Information for Sponsor and CRO Users

Oracle® Health Sciences Clinical One 1.0

Part number: E83768-01

Contents

CHAPTER 1

For system administrators: Create global users

In this chapter

Create a global user

Global users are responsible for setting up a study in Clinical One. Global users can create studies and give users access to them, as well as create other global users. Each organization typically has only a few global users.

An administrator must create a user's Oracle Single Sign-On (SSO) user account before the user can be created as a global user in Clinical One.

1 On the Home page, click **Global Settings**, along the top.

2 Click **Create Global User**.

3 From the **Full Name** drop-down, select the user's name.

4 Click into the **Global Roles** field and select one or more global roles to assign to the user:

- If the user creates studies, select **Study Creator**.
- If the user manages the users who have access to a study, select **Global User Manager Role - Sponsor**.

Tip: To view the permissions for a role, click **View Permissions**, and select a role from the **Roles** drop-down.

5 Click **Create**.

6 Contact the global users for your organization and ask them to ***create the study*** (on page 4) and ***give users access to it*** (on page 5).

Field descriptions

Field	Description
Full Name	No description
User Name	No description
Email	No description
Global Roles	Choose the user's roles across all studies in Clinical One

CHAPTER 2

Build a study

In this chapter

Create a study

1 On the Home page, click **Create Study**.

2 Fill in the fields and click **Save**.

The new study is added to the Home page. By default, the study contains a study version of 1.0.0.1 with a status of Draft.

3 ***Give users access to the study*** (on page 5) so that they can start working in it.

Field descriptions

Field	Description
Study Title	Enter the title of the protocol
Study ID	Enter a unique value, such as a protocol acronym and protocol number
Study Phase	No description
Therapeutic Area	No description
Open Label / Blinded	No description
Contract Code	Reserved for a future release.

Give a user access to a study

An administrator must create a user's Oracle Single Sign-On (SSO) user account before the user can be created in Clinical One.

You should give a limited number of sponsor users access to the study right after the study is created. You typically give access some or all of the following users:

- Study builder
- Study manager
- Clinical supply manager

One of those users can ***add additional users*** (on page 30), including site users, later.

1 On the Home page, click the study settings button ( ) on the study you want to edit, and select **Open Settings**.

2 Below the study name, click the **Users** tab.

3 Click **Create User**.

4 Fill in the fields in the wizard. To see the roles, sites, and depots typically assigned to users, see:

- ***Site users - Typical assignments*** (on page 30)
- ***Sponsor users - Typical assignments*** (on page 31)
- ***Depot users - Typical assignments*** (on page 37)

5 After you complete the wizard, click **Close**.

Tips

- You might want to consider your training requirements and your documentation of users' training before giving users access to Clinical One.

Field descriptions

Field	Description
Details & Roles	
Full Name	No description
User Name	No description
Email	No description
Effective Date Range	Specify when the user has access to the study
Study Design Roles	Choose the user's roles and notifications for building the study
Production Roles	Choose the user's roles, notifications, and reports while entering data in Production mode
Training Roles	Choose the user's roles, notifications, and reports while entering data in Training mode

Field	Description
Testing Roles	Choose the user's roles, notifications, and reports while entering data in Testing mode
Sites & Depots	
Production Sites	Choose one or more sites that the user can work with data for in Production mode
All Production Sites	Select if the user requires access to all Production sites that exist and that are created in the future
Training Sites	Choose one or more sites that the user can work with data for in Training mode
All Training Sites	Select if the user requires access to all Training sites that exist and that are created in the future
Testing Sites	Choose one or more sites that the user can work with data for in Testing mode
All Testing Sites	Select if the user requires access to all Testing sites that exist and that are created in the future
Production Depots	Choose one or more depots that the user can work with shipments and inventory for in Production mode
All Production Depots	Select if the user requires access to all Production depots that exist and that are created in the future
Training Depots	Choose one or more depots that the user can work with shipments and inventory for in Training mode
All Training Depots	Select if the user requires access to all Training depots that exist and that are created in the future
Testing Depots	Choose one or more depots that the user can work with shipments and inventory for Testing mode
All Testing Depots	Select if the user requires access to all Testing depots that exist and that are created in the future

Create a form

Learn more about forms and validation rules in the FAQs.

Task 1. Create the form

1 On the Home page, click the pencil button ( ) on the study you want to edit.

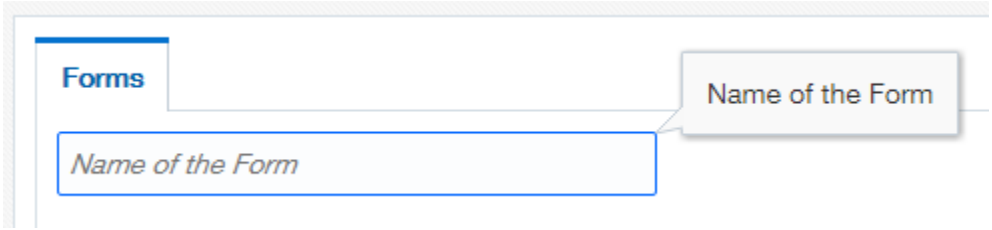
2 Choose the Draft version of the study.

3 Along the top, make sure that **Data Capture** is selected.

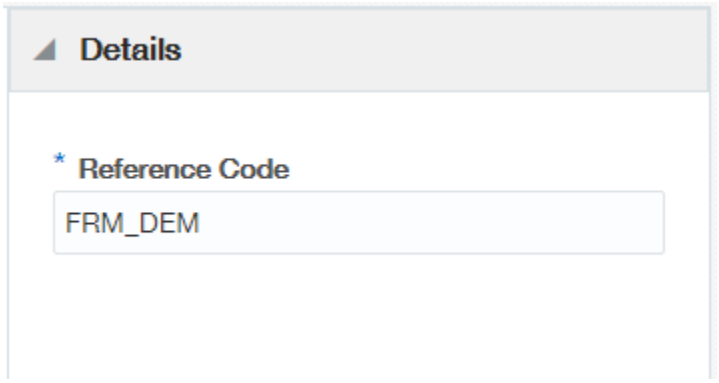
4 If you have no forms, click **Create Form**.

If you have one or more forms, click **Add Form** in the upper left.

5 In the upper left, enter a name for the form.



6 On the right, below Details, enter a reference code for the form.



Tip: As you create a form, consider documenting the test cases for its questions.

Task 2. Determine the kind of data that you need to collect and create questions

I want to capture...	Question to create
A value with either letters only or letters and numbers	***Text question*** (on page 9)
A value with numbers only	***Number question*** (on page 10)
A date value, with or without a time	***Date/Time question*** (on page 12)
One or more answers that site users select from a drop-down	***Drop-down question*** (on page 14)

Task 3. Save the form

- In the lower right of the form, click **Save**.

  Tip: If the **Save** button is disabled, make sure there are no blank questions on the form.

Tips

- Make sure you include a question that confirms that subjects have provided informed consent.

  Additionally, include a question that ensures that a subject meets the inclusion criteria for the study.

- When subjects need to meet age criteria to enroll in a study and the study allows the collection of date of birth, create two required questions on a form:

  - In one question, ask the subject's date of birth.
  - In another question, ask the subject's age.

  Create a validation rule on this question so that subjects who do not qualify cannot enroll.

- If you're collecting data where multiple values are related, create separate questions for each value. For example, to collect data about blood pressure, create two number questions, one for systolic blood pressure and the other for diastolic blood pressure.

Field descriptions

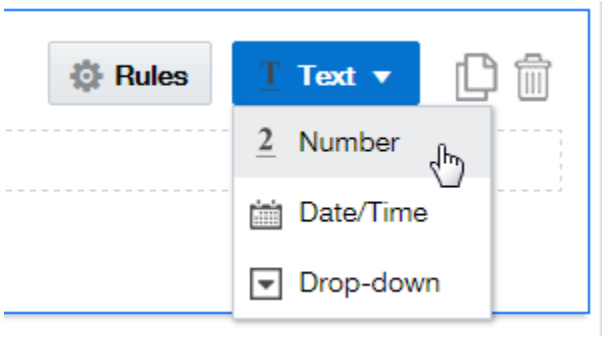
Field	Description
Form title	No description
Reference Code	Specify a one-word abbreviation for the form. This field is reserved for a future release.
Details	
Question	No description
Answer	No description
Reference Code	Specify a one-word abbreviation for the question. This field is reserved for a future release.
Question Hint	Enter additional information for site users
Required	Select if screening, randomization, and dispensation can't happen until a site user enters a valid answer for the question
Randomization Factor	Reserved for a future release
Multiple Line Answer	(Appears for Text questions only) Choose whether the answer field includes a single line or multiple lines
Character Limit	(Appears for Text questions only) Enter the character limit, up to the default limit of 4,000 characters

Field	Description
Include Unit of Measure	(Appears for Number questions only) Specify the label that appears next to the answer field
Format	(Appears for number questions only) Choose the number of allowed places after the decimal point
Input Type	(Appears for Date/Time questions only) Choose the format for collecting date and time values
Rules	
Error message	Enter the error message that appears when the answer is missing or invalid. Write what the validation rule is for and what the site user should do.
AND/OR	Choose AND if an answer must pass all rules to be valid, and choose OR if an answer must pass only one rule to be valid

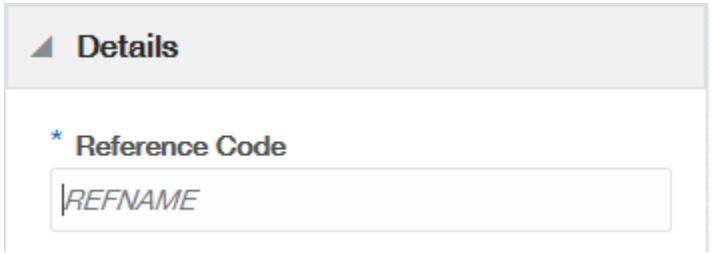
Specify details for a text question

1 Enter the question.

Tip: If you need to change the question type, select an option from the drop-down on the question.



2 Under Details, enter a reference code for the question.



Tip: Include the form name in the reference code for a question. For example, you might enter SCREENING_DOB.

3 In the **Question Hint** field, provide site users with guidelines for data entry.

4 If the question is required to complete the visit, click **Required**.

Randomization Factor is reserved for a future release.

5 If you expect site users to provide a long answer, select **Multiple Line Answer**.

6 Enter a character limit.

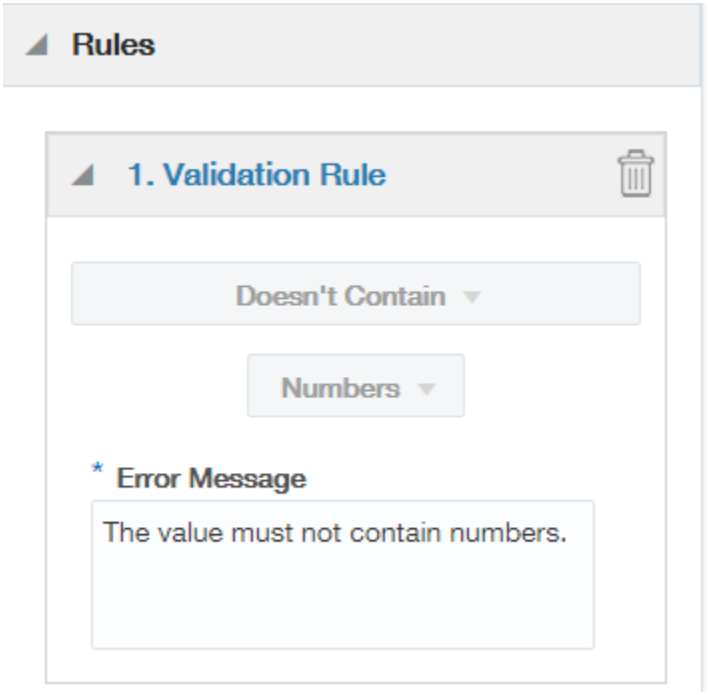
7 To create a validation rule:

a In the lower right, expand **Rules**.

