Back to Oracle Help Center

Study settings (one-time setup for all modes)

1. Add users at the sponsor or CRO
2. Specify Subject Settings
3. Add regions
4. Define SDV strategy and settings
5. Add depots
6. Add sites
7. Add site and depot users
8. Specify supply settings

Study supplies

9. Create a randomization list and kit list
10. Create lots to manage kit expiration dates
11. Create label groups

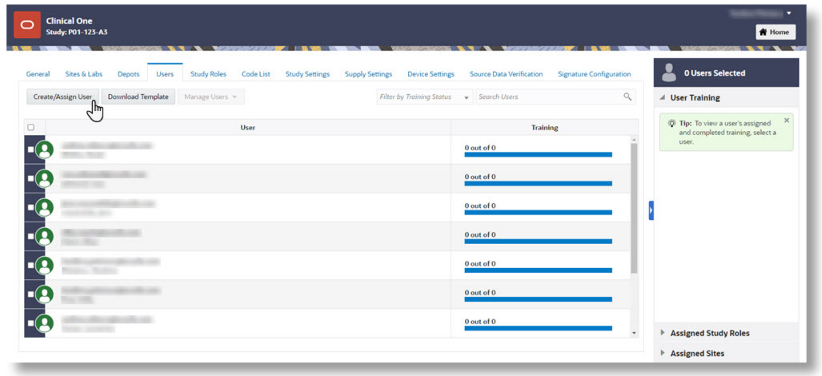
Final steps

12. Activate depots
13. Release kits to depots
14. Open a cohort
15. Assign a study version and resupply strategy to sites
16. Activate sites

Study settings (one-time setup for all modes)

1 Add users at the sponsor or CRO (done by several users)

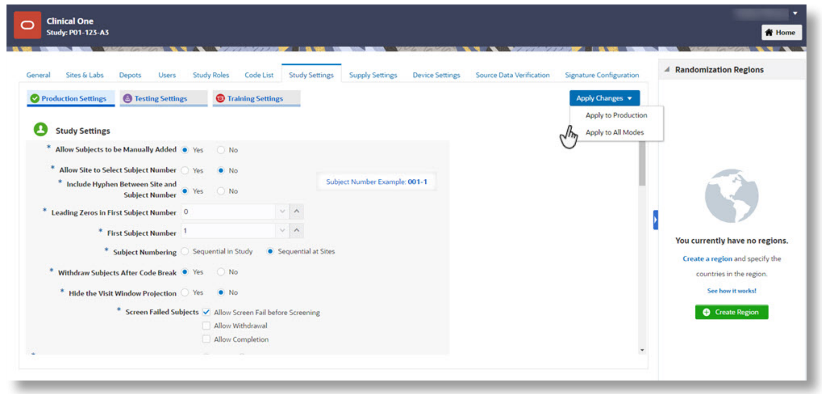
Users' roles determine the reports and notifications they see.



1. Create all users in Oracle Life Sciences Iadentity and Access Management Service (IAMS). Learn more.
2. On the Home page, click study settings ( ) and select **Open Settings**.
3. Click the **Users** tab.
4. Click **Create/Assign User** and fill in the fields, then add your study team members.

   Read step-by-step help for using study roles or watch training.

2 Specify study settings (done by study manager)



1. On the Home page, click study settings ( ) and select **Open Settings**.
2. Click the **Study Settings** tab.
3. Along the top, select a mode, and fill in the fields.
4. Near the upper-right corner, click **Apply Changes** and click **Apply to Production** or **Apply to All Modes**.

   Read step-by-step help for specifying study settings, or watch training.

3 Add regions (done by study manager)

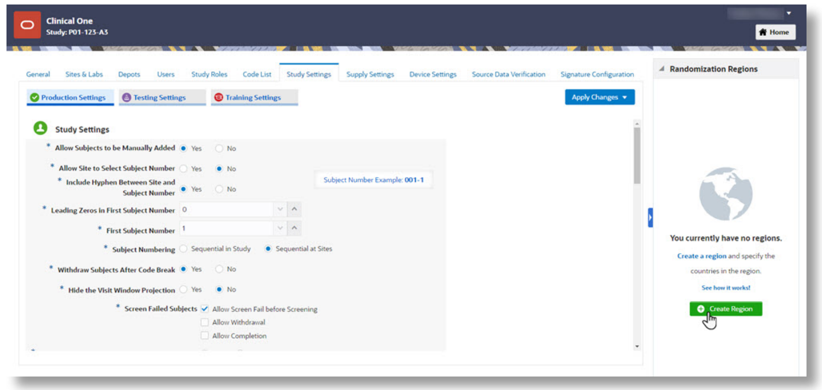
Create regions if you're using region-blocked randomization.

