sponsor company.
Trial	Name of the trial.
Logon Name	Logon name of the user.
First Name	First name of the user.
Last Name	Last name of the user.
Computer Description	Description of the computer on which the assessment is carried.
Assessment Date	Date on which the assessment is carried.
Browser Type	Type of the browser.
Browser Version	Version of the browser.
Browser SP	Service pack of the browser.
OS	Name of the operating system.
Internet Access	Type of the internet access used.
Slowest Rating	The slowest rating of the network speed.
Fastest Rating	The fastest rating of the network speed.
Average Rating	The average rating of the network speed.
User Assessment Result	The assessment result of the user, such as pass, fail, or borderline.
E-Mail	Email address of the user.

#### A.55 Generate Assessment Summary Report - Site Level

Table A-88 Generate Assessment Summary Report at Site Level - Field Information

Field Name	Description
Country	Select the country from the drop-down list.
Sponsor Company	Select the sponsor company from the drop-down list.
Trial	Select the trial from the drop-down list.
Site	Select the site from the drop-down list.
Assessment Status	Select the assessment status from the drop-down list. The available options are:
	<ul> <li>All</li> </ul>
	<ul><li>Pass</li></ul>
	<ul> <li>Border Line</li> </ul>
	■ Fail
Failure Due To	Select the reason for the failure of the assessment from the drop-down list. The available options are:
	<ul><li>All</li></ul>
	■ Browser
	<ul><li>Connection</li></ul>
	<ul> <li>Operating System</li> </ul>
From	Select the starting date from the calender available at the side of the text box.
То	Select the ending date from the calender available at the side of the text box.
Generate	Click to generate the report.
Report Details	
Assessment Result	The assessment result such as pass, borderline, or fail.
Number	The number of assessments based on the assessment result.
Percentage	The percentage of the assessments based on the assessment result.
Total	The total number of assessments and percentage for the specified trial, sponsor, and time.
Users Failed Due to Browser	The number of users failed due to issue in the browser.
Users Failed Due to Connection	The number of users failed due to issue in the connection.
Users Failed Due to O.S.	The number of users failed due to issue in the operating system.

## A.56 Generate Assessment Detail Report - Site Level

Generate Assessment Detail Report at Site Level - Field Information Table A-89

Field Name	Description
Country	Select the country from the drop-down list.
Sponsor Company	Select the sponsor company from the drop-down list.
Trial	Select the trial from the drop-down list.
Site	Select the site from the drop-down list.
Assessment Status	Select the assessment status from the drop-down list. The available options are:
	<ul> <li>All</li> </ul>
	<ul><li>Pass</li></ul>
	<ul> <li>Border Line</li> </ul>
	<ul> <li>Fail</li> </ul>

Table A-89 (Cont.) Generate Assessment Detail Report at Site Level - Field Information

Field Name	Description
Failure Due To	Select the reason for the failure of the assessment from the drop-down list. The available options are:
	<ul> <li>All</li> </ul>
	Browser
	<ul><li>Connection</li></ul>
	<ul><li>Operating System</li></ul>
From	Select the starting date from the calender available at the side of the text box.
То	Select the ending date from the calender available at the side of the text box.
Generate	Click to generate the report.
Report Details	
Sponsor	Name of the sponsor company.
Trial	Name of the trial.
First Name	First name of the user.
Last Name	Last name of the user.
Site Number	Number of the site.
Site Name	Name of the site
Site e-mail id	Email ID of the site.
City	City to which the sponsor belongs.
Country	Country to which the sponsor belongs.
Computer Description	Description of the computer on which the assessment is carried.
Assessment Date	Date on which the assessment is carried.
Browser Type	Type of the browser.
Browser Version	Version of the browser.
Browser SP	Service pack of the browser.
OS	Name of the operating system.
Slowest Rating	The slowest rating of the network speed.
Fastest Rating	The fastest rating of the network speed.
Average Rating	The average rating of the network speed.
User Assessment Result	The assessment result of the user, such as pass, fail, or borderline.
Site Assessment Result	The assessment result of the site.
E-Mail	Email ID of the user.

# A.57 Generate Master Summary Report - Site Level

Table A-90 Master Summary Report at Site Level - Field Information

Field Name	Description
Country	Select the country from the drop-down list.
Sponsor Company	Select the sponsor company from the drop-down list.
Trial	Select the trial from the drop-down list.
Site	Select the site from the drop-down list.
Assessment Status	Select the assessment status from the drop-down list.
Provisioning Status	Select the provisioning status from the drop-down list.

