Oracle® Life Sciences Clinical One Platform

Add Users

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Primary Author: Oracle Life Sciences Documentation Team

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Preface

This preface contains the following sections:

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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Account basics

Difference between access to Oracle products and access to clinical studies

You control access to Oracle products through Oracle Life Sciences Identity and Access Management Service (IAMS). You control access to studies through Oracle Clinical One Platform.

To provide access to Oracle products, you create Oracle Life Sciences Single Sign-On (SSO) accounts in Oracle Life Sciences IAMS and assign the appropriate product roles. But, you must add and manage global and study users in Oracle Clinical One Platform to access clinical studies in both Oracle Clinical One Platform and Oracle Clinical One Digital Gateway.

Global users in Oracle Clinical One Platform are product administrators who perform administrative tasks for the entire organization, such as:

- Create studies.
- 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.
- Set up integrations in Oracle Clinical One Digital Gateway.

> **Note:**
>
> To access Oracle Clinical One Digital Gateway you must have the appropriate product role in Oracle Life Sciences IAMS, and be added as a global user in Oracle Clinical One Platform with the appropriate global roles. See Provide user access to Oracle Clinical One Digital Gateway.

For details on the roles required for these and other available tasks, see Roles for global users in Oracle Clinical One Platform and Oracle Clinical One Digital Gateway.

Study users are added directly to the given study in Oracle Clinical One Platform. The different tasks you can perform, and the clinical data you have access to see, as a study user, depend on the permissions included in the study role you get assigned within the study. Some global users have access to studies in the organization, but their access within is restricted to the rigths granted by their global role. Global users can also be added to a study with a specific study role, but you don't need to be a global user to be added as a study user.

Related Topics

- Create an Oracle Life Sciences Single Sign-On (SSO)
  As the Customer Delegated Administrator (CDA), you use Oracle Life Sciences Identity and Access Management Service (IAMS) to create Oracle Life Sciences single sign-on (SSO) accounts for users in your organization. Users need an SSO account to access Oracle Clinical One Platform and Oracle Clinical One Digital Gateway.
- Create accounts for different types of users with access to specific products
- Add a global user in Oracle Clinical One Platform
  Every organization must have at least one global user who can take responsibility of the global level tasks, such as creating studies and adding the first user for them. An organization typically has a limited number of global users.
- Add a user to a study in Oracle Clinical One Platform
  A product administrator with *Study Creator* role 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 study user administrator.
- Types of study roles in Oracle Clinical One Platform
  Study roles represent a collection of permissions that, when assigned, allow users to perform specific tasks. You must be mindful to create the correct type of study role (*Sponsor*, *Site* or *Design*) and include only the relevant permissions to the role, without compromising the study blind.
- Descriptions of permissions in Oracle Clinical One Platform
  There are three different types of study roles: *Sponsor*, *Site* and *Design*. According to the study role type, a different set of permissions is availbale to assign. Browse descriptions and additional information for every study role permission available in the application.

Roles in user management

There are different roles involved in user management when it comes to clinical studies in Oracle Clinical One Platform. These roles are differentiated according to their responsibilities and the level of access they have. However, for some studies, one person can assume multiple roles and perform different tasks associated to different roles.

Customer Delegated Administrator (CDA)

The CDA is created by an Oracle business operations representative in Oracle Life Sciences Identity and Access Management Service (IAMS). Typically there are two CDAs, which are the first Oracle Life Sciences users for an organization.

Overall, CDAs are responsible of creating other user accounts in Oracle Life Sciences IAMS and provision them with the appropriate product roles to be able to access Oracle Clinical One Platform and Oracle Clinical One Digital Gateway. See Create an Oracle Life Sciences Single Sign-On (SSO) and Assign roles in Oracle Life Sciences IAMS.

> **Note:**
>
> To be able to create user accounts, CDAs must complete a series of Account creation prerequisites. These only need to be completed once.

Additionally, the CDA must add the first global user in Oracle Clinical One Platform as the product administrator. Typically, this first user is added as a *Global User Manager* so that they can add and manage other product administrators as global users to perform different tasks. See Create product administrator accounts.

Product administrators

Product administrators are global users in Oracle Clinical One Platform that perform administrative tasks for the entire organization. The first product administrator is typically added by a CDA with the *Global User Manager* role. Global user managers then take over from CDAs on the task to create other global users and assign them with the appropriate global roles to perform different tasks. See Add a global user in Oracle Clinical One Platform and Roles for global users in Oracle Clinical One Platform and Oracle Clinical One Digital Gateway.

Additionally, product administrators with the *Create Study Roles for your Organization* role have the ability to create and manage custom study roles that can be used in all studies. See Create a study role at the global level.

> **Note:**
>
> Oracle Clinical One Platform provides you with predefined study role templates for the different types of users a study may need. Each has a combination of permissions needed to perform tasks typically associated with the given role. The use of template roles is not recommended, but these can be used as the base of custom study roles. These can be created at the global level (to be used in all studies in the entire organization) and at the study level.

In terms of user management, besides managing global users and study roles, product administrators are responsible to add the first user of a study to act as study user administrator. Global users with the *Global User Manager* or *Study Creator* roles can add users to a study. However, study creators are the only global users who can assign study users with roles for the study design mode at the study level. This means they are the only ones capable to add study user administrators, which are typically the first study users added to further manage users at the study level. See Create study user accounts.

Study user administrator

A study user administrator is a study level user that is assigned with the User Administrator role, which includes the necessary permissions to *Add and Administer Study Users* and *Create Study Roles*. This user is typically the first user added to the study, so it must be added by a product administrator. An user administrator is then responsible to add other users to the study and assign them with the appropriate study roles. See Add a user to a study in Oracle Clinical One Platform.

A study user administrator is also responsible of creating and managing study-level study roles. This includes specifying data classifications that control access to view or edit specific types of questions in the study. See Create a study role at the study level and Specify data classifications for a study role.

User administrators are also responsible of site and depot assignment, which dictate to which sites or depots the user has access to. However, user administrators can only assign other users to the sites and depots for which they have access to. This task is part of the process to create study users. Ultimately, it is up to you and your study's needs to decide on what roles to assign and to which sites or depots a given user must have access to; however, we recomment you to review Best practices for role, site, and depot assignment.

Tasks that Oracle completes for you

As a Customer Delegated Administrator (CDA), 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 to facilitate user management and to save time when enabling your team to begin their work in the application.

Create single sign-on (SSO) accounts for and assign roles to the CDAs
As a CDA, you then use the SSO account to sign in to Oracle Life Sciences IAMS and Oracle Clinical One Platform.
In Oracle Life Sciences IAMS you can create SSO accounts and assign product roles for additional users. In Oracle Clinical One Platform you can add global and study users.
The Approver role allows you approve product roles and determine who gets access to Oracle Clinical One Platform. If you add more CDA users in the future, you might want to assign the Approver role to them.

Publish your organization’s roles and activate approval for them
The activities to publish organization roles 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.
The role approval activation allows users to request your organization roles with approval requests. These requests then need to be approved by a CDA user with the *Approver* role.

Set up an authorization request page
With an authorization request page, your team members and Oracle employees can open it and directly request access to Oracle Clinical One Platform for your organization. Approvers must approve or reject these 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.

Types of single sign-on accounts

You use a single sign-on (SSO) account to securely authenticate with Oracle sites or applications. 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 two types of SSO accounts you can use to access different Oracle or Oracle Life Sciences sites and applications.

> **Note:**
>
> For every Oracle Life Sciences SSO account, password expires every three months. Users receive a password reset reminder when approaching expiriation date.

SSO Account Name	Creation process	Products
Oracle SSO	You create your own account through the New User prompts at the sign in page for any of the applicable products. Once your account is created, you can access those applications.	• My Oracle Support (MOS) • Support Cloud • Oracle Life Sciences Learn (home of assigned training courses)

SSO Account Name	Creation process	Products
Oracle Life Sciences SSO accounts to access Oracle Life Sciences Identity and Access Management Service(IAMS)	1. An Oracle business operations representative contacts your organization and creates the first Oracle Life Sciences users (usually two) of your organization, known as the CDA. 2. CDAs at your organization complete Account creation prerequisites. 3. CDAs create other users accounts in Oracle Life Sciences IAMS and assigns them with specific product roles, necessary to access given products. See Create user accounts. 4. Once your account is created, you receive one or two notification messages, depending on your role and your organization's setup for user management. 5. You use the information in your notification messages to activate your account through Oracle Life Sciences IAMS. See Notifications for Oracle Life Sciences SSO account activation. ***Note***: • *Your account needs to include an approved role to access certain applications. Depending on how your organization set up accounts, you can request roles for your account or a CDA can assign them. In either case, an administrator (known as the Approver) must approve your role.* • *Some products require additional steps to get access. This is the case of Oracle Clinical One Platform and Oracle Clinical One Digital Gateway* *For roles and additional steps see* Roles in Oracle Life Sciences IAMS for all applications*.*	• 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
Oracle Life Sciences SSO accounts to access Oracle Clinical One Platform	1. A CDA provisions a specific user with the product administrator role and adds them as a global user manager in Oracle Clinical One Platform. See Create product administrator accounts. 2. The CDA creates the Oracle Life Sciences SSO account in Oracle Life Sciences IAMS for other users in the organization (as explained above). 3. Product administrators can then create other users in Oracle Clinical One Platform. Two types of users can be added, see: • Add a global user in Oracle Clinical One Platform • Add a user to a study in Oracle Clinical One Platform ***Note:*** *Users added to a study with user administrator permissions can also add other users to that study.*	• Oracle Clinical One Platform

Related Topics

- Roles in user management
  There are different roles involved in user management when it comes to clinical studies in Oracle Clinical One Platform. These roles are differentiated according to their responsibilities and the level of access they have. However, for some studies, one person can assume multiple roles and perform different tasks associated to different roles.
- Difference between access to Oracle products and access to clinical studies
  You control access to Oracle products through Oracle Life Sciences Identity and Access Management Service (IAMS). You control access to studies through Oracle Clinical One Platform.
- Notifications for Oracle Life Sciences SSO account activation
  Once your organization's Customer Delegated Administrator (CDA) creates your Oracle Life Sciences single sign-on (SSO) in Oracle Life Sciences IAMS, you receive one or two email messages with account activation instructions.
- Create an Oracle Life Sciences Single Sign-On (SSO)
  As the Customer Delegated Administrator (CDA), you use Oracle Life Sciences Identity and Access Management Service (IAMS) to create Oracle Life Sciences single sign-on (SSO) accounts for users in your organization. Users need an SSO account to access Oracle Clinical One Platform and Oracle Clinical One Digital Gateway.
- Assign roles in Oracle Life Sciences IAMS
  Having an Oracle Life Sciences Single Sign-On (SSO) account is not enough to start working on specific products. Customer Delegated Administrators (CDA) assign product roles to grant access to Oracle Clinical One Platform and Oracle Clinical One Digital Gateway as a whole. A product administrator or study user administrator then assigns study-specific roles to users from within Oracle Clinical One Platform.
- 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 access to different products and different sets of permissions.
- Create accounts for different types of users with access to specific products

About Oracle Life Sciences Identity and Access Management Service (IAMS)

Customer Delegated Administrators (CDA) use Oracle Life Sciences IAMS to create Oracle Life Sciences SSO accounts for other users in the organization. Once a CDA creates your Oracle Life Sciences SSO account, you can use Oracle Life Sciences IAMS to activate and manage your account, and to access secure Oracle Life Sciences applications.

Before CDAs can create user accounts, they must complete certain prerequisites. For more information, see Account creation prerequisites.

Your organization already has a CDA if you use any of the following products:

- Oracle InForm
- Oracle Central Coding
- Oracle Empirica Study
- Oracle Empirica Topics
- Oracle mHealth Connector
- Oracle Health Sciences Learn Manager

Your changes in Oracle Life Sciences IAMS could impact the CDA and other users' accounts to access other products. You must coordinate account management actions with other CDAs, for example:

- 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, a CDA must create your account. Then you receive one or two notification messages, depending on your organization setup, providing instructions and details that you must use to activate your account. See Notifications for Oracle Life Sciences SSO account activation.

You can then use your Oracle Life Sciences single sign-on (SSO) to access Oracle Life Sciences applications. But, to access studies, an administrator (known as the Approver) must approve your role. Roles provide specific permissions to perform different tasks. Depending on your organization setup for account management, you can request roles or a CDA 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 Health Sciences Cloud home page

Related Topics

- Bookmark and sign in directly to Oracle Life Sciences IAMS
  After you activate your Oracle Life Sciences SSO account, you can sign in to Oracle Life Sciences IAMS directly if you need to manage your SSO or create new Oracle Life Sciences SSO accounts. You must access the URL specific to your organization, which we recommend you to bookmark for quick access.
- Sign in through Oracle Health 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 the Oracle Health Sciences Cloud home page
  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.
- Notifications for Oracle Life Sciences SSO account activation
  Once your organization's Customer Delegated Administrator (CDA) creates your Oracle Life Sciences single sign-on (SSO) in Oracle Life Sciences IAMS, you receive one or two email messages with account activation instructions.
- Activate your account when you receive one notification message
  Users who reset their passwords with an email link receive only one notification message with the subject *New Account*. To activate your Oracle Life Sciences SSO account, create a new password and sign in to Oracle Life Sciences IAMS using the user name and links included in the email.
- Activate your account when you receive two notification messages
  Customer Delegated Administrators (CDAs) and users who reset their passwords through security questions receive two notification messages. The *New Account* message contains your user name and your organization's specific link to access Oracle Life Sciences IAMS.

The *Account Password* message contains a temporary password, which you should use to log in for the first time and activate your account.

- Assign roles in Oracle Life Sciences IAMS
  Having an Oracle Life Sciences Single Sign-On (SSO) account is not enough to start working on specific products. Customer Delegated Administrators (CDA) assign product roles to grant access to Oracle Clinical One Platform and Oracle Clinical One Digital Gateway as a whole. A product administrator or study user administrator then assigns study-specific roles to users from within Oracle Clinical One Platform.
- Request product roles
  You need specific product roles to access Oracle Clinical One Platform and Oracle Clinical One Digital Gateway. Depending on your organization setup for account management, if your organization set up self-service registration (including an authorization request page), you can navigate to the product web site and request these product roles yourself.
- Manage access requests
  If your organization uses the approval process to grant users access to applications, everytime a product role is assigned to a user generates an access requests. The Customer Delegated Administrator (CDA) with the Approver role must approve or reject these requests.

Notifications for Oracle Life Sciences SSO account activation

Once your organization's Customer Delegated Administrator (CDA) creates your Oracle Life Sciences single sign-on (SSO) in Oracle Life Sciences IAMS, you receive one or two email messages with account activation instructions.

The amount of notifications you receive depends on your role and the method your organization chooses to reset expired or forgotten passwords. These methods can be **Email Link** or **Security Questions**.

These notifications provide instructions to activate your account, and this process is slightly different depending on the used method for password configuration. Hence different depending on the amount of received notifications.

- Activate your account when you receive one notification message
  Users who reset their passwords with an email link receive only one notification message with the subject *New Account*. To activate your Oracle Life Sciences SSO account, create a new password and sign in to Oracle Life Sciences IAMS using the user name and links included in the email.
- Activate your account when you receive two notification messages
  Customer Delegated Administrators (CDAs) and users who reset their passwords through security questions receive two notification messages. The *New Account* message contains your user name and your organization's specific link to access Oracle Life Sciences IAMS. The *Account Password* message contains a temporary password, which you should use to log in for the first time and activate your account.

Activate your account when you receive one notification message

Users who reset their passwords with an email link receive only one notification message with the subject *New Account*. To activate your Oracle Life Sciences SSO account, create a new password and sign in to Oracle Life Sciences IAMS using the user name and links included in the email.

If you also received an *Account Password* message, see Activate your account when you receive two notification messages instead.

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

1. Locate your *Oracle Health Sciences Cloud – New Account* email message, sent by Oracle Identity Manager <OracleIdentityManager@oracleindustry.com>.
2. Open the message and click the link to setup your password.
3. Follow the prompts to enter and confirm your password and click **Continue**.
4. Navigate to the **Oracle Health Sciences Cloud account** link included in your *New Account* email.
5. Sign in with your Oracle Life Sciences SSO user name and the password you created.

Depending on your organization setup, you may land on Oracle Health Sciences My Oracle Bookmarks or the Oracle Health Sciences Cloud landing page. From either of them, you can access direct links to the specific Oracle Life Sciences applications and studies you use. To access Oracle Life Sciences IAMS specifically see:

- Sign in through Oracle Health Sciences My Oracle Bookmarks
- Sign in through the Oracle Health Sciences Cloud home page

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

Related Topics

- About Oracle Life Sciences Identity and Access Management Service (IAMS)
  Customer Delegated Administrators (CDA) use Oracle Life Sciences IAMS to create Oracle Life Sciences SSO accounts for other users in the organization. Once a CDA creates your Oracle Life Sciences SSO account, you can use Oracle Life Sciences IAMS to activate and manage your account, and to access secure Oracle Life Sciences applications.

Activate your account when you receive two notification messages

Customer Delegated Administrators (CDAs) and users who reset their passwords through security questions receive two notification messages. The *New Account* message contains your user name and your organization's specific link to access Oracle Life Sciences IAMS. The *Account Password* message contains a temporary password, which you should use to log in for the first time and activate your account.

After you login using the temporary password, you must follow the prompts to reset your password and complete your account activation.

If you only received one notification message, see Activate your account when you receive one notification message instead.

> **Note:**
>
> If you cannot locate these messages in your inbox, contact the Oracle Life Sciences IAMS CDA for your organization to get your user name, the temporary password and the URL to access Oracle Life Sciences IAMS.

1. Locate your *Oracle Health Sciences Cloud – New Account* and *Account Password* email messages, sent by Oracle Identity Manager <OracleIdentityManager@oracleindustry.com>.
2. Navigate to the **Oracle Health Sciences Cloud account** link included in your *New Account* email.
3. Sign in using the details from your two notification messages:
   - **User Name:** Use the Oracle Life Sciences SSO user name from the *New Account* email.
   - **Password:** Use the temporary password included in the *Account Password* email.
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 your organization setup, you may land on Oracle Health Sciences My Oracle Bookmarks or the Oracle Health Sciences Cloud landing page. From either of them, you can access direct links to the specific Oracle Life Sciences applications and studies you use. To access Oracle Life Sciences IAMS specifically see:

- Sign in through Oracle Health Sciences My Oracle Bookmarks
- Sign in through the Oracle Health Sciences Cloud home page

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

Related Topics

- About Oracle Life Sciences Identity and Access Management Service (IAMS)
  Customer Delegated Administrators (CDA) use Oracle Life Sciences IAMS to create Oracle Life Sciences SSO accounts for other users in the organization. Once a CDA creates your Oracle Life Sciences SSO account, you can use Oracle Life Sciences IAMS to activate and manage your account, and to access secure Oracle Life Sciences applications.

Sign in to Oracle Life Sciences IAMS

All users must open Oracle Life Sciences IAMS periodically to manage their Oracle Life Sciences SSO accounts, specially Customer Delegated Administrators (CDAs) who manage accounts for the entire organization.

You can save time if you create a bookmark of the URL specific to your organization to access Oracle Life Sciences IAMS directly.

> **Note:**
>
> The web address gets transformed in your browser after you sign in. You must bookmark the original web address. Do not bookmark the web address that displays after sign in.

You can also open Oracle Life Sciences IAMS from Oracle Health Sciences My Oracle Bookmarks or Oracle Health Sciences Cloud home page.

- Bookmark and sign in directly to Oracle Life Sciences IAMS
  After you activate your Oracle Life Sciences SSO account, you can sign in to Oracle Life Sciences IAMS directly if you need to manage your SSO or create new Oracle Life Sciences SSO accounts. You must access the URL specific to your organization, which we recommend you to bookmark for quick access.
- Sign in through Oracle Health 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 the Oracle Health Sciences Cloud home page
  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 and sign in directly to Oracle Life Sciences IAMS

After you activate your Oracle Life Sciences SSO account, you can sign in to Oracle Life Sciences IAMS directly if you need to manage your SSO or create new Oracle Life Sciences SSO accounts. You must access the URL specific to your organization, which we recommend you to bookmark for quick access.

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. See Notifications for Oracle Life Sciences SSO account activation.

If you cannot locate your New Account email message, contact your Oracle point of contact and ask for the Oracle Life Sciences IAMS web address for your organization.

> **Note:**
>
> The web address gets transformed in your browser after you sign in. You must bookmark the original web address. Do not bookmark the web address that displays after sign in.

1. **Create bookmark for Oracle Life Sciences IAMS (one-time task)**
   a. Open the *New Account* notification message you received from Oracle Identity Manager and copy the Oracle Life Sciences IAMS web address (URL).
   b. In your browser, create a bookmark for any web page and name it properly for Oracle Life Sciences IAMS.

c. Edit the bookmark and paste the web address for Oracle Life Sciences IAMS into the URL field. Make any other necessary edits, and click **Save**.

2. **To sign in to Oracle Life Sciences IAMS,** open the bookmark for Oracle Life Sciences IAMS in your browser or directly paste the web URL.
3. Enter your user name and password and click **Sign In**.

To manage your account and the accounts of other users in your organization, see:

- Create user accounts
- Manage Oracle Life Sciences Single Sign-On (SSO) accounts

Related Topics

- Sign in through Oracle Health 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 the Oracle Health Sciences Cloud home page
  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.
- Notifications for Oracle Life Sciences SSO account activation
  Once your organization's Customer Delegated Administrator (CDA) creates your Oracle Life Sciences single sign-on (SSO) in Oracle Life Sciences IAMS, you receive one or two email messages with account activation instructions.
- Activate your account when you receive one notification message
  Users who reset their passwords with an email link receive only one notification message with the subject *New Account*. To activate your Oracle Life Sciences SSO account, create a new password and sign in to Oracle Life Sciences IAMS using the user name and links included in the email.
- Activate your account when you receive two notification messages
  Customer Delegated Administrators (CDAs) and users who reset their passwords through security questions receive two notification messages. The *New Account* message contains your user name and your organization's specific link to access Oracle Life Sciences IAMS. The *Account Password* message contains a temporary password, which you should use to log in for the first time and activate your account.

Sign in through Oracle Health 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 Notifications for Oracle Life Sciences SSO account activation. To learn more about Oracle Health Sciences My Oracle Bookmarks, see the Oracle Help Center.

1. Open the My Oracle Bookmarks home page in your browser. You can either use a bookmark or manually enter the URL.

   > **Tip:**
   >
   > The URL specific to your organization is included in the *New Account* email.

2. Enter your SSO (user name and password) and click **Sign In**.
3. Open Oracle Life Sciences IAMS:
   - If the product includes a tile for Oracle Life Sciences IAMS, click it to open.
   - If the product does not include a tile for Oracle Life Sciences IAMS, click your user name in the top-right corner and select **Account Management**.

To manage your account and the accounts of other users in your organization, see:

- Create user accounts
- Manage Oracle Life Sciences Single Sign-On (SSO) accounts

Related Topics

- Bookmark and sign in directly to Oracle Life Sciences IAMS
  After you activate your Oracle Life Sciences SSO account, you can sign in to Oracle Life Sciences IAMS directly if you need to manage your SSO or create new Oracle Life Sciences SSO accounts. You must access the URL specific to your organization, which we recommend you to bookmark for quick access.
- Sign in through the Oracle Health Sciences Cloud home page
  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.
- Notifications for Oracle Life Sciences SSO account activation
  Once your organization's Customer Delegated Administrator (CDA) creates your Oracle Life Sciences single sign-on (SSO) in Oracle Life Sciences IAMS, you receive one or two email messages with account activation instructions.
- Activate your account when you receive one notification message
  Users who reset their passwords with an email link receive only one notification message with the subject *New Account*. To activate your Oracle Life Sciences SSO account, create a new password and sign in to Oracle Life Sciences IAMS using the user name and links included in the email.
- Activate your account when you receive two notification messages
  Customer Delegated Administrators (CDAs) and users who reset their passwords through security questions receive two notification messages. The *New Account* message contains your user name and your organization's specific link to access Oracle Life Sciences IAMS. The *Account Password* message contains a temporary password, which you should use to log in for the first time and activate your account.

Sign in through the Oracle Health Sciences Cloud home page

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 Notifications for Oracle Life Sciences SSO account activation.

1. Open the Oracle Health Sciences cloud home page in your browser. You can either use a bookmark or manually enter the URL.

   > **Tip:**
   >
   > The URL specific to your organization is included in the *New Account* email.

2. Enter your SSO (user name and password) and click **Sign In**.
3. Under Quick Links, click **Update Profile** to open Oracle Life Sciences IAMS.

To manage your account and the accounts of other users in your organization, see:

- Create user accounts
- Manage Oracle Life Sciences Single Sign-On (SSO) accounts

Related Topics

- Bookmark and sign in directly to Oracle Life Sciences IAMS
  After you activate your Oracle Life Sciences SSO account, you can sign in to Oracle Life Sciences IAMS directly if you need to manage your SSO or create new Oracle Life Sciences SSO accounts. You must access the URL specific to your organization, which we recommend you to bookmark for quick access.
- Sign in through Oracle Health 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.
- Notifications for Oracle Life Sciences SSO account activation
  Once your organization's Customer Delegated Administrator (CDA) creates your Oracle Life Sciences single sign-on (SSO) in Oracle Life Sciences IAMS, you receive one or two email messages with account activation instructions.
- Activate your account when you receive one notification message
  Users who reset their passwords with an email link receive only one notification message with the subject *New Account*. To activate your Oracle Life Sciences SSO account, create a new password and sign in to Oracle Life Sciences IAMS using the user name and links included in the email.
- Activate your account when you receive two notification messages
  Customer Delegated Administrators (CDAs) and users who reset their passwords through security questions receive two notification messages. The *New Account* message contains

your user name and your organization's specific link to access Oracle Life Sciences IAMS. The *Account Password* message contains a temporary password, which you should use to log in for the first time and activate your account.

2

Account creation prerequisites

- Prerequisites to create accounts
  A Customer Delegated Administrator (CDA) of an 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.
- About the 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 creation of 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 Customer Delegated Administrator (CDA) is responsible for requesting the Approver role.
- Create user account for the Approver
  The Customer Delegated Administrator (CDA) must create an Oracle Life Sciences single sign-on (SSO) for each user with the Approver role, typically two users. The Approver users are responsible to review and approve all requests to access Oracle Clinical One Platform for an organization.
- Activate approval for roles
  When you activate approval for roles, every time a role gets assigned to a user (either in Oracle Life Sciences IAMS or by a self-service registration) an access request is generated. The Customer Delegated Administrator (CDA) with the Approver role must review all access requests and either approve or reject them.
- Publish the roles
  A Customer Delegated Administrator (CDA) publishes roles so that Oracle users can see the roles and assign them to the Oracle Life Sciences Single Sign-Ons (SSOs) and to Life Sciences Support users. If you activated approval, Approvers see an access request for each assignment and can either 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

A Customer Delegated Administrator (CDA) of an 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.

Some of these tasks are completed by Oracle as part of your organization's set up. However, you can follow the step-by-step instructions in this section in case you need to perform any of these steps yourself. See Tasks that Oracle completes for you.

