Oracle® Life Sciences Clinical One Platform

Add Users

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Preface

This preface contains the following sections:

- Audience
- Documentation accessibility
- Diversity and Inclusion
- Related resources
- Access to Oracle Support
- Additional copyright information

Audience

This document is for anyone who needs to create user accounts for Oracle Clinical One Platform or Oracle Clinical One Digital Gateway.

The following users are typically responsible for creating user accounts:

- A delegated administrator, who creates user accounts for Oracle Clinical One Platform and Oracle Clinical One Digital Gateway users in Oracle Life Sciences Identity and Access Management Service (Oracle Life Sciences IAMS) or Oracle Life Sciences User Management Tool.
  For complete instructions on working in Oracle Life Sciences IAMS, see the Oracle Life Sciences Identity and Access Management Service Administrator Guide.
- An Oracle Clinical One Platform administrator who adds global users and study team members in Oracle Clinical One Platform.
- A study team member who adds site and depot users in Oracle Clinical One Platform.

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.

Diversity and Inclusion

Oracle is fully committed to diversity and inclusion. Oracle respects and values having a diverse workforce that increases thought leadership and innovation. As part of our initiative to build a more inclusive culture that positively impacts our employees, customers, and partners, we are working to remove insensitive terms from our products and documentation. We are also mindful of the necessity to maintain compatibility with our customers' existing technologies and the need to ensure continuity of service as Oracle's offerings and industry

standards evolve. Because of these technical constraints, our effort to remove insensitive terms is ongoing and will take time and external cooperation.

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

Account basics

- Tasks that Oracle completes for you
  As a delegated administrator, you do most of the work in Oracle Life Sciences Identity and Access Management Service. However, there is a list of tasks that Oracle completes for you. This makes it easier for you to manage user administration tasks and helps you save time when enabling your team to begin their work in the application.
- Single sign-on accounts
  You use a single sign-on (SSO) account to securely authenticate with Oracle sites or applications with one set of credentials (user name and password).
- Oracle Life Sciences Identity and Access Management Service
  Once a delegated administrator creates your Oracle Life Sciences SSO account, you can use Oracle Life Sciences Identity and Access Management Service (Oracle Life Sciences IAMS) to activate your account, access secure Oracle Life Sciences applications, and manage your account.
- Oracle Life Sciences SSO account notification
  Once your administrator creates your Oracle Life Sciences single sign-on (SSO) in Oracle Life Sciences IAMS, you receive up to two email messages with account activation instructions.
- Bookmarks
  All users must open Oracle Life Sciences IAMS periodically to manage their Oracle Life Sciences SSO accounts. (Delegated administrators at your organization use Oracle Life Sciences IAMS more frequently.) You can save time if you create a bookmark to Oracle Life Sciences IAMS.

Tasks that Oracle completes for you

As a delegated administrator, you do most of the work in Oracle Life Sciences Identity and Access Management Service. However, there is a list of tasks that Oracle completes for you. This makes it easier for you to manage user administration tasks and helps you save time when enabling your team to begin their work in the application.

Review the following list of tasks that Oracle completes for you:

Creates single sign-ons for and assign roles to the delegated administrators

As a delegated administrator, you then use the single sign-ons to sign in to Oracle Life Sciences IAMS and Oracle Clinical One Platform. The Approver role allows you to determine who gets access to Oracle Clinical One Platform. If you add more delegated administrators in the future, you might want to assign the Approver role to them.

Publishes your organization’s roles, and activates approval for them

These steps allow Oracle employees to request your roles and require an Approver to approve or reject the requests. The activities are one-time tasks for each role. You’ll need to complete these tasks in the future only if Oracle adds new roles for your organization.

Sets up an authorization request page

Your team members and Oracle employees can open the page and then request access to Oracle Clinical One Platform. Approvers must approve or reject the requests. Setting up the page is a one-time task.

If you need to perform any of these steps yourself, see step-by-step instructions in Account creation prerequisites.

Single sign-on accounts

You use a single sign-on (SSO) account to securely authenticate with Oracle sites or applications with one set of credentials (user name and password).

If your role requires you to access multiple sites and applications, you may use two different types of SSO accounts. The following table lists the names of the two types of SSO accounts you can use to access different Oracle or Oracle Life Sciences sites and applications.

SSO Account Name	Creator	Applications
Oracle SSO	You create your own account through the New User prompts at the sign in page for My Oracle Support, Support Cloud, or Oracle Life Sciences Learn. Once created, you can access those applications.	• My Oracle Support (MOS) • Support Cloud • Oracle Health Sciences Learn (home of assigned training courses)

SSO Account Name	Creator	Applications
Create Oracle Life Sciences SSO accounts in Oracle Life Sciences IAMS	1. An Oracle business operations representative contacts your organization to get the user names and email addresses needed to create the first designated Oracle Life Sciences users at your company (usually two administrators). 2. Delegated administrators at your organization use Oracle Life Sciences Identity and Access Management Service (Oracle Life Sciences IAMS) to complete the tasks required to set up user accounts. Once created, you receive one to two notification messages. 3. You use the information in your notification message(s) to activate your account through Oracle Life Sciences IAMS. **Note:** Your account needs to include an approved role (permissions) to access studies and perform certain actions. Depending on how your organization set up accounts, you can request roles for your account or a delegated administrator can assign them. But, another administrator (known as the Approver) must approve your role before you can access studies with your account.	• Oracle Life Sciences Central Coding • Oracle Clinical One Digital Gateway • Oracle Clinical One Platform • Oracle Life Sciences Empirica Signal • Oracle Life Sciences Empirica Study • Oracle Life Sciences Empirica Topics • Oracle Life Sciences IAMS • Oracle Health Sciences Learn Manager • Oracle Health Sciences mHealth Connector Cloud Service

SSO Account Name	Creator	Applications
Create Oracle Life Sciences SSO accounts in Oracle Clinical One Platform	User administrators, can perform a bulk user upload directly in the Oracle Clinical One Platform. For more information see, About creating user accounts using the upload template Each user account created through this process, is assigned to a study, and can have a role, sites and depots automatically associated to their account. Once created, you receive one to two notification messages. Use the information in your notification message(s) to activate your account through Oracle Life Sciences IAMS.	• Oracle Clinical One Platform **Note:** Accounts created in this manner are also created in Oracle Life Sciences IAMS by default.

Oracle Life Sciences Identity and Access Management Service

Once a delegated administrator creates your Oracle Life Sciences SSO account, you can use Oracle Life Sciences Identity and Access Management Service (Oracle Life Sciences IAMS) to activate your account, access secure Oracle Life Sciences applications, and manage your account.

Delegated administrators use Oracle Life Sciences IAMS to create Oracle Life Sciences SSO accounts. But, they must complete certain prerequisites to create the accounts. For more information, see Account creation prerequisites.

Using Oracle Life Sciences IAMS for other applications

Your organization already has delegated administrators if you use any of the following products: Oracle InForm, Oracle Central Coding, Oracle Empirica Study, Oracle Empirica Topics, Oracle mHealth Connector, and Oracle Health Sciences Learn Manager. Your changes in Oracle Life Sciences IAMS could impact the delegated administrators and users of the other products. For example, coordinate the following changes with other delegated administrators:

- Changing the password reset flow from Security Questions to Email Link. See Choose the password reset flow.
- Using Oracle Life Sciences My Oracle Bookmarks. See What roles do I need to assign to users of My Oracle Bookmarks?.

To start using Oracle Life Sciences IAMS

1. Receive up to two account notification messages from Oracle Identity Manager (OracleIdentityManager@oracle.com).
2. Find your account user name and links to Oracle Life Sciences IAMS in the message instructions.
3. Activate your account by opening Oracle Life Sciences IAMS, creating a password, answering challenge questions (if required), and signing in with the activated account.

You can then use your Oracle Life Sciences single sign-on (SSO) to access secure Oracle Life Sciences applications. But, you cannot access studies until an administrator (known as the Approver) approves your role. Roles provide certain permissions to perform activities. Depending on how your organization set up accounts, you can request roles or a delegated administrator can assign them. Once approved, you can access studies.

You can sign in to Oracle Life Sciences IAMS directly or through these applications:

- Oracle Health Sciences My Oracle Bookmarks
- Oracle Life Sciences Cloud home page

For more information on activating your account, see Oracle Life Sciences SSO account notification.

Oracle Life Sciences SSO account notification

Once your administrator creates your Oracle Life Sciences single sign-on (SSO) in Oracle Life Sciences IAMS, you receive up to two email messages with account activation instructions.

> **Note:**
>
> The delegated administrators at your organization are the first ones to activate their accounts in Oracle Life Sciences IAMS and complete the prerequisites to create Oracle Life Sciences SSO accounts. Other Oracle Life Sciences users do not receive details on activating their accounts until a delegated administrator creates them as described in this guide. For more details, see Account creation prerequisites.

The number of messages you get from Oracle Identity Manager depends on your role and the method your organization chose to reset expired or forgotten passwords. For example, you can receive one of the following:

- **New Account (one notification message):**
  Sent to users who reset their passwords through a web page (no security questions).

  A New Account message contains the Oracle Life Sciences SSO user name, a link to create a password, and a link to sign in through Oracle Life Sciences IAMS to activate the account. Depending on what your organization chose, you may open Oracle Life Sciences IAMS from Oracle Health Sciences My Oracle Bookmarks or the Oracle Health Science Cloud landing page.
- **New Account and Account Password (two notification messages):**

Sent to the first Oracle Life Sciences user (usually one to two administrators) and users who reset their passwords after answering security questions.

The New Account notification message contains the Oracle Life Sciences SSO user name. The Account Password message contains a temporary password to log in for first time with a link to open Oracle Life Sciences IAMS through Oracle Health Science Cloud. After you enter your temporary password, you see prompts to reset it.

For more details, see one of the following topics:

- Activate your account with one notification message
  To activate your Oracle Life Sciences SSO account, create a new password and sign in to Oracle Life Sciences IAMS with the user name shown in the New Account email.
- Activate your account with two notification messages
  To activate your Oracle Life Sciences SSO account, create a new password and sign in to Oracle Life Sciences IAMS with the user name shown in the New Account email. If you also received an Account Password message, you must enter the temporary password and add challenge questions before you create a new password.

Activate your account with one notification message

To activate your Oracle Life Sciences SSO account, create a new password and sign in to Oracle Life Sciences IAMS with the user name shown in the New Account email.

If you also received an Account Password message, see Activate your account with two notification messages instead of this procedure.

To activate your Oracle Life Sciences SSO:

1. Locate your Oracle Life Sciences New Account email message from Oracle Identity Manager.

   > **Note:**
   >
   > If you cannot locate the notification message from Oracle Identity Manager, contact the Oracle Life Sciences IAMS delegated administrator at your organization to get your user name and the URL for Oracle Life Sciences IAMS.

2. Open the message and click the link to create your password.
3. Follow the prompts to enter and confirm your password and click **Continue**.
4. Click the **Oracle Life Sciences Cloud account** link in your New Account email.
5. Sign in with your Oracle Life Sciences SSO user name and the password you created.

> **Tip:**
>
> Under My Applications, you can expand the applications and click links to open the studies you use. (Users cannot work on studies without administrators approving the roles for their accounts.)

For easier access to Oracle Life Sciences IAMS in the future, bookmark the web address as described in Bookmark Oracle Life Sciences IAMS.

Activate your account with two notification messages

To activate your Oracle Life Sciences SSO account, create a new password and sign in to Oracle Life Sciences IAMS with the user name shown in the New Account email. If you also received an Account Password message, you must enter the temporary password and add challenge questions before you create a new password.

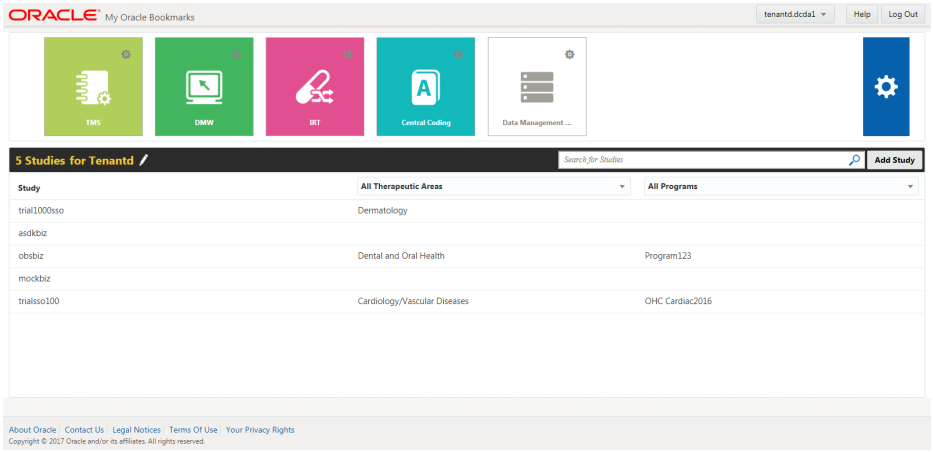
If you only received one notification message, see Activate your account with one notification message instead of this procedure.

To activate your Oracle Life Sciences SSO:

1. Locate your Oracle Life Sciences New Account and Account Password messages from Oracle Identity Manager.

   > **Note:**
   >
   > If you cannot locate the messages in your email, contact the Oracle Life Sciences IAMS delegated administrator at your organization to get your user name and the URL for Oracle Life Sciences IAMS. You also need your temporary password.

2. Open your New Account email message and click **Oracle Life Sciences Cloud account**.
3. Sign in with your Oracle Life Sciences SSO user name and your temporary password (located in the Account Password message).
4. Follow the prompts to reset the password.
5. Provide answers to three challenge questions that you can remember and click **Submit**.
6. Sign in with your Oracle Life Sciences SSO user name and the password you created. Depending on how your organization set up your access, you see one of the following pages:
   - Oracle Health Sciences My Oracle Bookmarks home page:



Use Oracle Health Sciences My Oracle Bookmarks to store the web addresses (URL) for Oracle Life Sciences products you use in one place.

- Oracle Life Sciences Cloud home page: Under My Applications, you can expand the applications and click links to open the studies you use. (Users cannot work on studies without administrators approving the roles for their accounts.)

For easier access to Oracle Life Sciences IAMS in the future, bookmark the web address as described in Bookmark Oracle Life Sciences IAMS.

Bookmarks

All users must open Oracle Life Sciences IAMS periodically to manage their Oracle Life Sciences SSO accounts. (Delegated administrators at your organization use Oracle Life Sciences IAMS more frequently.) You can save time if you create a bookmark to Oracle Life Sciences IAMS.

You can also open Oracle Life Sciences IAMS from Oracle Health Sciences My Oracle Bookmarks or Oracle Life Sciences Cloud. But, you must bookmark the original web address. Do not bookmark the web address that appears after you sign in to either of those applications.

- Bookmark Oracle Life Sciences IAMS
  Before you create a bookmark, locate the New Account email message you received from Oracle Identity Manager. That message contains the web address you need to use to create your Oracle Life Sciences IAMS bookmark.
- Sign in to Oracle Life Sciences IAMS directly
  After you activate your Oracle Life Sciences SSO account in Oracle Life Sciences IAMS, you can sign in to it directly if you need to manage your SSO or create new Oracle Life Sciences SSO accounts.
- Sign in through Oracle Life Sciences My Oracle Bookmarks
  After you activate your Oracle Life Sciences SSO account, you can access Oracle Life Sciences IAMS through Oracle Health Sciences My Oracle Bookmarks to manage your SSO or sign in to secure applications. My Oracle Bookmarks helps you keep track of your Oracle Life Sciences bookmarks in one place.
- Sign in through Oracle Life Sciences Cloud
  After you activate your Oracle Life Sciences SSO account, you can access Oracle Life Sciences IAMS through Oracle Life Sciences Cloud to manage your SSO or sign in to secure applications and studies.

Bookmark Oracle Life Sciences IAMS

Before you create a bookmark, locate the New Account email message you received from Oracle Identity Manager. That message contains the web address you need to use to create your Oracle Life Sciences IAMS bookmark.

If you cannot locate your New Account email message, contact your Oracle project manager and ask for the Oracle Life Sciences IAMS web address. (Do not bookmark the web address that you saw after you created a password and activated your account.)

To bookmark Oracle Life Sciences IAMS:

1. In your browser, create a bookmark for any Internet page and label the bookmark as your Oracle Life Sciences IAMS bookmark.
2. Open the New Account notification message you received from Oracle Identity Manager and copy the Oracle Life Sciences IAMS web address (URL).
3. Edit the bookmark by pasting the web address for Oracle Life Sciences IAMS into the web address field, make any necessary edits, and save it under your browser bookmarks.

> **Tip:**
>
> You can also open Oracle Life Sciences IAMS from Oracle Health Sciences My Oracle Bookmarks or Oracle Life Sciences Cloud. But, you must bookmark the original web address. Do not bookmark the web address that appears after you sign in to either of those applications. For detail on signing into Oracle Life Sciences IAMS, see Bookmarks.

Sign in to Oracle Life Sciences IAMS directly

After you activate your Oracle Life Sciences SSO account in Oracle Life Sciences IAMS, you can sign in to it directly if you need to manage your SSO or create new Oracle Life Sciences SSO accounts.

> **Note:**
>
> For details on activating your account, see Oracle Life Sciences SSO account notification.

To sign in to Oracle Life Sciences IAMS:

1. Open a browser and select the bookmark for Oracle Life Sciences IAMS to open the Sign In page.

> **Note:**
>
> Use a bookmark to save time accessing Oracle Life Sciences IAMS. If you need to create one, see Bookmark Oracle Life Sciences IAMS.

2. Enter your user name and password and click **Sign In**.

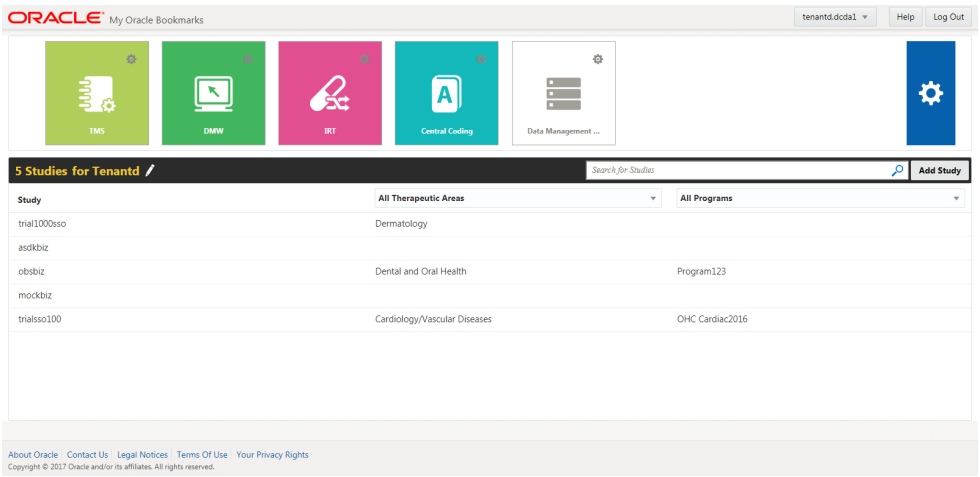
Sign in through Oracle Life Sciences My Oracle Bookmarks

After you activate your Oracle Life Sciences SSO account, you can access Oracle Life Sciences IAMS through Oracle Health Sciences My Oracle Bookmarks to manage your SSO or sign in to secure applications. My Oracle Bookmarks helps you keep track of your Oracle Life Sciences bookmarks in one place.

> **Note:**
>
> For details on activating your account, see Oracle Life Sciences SSO account notification. To learn more about Oracle Health Sciences My Oracle Bookmarks, see the Oracle Help Center.

To sign in to Oracle Life Sciences IAMS through Oracle Health Sciences My Oracle Bookmarks:

1. Open a browser and select the bookmark for it to open the My Oracle Bookmarks Home page. (Or, manually enter the web address.)



2. Choose one of the following:
   - If the product includes an Oracle Life Sciences IAMS tile, click it.
   - If the product does not include an Oracle Life Sciences IAMS tile, click your name in the top-right corner and select **Account Management**.
3. Enter your SSO (user name and password) and click **Sign In**.

Sign in through Oracle Life Sciences Cloud

After you activate your Oracle Life Sciences SSO account, you can access Oracle Life Sciences IAMS through Oracle Life Sciences Cloud to manage your SSO or sign in to secure applications and studies.

> **Note:**
>
> For details on activating your account, see Oracle Life Sciences SSO account notification.

To sign in to Oracle Life Sciences IAMS through Oracle Life Sciences Cloud:

1. Open a browser and select the bookmark for Oracle Life Sciences Cloud to open the Home page. (Or, manually enter the web address.)
2. Under Quick Links, click **Update Profile** to open Oracle Life Sciences IAMS.
3. Enter your user name and password and click **Sign In**.

2

Account creation prerequisites

- Prerequisites to create accounts
  You (as a delegated administrator at your organization) must complete some tasks before creating Oracle Life Sciences single sign-on (SSO) accounts. You only need to complete each task once. Then you can start creating accounts for users who need to access Oracle Clinical One Platform to create clinical studies and Oracle Clinical One Digital Gateway to manage integrations.
- Approval process
  The approval process is optional, but some organizations must use it. When you use the approval process, someone with the Approver role determines who gets access to Oracle Clinical One Platform.
- Specify a password for Support Cloud
  Anyone who enters support tickets must specify a password for a Support Cloud account. For example, a small group can create tickets for the entire organization, or everyone can create their own tickets.
- Request the Approver role
  Requesting the Approver role for your organization is the first of a multi-step process for using the approval process. The person with the Approver role determines who gets access to Oracle Clinical One Platform. The delegated administrator is responsible for requesting the Approver role.
- Create an Oracle SSO for the Approver
  The delegated administrator must create an Oracle Life Sciences single sign-on (SSO) for each user with the Approver role (approximately two users). The Approver user approves all requests to access Oracle Clinical One Platform.
- Assign the Approver role
  Assigning the Approver role is a one-time task. After you assign the role, users with that role can approve or decline the role assignments for other users. Oracle recommends assigning the Approver role to at least two people to ensure someone at your organization can approve or decline roles.
- Activate approval for roles
  When you activate approval, the administrator with the Approver role can approve all access requests.
- Publish the roles
  A delegated administrator publishes roles so that Oracle users can see the roles and assign them to the Oracle Life Sciences single sign-ons (SSOs) of SaaS Services and Life Sciences Support users. Because you activated approval, Approvers see an access request for each assignment and can approve or reject them.
- Set up an authorization request page
  Self-service registration allows users to request access to Oracle Clinical One Platform or Oracle Clinical One Digital Gateway by navigating to the product web site. Employees at your organization and external users, such as Oracle users, can request access.

Prerequisites to create accounts

You (as a delegated administrator at your organization) must complete some tasks before creating Oracle Life Sciences single sign-on (SSO) accounts. You only need to complete each task once. Then you can start creating accounts for users who need to access Oracle Clinical One Platform to create clinical studies and Oracle Clinical One Digital Gateway to manage integrations.

> **Note:**
>
> Do not perform these prerequisite tasks if you only need to create training studies for other products such as Oracle InForm, Oracle Central Designer, Oracle Central Coding, Oracle IRT, or Oracle InForm User Management Tool. Training studies do not require another person to approve requests when assigning roles to user accounts.

Order	Task	Product Used
1	Specify a password for Support Cloud	Support Cloud
2	Request the Approver role	Support Cloud
3	Create an Oracle SSO for the Approver	Oracle Life Sciences IAMS
4	Assign the Approver role	Oracle Life Sciences IAMS
5	Activate approval for roles	Oracle Life Sciences IAMS
6	Publish the roles	Oracle Life Sciences IAMS

Approval process

The approval process is optional, but some organizations must use it. When you use the approval process, someone with the Approver role determines who gets access to Oracle Clinical One Platform.

The following chart lists organizations that require the approval process and those that can make it optional.

Requires approval process	Optional approval process
• Organizations that use Oracle Clinical One Platform to create clinical studies • Organizations that use Oracle Clinical One Digital Gateway to manage integrations	Organizations that use Oracle Health Learn Manager only to create training studies for other products such as: • Oracle InForm • Oracle Central Designer • Oracle Central Coding • Oracle IRT • Oracle InForm User Management Tool

> **Note:**
>
> Leaving approval inactivate simplifies the process of creating users because you do not need another administrator (Approver) to approve access requests when assigning the roles.

For details about how to get started using the approval process, see Request the Approver role.

Specify a password for Support Cloud

Anyone who enters support tickets must specify a password for a Support Cloud account. For example, a small group can create tickets for the entire organization, or everyone can create their own tickets.

To get help figuring out the right support model for your organization, talk to your Oracle Project Manager.

To specify your password for Support Cloud:

1. Determine whether you have a Support Cloud account for another Oracle Life Sciences product. If so, skip the second step.
2. Specify your password for Support Cloud using one of the following steps:
   - If you are someone who manages access to Oracle Clinical One Platform (such as a delegated administrator), look for the Welcome email from *saas_provisioning@mailac.custhelp.com*. The email contains a subject line of *HSGBUCLINICALONE | Order #<order_number> | <organization_name>* and the following first line: *Welcome to Oracle Cloud and thank you for purchasing Oracle's products and services.*

> **Note:**
>
> This email is typically sent within a day or two of the point of contact setting up the Oracle Cloud account.

- If you are not a delegated administrator, after the people who manage access to Oracle Clinical One Platform receive the Welcome email (described above), open Support Cloud, and select **Register**.

3. If you need more help, you can:
   - Select **Tutorial** to watch a video.
   - At the bottom of the page, select **Global Support Numbers**, and then expand the section for **Clinical One Cloud Service**.

Related Topics

- Single sign-on accounts
  You use a single sign-on (SSO) account to securely authenticate with Oracle sites or applications with one set of credentials (user name and password).

Request the Approver role

Requesting the Approver role for your organization is the first of a multi-step process for using the approval process. The person with the Approver role determines who gets access to Oracle Clinical One Platform. The delegated administrator is responsible for requesting the Approver role.

> **Note:**
>
> You only need to follow the approval process if your organization plans to use Oracle Clinical One Platform to create clinical studies or Oracle Clinical One Digital Gateway to manage integrations.

To request the Approver role for your organization:

1. Open Oracle Life Sciences Support Cloud as described in Access to Oracle Support.
2. Submit a request to create the **Approver** role for your organization.
3. Wait to hear back about your request.

> **Note:**
>
> Request approval for at least two users to ensure someone can always manage and approve role requests.

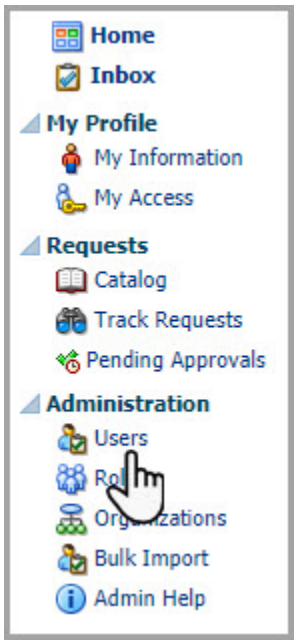
After Life Sciences Support contacts you, continue on to Create an Oracle SSO for the Approver to create the Approver. You can then activate the approval as described in Activate approval for roles.

Create an Oracle SSO for the Approver

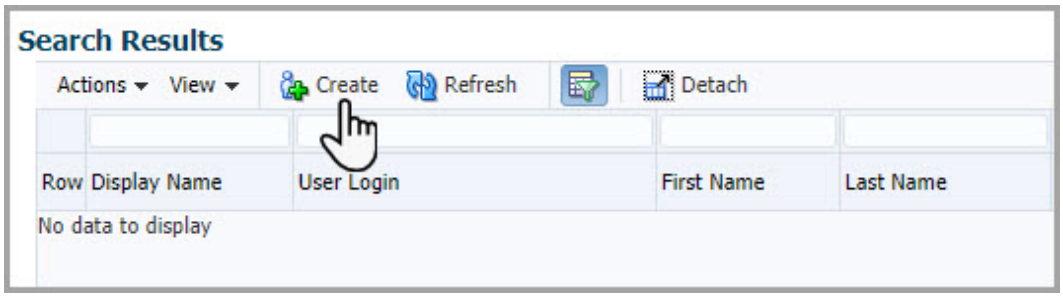
The delegated administrator must create an Oracle Life Sciences single sign-on (SSO) for each user with the Approver role (approximately two users). The Approver user approves all requests to access Oracle Clinical One Platform.

To create an Oracle Life Sciences SSO for the Approver:

1. Sign in to Oracle Life Sciences IAMS as described in Sign in to Oracle Life Sciences IAMS directly.
2. Expand **Administration** in the left panel and click **Users**.



3. Under Search Results, click **Create**.



4. Enter the user information in the following fields:
   - **First Name** and **Last Name**
   - **Email**
   - **Organization**: Enter your organization's ShortOrgId. This is the reference number that appears in the message heading of your New Account notification email message. (You can also click the search icon, select the row with **Company** in the **Type** column, and click .

- **User Login**: Enter the full name of the user login, such as *john.smith*.

> **Note:**
>
> If Password fields appear on the page, skip them if you entered an email address for the user.

5. Click **Submit** from the upper-right of the dialog box.

You created an Oracle Life Sciences SSO. You see a confirmation message and the User Details page for the new account.
Next step: See Assign the Approver role.

