

Oracle® Life Sciences InForm User Management Tool

User Guide



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The Oracle logo, consisting of a solid red square with the word "ORACLE" in white, uppercase, sans-serif font centered within it.

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Preface

This preface contains the following sections:

- [Documentation accessibility](#)
- [Related resources](#)
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- [Additional copyright information](#)

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>.

Related resources

All documentation and other supporting materials are available on the [Oracle Help Center](#).

Access to Oracle Support

Oracle customers that have purchased support have access to electronic support through Support Cloud.

Contact our Oracle Customer Support Services team by logging requests in one of the following locations:

- English interface Customer Support Portal (<https://hsgbu.custhelp.com/>)
- Japanese interface Customer Support Portal (<https://hsgbu-jp.custhelp.com/>)

You can also call our 24x7 help desk. For information, visit <https://www.oracle.com/life-sciences/support/> or visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs> if you are hearing impaired.

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1

Getting started

- [Main functions](#)
- [Getting a new password](#)
- [Changing the login password](#)
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- [Supported email formats](#)

Main functions



Note:

Oracle InForm User Management Tool is supported with Internet Explorer, Microsoft Edge, and Google Chrome.

The main functions of this application are:

- Delivers a robust, validated, secure, and intuitive user management environment that can be used across all Oracle InForm studies.
 - Lets you import information to the Oracle InForm User Management Tool 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 Oracle InForm study and Oracle Health Sciences Learn 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 Automated Authorization option, at both the sponsor and study level, that allows site and sponsor users (SSO and non-SSO) to be automatically authorized and to receive automated authorization emails.
- Provides an integrated training log for updating and reviewing the training status of study personnel.
- Provides a flexible environment for users to extract information from the Oracle InForm User Management Tool in a reportable format.
- Improves the user management experience for users and internal staff.
- Ensures full traceability.

- Ensures auditability.

Getting a new password

1. On the login page, click **Forgot Your Password?**.
2. Enter your user name, and click **Submit**.

 **Note:**

If you forget your user name, contact your Oracle InForm User Management Tool Administrator.

3. Enter the answer for your hint question, and click **Send New Password**.

The new password is sent to the email address associated with your user account in Oracle InForm User Management Tool.

Changing the login password

You need to change your password if it expires or if you exceed the maximum number of login attempts. Oracle recommends changing your password periodically.

 **Note:**

Passwords expire every 90 days, and passwords need to be reset after 3 failed login attempts.

1. In the upper right, from your user name drop-down list, select **Change Password**.
2. Fill in the fields, and click **Submit**.

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

When choosing a password, we recommend that you do not use special or language specific characters (for example, question marks or German Umlauts).

If the password you enter is not valid, an error message appears describing the password requirements. Passwords should:

- Contain at least 8 characters.
- Not have been used in the previous 5 passwords.
- Contain at least one uppercase and one lower case alphabetic character.
- Contain at least one numeric character.

Viewing audit trails

All the changes you make in Oracle InForm User Management Tool are recorded by the system. To view these changes, access the audit trail for the field that changed.

To view the audit trail, click the  icon for a field.

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

Logging out of the application

Oracle recommends that you log out of Oracle InForm User Management Tool before closing your browser window.

In the upper right, from your user name drop-down list, select **Log Out**.



Note:

Oracle InForm User Management Tool automatically logs you out when your session is inactive. The inactivity period is set on the UMT Settings page in the **Re-authentication inactivity period** field. The default is 30 minutes.

Getting Help

- In the upper right, from the **Help** drop-down list, do one of the following:
 - Select **HELP**.
The UMT Oracle Help Center page opens in a separate browser window from which you can access the *Release Notes* and product documentation.

Alternatively, go to <https://docs.oracle.com/en/industries/life-sciences/user-management-tool/index.html>.
 - Select **Help Desk Information**.
The Life Sciences Cloud Support page opens.

Alternatively, go to <https://www.oracle.com/life-sciences/support/>.

Supported email formats

A valid email address consists of a prefix (local-part) and a domain. The prefix (local-part) appears to the left of the @ symbol and the domain appears to the right of the @ symbol.

For example, in the email local-part@domain.com 'local-part' is the email prefix and 'domain.com' is the email domain

The domain may consist of one or more labels separated by a . (dot) - user@company.uk.clinic - where each domain label can have a maximum length of 63 characters.

Table 1-1 Supported email formats

InForm Version	Email character maximum	Prefix (local) Max characters	Domain max (per label)
7.0+	255	64	63
6.3	255	64	4
6.2	255	64	4
6.1	255	64	4

Additional email requirements

- No two dots can be next to each other anywhere in an email address.
- All subdomains are treated the same. There aren't any special restriction on the top domain.
- Only letters, numbers and hyphens are allowed.
Example: laura@hello.braze.com where "hello." Is the subdomain and "braze.com" is the domain.
- A hyphen cannot be at the start or end of each domain label.
- The local-part of an email can contain only letters, number, hyphen, dot and underline.
The following characters are not supported in the local-part of an email: ! # \$ % & ' * + / = ? ^ ` \ { | }

2

Regulatory requirements

- [Regulatory requirements for Oracle InForm User Management Tool](#)

Regulatory requirements for Oracle InForm User Management Tool

You or your delegate are responsible for:

- Ensuring that appropriate regional regulatory approvals are in place before allowing a site access to the initial study version or to any subsequent functionality changes (for example, a later study version, which may have resulted from a protocol amendment). This includes ensuring that regional regulatory approvals are in place for any study version, even if the study version wasn't yet made available to the site. For example, if you're associating a site to study version three, but the site was not yet associated to study version two, consider whether appropriate regional regulatory approvals are in place for study version two for that site before associating the site with study version three. This is because associating study version three to the site will incorporate the functionality changes for study version two as well as study version three.
- Ensuring that any user account created through Oracle InForm User Management Tool accurately reflects the user's training status for the product. Before distributing Oracle InForm or Oracle IRT account details to a user, you must mark the user as Trained in Oracle InForm User Management Tool.

These regulatory requirements apply for all Oracle InForm User Management Tool integrations, specifically Oracle InForm and Oracle IRT.

3

Workflow for giving users access to an Oracle InForm study

- [About the workflow for giving users access to an Oracle InForm study](#)
- [STEP 1: Create the study user account](#)
- [STEP 2: Assign and confirm training](#)
- [STEP 3: Ensure the study user is trained and approved](#)
- [STEP 4: Add the study user to Oracle InForm](#)
- [STEP 5: Lock the study in Oracle InForm User Management Tool for development](#)
- [STEP 6: Generate and upload the Oracle InForm study data](#)
- [STEP 7: Make sure the Oracle InForm study is live](#)
- [STEP 8: Send the study user the authorization email with the study URL details](#)

About the workflow for giving users access to an Oracle InForm study

Before Oracle InForm access can be provided to a new user, there are a few steps that must be completed as a one-time activity by a Oracle InForm User Management Tool user and by the Oracle InForm study user so that the study user can successfully access an Oracle InForm study.

In Oracle InForm User Management Tool, a customer-delegated Oracle InForm User Management Tool user creates the Oracle InForm study users, assigns the required training, authorizes study access, and sends the authorization email with the study URL.

**Note:**

The workflow steps are the same for single sign-on (SSO) and non-SSO users, except where noted.

STEP 1: Create the study user account

Users can access Oracle InForm using either a single sign-on (SSO) account, or a non-SSO account. The type of account is determined by the Study Administrator.

How are user accounts created?

A study user can be created manually through the Oracle InForm User Management Tool user interface, or with the Joint Template (also called the MUL or *Master Users List Template*).

- In the Oracle InForm User Management Tool user interface, create a user, and assign the sites and rights groups the user has access to. For more information, see [Creating Oracle InForm or Oracle IRT users](#) and [Viewing and modifying user details](#).

or

With the Joint Template, create and upload a user and their sites and rights.

For information on uploading the template, see [Importing administrative data for a trial](#).

When you create a new user for an SSO study, Oracle InForm User Management Tool checks to see if the user is already a Global User by matching the user name and email address against existing Global Users.

- If the user exists, Oracle InForm User Management Tool associates the new study user to the existing Global User.
- If the user does not exist in the Global User list, it is automatically created.

The new user appears in the user interface in both the Study Users list and the Global Users list.

For more information, see:

- [Single sign-on \(SSO\) study user accounts](#)
- [Non-SSO study user accounts](#)

Single sign-on (SSO) study user accounts

For each Sponsor, Oracle InForm study users can now access all Oracle InForm **single sign-on (SSO)** studies using a single account with one User Name and Password, which we refer to as a **Single sign-on (SSO)** or **Global User** account.

How is an SSO account created?

After you create an SSO user, Oracle InForm User Management Tool communicates with Oracle Life Sciences Identity and Access Management Service (Oracle Life Sciences IAMS) to create the user's SSO account. For more information, see the Oracle Life Sciences Identity and Access Management Service documentation on the Oracle Help Center (<https://docs.oracle.com/en/industries/life-sciences/identity-access-management-service/index.html>).

SSO account emails and account set up

After the SSO account is created, the study user receives one or two emails from **OracleIdentityManager@oracle.com** depending on the user's configuration in Oracle Life Sciences IAMS

- If, as a Sponsor, you configured the user in Oracle Life Sciences IAMS to *not* require challenge security questions, the user will receive **one email** with their user name and a link to set up (or reset) their password.
 - The link is valid for 5 days.
- If, as a Sponsor, you configured the user in Oracle Life Sciences IAMS to require challenge security questions, the user will receive **two emails**. One email contains the SSO user name, and the other contains a temporary password and a link to reset it and to set up their challenge questions.

- The temporary password must be reset within 90 days
If a user doesn't update their password within this time period, they need to contact their Study Administrator to have the two emails re-sent.
- The challenge questions must be set up within 90 days.
The challenge questions are used to verify the user's identity when they use the Forgot Password feature on the Login page to reset their password if they forget it, or if their password expires.

If the user doesn't set up the challenge questions, they cannot use the Forgot Password link to reset their password, and they will need to ask their Study Administrator to do it for them.



Note:

Study users only need to set up their SSO account information one time. Therefore, for each SSO account, the one or two emails are only sent the *first* time a study user works on a study for a particular Sponsor. They are not sent for each study.

Managing SSO accounts

After SSO accounts are set up, an Oracle Life Sciences Identity and Access Management Service (Oracle Life Sciences IAMS) Customer Delegated Administrator (CDA) can manage SSO accounts in Oracle Life Sciences IAMS.

- [Resetting user SSO passwords](#)
- [Locking user SSO accounts](#)
- [Unlocking user SSO accounts](#)

Non-SSO study user accounts

Non-SSO users are defined in Oracle InForm User Management Tool.

Oracle InForm User Management Tool generates a temporary password for each non-SSO user.

The Oracle InForm User Management Tool user sends the user name and password to the user by selecting **Send InForm Account Details** from the **Manage User** drop-down list on the **Users** page. For more information, see [Sending user account details](#).



Note:

A study user is required to change their password during their first login.

STEP 2: Assign and confirm training

The study user is required to take training for each Oracle InForm study they will have access to. You can assign the study user to Oracle Health Sciences Learn (HS Learn) training, or you can use an alternate training resource.

For more information, see:

- Oracle Health Sciences Learn (HS Learn) training
- Alternate training resource (optional)

Oracle Health Sciences Learn (HS Learn) training

To assign Oracle Health Sciences Learn training to the study user, see [Assigning HS Learn classes to a user](#).

Note:

When you assign a new user to a role that has training associated to it, the training is automatically assigned to the user, and this step is not required. The training is not assigned to users already associated with the role.

What happens after the HS Learn training is assigned?

After the Oracle Health Sciences Learn training is assigned, Oracle InForm User Management Tool communicates with Oracle Health Sciences Learn, and the study user receives **one email** from **Clinical_One@OracleIndustry.com** with the subject **Oracle Health Sciences Learn Course Assignment**, which is used to access the training:

- The first time the study user is assigned to any course by any Sponsor.
- When the study user is assigned to the same course by any Sponsor 12 months or more after the course was most recently completed.

What information is in the HS Learn email?

The **Oracle Health Sciences Learn Course Assignment** email contains a **Complete Training Now** link.

- If the user has an Oracle account, which is used to access the online training in Oracle Health Sciences Learn, a login page appears and the user can log in to Oracle Health Sciences Learn to complete the assigned training.

Note:

The Oracle account is not the same as your Oracle Life Sciences Identity and Access Management Service account.

- If the user doesn't have an Oracle account, they can create one by clicking **Create Account** on the login page.

Note:

When a user takes a course in Oracle Health Sciences Learn, Oracle InForm User Management Tool is notified and the course completion date will appear in Oracle InForm User Management Tool. After a user has completed all the assigned training, Oracle InForm User Management Tool updates the training status of the user to **Trained**.

How can users check the training status of a user?

Oracle InForm User Management Tool users can:

- Check the Training Status on the Users page. For more information, see [Viewing the list of Oracle InForm or Oracle IRT users](#).
- Go to Oracle Clinical One Platform to generate reports or to view the status of their users.

Oracle InForm study users can log into Oracle Health Sciences Learn to view, print, or download their training completion certificates.

Alternate training resource (optional)

If you are using an alternate training resource instead of Oracle Health Sciences Learn training, after the training is complete, manually mark the user as **Trained** in Oracle InForm User Management Tool.

For more information, see [Marking users as trained](#).



Note:

Marking a user as trained is always a manual process performed through the user interface; it cannot be done through the Joint (MUL) Template.

STEP 3: Ensure the study user is trained and approved

All study users must be both [Trained](#) and Approved.

- If an Approval process is required for the study, the study user must be manually marked as Approved.
For more information, see [Approving or rejecting users](#).
- For studies that don't require approvals, new study users are automatically created and identified in Oracle InForm User Management Tool as Approved.



Note:

If an Approval process is required for a study, the **Enforce UM/UA Approval Process** option is set to **Yes** in the **Trial Configurations** section on the **Configuration > UMT Configuration > Default configuration settings** page.

STEP 4: Add the study user to Oracle InForm

All new study users must be added to Oracle InForm. Oracle InForm users must exist before the study goes live, and before the study URL details are sent.


For more information, see:

- [SSO users—Authorize the study user to access the Oracle InForm study](#)
- [Non-SSO users—Mark users to upload to Oracle InForm](#)

SSO users—Authorize the study user to access the Oracle InForm study

To add an SSO study user to Oracle InForm, you must authorize the user to Oracle InForm. Study users must exist in Oracle InForm User Management Tool, Oracle Life Sciences IAMS, and Oracle InForm in order for them to be able to log in to a study.

Users can be automatically or manually authorized. When the authorization is successful:

- The **Uploaded to InForm** icon () appears to the left of the Username column.
- The word **Success** appears in the **Authorization Status** column to show that the user has been authorized in Oracle Life Sciences IAMS.

Automated Authorization and emails

The **Automated Authorization** option, which is disabled by default, can be enabled in the **Trial Configurations** section on the **Configuration settings** page at both the sponsor and study level to allow site and sponsor users (SSO and non-SSO) to be automatically authorized and to receive automated authorization emails.

- After users are trained and approved, SSO users will be automatically authorized to Oracle InForm and non-SSO users will be automatically marked for upload to Oracle InForm.
- For SSO users, the Authorization email will be sent automatically after the user is both successfully authorized in Oracle Health Sciences IAMS and created/reinstated in Oracle InForm.
- For non-SSO users, the account details email will be sent automatically to the user after they are successfully created/reinstated in Oracle InForm.

Enabling the Automated Authorization feature automatically authorizes newly approved and trained users and automatically sends their authorization emails. However:

- Previously approved and trained users must be manually authorized, and their authorization emails must be manually sent.
- Previously authorized users who have not received their authorization emails must have their emails manually sent.

Manual authorization

On the **Users** page, select the checkbox to the left of the user to authorize. Then, in the **Manage User** drop-down list, select **Authorize User**, and click **Go**.

For more information, see [Viewing and modifying user details](#).

Non-SSO users—Mark users to upload to Oracle InForm

Before a non-SSO user can be added to Oracle InForm, the user must be manually or automatically marked for upload to Oracle InForm. Study users must exist in Oracle InForm User Management Tool and Oracle InForm in order for them to be able to log in to a study.

- **Manual**—For more information, see [Marking users for upload to Oracle InForm or Oracle IRT](#). On the **Users** page, select the checkbox to the left of the user to authorize. Then, in the **Manage User** drop-down list, select **Mark upload to InForm**, enter a comment, and click **Go**.
- **Automated**—If the **Automated Authorization** option in the **Trial Configurations** section on the **Configuration settings** page is selected for your sponsor or study, after a non-SSO user is trained and approved the account details email will be sent automatically to the user after they are successfully created/reinstated in Oracle InForm.

When the authorization is successful, the **Uploaded to InForm** icon () appears to the left of the Username column.

STEP 5: Lock the study in Oracle InForm User Management Tool for development

Note:

This step is required only before a study goes live; it is not required every time you add a new user.

