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.

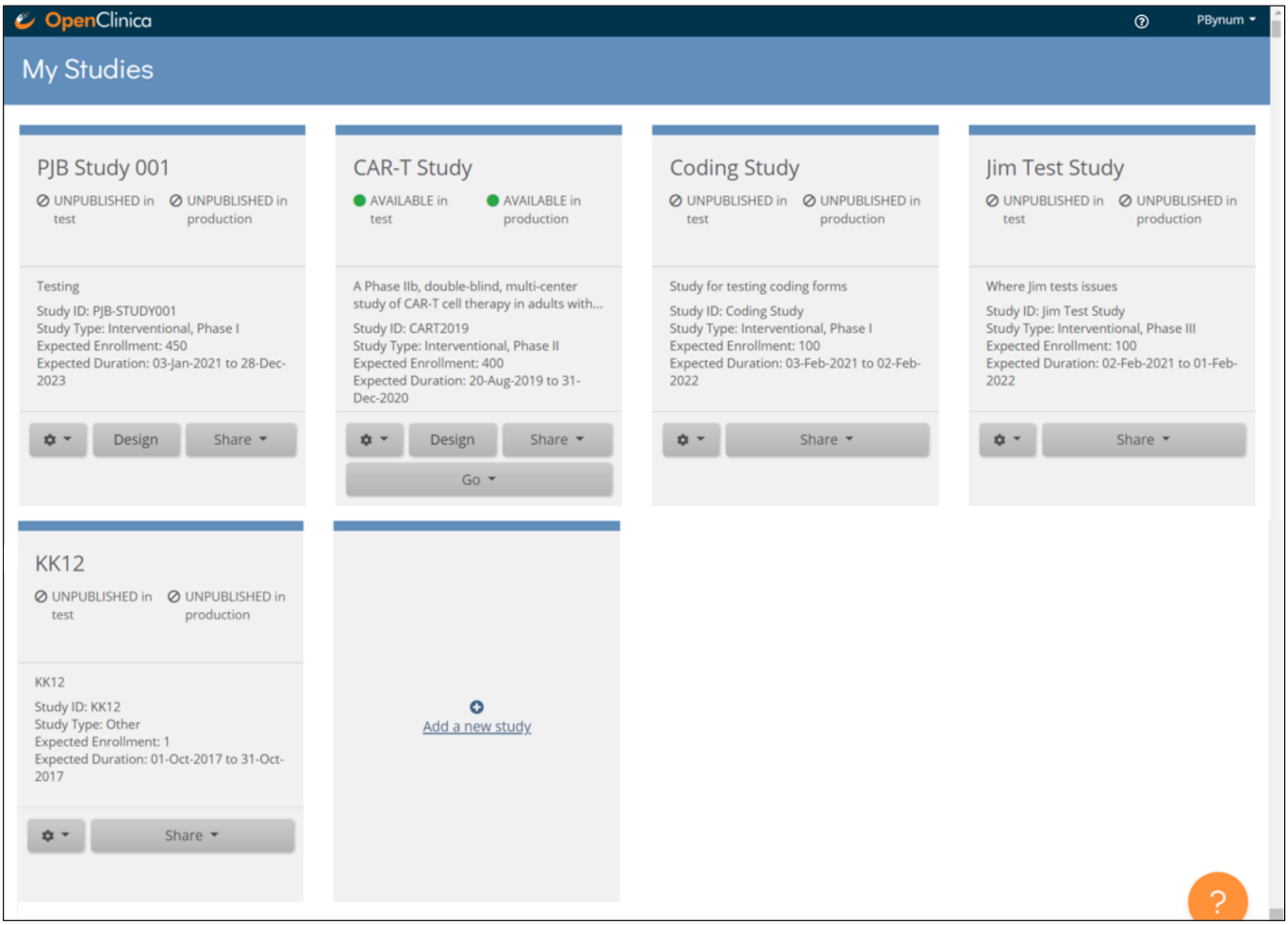
The process of creating a study starts in the Study Build System and continues in Study Runner.

