Oracle Life Sciences ClearTrial

System Administrator Guide

Release 6.0
F88420-01
May 2024

Oracle Life Sciences ClearTrial System Administrator Guide, Release 6.0

F88420-01

Contents

Preface

This preface contains the following sections:

- Documentation accessibility
- Related resources
- Access to Oracle Support

Documentation accessibility

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

Related resources

All documentation and other supporting materials are available on the Oracle Help Center at: https://docs.oracle.com/en/industries/life-sciences/cleartrial/index.html

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 of Oracle Life Sciences Customer Support Portal (https://hsgbu.custhelp.com/)
- Japanese interface of Oracle Health Sciences 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.

1 Administration basics

This chapter provides information on how to work as an assigned ClearTrial system administrator in ClearTrial.

Topics:

Introduction

This document is a reference for those users who are assigned the **ClearTrial System Administrator** role, who are responsible for managing and maintaining user accounts for all users at their organization.

Permissions of assigned ClearTrial system administrators

Assigned system administrators manage user accounts for their organization. In addition, they perform other administrative tasks, such as granting additional roles/capabilities per user, updating customer preferences for all users from the default values (if applicable), and resetting user accounts.

Please ensure you have at least two users in your organization who are assigned the ClearTrial system administrator role. In case one system administrator is unavailable and other users experience user account issues, there is a backup to support the other users. Your initially assigned ClearTrial system administrators are specified upon service activation. You can request additional users to be granted this role by contacting one of them, or, if needed, by contacting Oracle Support.

Edit customer preferences

Assigned ClearTrial system administrators manage the customer preferences impacting all users at your organization.

> **Important:**
>
> Please ensure that:
>
> - You visit this tab as soon as you have access to the service and review the default preferences set for all users. These configurations were set in your Service Activation Request form and are available here for you to change at any time, on demand, during your subscription.
> - You enter the name, email, and phone number for the contact whose details will be displayed in the service for other users to contact when their user accounts are locked. This should be you or another assigned ClearTrial system administrator.

1. From the **Admin** menu, select **Customer Preferences**.
2. Edit the default values shown, if necessary. For more information about a field, click the field name to display online help.
3. Enter values for the four customer preferences that are blank by default:
   - **List of valid email domains for users**—Enter a list of valid email domains for users. Users must be created with an email address ending in one of the listed values. Oracle discourages the use of personal email addresses.
   - **Name of support personnel/department responsible for this customer's user administration**—Enter the name of the assigned system administrator who will be managing and maintaining all user accounts. This information is displayed in the application when users are locked out and require assistance. Be sure to update this field and review it periodically, especially when there are updates to users owning and managing the governance of all users of ClearTrial.
   - **Email address of support personnel/department responsible for this customer's user administration**—Enter the email address of the current system administrator. This contact must be an assigned system administrator.
   - **Phone number of support personnel/department responsible for this customer's user administration**—Enter the phone number of the current system administrator. If email is the preferred medium of contact, you can leave this field blank. This contact must be an assigned system administrator.
4. Click **Save**.

Purge deleted items

A deletion in ClearTrial is a *soft deletion*, meaning ClearTrial updates the status of the item, displays it with strikethrough, grays out the item in the interface, and automatically purges it according to the customer preference you have specified for how many days deleted items remain before being purged.

The default duration is 30 days before an item is purged; to change it, select **Customer Preferences** from the **Admin** menu.

Assigned ClearTrial system administrators also have the flexibility to manually purge deleted items, as of x number of days ago that you specify per deleted item.

1. From the **Maintain** menu, select **Purge Deleted Items**.
2. From the **Purge Deleted** screen, select the types of deleted items you want to purge.
3. To change the duration default value, in the **deleted at least n days ago** field, specify the number of days since an item of that type was deleted.
4. Click **Purge Selected Items**.

2

Manage and maintain user accounts

To use ClearTrial, users must have an associated user account. This chapter provides information on how to create and edit user account details.

Only ClearTrial system administrators can create new user accounts.

Topics:

- Set up new users
  As a system administrator, you are responsible for setting up user accounts.
- Manage existing accounts
  As a system administrator, you are responsible for managing existing user accounts and assisting users with access issues.

Set up new users

As a system administrator, you are responsible for setting up user accounts.