In Oracle InForm User Management Tool, make sure the study is locked for development. When a study is locked for development, you cannot change Roles or Groups, but you can create new users and sites. However, you cannot mark them for upload to Oracle InForm while the study is locked.

For more information, see [Locking a trial for development](#).

STEP 6: Generate and upload the Oracle InForm study data

Note:

This step is required only before a study goes live; it is not required every time you add a new user.

The study data must be generated and uploaded to Oracle InForm. This process is automated, but can also be done manually.

- To use the automated process, see [Generating InForm XML for pre Go-Live production trials](#).
- To manually generate the Oracle InForm XML (MedML) and enter a ticket to have the user information uploaded to Oracle InForm, see [Generating an Oracle InForm XML ZIP file for upload to Oracle InForm](#).

STEP 7: Make sure the Oracle InForm study is live

Before you send the study URL to a study (site) user, make sure that the study is live and ready for data to be entered.

Note:

When a study is live, **Fast Forward** appears in the Trial Status column on the Trials page. The Automated Authorization option is visible at the study level, but the automation is active only after the status of the study is changed to Fast Forward in UMT.

STEP 8: Send the study user the authorization email with the study URL details

After all other pre-requisites are complete, the study URL details can be sent to the user. For SSO and non-SSO studies, the process to send the authorization email can be automated or can be done manually.

SSO and non-SSO study users receive one email with the study URL for each study they are given access to.

For more information, see:

- [SSO users—Send the authorization email](#)
- [Non-SSO users—Send the Oracle InForm account details](#)

SSO users—Send the authorization email

How do I send the authorization email to an SSO study user?

The authorization email can be sent automatically or manually to SSO users.

Automated—The Automated Authorization option, which is disabled by default, can be enabled in the Trial Configurations section on the Configuration settings page at both the sponsor and study level to allow approved and trained site and sponsor users to be automatically authorized and to receive automated authorization emails.

- After an SSO user is trained and approved, the user will be automatically authorized to Oracle InForm.
- The Authorization email will be sent automatically after the user is both successfully authorized in Oracle Life Sciences IAMS and created/reinstated in Oracle InForm.

However:

- Previously approved and trained users must be manually authorized, and their authorization emails must be manually sent.
- Previously authorized users who have not received their authorization emails must have their emails manually sent.

Manual—To manually send the study URL details to an SSO study user, you send an authorization email from the Oracle InForm User Management Tool user interface.

On the **Users** page, select the checkbox to the left of the user. Then, in the **Manage User** drop-down list, select **Send Authorization Email**, enter a comment, and click **Go**.

For more information, see [Sending user account details](#).

What happens after the authorization email is sent to the SSO study user?

The study user receives **one email for the study they are authorized to access** from **saasadminsupport_ww** with the Subject Line **Welcome to <Sponsor Customer Name> <Study Name> trial!**.



Note:

Although an SSO study user receives their user credentials email(s) only one time (see [Single sign-on \(SSO\) study user accounts](#)), an SSO study user receives a separate email for each study they are given access to because each email contains the study URL.

What information is in the authorization email?

The email contains the user name and study URL link.

Receiving this email confirms that the SSO account and study authorization process is complete. Users can log in to the specified study using their SSO user name and password.

- If the user is configured to *not* require challenge security questions, the user has all the information they need in the authorization email to reset their password themselves. The email contains their user name and the Study URL link. If they go to the Study URL and choose the Forgot Password link, they will receive an email with a link to reset their password.
- If the user is configured to require challenge security questions, and the questions were set up previously, the user can reset their own password.
- If the user is configured to require challenge security questions, and the questions were *not* set up previously, they cannot reset their own password. Instead, to have their password reset they need to contact their Oracle Life Sciences IAMS Customer Delegated Administrator (CDA) or enter a ticket with Oracle Global Support.

Non-SSO users—Send the Oracle InForm account details

How do I send the authorization email to a non-SSO study user?

The account details email can be sent to a non-SSO user automatically or manually.

Automated—The Automated Authorization option, which is disabled by default, can be enabled in the Trial Configurations section on the Configuration settings page at both the sponsor and study level to allow approved and trained site and sponsor users to be automatically authorized and to receive automated authorization emails.

- After a non-SSO user is trained and approved, the user will be automatically marked for upload to Oracle InForm.

- The account details email will be sent automatically to the user after they are successfully created/reinstated in Oracle InForm.

However:

- Previously approved and trained users must be manually authorized, and their authorization emails must be manually sent.
- Previously authorized users who have not received their authorization emails must have their emails manually sent.

Manual—To manually send the study URL details to a non-SSO study user, you send the Oracle InForm account details from the Oracle InForm User Management Tool user interface.

On the **Users** page, select the checkbox to the left of the user. Then, in the **Manage User** drop-down list, select **Send InForm Account Details**, enter a comment, and click **Go**. For more information, see [Sending user account details](#).

What happens after the authorization email is sent to the non-SSO study user?

The study user receives **one email for each study they are authorized to access** from **saasadminsupport_ww** with the Subject Line **Oracle – [Customer Name] INFORM [Study Name] - Access Authorization**.

What information is in the authorization email?

The email contains the Oracle InForm user name and password, and the study URL.

Receiving this email confirms that the account and study authorization process is complete. Users can log in to the specified study or studies using their user name and password.

4

Managing users

- [Oracle InForm and Oracle IRT users](#)
- [Oracle InForm User Management Tool users](#)
- [Global users](#)

Oracle InForm and Oracle IRT users

- [Viewing the list of InForm or IRT users](#)
- [Creating Oracle InForm or Oracle IRT users](#)
- [Viewing and modifying user details](#)
- [Viewing the sites a user is associated with](#)
- [Associating a user with a site](#)
- [Terminating users](#)
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- [Unterminating \(re-instating\) users](#)
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- [Marking users for upload to Oracle InForm or Oracle IRT](#)
- [Assigning Oracle Health Sciences Learn classes to a user](#)
- [Marking users as trained](#)
- [Sending user account details](#)
- [Exporting users](#)
- [Updating a user's name in email notifications](#)
- [Updating assessment status](#)
- [Assigning a preferred study locale to a user](#)

Viewing the list of InForm or IRT users

To view the list of users:

1. Select **Users** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.

Note the following information:

Authorization Status filter and column—Identifies users who are not yet authorized. This filter and column only appear for SSO studies and if the logged in user has the **Manage SSO** UMT Admin right.

- Failure—Includes fault and failure status.
- Success
- Not Authorized—If selected, any user that has no Authorization status appears in the list.
- Process Started
- Request Sent

Email Sent filter—Identifies whether users have had their authorization emails sent. This filter appears for SSO and non-SSO/native studies, but only after the study is set to **Fast Forward** and if the **InForm Go Live** option is enabled.

- Yes
- No

To search for users:

1. Enter the filter criteria, and click **Find**.
 - The most common filter options appear at the top right of each page. If you do not see the search criteria you want, click **More Filters** and more criteria will appear.
 - If you want to save your filter to use whenever you are on this page, click **Save** in the lower right corner of the filter criteria box.
 - You can sort the data by clicking on the column header.
2. To clear the filter criteria, click **Clear**.

Creating Oracle InForm or Oracle IRT users

You can create site and sponsor users for Oracle InForm or Oracle IRT depending on your product integration and Oracle InForm User Management Tool privileges.

When creating the user you must assign an Oracle InForm Rights Group and if you are using Oracle IRT, an Oracle IRT role. You can also assign a user to a Signature Group and a Query Group.

When you assign a Rights Group to a user, the user will get assigned to any groups the role is assigned to. If within a role you want different users assigned to different Signature Groups or Query Groups you can make those assignments when creating the user.

1. Select **Users** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. On the left, above the Users list, click **Create InForm User** or **Create IRT User**.
4. Below **Basic User Info**, **Contact Details**, and **User Misc** enter the user details, and click **Submit**.

 **Note:**

The available options for the Preferred Study Locale are based on the languages specified during the study design. In Oracle InForm, this setting is used for pages that can span multiple sites, and controls some study locale information presented outside of the CRFs, such as headings on the Time and Events Schedule page or choices in the Source Verification page filter control.

The Product Locale is the language—English or Japanese—of the product user interface. Menus, controls, commands, system screen labels, error messages, and so on are written in the selected language. Oracle creates product locales.

5. Below **User Association**, select one or more sites to give the user access to, and select the Rights Groups for the user.
 - a. Use the **Filter By** drop-down list to select all sites, all sites in a particular time zone within a country, or all sites in a particular country.
 - b. Select **Automatic Association** if you want to automatically associate this user to any sites created in the future for the selected country or timezone.
 - c. Select the site or sites to give the user access to.
 - You can associate a site user with only one site.
 - You can associate a sponsor user with multiple sites.
 - d. Assign the user to a Signature Group and a Query Group.
6. Complete one of the following:
 - To save the details and return to the previous page, click **Submit** and then click **Return**.

 **Note:**

If you added the user to an SSO-enabled trial, when you save the data Oracle InForm User Management Tool checks to see if the username, first name, last name, and email id match an existing Global User. If not, a Global User will be created.

For production trials, you cannot have more than one user with the same first name, last name, and email id. Therefore, if the first name, last name, and email id already exists for a Global User but with a different username, Oracle InForm User Management Tool displays an error.

- To save the details and create another user, click **Submit and Add Another**.
- To discard the details and return to the previous page, click **Return**.

Viewing and modifying user details

You can update the information for an Oracle InForm or Oracle IRT user at any time. Whenever you update the information, Oracle InForm User Management Tool records the changes to ensure that they are auditable.

1. Select **Users** from the menu bar.


2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. In the **Username** column, click a user.
4. Modify the user details.

Note the following fields:

- The **Authorize User** option (in the User Misc section) appears only for live studies, and indicates whether the SSO study is configured to allow site and sponsor users for a study to be automatically authorized after the user has an Approval status of Approved and a Training Status of Trained.
 - For a new study, if the configuration is set at the sponsor level, it will be the default for a new study. If not, when you create a new study, the configuration will not be enabled.
 - For an existing study, if you select this option, it applies only to new and existing users who are approved/trained after the option is selected. Any existing users who are already approved/trained, but are not yet authorized, will need to be manually authorized.
 - The available options for the **Preferred Study Locale** are based on the languages specified during the study design. In Oracle InForm, this setting is used for pages that can span multiple sites, and controls some study locale information presented outside of the CRFs, such as headings on the Time and Events Schedule page or choices in the Source Verification page filter control.
 - The **Product Locale** is the language—English or Japanese—of the product user interface. Menus, controls, commands, system screen labels, error messages, and so on are written in the selected language. Oracle creates product locales
5. In the **Reason for Change** field, enter the reason for modifying the user details.
 6. Complete one of the following:
 - To save the changes and return to the previous page, click **Submit** and then click **Return**.
 - To cancel the changes and return to the previous page, click **Return**.

Viewing the sites a user is associated with

When viewing the sites that a user is associated with, you can also request an equipment assessment for a site or update the site's assessment status.

1. Select **Users** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. In the **Site(s)** column, click the  icon.
4. Do one or all of the following:
 - To view the site associations for a different user, select the user from the **Select User** list and click **Go**.
 - To send an assessment request or update the assessment status for a site, select an option from the **Select** drop-down list, enter a reason for change, and click **Go**.

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

Associating a user with a site

Note:

Before proceeding, ensure that you comply with the regulatory requirements described in [Regulatory Requirements for Oracle InForm User Management Tool](#).

If you chose not to associate a user with a site while creating the user, you can do so now.

- If a user is not associated to any sites in Oracle InForm User Management Tool, the user will not see all the tabs in Oracle InForm.
 - Make sure to associate a site to a user before choosing to authorize the user to the trial that loads the user to Oracle InForm.
1. Select **Users** from the menu bar.
 2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
 3. In the **Username** column, click a user name.
 4. Below **User Association**, select one or more sites to give the user access to and select the Rights Groups for the user.
 - a. Use the **Filter By** drop-down list to select all sites, all sites in a particular time zone within a country, or all sites in a particular country.
 - b. Select **Automatic Association** if you want to automatically associate this user to any sites created in the future for the selected country or timezone.

Note:

Automatic Association is only available for Sponsor type users.

- c. Select the site or sites to give the user access to.
 - You can associate a site user with only one site.
 - You can associate a sponsor user with multiple sites.
 - d. Assign the user to a Signature Group and a Query Group.
5. In the **Reason for change field**, enter a reason for change.
 6. Click **Submit** and then click **Return**.

Terminating users

When you terminate a user, you revoke the user's access to a trial.

 **Note:**

For an SSO trial, terminating a user from a trial will not terminate the global user. That same global user can be assigned access to another trial in the future. If you want to terminate an SSO user across all trials, you must terminate the user from the Global Users page.

1. Select **Users** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Select the checkbox to the left of the user to terminate.
4. Select **Terminate User** from the **Select** drop-down list.
5. In the **Comments** field, enter the reason for terminating the user, and then click **Go**.
6. In the confirmation dialog box, click **OK**.

 **Note:**

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

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

Viewing terminated users

1. Select **Users** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. In the bottom left, click **Terminated User List**.
 - To go back to the previous page, click **Return**.

Unterminating (re-instating) users

If you need to return a user's access to a trial, you unterminate the user. This task is also referred to as re-instating a user.

1. Select **Users** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. In the bottom left, click **Terminated User List**.
4. Select the checkbox to the left of the user to unterminate, and click **UnTerminate**.

When you unterminate a user, you need to re-assign the user access to sites.

- If the user had auto-association configured, the user will be assigned to all the sites that currently match the criteria configured for their auto-association.

- If auto-association is not configured for the user, you will need to assign sites to the user after you unterminate them.
5. In the confirmation dialog box, click **OK**.
 - To go back to the previous page, click **Return**.

Approving or rejecting users



Note:

Before proceeding, ensure that you comply with the regulatory requirements described in [Regulatory Requirements for Oracle InForm User Management Tool](#).

You must approve or reject a user after the user is created and if the user details are modified. When a user needs to be approved or rejected, the user's approval status is changed to pending on the list of users page.

1. Select **Users** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Select the checkbox to the left of the user to approve or reject.
4. From the **Select** drop-down list, select **Approve** or **Reject**.
 - If you select **Approve**, complete the Electronic Signature Affidavit and click **Submit**.
 - If you select **Reject**, enter the reason for rejection in the **Comments** field.
5. Click **Go**.

Marking users for upload to Oracle InForm or Oracle IRT



Note:

Before proceeding, ensure that you comply with the regulatory requirements described in [Regulatory Requirements for Oracle InForm User Management Tool](#).

Before a user can be added to Oracle InForm or Oracle IRT, the user must be manually or automatically marked for upload. Study users must exist in UMT and Oracle InForm or Oracle IRT, and be marked as trained in Oracle InForm User Management Tool.


Automated—If the Automated Authorization option in the Trial Configurations section on the Configuration settings page is selected for your sponsor or study, after a non-SSO user is trained and approved the user will be automatically marked for upload to InForm.

Manual—If the Automated Authorization option in the Trial Configurations section on the Configuration settings page is not selected for your sponsor or study, after a non-SSO user is trained and approved you must manually mark the user for upload to InForm.

1. Select **Users** from the menu bar.

2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Select the checkbox to the left of the user to upload.
4. From the **Manage User** drop-down list:
 - For non-SSO users, select **Mark Upload to InForm** or **Mark Upload To IRT**.
 - For SSO users, select **Authorize User**, which automatically marks the user for upload to Oracle InForm.
5. Enter the reason for change in the **Comments** field, and click **Go**.

When the authorization is successful the following indicators appear on the Users page:

- For a user in a non-SSO trial or an SSO trial, the **Uploaded to InForm** icon () appears to the left of the Username column.
- For a user in an SSO trial, you must also see the word **Success** in the **Authorization Status** column to show that the user has been authorized in Oracle Life Sciences IAMS.

Assigning Oracle Health Sciences Learn classes to a user

You can assign an Oracle Health Sciences Learn class to a user only if you have a Oracle InForm User Management Tool-Oracle Health Sciences Learn integration.

To check whether Oracle Health Sciences Learn is enabled for the trial, select Configuration from the menu bar; Oracle Health Sciences Learn is enabled for the trial if **Switchoff HSLearn** in the Trial Configuration section is **not** selected.



Note:

When you assign a user to a role that has training associated to it, the training is automatically assigned to the user. The training is not assigned to users already associated with the role.

1. Select **Users** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Select the checkbox to the left of the user to assign the Oracle Health Sciences Learn class to.
4. From the **Manage User** drop-down list, select **Assign HS Learn Class**.
5. Enter a reason in the **Comments** field, and click **Go**.
6. In the **Select Classes** section, select the **Available** class or classes to assign to the user, and move them to the **Selected** list.
7. Click **Submit**.

Marking users as trained



Note:

Before proceeding, ensure that you comply with the regulatory requirements described in [Regulatory Requirements for Oracle InForm User Management Tool](#).

You can mark a user as trained after the user is created and approved.

