Oracle® Health Sciences ClearTrial Cloud Service System Administrator Guide



Release 5.9 F40928-01 June 2021

ORACLE

Oracle Health Sciences ClearTrial Cloud Service System Administrator Guide, Release 5.9

F40928-01

Copyright © 2018, 2021, Oracle and/or its affiliates.

This software and related documentation are provided under a license agreement containing restrictions on use and disclosure and are protected by intellectual property laws. Except as expressly permitted in your license agreement or allowed by law, you may not use, copy, reproduce, translate, broadcast, modify, license, transmit, distribute, exhibit, perform, publish, or display any part, in any form, or by any means. Reverse engineering, disassembly, or decompilation of this software, unless required by law for interoperability, is prohibited.

The information contained herein is subject to change without notice and is not warranted to be error-free. If you find any errors, please report them to us in writing.

If this is software or related documentation that is delivered to the U.S. Government or anyone licensing it on behalf of the U.S. Government, then the following notice is applicable:

U.S. GOVERNMENT END USERS: Oracle programs (including any operating system, integrated software, any programs embedded, installed or activated on delivered hardware, and modifications of such programs) and Oracle computer documentation or other Oracle data delivered to or accessed by U.S. Government end users are "commercial computer software" or "commercial computer software documentation" pursuant to the applicable Federal Acquisition Regulation and agency-specific supplemental regulations. As such, the use, reproduction, duplication, release, display, disclosure, modification, preparation of derivative works, and/or adaptation of i) Oracle programs (including any operating system, integrated software, any programs embedded, installed or activated on delivered hardware, and modifications of such programs), ii) Oracle computer documentation and/or iii) other Oracle data, is subject to the rights and limitations specified in the license contained in the applicable contract. The terms governing the U.S. Government's use of Oracle cloud services are defined by the applicable contract for such services. No other rights are granted to the U.S. Government.

This software or hardware is developed for general use in a variety of information management applications. It is not developed or intended for use in any inherently dangerous applications, including applications that may create a risk of personal injury. If you use this software or hardware in dangerous applications, then you shall be responsible to take all appropriate fail-safe, backup, redundancy, and other measures to ensure its safe use. Oracle Corporation and its affiliates disclaim any liability for any damages caused by use of this software or hardware in dangerous applications.

Oracle and Java are registered trademarks of Oracle and/or its affiliates. Other names may be trademarks of their respective owners.

Intel and Intel Inside are trademarks or registered trademarks of Intel Corporation. All SPARC trademarks are used under license and are trademarks or registered trademarks of SPARC International, Inc. AMD, Epyc, and the AMD logo are trademarks or registered trademarks of Advanced Micro Devices. UNIX is a registered trademark of The Open Group.

This software or hardware and documentation may provide access to or information about content, products, and services from third parties. Oracle Corporation and its affiliates are not responsible for and expressly disclaim all warranties of any kind with respect to third-party content, products, and services unless otherwise set forth in an applicable agreement between you and Oracle. Oracle Corporation and its affiliates will not be responsible for any loss, costs, or damages incurred due to your access to or use of third-party content, products, or services, except as set forth in an applicable agreement between you and Oracle.

Contents

Preface

| Documentation accessibility | iv |
|-----------------------------|----|
| Related resources | iv |
| Access to Oracle Support | iv |

1 System Administrator Guide

| Administration basics | 1-1 |
|----------------------------------------------------------------------|------|
| Edit customer preferences | 1-1 |
| Request changes to configuration parameters not exposed to customers | 1-2 |
| Purge deleted items | 1-2 |
| Manage your user profile | 1-3 |
| View your user profile | 1-3 |
| Edit your user profile | 1-3 |
| Change your password | 1-3 |
| Add other ClearTrial System Administrators | 1-3 |
| Manage other users | 1-4 |
| View existing users | 1-4 |
| Creating user accounts | 1-4 |
| User permissions | 1-5 |
| User roles and capabilities | 1-6 |
| Edit user accounts | 1-8 |
| Lock and unlock user accounts | 1-9 |
| Delete user accounts | 1-9 |
| Reset user passwords | 1-9 |
| Reset user accounts | 1-10 |
| View inactive users | 1-10 |



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/health-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 Health 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 http://www.oracle.com/us/ support/contact/health-sciences-cloud-support/index.html or visit http:// www.oracle.com/pls/topic/lookup?ctx=acc&id=trs if you are hearing impaired.



