



2.1 Create a Study

Definition: A study uses Events and Forms to collect Participant data for the study's purpose (e.g. to determine the safety and efficacy of a new treatment.)

Example: A study could be a trial of a new medication intended to treat diabetes.

The **Study Build System** is where you design and set up your study. **Study Runner** is where you collect and review data.

The process of creating a study starts in the Study Build System and continues in Study Runner.

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

For information on User Types and User Roles, see [User Access and Sharing](#).

To Create a Study:

1. With a **User Type** of **Administrator** and a **User Role** of **Data Manager**, log into the OpenClinica Study Build System.
2. Click the **Add a new study** link in the header or scroll to the bottom of the page and click **Add a new study**.

The screenshot shows the 'My Studies' page in OpenClinica. The page header includes the OpenClinica logo and the user name 'PBynum'. The main content area is a grid of study cards. The top row contains four cards: 'PJB Study 001', 'CAR-T Study', 'Coding Study', and 'Jim Test Study'. The bottom row contains one card 'KK12' and a large 'Add a new study' button. Each card displays study details such as ID, type, and duration, along with 'Design' and 'Share' buttons. The 'Add a new study' button is highlighted in blue.

4. Enter data in 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 *

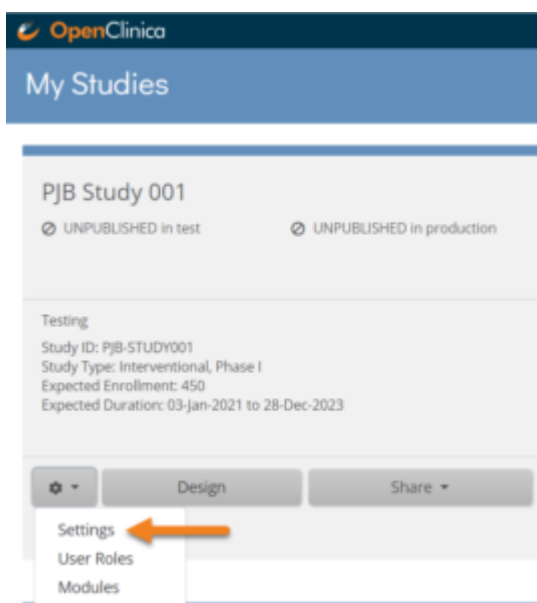
Cancel

Save

5. The Study ID cannot have more than 30 characters.
6. Click the **Save** button.

To Set a Limit on the Number of Participants:

1. On the **My Studies** page, click the **Gear** button  on your study's card and select **Settings**.



Settings

UserRoles



Modules

Study Settings [Edit](#)

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

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

Study Properties ✕

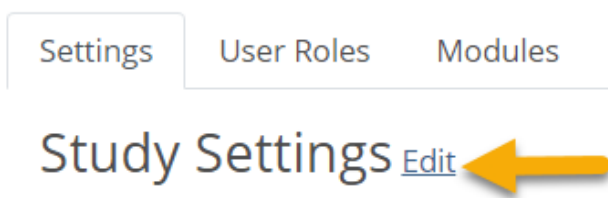
ID *	<input type="text" value="PJB-STUDY001"/>
Name *	<input type="text" value="PJB Study 001"/>
Description *	<input type="text" value="Testing"/>
Type *	<input type="text" value="Interventional"/>
Phase *	<input type="text" value="Phase I"/>
Expected Number of Participants *	<input type="text" value="450"/> 
	<input type="checkbox"/> Disable adding new participants when expected number is reached 
Expected Start Date *	<input type="text" value="03-Jan-2021"/>
Expected End Date *	<input type="text" value="28-Dec-2023"/>

For example, if you enter **100** in the **Expected Number of Participants** field, once the number of study Participants reaches **100**, site users will no longer be able to add Participants.

Note: The total number of Participants includes Participants with a **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 **Gear** 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 *	<input type="text" value="PJB-STUDY001"/>
Name *	<input type="text" value="PJB Study 001"/>
Description *	<input type="text" value="Testing"/>
Type *	<input type="text" value="Interventional"/>
Phase *	<input type="text" value="Phase I"/>
Expected Number of Participants *	<input type="text" value="450"/> <input type="checkbox"/> Disable adding new participants when expected number is reached
Expected Start Date *	<input type="text" value="03-Jan-2021"/>
Expected End Date *	<input type="text" value="28-Dec-2023"/>

4. Click the **Save** button.

Note: You can change settings at any time. The changes take effect immediately without requiring the study to be republished.

Navigating the My Studies Screen

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Functional approval by Kate Lambert. Signed on 2024-11-06 10:28AM

Approved for publication by Paul Bowen. Signed on 2025-02-10 1:23PM

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