Topics:

- Create a user account
  To use ClearTrial, users must have an associated user account, profile, and assigned roles and permissions.
- Assign user permissions and roles
  To use ClearTrial, users must have an associated user account, profile, and assigned permissions and roles.
- About user permissions and roles
  Permissions enable users to access certain features or perform specific actions in ClearTrial. You can assign primary roles and additional roles and capabilities to users.
- Add other ClearTrial system administrators
  As a ClearTrial best practice, Oracle recommends assigning multiple users to the ClearTrial System Administrator role as backup for performing these tasks, in case an assigned system administrator is not available.

Create a user account

To use ClearTrial, users must have an associated user account, profile, and assigned roles and permissions.

Only ClearTrial system administrators can create new user accounts.

1. From the **Admin** menu, select **Users**.
2. On the **Users** screen, click the **New** button.
3. On the **Profile** tab on the **Create User** screen, enter a login name, the first and last names of the user, and the email address.

4. From the **Maximum Edit Mode** drop-down list, select the maximum edit mode this user is permitted. This is the most advanced edit mode this user can access when creating or editing plans.
5. From the **Preferred Edit Mode** drop-down list, select the edit mode that will be used by default when the user is creating or editing plans.
   The edit modes control the precision of the plan by determining which assumptions the user can set.
6. In the **Password** and **Confirm Password** fields, enter and confirm a password for the user.
   - Passwords must be at least eight characters and contain at least one letter, one number, and one of the following special characters: !$*+-.=?@^_|~.
   - Passwords must not contain the login name or any of the following words: password, oracle, guest, admin, administrator, or cleartrial.
   - The user must provide this password to access ClearTrial and complete registration.
7. From the **Preferred Home Page** drop-down list, select the page that the user will be directed to each time upon logging in.
8. From the **Preferred Locale** drop-down list, select the appropriate locale to control how dates and numbers are entered and displayed.

   Locale is a term that refers to the local conventions and language that determine how a software application presents and understands information. In ClearTrial, the preferred locale determines how dates and numbers are displayed and interpreted by default. For example, in many non-US locales, dates are shown as dd/mm/yyyy rather than mmdd/yy and the decimal symbol is a comma (,) rather than a period (.). Normally, your computer settings communicate the locale to the application; you can override this setting by specifying a preferred locale.
9. Click **Save**.
   You must save these settings to enable the Roles tab.

Assign user permissions and roles

To use ClearTrial, users must have an associated user account, profile, and assigned permissions and roles.

1. On the **Roles** tab, click the **Primary Role** label and assign the user a primary role.
2. Click the **Additional Roles/Capabilities** label and assign additional roles and capabilities not granted by default.
   For more information about user roles, see About user permissions and roles.
3. Click **Save**.

- An automated email containing the customer code, login name, and link to complete the registration is sent to the user when a user account is created. This link expires in 72 hours, so the user should be encouraged to complete their registration promptly.
- Upon logging in, users are required to change the password you created and to set up a security question and answer that is used to verify the user's identity in the case of a request to reset a forgotten password.

About user permissions and roles

Permissions enable users to access certain features or perform specific actions in ClearTrial. You can assign primary roles and additional roles and capabilities to users.

Primary role permissions are generic actions that users can perform. Additional permissions are used for access or maintenance in certain parts of the application, such as the resources and reporting regions.

- To access the application, users must be assigned a primary role.
- Additional roles and capabilities can be assigned to users to grant them permissions to access certain features or perform specific job responsibilities.

The primary role you assign to the user determines which additional roles/capabilities are available for that user.

Table 2-1 Primary Roles

Primary Role	Description	Comments
Read-Only User	Can view most items in ClearTrial but cannot create, edit, or delete any of these items. This role does not grant permission to modify notes or export data, these permissions can be added as additional capabilities.	None.
User	Can view products (or compounds) and studies, and can create, edit, and view plans. Users can edit or delete plans they create but cannot edit or delete plans created by other users.	None.
Power User	Has all of the permissions of the User primary role and can create, edit, and delete their own templates. Power users can edit or delete plans created by other users. If Power users need to create studies, they can request that additional option be enabled by their ClearTrial System Administrator.	None.
Clinical Administrator	Has all of the permissions of the Power User primary role and can also create and maintain products, service providers, and billing rates. Clinical administrators can also edit or delete templates created by other users.	Clinical administrators can grant some additional roles/ capabilities to other users.
System Administrator	Has all of the permissions of the Clinical Administrator primary role and can manage all other ClearTrial users and their accounts at their organization	System administrators (please ensure you have two assigned) can grant all additional roles/capabilities to other users and are responsible for managing all user accounts at their organization.