1. On the Home page, click study settings (⚙) and select **Open Settings**

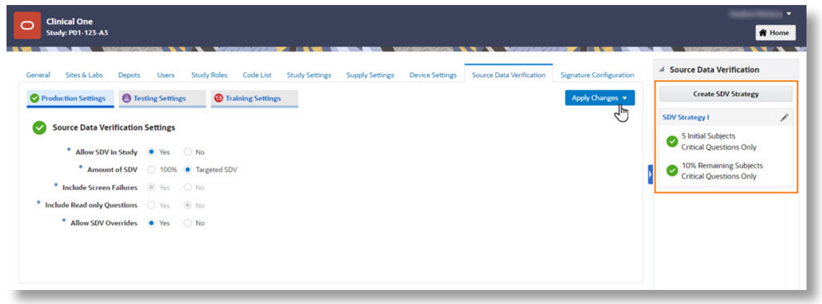
2. Click the **Study Settings** tab.

3. Along the top, select a mode, and create regions for each selected mode.

   Read step-by-step help or watch training.



4 Define the SDV strategy and settings (done by study manager)



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

2. Below the study name, click the **Source Data Verification** tab.

3. Along the top, select a mode and fill in the fields.

   Tip: To view tips on how to complete each field, click into a field or choose an option.

   Read step-by-step help and field descriptions for Specify settings for a SDV strategy.

4. On the upper right, click **Apply Changes** and choose an option to apply to a given mode or to all modes.

5. On the right side pane, under **Source Data Verification** section, click **Create SDV Strategy**.

6. In the newly opened dialog, fill in the fields and click **Create**.

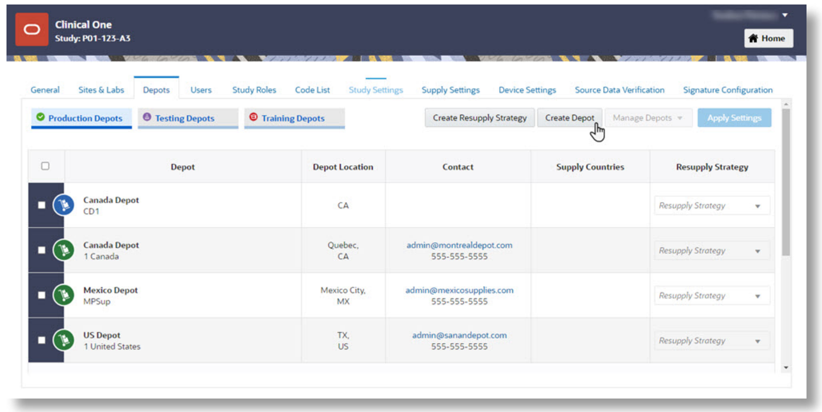
   Repeat to create as many SDV strategies as required.

7. Assign the SDV strategy to a site.

   Read step-by-step help for Create a SDV strategy and assign it to a site.

5 Add depots (done by clinical supply manager)

You typically create all depots when you're preparing for study verification, though you can create Production and Training depots later when you're preparing for study go-live.