Tip: For text questions, one validation rule is available. The rule limits the field to only alphabetic characters.

b Click **Add Validation Rule** and select **Doesn't Contain**.

c Enter an error message. The error message appears if a site user enters invalid data.



8 To add another question, in the lower left, select an option from the **Add Question** drop-down and fill in the details for the question.

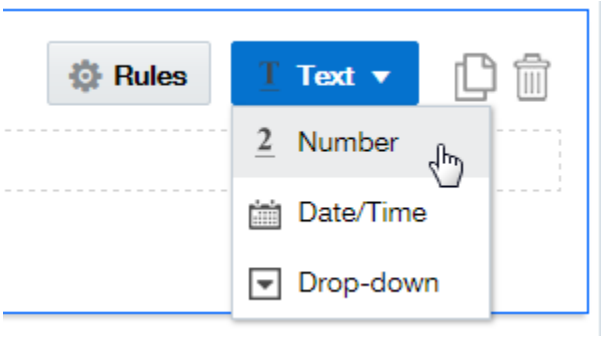
9 To save the form, in the lower right of the form, click **Save**.

Tip: If the **Save** button is disabled, make sure there are no blank questions on the form.

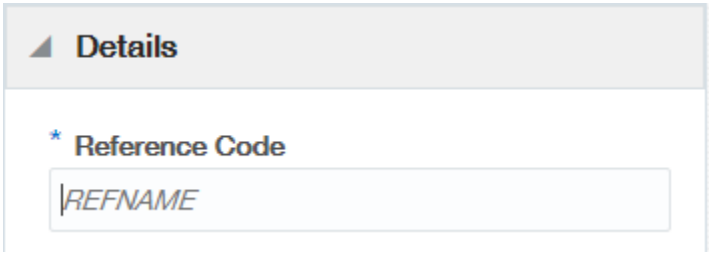
Specify details for a number question

1 Enter the question.

Tip: If you need to change the question type, select an option from the drop-down on the question.



2 Under Details, enter a reference code for the question.



Tip: Include the form name in the reference code for a question. For example, you might enter SCREENING_DOB.

3 In the **Question Hint** field, provide site users with guidelines for data entry.

4 If the question is required to complete the visit, click **Required**.

Randomization Factor is reserved for a future release.

5 If applicable, click **Include Unit of Measure** and enter a unit of measure.

6 From the **Format** drop-down, select the number of decimal places to record.

Tip: Selecting 1 records the value to the nearest whole number.

7 To create a validation rule:

a In the lower right, expand **Rules**.

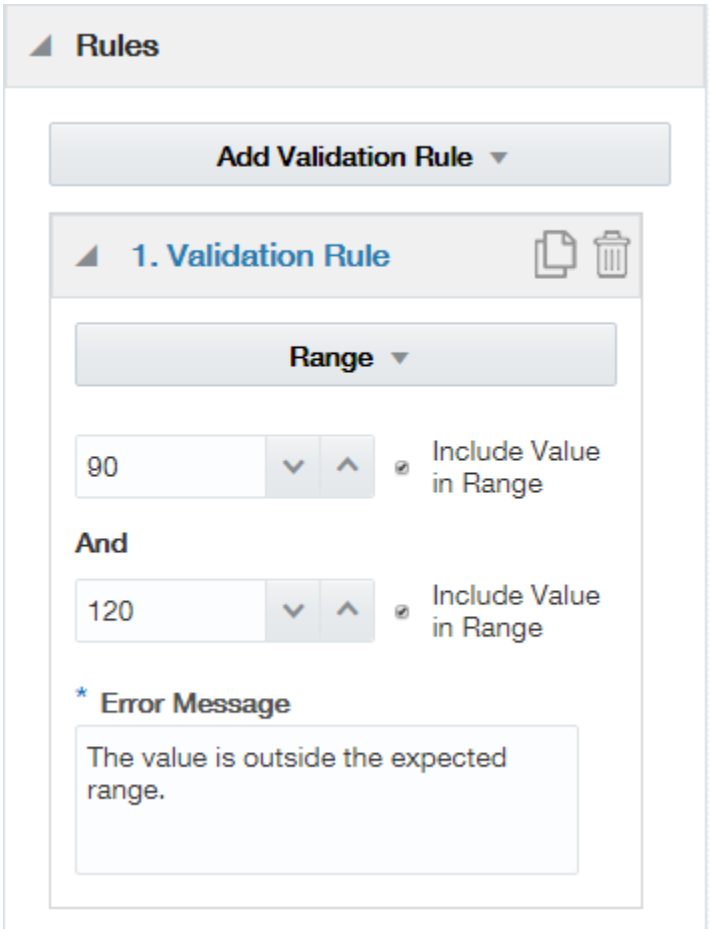
b From the **Add Validation Rule** drop-down, select an option and specify valid values.

c Enter an error message. The error message appears if a site user enters invalid data.

d To add another validation rule, select an option from the **Add Validation Rule** drop-down and select an option from the **AND** drop-down:

- If you select **AND**, the value must be valid for every validation rule.
- If you select **OR**, the value must be valid for exactly one validation rule.

Tip: You can select only one option per question. For example, if you have three validation rules on a question, you can select **AND** twice or **OR** twice, but you can't select **AND** followed by **OR**.



8 To add another question, in the lower left, select an option from the **Add Question** drop-down and fill in the details for the question.

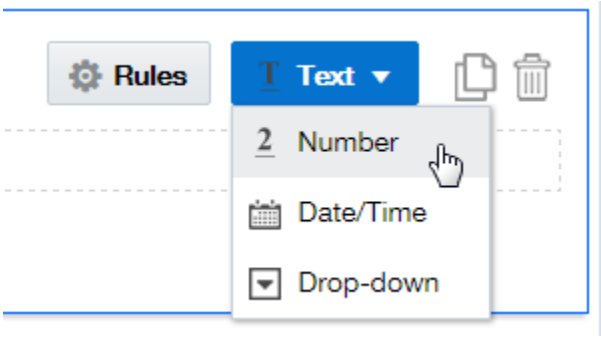
9 To save the form, in the lower right of the form, click **Save**.

Tip: If the **Save** button is disabled, make sure there are no blank questions on the form.

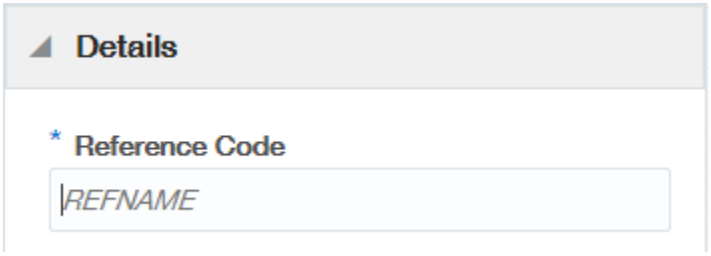
Specify details for a date/time question

1 Enter the question.

Tip: If you need to change the question type, select an option from the drop-down on the question.



2 Under Details, enter a reference code for the question.



Tip: Include the form name in the reference code for a question. For example, you might enter SCREENING_DOB.

3 In the **Question Hint** field, provide site users with guidelines for data entry.

4 If the question is required to complete the visit, click **Required**.

Randomization Factor is reserved for a future release.

5 From the **Input Type** drop-down, select the parts for the date to record.

6 To create a validation rule:

a In the lower right, expand **Rules**.

b From the **Add Validation Rule** drop-down, select an option and specify valid values.

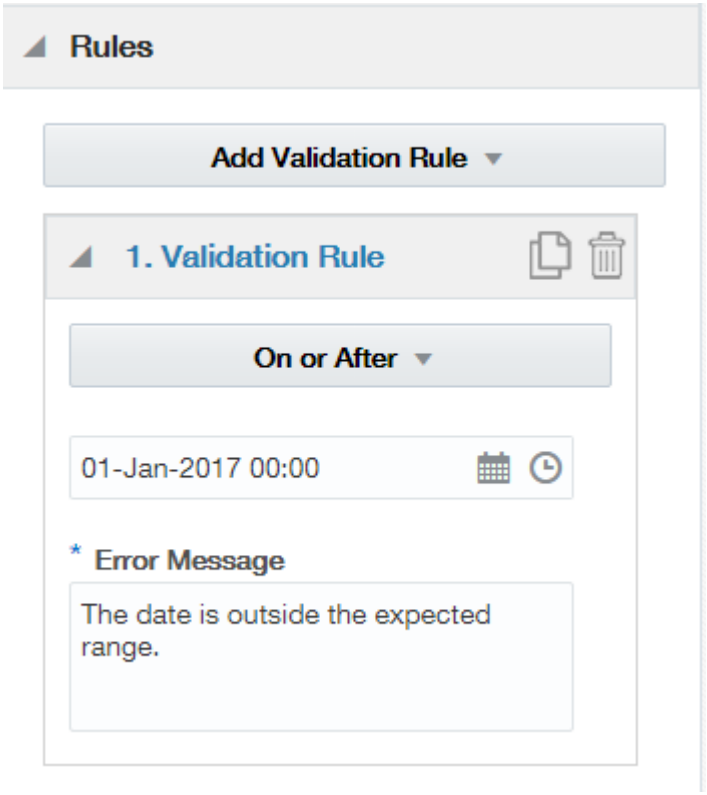
Tip: Click the calendar icon to select a date and click the clock icon to select a time.

c Enter an error message. The error message appears if a site user enters invalid data.

d To add another validation rule, select an option from the **Add Validation Rule** drop-down and select an option from the **AND** drop-down:

- If you select **AND**, the value must be valid for every validation rule.
- If you select **OR**, the value must be valid for exactly one validation rule.

Tip: You can select only one option per question. For example, if you have three validation rules on a question, you can select **AND** twice or **OR** twice, but you can't select **AND** followed by **OR**.



7 To add another question, in the lower left, select an option from the **Add Question** drop-down and fill in the details for the question.

8 To save the form, in the lower right of the form, click **Save**.

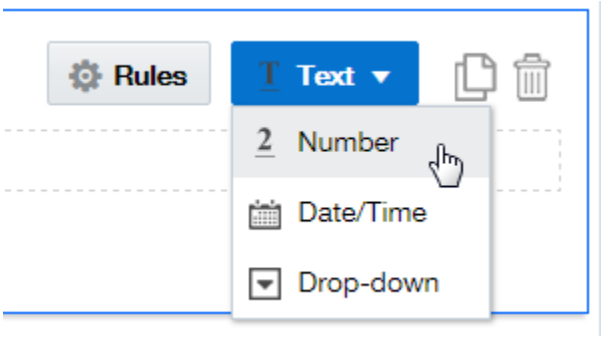
Tip: If the **Save** button is disabled, make sure there are no blank questions on the form.

Specify details for a drop-down question

For drop-down questions, site users can select one or more answers.

1 Enter the question.

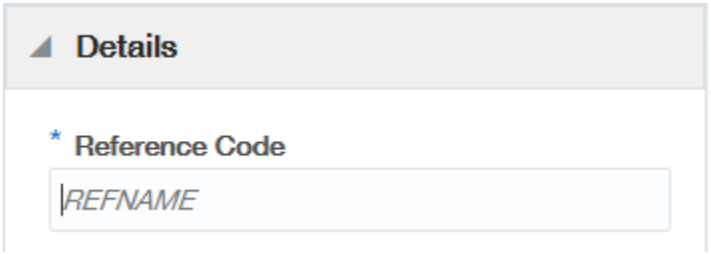
Tip: If you need to change the question type, select an option from the drop-down on the question.