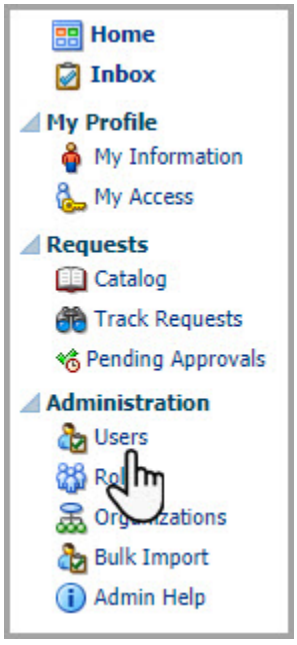
Assign the Approver role

Assigning the Approver role is a one-time task. After you assign the role, users with that role can approve or decline the role assignments for other users. Oracle recommends assigning the Approver role to at least two people to ensure someone at your organization can approve or decline roles.

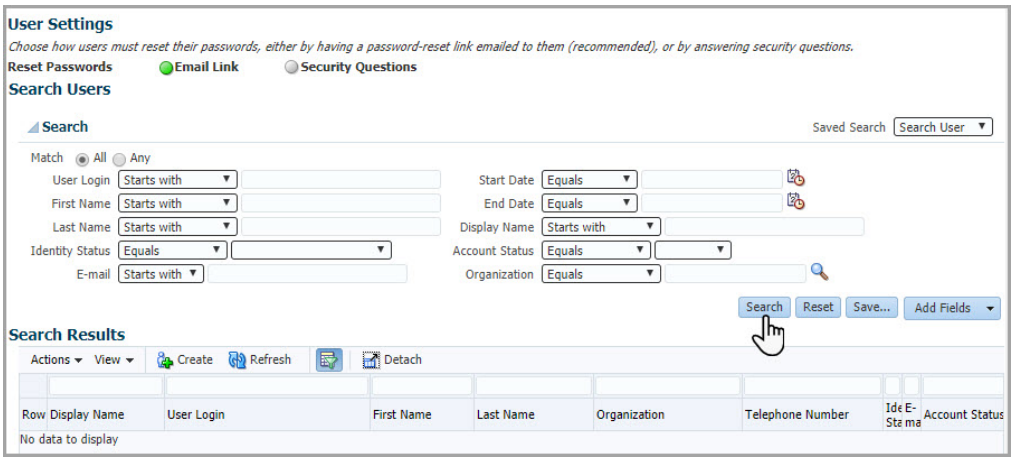
Before you can assign the Approver role to a user, create an account for the user and activate approval. See Create an Oracle SSO for the Approver for details.

To assign the Approver role to a user:

1. Sign in to Oracle Life Sciences IAMS as described in Sign in to Oracle Life Sciences IAMS directly.
2. Expand **Administration** in the left panel and click **Users**.

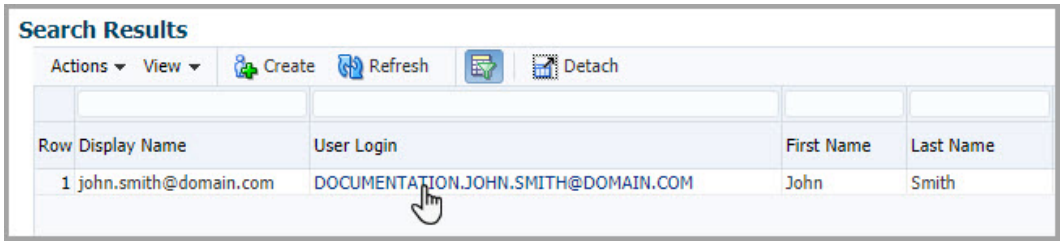


3. Choose one of the following options:
   - To see a list of all users, click **Search**, located below the filtering fields and to the right.

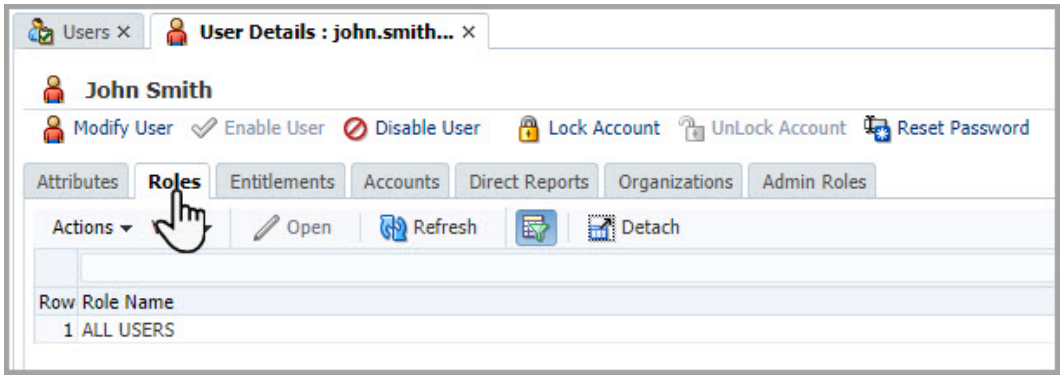


- To find a user, enter search criteria for the user, and then click **Search**, located below the filtering fields and to the right. For example, choose one of the following options:
  - From the **E-mail** drop-down, select **Equals**, and type the user's email address.
  - From the **Display Name** drop-down, select **Equals**, and type the user's display name.

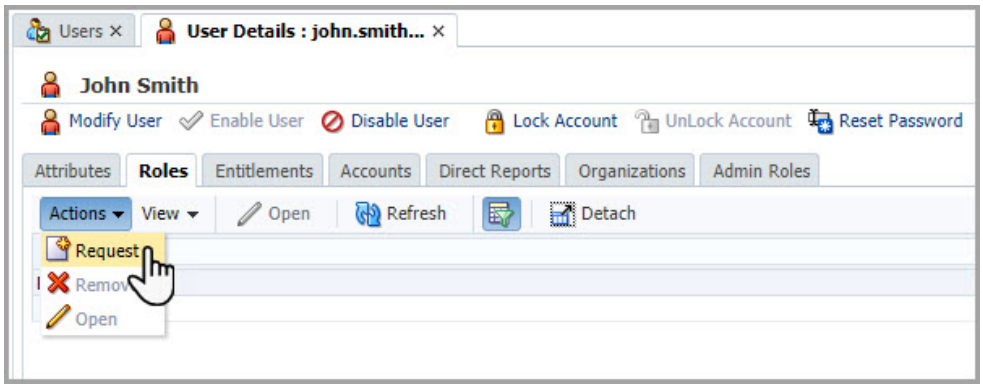
4. In the Search Results table, find the user, and in the **User Login** column, click the user's name.



5. On the User Details page, select the **Roles** tab.

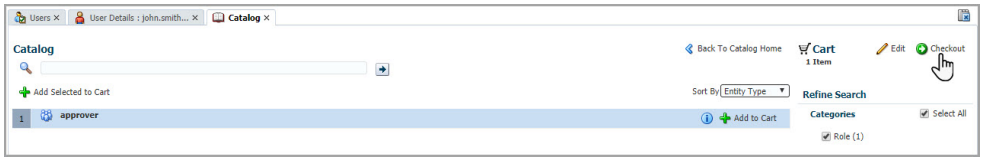


6. From the **Actions** drop-down, located above the table of roles, select **Request**.



7. To the right of the **approver** role, click **Add to cart**.

8. In the upper-right, click **Checkout**.



9. Review the roles in the cart.
10. In the upper-right, click **Submit**.

    The Request Summary page opens with a confirmation message at the top of the page.

Activate approval for roles

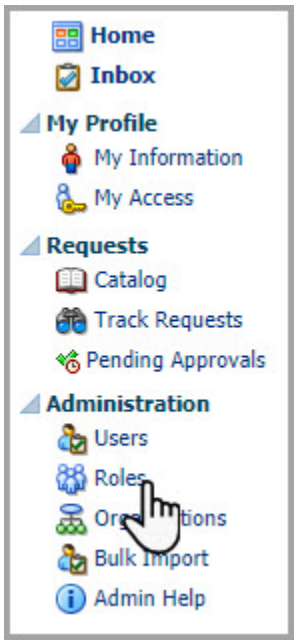
When you activate approval, the administrator with the Approver role can approve all access requests.

To learn more about access requests and administrator approval, see Access requests.

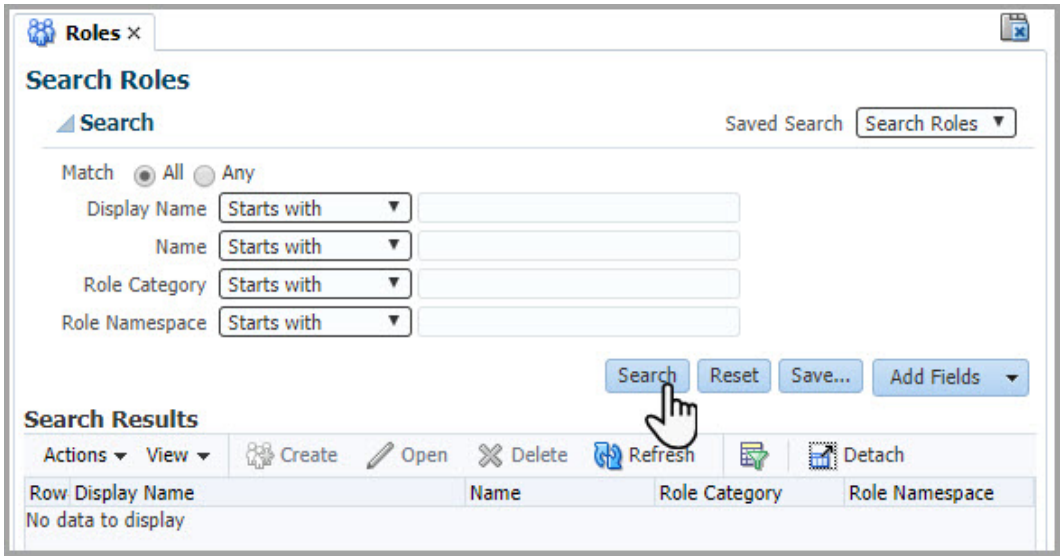
Before you can activate approvals, you must Request the Approver role, Create an Oracle SSO for the Approver, and Assign the Approver role.

To activate approval:

1. Sign in to Oracle Life Sciences IAMS as described in Sign in to Oracle Life Sciences IAMS directly.
2. Expand **Administration** in the left panel and click **Roles**.

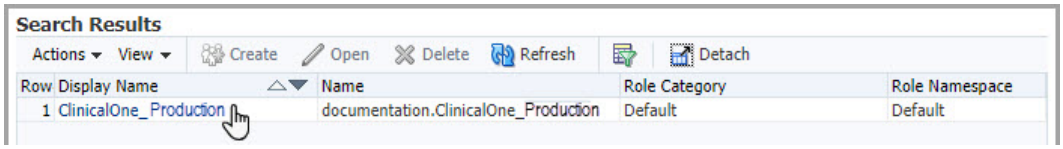


3. Above the Search Results section, click **Search**.

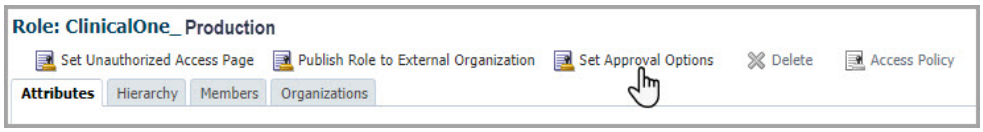


All of your organization's roles appear in the Search Results table.

4. In the list of roles, find the **clinicalone-CNE** user role.
5. Click the link in the Display Name column for the role.



6. In the row of controls at the top of the page, click **Set Approval Options**.



7. In the dialog box, select the following options:
   - **Activate Approval**
   - **Notify the user on request status**: When selected, users who request access receive a notification after the access request is approved or rejected.
8. Click **Submit**.

   The following message appears: `Approval activated for the role`.
9. Repeat steps 2-8 to activate approval for the Oracle Clinical One Platform administrator role: **clinicalone-CNE_AssignGlobalRoles**.
10. If your organization uses Oracle Clinical One Digital Gateway, repeat steps 2-8 in this procedure to activate approval for the required role: **inthub-CNE**.

Publish the roles

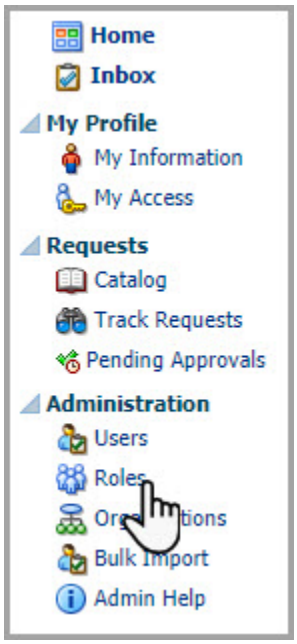
A delegated administrator publishes roles so that Oracle users can see the roles and assign them to the Oracle Life Sciences single sign-ons (SSOs) of SaaS Services and Life Sciences Support users. Because you activated approval, Approvers see an access request for each assignment and can approve or reject them.

Before you publish roles, you must activate approval as described in Activate approval for roles .

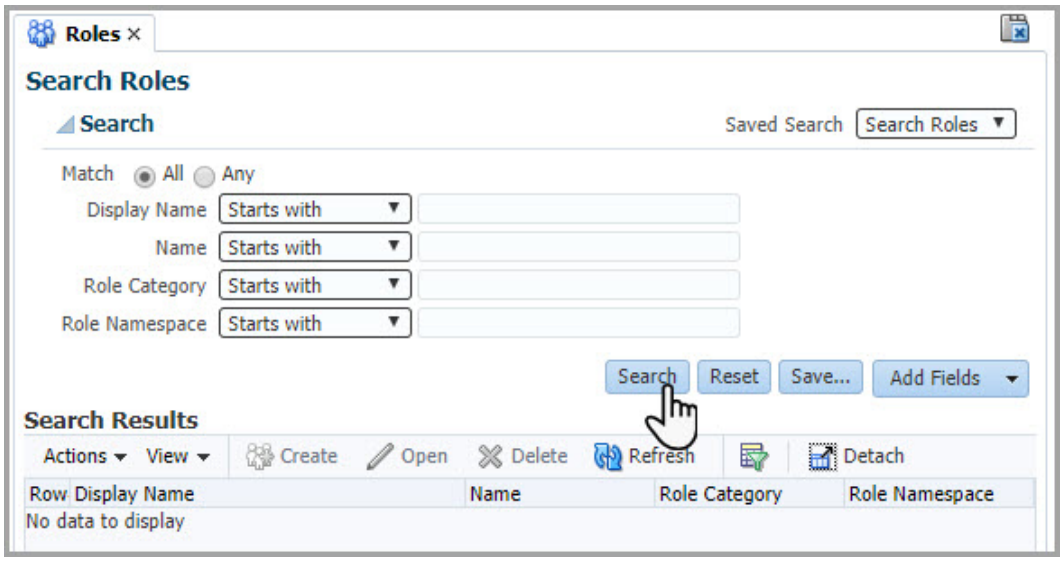
> **Note:**
>
> You cannot undo the publication of roles. To hide a role, submit a request through Oracle Life Sciences Support Cloud.

To publish the roles:

1. Sign in to Oracle Life Sciences IAMS as described in Sign in to Oracle Life Sciences IAMS directly.
2. Expand **Administration** in the left panel and click **Roles**.

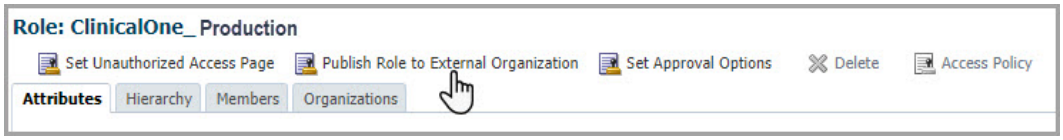


3. Above the Search Results section, click **Search**.

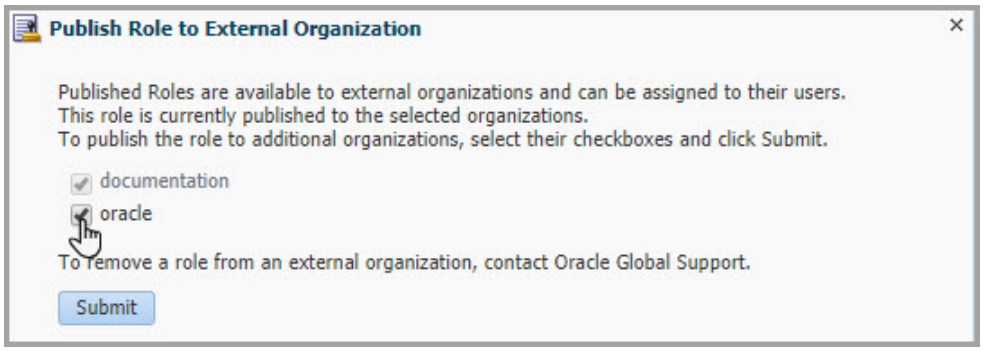


All of your organization's roles appear in the Search Results table.

4. In the list of roles, find the **clinicalone-CNE** user role.
5. Click the link in the Display Name column for the role.
6. In the row of controls at the top of the role page, click **Publish Role to External Organization**.



7. Select the **oracle** checkbox, leave the **documentation** checkbox selected, and click **Submit**.



The following message appears: `Role published to selected organizations appears.`

8. Repeat steps 2-7 to publish the Oracle Clinical One Platform administrator role: **clinicalone-CNE_AssignGlobal Roles**.
9. If your organization uses Oracle Clinical One Digital Gateway, repeat steps 2-7 to publish therequired role: **inthub-CNE**.

After you finish publishing all roles, share the update with your point of contact at Oracle, typically your project manager. An Oracle administrator assigns the roles to users' Oracle Life Sciences SSOs as needed. You must approve all requests.

Set up an authorization request page

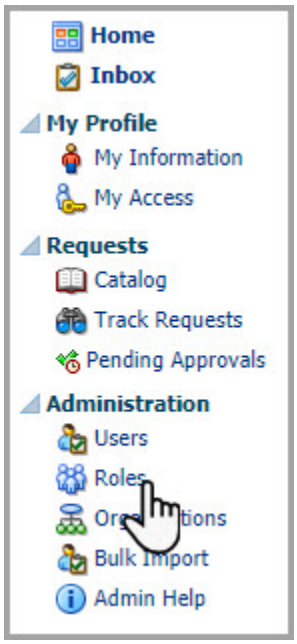
Self-service registration allows users to request access to Oracle Clinical One Platform or Oracle Clinical One Digital Gateway by navigating to the product web site. Employees at your organization and external users, such as Oracle users, can request access.

Setting up self-service registration is optional. However, if you decide to use self-service registration, you must activate approval for roles so that an Approver can approve or decline all access requests. For more information, see Activate approval for roles.

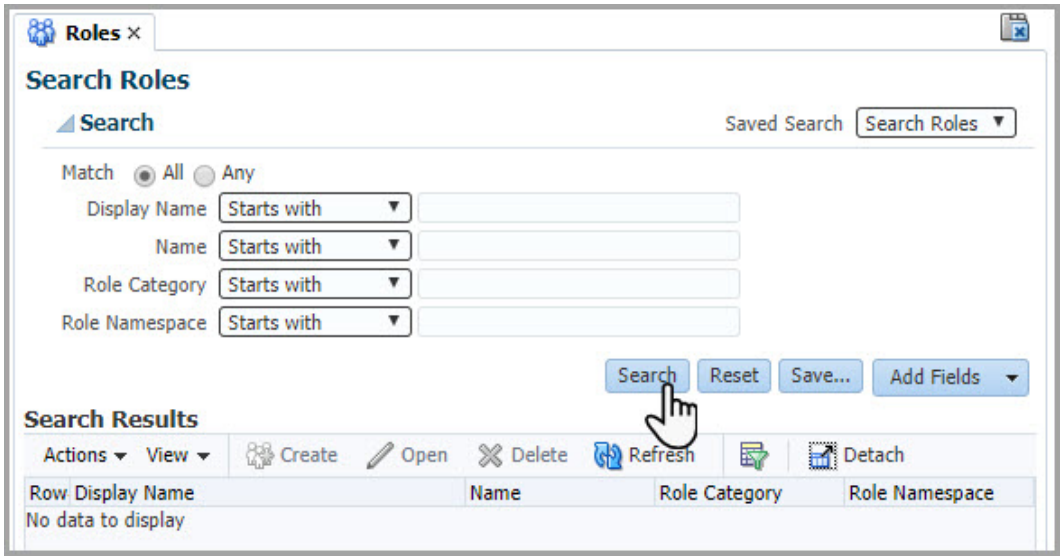
> **Caution:**
>
> If you don't set up approvals for self-service requests, anyone with an Oracle Life Sciences single sign-on (SSO) can navigate to your product web address and automatically gets access to your product instance.

To set up self-service registration:

1. Sign in to Oracle Life Sciences IAMS as described in Sign in to Oracle Life Sciences IAMS directly.
2. Expand **Administration** in the left panel and click **Roles**.

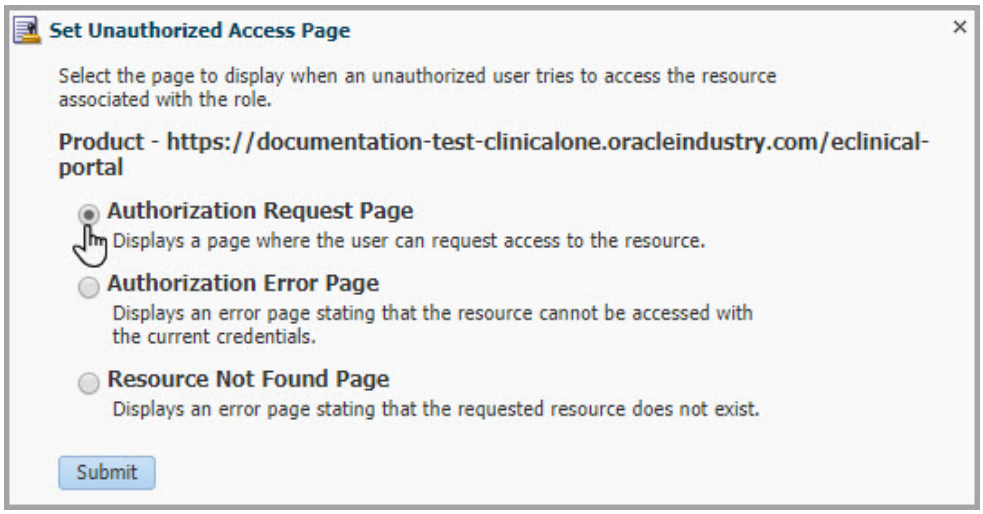


3. Above the Search Results section, click **Search**.



All of your organization's roles appear in the Search Results table.

4. Set up self-service registration for the Oracle Clinical One Platform **clinicalone-CNE** user role.
5. Click the link in the Display Name column for the role.
6. In the row of controls at the top of the role page, click **Set Unauthorized Access Page**.
7. Select **Authorization Request Page** and click **Submit**.



8. Repeat steps 2-7 to set up self-service registration the Oracle Clinical One Platform administrator role: **clinicalone-CNE_AssignGlobalRoles**
9. If your organization uses Oracle Clinical One Digital Gateway, repeat steps 2-7 to set up self-service registration for the required role: **inthub-CNE**.

After you finish these steps, notify your Oracle project manager that you set up approvals and self-service registration. The Oracle project manager notifies Oracle employees that they can start requesting access.
After you create Oracle Life Sciences SSO accounts for all users, you can notify them that they can request roles for Oracle Clinical One Platform. Or, you (as an administrator) can assign the roles to the users. For more information, see Request roles or Assign roles in Oracle Life Sciences IAMS.

3

Create user accounts in Oracle Life Sciences Identity and Access Management Service (IAMS)

- Oracle Life Sciences SSO accounts
  You can create Oracle Life Sciences SSO accounts for product administrators, Oracle Clinical One Platform study users, and Oracle Clinical One Digital Gateway users in Oracle Life Sciences Identity and Access Management Service (IAMS). But, you must use Oracle Clinical One Platform to add a user to a study in Oracle Clinical One Platform and add an Oracle Clinical One Digital Gateway global user.
- Create an Oracle Life Sciences single sign-on
  You (as the delegated administrator) can use Oracle Life Sciences Identity and Access Management Service (IAMS) to create Oracle Life Sciences single sign-on (SSO) account for each Oracle Clinical One Platform or Oracle Clinical One Digital Gateway user.
- About creating user accounts using the upload template
  The **User Upload Template** lets a user administrator create Single Sign-On (SSO) user accounts, assign users to a study, and assign roles, sites, and depots directly in Oracle Clinical One Platform.
- User roles in Oracle Life Sciences IAMS for all applications
  Roles provide permissions for users to work in studies in Oracle Life Sciences products. Different roles provide different sets of permissions. When you assign roles to a user account, the application checks the permissions when users sign in with their accounts and only allows permitted actions.
- Create product administrator accounts
  To create a product administrator for Oracle Clinical One Platform, a delegated administrator must create an Oracle Life Sciences single sign-on (SSO) in Oracle Life Sciences IAMS, assign roles, and then add the user as a global user in Oracle Clinical One Platform. The product administrator is typically the first user account you create.
- Provide user access to Oracle Clinical One Digital Gateway
  To provide a user access to Oracle Clinical One Digital Gateway, a Customer Delegated IAMS Administrator (CDA) must create an Oracle Life Sciences single sign-on (SSO) user account and assign the appropriate product roles in Oracle Life Sciences Identity and Access Management Service (IAMS). Then, add the user account as a global user and assign the appropriate global roles in Oracle Clinical One Platform.
- Access requests
  If you use the approval process to grant users access to applications, it generates access requests. The user with the Approver role must approve or reject these requests. If approved, the user can access the application. If your organization does not use the approval process, assigned roles take effect immediately.

Oracle Life Sciences SSO accounts

You can create Oracle Life Sciences SSO accounts for product administrators, Oracle Clinical One Platform study users, and Oracle Clinical One Digital Gateway users in Oracle Life Sciences Identity and Access Management Service (IAMS). But, you must use Oracle Clinical One Platform to add a user to a study in Oracle Clinical One Platform and add an Oracle Clinical One Digital Gateway global user.

You also have the option to create Oracle Clinical One Platform study users directly in the Oracle Clinical One Platform user interface using the upload template, see About creating user accounts using the upload template.

You control access to products through Oracle Life Sciences IAMS. You control access to studies through Oracle Clinical One Platform.

In Oracle Clinical One Platform, users get product-level access or study-level access, build studies, and perform randomization, trial supply management, and data collection for the studies. Global users in Oracle Clinical One Platform are product administrators who can perform the following tasks:

- Add the first user to a study. (Only global users can perform this task.)
- Add any user to any study.
- Act as a training manager or training administrator for training in other Oracle Life Sciences products.

In Oracle Clinical One Digital Gateway, every user must be added as a global user. These users can set up integrations.

Global users cannot assign users to sites and depots.

Related Topics

- Roles for global users in Oracle Clinical One Platform and Oracle Clinical One Digital Gateway
  Global users perform administrative tasks, such as creating studies, adding users to studies, managing integrations, and managing training.

Create an Oracle Life Sciences single sign-on

You (as the delegated administrator) can use Oracle Life Sciences Identity and Access Management Service (IAMS) to create Oracle Life Sciences single sign-on (SSO) account for each Oracle Clinical One Platform or Oracle Clinical One Digital Gateway user.

You also have the option to create Oracle Clinical One Platform users directly in the Oracle Clinical One Platform user interface using the upload template, see About creating user accounts using the upload template. Oracle Clinical One Digital Gateway users can only be created in Oracle Life Sciences Identity and Access Management Service

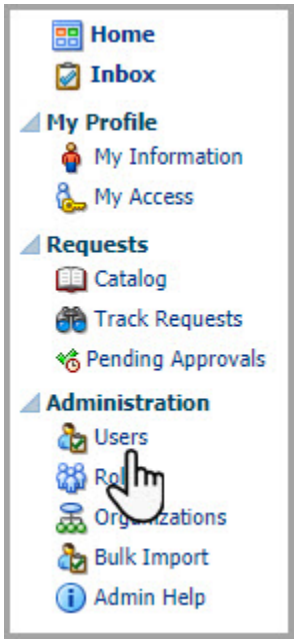
Show me how, in Oracle Life Sciences Identity and Access Management Service (IAMS)!

Video

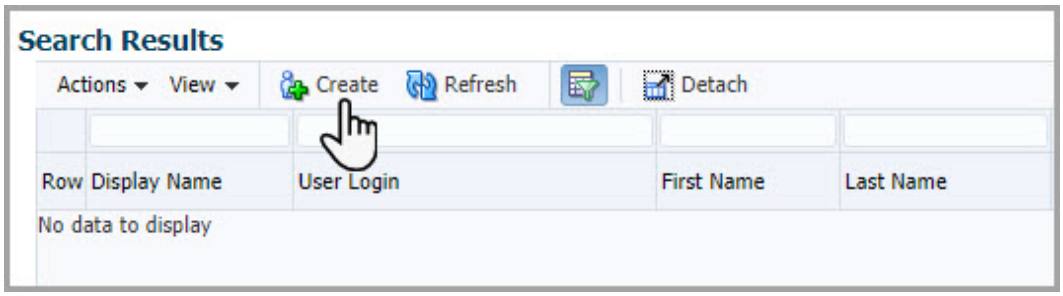
To create an Oracle Life Sciences SSO:

> **Tip:**
>
> If you need to create an Oracle Life Sciences SSO for more than one user, the bulk import feature might save you some time. For instructions, see Manage Oracle Life Sciences single sign-ons in bulk.

