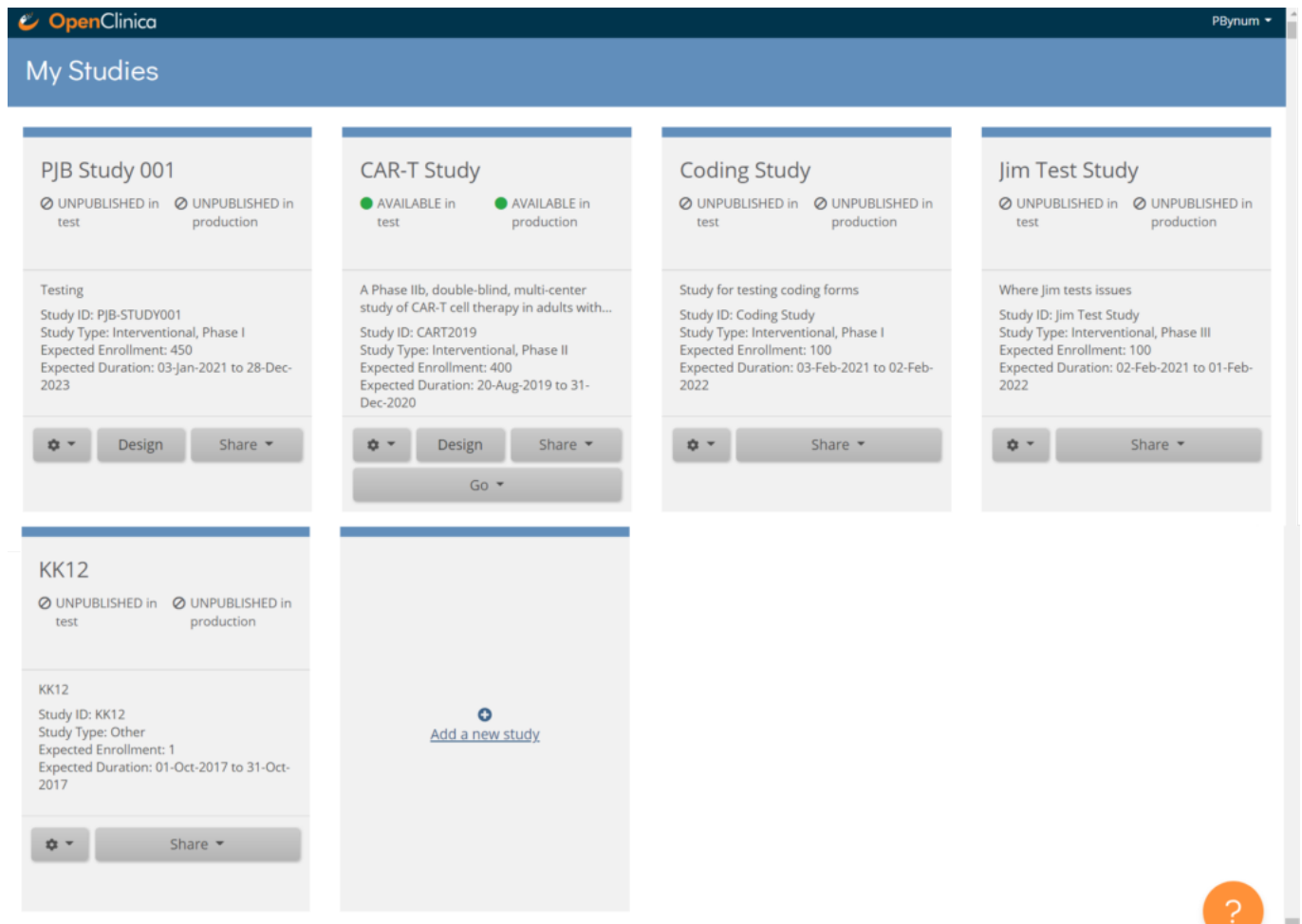# 2.1 Create a Study

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**.

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 *   📅 [DD-MMM-YYYY   ]

Expected End Date *   📅 [DD-MMM-YYYY   ]

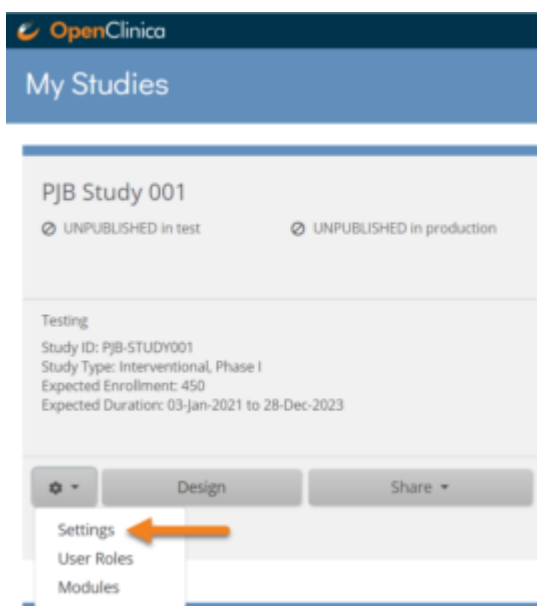   [Cancel] [Save]

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.**

OpenClinica

My Studies

PJB Study 001

⊘ UNPUBLISHED in test   ⊘ UNPUBLISHED in production

Testing

Study ID: PJB-STUDY001
Study Type: Interventional, Phase I
Expected Enrollment: 450
Expected Duration: 03-Jan-2021 to 28-Dec-2023

[⚙ ▾]   [Design]   [Share ▾]

Settings ◀
User Roles
Modules

| Settings | UserRoles | Modules |

Study Settings Edit

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

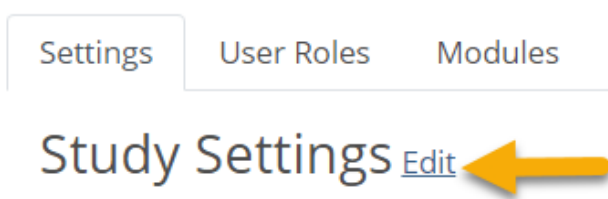3. Check the **Disable adding new participants when expected number is reached** checkbox.

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 * — PJB-STUDY001

Name * — PJB Study 001

Description * — Testing

Type * — Interventional

Phase * — Phase I

Expected Number of Participants * — 450

☐ Disable adding new participants when expected number is reached

Expected Start Date * — 📅 03-Jan-2021

Expected End Date * — 📅 28-Dec-2023

Cancel Save

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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