1. Select **Users** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Select the checkbox to the left of the user to mark as trained.
4. From the **Manage User** drop-down list, select **Mark as Trained**.
5. Enter the reason for change in the **Comments** field, and click **Go**.

Sending user account details



Note:

Before proceeding, ensure that you comply with the regulatory requirements described in [Regulatory Requirements for Oracle InForm User Management Tool](#).

You can email user account details for an Oracle InForm or Oracle IRT study. To send user account details, the user must be uploaded to the product and the study must be live.

1. Select **Users** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Select the checkbox to the left of the user to send the InForm account details to.
4. From the **Manage User** drop-down list:
 - For non-SSO users, select **Send InForm Account Details**.
The email contains the Oracle InForm user name and password and the study URL.
 - For SSO users, select **Send Authorization Details**.
The email contains the username and study URL.
5. Enter a comment, and click **Go**.

Exporting users

You can export Oracle InForm user details either to an Excel spreadsheet or to a DAT file.

1. Select **Users** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.

3. Select the checkboxes to the left of the users to export.
4. Above the list of users, do one of the following:
 - To export the user details as an Excel spreadsheet, click **Export**, and select **Export To Excel**.
 - To export the user details to a DAT file, click **Export**, and select **Export To File**.
5. In the browser window, click **Open** or click **Save**.

Updating a user's name in email notifications

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



Note:

This functionality is for non-SSO users only.

1. Select **Users** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Select the checkbox to the left of the user to update.
4. From the **Manage User** drop-down list, select **Update User Name in Email Notifications**.
5. From the **User Name Order** drop-down list, select an option.
6. In the **Comments** field, enter a reason for change, and click **Go**.

Updating assessment status

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

1. Select **Users** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Select the checkbox to the left of the user to update.
4. From the **Manage User** drop-down list, select **Update Assessment Status**.
5. In the **Comments** field, enter a reason for change, and click **Go**.
6. Below Update Assessment Status, select an option.
7. In the **Assessment Summary Box** field, enter a reason for change.
8. Click **Update**, and then click **Return**.

Assigning a preferred study locale to a user

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

1. Select **Users** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Select the checkbox to the left of the user to update.
4. From the **Select** drop-down list, select **Assign Preferred Study Locale**.
5. From the **Language** drop-down list, select an option.
6. In the **Comments** field, enter a reason for change, and click **Go**.

Oracle InForm User Management Tool users

- [Viewing the list of Oracle InForm User Management Tool users](#)
- [Creating Oracle InForm User Management Tool users](#)
- [Viewing and modifying Oracle InForm User Management Tool user details](#)
- [Activating Oracle InForm User Management Tool users](#)
- [Terminating Oracle InForm User Management Tool users](#)
- [Viewing terminated Oracle InForm User Management Tool users](#)
- [Unterminating Oracle InForm User Management Tool users](#)
- [Resetting the password for a Oracle InForm User Management Tool user](#)
- [Resending Oracle InForm User Management Tool login details](#)

Viewing the list of Oracle InForm User Management Tool users

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

To view the list of users:

1. Select **Users** from the menu bar.
2. In the upper left, click **UMT Users**.
3. From the **Current Sponsor Company** drop-down list, select the sponsor company.

To search for users:

1. Enter the filter criteria, and click **Find**.
 - The most common filter options appear at the top right of each page. If you do not see the search criteria you want, click **More Filters** and more criteria will appear.

- If you want to save your filter to use whenever you are on this page, click **Save** in the lower right corner of the filter criteria box.
 - You can sort the data by clicking on the column header.
2. To clear the filter criteria, click **Clear**.

Creating Oracle InForm User Management Tool users

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

1. Select **Users** from the menu bar.
2. Click the **UMT Users** tab.
3. Select the sponsor company from the **Current Sponsor Company** drop-down list.
4. On the left, above the Users list, click **Create UMT User**.
5. Enter the user details and select a role.

 **Note:**

Set the **Change Password on Next Login** option to **Yes** if you want the Oracle InForm User Management Tool user you create to be required to change their password the first time they login.

6. Select one or more countries and one or more trials to associate the user with.
7. Complete one of the following:
 - To save the details and return to the previous page, click **Submit** and then click **Return**.
 - To save the details and create another object, click **Submit and Add Another**.
 - To discard the details and return to the previous page, click **Return**.

Viewing and modifying Oracle InForm User Management Tool user details

The UMT User Details page lets you view and modify Oracle InForm User Management Tool 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.

1. Select **Users** from the menu bar.
2. In the upper left, click **UMT Users**.
3. Select the sponsor company from the **Current Sponsor Company** drop-down list.
4. In the **Username** column, click a user name.
5. Modify the user details.
6. In the **Reason for Change** field, enter the reason for modifying the user details.
7. Complete one of the following:

- To save the changes and return to the previous page, click **Submit** and then click **Return**.
- To cancel the changes and return to the previous page, click **Return**.

Activating Oracle InForm User Management Tool users

The UMT Users page also lets you activate Oracle InForm User Management Tool users.

1. Select **Users** from the menu bar.
2. In the upper left, click **UMT Users**.
3. Select the sponsor company from the **Current Sponsor Company** drop-down list.
4. Select the checkbox to the left of the user to activate.
5. From the **Select** drop-down list, select **Activate**.
6. In the **Comments** field, enter the reason for activating the user, and click **Go**.

Terminating Oracle InForm User Management Tool users

The UMT Users page lets you terminate Oracle InForm User Management Tool users. You can also view the list of terminated users.

1. Select **Users** from the menu bar.
2. In the upper left, click **UMT Users**.
3. Select the sponsor company from the **Current Sponsor Company** drop-down list.
4. Select the checkbox to the left of the user to terminate.
5. From the **Select** drop-down list, select **Terminate**.
6. In the **Comments** field, enter a reason for terminating the user, and click **Go**.

Viewing terminated Oracle InForm User Management Tool users

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

1. Select **Users** from the menu bar.
2. In the upper left, click **UMT Users**.
3. Select the sponsor company from the **Current Sponsor Company** drop-down list.
4. In the lower left, click **Terminated User List**.
 - To go back to the previous page, click **Return**.

Unterminating Oracle InForm User Management Tool users

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

1. Select **Users** from the menu bar.
2. In the upper left, click **UMT Users**.

3. Select the sponsor company from the **Current Sponsor Company** drop-down list.
4. In the lower left, click **Terminated User List**.
5. Select the checkbox to the left of the user to unterminate, and click **UnTerminate**.
 - To go back to the previous page, click **Return**.

Resetting the password for a Oracle InForm User Management Tool user

The login password for an Oracle InForm User Management Tool user can be reset in case the password is blocked or expired.

1. Select **Users** from the menu bar.
2. In the upper left, click **UMT Users**.
3. Select the sponsor company from the **Current Sponsor Company** drop-down list.
4. Select the checkbox to the left of the user to resend a password for.
5. From the **Select** drop-down list, select **Reset Password**.
6. In the **Comments** field, enter the reason for resetting the password, and click **Go**.

Resending Oracle InForm User Management Tool login details

The UMT Users page also lets you resend Oracle InForm User Management Tool login details to a user.

1. Select **Users** from the menu bar.
2. In the upper left, click **UMT Users**.
3. Select the sponsor company from the **Current Sponsor Company** drop-down list.
4. Select the checkbox to the left of the user to resend login details to.
5. From the **Select** drop-down list, select **Resend UMT Login Details**.
6. In the **Comments** field, enter the reason for resending the login details, and click **Go**.

Global users

- [Viewing the list of Global users](#)
- [Creating Global users](#)
- [Assigning a product to a Global user](#)
- [Viewing and modifying global user details](#)
- [Terminating a Global user](#)
- [Viewing the terminated user list](#)
- [Unterminating Global users](#)

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 users:

1. Select **Users** from the menu bar.
2. In the upper left, click **Global Users**.
3. Select the sponsor company from the **Current Sponsor Company** drop-down list.

To search for users:

1. Enter the filter criteria, and click **Find**.
 - The most common filter options appear at the top right of each page. If you do not see the search criteria you want, click **More Filters** and more criteria will appear.
 - If you want to save your filter to use whenever you are on this page, click **Save** in the lower right corner of the filter criteria box.
 - You can sort the data by clicking on the column header.
2. To clear the filter criteria, click **Clear**.

Creating Global users

A Global user is a user managed by Oracle Identity Manager suite. Global users must be enabled for single sign-on (SSO) and can be site or sponsor users. You can assign a Global user to multiple 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.

Note:

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

1. Select **Users** from the menu bar.
2. In the upper left, click **Global Users**.
3. Select the sponsor company from the **Current Sponsor Company** drop-down list.
4. On the left, above the Users list, click **Create Global User**.
5. Enter the user details.

Note:

The Username, First Name, Last Name, and Email Address must be unique.

6. Complete one of the following:

- To save the details and return to the previous page, click **Submit** and then click **Return**.
- To save the details and create another object, click **Submit and Add Another**.
- To discard the details and return to the previous page, click **Return**.

Assigning a product to a Global user

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

1. Select **Users** from the menu bar.
2. In the upper left, click **Global Users**.
3. Select the sponsor company from the **Current Sponsor Company** drop-down list.
4. Select the checkboxes to the left of the user to assign a product to.
5. From the **Select** drop-down list, select **Assign Product**.
6. From the **Product** drop-down list, select the product.
 - If you selected **InForm**:
 - a. Select the trial version from the **Trial Version** drop-down list.
 - b. Select the trial from the **Trial** drop-down list.
 - c. If you need to edit the user details, make the changes in the list of Global users.
7. Associate the user with a site:
 - a. On the far right of the list of users, click the **+** icon.
 - b. Select one or more sites to associate the user with.
 - c. Click **Save**, and then click **OK**.
8. In the **Comments** field, enter a reason for change, and click **Submit**.

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. If the Global user record is modified, the changes are reflected across all trials the user is associated to.

1. Select **Users** from the menu bar.
2. In the upper left, click **Global Users**.
3. Select the sponsor company from the **Current Sponsor Company** drop-down list.
4. In the **Username** column, click a user name.
5. Modify the user details.

 **Note:**

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

6. In the **Reason for Change** field, enter the reason for modifying the user details.
7. To save the changes and return to the previous page, click **Submit** and then click **Return**.

To cancel the changes and return to the previous page, click **Return**.

Terminating a Global user

The Global Users page lets you terminate a Global user.

 **Caution:**

Terminating a Global user will terminate the user across all products the user is assigned to. This means that if you terminate a user on the Global Users page, it will not only terminate the user from all Oracle InForm studies, it will also terminate the user from other products that use Oracle Life Sciences IAMS for authentication, such as Oracle Central Coding and Oracle Clinical One Platform.

1. Select **Users** from the menu bar.
2. In the upper left, click **Global Users**.
3. Select the sponsor company from the **Current Sponsor Company** drop-down list.
4. Select the checkbox to the left of the user to terminate.
5. From the **Select** drop-down list, select **Terminate User**.
6. In the **Comments** field, enter the reason for terminating the user, and then click **Submit**.

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.

1. Select **Users** from the menu bar.
2. In the upper left, click **Global Users**.
3. Select the sponsor company from the **Current Sponsor Company** drop-down list.
4. In the lower left, click **Terminated User List**.
 - To go back to the previous page, click **Return**.

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.

1. Select **Users** from the menu bar.

2. In the upper left, click **Global Users**.
3. Select the sponsor company from the **Current Sponsor Company** drop-down list.
4. In the lower left, click **Terminated User List**.
5. Select the checkbox to the left of the user to unterminate, and click **Untermine**.
 - To go back to the previous page, click **Return**.

5

Managing trials

- [Viewing the list of trials](#)
- [Viewing and modifying trial details](#)
- [Bulk copying](#)
- [Selective copying](#)
- [Archiving trials](#)
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- [Exporting trials](#)
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- [Locking a trial for development](#)
- [Generating Oracle InForm XML](#)

Viewing the list of trials

The 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:

1. Select **Trials** from the menu bar.
2. Select the sponsor company from the **Current Sponsor Company** drop-down list.

To search for trials:

1. Enter the filter criteria, and click **Find**
 - The most common filter options appear at the top right of each page. If you do not see the search criteria you want, click **More Filters** and more criteria will appear.
 - If you want to save your filter to use whenever you are on this page, click **Save** in the lower right corner of the filter criteria box.
 - You can sort the data by clicking on the column header.
2. To clear the filter criteria, click **Clear**.

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.

1. Select **Trials** from the menu bar.
2. Select the sponsor company from the **Current Sponsor Company** drop-down list.

3. In the **Trial Name** column, click a trial.
4. Modify the trial details.
5. In the **Reason for Change** field, enter the reason for modifying the trial details.
6. To save the changes and return to the previous page, click **Submit** and then click **Return**.

To cancel the changes and return to the previous page, click **Return**.


Bulk copying



Note:

Bulk copying is available only for non-SSO trials.

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

1. Select **Trials** from the menu bar.
2. Select the sponsor company from the **Current Sponsor Company** drop-down list.
3. In the **Copy** column, click the  icon for a trial.
4. In the upper left, click **Bulk Copy**.
5. From the **Source Trial** drop-down list, select the source trial.
6. Select the checkboxes to the left of the items to copy.
7. Click **Submit**, and then click **Return**.


Selective copying



Note:

Selective copying is available for SSO and non-SSO trials. However, you can only copy from an SSO trial to another SSO trial, or from a non-SSO trial to another non-SSO trial.

You can selectively copy a single type of trial data to another trial.

1. Select **Trials** from the menu bar.
2. Select the sponsor company from the **Current Sponsor Company** drop-down list.
3. In the **Copy** column, click the **Copy** icon () for a trial.
4. From the **Source Trial** drop-down list, select the source trial.
5. From the **Select Type** drop-down list, select the trial details to copy.

Additional checkboxes may appear on the lower left of page, depending on the option you select.

6. Move the trial details you want to copy from the **Available** list to the **Selected** list.
7. Optionally, select the checkboxes at the lower left of the page to copy the additional data.
For example, if you select **Sites** from the **Select Type** drop-down list, the **Associated Sponsor Users** and **Associated Site Users** checkboxes appear on the page.
 - If you select the **Associated Sponsor Users** checkbox, the sponsor users that are associated to the sites you have selected from the source trial are copied to the destination trial. If you do not select the checkbox, only the sites will be copied.
 - If you select the **Associated Site Users** checkbox, the site users that are associated to the sites you have selected from the source trial are copied to the destination trial. If you do not select the checkbox, only the sites will be copied.
8. Click **Submit**, and then click **Return**.

Archiving trials

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

1. Select **Trials** from the menu bar.
2. Select the sponsor company from the **Current Sponsor Company** drop-down list.
3. Select the checkbox to the left of the trial to archive.
4. From the **Manage Trial** drop-down list, select **Archive**.
5. In the **Comments** field, enter the reason for archiving the trial, and click **Go**.

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.

1. Select **Trials** from the menu bar.
2. Select the sponsor company from the **Current Sponsor Company** drop-down list.
3. In the lower left, click **View Archive of Trials**.
 - To go back to the previous page, click **Back**.

Exporting trial details

On the Trials page, you can export trial details that appear on the page. You can export the trial details either to an Excel spreadsheet or to a flat file.

1. Select **Trials** from the menu bar.
2. Select the sponsor company from the **Current Sponsor Company** drop-down list.
3. Select the checkbox to the left of the trial to export.
4. Above the list of trials, do one of the following:
 - To export the trial details as an Excel spreadsheet, click **Export**, and then select **Export to Excel**.
 - To export the trials details to a DAT file, click **Export**, and then select **Export to File**.

5. In the browser window, click **Open** or click **Save**.

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.

1. Select **Trials** from the menu bar.
2. Select the sponsor company from the **Current Sponsor Company** drop-down list.
3. Select the checkbox to the left of the trial to export.
4. Above the list of trials, click **Export**, and then select **Export Trial Data**.
5. In the browser window, click **Open** or click **Save**.

Importing administrative data for a trial

To import trial data, you must have the Import Data right.

You can perform a bulk import of trial data using the Master User List (MUL) Template (also referred to as a *Joint Template* or *Composite Template*). The template is an Excel spreadsheet you use to create and upload users and their sites and rights. You can download this template directly from Oracle InForm User Management Tool.



Note:

For instructions on how to download the template and enter your trial data, see [Loading data into the User Management Tool](#).

1. Select **Trials** from the menu bar.
2. Select the sponsor company from the **Current Sponsor Company** drop-down list.
3. On the left, above the Trials list, click **Upload**.
The Upload Data File dialog box appears.
4. In the **Filename** field, enter the name for your MUL Template, or browse to select the template file you want to upload.
5. In the **Trial name** drop-down list, select the trial name you want to upload data for.
6. In the **Import** section, select the trial details to import.
7. Click **Validate and Import**.

Locking a trial for development

When a study is locked for development, you cannot change Roles or Groups, but you can create new users and sites. However, you cannot mark them for upload to InForm while the study is locked.

1. Select **Trials** from the menu bar.
2. Select the sponsor company from the **Current Sponsor Company** drop-down list.