1 System Administrator Guide

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.

It includes the following information:

- Administration basics
- Manage your user profile
- Add other ClearTrial System Administrators
- Manage other users

Administration basics

This section provides information on how to work as an assigned ClearTrial System Administrator in ClearTrial.

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, so in case you are unavailable and other users experience user account issues, there is a backup to support the other users.

Your initial 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
- Request changes to configuration parameters not exposed to customers
- Purge deleted items

Edit customer preferences

Assigned ClearTrial System Administrators can 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 in the name, email, and phone number whose contact 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, if needed. For more information about a field, click the field name to display online help.
- 3. Click Save.

Request changes to configuration parameters not exposed to customers

Assigned System Administrators can configure most settings for users. However, to change any of the following configurations for your environment, please contact Oracle Support by filing a Service Request in My Oracle Support.

The following custom configurations are available:

- Login Attempts Limit: Number of login attempts permitted before a user is locked out of the application. Is set to 5 by default.
- Allow Affiliates: If you have affiliates that need to be represented in the service, this allows you to define service providers as affiliates/business units. Is set to False by default.

Purge deleted items

When you delete anything in ClearTrial, it is known as a *soft delete*, 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 value 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. Choose the type of deleted items you want to purge.
- 3. In the **deleted at least n days ago** field, specify the number of days since an item of that type was deleted if you want to change the default.



4. Click Purge Deleted Items.

Manage your user profile

This section provides information on how to view and edit your account details.

- View your user profile
- Edit your user profile
- Change your password

View your user profile

1. Click your **name** in the upper right corner of the main menu bar to view your user profile details.

You will see all existing settings for your account, such as your login username, email address, preferred locale, and all your assigned roles, such as your primary role to access the service along with all existing additional roles/capabilities currently assigned to you.

- If you click on each role/additional capability, you can see the permissions associated with that role.
- 3. Click Done.

Edit your user profile

- 1. From the View User Profile screen, click Edit Profile to edit any of your account details.
- Edit any of the fields to reflect the most current and accurate information.
 For more information about a field, click on the field to display the online help.
- 3. Click Save.

Change your password

- 1. From the View User Profile screen, click Change Password.
- 2. In the Current Password field, enter your password.
- 3. In the New Password field, enter your new password.
- 4. In the Verify New Password field, retype your new password.
- 5. Click Save.

Add other ClearTrial System Administrators

As a ClearTrial Best Practice, we recommend assigning multiple users to the ClearTrial System Administrator role for backup to perform these tasks, in case one is not available.

Only other assigned ClearTrial System Administrators can change the roles/additional capabilities of an existing ClearTrial System Administrator, in case you need them changed or you are locked out.

1. Create a new user and enter in all minimum required data or edit an existing user.



- 2. Click on the **Roles** tab, and set that user's primary role to the **System** Administrator.
- 3. Grant any other additional capabilities that the user needs.

Manage other users

This section provides information on how to create, edit, delete, assign/update user roles or additional capabilities, and reset user accounts/passwords.

- View existing users
- Creating user accounts
- User permissions
- User roles and capabilities
- Edit user accounts
- Lock and unlock user accounts
- Delete user accounts
- Reset user passwords
- Reset user accounts
- View inactive users

View existing users

To access ClearTrial, every user must have a user account and have a primary role assigned to it.

Assigned ClearTrial System Administrators are responsible for managing all other user accounts for their organization.

- **1.** From the **Admin** menu, click **Users** to get to the User list screen.
- 2. Filter the **Users** list as necessary from the user-defined filter along the top of the screen to identify those users whose details you need to update.
- 3. Once you have identified the user you are looking for, select that user and click edit if you need to edit any of their details or update their roles.

