With the exception of the one-time setup tasks, you do the other tasks to:

- Prepare for **study verification**: Perform these tasks for **Testing mode** when the study version is in the **Testing container**.

- Prepare for **study go-live**: Perform these tasks for **Production and Training modes** when the study version is in the **Approved container**.

User accounts, depots, and sites (one-time setup for all modes)

1. Add users at the sponsor or CRO

2. Add depots

3. Add sites

4. Add site and depot users

Study settings

5. Specify subject settings

6. Specify supply settings

7. Create a randomization list and kit list

8. Create lots to manage kit expiration dates

9. Create label groups

Final steps

10. Activate depots

11. Release kits to depots

12. Assign a study version and resupply strategy to sites

13. Activate sites

User accounts, depots, and sites (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. On the Home page, click study settings ⚙ and select **Open Settings**.

2. Click the **Users** tab.

3. Click **Create User** and fill in the fields, then add a:

   a. site and user manager (done by the study creator or a global user manager).

   b. clinical supply manager (done by the site and user manager).

   c. randomization manager (done by the site and user manager).

   d. study designer (done by the global user manager who is also a site and user manager).

   e. study manager (done by the site and user manager).

   f. clinical research associate (CRA) (done by the site and user manager).

   g. data manager (done by the site and user manager).

   h. safety monitor (done by the site and user manager).
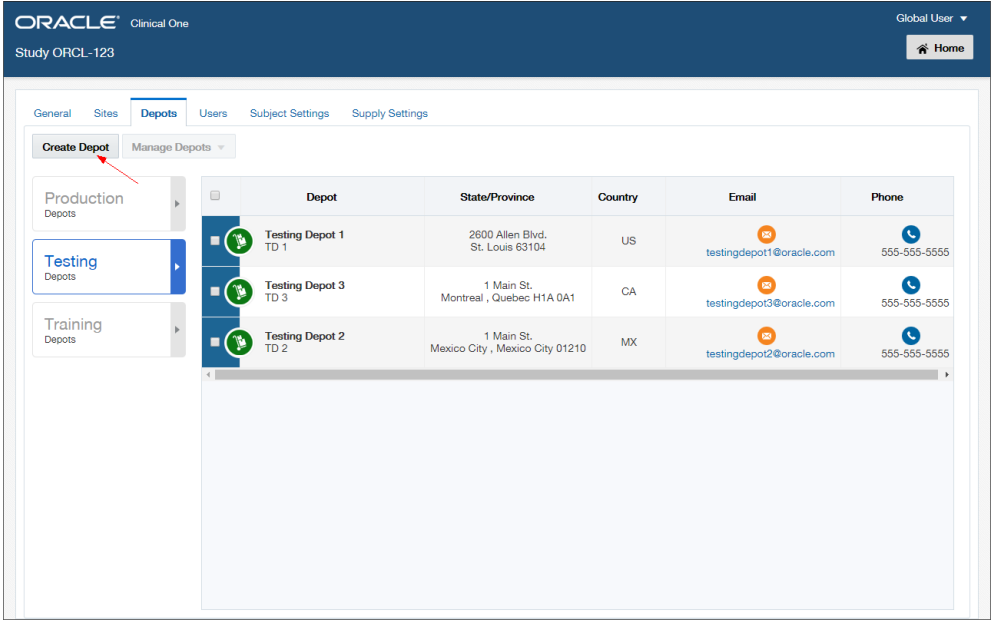
   ▶ Watch training.
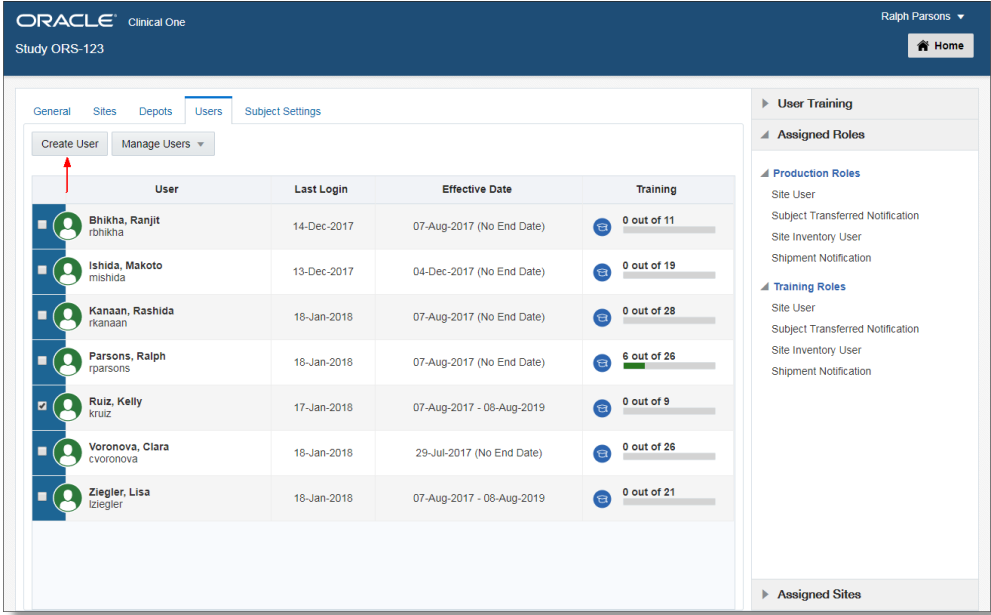
2   Add depots (done by clinical supply manager)