3. Select the checkbox to the left of the trial you want to lock.
4. From the **Manage Trial** drop-down list, select **LockTrial**.
5. In the **Comments** field, enter the reason for locking the trial, and click **Go**.
6. Complete the Electronic Signature Affidavit, and click **Submit**.

Generating Oracle InForm XML

There are two ways to generate Oracle InForm XML to have user information uploaded to Oracle InForm.

- **Automated**—For the initial load of Admin data for pre Go-Live production trials, Oracle InForm User Management Tool provides an automated process for generating and uploading Oracle InForm Admin data. Automation is also available for UAT trials for testing purposes.
- **Manual**—Create a ZIP file that contains the XML that needs to be uploaded to Oracle InForm. Then, enter a ticket with the XML ZIP file attached, to have the user information uploaded to Oracle InForm.

For more information, see the following:

- [Generating Oracle InForm XML for pre Go-Live production trials](#)
- [Generating Oracle InForm XML for UAT trials](#)
- [Generating an Oracle InForm XML ZIP file for upload to Oracle InForm](#)

Generating Oracle InForm XML for pre Go-Live production trials

To use this feature, you must have the Oracle InForm User Management Tool right, called **SendInFormXML** (in the User/Sponsor/Site Details category). When you have this right, the **Send to InForm** button appears on the **Trials** page.

1. Select **Trials** from the menu bar.
2. Select the sponsor company from the **Current Sponsor Company** drop-down list.
3. Select the checkbox to the left of a trial.

 **Note:**

Before proceeding to step 4, make sure that the trial is locked for edits, and that the trial has a Fast Start status. This option can only be used for trials that have the Oracle InForm User Management Tool automation to Oracle InForm enabled.

4. Click **Send to InForm**.

The user receives an email when the load has completed.

- If the load fails, click the icon in the **Send To InForm History** column on the **Trials** listing page to view the reason why the load failed, and to see the audit history of when the **Send To InForm** button was pressed.
- The **Send to InForm** button can only be pressed a second time if an error occurred during the first load.

- After the Send To Oracle InForm process is completed successfully, any future changes to the data in Oracle InForm User Management Tool will flow directly to Oracle InForm. However, data will not flow to Oracle InForm while the trial is locked for edits in Oracle InForm User Management Tool.

Generating Oracle InForm XML for UAT trials

To use this feature, you must have the Oracle InForm User Management Tool right, called SendInFormXML (in the User/Sponsor/Site Details category). When you have this right, the **Send to InForm** button appears on the **Trials** page.

1. Select **Trials** from the menu bar.
2. Select the sponsor company from the **Current Sponsor Company** drop-down list.
3. Select the checkbox to the left of a trial.

Note:

Before proceeding to step 4, make sure that the UAT trial is locked for edits and that it has a Fast Start or Trial Reset status. This option can only be used for trials that have the Oracle InForm User Management Tool automation to Oracle InForm enabled.

4. Click **Send to InForm**.

If the UAT trial has a Trial Reset status, a dialog box appears. Click **OK** to send only user data or **Cancel** to send all trial data.

When the Send to InForm process is completed, the user receives an email.

- If the load fails, click the icon in the **Send To InForm History** column on the **Trials** listing page to view the reason why the load failed, and to see the audit history of when the **Send To InForm** button was pressed.
- The **Send to InForm** button can only be pressed a second time if an error occurred during the first load.
- After the Send To Oracle InForm process is completed successfully, any future changes to the data in Oracle InForm User Management Tool will flow directly to Oracle InForm. However, data will not flow to Oracle InForm while the trial is locked for edits in Oracle InForm User Management Tool.

Generating an Oracle InForm XML ZIP file for upload to Oracle InForm

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.

1. Select **Trials** from the menu bar.
2. Select the sponsor company from the **Current Sponsor Company** drop-down list.
3. Select the checkbox to the left of a trial.
4. Above the list of trials, click **Export**, and select **Generate InFormXML**.

This step creates a ZIP file that contains the XML that needs to be uploaded to Oracle InForm.

5. Enter a ticket with the XML ZIP file attached, to have the user information uploaded to Oracle InForm.

6

Managing sites

- [Viewing the list of sites](#)
- [Creating sites](#)
- [Viewing and modifying site details](#)
- [Changing a site mnemonic](#)
- [Approving or rejecting sites](#)
- [Marking sites as uploaded to Oracle InForm or Oracle IRT](#)
- [Marking sites as not participating](#)
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- [Marking a not participating site as participating](#)
- [Assigning or updating the study version](#)
- [Exporting sites](#)
- [Updating the assessment status for a site](#)
- [Sending an assessment email to a site](#)
- [Stopping the assessment process for a site](#)
- [Assigning a preferred study locale to a site](#)

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:

1. Select **Sites** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.

To search for sites:

1. Enter the filter criteria, and click **Find**.
 - The most common filter options appear at the top right of each page. If you do not see the search criteria you want, click **More Filters** and more criteria will appear.
 - If you want to save your filter to use whenever you are on this page, click **Save** in the lower right corner of the filter criteria box.
 - You can sort the data by clicking on the column header.
2. To clear the filter criteria, click **Clear**.

Creating sites

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

1. Select **Sites** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. On the left, above the Sites list, click **Create Site**.
4. Enter the site details.

 **Note:**

The Site Study Locale must match the settings of your Oracle InForm study. Contact your Oracle Product Manager if you need guidance.

5. Below **User Association Details**, select the users to associate with the site.
6. Complete one of the following:
 - To save the details and return to the previous page, click **Submit** and then click **Return**.
 - To save the details and create another object, click **Submit and Add Another**.
 - To discard the details and return to the previous page, click **Return**.

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.

1. Select **Sites** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. In the **Site Name** column, click a site.
4. Modify the site details.
5. In the **Reason for Change** field, enter the reason for modifying the site details.
6. Complete one of the following:
 - To save the changes and return to the previous page, click **Submit** and then click **Return**.
 - To cancel the changes and return to the previous page, click **Return**.

Changing a site mnemonic

In Oracle InForm User Management Tool, you can change the site mnemonic through the user interface. However, in the MUL Template or the .DAT file, the site mnemonic is the unique identifier for the site, and it cannot be changed.

If you need to change a site mnemonic, we recommend you edit the site through the user interface. For more information, see [Viewing and modifying site details](#).

If you want to change a site mnemonic using the MUL Template or .DAT file, you can:

1. Create a new site with the new mnemonic and same name as an existing site.
For more information, see [Creating sites](#).
2. Associate any site or sponsor users assigned to the existing site to the new site.
Some users may be automatically assigned to the new site due to an auto-association.
For more information, see [Associating a user with a site](#).
3. Terminate the site with the original mnemonic.

Approving or rejecting sites

Note:

Before proceeding, ensure that you comply with the regulatory requirements described in [Regulatory Requirements for Oracle InForm User Management Tool](#).

The List of Sites page lets you approve and reject sites. A site must be approved before you carry out any clinical trials.

1. Select **Sites** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Select the checkbox to the left of the site to approve or reject.
4. From the **Select** drop-down list, select **Approve** or **Reject**.
 - If you select **Approve**, complete the Electronic Signature Affidavit and click **Submit**.
 - If you select **Reject**, enter the reason for rejection in the **Comments** field.
5. Click **Go**.

Marking sites as uploaded to Oracle InForm or Oracle IRT

Note:

Before proceeding, ensure that you comply with the regulatory requirements described in [Regulatory Requirements for Oracle InForm User Management Tool](#).

To upload site details to Oracle InForm or Oracle IRT you must mark the site for upload in Oracle InForm User Management Tool.

1. Select **Sites** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.

3. Select the checkbox to the left of the site to mark for upload to Oracle InForm.
4. From the **Select** drop-down list, select **Mark Upload To InForm** or **Mark Upload to IRT**.
5. In the **Comments** field, enter the reason for change, and click **Go**.

Marking sites as not participating

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

1. Select **Sites** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Select the checkbox to the left of the site to mark as not participating.
4. From the **Select** drop-down list, select **Mark as Not Participating**.
5. In the **Comments** field, enter the reason for change, and click **Go**.

Viewing not participating sites

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

1. Select **Sites** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. In the lower left, click **View Not Participating Sites**.
 - To go back to the previous page, click **Return**.

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.

1. Select **Sites** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. In the lower left, click **View Not Participating Sites**.
4. Select the checkbox to the left of the site to mark as participating.
5. Click **Mark as Participating**.
 - When a site is terminated (marked as not participating) and then reinstated (marked as participating):
 - The same criteria that is used for the automatic association of users to new sites is used for the reinstated site.
 - The audit history in the Sites tab now tracks when a site is terminated and then reinstated. To see the audit history, click the History icon for the Site Number field on the Site Details page.

- If the Oracle InForm User Management Tool configuration setting **Default Study Version** is set to **Multiple**, you can select a specific study version when you reinstate a site through the user interface.
6. To go back to the previous page, click **Return**.

Assigning or updating the study version



Note:

Before proceeding, ensure that you comply with the regulatory requirements described in [Regulatory Requirements for Oracle InForm User Management Tool](#).

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

1. Select **Sites** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Select the checkbox to the left of the site to update the study version for.
4. From the **Select** drop-down list, select **Assign study version**.
5. From the **study version** drop-down list, select the study version.
6. In the **Comments** field, enter the reason for change, and click **Go**.

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 DAT file.

1. Select **Sites** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Select the checkbox to the left of the site to export.
4. Above the list of sites, do one of the following:
 - To export the site details as an Excel spreadsheet, click **Export to Excel**.
 - To export the site details to a DAT file, click **Export to File**.
5. In the browser window, click **Open** or click **Save**.

Updating the assessment status for a site

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

1. Select **Sites** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.

3. Select the checkbox to the left of the site to update.
4. From the **Select** drop-down list, select **Update Assessment Status**.
5. In the **Comments** field, enter the reason for change, and click **Go**.
6. Select an assessment status to assign to all users associated with the site.
7. In the **Assessment Summary Box** field, enter the reason for change.
8. Click **Update**, and then click **Return**.

Sending an assessment email to a site

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

1. Select **Sites** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Select the checkbox to the left of the site to send an assessment email to.
4. From the **Select** drop-down list, select **Send Assessment Email**.
5. In the **Comments** field, enter the reason for change, and click **Go**.

Stopping the assessment process for a site

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

1. Select **Sites** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Select the checkbox to the left of the site to stop the assessment process for.
4. From the **Select** drop-down list, select **Stop Assessment Process**.
5. In the **Comments** field, enter the reason for change, and click **Go**.

Assigning a preferred study locale to a site

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

1. Select **Sites** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Select the checkbox to the left of the site to update.
4. From the **Select** drop-down list, select **Assign Preferred Study Locale**.
5. From the **Language** drop-down list, select the study locale.
6. In the **Comments** field, enter the reason for change, and click **Go**.

7

Managing roles

- [Managing Oracle InForm roles](#)
- [Managing Oracle IRT roles](#)
- [Managing Oracle InForm User Management Tool roles](#)

Managing Oracle InForm roles

- [Viewing the list of Oracle InForm roles](#)
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- [Viewing and modifying Oracle InForm role details](#)
- [Assigning an Oracle InForm role to a user](#)
- [Assigning Oracle Health Sciences Learn classes to a role](#)
- [Setting the display override option](#)
- [Approving or rejecting Oracle InForm roles](#)
- [Transferring Oracle InForm roles](#)

Viewing the list of Oracle InForm roles

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

To view the list of roles:

1. Select **Roles** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down list.

To search for roles:

1. Enter the filter criteria, and click **Find**.
2. To clear the filter criteria, click **Clear**.

Creating Oracle InForm roles

The Create InForm Role page lets you create a role, assign its rights, and select the training classes you want assigned to the role. You can assign the roles to each user, which defines the access level of the account to the system.

When a new user is created and associated to this role, the selected training classes will automatically be assigned to the user. The training is not assigned to users already associated with the role.

1. Select **Roles** from the menu bar.

2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. On the left, above the Roles list, click **Create InForm Role**.
4. Enter the role details.
5. In the **Select Classes** section, select the training classes you want to assign to this role.

 **Note:**

When a new user is created and associated to this role, the selected training classes will automatically be assigned to the user. The training is not assigned to users already associated with the role.

6. Complete one of the following:
 - To save the details and return to the previous page, click **Submit** and then click **Return**.
 - To save the details and create another object, click **Submit and Add Another**.
 - To discard the details and return to the previous page, click **Return**.
 - [Creating Oracle Central Coding roles in Oracle InForm User Management Tool](#)
 - [Creating IVRS roles in Oracle InForm User Management Tool](#)
 - [Creating LNMT roles in Oracle InForm User Management Tool](#)
 - [Creating ODM roles in Oracle InForm User Management Tool](#)

Creating Oracle Central Coding roles in Oracle InForm User Management Tool

Before creating roles, groups, and users, be aware that:

- All role names, group names and user names are case-sensitive.
- For Fast Start production and UAT studies, all integration roles, groups and users will be created as part of the generated XML file. For Fast Forward production and UAT studies, all integration roles, groups and users will be created through automated worklists.

To integrate Oracle Central Coding in Oracle InForm User Management Tool, you need to set up the following roles, groups, and users.

1. For the integration role, create a sponsor role called **Coding Integration Rights Group** with the following rights:
 - *Change Query State from Answered to Closed*
 - *Change Query State from Open to Closed*
 - *Answer Query*
 - *Enter Query in Open State*
2. Create a query group called **Coding Query Group** and associate the Coding Integration Rights Group role to this query group.

3. For the integration user, create a sponsor user called **cc_integration**, assign it the Coding Integration Rights Group and the Coding Query Group, then authorize it for Oracle InForm access.
4. For the authentication role, create a sponsor role called **Coding Authentication Rights Group**, with the following right:
 - *Print.*
5. For the authenticator user, create a sponsor user called **cc_auth**, assign it the Coding Authentication Rights Group role, then authorize it for Oracle InForm access.

 **Note:**

If you are creating the user through a MUL import, user mode must be set to **Interactive User** (column AS in the Users tab).

Creating IVRS roles in Oracle InForm User Management Tool

Before creating roles, groups, and users, be aware that:

- All role names, group names and user names are case-sensitive.
- For Fast Start production and UAT studies, all integration roles, groups and users will be created as part of the generated XML file. For Fast Forward production and UAT studies, all integration roles, groups and users will be created through automated worklists.

To integrate IVRS in Oracle InForm User Management Tool, you need to set up the following roles, groups, and users.

1. For the integration role, create a sponsor role called **solIVRSVendornamehere Rights Group** with the following rights:
 - *Enroll Patients*
 - *View CRF*
 - *Enter Data into a CRF*
 - *Edit Data on a CRF*
 - *Enter Comments into a CRF*
 - *Freeze a CRF*
 - *Unfreeze a CRF*
 - *Lock a CRF*
 - *Unlock a CRF*

This role also needs access to the following groups:

- *Authors*
 - *Publishers*
 - *Sponsor Users Report*
2. Create an item group called **solIVRSVendornamehere**.

 **Note:**

If you want to have multiple item groups, add an incremental number at the end of the group name. For example, solIVRSVendornamehere1, solIVRSVendornamehere2, etc.

3. Set the solIVRSVendornamehere group from the previous step as **Editable**.
This will set a display override for the solIVRSVendornamehere Rights Group role created in step 1.
4. For the integration user, create a sponsor user called **solIVRSVendornamehere** and assign it the solIVRSVendornamehere Rights Group role and solIVRSVendornamehere item group.

 **Note:**

If you are creating the user through a MUL import, user mode must be set to **Interactive User** (column AS in the Users tab).

5. For the configuration role, create a sponsor role called **solAdmin Rights Group**, with the following rights:
 - *Modify System Configuration*
 - *Create User*
 - *Modify User Information*
 - *Manage Rights Groups*
 - *Manage Other Groups*
 - *Manage Sites*
 - *View CRF*
 - *View CRF Signature Information*
 - *View Case Book Signature Information*
 - *Reports*
 - *Deactivate a Rule*
 - *Run a Rule*
 - *Modify a Rule*
 - *View Connections*
 - *View Default Connection*
 - *Navigate by Visit*
 - *Navigate by Form*

 **Note:**

Some of these rights are version-specific. Ignore any rights that do not appear as options in Oracle InForm User Management Tool.

This role also needs access to the following report groups:

- *Authors*
 - *Publishers*
 - *Sponsor Users Report*
6. For the configuration user, create a sponsor user, assign it the configuration role and authorize it for Oracle InForm.

 **Note:**

If you are creating the user through a MUL import, user mode must be set to **Interactive User** (column AS in the Users tab).

Creating LNMT roles in Oracle InForm User Management Tool

Before creating roles, groups, and users, be aware that:

- All role names, group names and user names are case-sensitive.
- For Fast Start production and UAT studies, all integration roles, groups and users will be created as part of the generated XML file. For Fast Forward production and UAT studies, all integration roles, groups and users will be created through automated worklists.

To integrate LNMT in Oracle InForm User Management Tool, you need to set up the following roles, groups, and users.