1. Click the **Depots** tab.

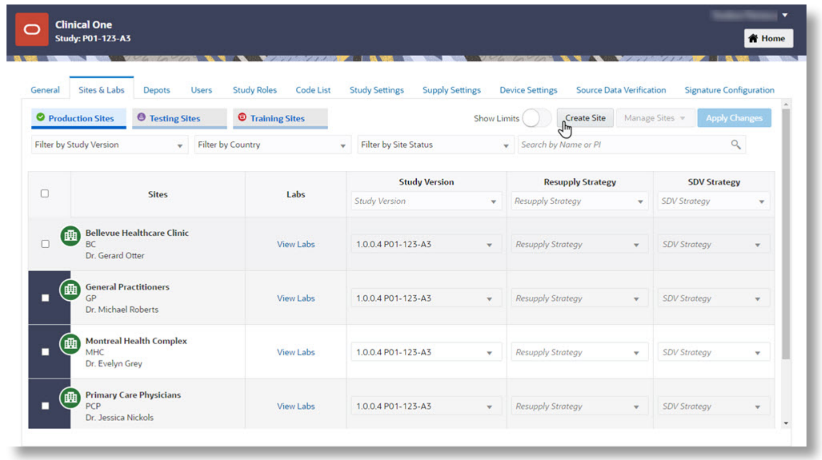
2. Along the top, select a mode, and create depots for each selected mode. If you already used a depot in a previous study, use the search field to find it. When you select it, certain fields will automatically appear.

   Tip: If you're getting the study ready for verification in Testing mode, you can activate your Testing depots now.

   Read step-by-step help or watch training.

6 Add sites (done by site manager)

You typically create all sites when you're preparing for study verification, though you can create Production and Training sites later when you're preparing for study go-live.



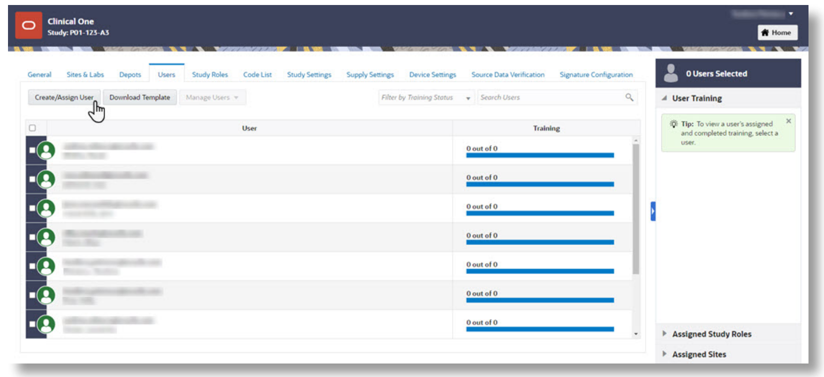
1. Click the **Sites** tab.

2. Along the top, select a mode, and create sites for each selected mode.

   Note: You can only delete a site if its status is **New**.

   Read step-by-step help or watch training.

7 Add site and depot users (done by site and user manager)



1. Provision all users in Oracle Life Sciences IAMS. Learn more.

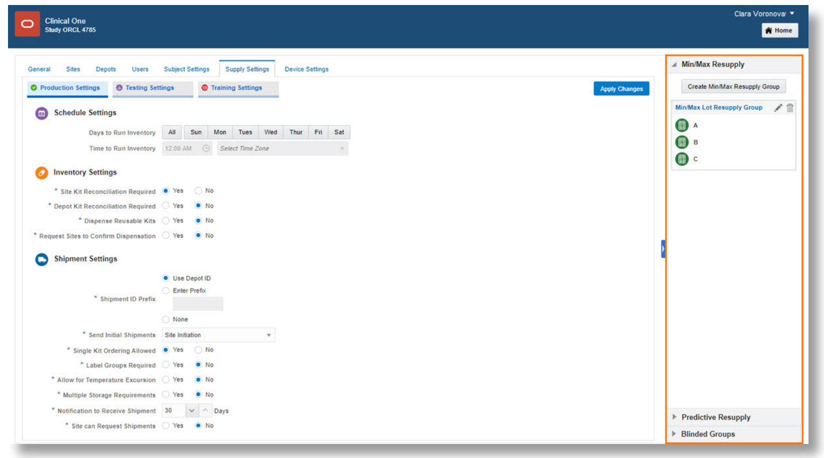
2. On the Home page, click study settings ( ) and select **Open Settings**.

3. Click the **Users** tab.

4. Add site and depot users.

   Read step-by-step help for using study roles or watch training.

8 Specify supply settings, create resupply strategies, and create blinded groups (done by clinical supply manager)



1. On the Home page, click study settings ( ) and select **Open Settings**.

2. Click the **Supply Settings** tab.

3. Along the top, select a mode and fill in the fields.

   Tip: If you're working to verify the study in Testing mode, define settings for Testing. If you're preparing to go live with the study in Production mode, define settings for both Production and Training. (We won't keep telling you this, we promise.)