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. On the left, select a mode, and create depots for all modes.

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

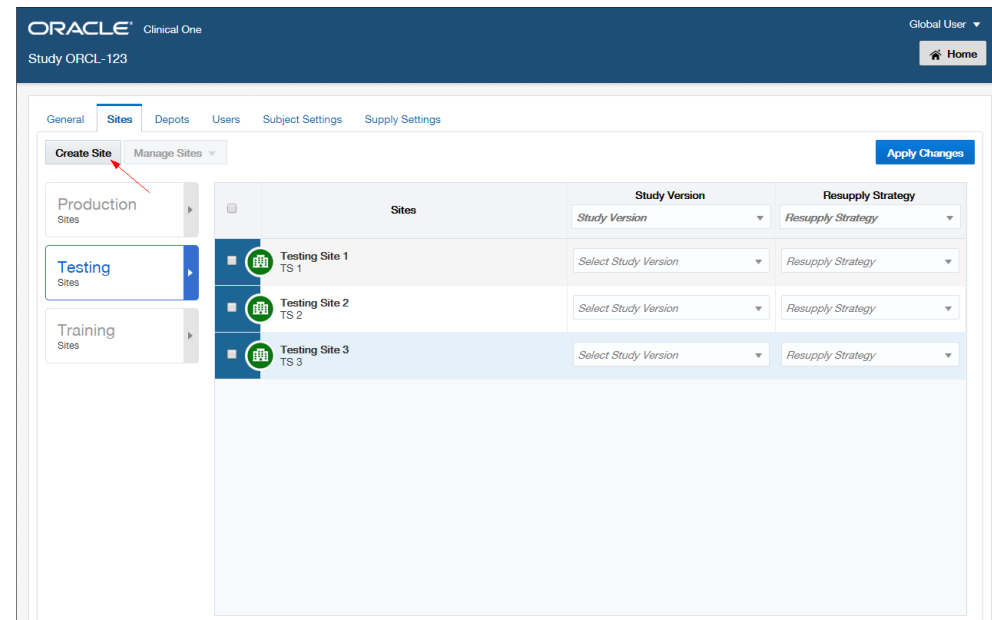   Read step-by-step help or ▶ watch training.