2 In the **Answer** fields, enter at least two options for the drop-down.

3 To add another answer field, click **Add Answer**.

4 Under Details, enter a reference code for the question.



Tip: Include the form name in the reference code for a question. For example, you might enter SCREENING_DOB.

5 In the **Question Hint** field, provide site users with guidelines that reflect the validation rules for the question. For example, you might enter Select at least one option.

6 If the question is required to complete the visit, click **Required**.

Randomization Factor is reserved for a future release.

7 To create a validation rule:

a In the lower right, expand **Rules**.

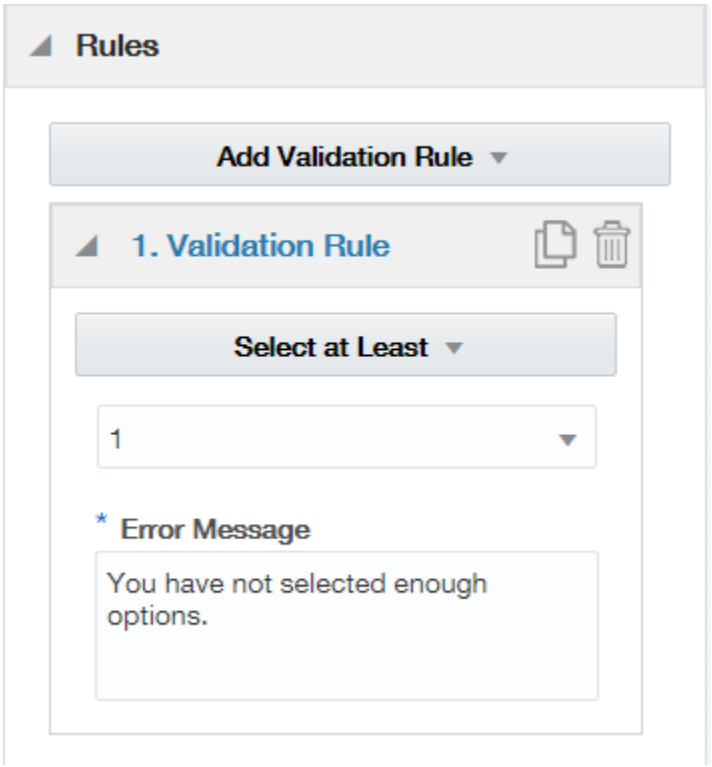
b From the **Add Validation Rule** drop-down, choose an option and specify the number of options for site users to select.

c Enter an error message. The error message appears if a site user enters invalid data.

d To add another validation rule, select an option from the **Add Validation Rule** drop-down and select an option from the **AND** drop-down:

- If you select **AND**, the value must be valid for every validation rule.
- If you select **OR**, the value must be valid for exactly one validation rule.

Tip: You can select only one option per question. For example, if you have three validation rules on a question, you can select **AND** twice or **OR** twice, but you can't select **AND** followed by **OR**.



8 To add another question, in the lower left, select an option from the **Add Question** drop-down and fill in the details for the question.

9 To save the form, in the lower right of the form, click **Save**.

Tip: If the **Save** button is disabled, make sure there are no blank questions on the form.

Create a visit

Learn more about visits in the FAQs.

1 On the Home page, click the pencil button () on the study you want to edit.

2 Choose the Draft version of the study.

3 Along the top, make sure that **Data Capture** is selected.

4 If you have no visits, on the right, in Visits & Events, click **Create Visit**.

If you have one or more visits, in the upper right of Visits & Events, click the **+** button.

5 Fill in the fields and click **Save**.

The new visit appears under Visits & Events.

Tips

- Since you have to create visits before you can design the visit schedule, create the visits in the order that they will be scheduled. For example, create Screening, Week 1, Week 2, and so on.

Field descriptions

Field	Description
Title	Enter the name of the visit, such as Screening
Repeating Visit	Reserved for a future release
Screening Visit	Select if the visit is for screening. You must have one Screening visit in a study.
Required Visit	Select if all subjects must complete the visit

Add a form to a visit

Every visit must have at least one form.

1 On the Home page, click the pencil button () on the study you want to edit.

2 Choose the Draft version of the study.

3 Along the top, make sure that **Data Capture** is selected.

4 On the left, drag a form to the visit you want to add it to on the right.

Tip: You can add forms to visits in any order, but you'll save some time if you add forms in the order they should appear to site users.

5 Select the checkboxes to the left of the visits that you want to associate the form with, and then click **Save**.

The form icon on a visit lists the number of forms in the visit.

Tips

- To check the work you did on a visit, reorder forms in a visit, or add more forms to a visit, click the visit in Visits & Events.

Design the visit schedule

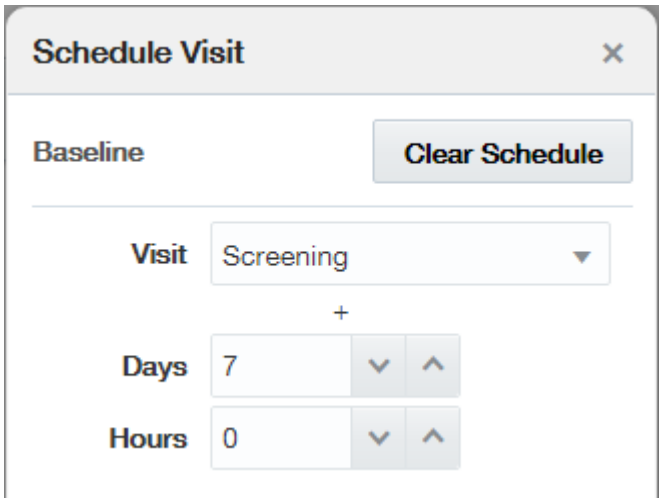
1 On the Home page, click the pencil button ( ) on the study you want to edit.

2 Choose the Draft version of the study.

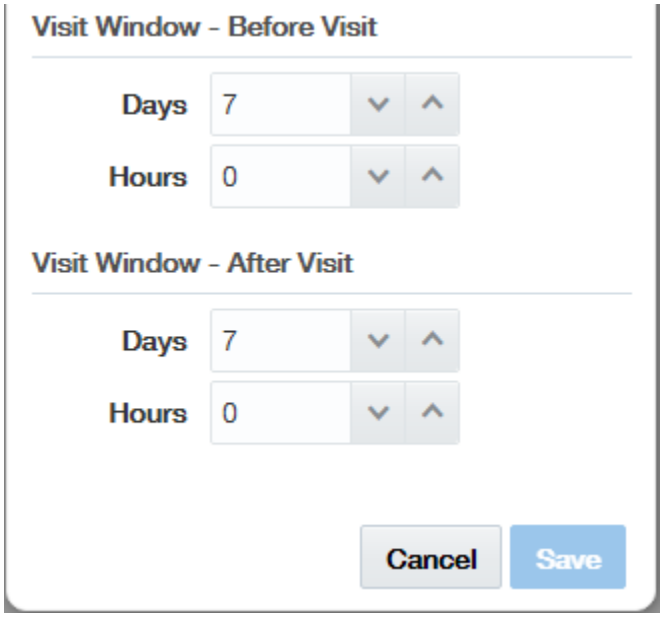
3 In Visits & Events, click the gray clock icon leading to the visit you want to schedule.

The name of the visit you're scheduling appears in the upper left of the window.

4 From the **Visit** drop-down, select a visit to schedule time from, and specify the number of days and hours between the visits.



5 In the **Visit Window** fields, specify the plus or minus days from the study protocol and click **Save**.



The clock icon leading to the visit you just scheduled turns blue to indicate that the visit has been scheduled.

Tips

- As you schedule visits, the visits are reordered in Visits & Events so that they appear in the

planned order.

- To remove the scheduling for a visit, click the clock icon leading to the visit, and click **Clear Schedule**.

Field descriptions

Field	Description
Visit	Select the visit to schedule from
Days	Specify the days between the visits
Hours	Specify the hours between the visits
Visit Window - Before Visit	
Days	Specify how many days before the scheduled date and time the visit can occur
Hours	Specify how many hours before the scheduled date and time the visit can occur
Visit Window - After Visit	
Days	Specify how many days after the scheduled date and time the visit can occur
Hours	Specify how many hours after the scheduled date and time the visit can occur

Create a new Draft version of a study to update the Testing version

Need to perform this task for a *production study* (on page 78)?

1 On the Home page, click the pencil button () on a study.

2 In Draft, click **Create Study Version**.

Tip: The new Draft version is a copy of the latest version of the study. The latest version of the study has the highest fourth number (for instance, 4 in 1.0.0.4). When you create a new Draft version of a study, this number increases by 1. For example, 1.0.0.1 becomes 1.0.0.2.

3 Drag the old study version from Testing to Archived.

Because you must make changes to the new Draft version, you no longer need the old Testing version.

4 In Draft, edit the new study version and then drag it from Draft to Testing.

Tips

- You can modify details about the study, including its title, phase, and blinding status at any time, without creating a new version of a study.
- To rename a study version, click the pencil button on the study (). Click the menu button () on the study version, and select **Rename**. You can change the name of the study version, but not the version number.

CHAPTER 3

Specify study settings

In this chapter

Specify subject settings for Testing mode

Need to perform this task for a *production study* (on page 52)?

1 On the Home page, click the study settings button ( ) on the study you want to edit, and select **Open Settings**.

2 Below the study name, click the **Subject Settings** tab.

3 On the left, select **Testing Settings**.

4 Fill in the fields.

5 In the upper right, click **Apply Changes**.

Tips

- You can edit these settings at any time. The settings apply to all versions of the study.

Field descriptions

Field	Description
First Subject Number	Enter the number assigned to the first subject in the study
Withdraw Subjects After Code Break	Choose Yes if subjects are withdrawn from the study after a code break. A code break is the unblinding of a subject's treatment arm.
Limit Screened Subjects	Choose Yes to place a limit on the number of subjects who can be screened in the study
Limit	Enter the number of subjects who can be screened in the study
Limit Randomized Subjects	Choose Yes to place a limit on the number of subjects who can be randomized in the study
Limit	Enter the number of subjects who can be randomized in the study
Notify When Randomized	Reserved for a future release

Specify supply settings for Testing mode

Need to perform this task for a *production study* (on page 53)?

1 On the Home page, click the study settings button ( ) on the study you want to edit, and select **Open Settings**.

2 Below the study name, click the **Supply Settings** tab.

3 On the left, make sure **Testing Settings** is selected.

Tip: You can specify Production and Training settings only after you move a study version to Approved.

4 Fill in the fields.

5 In the upper right, click **Apply Changes**.

Tips

- You can edit these settings at any time. The settings apply to all versions of the study.

Field descriptions

Field	Description
Send Initial Shipments	Choose whether initial shipments are sent to sites when each sites is activated, or after the first subject starts a particular visit, which you choose
Visit Number	(Available only when First Subject in Visit Number is selected for the previous field) Choose the visit that the first subject must start for initial shipments to be sent to a site
Days to Run Inventory	Choose the days of the week when the resupply process runs for every site
Time to Run Inventory	Choose the time when the resupply process runs
Single Kit Ordering Allowed	Select Yes if a shipment can contain one kit. If the study is blinded, you typically select No.
Blinded Groups Required	(Available only when single kit ordering isn't allowed) Select Yes if kits have different packaging requirements. Create blinded groups of the kits that ship together to protect the study blind. If you select No, specify the kit that is added to single-kit shipments to protect the study blind.