Table A-90 (Cont.) Master Summary Report at Site Level - Field Information

Field Name	Description
Provisioned By	Select the user who provisioned the asset from the drop-down list.
Category	Select the category of the asset from the drop-down list.
From	Select the starting date from the calender available at the side of the text box.
То	Select the ending date from the calender available at the side of the text box.
Generate	Click to generate the report.
Report Details	
Assessment Status	Status of the assessment.
Number	Number of assets based on the assessment status.
Percentage	Percentage of assets based on the assessment status.
Total	Total number and percentage of assets based on the assessment status.
Provisioning Status	Status of the provisioning.
Number	Number of assets based on the provisioning status.
Percentage	Percentage of assets based on the provisioning status.
Total	Total number and percentage of assets based on the provisioning status.

#### A.58 Generate Master Detail Report - Site Level

Table A-91 Master Detail Report at Site Level - Field Information

Field Name	Description
Country	Select the country from the drop-down list.
Sponsor Company	Select the sponsor company from the drop-down list.
Trial	Select the trial from the drop-down list.
Site	Select the site from the drop-down list.
Assessment Status	Select the assessment status from the drop-down list.
Provisioning Status	Select the provisioning status from the drop-down list.
Provisioned By	Select the user who provisioned the asset from the drop-down list
Category	Select the category of the asset.
From	Select the starting date from the calender available at the side of the text box.
То	Select the ending date from the calender available at the side of the text box.
Generate	Click to generate the report.
Report Details	
Sponsor	Name of the sponsor company.
Trial	Name of the trial.
Site	Name of the site.
Assessment Status	Status of the assessment.
Provisioning Status	Status of the provisioning.
Asset	Name of the asset.

## A.59 Generate Billing Details Report

Table A-92 Billing Details Report - Field Information

Field Name	Description
Sponsor Company	Select the sponsor company from the drop-down list.
Trial	Select the trial from the drop-down list.
From	Select the starting date from the calender available at the side of the text box.
То	Select the ending date from the calender available at the side of the text box.
Generate	Click to generate the report.
Report Details	
Sponsor Company	Name of the sponsor company.
Trial	Name of the trial.
Reference	Name of the reference.
Protocol	Protocol number of the trial.
Contracted No of Sites	Number of sites contracted for performing the trial.
No of Sites Associated	Number of sites associated with the trial.
Contracted No of Site Assessments	Number of contracted site assessments.
No of Site Assessments	Number of site assessments.
Contracted No of Users	Number of users contracted for performing the trial.
No of Users	Number of users in the trial.
Contracted No of Countries	Number of countries contracted for performing the trial.
Selected No of Countries	Number of countries selected.
Contracted No of IOL Accounts	Number of IOL accounts contracted for performing the trial.
IOL Accounts Created	Number of IOL accounts created.
No of Provisioning	Number of provisions for the trail.

# A.60 Generate Training Details Report

Table A-93 Training Details Report - Field Information

Field Name	Description
Sponsor Company	Select the sponsor company from the drop-down list.
Training Course	Select the training course from the drop-down list.
From	Select the starting date from the calender available at the side of the text box.
То	Select the ending date from the calender available at the side of the text box.
Generate	Click to generate the report.
Report Details	
Sponsor	Name of the sponsor company.
Training Course	Name of the training course.
User Count	Count of the users attended the training course.

## A.61 Generate User Detail Report

Table A-94 User Detail Report - Field Information

Field Name	Description
Country	Select the country from the drop-down list.
Sponsor Company	Select the sponsor company from the drop-down list.
Trial	Select the trial from the drop-down list.
User Type	Select the type of the user from the drop-down list.
From	Select the starting date from the calender available at the side of the text box.
То	Select the ending date from the calender available at the side of the text box.
Generate	Click to generate the report.
Report Details	
Sponsor	Name of the sponsor company.
Trial	Name of the trial.
First Name	First name of the user.
Last Name	Last name of the user.
User Name	User name.
Country	Name of the country.
Email	Email ID of the user.
User Type	Type of the user.
Role	Role of the user.
User Status	Status of the user.
Site Association Description	Description of the site association.