Table 2-2 Additional Roles and Capabilities

Additional Role/ Capability	Description	Comments
Exchange Rates Administrator	Users can create, edit, view, and delete shared exchange rate tables.	None.
Resources Administrator	Users can create, edit, view, and delete user-defined resources.	Custom resource configuration capabilities are only available to Enterprise Licensed users.
Reporting Regions Administrator	Users can create, edit, and delete custom reporting regions and map countries to those regions for reporting purposes.	Only available to Enterprise Licensed users.
Department/GL Codes Administrator	Users can create user-defined departments or GL codes available for use in plans. They can also edit existing ClearTrial-defined departments and GL codes being displayed in plans.	None.
RFP Administrator	Users can create, edit, and delete RFPs and bids.	System administrators have these permissions by default.
RFP/Bid Reader	Users can view RFPs and bids.	The System Administrator and RFP Administrator can grant these permissions to those assigned the Clinical Administrator role.
Custom Fields Designer	Users can create, edit, and delete custom fields in custom field models to publish for use in plans. ClearTrial comes out of the box with the ClearTrial-defined assumptions model which are the input fields you see displayed in the service. If you would like to add custom input fields for other users to enter, then you need this role to create custom fields in your custom field models.	Only available to Enterprise licensed users. The System Administrator can grant these permissions to users that are assigned a primary role of Clinical Administrator or System Administrator.

Table 2-2 (Cont.) Additional Roles and Capabilities

Additional Role/ Capability	Description	Comments
Advanced Algorithm Editor	Users can create/edit user-defined algorithms with multiple expressions.	Only available to Enterprise licensed users. The System Administrator can grant these permissions to users that are assigned a primary role of Power User, Clinical Administrator, or System Administrator.
Expert Algorithm Editor	Users can create or edit scripted algorithms for costs or resources.	Only available to Enterprise licensed users. The System Administrator can grant these permissions to users that are assigned a primary role of Power User, Clinical Administrator, or System Administrator.
WBS Editor	Users can create, edit, and delete ClearTrial-defined major tasks, tasks, and resources in the Work Breakdown Structure (WBS) in plans created by the user. This role allows the user to view and edit the Level of Effort algorithm for a plan-specific task and resource.	Only available to Enterprise Licensed users.
WBS Manager	Users have WBS Editor permissions plus additional capabilities to edit and delete user-defined/ClearTrial-defined major tasks, tasks, and resources in the WBS of plans created by other users.	Only available to Enterprise Licensed users
Can edit notes	Users can edit notes associated with plans or other items for review purposes.	Can be granted to read-only users.
Can export report data	Users can export reports in multiple formats offered (for example, HTML, PDF, Excel, or CSV).	Can be granted to read-only users.
Can access WS-API	Users who are licensed Enterprise Edition customers, can leverage the ClearTrial Web Services API.	Only available to customers who have Enterprise Edition licensed.

Add other ClearTrial system administrators

As a ClearTrial best practice, Oracle recommends assigning multiple users to the ClearTrial System Administrator role as backup for performing these tasks, in case an assigned system administrator is not available.

Only other assigned ClearTrial system administrators can change the roles and additional capabilities of an existing ClearTrial system administrator, in case you need them changed or you are locked out.

1. From the **Admin** menu select **Users**.
2. On the **Users List** screen, choose whether to create a new user and grant them the System Administrator primary role or select an existing user and update their role on the Roles tab.
   - To create a new user account, click **New** to display the Create User screen.
   - To open an existing user account for editing, select a user and click **Edit** to display the Edit User screen.

   The Create User and Edit User screens are identical with two tabs: Profile and Roles.
3. Click the **Roles** tab, and select **System Administrator** from the **Primary Role** drop-down list.
4. From the **Additional Roles/Capabilities** list, select additional capabilities that the user needs.
5. Click **Save**.

Manage existing accounts

As a system administrator, you are responsible for managing existing user accounts and assisting users with access issues.