Field	Description
Kits Added to Prevent Unblinding	(Available only when single kit ordering isn't allowed) Select how kits are added to a shipment to protect the study blind when single-kit ordering isn't allowed. If you choose to send a specific kit type, the location where you choose the kit type depends on whether you have blinded groups. If you don't have blinded groups, you choose the kit type to add to the shipment on this page. If you have blinded groups, you choose the kit type to add to the shipment when you create a blinded group.
Kit Type	(Available only when single kit ordering isn't allowed, blinded groups aren't required, and you chose to send a specific kit type to prevent unblinding) Choose the kit type to add to a single-kit shipment to protect the study blind.
Label Groups Required	Select Yes if a kit type has more than one label. A label group is a collection of kits that use the same label.
Allow for Temperature Excursion	Select Yes if any kits are sensitive to temperature excursions. A kit that experiences a temperature excursion cannot be dispensed until data about the excursion has been reviewed.
Allow Single Kit Quarantine	(Available only when Yes is selected for Allow for Temperature Excursion) Reserved for a future release
Multiple Storage Requirements	Select Yes to create shipments according to the storage needs of the kit types. For example, kits requiring refrigeration are shipped separately from kits that require ambient storage. Select No if all kits have the same storage needs.
Notification to Receive Shipment	Enter the number of days after the ship date (or the raise date, if the ship date isn't defined) when a site user receives a notification to mark a shipment as received
Site Can Request Shipments	Select Yes if sites can order a blinded shipment that you don't have to approve. You define the contents of the shipment in the resupply strategy that you assign to the site. Select No if the clinical supply manager will specify the contents of manual shipments that sites request.

Create a resupply strategy for Testing mode

Need to perform this task for a *production study* (on page 54)?

1 On the Home page, click the study settings button () on the study you want to edit, and select **Open Settings**.

2 Below the study name, click the **Supply Settings** tab.

3 On the left, make sure **Testing Settings** is selected.

4 On the right, expand **Min/Max Resupply** or **Predictive Resupply**.

Tip: To resupply a site only when inventory is low at the site, use Min/Max Resupply. To resupply a site based on actual enrollment and planned dispensation visits, use Predictive Resupply.

5 Click **Create Min/Max Resupply Group** or **Create Predictive Resupply Group**.

6 Fill in the fields and click **Add**.

Tips

- You will assign resupply strategies to sites when you add the sites.

Field descriptions

Field	Description
Min/Max Resupply	
Min/Max Resupply Title	Enter the name of the resupply strategy. If you create multiple resupply strategies, consider using names that tell you the sites that use each strategy.
Minimum Buffer	Enter the number of kits that trigger a shipment when the resupply strategy runs. When a single kit type reaches the number specified in the buffer, a shipment is created so that all kit types in the resupply strategy are raised to the maximum buffer at the site.
Maximum Buffer	Enter the number of kits that will be present at the site after a resupply shipment arrives. When a single kit type reaches the minimum buffer, a shipment is created so that all kit types in the resupply strategy are raised to the maximum buffer at the site.
First Shipment	Enter the number of kits of each type that are in the initial shipment. The number should be higher than the minimum buffer so that a new shipment isn't created after the resupply strategy runs the first time.
Manual Shipment	Enter the number of kits of each type that are included in a manual shipment when you allow sites to request manual blinded shipments
Predictive Resupply	
Title	No description

Field	Description
Trigger Weeks	Enter the number of weeks that the resupply strategy looks out to determine the supply that is required for subjects who have already been randomized. If additional supply is required, a shipment is created based on the resupply weeks.
Resupply Weeks	Enter the number of weeks that the resupply strategy resupplies for. For example, if you specify 2 trigger weeks and 4 resupply weeks, the resupply strategy determines the supply needed for the next 2 weeks for subjects who have been randomized. If the on-site supply is insufficient for that time, enough supply is sent so that the site can dispense for the next 4 weeks.
Minimum Buffer	No description
Maximum Buffer	No description
First Shipment	No description
Manual Shipment	No description

Create a blinded group of kits for Testing mode

Create blinded groups if you don't allow single kit ordering, and if the kits in your study use different packaging. Blinded groups determine the kit or kits that are added to a single-kit shipment to protect the study blind.

Need to perform this task for a *production study* (on page 55)?

1 On the Home page, click the study settings button () on the study you want to edit, and select **Open Settings**.

2 Below the study name, click the **Supply Settings** tab.

3 On the left, make sure **Testing Settings** is selected.

4 In the lower right, expand **Blinded Groups**.

Tip: If **Blinded Groups** doesn't appear, ***make sure that Yes is selected for Blinded Groups required*** (on page 25) and click **Apply Changes**.

5 Click **Create Blinded Group**.

6 Fill in the fields, and then click **Create**.

Field descriptions

Field	Description
Title	No description
Select kits to create blinded group	Select the kit types to include in the blinded group
Kits added to prevent unblinding	(Available only if you choose to send a kit type to prevent unblinding) Select the kit type that is added to a shipment to protect the study blind. Consider choosing the placebo or the kit with the highest number in the treatment ratio.

Add a user and assign roles

An administrator must create a user's Oracle Single Sign-On (SSO) user account before the user can be created in Clinical One.

Add all users who will work with the study, including all site users and any sponsor users who haven't been added yet.

1 On the Home page, click the study settings button ( ) on the study you want to edit, and select **Open Settings**.

2 Below the study name, click the **Users** tab.

3 Click **Create User**.

4 Fill in the fields in the wizard. To see the roles, sites, and depots typically assigned to users, see:

- ***Site users - Typical assignments*** (on page 30)
- ***Sponsor users - Typical assignments*** (on page 31)
- ***Depot users - Typical assignments*** (on page 37)

5 After you complete the wizard, click **Close**.

Tips

- You might want to consider your training requirements and your documentation of users' training before giving users access to Clinical One.
- You can add and edit users at any time, without creating a new version of a study.

Site users - Typical assignments

Tip: A user's role in Production, Training, and Testing modes determines settings for permissions and notifications. To view the permissions for a role, click **View Permissions**, and select a role from the **Roles** drop-down.

Principal investigators

Study Design roles	None
Production and Training roles	• Blinded Site User - Site • Blinded Site Inventory User - Site • CodeBreak - Site • Shipment Notification • Subject Transferred Notification
Testing roles	None

Sites	• Only the Production and Training sites that the user works at • No Testing sites **Tip:** If sites aren't defined yet, leave this field blank for now. If an administrator created users before anyone created sites, you might want to make sure users are assigned to the correct sites and depots.
Depots	All depots so users can see whether a depot has sent an order **Tip:** If depots aren't defined yet, leave this field blank for now. If an administrator created users before anyone created depots, you might want to make sure users are assigned to the correct sites and depots.

Non-PI site users

Study Design roles	None
Production and Training roles	• Blinded Site User - Site • Shipment Notification • Subject Transferred Notification • If the user receives and manages inventory: Blinded Site Inventory User - Site
Testing roles	None
Sites	• Only the Production and Training sites that the user works at • No Testing sites **Tip:** If sites aren't defined yet, leave this field blank for now. If an administrator created users before anyone created sites, you might want to make sure users are assigned to the correct sites and depots.
Depots	All depots so users can see whether a depot has sent an order **Tip:** If depots aren't defined yet, leave this field blank for now. If an administrator created users before anyone created depots, you might want to make sure users are assigned to the correct sites and depots.

Sponsor users - Typical assignments

Tip: A user's role in Production, Training, and Testing modes determines settings for permissions and notifications. To view the permissions for a role, click **View Permissions**, and select a role from the **Roles** drop-down.

Study builders

Study Design roles	• If the user designs randomization: Designer Role - Sponsor • If the user doesn't design randomization: Designer Role - Blinded - Sponsor • If the user manages the users who have access to a study: User Manager Role - Sponsor
Production and Training roles	None
Testing roles	• Design Import • Site Manager Role - Sponsor Additionally, assign logical combinations of roles based on the user's responsibilities in the study. For instance: • If the user will perform tasks typically performed by a clinical supply manager or test the study as a clinical supply manager: Clinical Supply Manager - Sponsor • If the user will validate the study, consider assigning some or all of the following roles: ▪ Blinded Site User - Site ▪ Blinded Site Inventory User - Site ▪ CodeBreak - Site **Important notes about giving users both site and sponsor roles:** A study has both a blinded and unblinded view: • Users with a site user role have a blinded view. • Users with the Clinical Supply Manager - Sponsor role have an unblinded view. If a user has the Clinical Supply Manager - Sponsor role, the user cannot access the blinded view of data. You must remove the Clinical Supply Manager role for the user for the user to open the blinded view of data.
Sites	• No Production or Training sites • All Testing sites **Tip:** If sites aren't defined yet, leave this field blank for now. If an administrator created users before anyone created sites, you might want to make sure users are assigned to the correct sites and depots.

Depots	• No Production or Training depots • All Testing depots so users can see whether a depot has sent an order **Tip:** If depots aren't defined yet, leave this field blank for now. If an administrator created users before anyone created depots, you might want to make sure users are assigned to the correct sites and depots.

Study managers

Study Design roles	• View Design - Sponsor • If the user manages the users who have access to a study: User Manager Role - Sponsor
Production and Training roles	• Study Manager - Sponsor • Subject Transfer • Design Import • If the user manages sites, including when they go live: Site Manager Role - Sponsor

Testing roles	• Study Manager - Sponsor • Subject Transfer • Design Import • If the user manages sites, including when they go live: Site Manager Role - Sponsor Additionally, assign logical combinations of roles based on the user's responsibilities in the study. For instance: • If the user will perform tasks typically performed by a clinical supply manager or test the study as a clinical supply manager: Clinical Supply Manager - Sponsor • If the user will validate the study, consider assigning some or all of the following roles: ▪ Blinded Site User - Site ▪ Blinded Site Inventory User - Site ▪ CodeBreak - Site **Important notes about giving users both site and sponsor roles:** A study has both a blinded and unblinded view: • Users with a site user role have a blinded view. • Users with the Clinical Supply Manager - Sponsor role have an unblinded view. If a user has the Clinical Supply Manager - Sponsor role, the user cannot access the blinded view of data. You must remove the Clinical Supply Manager role for the user for the user to open the blinded view of data.
Sites	All Production, Training, and Testing sites **Tip:** If sites aren't defined yet, leave this field blank for now. If an administrator created users before anyone created sites, you might want to make sure users are assigned to the correct sites and depots.
Depots	All Production, Training, and Testing depots **Tip:** If depots aren't defined yet, leave this field blank for now. If an administrator created users before anyone created depots, you might want to make sure users are assigned to the correct sites and depots.

Clinical supply managers

Study Design roles	• View Design - Sponsor • If the user manages the users who have access to a study: User Manager Role - Sponsor
Production, Training, and Testing roles	• Clinical Supply Manager - Sponsor • Subject Transferred Notification • If the user manages sites, including when they go live: Site Manager Role - Sponsor
Sites	All Production, Training, and Testing sites **Tip:** If sites aren't defined yet, leave this field blank for now. If an administrator created users before anyone created sites, you might want to make sure users are assigned to the correct sites and depots.
Depots	All Production, Training, and Testing depots **Tip:** If depots aren't defined yet, leave this field blank for now. If an administrator created users before anyone created depots, you might want to make sure users are assigned to the correct sites and depots.

Clinical research associates (CRAs)

Study Design roles	• View Design - Sponsor • If the user manages the users who have access to a study: User Manager Role - Sponsor
Production and Training roles	• CRA - Sponsor • One of the following: ▪ Subject Transfer, if the user transfers subjects. ▪ Subject Transferred Notification, if the user doesn't transfer subjects. • If the user manages sites, including when they go live: Site Manager Role - Sponsor

Testing roles	• CRA - Sponsor
	• One of the following:
	  ▪ Subject Transfer, if the user transfers subjects.
	  ▪ Subject Transferred Notification, if the user doesn't transfer subjects.
	• If the user manages sites, including when they go live:
	Site Manager Role - Sponsor
	If the user validates the study, consider assigning one or more of the following roles:
	• Blinded Site User - Site
	• Blinded Site Inventory User - Site

Sites	• If the CRA is responsible for site management, all Production and Training sites Otherwise, only the Production and Training sites that the CRA manages • All Testing sites **Tip:** If sites aren't defined yet, leave this field blank for now. If an administrator created users before anyone created sites, you might want to make sure users are assigned to the correct sites and depots.
Depots	All Production, Training, and Testing depots so users can see whether a depot has sent an order **Tip:** If depots aren't defined yet, leave this field blank for now. If an administrator created users before anyone created depots, you might want to make sure users are assigned to the correct sites and depots.