# A.62 Generate Site-User Detail Report

Table A-95 Site-User Detail Report - Field Information

Field Name	Description
Sponsor Company	Select the sponsor company from the drop-down list.
Trial	Select the trial from the drop-down list.
Module	Select the module from the drop-down list.
From	Select the starting date from the calender available at the side of the text box.
То	Select the ending date from the calender available at the side of the text box.
Generate	Click to generate the report.
User Detail Report	
Trial Name	Name of the trial.
User Name	Name of the user.
First Name	First name of the user.
Last Name	Last name of the user.
Rights Group	Rights group.
Email	Email ID of the user.
Newly Associated Sites	Sites that are newly associated.
Newly Dis-associated Sites	Sites that are newly disassociated.
Associated Groups	Groups that are associated.
Dis-associated Groups	Groups that are disassociated.

Table A-95 (Cont.) Site-User Detail Report - Field Information

Field Name	Description
Modified By	Name of the user who modified.
Modified Date	Date on which the user is modified.
Status	Status of the user.
Site Detail Report	
Trial Name	Name of the trial.
Site Number	Number of the site.
Site Name	Name of the site.
Address1	Communication address of the site.
Address2	
City	Name of the city where the site is located.
State	Name of the state where the site is located.
Country	Name of the country where the site is located.
Postal Code	Postal code of the site.
E-mail Address	Email ID of the user associated to the site.
Phone	Phone number of the site.
Study Version	Version of the study.
Modified By	Name of the user who modified the site.
Modified Date	Date on which the site is modified.
Status	Status of the site.

## A.63 Generate Trial Archive Package (TAP) Report

Table A-96 Trial Archive Package (TAP) Report - Field Information

Field Name	Description	
Sponsor Company	Select the sponsor company from the drop-down list.	
Trial	Select the trial from the drop-down list.	
Generate Report	Click to generate the report.	

#### A.64 List of Oracle Users

Table A-97 List of Oracle Users - Field Information

Field Name	Description	Field Size (In Character)
Username	Enter the name of the user.	32
First Name	Enter the first name of the user.	127
Last Name	Enter the last name of the user.	127
User Status	Select the status of the user from the drop-down list.	NA
User Type	Select the user type from the drop-down list.	NA
Role	Select the role from the drop-down list.	NA
Approval Status	Select the approval status from the drop-down list.	NA
Training Status	Select the training status from the drop-down list.	NA

Table A-97 (Cont.) List of Oracle Users - Field Information

Field Name	Description	Field Size (In Character)
Country	Select the country from the drop down.	NA
Uploaded to InForm	Select the Yes or No option from the drop-down list.	NA
Description	Select the description of the user from the drop-down list.	NA
	Displays the icon,	NA
	if the user is marked Upload to InForm.	
	🔄 if the user is marked Upload to IRT.	
	if the user is marked Upload to InForm/IRT.	
Username	Displays the user name. Click the hyperlink to view the corresponding user details.	NA
First Name	Displays the first name of the user.	NA
Last Name	Displays the last name of the user.	NA
User Status	Displays the status of the user.	NA
User Type	Displays the user type.	NA
Role	Displays the user's role.	NA
Approval Status	Displays the approval status. The approval status can be Approved, Rejected, or Pending.	NA
Training Status	Displays the Training status. The training status can be Trained or Not Trained.	NA
Trained Date	Displays the trained date of the user.	NA
Site(s)	Displays the sites associated with the user. If the user is associated	NA
	to multiple sites, the icon is displayed. Click the icon to view the association details. The icon is disabled for the user type Sponsor.	
Country	Displays the country name of the user.	NA
Provisioning Status	Displays the provisioning status of the user.	NA
Description	Displays the description of the user.	NA
PRD SSO Status	Displays the production environment SSO status of the user.	NA
TRN SSO Status	Displays the training environment SSO status of the user.	NA
UAT SSO Status	Displays the UAT SSO status of the user.	NA

## A.65 InForm Terminated User List

InForm Terminated User List - Field Information Table A-98

Field Name	Description	Field Size (In Character)
Filter Section		
Username	Enter the name of the user.	25
First Name	Enter the first name of the user.	127
Last Name	Enter the last name of the user.	127
Country	Select the country from the drop down.	NA
Filter Result		