1. For the integration role, create a sponsor role called **solLNMTImport Rights Group** with the following rights:
 - *Enroll Patients*
 - *View CRF*
 - *Enter Data into a CRF*
 - *Edit Data on a CRF*
 - *Enter Comments into a CRF*
 - *Freeze a CRF*
 - *Unfreeze a CRF*
 - *Lock a CRF*
 - *Unlock a CRF*

This role also needs access to the following groups:

- *Authors*
- *Publishers*
- *Sponsor Users Report*

2. Create an item group called **solLNMTImport**.

 **Note:**

If you want to have multiple item groups, add an incremental number at the end of the group name. For example, solLNMTImport1, solLNMTImport2, etc.

3. Set the solLNMTImport item group from the previous step as **Editable**.

This will set a display override for the solLNMTImport Rights Group role created in step 1.

4. For the integration user, create a sponsor user called **solLNMTImport** and assign it the **solLNMTImport Rights Group** role and **solLNMTImport** item group.

If you are creating the user through a MUL import, user mode must be set to **Interactive User** (column AS in the users tab).

5. For the configuration role, create a sponsor role called **solAdmin Rights Group**, with the following rights:

- *Modify System Configuration*
- *Create User*
- *Modify User Information*
- *Manage Rights Groups*
- *Manage Other Groups*
- *Manage Sites*
- *View CRF*
- *View CRF Signature Information*
- *View Case Book Signature Information*
- *Reports*
- *Deactivate a Rule*
- *Run a Rule*
- *Modify a Rule*
- *View Connections*
- *View Default Connection*
- *Navigate by Visit*
- *Navigate by Form*

 **Note:**

Some of these rights are version-specific. Ignore any rights that do not appear as options in Oracle InForm User Management Tool.

This role also needs access to the following report groups:

- *Authors*
 - *Publishers*
 - *Sponsor Users Report*
6. For the configuration user, create a sponsor user, assign it the configuration role and authorize it for Oracle InForm.

 **Note:**

If you are creating the user through a MUL import, user mode must be set to **Interactive User** (column AS in the Users tab).

Creating ODM roles in Oracle InForm User Management Tool

Before creating roles, groups, and users, be aware that:

- All role names, group names and user names are case-sensitive.
- For Fast Start production and UAT studies, all integration roles, groups and users will be created as part of the generated XML file. For Fast Forward production and UAT studies, all integration roles, groups and users will be created through automated worklists.

To integrate ODM in Oracle InForm User Management Tool, you need to set up the following roles, groups, and users.

1. For the integration role, create a sponsor role called **ODM Rights Group** with the following right:
 - *Print*
2. For the ODM user, create a sponsor user called **odm_user**, assign it the authentication role and authorize it for Oracle InForm access.

 **Note:**


If you are creating the user through a MUL import, user mode must be set to **Interactive User** (column AS in the Users tab).

Viewing and modifying Oracle 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.

1. Select **Roles** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. In the **Role Name** column, click a role.
4. Modify the role details.


 **Note:**

To associate users to a role, click the **Associate Users icon** () to the right of the Role field.

5. In the **Reason for Change** field, enter the reason for modifying the role details.
6. Complete one of the following:
 - To save the changes and return to the previous page, click **Submit** and then click **Return**.
 - To cancel the changes and return to the previous page, click **Return**.

Assigning an Oracle InForm role to a user

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.

1. Select **Roles** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. In the **User Association** column, click the  icon for a role.
4. Select the users to give the role to.

When you assign a user to a role that has training associated to it, the training is automatically assigned to the user. The training is not assigned to users already associated with the role.

5. Click **Submit**, and then click **Return**.

Assigning Oracle Health Sciences Learn classes to a role

To check whether Oracle Health Sciences Learn is enabled for the trial, select **Configuration** from the menu bar; Oracle Health Sciences Learn is enabled for the trial if **Switchoff HSLearn** in the Trial Configuration section is **not** selected.

 **Note:**

When you assign a user to a role that has training associated to it, the training is automatically assigned to the user. The training is not assigned to users already associated with the role.


1. Select **Roles** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Click the **Role Name** link, and scroll down to the bottom of the Role Details page.
4. In the **Select Classes** section, select the **Available** class or classes to assign to the role, and move them to the **Selected** list.
5. Click **Submit**.

Setting the display override option

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

Note:

For Oracle InForm 6.1 and above, display overrides should only be defined in Oracle Central Designer and not Oracle InForm User Management Tool.

1. Select **Roles** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. In the **Display Override** column, click the  icon for a role.
4. Select the item groups for the display override, and then select **Read-only**, **Editable**, or **Hidden**.
5. Click **Submit**, and then click **Return**.


Approving or rejecting Oracle InForm roles

The InForm Roles page lets you approve and reject Oracle InForm roles. You can either approve or reject Oracle InForm roles depending on your access rights. You can approve or reject only those roles which are in the Pending status.

1. Select **Roles** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Select the checkbox to the left of the role to approve or reject.
4. From the **Select** drop-down list, select **Approve** or **Reject**.
 - If you select **Approve**, complete the Electronic Signature Affidavit and click **Submit**.
 - If you select **Reject**, enter the reason for rejection in the **Comments** field.
5. Click **Go**.

Transferring Oracle InForm roles

The InForm Roles page also lets you transfer Oracle InForm roles.

1. Select **Roles** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. In the **Transfer Role** column, click the  icon for a role.

 **Note:**

At least one user must be associated to the role.

4. Select one or more users from the **User(s) Available** list, and click the arrow buttons to move them to the **Transfer to** list.
5. From the **Transfer to** drop-down list, select a role to transfer the user to.
6. Click **Submit**, and then click **Return**.

Managing Oracle IRT roles

- [Viewing the list of Oracle IRT roles](#)
- [Creating Oracle IRT roles](#)
- [Approving or rejecting Oracle IRT roles](#)

Viewing the list of Oracle IRT roles

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

To view the list of Oracle IRT roles:

1. Select **Roles** from the menu bar.
2. In the upper left, click **IRT Roles**.
3. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.

To search for Oracle IRT roles:

1. Enter the filter criteria, and click **Find**.
2. To clear the filter criteria, click **Clear**.

Creating Oracle 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.

1. Select **Roles** from the menu bar.
2. On the left, click the **IRT Roles** tab.
3. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
4. On the left, above the Roles list, click **Create IRT Role**.
5. Enter the role details.
6. Complete one of the following:

- To save the details and return to the previous page, click **Submit** and then click **Return**.
- To save the details and create another object, click **Submit and Add Another**.
- To discard the details and return to the previous page, click **Return**.

Approving or rejecting Oracle IRT roles

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

1. Select **Roles** from the menu bar.
2. In the upper left, click **IRT Roles**.
3. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
4. Select the checkbox to the left of the role to approve or reject.
5. In the **Comments** field, enter a reason for change, and then click **Go**.

Managing Oracle InForm User Management Tool roles

- [Oracle InForm User Management Tool roles and rights](#)
- [Viewing the list of Oracle InForm User Management Tool roles](#)
- [Creating Oracle InForm User Management Tool roles](#)
- [Assigning SSO roles](#)
- [Viewing and modifying Oracle InForm User Management Tool role details](#)
- [Assigning a Oracle InForm User Management Tool role to a user](#)
- [Deleting Oracle InForm User Management Tool roles](#)

Oracle InForm User Management Tool roles and rights

Oracle InForm User Management Tool roles are assigned certain rights and privileges that help them perform different tasks.

Note:

If you are a Oracle InForm User Management Tool Admin who creates and modifies Oracle InForm User Management Tool roles in Oracle InForm User Management Tool, if you do not see one of the rights listed in this section and want to grant that right to a Oracle InForm User Management Tool role, you must enter a ticket in the HSGBU Support Cloud (<https://hsgbu.custhelp.com>) to request the right to be added to the appropriate Admin role for your Sponsor. After the right is added you can assign it to any Oracle InForm User Management Tool role.

- [UMT Admin rights](#)
- [Import/Export rights](#)
- [User/Sponsor/Site details rights](#)

- [Log file rights](#)
- [Approval rights](#)
- [InForm rights](#)
- [Miscellaneous rights](#)

UMT Admin rights

Rights	Description
Create UMT User	Create a Oracle InForm User Management Tool user.
Modify UMT User	Edit Oracle InForm User Management Tool user details.
View UMT User	View Oracle InForm User Management Tool user details.
Manage UMT User	Edit Oracle InForm User Management Tool user country details and user association with trials.
Create UMT Role	Create a Oracle InForm User Management Tool role.
Modify UMT Role	Sponsor Role Users: Modify sponsor role user details. PF Role Users: Update default role settings of PF role.
View UMT Role	View Oracle InForm User Management Tool user role details.
Manage UMT Role	Edit the association between a user and a role.
Manage HSLearn Training	Configure and edit Oracle Health Learn settings.
Manage SSO	Authorize a user to an Oracle InForm study. Send the authorization email to an Oracle InForm SSO user.
Assign SSO Role	Give access to the SSO Roles tab in Oracle InForm User Management Tool, which shows all sponsor type global users for a tenant and lets you assign particular CDA rights for Oracle Life Sciences IAMS to any of these users. Assign the Assign SSO Role right to give users access to all sponsor type global users for the a tenant.

- [SSO roles](#)

SSO roles

SSO roles give an Oracle InForm user the right to reset passwords for other users in Oracle Life Sciences IAMS. These roles should only be given to CDA or Support users. If a user's UMT role has the Assign SSO Roles right, the SSO Roles tab is visible in the UMT user interface.

Roles	Description
GlobalResetPasswordRole	Gives access to all types of users.
ResetPasswordRole	Gives access to accounts that have access to production studies.
IntegrationResetPasswordRole	Provides ability to reset passwords for IAMS Integration type accounts.
TrainingResetPasswordRole	Provides ability to reset passwords for users with access to training studies only.
UATResetPasswordRole	Provides ability to reset passwords for users with access to UAT studies only.

Import/Export rights

Rights	Description
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 rights

Rights	Description
Create Sponsor	Create a sponsor.
Modify Sponsor Details	Edit sponsor details.
View Sponsor Details	View sponsor details.
Create Trial	Create a trial.
Modify Trial Details	Edit trial details.
Create InForm User	Create Oracle InForm user.
Modify InForm User	Edit Oracle InForm user details.
View InForm User	View Oracle 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 Oracle InForm.
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.

Rights	Description
View IRT User Details	Rights to view the Oracle IRT user details.
View IRT Site Details	Rights to view the Oracle IRT site details.
View IRT Right and Roles	Rights to view the Oracle IRT right and roles.
Manage IRT User Details	Rights to edit the Oracle IRT user details.
Manage IRT Site Details	Rights to edit the Oracle IRT site details.
Manage IRT Right and Roles	Rights to edit the Oracle IRT right and roles.
Load to IRT	Load user and site details to Oracle IRT.
SendInFormXML	Gives access to the Send to InForm button on the Trials page Use this button to bulk load Admin data to a UAT trial or a pre Go-Live production trial. For more information, see GeneratingOracle InForm XML .

Log file rights

Rights	Description
View Import/Export Log File	View Oracle InForm User Management Tool Import Excel for Oracle InForm application log files.

Approval rights

Rights	Description
Approve Site Details	Approve or reject site details.
Approve InForm User Details	Approve, reject or terminate Oracle InForm user.
Approve InForm Rights and Role	Approve or reject Oracle InForm role.
Approve InForm Groups	Approve or reject Oracle InForm group.
Approve InForm Configuration	Approve or reject Oracle InForm settings.
Approve IRT Rights and Role	Approve or reject Oracle IRT role.

InForm rights

Rights	Description
Edit InForm Config Settings	Edit the Oracle InForm configuration settings.
Create InForm Rights and Role	Create Oracle InForm rights and roles.
Modify InForm Rights and Role	Edit Oracle InForm rights and roles.
Manage InForm Rights and Role	Manage the user-role associations.
Create InForm Groups	Create Oracle InForm group details.
Modify InForm Groups	Edit Oracle InForm group details.

Rights	Description
Manage InForm Groups	To enable user, role association with groups. Associate an Oracle InForm group with a user and a group.
View InForm Config	View Oracle InForm configuration details.
View InForm Rights and Roles	View Oracle InForm rights and roles.
View InForm Groups	View Oracle InForm groups.

Miscellaneous rights

Rights	Description
View Reports	To view the billing details report, training report, and assessment detail report.
View Rights Groups	For Oracletype users only. Allows users in a support role to view Rights Groups information.

 **Note:**

You can only add this right through the Oracle InForm User Management Tool user interface. MUL template provisioning is not supported.

View Other Groups	For Oracletype users only. Allows users in a support role to view Other Groups information.
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 **Note:**

You can only add this right through the Oracle InForm User Management Tool user interface. MUL template provisioning is not supported.

Rights	Description
View Sites	For Oracletype users only. Allows users in a support role to view Sites information.

 **Note:**

You can only add this right through the Oracle InForm User Management Tool user interface. MUL template provisioning is not supported.

Viewing the list of Oracle InForm User Management Tool roles

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

To view the list of Oracle InForm User Management Tool roles:

1. Select **Roles** from the menu bar.
2. Select the sponsor company from the **Current Sponsor Company** drop-down list.
3. In the upper left, click **UMT Roles**.

To search for Oracle InForm User Management Tool roles:

1. Enter the filter criteria, and click **Find**.
2. To clear the filter criteria, click **Clear**.

Creating Oracle InForm User Management Tool 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.

1. Select **Roles** from the menu bar.
2. Select the sponsor company from the **Current Sponsor Company** drop-down list.
3. On the left, click the **UMT Roles** tab.
4. On the left, above the Roles list, click **Create UMT Role**.
5. Enter a name for the role, and select the rights as needed in each category.
6. Complete one of the following:

- To save the details and return to the previous page, click **Submit** and then click **Return**.
- To save the details and create another object, click **Submit and Add Another**.
- To discard the details and return to the previous page, click **Return**.

Assigning SSO roles

SSO roles give an InForm user the right to reset passwords for other users in Oracle Life Sciences IAMS. These roles should only be given to CDA or Support users.

1. Select **Roles** from the menu bar.
2. Select the sponsor company from the **Current Sponsor Company** drop-down list.
3. Click the **SSO Roles** tab.
The SSO Roles tab is only visible if your UMT role has the Assign SSO Roles right.
4. Make sure that the **Oracle Users** option is selected.
5. In the **Selected Users** list, select the users you want to give the SSO roles to.
6. In the **Selected Roles** list, select the roles to assign to the users selected in step 5.
7. Enter a **Reason For Change** , and click **Submit**.

Viewing and modifying Oracle InForm User Management Tool 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.

1. Select **Roles** from the menu bar.
2. Select the sponsor company from the **Current Sponsor Company** drop-down list.
3. In the upper left, click **UMT Roles**.
4. In the **Role Name** column, click a role.
5. Modify the Oracle InForm User Management Tool role details.
6. In the **Reason For Change** field, enter the reason for modifying the role details.
7. Complete one of the following:
 - To save the changes and return to the previous page, click **Submit** and then click **Return**.
 - To cancel the changes and return to the previous page, click **Return**.

Assigning a Oracle InForm User Management Tool role to a user

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.

1. Select **Roles** from the menu bar.
2. In the upper left, click **UMT Roles**.
3. Select the sponsor company from the **Current Sponsor Company** drop-down list.

4. Click the  icon for a role.
5. Select the users to assign to the role.
6. Click **Submit**, and then click **Return**.

Deleting Oracle InForm User Management Tool roles

The UMT Roles page lets you delete roles. However, you must specify the reason for deleting the Oracle InForm User Management Tool role.

1. Select **Roles** from the menu bar.
2. In the upper left, click **UMT Roles**.
3. Select the sponsor company from the **Current Sponsor Company** drop-down list.
4. Select the checkbox to the left the role to delete.
5. In the **Comments** field, enter the reason for deleting the role and then click **Delete**.

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Managing groups

- [Viewing the list of groups](#)
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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:

1. Select **Groups** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.

To search for groups:

1. Enter the filter criteria, and click **Find**.
2. To clear the filter criteria, click **Clear**.

Creating groups

1. Select **Groups** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. On the left, above the Groups list, click **Create Group**.
4. Enter the group details.
5. Complete one of the following:
 - To save the details and return to the previous page, click **Submit** and then click **Return**.
 - To save the details and create another object, click **Submit and Add Another**.
 - To discard the details and return to the previous page, click **Return**.

Importing group data from Oracle Central Designer with the Shell Report

For Oracle InForm 6.1 and above, Display Overrides and System configuration settings are defined in Oracle Central Designer and not Oracle InForm. Rights Groups that need Display Overrides need to be defined in Oracle Central Designer as well.

Signature Group content should be defined in Oracle Central Designer. Query Group names may be defined in Oracle Central Designer as well.

Signature Groups, Rights Groups and Query Groups must also be defined in Oracle InForm User Management Tool to assign roles/users to them. If this is done manually, there is a risk of introducing errors.