Data managers

Study Design roles	None
Production and Training roles	Data Manager - Sponsor
Testing roles	None

Sites	• All Production and Training sites • If the data manager is involved in the validation of the study, all Testing sites Otherwise, no Testing sites **Tip:** If sites aren't defined yet, leave this field blank for now. If an administrator created users before anyone created sites, you might want to make sure users are assigned to the correct sites and depots.
Depots	None

Safety monitors

Study Design roles	None
Production and Training roles	• Data Manager - Sponsor • Code View - Sponsor
Testing roles	None
Sites	• All Production and Training sites • No Testing sites **Tip:** If sites aren't defined yet, leave this field blank for now. If an administrator created users before anyone created sites, you might want to make sure users are assigned to the correct sites and depots.
Depots	None

Depot users - Typical assignments

Tip: A user's role in Production, Training, and Testing modes determines settings for permissions and notifications. To view the permissions for a role, click **View Permissions**, and select a role from the **Roles** drop-down.

Study Design roles	None
Production and Training roles	Clinical Supply Manager - Sponsor
Testing roles	None

Sites	• Only the Production and Training sites that the user's depot ships to • No Testing sites **Tip:** If sites aren't defined yet, leave this field blank for now. If an administrator created users before anyone created sites, you might want to make sure users are assigned to the correct sites and depots.
Depots	• Only the Production and Training depot that the user works with • No Testing depots **Tip:** If depots aren't defined yet, leave this field blank for now. If an administrator created users before anyone created depots, you might want to make sure users are assigned to the correct sites and depots.

CHAPTER 4

Prepare a study for validation

In this chapter

Specify and review settings before validating a study

1 On the Home page, click the pencil button ( ) on a study, and make sure a study version is below either Testing or Approved.

2 Review supply settings for Testing mode:

   a On the Home page, click the study settings button ( ) on the study you want to edit, and select **Open Settings**.

   b Below the study name, click the **Supply Settings** tab.

   c On the left, make sure **Testing Settings** is selected.

   d Fill in the fields.

   Tip: You can edit these settings at any time, including during the study conduct period.

   e In the upper right, click **Apply Changes**.

3 Review the read-only kit types in the study:

   a On the Home page, click the pencil button ( ) on the study you want to review.

   b Click the menu button ( ) on the Testing version of the study, and select **View Study Design**.

   c Along the top, click **Study Supplies**.

   d Below the study name, click the **Kits** tab.

   e Review the settings for each kit type.

   Tip: To edit the settings, ***create a new Draft version of the study*** (on page 21). You can edit the settings in the Draft version of the study.

4 Make sure the dispensation schedule was defined correctly:

   a On the Home page, click the pencil button ( ) on the study you want to review.

   b Click the menu button ( ) on the Testing version of the study, and select **View Study Design**.

   c Along the top, click **Study Supplies**.

   d Below the study name, click the **Kits** tab.

   The visit schedule appears on the right, with the pill icon representing a dispensation visit.

   e Click a visit to review its details.

   Tip: To change the dispensation schedule, you must ***create a new Draft version of the study*** (on page 21).

   f To review the dispensation settings for a kit type, click the pencil button on a treatment arm, and select the kit type.

Create label groups in Testing mode

This task is optional. If a country in your study has special label requirements, you must create one or more label groups, which are a collection of kits. Label groups ensure that kits are shipped to countries with appropriate labels.

Create label groups in Testing mode if the study requires them and you want to validate the complete end-to-end business process.

Need to perform this task for a *production study* (on page 60)?

To create a label group:

1 On the Home page, click the pencil button () on a study, and make sure a study version is in Testing.

2 Click the beaker button () on the study.

3 Along the top, click **Supplies**.

4 Below the study name, click the **Inventory** tab.

5 In the lower right, expand **Label Groups**.

6 Click **Create Label Group**, and fill in the fields.

7 Select the countries to include in the label group by clicking the arrow buttons, and then click **Create**.

To assign kits to a label group:

1 On the Home page, click the pencil button () on a study, and make sure a study version is in Approved.

2 Click the beaker button () on the study.

3 Along the top, click **Supplies**.

4 Below the study name, click the **Inventory** tab.

5 Click a kit type.

6 Above the kit list, use the filters to return only the kits you want to assign to the label group:

   a Below Location, click **Depots**, and select the depot that is supplying kits for the country from the **All Depots** drop-down.

   b Above the kit list, from the **Status** drop-down, select **Available**.

   c If necessary, narrow your view further by clicking **Kit** or **Sequence**, and enter a range of kit or sequence numbers.

7 In the list, select a kit, and make sure **Kit Settings** is expanded on the right.

8 From the **Label Group** drop-down, select the label group.

9 Below Kits to Update, select **All Kits**.

Tip: Selecting All Kits updates every kit that meets the filtering criteria. To update only the

kits that you choose, select additional kits with the same status, and choose **Selected Kits**.

10 From the **Reason for Change** drop-down, select an option and click **Update Kits**.

11 Repeat this procedure for every kit type included in the label group.

Tip: To return to the list of kit types, above the kit list and to the left of the kit type, click **Back**.

Field descriptions for the Create Label Group window

Field	Description
Label Group Title	No description

Field descriptions for the Kit Settings panel

Field	Description
Status	Select the status to apply to the kits you selected
Location	Select the location of the kits you selected
Label Group	Select the label group for the kits you selected
Kits to Update	Choose whether to update only the kits you select or all kits in view
Reason for Change	No description

Manage expiration dates with lots in Testing mode

Need to perform this task for a ***production study*** (on page 56)?

What type of lot should I create?

Type of lot	When to use it
Manufacturing lot	In every study. You must create at least one manufacturing lot in Testing mode so that you can assign kits an expiration date in Clinical One.
Blinded lot	Creating blinded lots is optional. You combine one or more manufacturing lots into a blinded to monitor batches of kits while protecting the study blind. Create a blinded lot in Testing mode if the study or organization requires blinded lot numbers, and you want to validate the complete end-to-end business process.

To create a manufacturing lot:

1 On the Home page, click the pencil button () on a study, and make sure a study version is in Testing.

2 Click the beaker button () on the study.

3 Along the top, click **Supplies**.

4 Below the study name, click the **Inventory** tab.

5 On the right, make sure **Lots** is expanded.

6 From the **Create Lot** drop-down, select **Manufacturing Lot**.

7 Fill in the fields, and click **Create**.

8 ***Assign kits to the manufacturing lot*** (on page 45) to manage their expiration dates.

To create a blinded lot:

1 On the Home page, click the pencil button () on a study, and make sure a study version is in Testing.

2 Click the beaker button () on the study.

3 Along the top, click **Supplies**.

4 Below the study name, click the **Inventory** tab.

5 On the right, make sure **Lots** is expanded.

6 From the **Create Lot** drop-down, select **Blinded Lot** and fill in the fields.

7 If you know the manufacturing lots that you want to combine into the blinded lot, select the manufacturing lots. Otherwise, ***combine manufacturing lots into the blinded lot*** (on page 46)

later.

8 Click **Create**.

Tips

- You can update the expiration date for a manufacturing lot or a blinded lot at any time.
- After the expiration date of a lot passes, its kits are not distributed to sites and are not dispensed to subjects.

Field descriptions for the Create Manufacturing Lot window

Field	Description
Manufacturing Lot Title	Enter a unique name for the manufacturing lot
Short Name	Enter an alternative manufacturing lot label. For example, you might enter a short name if your organization's labeling conventions differ from the lot name supplied by the depot.
Expiration	Choose the expiration date for the kits in the manufacturing lot
Do Not Ship (DNS) Days	Enter the number of days before the expiration date when a kit can no longer be shipped from a depot to a site
Do Not Count (DNC) Days	Enter the number of days before the expiration date when the kit is no longer counted in a site's inventory

Field descriptions for the Create Blinded Lot window

Field	Description
Blinded Lot Title	No description
Short Name	Enter a short name for the blinded lot. This field is useful when multiple depots use the same lot and have different naming conventions. One depot can use the title, and another can use the short name.
Expiration	Choose the expiration date for the blinded lot. The date must be on or before the earliest expiration date of the manufacturing lots in the blinded lot.
Do Not Ship (DNS) Days	Enter the number of days before the expiration date when a kit can no longer be shipped from a depot to a site
Do Not Count (DNC) Days	Enter the number of days before the expiration date when the kit is no longer counted in a site's inventory

Assign kits to a manufacturing lot in Testing mode

efore you can work with kits in Testing mode, you need to generate or upload a kit list.

Need to perform this task for a *production study* (on page 58)?

1 On the Home page, click the pencil button () on a study, and make sure a study version is in Testing.

2 Click the beaker button () on the study.

3 Along the top, click **Supplies**.

4 Below the study name, click the **Inventory** tab.

5 Click a kit type.

6 Above the kit list, from the Lots drop-down, click **Unassigned** so you see only kits that aren't assigned to any lots.

   Tip: You can narrow your view further using the filters above the kit list.

7 Select the kits to include in the manufacturing lot.

8 From the **Add to Lot** drop-down, located to the right of the filters, select the manufacturing lot.

9 Select a reason for the change, and click **Continue**.

10 Above the kit list, use the filters to check your work:

   a In the upper right, click **Clear Filters**.

   b Above the kit list, from the **Lots** drop-down, select the manufacturing lot that you assigned the kits to.

Combine manufacturing lots into a blinded lot in Testing mode

Need to perform this task for a *production study* (on page 59)?

1 On the Home page, click the pencil button () on a study, and make sure a study version is in Testing.

2 Click the beaker button () on the study.

3 Along the top, click **Supplies**.

4 Below the study name, click the **Inventory** tab.

5 On the right, expand **Lots**.

6 Drag one or more manufacturings lot to the blinded lot that you want to combine them in.

Release kits to sites or depots in Testing mode

Releasing kits to a depot associates the kits with the depot. After kits are released, you can begin testing distribution in Testing mode.

Need to perform this task for a *production study* (on page 64)?

1 On the Home page, click the pencil button () on a study, and make sure a study version is in Testing.

2 Click the beaker button () on the study.

3 Along the top, click **Supplies**.

4 Below the study name, click the **Inventory** tab.

5 Click a kit type.

6 Above the kit list, use the filters to return only the kits you want to release to the site or depot:

Tip: We recommend releasing many kits in Testing mode so you don't run out while testing.

a Below Location, click **Unassigned**.

b Above the kit list, from the **Status** drop-down, select **Available**.

c To view kits from the same lot, select a blinded or manufacturing lot from the **Lots** drop-down.

d If necessary, narrow your view further by clicking **Kit** or **Sequence**, and enter a range of kit or sequence numbers.

7 In the list, select a kit, and make sure **Kit Settings** is expanded on the right.

8 To test creating manual shipments, from the **Location** drop-down, select the depot to associate the kits with.

or

To test dispensing kits, from the **Location** drop-down, select a site to associate the kits with.

9 Below Kits to Update, select **All Kits**.

Tip: Selecting All Kits updates every kit that meets the filtering criteria. To update only the kits that you choose, select additional kits with the same status, and choose **Selected Kits**.