3   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. On the left, select a mode, and create sites for all modes.
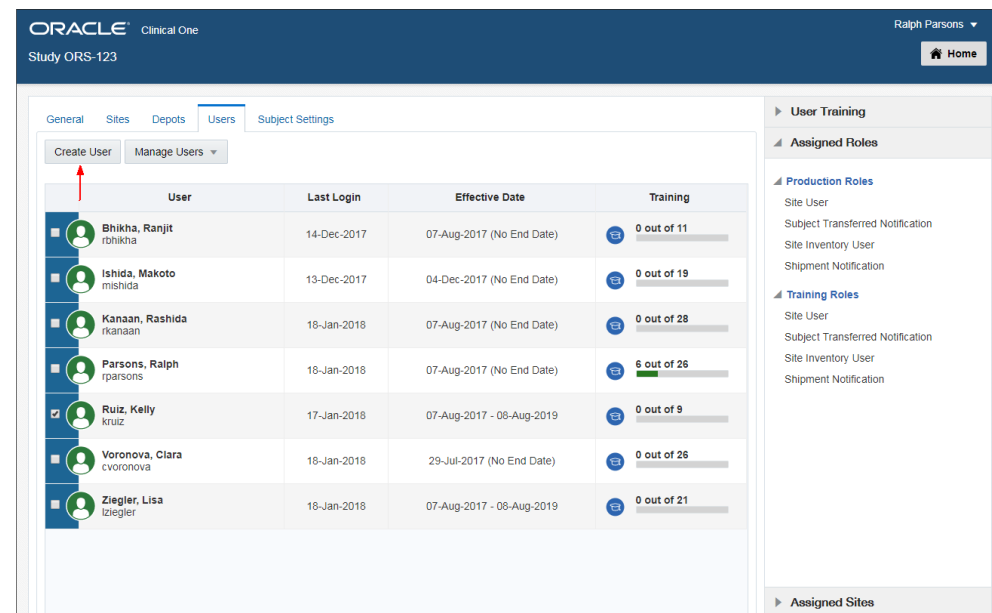
   Read step-by-step help or ▶ watch training.

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

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

2. Click the **Users** tab.

3. Add site and depot users.
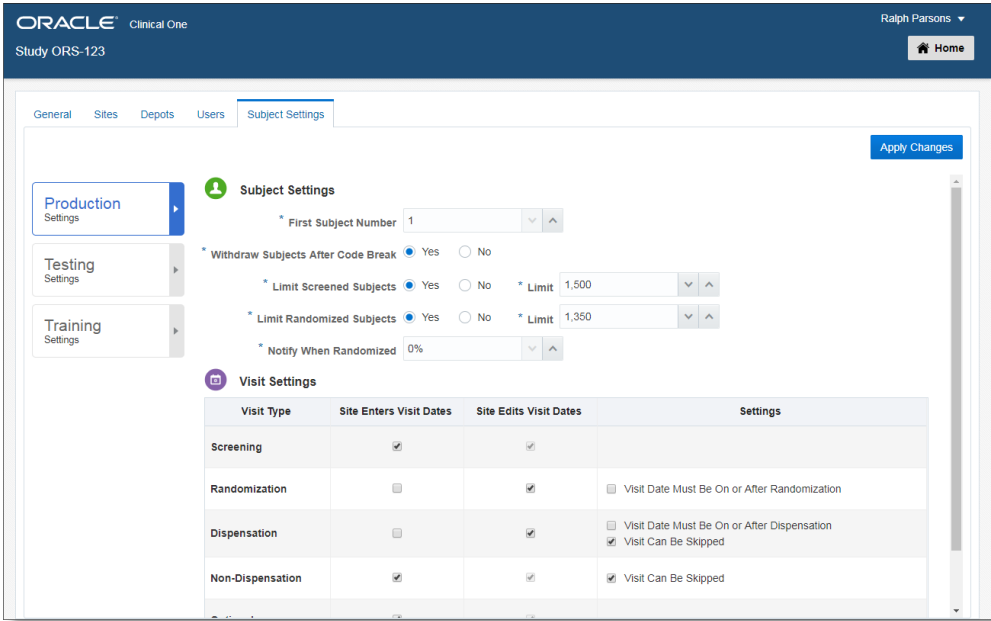
   ▶ Watch training.

5 — Specify subject settings (done by study manager)

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

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

3. **Specify subject settings:** On the left, select a mode, and fill in the fields.

   Tip: If the study version is in the Testing container, define settings for Testing. If the study version is in the Approved container, define settings for both Production and Training.

   Read step-by-step help for study verification or study go-live, or ▶ watch training.

