

## 2.1 Create a Study

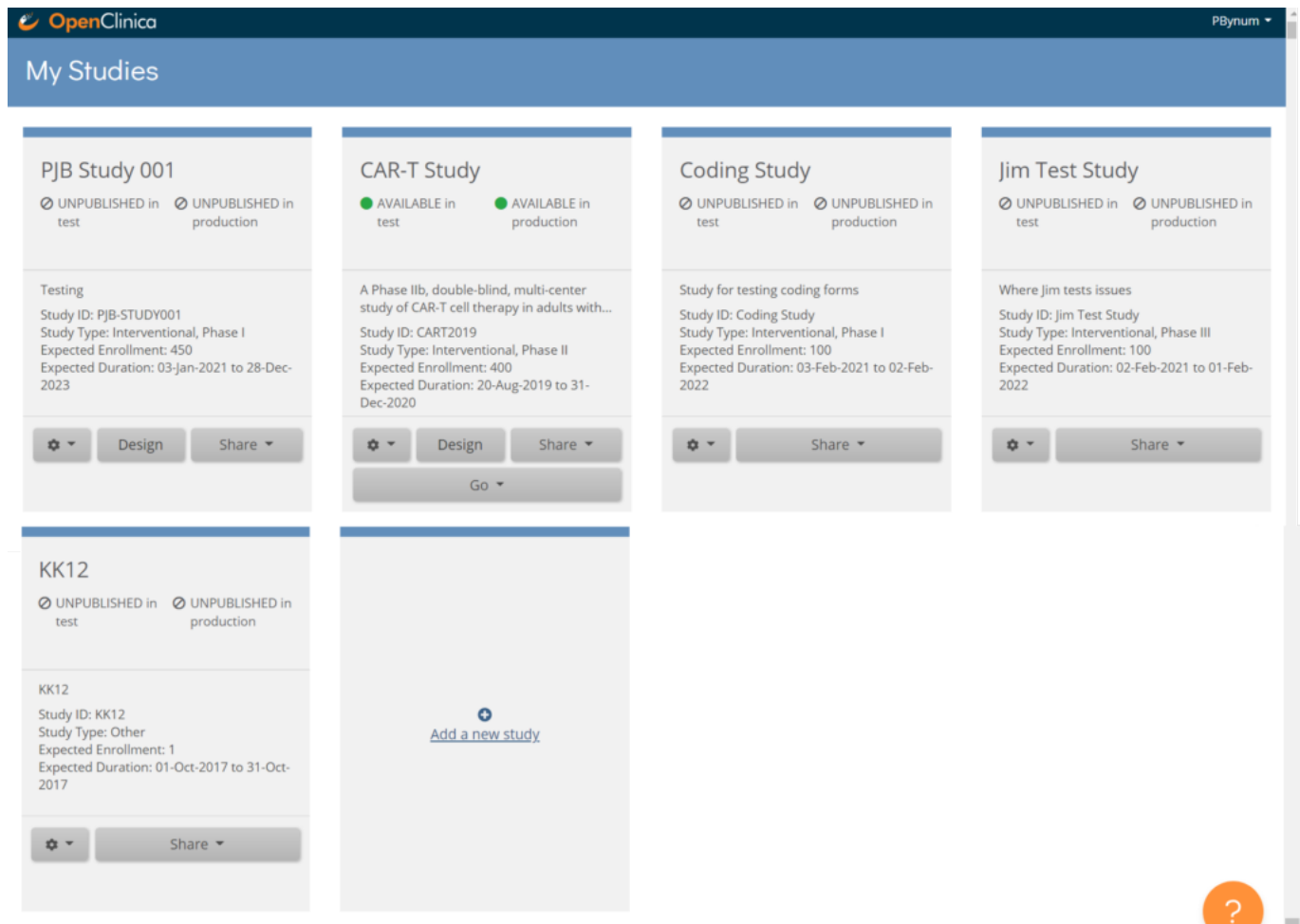
**Definition:** A study uses Events and Forms to collect Participant data for the study's purpose (e.g. to determine the safety and efficacy of a new treatment.)

**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 titled 'My Studies' and displays a grid of study cards. Each card represents a study and includes the following information:

- Study Name:** PJB Study 001, CAR-T Study, Coding Study, Jim Test Study, and KK12.
- Status:** UNPUBLISHED in test and UNPUBLISHED in production (for PJB, Coding, and Jim Test). AVAILABLE in test and AVAILABLE in production (for CAR-T).
- Study ID:** PJB-STUDY001, CART2019, Coding Study, Jim Test Study, and KK12.
- Study Type:** Interventional, Phase I; Interventional, Phase II; Interventional, Phase I; Interventional, Phase III; and Other.
- Expected Enrollment:** 450, 400, 100, 100, and 1.
- Expected Duration:** 03-Jan-2021 to 28-Dec-2023; 20-Aug-2019 to 31-Dec-2020; 03-Feb-2021 to 02-Feb-2022; 02-Feb-2021 to 01-Feb-2022; and 01-Oct-2017 to 31-Oct-2017.

At the bottom of the grid, there is a link to [Add a new study](#). A help icon (question mark) is visible in the bottom right corner of the page.

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 \*

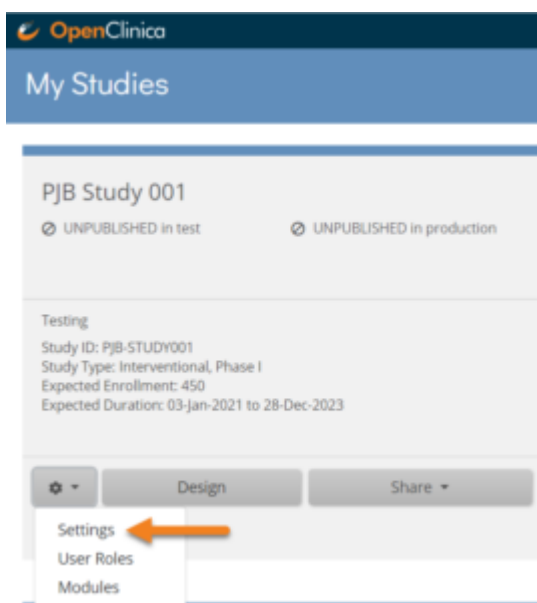
Cancel

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 ✕

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ID \*


Name \*

Description \*

Type \*

Phase \*

Expected Number of Participants \*  

Disable adding new participants when expected number is reached 

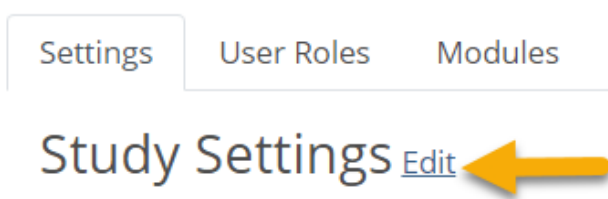
Expected Start Date \*

Expected End Date \*

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

[table id=6 /]

Approved for publication by Paul Bowen. Signed on 2023-11-30 11:35PM

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