10 From the **Reason for Change** drop-down, select an option and click **Update Kits**.

Assign blocks of randomization numbers to a site in Testing mode

You must assign blocks of randomization numbers to a site if you selected a type of randomization with Fixed in its name, and you either generated a randomization list in Clinical One or uploaded a randomization list that didn't identify sites for blocks.

Need to perform this task for a *production study* (on page 62)?

1 On the Home page, click the pencil button () on a study, and make sure a study version is in Testing.

2 Click the beaker button () on the study.

3 Along the top, click **Supplies**.

4 Below the study name, click the **Randomizations** tab.

5 From the **Randomizations List** drop-down, select the randomization list.

6 To the right of the **Randomization List** drop-down, click **Block Assignment**.

7 For each block number, select a site, and click **Save**.

CHAPTER 5

Validate a study

CHAPTER 6

Prepare a study to go live

In this chapter

Specify subject settings for Production and Training modes

Need to perform this task for a *study you need to validate* (on page 24)?

1 On the Home page, click the study settings button ( ) on the study you want to edit, and select **Open Settings**.

2 Below the study name, click the **Subject Settings** tab.

3 Specify subject settings for Production mode:

   a On the left, make sure **Production Settings** is selected.

   b Fill in the fields, and click **Apply Changes**, in the upper right.

4 Specify subject settings for Training mode:

- On the left, select **Training Settings**, and use the previous steps to specify subject settings for Training mode.

Tips

- You can edit these settings at any time. The settings apply to all versions of the study.

Specify supply settings for Production and Training modes

Need to perform this task for a ***study you need to validate*** (on page 25)?

1 On the Home page, click the study settings button () on the study you want to edit, and select **Open Settings**.

2 Below the study name, click the **Supply Settings** tab.

3 Specify supply settings for Production mode:

   a On the left, make sure **Production Settings** is selected.

   b Fill in the fields.

   c In the upper right, click **Apply Changes**.

4 Specify supply settings for Training mode:

   - On the left, select **Training Settings**, and use the previous steps to specify supply settings for Training mode.

Tips

- You can edit these settings at any time. The settings apply to all versions of the study.

Create a resupply strategy for Production and Training modes

Need to perform this task for a ***study you need to validate*** (on page 27)?

1 On the Home page, click the study settings button () on the study you want to edit, and select **Open Settings**.

2 Below the study name, click the **Supply Settings** tab.

3 Create resupply strategies for Production mode:

   a On the left, select **Productions Settings**.

   b On the right, expand **Min/Max Resupply** or **Predictive Resupply**.

   Tip: To resupply a site only when inventory is low at the site, use Min/Max Resupply. To resupply a site based on actual enrollment and planned dispensation visits, use Predictive Resupply.

   c Click **Create Min/Max Resupply Group** or **Create Predictive Resupply Group**.

   d Fill in the fields and click **Add**.

4 Create resupply strategies for Training mode:

   - On the left, select **Training Settings**, and use the previous steps to create resupply strategies for Training mode.

Tips

- You can assign resupply strategies to sites now or when you're ready to make the study live.

Create a blinded group of kits for Production and Training modes

Create blinded groups if you don't allow single kit ordering, and if the kits in your study use different packaging. Blinded groups determine the kit or kits that are added to a single-kit shipment to protect the study blind.

Need to perform this task for a ***study you need to validate*** (on page 29)?

1 On the Home page, click the study settings button () on the study you want to edit, and select **Open Settings**.

2 Below the study name, click the **Supply Settings** tab.

3 Create a blinded group of kits for Production mode:

   a On the left, make sure **Production Settings** is selected.

   b In the lower right, expanded **Blinded Groups**.

   Tip: If **Blinded Groups** doesn't appear, ***make sure that Yes is selected for Blinded Groups required*** (on page 25) and click **Apply Changes**.

   c Click **Create Blinded Group**.

   d Fill in the fields, and click **Add**.

4 Create a blinded group of kits for Training mode:

- On the left, select **Training Settings**, and use the previous steps to create a blinded group of kits for Training mode.

Manage expiration dates with lots in Production and Training modes

Need to perform this task for a ***study you need to validate*** (on page 43)?

What type of lot should I create?

Type of lot	When to use it
Manufacturing lot	In every study. You must create a least one manufacturing lot in each mode so that you can assign kits an expiration date in Clinical One.
Blinded lot	Creating blinded lots is optional. You combine one or more manufacturing lots into a blinded to monitor batches of kits while protecting the study blind. Create a blinded lot in Production mode if the study or organization requires blinded lot numbers. You can also create a blinded lot in Training mode if you want users to be able to practice the complete end-to-end business process.

To create a manufacturing lot:

1 On the Home page, click the pencil button ( ) on a study, and make sure a study version is in Approved.

2 Create a manufacturing lot in Production mode:

   a Click the title of the study.

   b Along the top, click **Supplies**.

   c Below the study name, click the **Inventory** tab.

   d On the right, make sure **Lots** is expanded.

   e From the **Create Lot** drop-down, select **Manufacturing Lot**.

   f Fill in the fields, and click **Create**.

   g When you're ready, ***assign kits to the manufacturing lot*** (on page 58) to manage the expiration dates of the kits.

3 Create a manufacturing lot in Training mode:

   a On the Home page, click the graduation cap button ( ) on the study.

   Tip: To return to the Home page, in the upper right, click **Home**.

   b Use the previous steps to create a manufacturing lot in Training mode.

To create a blinded lot:

1 On the Home page, click the pencil button ( ) on a study, and make sure a study version is in

Approved.

2 Create a blinded lot in Production mode:

a Click the title of the study.

b Along the top, click **Supplies**.

c Below the study name, click the **Inventory** tab.

d On the right, make sure **Lots** is expanded.

e From the **Create Lot** drop-down, select **Blinded Lot** and fill in the fields.

f If you know the manufacturing lots that you want to combine into the blinded lot, select the manufacturing lots. Otherwise, ***combine manufacturing lots into the blinded lot*** (on page 59) later.

g Click **Create**.

3 Create a blinded lot in Training mode:

a On the Home page, click the graduation cap button () on the study.

Tip: To return to the Home page, in the upper right, click **Home**.

b Use the previous steps to create a blinded lot in Training mode.

Tips

- Consider creating one manufacturing lot for each batch of kits. Grouping kits by batch helps you monitor and search for kits to ensure quality. If multiple batches have the same expiration date, name the lots appropriately so you can identify them.
- You typically create a manufacturing lot before a study goes live and as needed during the study conduct period, such as when a new batch of product is released.
- You can update the expiration date for a manufacturing lot or a blinded lot at any time. The blinded lot must always have the earliest expiration date of all its manufacturing lots.
- After the expiration date of a lot passes, its kits are not distributed to sites and are not dispensed to subjects.

Assign kits to a manufacturing lot in Production and Training modes

Before you can work with kits in Production and Training modes, you need to generate or upload a kit list.

Need to perform this task for a *study you need to validate* (on page 45)?

1 On the Home page, click the pencil button () on a study, and make sure a study version is in Approved.

2 Assign kits to a manufacturing lot in Production mode:

   a Click the title of the study.

   b Along the top, click **Supplies**.

   c Below the study name, click the **Inventory** tab.

   d Click a kit type.

   e Above the kit list, from the Lots drop-down, click **Unassigned** so you see only kits that aren't assigned to any lots.

   Tip: You can narrow your view further using the filters above the kit list.

   f Select the kits to include in the manufacturing lot.

   g From the **Add to Lot** drop-down, located to the right of the filters, select the manufacturing lot.

   h Select a reason for the change, and click **Continue**.

3 Assign kits to a manufacturing lot in Training mode:

   a On the Home page, click the graduation cap button () on the study.

   Tip: To return to the Home page, in the upper right, click **Home**.

   b Use the previous steps to assign kits to a manufacturing lot in Training mode.

Tips

- You typically assign kits to a manufacturing lot before a study goes live and as needed during the study conduct period, such as when a new batch is released.

Combine manufacturing lots into a blinded lot in Production and Training modes

Need to perform this task for a *study you need to validate* (on page 46)?

1 On the Home page, click the pencil button () on a study, and make sure a study version is in Approved.

2 Combine manufacturing lots into a blinded lot in Production mode:

   a Click the title of the study.

   b Along the top, click **Supplies**.

   c Below the study name, click the **Inventory** tab.

   d On the right, make sure **Lots** is expanded.

   e Drag one or more manufacturings lot to the blinded lot that you want to combine them in.

3 Combine manufacturing lots into a blinded lot in Training mode:

   a On the Home page, click the graduation cap button () on the study.

   Tip: To return to the Home page, in the upper right, click **Home**.

   b Use the previous steps to combine manufacturing lots into a blinded lot in Training mode.

Create label groups in Production and Training modes

This task is optional. If a country in your study has special label requirements, you must create one or more label groups, which are a collection of kits. Label groups ensure that kits are shipped to countries with appropriate labels.

If you create label groups in Production mode, you can create them in Training mode if you want users to be able practice the complete end-to-end business process.

Need to perform this task for a *study you need to validate* (on page 41)?

To create a label group:

1 On the Home page, click the pencil button ( ) on a study, and make sure a study version is in Approved.

2 Create label groups in Production mode:

   a Click the title of the study.

   b Along the top, click **Supplies**.

   c Below the study name, click the **Inventory** tab.

   d In the lower right, expand **Label Groups**.

   e Click **Create Label Group**, and fill in the fields.

   f Select the countries to include in the label group by clicking the arrow buttons, and then click **Create**.

3 Create label groups in Training mode:

   a On the Home page, click the graduation cap button ( ) on the study.

   Tip: To return to the Home page, in the upper right, click **Home**.

   b Use the previous steps to create label groups in Training mode.

To assign kits to a label group:

1 On the Home page, click the pencil button ( ) on a study, and make sure a study version is in Approved.

2 Assign kits to a label group in Production mode:

   a Click the title of the study.

   b Along the top, click **Supplies**.

   c Below the study name, click the **Inventory** tab.

   d Click a kit type.

   e Above the kit list, use the filters to return only the kits you want to assign to the label group:

      a Below Location, click **Depots**, and select the depot that is supplying kits for the country from the **All Depots** drop-down.

      b Above the kit list, from the **Status** drop-down, select **Available**.

c If necessary, narrow your view further by clicking **Kit** or **Sequence**, and enter a range of kit or sequence numbers.

f In the list, select a kit, and make sure **Kit Settings** is expanded on the right.

g From the **Label Group** drop-down, select the label group.

h Below Kits to Update, select **All Kits**.

Tip: Selecting All Kits updates every kit that meets the filtering criteria. To update only the kits that you choose, select additional kits with the same status, and choose **Selected Kits**.

i From the **Reason for Change** drop-down, select an option and click **Update Kits**.

j Repeat this procedure for every kit type included in the label group.

Tip: To return to the list of kit types, above the kit list and to the left of the kit type, click **Back**.

3 Assign kits to label group in Training mode:

a On the Home page, click the graduation cap button () on the study.

Tip: To return to the Home page, in the upper right, click **Home**.

b Use the previous steps to assign kits to a label group in Training mode.

Assign blocks of randomization numbers to a site in Production and Training modes

You must assign blocks of randomization numbers to a site if you selected a type of randomization with Fixed in its name, and you either generated a randomization list in Clinical One or uploaded a randomization list that didn't identify sites for blocks.

Need to perform this task for a *study you need to validate* (on page 48)?

1 On the Home page, click the pencil button () on a study, and make sure a study version is in Approved.

2 Assign blocks of randomization numbers to a site in Production mode:

   a Click the title of the study.

   b Along the top, click **Supplies**.

   c Below the study name, click the **Randomizations** tab.

   d From the **Randomizations List** drop-down, select the randomization list.

   e To the right of the **Randomization List** drop-down, click **Block Assignment**.

   f For each block number, select a site, and click **Save**.