The information defined in Oracle Central Designer can be exported to an XML file called a Shell Report. You can import the Shell Report into Oracle InForm User Management Tool to load the data defined in Oracle Central Designer into Oracle InForm User Management Tool. Users or roles can then be assigned to these groups, and the system configuration settings will be set.




Note:

Item groups and display overrides should only be defined in Oracle Central Designer. Importing the Shell Report will not import these into Oracle InForm User Management Tool. Importing the Shell Report will only import signature groups, rights groups and query groups.

1. Select **Groups** from the menu bar.
2. Select the trial from the **Trial** drop-down list.
3. On the left, click **Import Shell Report**.
4. In the **Import Shell Report** dialog box, browse to the XML file created in Oracle Central Designer, and click **Import**.

Viewing and modifying user and group associations

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

1. Select **Groups** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. In the **User Association** column, click the  icon for a group.
4. Select the users to include in the group.
5. Click **Submit**, and then click **Return**.

Validating AutoQuery groups

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

1. Select **Groups** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Below the list of groups, click **AutoQuery/CTValidation**.
4. Select the **AutoQuery User** and the **CT Validation User**.
5. Click **Submit**, and then click **Return**.

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.

1. Select **Groups** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. In the **Group Name** column, click a group.
4. Modify the group details.
5. In the **Reason For Change** field, enter a reason for change.
6. Click **Submit**, and then click **Return**.

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.

1. Select **Groups** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Select the checkbox to the left of the group to approve or reject.
4. From the **Manage Group** drop-down list, select **Approve** or **Reject**.
 - If you select **Approve**, complete the Electronic Signature Affidavit and click **Submit**.
 - If you select **Reject**, enter the reason for rejection in the **Comments** field.

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Managing reports

- [Generating reports](#)
- [Billing details reports](#)
- [Training reports](#)
- [User detail reports](#)
- [Worklist — Site report](#)
- [Worklist — User report](#)
- [Trial archive package \(TAP\) report](#)
- [Data entry worklist statistics reports](#)

Generating reports

1. Select **Reports** from the menu bar.
2. On the left, select **General** reports.
3. On the right, select the report to run.

 **Note:**

For worklist reports you must also select either **Site** or **User** to generate the appropriate report.

4. Fill in the fields, and click **Generate**.
 - To download the report as an Excel spreadsheet, click **Export to Excel**.
 - To download the report as a DAT file, click **Export to File**.
 - To print the report, click **Print**.

 **Note:**

Both assessment reports and master reports can still be generated, but since they refer to outdated processes, no data is populated in these reports.

Billing details reports

Billing details report shows a comparison between the approved Statement of Work (SOW) and the current study status.

Field	Description
Sponsor Company	The sponsor company name associated with the study. For example, "Pharma Company ABC"
Reference	SOW contract number.
Contracted No of Sites	Number of sites contracted for the study according to the approved SOW.
Contracted No of Site Assessments	Related to an outdated process. No longer in use.
Contracted No of Users	Number of users contracted for the study according to the approved SOW.
Contracted No of Countries	Number of countries associated with the study according the approved SOW.
Contracted No of IOL Accounts	Number of HS Learn accounts contracted for the study according to the approved SOW.
No of Provisioning	Related to an outdated process. No longer in use.
Trial	Name of the study. For example, "Trial123".
Protocol	Protocol number associated with the study. For example, "Protocol123".
No of Sites Associated	Actual number of sites associated with the study at the time the report is generated.
No of Site Assessments	Related to an outdated process. No longer in use.
No of Users	Actual number of users associated with the study at the time the report is generated.
Selected No of Countries	Actual number of countries associated with the study at the time the report is generated.
IOL Accounts Created	Actual number of HS Learn accounts associated with the study at the time the report is generated.

Training reports

Although **Training** is a selectable report within **General** reports, this report is no longer provided by the **Reports** option from the menu bar. Instead, training reports can be obtained through **HSLearn Training**.

For more information, see Managing training.

User detail reports

This report provides high level details about all users associated with the study.

Field	Description
Sponsor	Sponsor name associated with the user. For example, "Pharma Company ABC".
Trial	Name of the study associated with the user. For example, "Trial123".

Field	Description
First name	First name of the user.
Last name	Last name of the user.
User name	User name associated with the user. For example, "jdoe".
Country	Country associated with the user.
Email	Email address associated with the user.
User type	User type associated with the user. Options are: <ul style="list-style-type: none"> • Site • Sponsor • PF
Role	Role name the user has been assigned to. For example, "johnsiteuser".
User status	Current status of the user. Options are: <ul style="list-style-type: none"> • Active • Inactive • Terminated
Site Association Description	Site or sites that the user currently has access to.

Worklist — Site report

Site reports show all worklists generated at the site level for a study within a particular period.

Field	Description
Trial Name	Name of the study.
Site number	Number of the site associated with the study.
Site number	Name of the site associated with the study. For example, "Metropolis General".
Address1	First address line for the associated site. For example, "344 Clinton Street".
Address2	Second address line for the associated site. For example, "Suite 100".
City	Name of the city where the associated site is located.
State	Name or initials of the state where the associated site is located.
Country	Name of the country where the associated site is located.
Postal code	Postal code for where the associated site is located.
E-mail address	E-mail address associated with the site.
Phone	Phone number associated with the site.
Study Version	Version of the study entered in for the report. Otherwise, "latest" is shown.
Modified By	User name of the user who last made any updates to the site details.

Field	Description
Modified Date	Time stamp for when site details were last updated. For example, "02/11/2022 14:11".
Status	Current status. Options are: <ul style="list-style-type: none"> • New • Change • Delete • Reinstate

Worklist — User report

User reports show all worklists generated at the user level for a study within a particular period.

Field	Description
Trial Name	Name of the study.
User Name	User name of the associated user. For example, "jdoe".
First Name	First name of the user.
Last Name	Last name of the user.
Rights Group	Rights group associated with the user.
Email	Email associated with the user.
Newly Associated Sites	The associated sites that have been added to the current worklist after the previous worklist was processed.
Newly Dis-Associated Sites	The associated sites that have been removed in the current worklist after the previous worklist was processed.
Associated Groups	Any groups associated with the user. For example, "Ad Hoc Users".
Dis-Associated Groups	Any groups disassociated with the user. For example, "User InFo Data users".
MODIFIEDBY	User name of the user who last made any updates to this user details. For example, "pwhite".
MODIFIEDDATE	Time stamp from when user details were last updated. For example, "02/11/2022 14:11".
STATUS	Audit update information. Options are: <ul style="list-style-type: none"> • New • Change • Delete • Reinstate

Trial archive package (TAP) report

The trial archive package (TAP) report is an audit report that shows changes to studies, users, and sites.

Field	Description
SponsorName	Name of the sponsor company. For example, "Pharma Company ABC".
TrialName	Name of the study. For example, "Trial123".
ENTITY	Entity that is being reported on. Options are: <ol style="list-style-type: none"> 1. Trial 2. User 3. Site
RECORDID	Record ID number.
ACTION	Executed action for the entity being reported on. Options are: <ul style="list-style-type: none"> • Add • Update
FIELDNAME	Field name that was added or modified. For example, "SITENAME".
FIELDVALUE	Value of the modified field. For example, "Gotham General".
MODIFIEDBY	User name of the user who added or modified the entity. For example, "jdoe".
MODIFIEDDATE	Time stamp from when the entity was last updated. For example, "02/11/2022 14:11".
REASONCHANGED	Reason for change. For added entities, this field will display "Initial Entry"; for modified entities, this field will display the comment the updating user entered when they modified the field.

Data entry worklist statistics reports

The data entry worklist statistics report encompasses all changes made on users, studies, and sites, as well as the reasons and times for each change.

Field	Description
Sponsor Company	Name of the sponsor company. For example, "Pharma Company ABC".
Trial	Name of the study. For example, "Trial123".
User	User name of the associated user. For example, "jdoe".
Site	Name of the site. For example, "Gotham General".
Status	Current status. Options are: <ul style="list-style-type: none"> • Change • New • Delete • Reinstate
Date Modified	Time stamp from when the item was last updated. For example, "02/11/2022 14:11".
UM	User name of the user who performed the UM (user manager) tasks. For example, EUH member if the UM tasks were performed by Oracle.

Field	Description
UA	User name of the user who performed the UA (user approver) tasks. For example, EUH member if the UA tasks were performed by Oracle.
Completion Time	Time stamp from when the worklist was last updated. For example, "02/11/2022 14:11".
QC	User name of the user performing quality check (QC).
Completion Time (QC)	Time stamp from when the quality check (QC) was completed. For example, "02/11/2022 14:11".
QC Rejected (Yes/No)	Shows if the quality check (QC) was rejected or not. Options are: <ul style="list-style-type: none">• Yes• No
Completion SLA (Yes/No)	Related to an outdated process. No longer in use.
Within QC SLA (Yes/No)	Related to an outdated process. No longer in use.
Comments	Displays the comment added when the change was made

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Managing assessment

- [Viewing the list of assessed users](#)
- [Updating assessment status for an assessed user](#)
- [Viewing assessment comment history](#)
- [Adding, editing, and deleting assessment comments](#)

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:

1. Select **Assessments** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. From the **Site** drop-down list, select the site associated with the assessed users.

To search for assessed users at a site:

1. Enter the filter criteria, and click **Find**.
2. To clear the filter criteria, click **Clear**.

Updating assessment status for an assessed user

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

1. Select **Assessments** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. From the **Site** drop-down list, select the site associated with the assessed users.
4. Select the checkbox to the left of the user to update.
5. From the **Select** drop-down list, select **Update Assessment Status**.
6. In the **Comments** field, enter the reason for the update, and then click **Go**.
7. Below Update Assessment Status, select an option.
8. Enter a summary of the update in the **Assessment Summary Box** field.
9. Click **Update**, and then click **Return**.

Viewing assessment comment history

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

1. Select **Assessments** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. From the **Site** drop-down list, select the site associated with the assessed users.
4. In the right-most column, click the book icon for a user.
 - To go back to the previous page, click **Return**.

Adding, editing, and deleting assessment comments

The Add New Comments link on the Assessments Comments History Page lets you add new comments to an assessed user's comments history. The Edit or Delete link on the Assessment Comments History page lets you edit or delete comments from an assessed user's assessments comments history.

To add comments:

1. Select **Assessments** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. From the **Site** drop-down list, select the site associated with the assessed users.
4. In the right-most column, click the book icon for a user.
5. Click **Add New Comments**.
6. Enter the comments in the **Public Comments** and **Private Comments** fields.

 **Note:**

You must enter comments in both fields.

7. Click **Submit**.
 - To go back to the previous page, click **Return**.
 - To clear the entered comments, click **Clear**.

To edit comments:

1. Click **Edit/Delete** on a comment.
2. Edit the comment.

 **Note:**

In the Comment Type column, you can change the comment to public or private.

3. Below the list of comments, enter the reason for change in the **Comments** field.
4. In the **Edit/Delete** column for a comment, click **Update**.
 - To go back to the previous page, click **Return**.

To delete comments:

1. Click **Edit/Delete** on a comment.
2. Below the list of comments, enter the reason for deletion in the **Comments** field.
3. In the **Edit/Delete** column, click the trash can icon.
 - To go back to the previous page, click **Return**.

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Managing log files

- [Viewing the list of log files and transferred data](#)
- [Archiving log files](#)
- [Viewing archived log files](#)

Viewing the list of log files and transferred data

The Log Files page displays the list of log files and its details.

1. Select **Log Files** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Enter the filter criteria and click **Find**.
 - To view the list of transferred data, click **HTML Log View**.
 - To clear the filter, click **Clear**.

Archiving log files

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

1. Select **Log Files** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Enter the filter criteria and click **Find**.
4. Select the checkbox to the left of the log file to archive.
5. In the **Comments** field, enter the reason for change, and click **Archive**.

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.

1. Select **Log Files** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. In the lower left, click **View Archive of Log Files**.
 - To view list of transferred data, click **Batch ID**.
 - To go back to the previous page, click **Return**.

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Oracle Health Sciences Learn (HS Learn) training

- [Assigning an Oracle Health Sciences Learn class to a trial](#)
- [Managing training](#)

Assigning an Oracle Health Sciences Learn class to a trial



Note:

You must disable the **Switchoff HSLearn** option before you can assign Oracle Health Sciences Learn classes for a trial. To check whether Oracle Health Sciences Learn is enabled for the trial, select Configuration from the menu bar; Oracle Health Sciences Learn is enabled for the trial if **Switchoff HSLearn** in the Trial Configuration section is **not** selected.

1. Select **HSLearn Training** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. In the **Assign Classes to Trial** tab, select the classes to assign to the trial and specify a number of seats.
4. Click **Submit**.

You can also assign Oracle Health Sciences Learn training to a user or a role. For more information, see:

- [Assigning HS Learn classes to a user](#)
- [Assigning HS Learn classes to a role](#)

Managing training

The Manage Training page lets you view the list of classes assigned to the users and their statuses, and to assign and reassign classes to the users.

1. Select **HSLearn Training** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. On the left, click the **Manage Training** tab.
4. Enter the filter criteria and click **Find**.

Oracle InForm User Management Tool users can go to Oracle Clinical One Platform to generate reports or to view the status of their users.

Oracle InForm study users can log into Oracle Health Sciences Learn to view, print, or download their training completion certificates.

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Configuring settings

- [Configuring Oracle InForm settings](#)
- [Oracle InForm User Management Tool Settings](#)
- [Configuring assessment](#)
- [Configuring assessment benchmark](#)

Configuring Oracle InForm settings

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



Note:

For Oracle InForm 6.1 and above, most Oracle InForm configuration options will be grayed out because these should be configured in Oracle Central Designer instead.

- [Configuring editable system configuration options for trials on the trial level](#)
- [Configuring editable system configuration options for new and existing trials on the sponsor company level](#)
- [Configuring a custom review state](#)
- [Exporting Oracle InForm configuration settings](#)

Configuring editable system configuration options for trials on the trial level

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

1. Select **Configuration** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Enter the settings required.



Note:

The Product Locale is the language—English or Japanese—of the product user interface. Menus, controls, commands, system screen labels, error messages, and so on are written in the selected language. Oracle creates product locales.

4. Enter the reason for modifying the settings in the **Comments** field, and click **Submit**.
5. To discard the changes, click **Return**.

Configuring editable system configuration options for new and existing trials on the sponsor company level



Note:

Updating a configuration setting at the sponsor level does not update all existing trials. It only impacts new trials created after the setting is updated.

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.

1. Select **Configuration** from the menu bar.
2. Select the current sponsor company from the **Current Sponsor Company** drop-down list, and a trial from the **Trial** drop-down list.
3. On the upper left, click the **InForm Config** tab.
4. In the **Editable System Config Options** and **Settings** sections, set the configuration options.

This updates all existing trials and sets the default value for new trials to be created under the selected sponsor company.

- The value you select for the **Date Format** is used by Oracle InForm User Management Tool as the default value when creating new users in Oracle InForm User Management Tool, and is the value that will be used for the users in Oracle InForm. The date format for a specific user can be changed on the Users Details page
 - The **Product Locale** field is required. The **Product Locale** is the language—English or Japanese—of the product user interface. Menus, controls, commands, system screen labels, error messages, and so on are written in the selected language. Oracle creates product locales.
5. Enter the reason for modifying the settings in the **Comments** field, and click **Submit**.
 6. To discard the changes, click **Return**.

Configuring a custom review state

The Custom Review settings page lets you configure custom review states and custom review stages for Oracle InForm 5.5 trials. Custom Review states should be defined in Oracle Central Designer only for Oracle InForm 6.0 and above.

1. Select **Configuration** from the menu bar.
2. Click **Custom Review State Config**.
3. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.

 **Note:**

Select an Oracle InForm 5.5 trial.

4. Enter the settings.
5. Enter the comments for modifying the configurations in the **Comments** field, and click **Submit**.
6. Click **Remove Review Stage** to delete the custom review stages.

Exporting Oracle InForm configuration settings

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

1. Select **Configuration** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Click the **Export to Excel** or **Export to File**.
4. In the browser window, click **Open** or click **Save**.

Oracle InForm User Management Tool Settings

- [Configuring Oracle InForm User Management Tool settings](#)
- [Configuring default trials, sites, and user settings](#)
- [Exporting Oracle InForm User Management Tool configuration settings](#)

Configuring Oracle InForm User Management Tool 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 Oracle InForm User Management Tool users during creation is based on the settings configured on the UMT Settings page.

1. Select **UMT Settings** from the menu bar.
2. Modify the Oracle InForm User Management Tool configuration settings.
3. Enter the reason for modification in the **Reason for change** field, and click **Submit**.
4. To discard the changes, click **Return**.

Configuring default trials, sites, and user settings

The Configuration settings page lets you configure Oracle InForm User Management Tool settings for trial configuration, site configuration, and user configuration. New sites and Oracle InForm users created under a selected trial reflect these settings.

1. Select **Configuration** from the menu bar.

2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Select **UMT Config**.
4. Enter the settings in the **Trial Configurations** sections.