1. Sign in to Oracle Life Sciences IAMS as described in Sign in to Oracle Life Sciences IAMS directly.
2. Expand **Administration** in the left panel and click **Users**.



3. Under Search Results, click **Create**.



4. Fill in the fields with the new user's information.
   - **First Name** and **Last Name**
   - **Email**
   - **Organization**: Enter your organization's ShortOrgId. (See How do I find my company's ShortOrgId? if you do not know the ShortOrgId.)
   - **User Login**: Enter the name part of a user's login, such as *john.smith*.

> **Note:**
>
> If you see Password fields, skip them if you entered an email address for the user.

5. In the upper-right, click **Submit**.

   You created an Oracle Life Sciences SSO. You see a confirmation message and the User Details page for the new account.

Next step: See Assign roles in Oracle Life Sciences IAMS to assign roles to the user accounts.

About creating user accounts using the upload template

The **User Upload Template** lets a user administrator create Single Sign-On (SSO) user accounts, assign users to a study, and assign roles, sites, and depots directly in Oracle Clinical One Platform.

For more information about using the upload template, see Create user accounts using the upload template.

> **Note:**
>
> You cannot create accounts for product administrators and Oracle Clinical One Digital Gateway users using the upload template. For more information, see Oracle Life Sciences SSO accounts.

Permissions

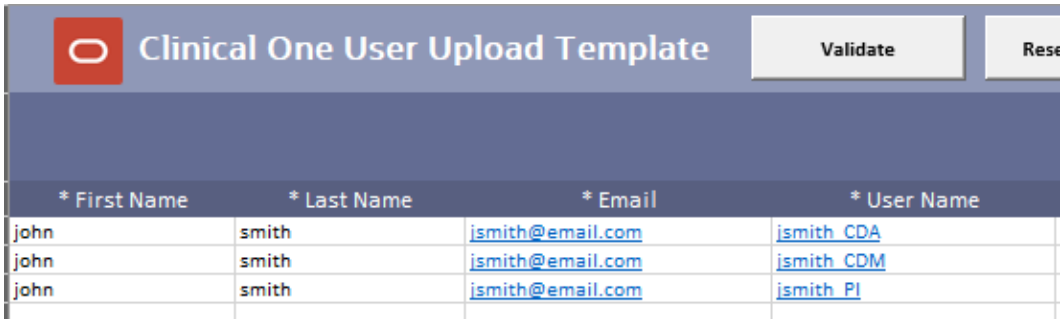
Users assigned to a role that includes the *Upload Users in Bulk* permission can access the template.

Key features

> **Note:**
>
> You cannot create Oracle users in your study using the upload template. If you choose to include the details of an Oracle user, you will receive an error message which states that the upload of Oracle users is not supported. You must assign an Oracle user to a study manually.

- Errors are tracked in the User Upload Error report.
- By default, user accounts are created at the global level in Oracle Clinical One Platform.
- User accounts are automatically created in Oracle Life Sciences Identity and Access Management Service **(IAMS)**.
- You can create both Oracle Clinical One Platform (SSO) and Federated (SSO) user accounts.

- In a single file, you can include details for new users and edits for existing users, such as the end date for a user.
- After you click **Validate**, macros run to ensure required data is present and adheres to the required format.
- Macros do not check for duplicate records that may appear during import. To avoid additional work, make sure all user names are unique.
- A file can be saved without running validation or addressing the issues found. Such a file imports successfully with errors tracked in the User Upload Error report.
- Multiple user accounts (user names) can be associated with the same email address, as seen in the image below. This allows users to have accounts for multiple roles making testing faster and easier.



- The upload template has a suggested limit of 600 records. This limit is not enforced but keep in mind that the larger the file, the longer the import time.
- By default users are uploaded in Production mode. During the upload process, to upload users for both Production and Training modes, enable **Upload users to training mode**.
- You can associate users to a single site, all sites, or retired sites.

Notifications

The following notifications are sent once an import completes:

- The user administrator receives an email notification with the subject: **Bulk User Upload notification**. This notification contains details about the number of users created successfully and the ones that encountered issues. For more information about how to address import issues, see the User Upload Error report.
- Newly created users receive two email notifications. Existing users being added to a study only receive the second email notification.
  1. The first email contains login details.
  2. The second email includes the study URL and the date the user can log in.

Reporting Impact

- Comments entered in the optional comment field, on the upload screen, appear in the User Upload Error report.
- Comments also appear in the User Assignment and User Assignment by Site report and are displayed in the last column in the output file.

- Create user accounts using the upload template
  The User Upload Template can be used to create Single Sign-On (SSO) user accounts, assign users to a study, assign roles, sites, and depots, and update existing accounts at the study level.

Create user accounts using the upload template

The User Upload Template can be used to create Single Sign-On (SSO) user accounts, assign users to a study, assign roles, sites, and depots, and update existing accounts at the study level.

For more information, see About creating user accounts using the upload template.

Permissions
Users assigned to a role that includes the *Upload Users in Bulk* permission can access the template.

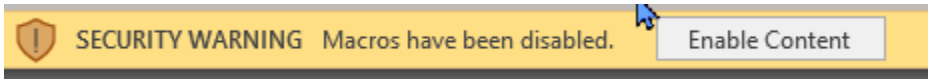
How to obtain and use the upload template.

1. From the Home screen click **Study Settings** ( ) for your study, then select **Open Settings**.
2. Go to the **Users** tab and click **Download Template**.

   The Role drop-down on the Clinical One Users tab and the Study Roles tab are populated with the roles for the study, this includes template roles. Retired roles and design roles are not included.

   > **Tip:**
   >
   > Always download a new copy to pick up any changes applied to your study.

3. Open the template, if it did not open by default, and enable the macros.



4. Go to the **Clinical One Users** tab, enter details for each account to be created or updated, then click **Validate**. If applicable, address any issues identified by the macros.
5. Save and close the file.
6. Return to the Home page in Oracle Clinical One Platform, click **Study Settings** then select **Open Settings**.

7. Go to the **Users** tab and click **Create/Assign User**.

   The **Create/Assign Users** window opens.

8. Click **Upload File** for one of the following options:

   - Upload Clinical One SSO users
   - Assign a user (do not select)

     > **Note:**
     >
     > This is not an upload option. For more information about assigning users, see Add a user to a study in Oracle Clinical One Platform

   - Upload federated SSO users

9. When prompted, select the user upload template (or error report) previously saved.

   The Map Roles window opens. The roles in the import file are mapped to the roles in the study.

10. Review the content then click **Next**.

    A preview window opens allowing you to review the user details before initiating the import.

11. (Optional) Enable **Upload users to training mode** if users should be created in both Production and Training mode.

12. (Optional) Enter comments if applicable. Comments appear in the User Assignment and User Assignment by Site reports and in the User Upload Error report.

13. Click **Upload**.

    A confirmation email is sent with the subject, Bulk User Upload notification. If the row, **User with error,** is one (1) or more, view the User Upload Error report to address any import issues.

User roles in Oracle Life Sciences IAMS for all applications

Roles provide permissions for users to work in studies in Oracle Life Sciences products. Different roles provide different sets of permissions. When you assign roles to a user account, the application checks the permissions when users sign in with their accounts and only allows permitted actions.

The following table lists the roles users need you to assign in Oracle Life Sciences IAMS. For details on assigning the roles, see Assign roles in Oracle Health IAMS.

Product	Type of study	Roles that must be assigned in Oracle Life Sciences IAMS	Additional roles needed in the product?
Oracle Clinical One Platform	Clinical study For randomization and trial supply management and data collection or Training study Only for assigning training for Oracle Life Sciences products	• User role The **clinicalone-CNE** role is required for all users. • Administrator role This role is required only if the user is responsible for creating studies and global users in Oracle Clinical One Platform. Usually, only a limited number of users need this role. Users who have the **clinicalone-CNE_AssignGlobalRoles** role can give themselves and others access to studies. This role's Display Name in Oracle Life Sciences IAMS is AssignGlobalRoles.	Yes: • All users who will work in a study must be granted study-level roles. • Users with the administrator role must also be created as global users in Oracle Clinical One Platform.
Oracle Clinical One Digital Gateway	Not applicable Oracle Clinical One Digital Gateway is a separate system from Oracle Clinical One Platform.	The following roles are required to access Oracle Clinical One Digital Gateway. • Assign the following Oracle Clinical One Platform role. **clinicalone-CNE** • Assign the following Oracle Clinical One Digital Gateway role. **inthub-CNE**	No. Users with these roles can start working right away.
Oracle Life Sciences IAMSOAuth Admin Console	Not applicable. A customer-delegated administrator assigns this role to themselves in order to work in the Oracle Life Sciences IAMS OAuth Admin Console. The Oracle Life Sciences IAMS OAuth Admin Console is an application used to generate client IDs and secrets, as well as provision API developers with the right permissions for them to make API calls.	The following role is required for any customer-delegated administrator working in this application: • **system-admin**	No.

- Request roles
  A delegated administrator at your organization must assign product roles to your Oracle Life Sciences single sign-on (SSO) so that you can work in Oracle Clinical One Platform and Oracle Clinical One Digital Gateway. If you cannot access studies, you can navigate to the product web site and request access to

automatically generate a request for roles (if your organization set up self-service registration).

Request roles

A delegated administrator at your organization must assign product roles to your Oracle Life Sciences single sign-on (SSO) so that you can work in Oracle Clinical One Platform and Oracle Clinical One Digital Gateway. If you cannot access studies, you can navigate to the product web site and request access to automatically generate a request for roles (if your organization set up self-service registration).

A user with the Approver role, typically a delegated administrator, must review all access requests and approve only the valid requests from users. Once approved, the user can sign in to the requested application with that role.

Roles grant access to Oracle Clinical One Platform and/or Oracle Clinical One Digital Gateway as a whole and not to specific studies. A product administrator still must assign study-specific roles to you from within Oracle Clinical One Platform for you to work in individual studies.

Before you can request roles, a delegated administrator must complete the account creation prerequisites as described in Prerequisites to create accounts. Once you get your role approved for your account, you can access your studies.

> **Note:**
>
> To learn more about the roles that users need, see User roles in Oracle Life Sciences IAMS for all applications. For details on an administrator assigning roles, see Assign roles in Oracle Life Sciences IAMS.

To request a role for Oracle Clinical One Platform and Oracle Clinical One Digital Gateway:

1. As an Oracle Clinical One Platform and Oracle Clinical One Digital Gateway user, navigate to the Oracle Clinical One Platform web site. (See Oracle Clinical One Platform web address if you do not know the web address.)

   The Request for Authorization page opens.

2. Type a justification, and click **Submit**.

   This sends an access request message to the Approver at your organization for the Oracle Clinical One Platform user role: **clinicalone-CNE**.

3. As an Oracle Clinical One Digital Gateway user, navigate to the Oracle Clinical One Digital Gateway web site.
4. Sign in with your Oracle Life Sciences SSO account.
5. Type a justification, and submit it.

   This sends an access request message to the Approve at your organization for the Oracle Clinical One Digital Gateway role: **inthub-CNE**.

Create product administrator accounts

To create a product administrator for Oracle Clinical One Platform, a delegated administrator must create an Oracle Life Sciences single sign-on (SSO) in Oracle Life Sciences IAMS, assign roles, and then add the user as a global user in Oracle Clinical One Platform. The product administrator is typically the first user account you create.

Once created, the global administrator can assign users to studies in Oracle Clinical One Platform and act as a training manager or training administrator for training in other Oracle Life Sciences products.

> **Note:**
>
> Create more than one global user to ensure someone is available to add users to a study. For example, if you need to perform the listed tasks of a global user, add yourself as a global user and another responsible person.

Workflow for creating an account for a product administrator

The following table lists the tasks required to create a product administrator account. You must complete the prerequisites as described in Account creation prerequisites to complete the tasks in this section.

Order	Task	Product	User
1	Create the product administrator account as described in Create an Oracle Life Sciences single sign-on .	Oracle Life Sciences IAMS	Delegated administrator

Order	Task	Product	User
2	Choose one of the following options: • Assign product roles manually as described in Assign roles in Oracle Life Sciences IAMS or through bulk upload as described in Manage Oracle Life Sciences single sign-ons in bulk. • Notify users they can request roles themselves as described in Request roles	Oracle Life Sciences IAMS	Delegated administrator
3	Add an administrator as a global user as described in Add a global user in Oracle Clinical One Platform.	Oracle Clinical One Platform	Delegated administrator, another administrator, or study team member

- Assign roles in Oracle Life Sciences IAMS
  A user with an Oracle Life Sciences single sign-on (SSO) can't start working until they have been assigned one or more product roles. The roles grant access to Oracle Clinical One Platform and/or Oracle Clinical One Digital Gateway as a whole, rather than to specific studies. A product administrator will assign study-specific roles to users from within Oracle Clinical One Platform.
- Manage Oracle Life Sciences single sign-ons in bulk
  If you need to create or update more than one Oracle Life Sciences single sign-on (SSO) in Oracle Life Sciences IAMS, you can make your changes in bulk. Changes that you can make in bulk include creating Oracle Life Sciences SSO accounts, assigning and removing roles, and disabling Oracle Life Sciences SSO accounts.
- Add a global user in Oracle Clinical One Platform
  An organization typically has a limited number of global users. Every organization must have at least one global user.
- Roles for global users in Oracle Clinical One Platform and Oracle Clinical One Digital Gateway
  Global users perform administrative tasks, such as creating studies, adding users to studies, managing integrations, and managing training.

Assign roles in Oracle Life Sciences IAMS

A user with an Oracle Life Sciences single sign-on (SSO) can't start working until they have been assigned one or more product roles. The roles grant access to Oracle Clinical One Platform and/or Oracle Clinical One Digital Gateway as a whole, rather than to specific studies. A product administrator will assign study-specific roles to users from within Oracle Clinical One Platform.

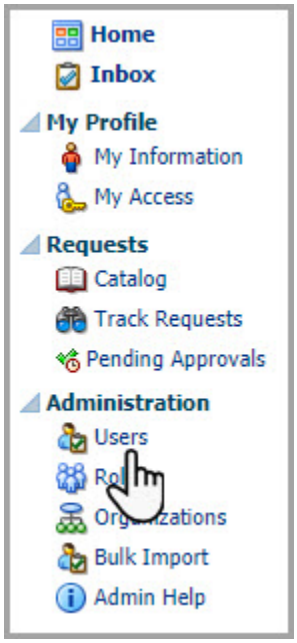
Before you can assign roles to a user, you must complete the steps in Create an Oracle Life Sciences single sign-on .

The following users can assign or request roles:

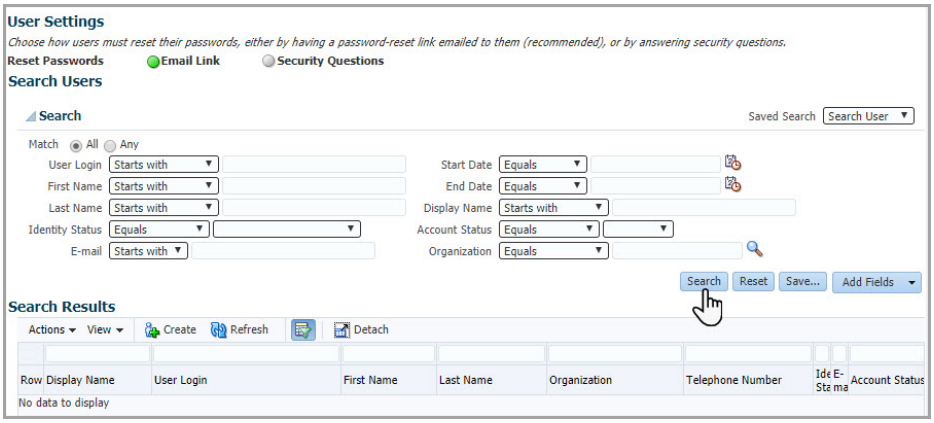
- Delegated administrators can assign roles to Oracle Life Sciences SSO accounts (as described in this procedure)
- Users with Oracle Life Sciences SSO accounts request roles for themselves as described in Request roles

To assign roles to a user:

1. Sign in to Oracle Life Sciences IAMS as described in Sign in to Oracle Life Sciences IAMS directly with your Oracle Life Sciences SSO administrator account.
2. Expand **Administration** in the left panel and click **Users**.



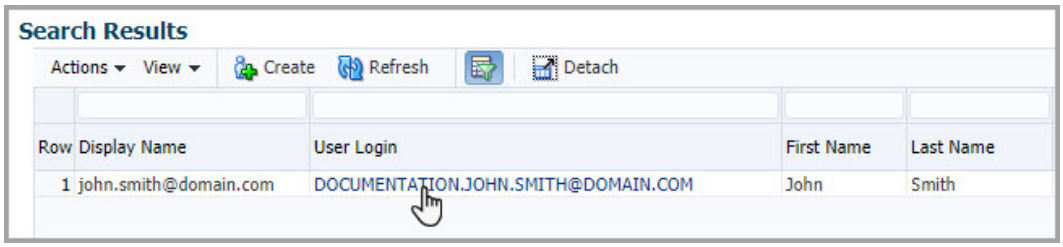
3. Choose one of the following options:
   - To see a list of all users, click **Search**, located below the filtering fields and to the right.



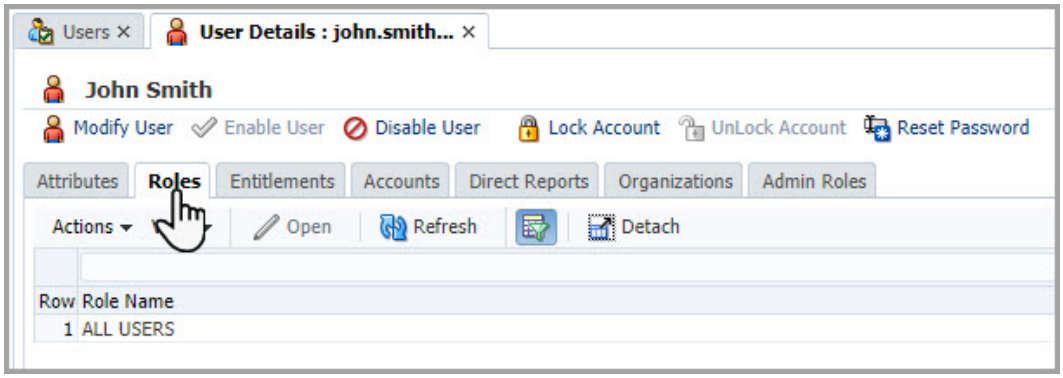
   - To find a user, enter search criteria for the user, and then click **Search**, located below the filtering fields and to the right. For example, choose one of the following options:

- From the **E-mail** drop-down, select **Equals**, and type the user's email address.
- From the **Display Name** drop-down, select **Equals**, and type the user's display name.

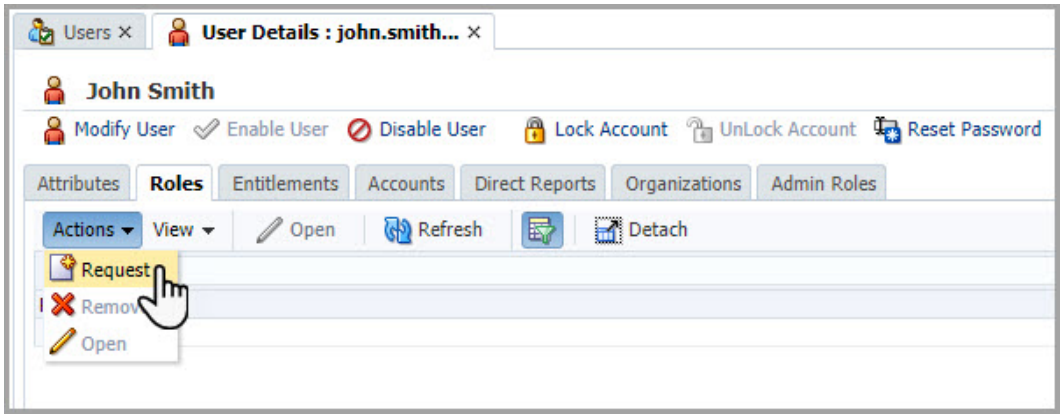
4. In the Search Results table, find the user, and in the **User Login** column, click the user's name.



5. On the User Details page, select the **Roles** tab.



6. From the **Actions** drop-down, located above the table of roles, select **Request**.



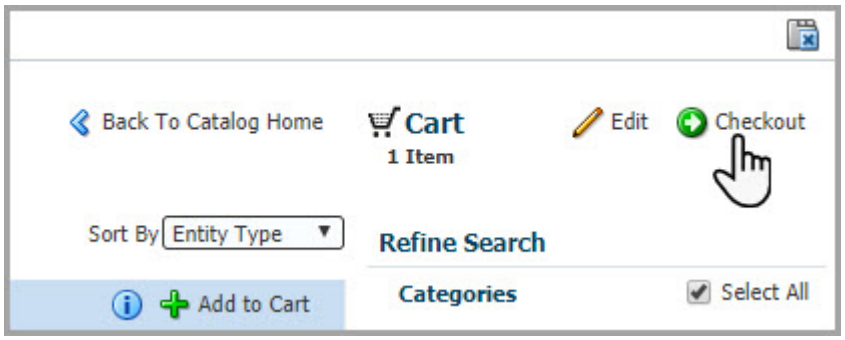
7. Find the roles that the user needs:

> **Tip:**
>
> If you're not sure of the roles that users need, see Which roles do users need in Oracle Life Sciences IAMS?

a. In the search box, type the name of the role and press **Enter**.

b. To the right of each role that the user needs, click **Add to cart**.

8. In the upper-right, click **Checkout**.



9. Review the roles in the cart.
10. In the upper-right, click **Submit**.

    The Request Summary page opens, and a confirmation message appears at the top of the page.
11. If your organization activated approval for the role, ask someone with the Approver role to approve the access requests so that the user receives the role(s) you assigned.

> **Note:**
>
> You cannot approve your own requests, so someone else at your organization with the Approver role must approve them.

Manage Oracle Life Sciences single sign-ons in bulk

If you need to create or update more than one Oracle Life Sciences single sign-on (SSO) in Oracle Life Sciences IAMS, you can make your changes in bulk. Changes that you can make in bulk include creating Oracle Life Sciences SSO accounts, assigning and removing roles, and disabling Oracle Life Sciences SSO accounts.

See the following sections for details.

- Requirements for the bulk import template
  When you update the bulk import template, you must meet certain requirements, including starting every command on a new line, removing angle brackets, and removing spaces.
- Commands for the bulk import template
  When you update the template for a bulk import, you must use the correct commands for creating users, disabling users, assigning roles, and removing roles.

- Download the template for bulk import
  A spreadsheet template for the bulk import file is available in Oracle Identity Self Service. You can download it and reuse it as necessary to create bulk import files.
- Update the bulk import template
  Include commands in the bulk import template for the actions that you want to perform, such as creating or disable Oracle Life Sciences single sign-ons (SSOs) or assigning and removing roles. You can work in a spreadsheet tool, such as Microsoft Excel, or a text editor, such as Notepad.
- Import the template
  After you download and update the bulk import file, you can import it into Oracle Life Sciences IAMS .

Requirements for the bulk import template

When you update the bulk import template, you must meet certain requirements, including starting every command on a new line, removing angle brackets, and removing spaces.

The following list explains the requirements for the file:

- You started every command on a new line, started every command with the appropriate command name, and included all information for a command on a single line.
- If you're working in a text editor, you included a comma after every value except the last value in a row.
- You removed all angle brackets (<>).
- You removed all spaces, including spaces before and after commas in a text editor.

To learn more about working with the template, see Commands for the bulk import template.

Commands for the bulk import template

When you update the template for a bulk import, you must use the correct commands for creating users, disabling users, assigning roles, and removing roles.

To learn more about working with the template, see Update the bulk import template.

Commands for the bulk import template in a text file

Task	Command to use in a text file	Sample command for a text file
Create an Oracle Life Sciences single sign-on (SSO)	`create,<organization id>,<user login>,<email id>,<middle name>,<first name>,<last name>`	`create,Oracle,john.smith@example.com,john.smith@example.com,,john.smith` In the previous example, the user has no middle name. When you don't specify a value for middle name, include no value between the commas, not even a space.
Assign a role to a user	`authorize,<organizatoin id>,<user login>,<role name>`	`authorize,Oracle,john.smith@example.com,ClinicalOne_Production` Want help figuring out the roles to assign?.

Task	Command to use in a text file	Sample command for a text file
Remove a role from a user	`deauthorize,<organizatoin id>,<user login>,<role name>`	`deauthorize,Oracle,john.smith@example.com,ClinicalOne_Production` Want help figuring out the roles to assign?.
Disable a user's Oracle Life Sciences SSO	`disable,<organization id>,<user login>`	`disable,Oracle,john.smith@example.com`

Commands for bulk import in a text Microsoft Excel file

You use the same commands in the same order when using Microsoft Excel for the bulk import, but each value must be in its own cell, as shown in the following example.

	A	B	C	D	E	F
1	create	Oracle	john.smith@example.com	john.smith@example.com		john.smith
2	authorize	Oracle	john.smith@example.com	ClinicalOne_Production		
3	deauthorize	Oracle	john.smith@example.com	ClinicalOne_Production		
4	disable	Oracle	john.smith@example.com			

Command values

Value	Description
`<email id>`	Enter the user's email address.
`<first name>`	Enter the user's first name.
`<last name>`	Enter the user's surname or family name.
`<middle name>`	(Optional) Enter the user's middle name. If you don't enter a value, leave the cell blank in Microsoft Excel; or in a text editor, delete the placeholder text and leave the comma.
`<organization id>`	Enter your company's ShortOrgId. Need help finding your company's ShortOrgId?
`<role name>`	Enter the role you are granting or removing, including the ShortOrgId as a prefix. For example, mypharma.Approver
`<user login>`	Enter the user's email address.

Download the template for bulk import

A spreadsheet template for the bulk import file is available in Oracle Identity Self Service. You can download it and reuse it as necessary to create bulk import files.

To download the template for bulk import:

1. Sign in to Oracle Life Sciences IAMS as described in Sign in to Oracle Life Sciences IAMS directly.
2. Expand **Administration** in the left panel and click **Bulk Import**.
3. Click **Import a File**.

4. Click **Help**.
5. Click **Download Sample File**.

Update the bulk import template

Include commands in the bulk import template for the actions that you want to perform, such as creating or disable Oracle Life Sciences single sign-ons (SSOs) or assigning and removing roles. You can work in a spreadsheet tool, such as Microsoft Excel, or a text editor, such as Notepad.

Before you begin, you must download the template as described in Download the template for bulk import.

To update the bulk import template:

1. Open the file using either Microsoft Excel or a text editor, such as Notepad.
2. Add the appropriate commands to the template, using one row for each command. (For details on commands, see Commands for the bulk import template and Requirements for the bulk import template.)
3. Save the file in CSV or TXT format.

Import the template

After you download and update the bulk import file, you can import it into Oracle Life Sciences IAMS .

For details on downloading or updating the bulk import file, see Download the template for bulk import and Update the bulk import template.

To import the template file:

1. Sign in to Oracle Life Sciences IAMS as described in Sign in to Oracle Life Sciences IAMS directly.
2. Expand **Administration** in the left panel and click **Bulk Import**.
3. Click **Import a File**.
4. On the Upload File page, click **Browse**.
5. Navigate to your bulk import file, select it, and click **Open**.

   The file name appears in the Select a file field.
6. Click **Upload**.

   After the file uploads, the Confirm Data to Import page opens, showing a preview of the uploaded commands.
7. Review the commands for accuracy and then perform one of the following steps:
   - Click **Import** if you approve the commands.
   - Fix any invalid commands. See the following topics for details on commands: Commands for the bulk import template and Requirements for the bulk import template.
   - If the commands look correct, but the **Import** button appears inactive, locate operations with a red X icon in the Status column and check the Message column for details. Then correct the errors in your bulk import file and restart the upload process. Contact Life Sciences Support if you cannot upload the file.

8. On the Result Details page, review the **Status** column for all entries:
   - A green checkmark appears for successful operations.
   - A red X appears for operations that were not valid and were not executed. Check the **Message** column for details about the error. Point to a cell to see the full message. To view the full text of the messages, download the file as described in Download a file from a previous bulk import.
9. For operations that did not execute, choose one of the following to complete the operations:
   - If only a few operations failed, manually perform the remaining operations.
   - If a large number of operations failed, resubmit the bulk import file with only those operations that failed, after correcting the errors. For assistance, see Requirements for the bulk import template or contact Life Sciences Support.

- Download a file from a previous bulk import
  If you or someone else at your organization previously did a bulk import, you can download the file to see the changes that were made.

Download a file from a previous bulk import

If you or someone else at your organization previously did a bulk import, you can download the file to see the changes that were made.

To download a file from a previous bulk import:

1. Sign in to Oracle Life Sciences IAMS as described in Sign in to Oracle Life Sciences IAMS directly.
2. Expand **Administration** in the left panel and click **Bulk Import**.
3. Click **View Imported Files**.
4. In the **File Name** column, click the item you want to review.

   The Result Data page opens, showing the import details.
5. To download the file, click and save it locally.

Add a global user in Oracle Clinical One Platform

An organization typically has a limited number of global users. Every organization must have at least one global user.

