

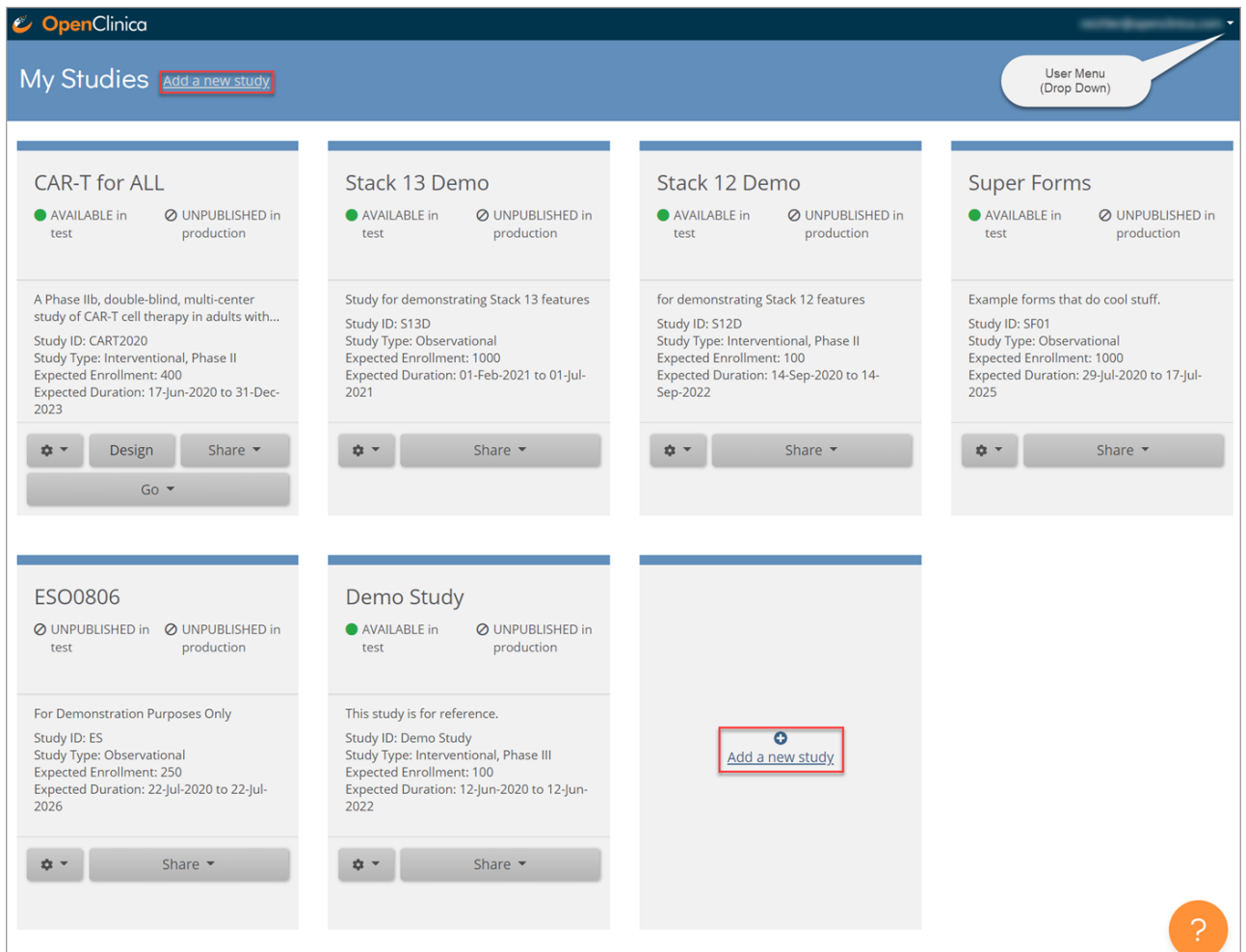
2.1 Create a Study

The **Study Build** system is where you design and set up your study. **Study Runner** is part of your the system where your study is carried out (though certain configurations are also set in Study Runner).

Only users with a **User Type** of **Administrator** and a **User Role** of **Data Manager** can create a study.