Table A-98 (Cont.) InForm Terminated User List - Field Information

Field Name	Description	Field Size (In Character)
<b>3</b>	Displays the icon,	NA
	if the user is marked Upload to InForm.	
	$f \Xi$ if the user is marked Upload to IRT.	
	if the user is marked Upload to InForm/IRT.	
Username	Displays the user name. Click the hyperlink to view the corresponding user details.	NA
First Name	Displays the first name of the user.	NA
Last Name	Displays the last name of the user.	NA
Country Name	Displays the country name of the user.	NA
Terminated Date	Displays the date on which the user is terminated.	NA
Approval Status	The approval status of the terminated user.	NA

#### A.66 List of Trials

Table A-99 List of Trials - Field Information

Field Name	Description
Filter Section	
Trial Name	Enter the trial name.
Study Name	Enter the study name.
Trial Associated To	Enter the trial to which the sponsor is associated to.
Reference	Enter the reference name.
Trial Status	Select the status of the trial from the drop-down list.
Trial Type	Select the type of the trial from the drop-down list.
Product	Select the product to which the trial belongs from the drop-down list.
InForm Version	Select the InForm version from the drop-down list.
IRT Version	Select the IRT version from the drop-down list.
OLx Version	Select the OLx version from the drop-down list.
IPMs Version	Select the IPMs version from the drop-down list.
Filter Result	
Duplicates	Displays the manual duplicate trials.
Automatic Duplicates	Displays the automatic duplicate trials.
Trial Name	Displays the name of the trial.
Study Name	Displays the name of the study.
Trial Associated To	Displays the name of the sponsor to which the trial is associated.
Reference	Displays the name of the reference.
Product	Displays the name of the product.
InForm Version	Displays the InForm version.
IRT Version	Displays the IRT version.
OLx Version	Displays the OLx version.
IPMs Version	Displays the IPMs version.

Table A-99 (Cont.) List of Trials - Field Information

Field Name	Description
Trial Status	Displays the status of the trial.
Trial Type	Displays the type of the trial.
Сору	Click the icon to copy the trial.
Pivotal	Displays the pivotal details of the trial.
FastLock Report	Displays the FastLock report for the trial.

#### A.67 List of Archived Trials

Table A-100 List of Archived Trials - Field Information

Field Name	Description
Study Name	Displays the study name.
Reference	Displays the reference name.
Protocol Number	Displays the protocol number of the trial.
Therapeutic Area	Displays the therapeutic area of the trial.
Status	Displays the status of the trial.
Date & Time of Archival	Displays the date and time on which the trial is archived.

# **A.68 Managing Training**

Table A-101 List of Archived Trials - Field Information

Field Name	Description
Trial Name	Select the trial name from the drop-down list.
First Name	Enter the first name of the user.
Last Name	Enter the last name of the user.
IOL Email id	Enter the IOL email ID of the user.
Class(es)	Select the IOL class from the drop-down list.
IOL Status	Select the status of the IOL class. The available options are:
	<ul> <li>Not Completed</li> </ul>
	<ul><li>Completed</li></ul>
Filter Result	
Trial Name	Displays the trial name.
First Name	Displays the first name of the user.
Last Name	Displays the last name of the user.
IOL Email id	Displays the IOL email ID of the user.
Class(es)	Displays the classes the user assigned to.
IOL Status	Displays the status of the IOL class.
Download Certificate	Click the hyperlink to download the class completion certificate in PDF format.

# A.69 Custom Review State Configuration Settings

Table A-102 List of Archived Trials - Field Information

Field Name	Description
Add Review State	
Review State1:	
RefName	Enter the reference name.
Activated	Selected the required option from the drop-down menu. The available options are:
	■ True
	■ False
Label	Enter the label name.
Mnemonic	Enter the mnemonic.
Language	Select the required language from the drop-down list.
Translations	
Label Display Text	Enter text for label display.
Mnemonic Display Text	Enter text for mnemonic display.
Locale	Select the required locale from the drop-down list.
Add Review Stage	
Stage1:	
RefName	Enter the reference name.
Label	Enter the label name.
Mnemonic	Enter the mnemonic.
Language	Select the required language from the drop-down list.
Translations	
Label Display Text	Enter text for label display.
Mnemonic Display Text	Enter text for mnemonic display.
Locale	Select the required locale from the drop-down list.