To decide which users to add as global users, see Create product administrator accounts.

Before you can add a global user, you must:

- Create an account for the user as described in Create an Oracle Life Sciences single sign-on .
- Check that your account includes the ClinicalOne-CNE_AssignGlobalRoles role as described in Assign roles in Oracle Life Sciences IAMS.

Show me how!

Video

To add a global user:

1. Open Oracle Clinical One Platform by navigating to the web site and signing in with your Oracle Life Sciences SSO.
2. On the Home page, click **Global Settings**, along the top.
3. Click **Create Global User**.
4. From the **Full Name** drop-down, select the user's name.
5. Click into the **Global Roles** field and select one or more global roles to assign to the user across all studies in Oracle Clinical One Platform.

   To view the rights of each global role, click **View Permissions**, and select the role from the **Roles** drop-down.

   For more information on the global roles, see Roles for global users in Oracle Clinical One Platform and Oracle Clinical One Digital Gateway.
6. Click **Create**.

After Oracle creates the study, an administrator can add a user to a study as described in Add a user to a study in Oracle Clinical One Platform.

Roles for global users in Oracle Clinical One Platform and Oracle Clinical One Digital Gateway

Global users perform administrative tasks, such as creating studies, adding users to studies, managing integrations, and managing training.

Besides the required roles assigned to users in Oracle Life Sciences IAMS, global users must be assigned the appropriate roles to complete their assigned tasks in Oracle Clinical One Platform and Oracle Clinical One Digital Gateway. You can assign one or more of the following roles to global users.

Role	Description
Assign Site to a Study	Assigns sites to studies within the Oracle Clinical One Platform.
Change Library Objects Status	Updates the status of an object in an organization's library.
Code List Manager	• Creates study roles that are available at an organization level. These study roles are populated in each of your studies when the study is created. • Creates and manages different types of code lists at a global level (for all studies at your organization): creates new system code lists, edits existing system default code lists, creates and manages custom code lists. • Builds reports and visualizations using the Tenant Codelists Dataset in Oracle Clinical One Analytics. **Note:** This role may be assigned to users at a sponsor or CRO in order for them to create and manage code lists for all studies at their organization.
Coding Integration	Configures and manages an integration between the Oracle Clinical One Platform and Oracle Central Coding

Role	Description
Create Study Roles for your Organization	Creates study roles that are available at an organization-level. Typically, this role may be assigned to someone who performs standard study design tasks and can also create organization-level study roles.
DataHubInternal	A global role internal to Oracle, which should not be associated with external global users. This role is typically assigned to internal Oracle users who configure integrations with Oracle Clinical One Analytics.
DMW Integration	Manages the integration of Oracle Life Sciences Data Management Workbench with Oracle Clinical One Platform. **Note:** Users with this permission must also ensure production data is appropriately synchronized between Oracle Clinical One Platform and Oracle DMW.
Global User Manager	Adds users to a study and assigns all roles, including global users, and manages the training requirements for your organization. **Note:** If the user is responsible for assigning other users to sites, the user must also be a site and user manager, and be assigned to all sites and depots that they have to associate users with. See Best practices for role, site, and depot assignment for more information.
Intake Designer	Designs and configures Recipes required to process incoming Release Assessment Environment documents, to extract data within Oracle Safety One Intake.
Intake Integration	Integrates data with external systems from the Oracle Safety One Intake business service. **Note:** This role is only for API Integration users.

Role	Description
Intake Processing	A Oracle Life Sciences Safety One Intake Cloud Service user who processes Release Assessment Environment documents. **Note:** This role is only for the Oracle Safety One Intake business service.
Intake Service User	A Oracle Safety One Intake user who executes the background services necessary for processing Release Assessment Environment documents. **Note:** This role is only for users of the Oracle Safety One Intake business background service.
Intake View Only	A Oracle Safety One Intake user who provides read-only access to support users. Can be used to provision restrictive access to support users.
Integration Builder	This Oracle internal role should not be assigned to your users even though it is visible in the Oracle Clinical One Platform user interface.
Integration Developer	This Oracle internal role should not be assigned to your users even though it is visible in the Oracle Clinical One Platform user interface.
Integration Manager	Configures integration templates and monitors integrations once they are live. **Note:** Error messages for failed jobs may contain integrated data that could be unblinding. Users who can review error messages should not be blinded study users.
Integration Viewer	This role grants users read-only access to all Oracle Clinical One Digital Gateway areas, mainly for monitoring purposes.
Create and Edit Library Kits for Pool Supplies	Creates and edits kits (including pooled kits) in a library study only in Draft mode.
Approve Library Kits for Pooled Supplies	Approves and edits kits in a library study whether the kit has a status of Draft, Approved, or Published.
Delete Library Kits	Deletes kits from a library study.
Manage Contacts and Organizations	Manage contacts and organizations to create your sites in Oracle Clinical One Platform. Users with this role also have the ability to transfer organizations and contacts associated with active studies.
Manage Library Objects	Allows a library user to manage an object within the library, such as editing an object's attributes, updating its details in a library study, or updating an object's status.

Role	Description
Oracle Admin	A global role internal to Oracle, which should not be associated with external global users.
Service Account	A global role internal to Oracle, which should not be associated with external global users.
Study Creator	Creates studies, manages global users and assigns roles to users in Oracle Clinical One studies. This user does not have access to individual sites in the studies. You must assign User and Site Manager roles in the study. The only users who can assign study design roles are global users with the Study Creator role. Study design roles include: • Study designer • User administrator • View study design If the user is also responsible for assigning other users to sites and depots, the user must be added to the study as a site and user administrator, and be assigned to all sites and depots that they have to associate users with. See Best practices for role, site, and depot assignment for more information.
Training Administrator	Creates training studies for and assign training managers across Oracle Life Sciences products: • Oracle InForm • Oracle Central Designer • Oracle Central Coding • Oracle InForm User Management Tool • Oracle IRT **Note:** You need to assign this role to users only if you're using Oracle Health Sciences Learn Manager to create training studies for all previously mentioned products.
Training Manager	Assigns training to users and sends reminders across Oracle Life Sciences products: • Oracle InForm • Oracle Central Designer • Oracle Central Coding • Oracle InForm User Management Tool • Oracle IRT Checks the training that a user has completed and runs reports for assigned and completed training. **Note:** You need to assign this role to users only if you're using Oracle Health Sciences Learn Manager to create training studies for all previously mentioned products.

Role	Description
View Contacts and Organizations	Manages contacts and organizations to create your sites in Oracle Clinical One Platform.
View Library Objects	Views objects in an organization's library without the ability to edit or manage them.

Provide user access to Oracle Clinical One Digital Gateway

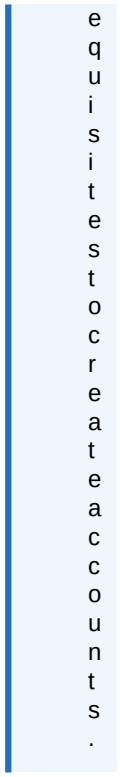
To provide a user access to Oracle Clinical One Digital Gateway, a Customer Delegated IAMS Administrator (CDA) must create an Oracle Life Sciences single sign-on (SSO) user account and assign the appropriate product roles in Oracle Life Sciences Identity and Access Management Service (IAMS). Then, add the user account as a global user and assign the appropriate global roles in Oracle Clinical One Platform.

The following table provides the details to complete these tasks.

Order	Task	Product	User
1	Create an Oracle Life Sciences SSO account; for details, see Create an Oracle Life Sciences single sign-on .	Oracle Life Sciences IAMS	CDA

Note:

Before starting, consider reviewing the Prer

Order	Task	Product	User
			
2	Assign the following product roles as described in Assign roles in Oracle Life Sciences IAMS. • clinicalone-CNE • inthub-CNE For more information, see User roles in IAMS for all applications.	Oracle Life Sciences IAMS	CDA
3	Add the user as a global user as described in Add a global user in Oracle Clinical One Platform, and assign the following global roles. • Integration Manager • Integration Viewer For more information, see Roles for global users.	Oracle Clinical One Platform	CDA, another administrator, or study team member

Access requests

If you use the approval process to grant users access to applications, it generates access requests. The user with the Approver role must approve or reject these requests. If approved,

the user can access the application. If your organization does not use the approval process, assigned roles take effect immediately.

An organization can generate a request in any of the following ways:

- An administrator assigns an Oracle Clinical One Platform role to a user. If an Approver assigns the role, another Approver must approve the request.
- A user submits an access request through the page the administrator set up as described in Set up an authorization request page.

For details about how to request access, see Request access to Oracle Clinical One Platform. For details on the Approver role, see Request the Approver role.

- Review and approve an access request
  When an organization requires approval for roles, an access request is generated when a delegated administrator assigns a role to a user and when a user opens the product URL and submits a request. A role is assigned to a user only the access request is approved.
- Customize your view of access requests
  If you have the Approver role, you approve or reject access requests. You can customize your view of the access requests so you can see all the information you need about a request.
- Notify users they can access studies
  After you approve an access request, let users know that they can start working in Oracle Clinical One Platform. This process occurs outside Oracle Life Sciences IAMS.

Review and approve an access request

When an organization requires approval for roles, an access request is generated when a delegated administrator assigns a role to a user and when a user opens the product URL and submits a request. A role is assigned to a user only the access request is approved.

We recommend checking your pending approvals in Oracle Life Sciences IAMS frequently to see whether any new requests have come in. A number next to Pending Approvals in the menu on the left indicates the number of open access requests. Keep in mind that you can't approve a request that you requested for yourself or someone else.

To review and approve or reject an access request:

1. Sign in to Oracle Life Sciences IAMS as described in Sign in to Oracle Life Sciences IAMS directly.
2. If you have a custom view, select it under My Views on the left.

   > **Tip:**
   >
   > To see additional information about each access request, you can customize the columns. See Customize your view of access requests for details.

3. If multiple users in your organization have the Approver role, claim the pending request that you intend to approve or reject:

If you're the only approver, you can skip this step.

a. Select the row of the request.

b. From the **Actions** list at the top of the page, select **Claim**.

4. Double-click the row of the request.
5. Determine whether to approve or reject the request.

   For guidance on the roles that everyone needs, see User roles in Oracle Life Sciences IAMS for all applications.
6. If you're rejecting a request, add a comment:

   Adding a comment is optional if you approve the request.

   a. Select the **Approval** tab.

   b. In the upper right of the Comments text box, click **Create**.

   c. Type your comment and click **OK**.
7. In the top right of the page, click either **Approve** or **Reject**.

After you approve requests, make sure you notify users as described in Notify users they can access studies.

Customize your view of access requests

If you have the Approver role, you approve or reject access requests. You can customize your view of the access requests so you can see all the information you need about a request.

Any custom views that you create are visible only to you.

To customize your view of the Approval Details page:

1. Sign in to Oracle Life Sciences IAMS as described in Sign in to Oracle Life Sciences IAMS directly.
2. Under the **Requests** menu on the left, click **Pending Approvals**.
3. On the Approval Details page, click the **Add View** icon on the toolbar.
4. On the Definition tab, edit the **Name** field to give your view a name.
5. Select the task types that appear in your view:

   a. To the right of Task Type, click the search icon.

   b. Press **Ctrl**, and select **RoleLevelApprovalFlow** and **RoleLevelApprovalFlowNoMail**.

   c. Click **OK**.
6. Select the columns to appear in your view:

   a. Select the **Display** tab.

   b. Move columns from the **Available** list to the **Selected** list to add them to your view.

      We recommend that you include the following columns in your view:

      - **Title**: Contains the link to the Request Details page.
      - **Requester**: Displays the requesting user's full name, including the ShortOrgId.

- **RequesterDisplayName**: Shows the requesting user's display name.
- **RequestID**: Contains the unique identifier for the access request in Oracle Life Sciences IAMS.
- **Acquired By**: Shows the display name of the Approver who claimed the request, useful if there are multiple users with the Approver role in your organization.

c. Click **OK**.

Your view is created and is available from the **Views** menu, under **My Views**.

Notify users they can access studies

After you approve an access request, let users know that they can start working in Oracle Clinical One Platform. This process occurs outside Oracle Life Sciences IAMS.

Users who were assigned the Oracle Clinical One Platform administrator role (either ClinicalOne_Production_AssignGlobalRoles or clinicalone-CNE_AssignGlobalRoles, depending on your environment) can start adding users in Oracle Clinical One Platform. If you are a delegated administrator, the person with this role might be you.

> **Note:**
>
> If an administrator created the appropriate Oracle Life Sciences SSO and approved your role assignment for Oracle Clinical One Digital Gateway, you can access that application. See the email notification you received to activate your account and for details on the Oracle Clinical One Digital Gateway web address. For more details, see Oracle Life Sciences SSO account notification.

4

Manage roles in Oracle Clinical One Platform

- Oracle Clinical One Platform web address
  You receive the web address (URL) for signing in to Oracle Clinical One Platform in an email after an administrator assigns the product roles to you in Oracle Life Sciences IAMS.
- Sign in and out of Oracle Clinical One Platform
  You sign in using your Oracle Life Sciences single sign-on (SSO) user name and password. You receive your Oracle Life Sciences SSO details over email after your SSO is created.
- Create study user accounts
  To create a study user in Oracle Clinical One Platform, a delegated administrator must create an Oracle Life Sciences single sign-on (SSO) in Oracle Life Sciences IAMS, assign roles, and then add the user to the appropriate study. Whether the user works at the sponsor, CRO, site, or depot, the workflow for creating the user account is the same.
- Study roles in Oracle Clinical One Platform
  Study roles represent a collection of permissions that - when assigned appropriately to a user - let them perform their tasks in the system in an efficient manner, without compromising the study blind.
- Edit a study role that is already assigned to users
  As a global user manager or study user administrator, you can edit an existing study role created for both all studies or just an individual study, even if the study role is already assigned to users.
- Retire a study role
  Study roles can never be completely removed, but they can be retired. If a study role is no longer of use in your study, you can always retire it. Users who have previously been assigned the now retired study role will not lose their permissions. Retired study roles are simply made unavailable for new use.
- Remove a user in Oracle Clinical One Platform
  In Oracle Clinical One Platform, you can remove a study user (someone who is assigned to one or multiple studies) or you can remove a global user (someone who is assigned a global role and may have access to all studies in your organization).
- Specify data classifications for a study role
  Data classifications allow you to control which users can view or edit a specific type of question in the study. As a global user administrator or study user administrator, you can assign specific permissions to users depending on what type of classified data they should get access to.

Oracle Clinical One Platform web address

You receive the web address (URL) for signing in to Oracle Clinical One Platform in an email after an administrator assigns the product roles to you in Oracle Life Sciences IAMS.

The sender of the email is **Alerts@clinicalone.oraclecloud.com** with a subject of **Access information for the study_name study in Clinical One**.

Everyone who is supposed to work in receives this email. Besides the web address (URL), the email also contains the date when access begins and the name of the study.

This guide does not include the format of the web address for Oracle Clinical One Platform for security reasons. If you did not receive an email with the web address or you cannot locate it, contact the delegated administrator at your organization or your Oracle project manager.

Sign in and out of Oracle Clinical One Platform

You sign in using your Oracle Life Sciences single sign-on (SSO) user name and password. You receive your Oracle Life Sciences SSO details over email after your SSO is created.

Before you can sign in to Oracle Clinical One Platform, you must activate your account. For more information, see Oracle Life Sciences SSO account notification .

To sign in Oracle Clinical One Platform:

1. Enter the Oracle Clinical One Platform web address in your browser.
2. Sign in with your Oracle Life Sciences SSO user name and password.

After you sign out of the application, for security reasons, you are redirected to a specific sign out page. To sign in the application again, you must initiate a new browser session.

Create study user accounts

To create a study user in Oracle Clinical One Platform, a delegated administrator must create an Oracle Life Sciences single sign-on (SSO) in Oracle Life Sciences IAMS, assign roles, and then add the user to the appropriate study. Whether the user works at the sponsor, CRO, site, or depot, the workflow for creating the user account is the same.

When you add the user to a study, you must choose the appropriate roles so the user's access to the product allows them to complete their job tasks.

Workflow for creating an account for a study user

The following table walks you through the tasks for creating accounts for study users. Before completing the tasks in this table, complete the prerequisite tasks and create a product administrator.

Order	Task	Product	User
1	Create an Oracle Life Sciences SSO as described in Create an Oracle Life Sciences single sign-on .	Oracle Life Sciences IAMS	Delegated administrator

Order	Task	Product	User
2	Choose one of the following options: • Assign product roles manually as described in Assign roles in Oracle Life Sciences IAMS or through bulk upload as described in Manage Oracle Life Sciences single sign-ons in bulk. • Notify users they can request roles themselves as described in Request roles	Oracle Life Sciences IAMS	Delegated administrator
3	Create the study roles as described in Create a study role for one study or Create a study role for all studies.	Oracle Clinical One Platform	Delegated administrator or study administrator
4	Add the user to the study as described in Add a user to a study in Oracle Clinical One Platform.	Oracle Clinical One Platform	Delegated administrator or study administrator

- Create a study role for all studies
  As a global user manager, you may want to a create study role that is available to users for all studies in the application. This allows you to assign study roles consistently to users across all studies in your organization.
- Create a study role for one study
  You can create a study role that is available only to users in a single study in the application.
- Add a user to a study in Oracle Clinical One Platform

Create a study role for all studies

As a global user manager, you may want to a create study role that is available to users for all studies in the application. This allows you to assign study roles consistently to users across all studies in your organization.

When you create a study role at the organization level, it is automatically available to each newly created study in your organization. When a study role of this type is made available in your new study, you can assign it to any user in your study. Newly created study roles, as well as updates to existing study roles at the organization level do not automatically propagate into existing studies.

1. Follow the steps in Create an Oracle Life Sciences single sign-on to create the Oracle Life Sciences SSO.
2. Do one of the following:
   - Assign roles manually as described in Assign roles in Oracle Life Sciences IAMS.

- Assign roles in bulk as described in Manage Oracle Life Sciences single sign-ons in bulk.
- Let users request roles as described in Request roles.

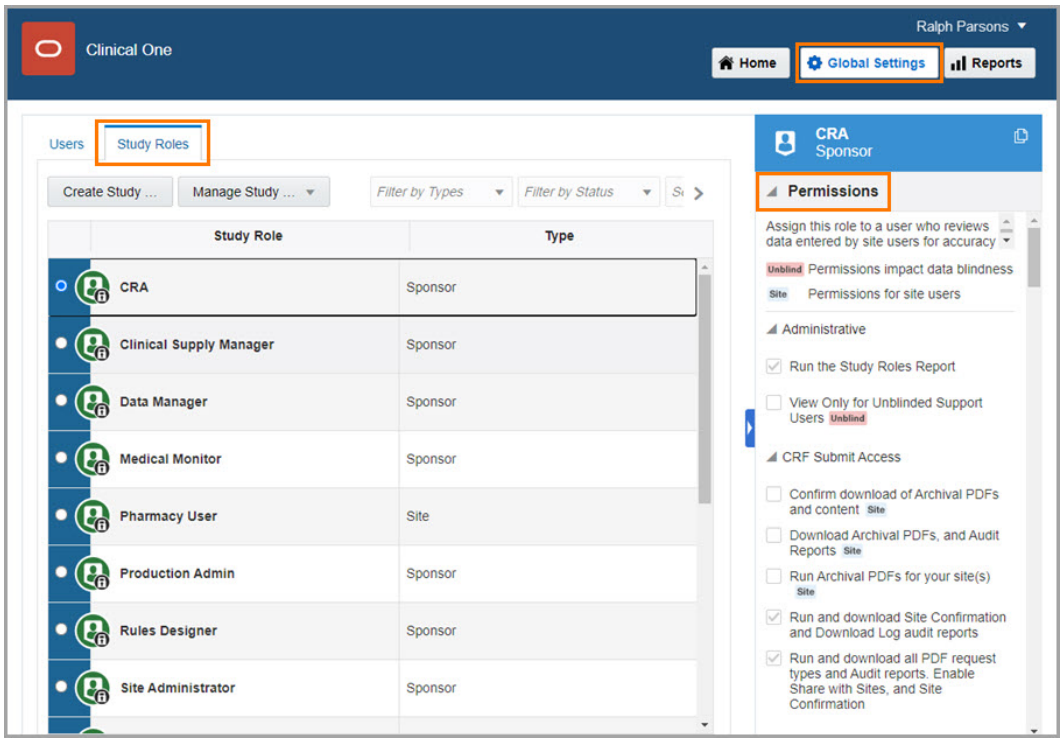
To create a study role that's available in all studies:

1. On the Home page, along the top, click **Global Settings**.
2. Go to the **Study Roles** tab.
3. You can either:
   - Copy an existing study role by selecting an existing study role from the list and then, from the **Manage Study Role** drop-down, select **Copy**.
   - Create your own custom study role by clicking **Create Study Role**.
4. On the left, fill in the fields:
   - **Role Name**: Enter a name for the study role. We recommend using a descriptive name so you'll remember the roles that are in the template later.
   - **Type**: Select **Sponsor** if the role will be assigned to a member of the study team at either the sponsor or CRO, **Site** if the role will be assigned to a site user, or **Design** if the role will be assigned to a study designer.
   - **Description**: This is optional, but you can add a short description of the study role in this field.
5. On the right, select the permissions to include in the study role.

   The search is performed across all three groups of rights: sponsor, site, and design. If you try to add an unblinding role, you'll get a warning message to confirm that you want to take this action.
6. Click **Save**.

   You now can start assigning this study role to users.

Figure 4-1 How a global user manager creates a study role



Related Topics

- Edit a study role that is already assigned to users
  As a global user manager or study user administrator, you can edit an existing study role created for both all studies or just an individual study, even if the study role is already assigned to users.
- Retire a study role
  Study roles can never be completely removed, but they can be retired. If a study role is no longer of use in your study, you can always retire it. Users who have previously been assigned the now retired study role will not lose their permissions. Retired study roles are simply made unavailable for new use.
- Specify data classifications for a study role
  Data classifications allow you to control which users can view or edit a specific type of question in the study. As a global user administrator or study user administrator, you can assign specific permissions to users depending on what type of classified data they should get access to.
- Roles for study designers
  Learn more about the responsibilities and the roles of a study designer.
- Roles for blinded study users
  Learn more about the roles and responsibilities of a blinded study user, such as a CRA or a data manager.
- Roles for unblinded study users
  Learn more about the roles and responsibilities of an unblinded study user, such as a clinical supply manager or statistician.
- Roles for site users
  Learn more about the roles and responsibilities of a site user.

Create a study role for one study

You can create a study role that is available only to users in a single study in the application.

When you create a study role at a study level, it is only available for the specific study where it is created. When a study role of this type is available in your study, you can assign it to any user that will be part of that study.

1. Follow the steps in Create an Oracle Life Sciences single sign-on to create the Oracle Life Sciences SSO.
2. Do one of the following:
   - Assign roles manually as described in Assign roles in Oracle Life Sciences IAMS.
   - Assign roles in bulk as described in Manage Oracle Life Sciences single sign-ons in bulk.
   - Let users request roles as described in Request roles.

To create a study role that is available in a single study:

1. On the Home page, click the study settings button ( ) for the study you want to edit, and select **Open Settings**.
2. Below the study name, click the **Study Roles** tab.
3. You can either:
   - Copy an existing study role by selecting an existing study role from the list and then, from the **Manage Study Role** drop-down, select **Copy**.
   - Create your own custom study role by clicking **Create Study Role**.

> **Note:**
>
> If you want to create a study role that is similar to one that you have already retired, you can copy a retired role by selecting the retired study role, and then selecting **Copy** from the **Manage Study Role** drop-down.

4. On the left, fill in the fields:
   - **Role Name**: Enter a name for the study role. We recommend using a descriptive name so you'll remember the roles that are in the template later.
   - **Type**: Select **Sponsor** if the role will be assigned to a member of the study team at either the sponsor or CRO, **Site** if the role will be assigned to a site user, or **Design** if the role will be assigned to a study designer.

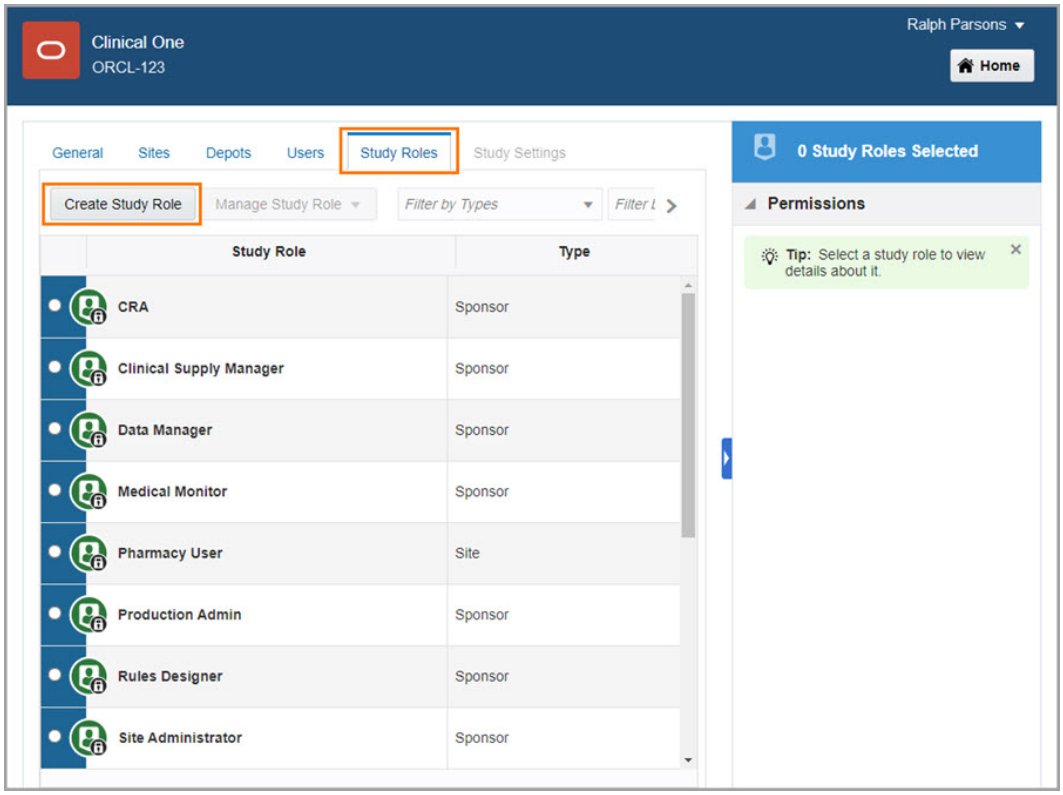
> **Note:**
>
> If you try to add an unblinding role, you'll get a warning message to help confirm that you want to take this action.

- **Description**: This is optional, but you can add a short description of the study role in this field.

5. On the right, select the permissions to include in the study role.
6. Click **Save**.

   You now can start assigning this study role to users.

Figure 4-2 How a user administrator creates a study role



Related Topics

- Edit a study role that is already assigned to users
  As a global user manager or study user administrator, you can edit an existing study role created for both all studies or just an individual study, even if the study role is already assigned to users.
- Retire a study role
  Study roles can never be completely removed, but they can be retired. If a study role is no longer of use in your study, you can always retire it. Users who have previously been assigned the now retired study role will not lose their permissions. Retired study roles are simply made unavailable for new use.
- Specify data classifications for a study role
  Data classifications allow you to control which users can view or edit a specific type of question in the study. As a global user administrator or study user administrator, you can assign specific permissions to users depending on what type of classified data they should get access to.
- Roles for study designers
  Learn more about the responsibilities and the roles of a study designer.

- Roles for blinded study users
  Learn more about the roles and responsibilities of a blinded study user, such as a CRA or a data manager.
- Roles for unblinded study users
  Learn more about the roles and responsibilities of an unblinded study user, such as a clinical supply manager or statistician.
- Roles for site users
  Learn more about the roles and responsibilities of a site user.

Add a user to a study in Oracle Clinical One Platform

A product administrator who was created as a global user adds the first user to a study and assigns study roles. The first user in a study is typically an administrator who is responsible for adding other users to the study. This user is called a user and site administrator.After the user and site administrator is added to a study, the global user can continue adding users, or the user and site administrator can add the remaining users.

Before you can add a user to a study, you must:

- Create an account for the user as described in Create an Oracle Life Sciences single sign-on .
- Check that your account includes the Global User Manager or Study Creator role as described in Assign roles in Oracle Life Sciences IAMS.
- Verify that the user took the relevant training assigned to their roles before starting to work. Your organization implements mechanisms that address regulatory requirements for training.
- Sign in to Oracle Clinical One. For details, see Sign in and out of Oracle Clinical One Platform.

To add a user to a study in Oracle Clinical One Platform:

1. On the Home page, click **Study Settings** ( ) , then select **Open Settings**.
2. Select the **Users** tab, and then click **Create/Assign User**.

   The **Create/Assign User** window opens.
3. Click **Assign a User** and complete the following fields.

Item	Description
Full Name	Select the name of the user that you want to add to the study.
User Name	This field is automatically populated and cannot be edited.
Email	This field is automatically populated and cannot be edited.