6 — 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. **Specify supply settings:** On the left, 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.)
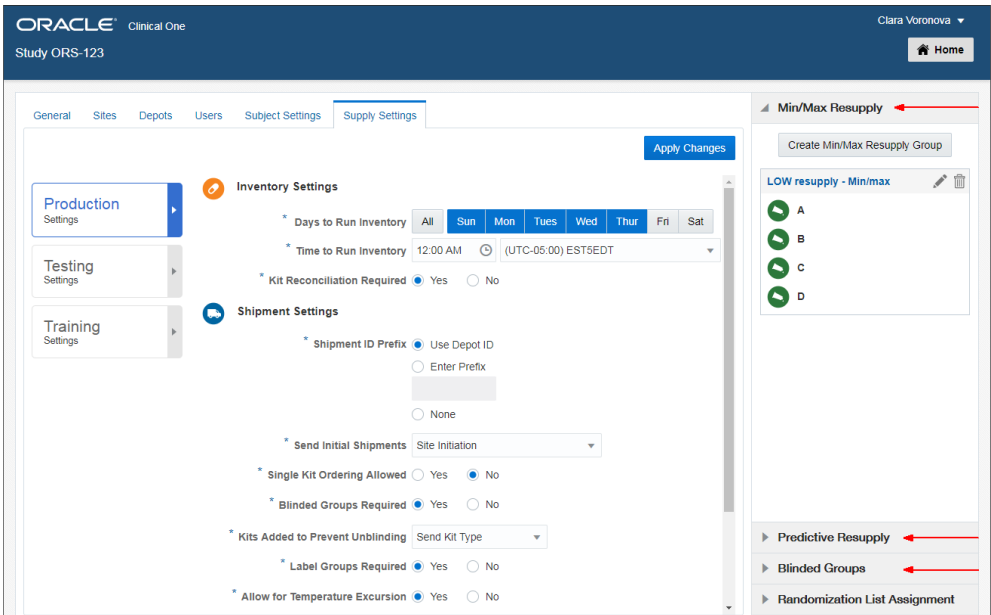
   Read step-by-step help for study verification or study go-live, or ▶ watch training.