Note the following fields:

- **Trial Level Duplicate**—This trial level setting is dependent on how the Sponsor level setting **Is Duplicate Validation trial specific?** is configured.
If the Sponsor level setting is **not** selected, the trial level setting is used.
 - **Trial Level Duplicate = Yes**—Select to allow duplicate user name validation.
 - **Trial Level Duplicate = No**—Select to allow duplicate user names to be created in other studies for this Sponsor.

If the Sponsor level setting is selected, duplicate user name validation is not run at the Sponsor or study level.
- **Sponsor Name for UMT Mails**—Select the required option to use the sponsor name for Oracle InForm User Management Tool 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 name with sponsor customer name.
- **Automated Authorization**—Select to allow site or sponsor users (SSO and non-SSO) for a study to be automatically authorized and to receive automated authorization emails.

 **Note:**

The Automated Authorization option is visible at the study level, but the automation is active only after the status of the study is changed to Fast Forward in UMT.

- After users are trained and approved, SSO users will be automatically authorized to Oracle InForm and non-SSO users will be automatically marked for upload to Oracle InForm.
- For SSO users, the Authorization email will be sent automatically after the user is both successfully authorized in Oracle Life Sciences IAMS and created/reinstated in Oracle InForm.
- For non-SSO users, the account details email will be sent automatically to the user after they are successfully created/reinstated in Oracle InForm.
- Enabling the Automated Authorization feature automatically authorizes newly approved and trained users and automatically sends their authorization emails. However:
 - * Previously approved and trained users must be manually authorized, and their authorization emails must be manually sent.

- * Previously authorized users who have not received their authorization emails must have their emails manually sent.
- **Free Phone Number URL**—Select the required free phone number URL. The available options are:
 - **Oracle Helpdesk**
 - **Sponsor Specific**—If you select Sponsor Specific, enter the URL in the Sponsor Specific URL text box.
- 5. Enter the settings in the **Site Configuration** sections.
Note the following field:
 - **Default Study Version**
 - **Latest**—Select this option to set the latest study version as the default. New sites and reinstated sites will always be assigned the latest study version.
 - **Multiple**—Select this option to set multiple study versions as the default. You can select a specific study version for newly created sites and for reinstated sites. For more information, see [Marking a not participating site as participating](#). To add a new study version, select **Multiple**.
- 6. Enter the settings in the **User Configuration** sections.
- 7. Enter the reason for modifying the settings in the **Comments** field, and click **Submit**.
- 8. To discard the changes, click **Return**.

Exporting Oracle InForm User Management Tool configuration settings

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

1. Select **Configuration** from the menu bar.
2. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
3. Click the **Export to Excel** or **Export to File**.
4. In the browser window, click **Open** or click **Save**.

Configuring assessment

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

1. Select **Configuration** from the menu bar.
2. Click **Assessment Config**.
3. Select the sponsor company and trial from the **Current Sponsor Company** and **Trial** drop-down lists.
4. Enter the comments for modifying the configurations in the **Comments** field, and click **Submit**.
5. To discard the changes, click **Return**.

Configuring assessment benchmark

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

1. Select **Configuration** from the menu bar.
2. Click **Assessment Benchmark**.
3. 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 the sponsor company level by not selecting a trial.

4. Enter the comments for modifying the configurations in the **Comments** field, and click **Submit**.
5. To discard the changes, click **Return**.


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Loading data into the Oracle InForm User Management Tool

- [About loading data into the Oracle InForm User Management Tool](#)
- [Using the MUL Template to add or change data](#)
- [Creating a master template from the MUL Template](#)
- [Entering data in the MUL Template](#)

About loading data into the Oracle InForm User Management Tool

You can create users and assign sites and user rights in the Oracle InForm User Management Tool user interface. However, to upload large amounts of user and site data, Oracle recommends that you perform a bulk import from a Microsoft Excel spreadsheet. To facilitate this process, Oracle provides a Master User List (MUL) Template (also referred to as a *Joint Template* or *Composite Template*) to create and upload users and their sites and rights. You can download this template directly from Oracle InForm User Management Tool.

Depending on how your Excel options are configured, you may see an Excel error icon () in the Oracle InForm Version field on the Welcome page after you open a template that you downloaded from Oracle InForm User Management Tool using Microsoft Excel. You can ignore the icon and associated message, or you can update your Excel options to remove it. For more information, see [Updating your Excel options](#).

This template can be used for multiple workflows:

- To update data for a specific trial.
Download the template specifying an existing trial. You can then add or change existing data for this trial in the spreadsheet and re-import the data as needed. For more information, see [Using the MUL Template to add or change data](#).
- To create a template to use as a common starting point for all trials.
Download the template without specifying a trial. This allows you to reuse a single template with common rights and roles as a starting point for all trials.

For example, if you use the same Rights & Roles for all of your trials, you could populate them in the template and then use that template as the starting point for all of your trials.


For more information, see [Creating a master template from the MUL Template](#).

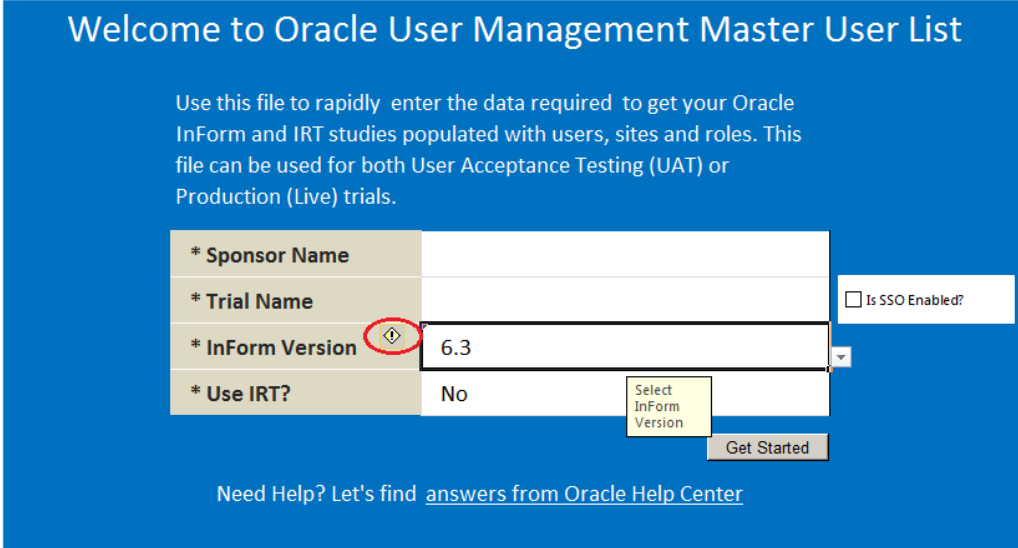
Regardless of which workflow you are using:

- You must have macros enabled.
- Columns labeled in blue are required fields and must be populated.
- Ensure that no blank rows exist between completed rows.

- For Oracle InForm 6.0 and above, Oracle recommends that the username is set to the user's email address (for example, *john.doe@acompany.com*). The character length of the username cannot exceed 63 characters. As an alternative, you can use the first initial plus the last name. For example, the username for the user John Doe is *jdoe*.
- Site numbers must include all digits, including leading zeros.
- Do not use special or foreign characters in template cells.
- You cannot have duplicate sites or users.
- Do not use carriage returns when entering address data.
- If you copy and paste into cells with drop-down lists, be sure the value exactly matches the value provided in the drop-down list.
- [Updating your Excel options](#)


Updating your Excel options

Depending on how your Excel options are configured, you may see an Excel error icon () in the Oracle InForm Version field on the Welcome page after you open a template that you downloaded from Oracle InForm User Management Tool using Microsoft Excel.



Welcome to Oracle User Management Master User List

Use this file to rapidly enter the data required to get your Oracle InForm and IRT studies populated with users, sites and roles. This file can be used for both User Acceptance Testing (UAT) or Production (Live) trials.

* Sponsor Name		
* Trial Name		<input type="checkbox"/> Is SSO Enabled?
* InForm Version	6.3	
* Use IRT?	No	<input type="button" value="Select InForm Version"/>

Need Help? Let's find [answers from Oracle Help Center](#)

You can ignore the icon and associated message, or you can update your Excel options to remove it.

To remove the icon:

1. Click in the version number box to display the icon in the **InForm Version** label field.
2. Hover over the Excel error icon, and select **Error Checking Options** from the menu.
3. In the Excel Options dialog box, in the Error checking rules section, deselect the **Numbers formatted as text or preceded by an apostrophe** option.
4. Click **OK**.

Using the MUL Template to add or change data

If you want to change, delete, or add data for an existing trial using the MUL Template, you must:

1. Use the Oracle InForm User Management Tool user interface to download the MUL (Composite) template with your trial data.
 2. Update the template data in the spreadsheet using Microsoft Excel and run a validation check for duplicate user names or emails.
 3. Use the Oracle InForm User Management Tool user interface to upload the updated data to Oracle InForm User Management Tool.
- [Download the template for a trial](#)
 - [Update the template for a trial](#)
 - [Upload the updated data to Oracle InForm User Management Tool](#)

Download the template for a trial

1. Select **Trials** from the menu bar.
2. On the left, above the Trials list, click **Download**.
The Download Data File dialog appears.
3. In the **Trial name** drop-down list, select the trial you want to update.
4. In the **Excel Template for All Products and Version** drop-down list, select **Composite Template**.

You are prompted to save or open the template for your selected trial.

Note:

The trial-specific template you download only includes data for user roles and groups. You can make changes and add additional data for upload. For more information, see [Entering data in the MUL Template](#).

5. Save the template.
Oracle recommends you save the template before editing any data. The file must be saved with the `.xls` extension.

Update the template for a trial

1. If it is not already open, open the trial-specific template you downloaded from Oracle InForm User Management Tool using Microsoft Excel.

Because you selected a download for a specific trial, the Welcome tab is pre-filled with the appropriate values for your trial.

 **Note:**

To add data and update the template, you must have macros enabled.

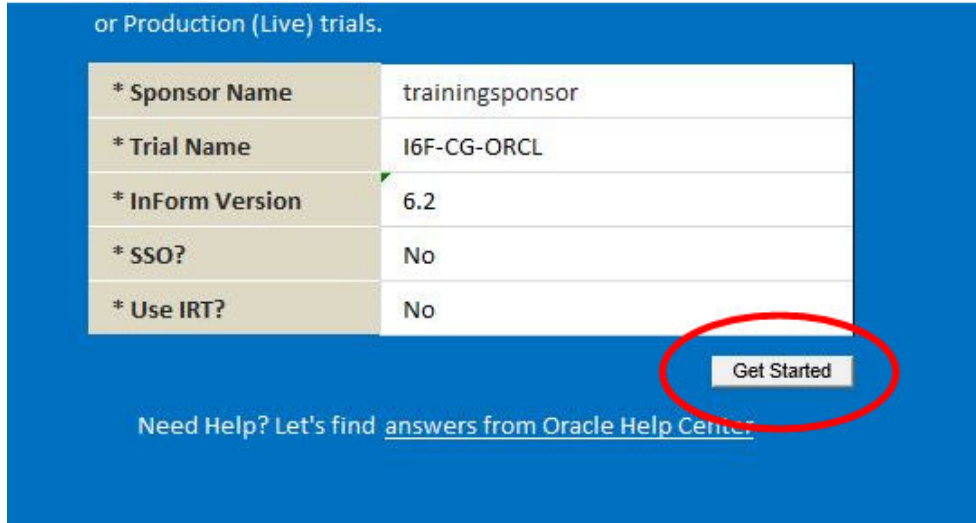
2. Click **Get Started**.

or Production (Live) trials.


* Sponsor Name	trainingsponsor
* Trial Name	I6F-CG-ORCL
* InForm Version	6.2
* SSO?	No
* Use IRT?	No

Get Started

Need Help? Let's find [answers from Oracle Help Center](#)



 **Note:**

Depending on how your Excel options are configured, you may see an Excel error icon () in the Oracle InForm Version field on the Welcome page. You can ignore the icon and associated message, or you can update your Excel options to remove it. For more information, see [Updating your Excel Options](#).

3. Select the tab for the worksheet containing the data you want to modify.
For example, select the **UserRoles** tab to create new user roles or mark existing user roles as applicable or not applicable to the study.

 **Note:**

Many types of trial data including sites and groups can be modified using the template. For information on modifying specific types of data using the MUL Template, see [Entering data in the MUL Template](#).

4. Enter your data and run any validation or population macros as indicated.

Blue labeled columns indicate required data.

Scroll right to see all available columns as needed.

The MUL Template can be used to update many types of data. Each worksheet covers a different data type and has specific steps and caveats you must follow when making updates. For more information, see [Entering data in the MUL Template](#).

Depending on the worksheet you select, you may need to run a macro to populate or validate data. This is typically done by clicking a button on the worksheet. For example, after you enter data for the desired user roles on the **UserRoles** worksheet, click the **Populate User Roles** button to run the applicable macro. This macro propagates data to the other worksheets, as needed. For more information, see [Entering user roles](#).



5. Save the template.

 **Note:**

The template must be saved with an **.xls** extension. Other extensions are not valid for upload.

Upload the updated data to Oracle InForm User Management Tool

1. Select **Trials** from the menu bar.
2. On the left, above the Trials list, click **Upload**.
The Upload Data File dialog box appears.
3. Select a saved template file.
The file must have an **.xls** extension.
4. In the **Filename** field, enter the name for your MUL Template, or browse to select the template file you want to upload.
5. In the **Trial name** drop-down list, select the trial name you want to upload data for.
6. In the **Import** section, select the trial details to import.
7. Click **Validate and Import**.

Your data is now available in Oracle InForm User Management Tool.

 **Note:**

If there are any failures with the upload, you will receive an email. Logs are available to help you troubleshoot your issues.

Creating a master template from the MUL Template

While the MUL Template can be used to bulk update data for existing trials, you can also use it to create a master template that you can use to import common information (such as user roles and rights) into any study. To create a master template, use the following workflow:

1. Use the Oracle InForm User Management Tool user interface to download an empty MUL (composite) Template.
 2. Enter any data you want to maintain as part of your master template.
 3. Save the spreadsheet for future use and use the Oracle InForm User Management Tool user interface to upload the data to Oracle InForm User Management Tool for future trials.
- [Download a blank template](#)
 - [Add additional study locale languages to the MUL Template](#)
 - [Update the spreadsheet](#)

Download a blank template

1. Select **Trials** from the menu bar.
2. On the left, above the Trials list, click **Download**.
The Download Data File dialog appears.
3. Leave the **Trial name** drop-down as is.
When you leave the trial unspecified, the downloaded template does not include any pre-filled data.
If you select a trial, the downloaded spreadsheet includes information set according to the trial specifics (Oracle InForm version, Oracle IRT use, and SSO enablement) and any roles and rights as specified for that trial.
4. In the **Excel Template for All Products and Version** drop-down list, select **Composite Template**.
You are prompted to save or open the template.
5. Save the template.
Oracle recommends you save the template before editing any data. The file must be saved with the `.xls` extension.

Add additional study locale languages to the MUL Template

The list of values for the Study Locale includes only two values: English (United States) and Japanese (Japan). If your study design has additional values for the Study Locale, you can modify the template so that the Study Locale drop-down list displays the additional values.

1. Click the **Lookups** tab.
You may need to unhide this tab by right clicking on a visible tab and then selecting Unhide, selecting Lookups, and then clicking OK.

2. In the **Study Locale** column, add the language you are looking for using the convention shown on Trial Configurations page when selecting a language.

 **Note:**

The language you select must be configured for that trial (for example, French (France)).

3. Save the template.

Your selection will be available in the Study Locale drop-down list on the Sponsor Users and Site Users tabs.

Update the spreadsheet

When creating a master template to be used across multiple trials with varying Oracle InForm versions and other trial specifics, you can repeat the getting started process, filling in new Welcome values each time. You can repeat this process as many times as needed (version-specific data is not overridden, simply hidden from view).

1. If it is not already open, open the empty template you downloaded from Oracle InForm User Management Tool using Microsoft Excel.

The blank template presents you with a Welcome tab. The information provided on the Welcome tab is used to make relevant tabs available in the spreadsheet.

 **Note:**


To add data and update the template, you must have macros enabled.

2. Enter the trial specifics on the **Welcome** tab.

If you are working with multiple versions of InForm or trials that vary with respect to use of SSO or IRT, populating your data is an iterative process.

The information provided on the **Welcome** tab is used to make relevant tabs available in the spreadsheet. Complete the **Welcome** tab using specifics that most closely match a trial you will use this master template for in the future. You can repeat these steps in the future using different Welcome values.

The Welcome tab requires the following information:

- **Sponsor Name**—Oracle InForm User Management Tool sponsor name.
- **Trial Name**—Oracle InForm User Management Tool trial name.
- **InForm Version**—The Oracle InForm version used with this trial. Depending on how your Excel options are configured, you may see an Excel error icon () in the Oracle InForm Version field on the Welcome page. You can ignore the icon and associated message, or you can update your Excel options to remove it. For more information, see [Updating your Excel Options](#).
- **SSO?**—Indicates whether or not single sign on is enabled for this trial.
- **Use IRT?**—Indicates whether or not your trial is part of an Oracle IRT study.

