Clinical One
Quick Study Design

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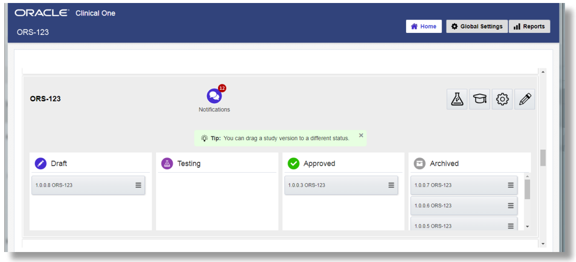
Set up forms and visits

1 Sign in to Clinical One

1. Sign in to Clinical One.

   Need help getting the product URL or your user name and password?



2 Create visits and events

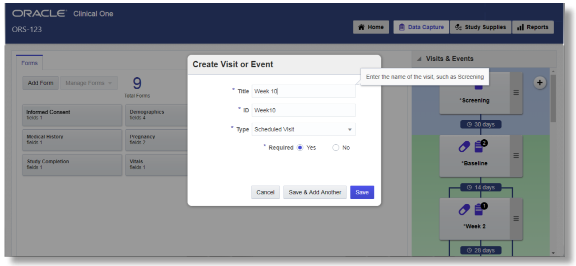
1. On the Home page, click the pencil button on the study you want to edit.
2. Below Draft, click the study version.
3. Along the top, make sure that **Data Capture** is selected.
4. If you have no visits, on the right, in Visits & Events, click **Create Visit**.

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

   Since you have to create visits before you can define the visit schedule, create the visits in the order they will be scheduled. For example, create Screening, Week 1, Week 2, and so on.
5. Fill in the fields and click **Save**. To view tips for completing a field, click into the field or choose an option.

   The new visit appears under Visits & Events.
6. Create additional visits as needed.

   Read step-by-step help or watch training.



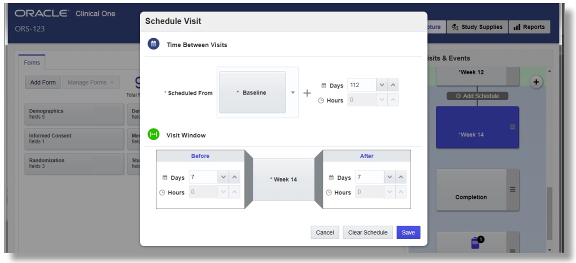
3 Define the visit schedule

1. On the Home page, click the pencil button ✎ on the study you want to edit.
2. Below Draft, click the study version.
3. In Visits & Events, click the **Add Schedule** button above the visit you want to schedule.

   The name of the visit you're scheduling appears next to Scheduled From near the top of the window.
4. Fill in the fields, and click **Save**. To view tips for completing a field, click into the field or choose an option.

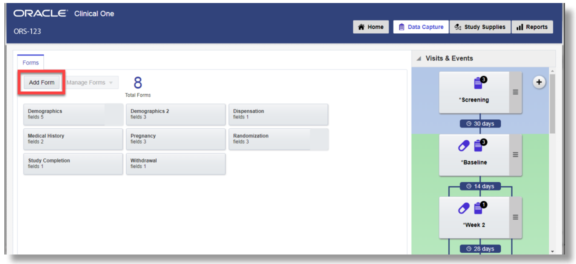
   The Add Schedule button in Visits & Events is replaced with the number of days between visits. Point to the text to view visit window details.
5. Schedule the remaining visits as needed.

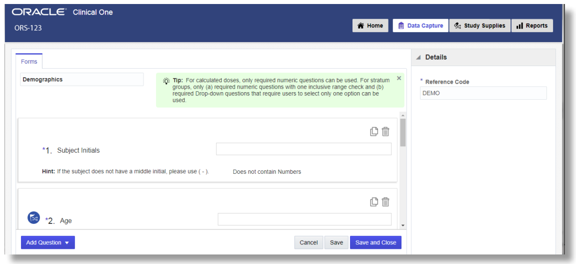
   Read step-by-step help or watch training.



4 Create forms

1. On the Home page, click the pencil button ✎ on the study you want to edit.
2. Below **Draft**, click the study version.
3. Along the top, make sure **Data Capture** is selected.
4. Create a form:
   a. If you have no forms, click **Create Form**.
   If you have one or more forms, click **Add Form** in the upper left.
   b. In the upper left, enter a name for the form (for example, Demographics).
   c. On the right, below Details, enter a one-word reference code for the form (for example, DEMO). This field is reserved for a future release, and any value you enter isn't used anywhere else.
5. Create questions for the data you need to capture:
   a. Create a text question to capture a value with either letters only or letters and numbers (for example, Subject Initials).
   b. Create a number question to capture a value with either numbers only (for example, Weight).
   c. Create a date/time question to capture a date value, with or without a time (for example, Date of informed consent).
   d. Create a drop-down question to capture one or more answers that site users select from a drop-down (for example, Gender).
   e. Create an age question to insert a Date of Birth question and a read-only calculated age field.
6. In the lower right of the form, click **Save**.
7. Create additional forms as needed.