Item	Description
Effective Date Range	Enter a **From** and **To** date, defining when the user can access the study. **Note:** Oracle Clinical One Platform uses Coordinated Universal Time (UTC) to determine study access. For example, a user with an effective from date of 03 Apr can access the study as of 12:01 AM UTC on the 3rd. If the user is on the United States East Coast, they can access the study at 8:01 PM ET on the 2nd. It would be an hour earlier when observing daylight saving time. Select **No End Date** to allow the user access without expiring. However, we recommend specifying an end date to ensure you can record when a user had access to the study after it ends. Specifying an end date is also recommended in place of removing a user, making it easier to reinstate a user if needed.

4. Select the appropriate **Study Roles** for each mode, then click **Next**. For a list of permissions assigned to each study role, click **View Permissions for Study Roles**, then select the role to see the permissions.

Item	Description
Study Design Mode	Select a study role if the user needs to be part of the study design process.
Testing Mode	Select a study role if the user needs to be included in testing before the study goes live.
Production Mode	Select a study role if the user needs to access the study during the study conduct period.
Training Mode	Select a study role if the user needs to complete training. **Note:** Users typically have the same study role in training and production modes. If that is the case, click **Same as production mode**.

5. Select the sites and depots the user needs access to. For more details, see Best practices for role, site, and depot assignment.

> **Note:**
>
> You can select **All Sites** and **All Depots** or you can select individual sites and depots.

6. Click **Finish**.

   You are presented with the system message, Success, The <user name> user has been created.

The user receives an email with the name of the study, the URL for Oracle Clinical One Platform, and the date when they can start working.

Related Topics

- Edit a study role that is already assigned to users
  As a global user manager or study user administrator, you can edit an existing study role created for both all studies or just an individual study, even if the study role is already assigned to users.
- Retire a study role
  Study roles can never be completely removed, but they can be retired. If a study role is no longer of use in your study, you can always retire it. Users who have previously been assigned the now retired study role will not lose their permissions. Retired study roles are simply made unavailable for new use.
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  Learn more about the roles and responsibilities of an unblinded study user, such as a clinical supply manager or statistician.
- Roles for site users
  Learn more about the roles and responsibilities of a site user.

Study roles in Oracle Clinical One Platform

Study roles represent a collection of permissions that - when assigned appropriately to a user - let them perform their tasks in the system in an efficient manner, without compromising the study blind.

As a user administrator, you can leverage the existing study role templates that you can use for all studies in your organization.

Starting with a template study role provided by Oracle is the recommended course of action. Template study roles already contain the standard combinations of permissions for each type of user that must be created in a study. If you want to further customize a user's study role and permissions, we recommend you copy the template study role

(found available for all studies in your organization) for your single study and then proceed to add or remove permissions for each study role, as needed. This is considered the recommended and safest option for you, as a user administrator.

What are my documentation resources to create the best study roles for my users?

To ensure that you make the best decision when it comes to your user management strategy, we have prepared a complete list of useful documentation resources. See a list of all resources below.

Resource	Description
Study role examples	These topics describe the combinations of permissions that are included in the template study roles for every user in a study, from site users to support or integration users.
Descriptions of permissions in Oracle Clinical One Platform	As the title suggests, this chapter contains specific descriptions of each permission that exists in the application. With this reference material, you can better understand the scope of each permission to know exactly what you are assigning to your study users.
Best practices for study role, site, and depot assignments	Besides permissions and study roles, site and depot assignments are also a key part of the user provisioning process. We offer you clear guidelines and best practices for how to assign users to every type of site and depot in every study mode.
Step-by-step instructions to create and manage roles in Oracle Clinical One Platform	We have documentation to guide you every step of the way when creating study user accounts and assigning the appropriate roles to users.

- Roles for study designers
  Learn more about the responsibilities and the roles of a study designer.
- Roles for blinded study users
  Learn more about the roles and responsibilities of a blinded study user, such as a CRA or a data manager.
- Roles for unblinded study users
  Learn more about the roles and responsibilities of an unblinded study user, such as a clinical supply manager or statistician.
- Roles for site users
  Learn more about the roles and responsibilities of a site user.
- Best practices for role, site, and depot assignment
  Users with different responsibilities require different roles. For example, some users need the ability to add users to a study. Some need to only add to add site and depot users.

Roles for study designers

Learn more about the responsibilities and the roles of a study designer.

About these study roles

- **Modes**: These study roles are only available in Study Design Mode.

- **Users**: You typically assign these study roles to a study designer or user administrator in your study.
- **Type**: These study roles fall under the Design Study category. Permissions in these study roles are both blinded and unblinding. Unblinding permissions allow users to view a study's design or design a study's randomization.

Designer roles and their responsibilities

> **Note:**
>
> If you are a rules designer who must add or edit custom JavaScript rules, besides the Rule Designer study role, you also need a study design role to be able to use the Rules sidebar in a form. At a minimum, you should be assigned the *View Study Design* template study role.

Role	Responsibilities	Notes
Study Designer	• Design a study with all of its data collection and supply elements, such as forms, visits, kit types, randomization designs. • Run reports related to a study's design. • View and analyze a study's design. • Test a study's design in Testing mode.	A study designer typically has a global-level access, too, by being assigned the Study Creator global role. For more information, see Roles for global users in Oracle Clinical One Platform and Oracle Clinical One Digital Gateway.
User Administrator	• Add and administer users and study role, site, and depot assignments.	None.
View Study Design	• View a study's design.	This is a standalone study role that a user administrator or global user manager can assign to an unblinded study team member or site user who should view the study's design. This study role can be found as a predefined template role in all studies, but it can also be recreated as a customized study role for a single study.

Roles for blinded study users

Learn more about the roles and responsibilities of a blinded study user, such as a CRA or a data manager.

About these study roles

- **Modes**: You can assign these study roles in Testing, Training, and Production mode.

- **Users**: You typically assign these study roles to a blinded study team member, such as a Clinical Research Associate (CRA), data manager, medical monitor, or blinded depot user.
- **Type**: These study roles fall under the Sponsor category.

Blinded study team member roles and their responsibilities

Role	Responsibilities	Notes
Adjudicator	• View, edit, and manage classified subject data.	None.
Blinded depot user	• View and manage their associated depots' inventory: receive shipments, process shipments, update kit status. • View and manage shipments *only* at depots they are assigned to.	The Blinded Depot User role hides full details and descriptions of kits to protect blinding. However, the study role provides access to view the kit numbers for all blinded, unblinded, and unblinded pharmacist kits when assigned. For a depot user to see the site inventory, they need to be associated to the given sites.
Clinical Research Associate (CRA)	• Review and verify subject-entered data at a site. • Perform kit reconciliation tasks, such as verifying returned kits and correcting site reconciliation. • Generate and manage Oracle CRF Submit archives. • Create custom reports and visualizations in Oracle Clinical One Analytics • Review Unblinded Pharmacist kits in a site's inventory	Although a Clinical Research Associate (CRA) is typically a blinded study team member, a CRA can also be unblinded when they need to review Unblinded Pharmacist kits and are assigned the appropriate permission.
Data Manager	• Review data and run reports. • Generate and manage Oracle CRF Submit archives. • Create custom reports and visualizations in Oracle Clinical One Analytics. • Extract form data in a study. • Create labs and define lab normal ranges. • Run reports and view role assignments for study users, view a study's design, and view configured subject settings.	None.

Role	Responsibilities	Notes
Medical Monitor	• View data in a study. • Run reports. • Create custom reports and visualizations in Oracle Clinical One Analytics. • View, close, and create queries. • View unblinded kits, role assignments for study users, and a study's design.	None.
Site Administrator	• Run reports and perform study setup tasks. • Create, view, and manage depots.	None.
Study Manager	• View study data. • Edit study settings. • Edit the custom welcome letter content. • Run reports. • Perform tasks related to a study's randomization strategy and inventory. • Generate and manage Oracle CRF Submit archives. • Create custom reports and visualizations in Oracle Clinical One Analytics. • Perform other study setup and study management tasks, such as transfering subjects between sites, assigning resupply strategies to sites, study versions, or moving a study's design to Testing or Production.	None.

Roles for unblinded study users

Learn more about the roles and responsibilities of an unblinded study user, such as a clinical supply manager or statistician.

About these study roles

- **Modes**: You can assign these study roles in Testing, Training, and Production mode.
- **Users**: You typically assign these study roles to an unblinded study team member, such as a clinical supply manager, statistician, or unblinded depot user.
- **Type**: These study roles fall under the Sponsor category.

Unblinded study team member roles and their responsibilities

Role	Responsibilities	Notes
Clinical Supply Manager - Unblinded	• View data, create and manage resupply strategies, as well as create and manage depots. • Run reports. • Create custom reports and visualizations in Oracle Clinical One Analytics • Perform other study setup tasks such as assigning a resupply strategy to a site, creating and managing sites, editing regions, or viewing role assignments for study users.	None.
Production Admin	• Assist your organization, as needed, throughout the study process or study conduct period. • Create custom reports and visualizations in Oracle Clinical One Analytics • Edit the custom welcome letter content.	None.
ODM Extract	Extract several types of data in an ODM-XML format: • Administrative data • Clinical data • Metadata	None.
Rules Designer	• Design, test, approve, and publish rules in a study. • Create custom reports and visualizations in Oracle Clinical One Analytics • Edit the custom welcome letter content.	None.
Statistician - Unblinded	• View data and manage randomization lists. • Create custom reports and visualizations in Oracle Clinical One Analytics • Perform other study setup and study management tasks such as editing regions, uploading and generating inventory lists, viewing unblinded pharmacist kits, and performing a code break.	None.
Unblinded Depot User	• View data and manage shipments at a depot.	None.

Role	Responsibilities	Notes
View Only for Unblinded Support Users	• View details about a study to assist with troubleshooting and integrations, as needed. • Create custom reports and visualizations in Oracle Clinical One Analytics	None.

Roles for site users

Learn more about the roles and responsibilities of a site user.

About these study roles

- **Modes**: You can assign these study roles in Testing, Training, and Production mode.
- **Users**: You typically assign these study roles to a blinded site user, principal investigator or unblinded pharmacist. If the study role contains the appropriate permissions, you might also assign it to a sponsor or CRO user for validation purposes, in Testing mode.
- **Type**: These study roles fall under the Site category. Permissions in these study roles are both blinded and unblinding. Unblinding permissions allow users to view treatment arm details, kit descriptions, or dispense certain types of kits.

Site user roles and their reponsibilities

Role	Responsibilities	Notes
Blinded site user	• Randomize subjects and view a site's inventory. • Collect data from subjects. • Perform kit reconciliation. • Performing other data collection and inventory management tasks, such as dispensing kits with calculated doses and creating manual shipments. • Generate and manage Oracle CRF Submit archives.	None.
Pharmacy User - Unblinded	• View collected data at a site. • Manage a site's inventory. • Run reports.	None.
Principal investigator	• Approve and sign data. • Edit data in order to sign it. • Run reports.	None.

Best practices for role, site, and depot assignment

Users with different responsibilities require different roles. For example, some users need the ability to add users to a study. Some need to only add to add site and depot users.

When you create a user and assign a study role to them, you must take into consideration all three modes of a study. Moreover, you must also assign each user to sites and depots in all three study modes, depending on what type of access they should get.

The guidelines in this chapter help you assign the appropriate study roles to each user in each mode, as well as assign them to the correct sites and depots. However, it is ultimately up to you to make a decision on what roles a user must get in a certain mode or what sites and depots they should be assigned to.

- Assignments for user administrators
  After a delegated administrator creates accounts for all of the users at an organization, a user administrator must add these users to the study and assign them to individual sites and depots.
- Assignments for study team members
  As a user administrator, you must assign the appropriate study role to each study team member, in each mode (Study Design, Testing, Training, or Production mode). Moreover, you must assign each study team member to the appropriate sites and depots in a study.
- Assginments for site and depot users
  As a user administrator, you must assign the appropriate study role to anyone who needs to work at a site or depot during the study conduct period. Moreover, you must assign them to the appropriate sites and depots for each mode (Testing, Training, and Production).

Related Topics

- Add a user to a study in Oracle Clinical One Platform
- Assignments for user administrators
  After a delegated administrator creates accounts for all of the users at an organization, a user administrator must add these users to the study and assign them to individual sites and depots.
- Assignments for study team members
  As a user administrator, you must assign the appropriate study role to each study team member, in each mode (Study Design, Testing, Training, or Production mode). Moreover, you must assign each study team member to the appropriate sites and depots in a study.
- Assginments for site and depot users
  As a user administrator, you must assign the appropriate study role to anyone who needs to work at a site or depot during the study conduct period. Moreover, you must assign them to the appropriate sites and depots for each mode (Testing, Training, and Production).

Assignments for user administrators

After a delegated administrator creates accounts for all of the users at an organization, a user administrator must add these users to the study and assign them to individual sites and depots.

Even though you may have one or more global users at your organization, you must have a user administrator assigned in the system, too.

If you are a user administrator, consider adding yourself to the study. A user administrator might have other roles, too. For example, a user can be a Clinical Research Associate (CRA) in Production mode, but they can also be a user administrator in Testing mode. If you are a user administrator, you can add your

The table below describes typical study role, site, and depot assignments for a user administrator.

Table 4-1 Study roles, site, and depot assignments for user administrators

Job role	Study role assignment	Site assignment	Depot assignment
User administrator	For Study Design Mode, select the **User Administrator** role. For Production, Testing, and Training mode, select the **Site Administrator** role.	For all three categories of sites (Production, Testing, and Training Sites), select the checkbox for any site where the user administrator must be able to assign other users. For example, if the user administrator must assign users to Hospital Roma (a site created in Testing mode), then the user administrator must also be assigned to Hospital Roma in Testing mode.	For all three categories of depots (Production, Testing, and Training depots), select the checkbox for any depot where the user administrator must be able to assign other users. For example, if the user administrator must assign users to the Canada Depot (a depot created in Production mode), then the user administrator must also be assigned to the Canada Depot in Production mode.

Related Topics

- Add a user to a study in Oracle Clinical One Platform
- Assignments for study team members
  As a user administrator, you must assign the appropriate study role to each study team member, in each mode (Study Design, Testing, Training, or Production mode). Moreover, you must assign each study team member to the appropriate sites and depots in a study.
- Assginments for site and depot users
  As a user administrator, you must assign the appropriate study role to anyone who needs to work at a site or depot during the study conduct period. Moreover, you must assign them to the appropriate sites and depots for each mode (Testing, Training, and Production).

Assignments for study team members

As a user administrator, you must assign the appropriate study role to each study team member, in each mode (Study Design, Testing, Training, or Production mode). Moreover, you must assign each study team member to the appropriate sites and depots in a study.

The table below describes typical study role, site, and depot assignments for every study team member.

Table 4-2 Study roles, site, and depot assignments for study team members

Job role	Study role assignment	Site assignment	Depot assignment
Clinical supply manager	For Testing, Production, and Training mode, select the **Clinical Supply Manager** role.	Choose **All Sites**.	Choose **All Depots**.
Statistician	For Testing, Production, and Training mode, select the **Statistician** role.	Choose **All Sites**.	Assign no depots.
Study designer	For Study Design Mode, select the **Study Designer** role. For Testing mode, depending on what other tasks the study designer might need to perform, select one of the following study roles: • **Study Manager** • **Clinical Supply Manager** • **Statistician** • **Production Admin**, if the study designer is also responsible for setting up the connection to Oracle mHealth Connector • **Rule Designer**, if the study designer is also responsible for designing rules For Training and Production mode, depending on what other tasks the study designer might need to perform, select one of the following study roles: • **Study Manager** • **Production Admin**, if the study designer is also responsible for setting up the connection to Oracle mHealth Connector	• Choose **All Testing Sites**. • Assign no Production or Training sites.	Assign no depots.
Study manager	For Testing, , Production, and Training mode, select the **Study Manager** role.	Choose **All Sites**.	Assign no depots.

Table 4-2 (Cont.) Study roles, site, and depot assignments for study team members

Job role	Study role assignment	Site assignment	Depot assignment
Clinical Research Associate (CRA)	For Testing, Production, and Training mode select the **CRA** role.	If the CRA is responsible for site management, choose **All Production Sites** and **All Training Sites**. Otherwise, select only the Production and Training sites that the user manages as well as any Testing sites that the user will work in.	Assign no depots.
Data manager	For Testing, Production, and Training mode, select the **Data Manager** role.	Choose **All Production Sites** and **All Training Sites**.	Assign no depots.
Safety monitor	For Testing, Production, and Training mode, select the **Medical Monitor** role.	• Choose **All Production Sites** and **All Training Sites**. • Select any Testing sites that the user will work in.	Assign no depots.
Production administration	For Testing, Production, and Training mode, select the P**roduction Admin** role.	• Select **All Production Sites** and **All Training Sites**. • Select any Testing sites that the user will work in.	Assign no depots.

Related Topics

- Add a user to a study in Oracle Clinical One Platform
- Assignments for user administrators
  After a delegated administrator creates accounts for all of the users at an organization, a user administrator must add these users to the study and assign them to individual sites and depots.
- Assginments for site and depot users
  As a user administrator, you must assign the appropriate study role to anyone who needs to work at a site or depot during the study conduct period. Moreover, you must assign them to the appropriate sites and depots for each mode (Testing, Training, and Production).

Assginments for site and depot users

As a user administrator, you must assign the appropriate study role to anyone who needs to work at a site or depot during the study conduct period. Moreover, you must

assign them to the appropriate sites and depots for each mode (Testing, Training, and Production).

The table below describes typical study role, site, and depot assignments for every site and depot user.

Table 4-3 Study roles, site, and depot assignments for site and depot users

Job role	Study role assignment	Site assignment	Depot assignment
Site user	For Testing, Production, and Training mode, select the: • **Site User** study role, if the user is only responsible for dispensation. • **Pharmacy User** study role, if the user is responsible with dispensing Unblinded Pharmacist kits in a study.	• Select only the Production and Training sites that the user works at. • Choose **Testing sites** only if the user is involved in the verification of the study.	Assign no depots.
Pharmacist	For Testing, Production, and Training mode, select the **Pharmacy** study role, particularly if the user is responsible for dispensing Unblinded Pharmacist kits in a study.	• Select only the Production and Training sites that the user works at. • Choose **Testing Sites** only if the user is involved in the verification of the study.	Assign no depots.
Depot user	For Testing mode, choose no roles unless the user is involved in the verification of the study. For Production andTraining mode, select the **Unblinded Depot User** role.	• Select only the Production and Training sites that the user's depot ships to. • Select no Testing sites unless the user is involved in the verification of the study.	• Select only the Production and Training depots that the user works at. • Select no Testing depots unless the user is involved in the verification of the study.

Related Topics

- Add a user to a study in Oracle Clinical One Platform
- Assignments for user administrators
  After a delegated administrator creates accounts for all of the users at an organization, a user administrator must add these users to the study and assign them to individual sites and depots.
- Assignments for study team members
  As a user administrator, you must assign the appropriate study role to each study team member, in each mode (Study Design, Testing, Training, or Production mode). Moreover, you must assign each study team member to the appropriate sites and depots in a study.

Edit a study role that is already assigned to users

As a global user manager or study user administrator, you can edit an existing study role created for both all studies or just an individual study, even if the study role is already assigned to users.

You cannot edit a predefined study role template provided by Oracle. Those study roles are read-only. To recognize them in the user interface, look for the icon containing a lock ( ).

> **Note:**
>
> For study-level roles, the changes that you make are automatically reflected in the already-assigned study roles. For organization-level roles, the changes that you make will apply to newly created studies but won't automatically propagate to existing studies.

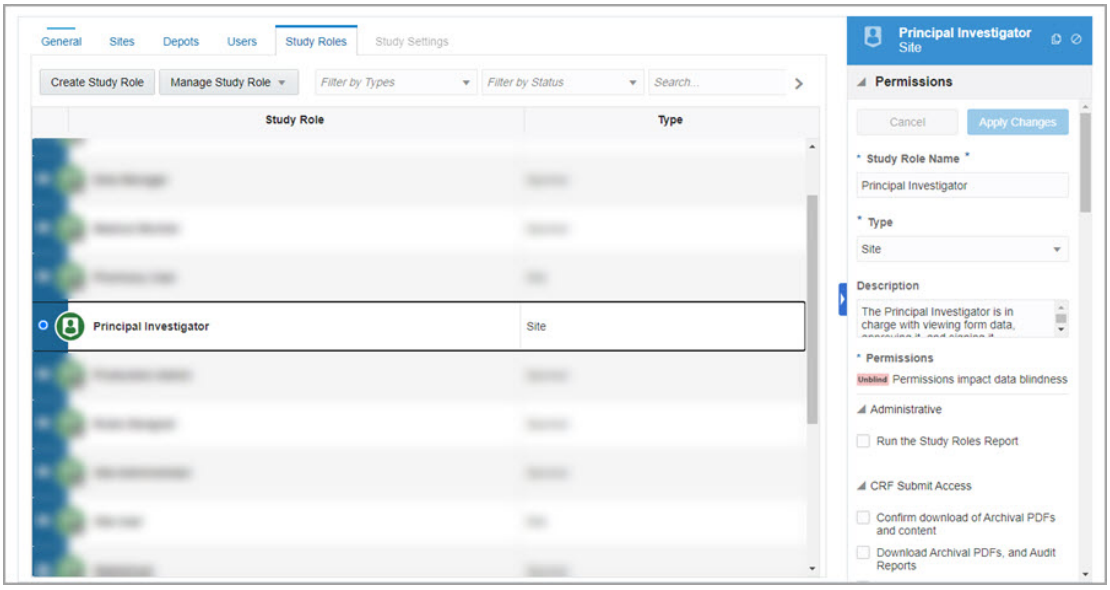
To edit a study role that is already assigned to users:

1. On the Home page, click the study settings button ( ) on the study you want to edit and select **Open Settings**.
2. Below the study name, click the **Study Roles** tab.
3. Select an existing study role from the list (that was created for a single study only), and go to the **Permissions** pane on the right.
4. Make any desired changes to the following fields:
   - **Role Name**: Enter a name for the study role. We recommend using a descriptive name so you'll remember the roles that are in the template later.
   - **Type**: Select **Sponsor** if the role will be assigned to a member of the study team at either the sponsor or CRO, **Site** if the role will be assigned to a site user, or **Design** if the role will be assigned to a study designer.
   - **Description**: This is optional, but you can add a short description of the study role in this field.
5. Select or deselect the permissions that you want to include in this study role.

> **Note:**
>
> The search is performed across all three groups of rights: sponsor, site, and design. Changes to the study role at the study level are applied to users that already have this study role assigned to them. Pay attention to the soft warning messages in the product for when you are about to add a permission that does not typically belong in the study role. You must be careful to not add any unblinding permissions without considering the consequence of unblinding the wrong user.

6. Click **Apply Changes**.

Figure 4-3 How a global user manager or user manager edits a study role assigned to users



Retire a study role

Study roles can never be completely removed, but they can be retired. If a study role is no longer of use in your study, you can always retire it. Users who have previously been assigned the now retired study role will not lose their permissions. Retired study roles are simply made unavailable for new use.

This task can be performed by both a global user manager and a user administrator. You can retire a study role anytime you want, except for when it's a predefined read-only study role provided by Oracle.

Users who have been assigned a retired study role do not lose their permissions. Retired study roles are simply made unavailable for new assignment.

1. On the Home page, click the study settings button ( ) on the study you want to edit, and select **Open Settings**.
2. Below the study name, click the **Study Roles** tab.
3. Search for the study role that you want to retire and select it.
4. Along the top, from the **Manage Study Roles** drop-down, select **Retire**.

> **Tip:**
>
> If you want to create a similar study role with one that you retired, you can always copy it. Select the retired study role, and from the **Manage Study Role** drop-down, select **Copy**.

The icon of a retired study role is grayed out ( ).

Remove a user in Oracle Clinical One Platform

In Oracle Clinical One Platform, you can remove a study user (someone who is assigned to one or multiple studies) or you can remove a global user (someone who is assigned a global role and may have access to all studies in your organization).

This task can be performed by both a global user manager and a user administrator. We recommend you only perform this task if a user has been added to the study or the application in error.

> **Note:**
>
> To keep a record of when a user had access to the study, we recommend you carefully specify the end date of a user's access to the study. This date is specified when you add a user in the study. For step-by-step instructions, see Add a user to a study in Oracle Clinical One Platform.

First, you must sign in to Oracle Clinical One Platform. For details, see Sign in and out of Oracle Clinical One Platform.

For step-by-step instructions on how to remove a user in Oracle Life Sciences IAMS, see Terminate or reinstate an account.

Remove a user from a study

1. On the Home page, click the study settings ( ) on the study you want to edit, and select **Open Settings**.
2. Below the study name, click the **Users** tab.
3. Select the user that you want to remove.
4. Below the study name, click **Manage Users**, and select **Remove**.
5. On the Confirmation dialog, click **Yes**.

Remove a global user from the application

1. On the Home page, under your name, click **Global Settings**.
2. Make sure the Users tab is selected.
3. Select the user that you want to remove.
4. Along the top menu, click **Manage Users**, and select **Delete**.

Specify data classifications for a study role

Data classifications allow you to control which users can view or edit a specific type of question in the study. As a global user administrator or study user administrator, you

can assign specific permissions to users depending on what type of classified data they should get access to.

Data classifications are types of data that study designers assign to hidden questions when they want to show those questions only to certain users.

Each type of data classification has two corresponding permissions, to either view or edit that specific type of data. When the right permissions are assigned to a user, data classifications work as exceptions for that user to be able to see any hidden questions in a form.

A user who can view or edit classified types of data in a study, must also be assigned two other separate permissions in the context of a study role. For more details on these permissions, see the Adjudicator topic.

1. On the Home page, click the study settings button ( ) for the study you want to edit and select **Open Settings**.
2. Below the study name, click the **Study Roles** tab.

> **Note:**
>
> You can only modify data classifications at an individual study level. You cannot update data classifications for a study role available for all studies in your organization, unless you copy that study role template and customize it at a study level.

3. Select the study role for which you want to specify data classifications.
4. On the right pane, click **Data Classifications.**
5. Select the appropriate permissions to View or Edit data classifications:
   - **Adjudication Data:** Data findings generated by an adjudicator from adjudication events or safety and efficacy clinical endpoints
   - **Blinded Data:** Data that can reveal information bias in a study
   - **PII Data:** Personal Identifiable Information Data
   - **Sponsor Data:** Data accessible to a sponsor user
   - **Public Data:** Data accessible to sites or other users
6. Click **Save**.

5

Manage an Oracle Life Sciences single sign-on

- Recover your Oracle Life Sciences single sign-on user name
  To obtain the user name for Oracle Life Sciences single sign-on (SSO), you must know the email address used to create the SSO account.
- Unlock a locked account
  If you enter an incorrect password 5 times in a row, your Oracle Life Sciences single sign-on (SSO) is locked. To unlock your SSO, you must reset your password.
- Change your password
  You can change your password at any time in Oracle Life Sciences IAMS.
- Change your challenge questions
  If your organization uses challenge (security) questions to reset passwords, you can change your questions at any time in Oracle Life Sciences IAMS.
- Update your name or telephone number
  You change the name and telephone number associated with your Oracle Life Sciences single sign-on (SSO) in Oracle Life Sciences IAMS.
- View roles assigned to you
  The roles assigned to you in Oracle Life Sciences IAMS determine which products you can access. You can view your assigned roles at any time.
- Request access to Oracle Clinical One Platform
  If someone at your organization told you to request access to a product or study, all you need is the web address for the product or study.

Recover your Oracle Life Sciences single sign-on user name

To obtain the user name for Oracle Life Sciences single sign-on (SSO), you must know the email address used to create the SSO account.

If your organization uses email links to reset passwords, you can obtain your user name from within Oracle Life Sciences IAMS. If your organization uses challenge questions to reset passwords, you'll have contact the delegated administrator for your organization or Life Sciences Support to get your user name.

To obtain your user name from Oracle Life Sciences IAMS:

1. On the Sign In page, click **Trouble Signing In?**.
2. Enter your email address, and click **Continue**.
3. Click **Send**.

   An email containing your Oracle Life Sciences SSO user name is sent to your email address.

> **Note:**
>
> If you don't receive the email, click **Send Another Email**. If you don't receive the email after three attempts, contact your delegated administrator or Life Sciences Support.

Unlock a locked account

If you enter an incorrect password 5 times in a row, your Oracle Life Sciences single sign-on (SSO) is locked. To unlock your SSO, you must reset your password.

If you can't reset your password using these steps, contact another delegated administrator at your organization or Life Sciences Support, and ask them to reset the password for you.

To unlock your account by resetting your password:

1. On the Sign in page, click **Trouble Signing In?**.
2. Enter your Oracle Life Sciences single sign-on (SSO) user name, and proceed to the next page. The button to proceed is either **Next** or **Continue**, depending on your setup.
3. Perform one of the following steps:
   - If you see a **Send** button, complete the following steps:
     a. Click **Send**.
     An email containing a link to reset your password is sent to your email address.
     b. Click the link in the email.
     c. Enter your new password and confirm the password.
     d. Click **Continue**.
   - If you are prompted to enter questions to security questions, complete the following steps:
     a. Enter answers for the challenge questions, and click **Next**.
     b. Enter your new password, and confirm the password.
     c. Click **Save**.

Your password is reset.

Change your password

You can change your password at any time in Oracle Life Sciences IAMS.

To change your password:

1. Sign in to Oracle Life Sciences IAMS as described in Sign in to Oracle Life Sciences IAMS directly.

   Depending on how your organziation set up the applications, you see the Oracle Health Sciences My Oracle Bookmarks or Oracle Life Sciences Cloud home page.
2. Perform one of the following:

- If you see Oracle Health Sciences My Oracle Bookmarks: In the upper-right, click your name and select **Account Management**.
- If you see Oracle Life Sciences Cloud: On the left, under **Quick Links**, click **Update Profile**.