To Create a Study:

1. With a **User Type** of **Administrator** and a **User Role** of **Data Manager**, log into the OpenClinica Study Manager.
2. Click the **Add a new study** link at the top of bottom of the screen.



The screenshot displays the OpenClinica Study Manager interface. At the top, there is a navigation bar with the OpenClinica logo, the text "My Studies", and a red-bordered button labeled "Add a new study". A "User Menu (Drop Down)" is visible in the top right corner. The main content area is a grid of study cards. Each card displays the study title, status (e.g., "AVAILABLE in test" or "UNPUBLISHED in production"), a brief description, study ID, type, enrollment, and duration. Below each card are "Design" and "Share" buttons. A red-bordered button labeled "Add a new study" is also visible in the bottom right corner of the grid area.

3. Enter data into the fields that appear on the **Add a new study** window.

Add a new study ✕

ID *

Name *

Description *

Type *

Expected Number of Participants *
 Disable adding new participants when expected number is reached


Expected Start Date *

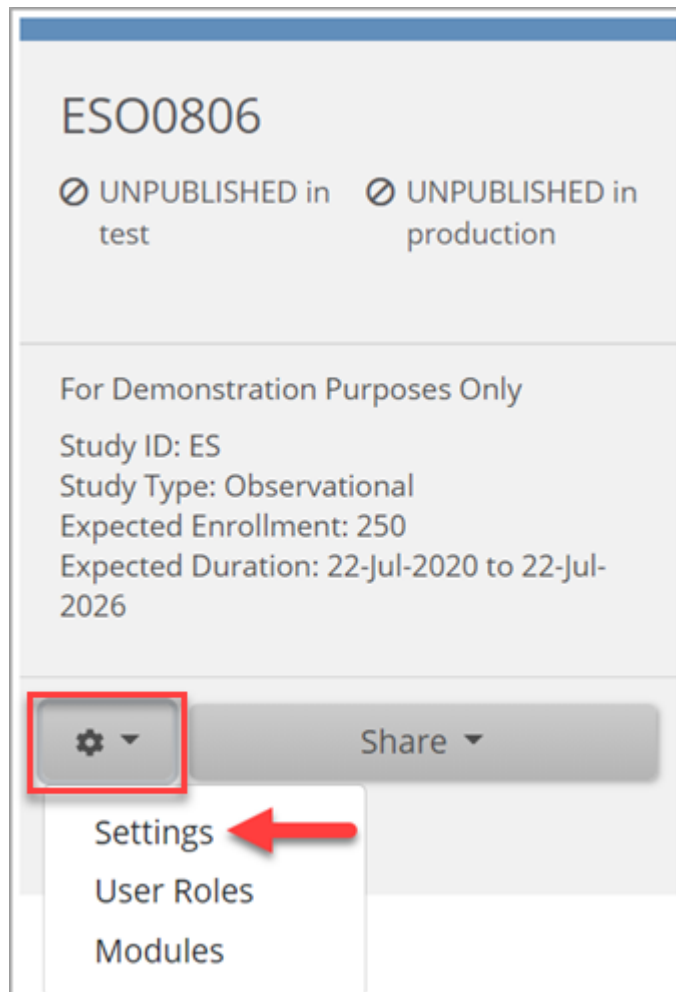
Expected End Date *

If you wish to set a limit on the number of participants that can be added to your study, enter the number in the **Expected Number of Participants** field and click the checkbox for **Disable adding new participants when expected number is reached**.