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

Related Topics

- Roles in user management
  There are different roles involved in user management when it comes to clinical studies in Oracle Clinical One Platform. These roles are differentiated according to their responsibilities and the level of access they have. However, for some studies, one person can assume multiple roles and perform different tasks associated to different roles.
- Create an Oracle Life Sciences Single Sign-On (SSO)
  As the Customer Delegated Administrator (CDA), you use Oracle Life Sciences Identity and Access Management Service (IAMS) to create Oracle Life Sciences single sign-on (SSO) accounts for users in your organization. Users need an SSO account to access Oracle Clinical One Platform and Oracle Clinical One Digital Gateway.
- Assign roles in Oracle Life Sciences IAMS
  Having an Oracle Life Sciences Single Sign-On (SSO) account is not enough to start working on specific products. Customer Delegated Administrators (CDA) assign product roles to grant access to Oracle Clinical One Platform and Oracle Clinical One Digital Gateway as a whole. A product administrator or study user administrator then assigns study-specific roles to users from within Oracle Clinical One Platform.
- About the 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.
- Manage access requests
  If your organization uses the approval process to grant users access to applications, everytime a product role is assigned to a user generates an access requests. The Customer Delegated Administrator (CDA) with the Approver role must approve or reject these requests.

About the 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.

Use cases that require approval process

You must activate approval for roles so that an Approver can review all access requests and either approve or decline them. For more information, see Activate approval for roles.

> **Caution:**
>
> If you decide to use self-service registration and don't set up approvals, 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.

It is highly recommended to activate the approval process in the following use cases:

- Organizations that use Oracle Clinical One Platform to create clinical studies
- Organizations that use Oracle Clinical One Digital Gateway to manage integrations

Uses cases in which approval process is optional

Whe approval proces is disabled, this simplifies the process of creating users because you do not need another administrator (Approver) to approve access requests when assigning the roles.
Organizations that use Oracle Health Learn Manager only to create training studies for other products don't need to activate the approval process. These other products include:

- Oracle InForm
- Oracle Central Designer
- Oracle Central Coding
- Oracle IRT
- Oracle InForm User Management Tool

Related Topics

- Request the creation of 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 Customer Delegated Administrator (CDA) is responsible for requesting the Approver role.
- Create user account for the Approver
  The Customer Delegated Administrator (CDA) must create an Oracle Life Sciences single sign-on (SSO) for each user with the Approver role, typically two users. The Approver users are responsible to review and approve all requests to access Oracle Clinical One Platform for an organization.
- Activate approval for roles
  When you activate approval for roles, every time a role gets assigned to a user (either in Oracle Life Sciences IAMS or by a self-service registration) an access request is

generated. The Customer Delegated Administrator (CDA) with the Approver role must review all access requests and either approve or reject them.

- Publish the roles
  A Customer Delegated Administrator (CDA) publishes roles so that Oracle users can see the roles and assign them to the Oracle Life Sciences Single Sign-Ons (SSOs) and to Life Sciences Support users. If you activated approval, Approvers see an access request for each assignment and can either approve or reject them.
- Create user accounts
- Manage access requests
  If your organization uses the approval process to grant users access to applications, everytime a product role is assigned to a user generates an access requests. The Customer Delegated Administrator (CDA) with the Approver role must approve or reject these requests.
- Request product roles
  You need specific product roles to access Oracle Clinical One Platform and Oracle Clinical One Digital Gateway. Depending on your organization setup for account management, if your organization set up self-service registration (including an authorization request page), you can navigate to the product web site and request these product roles yourself.
- Roles in user management
  There are different roles involved in user management when it comes to clinical studies in Oracle Clinical One Platform. These roles are differentiated according to their responsibilities and the level of access they have. However, for some studies, one person can assume multiple roles and perform different tasks associated to different roles.

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, reach out to your Oracle point of contact.

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 Customer Delegated Administrator (CDA)), 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 CDA, 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

- Types of single sign-on accounts
  You use a single sign-on (SSO) account to securely authenticate with Oracle sites or applications. If your role requires you to access multiple sites and applications, you may use two different types of SSO accounts.

Request the creation of 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 Customer Delegated Administrator (CDA) is responsible for requesting the Approver role.

> **Note:**
>
> - This task is completed by Oracle as part of your organization's initial set up. However, you can follow the step-by-step instructions in this document in case you need to do it yourself. See Tasks that Oracle completes for you.
> - 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.

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.

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

After Life Sciences Support resolves your request and contacts you, continue on to Create user account for the Approver to create the Approver account. You can then activate the approval as described in Activate approval for roles.

Related Topics

- Roles in user management
  There are different roles involved in user management when it comes to clinical studies in Oracle Clinical One Platform. These roles are differentiated according to their responsibilities and the level of access they have. However, for some studies, one person can assume multiple roles and perform different tasks associated to different roles.

- Tasks that Oracle completes for you
  As a Customer Delegated Administrator (CDA), 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 to facilitate user management and to save time when enabling your team to begin their work in the application.
- Assign roles in Oracle Life Sciences IAMS
  Having an Oracle Life Sciences Single Sign-On (SSO) account is not enough to start working on specific products. Customer Delegated Administrators (CDA) assign product roles to grant access to Oracle Clinical One Platform and Oracle Clinical One Digital Gateway as a whole. A product administrator or study user administrator then assigns study-specific roles to users from within Oracle Clinical One Platform.
- Prerequisites to create accounts
  A Customer Delegated Administrator (CDA) of an 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.
- About the 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.
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  The Customer Delegated Administrator (CDA) must create an Oracle Life Sciences single sign-on (SSO) for each user with the Approver role, typically two users. The Approver users are responsible to review and approve all requests to access Oracle Clinical One Platform for an organization.
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- 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.
- Manage access requests
  If your organization uses the approval process to grant users access to applications, everytime a product role is assigned to a user generates an access requests. The Customer Delegated Administrator (CDA) with the Approver role must approve or reject these requests.

Create user account for the Approver

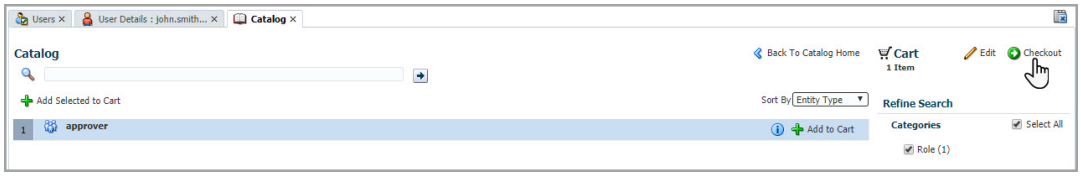
The Customer Delegated Administrator (CDA) must create an Oracle Life Sciences single sign-on (SSO) for each user with the Approver role, typically two users. The Approver users

are responsible to review and approve all requests to access Oracle Clinical One Platform for an organization.

> **Note:**
>
> This task is sometimes completed by Oracle as part of your organization's initial set up. However, you can follow the step-by-step instructions in this document in case you need to do it yourself. For example, if a new Approver user is added to your organization. See Tasks that Oracle completes for you.

Before you create the account for the Approver user, make sure the Approver role is created. See Request the creation of the Approver role.

1. Create the account for the approver user as described in Create an Oracle Life Sciences Single Sign-On (SSO).
2. Assign the **approver** role as described in Assign roles in Oracle Life Sciences IAMS.



Next step: Activate approval for roles.

Related Topics

- Roles in user management
  There are different roles involved in user management when it comes to clinical studies in Oracle Clinical One Platform. These roles are differentiated according to their responsibilities and the level of access they have. However, for some studies, one person can assume multiple roles and perform different tasks associated to different roles.
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  Having an Oracle Life Sciences Single Sign-On (SSO) account is not enough to start working on specific products. Customer Delegated Administrators (CDA) assign product roles to grant access to Oracle Clinical One Platform and Oracle Clinical One Digital Gateway as a whole. A product administrator or study user administrator then assigns study-specific roles to users from within Oracle Clinical One Platform.
- Prerequisites to create accounts
  A Customer Delegated Administrator (CDA) of an 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.
- Request the creation of 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 Customer Delegated Administrator (CDA) is responsible for requesting the Approver role.

- Activate approval for roles
  When you activate approval for roles, every time a role gets assigned to a user (either in Oracle Life Sciences IAMS or by a self-service registration) an access request is generated. The Customer Delegated Administrator (CDA) with the Approver role must review all access requests and either approve or reject them.
- Publish the roles
  A Customer Delegated Administrator (CDA) publishes roles so that Oracle users can see the roles and assign them to the Oracle Life Sciences Single Sign-Ons (SSOs) and to Life Sciences Support users. If you activated approval, Approvers see an access request for each assignment and can either 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.
- About the 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.
- Manage access requests
  If your organization uses the approval process to grant users access to applications, everytime a product role is assigned to a user generates an access requests. The Customer Delegated Administrator (CDA) with the Approver role must approve or reject these requests.

Activate approval for roles

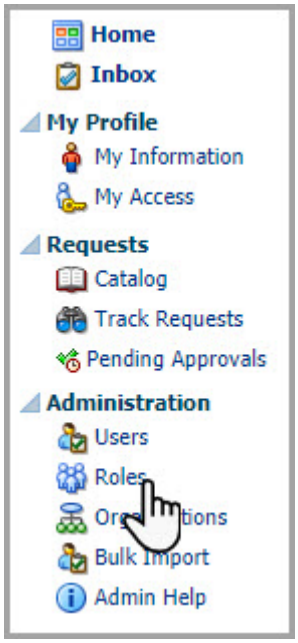
When you activate approval for roles, every time a role gets assigned to a user (either in Oracle Life Sciences IAMS or by a self-service registration) an access request is generated. The Customer Delegated Administrator (CDA) with the Approver role must review all access requests and either approve or reject them.

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

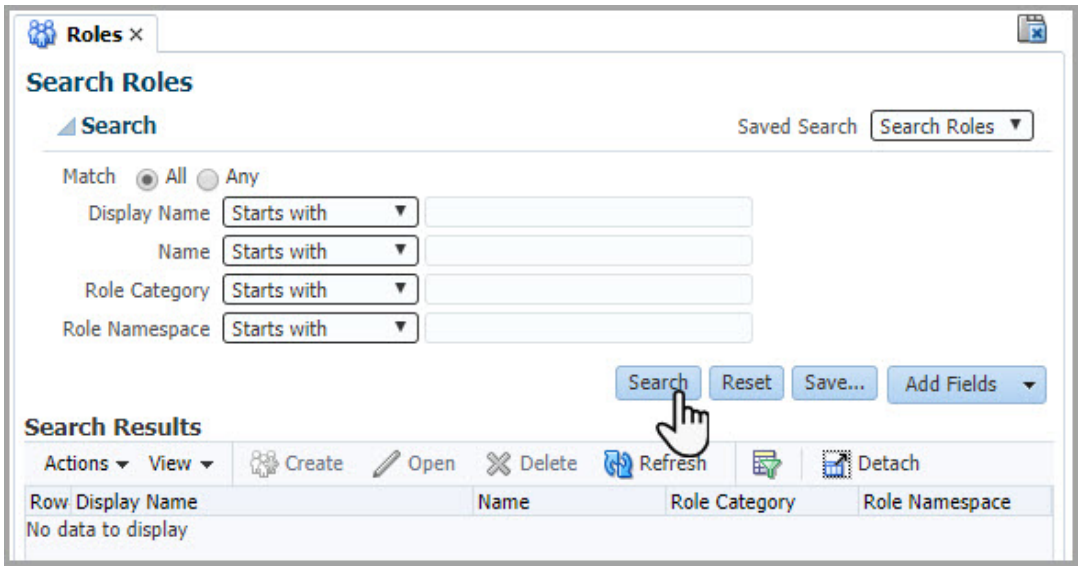
> **Note:**
>
> This task is completed by Oracle as part of your organization's initial set up. However, you can follow the step-by-step instructions in this document in case you need to do it yourself. For example, if new roles get added for your organization. See Tasks that Oracle completes for you.

Before you can activate approvals, you must Request the creation of the Approver role and Create user account for the Approver.

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



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



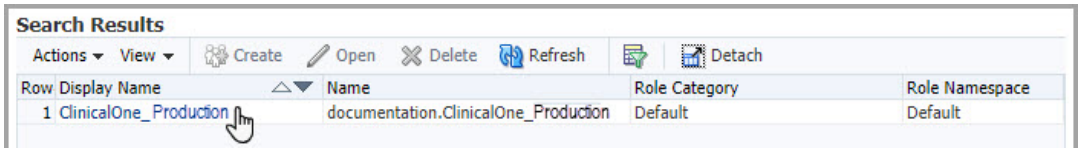
All of your organization's roles appear in the Search Results table.

4. In the list of roles, find the given user role.

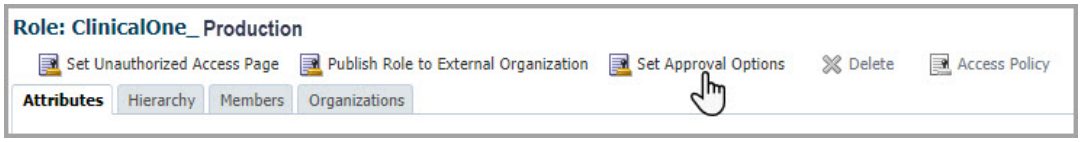
   Make sure you repeat these stepas to activate approval for all the necessary roles in all the applicable environments. These are:

   - **clinicalone-CNE** needed to access Oracle Clinical One Platform
   - **clinicalone-CNE_AssignGlobalRoles** needed for product administrators that need to assign global roles in Oracle Clinical One Platform.
   - **inthub-CNE** needed to access Oracle Clinical One Digital Gateway if your organization requires to manage integrations.

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.`

Next step: Publish the roles.

Related Topics

- Roles in user management
  There are different roles involved in user management when it comes to clinical studies in Oracle Clinical One Platform. These roles are differentiated according to their responsibilities and the level of access they have. However, for some studies, one person can assume multiple roles and perform different tasks associated to different roles.
- Assign roles in Oracle Life Sciences IAMS
  Having an Oracle Life Sciences Single Sign-On (SSO) account is not enough to start working on specific products. Customer Delegated Administrators (CDA) assign product roles to grant access to Oracle Clinical One Platform and Oracle Clinical One Digital Gateway as a whole. A product administrator or study user administrator then assigns study-specific roles to users from within Oracle Clinical One Platform.
- 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 access to different products and different sets of permissions.
- Request product roles
  You need specific product roles to access Oracle Clinical One Platform and Oracle Clinical One Digital Gateway. Depending on your organization setup for account management, if your organization set up self-service registration (including an authorization request page), you can navigate to the product web site and request these product roles yourself.
- Prerequisites to create accounts
  A Customer Delegated Administrator (CDA) of an 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.
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  The Customer Delegated Administrator (CDA) must create an Oracle Life Sciences single sign-on (SSO) for each user with the Approver role, typically two users. The Approver users are responsible to review and approve all requests to access Oracle Clinical One Platform for an organization.
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  A Customer Delegated Administrator (CDA) publishes roles so that Oracle users can see the roles and assign them to the Oracle Life Sciences Single Sign-Ons (SSOs) and to Life Sciences Support users. If you activated approval, Approvers see an access request for each assignment and can either approve or reject them.
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  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.
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  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.
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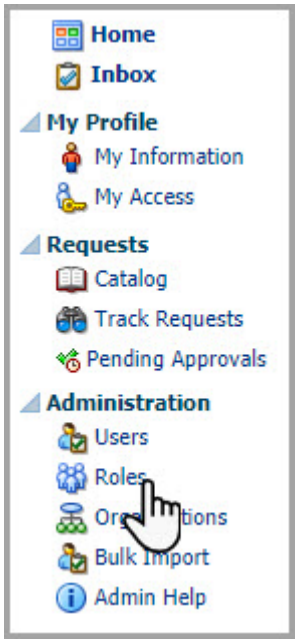
> **Note:**
>
> This task is completed by Oracle as part of your organization's initial set up. However, you can follow the step-by-step instructions in this document in case you need to do it yourself. For example, if new roles get added for your organization. See Tasks that Oracle completes for you.

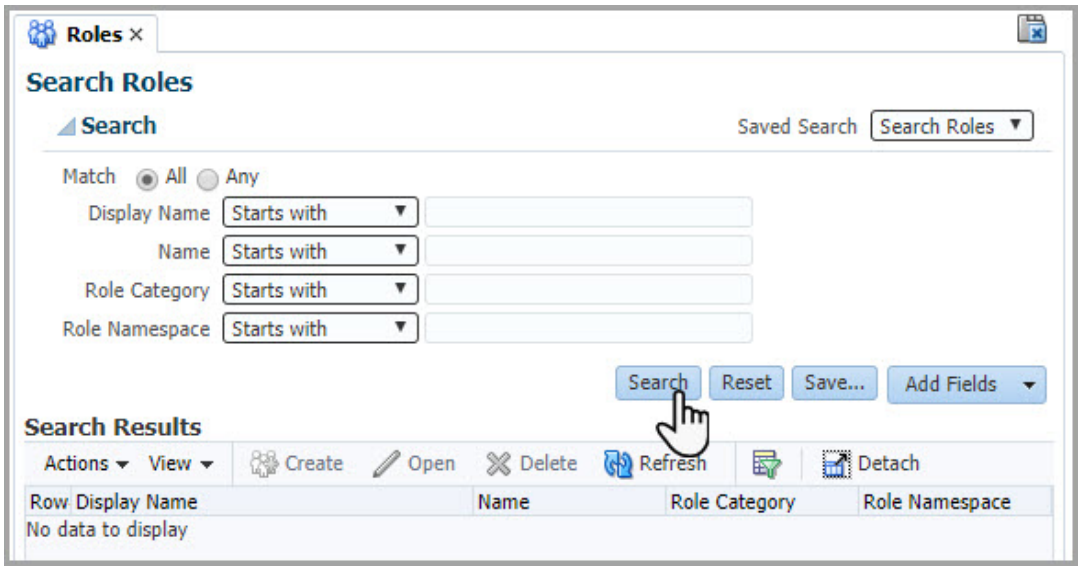
Before you publish roles, make sure you activate approval as described in Activate approval for roles .

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

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



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



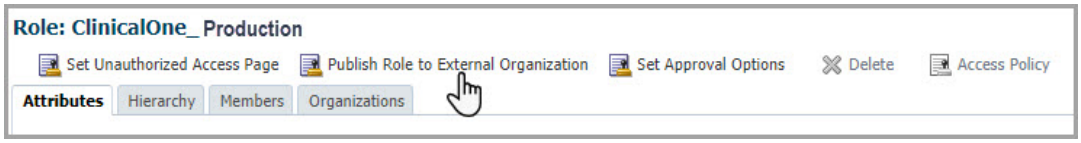
All of your organization's roles appear in the Search Results table.

4. In the list of roles, find the given user role to publish.

   Make sure you repeat these stepas to publish all the necessary roles in all the applicable environments. These are:

   - **clinicalone-CNE** needed to access Oracle Clinical One Platform
   - **clinicalone-CNE_AssignGlobalRoles** needed for product administrators that need to assign global roles in Oracle Clinical One Platform.
   - **inthub-CNE** needed to access Oracle Clinical One Digital Gateway if your organization requires to manage integrations.

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.`

After you finish publishing all roles, notify your Oracle point of contact. An Oracle administrator assigns the roles to the users' Oracle Life Sciences SSOs as needed. A CDA with an approver role must approve all requests.
If you want to activate self-service registration, see Set up an authorization request page.

Related Topics

- Roles in user management
  There are different roles involved in user management when it comes to clinical studies in Oracle Clinical One Platform. These roles are differentiated according to their responsibilities and the level of access they have. However, for some studies, one person can assume multiple roles and perform different tasks associated to different roles.
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  As a Customer Delegated Administrator (CDA), 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 to facilitate user management and to save time when enabling your team to begin their work in the application.
- Assign roles in Oracle Life Sciences IAMS
  Having an Oracle Life Sciences Single Sign-On (SSO) account is not enough to start working on specific products. Customer Delegated Administrators (CDA) assign product roles to grant access to Oracle Clinical One Platform and Oracle Clinical One Digital Gateway as a whole. A product administrator or study user administrator then assigns study-specific roles to users from within Oracle Clinical One Platform.
- 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 access to different products and different sets of permissions.
- Request product roles
  You need specific product roles to access Oracle Clinical One Platform and Oracle Clinical One Digital Gateway. Depending on your organization setup for account management, if your organization set up self-service registration (including an authorization request page), you can navigate to the product web site and request these product roles yourself.

- Prerequisites to create accounts
  A Customer Delegated Administrator (CDA) of an 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.
- About the 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.
- Request the creation of 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 Customer Delegated Administrator (CDA) is responsible for requesting the Approver role.
- Create user account for the Approver
  The Customer Delegated Administrator (CDA) must create an Oracle Life Sciences single sign-on (SSO) for each user with the Approver role, typically two users. The Approver users are responsible to review and approve all requests to access Oracle Clinical One Platform for an organization.
- Activate approval for roles
  When you activate approval for roles, every time a role gets assigned to a user (either in Oracle Life Sciences IAMS or by a self-service registration) an access request is generated. The Customer Delegated Administrator (CDA) with the Approver role must review all access requests and either 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.

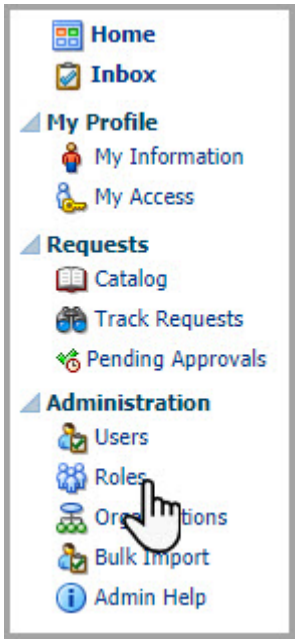
Set up an authorization request page

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.

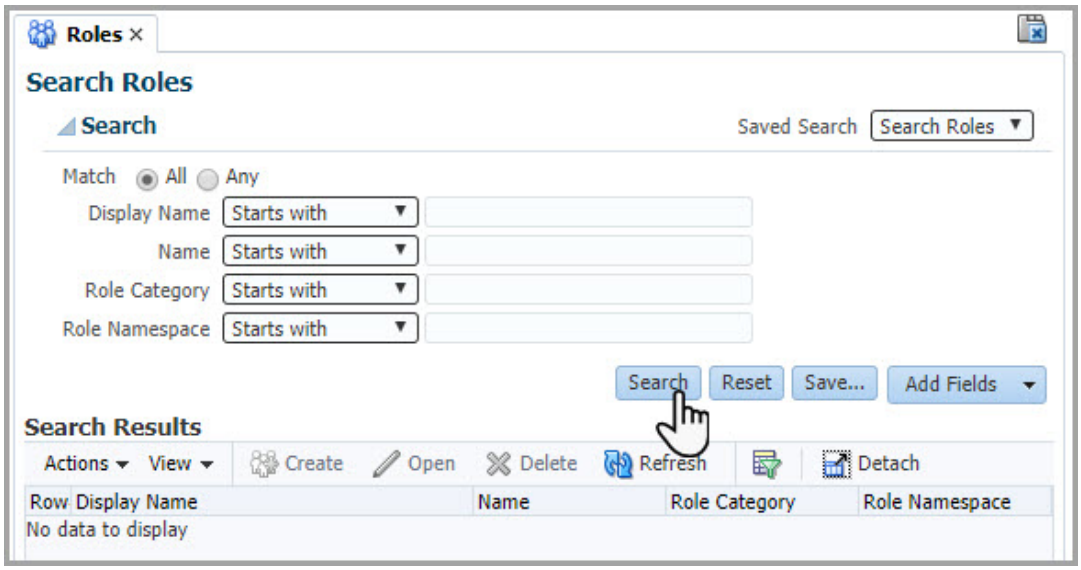
Setting up self-service registration is optional. However, if you decide to use self-service registration, you must activate approval for roles so that an Approver can review all access requests and either approve or decline them. For more information, see Activate approval for roles.

> **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.

1. Sign in to Oracle Life Sciences IAMS as described in Bookmark and sign in directly to Oracle Life Sciences IAMS.
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 a given user role.

   Make sure you set up the self-service registration for all the necessary roles in all the applicable environments. These are:

   - **clinicalone-CNE** to access Oracle Clinical One Platform
   - **clinicalone-CNE_AssignGlobalRoles** for product administrators that need to assign global roles in Oracle Clinical One Platform.
   - **inthub-CNE** to access Oracle Clinical One Digital Gateway if your organization requires to manage integrations.

   a. Click the link in the Display Name column for the role.

   b. In the row of controls at the top of the role page, click **Set Unauthorized Access Page**.

c. Select **Authorization Request Page** and click **Submit**.

After you finish these steps, notify your Oracle point of contact when approvals and self-service registration are all set. The Oracle point of contact then 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 a Customer Delegated Administrator (CDA)) can assign the roles to the users. For more information, see Request product roles or Assign roles in Oracle Life Sciences IAMS.

Related Topics

- Roles in user management
  There are different roles involved in user management when it comes to clinical studies in Oracle Clinical One Platform. These roles are differentiated according to their responsibilities and the level of access they have. However, for some studies, one person can assume multiple roles and perform different tasks associated to different roles.
- Tasks that Oracle completes for you
  As a Customer Delegated Administrator (CDA), 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 to facilitate user management and to save time when enabling your team to begin their work in the application.
- Assign roles in Oracle Life Sciences IAMS
  Having an Oracle Life Sciences Single Sign-On (SSO) account is not enough to start working on specific products. Customer Delegated Administrators (CDA) assign product roles to grant access to Oracle Clinical One Platform and Oracle Clinical One Digital Gateway as a whole. A product administrator or study user administrator then assigns study-specific roles to users from within Oracle Clinical One Platform.
- 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 access to different products and different sets of permissions.
- Request product roles
  You need specific product roles to access Oracle Clinical One Platform and Oracle Clinical One Digital Gateway. Depending on your organization setup for account management, if your organization set up self-service registration (including an authorization request page), you can navigate to the product web site and request these product roles yourself.

- Prerequisites to create accounts
  A Customer Delegated Administrator (CDA) of an 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.
- Request the creation of 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 Customer Delegated Administrator (CDA) is responsible for requesting the Approver role.
- Create user account for the Approver
  The Customer Delegated Administrator (CDA) must create an Oracle Life Sciences single sign-on (SSO) for each user with the Approver role, typically two users. The Approver users are responsible to review and approve all requests to access Oracle Clinical One Platform for an organization.
- Activate approval for roles
  When you activate approval for roles, every time a role gets assigned to a user (either in Oracle Life Sciences IAMS or by a self-service registration) an access request is generated. The Customer Delegated Administrator (CDA) with the Approver role must review all access requests and either approve or reject them.
- Publish the roles
  A Customer Delegated Administrator (CDA) publishes roles so that Oracle users can see the roles and assign them to the Oracle Life Sciences Single Sign-Ons (SSOs) and to Life Sciences Support users. If you activated approval, Approvers see an access request for each assignment and can either approve or reject them.
- About the 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.
- Create user accounts
- Manage access requests
  If your organization uses the approval process to grant users access to applications, everytime a product role is assigned to a user generates an access requests. The Customer Delegated Administrator (CDA) with the Approver role must approve or reject these requests.