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

   Read step-by-step help for study verification or study go-live, or ▶ watch training.
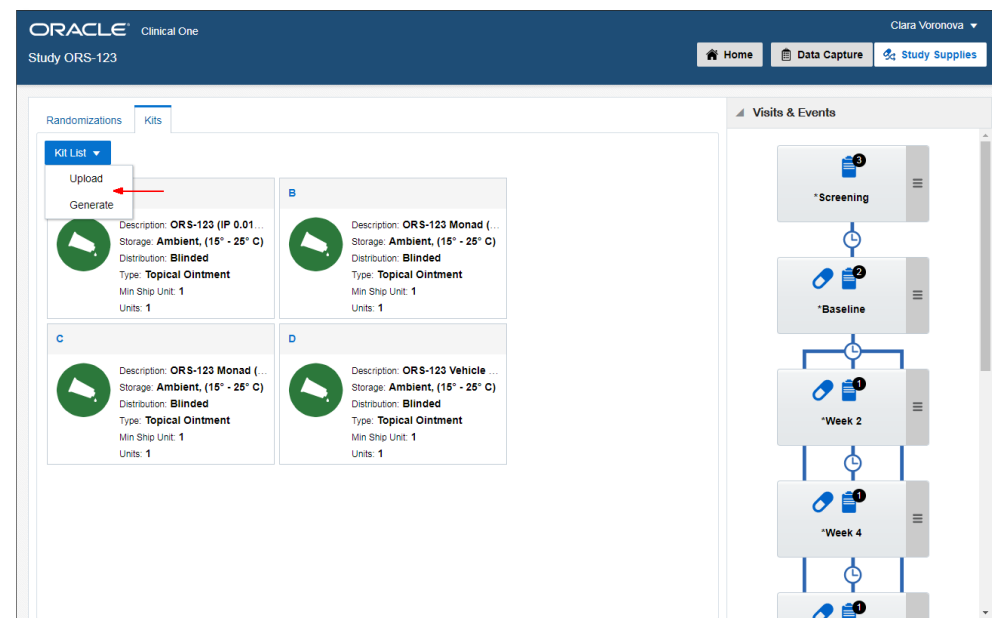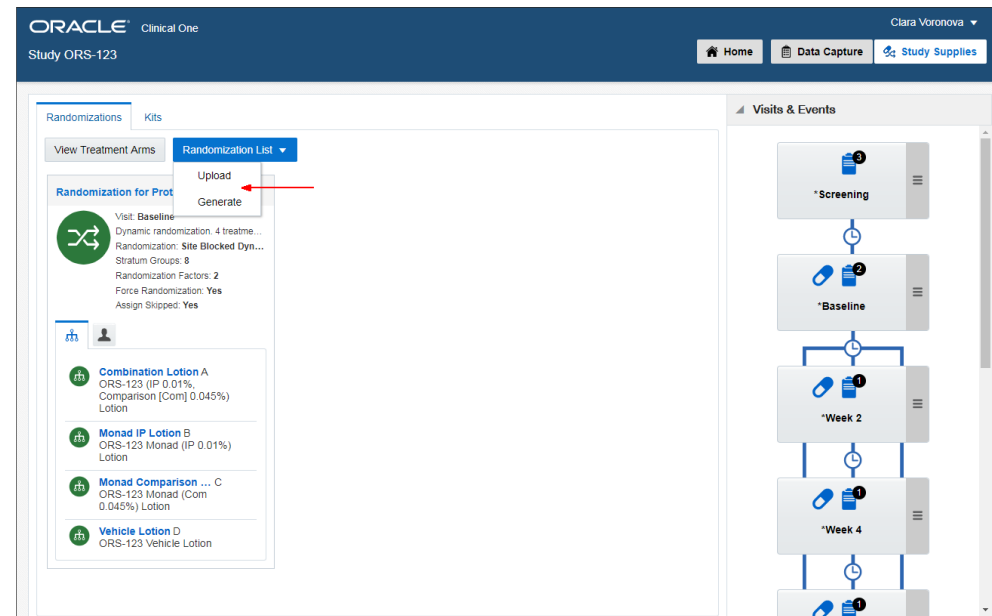
5. **Create blinded groups:** On the right, select **Blinded Groups**.

   Read step-by-step help for study verification or study go-live, or ▶ watch training.

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:** Either upload or generate it.

   Read step-by-step help for study verification or study go-live, 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 study verification or study go-live, or ▶️ watch training.

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

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 **Inventory** tab.

4. **Create lots:** In **Lots**, on the right, create manufacturing lots (and blinded lots, if needed).
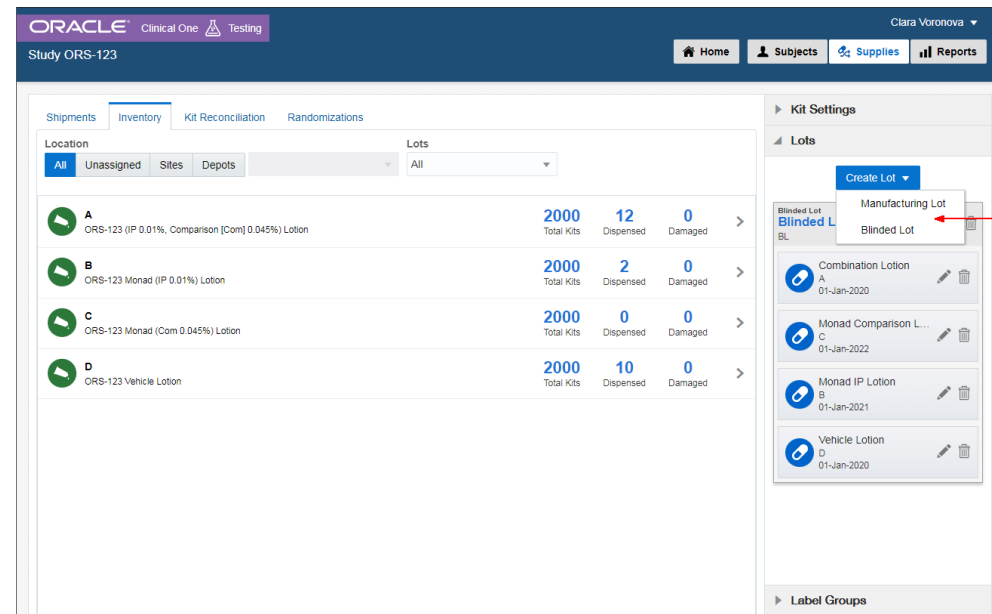
   Read step-by-step help for study verification or study go-live, or ▶ watch training.