3. Under **My Profile**, click **My Information**.
4. Expand the **Change Password** section.
5. Enter your old password.
6. Enter your new password and confirm it.
7. In the Change Password section, click **Apply**.

Change your challenge questions

If your organization uses challenge (security) questions to reset passwords, you can change your questions at any time in Oracle Life Sciences IAMS.

To change your challenge questions:

1. Sign in to Oracle Life Sciences IAMS as described in Sign in to Oracle Life Sciences IAMS directly.

   Depending on how your organziation set up the applications, you see the Oracle Health Sciences My Oracle Bookmarks or Oracle Life Sciences Cloud home page.
2. Perform one of the following:
   - If you see Oracle Health Sciences My Oracle Bookmarks: In the upper-right, click your name and select **Account Management**.
   - If you see Oracle Life Sciences Cloud: On the left, under **Quick Links**, click **Update Profile**.
3. Under **My Profile**, click **My Information**.
4. Expand the **Challenge Questions** section.
5. Choose three challenge questions and enter answers.
6. In the Challenge Questions section, click **Apply**.

Update your name or telephone number

You change the name and telephone number associated with your Oracle Life Sciences single sign-on (SSO) in Oracle Life Sciences IAMS.

To update your name or telephone number:

1. Sign in to Oracle Life Sciences IAMS as described in Sign in to Oracle Life Sciences IAMS directly.

   Depending on how your organziation set up the applications, you see the Oracle Health Sciences My Oracle Bookmarks or Oracle Life Sciences Cloud home page.
2. Perform one of the following steps:
   - If you see Oracle Health Sciences My Oracle Bookmarks: In the upper-right, click your name and select **Account Management**.

- If you see Oracle Life Sciences Cloud: On the left, under **Quick Links**, click **Update Profile**.

3. Under **My Profile**, click **My Information**.
4. Review the information in the **First Name** and **Last Name** fields and edit, if required.
5. (Optional) Add your telephone number.
6. In the Basic User Information section, click **Apply**.

View roles assigned to you

The roles assigned to you in Oracle Life Sciences IAMS determine which products you can access. You can view your assigned roles at any time.

To view roles assigned to you:

1. Sign in to Oracle Life Sciences IAMS as described in Sign in to Oracle Life Sciences IAMS directly.
2. Perform one of the following steps:
   - If the Oracle Health Sciences My Oracle Bookmarks page appears: In the upper-right, click your name, and select **Account Management**.
   - If the Oracle Life Sciences Cloud landing page appears: On the left, under **Quick Links**, click **Update Profile**.
3. Under **My Profile**, click **My Access**.

   You see a list of roles assigned to your Oracle Life Sciences single sign-on (SSO).
4. Review your roles.
5. If you need to remove a role, select the role from the list and click **Remove Roles** or **Revoke**.

> **Note:**
>
> If you accidentally remove a role, a delegated administrator needs to reassign the role to your account.

Request access to Oracle Clinical One Platform

If someone at your organization told you to request access to a product or study, all you need is the web address for the product or study.

To request access to a product or study:

1. Enter the Oracle Clinical One Platform web address in your browser and sign in with your Oracle Life Sciences single sign-on (SSO) to open the access request page.
2. Enter a justification to for the request.
3. Click **Submit**.

The delegated administrator for your organization receives the request and can approve or reject it.

If the delegated administrator approves the request, you can access the product or study. To confirm your role, open the application or study. If you continue to see the access request page, wait for the approval to clear or check with your administrators to see if they denied your request.

6

Run user management reports

- Run and download report
  As a global user manager or user administrator, you typically run reports that offer you information on the study roles and users within your study or overall organization.

Run and download report

As a global user manager or user administrator, you typically run reports that offer you information on the study roles and users within your study or overall organization.

For step-by-step instructions on how to run and download a report, see the Reporting Guide.

7

Learn: Frequently asked questions

- Can I update a user's Oracle Life Sciences single sign-on?
  Yes, an administrator can update the SSO of another user. In addition, users can manage their own Oracle Life Sciences single sign-on (SSO) accounts.
- Do I need to revoke access for SaaS Services users after collaboration is complete?
  No. SaaS Services users need to retain access rights for your instance of Oracle Clinical One Platform throughout its existence, so you should not revoke the access roles from these users. After a project ends, the accounts of the SaaS Services users expire within 60 days.
- Do I need to revoke access for Life Sciences Support users after a ticket is resolved?
  You can revoke access for Support if necessary. But, the Life Sciences Support team members working on the ticket can access your Oracle Clinical One Platform instance for two weeks (with the option to extend for one more week). After the two or three weeks, Support access expires automatically.
- How do I control users' access to the application?
- What happens if I change the roles assigned to a user while the user works in the product?
  The application updates every 15 minutes (approximately) while the user works in it.
- Does my organization need a user and site administrator?
  Every organization must have one or more user and site administrators and one or more global users.
- Can I create Oracle Life Sciences single sign-ons in Oracle InForm User Management Tool?
  If a site or sponsor user also works in Oracle InForm, you can create the Oracle Life Sciences single sign-on (SSO) for the user in Oracle Life Sciences IAMS or Oracle InForm User Management Tool.
- Who creates Oracle team members?
  Your Oracle project manager creates Oracle team members.
- How do I find my company's ShortOrgId?
  The <ShortOrgId> for your company appears in bold text in the New Account email you received from Oracle Identity Manager to activate your Oracle Life Sciences SSO.
- What should I do if I have a study that requires users to screen subjects and enter data before and after randomization, but not randomize them?
  This design solution gives you more control over when the Randomize button is available.

Can I update a user's Oracle Life Sciences single sign-on?

Yes, an administrator can update the SSO of another user. In addition, users can manage their own Oracle Life Sciences single sign-on (SSO) accounts.

For more information, see Manage an Oracle Life Sciences single sign-on.

Do I need to revoke access for SaaS Services users after collaboration is complete?

No. SaaS Services users need to retain access rights for your instance of Oracle Clinical One Platform throughout its existence, so you should not revoke the access roles from these users. After a project ends, the accounts of the SaaS Services users expire within 60 days.

Do I need to revoke access for Life Sciences Support users after a ticket is resolved?

You can revoke access for Support if necessary. But, the Life Sciences Support team members working on the ticket can access your Oracle Clinical One Platform instance for two weeks (with the option to extend for one more week). After the two or three weeks, Support access expires automatically.

How do I control users' access to the application?

You assign users to roles at several levels.

- Product roles assigned in Oracle Life Sciences IAMS allow the user to sign in to Oracle Clinical One Platform, but not work in any studies.
- Global roles assigned in Oracle Clinical One Platform allow certain users to perform administrative tasks.
- Study-level roles assigned in Oracle Clinical One Platform allow the user to work in individual studies.
  You can assign a user to different roles in each model. For instance, a study designer might be able to screen and randomize in Testing mode. But, they cannot do the same activities in Production mode.

You cannot change the permissions that are associated with any roles, but all the roles are granular enough that you can tailor the access for users as needed.

For more information on global and study user roles, see User roles in Oracle Life Sciences IAMS for all applications.

What happens if I change the roles assigned to a user while the user works in the product?

The application updates every 15 minutes (approximately) while the user works in it.

If you remove permissions, the restrictions take place immediately even if the user continues to perform denied tasks. For instance, if you remove the ability to design a study for a user, that user may continue to see forms. But, the user cannot save any changes to the forms. Within approximately 15 minutes, the application refreshes and the user can no longer access any of the denied tasks.

Does my organization need a user and site administrator?

Every organization must have one or more user and site administrators and one or more global users.

A global user can create users in any study but can't assign them to individual sites and depots. Only a site and user manager for a specific study can assign users to individual sites and depots.

Can I create Oracle Life Sciences single sign-ons in Oracle InForm User Management Tool?

If a site or sponsor user also works in Oracle InForm, you can create the Oracle Life Sciences single sign-on (SSO) for the user in Oracle Life Sciences IAMS or Oracle InForm User Management Tool.

This guide only contains information on working in Oracle Life Sciences IAMS. For details on working in Oracle InForm User Management Tool, see Creating Oracle InForm or Oracle IRT users in the *Oracle Life Sciences User Management Tool User Guide*.

Who creates Oracle team members?

Your Oracle project manager creates Oracle team members.

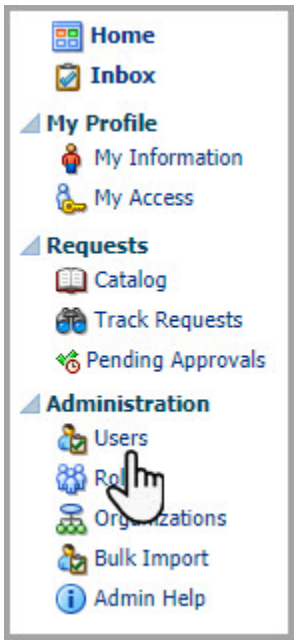
How do I find my company's ShortOrgId?

The <ShortOrgId> for your company appears in bold text in the New Account email you received from Oracle Identity Manager to activate your Oracle Life Sciences SSO.

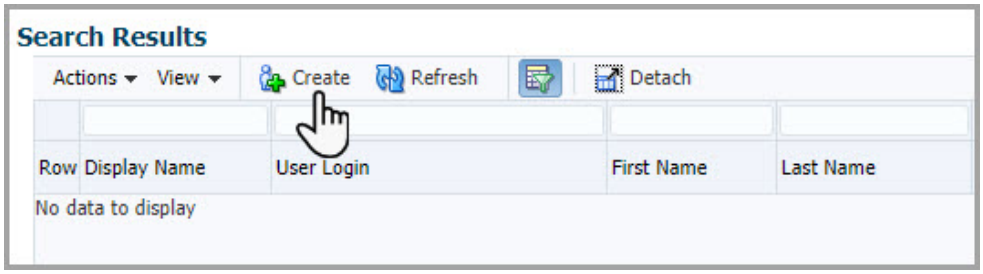
If you cannot locate your notification message, you can find the <ShortOrgId> in Oracle Life Sciences IAMS.

To find the ShortOrgID for your organization:

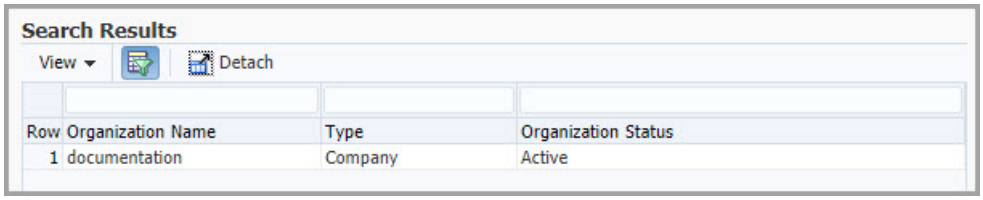
1. Sign in to Oracle Life Sciences IAMS as described in Sign in to Oracle Life Sciences IAMS directly.
2. Expand **Administration** in the left panel and click **Users**.



3. Under Search Results, click **Create**.



4. Next to the **Organization** field, click the search icon .
5. Click **Search**.
6. In the Search Results section, select the row where **Company** appears in the **Type** column.



7. Click **Select**.

What should I do if I have a study that requires users to screen subjects and enter data before and after randomization, but not randomize them?

This design solution gives you more control over when the Randomize button is available.

If you have a study that requires users to screen subjects and enter and edit form data before and after randomization, but do not want them to be able to randomize subjects, review the following details as a possible solution. Contact your Oracle consultant for additional information if this does not meet your needs.

The *Edit Form Data for Subjects* permission enables the **Screen** and **Randomize** buttons in the user interface.

> **Note:**
>
> For more information about this permission, see Descriptions of permissions in Clinical One in the *Add Users Guide*.

The Randomize button is enabled when the Randomization visit is complete, and the visit is only complete when all required questions have been answered.

The following design gives you more control over when the Randomize button is available.

1. Start by adding a required question to a form in the Randomization visit. For example, Are you ready to randomize the subject?
2. Then, use data classifications to:
   a. Grant view-only access to the new question for users who must screen subjects and enter data before and after randomization.
   b. Grant edit access to the new question for users who need to randomize subjects. The Randomize button is enabled only when all required questions in the visit, including the new question, are answered.

> **WARNING:**
>
> Users with edit access to the new required question should randomize the subject soon after answering it. This reduces the possibility of another user randomizing a subject when they should not.

8

Examples of study roles

- About predefined study roles
  You can find predefined study roles on the Study Roles tab, both on the **Global Settings** tab and in a study's settings. Predefined study roles created by Oracle display a lock icon and use the word "Template" in their title.
- Adjudicator
  This topic describes the permissions included in the Adjudicator (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.
- Clinical Research Associate (CRA)
  This topic describes the permissions included in the CRA (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.
- Clinical Supply Manager - Unblinded
  This topic describes the permissions included in the Clinical Supply Manager - Unblinded (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.
- Data Manager
  This topic describes the permissions included in the Data Manager (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.
- Blinded Depot User
  This topic describes the permissions included in the **Blinded Depot User** (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.
- ODM Extract
  This topic describes the permissions included in the ODM Extract (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.
- Medical Monitor
  This topic describes the permissions included in the Medical Monitor (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.
- Pharmacy User - Unblinded
  This topic describes the permissions included in the Pharmacy User - Unblinded (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.
- Production Admin
  This topic describes the permissions included in the Production Admin (template) study role in the application. This template study role is available for all studies in your

organization. You can copy the study role and customize it for each individual study you work in.

- Rules Designer
  This topic describes the permissions included in the Rules Designer (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.
- Site Administrator
  This topic describes the permissions included in the Site Administrator (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.
- Site User
  This topic describes the permissions included in the Site User (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.
- Statistician - Unblinded
  This topic describes the permissions included in the Statistician - Unblinded (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.
- Study Designer
  This topic describes the permissions included in the Study Designer (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.
- Study Manager
  This topic describes the permissions included in the Study Manager (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.
- Unblinded Depot User
  This topic describes the permissions included in the Unblinded Depot User (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.
- User Administrator
  This topic describes the permissions included in the User Administrator (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.
- View Only for Unblinded Support Users
  This topic describes the permissions included in the View Only for Unblinded Support Users (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.
- View Study Design
  This topic describes the permissions included in the View Study Design (template) study role in the application. This template study role is available for all studies in

your organization. You can copy the study role and customize it for each individual study you work in.

About predefined study roles

You can find predefined study roles on the Study Roles tab, both on the **Global Settings** tab and in a study's settings. Predefined study roles created by Oracle display a lock icon and use the word "Template" in their title.

> **Note:**
>
> You can also learn more about the permissions included in each of the predefined study roles by running the Global Study Roles report and the Study Roles report (by study). For more information, see the Reporting Guide.

Adjudicator

This topic describes the permissions included in the Adjudicator (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.

Permissions given to an adjudicator based on their responsibilities

> **Note:**
>
> To see an overview of all permissions that can be included in study roles, see the **View Permissions** window in the application.

Table 8-1 Blinded study team member study role

Responsibilities of an adjudicator	Permissions required to fulfill those responsibilities
View and manage classified subject data	**Clinical Data Collection**: • Edit Classified Subject Data Only • View Classified Subject Data Only **Study Setup**: • View Sites

Clinical Research Associate (CRA)

This topic describes the permissions included in the CRA (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.

> **Note:**
>
> To see an overview of all permissions that can be included in study roles, see the **View Permissions** window in the application.

Table 8-2 CRA (template) study role

Category	Permissions assigned
CRF Submit Access	• Run and Download Site Confirmation and Download Log Audit Reports • Run and Download all PDF Request Types and Audit Reports. Enable Share with Sites, and Site Confirmation
Clinical Data Collection	• Edit Classified Subject Data Only • Unfreeze subject data entered at a site • Verify subject data entered at a site • View Blinded Dispensation Details with Calculated Doses • View Blinded Dispensation Details without Calculated Doses • View Classified Subject Data Only • View Form Data for Subjects • View Queries
Inventory Management	• Create Manual Shipments • Perform Supplies Reconciliation at Site • View Shipments to Sites • View Site Inventory

Table 8-2 (Cont.) CRA (template) study role

Category	Permissions assigned
Notifications	• Receive Notification of Shipments • Receive Site has been Updated Notification • Receive the Code Break Notification • Receive the Dispensation Notification • Receive the Randomization Notification • Receive the Rule Failure Notification for Locked Data • Receive the Study Limits Notifications • Receive the Subject Completion Notification • Receive the Subject Rollover Notification • Receive the Subject Screening Notification • Receive the Subject Transferred Notification • Receive the Subject Visit Notification • Receive the Subject Withdrawal Notification • Receive the Unscheduled Visit Notification
Reports	• Schedule Reports to Run • Run the Blinded Inventory Report • Run the Blinded Subject Events Dataset • Run the Enrollment Report • Run the Kit Dispensation Report • Run the Kit Reconciliation Report • Run the Order Summary Report • Run the Site and Depot Report • Run the Study Codelist Dataset (planned for a future release) • Run the Study Design Report • Run the Study Query Dataset • Run the Rules Report • Run the Subject Data Report • Run the Subject Dataset • Run the Subject Events Report • Run the Subject Form Items Dataset • Run the Subject Forms Dataset • Run the Subject Query Report • Run the Subject Visit Report • Run the Titration Summary Report • Run the Training Report • Run the User Assignment Report

Table 8-2 (Cont.) CRA (template) study role

Category	Permissions assigned
Study Management	• Answer Assigned Queries • Close Queries • Create Candidate Queries • Create Queries • Create Shipments to DDF • Delete Candidate Queries • Perform Source Data Verification and Reconcile Inventory • Transfer subjects between sites • View All Queries
Study Setup	• Assign a Study Version to a Site • View Depots • View Regions • View Roles Assignments for Study Users • View Sites • View Study Design • View Study Settings

Clinical Supply Manager - Unblinded

This topic describes the permissions included in the Clinical Supply Manager - Unblinded (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.

A user who is assigned this predefined study role template can also manage tasks related to integrations between Oracle Clinical One Platform and:

- Almac Global Depot Network
- Fisher Clinical Services
- SmartSupplies PMD
- Catalent Clinical Supply Services

Permissions given to a clinical supply manager based on their responsibilities

> **Note:**
>
> To see an overview of all permissions that can be included in study roles, see the **View Permissions** window in the application.

Table 8-3 Clinical Supply Manager - Unblinded (template) study role

Category	Permissions assigned
Clinical Data Collection	• Edit Classified Subject Data Only • View Blinded Dispensation Details with Calculated Doses • View Blinded Dispensation Details without Calculated Doses • View Classified Subject Data Only • View Form Data for Subjects
Data Extract	• Run the Subject Data Extract
Inventory Management	• Blinded Depot User • Create Manual Shipments • Create Shipments to Depots • Receive New Shipments at the Depot • Receive and Reconcile Shipments at the Depot • Release Shipments from Quarantine • Update Supplies after Design Approval (Unblinded) • Update the Shipment Order Form • View Shipments to Sites • View Site Inventory
Notifications	• Receive Notification of Depot Shipments • Receive Notification of Shipments • Receive Site has been Updated Notification • Receive the Study Limits Notifications • Receive the Subject Rollover Notification • Receive the Unblinded Dispensation Notification • Receive the Unblinded Dose Hold Notification • Receive the Unblinded Kit Misallocation Notification • Receive the Unscheduled Visit Notification

Table 8-3 (Cont.) Clinical Supply Manager - Unblinded (template) study role

Category	Permissions assigned
Reports	• Run the Blinded Chain of Custody Report • Run the Blinded Inventory Report • Run the Blinded Subject Events Dataset • Run the Enrollment Report • Run the Kit Dispensation Report • Run the Kit Reconciliation Report • Run the Order Summary Report • Run the Site and Depot Report • Run the Study Codelist Dataset • Run the Study Design Report • Run the Study Query Dataset • Run the Subject Data Report • Run the Subject Dataset • Run the Subject Events Report • Run the Subject Form Items Dataset • Run the Subject Forms Dataset • Run the Subject Visit Report • Run the Titration Summary Report • Run the Training Report • Run the Unblinded Chain of Custody Report • Run the Unblinded Inventory Report • Run the Unblinded Kits Dataset • Run the Unblinded Subject Events Dataset • Run the Unblinded Subject Visit Schedule Report • Run the Unblinded Titration Summary Report • Run the User Assignment Report • Schedule Reports to Run
Study Management	• Perform Source Data Verification and Reconcile Inventory
Study Setup	• Assign a Resupply Strategy to a Depot • Assign a Resupply Strategy to a Site • Assign a Study Version to a Site • Create and Manage Depots • Create and Manage Lots (Unblinded) • Create and Manage Sites • Edit Regions • Edit Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies (Unblinded) • Upload and Generate Inventory Lists (Unblinded) • View Depots • View Role Assignments for Study Users • View Sites • View Study Design • View Study Settings • View Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies (Unblinded)

Table 8-3 (Cont.) Clinical Supply Manager - Unblinded (template) study role

Category	Permissions assigned
Unblinded Study Management	• Manage Study Inventory for Unblinded Users • Update Inventory Lists (Unblinded)

Data Manager

This topic describes the permissions included in the Data Manager (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.

A user who is assigned this predefined study role template can also manage tasks related to integrations between Oracle Clinical One Platform and:

- A third-party electronic data capture system
- Oracle Life Sciences InForm
- Veeva Vault CTMS
- Oracle Siebel Clinical Trial Management System

Permissions given to a data manager based on their responsibilities

> **Note:**
>
> To see an overview of all permissions that can be included in study roles, see the **View Permissions** window in the application.

Table 8-4 Data Manager (template) study role

Category	Permissions assigned
CRF Submit Access	• Run and Download Site Confirmation and Download Log Audit Reports • Run and Download all PDF Request Types and Audit Reports. Enable Share with Sites, and Site Confirmation

Table 8-4 (Cont.) Data Manager (template) study role

Category	Permissions assigned
Clinical Data Collection	**Note:** When a data manager is assigned this permission, they may notice that they have the ability to edit forms that don't contain classified data. Advise data managers to only work with the forms that contain classified data. • Add a Lab to a Site • Add and Update Lab Normal Ranges • Create and Add Labs to a Site • Edit Classified Subject Data Only • Freeze subject data entered at a site • Lock Subject Data at a Site • Unfreeze subject data entered at a site • View Classified Subject Data Only • View Form Data for Subjects • View Queries
Data Extract	• Run the Subject Data Extract
Notifications	• Receive the Code Break Notification • Receive the Study Limits Notifications • Receive the Subject Completion Notification • Receive the Subject Rollover Notification
Reports	• Schedule Reports to Run • Run the Blinded Randomization Report • Run the Blinded Subject Events Dataset • Run the Data Collection Design Dataset • Run the Kit Dispensation Report • Run the Kits and Randomization Design Dataset • Run the Study Codelist Dataset (planned for a future release) • Run the Study Design Report • Run the Study Query Dataset • Run the Subject Data Report • Run the Subject Data for CTMS Report • Run the Subject Events Report • Run the Subject Form Items Dataset • Run the Subject Forms Dataset • Run the Subject Query Report

Table 8-4 (Cont.) Data Manager (template) study role

Category	Permissions assigned
Study Management	• Close Queries • Create Candidate Queries • Create Queries • Delete Candidate Queries • View All Queries
Study Setup	• View Role Assignments for Study Users • View Study Design • View Subject Settings

Blinded Depot User

This topic describes the permissions included in the **Blinded Depot User** (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.

Permissions given to an blinded depot user based on their responsibilities

> **Note:**
>
> To see an overview of all permissions that can be included in study roles, see the **View Permissions** window in the application.

> **Tip:**
>
> A Blinded Depot user can become 'unblinded' by adding the permission *Create Shipments to Depots* which exposes all kit descriptions to the user.

Table 8-5 Blinded Depot User (template) study role

Category	Permissions assigned
Inventory Management	• *Blinded Depot User* • *Receive New Shipments at the Depot* • *Receive and Reconcile Shipments at the Depot* • *Update the Shipment Order Form*
Notifications	• *Receive Notification of Depot Shipments* • *Receive the Quarantined Depot Shipment Notification* • *Receive the Released from Quarantine Notification (Depot)*
Reports	• *Run the Blinded Chain of Custody Report* • *Run the Blinded Inventory Report* • *Run the Kit Reconciliation Report* • *Run the Order Summary Report*

Table 8-5 (Cont.) Blinded Depot User (template) study role

Category	Permissions assigned
Study Management	• *Create Shipments to DDF*

ODM Extract

This topic describes the permissions included in the ODM Extract (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.

Permissions given ODM Extract (template) based on their responsibilities

> **Note:**
>
> To see an overview of all permissions that can be included in study roles, see the **View Permissions** window in the application.

Table 8-6 ODM Extract (template) study role

Category	Permissions assigned
Data Extract	• Execute ODM Clinical Data API with Hidden Data • Execute ODM Clinical Data API without Hidden Data • Execute ODM Metadata API • Execute ODM Administrative Data API **Note:** If the Hidden Data permission was selected, this user must also receive the View permission on each of the types of hidden data such as: Adjudication, Blinded, PII, Public Data, or Sponsor Data. For more information on data classification for a study role, see Specify data classifications for a study role.
Reports	• Schedule Reports to Run

Medical Monitor

This topic describes the permissions included in the Medical Monitor (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.

Permissions given to a medical monitor based on their responsibilities

Note:

To see an overview of all permissions that can be included in study roles, see the **View Permissions** window in the application.

Table 8-7 Medical Monitor (template) study role

Category	Permissions assigned
Clinical Data Collection	• Edit Classified Subject Data Only • View Blinded Dispensation Details with Calculated Doses • View Blinded Dispensation Details without Calculated Doses • View Classified Subject Data Only • View Form Data for Subjects • View Queries
Notifications	• Receive the Code Break Notification
Reports	• Run the Blinded Subject Events Dataset • Run the Kit Dispensation Report • Run the Study Codelist Dataset (planned for a future release) • Run the Study Design Report • Run the Study Query Dataset • Run the Subject Data Report • Run the Subject Events Report • Run the Subject Form Items Dataset • Run the Subject Forms Dataset • Run the Subject Query Report • Run the Training Report • Run the User Assignment Report
Study Management	• Close Queries • Create Candidate Queries • Create Queries • View All Queries
Study Setup	• View Role Assignments for Study Users • View Sites • View Study Design • View Study Settings
Unblinded Study Management	• Reveal the Treatment Arm for a Subject or Code View

Pharmacy User - Unblinded

This topic describes the permissions included in the Pharmacy User - Unblinded (template) study role in the application. This template study role is available for all

studies in your organization. You can copy the study role and customize it for each individual study you work in.

Permissions given to a pharmacist or unblinded site user based on their responsibilities

> **Note:**
>
> To see an overview of all permissions that can be included in study roles, see the **View Permissions** window in the application.

Table 8-8 Pharmacy User - Unblinded (template) study role

Category	Permissions assigned
Clinical Data Collection	• Edit Classified Subject Data Only • View Blinded Dispensation Details with Calculated Doses • View Blinded Dispensation Details without Calculated Doses • View Classified Subject Data Only • View Form Data for Subjects
Inventory Management	• Create Manual Shipments • Perform Supplies Reconciliation at Site • Receive Shipments and Update Site Inventory • View Shipments to Site • View Site Inventory • View Unblinded Pharmacist Kits
Notifications	• Receive Notification of Shipments • Receive the Code Break Notification • Receive the Dispensation with Dosing Instructions Notification • Receive the Unblinded Pharmacist Dispensation Notification
Reports	• Run the Blinded Inventory Report • Run the Blinded Subject Events Dataset • Run the Enrollment Report • Run the Kit Dispensation Report • Run the Kit Reconciliation Report • Run the Order Summary Report • Run the Study Codelist Dataset (planned for a future release) • Run the Study Query Dataset • Run the Subject Data Report • Run the Subject Dataset • Run the Subject Events Report • Run the Subject Form Items Dataset • Run the Subject Forms Dataset • Run the Titration Summary Report
Study Management	• Create Shipments to DDF (Drug-Destruction Facility)

Production Admin

This topic describes the permissions included in the Production Admin (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.

Typically assigned to an Oracle user who must assist you in your work, this study role can also be found as a predefined template at a global level. Alternatively, you can also create your own study role that might be different from the predefined one, at either a global level or in the context of a study.

> **Note:**
>
> To see an overview of all permissions that can be included in study roles, see the **View Permissions** window in the application.