3
Create user accounts

- Create an Oracle Life Sciences Single Sign-On (SSO)
  As the Customer Delegated Administrator (CDA), you use Oracle Life Sciences Identity and Access Management Service (IAMS) to create Oracle Life Sciences single sign-on (SSO) accounts for users in your organization. Users need an SSO account to access Oracle Clinical One Platform and Oracle Clinical One Digital Gateway.
- Assign roles in Oracle Life Sciences IAMS
  Having an Oracle Life Sciences Single Sign-On (SSO) account is not enough to start working on specific products. Customer Delegated Administrators (CDA) assign product roles to grant access to Oracle Clinical One Platform and Oracle Clinical One Digital Gateway as a whole. A product administrator or study user administrator then assigns study-specific roles to users from within Oracle Clinical One Platform.
- 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 access to different products and different sets of permissions.
- Create and manage Oracle Life Sciences Single Sign-Ons (SSO) 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.
- Create accounts for different types of users with access to specific products

Create an Oracle Life Sciences Single Sign-On (SSO)

As the Customer Delegated Administrator (CDA), you use Oracle Life Sciences Identity and Access Management Service (IAMS) to create Oracle Life Sciences single sign-on (SSO) accounts for users in your organization. Users need an SSO account to access Oracle Clinical One Platform and Oracle Clinical One Digital Gateway.

Before you start with this task, make sure you complete the Prerequisites to create accounts.

> **Note:**
>
> For every Oracle Life Sciences SSO account, password expires every three months. Users receive a password reset reminder when approaching expiriation date.

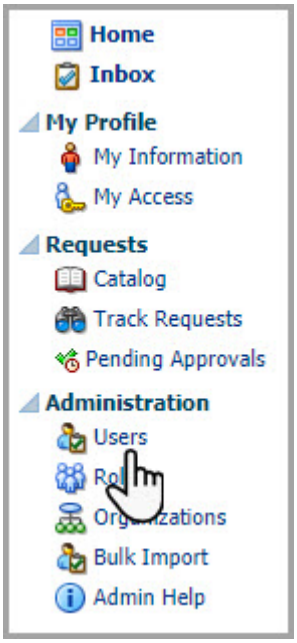
If you need to create an Oracle Life Sciences SSO for more than one user, the bulk import feature might save you some time. See Create and manage Oracle Life Sciences Single Sign-Ons (SSO) in bulk.

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

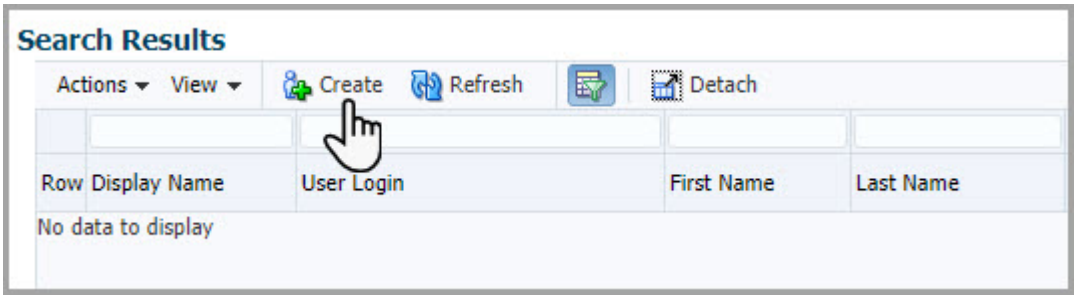
Video

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

2. In the left panel, expand **Administration** and click **Users**.



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



4. Fill in the fields with the new user's information.

> **Note:**
>
> Besides letters and numbers, a user's login can only contain the following special characters: hyphens (-), underscores (_), and dots (.).

Field	Description
First Name	Enter a user's first name.
Last Name	Enter a user's last name.
Email	Specify a user's organization email address.
Organization	Enter your organization's ShortOrgId. This is the reference number that appears in the message heading of your New Account notification email message. ***Tip:*** *You can also click the search icon, select the row with* ***Company*** *in the* ***Type*** *column, and click* ***Select****. See* How do I find my company's ShortOrgId?

Field	Description
User Login	Enter the user name that shoulb be used by the user to login. For example, *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**.

Once the Oracle Life Sciences SSO account is created, you see a confirmation message and a new User Details tab opens with the details of the new account.
Next step: See Assign roles in Oracle Life Sciences IAMS to assign roles to the user accounts.

Related Topics

- Difference between access to Oracle products and access to clinical studies
  You control access to Oracle products through Oracle Life Sciences Identity and Access Management Service (IAMS). You control access to studies through Oracle Clinical One Platform.
- Roles in user management
  There are different roles involved in user management when it comes to clinical studies in Oracle Clinical One Platform. These roles are differentiated according to their responsibilities and the level of access they have. However, for some studies, one person can assume multiple roles and perform different tasks associated to different roles.
- Types of single sign-on accounts
  You use a single sign-on (SSO) account to securely authenticate with Oracle sites or applications. If your role requires you to access multiple sites and applications, you may use two different types of SSO accounts.
- About Oracle Life Sciences Identity and Access Management Service (IAMS)
  Customer Delegated Administrators (CDA) use Oracle Life Sciences IAMS to create Oracle Life Sciences SSO accounts for other users in the organization. Once a CDA creates your Oracle Life Sciences SSO account, you can use Oracle Life Sciences IAMS to activate and manage your account, and to access secure Oracle Life Sciences applications.

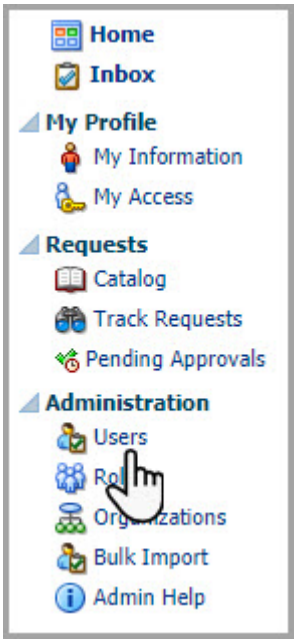
Assign roles in Oracle Life Sciences IAMS

Having an Oracle Life Sciences Single Sign-On (SSO) account is not enough to start working on specific products. Customer Delegated Administrators (CDA) assign product roles to grant access to Oracle Clinical One Platform and Oracle Clinical One Digital Gateway as a whole. A product administrator or study user administrator then assigns study-specific roles to users from within Oracle Clinical One Platform.

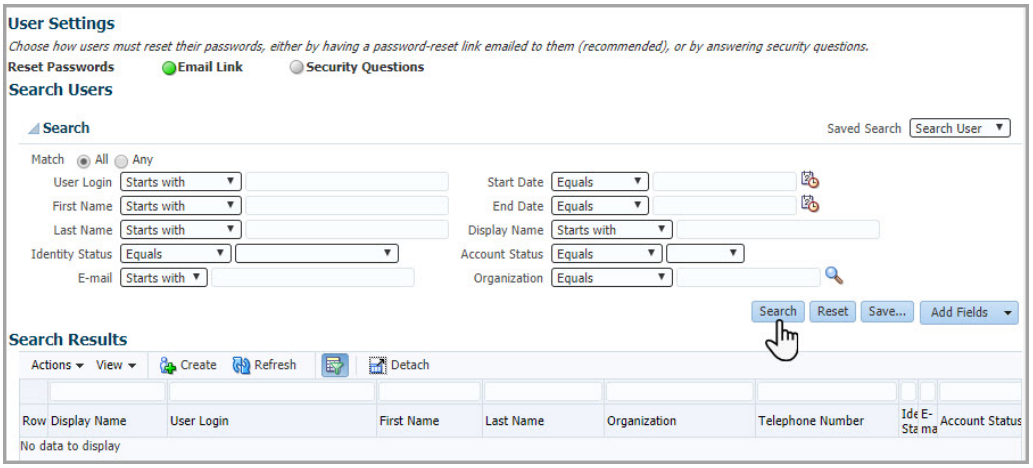
Before you can assign roles to a user, you must complete the steps in Create an Oracle Life Sciences Single Sign-On (SSO).

CDAs can assign roles to Oracle Life Sciences SSO accounts, as described in this procedure. If your organization has set up an authorization request page, users with an Oracle Life Sciences SSO account can access it directly and request roles for themselves. See Set up an authorization request page and Request product roles.

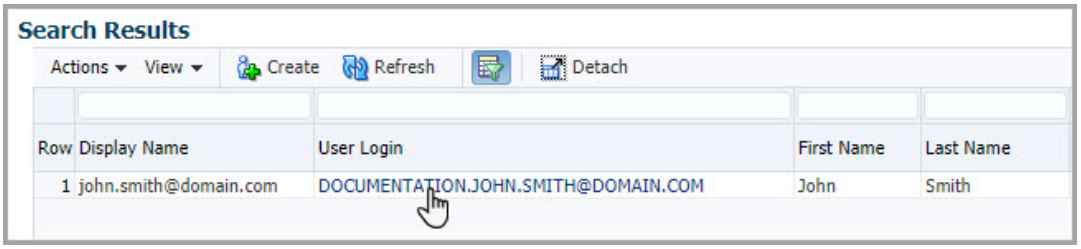
1. Sign in to Oracle Life Sciences IAMS as described in Bookmark and sign in directly to Oracle Life Sciences IAMS.
2. In the left panel, expand **Administration** and click **Users**.



3. Search for the user you want to assign product roles to.
   - To find a specific user, enter search criteria for the user, and then click **Search**, located below the filtering fields and to the right.
     To properly use the filters, from the drop-down on the filter of your choice, select a comparisson operator. Then type a value in the text box. For example, in the **E-mail** filter select **Equals** from the dropdown, and type the user's email address.
   - To see a list of all users, just click **Search**, located below the filtering fields and to the right.

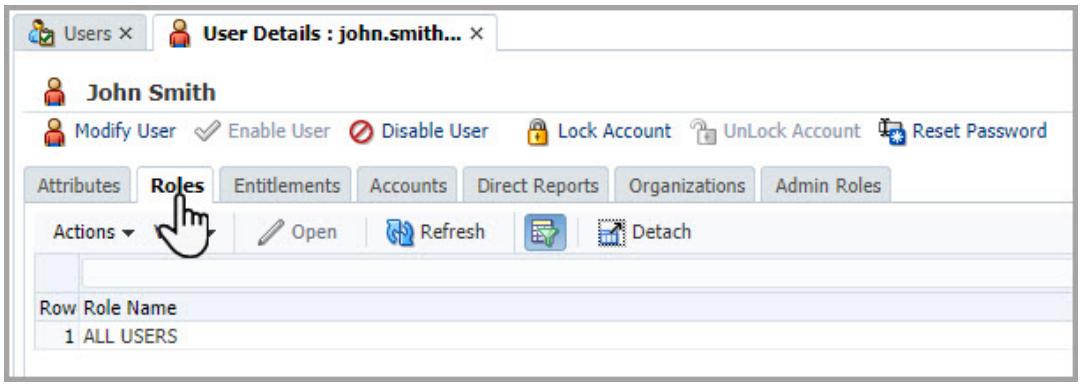


4. In the Search Results table, locate the user and click the user's name from the **User Login** column.

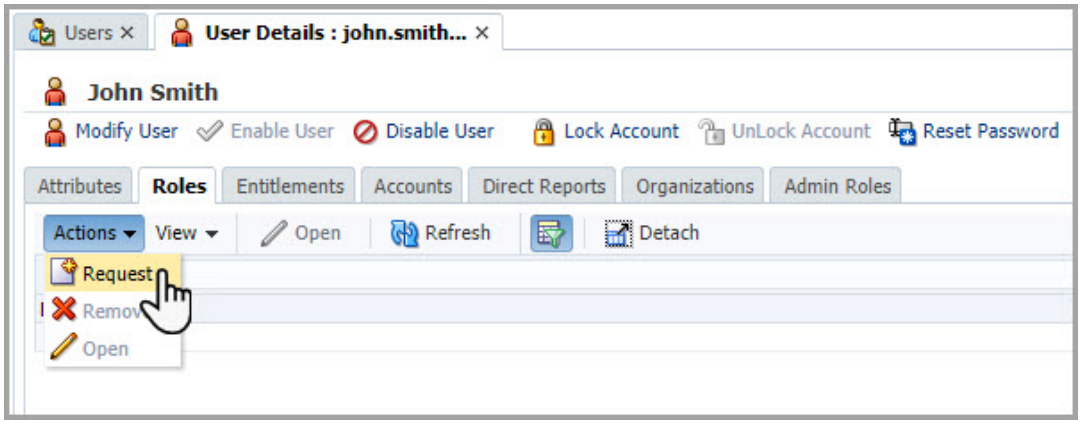


The user details open a new tab.

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



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



The roles catalog opens on a separate tab.

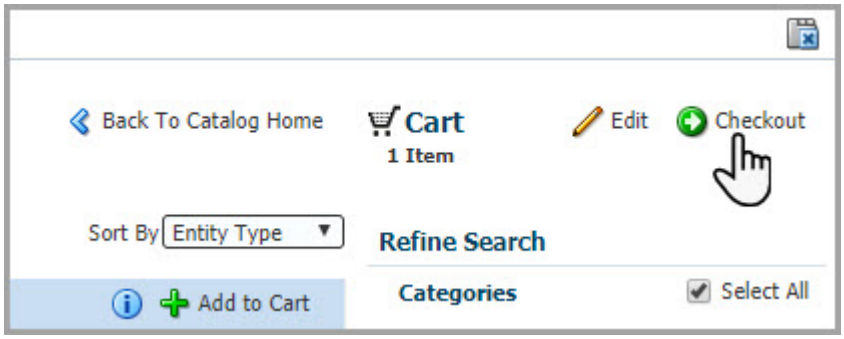
7. In the catalog tab, browse for the roles that the user needs:

> **Tip:**
>
> If you're not sure of the roles that users need, see Roles in Oracle Life Sciences IAMS for all applications.

   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.

Related Topics

- 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 access to different products and different sets of permissions.
- Difference between access to Oracle products and access to clinical studies
  You control access to Oracle products through Oracle Life Sciences Identity and Access Management Service (IAMS). You control access to studies through Oracle Clinical One Platform.
- Types of single sign-on accounts
  You use a single sign-on (SSO) account to securely authenticate with Oracle sites or applications. If your role requires you to access multiple sites and applications, you may use two different types of SSO accounts.
- About Oracle Life Sciences Identity and Access Management Service (IAMS)
  Customer Delegated Administrators (CDA) use Oracle Life Sciences IAMS to create Oracle Life Sciences SSO accounts for other users in the organization. Once a CDA creates your Oracle Life Sciences SSO account, you can use Oracle Life Sciences IAMS to activate and manage your account, and to access secure Oracle Life Sciences applications.
- Request product roles
  You need specific product roles to access Oracle Clinical One Platform and Oracle Clinical One Digital Gateway. Depending on your organization setup for account management, if your organization set up self-service registration (including an authorization request page), you can navigate to the product web site and request these product roles yourself.
- Review and approve an access request
  When an organization requires approval for roles, an access request generates when a Customer Delegated Administrator (CDA) assigns a role to a user or when a user submits

a self-service request through the authorization request page. The role gets assigned to the user only once the access request is approved.

- About the 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.
- Activate approval for roles
  When you activate approval for roles, every time a role gets assigned to a user (either in Oracle Life Sciences IAMS or by a self-service registration) an access request is generated. The Customer Delegated Administrator (CDA) with the Approver role must review all access requests and either approve or reject them.

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 access to different products and different sets of permissions.

The following table lists the roles that users need to be assigned with, in Oracle Life Sciences IAMS, to access different applications. For details on assigning the roles, see Assign roles in Oracle Health IAMS.

> **Note:**
>
> For every Oracle Life Sciences SSO account, password expires every three months. Users receive a password reset reminder when approaching expiriation date.

Product	Roles in Oracle Life Sciences IAMS	Additional information
Oracle Clinical One Platform	• **clinicalone-CNE**: this role is required for all users. • **clinicalone-CNE_AssignGlobalRoles**: this role is required for product administrators only. ***Note:*** *Product administrators are responsible for creating studies and global users in Oracle Clinical One Platform. Users who have this role can give access to studies for themselves and other users.*	Once Oracle Life Sciences SSO accounts are created in Oracle Life Sciences IAMS with the required roles approved, administrators must set up users' accounts in Oracle Clinical One Platform. This is required to access either as a global user or as a study user: • To create global users see Add a global user in Oracle Clinical One Platform • To create study users see Add a user to a study in Oracle Clinical One Platform
Oracle Clinical One Digital Gateway	• **inthub-CNE**: this role provides access Oracle Clinical One Digital Gateway. • **clinicalone-CNE**: this role provides access to Oracle Clinical One Platform, which is also required for Oracle Clinical One Digital Gateway users.	Oracle Clinical One Digital Gateway is a separate system from Oracle Clinical One Platform. Users with these roles can start working right away.
Oracle Life Sciences IAMSOAuth Admin Console	• **system-admin**: this role is required for any Customer Delegated Administrator (CDA) 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. Users with this role can start working right away. See the Get started as a system administrator section in the *REST API guide for the Clinical One Platform*.

Related Topics

- Difference between access to Oracle products and access to clinical studies
  You control access to Oracle products through Oracle Life Sciences Identity and Access Management Service (IAMS). You control access to studies through Oracle Clinical One Platform.
- Types of single sign-on accounts
  You use a single sign-on (SSO) account to securely authenticate with Oracle sites or applications. If your role requires you to access multiple sites and applications, you may use two different types of SSO accounts.
- Notifications for Oracle Life Sciences SSO account activation
  Once your organization's Customer Delegated Administrator (CDA) creates your Oracle Life Sciences single sign-on (SSO) in Oracle Life Sciences IAMS, you receive one or two email messages with account activation instructions.
- Create an Oracle Life Sciences Single Sign-On (SSO)
  As the Customer Delegated Administrator (CDA), you use Oracle Life Sciences Identity and Access Management Service (IAMS) to create Oracle Life Sciences single sign-on (SSO) accounts for users in your organization. Users need an SSO account to access Oracle Clinical One Platform and Oracle Clinical One Digital Gateway.
- Assign roles in Oracle Life Sciences IAMS
  Having an Oracle Life Sciences Single Sign-On (SSO) account is not enough to start working on specific products. Customer Delegated Administrators (CDA) assign product roles to grant access to Oracle Clinical One Platform and Oracle Clinical One Digital Gateway as a whole. A product administrator or study user administrator then assigns study-specific roles to users from within Oracle Clinical One Platform.
- Create accounts for different types of users with access to specific products

Create and manage Oracle Life Sciences Single Sign-Ons (SSO) 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.

- Download a bulk import sample file
  A spreadsheet sample file for the bulk import is available in Oracle Life Sciences Identity and Access Management Service (IAMS). You can download it and update it as necessary to create bulk import files.
- Update the bulk import file
  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.
- Guidelines for updating the bulk import file
  When you update a bulk import file, you must follow some guidelines and meet certain requirements for the bulk updates to proceed.

- Commands available to include in a bulk import file
  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.
- Import a file for bulk updates
  After you complete the bulk import file, you can import it into Oracle Life Sciences IAMS to create and manage Oracle Life Sciences Single Sign-On (SSO) accounts in bulk.
- 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 bulk import sample file

A spreadsheet sample file for the bulk import is available in Oracle Life Sciences Identity and Access Management Service (IAMS). You can download it and update it as necessary to create bulk import files.

1. Sign in to Oracle Life Sciences IAMS as described in Bookmark and sign in directly to Oracle Life Sciences IAMS.
2. In the left panel, expand **Administration** and click **Bulk Import**.
3. Select **Import a File**.
4. Click **Help**.
5. Click **Download Sample File**.

A CSV file downloads, which you can open and update as a spreadsheet or using any text editor. See Guidelines for updating the bulk import file.

Related Topics

- Update the bulk import file
  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.
- Guidelines for updating the bulk import file
  When you update a bulk import file, you must follow some guidelines and meet certain requirements for the bulk updates to proceed.
- Commands available to include in a bulk import file
  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.
- Import a file for bulk updates
  After you complete the bulk import file, you can import it into Oracle Life Sciences IAMS to create and manage Oracle Life Sciences Single Sign-On (SSO) accounts in bulk.

Update the bulk import file

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.

1. Open a new CSV file using either Microsoft Excel or a text editor.

> **Tip:**
>
> You can start from a sample file, see Download a bulk import sample file.

2. Add all the commands to file, each on individual lines.
   - Make sure you follow the Guidelines for updating the bulk import file for the import to complete successfully.
   - For details and examples on the commands you can include, see Commands available to include in a bulk import file.
3. Save the file in CSV format.

Next step: Import a file for bulk updates.

Related Topics

- Download a bulk import sample file
  A spreadsheet sample file for the bulk import is available in Oracle Life Sciences Identity and Access Management Service (IAMS). You can download it and update it as necessary to create bulk import files.
- Guidelines for updating the bulk import file
  When you update a bulk import file, you must follow some guidelines and meet certain requirements for the bulk updates to proceed.
- Commands available to include in a bulk import file
  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 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.

Guidelines for updating the bulk import file

When you update a bulk import file, you must follow some guidelines and meet certain requirements for the bulk updates to proceed.

The bulk import file must be a CSV file, which you can update using a spreadsheet tool, such as Microsoft Excel, or a text editor, such as Notepad. The tool you use to update the file determines how you see each command line:

- In a text editor, the whole command is a single line with each value separated by a comma (with no blank spaces).
- In a spreadsheet tool, each value for a single command is included in its own cell.

In either case, consider the following list of requirements for the file:

- Start every command on a new line.
- Start every command with the appropriate command name.
- Include all information for a command on a single line.
- For the `create` command, the middle name is the only optional variable. If the user doesn't have a middle name:
  - When using a spreadsheet tool, leave the cell empty.
  - When using a text editor, omit the value leaving two consecutive commas.

- If you're working in a text editor, include a comma after every value except the last value in a row.
- If you're working in a text editor, remove all spaces, including spaces before and after commas for every command.
- If you start from a sample file, remove all angle brackets (<>).
  To know how to download a sample file see Download a bulk import sample file.

For more details and examples on the commands you can include in a bulk import file, see Commands available to include in a bulk import file.

Related Topics

- Download a bulk import sample file
  A spreadsheet sample file for the bulk import is available in Oracle Life Sciences Identity and Access Management Service (IAMS). You can download it and update it as necessary to create bulk import files.
- Update the bulk import file
  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 a file for bulk updates
  After you complete the bulk import file, you can import it into Oracle Life Sciences IAMS to create and manage Oracle Life Sciences Single Sign-On (SSO) accounts in bulk.
- Commands available to include in a bulk import file
  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 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.

Commands available to include in a bulk import file

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 Guidelines for updating the bulk import file.

The following command are available for you to apply updates using a bulk import file.

Task	Command name	Command to use in a text file
Create an Oracle Life Sciences single sign-on (SSO)	**create**	`create,<organization id>,<user login>,<email id>,<middle name>,<first name>,<last name>`
Assign a role to a user	**authorize**	`authorize,<organizatoin id>,<user login>,<role name>`
Remove a role from a user	**deauthorize**	`deauthorize,<organizatoin id>,<user login>,<role name>`
Disable a user's Oracle Life Sciences SSO	**disable**	`disable,<organization id>,<user login>`

Command variables

This table describes all the variables used in the commands available for bulk import.

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 the user doesn't have a middle name: • When using a spreadsheet tool, leave the cell empty. • When using a text editor, omit the value leaving two consecutive commas.
`<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` Need help figuring out the roles to assign?
`<user login>`	Enter the user's email address.

Examples

Example 3-1 Commands added to a bulk import file using a text editor

```
create,Oracle,john.smith@example.com,john.smith@example.com,,john.smith
authorize,Oracle,john.smith@example.com,ClinicalOne_Production
deauthorize,Oracle,john.smith@example.com,ClinicalOne_Production
disable,Oracle,john.smith@example.com
```

Example 3-2 Same commands added to a bulk import file using a spreadsheet tool

You use the same commands in the same order when using a spreadsheet tool (such as Microsoft Excel), 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			

Related Topics

- Download a bulk import sample file
  A spreadsheet sample file for the bulk import is available in Oracle Life Sciences Identity and Access Management Service (IAMS). You can download it and update it as necessary to create bulk import files.

- Guidelines for updating the bulk import file
  When you update a bulk import file, you must follow some guidelines and meet certain requirements for the bulk updates to proceed.
- Update the bulk import file
  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 a file for bulk updates
  After you complete the bulk import file, you can import it into Oracle Life Sciences IAMS to create and manage Oracle Life Sciences Single Sign-On (SSO) accounts in bulk.
- 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.
- Create an Oracle Life Sciences Single Sign-On (SSO)
  As the Customer Delegated Administrator (CDA), you use Oracle Life Sciences Identity and Access Management Service (IAMS) to create Oracle Life Sciences single sign-on (SSO) accounts for users in your organization. Users need an SSO account to access Oracle Clinical One Platform and Oracle Clinical One Digital Gateway.
- 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 access to different products and different sets of permissions.
- Manage Oracle Life Sciences Single Sign-On (SSO) accounts

Import a file for bulk updates

After you complete the bulk import file, you can import it into Oracle Life Sciences IAMS to create and manage Oracle Life Sciences Single Sign-On (SSO) accounts in bulk.

For details on updating the bulk import file, see Update the bulk import file.

1. Sign in to Oracle Life Sciences IAMS as described in Bookmark and sign in directly to Oracle Life Sciences IAMS.
2. In the left panel, expand **Administration** and click **Bulk Import**.
3. Select **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:
   - Locate any invalid commands.
   - If the commands look correct but the **Import** button appears inactive, look for operations with a red **x** icon in the Status column and check the Message column for details.

   If there are any errors, click **Cancel**. 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. Click **Import**.

The Result Details of the import display. You can track progress of the import and view the amount of processed records out of the total, in the Progress bar.
A table displays including each update record. Check the **Status**column for successful and failed operations:

- A green checkmark displays for successful operations.
- A red **x** displays for operations that were not valid and were not executed.

> **Tip:**
>
> For these cases, review the **Message** column for details about the error. Hover over the cell to see the full message or download the file by clicking **Export**.

For operations that did not execute, you can choose between manually perform the remaining operations or resubmit a bulk import file including only those operations that failed, after correcting the errors. For assistance, refer to Guidelines for updating the bulk import file or contact Life Sciences Support.