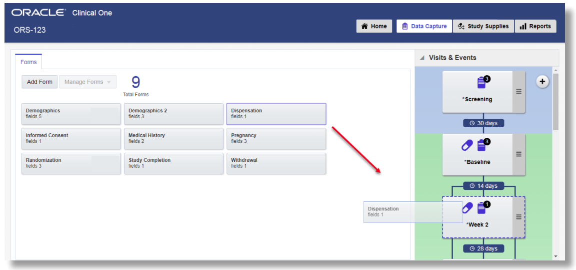
Read step-by-step help or watch training.

5 Add forms to visits

1. On the Home page, click the pencil button on the study you want to edit.
2. Below Draft, click the study version.
3. Along the top, make sure that **Data Capture** is selected.
4. Drag each form from the left to the visit you want to add it to on the right.

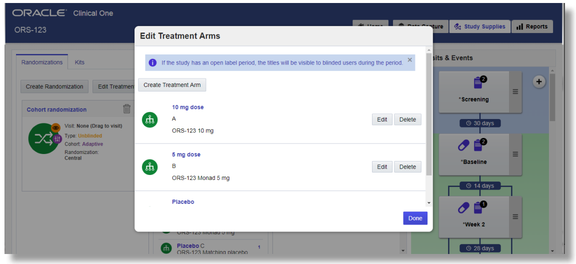
   Tip: You can add forms to visits in any order, but you'll save some time if you add forms in the order they should appear to site users.

   Read step-by-step help or watch training.



Define treatments and randomization

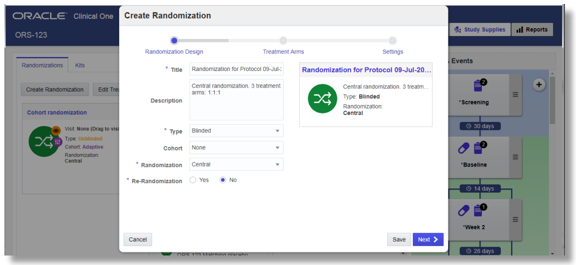
6 Define the treatment arms



1. On the Home page, click the pencil button ✎ on the study you want to edit.
2. Below Draft, click the study version.
3. Along the top, click **Study Supplies**.
4. Below the study name, make sure the **Randomizations** tab is selected.
5. If you have no treatment arms, click **Create Treatment Arms**.
   If you have one or more treatment arms, click **Edit Treatment Arms** in the upper left.
6. Fill in the fields, and click **Add**. To view tips for completing a field, click into the field.
7. Enter the details for the next treatment arm.
8. After you finish, click **Done**.

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

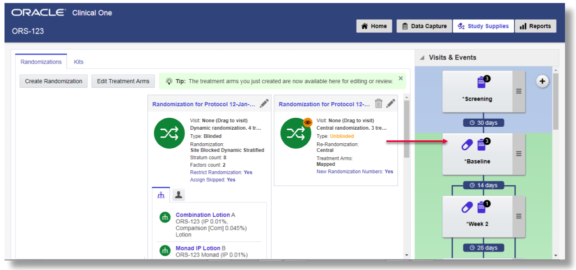
7 Define the randomization



1. On the Home page, click the pencil button ✎ on the study you want to edit.
2. Below Draft, click the study version.
3. Along the top, click **Study Supplies**.
4. Below the study name, make sure the **Randomizations** tab is selected.
5. Click **Create Randomization Design**.
6. Fill in the fields in the wizard, and click **Save** when you reach the end of the wizard.
   Want help completing these fields?
7. Create additional randomization designs as needed.

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

8 Add randomization to a visit

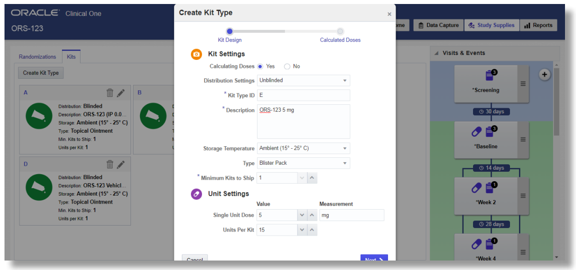


1. On the Home page, click the pencil button on the study you want to edit.
2. Below Draft, click the study version.
3. Along the top, click **Study Supplies**
4. Below the study name, make sure the **Randomizations** tab is selected.
5. On the right in Visits & Events, locate the scheduled visit the study protocol defines as the randomization event.
6. On the left, identify the randomization design to assign to a visit.
7. Drag the randomization design to the visit. The visit must be required and scheduled, and it cannot be the study completion or withdrawal visit.