Creating user accounts

Only assigned ClearTrial System Administrators can create new user accounts for other users.

- 1. From the Admin menu, select Users.
- 2. On the Users screen, click New.
- 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.
- Specify the maximum edit mode by selecting it from the Maximum Edit Mode drop-down list. Select the preferred edit mode from the Preferred Edit Mode dropdown list.



The edit modes control the precision of the plan by determining which assumptions the user can set. The maximum edit mode is the most advanced edit mode the user can access when creating or editing plans. The preferred edit mode is the mode that is used by default when the user is using the service.

- 5. 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.
- 6. From the **Preferred Home Page** drop-down list, select the user will be directed to each time upon login.
- 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 MM/dd/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.

- 8. Click Save.
 - You must save these settings to enable the Roles tab.
 - 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 setup 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.
- 9. On the Roles tab:
 - a. Assign the user a primary role.
 - Assign any additional roles/capabilities to grant access to those functional capabilities not granted by default

For more information about user roles, see User roles and capabilities.

10. Click Save.

User permissions

Permissions enable users to access certain features or perform specific actions in ClearTrial.

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

For more information on user roles, see User roles and capabilities.



User roles and capabilities

You can assign primary roles and additional roles/capabilities to other users.

- 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.

| 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. | None. |
| | If Power Users need to create studies, they can request that additional option be enabled by their ClearTrial System Administrator. | |
| 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 Administrator 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 1-1 Primary Roles



| 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 Clinical Administrators. |
| 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 | Only available to Enterprise licensed users. |
| | 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. | Administrator can grant these permissions to users that are assigned a primary role of Clinical Administrator or System Administrator. |
| 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 |



| Additional Role/ Capability | Description | Comments |
|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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. | Only available to Enterprise Licensed users. |
| | This role allows the user to view and edit the Level of Effort algorithm for a plan-specific task and resource. | |
| 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 (i.e., 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. |

| Table 1-2 | (Cont.) | Additional | Roles | and | Capabilities |
|-----------|---------|------------|-------|-----|--------------|
|-----------|---------|------------|-------|-----|--------------|

Edit user accounts

- 1. From the Admin menu, select Users.
- 2. Select a user and click Edit.
- 3. On the **Profile** tab, 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.

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. For more information about a field, click the field name to display online help.
- 6. Click Save.



Lock and unlock user accounts

Users will occasionally get locked out of their accounts. They will come to their assigned ClearTrial System Administrator (you) to unlock or reset their account if they have already tried clicking on the Forgot my password link and can't remember the customer ID or their username.

To unlock users:

- 1. From the Admin menu, select Users.
- 2. Click Reset Account and confirm the action.

OR

Select the user and click Edit.

- 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.

Delete user accounts

System administrators can delete user accounts for users who have left the organization or no longer need access to the service. We recommend verifying all user accounts periodically (quarterly or monthly if needed) to ensure that users who require access have user accounts and have 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.

Restore a deleted user account by selecting the user and clicking Restore.

Reset user passwords

Occasionally, users will contact you because they need their password reset when they have forgotten it. As a reminder, all users can reset their password by clicking on the Forgot Your Password? link on the login screen. To reset their password, users will need to provide their customer code, username, and email address.

If users have forgotten any of their credentials, assigned ClearTrial System Administrators 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 the 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.

Reset user accounts

Resetting a user account:

- Clears the security question and answer associated with the account.
- Unlocks the user account if it is locked.
- Forces the user to reset the password upon login.
- 1. From the Admin menu, select Users.
- 2. Select a user and click Reset Account.

An account reset confirmation message appears.

3. Click OK.

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

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, as per your preference/needs.

- 1. From the Report menu, select Inactive Users Report.
- 2. On the **Inactive Report Options** screen, in the **Days Since Last Login** field, enter the number of days since the last login, if changing the default.
- 3. Click Ok.