Related Topics

- 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.
- Update the bulk import file
  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.
- Guidelines for updating the bulk import file
  When you update a bulk import file, you must follow some guidelines and meet certain requirements for the bulk updates to proceed.
- Commands available to include in a bulk import file
  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.
- Create an Oracle Life Sciences Single Sign-On (SSO)
  As the Customer Delegated Administrator (CDA), you use Oracle Life Sciences Identity and Access Management Service (IAMS) to create Oracle Life Sciences single sign-on (SSO) accounts for users in your organization. Users need an SSO account to access Oracle Clinical One Platform and Oracle Clinical One Digital Gateway.
- Assign roles in Oracle Life Sciences IAMS
  Having an Oracle Life Sciences Single Sign-On (SSO) account is not enough to start working on specific products. Customer Delegated Administrators (CDA) assign product roles to grant access to Oracle Clinical One Platform and Oracle Clinical One Digital Gateway as a whole. A product administrator or study user administrator then assigns study-specific roles to users from within Oracle Clinical One Platform.
- Manage Oracle Life Sciences Single Sign-On (SSO) accounts

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.

1. Sign in to Oracle Life Sciences IAMS as described in Bookmark and sign in directly to Oracle Life Sciences IAMS.
2. In the left panel, expand **Administration** 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. Click **Export** to download the file.

If you identify any operations that failed to execute, you can choose between manually perform those operations or resubmit a bulk import file including only those operations that failed, after correcting the errors. For assistance, refer to Guidelines for updating the bulk import file or contact Life Sciences Support.

Related Topics

- Import a file for bulk updates
  After you complete the bulk import file, you can import it into Oracle Life Sciences IAMS to create and manage Oracle Life Sciences Single Sign-On (SSO) accounts in bulk.
- Create an Oracle Life Sciences Single Sign-On (SSO)
  As the Customer Delegated Administrator (CDA), you use Oracle Life Sciences Identity and Access Management Service (IAMS) to create Oracle Life Sciences single sign-on (SSO) accounts for users in your organization. Users need an SSO account to access Oracle Clinical One Platform and Oracle Clinical One Digital Gateway.
- Assign roles in Oracle Life Sciences IAMS
  Having an Oracle Life Sciences Single Sign-On (SSO) account is not enough to start working on specific products. Customer Delegated Administrators (CDA) assign product roles to grant access to Oracle Clinical One Platform and Oracle Clinical One Digital Gateway as a whole. A product administrator or study user administrator then assigns study-specific roles to users from within Oracle Clinical One Platform.
- Manage Oracle Life Sciences Single Sign-On (SSO) accounts

Create accounts for different types of users with access to specific products

- Create product administrator accounts
  To create a product administrator for Oracle Clinical One Platform, a Customer Delagated Administrator (CDA) must create an Oracle Life Sciences Single Sign-on (SSO) in Oracle Life Sciences IAMS and assign product roles. Then the user can be added as a global user in Oracle Clinical One Platform. The product administrator is typically the first user account you create.
- Create study user accounts
  To create a study user in Oracle Clinical One Platform, a Customer Delagated Administrator (CDA) must create an Oracle Life Sciences Single Sign-on (SSO) in Oracle Life Sciences IAMS and assign product roles. Then the user can be added to the appropriate study in Oracle Clinical One Platform.

- Provide user access to Oracle Clinical One Digital Gateway
  To provide a user access to Oracle Clinical One Digital Gateway, a Customer Delegated Administrator (CDA) must create an Oracle Life Sciences Single Sign-On (SSO) 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.

Create product administrator accounts

To create a product administrator for Oracle Clinical One Platform, a Customer Delagated Administrator (CDA) must create an Oracle Life Sciences Single Sign-on (SSO) in Oracle Life Sciences IAMS and assign product roles. Then the user can be added 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.

> **Tip:**
>
> Make sure you create more than one global user as a product administrator. This is to ensure there is someone available to manage users at any time.

For more information on product administrators and their responsabilities, see Roles in user management.

Workflow for creating an account for a product administrator

The following table lists the tasks required to create a product administrator account.

> **Note:**
>
> Before you can manage users for your organization in Oracle Life Sciences IAMS and complete the tasks in this section, you must complete the prerequisites described in Account creation prerequisites.

Order	Task	Product	User
1	Create the Oracle Life Sciences SSO account for the product administrator. See Create an Oracle Life Sciences Single Sign-On (SSO).	Oracle Life Sciences IAMS	CDA

Order	Task	Product	User
2	Assign the appropriate product roles. See Assign roles in Oracle Life Sciences IAMS and refer to Roles in Oracle Life Sciences IAMS for all applications. ***Tip:*** *The CDA at your organization typically assigns product roles to your Oracle Life SSO account. However, if your organization allows self-service registration, users can individually generate a request for product access.* • *To enable self-service registration for specific roles, see*Set up an authorization request page*.* • *If self-service registration is enabled, notify users they can request roles as described in* Request product roles*.*	Oracle Life Sciences IAMS	CDA
3	*Only required when approval is activated for the given role.* Approve the access request to complete product role assignment to the account. Whether the user generated a self-service request, or another CDA manually assigned the product roles for an account. See Review and approve an access request.	Oracle Life Sciences IAMS	CDA with an approver role. ***Note:*** *You cannot approve your own requests. So if you as a CDA assigned the product role for an account, someone else at your organization with the Approver role must approve them.*
4	Add the product administrator as a global user in Oracle Clinical One Platform. See Add a global user in Oracle Clinical One Platform.	Oracle Clinical One Platform	• CDA • Another product administrator with *Global User Manager* privileges.

You can simplify the process in Oracle Life Sciences IAMS by managing user accounts in bulk. This supports the tasks for creating the SSO account and assigining product roles to it. See Create and manage Oracle Life Sciences Single Sign-Ons (SSO) in bulk.

Related Topics

- Roles in user management
  There are different roles involved in user management when it comes to clinical studies in Oracle Clinical One Platform. These roles are differentiated according to their responsibilities and the level of access they have. However, for some studies, one person can assume multiple roles and perform different tasks associated to different roles.
- Types of single sign-on accounts
  You use a single sign-on (SSO) account to securely authenticate with Oracle sites or applications. If your role requires you to access multiple sites and applications, you may use two different types of SSO accounts.
- Difference between access to Oracle products and access to clinical studies
  You control access to Oracle products through Oracle Life Sciences Identity and Access Management Service (IAMS). You control access to studies through Oracle Clinical One Platform.

- About the 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.
- 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.
- Manage access requests
  If your organization uses the approval process to grant users access to applications, everytime a product role is assigned to a user generates an access requests. The Customer Delegated Administrator (CDA) with the Approver role must approve or reject these requests.
- 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 access to different products and different sets of permissions.
- 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 study user accounts

To create a study user in Oracle Clinical One Platform, a Customer Delagated Administrator (CDA) must create an Oracle Life Sciences Single Sign-on (SSO) in Oracle Life Sciences IAMS and assign product roles. Then the user can be added to the appropriate study in Oracle Clinical One Platform.

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. Whether the user works at the sponsor, CRO, site, or depot, the workflow for creating the user account is the same.

The first study user is typically added by a product administrator with the *Global User Manager* or *Study Creator* roles. Subsequent study users can be added by the study user administrator (which is a special type of study user and typically the first one, added by the product administrator). Refer to Roles in user management.

Workflow for creating an account for a study user

The following table walks you through the tasks for creating accounts for study users.

> **Note:**
>
> Before a CDA can manage users for your organization in Oracle Life Sciences IAMS, they must complete the prerequisites described in Account creation prerequisites. A CDA must also add a product administrator to complete the tasks in this section, see Create product administrator accounts.

Order	Task	Product	User
1	Create the Oracle Life Sciences SSO account for the product administrator. See Create an Oracle Life Sciences Single Sign-On (SSO).	Oracle Life Sciences IAMS	CDA

Order	Task	Product	User
2	Assign the appropriate product roles. See Assign roles in Oracle Life Sciences IAMS and refer to Roles in Oracle Life Sciences IAMS for all applications. ***Tip:*** *The CDA at your organization typically assigns product roles to your Oracle Life SSO account. However, if your organization allows self-service registration, users can individually generate a request for product access.* • *To enable self-service registration for specific roles, see*Set up an authorization request page*.* • *If self-service registration is enabled, notify users they can request roles as described in* Request product roles*.*	Oracle Life Sciences IAMS	CDA
3	*Only required when approval is activated for the given role.* Approve the access request to complete product role assignment to the account. Whether the user generated a self-service request, or another CDA manually assigned the product roles for an account. See Review and approve an access request.	Oracle Life Sciences IAMS	CDA with an approver role. ***Note:*** *You cannot approve your own requests. So if you as a CDA assigned the product role for an account, someone else at your organization with the Approver role must approve them.*
4	Create the study roles to be assigned to the user. See: • Create a study role at the global level • Create a study role at the study level	Oracle Clinical One Platform	• Product administrator with the *Global User Manager* role (global level) • Study user administrator (study level)

Order	Task	Product	User
5	Add the user to the study as described in Add a user to a study in Oracle Clinical One Platform.	Oracle Clinical One Platform	• Product administrator with the *Global User Manager* role • Product administrator with the *Study Creator* role • Study user administrator ***Note:*** *Study Creators are the only users who can assign study users with roles for the study design mode. This means they are the only ones capable to add study user administrators, which are typically the first study users added and who further manage other users at the study level.*

CDAs can simplify the process in Oracle Life Sciences IAMS by managing user accounts in bulk. This supports the tasks for creating the SSO account and assigining product roles to it. See Create and manage Oracle Life Sciences Single Sign-Ons (SSO) in bulk.

Study user administrators can simplify the process and add study users in bulk, using the user upload template. With this bulk process you can also create the Oracle Life Sciences SSO account in Oracle Life Sciences IAMS (including the necessary product roles) for users that don't yet have an account. However, study roles must already be created. See Manage study users in bulk.

Related Topics

- Roles in user management
  There are different roles involved in user management when it comes to clinical studies in Oracle Clinical One Platform. These roles are differentiated according to their responsibilities and the level of access they have. However, for some studies, one person can assume multiple roles and perform different tasks associated to different roles.
- Types of single sign-on accounts
  You use a single sign-on (SSO) account to securely authenticate with Oracle sites or applications. If your role requires you to access multiple sites and applications, you may use two different types of SSO accounts.
- Difference between access to Oracle products and access to clinical studies
  You control access to Oracle products through Oracle Life Sciences Identity and Access Management Service (IAMS). You control access to studies through Oracle Clinical One Platform.

- About the 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.
- 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.
- Manage access requests
  If your organization uses the approval process to grant users access to applications, everytime a product role is assigned to a user generates an access requests. The Customer Delegated Administrator (CDA) with the Approver role must approve or reject these requests.
- 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 access to different products and different sets of permissions.
- About the User Upload template
  From Oracle Clinical One Platform you can download the User Upload template file to manage study users in bulk. In the User Upload template you define the details of new users to be added or existing users to be updated. This template is only to manage study users within a given study.
- Manage study roles
  In Oracle Clinical One Platform you can have study roles created at the global level and at the study level. Global-level study roles are available for the entire organization and can be used in all studies. Study roles at the study level only exist for the particular study in which they were created.
- Types of study roles in Oracle Clinical One Platform
  Study roles represent a collection of permissions that, when assigned, allow users to perform specific tasks. You must be mindful to create the correct type of study role (*Sponsor*, *Site* or *Design*) and include only the relevant permissions to the role, without compromising the study blind.
- Best practices for role, site, and depot assignment
  Users with different responsibilities require different assignements. For example, some users need the ability to add users to a study, some others need permissions for study design or study management tasks. Similarly, some users need access to all sites and depots, while some others need access only to specific facilities.

Provide user access to Oracle Clinical One Digital Gateway

To provide a user access to Oracle Clinical One Digital Gateway, a Customer Delegated Administrator (CDA) must create an Oracle Life Sciences Single Sign-On (SSO) 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.

Workflow for creating an account for an Oracle Clinical One Digital Gateway user

The following table provides the details to complete these tasks.

> **Note:**
>
> Before you can manage users for your organization in Oracle Life Sciences IAMS and complete the tasks in this section, you must complete the prerequisites described in Account creation prerequisites.

Order	Task	Product	User
1	Create the Oracle Life Sciences SSO account for the product administrator. See Create an Oracle Life Sciences Single Sign-On (SSO).	Oracle Life Sciences IAMS	CDA
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. ***Tip:*** *The CDA at your organization typically assigns product roles to your Oracle Life SSO account. However, if your organization allows self-service registration, users can individually generate a request for product access.* • *To enable self-service registration for specific roles, see*Set up an authorization request page*.* • *If self-service registration is enabled, notify users they can request roles as described in* Request product roles*.*	Oracle Life Sciences IAMS	CDA
3	*Only required when approval is activated for the given role.* Approve the access request to complete product role assignment to the account. Whether the user generated a self-service request, or another CDA manually assigned the product roles for an account. See Review and approve an access request.	Oracle Life Sciences IAMS	CDA with an approver role. ***Note:*** *You cannot approve your own requests. So if you as a CDA assigned the product role for an account, someone else at your organization with the Approver role must approve them.*

Order	Task	Product	User
4	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* To configure Oracle Clinical One Digital Gateway integrations, the user must also be assigned the following global role. • *Integration Builder* For more information, see Roles for global users.	Oracle Clinical One Platform	• CDA • Another product administrator with *Global User Manager* privileges.

You can simplify the process in Oracle Life Sciences IAMS by managing user accounts in bulk. This supports the tasks for creating the SSO account and assigining product roles to it. See Create and manage Oracle Life Sciences Single Sign-Ons (SSO) in bulk.

Related Topics

- Roles in user management
  There are different roles involved in user management when it comes to clinical studies in Oracle Clinical One Platform. These roles are differentiated according to their responsibilities and the level of access they have. However, for some studies, one person can assume multiple roles and perform different tasks associated to different roles.
- Types of single sign-on accounts
  You use a single sign-on (SSO) account to securely authenticate with Oracle sites or applications. If your role requires you to access multiple sites and applications, you may use two different types of SSO accounts.
- Difference between access to Oracle products and access to clinical studies
  You control access to Oracle products through Oracle Life Sciences Identity and Access Management Service (IAMS). You control access to studies through Oracle Clinical One Platform.
- About the 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.
- 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.
- Manage access requests
  If your organization uses the approval process to grant users access to applications, everytime a product role is assigned to a user generates an access requests. The Customer Delegated Administrator (CDA) with the Approver role must approve or reject these requests.
- 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 access to different products and different sets of permissions.

- 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.
- *Digital Gateway User Guide*

4

Manage Oracle Life Sciences Single Sign-On (SSO) accounts

- 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 product roles
  You need specific product roles to access Oracle Clinical One Platform and Oracle Clinical One Digital Gateway. Depending on your organization setup for account management, if your organization set up self-service registration (including an authorization request page), you can navigate to the product web site and request these product roles yourself.
- Manage access requests
  If your organization uses the approval process to grant users access to applications, everytime a product role is assigned to a user generates an access requests. The Customer Delegated Administrator (CDA) with the Approver role must approve or reject these requests.

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.

> **Note:**
>
> 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 Customer Delegated Administrator (CDA) for your organization or Life Sciences Support to get your user name.

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 CDA 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 Customer Delegated Administrator (CDA) at your organization or Life Sciences Support, and ask them to reset the password for you.

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.

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

   Depending on your organization setup, you may land on Oracle Health Sciences My Oracle Bookmarks or the Oracle Health Sciences Cloud landing page.

2. Depending on your landing page, do 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**.

Related Topics

- About Oracle Life Sciences Identity and Access Management Service (IAMS)
  Customer Delegated Administrators (CDA) use Oracle Life Sciences IAMS to create Oracle Life Sciences SSO accounts for other users in the organization. Once a CDA creates your Oracle Life Sciences SSO account, you can use Oracle Life Sciences IAMS to activate and manage your account, and to access secure Oracle Life Sciences applications.
- Sign in to Oracle Life Sciences IAMS
  All users must open Oracle Life Sciences IAMS periodically to manage their Oracle Life Sciences SSO accounts, specially Customer Delegated Administrators (CDAs) who manage accounts for the entire organization.
- Notifications for Oracle Life Sciences SSO account activation
  Once your organization's Customer Delegated Administrator (CDA) creates your Oracle Life Sciences single sign-on (SSO) in Oracle Life Sciences IAMS, you receive one or two email messages with account activation instructions.
- 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 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.

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.

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

   Depending on your organization setup, you may land on Oracle Health Sciences My Oracle Bookmarks or the Oracle Health Sciences Cloud landing page.

2. Depending on your landing page, do 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**.

Related Topics

- About Oracle Life Sciences Identity and Access Management Service (IAMS)
  Customer Delegated Administrators (CDA) use Oracle Life Sciences IAMS to create Oracle Life Sciences SSO accounts for other users in the organization. Once a CDA creates your Oracle Life Sciences SSO account, you can use Oracle Life Sciences IAMS to activate and manage your account, and to access secure Oracle Life Sciences applications.
- Sign in to Oracle Life Sciences IAMS
  All users must open Oracle Life Sciences IAMS periodically to manage their Oracle Life Sciences SSO accounts, specially Customer Delegated Administrators (CDAs) who manage accounts for the entire organization.
- Notifications for Oracle Life Sciences SSO account activation
  Once your organization's Customer Delegated Administrator (CDA) creates your Oracle Life Sciences single sign-on (SSO) in Oracle Life Sciences IAMS, you receive one or two email messages with account activation instructions.
- 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.
- 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.

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.

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

   Depending on your organization setup, you may land on Oracle Health Sciences My Oracle Bookmarks or the Oracle Health Sciences Cloud landing page.
2. Depending on your landing page, do 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. 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**.

Related Topics

- About Oracle Life Sciences Identity and Access Management Service (IAMS)
  Customer Delegated Administrators (CDA) use Oracle Life Sciences IAMS to create Oracle Life Sciences SSO accounts for other users in the organization. Once a CDA creates your Oracle Life Sciences SSO account, you can use Oracle Life Sciences IAMS to activate and manage your account, and to access secure Oracle Life Sciences applications.
- Sign in to Oracle Life Sciences IAMS
  All users must open Oracle Life Sciences IAMS periodically to manage their Oracle Life Sciences SSO accounts, specially Customer Delegated Administrators (CDAs) who manage accounts for the entire organization.
- Notifications for Oracle Life Sciences SSO account activation
  Once your organization's Customer Delegated Administrator (CDA) creates your Oracle Life Sciences single sign-on (SSO) in Oracle Life Sciences IAMS, you receive one or two email messages with account activation instructions.
- 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.

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 Bookmark and sign in directly to Oracle Life Sciences IAMS.

   Depending on your organization setup, you may land on Oracle Health Sciences My Oracle Bookmarks or the Oracle Health Sciences Cloud landing page.
2. Depending on your landing page, do one of the following:

- 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 Customer Delegated Administrator (CDA) needs to reassign the role to your account. Refer to Assign roles in Oracle Life Sciences IAMS.

Related Topics

- About Oracle Life Sciences Identity and Access Management Service (IAMS)
  Customer Delegated Administrators (CDA) use Oracle Life Sciences IAMS to create Oracle Life Sciences SSO accounts for other users in the organization. Once a CDA creates your Oracle Life Sciences SSO account, you can use Oracle Life Sciences IAMS to activate and manage your account, and to access secure Oracle Life Sciences applications.
- Sign in to Oracle Life Sciences IAMS
  All users must open Oracle Life Sciences IAMS periodically to manage their Oracle Life Sciences SSO accounts, specially Customer Delegated Administrators (CDAs) who manage accounts for the entire organization.
- Notifications for Oracle Life Sciences SSO account activation
  Once your organization's Customer Delegated Administrator (CDA) creates your Oracle Life Sciences single sign-on (SSO) in Oracle Life Sciences IAMS, you receive one or two email messages with account activation instructions.
- Assign roles in Oracle Life Sciences IAMS
  Having an Oracle Life Sciences Single Sign-On (SSO) account is not enough to start working on specific products. Customer Delegated Administrators (CDA) assign product roles to grant access to Oracle Clinical One Platform and Oracle Clinical One Digital Gateway as a whole. A product administrator or study user administrator then assigns study-specific roles to users from within Oracle Clinical One Platform.
- 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.
- 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 access to different products and different sets of permissions.
- Request product roles
  You need specific product roles to access Oracle Clinical One Platform and Oracle Clinical One Digital Gateway. Depending on your organization setup for account management, if your organization set up self-service registration (including an authorization request page), you can navigate to the product web site and request these product roles yourself.

Request product roles

You need specific product roles to access Oracle Clinical One Platform and Oracle Clinical One Digital Gateway. Depending on your organization setup for account management, if your organization set up self-service registration (including an authorization request page), you can navigate to the product web site and request these product roles yourself.

A Customer Delegated Administrator (CDA) at your organization typically assigns product roles to your Oracle Life Sciences Single Sign-on (SSO) account. However, if your organization allows self-service registration, you can generate a request for product access. A CDA with an Approver role must review and approve your request. Once approved, you can access the application associated with the approved role.

> **Note:**
>
> Product roles grant access to Oracle Clinical One Platform and Oracle Clinical One Digital Gateway as a whole and not to specific studies. A product administrator must assign study-specific roles to you from within Oracle Clinical One Platform for you to work in individual studies. Refer to Create study user accounts.

If you are a CDA and want to set up your organization for self-service registration, see Set up an authorization request page.

1. As an Oracle Clinical One Platform and Oracle Clinical One Digital Gateway user, navigate to the Oracle Clinical One Platform web site for your organization.

   See Identify the Oracle Clinical One Platform web address for your organization if you do not know the web address.

2. Sign in with your Oracle Life Sciencess SSO account.

   To get your credentials and activate your account see Notifications for Oracle Life Sciences SSO account activation.

   The Request for Authorization page opens.

3. 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**.

> **Note:**
>
> Both Oracle Clinical One Platform and Oracle Clinical One Digital Gateway users need access to Oracle Clinical One Platform. However, Oracle Clinical One Digital Gateway users, in particular, also need to request additional access to the Oracle Clinical One Digital Gateway application.

If you need access to Oracle Clinical One Digital Gateway, navigate to the Oracle Clinical One Digital Gateway web site and repeat the steps described above. After you sign in and submit your request with a justification, an access request message is sent to the Approver at your organization for the Oracle Clinical One Digital Gateway role: **inthub-CNE**.
The CDA with the Approver role for your organization receives the request and can either approve it or reject it. Once your requests are approved, you can access the applications associated with your assigned roles. If you continue to see the access request page after sign in, your request might not be approved yet. You must wait for the approval or check with your CDAs to confirm that your request was not denied.

Related Topics

- Roles in user management
  There are different roles involved in user management when it comes to clinical studies in Oracle Clinical One Platform. These roles are differentiated according to their responsibilities and the level of access they have. However, for some studies, one person can assume multiple roles and perform different tasks associated to different roles.
- Assign roles in Oracle Life Sciences IAMS
  Having an Oracle Life Sciences Single Sign-On (SSO) account is not enough to start working on specific products. Customer Delegated Administrators (CDA) assign product roles to grant access to Oracle Clinical One Platform and Oracle Clinical One Digital Gateway as a whole. A product administrator or study user administrator then assigns study-specific roles to users from within Oracle Clinical One Platform.
- 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 access to different products and different sets of permissions.
- Create and manage Oracle Life Sciences Single Sign-Ons (SSO) 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.
- Manage access requests
  If your organization uses the approval process to grant users access to applications, everytime a product role is assigned to a user generates an access requests. The Customer Delegated Administrator (CDA) with the Approver role must approve or reject these requests.
- Review and approve an access request
  When an organization requires approval for roles, an access request generates when a Customer Delegated Administrator (CDA) assigns a role to a user or when a user submits a self-service request through the authorization request page. The role gets assigned to the user only once the access request is approved.

Manage access requests

If your organization uses the approval process to grant users access to applications, everytime a product role is assigned to a user generates an access requests. The Customer Delegated Administrator (CDA) with the Approver role must approve or reject these requests.

A product role can be assigned by a CDA directly in Oracle Life Sciences IAMS, or through self-service requests submitted by the user. See Assign roles in Oracle Life Sciences IAMS and Request product roles.

> **Caution:**
>
> If your organization doesn't set up approvals, assigned roles take effect immediately. This means that, in case of 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 organization instance. Refer to Set up an authorization request page

- Review and approve an access request
  When an organization requires approval for roles, an access request generates when a Customer Delegated Administrator (CDA) assigns a role to a user or when a user submits a self-service request through the authorization request page. The role gets assigned to the user only once 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.

Review and approve an access request

When an organization requires approval for roles, an access request generates when a Customer Delegated Administrator (CDA) assigns a role to a user or when a user submits a self-service request through the authorization request page. The role gets assigned to the user only once 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.

> **Note:**
>
> Keep in mind that you can't approve a request that you requested for yourself or someone else.

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

3. If multiple CDA 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 different roles that users need for different products, see 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 that they can start working in Oracle Clinical One Platform, and Oracle Clinical One Digital Gateway when applicable. This process occurs outside Oracle Life Sciences IAMS.
Make sure you notify users who were assigned the Oracle Clinical One Platform administrator role that they can start adding users in Oracle Clinical One Platform. This role might be either **ClinicalOne_Production_AssignGlobalRoles** or **clinicalone-CNE_AssignGlobalRoles**, depending on your environment.

Some users might still need to acativate their accounts. Look for the email notification and identify the user account details and web address specific for your organization to access either Oracle Clinical One Platform or Oracle Clinical One Digital Gateway. Refer to Notifications for Oracle Life Sciences SSO account activation.

Related Topics

- Request product roles
  You need specific product roles to access Oracle Clinical One Platform and Oracle Clinical One Digital Gateway. Depending on your organization setup for account management, if your organization set up self-service registration (including an authorization request page), you can navigate to the product web site and request these product roles yourself.
- Assign roles in Oracle Life Sciences IAMS
  Having an Oracle Life Sciences Single Sign-On (SSO) account is not enough to start working on specific products. Customer Delegated Administrators (CDA) assign product roles to grant access to Oracle Clinical One Platform and Oracle Clinical One Digital Gateway as a whole. A product administrator or study user administrator then assigns study-specific roles to users from within Oracle Clinical One Platform.
- 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 access to different products and different sets of permissions.

- 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.
- 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.
- Roles in user management
  There are different roles involved in user management when it comes to clinical studies in Oracle Clinical One Platform. These roles are differentiated according to their responsibilities and the level of access they have. However, for some studies, one person can assume multiple roles and perform different tasks associated to different roles.

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.

1. Sign in to Oracle Life Sciences IAMS as described in Bookmark and sign in directly to Oracle Life Sciences IAMS.
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 CDA 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**.

Related Topics

- Request product roles
  You need specific product roles to access Oracle Clinical One Platform and Oracle Clinical One Digital Gateway. Depending on your organization setup for account management, if your organization set up self-service registration (including an authorization request page), you can navigate to the product web site and request these product roles yourself.
- Assign roles in Oracle Life Sciences IAMS
  Having an Oracle Life Sciences Single Sign-On (SSO) account is not enough to start working on specific products. Customer Delegated Administrators (CDA) assign product roles to grant access to Oracle Clinical One Platform and Oracle Clinical One Digital Gateway as a whole. A product administrator or study user administrator then assigns study-specific roles to users from within Oracle Clinical One Platform.
- 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 access to different products and different sets of permissions.
- 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.
- Review and approve an access request
  When an organization requires approval for roles, an access request generates when a Customer Delegated Administrator (CDA) assigns a role to a user or when a user submits a self-service request through the authorization request page. The role gets assigned to the user only once the access request is approved.