 **Note:**

You must enter a Sponsor Name and a Trial Name but these values are not used in the spreadsheet or during upload. They are for labeling purposes only. The Oracle InForm version must match the Oracle InForm version in Oracle InForm User Management Tool when uploading for a trial.

3. Click **Get Started**.

The getting started macro runs. When the macro completes, tabs relevant to your trial specifics, such as a version-specific tab for InForm rights and roles, appear.

4. After the getting started process completes, populate the template with data, beginning with the user roles worksheet.

For more information, see [Entering user roles](#).

 **Note:**

Be sure to start with the user roles worksheet. Other worksheets are dependent on this data.

You can populate as much or as little data as you like when creating this master template. Master templates are commonly used to populate roles and rights that are common across all studies. However, you may wish to include other common data such as sponsor users that have access to all studies. For more information, see [Entering data in the MUL Template](#).

5. Save the master template for future use or upload the data for a new trial using the Oracle InForm User Management Tool user interface.

 **Note:**

The file must be saved with the `.xls` extension.

After you have created your master template, you can use the Oracle InForm User Management Tool user interface to upload the template for any study by clicking the Upload button and selecting the master template file for upload and selecting what type of data you want to upload. You can then customize the trial data manually using the Oracle InForm User Management Tool user interface or by downloading and using a trial-specific template as described in [Using the MUL Template to add or change data](#).

Entering data in the MUL Template

Whether you use the MUL Template to perform bulk updates of data for an existing trial or you use it to create a master template, you must update the data tabs as directed in the template. Some tabs in the MUL Template have dependencies on other tabs. It is important that you fill in the template as directed.

**Note:**

You must have macros enabled in the template to properly propagate and validate data.

- [Adding or updating user roles](#)
- [Assigning rights and roles](#)
- [Adding groups and assigning a group type](#)
- [Assigning reporting groups to roles](#)
- [Entering site data](#)
- [Entering Sponsor and Site users](#)
- [Entering UAT users \(Single sign-on trials only\)](#)
- [Entering signature groups](#)

Adding or updating user roles

You enter data for user roles on the UserRoles worksheet. You can assign user roles for InForm or IRT, depending on your trial details.

**Caution:**

You must always modify this worksheet first and propagate these changes to the other worksheets using the **Populate User Roles** button before modifying other worksheets.

New entries and modifications to existing roles are propagated to the related **SponsorUsers** and **SiteUsers** worksheets. Role information is also propagated to the **Rights&Roles** and **ReportGroups** worksheets.

To add a new role:

1. In a new row, add a name for the role in the **User Role** column.
2. Optionally, add a description for this role in the **Description** column.
3. Mark the role as applicable or not applicable to the current study by selecting **Applicable** or **Not Applicable** from the drop-down list in the **Role required** column.
4. Click **Populate User Roles** to propagate the data to the dependent worksheets.

**Note:**

You may need to enable macros for this to operate correctly.

To update an existing role:

1. To change the data in the existing rows, perform one of the following:

- Update the role description in the **Description** column.
 - Mark a role as applicable or not applicable to the study by selecting the desired value (**Applicable** or **Not Applicable**) from the drop-down list in column C.
 - Marking a role as **Applicable** adds information for that role to the **SponserUsers**, **SiteUsers**, and **ReportGroups** worksheets.
 - Marking a role as **Not Applicable** removes information from the **SponserUsers**, **SiteUsers**, **Rights&Roles**, and **ReportGroups** worksheets.
2. Click **Populate User Roles** to propagate the data to the dependent worksheets.

Assigning rights and roles

Rights and roles are assigned on a product- and version-specific **Rights&Roles** worksheet (for example, the worksheet for updating the rights and roles associated with Oracle InForm 6.2 is labeled **InForm 6.2 Rights&Roles**).



Note:

User role information included on these worksheets is propagated from the **UserRoles** worksheet. You must complete the UserRoles worksheet and propagate your changes before updating any Rights&Roles worksheet. For more information, see [Entering user roles](#).

- To assign or update the role type or rights for a given user role, type an X in the cell that corresponds to the role type or right you want to apply.

Adding groups and assigning a group type

You add groups and assign them a group type in the **Groups** worksheet. Group data entered in this worksheet is populated to the **SiteUsers** and **SponsorUsers** worksheets.

You can update data for existing groups by selecting a new **Type** or editing the **Description**.



Note:

Do not change the **Group Name** for a group if you have already uploaded group data to a trial in Oracle InForm User Management Tool, or if you have downloaded a trial-specific template from Oracle InForm User Management Tool.

To add a new group:

1. Enter a name for the group in the **Group Name** column.
2. Select a group type from the available list using the drop-down list in the **Type** column.

You can select either **Signature Group** or **Query Group**.

3. Optionally, add a description for the group in the **Description** column.
4. Click **Populate Groups** to propagate group data to the dependent worksheets.

 **Note:**

The **Groups** worksheet is only for assigning signature and query groups.

Item groups and display overrides are defined in Oracle Central Designer for Oracle InForm 6.1 and above, and in the Oracle InForm User Management Tool user interface for earlier versions.

For signature groups, the content of the group is defined in Oracle Central Designer for Oracle InForm 6.0 and above, and in the Oracle InForm User Management Tool user interface for earlier versions.

Assigning reporting groups to roles

Use the **ReportGroups** worksheet to assign your user roles (as defined in the **UserRoles** worksheet) to specific report groups. The report groups provide access to Cognos Reporting and are pre-defined.

 **Note:**

Do not change the **Report Groups** column on this worksheet and do not add new rows.

If you have properly propagated your role information, you see a column for each role on this worksheet. If you don't see columns for your roles, see [Entering user roles](#).

- To assign a role to a reporting group, type an X in the cell corresponding to the reporting group you want your role to be assigned to.

Entering site data

You enter data for sites on the **Sites** worksheet. You can add new sites, change data for existing sites, delete existing sites, or re-instate a site.

Blue-labeled columns are required fields and data must be filled in according to the formats specified in the spreadsheet. For example, when entering phone numbers only include digits and start the number with the appropriate country code.

- Do not leave blank rows between entries.
This prevents the data from being properly validated.
- For site names only, you can use alpha numeric characters or apostrophe ('), comma (,), dash (-), period (.), semi-colon (;), colon (:), or underscore (_) characters. The apostrophe (') character can only be used in Oracle InForm 6.2 and above. No foreign accents or special characters are allowed. Do not use carriage returns in addresses.

- For Oracle IRT trials only, leaving the **Limit ship address field to 30** checkbox unchecked allows you to provide a shipping address up to 255 characters.
- You must select a time zone in the **Time Zone** column. However, the time zone-related data in the **Time Zones 2011/Time Zones Dec 2012 conversion time** column is populated for you based on the time zone you select.
- The optional Date Format column allows the trial's default date format to be overridden on a site-by-site basis. This is configured in the Oracle InForm User Management Tool configuration for a trial. If you are using a trial configuration document and this is left blank, the date format provided in the trial configuration document is used.
- The mandatory **Accept Date** column should be populated with the date that the site was added to the MUL template.
- If the Oracle InForm User Management Tool configuration for the trial is set to **MULTIPLE** and you are re-instating a site, the **Study Version** column is mandatory (this value is checked as part of the upload to Oracle InForm User Management Tool).
 - If your trial is configured for **MULTIPLE** and you create a new site, you can either specify a study version in this column or the version will default to the earliest study version entered in Oracle InForm User Management Tool.
 - If your trial is configured for **LATEST**, a study version is not required.



Note:

When specifying a trial version, you must enter it exactly as it appears in Oracle Central Designer.

- [Updating site data](#)

Updating site data

To update site data using the **Sites** worksheet:

1. Update the site data.

Keep in mind the requirements listed in [Entering site data](#), any formatting information provided in the spreadsheet, and any optional information that might be required due to your trial configuration.

If you want to change a site mnemonic using the MUL Template or .DAT file, see [Changing a site mnemonic](#).

2. Set the status for each site.

Choose one of the following selections from the drop-down list in the **Status** column:

- **New**—Creates a new site entry in Oracle InForm User Management Tool.
- **No Change**—Identifies a site already created and uploaded in Oracle InForm User Management Tool.

- If you leave the status as New instead of changing it to No Change after the site has been created in Oracle InForm User Management Tool, the import will fail for the site.
 - After a site is successfully uploaded as New, if you want to leave the site in the template for the next load, you **must** change the status to No Change unless you are changing, deleting (marking as not participating), or re-instating (marking as participating) the site.
 - **Change**—Change the data for an existing site in Oracle InForm User Management Tool.
 - **Delete**—Mark a site as **Not Participating** in Oracle InForm User Management Tool.
 - **Re-instate**—Return the site to **Participating** status in Oracle InForm User Management Tool. Sponsor users that have auto-association set to be assigned to the site get assigned.
3. Click **Validate**.

If an error is encountered during validation, the required field will be highlighted. Review the error message provided in the **Error Message** column for more information (you may need to scroll right to see the column).

Entering Sponsor and Site users

Use the **SponsorUsers** worksheet and the **SiteUsers** worksheet to enter or change information for users at the sponsor level and site level, respectively. The instructions are the same regardless of which type of user you are entering.

Blue-labeled columns are required fields and data must be filled in according to the formats specified in the spreadsheet. For example, when entering phone numbers only include digits and start the number with the appropriate country code.

- Role columns are populated from the **UserRoles** worksheet. You must complete the **UserRoles** worksheet and populate the data before you enter user information. For more information, see [Entering user roles](#).
- The signature group and query group drop-downs are populated from the information you provide on the **Groups** tab. If you want to assign users to signature or query groups, be sure you have created and populated these groups. For more information, see [Entering groups](#).
- The username entered in the User Name field must not have spaces and must be in lowercase. The maximum length is 63 characters for Oracle InForm 6.0 and above (older versions have a 32 character limit).

Usernames must be unique.

Oracle recommends you use the user's email address as their username. If this is not permitted due to the character limitation, use the first initial of the user's first name plus their last name. For example, *jdoe* for the user John Doe.

Note:

For SSO-enabled trials, usernames must be at least 4 characters.

- The **Display Name** column sets the name that appears in the left corner of Oracle InForm under the user photo.
- When you upload a new user for an SSO study, Oracle InForm User Management Tool checks to see if the user is already a Global User by matching the user name and email address against existing Global Users.
 - If the user exists, Oracle InForm User Management Tool associates the new study user to the existing Global User.
 - If the user does not exist in the Global User list, it is automatically created.The new user appears in the user interface in both the Study Users list and the Global Users list.
- [Updating Sponsor and Site users](#)

Updating Sponsor and Site users

You can update users using the **SiteUsers** or **SponsorUsers** worksheet.

1. Update the site user or sponsor user data.

Be sure you are adding the user data to the correct worksheet for that user type, site or sponsor.

For UAT users, see [Entering UAT users \(Single sign-on trials only\)](#)

Keep in mind the requirements listed in [Entering site data](#), and follow any formatting information provided in the spreadsheet.

2. Set the status for each user.

Choose one of the following selections from the drop-down list in the **Status** column:

- **New**—Creates a new user entry in Oracle InForm User Management Tool.
- **No Change**—Identifies a user already created and uploaded in Oracle InForm User Management Tool.
 - If you leave the status as New instead of changing it to No Change after the user has been created in Oracle InForm User Management Tool, the import will fail for the user.
 - After a user is successfully uploaded as New, if you want to leave the user in the template for the next load, you **must** change the status to No Change unless you are changing, deleting (terminating), or re-instating (unterminating) the user.
- **Change**—Change the data for an existing user in Oracle InForm User Management Tool.
- **Delete**—Mark a user as **Terminated** in Oracle InForm User Management Tool.
- **Re-instate**—Un-terminate (re-instate) the user in Oracle InForm User Management Tool.

3. Click **Validate**.

If an error is encountered during validation, the required field will be highlighted. Review the error message provided in the **Error Message** column for more information (you may need to scroll right to see the column).

Entering UAT users (Single sign-on trials only)

If you are entering data for a Single Sign-On (SSO) trial, you must create your users in Oracle InForm User Management Tool. Because an Oracle InForm user can only have one role, you must have multiple user accounts, one for each role that you need to test. The UAT users tab helps you create these users.

To create UAT users:

1. Update the user data.

Blue-labeled columns indicate required data. Data must be filled in according to the formats specified in the spreadsheet. For example, when entering phone numbers only include digits and start the number with the appropriate country code. The values for some fields, such as **Product Locale**, are selected from a drop-down list.

2. Select the applicable roles that you need the UAT user accounts created for.

Select the applicable roles by typing an X in the column that corresponds to the required role.

Note:

Role columns are populated from the **UserRoles** worksheet. You must complete the **UserRoles** worksheet and populate the data before you enter user information. For more information, see [Entering user roles](#). You must also enter the role type on the **Rights&Roles** worksheet and propagate that data as well. For more information, see [Entering rights and roles](#).

3. Click **Create UAT Users**.

For each role that is a site type role, the macro creates a user on the SiteUsers tab as username_uat_role. Similarly, for each role that is a sponsor type, the macro creates a user on the SponsorUsers tab with the same format.

Entering signature groups

The **Signature** worksheet is not used with Oracle InForm versions 6.1 and above. If you are working with a release prior to 6.1, you can unhide this tab by right-clicking on any worksheet tab and selecting **Unhide > Signature**. In Oracle InForm 6.1 and above, signature groups are defined in Oracle Central Designer.

Data must be filled for all columns.

1. Before you begin entering data, click the **Populate Signature Group** button to populate the list of signature group type group names in the **Signature Group** column.

Values can be chosen from this list.

2. In the **Final CRF** column for the form, choose **Casebook Signature** or **CRF Signature**.

Managing SSO accounts—Oracle Life Sciences IAMS Customer Delegated Administrator (CDA)

- [Resetting a user SSO password](#)
- [Locking a user SSO account](#)
- [Unlocking a user SSO account](#)

Resetting a user SSO password

To manually reset the password for a user account:

1. Access **Oracle Life Sciences Identity and Access Management Service (Oracle Life Sciences IAMS)** using the link in the email you received with the temporary password from **OracleIdentityManager@oracle.com** when your CDA account was created.
2. Navigate to the **User Details** page.
 - a. Under **Administration** in the menu on the left, click **Users**.
 - b. For the **Display Name**:
 - From the list, select **Equals**.
 - Type the user name in the field.
 - c. Click **Search** on the right.
 - d. In the **Search Results** section, click the link in the **User Login** column to open the User Details page.
3. In the row of controls at the top of the page, click **Reset Password**.
4. Perform one of the following depending on the password reset flow you have set:
 - If the user is not required to use challenge questions, click **Send** on the Confirmation screen.
 - If the user is required to use challenge questions, select **Auto-generate the Password**.

 **Note:**

Although it is not recommended, you can manually define a new password: Select **Manually change the Password**, fill in the password fields, and select the checkbox **E-mail the new password to the user**.

5. Click **Reset Password**.

Locking a user SSO account

When a delegated administrator explicitly locks an account, the user cannot use the Forgot Password link to regain access. Lock a user account to prevent the user from logging in before you disable the account for termination of employment or for other reasons.

1. Access **Oracle Life Sciences Identity and Access Management Service (Oracle Life Sciences IAMS)** using the link in the email you received with the temporary password from **OracleIdentityManager@oracle.com** when your CDA account was created.
2. Navigate to the **User Details** page.
 - a. Under **Administration** in the menu on the left, click **Users**.
 - b. For the **Display Name**:
 - From the list, select **Equals**.
 - Type the user name in the field.
 - c. Click **Search** on the right.
 - d. In the Search Results section, click the link in the **User Login** column to open the User Details page.
3. In the row of controls at the top of the page, click **Lock Account**.
4. In the confirmation dialog, click **Lock**.

Unlocking a user SSO account

If the account was explicitly locked by a delegated administrator, you need to unlock the account before it can be used again. Users who lock their accounts by entering an incorrect password too many times can use the Forgot Password link on the login page to reset their passwords and unlock their account.

Before unlocking an account, check the reason for which it was locked in the first place and check that the person asking to have the account unlocked is the owner. To ensure system security, we recommend that you establish a process to confirm the requester's identity.

1. Access **Oracle Life Sciences Identity and Access Management Service (Oracle Life Sciences IAMS)** using the link in the email you received with the temporary password from **OracleIdentityManager@oracle.com** when your CDA account was created.
2. Navigate to the User Details page.
 - a. Under **Administration** in the menu on the left, click **Users**.
 - b. For the **Display Name**:
 - From the list, select **Equals**.
 - Type the user name in the field.
 - c. Click **Search** on the right.
 - d. In the Search Results section, click the link in the **User Login** column to open the User Details page.

3. In the row of controls at the top of the page, click **Unlock Account**.
4. In the confirmation dialog, click **Unlock**.
5. Reset the password.

For more information, see [Resetting a user SSO password](#).