4. Click **Save**.

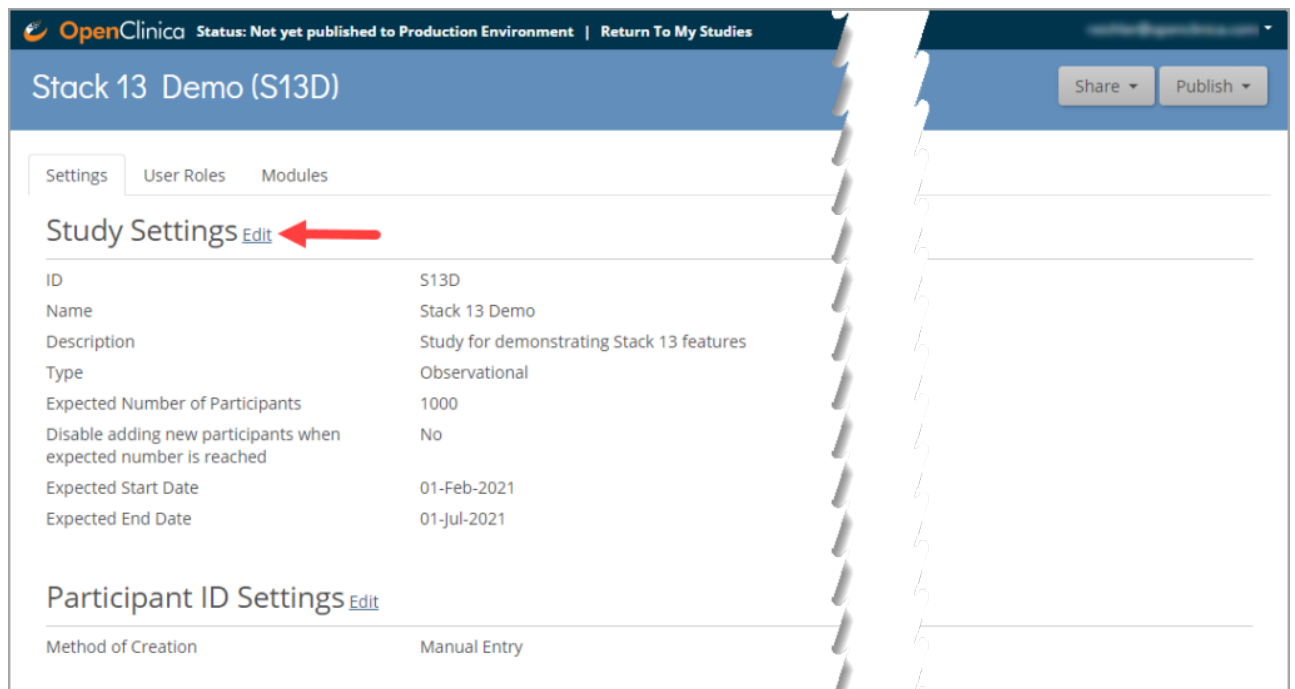
To Set a Limit on the Number of Participants (after study creation):

1. Click the  button and select **Settings** from any of the following locations:
 - The **My Studies** screen
 - The **Design** screen



◦ The **Share** screen

2. In the **Settings** tab, click **Edit**.




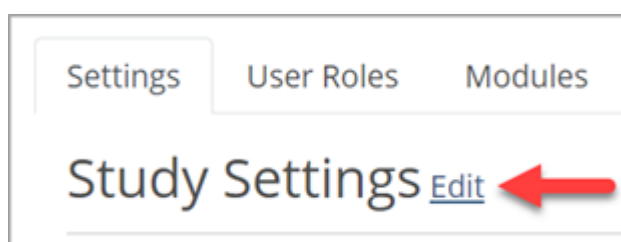
3. Check the **Disable adding new participants when expected number is reached** checkbox.

For example, if you enter 450 in the **Expected Number of Participants** field, once the number of study Participants reaches 450, site users will no longer be able to add Participants.

Note: The total number of Participants that will be allowed includes Participants with status of **Available** or **Signed**. **Participants with a status of Removed are not included in the total number. You can view the current number or percentage of Participants in each status in the Participant Status Count table on the home screen of your study.**

To Change the Study Settings:

1. Click the  button and select **Settings** from the drop-down list in any of the following locations:
 - The **My Studies** screen
 - The **Design** screen
 - The **Share** screen
2. To open the **Study Properties** screen, click the **Edit** link to the right of **Study Settings**.



3. Change data in the appropriate field(s).

Study Properties

ID *

Name *

Description *

Type *

Expected Number of Participants *
 Disable adding new participants when expected number is reached

Expected Start Date *

Expected End Date *

4. Click the **Save** button.

Note: You can change settings at any time. The changes take effect immediately, and you do not need to republish the study.

Navigating the My Studies Screen

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Approved for publication by Ray Eichler. Signed on 2021-06-11 4:06PM

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