   A blue line appears between the randomization event and the next scheduled visit, and the randomization design displays the visit you assigned it to.
8. If you dragged the second or later randomization design to a visit, choose the treatment arms that subjects should move to, and click **Map Treatment Arms**.
9. Add additional randomization designs to visits as needed.

   Read step-by-step help or watch training.

9 Define the kits



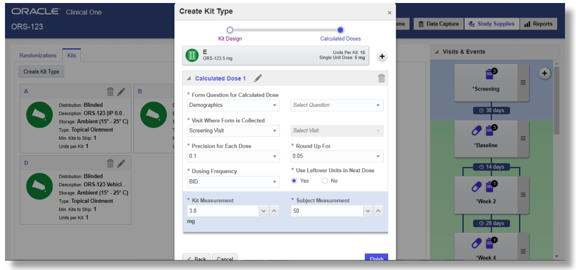
1. On the Home page, click the pencil button on the study you want to edit.
2. Below Draft, click the study version.
3. Along the top, click **Study Supplies**.
4. Below the study name, click the **Kits** tab.
5. Click **Create Kit Type**.
6. For **Calculating Doses**, choose **Yes** if you need to define calculations for this kit type based on subjects' answers to one or more questions. Choose **No** if calculations aren't required for dispensation.
7. Fill in the remaining fields. To view tips for completing a field, click the field or choose an option.

8. If you chose **No** for Calculating Doses, click **Add**. You're now finished creating the kit type.

9. If you chose **Yes** for Calculating Doses, click **Next**, define your calculated doses, and click **Finish**.

10. Define additional kits as needed.

Read step-by-step help or watch training.



10 Define the dispensation schedule

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

2. Below Draft, click the study version.

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

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

5. On the right in Visits & Events, locate the first dispensation event defined in the study protocol.

6. Drag the kit type to the visit.

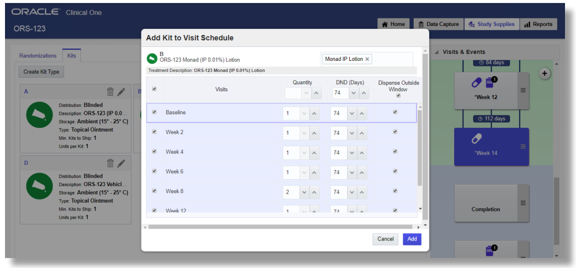
7. Click in the **Select Treatment Arm** field, and select an option from the drop-down:
   - If the visit occurs before randomization, select **All Subjects**.
   - If the visit occurs during or after randomization, select one or more treatment arms to associate the kit type with, or select All Treatment Arms.

8. Using the checkboxes on the left (or the column-level checkbox, to select all visits), select any other visits in which the kit must be dispensed.

9. Fill in the fields, and click **Add**. To view tips for completing a field, click into the field.

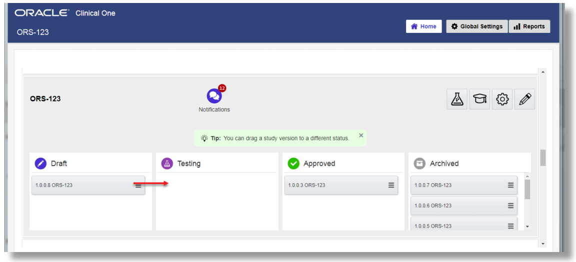
10. Define dispensation for additional kit types as needed.

Read step-by-step help or watch training.



The study design is finished! What's next?

11 Next steps



What do I do after I finish my study design? Move the study version to Testing on the Home page so you or another member of the study team can specify randomization and trial supply settings.

1. On the Home page, click the pencil button on the study you want to edit.
2. Drag the Draft version of the study to Testing.
3. Use the Quick Study Setup guide to finish configuring your study design in Testing mode, and then verify the study with test data before it goes live.

   Read step-by-step help or watch training.

12 What if I need to update the study design?

All you have to do is create a new Draft version of the study.

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

   If there is a study version below Draft, move it to Testing or Archived.
2. Below Draft, click **Create Study Version**.
3. Make any necessary updates to the new Draft version of your study.

   Already started the study conduct period? Read guidance on how to make changes.

   Read step-by-step help or watch training.

You're done!

*Find out more about **Clinical One***

Get more information

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

Other resources

Watch short training videos on the Oracle Help Center.

Contact Support

For assistance, contact Health Sciences Cloud Support.

Can't find what you need?

Write to us at clinical_one_doc_feedback_us_grp@oracle.com .