Permissions given to a production admin

Table 8-9 Production Admin (template) study role

Category	Permissions assigned
Clinical Data Collection	• Add a Lab to a Site • Add and Update Lab Normal Ranges • Create and Add Labs to a Site • Integrate Subject Data • Verify Subject Data Entered at a Site • View Blinded Dispensation Details with Calculated Doses • View Blinded Dispensation Details without Calculated Doses • View Form Data for Subjects • View Queries
Inventory Management	• Create Shipments to Depots • Receive New Shipments at the Depot • View Shipments to Sites • View Site Inventory

Table 8-9 (Cont.) Production Admin (template) study role

Category	Permissions assigned
Reports	• Schedule Reports to Run • Run the Blinded Inventory Report • Run the Blinded Randomization Report • Run the Blinded Subject Events Dataset • Run the Enrollment Report • Run the Kit Dispensation Report • Run the Kit Reconciliation Report • Run the Site and Depot Report • Run the Study Codelist Dataset (planned for a future release) • Run the Study Design Report • Run the Study Query Dataset • Run the Subject Data Report • Run the Subject Data for CTMS Report • Run the Subject Dataset • Run the Subject Events Report • Run the Subject Form Items Dataset • Run the Subject Forms Dataset • Run the Subject Query Report • Run the Training Report • Run the Unblinded Chain of Custody Report • Run the Unblinded Inventory Report • Run the User Assignment Report
Rules Management	• Re-run Rules
Settings	• Configure Connected Device Study Settings • Edit Welcome Details in General Study Settings
Study Setup	• Assign a Resupply Strategy to a Depot • Assign a Study Version to a Site • Edit General Study Settings • Edit Regions • Edit Study Settings • Edit Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies • Move a Study Design to Testing or Production • Upload and Generate Inventory Lists • Upload and Generate Randomization Lists • View Depots • View Regions • View Role Assignments for Study Users • View Sites • View Study Design • View Study Settings • View Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies

Table 8-9 (Cont.) Production Admin (template) study role

Category	Permissions assigned
Unblinded Study Management	• Manage Randomization Lists • Update Inventory Lists

Rules Designer

This topic describes the permissions included in the Rules Designer (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.

Permissions given to a rule designer based on their responsibilities

> **Note:**
>
> To see an overview of all permissions that can be included in study roles, see the **View Permissions** window in the application.

Table 8-10 Rules Designer (template) study role

Category	Permissions assigned
Administrative	• Run the Study Roles Report
CRF Submit Access	• Run Archival PDFs for your site(s)
Clinical Data Collection	• Add a Lab to a Site • Add and Update Lab Normal Ranges • Create and Add Labs to a Site • Dispense Kits with Calculated Doses • Edit Classified Subject Data Only • Edit Form Data for Subjects • Edit Visit Dates • Randomize Subjects • Skip Visits • Take Action on Connected Devices • Unblind the Treatment Arm for a Subject or Code Break • View Classified Subject Data Only • View Form Data for Subjects • View Queries
Data Extract	• Run the Subject Data Extract
Inventory Management	• View Shipments to Sites • View Unblinded Pharmacist Kits

Table 8-10 (Cont.) Rules Designer (template) study role

Category	Permissions assigned
Reports	• Run the Blinded Inventory Report • Run the Blinded Randomization Report • Run the Data Collection Design Dataset • Run the Enrollment Report • Run the Kit Dispensation Report • Run the Kit Reconciliation Report • Run the Kits and Randomization Design Dataset • Run the Order Summary Report • Run the Site and Depot Report • Run the Study Codelist Dataset (planned for a future release) • Run the Study Design Report • Run the Study Query Dataset • Run the Study Rules Report • Run the Subject Data Report • Run the Subject Events Report • Run the Subject Form Items Dataset • Run the Subject Query Report • Run the Subject Visit Report • Run the Titration Summary Report • Run the Training Report • Run the Unblinded Chain of Custody Report • Run the Unblinded Inventory Report • Run the Unblinded Randomization Report • Run the Unblinded Subject Visit Schedule Report • Run the Unblinded Titration Summary Report • Run the User Assignment Report
Rules Management	• Design Custom Rules • Publish Custom Rules • Re-run Rules • Test Custom Rules
Settings	• Configure Connected Device Study Settings • Edit Welcome Details in General Study Settings
Study Management	• Transfer subjects between sites • View All Queries

Table 8-10 (Cont.) Rules Designer (template) study role

Category	Permissions assigned
Study Setup	• Assign a Resupply Strategy to a Site • Assign a SDV Strategy to a Site • Assign a Study Version to a Site • Create and Manage Lots • Create and Manage SDV Properties • Create and Manage Sites • Edit General Study Settings • Edit Regions • Edit Study Settings • Edit Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies • Move a Study Design to Testing or Production • Upload and Generate Inventory Lists • Upload and Generate Randomization Lists • View Role Assignments for Study Users • View Sites • View Study Design

Site Administrator

This topic describes the permissions included in the Site Administrator (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.

Permissions given to a site administrator based on their responsibilities

> **Note:**
>
> To see an overview of all permissions that can be included in study roles, see the **View Permissions** window in the application.

Table 8-11 Site Administrator (template) study role

Category	Permissions assigned
Clinical Data Collection	• Add a Lab to a Site • Create and Add Labs to a Site
Notifications	• Receive Site has been Updated Notification
Reports	• Run the Site and Depot Report • Run the Training Report • Run the User Assignment Report

Table 8-11 (Cont.) Site Administrator (template) study role

Category	Permissions assigned
Study Setup	• Assign a Resupply Strategy to a Site • Assign a SDV Strategy to a Site • Assign a Study Version to a Site • Create and Manage Depots • Create and Manage Sites • View Depots • View Role Assignment for Study Users • View Sites

Site User

This topic describes the permissions included in the Site User (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.

> **Note:**
>
> To see an overview of all permissions that can be included in study roles, see the **View Permissions** window in the application.

Table 8-12 Site User (template) study role

Category	Permissions assigned
CRF Submit Access	• Confirm download of the Archival PDF • Download the Archival PDF • Run the Archival PDF for your site

Table 8-12 (Cont.) Site User (template) study role

Category	Permissions assigned
Clinical Data Collection	• Add a Lab to a Site • Add and Update Lab Normal Ranges • Answer Queries • Approve and sign subject data • Create and Add Labs to a Site • Dispense Kits with Calculated Doses • Dispense Kits without Calculated Doses • Edit Classified Subject Data Only • Edit Form Data for Subjects • Edit Visit Dates • Randomize Subjects • Skip Visits • Take Action on Connected Devices • Unblind the Treatment Arm for a Subject, or Code Break • View Blinded Dispensation Details with Calculated Doses • View Blinded Dispensation Details without Calculated Doses • View Classified Subject Data Only • View Form Data for Subjects • View Queries
Inventory Management	• Create Manual Shipments • Perform Supplies Reconciliation at Site • Receive Shipments and Update Site Inventory • View Shipments to Sites • View Site Inventory
Notifications	• Receive Notification of Shipments • Receivce the Code Break Notification • Receive the Dispensation Notification • Receive the Randomization Notification • Receive the Subject Screening Notification • Receive the Subject Transferred Notification • Receive the Subject Visit Notification • Receive the Subject Withdrawal Notification
Reports	• Run the Blinded Inventory Report • Run the Enrollment Report • Run the Kit Dispensation Report • Run the Kit Reconciliation Report • Run the Order Summary Report • Run the Subject Data Report • Run the Subject Events Report • Run the Subject Query Report • Run the Subject Visit Report • Run the Titration Summary Report • Run the Training Report • Run the User Assignment Report
Study Management	• Create Shipments to DDF

Statistician - Unblinded

This topic describes the permissions included in the Statistician - Unblinded (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.

Permissions given to a statistician based on their responsibilities

> **Note:**
>
> To see an overview of all permissions that can be included in study roles, see the **View Permissions** window in the application.

Table 8-13 Statistician - Unblinded (template) study role

Category	Permissions assigned
Clinical Data Collection	• Edit Classified Subject Data Only • View Blinded Dispensation Details with Calculated Doses • View Blinded Dispensation Details without Calculated Doses • View Classified Subject Data Only • View Form Data for Subjects • View Queries **Study Setup**: • Upload and Generate Randomization Lists • View Regions • View Sites • View Study Design • View Subject Settings **Unblinded Study Management**: • Manage Randomization Lists
Data Extract	• Run the Subject Data Extract
Notifications	• Receive the Code Break Notification • Receive the Unblinded Randomization Notification

Table 8-13 (Cont.) Statistician - Unblinded (template) study role

Category	Permissions assigned
Reports	• Run the Blinded Subject Events Dataset • Run the Enrollment Report • Run the Kit Dispensation Report • Run the Study Codelist Dataset (planned for a future release) • Run the Study Design Report • Run the Study Query Dataset • Run the Subject Data Report • Run the Subject Dataset • Run the Subject Events Report • Run the Subject Form Items Dataset • Run the Subject Forms Dataset • Run the Subject Query Report • Run the Unblinded Randomization Report • Run the Blinded Randomization Report • Run the Unblinded Kits Dataset
Study Setup	• Edit Regions • Upload and Generate Inventory Lists • Upload and Generate Randomization Lists • View Regions • View Role Assignments for Study Users • View Sites • View Study Design • View Study Settings
Unblinded Study Management	• Manage Randomization Lists • Reveal the Treatment Arm for a Subject or Code View

Study Designer

This topic describes the permissions included in the Study Designer (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.

Permissions given to a study designer based on their responsibilities

> **Note:**
>
> To see an overview of all permissions that can be included in study roles, see the **View Permissions** window in the application.

Table 8-14 Study Designer (template) study role

Category	Permissions assigned
Reports	• Run the Analytics Study Codelist Dataset • Run the Data Collection Design Dataset • Run the Kits and Randomization Design Dataset
Study Design	• Add and Administer Study Users • Delete Custom Code Lists • Design Forms • Design Randomization • Design SDV Properties on Forms • Design Supplies and Dispensation • Design Visits and Events • Manage Study Code Lists • Run the Draft Study Design Report • Run the Study Roles and User Assignment Report (Design Mode) • View Design

Study Manager

This topic describes the permissions included in the Study Manager (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.

Permissions given to a study manager based on their responsibilities

> **Note:**
>
> To see an overview of all permissions that can be included in study roles, see the **View Permissions** window in the application.

Table 8-15 Study Manager (template) study role

Category	Permissions assigned
CRF Submit Access	• Run and Download Site Confirmation and Download Log Audit Reports • Run and Download all PDF Request Types and Audit Reports. Enable Share with Sites, and Site Confirmation
Clinical Data Collection	• Edit Classified Subject Data Only • View Blinded Dispensation Details with Calculated Doses • View Blinded Dispensation Details without Calculated Doses • View Classified Subject Data Only • View Queries

Table 8-15 (Cont.) Study Manager (template) study role

Category	Permissions assigned
Inventory Management	• Create Manual Shipments • View Shipments to Sites • View Site Inventory
Notifications	• Receive Site has been Updated Notification • Receive the Code Break Notification • Receive the Study Limits Notification • Receive the Subject Transferred Notification,
Reports	• Run the Blinded Chain of Custody Report • Run the Blinded Kits Dataset • Run the Blinded Randomization Report • Run the Blinded Subject Events Dataset • Run the Enrollment Report • Run the Kit Dispensation Report • Run the Site and Depot Report • Run the Study Codelist Dataset • Run the Study Design Report • Run the Study Query Dataset • Run the Subject Data Report • Run the Subject Dataset • Run the Subject Events Report • Run the Subject Form Items Dataset • Run the Subject Forms Dataset • Run the Subject Query Report • Run the Training Report • Run the User Assignment Report • Schedule Reports to Run
Settings	• Edit Welcome Details in General Study Settings • Manage Signature Settings
Study Management	• Transfer Subjects Between Sites
Study Setup	• Assign a Study Version to a Site • Create and Manage SDV Strategies • Edit General Study Settings • Edit Regions • Edit Study Settings • Manage Archives Settings • Move a Study Design to Testing or Production • View Depots • View Regions • View Role Assignments for Study Users • View Sites • View Study Design • View Study Settings

Unblinded Depot User

This topic describes the permissions included in the Unblinded Depot User (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.

Permissions given to an unblinded depot user based on their responsibilities

> **Note:**
>
> To see an overview of all permissions that can be included in study roles, see the **View Permissions** window in the application.

Table 8-16 Unblinded Depot User (template) study role

Category	Permissions assigned
Inventory Management	• Create Manual Shipments • Create Shipments to Depots • Receive New Shipments at the Depot • Receive and Reconcile Shipments at the Depot • View Shipments to Sites • View Site Inventory • View Unblinded Pharmacist Kits
Notifications	• Receive Notification of Depot Shipments • Receive Notification of Shipments • Receive Site has been Updated Notification
Reports	• Schedule Reports to Run • Run the Blinded Inventory Report • Run the Kit Reconciliation Report • Run the Order Summary Report
Study Setup	• View Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies
Unblinded Study Management	• Manage Study Inventory for Unblinded Users

User Administrator

This topic describes the permissions included in the User Administrator (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.

Permissions given to user administrators based on their responsibilities

> **Note:**
>
> To see an overview of all permissions that can be included in study roles, see the **View Permissions** window in the application.

Table 8-17 User Administrator (template) study role

Category	Permissions assigned
Study Design	• Add and Administer Study Users • Create Study Roles • Run the Study Roles Report (Design Mode) • View Design • Upload Users in Bulk
Reports	• Schedule Reports to Run

View Only for Unblinded Support Users

This topic describes the permissions included in the View Only for Unblinded Support Users (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.

Typically assigned to a member of the Life Sciences Support who should assist with troubleshooting, this study role can also be found as a predefined template, at a global level. Support users who are assigned the **View Only for Unblinded Support Users (template)** role are automatically updated with any new permission introduced for a given release. Alternatively, you can also create your own study role that might be different from the predefined one, at either a global level or in the context of a study.

> **Note:**
>
> To see an overview of all permissions that can be included in study roles, see the **View Permissions** window in the application.

Permissions given to a Life Sciences Support user

Table 8-18 View Only for Unblinded Support Users (template) study role

Category	Permissions assigned
Administrative	• Run the Study Roles Report • View Only for Unblinded Support Users
CRF Submit Access	• Download Archival PDFs, and Audit Reports • Run the Archival PDF for your site(s)
Clinical Data Collection	• View Blinded Dispensation Details with Calculated Doses • View Blinded Dispensation Details without Calculated Doses • View Classified Subject Data Only • View Form Data for Subjects • View Queries

Table 8-18 (Cont.) View Only for Unblinded Support Users (template) study role

Category	Permissions assigned
Data Extract	• Execute ODM Administrative Data API • Execute ODM Clinical Data API with Hidden Data • Execute ODM Clinical Data API without Hidden Data • Execute ODM Metadata API • Run the Subject Data Extract
Inventory Management	• View Shipments to Sites • View Site Inventory • View Unblinded Pharmacist Kits
Reports	• Run the Blinded Chain of Custody Report • Run the Blinded Inventory Report • Run the Blinded Kits Dataset • Run the Blinded Randomization Report • Run the Blinded Subject Events Dataset • Run the Enrollment Report • Run the Kit Dispensation Report • Run the Kit Reconciliation Report • Run the Order Summary Report • Run the Site and Depot Report • Run the Study Codelist Dataset • Run the Study Design Report • Run the Study Kits Dataset • Run the Study Query Dataset • Run the Study Rules Report • Run the Subject Data for CTMS Report • Run the Subject Dataset • Run the Subject Events Report • Run the Subject Form Items Dataset • Run the Subject Forms Dataset • Run the Subject Query Report • Run the Subject Visit Report • Run the Titration Summary Report • Run the Training Report • Run the Unblinded Chain of Custody Report • Run the Unblinded Inventory Report • Run the Unblinded Kits Dataset • Run the Unblinded Randomization Report • Run the Unblinded Subject Events Dataset • Run the Unblinded Subject Visit Schedule Report • Run the Unblinded Titration Summary Report • Run the User Assignment Report • Run the User Upload Error Report • Schedule Reports to Run
Rules Management	• Re-run Rules

Table 8-18 (Cont.) View Only for Unblinded Support Users (template) study role

Category	Permissions assigned
Study Management	• View All Queries
Study Setup	• View Depots • View Regions • View Role Assignments for Study Users • View Sites • View Study Design • View Study Settings • View Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies
Trial Management	• View Actions on Trial Management Event Records • View Blinded Trial Management Records • View Trial Management Event Records • View Unblinded Trial Management Records
Unblinded Study Management	• Reveal the Treatment Arm for a Subject, or Code View

View Study Design

This topic describes the permissions included in the View Study Design (template) study role in the application. This template study role is available for all studies in your organization. You can copy the study role and customize it for each individual study you work in.

Typically assigned to an unblinded study team member or site who should view the study's design, this study role can also be found as a predefined template at a global level. Alternatively, you can also create your own study role that might be different from the predefined one, at either a global level or in the context of a study.

> **Note:**
>
> To see an overview of all permissions that can be included in study roles, see the **View Permissions** window in the application.

Permissions given to a user who must view a study's design

Table 8-19 View Study Design (template) study role

Category	Permissions assigned
Reports	• Run the Analytics Study Codelists Dataset
Study Design	• View Design

9 Revision history

Date	Part number	Description
May 2024	F87772-01	Original version of this document.

A

Descriptions of permissions in Oracle Clinical One Platform

Browse descriptions and additional information for every study role permission available in the application.

For global user roles descriptions see Roles for global users in Oracle Clinical One Platform and Oracle Clinical One Digital Gateway.

Sponsor and site permissions

On the Create Study Role dialog, when you select the Sponsor type of study role, you see the following permissions to select for your study role.

Table A-1 Administrative

Permission	Description	Notes
Run the Study Roles Report	Allows a user to generate the *Study Roles* report, in the Draft (Study Design) mode for a specific study.	This is a permission only for study-level users. If a user wants to run the report at a global level, they need a global role assigned to them to run the *Study Roles Report By Study*.

Table A-1 (Cont.) Administrative

Permission	Description	Notes
View Only for Unblinded Support Users	Allows a user to view the study data. Typically assigned to Oracle Support users.	Does not require any other permission to have access to this report. **Caution:** Can unblind users. Use with caution.

Table A-2 CRF Submit Access

Permission	Description	Notes
Confirm download of Archival PDFs and content (Site)	• Allows a user to confirm that they downloaded an Archival PDF, Custom PDF, or Kit Chain of Custody (Blinded) report generated and shared by a sponsor user. • Allows a site user to generate the Site Confirmation report. Must be assigned along with the *Download Archival PDFs and Audit Report* permission.	This is a permission for site users, but can also be assigned to a sponsor user. **Caution:** Assigning site permissions, in addition to sponsor permissions to a sponsor study role, can result in permission conflicts that could

Table A-2 (Cont.) CRF Submit Access

Permission	Description	Notes
		imp act a use r's abil ity to per for m cert ain tas ks.
Download Archival PDFs and Audit Reports (Site)	Allows a user to download an Archival PDF and audit reports. Must be assigned along with the *Confirm download of Archival PDFs and content* permission.	This is a permission for site users, but can also be assigned to a sponsor user.
Run Archival PDFs for your site(s) (Site)	Allows a user to generate the Archival PDF and audit reports for their site.	This is a permission for site users, but can also be assigned to a sponsor user. Does not require any other permission to have access to this report.
Run and download Site Confirmation and Download Log audit reports	Allows a user to generate and download the Site Confirmation and Download Log reports.	This is a permission for sponsor users. Does not require any other permission to have access to these reports.
Run and download all PDF request types and Audit reports. Enable Share with Sites, and Site Confirmation	Allows a user to generate and download all PDF Archives request types and audit reports. When assigned, this enables the settings, **Share with Sites**, and **Confirm Site Downloads** for Archival and Custom requests.	This is a permission for sponsor users.

Table A-3 Clinical Data Collection

Permission	Description	Notes
Add a Lab to a Site	Allows a user to associate a lab with a site.	This is a permission for site users, but can also be assigned to a sponsor user. Must be assigned along with the *View Sites* permission.

Table A-3 (Cont.) Clinical Data Collection

Permission	Description	Notes
Add and Update Lab Normal Ranges	Allows a user to create and update lab normal ranges for each lab.	This is a permission for both sponsor and site users. Must be assigned along with the *View Sites* permission.
Answer Queries	Allows a user to answer queries in a form.	This is a permission for site users, but can also be assigned to a sponsor user. Must be assigned along with the following permissions: • *View Form Data for Subjects* • *View Queries* • *View All Queries* (optional) • *View Sites*
Approve and Sign Assigned Data Only	Allows a user to only sign data that has been assigned to their role at the form or visit level.	This is a permission for both sponsor and site users. Must be assigned along the following permissions: • *View Form Data for Subjects* • *View Sites*
Approve and sign subject data	Allows a user to sign a subject's data in the application at the casebook, form, and visit level.	This is a permission for site users, but can also be assigned to a sponsor user. Must be assigned along the following permissions: • *Edit Form Data for Subjects* • *View Form Data for Subjects* • *View Sites*
Create and Add Labs to a Site	Allows a user to create and associate a lab to a site.	This is a permission for both sponsor and site users. Must be assigned along with the *View Sites* permission.
Dispense Kits with Calculated Doses	Allows a user to dispense kits with calculated doses.	This is a permission for site users, but can also be assigned to a sponsor user. Must be assigned along with the following permissions: • *View Sites* • *View Form Data for Subjects* • *View Blinded Dispensation Details with Calculated Doses*

Table A-3 (Cont.) Clinical Data Collection

Permission	Description	Notes
Dispense Kits without Calculated Doses	Allows a user to dispense kits without calculated doses, such as kits containing the investigational product or kits required for titration.	This is a permission for site users, but can also be assigned to a sponsor user. Must be assigned along with the following permissions: • *View Sites* • *View Form Data for Subjects* • *View Blinded Dispensation Details with Calculated Doses*

Table A-3 (Cont.) Clinical Data Collection

Permission	Description	Notes
Edit Classified Subject Data Only	Allows a user to edit classified subject data only, in a form. **Note:** When a data manager is assigned this permission	This is a permission for both sponsor and site users. Must be assigned along with the following permissions: • *View Sites* • *View Form Data for Subjects* • *View Classified Subject Data Only*

Table A-3 (Cont.) Clinical Data Collection

Permission	Description	Notes
		, they may notice that they have the ability to edit forms that don't co

Table A-3 (Cont.) Clinical Data Collection

Permission	Description	Notes
	ntainclassifieddata.Advisedatamanagerstoonlyworkwiththe	

Table A-3 (Cont.) Clinical Data Collection

Permission	Description	Notes
	forms that contain classified data.	

Table A-3 (Cont.) Clinical Data Collection

Permission	Description	Notes
Edit Form Data for Subjects	Allows a user to perform the following: • Complete and edit forms for a subject. • Clear the Visit Date and data on forms. • Undo subjects if added in error, when no data collection has occurred. • Enables the **Screen** and **Randomize** buttons. **Note:** If users need to screen subjects and enter data but not randomize them, see What should I do when users need to screen data?	This is a permission for site users, but can also be assigned to a sponsor user. Must be assigned along with the following permissions: • *View Sites* • *View Form Data for Subjects*
Edit Visit Dates	Allows a user to fill-in or update the Visit Date field in a form.	This is a permission for site users, but can also be assigned to a sponsor user. Must be assigned along with the following permissions: • *View Sites* • *View Form Data for Subjects*
Integrate Subject Data	Allows a user to integrate subject data across applications, through integrations.	Typically, this is a permission assigned to an integration user who is part of your study. The user account that is assigned this permission doesn't usually sign into the application. They simply need this permission in the application, so they can operate with the integration data.
Randomize Subjects	Allows a user to start a randomization visit, complete associated forms, and randomize a subject.	This is a permission for site users, but can also be assigned to a sponsor user. Must be assigned along with the following permissions: • *View Sites* • *View Form Data for Subjects*

Table A-3 (Cont.) Clinical Data Collection

Permission	Description	Notes
Skip Visits	Allows a user to skip visits in a subject's schedule.	This is a permission for site users, but can also be assigned to a sponsor user. Must be assigned along with the following permissions: • *View Sites* • *View Form Data for Subjects*
Take Action on Connected Devices	Allows a user to refresh, activate, and dispense medical devices to a subject.	This is a permission for site users, but can also be assigned to a sponsor user. Must be assigned along with the following permissions: • *View Sites* • *View Form Data for Subjects*

Table A-3 (Cont.) Clinical Data Collection

Permission	Description	Notes
Unblind the Treatment Arm for a Subject or Code Break	Allows a user to perform a code break on a subject during the study conduct period.	This is a permission for site users, but can also be assigned to a sponsor user. **Caution:** Can unblind users. Use with caution. Must be assigned along with the following permissions: • *View Sites* • *View Form Data for Subjects*

Table A-3 (Cont.) Clinical Data Collection

Permission	Description	Notes
Update Subject Number after Creation	Allows a user to update a subject number during the study conduct period.	This is a permission for both sponsor and site users.
View Blinded Dispensation Details with Calculated Doses	Allows a user to view blinded dispensation details when a kit with calculated doses is dispensed to a subject.	This is a permission for site users, but can also be assigned to a sponsor user. This permission can be assigned in conjunction with other permissions related to dispensation or randomization, so the appropriate blinded site users can view dispensation details.
View Blinded Dispensation Details without Calculated Doses	Allows a user to view blinded dispensation details when a kit without calculated doses is dispensed to a subject. For example, a blinded site user can view dispensation details when a kit with the investigational product or titration is dispensed.	This is a permission for site users, but can also be assigned to a sponsor user. This permission can be assigned in conjunction with other permissions related to dispensation or randomization, so the appropriate blinded site users can view dispensation details.
View Classified Subject Data Only	Allows a user to view only classified data in a form.	This is a permission for both sponsor and site users. This permission must always be assigned along with the *Edit Classified Subject Data Only* permission.
View Form Data for Subjects	Allows a user to view data in forms for subjects.	This is a permission for both sponsor and site users. This permission must be assigned in conjunction with other permissions related to data collection, so the site user can view and complete forms.
View Queries	Allows a user to view queries raised against answer fields in forms.	This is a permission for site users, but can also be assigned to a sponsor user. This permission must be assigned in conjunction with other permissions related to query management, so a user can view, answer, create, or close queries.

Table A-4 Data Extract

Permission	Description	Notes
Execute ODM Administrative Data API	Allows a user to use specific API endpoints to extract administrative data in an ODM-XML format.	This permission is available for sponsor users only.
Execute ODM Clinical Data API with Hidden Data	Allows a user to use specific API endpoints to extract clinical data and hidden study data in an ODM-XML format.	This permission is available for sponsor users only. **Caution:** Can unblind users. Use with caution.
Execute ODM Clinical Data API without Hidden Data	Allows a user to use specific API endpoints to extract clinical data without any hidden study data in an ODM-XML format.	This permission is available for sponsor users only.
Execute ODM Metadata API	Allows a user to use specific API endpoints to extract API Metadata in an ODM-XML format.	This permission is available for sponsor users only.

Table A-4 (Cont.) Data Extract

Permission	Description	Notes
Run the Subject Data Extract	Allows a user to extract study data in a CSV, XPORT, and CPORT format by running the Subject Data Extract.	This permission is available for sponsor users only. **Caution:** Can unblind users. Use with caution.

Table A-5 Inventory Management

Permission	Description	Notes
Blinded Depot User	Allows a user to see the blinded supply inventory: • **Depot Inventory** tab; • Kit numbers for all blinded, unblinded, and unblinded pharmacist kit types;	**Caution:** Use with caution. The Blinded Depot User permission grants access to view the Sequence Number, which could potentially unblind the stu

Table A-5 (Cont.) Inventory Management

Permission	Description	Notes
		dy for blinded site users and blinded sponsor users.
		This permission is for both sponsor and site users.
		Note: This permission only lets a user view supplies from depots or sites that they're

Table A-5 (Cont.) Inventory Management

Permission	Description	Notes
		assigned to. They cannot see the full description of kits for blinded and unblinded pharmacist kits. This permission can be found in the following predefined study role templates: • Blinded Depot User (template) • Clinical Supply Manager (template)

Table A-5 (Cont.) Inventory Management

Permission	Description	Notes
Create Manual Shipments	Allows a user to create manual shipments to be delivered to sites.	This permission is for both sponsor and site users.

Note:

Site users cannot create manual shipments but can request a shipment to be created. In addition, blinded sponsor users are not able to create ma

Table A-5 (Cont.) Inventory Management

Permission	Description	Notes
		nual shipments. Must be assigned along with the following permissions: • *View Sites* • *View Site Inventory* • *View Shipments to Sites* This permission can be found in the following predefined study role templates: • Site User (template) • Clinical Supply Manager (template) • CRA (template) • Study Manager (template) • Unblinded Depot User (template) • Pharmacy User (template)
Create Shipments to Depots	Allows a user to create a supplying or a destruction shipment to be sent to another depot.	This permission is available for sponsor users only. **Caution:** Can unblind users. Use with caution.

Table A-5 (Cont.) Inventory Management

Permission	Description	Notes
Perform Supplies Reconciliation at Site	Allows a user to perform kit reconciliation at a site.	This permission is for both sponsor and site users. Must be assigned along with the following permissions: • *View Sites* • *View Site Inventory*
Receive New Shipments at the Depot	Allows a user to register shipments and add them to a depot's inventory.	This permission is available for sponsor users only. **Caution:** Can unblind users. Use with caution.
Receive Shipments and Update Site Inventory	Allows a user to receive shipments at a site and update the site inventory.	This permission is for site users, but can also be assigned to sponsor users. Must be assigned along with the following permissions: • *View Sites* • *View Site Inventory* • *View Shipments to Sites*

Table A-5 (Cont.) Inventory Management

Permission	Description	Notes
Receive and Reconcile Shipments at the Depot	Allows a user to receive shipments sent by a depot and reconciling shipments at a depot level.	This permission is available for sponsor users only. **Caution:** Can unblind users. Use with caution. Must be assigned along with the following permissions: • *View Depots* • *View Sites*

Table A-5 (Cont.) Inventory Management

Permission	Description	Notes
Release Shipments from Quarantine	Allows a user to release all kits in a shipment from Quarantine and update their status to Available.	This permission is for sponsor users, typically Clinical Supply Managers.

Caution:

Can unblind users. Use with caution.