Topics:

- View existing users
  To access ClearTrial, every user must have a user account and a primary role assignment.
- Edit user accounts
  You can edit a user's profile and the roles assigned to them.
- Unlock a locked user account
  Users will occasionally get locked out of their accounts and ask you to unlock or reset their account.
- Reset user accounts
  Resetting an account clears the security question and answer, unlocks a locked account, and forces the user to reset their password when they next log in.
- Reset user passwords
  Occasionally, users will contact you because they need their password reset.
- View inactive users
  Use the Inactive Users Report to view users that have not logged into ClearTrial within the number of days specified on the report input screen.

- Delete user accounts
  System administrators can delete user accounts for users who have left the organization or no longer need access to the service.

View existing users

To access ClearTrial, every user must have a user account and a primary role assignment.

Assigned ClearTrial system administrators are responsible for managing all other user accounts for their organization.

1. From the **Admin** menu, select **Users**.
2. On the **Users** screen, filter the list as necessary to identify those users whose details you wish to view.
3. Select one or more users and the button corresponding to the action you'd like to perform; for example, Edit, Delete, Restore, etc. Click **Edit** to edit any of their details or update their roles.

Edit user accounts

You can edit a user's profile and the roles assigned to them.

1. From the **Admin** menu, select **Users**.
2. On the **Users** screen, select a user and click **Edit**.
3. On the **Profile** tab on the **Edit User** screen, edit the user's account details, as necessary. For more information about a field, click the field name to display online help.
4. Click **Save**, and then select the **Roles** tab.

   > **Note:**
   >
   > You must save these settings before you can access the Roles tab.

5. On the **Roles** tab, change the primary role, if needed, and select or remove additional roles and capabilities.
6. Click **Save**.

Unlock a locked user account

Users will occasionally get locked out of their accounts and ask you to unlock or reset their account.

Make sure you ask them if they have already tried clicking the **Forgot my password** link and if they can't remember their customer ID or username.

Unlock a user

1. From the **Admin** menu, select **Users**.
2. Select the user, click **Reset Account**, and then confirm the action.
3. On the **Profile** tab, set the **Account Locked** field to **No**.
4. Click **Save**.

If you lock an account when the user is logged in, the user remains logged in until the session expires or is terminated. ClearTrial denies subsequent log-in attempts.

Reset user accounts

Resetting an account clears the security question and answer, unlocks a locked account, and forces the user to reset their password when they next log in.

1. From the **Admin** menu, select **Users**.
2. Select a user and click the **Reset Account** button.
3. Confirm the reset, and then click **Ok**.

   ClearTrial clears the security question and answer and sends the user an email with a link to reset the password.

Reset user passwords

Occasionally, users will contact you because they need their password reset.

All users can reset their password by clicking the **Forgot Your Password?** link on the **Please Log In** screen. However, to reset their password, they must provide their customer code, username, and email address. If they have forgotten any of these credentials, only an assigned ClearTrial system administrator can reset passwords directly for them.

1. From the **Admin** menu, select **Users**.
2. Select a user and click **Edit Password**.
3. In the **New Password** and **Verify New Password** fields, enter and confirm a new password for the user.
4. Click **Save**.

   The user receives an email stating that their password has changed. The email does not contain the new password. You must provide the user with the new password through a secure form of communication. ClearTrial prompts the user to change the password upon successfully logging in.

View inactive users

Use the Inactive Users Report to view users that have not logged into ClearTrial within the number of days specified on the report input screen.

You can generate the report in various formats.

1. From the **Report** menu, select **Inactive Users Report**.
2. On the **Inactive Users Report** screen, in the **Options** section, in the **Days Since Last Login** field, specify a default for the number of days since the last login.
3. Click **Ok**.

Delete user accounts

System administrators can delete user accounts for users who have left the organization or no longer need access to the service.

Oracle recommends that you verify all user accounts periodically (quarterly or monthly, if needed) to ensure that users who require access have user accounts and all required permissions enabled to use the service.

User accounts are not immediately deleted and can be restored before they are purged according to the customer preference set for your users. The default is 30 days before all items in a deleted state are purged.

1. From the **Admin** menu, select **Users**.
2. Select one or more users and click **Delete**.

   When you display all users, the deleted user is greyed out and a line appears through the information.

   You can restore a deleted user account by selecting the user and clicking **Restore**.