5

Manage users and roles in Oracle Clinical One Platform

- Access Oracle Clinical One Platform
  To access Oracle Clinical One Platform you must sign in using the web address (URL) specific to your organization.
- Add a global user in Oracle Clinical One Platform
  Every organization must have at least one global user who can take responsibility of the global level tasks, such as creating studies and adding the first user for them. An organization typically has a limited number of global users.
- Add a global role to an existing global user
  Every organization must have at least one global user who can take responsibility of the global level tasks. The particular administrative tasks you can perform at the global level for your organization depend on the global roles assignied.
- 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.
- Remove a global user in Oracle Clinical One Platform
  You can remove a global user if the user is no longer part of your team or should no longer have access to your organization at the global level.
- Add a user to a study in Oracle Clinical One Platform
  A product administrator with *Study Creator* role 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 study user administrator.
- Edit a study user
  A study user administrator or a product administrator with the *Study Creator* or *Global User Manager* roles can modify a study user at any time. The details that can be edited for a study user include: the effective date range for their access, their assigned study roles and their site and depot assignments.
- Manage study users in bulk
  User administrators can use the user upload template to add new and update existing study users in bulk. In this template you define user details, such as the effective date range for their access, their assigned study roles, and their site, and depot assignments.
- Remove a study user
  You can remove a user from a study if the user is no longer part of it or if they should no longer have access.
- Manage study roles
  In Oracle Clinical One Platform you can have study roles created at the global level and at the study level. Global-level study roles are available for the entire organization and can be used in all studies. Study roles at the study level only exist for the particular study in which they were created.

- Types of study roles in Oracle Clinical One Platform
  Study roles represent a collection of permissions that, when assigned, allow users to perform specific tasks. You must be mindful to create the correct type of study role (*Sponsor*, *Site* or *Design*) and include only the relevant permissions to the role, without compromising the study blind.
- Best practices for role, site, and depot assignment
  Users with different responsibilities require different assignements. For example, some users need the ability to add users to a study, some others need permissions for study design or study management tasks. Similarly, some users need access to all sites and depots, while some others need access only to specific facilities.
- 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.

Access Oracle Clinical One Platform

To access Oracle Clinical One Platform you must sign in using the web address (URL) specific to your organization.

- Identify the Oracle Clinical One Platform web address for your organization
  You receive the web address (URL) for signing in to Oracle Clinical One Platform in an email after a Custome Delegated Administrator (CDA) assigns the product roles to your user account 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.

Identify the Oracle Clinical One Platform web address for your organization

You receive the web address (URL) for signing in to Oracle Clinical One Platform in an email after a Custome Delegated Administrator (CDA) assigns the product roles to your user account 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 CDA at your organization or your Oracle point of contact.

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 Notifications for Oracle Life Sciences SSO account activation .

1. Enter the Oracle Clinical One Platform web address in your browser.

   See Identify the Oracle Clinical One Platform web address for your organization.

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.

Add a global user in Oracle Clinical One Platform

Every organization must have at least one global user who can take responsibility of the global level tasks, such as creating studies and adding the first user for them. An organization typically has a limited number of global users.

To get a general idea of the tasks a global user can perform, see Roles for global users in Oracle Clinical One Platform and Oracle Clinical One Digital Gateway. The available roles should help you define which global users you need to create for your organization.

Typically, a Customer Delegated Administrator (CDA) adds the first global user with the *Global User Manager* role. A global user manager can subsequently add other global users. See Roles in user management.

These two types of users, the CDA and the global user manager, must be assigned with the *ClinicalOne-CNE_AssignGlobalRoles* product role in Oracle Life Sciences IAMS to be able to create global users in Oracle Clinical One Platform. Also, before you can add a global user, the CDA must create an Oracle Life Sciences SSO account for the user. For the general workflow, see Create product administrator accounts.

Show me how!

Video

1. On the Oracle Clinical One Platform Home page, click **Global Settings**, along the top.
2. Navigate to the **Users** tab.
3. Click **Create Global User**.
4. Fill in the fields in the Create Global User dialog:
   a. From the **Full Name** drop-down, select the user's name.

      This drop-down only lists the users for which an SSO account has been created.

   b. Confirm that the autocompleted **User Name** and **Email** details are correct.

   c. Click into the **Global Roles** field and select one or more global roles from the drop-down.

      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.
5. Click **Create**.

Depending on the global roles you are assigned with, you can proceed with particular administrative tasks for your organization. As a study creator or global user manager, you can continue to manage users at the study level, see Add a user to a study in Oracle Clinical One Platform.

Related Topics

- Roles in user management
  There are different roles involved in user management when it comes to clinical studies in Oracle Clinical One Platform. These roles are differentiated according to their

responsibilities and the level of access they have. However, for some studies, one person can assume multiple roles and perform different tasks associated to different roles.

- 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 product administrator accounts
  To create a product administrator for Oracle Clinical One Platform, a Customer Delagated Administrator (CDA) must create an Oracle Life Sciences Single Sign-on (SSO) in Oracle Life Sciences IAMS and assign product roles. Then the user can be added as a global user in Oracle Clinical One Platform. The product administrator is typically the first user account you create.
- Create an Oracle Life Sciences Single Sign-On (SSO)
  As the Customer Delegated Administrator (CDA), you use Oracle Life Sciences Identity and Access Management Service (IAMS) to create Oracle Life Sciences single sign-on (SSO) accounts for users in your organization. Users need an SSO account to access Oracle Clinical One Platform and Oracle Clinical One Digital Gateway.
- Assign roles in Oracle Life Sciences IAMS
  Having an Oracle Life Sciences Single Sign-On (SSO) account is not enough to start working on specific products. Customer Delegated Administrators (CDA) assign product roles to grant access to Oracle Clinical One Platform and Oracle Clinical One Digital Gateway as a whole. A product administrator or study user administrator then assigns study-specific roles to users from within Oracle Clinical One Platform.
- 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 access to different products and different sets of permissions.
- Request product roles
  You need specific product roles to access Oracle Clinical One Platform and Oracle Clinical One Digital Gateway. Depending on your organization setup for account management, if your organization set up self-service registration (including an authorization request page), you can navigate to the product web site and request these product roles yourself.
- Add a global role to an existing global user
  Every organization must have at least one global user who can take responsibility of the global level tasks. The particular administrative tasks you can perform at the global level for your organization depend on the global roles assignied.

Add a global role to an existing global user

Every organization must have at least one global user who can take responsibility of the global level tasks. The particular administrative tasks you can perform at the global level for your organization depend on the global roles assignied.

For the complete list of global roles you can assign users with, see Roles for global users in Oracle Clinical One Platform and Oracle Clinical One Digital Gateway.

Typically, a Customer Delegated Administrator (CDA) adds the first global user with the *Global User Manager* role. A global user manager can subsequently add or update other global users. See Roles in user management.

These two types of users, the CDA and the global user manager, must be assigned with the *ClinicalOne-CNE_AssignGlobalRoles* product role in Oracle Life Sciences IAMS to be able to update global users in Oracle Clinical One Platform. Also, make sure the global user role you want to update already exists, otherwise seeAdd a global user in Oracle Clinical One Platform.

1. On the Oracle Clinical One Platform Home page, click **Global Settings**, along the top.
2. Navigate to the **Users** tab.
3. From the table, select the user you want to update.
4. Click **Manage Users** and select **Edit** from the drop-down.
5. In the Create Global User dialog, click the **Global Roles** field and select one or more global roles from the drop-down.

   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**.

Related Topics

- Add a global user in Oracle Clinical One Platform
  Every organization must have at least one global user who can take responsibility of the global level tasks, such as creating studies and adding the first user for them. An organization typically has a limited number of global users.
- 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 product administrator accounts
  To create a product administrator for Oracle Clinical One Platform, a Customer Delagated Administrator (CDA) must create an Oracle Life Sciences Single Sign-on (SSO) in Oracle Life Sciences IAMS and assign product roles. Then the user can be added as a global user in Oracle Clinical One Platform. The product administrator is typically the first user account you create.
- Assign roles in Oracle Life Sciences IAMS
  Having an Oracle Life Sciences Single Sign-On (SSO) account is not enough to start working on specific products. Customer Delegated Administrators (CDA) assign product roles to grant access to Oracle Clinical One Platform and Oracle Clinical One Digital Gateway as a whole. A product administrator or study user administrator then assigns study-specific roles to users from within Oracle Clinical One Platform.
- 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 access to different products and different sets of permissions.
- Add a user to a study in Oracle Clinical One Platform
  A product administrator with *Study Creator* role 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 study user administrator.
- Roles in user management
  There are different roles involved in user management when it comes to clinical studies in Oracle Clinical One Platform. These roles are differentiated according to their responsibilities and the level of access they have. However, for some studies, one person can assume multiple roles and perform different tasks associated to different roles.

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
Analytics: BI Publisher Authoring.	Provides access to Oracle Business Intelligence (BI) Publisher functionality in the Oracle Analytics Classic View (accessed from the Oracle Clinical One Analytics portal). ***Note:*** *Oracle BI Publisher is mainly used to create, edit and manage pixel-perfect reports. See Create a pixel-perfect report.*
Analytics: Data Visualizer Authoring	Provides complete authoring access to Oracle Clinical One Analytics, which allows you to: • Create and modify reports and dashboards in the Data Visualizer interface . • Access Oracle Business Intelligence (BI) Publisher functionality in the Oracle Analytics Classic View. ***Note****: This role includes the privileges from the* Analytics: BI Publisher Authoring *role. Users do not need to be assigned with both roles.*
Approve Library Kits for Pooled Supplies	Allows users to approve and edit kits in a library study, whether the kit has a status of Draft, Approved, or Published.
Assign Site to a Study	Allows to assign sites to studies within the Oracle Clinical One Platform.
Change Library Objects Status	Allows to update the status of an object in an organization's library.
Code List Manager	Allows users to manage code lists in the following ways: • Create and manage different types of code lists at a global level (for all studies at your organization): – Create new system code lists. – Edit existing system default code lists. – Create and manage custom code lists. • Build reports and visualizations including global-level codelists data when using the Study Codelist Dataset in Oracle Clinical One Analytics.
Coding Integration	Allows to configure and manage an integration between the Oracle Clinical One Platform and Oracle Central Coding
Create Study Roles for your Organization	Allows to create study roles that are available for all studies at an organization level. Typically, this role may be assigned to someone who performs standard study design tasks.
Create and Edit Library Kits for Pool Supplies	Allows to create and edit kits (including pooled kits) in a library study, only in Draft mode.
DMW Integration	Allows to manage 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.*

Role	Description
DataHubInternal	This role is typically assigned to internal Oracle users who configure integrations with Oracle Clinical One Analytics. ***Note:*** *This is a global role internal to Oracle, which should not be associated with external global users.*
Delete Library Kits	Allows user to delete kits from a library study.
Global User Manager	Provisions users to add and manage global users and their roles. This user also has the capability to add users to a study and to manage training requirements for the entire organization. ***Note:*** *This user does not have access to individual sites in the studies. If the user is responsible for assigning other users to sites, they must also be assigned site and user administrator role at the study level, and be assigned to all sites and depots that they need to associate other users with. See* Best practices for role, site, and depot assignment.
Intake Designer	Designs and configures Recipes required to process incoming Release Assessment Environment (RAE) documents, to extract data within Oracle Safety One Intake.
Intake Integration	Enables the Oracle Safety One Intake business service to integrate data with external systems. ***Note:*** *This role is only for API Integration users.*
Intake Processing	Provisions Oracle Life Sciences Safety One Intake Cloud Service users who process RAE documents. ***Note:*** *This role is only for the Oracle Safety One Intake business service.*
Intake Service User	Provisions Oracle Safety One Intake users who execute the background services necessary for processing RAE documents. ***Note:*** *This role is only for users of the Oracle Safety One Intake business background service.*
Intake View Only	Provides read-only access to Oracle Safety One Intake users. Can be used to provision restrictive access to support users.
Integration Builder	Allows users to access Oracle Clinical One Digital Gateway integration templates. ***Note****: In order to configure integrations, users must also be assigned the Integration Manager global role.*
Integration Developer	This is an Oracle internal role, allowing access to Oracle Clinical One Digital Gateway, and should not be assigned to external users.
Integration Manager	Allows user to configure integration templates and monitor and manage integrations in Oracle Clinical One Digital Gateway. ***Caution:*** *Error messages for failed jobs may contain potentially unblinding data. Do not assign this role to blinded study users.*
Integration Viewer	Provides users with read-only access to Oracle Clinical One Digital Gateway, primarily for the purpose of monitoring integrations.
Manage Contacts and Organizations	Allows users to manage contacts and organizations at the global level. This allows to create sites to be used in all your organization studies. 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: • Edit objects' attributes. • Update objects' details in a library study. • Update objects' status.
Oracle Admin	This is an Oracle internal role and should not be assigned to external users.
Service Account	This is an Oracle internal role and should not be assigned to external users.

Role	Description
Study Creator	Provisions users to create studies, manage global users and assign roles to users in Oracle Clinical One Platform studies. Users with the *Study Creator* role are the only ones who can assign study roles for users in the study design mode. Study design roles include: • *Study designer* • *User administrator* • *View study design* ***Note:*** *This user does not have access to individual sites in the studies. If the user is responsible for assigning other users to sites, they must also be assigned site and user administrator role at the study level, and be assigned to all sites and depots that they need to associate other users with. See* Best practices for role, site, and depot assignment.
Training Administrator	Allows user to create training studies 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:*** *Only assign this role to users using Oracle Health Sciences Learn Manager.*
Training Manager	Allows to assign training to other users, review training completion status, run reports for assigned and complete training, and send reminders across the following Oracle Life Sciences products: • Oracle InForm • Oracle Central Designer • Oracle Central Coding • Oracle InForm User Management Tool • Oracle IRT ***Note:*** *Only assign this role to users using Oracle Health Sciences Learn Manager.*
View Contacts and Organizations	Provisions users with read-only access for global-level contacts and organizations used across all studies in the organization.
View EHR Connectors	Allows users to access the **EHR Connectors** tab under Global Settings to view a list of Oracle Clinical Connectors. For more information, see Enable Electronic Health Record (EHR) data import.
View Library Objects	Provisions users with read-only access to objects in an organization's library. Users with read-only access cannot edit or manage library objects.

Remove a global user in Oracle Clinical One Platform

You can remove a global user if the user is no longer part of your team or should no longer have access to your organization at the global level.

This task can be performed by a global user manager.

To remove a user in Oracle Life Sciences IAMS, reach out to the Customer Delegated Administrator (CDA) for your organization and refer to Terminate or reinstate an account.

1. On the Home page, under your name, click **Global Settings**.
2. Navigate to the **Users** tab.
3. Locate the user that you want to remove and select it.

> **Caution:**
>
> There is no confimartion step in this process, so make sure you select the correct user.

4. Along the top menu, click **Manage Users**, and select **Delete**.

Related Topics

- Add a global user in Oracle Clinical One Platform
  Every organization must have at least one global user who can take responsibility of the global level tasks, such as creating studies and adding the first user for them. An organization typically has a limited number of global users.
- Add a global role to an existing global user
  Every organization must have at least one global user who can take responsibility of the global level tasks. The particular administrative tasks you can perform at the global level for your organization depend on the global roles assignied.
- Remove a study user
  You can remove a user from a study if the user is no longer part of it or if they should no longer have access.

Add a user to a study in Oracle Clinical One Platform

A product administrator with *Study Creator* role 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 study user administrator.

> **Note:**
>
> Study creators are the only users who can assign study users with roles for the study design mode. The user administrator permissions are associated to the study design. This means they are the only ones capable to add study user administrators. See Roles in user management.

After the user administrator is added to a study, either the global user (*Study Creator* or *Global User Manager*) can continue adding users, or the study user administrator can add the remaining users. Make sure you are added with the required permissions, either as a global user or a study user.

Before you can add a user to a study, the Customer Delgated Administrator (CDA) for your organization must create an Oracle Life Sciences SSO account for the user. For the general workflow, see Create study user accounts.

> **Caution:**
>
> 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.

1. From the Home page, Open the study's settings.

2. Navigate to 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.

> **Note:**
>
> Only the users with an existing Oracle Life Sciences SSO account in the organization are available to be added to the study. If you cannot find a specific user, reach out to your organization's CDA or your Oracle point of contact.

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 with the selected user's user name and cannot be edited.
Email	This field is automatically populated with the selected user's email address and cannot be edited.
Effective Date Range	Enter a **From** and **To** date, defining when the user can access the study. Or select **No End Date** to allow the user access without expiring. ***Tip:*** *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.* ***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 (or an hour earlier when observing daylight saving time).*

4. Select the appropriate **Study Roles** for each mode, then click **Next**.

> **Tip:**
>
> For a list of permissions assigned to each study role, click **View Permissions for Study Roles**, then select the role to see the permissions.

> **Note:**
>
> You should not assign template study roles. See Manage study roles.

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.

Item	Description
Training Mode	• Users typically have the same study role in training and production modes. If that is the case, activate **Same as production mode** *(active by default)*. • To select a different study role for training mode, deactivate **Same as production mode** and select a study role for the user to complete training.

5. In the Sites & Depots screen, select the sites and depots the user needs access to for every mode.

   You can either select **All Sites** and **All Depots** or you can select individual sites and depots. To select individual facilities, you must deactivate the **All Sites** or **All Depots** options respectively.
   For more details, see Best practices for role, site, and depot assignment.

6. Click **Finish**.

   You are presented with a confirmation message stating the user has been successfully 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 user
  A study user administrator or a product administrator with the *Study Creator* or *Global User Manager* roles can modify a study user at any time. The details that can be edited for a study user include: the effective date range for their access, their assigned study roles and their site and depot assignments.
- Manage study users in bulk
  User administrators can use the user upload template to add new and update existing study users in bulk. In this template you define user details, such as the effective date range for their access, their assigned study roles, and their site, and depot assignments.
- Manage study roles
  In Oracle Clinical One Platform you can have study roles created at the global level and at the study level. Global-level study roles are available for the entire organization and can be used in all studies. Study roles at the study level only exist for the particular study in which they were created.
- Edit a study role
  As a global user manager or study user administrator you can edit an existing study role. Study roles can be modified even if the study role is already assigned to users.
- Specify data classifications for a study role
  Data classifications allow you to control the type of data users can view or edit in a study. Data classifications defined for a study role dictate the type of data a study role provides access to with either view or edit privileges.
- Types of study roles in Oracle Clinical One Platform
  Study roles represent a collection of permissions that, when assigned, allow users to perform specific tasks. You must be mindful to create the correct type of study role (*Sponsor*, *Site* or *Design*) and include only the relevant permissions to the role, without compromising the study blind.
- User Administrator
  View the permissions included in the User Administrator template study role. This template study role is of *Design* type and is available for all studies at your organization.

- Best practices for role, site, and depot assignment
  Users with different responsibilities require different assignements. For example, some users need the ability to add users to a study, some others need permissions for study design or study management tasks. Similarly, some users need access to all sites and depots, while some others need access only to specific facilities.
- Template study roles
- Add a global user in Oracle Clinical One Platform
  Every organization must have at least one global user who can take responsibility of the global level tasks, such as creating studies and adding the first user for them. An organization typically has a limited number of global users.

Edit a study user

A study user administrator or a product administrator with the *Study Creator* or *Global User Manager* roles can modify a study user at any time. The details that can be edited for a study user include: the effective date range for their access, their assigned study roles and their site and depot assignments.

> **Note:**
>
> Study creators are the only users who can assign study users with roles for the study design mode.

1. From the Home page, Open the study's settings.
2. Navigate to the **Users** tab.
3. Locate the user you want to update and select it.
4. From the **Manage Users** drop-down select **Edit**.

   The Edit User window opens.
5. Modify the available fields as applicable.

Item	Description
Full Name	This field is automatically populated with the name of the user and cannot be modified.
User Name	This field is automatically populated with the selected user's user name and cannot be edited.
Email	This field is automatically populated with the selected user's email address and cannot be edited.

Item	Description
Effective Date Range	Enter a **From** and **To** date, defining when the user can access the study. Or select **No End Date** to allow the user access without expiring. ***Tip:*** *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.* ***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 (or an hour earlier when observing daylight saving time).*

6. Select the appropriate **Study Roles** for each mode as applicable, then click **Next**.

> **Tip:**
>
> For a list of permissions assigned to each study role, click **View Permissions for Study Roles**, then select the role to see the permissions.

> **Note:**
>
> You should not assign template study roles. See Manage study roles.

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	• Users typically have the same study role in training and production modes. If that is the case, activate **Same as production mode** *(active by default)*. • To select a different study role for training mode, deactivate **Same as production mode** and select a study role for the user to complete training.

7. In the Sites & Depots screen, modify the site and depot assignements as applicable. For more details, see Best practices for role, site, and depot assignment.
8. Click **Finish** to save your updates.

   You are presented with a confirmation message stating the user has been successfully modified.

Related Topics

- Add a user to a study in Oracle Clinical One Platform
  A product administrator with *Study Creator* role 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 study user administrator.

- Manage study users in bulk
  User administrators can use the user upload template to add new and update existing study users in bulk. In this template you define user details, such as the effective date range for their access, their assigned study roles, and their site, and depot assignments.
- Manage study roles
  In Oracle Clinical One Platform you can have study roles created at the global level and at the study level. Global-level study roles are available for the entire organization and can be used in all studies. Study roles at the study level only exist for the particular study in which they were created.
- Edit a study role
  As a global user manager or study user administrator you can edit an existing study role. Study roles can be modified even if the study role is already assigned to users.
- Specify data classifications for a study role
  Data classifications allow you to control the type of data users can view or edit in a study. Data classifications defined for a study role dictate the type of data a study role provides access to with either view or edit privileges.
- Roles for Study Design mode
  Learn more about the roles that can be assigned to users for the Design mode of a study.
- Roles for blinded study team 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 team 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.
- User Administrator
  View the permissions included in the User Administrator template study role. This template study role is of *Design* type and is available for all studies at your organization.
- Template study roles

Manage study users in bulk

User administrators can use the user upload template to add new and update existing study users in bulk. In this template you define user details, such as the effective date range for their access, their assigned study roles, and their site, and depot assignments.

- About the User Upload template
  From Oracle Clinical One Platform you can download the User Upload template file to manage study users in bulk. In the User Upload template you define the details of new users to be added or existing users to be updated. This template is only to manage study users within a given study.
- Add and update study users in bulk
  Download and use the User Upload template to add new and update existing study users in bulk.
- Guidelines for updating the User Upload template
  Consider the following guidelines to make proper use of the template and avoid errors during the import.

About the User Upload template

From Oracle Clinical One Platform you can download the User Upload template file to manage study users in bulk. In the User Upload template you define the details of new users to be added or existing users to be updated. This template is only to manage study users within a given study.

By default, users are uploaded in Production mode. However, during the upload process, you can enable **Upload users to training mode** to upload users for both Production and Training modes.

- For step-by-step instructions on how to download and use the upload template, see Add and update study users in bulk.
- For more information to fill in the template, see Guidelines for updating the User Upload template.

> **Note:**
>
> While you can manage a study's users with the User Upload template, you cannot use this template to create or manage accounts for global users, including Oracle Clinical One Digital Gateway users. For more information on how to create product administrator users, see Create accounts for different types of users with access to specific products.

For each user you add in the template, you define the user account details (such as user name and email address) and the details for the user's access within the study. These include the date range in which the access is effective, the study role, and the associated sites and depots.

When you enter a user account in the template that doesn't exist in Oracle Life Sciences IAMS, the upload process also creates the Oracle Life Sciences Single Sign-On (SSO) account for the user in Oracle Life Sciences IAMS. However, this is only supported for Clinical One SSO users, which are managed directly in Oracle Life Sciences IAMS. This behavior is not applicable to federated SSO users, which are managed outside of Oracle Life Sciences IAMS.

> **Caution:**
>
> It is important that you closely review the user account details entered in the template. If you mistype an email or user name for an existing account, it may result in the creation of a new account.

About the two available download options

In Oracle Clinical One Platform, there are two available options to download the user upload template and cover different use cases:

- **Create Users**
- **Update Users**

When you download a template to **Create Users**, you generate a file with an empty table for you to specify new users' details. When you download a template to **Update Users**, the

generated file is populated with current details of the existing study users in Production mode, to facilitate the task of updating those users.

In both cases, the template is validated and processed in the same way. This means both options support the functionality to add and update study users, as well as to create Oracle Life Sciences SSO accounts when applicable. For instance, you can add rows with updated details for existing users in the template generated to **Create Users**. And you can add rows with details for new users in the template generated to **Update Users**. All updates will be applied in your study as expected and regardless of the option used to generate the template.

Related Topics

- Add and update study users in bulk
  Download and use the User Upload template to add new and update existing study users in bulk.
- Add a user to a study in Oracle Clinical One Platform
  A product administrator with *Study Creator* role 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 study user administrator.
- Create study user accounts
  To create a study user in Oracle Clinical One Platform, a Customer Delagated Administrator (CDA) must create an Oracle Life Sciences Single Sign-on (SSO) in Oracle Life Sciences IAMS and assign product roles. Then the user can be added to the appropriate study in Oracle Clinical One Platform.
- Create an Oracle Life Sciences Single Sign-On (SSO)
  As the Customer Delegated Administrator (CDA), you use Oracle Life Sciences Identity and Access Management Service (IAMS) to create Oracle Life Sciences single sign-on (SSO) accounts for users in your organization. Users need an SSO account to access Oracle Clinical One Platform and Oracle Clinical One Digital Gateway.
- Create and manage Oracle Life Sciences Single Sign-Ons (SSO) 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.
- Download a report
- User Upload Error report

Add and update study users in bulk

Download and use the User Upload template to add new and update existing study users in bulk.

Before using this template, consider the following:

- This template is only to manage study users within a given study. For more information, see About the User Upload template.
- If the account for a new user included in the template doesn't exist, this template also creates the Oracle Life Sciences Single Sign-On (SSO) account for the user in Oracle Life Sciences Identity and Access Management Service (IAMS).

> **Caution:**
>
> It is important that you closely review the user account details entered in the template. If you mistype an email or user name for an existing account, it may result in the creation of a new account.

- For more information to fill in the template, see Guidelines for updating the User Upload template.

The User Upload Error report generates automatically after every import completed with errors, and includes details about the errors occurred during the upload. This report uses the same format as the User Upload template.

> **Tip:**
>
> You can fix errors directly in the User Upload Error report and re-upload that report, instead of filling a new User Upload template to upload it.

1. On the Home page, open the study's settings.
2. Navigate to the **Users** tab.

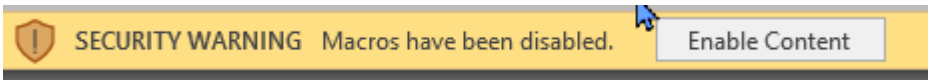
   If you are using an User Upload Error report instead of a new template file, skip to step number 9.
3. Click **Download Template** and select either one of the following options to download the template that you need:
   - **Create Users**: this option downloads a template with an empty users table.
   - **Update Users**: this option downloads a template populated with all current study users.