   Read step-by-step help for specifying supply settings, or watch training.

4. **Create resupply strategies:** On the right, select **Min/Max Resupply** or **Predictive Resupply**.

   Read step-by-step help for creating resupply strategies, or watch training.

5. **Create blinded groups:** On the right, select **Blinded Groups**.

   Read step-by-step help for creating blinded groups, or watch training.

Study supplies

9 Create a randomization list (done by randomization list manager) and a kit list (done by clinical supply manager)

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

2. Click the study version below Testing (for study verification) or the study version below Approved (for study go-live).

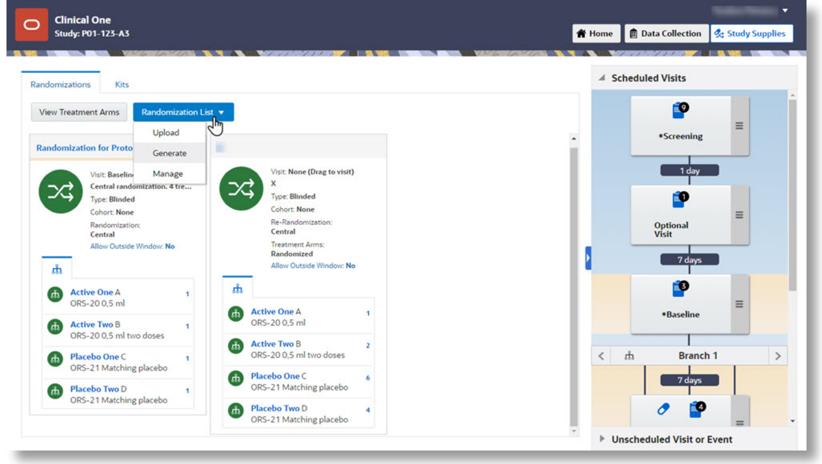
3. Along the top, click **Study Supplies**.

4. **Create a randomization list:** Make sure you're on the Randomizations tab and either upload or generate the list.

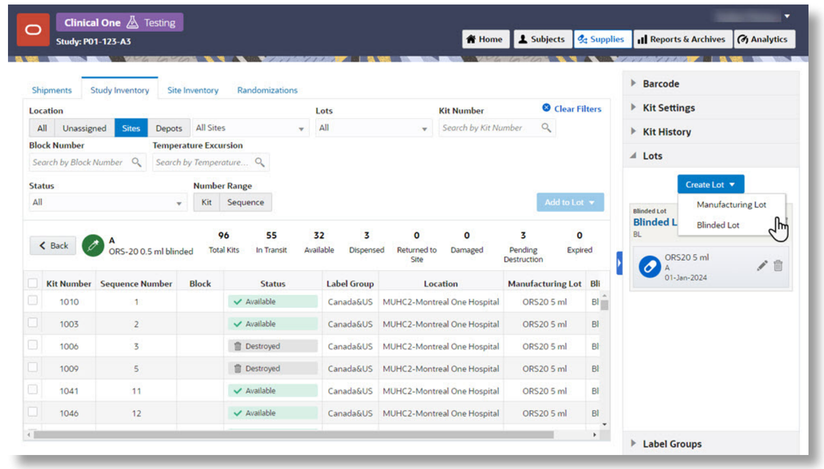
   Read step-by-step help for creating a randomization list, or watch training.

5. **Create a kit list:** Click the **Kits** tab, and upload or generate a kit list.

   Read step-by-step help for creating a kit list, or watch training.



10 Create lots, assign kits to them, and combine them as needed (done by clinical supply manager)



1. On the Home page, click either the Testing Mode button ( ) (for study verification) or the name of the study (for study go-live).

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

3. Click the **Study Inventory** tab.

4. **Create lots:** In **Lots**, on the right, create manufacturing lots (and blinded lots, if needed).

   Read step-by-step help for creating lots, or watch training.