3 Assign blocks of randomization numbers to a site in Training mode:

   a On the Home page, click the graduation cap button () on the study.

   Tip: To return to the Home page, in the upper right, click **Home**.

   b Use the previous steps to assign blocks of randomization numbers to a site in Training mode.

CHAPTER 7

Make a study live

In this chapter

Release kits to depots in Production and Training modes

Releasing kits to a depot associates the kits with the depot. After kits are released in Production mode, depots can begin distributing. After kits are released in Training mode, users can begin practicing distribution.

Need to perform this task for a *study you need to validate* (on page 47)?

1 On the Home page, click the pencil button () on a study, and make sure a study version is in Approved.

2 Release kits to depots in Production mode:

   a Along the top, click **Supplies**.

   b Below the study name, click the **Inventory** tab.

   c Click a kit type.

   d Above the kit list, use the filters to return only the kits you want to release to the depot:

      a Below Location, click **Unassigned**.

      b Above the kit list, from the **Status** drop-down, select **Not in Use**.

      c To view kits from the same lot, select a blinded or manufacturing lot from the **Lots** drop-down.

      d If necessary, narrow your view further by clicking **Kit** or **Sequence**, and enter a range of kit or sequence numbers.

   e In the list, select a kit, and make sure **Kit Settings** is expanded on the right.

   f Below Kit Settings, from the **Status** drop-down, select **Available**.

   g From the **Location** drop-down, select the depot.

   If you don't see the depot you need, make sure it was created and activated.

   h Below Kits to Update, select **All Kits**.

   Tip: Selecting All Kits updates every kit that meets the filtering criteria. To update only the kits that you choose, select additional kits with the same status, and choose **Selected Kits**.

   i From the **Reason for Change** drop-down, select an option and click **Update Kits**.

   j Above the kit list, use the filters to check your work:

      a On the left, below Location, click **Depots**, and select the depot that you just released the kits to, from the **All Depots** drop-down.

      b Above the kit list, from the **Status** drop-down, select **Available**.

      c If necessary, narrow your view further by clicking **Kit** or **Sequence**, and enter a range of kit or sequence numbers.

   Tip: To the upper right of the kit list, the Total Kits number tells you the number of available kits at the depot.

   k Above the kit list and to the left of the kit type, click **Back**, and repeat the previous steps for each kit type.

3 Release kits to depots in Training mode:

a On the Home page, click the graduation cap button () on the study.

Tip: To return to the Home page, in the upper right, click **Home**.

b Use the previous steps to release kits to depots in Training mode.

CHAPTER 8

Manage shipments, kits, and randomization numbers

In this chapter

Create a manual shipment

You create a manual shipment if a site anticipates an enrollment surge, such as for a clinic day, and requires additional supply. Otherwise, you shouldn't need to create a manual shipment. If the automatic shipments do not meet a site's needs, select a more appropriate resupply strategy, or ***create a new resupply strategy*** (on page 54) and assign it to the site.

1 On the Home page, click the pencil button () on the study, and make sure a study version is below Approved.

2 Determine where to work:

- To work with real data in Production mode, click the title of the study.
- To work with mock data in Testing mode, click the beaker button () on the study.
- To work with mock data in Training mode, click the graduation cap button () on the study.

3 Along the top, click **Supplies**.

4 Below the study name, make sure that the **Shipments** tab is selected.

5 Click **Create Shipment**.

6 Fill in the fields and click **Create**.

Tip: Clinical One adds a kit to the shipment if ***the study doesn't allow single kit ordering*** (on page 53).

Field descriptions

Field	Description
Site	Select the site that anticipates an enrollment surge
Quantity	Enter the number of kits of this type to include in the shipment

Transfer the product to another location

1 On the Home page, click the pencil button () on the study, and make sure a study version is below Approved.

2 Determine where to work:

- To work with real data in Production mode, click the title of the study.
- To work with mock data in Testing mode, click the beaker button () on the study.
- To work with mock data in Training mode, click the graduation cap button () on the study.

3 Along the top, click **Supplies**.

4 Below the study name, click the **Inventory** tab.

5 Click a kit type.

6 Above the kit list, use the filters to return only the kits you want to transfer:

a Below Location, click **Sites**, and select the location of the kits from the **All Sites** drop-down.

b Above the kit list, from the **Status** drop-down, select **Available**.

c To view kits from the same lot, select a blinded or manufacturing lot from the **Lots** drop-down.

d If necessary, narrow your view further by clicking **Kit** or **Sequence**, and enter a range of kit or sequence numbers.

7 In the list, select a kit, and make sure **Kit Settings** is expanded on the right.

8 From the **Location** drop-down, select the site to transfer the kits to.

9 Below Kits to Update, select **All Kits**.

Tip: Selecting All Kits updates every kit that meets the filtering criteria. To update only the kits that you choose, select additional kits with the same status, and choose **Selected Kits**.

10 From the **Reason for Change** drop-down, select an option and click **Update Kits**.

11 Above the kit list, use the filters to check your work:

a Below Location, click **Sites**, and select the site that you transfered the kits to from the **All Sites** drop-down.

b Above the kit list, from the **Status** drop-down, select **Available**.

c If necessary, narrow your view further by clicking **Kit** or **Sequence**, and enter a range of kit or sequence numbers.

Tips

- You can transfer an investigational product to another site to minimize waste, such as when a site doesn't enroll as anticipated.

Mark a kit as missing or damaged

1 On the Home page, click the pencil button ( ) on the study, and make sure a study version is below Approved.

2 Determine where to work:

- To work with real data in Production mode, click the title of the study.
- To work with mock data in Testing mode, click the beaker button ( ) on the study.
- To work with mock data in Training mode, click the graduation cap button ( ) on the study.

3 Along the top, click **Supplies**.

4 Below the study name, click the **Inventory** tab.

5 Click a kit type.

6 Above the kit list, use the filter to find the kits to update:

a If the kits were at a site or a depot, below Location, click **Sites** or **Depots** and select an option from the **All Sites** or **All Depots** drop-down.

If the kits weren't at a site or depot, click **Unassigned**.

b Above the kit list, from the **Status** drop-down, select the status the kit had before it went missing or was damaged.

c To view kits from the same lot, select a blinded or manufacturing lot from the **Lots** drop-down.

d If necessary, narrow your view further by clicking **Kit** or **Sequence**, and enter a range of kit or sequence numbers.

7 Select the kits to update.

8 In the list, select a kit, and make sure **Kit Settings** is expanded on the right.

9 Below Kit Settings, from the **Status** drop-down, select **Missing** or **Damaged**.

10 Below Kits to Update, make sure **Selected Kits** is selected.

Tip: Selecting Selected Kits updates only the selected kits. To update all kits in the view, choose **All Kits**.

11 From the **Reason for Change** drop-down, select an option and click **Update Kits**.

12 Above the kit list, use the filters to check your work:

a If the kits were at a site or a depot, below Location, click **Sites** or **Depots** and select an option from the **All Sites** or **All Depots** drop-down.

If the kits weren't at a site or depot, click **Unassigned**.

b Above the kit list, from the **Status** drop-down, select **Missing** or **Damaged**.

c If necessary, narrow your view further by clicking **Kit** or **Sequence**, and enter a range of kit or sequence numbers.

Tips

- If you marked a kit in error as Missing or Damaged, you can set the kit back to Available by following the previous steps.

Reserve kits for a quality check

Task 1. Make kits unavailable for distribution

1 On the Home page, click the pencil button () on the study, and make sure a study version is below Approved.

2 Determine where to work:

- To work with real data in Production mode, click the title of the study.
- To work with mock data in Testing mode, click the beaker button () on the study.
- To work with mock data in Training mode, click the graduation cap button () on the study.

3 Along the top, click **Supplies**.

4 Below the study name, click the **Inventory** tab.

5 Click a kit type.

6 Above the kit list, use the filter to return only the kits you want to perform a quality check on:

a If the kits were at a site or a depot, below Location, click **Sites** or **Depots** and select an option from the **All Sites** or **All Depots** drop-down.

If the kits weren't at a site or depot, click **Unassigned**.

b Above the kit list, from the **Status** drop-down, select **Available**.

c To view kits from the same lot, select a blinded or manufacturing lot from the **Lots** drop-down.

d If necessary, narrow your view further by clicking **Kit** or **Sequence**, and enter a range of kit or sequence numbers.

7 In the list, select a kit, and make sure **Kit Settings** is expanded on the right.

8 Below Kit Settings, from the **Status** drop-down, select one of the following:

- **Not in Use**, if you want the kit to be counted in site inventory.

  The kit must currently be marked as Available or Temporarily Unavailable.

- **Temporarily Unavailable**, if you don't want the kit to be counted in site inventory.

  The kit must currently be marked as Available, Missing, Pre-Quarantined, Quarantined, or Not in Use.

Tip: Kits marked as Not in Use or Temporarily Unavailable can't be dispensed or shipped.

9 Below Kits to Update, select **All Kits**.

Tip: Selecting All Kits updates every kit that meets the filtering criteria. To update only the kits that you choose, select additional kits with the same status, and choose **Selected Kits**.

10 From the **Reason for Change** drop-down, select an option and click **Update Kits**.

11 Above the kit list, use the filters to check your work:

a If the kits were at a site or a depot, below Location, click **Sites** or **Depots** and select an option

from the **All Sites** or **All Depots** drop-down.

If the kits weren't at a site or depot, click **Unassigned**.

b Above the kit list, from the **Status** drop-down, select **Not in Use** or **Temporarily Unavailable**.

c If necessary, narrow your view further by clicking **Kit** or **Sequence**, and enter a range of kit or sequence numbers.

Task 2. Update the status of kits after testing them

1 On the Home page, click the pencil button () on the study, and make sure a study version is below Approved.

2 Determine where to work:

- To work with real data in Production mode, click the title of the study.
- To work with mock data in Testing mode, click the beaker button () on the study.
- To work with mock data in Training mode, click the graduation cap button () on the study.

3 Along the top, click **Supplies**.

4 Below the study name, click the **Inventory** tab.

5 Click a kit type.

6 Above the kit list, use the filter to return only the kits you want to update:

a If the kits were at a site or a depot, below Location, click **Sites** or **Depots** and select an option from the **All Sites** or **All Depots** drop-down.

If the kits weren't at a site or depot, click **Unassigned**.

b Above the kit list, from the **Status** drop-down, select **Not in Use** or **Temporarily Unavailable**.

c To view kits from the same lot, select a blinded or manufacturing lot from the **Lots** drop-down.

d If necessary, narrow your view further by clicking **Kit** or **Sequence**, and enter a range of kit or sequence numbers.

7 In the list, select a kit, and make sure **Kit Settings** is expanded on the right.

8 Below Kit Settings, from the **Status** drop-down, select one of the following:

- **Available**, if the kits passed the quality check.
- **Damaged**, if the kits didn't pass the quality check, and are currently marked as Temporarily Unavailable.
- **Temporarily Unavailable**, if the kits didn't pass the quality check, and are currently marked as Not in Use. After you mark the kits as Temporarily Unavailable, mark them as Damaged by following the previous steps.

9 Below Kits to Update, select **All Kits**.

Tip: Selecting All Kits updates every kit that meets the filtering criteria. To update only the kits that you choose, select additional kits with the same status, and choose **Selected Kits**.

10 From the **Reason for Change** drop-down, select an option and click **Update Kits**.

11 Above the kit list, use the filters to check your work:

a If the kits were at a site or a depot, below Location, click **Sites** or **Depots** and select an option from the **All Sites** or **All Depots** drop-down.

If the kits weren't at a site or depot, click **Unassigned**.

b Above the kit list, from the **Status** drop-down, select **Available** or **Damaged**.

c If necessary, narrow your view further by clicking **Kit** or **Sequence**, and enter a range of kit or sequence numbers.