   > **Tip:**
   >
   > In both cases, the template is populated with the current active study roles available in the study. You should always download a new template to pick up any changes applied to your study.
4. Open the template.
5. In the **Clinical One Users** tab, enter details for each user:
   - In the template generated to **Create Users**, enter the details for new users to be added.
   - In the template generated to **Update Users**, locate the existing user you want to update, and edit the necessary details.

> **Note:**
>
> Both templates support the functionality to add and update study users, as well as to create SSO accounts when they don't exist.
> For instance, you can add rows with updated details for existing users in the template generated to **Create Users**, or add rows with details for new users in the template generated to **Update Users**. In both cases your updates will get properly applied.

6. Click **Validate** and then click **OK** in the confirmation dialog.

   After you click **Validate**, macros run to ensure required data is present and adheres to the required format. To do this, make sure macros are enabled on the file.



7. If applicable, address any issues identified by the macros. Cells with errors get highlighted after the validation.
8. Save and close the file.
9. In Oracle Clinical One Platform, return to the **Users** tab in your study's settings, and click **Create/Assign User**.
10. In the Create/Assign Users dialog, click **Upload File** for one of the following options:
    - Upload Clinical One SSO users
    - Upload federated SSO users
11. When prompted, select the file (*user upload template* or *user upload error report*) previously saved, and click **Open**.

    A screen to Map Roles opens in the Upload Users dialog. The roles in the import file are automatically mapped to the roles available in the study. However, you can manually map roles differently using the drop-downs on this screen.
12. Review the role mappings and click **Next**.
13. In the preview window, review the user details to be uploaded and do the following:
    - (Optional) Select the **Upload users to training mode** checkbox if users should be created or updated in both Production and Training mode.
    - (Optional) Enter comments in the comment box. Comments are included in the User Assignment report, the User Assignment by Site report and the User Upload Error report.
14. Click **Upload**.

An information message displays in the Users tab summarizing the amount of users being uploaded. When the upload completes, a confirmation email is sent with the subject *Bulk User Upload notifications*.
Check the notification for any users with errors. If there are any errors, download the User Upload Error report to review and address any import issues. You can fix errors directly in the report and upload it (following these same steps) for a successful import.

Related Topics

- About the User Upload template
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users to be added or existing users to be updated. This template is only to manage study users within a given study.

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  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.
- Download a report
- User Upload Error report

Guidelines for updating the User Upload template

Consider the following guidelines to make proper use of the template and avoid errors during the import.

- You should always download a new template to pick up any changes applied to your study. This includes an updated list of study roles and, for the pre-populated template to update users, the current details of all extisting study users in production mode.
- In the User Upload template, you must add one row for each user you want to add or update.

> **Tip:**
>
> If you are using a pre-populated template to update users, you don't need to add a row for an existing user, but locate it in the table to update directly.

- Users assigned with retired roles are not included in the auto-populated table of the template to update users. To update such users you must add them manually including the desired changes.
- For each study user, you must complete the following details in the given columns:

> **Note:**
>
> Even though there is no distinction between the type of fields in the template, we can group the available columns into two different categories, user account details and user access details.

User account details

Column	Required or Optional	Description
First Name	Required	Enter the first name of the user, as defined in the Oracle Life Sciences Single Sign-On (SSO) account.
Last Name	Required	Enter the last name of the user, as in the SSO account.
Email	Required	Enter the email address associated to the user account.
User Name	Required	Enter the user name for the user account. This is the user name used to login to Oracle Clinical One Platform.

User access details

Column	Required or Optional	Description
Start Date	Required	Enter the start date of the effective date range for the user access.
End Date	Optional	Enter the end date of the effective date range for the user access. If no end date is entered the user will have access until an end date is entered or the study is decomissioned.
Role	Required	Select a role from the drop-down. This drop-down is pre-populated with all active study roles available in the given study, including template roles. ***Note:*** *This template is for study roles to be assigned in production and training modes, so retired roles and design roles are not included.*
Site IDs	Optional	Enter the site IDs for which the user must have access. Use a semicolon to separate multiple sites or enter *All* if user must have access to all sites.
Depot IDs	Optional	Enter the depot IDs for which the user must have access. Use a semicolon to separate multiple depots or enter *All* if user must have access to all depots.

- 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 time to import.
- Existing study users included in the template with no updates won't be impacted and an audit record for the user update won't be created. If you work with the pre-populated template to update users, you don't need to remove rows for non-updated users. However, all uploaded users are included in the counts for the Bulk User Upload notifications, even users that were not updated. If you want to keep the non-updated users out of these counts for better assessment, we do recommend you delete non-updated users from the pre-populated template.
- After you click **Validate**, macros run to ensure required data is present and adheres to the required format. To do this, make sure macros are enabled on the file.

- 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. A file with errors might import successfully but the user may not be created or updated appropriately. Such errors are tracked in the User Upload Error report.
- The User Upload report report generates automatically after every import completed with errors, and includes details about what has failed.

> **Tip:**
>
> This report uses the same format as the User Upload template. You can fix errors directly in the report and upload it instead of the user upload template.

- 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 upload the user upload template for both Oracle Clinical One Platform SSO users and Federated users.
- You cannot upload details for Oracle users in your study using the upload template. Doing so throws an error message which states that the upload of Oracle users is not supported. These users must be individually assigned to a study. See Add a user to a study in Oracle Clinical One Platform.

Related Topics

- Add and update study users in bulk
  Download and use the User Upload template to add new and update existing study users in bulk.
- About the User Upload template
  From Oracle Clinical One Platform you can download the User Upload template file to manage study users in bulk. In the User Upload template you define the details of new users to be added or existing users to be updated. This template is only to manage study users within a given study.
- Add a user to a study in Oracle Clinical One Platform
  A product administrator with *Study Creator* role 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 study user administrator.
- Create study user accounts
  To create a study user in Oracle Clinical One Platform, a Customer Delagated Administrator (CDA) must create an Oracle Life Sciences Single Sign-on (SSO) in Oracle Life Sciences IAMS and assign product roles. Then the user can be added to the appropriate study in Oracle Clinical One Platform.
- Create an Oracle Life Sciences Single Sign-On (SSO)
  As the Customer Delegated Administrator (CDA), you use Oracle Life Sciences Identity and Access Management Service (IAMS) to create Oracle Life Sciences single sign-on (SSO) accounts for users in your organization. Users need an SSO account to access Oracle Clinical One Platform and Oracle Clinical One Digital Gateway.
- Create and manage Oracle Life Sciences Single Sign-Ons (SSO) 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.

- Download a report
- User Upload Error report

Remove a study user

You can remove a user from a study if the user is no longer part of it or if they should no longer have access.

This task can be performed by both a global user manager and a study user administrator.

We recommend you only perform this task if a user has been added to the study or the application in error. If you must terminate access for the user to your study, it is recommended to upadate the end date for their effective date range instead of removing them. See Edit a study user.

To remove a user in Oracle Life Sciences IAMS, reach out to the Customer Delegated Administrator (CDA) for your organization and refer to Terminate or reinstate an account.

1. From the Home page, Open the study's settings.
2. Navigate to the **Users** tab.
3. Locate the user you want to remove and select it.
4. From the **Manage Users** drop-down select **Remove**.
5. On the Confirmation dialog, click **Yes**.

Related Topics

- Remove a global user in Oracle Clinical One Platform
  You can remove a global user if the user is no longer part of your team or should no longer have access to your organization at the global level.
- Add a user to a study in Oracle Clinical One Platform
  A product administrator with *Study Creator* role 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 study user administrator.
- Edit a study user
  A study user administrator or a product administrator with the *Study Creator* or *Global User Manager* roles can modify a study user at any time. The details that can be edited for a study user include: the effective date range for their access, their assigned study roles and their site and depot assignments.

Manage study roles

In Oracle Clinical One Platform you can have study roles created at the global level and at the study level. Global-level study roles are available for the entire organization and can be used in all studies. Study roles at the study level only exist for the particular study in which they were created.

Oracle Clinical One Platform provides a list of template study roles available for your entire orgnaization, which contain standard combinations of permissions. However it is not recommended to assign template roles to users, as these don't have any data classification assignment and cannot be modified. Instead, you should create and assign custom study roles which can be modified at any time, even when already assigned to users.

> **Tip:**
>
> Template study roles can be copied into new custom study roles. For details on the available template roles and their permissions see Template study roles.

- Create a study role at the global level
  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 at the study level
  You can create a study role that 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 is part of that study.
- Edit a study role
  As a global user manager or study user administrator you can edit an existing study role. Study roles can be modified even if the study role is already assigned to users.
- Specify data classifications for a study role
  Data classifications allow you to control the type of data users can view or edit in a study. Data classifications defined for a study role dictate the type of data a study role provides access to with either view or edit privileges.
- Retire a study role
  Study roles can never be completely removed, but if a study role is no longer of use in your study, you can always retire it. Users assigned with the now retired study role will not lose their permissions. Retired study roles are simply made unavailable for new use.

Create a study role at the global level

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.

> **Note:**
>
> Newly created global-level study roles, as well as updates to existing ones, do not automatically propagate into existing 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 it from the list and then, from the **Manage Study Role** drop-down, select **Copy**.

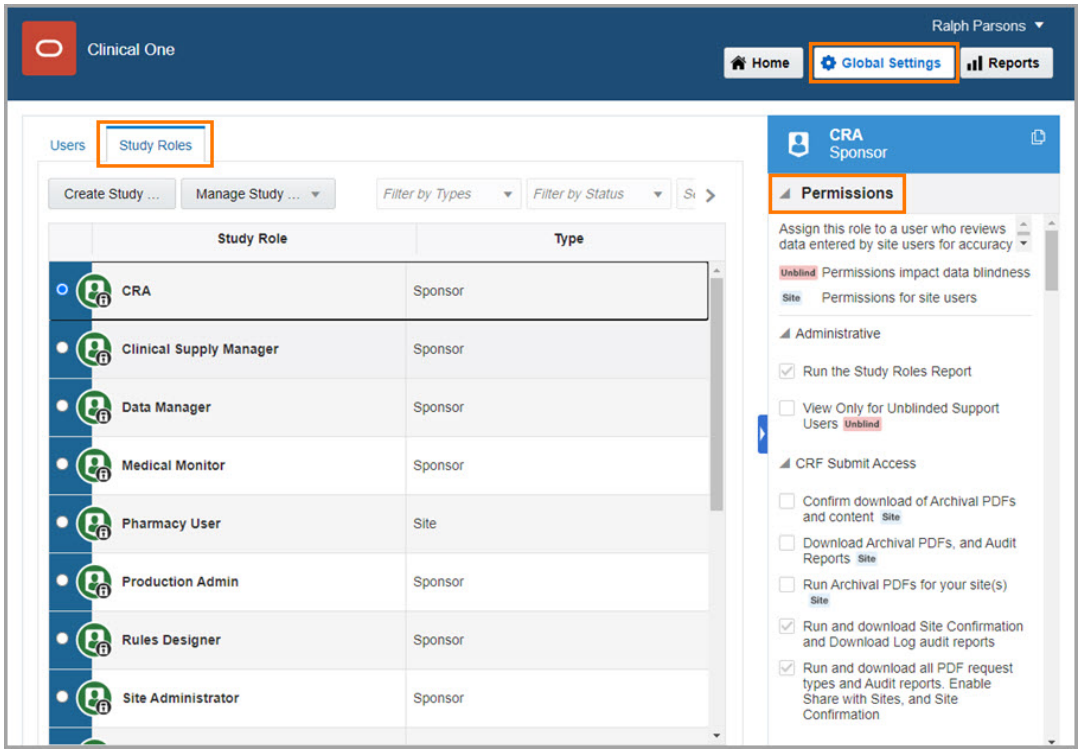
> **Tip:**
>
> You can copy and customize template study roles as well as retired study roles. Remember template study roles should not be assigned to users.

- 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 is for members of the study team at either the sponsor or CRO.
     - Select **Site** if the role is for site users.
     - Select **Design** if the role is for the study design mode.
   - **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. For more information on the available permissions see Descriptions of permissions in Oracle Clinical One Platform.
6. Click **Save**.

   You now can start assigning this study role to users.



Related Topics

- Create a study role at the study level
  You can create a study role that 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 is part of that study.
- Edit a study role
  As a global user manager or study user administrator you can edit an existing study role. Study roles can be modified even if the study role is already assigned to users.
- Retire a study role
  Study roles can never be completely removed, but if a study role is no longer of use in your study, you can always retire it. Users assigned with 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 the type of data users can view or edit in a study. Data classifications defined for a study role dictate the type of data a study role provides access to with either view or edit privileges.
- Roles for Study Design mode
  Learn more about the roles that can be assigned to users for the Design mode of a study.
- Roles for blinded study team 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 team 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.
- Descriptions of permissions in Oracle Clinical One Platform
  There are three different types of study roles: *Sponsor*, *Site* and *Design*. According to the study role type, a different set of permissions is availbale to assign. Browse descriptions and additional information for every study role permission available in the application.

Create a study role at the study level

You can create a study role that 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 is part of that study.

1. From the Home page, Open the study's settings.
2. Navigate to the **Study Roles** tab.
3. You can either:
   - Copy an existing study role by selecting it from the list and then, from the **Manage Study Role** drop-down, select **Copy**.

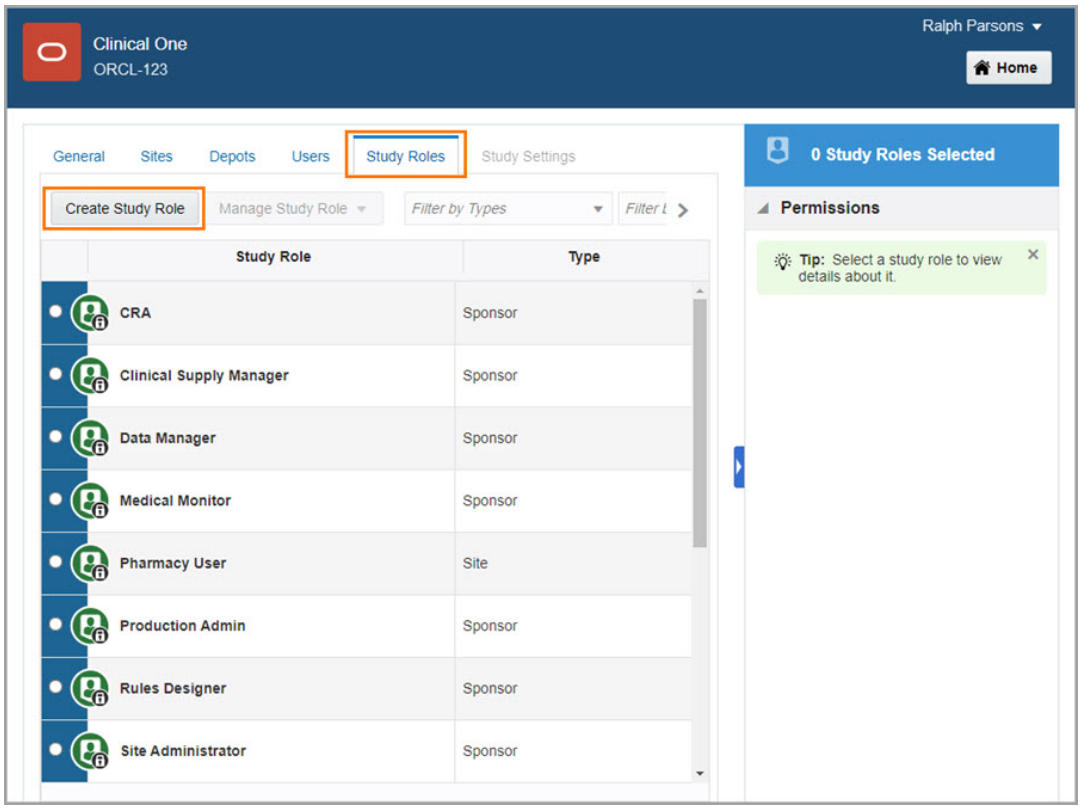
     > **Tip:**
     >
     > You can copy and customize template study roles as well as retired study roles. Remember template study roles should not be assigned to users.

   - 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 is for members of the study team at either the sponsor or CRO.
     - Select **Site** if the role is for site users.
     - Select **Design** if the role is for the study design mode.
   - **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. For more information on the available permissions see Descriptions of permissions in Oracle Clinical One Platform.
6. Click **Save**.

   You now can start assigning this study role to users.



Next step: Specify data classifications for a study role.

Related Topics

- Edit a study role
  As a global user manager or study user administrator you can edit an existing study role. Study roles can be modified even if the study role is already assigned to users.

- Retire a study role
  Study roles can never be completely removed, but if a study role is no longer of use in your study, you can always retire it. Users assigned with 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 the type of data users can view or edit in a study. Data classifications defined for a study role dictate the type of data a study role provides access to with either view or edit privileges.
- Roles for Study Design mode
  Learn more about the roles that can be assigned to users for the Design mode of a study.
- Roles for blinded study team 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 team 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.
- Descriptions of permissions in Oracle Clinical One Platform
  There are three different types of study roles: *Sponsor*, *Site* and *Design*. According to the study role type, a different set of permissions is availbale to assign. Browse descriptions and additional information for every study role permission available in the application.

Edit a study role

As a global user manager or study user administrator you can edit an existing study role. Study roles can be modified even if the study role is already assigned to users.

While global user managers can edit study roles at both the global and the study level, study user administrators can only edit study roles at the study level.

> **Note:**
>
> The changes that you apply in study roles at the study level are automatically reflected for the users already assigned with them. Updates to existing global study roles only apply to newly created studies but do not automatically propagate to existing studies.

You can edit a study role anytime you want, but you cannot update template study roles provided by Oracle. Template study roles are read-only and locked from any type of modification.

1. From the Home page, Open the study's settings.
2. Navigate to the **Study Roles** tab.
3. Locate the existing study role that you want to edit and select it.
4. On the **Permissions** pane on the right, 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 can easily identify which users can be assigned with this role.
   - **Type**:

  - Select **Sponsor** if the role is for members of the study team at either the sponsor or CRO.
  - Select **Site** if the role is for site users.
  - Select **Design** if the role is for the study design mode.
- **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.

> **Caution:**
>
> 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.

For more information on the available permissions see Descriptions of permissions in Oracle Clinical One Platform.

6. Click **Apply Changes**.

Related Topics

- Create a study role at the study level
  You can create a study role that 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 is part of that study.
- Specify data classifications for a study role
  Data classifications allow you to control the type of data users can view or edit in a study. Data classifications defined for a study role dictate the type of data a study role provides access to with either view or edit privileges.
- Retire a study role
  Study roles can never be completely removed, but if a study role is no longer of use in your study, you can always retire it. Users assigned with the now retired study role will not lose their permissions. Retired study roles are simply made unavailable for new use.
- Add a user to a study in Oracle Clinical One Platform
  A product administrator with *Study Creator* role 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 study user administrator.
- Edit a study user
  A study user administrator or a product administrator with the *Study Creator* or *Global User Manager* roles can modify a study user at any time. The details that can be edited for a study user include: the effective date range for their access, their assigned study roles and their site and depot assignments.
- Manage study users in bulk
  User administrators can use the user upload template to add new and update existing study users in bulk. In this template you define user details, such as the effective date range for their access, their assigned study roles, and their site, and depot assignments.

- Descriptions of permissions in Oracle Clinical One Platform
  There are three different types of study roles: *Sponsor*, *Site* and *Design*. According to the study role type, a different set of permissions is availbale to assign. Browse descriptions and additional information for every study role permission available in the application.

Specify data classifications for a study role

Data classifications allow you to control the type of data users can view or edit in a study. Data classifications defined for a study role dictate the type of data a study role provides access to with either view or edit privileges.

In form design, labels for data classifications are assigned to hidden form questions to categorize them as different types of data. Study designers assign these data classification labels when defining a hidden question. Work with your study designer and refer to Define data classifications for a hidden question.

As part of your user management tasks, you define data classifications of a study role to allow either view or edit privileges for each data classification. These study role data classifications can be defined by global user managers or study user administrators, but are only defined at the study level.

How do data classifications work? For instance, study designers can add and hide a question for a subject's Social Security Number in a form and then classify the data as Personal Identifiable Information (PII) data. From the user management side, you assign to the *site user* and *unblinded data manager* study roles with the privileges to view or edit PII Data. As a reult, that field gets hidden to all users except for site users and unblinded data managers.

1. From the Home page, Open the study's settings.
2. Navigate to the **Study Roles** tab.
3. Select the study role for which you want to specify data classifications.
4. On the right pane, expand **Data Classifications**.
5. Select the appropriate check boxes to grant either View or Edit privileges for the available 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**.

Related Topics

- Create a study role at the study level
  You can create a study role that 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 is part of that study.
- Edit a study role
  As a global user manager or study user administrator you can edit an existing study role. Study roles can be modified even if the study role is already assigned to users.

- Retire a study role
  Study roles can never be completely removed, but if a study role is no longer of use in your study, you can always retire it. Users assigned with the now retired study role will not lose their permissions. Retired study roles are simply made unavailable for new use.
- Add a user to a study in Oracle Clinical One Platform
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- Edit a study user
  A study user administrator or a product administrator with the *Study Creator* or *Global User Manager* roles can modify a study user at any time. The details that can be edited for a study user include: the effective date range for their access, their assigned study roles and their site and depot assignments.
- Manage study users in bulk
  User administrators can use the user upload template to add new and update existing study users in bulk. In this template you define user details, such as the effective date range for their access, their assigned study roles, and their site, and depot assignments.
- Descriptions of permissions in Oracle Clinical One Platform
  There are three different types of study roles: *Sponsor*, *Site* and *Design*. According to the study role type, a different set of permissions is availbale to assign. Browse descriptions and additional information for every study role permission available in the application.
- Define data classifications for a hidden question

Retire a study role

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

You can retire a study role anytime you want, but you cannot retire template study roles provided by Oracle. Template study roles are read-only and locked from any type of modification.

This task can be performed by both a global user manager and a study user administrator.

1. From the Home page, Open the study's settings.
2. Navigate to the **Study Roles** tab.
3. Locate 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 to the one that you retired, you can always copy it. See Create a study role at the study level.

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

Related Topics

- Create a study role at the study level
  You can create a study role that 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 is part of that study.
- Edit a study role
  As a global user manager or study user administrator you can edit an existing study role. Study roles can be modified even if the study role is already assigned to users.
- Specify data classifications for a study role
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- Edit a study user
  A study user administrator or a product administrator with the *Study Creator* or *Global User Manager* roles can modify a study user at any time. The details that can be edited for a study user include: the effective date range for their access, their assigned study roles and their site and depot assignments.
- Manage study users in bulk
  User administrators can use the user upload template to add new and update existing study users in bulk. In this template you define user details, such as the effective date range for their access, their assigned study roles, and their site, and depot assignments.

Types of study roles in Oracle Clinical One Platform

Study roles represent a collection of permissions that, when assigned, allow users to perform specific tasks. You must be mindful to create the correct type of study role (*Sponsor*, *Site* or *Design*) and include only the relevant permissions to the role, without compromising the study blind.

Oracle Clinical One Platform provides a list of template study roles available for your entire orgnaization. Template study roles already contain the standard combinations of permissions for each type of user that typically takes part in a study. However, it is not recommended to assign template roles to users, as these don't have any data classification assignment and cannot be modified. See Template study roles.

As a user administrator, you can leverage the existing study role templates using them as a starting point to create custom study roles. By creating a copy of a template study role, you have a new study role with a specific combination of permissions which you can modify at any time, even when already assigned to study users. Working with custom study roles allows you to add or remove permissions and data classifications as required. See Manage study roles.

For more details on the available permissions, to identify which to include in (or remove from) a given study role, see Descriptions of permissions in Oracle Clinical One Platform.

Browse the different types of study roles available in Oracle Clinical One Platform:

- Roles for Study Design mode
  Learn more about the roles that can be assigned to users for the Design mode of a study.

- Roles for blinded study team 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 team 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.

Roles for Study Design mode

Learn more about the roles that can be assigned to users for the Design mode of a study.

- **Type**: Design.
- **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.

> **Note:**
>
> Global users with the *Study Creator* role are the only users who can assign study users with roles for the study design mode. This means they are the only ones capable to add users as study user administrators and study designers. See Roles in user management.

Role	Responsibilities
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. ***Note:*** *A study designer typically has a global-level access as a* Study Creator*. 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.
View Study Design	• View a study's design. ***Note:*** This is a standalone study role that can be assigned to an unblinded study team member or site user who should view the study's design.

Roles for blinded study team users

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

- **Type**: Sponsor.
- **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.

Role	Responsibilities
Adjudicator	• View, edit, and manage classified subject data.
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. ***Note:*** *The Blinded Depot User role hides full details and descriptions of kits to protect blinding. However, kit numbers for all blinded, unblinded, and unblinded pharmacist kits are displayed.* *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 ***Note:*** *Although a CRA is typically a blinded study team member, they can also be unblinded when they need to review Unblinded Pharmacist kits, as long as they 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.
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.
Site Administrator	• Run reports and perform study setup tasks. • Create, view, and manage depots.
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.

Roles for unblinded study team users

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

- **Type**: Sponsor.
- **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.

Role	Responsibilities
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.
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.
ODM Extract	Extract several types of data in an ODM-XML format: • Administrative data • Clinical data • Metadata
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. ***Note:*** *Rule designers who must add or edit custom JavaScript rules, besides the Rule Designer study role, also need a* study design role *to be able to use the Rules sidebar in a form. At a minimum, assign the* View Study Design *study role.*
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.
Unblinded Depot User	• View data and manage shipments at a depot.
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

Roles for site users

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

- **Type**: Site
- **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.

Role	Responsibilities
Site User (Blinded)	• 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.
Pharmacy User - Unblinded	• View collected data at a site. • Manage a site's inventory. • Run reports.
Principal investigator	• Approve and sign data. • Edit data in order to sign it. • Run reports.

Best practices for role, site, and depot assignment

Users with different responsibilities require different assignements. For example, some users need the ability to add users to a study, some others need permissions for study design or study management tasks. Similarly, some users need access to all sites and depots, while some others need access only to specific facilities.

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 decide 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
  Even if you have global user managers at your organization, you must have a user administrator in each study to manage other study users and assign them to individual sites and depots. The user administrator site and depot assignments determine which sites and depots they can assign to other users.
- Assignments for study team members
  As a study 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
  A product administrator with *Study Creator* role 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 study user administrator.

Assignments for user administrators

Even if you have global user managers at your organization, you must have a user administrator in each study to manage other study users and assign them to individual sites and depots. The user administrator site and depot assignments determine which sites and depots they can assign to other users.

The user administrator study role is of *Design* type and can only be assigned for the Study Design mode, but user administrators might have other roles too. For example, a user who is a user administrator in Study Design mode can be assigned with any other *Sponsor* or *Site* type study role in Production, Testing or Training modes. Typically, study user administrators are site administrators in Production, Testing and Training modes. See, Types of study roles in Oracle Clinical One Platform.

> **Note:**
>
> Global users with the *Study Creator* role are the only users who can assign study users with roles for the study design mode. This means they are the only ones capable to add users as study user administrators and study designers. See Roles in user management.

Even though study creators can add other study users, they do not have access to individual sites. If you are a study creator and must manage other study users and their assignments, consider adding yourself to the study as the study user administrator.