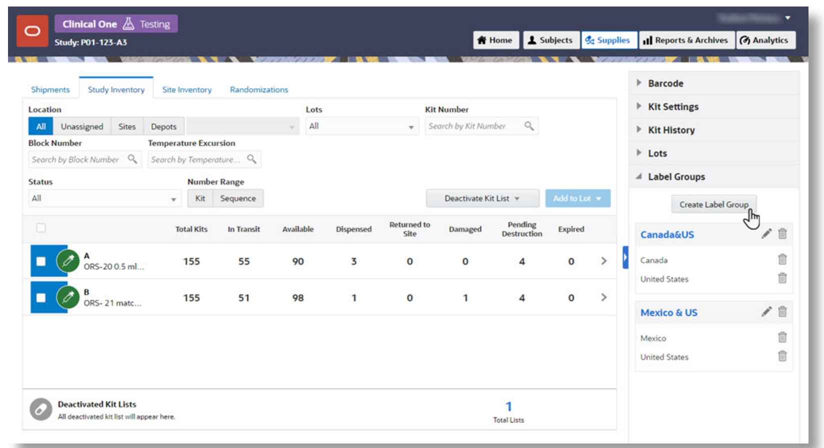
5. **Assign kits to manufacturing lots:** Filter and select kits, and add them to lots.

   Read step-by-step help for assigning kits to a manufactoring lot, or watch training.

6. **If using blinded lots, combine manufacturing lots into blinded lots:** Drag manufacturing lots into blinded lots.

   Read step-by-step help for combining manufacturing lots into blinded lots, or watch training.

11 Create label groups, and assign kits to them (done by clinical supply manager)



1. Stay on the Inventory tab and expand **Label Groups** on the right.

2. **Create label groups:** If the study requires them.

3. **Assign kits to the label groups:** Select a kit type, filter and select kits, and select the label group on the right.

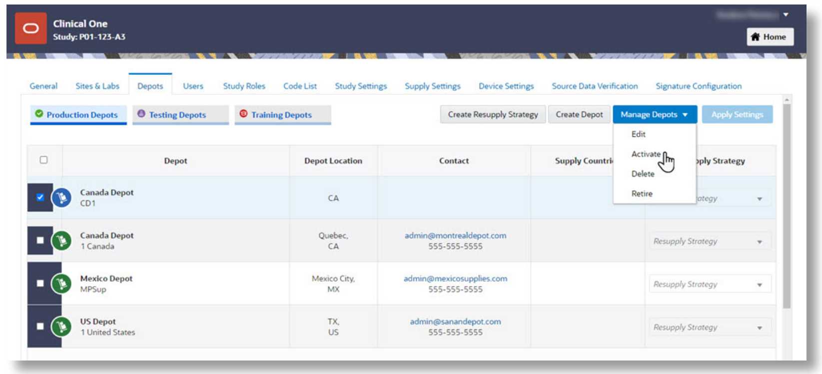
   Read step-by-step help for assigning kits to label groups, or watch training.

12 Activate depots (done by clinical supply manager)

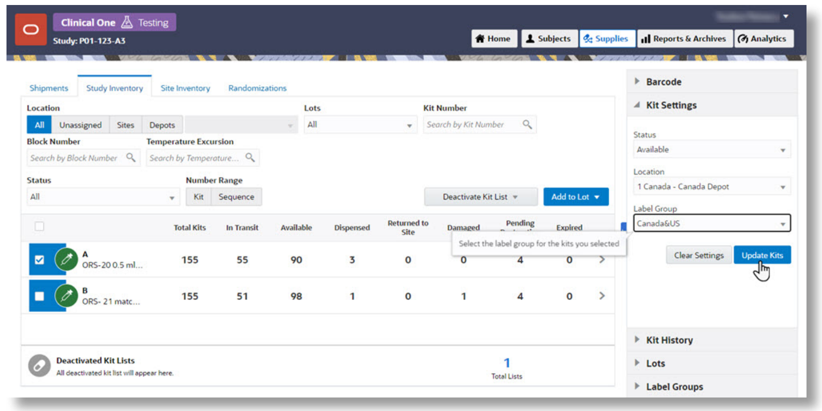
1. On the Home page, click study settings (⚙), and select **Open Settings**.
2. Click the **Depots** tab.
3. Along the top, select a mode, and activate depots for each selected mode.

   If you're preparing for study verification, you may have already activated depots for Testing mode.

Read step-by-step help for activating depots, or ▶ watch training.



13 Release kits to depots (done by clinical supply manager)



1. On the Home page, click the pencil button ( ) on your study to make sure your study version is either in Testing or Approved mode.