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

   Read step-by-step help for study verification or study go-live, or ▶ watch training.

6. **If using blinded lots, combine manufacturing lots into blinded lots:** Drag manufacturing lots into blinded lots.
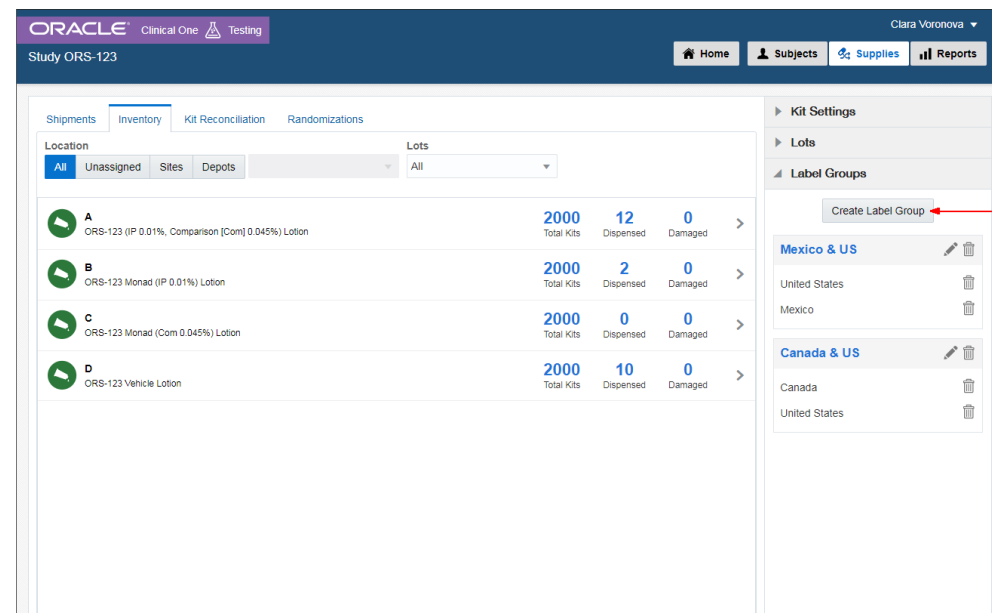
   Read step-by-step help for study verification or study go-live, or ▶ watch training.

9   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 study verification or study go-live, or ▶ watch training.

Final steps

10   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. On the left, select a mode, and activate depots for the mode.

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

   Read step-by-step help for study verification or study go-live, or ▶ watch training.
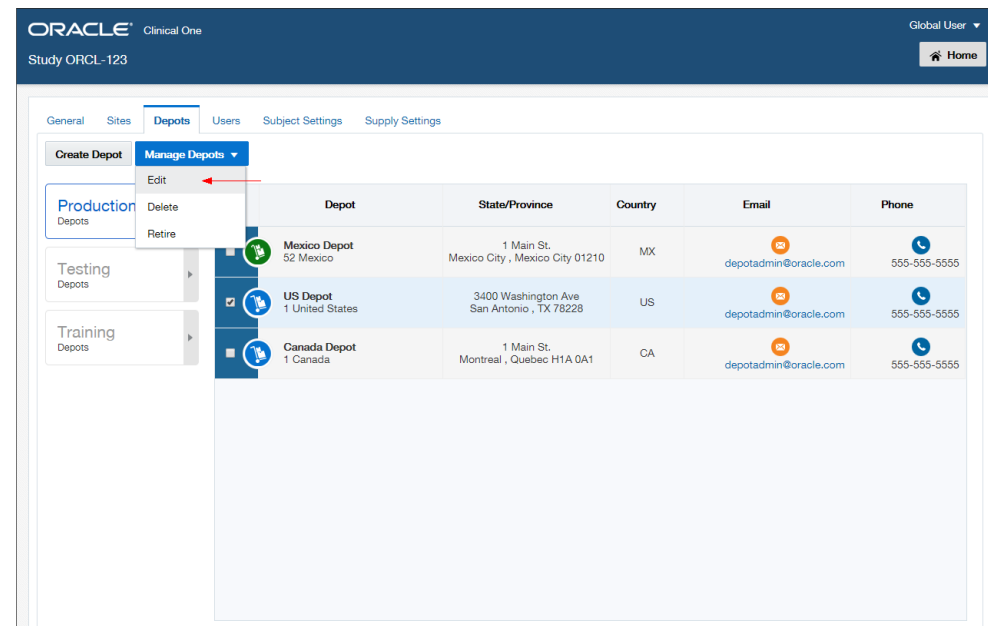