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

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 modes, select the desired role. This would typically be 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
  A product administrator with *Study Creator* role 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 study user administrator.
- Assignments for study team members
  As a study 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 study 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. However, it is ultimately up to you and your study's needs to decide on which sites and depots users should be assigned to.

Job role	Study role assignment	Site assignment	Depot assignment
Clinical supply manager	• You don't need to select any study role for the Study Design mode. • For Testing, Production, and Training mode, select the **Clinical Supply Manager** role.	Choose **All Sites**.	Choose **All Depots**.

Job role	Study role assignment	Site assignment	Depot assignment
Statistician	• You don't need to select any study role for the Study Design Mode. • 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.

Job role	Study role assignment	Site assignment	Depot assignment
Study manager	• You don't need to select any study role for the Study Design mode. • For Testing, , Production, and Training mode, select the **Study Manager** role.	Choose **All Sites**.	Assign no depots.
Clinical Research Associate (CRA)	• You don't need to select any study role for the Study Design mode. • 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	• You don't need to select any study role for the Study Design mode. • For Testing, Production, and Training mode, select the **Data Manager** role.	Choose **All Production Sites** and **All Training Sites**.	Assign no depots.
Safety monitor	• You don't need to select any study role for the Study Design mode. • For Testing, Production, and Training mode, select the **Medical Monitor** role.	• Select **All Production Sites** and **All Training Sites**. • Select any Testing sites that the user will work in.	Assign no depots.
Production administration	• You don't need to select any study role for the Study Design mode. • 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
  A product administrator with *Study Creator* role 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 study user administrator.
- Assignments for user administrators
  Even if you have global user managers at your organization, you must have a user administrator in each study to manage other study users and assign them to individual

sites and depots. The user administrator site and depot assignments determine which sites and depots they can assign to other users.

- 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. However, it is ultimately up to you and your study's needs to decide on which sites and depots users should be assigned to.

Job role	Study role assignment	Site assignment	Depot assignment
Site user	• You don't need to select any study role for the Study Design mode. • 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 of 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	• You don't need to select any study role for the Study Design mode. • For Testing, Production, and Training mode, select the **Pharmacy** study role, particularly if the user is responsible of 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.

Job role	Study role assignment	Site assignment	Depot assignment
Depot user	• You don't need to select any study role for the Study Design mode. • For Testing mode, don't select any 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
  A product administrator with *Study Creator* role 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 study user administrator.
- Assignments for user administrators
  Even if you have global user managers at your organization, you must have a user administrator in each study to manage other study users and assign them to individual sites and depots. The user administrator site and depot assignments determine which sites and depots they can assign to other users.
- Assignments for study team members
  As a study 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.

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.

6

Template study roles

- Statistician - Unblinded
  View the permissions included in the Statistician - Unblinded template study role. This template study role is of *Sponsor* type and is available for all studies at your organization.
- Study Designer
  View the permissions included in the Statistician - Unblinded template study role. This template study role is of *Design* type and is available for all studies at your organization.
- Study Manager
  View the permissions included in the Study Manager template study role. This template study role is of *Sponsor* type and is available for all studies at your organization.
- Unblinded Depot User
  View the permissions included in the Unblinded Depot User template study role. This template study role is of *Sponsor* type and is available for all studies at your organization.
- User Administrator
  View the permissions included in the User Administrator template study role. This template study role is of *Design* type and is available for all studies at your organization.
- View Only for Unblinded Support Users
  View the permissions included in the View Only for Unblinded Support Users template study role. This template study role is of *Sponsor* type and is available for all studies at your organization.
- View Study Design
  View the permissions included in the View Study Design template study role. This template study role is of *Design* type and is available for all studies at your organization.

About template study roles

You can find predefined study roles as templates on the Study Roles tab, both on the **Global Settings** and in a study's settings. Template study roles are created by Oracle and can't be modified, hence they display a lock icon and include the word *"Template"* in their names for easy identification.

> **Note:**
>
> Changes to global study roles do not propagate into existing studies. This applies to template study roles, which may get updated with the introduction of new permissions to support new features in the product. All template study roles described in this chapter specify permissions as in the **Global Settings**.

Consider the following about template study roles:

- Do not assign template study roles. Template study roles should always be copied and customized to be used.
  Template study roles do not have any data classification assignments and cannot be modified. Use custom study roles to control data classifications and to add or remove permissions as required.
- You can create customized copies of template study roles at the study level or at the global level (for all studies in your organization).
- When you create a copy, make sure you add or remove any permissions that may or may not be required for your study team, based on their responsibilities. For more information on the available permissions, see Descriptions of permissions in Oracle Clinical One Platform.

- You can also learn more about the permissions included in each of the template and custom study roles by running the Global Study Roles report and the Study Roles report (by study).

Adjudicator

View the permissions included in the Adjudicator template study role. This template study role is of *Sponsor* type and is available for all studies at your organization.

> **Note:**
>
> You should always copy a template role and begin customizing it within the context of your study. For more information, see About template study roles.

Table 6-1 Permissions included in the Adjudicator template study role

Category	Assigned permissions
Clinical Data Collection	• *Approve and Sign Assigned Data Only* • *Edit Classified Subject Data Only* • *View Classified Subject Data Only*

For more information on each of these permissions, see Descriptions of permissions in Oracle Clinical One Platform.

Blinded Depot User

View the permissions included in the Blinded Depot User template study role. This template study role is of *Sponsor* type and is available for all studies at your organization.

> **Caution:**
>
> Use this template study role with caution. The Blinded Depot User permission grants access to view the Sequence Number, which could potentially unblind the study for blinded site and sponsor users.

Before you use this template study role, consider the following:

- The Blinded Depot User is both a template study role and an individual permission. The Blinded Depot User template study role contains the specific *Blinded Depot User* permission, along with other permissions.
- Before you use this template study role, consider that the Blinded Depot User study role can become unblinded by adding the permission *Create Shipments to Depots* [Unblind] to it. This permission exposes all kit descriptions to the user.

> **Note:**
>
> You should always copy a template role and begin customizing it within the context of your study. For more information, see About template study roles.

Table 6-2 Permissions included in the Blinded Depot User template study role

Category	Assigned permissions
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 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*
Study Management	• *Create Shipments to DDF*

For more information on each of these permissions, see Descriptions of permissions in Oracle Clinical One Platform.

Clinical Research Associate (CRA)

View the permissions included in the CRA template study role. This template study role is of *Sponsor* type and is available for all studies at your organization.

> **Note:**
>
> You should always copy a template role and begin customizing it within the context of your study. For more information, see About template study roles.

Table 6-3 Permissions included in the CRA template study role

Category	Assigned permissions
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* • *Update Subject Number after Creation* • *View Blinded Dispensation Details with Calculated Doses* [Site] • *View Blinded Dispensation Details without Calculated Doses* [Site] • *View Classified Subject Data Only* • *View Form Data for Subjects* • *View Queries* [Site]
Inventory Management	• *Create Manual Shipments* • *Perform Supplies Reconciliation at Site* • *View Shipments to Sites* • *View Site Inventory*

Table 6-3 (Cont.) Permissions included in the CRA template study role

Category	Assigned permissions
Notifications	• *Receive Notification of Shipments* • *Receive Rule Failure Notification for Locked Data* • *Receive Site has been Updated Notification* • *Receive the Code Break Notification* • *Receive the Dispensation Notification* • *Receive the Pending Signatures Notification* • *Receive the Randomization Notification* • *Receive the Study Limits Notifications* • *Receive the Subject Completion Notification* • *Receive the Subject Number Update Notification* • *Receive the Subject Rollover Notification* • *Receive the Subject Screening Notification* • *Receive the Subject Transferred Notification* • *Receive the Subject Undo Completion Notification* • *Receive the Subject Undo Screen Failure Notification* • *Receive the Subject Undo Withdrawal Notification* • *Receive the Subject Visit Notification* • *Receive the Subject Withdrawal Notification* • *Receive the Unscheduled Visit Notification*
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 Lab Normal Range 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 Query Report* • *Run the Subject Visit Report* • *Run the Titration Summary Report* • *Run the Training Report* • *Run the User Assignment Report* • *Schedule Reports to Run*
Settings	• *Manage Signature Settings*

Table 6-3 (Cont.) Permissions included in the CRA template study role

Category	Assigned permissions
Study Management	• *Answer Assigned Queries* • *Close All Queries* • *Close Auto Queries* (planned for a future release) • *Close Queries By Role* (planned for a future release) • *Create Candidate Queries* • *Create Queries* • *Create Shipments to DDF* • *Delete Candidate Queries* • *Perform Source Data Verification and Reconcile Inventory* • *Transfer subjects between sites* • *Unfreeze subject data entered at a site* • *Verify subject data entered at a site* • *View All Queries*
Study Setup	• *Assign a Study Version to a Site* • *Create and Manage SDV Strategies* • *Manage Archives Settings* • *View Depots* • *View Regions* • *View Roles Assignments for Study Users* • *View Sites* • *View Study Design* • *View Study Settings*
Trial Management	**Note**: All permissions listed in this category are planned for a future release. • *Close Trial Management Events* • *Create Actions on Trial Management Event Records* • *Create Trial Management Event Records* • *Create Unblinded Trial Management Records* [Unblind] • *Edit Actions on Trial Management Event Records* • *Edit Trial Management Event Records* • *Edit Unblinded Trial Management Records* [Unblind] • *Open Trial Management Events* • *View Actions on Trial Management Event Records* • *View Blinded Trial Management Records* • *View Trial Management Event Records* • *View Trial Management Event Records with Actions Assigned to me* • *View Unblinded Trial Management Records* [Ublind]

For more information on each of these permissions, see Descriptions of permissions in Oracle Clinical One Platform.

Clinical Supply Manager - Unblinded

View the permissions included in the Clinical Supply Manager - Unblinded template study role. This template study role is of *Sponsor* type and is available for all studies at your organization.

> **Note:**
>
> You should always copy a template role and begin customizing it within the context of your study. For more information, see About template study roles.

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

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

Table 6-4 Permissions included in the Clinical Supply Manager - Unblinded template study role

Category	Assigned permissions
Clinical Data Collection	• *Edit Classified Subject Data Only* • *View Blinded Dispensation Details with Calculated Doses* [Site] • *View Blinded Dispensation Details without Calculated Doses* [Site] • *View Classified Subject Data Only* • *View Form Data for Subjects*
Data Extract	• *Run the Subject Data Extract* [Unblind]
Inventory Management	• *Blinded Depot User* • *Create Manual Shipments* • *Create Manual Shipments (Unblinded)* [Unblind] • *Create Shipments to Depots* [Unblind] • *Create and Manage Dispensation Exceptions* • *Receive New Shipments at the Depot* • *Receive and Reconcile Shipments at the Depot* • *Release Shipments from Quarantine* • *Update Supplies after Design Approval* [Unblind] • *Update the Shipment Order Form* • *View Shipments to Sites* • *View Site Inventory*

Table 6-4 (Cont.) Permissions included in the Clinical Supply Manager - Unblinded template study role

Category	Assigned permissions
Notifications	• *Receive Notification of Depot Shipments* [Unblind] • *Receive Notification of Shipments* • *Receive Notification of Shipments Not Received for All Sites* • *Receive Site has been Updated Notification* • *Receive the Quarantined Depot Shipment Notification* • *Receive the Quarantined Site Shipment Notification* • *Receive the Released from Quarantine Notification (Depot)* • *Receive the Study Limits Notifications* • *Receive the Subject Rollover Notification* • *Receive the Unblinded Dispensation Notification* [Unblind] • *Receive the Unblinded Dose Hold Notification* [Unblind] • *Receive the Unblinded Kit Misallocation Notification* [Unblind] • *Receive the Unscheduled Visit Notification*
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 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 Supply Prediction Report* [Unblind] • *Run the Titration Summary Report* • *Run the Training Report* • *Run the Unblinded Chain of Custody Report* [Unblind] • *Run the Unblinded Inventory Report* [Unblind] • *Run the Unblinded Kits Dataset* [Unblind] • *Run the Unblinded Subject Events Dataset* [Unblind] • *Run the Unblinded Subject Visit Schedule Report* [Unblind] • *Run the Unblinded Titration Summary Report* [Unblind] • *Run the User Assignment Report* • *Schedule Reports to Run*
Study Management	• *Perform Source Data Verification and Reconcile Inventory*

Table 6-4 (Cont.) Permissions included in the Clinical Supply Manager - Unblinded template study role

Category	Assigned permissions
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* [Unblind] • *Create and Manage Sites* • *Edit Regions* • *Edit Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies* [Unblind] • *Upload and Generate Inventory Lists* [Unblind] • *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* [Unblind]
Unblinded Study Management	• *Manage Study Inventory for Unblinded Users* [Unblind] • *Update Inventory Lists* [Unblind]

For more information on each of these permissions, see Descriptions of permissions in Oracle Clinical One Platform.

Data Manager

View the permissions included in the Data Manager template study role. This template study role is of *Sponsor* type and is available for all studies at your organization.

> **Note:**
>
> You should always copy a template role and begin customizing it within the context of your study. For more information, see About template study roles.

A user who is assigned this template 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

Table 6-5 Permissions included in the 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*
Clinical Data Collection	• *Add a Lab to a Site* [Site] • *Add and Update Lab Normal Ranges* • *Create and Add Labs to a Site* • *Edit Classified Subject Data Only* • *View Classified Subject Data Only* • *View Form Data for Subjects* • *View Queries* [Site] **Note**: When a data manager is assigned the *Edit Classified Subject Data Only* permission, 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.
Data Extract	• *Run the Subject Data Extract* [Unblind]
Notifications	• *Receive the Code Break Notification* • *Receive the Pending Signatures Notification* • *Receive the Study Limits Notifications* • *Receive the Subject Completion Notification* • *Receive the Subject Number Update Notification* • *Receive the Subject Rollover Notification* • *Receive the Subject Undo Completion Notification* • *Receive the Subject Undo Screen Failure Notification* • *Receive the Subject Undo Withdrawal Notification*
Reports	• *Run the Blinded Chain of Custody Report* • *Run the Blinded Randomization Report* • *Run the Blinded Subject Events Dataset* • *Run the Kit Dispensation Report* • *Run the Lab Normal Range Report* • *Run the Study Codelist Dataset* • *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* • *Schedule Reports to Run*
Settings	• *Manage Signature Settings*

Table 6-5 (Cont.) Permissions included in the Data Manager template study role

Category	Permissions assigned
Study Management	• *Close All Queries* • *Close Auto Queries (planned for a future release)* • *Close Queries By Role (planned for a future release)* • *Create Candidate Queries* • *Create Queries* • *Delete Candidate Queries* • *Freeze subject data entered at a site* • *Lock subject data entered at a site* • *Unfreeze subject data entered at a site* • *View All Queries*
Study Setup	• *View Role Assignments for Study Users* • *View Study Design* • *View Subject Settings*

For more information on each of these permissions, see Descriptions of permissions in Oracle Clinical One Platform.

Medical Monitor

View the permissions included in the Medical Monitor template study role. This template study role is of *Sponsor* type and is available for all studies at your organization.

> **Note:**
>
> You should always copy a template role and begin customizing it within the context of your study. For more information, see About template study roles.

Table 6-6 Permissions included in the Medical Monitor template study role

Category	Permissions assigned
Clinical Data Collection	• *Edit Classified Subject Data Only* • *Safety Case Submit* (planned for a future release) • *View Blinded Dispensation Details with Calculated Doses* [Site] • *View Blinded Dispensation Details without Calculated Doses* [Site] • *View Classified Subject Data Only* • *View Form Data for Subjects* • *View Queries* [Site]
Notifications	• *Receive the Code Break Notification*

Table 6-6 (Cont.) Permissions included in the Medical Monitor template study role

Category	Permissions assigned
Reports	• *Run the Blinded Subject Events Dataset* • *Run the Kit Dispensation Report* • *Run the Study Codelist Dataset* • *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 All Queries* • *Close Auto Queries* (planned for a future release) • *Close Queries By Role* (planned for a future release) • *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* [Unblind]

For more information on each of these permissions, see Descriptions of permissions in Oracle Clinical One Platform.

ODM Extract

View the permissions included in the ODM Extract template study role. This template study role is of *Sponsor* type and is available for all studies at your organization.

> **Note:**
>
> You should always copy a template role and begin customizing it within the context of your study. For more information, see About template study roles.

Table 6-7 Permissions included in the ODM Extract template study role

Category	Assigned permissions
Clinical Data Collection	• *View Classified Subject Data Only*

Table 6-7 (Cont.) Permissions included in the ODM Extract template study role

Category	Assigned permissions
Data Extract	• *Execute ODM Administrative Data API* • *Execute ODM Clinical Data API with Hidden Data* [Unblind] • *Execute ODM Clinical Data API without Hidden Data* • *Execute ODM Metadata API* **Note**: To work with the *Execute ODM Clinical Data API with Hidden Data* permission, the user must also receive View privileges for each of the hidden data classifications (*Adjudication*, *Blinded*, *PII*, *Public Data*, and *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*

For more information on each of these permissions, see Descriptions of permissions in Oracle Clinical One Platform.

Pharmacy User - Unblinded

View the permissions included in the Pharmacy User - Unblinded template study role. This template study role is of *Site* type and is available for all studies at your organization.

> **Note:**
>
> You should always copy a template role and begin customizing it within the context of your study. For more information, see About template study roles.

Table 6-8 Permissions included in the Pharmacy User - Unblinded template study role

Category	Assigned permissions
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* [Unblind]
Notifications	• *Receive Notification of Shipments* • *Receive the Code Break Notification* • *Receive the Dispensation with Dosing Instructions Notification* • *Receive the Unblinded Pharmacist Dispensation Notification* [Unblind]

Table 6-8 (Cont.) Permissions included in the Pharmacy User - Unblinded template study role

Category	Assigned permissions
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 Study Codelist Dataset* • *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*

For more information on each of these permissions, see Descriptions of permissions in Oracle Clinical One Platform.

Production Admin

View the permissions included in the Production Admin template study role. This template study role is of *Sponsor* type and is available for all studies at your organization.

> **Note:**
>
> You should always copy a template role and begin customizing it within the context of your study. For more information, see About template study roles.

Table 6-9 Permissions included in the Production Admin template study role

Category	Assigned permissions
Clinical Data Collection	• *Add a Lab to a Site* [Site] • *Add and Update Lab Normal Ranges* • *Create and Add Labs to a Site* • *Integrate Subject Data* • *View Blinded Dispensation Details with Calculated Doses* [Site] • *View Blinded Dispensation Details without Calculated Doses* [Site] • *View Form Data for Subjects* • *View Queries* [Site]

Table 6-9 (Cont.) Permissions included in the Production Admin template study role

Category	Assigned permissions
Inventory Management	• *Create Shipments to Depots* [Unblind] • *Create and Manage Dispensation Exceptions* • *Receive New Shipments at the Depot* • *Release Shipments from Quaratine* • *Update the Shipment Order Form* • *View Shipments to Sites* • *View Site Inventory*
Reports	• *Run the Blinded Chain of Custody Report* • *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 Lab Normal Range 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 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* [Unblind] • *Run the Unblinded Inventory Report* [Unblind] • *Run the User Assignment Report* • *Run the User Upload Error Report* • *Schedule Reports to Run*
Rules Management	• *Re-run Rules*
Settings	• *Configure Connected Device Study Settings* • *Edit Welcome Details in General Study Settings* • *Manage Signature Settings*

Table 6-9 (Cont.) Permissions included in the Production Admin template study role

Category	Assigned permissions
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 Lots* [Unblind] • *Create and Manage Sites* • *Edit General Study Settings* • *Edit Regions* • *Edit Study Settings* • *Edit Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies* [Unblind] • *Manage Archives Settings* • *Move a Study Design to Testing or Production* • *Upload and Generate Inventory Lists* [Unblind] • *Upload and Generate Randomization Lists* [Unblind] • *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* [Unblind]
Unblinded Study Management	• *Manage Randomization Lists* [Unblind] • *Update Inventory Lists* [Unblind]

For more information on each of these permissions, see Descriptions of permissions in Oracle Clinical One Platform.

Rules Designer

View the permissions included in the Rules Designer template study role. This template study role is of *Sponsor* type and is available for all studies at your organization.

> **Note:**
>
> You should always copy a template role and begin customizing it within the context of your study. For more information, see About template study roles.

Table 6-10 Permissions included in the Rules Designer template study role

Category	Permissions assigned
Administrative	• *Run the Study Roles Report*
CRF Submit Access	• *Run Archival PDFs for your site(s)* [Site]

Table 6-10 (Cont.) Permissions included in the Rules Designer template study role

Category	Permissions assigned
Clinical Data Collection	• *Add a Lab to a Site* [Site] • *Add and Update Lab Normal Ranges* • *Create and Add Labs to a Site* • *Dispense Kits with Calculated Doses* [Site] • *Edit Classified Subject Data Only* • *Edit Form Data for Subjects* [Site] • *Edit Visit Dates* [Site] • *Randomize Subjects* [Site] • *Safety Case Creation* [Site] (planned for a future release) • *Safety Case Submit* [Site] (planned for a future release) • *Skip Visits* [Site] • *Take Action on Connected Devices* [Site] • *Unblind the Treatment Arm for a Subject or Code Break* [Site] [Unblind] • *View Classified Subject Data Only* • *View Form Data for Subjects* • *View Queries* [Site]
Data Extract	• *Run the Subject Data Extract* [Unblind]
Inventory Management	• *View Shipments to Sites* • *View Unblinded Pharmacist Kits* [Unblind]
Reports	• *Run the Blinded Inventory Report* • *Run the Blinded Randomization Report* • *Run the Enrollment Report* • *Run the Kit Dispensation Report* • *Run the Kit Reconciliation Report* • *Run the Lab Normal Range 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 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* [Unblind] • *Run the Unblinded Inventory Report* [Unblind] • *Run the Unblinded Randomization Report* [Unblind] • *Run the Unblinded Subject Visit Schedule Report* [Unblind] • *Run the Unblinded Titration Summary Report* [Unblind] • *Run the User Assignment Report*
Rules Management	• *Design Custom Rules* • *Publish Custom Rules* • *Re-run Rules* • *Test Custom Rules*

Table 6-10 (Cont.) Permissions included in the Rules Designer template study role

Category	Permissions assigned
Settings	• *Configure Connected Device Study Settings* • *Edit Welcome Details in General Study Settings* • *Manage Signature Settings*
Study Management	• *Transfer subjects between sites* • *View All Queries*
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* [Unblind] • *Create and Manage SDV Strategies* • *Create and Manage Sites* • *Edit General Study Settings* • *Edit Regions* • *Edit Study Settings* • *Edit Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies* [Unblind] • *Manage Archives Settings* • *Move a Study Design to Testing or Production* • *Upload and Generate Inventory Lists* [Unblind] • *Upload and Generate Randomization Lists* [Unblind] • *View Role Assignments for Study Users* • *View Sites* • *View Study Design*

For more information on each of these permissions, see Descriptions of permissions in Oracle Clinical One Platform.

Site Administrator

View the permissions included in the Site Administrator template study role. This template study role is of *Sponsor* type and is available for all studies at your organization.

> **Note:**
>
> You should always copy a template role and begin customizing it within the context of your study. For more information, see About template study roles.

Table 6-11 Permissions included in the Site Administrator template study role

Category	Assigned permissions
Clinical Data Collection	• *Add a Lab to a Site* [Site] • *Create and Add Labs to a Site*
Notifications	• *Receive Site has been Updated Notification*

Table 6-11 (Cont.) Permissions included in the Site Administrator template study role

Category	Assigned permissions
Reports	• *Run the Site and Depot Report* • *Run the Training Report* • *Run the User Assignment Report* • *Run the User Upload Error Report*
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*

For more information on each of these permissions, see Descriptions of permissions in Oracle Clinical One Platform.

Site User

View the permissions included in the Site User template study role. This template study role is of *Site* type and is available for all studies at your organization.

> **Note:**
>
> You should always copy a template role and begin customizing it within the context of your study. For more information, see About template study roles.

Table 6-12 Permissions included in the Site User template study role

Category	Assigned permissions
CRF Submit Access	• *Confirm download of the Archival PDF* • *Download the Archival PDF* • *Run the Archival PDF for your site*

Table 6-12 (Cont.) Permissions included in the Site User template study role

Category	Assigned permissions
Clinical Data Collection	• *Add a Lab to a Site* • *Add and Update Lab Normal Ranges* • *Answer Queries* • *Approve and Sign Assigned Data Only* • *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* • *Safety Case Creation* (planned for a future release) • *Safety Case Submit* (planned for a future release) • *Skip Visits* • *Take Action on Connected Devices* • *Unblind the Treatment Arm for a Subject, or Code Break* [Unblind] • *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* • *Receive the Code Break Notification* • *Receive the Dispensation Notification* • *Receive the Randomization Notification* • *Received the Released from Quarantine Notification (Site)* • *Receive the Subject Number Update Notification* • *Receive the Subject Screening Notification* • *Receive the Subject Transferred Notification* • *Receive the Subject Undo Completion Notification* • *Receive the Subject Undo Screen Failure Notification* • *Receive the Subject Undo Withdrawal Notification* • *Receive the Subject Visit Notification* • *Receive the Subject Withdrawal Notification*

Table 6-12 (Cont.) Permissions included in the Site User template study role

Category	Assigned permissions
Reports	• *Run the Blinded Chain of Custody Report* • *Run the Blinded Inventory Report* • *Run the Enrollment Report* • *Run the Kit Dispensation Report* • *Run the Kit Reconciliation Report* • *Run the Lab Normal Range 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*
Trial Management	**Note**: All permissions listed in this category are planned for a future release. • *Create Trial Management Event Records from Subjects Tab* • *Edit Actions on Trial Management Event Records* • *Edit Trial Management Event Records from Subjects Tab* • *View Actions on Trial Management Event Records* • *View Blinded Trial Management Records* • *View Trial Management Event Records from Subjects Tab* • *View Trial Management Event Records with Actions Assigned to me*

For more information on each of these permissions, see Descriptions of permissions in Oracle Clinical One Platform.

Statistician - Unblinded

View the permissions included in the Statistician - Unblinded template study role. This template study role is of *Sponsor* type and is available for all studies at your organization.

> **Note:**
>
> You should always copy a template role and begin customizing it within the context of your study. For more information, see About template study roles.

Table 6-13 Permissions included in the Statistician - Unblinded template study role

Category	Assigned permissions
Clinical Data Collection	• *Edit Classified Subject Data Only* • *View Blinded Dispensation Details with Calculated Doses* [Site] • *View Blinded Dispensation Details without Calculated Doses* [Site] • *View Classified Subject Data Only* • *View Form Data for Subjects* • *View Queries* [Site]
Data Extract	• *Run the Subject Data Extract* [Unblind]
Notifications	• *Receive the Code Break Notification* • *Receive the Unblinded Randomization Notification* [Unblind]
Reports	• *Run the Blinded Randomization Report* • *Run the Blinded Subject Events Dataset* • *Run the Enrollment Report* • *Run the Kit Dispensation 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 Subject Randomization Data Extract Report* [Unblind] • *Run the Unblinded Kits Dataset* [Unblind] • *Run the Unblinded Randomization Report* [Unblind]
Study Setup	• *Edit Regions* • *Upload and Generate Inventory Lists* [Unblind] • *Upload and Generate Randomization Lists* [Unblind] • *View Regions* • *View Role Assignments for Study Users* • *View Sites* • *View Study Design* • *View Study Settings*
Unblinded Study Management	• *Manage Randomization Lists* [Unblind] • *Reveal the Treatment Arm for a Subject or Code View* [Unblind]

For more information on each of these permissions, see Descriptions of permissions in Oracle Clinical One Platform.