2. For study verification, click the Testing Mode button ( ). For the Approved version, click the study name.

3. Along the top, click **Supplies**, and then click the **Inventory** tab.

4. Click the kit type to release.

5. Select the kits to release, update the fields in Kit Settings (including changing their statuses to Available), and update the kits.

   Read step-by-step help for releasing kits to depots, or watch training.

14 Open a cohort (done by study manager)

When do I do this? Just before you activate a site, open the first cohort. After the limit for a cohort is reached, make sure you open the next cohort, or randomization errors will occur for site users.

1. On the Home page, click study settings ( ) and select **Open Settings**.

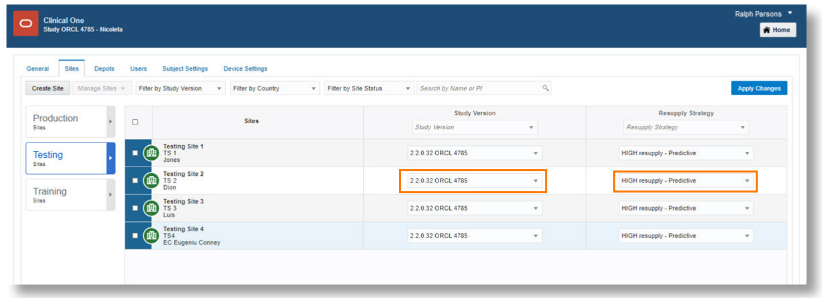
2. Click the **Subject Settings** tab.

3. Along the top, select a mode.

4. Scroll to the **Enrollment Settings**, expand **Cohort**, and click a toggle to the left of a cohort to open it.

   Read step-by-step help for opening and closing a cohort or watch training.

15 Assign a study version and resupply strategy to each site (done by site manager)



1. On the Home page, click study settings ( ) and select **Open Settings**.

2. Click the **Sites** tab.

3. On the left, select a mode.

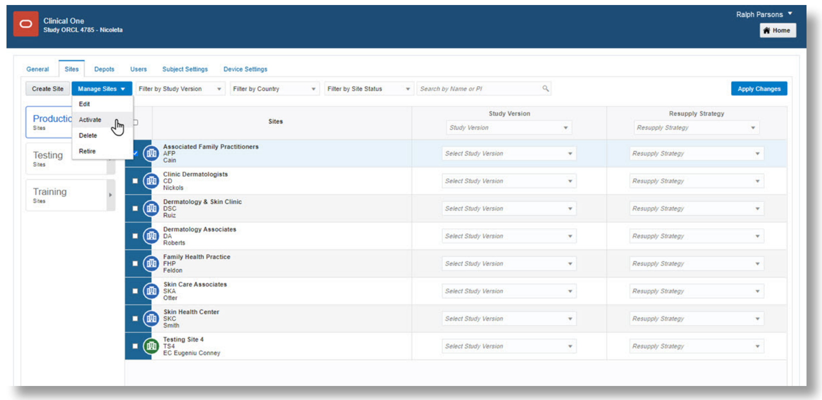
4. **Select a study version for each site:** In the **Study Version** column.

   Read step-by-step help for assigning a study version to a site, or watch training.

5. **Select a resupply strategy for each site:** In the **Resupply Strategy** column.

   Read step-by-step help for assigning a resupply strategy to a site, or watch training.

16 Activate sites (done by site manager)



This makes the study ready for verification or go-live.

1. On the Home page, click study settings ( ) and select **Open Settings**.

2. Click the **Sites** tab.

3. Activate each site that's ready for either study verification or study go-live.

   Note: After you activate a site, you cannot delete it. You can only retire it.

   Read step-by-step help for activating a study, or watch training.

4. Having problems in the study? We can help!

   Read troubleshooting tips for study verification or study conduct period.

You're now ready for study verification or study go-live!

Find out more about the **Oracle Clinical One Platform**!

Get more information

See the Oracle Clinical One Platform documentation library on the Oracle Help Center.

Other resources

Watch short training videos on the Oracle Help Center for configuring settings, setting up supplies, or managing a study during the study conduct period.

Contact Support

For assistance, contact Life Sciences Support.

Can't find what you need?

Write to us at clinical_one_doc_feedback_us_grp@oracle.com