Table A-5 (Cont.) Inventory Management

Permission	Description	Notes
Update Supplies after Design Approval	Allows a user to update study supply attributes after a study version has been approved. This is typically done to correct mistakes made during kit creation. **WARNING:** A user with this permission can modify kits in ways that can be detrimental to approved study versions. Th	This permission is available for sponsor users only. **Caution:** Can unblind users. Use with caution. Must be assigned along with the following permission to update kits. • *Design Supplies and Dispensation*

Table A-5 (Cont.) Inventory Management

Permission	Description	Notes
		e permission should be removed after the updates are made.
Update the Shipment Order Form	Allows a user to restrict a sites' ability to resend depot order forms after orders have been fulfilled.	This permission is for sponsor users, typically Clinical Supply Managers. Must be assigned along with the *Receive and Reconcile Shipments at the Depot* permission.
View Shipments to Sites	Allows a user to view shipments sent to sites.	This permission is for both sponsor and site users. Must be assigned along with the *View Site Inventory* permission.
View Site Inventory	Allows a user to view a site's inventory.	This permission is for both sponsor and site users.

Table A-5 (Cont.) Inventory Management

Permission	Description	Notes
View Unblinded Pharmacist Kits	Allows a user to view unblinded pharmacist kits in both inventories: site and study inventory.	This permission is for both sponsor and site users. **Caution:** Can unblind users. Use with caution. Must be assigned along with the following permissions: • *View Sites* • *View Depots* • *View Site Inventory* • *Manage Study Inventory for Unblinded Users*

Table A-6 Notifications

Permission	Description	Notes
Receive Notification of Depot Shipments	Allows a user to receive a notification whenever a depot shipment is created or updated.	This permission is available for sponsor users only. **Caution:** Can unbind users. Use with caution.

Table A-6 (Cont.) Notifications

Permission	Description	Notes
Receive Notification of Shipments	Allows a user to receive a notification whenever: • A new shipment request is created; • A new shipment for destruction was created; • A kit is missing for a shipment sent for destruction • A shipment for destruction is not received by a depot • A shipment cannot be created • A shipment is cancelled	This permission is for both sponsor and site users.
Receive Rule Failure Notification for Locked Data	Allows a user to receive a notification when a rule is unable to update a target because it is locked.	This permission is available for sponsor users only.
Receive Site has been Updated Notification	Allows a user to receive a notification when a site changes status, such as from going from New to Active.	This permission is for both sponsor and site users.
Receive the Code Break Notification	Allows a user to receive a notification when a subject is unblinded due to a code break.	This permission is for both sponsor and site users.
Receive the Dispensation Notification	Allows a user to receive the Subject Dispensation notification, whether the dispensation succeeded or failed.	This permission is for both sponsor and site users.
Receive the Dispensation with Dosing Instructions Notification	Allows a user to receive the Subject Dispensation notification with dosing instructions for kits with calculated doses, whether the dispensation succeeded or failed.	This permission is for both sponsor and site users.
Receive the Pending Signatures Notification	Allows a user to receive a notification informing them when a signature, for a site they are assigned to, has a defined target date that has become overdue.	This permission is for both sponsor and site users.
Receive the Quarantined Depot Shipment Notification	Allows a user to receive a notification whenever a depot shipment or kits are quarantined.	This permission is available for sponsor users only.

Table A-6 (Cont.) Notifications

Permission	Description	Notes
Receive the Quarantined Site Shipment Notification	Allows a user to receive a notification whenever a site shipment or kits are quarantined.	This permission is for both sponsor and site users.
Receive the Randomization Notification	Allows a user to receive a notification when a subject is either successfully randomized or their randomization failed at a site they are assigned to.	This permission is for both sponsor and site users.
Receive the Released from Quarantine Notification (Depot)	Allows a user to receive a notification whenever a depot shipment or kits are released from quarantine.	This permission is available for sponsor users only.
Receive the Released from Quarantine Notification (Site)	Allows a user to receive a notification whenever a site shipment or kits are released from quarantine.	This permission is for both sponsor and site users.
Receive the Study Limits Notification	Allows a user to receive a notification when the randomization limit is reached for a study, site, country, or cohort; or a percentage of the randomization limit is reached for a study, site, country, or cohort.	This permission is for both sponsor and site users.
Receive the Subject Completion Notification	Allows a user to receive a notification when a subject at a site they are assigned to completes a study.	This permission is for both sponsor and site users.
Receive the Subject Number Update Notification	Allows a user to receive a notification when a subject's number is updated in a system.	This permission is for both sponsor and site users.
Receive the Subject Rollover Notification	Allows a user to receive a notification when a subject at a site they are assigned to is enrolled into a rollover study.	This permission is for both sponsor and site users.
Receive the Subject Screening Notification	Allows a user to receive a notification when a subject is either successfully screened or their screening failed at a site they are assigned to.	This permission is for both sponsor and site users.
Receive the Subject Transferred Notification	Allows a user to receive a notification when a subject transfers to another site.	This permission is for both sponsor and site users.

Table A-6 (Cont.) Notifications

Permission	Description	Notes
Receive the Subject Visit Notification	Allows a user to receive a notification when a subject completes a non-dispensation or optional visit at a site they are assigned to. The notification is sent both when the subject successfully completes the visit and when one or more questions have errors.	This permission is for both sponsor and site users.
Receive the Subject Withdrawal Notification	Allows a user to receive a notification when a subject withdraws from a study.	This permission is for both sponsor and site users.

Table A-6 (Cont.) Notifications

Permission	Description	Notes
Receive the Unblinded Dispensation Notification	Allows a user to receive a notification when an unblinded dispensation event is successfully completed or when the unblinded dispensation failed at a site they are assigned to.	This permission is for both sponsor and site users. **Caution:** Can unblind users. Use with caution.

Table A-6 (Cont.) Notifications

Permission	Description	Notes
Receive the Unblinded Dose Hold Notification	Allows a user to receive a notification when an unblinded dose hold event is successfully completed at a site they are assigned to.	This permission is for both sponsor and site users. **Caution:** Can unblinded users. Use with caution.

Table A-6 (Cont.) Notifications

Permission	Description	Notes
Receive the Unblinded Kit Misallocation Notification	Allows a user to receive a notification when a kit status is manually updated to Missallocated when dispensed in error. For example, someone at the site might have dispensed a subject with kit different from the one indicated by Oracle Clinical One Platform; or a site user might have entered data in the wrong subject's visit and dispensed a kit that was not supposed to be dispensed.	This permission is for both sponsor and site users. **Caution:** Can unblind users. Use with caution.

Table A-6 (Cont.) Notifications

Permission	Description	Notes
Receive the Unblinded Pharmacist Dispensation Notification	Allows a user to receive a notification when an unblinded pharmacist kit is successfully dispensed or not by an unblinded site user.	This permission is for both sponsor and site users. **Caution:** Can unblinded users. Use with caution.

Table A-6 (Cont.) Notifications

Permission	Description	Notes
Receive the Unblinded Randomization Notification	Allows a user to receive a notification when a subject is either successfully randomized with unblinded kits or their unblinded randomization failed at a site they are assigned to.	This permission is for both sponsor and site users. **Caution:** Can unblind users. Use with caution.

Table A-6 (Cont.) Notifications

Permission	Description	Notes
Receive the Unscheduled Visit Notification	Allows a user to receive a notification when a subject completes an unscheduled visit at a site they are assigned to. The notification is sent both when the subject successfully completes the visit and when one or more questions have errors.	This permission is for both sponsor and site users.

Table A-7 Reports

Permission	Description	Notes
Run the Blinded Chain of Custody Report	Allows a user to run the Kit Chain of Custody (blinded) report.	This permission is for both sponsor and site users. **Caution:** Can unblind users. Use with caution.
Run the Blinded Inventory Report	Allows a user to run the Kit Inventory (Blinded) report.	This permission is for both sponsor and site users.
Run the Blinded Kits Dataset	Allows a user to operate the Blinded Kits Dataset in Oracle Clinical One Analytics	This permission is for both sponsor and site users.
Run the Blinded Randomization Report	Allows a user to run the Blinded Randomization Report.	This permission is for sponsor users and CRAs.
Run the Blinded Subject Events Dataset	Allows a user to operate the Blinded Subject Events Dataset in Oracle Clinical One Analytics	This permission is for both sponsor and site users.

Table A-7 (Cont.) Reports

Permission	Description	Notes
Run the Enrollment Report	Allows a user to run the Study Enrollment report.	This permission is for both sponsor and site users.
Run the Kit Dispensation Report	Allows a user to run the Kit Dispensation report.	This permission is for both sponsor and site users.
Run the Kit Reconciliation Report	Allows a user to run the Kit Reconciliation report.	This permission is for both sponsor and site users.
Run the Order Summary Report	Allows a user to run the Shipment Order Summary report.	This permission is for both sponsor and site users.
Run the Site and Depot Report	Allows a user to run the Audit Report Site and Depot report.	This permission is for both sponsor and site users.
Run the Study Codelist Dataset	Allows a user to operate the Study Codelist dataset in Oracle Clinical One Analytics.	This permission is for both sponsor and site users.
Run the Study Design Report	Allows a user to run the Study Design report.	This permission is available for sponsor users only.
Run the Study Kits Dataset	Allows a user to operate the Study Kits dataset in Oracle Clinical One Analytics (which is planned for a future release).	*Planned for future release.* This permission is for both sponsor and site users.
Run the Study Query Dataset	Allows a user to operate the Study Query dataset in Oracle Clinical One Analytics.	This permission is for both sponsor and site users.
Run the Study Rules Report	Allows a user to run the Rules report.	This permission is available for sponsor users only.
Run the Subject Data Report	Allows a user to run the Subject Data report.	This permission is for both sponsor and site users.
Run the Subject Data for CTMS Report	Allows a user to run the Subject Data for CTMS report.	This permission is available for sponsor users only.
Run the Subject Dataset	Allows a user to operate the Subject dataset in Oracle Clinical One Analytics	This permission is for both sponsor and site users.
Run the Subject Events Report	Allows a user to run the Subject Events report.	This permission is for both sponsor and site users.
Run the Subject Form Items Dataset	Allows a user to operate the Subject Form Items dataset in Oracle Clinical One Analytics	This permission is for both sponsor and site users.
Run the Subject Forms Dataset	Allows a user to operate the Subject Forms dataset in Oracle Clinical One Analytics	This permission is for both sponsor and site users.
Run the Subject Query Report	Allows a user to run the Subject Queries report.	This permission is for both sponsor and site users.
Run the Subject Visit Report	Allows a user to run the Subject Visits report (Blinded).	This permission is for both sponsor and site users.
Run the Titration Summary Report	Allows a user to run the Titration Summary report (Blinded).	This permission is for both sponsor and site users.

Table A-7 (Cont.) Reports

Permission	Description	Notes
Run the Training Report	Allows a user to run the Clinical One Training report.	This permission is for both sponsor and site users.
Run the Unblinded Chain of Custody Report	Allows a user to run the Kit Chain of Custody (Unblinded) report.	This permission is available for sponsor users only. **Caution:** Can unblind users. Use with caution.

Table A-7 (Cont.) Reports

Permission	Description	Notes
Run the Unblinded Inventory Report	Allows a user to run the Kit Inventory (Unblinded) report.	This permission is available for sponsor users only. **Caution:** Can unblind users. Use with caution.
Run the Unblinded Kits Dataset	Allows a user to run the Unblinded Kits Dataset.	This permission is for both sponsor and site users. **Caution:** Can unblind users. Use with caution.

Table A-7 (Cont.) Reports

Permission	Description	Notes
Run the Unblinded Randomization Report	Allows a user to run the Randomization List report (Unblinded).	This permission is available for sponsor users only. **Caution:** Can unblind users. Use with caution.
Run the Unblinded Subject Events Dataset	Allows a user to operate the Unblinded Subject Events dataset in Oracle Clinical One Analytics	This permission is for both sponsor and site users. **Caution:** Can unblind users. Use with caution.

Table A-7 (Cont.) Reports

Permission	Description	Notes
Run the Unblinded Subject Visit Schedule Report	Allows a user to run the Subject Visits (Unblinded) report.	This permission is available for sponsor users only. **Caution:** Can unblind users. Use with caution.
Run the Unblinded Titration Summary Report	Allows a user to run the Titration Summary (Unblinded) report.	This permission is available for sponsor users only. **Caution:** Can unblind users. Use with caution.

Table A-7 (Cont.) Reports

Permission	Description	Notes
Run the User Assignment Report	Allows a user to run the User Assignment and User Assignment by Site reports.	This permission is for both sponsor and site users.
Run the User Upload Error Report	Allows a user to run the User Upload Error report.	This permission is available for sponsor users only.
Schedule Reports to Run	Allows a user to access the Schedule Reports side panel to create automated schedules for specific reports.	This permission is available for sponsor users only.
Study Design Report Suppress Randomization	Hides the Generated Randomization List details from the Study Design report from the user who has the permission assigned.	This permission is available for sponsor users only. **Caution:** Can unblind users. Use with caution.

Table A-8 Rules Management

Permission	Description	Notes
Design Custom Rules	Allows a rule designer to design custom JavaScript rules. Gives access to the Rule Management page.	This permission is for sponsor users only. Must be assigned along with the following permissions: • *View Sites* • *View Form Data for Subjects* • *Edit Form Data for Subjects*

Table A-8 (Cont.) Rules Management

Permission	Description	Notes
Publish Custom Rules	Allows a rule publisher to publish custom rules. Gives access to the Rule Management page.	This permission is for sponsor users only. Must be assigned along with the following permissions: • *View Sites* • *View Form Data for Subjects* • *Edit Form Data for Subjects*
Re-run Rules	Allows a sponsor user to re-run a rule that was modified during the study conduct period. Gives access to the Rule Management page.	This permission is for sponsor users only. Must be assigned along with the following permissions: • *View Sites* • *View Form Data for Subjects* • *Edit Form Data for Subjects*
Test Custom Rules	Allows a rule tester to test custom rules built by a rule designer. Gives access to the Rule Management page.	This permission is for sponsor users only. Must be assigned along with the following permissions: • *View Sites* • *View Form Data for Subjects* • *Edit Form Data for Subjects*

Table A-9 Settings

Permission	Description	Notes
Configure Connected Device Study Settings	Allows a user to configure the settings and connection between Oracle Clinical One Platformand Oracle Health Sciences mHealth Connector Cloud Service to enable study designers and site users to create and dispense medical devices to subjects.	This permission is for sponsor users only. Must be assigned along with the *View Study Settings* permission.
Edit Welcome Details in General Study Settings	Allows a user to customize the welcome letter that study team members receive upon being provisioned in a study in Oracle Clinical One Platform. This permission gives a user the ability to edit the Welcome Letter field for an individual study.	This permission is for Sponsor users only. To customize the welcome letter at a global level, for all studies in an organization, the user must be assigned the *Study Creator* global role.

Table A-9 (Cont.) Settings

Permission	Description	Notes
Manage Signature Settings	Allows a user to create and manage a Signature Configuration.	This is a permission for sponsor users only. Must be assigned along with the following permissions: • *View Form Data for Subjects* • *View Study Settings*

Table A-10 Study Management

Permission	Description	Notes
Answer Assigned Queries	Allows a user to answer queries that are assigned to a specific user role.	This permission is for both sponsor and site users. Must be assigned along with the following permissions: • *View Sites* • *View Form Data for Subjects* • *View All Queries*
Close Queries	Allows a user to close queries in a study.	This permission is for sponsor users only. Must be assigned along with the following permissions: • *View Sites* • *View Form Data for Subjects* • *View Queries* • *View All Queries*
Create Candidate Queries	Allows a user to create candidate queries against answer fields.	This permission is for sponsor users only and is required only for users who do not already have the *Create Queries* permission. Must be assigned along with the following permissions: • *View Sites* • *View Form Data for Subjects* • *View Queries* • *View All Queries*

Table A-10 (Cont.) Study Management

Permission	Description	Notes
Create Queries	Allows a user to create all types of manual queries, such as standard queries, candidate queries, and assigned queries. A standard query appears for any user who has either one of these permissions: • *View Queries* • *View All Queries* If a user needs to view or answer an assigned query, they must be assigned the *Answer Assigned Queries* permission.	This permission is for sponsor users only. The Create Queries permission must be assigned along with these other permissions: • *View Sites* • *View Form Data for Subjects*
Create Shipments to DDF	Allows a user to create a shipment that must be sent to a drug-destruction facility.	This permission is for both sponsor and site users. Must be assigned along with the following permissions: • *View Depots* • *View Shipments to Sites* • *Manage Study Inventory for Unblinded Users*
Delete Candidate Queries	Allows a user to delete candidate queries created by a sponsor user.	This permission is for sponsor users only. Must be assigned along with the following permissions: • *View All Queries* • *View Queries* • *View Sites* • *View Form Data for Subjects*
Freeze subject data entered at a site	Allows a user to freeze data in forms. Frozen data can not be modified.	This is a permission for sponsor users only, such as a data manager or CRA. Must be assigned along with the following permissions: • *View Sites* • *View Form Data for Subjects*
Lock Subject Data at a Site	Allows a user to lock and unlock data at the visit, form, and question level. If they have the *View Form Data for Subjects* permission, they are able to see if the visit, form, or question is locked.	This permission is for sponsor users only.

Table A-10 (Cont.) Study Management

Permission	Description	Notes
Perform Source Data Verification and Reconcile Inventory	Allows a user to perform two tasks: • Perform source data verification according to the configured source data verification strategy; • Perform kit reconciliation in the study inventory.	This permission is for sponsor users only. Must be assigned along with the following permissions: • *View Sites* • *View Form Data for Subjects* • *View Queries*
Transfer subjects between sites	Allows a user to transfer a subject from one site to another.	This permission is for sponsor users only. Must be assigned along with the following permissions: • *View Sites* • *View Form Data for Subjects*
Unfreeze subject data entered at a site	Allows a user to unfreeze data in forms.	This is a permission for sponsor users only, such as a data manager or CRA. Must be assigned along with the following permissions: • *View Sites* • *View Form Data for Subjects*
Undo Add Subject	Allows a user to undo (cancel) the addition of a subject added in error if no data collection has occurred.	This is a permission for site users.
Verify subject data entered at a site	Allows a user to verify data in forms.	This permission is for sponsor users only. Must be assigned along with the following permissions: • *View Sites* • *View Form Data for Subjects*
View All Queries	Allows a user to view all queries in a study, including queries assigned to a specific user role.	This permission is for sponsor users only. Must be assigned along with the permissions: • *View Sites* • *View Form Data for Subjects*

Table A-11 Study Setup

Permission	Description	Notes
Assign a Resupply Strategy to a Depot	Allows a user to assign a min/max resupply strategy to a depot.	This permission is for sponsor users only.

Table A-11 (Cont.) Study Setup

Permission	Description	Notes
Assign a Resupply Strategy to a Site	Allows a user to assign a resupply strategy to a site.	This permission is for sponsor users only. Must be assigned along with the following permissions: • *View Sites* • *Create and Manage Sites*
Assign a SDV Strategy to a Site	Allows a user to assign an SDV strategy to a site.	This permission is for sponsor users only. Must be assigned along with the following permissions: • *View Sites* • *Create and Manage Sites* • *Create and Manage SDV Strategies*
Assign a Study Version to a Site	Allows a user to assign a study version to a site.	This permission is for sponsor users only. Must be assigned along with the following permissions: • *View Sites* • *Create and Manage Sites*
Create and Manage Depots	Allows a user to create and manage depots.	This permission is for sponsor users only. Must be assigned along with the following permissions: • *View Depots*
Create and Manage Dispensation Exceptions	Allows a user to create and manage dispensation exceptions.	This permission is for sponsor users only. Must be assigned along with the following permissions: • *View Dispensation Exceptions*

Table A-11 (Cont.) Study Setup

Permission	Description	Notes
Create and Manage Lots	Allows a user to create and manage lots.	This permission is for sponsor users only. **Caution:** Can unblind users. Use with caution.
Create and Manage SDV Strategies	Allows a user to create and manage source data verification strategies.	This permission is for sponsor users only.
Create and Manage Sites	Allows a user to create and manage sites.	This permission is for sponsor users only. Must be assigned along with the *View Sites* permission.
Edit General Study Settings	Allows a user to edit study settings located on the General tab.	This permission is for sponsor users only.
Edit Regions	Allows a user to edit regions in a study.	This permission is for sponsor users only. Must be assigned along with the *View Study Settings* permission.
Edit Study Settings	Allows a user to edit study settings located on the Study Settings tab.	This permission is for sponsor users only. Must be assigned along with the *View Study Settings* permission.

Table A-11 (Cont.) Study Setup

Permission	Description	Notes
Edit Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies	Allows a user to edit supply settings, blinded groups, label groups, and resupply strategies located on the Supply Settings tab.	This permission is for sponsor users only. **Caution:** Can unblind users. Use with caution. Must be assigned along with the *View Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies* permission.
Manage Archives Settings	Allows a user access to the **Archives Settings** tab to manage Oracle CRF Submit notifications.	For more information about Oracle CRF Submit notifications, see Email and in-application notifications.
Manage Subject Number Configuration	When this permission is added to a study role, the Study Setting, **Replace Subject Number with Randomization Number** appears under the Study Settings section on the Study Settings tab for that study role.	For more information about this setting, see Specify study, enrollment, and visits settings.
Move a Study Design to Testing or Production	Allows a user to move a study version from Draft to Testing and from Testing to Production.	This permission is for sponsor users only.

Table A-11 (Cont.) Study Setup

Permission	Description	Notes
Upload and Generate Inventory Lists	Allows a user to upload and generate kit lists.	This permission is for sponsor users only. **Caution:** Can unblind users. Use with caution. Must be assigned along with the *View Study Design* permission.

Table A-11 (Cont.) Study Setup

Permission	Description	Notes
Upload and Generate Randomization Lists	Allows a user to upload and generate randomization lists.	This permission is for sponsor users only. **Caution:** Can unblind users. Use with caution. Must be assigned along with the *View Study Design* permission.
View Depots	Allows a user to view depots in a study.	This permission is for sponsor users only.
View Dispensation Exceptions	Allows a user to view dispensation exceptions that have been created.	This permission is for sponsor users only.
View Regions	Allows a user to view regions in a study.	This permission is for sponsor users only. Must be assigned along with the *View Study Settings* permission.
View Role Assignments for Study Users	Allows a user to view what roles and permissions are assigned to users in a study they are a part of.	This permission is for sponsor users only.
View Sites	Allows a user to view sites created in a study.	This permission is for sponsor users only.

Table A-11 (Cont.) Study Setup

Permission	Description	Notes
View Study Design	Allows a user to view all study design elements in the Draft version of a study and lets them enter and manage comments in Study Design and Testing Mode. Specifically offers view only access to the Data Collection and Study Supplies tabs in Study Design and Testing mode.	This permission is for sponsor users only.
View Study Settings	Allows a user to view all fields and settings located on the Study Settings tab.	This permission is for sponsor users only.
View Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies	Allows a user to view all fields and settings located on the Supply Settings tab.	This permission is for sponsor users only.

Caution:

Can unblind users. Use with caution.

Table A-12 Trial Management

Permission	Description	Notes
Close Trial Management Events	Allows a user to close any events related to the management of their study.	Planned for a future release. This permission is available for sponsor users only.
Create Actions on Trial Management Event Records	Allows a user to create actions for every trial management event record in the system.	Planned for a future release. This permission is available for sponsor users only.

Table A-12 (Cont.) Trial Management

Permission	Description	Notes
Create Trial Management Event Records	Allows a user to create records for every trial management event.	Planned for a future release. This permission is available for sponsor users only.
Create Trial Management Event Records from Subjects Tab	Allows a user to create a trial management event record on the Subjects page.	Planned for a future release. This is a permission for site users, but can also be assigned to a sponsor user.
Create Unblinded Trial Management Records	Allows a user to create unblinded trial management records in their study.	Planned for a future release. This permission is available for sponsor users only. **Caution:** Can unblind users. Use with caution.
Edit Actions on Trial Management Event Records	Allows a user to edit the associated actions of a trial management event record.	Planned for a future release. This permission is for both sponsor and site users.
Edit Trial Management Event Records	Allows a user to edit records for trial management events.	Planned for a future release. This permission is available for sponsor users only.
Edit Trial Management Event Records from Subjects Tab	Allows a user to edit records for trial management events on the Subjects page.	Planned for a future release. This is a permission for site users, but can also be assigned to a sponsor user.

Table A-12 (Cont.) Trial Management

Permission	Description	Notes
Edit Unblinded Trial Management Records	Allows a user to edit unblinded record of trial management.	Planned for a future release. This permission is available for sponsor users only. **Caution:** Can unblind users. Use with caution.
Open Trial Management Events	Allows a user to open new trial management events.	Planned for a future release. This permission is available for sponsor users only.
View Actions on Trial Management Event Records	Allows a user to view records of trial management events.	Planned for a future release. This permission is for both sponsor and site users.
View Blinded Trial Management Records	Allows a user to view blinded records of trial management.	Planned for a future release. This permission is for both sponsor and site users.
View Trial Management Event Records	Allows a user to view all records of trial management events.	Planned for a future release. This permission is available for sponsor users only.
View Trial Management Event Records from Subjects Tab	Allows a user to view records of trial management events on the Subjects page.	Planned for a future release. This is a permission for site users, but can also be assigned to a sponsor user.
View Trial Management Event Records with Actions Assigned to me	Allows a user to view records of trial management events with actions assigned to them in the system.	Planned for a future release. This permission is for both sponsor and site users.

Table A-12 (Cont.) Trial Management

Permission	Description	Notes
View Unblinded Trial Management Records	Allows a user to view unblinded record of trial management.	Planned for a future release. This permission is available for sponsor users only. **Caution:** Can unblind users. Use with caution.

Table A-13 Unblinded Study Management

Permission	Description	Notes
Manage Randomization Lists	Allows a user to update randomization lists.	This permission is for sponsor users only. **Caution:** Can unblind users. Use with caution. Must be assigned along with the following permissions: • *View Study Design* • *Upload and Generate Randomization Lists*

Table A-13 (Cont.) Unblinded Study Management

Permission	Description	Notes
Manage Study Inventory for Unblinded Users	Allows a user to manage kits and shipments on the Study Inventory tab.	This permission is for sponsor users only. **Caution:** Can unblind users. Use with caution.
Reveal the Treatment Arm for a Subject or Code View	Allows a user to perform a code view for a subject.	This permission is for sponsor users only. **Caution:** Can unblind users. Use with caution.

Table A-13 (Cont.) Unblinded Study Management

Permission	Description	Notes
Update Inventory Lists	Allows a user to update and delete kit lists. A user should only delete a kit list if it was created in error, and it should be done before dispensing activities begin. **WARNING:** Deleting an entire kit list can negatively impact dispensation activities, downstream reporting, and data extr	This permission is for sponsor users only. **Caution:** Can unblind users. Use with caution. Must be assigned along with the following permissions: • *View Study Design* • *Upload and Generate Inventory Lists* (is needed to delete a list).

Table A-13 (Cont.) Unblinded Study Management

Permission	Description	Notes
		act s.

Design permissions

> **Note:**
>
> The following permissions are for sponsor users with a design type role only. These permissions are not available for sponsor and site user type study roles.

Table A-14 Reports

Permission	Description	Notes
Run the Data Collection Design Dataset	Allows a user to run the Study Design Delta report and operate the Data Collection Design dataset in Oracle Clinical One Analytics	This permission is for design type role only.
Run the Kits and Randomization Design Dataset	Allows a user to operate the Kits and Randomization Design dataset in Oracle Clinical One Analytics	This permission is for design type role only.

Table A-15 Study Design

Permission	Description	Notes
Add and Administer Study Users	Allows a user to add and manage users created in a study.	This permission is for design type role only.
Create Study Roles	Allows a user to create custom study roles.	This permission is for design type role only.
Delete Custom Code Lists	Allows a user to remove code lists.	This permission is for design type role only.
Design Forms	Allows a user to design all elements of a form, whether it is a one-section form, a two section form, a lab form, and many more.	This permission is for design type role only.

Table A-15 (Cont.) Study Design

Permission	Description	Notes
Design Clinical Supplies Forms	Allows a user to design drug reconciliation forms.	This permission is for design type role only. Must be assigned along with the *Design Supplies and Dispensation*permission.
Design Randomization	Allows a user to design all elements of a randomization.	This permission is for design type role only.

Caution: Can unblind users. Use with caution.

Table A-15 (Cont.) Study Design

Permission	Description	Notes
Design SDV Properties on Forms	Allows a user to specify SDV properties for each question in a form.	This permission is for design type role only.
Design Supplies and Dispensation	Allows a user to design kit types, treatment arms, and drug reconciliation forms.	This permission is for design type role only.

Caution: Can unblind users. Use with caution.

Table A-15 (Cont.) Study Design

Permission	Description	Notes
Design Visits and Events	Allows a user to design all available types of visits and events.	This permission is for design type role only.
Manage Study Code Lists	Allows a user to create and manage system and custom code lists for the study they are assigned to.	This permission is for design type role only.
Run the Draft Study Design Report	Allows a user to run the Study Design report in Draft.	This permission is for design type role only.
Run the Study Roles and User Assignment Report (Design Mode)	Allows a user to run the Study Roles and User Assignment reports in Draft.	This permission is for design type role only.
Upload Users in Bulk	Allows a user to download and import the User Upload Template and provides access the User Upload Error report.	This permission is for design type role only.
View Design	Allows a user to view a study's design in Draft.	This permission is for design type role only.