11   Release kits to depots (done by clinical supply manager)

1. On the Home page, click the pencil button 🖉 for your study.

2. On the Testing version (for study verification) or the Approved version (for study go-live), click the menu button ≡ and select **View Study Design**.

3. Along the top, click **Supplies**, and 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.
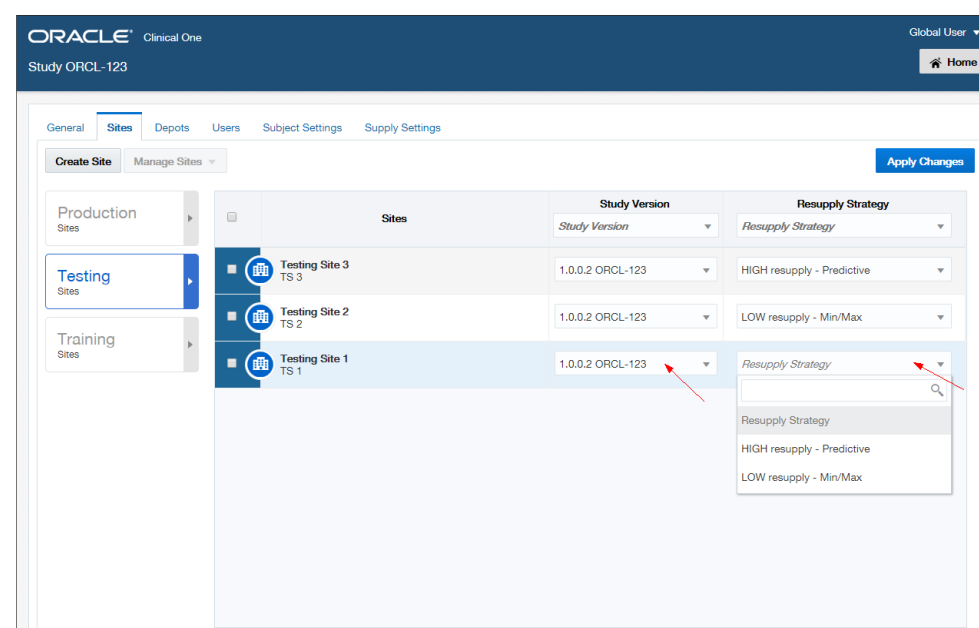
   Read step-by-step help for study verification or study go-live, or ▶ watch training.
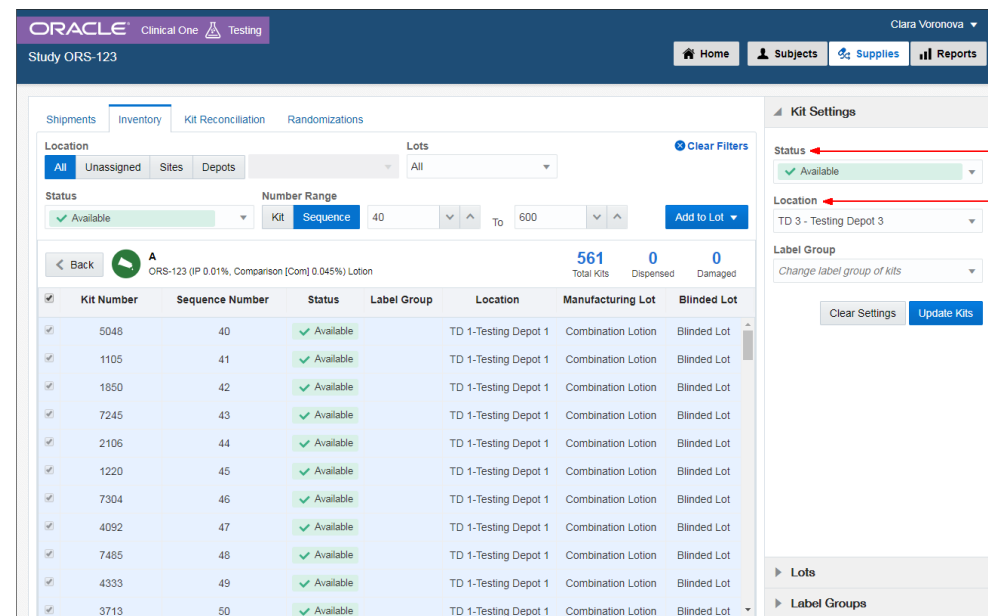
12   Assign a study version and resupply strategy to each site (done by site manager)