Study Designer

View the permissions included in the Statistician - Unblinded template study role. This template study role is of *Design* type and is available for all studies at your organization.

> **Note:**
>
> You should always copy a template role and begin customizing it within the context of your study. For more information, see About template study roles.

Table 6-14 Permissions included in the Study Designer template study role

Category	Assigned permissions
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 Clinical Supplies Forms* • *Design Forms* • *Design Randomization* [Unblind] • *Design SDV Properties on Forms* • *Design Safety Case* (planned for a future release) • *Design Supplies and Dispensation* [Unblind] • *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*

For more information on each of these permissions, see Descriptions of permissions in Oracle Clinical One Platform.

Study Manager

View the permissions included in the Study Manager template study role. This template study role is of *Sponsor* type and is available for all studies at your organization.

> **Note:**
>
> You should always copy a template role and begin customizing it within the context of your study. For more information, see About template study roles.

Table 6-15 Permissions included in the Study Manager template study role

Category	Assigned permissions
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* [Site] • *View Blinded Dispensation Details without Calculated Doses* [Site] • *View Classified Subject Data Only* • *View Queries* [Site]
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*

Table 6-15 (Cont.) Permissions included in the Study Manager template study role

Category	Assigned permissions
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*

For more information on each of these permissions, see Descriptions of permissions in Oracle Clinical One Platform.

Unblinded Depot User

View the permissions included in the Unblinded Depot User template study role. This template study role is of *Sponsor* type and is available for all studies at your organization.

> **Note:**
>
> You should always copy a template role and begin customizing it within the context of your study. For more information, see About template study roles.

Table 6-16 Permissions included in the Unblinded Depot User template study role

Category	Assigned permissions
Inventory Management	• *Create Manual Shipments* • *Create Shipments to Depots* [Unblind] • *Receive New Shipments at the Depot* • *Receive and Reconcile Shipments at the Depot* • *Release Shipments from Quarantine* • *Update the Shipment Order Form* • *View Shipments to Sites* • *View Site Inventory* • *View Unblinded Pharmacist Kits* [Unblind]
Notifications	• *Receive Notification of Depot Shipments* [Unblind] • *Receive Notification of Shipments* • *Receive Site has been Updated Notification* • *Receive the Quarantined Depot Shipment Notification* • *Receive the Released from Quarantine Notification (Depot)*

Table 6-16 (Cont.) Permissions included in the Unblinded Depot User template study role

Category	Assigned permissions
Reports	• *Run the Blinded Chain of Custody Report* • *Run the Blinded Inventory Report* • *Run the Kit Reconciliation Report* • *Run the Order Summary Report* • *Schedule Reports to Run*
Study Setup	• *View Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies* [Unblind]
Unblinded Study Management	• *Manage Study Inventory for Unblinded Users* [Unblind]

For more information on each of these permissions, see Descriptions of permissions in Oracle Clinical One Platform.

User Administrator

View the permissions included in the User Administrator template study role. This template study role is of *Design* type and is available for all studies at your organization.

> **Note:**
>
> You should always copy a template role and begin customizing it within the context of your study. For more information, see About template study roles.

Table 6-17 Permissions included in the 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)* • *Upload Users in Bulk* • *View Design*

For more information on each of these permissions, see Descriptions of permissions in Oracle Clinical One Platform.

View Only for Unblinded Support Users

View the permissions included in the View Only for Unblinded Support Users template study role. This template study role is of *Sponsor* type and is available for all studies at your organization.

> **Note:**
>
> You should always copy a template role and begin customizing it within the context of your study. For more information, see About template study roles.

Typically assigned to a member of the Life Sciences Support team 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)* template study role are automatically updated with any new permission introduced for a given release.

Table 6-18 Permissions included in the View Only for Unblinded Support Users template study role

Category	Assigned permissions
Administrative	• *Run the Study Roles Report* • *View Only for Unblinded Support Users* [Unblind]
CRF Submit Access	• *Download Archival PDFs, and Audit Reports* [Site] • *Run the Archival PDF for your site(s)* [Site]
Clinical Data Collection	• *View Blinded Dispensation Details with Calculated Doses* [Site] • *View Blinded Dispensation Details without Calculated Doses* [Site] • *View Classified Subject Data Only* • *View Form Data for Subjects* • *View Queries* [Site]
Data Extract	• *Execute ODM Administrative Data API* • *Execute ODM Clinical Data API with Hidden Data* [Unblind] • *Execute ODM Clinical Data API without Hidden Data* • *Execute ODM Metadata API* • *Run the Subject Data Extract* [Unblind]
Inventory Management	• *View Dispensation Exceptions* • *View Shipments to Sites* • *View Site Inventory* • *View Unblinded Pharmacist Kits* [Unblind]

Table 6-18 (Cont.) Permissions included in the View Only for Unblinded Support Users template study role

Category	Assigned permissions
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 Lab Normal Range 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 Study Rules Report* • *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 Subject Randomization Data Extract Report [Unblind]* • *Run the Subject Visit Report* • *Run the Supply Prediction Report* [Unblind] • *Run the Titration Summary Report* • *Run the Training Report* • *Run the Unblinded Chain of Custody Report* [Unblind] • *Run the Unblinded Inventory Report* [Unblind] • *Run the Unblinded Kits Dataset* [Unblind] • *Run the Unblinded Randomization Report* [Unblind] • *Run the Unblinded Subject Events Dataset* [Unblind] • *Run the Unblinded Subject Visit Schedule Report* [Unblind] • *Run the Unblinded Titration Summary Report* [Unblind] • *Run the User Assignment Report* • *Run the User Upload Error Report* • *Schedule Reports to Run*
Rules Management	• *Test Custom Rules*
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* [Unblind]

Table 6-18 (Cont.) Permissions included in the View Only for Unblinded Support Users template study role

Category	Assigned permissions
Trial Management	**Note**: All permissions listed in this category are planned for a future release. • *View Actions on Trial Management Event Records* • *View Blinded Trial Management Records* • *View Trial Management Event Records* • *View Unblinded Trial Management Records* [Unblind]
Unblinded Study Management	• *Reveal the Treatment Arm for a Subject, or Code View* [Unblind]

For more information on each of these permissions, see Descriptions of permissions in Oracle Clinical One Platform.

View Study Design

View the permissions included in the View Study Design template study role. This template study role is of *Design* type and is available for all studies at your organization.

> **Note:**
>
> You should always copy a template role and begin customizing it within the context of your study. For more information, see About template study roles.

This template study role is typically assigned to an unblinded study team member or site who should view the study's design.

Table 6-19 Permissions included in the View Study Design template study role

Category	Assigned permissions
Reports	• *Run the Analytics Study Codelists Dataset* • *Run the Data Collection Design Dataset* • *Run the Kits and Randomization Design Dataset*
Study Design	• *Run the Draft Study Design Report* • *View Design*

For more information on each of these permissions, see Descriptions of permissions in Oracle Clinical One Platform.

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Descriptions of permissions in Oracle Clinical One Platform

There are three different types of study roles: *Sponsor*, *Site* and *Design*. According to the study role type, a different set of permissions is availbale to assign. 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

When you create a **Sponsor** or **Site** type of study role, you see the following permissions that can be assigned to it:

> **Note:**
>
> These permissions are not available for other Design type study roles.

- Administrative
- CRF Submit Access
- Clinical Data Collection
- Data Extract
- Inventory Management
- Notifications
- Reports
- Rules Management
- Settings
- Study Management
- Study Setup
- Trial Management
- Unblinded Study Management

Administrative

Permission	Description	Additional information
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*.
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.*

CRF Submit Access

Permission	Description	Additional information
Confirm download of Archival PDFs and content	• 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 impact a user's ability to perform certain tasks.*
Download Archival PDFs and Audit Reports	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)	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.

Permission	Description	Additional information
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. ***Note**: When assigned, this permission also lets a user run the **Subject Data report**.*

Clinical Data Collection

Permission	Description	Additional information
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.
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* ***Note:** An Oracle employee who has an Oracle Single Sign-On (SSO) account cannot sign data, even if they are assigned with this permission in the application.*

Permission	Description	Additional information
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* ***Note:*** *An Oracle employee who has an Oracle Single Sign-On (SSO) account cannot sign data, even if they are assigned with this permission in the application.*
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.	***Note****: When assigned, this permission lets a user view and edit questions in a form irrespective of their associated data classification.* 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*
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.	***Note****: When assigned, this permission lets a user view and edit questions in a form irrespective of their associated data classification.* 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*

Permission	Description	Additional information
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, 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.*	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*
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.
Link and Unlink Subject with EHR Patient	Allows site users to link a subject number to the subject's Medical Record Number (MRN), making it possible to import their Electronic Health Record (EHR) data.	For more information, see Link subjects for EHR data import.
Manually Update EHR Imported Data	Allows site users to update, delete, and clear Electronic Health Record (EHR) data after import.	For more information, see Import Electronic Health Record (EHR) data.

Permission	Description	Additional information
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*
Safety Case Creation	Allows a user to create an integration with a safety system to report safety cases.	*Planned for a future release.*
Safety Case Submit	Allows a user to submit a safety case report when integration with a safety system is enabled.	*Planned for a future release.*
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*
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.	***Caution**: Can unblind users. Use with caution.* 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*
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.

Permission	Description	Additional information
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.

Data Extract

Permission	Description	Additional information
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.

Permission	Description	Additional information
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.*

Inventory Management

Permission	Description	Additional information
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**: The Blinded Depot User permission grants access to view the Sequence Number, which could potentially unblind the study for blinded site users and blinded sponsor users.* This permission is for both sponsor and site users. This permission only allows a user to view supplies from depots or sites that they're assigned to. They cannot see the full description of kits for blinded and unblinded pharmacist kits.
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 manual shipments.* Must be assigned along with the following permissions: • *View Sites* • *View Site Inventory* • *View Shipments to Sites*
Create Manual Shipments (Unblinded)	Allows a user to create manual shipments that include pooled kits to be delivered to sites.	This permission is for sponsor users only. Must be assigned along with the following permissions: • *View Sites* • *View Site Inventory* • *View Shipments to Sites*
Create Shipments to Depots	Allows a user to create a supplying or a destruction shipment to be sent to another depot.	***Caution**: Can unblind users. Use with caution.* This permission is available for sponsor users only.

Permission	Description	Additional information
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*
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.	***Caution**: Can unblind users. Use with caution.* This permission is available for sponsor users only.
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*
Receive and Reconcile Shipments at the Depot	Allows a user to receive shipments sent by a depot and reconciling shipments at a depot level.	***Caution**: Can unblind users. Use with caution.* This permission is available for sponsor users only. Must be assigned along with the following permissions: • *View Depots* • *View Sites*
Release Shipments from Quarantine	Allows a user to release all kits in a shipment from Quarantine and update their status to Available.	***Caution**: Can unblind users. Use with caution.* This permission is for sponsor users, typically Clinical Supply Managers.
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. The permission should be removed after the updates are made.*	***Caution**: Can unblind users. Use with caution.* This permission is available for sponsor users only. Must be assigned along with the following permission to update kits. • *Design Supplies and Dispensation*

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

Notifications

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

Permission	Description	Additional information
Receive Notification of Shipments Not Received for All Sites	Allows a user to receive a notification when a shipment was not marked as received after the specified amount of days. The number of days after which the notification is sent is defined in the study's supply settings. See Specify supply settings.	This permission is available for sponsor users only.
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.
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.

Permission	Description	Additional information
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.
Receive the Subject Undo Completion Notification	Allows a user to receive a notification when a subject's completion is undone.	This permission is for both sponsor and site users.
Receive the Subject Undo Screen Failure Notification	Allows a user to receive a notification when a subject's screen failure is undone.	This permission is for both sponsor and site users.
Receive the Subject Undo Withdrawal Notification	Allows a user to receive a notification when a subject's withdrawal is undone.	This permission is for both sponsor and site users.
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.
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.	***Caution**: Can unblind users. Use with caution.* This permission is for both sponsor and site users.

Permission	Description	Additional information
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.	***Caution**: Can unblind users. Use with caution.* This permission is for both sponsor and site users.
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.	***Caution**: Can unblind users. Use with caution.* This permission is for both sponsor and site users.
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.	***Caution**: Can unblind users. Use with caution.* This permission is for both sponsor and site users.
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.	***Caution**: Can unblind users. Use with caution.* This permission is for both sponsor and site users.
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.
State Set to Null Notification	Allows a user to receive a notification whenever an address is entered or updated and the state field is set as `Null`. For an address, the state field is not required by system design.	This permission is available for sponsor users only.

Reports

Permission	Description	Additional information
Run the Blinded Chain of Custody Report	Allows a user to run the Kit Chain of Custody (blinded) report.	***Caution**: Can unblind users. Use with caution.* This permission is for both sponsor and site users.

Permission	Description	Additional information
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. This study-level permission alone provides read only access to Oracle Clinical One Analytics and to the given dataset. To provide authoring access user must be provisioned with additional global roles. See About your access to Clinical One Analytics.
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. This study-level permission alone provides read only access to Oracle Clinical One Analytics and to the given dataset. To provide authoring access user must be provisioned with additional global roles. See About your access to Clinical One Analytics.
Run the Enrollment Report	Allows a user to run the Study Enrollment report.	This permission is for both sponsor and site users. Users must have the following permission or role to run the report: • *View Form Data for Subjects*
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 Lab Normal Range Report	Allows a user to run the Lab Normal Range report.	This permission is for both sponsor and site users. Users must have the following permission or role to run the report: • *Add and Update Lab Normal Ranges* permission • *View Only Unblinded Support* template role
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.

Permission	Description	Additional information
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. This study-level permission alone provides read only access to Oracle Clinical One Analytics and to the given dataset. To provide authoring access user must be provisioned with additional global roles. See About your access to Clinical One Analytics.
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 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. This study-level permission alone provides read only access to Oracle Clinical One Analytics and to the given dataset. To provide authoring access user must be provisioned with additional global roles. See About your access to Clinical One Analytics.
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. This study-level permission alone provides read only access to Oracle Clinical One Analytics and to the given dataset. To provide authoring access user must be provisioned with additional global roles. See About your access to Clinical One Analytics.
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. This study-level permission alone provides read only access to Oracle Clinical One Analytics and to the given dataset. To provide authoring access user must be provisioned with additional global roles. See About your access to Clinical One Analytics.

Permission	Description	Additional information
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. This study-level permission alone provides read only access to Oracle Clinical One Analytics and to the given dataset. To provide authoring access user must be provisioned with additional global roles. See About your access to Clinical One Analytics.
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 Randomization Data Extract Report	Allows a user to generate the Subject Randomization Data Extract.	This permission is for sponsor users. To view the unblinding fields (Treatment Arm and Block ID) it must be assigned along with at least one of the following permissions: • *Receive the Unblinded Dose Hold Notification* • *Upload and Generate Inventory Lists* • *View Dispensation Exceptions* • *Create and Manage Dispensation Exceptions* • *Edit Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies* • *Manage Study Inventory for Unblinded Users* • *Manage Randomization Lists* • *Create and Manage Lots* • *Create Shipments to Depots* • *Upload and Generate Randomization Lists* • *Receive the Unblinded Kit Misallocation Notification* • *View Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies* • *Run the Unblinded Randomization Report*
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 Supply Prediction Report	Allows a user to run the Projected Supply (Unblinded) Report.	***Caution**: Can unblind users. Use with caution.* This permission is available for sponsor users only.
Run the Titration Summary Report	Allows a user to run the Titration Summary report (Blinded).	This permission is for both sponsor and site users.

Permission	Description	Additional information
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.	***Caution**: Can unblind users. Use with caution.* This permission is available for sponsor users only. Must be assigned along with the *View Supply Settings, Blinded Groups, Label Groups, and Resupply Strategies* permission.
Run the Unblinded Inventory Report	Allows a user to run the Kit Inventory (Unblinded) report.	***Caution**: Can unblind users. Use with caution.* This permission is available for sponsor users only.
Run the Unblinded Kits Dataset	Allows a user to to operate the Unblinded Kits dataset in Oracle Clinical One Analytics.	***Caution**: Can unblind users. Use with caution.* This permission is for both sponsor and site users. This study-level permission alone provides read only access to Oracle Clinical One Analytics and to the given dataset. To provide authoring access user must be provisioned with additional global roles. See About your access to Clinical One Analytics.
Run the Unblinded Randomization Report	Allows a user to run the Randomization List report (Unblinded).	***Caution**: Can unblind users. Use with caution.* This permission is available for sponsor users only.
Run the Unblinded Subject Events Dataset	Allows a user to operate the Unblinded Subject Events dataset in Oracle Clinical One Analytics.	***Caution**: Can unblind users. Use with caution.* This permission is for both sponsor and site users. This study-level permission alone provides read only access to Oracle Clinical One Analytics and to the given dataset. To provide authoring access user must be provisioned with additional global roles. See About your access to Clinical One Analytics.
Run the Unblinded Subject Visit Schedule Report	Allows a user to run the Subject Visits (Unblinded) report.	***Caution**: Can unblind users. Use with caution.* This permission is available for sponsor users only.
Run the Unblinded Titration Summary Report	Allows a user to run the Titration Summary (Unblinded) report.	***Caution**: Can unblind users. Use with caution.* This permission is available for sponsor users only.

Permission	Description	Additional information
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 generates it.	This permission is available for sponsor users only.

Rules Management

Permission	Description	Additional information
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*
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*
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*

Settings

Permission	Description	Additional information
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.
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*

Study Management

Permission	Description	Additional information
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 All 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 All Queries*
Close Auto Queries	Allows a user to close automated queries created by a custom JavaScript rule.	*Planned for a future release.* 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*

Permission	Description	Additional information
Close Queries By Role	Allows a user to close manual queries that were opened by users that had the same role assigned to them when the query was open.	*Planned for a future release.* 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*
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*
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*

Permission	Description	Additional information
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 entered at a site	Allows a user to lock and unlock data at the visit, form, and question level.	This permission is for sponsor users only. If users have the *View Form Data for Subjects* permission, they are able to see if the visit, form, or question is locked.
Perform Source Data Verification and Reconcile Inventory	Allows a user to verify subject data as well as to 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*
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*

Study Setup

Permission	Description	Additional information
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.
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 Lots	Allows a user to create and manage lots.	***Caution**: Can unblind users. Use with caution.* This permission is for sponsor users only.
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. ***Note**: If Electronic Health Record (EHR) data import is enabled for your study, users with this permission can map sites to Oracle Clinical Connectors.*	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.

Permission	Description	Additional information
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.
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.	***Caution**: Can unblind users. Use with caution.* This permission is for sponsor users only. 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 **Blind Randomization Number** appears under the Study Settings section on the Study Settings tab for that study role. Additionally, **Replace Subject Number with Randomization Number** appears under the Study Settings section under the Study Settings tab.	***Note**: This permission is not assigned by default to any template user 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.
Upload and Generate Inventory Lists	Allows a user to upload and generate kit lists.	***Caution**: Can unblind users. Use with caution.* This permission is for sponsor users only. Must be assigned along with the *View Study Design* permission.
Upload and Generate Randomization Lists	Allows a user to upload and generate randomization lists.	***Caution**: Can unblind users. Use with caution.* This permission is for sponsor users only. 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 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.

Permission	Description	Additional information
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.
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.	***Caution**: Can unblind users. Use with caution.* This permission is for sponsor users only.

Trial Management

> **Note:**
>
> All permissions in this category are planned for a future release. Given that the functionality associated to these permissions is not yet implemented, they will not impact users assigned with them.

Permission	Description	Additional information
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.
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.

Permission	Description	Additional information
Create Unblinded Trial Management Records	Allows a user to create unblinded trial management records in their study.	*Planned for a future release.* ***Caution**: Can unblind users. Use with caution.* This permission is available for sponsor users only.
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.
Edit Unblinded Trial Management Records	Allows a user to edit unblinded record of trial management.	*Planned for a future release.* ***Caution**: Can unblind users. Use with caution.* This permission is available for sponsor users only.
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.
View Unblinded Trial Management Records	Allows a user to view unblinded record of trial management.	*Planned for a future release.* ***Caution**: Can unblind users. Use with caution.* This permission is available for sponsor users only.

Unblinded Study Management

Permission	Description	Additional information
Manage Randomization Lists	Allows a user to update randomization lists.	***Caution**: Can unblind users. Use with caution.* This permission is for sponsor users only. Must be assigned along with the following permissions: • *View Study Design* • *Upload and Generate Randomization Lists*
Manage Study Inventory for Unblinded Users	Allows a user to manage kits and shipments on the Study Inventory tab.	***Caution**: Can unblind users. Use with caution.* This permission is for sponsor users only.
Reveal the Treatment Arm for a Subject or Code View	Allows a user to perform a code view for a subject.	***Caution**: Can unblind users. Use with caution.* This permission is for sponsor users only.
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 extracts.*	***Caution**: Can unblind users. Use with caution.* This permission is for sponsor users only. Must be assigned along with the following permissions: • *View Study Design* • *Upload and Generate Inventory Lists* (is needed to delete a list).

Design permissions

When you create a **Design** type of study role, you see the following permissions that can be assigned to it:

> **Note:**
>
> These permissions are not available for other Sponsor and Site type study roles.

- Reports
- Study Design

Reports

Permission	Description	Additional information
Run the Analytics Study Codelist Dataset	Allows a user to operate the Study Codelist dataset in Oracle Clinical One Analytics.	This permission is for design type role only. This study-level permission alone provides read only access to Oracle Clinical One Analytics and to the given dataset. To provide authoring access user must be provisioned with additional global roles. See About your access to Clinical One Analytics.
Run the Data Collection Design Dataset	Allows a user to run the Study Design Delta report and operate the Study Design dataset in Oracle Clinical One Analytics.	This permission is for design type role only. This study-level permission alone provides read only access to Oracle Clinical One Analytics and to the given dataset. To provide authoring access user must be provisioned with additional global roles. See About your access to Clinical One Analytics.
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. This study-level permission alone provides read only access to Oracle Clinical One Analytics and to the given dataset. To provide authoring access user must be provisioned with additional global roles. See About your access to Clinical One Analytics.

Study Design

Permission	Description	Additional information
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 Clinical Supplies Form	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 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.

Permission	Description	Additional information
Design Randomization	Allows a user to design all elements of a randomization.	***Caution**: Can unblind users. Use with caution.* This permission is for design type role only.
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 Safety Case	Allows a user to edit Safety Case design elements in form design.	*Planned for a future release.* 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.	***Caution**: Can unblind users. Use with caution.* This permission is for design type role only.
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.

8

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 point of contact 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 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?

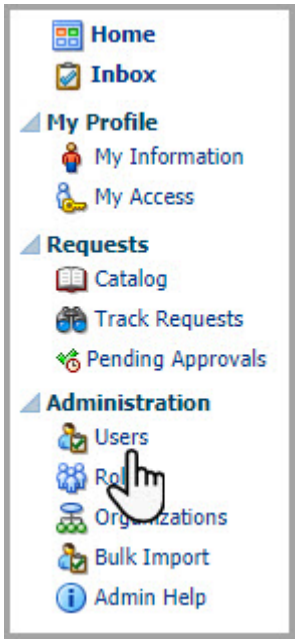
Your Oracle point of contact creates Oracle team members.

How do I find my company's ShortOrgId?

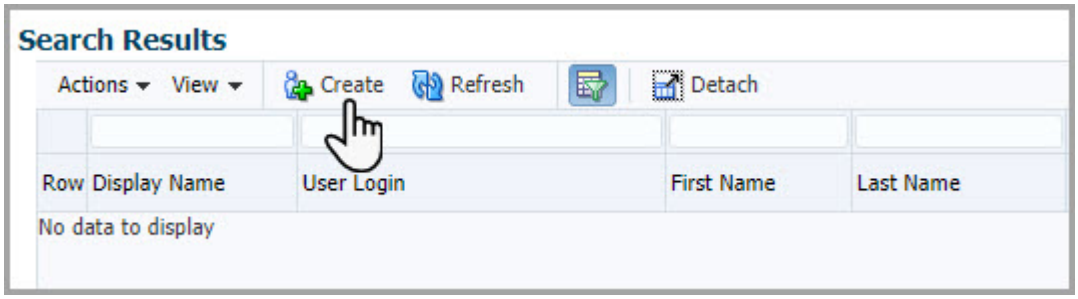
The <ShortOrgId> for your company appears in bold text in the New Account email you received from Oracle Identity Manager to activate your Oracle Life Sciences SSO.

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

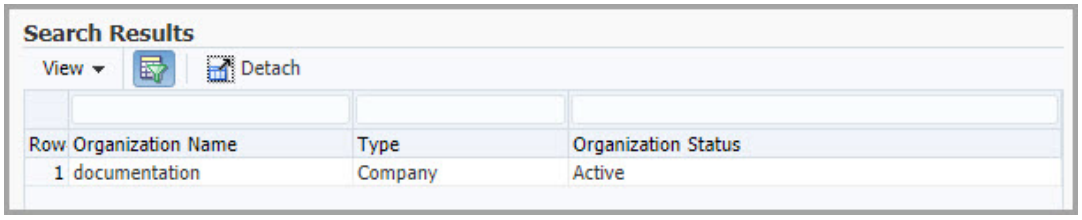
1. Sign in to Oracle Life Sciences IAMS as described in Bookmark and sign in directly to Oracle Life Sciences IAMS.
2. Expand **Administration** in the left panel and click **Users**.



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, locate the row where **Company** appears in the **Type** column. The <ShortOrgId> would be as displayed in the Organization Name column for that row.



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.

9 Revision history

Date	Part number	Description
09-April-2025	G16747-05	Removed the *Edit Form Data for Subjects* permission previously documented as required along with the *Re-run rules* permission. For more information, see Rules Management.
18-March-2025	G16747-04	Updated the following topics: • Included new permissions *Link and Unlink Subject with EHR Patient* and *Manually Update EHR Imported Data*. See Clinical Data Collection. • Included new permissions *Receive the Subject Undo Completion Notification*, *Receive the Subject Undo Withdrawal Notification*, and *Receive the Subject Undo Screen Failure Notification*. See the following topics: Notifications, Clinical Research Associate (CRA), Data Manager, and Site User. • Included a new note about the *Create and Manage Sites* permission. See Study Setup. • Documented a new global role *View EHR Connectors*. See Roles for global users in Oracle Clinical One Platform and Oracle Clinical One Digital Gateway.
14-February-2025	G16747-03	Updated the list of permissions of template study roles.
20-January-2025	G16747-02	Included details for the Create a Manual Shipment (Unblinded) permission.
17-January-2025	G16747-01	Original version of the document.