Mark randomization numbers that were used in error

If a subject was randomized in error, you must correct the error in the randomization list. For example, a site user might have randomized a subject in Clinical One without the subject present, but the subject never arrived for the visit.

1 On the Home page, click the pencil button () on the study, and make sure a study version is below Approved.

2 Determine where to work:

- To work with real data in Production mode, click the title of the study.
- To work with mock data in Testing mode, click the beaker button () on the study.
- To work with mock data in Training mode, click the graduation cap button () on the study.

3 Along the top, click **Supplies**.

4 Below the study name, click the **Randomizations** tab.

5 From the **Randomizations List** drop-down, select the randomization list.

6 From the **Filter by Site** drop-down, select the subject's site.

7 In the Subject Number column of the randomization list, locate the subject that was randomized in error, and select their randomization number.

8 On the right, below Randomization Settings, select **Randomized in Error** from the **Select Status** drop-down.

9 Enter a reason for the change, and click **Update**.

10 If a kit was dispensed to the subject after they were randomized in error, ensure that someone at the site marks the kit as Misallocated.

CHAPTER 9

Make changes during the study conduct period

In this chapter

Create a new Draft version of a study to update the Approved version

Need to perform this task for a *study you need to validate* (on page 21)?

1 On the Home page, click the pencil button () on the study you want to edit.

2 In Draft, click **Create Study Version**.

Tip: If you already have a Draft version of the study, **Create Study Version** doesn't appear below Draft. To create a new version of the study, you must first drag the Draft version of the study to either Testing or Archived.

The new Draft version is a copy of the latest version of the study. The latest version of the study has the highest fourth number (for instance, 4 in 1.0.0.4). When you create a new Draft version of a study, this number increases by 1. For example, 1.0.0.1 becomes 1.0.0.2.

Tips

- Clinical One allows you to make only changes that won't create issues for data that has already been collected.

  Additionally, consider the implications for subjects who are already in the study before changing visits, particularly if the edits change the visit schedule.

  For example, changing the visit window could affect the ability of active subjects to get a dispensation.

  If you need to change a visit, we recommend editing an existing visit rather than adding a new one.

- You can modify details about the study, including its title, phase, and blinding status at any time, without creating a new version of a study.

- To rename a study version, click the pencil button on the study (). Click the menu button () on the study version, and select **Rename**. You can change the name of the study version, but not the version number.

CHAPTER 10

Monitor subjects and sites

CHAPTER 11

Archive and retire a study version

In this chapter

Revoke a user's access to the study

1. On the Home page, click the study settings button () on the study you want to edit, and select **Open Settings**.
2. Below the study name, click the **Users** tab.
3. Select the user whose access you want to revoke.
4. From the **Manage Users** drop-down, select **Edit**.
5. On the first page of the wizard, modify the user's **Effective Date Range** to the appropriate date.

   The user can no longer see the study on their Home page.
6. In the lower right, click **Next**.
7. Click **Finish**, and then click **Close**.

Retire a site

Most of the time, you retire a site because the site has decided to stop participating in the study or because the study is ending. You might also retire a site that was activated in error to prevent site users from adding subjects. When the site is ready to be activated, switch it back to Active.

1 On the Home page, click the study settings button ( ) on the study you want to edit, and select **Open Settings**.

2 Below the study name, click the **Sites** tab.

3 On the left, make sure **Production Sites** is selected.

4 Remove the site from a study version:

   a In the table, locate the site to retire, and from the **Study Version** drop-down, select **Select Study Version**.

   The site is no longer assigned to a study version. Removing sites from a study version as you retire them ensures that you can ***archive the study version*** (on page 85) when the study conduct period is over.

   b In the upper right, click **Apply Changes**.

   c If you're retiring sites because the study is ending, make sure that you repeat these steps for all sites in each mode.

   You won't be able to archive a study version if any sites are assigned to it.

5 Retire the site:

   a Select one or more sites.

   b From the **Manage Sites** drop-down, select **Retire**.

   c In the window, confirm the name of the site, select the checkbox, and click **Yes**.

Tips

- After a site is retired, most study activities such as adding subjects, editing data, dispensing kits, and randomizing subjects become unavailable. However, site users can still view the data that they entered.

Retire a depot

Most of the time, you retire a depot because you changed distribution vendors for the study. You might also retire a depot that was activated in error to prevent depot users from accessing the study. When the depot is ready to be activated, switch it back to Active.

1 On the Home page, click the study settings button () on the study you want to edit, and select **Open Settings**.

2 Below the study name, click the **Depots** tab.

3 On the left, make sure **Production Depots** is selected.

Tip: You're not required to retire Testing or Training depots.

4 Select one or more depots.

5 From the **Manage Depots** drop-down, select **Retire**.

6 In the window, confirm the name of the depot, select the checkbox, and click **Yes**.

Tips

- Automatic shipments are stopped for a depot after its retired.

Archive a study version

1 Make sure that there are no sites are assigned to the study version:

   a On the Home page, click the study settings button () on the study you want to edit, and select **Open Settings**.

   b Below the study name, click the **Sites** tab.

   c In the table, review the Study Version column for Production, Testing, and Training modes, and make sure that no sites are using the study version that you want to archive:

   - If the study version you are archiving is assigned to a site, and the study is ending, ***remove the site from the study version and then retire the site*** (on page 83).
   - If the study version you are archiving is assigned to a site, and the sites are moving to a new study version, assign the sites to a new study version.
   - If the study version you are archiving isn't assigned to any sites, proceed to the next step.

   d In the upper right, click **Home**.

2 On the Home page, click the pencil button () on the study.

3 Locate the study version that you want to archive, and drag it to Archived.

Tips

- You can move a study version out of the archive only if it was previously approved, and only if you move it back to Approved.
- Archive a study version when you no longer need the study version, such as if you found an issue during validation, or when sites are no longer using it because they have switched to a newer study version.
- If a study version contains mistakes—for example, a typo on the name of a form—it's a good idea to archive the study version so that no sites are assigned to it accidentally.
- You might want to rename the Archived version to something like RETIRED - V1 DESIGN to make it clear that it isn't meant for use.

  To rename a study version, click the pencil button on the study (). Click the menu button () on the study version, and select **Rename**. You can change the name of the study version, but not the version number.

Delete a study

You can delete a study only if nothing has been created in it.

To archive a study that you've worked in:

1 ***Move the study version that has mistakes to the archive*** (on page 85).

2 Correct the mistakes by ***creating a new study version*** (on page 21).

To delete a study that no one has worked in:

1 On the Home page, click the study settings button () for the study you want to delete, and select **Delete Study**.

2 In the confirmation window, click **Yes**.

CHAPTER 12

Run reports and view notifications

In this chapter

Run and download a report

To run a report:

1 On the Home page, determine where to work. The content of each report is the same, regardless of the mode that you run it in.

- To work with real data in Production mode, click the title of the study.
- To work with mock data in Testing mode, click the beaker button ( ) on the study.
- To work with mock data in Training mode, click the graduation cap button ( ) on the study.

2 Along the top, click **Reporting**.

3 Select the report you want to run.

4 On the right, make sure **Report Settings** is expanded, and fill in the fields.

Tips:

- Study Organization Name includes only sites or sites and depots, depending on the report.
- To filter and sort the data in the Microsoft Excel spreadsheet software, choose CSV as the file type. We recommend choosing CSV for the Kit Chain of Custody (Unblinded) report and the Subject Events report, so that you can narrow your view of the data. For the Kit Chain of Custody (Unblinded) report, you can sort by Sequence Number and Transaction Date to see the complete lifestyle.

5 Click **Run Report**.

You get a notification when the report is available to download.

Tip: While the report is running, you can navigate away from the Reporting page and do more work in the study.

To download a report:

1 On the Home page, determine where to work. The content of each report is the same, regardless of the mode that you run it in.

- To work with real data in Production mode, click the title of the study.
- To work with mock data in Testing mode, click the beaker button ( ) on the study.
- To work with mock data in Training mode, click the graduation cap button ( ) on the study.

2 Along the top, click **Reporting**.

3 Select the report you want to download.

4 In the lower right, expand **Download Reports** and locate the report that you want to view.

Tip: The timestamp below each report tells you when it was run.

5 If the report is a CSV file, click **Download**.

If the report is an HTML file, click **Open**.

Tip: To view HTML files, make sure your browser isn't blocking pop-ups.

Available reports

Report	Description
Kit Inventory (Blinded)	View the status of kits.
Kit Inventory (Unblinded)	View unblinded details about kits, including their types, statuses, and sites. Useful for unblinded users, typically clinical supply managers.
Kit Chain of Custody (Unblinded)	View the history of a single kit in a study.
Randomization List (Unblinded)	View either used randomization numbers or the full randomization list.
Subject Data	View all data captured for a subject during site visits.
Subject Events	View actions that have occurred to each subject, including creation, screening, randomization, and withdrawal.

View notifications

1 On the Home page, click the notification button ( ) on a study.

2 In the upper right, from the **Study Mode** drop-down, select the mode that you want to view notifications for.

3 Filter your view as needed:

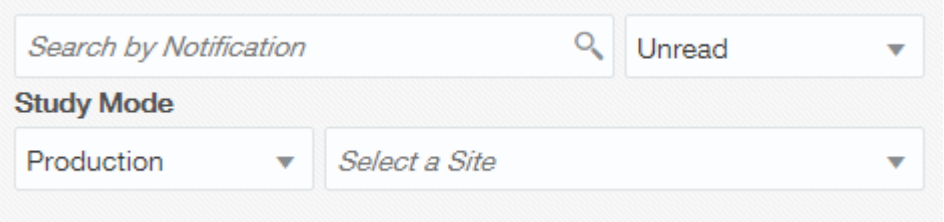
- To view notifications about specific sites, choose a site from the **Select a Site** drop-down.

  Tip: If the Select a Site drop-down is disabled, remove the search terms from the Search by Notification field.

- To find notifications by name, enter the notification name in the **Search by Notification** field.

  Tip: If the Search by Notification field is disabled, remove any filters for sites.

- To sort notifications, select an option from the drop-down to the right of the Search by Notification field.



4 Click a notification to view its details.

Tip: A blue circle appears to the left of an unread notification.

Tips

- The notifications that you get depend on your role during each mode of the study. If you're not getting the notifications that you expect, contact your system administrator.
- The notifications that you receive in Clinical One are also sent to your email.

Available notifications

Notification	When the notification is created
State of a site has changed For example, Site Dermatology Associates is now in Active state.	When a site changes status, such as going from New to Active.
New Shipment Request	When a site requests an automatic or manual shipment from the depot.
Code Break	When a subject has been unblinded due to a code break. The notification does not include unblinded data.

Notification	When the notification is created
Subject transferred For example, Subject 1DA4007 transferred from Site Dermatology Associates to Site Clinic Dermatologists.	When a subject transfers to another site.
Report is ready For example, Subject Data Report is ready in Clinical One.	When a report is ready.
Report failed to generate For example, ERROR: Subject Data Report was not created.	When a report didn't generate correctly.

Where to find the product documentation

The product documentation is available from the following locations:

- My Oracle Support (https://support.oracle.com)—*What's New, What's Fixed,* and *Known Issues*.
- Oracle Help Center (http://docs.oracle.com/health-sciences/clinicalone/index.html) ***(http://docs.oracle.com/health-sciences/clinicalone/index.html)*** (***http://docs.oracle.com/health-sciences/clinicalone/index.html***)—The most current documentation set.

Documentation accessibility

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

Access to Oracle Support

Oracle customers that have purchased support have access to electronic support through My Oracle Support. For information, visit or visit
http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs
(***http://www.oracle.com/pls/topic/lookup?ctx=acc&id=info***) if you are hearing impaired.