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 study verification or study go-live, or ▶ watch training.

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

   Read step-by-step help for study verification or study go-live, or ▶ watch training.

13   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.

   Read step-by-step help for study verification or study go-live, or ▶ watch training.

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

   Read troubleshooting tips for study verification or study go-live.
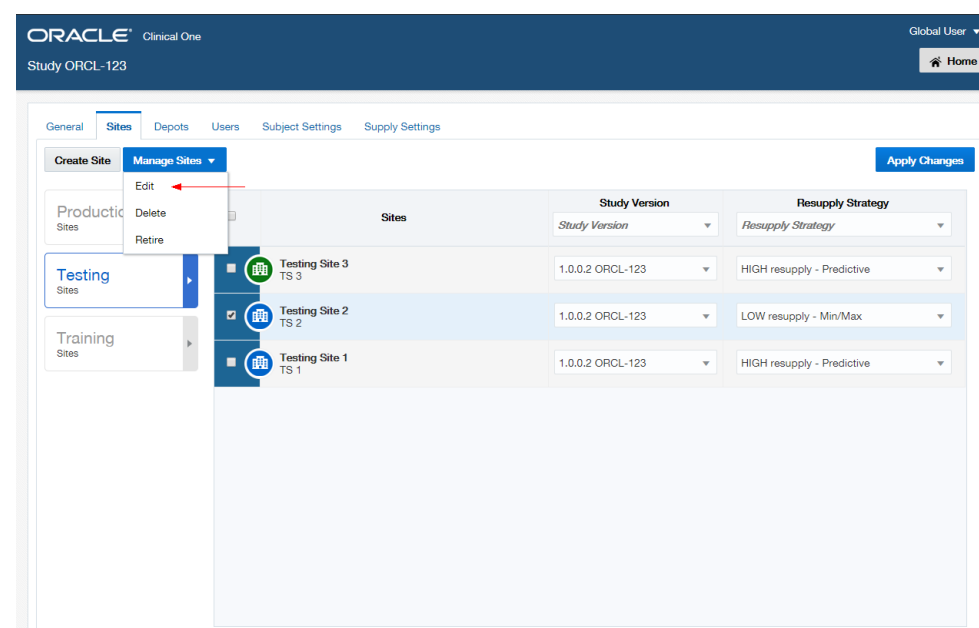
✅ **You're now ready for study verification or study go-live!**

Find out more about *Clinical One*

Get more information

See Oracle Health Sciences Clinical One, and review the books for sponsor users, site users, and depot users, on the Oracle Help Center.

Other resources

Read frequently asked questions on the Oracle Help Center.
Watch short training videos on the Oracle Help Center.

Contact Support

For assistance, contact Clinical One Cloud Service Support.

Can't find what you need?

Write to us at clinical_one_doc_feedback_us_grp@oracle.com.