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

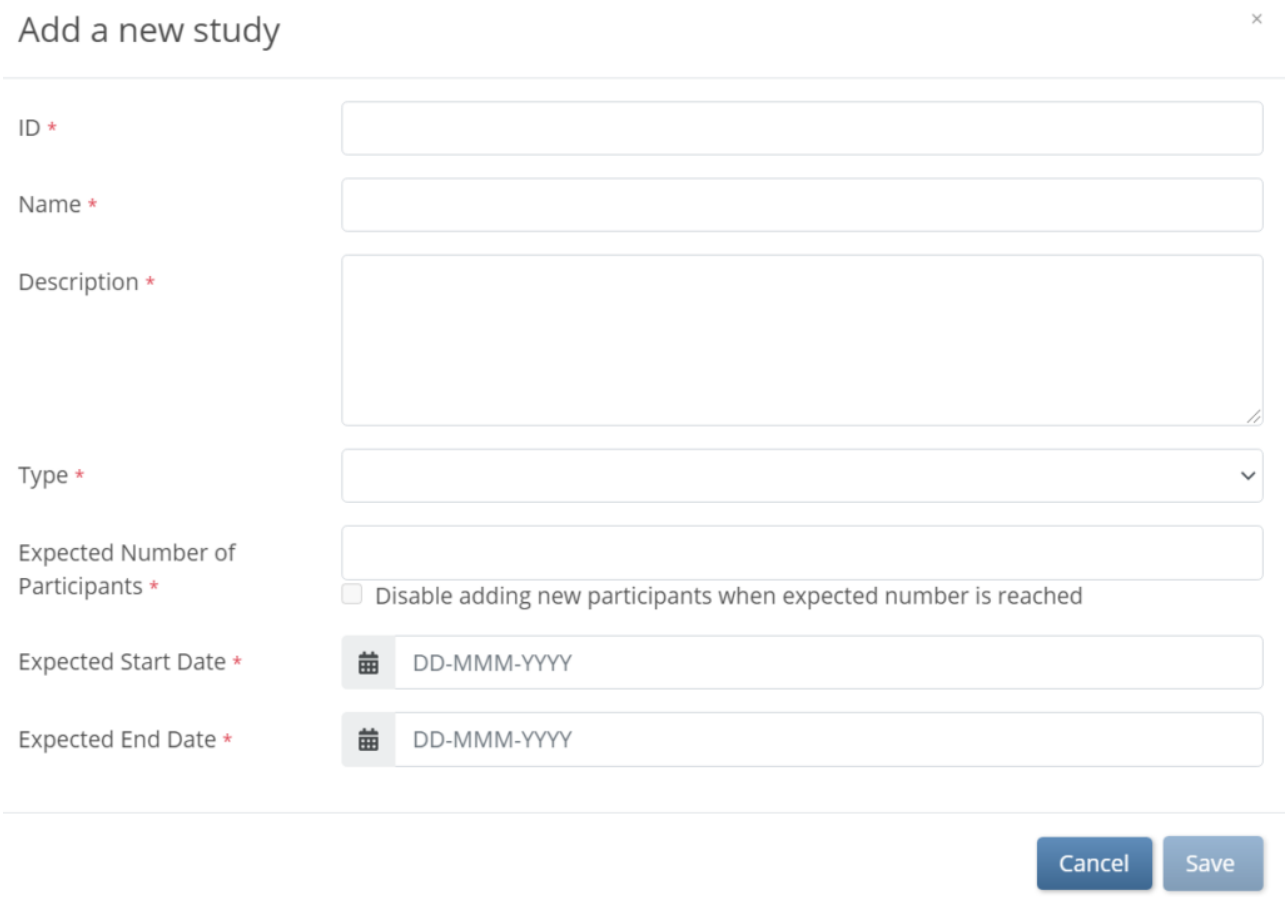
For information on User Types and User Roles, see **User Access and Sharing**.

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**.



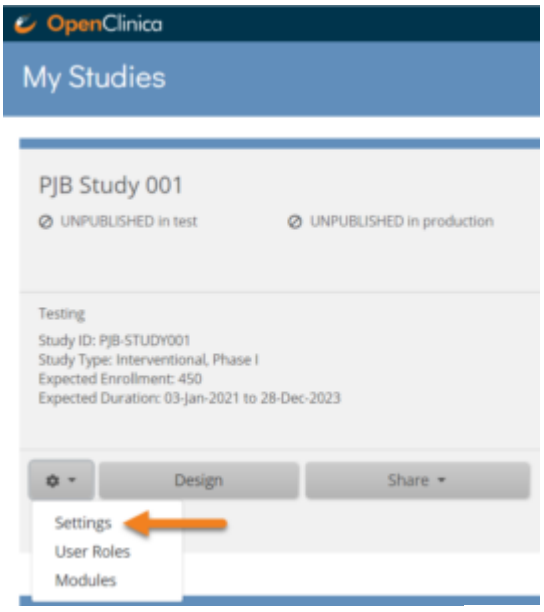
4. Enter data in the fields that appear on the **Add a new study** window.



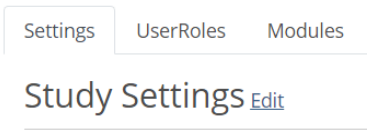
5. The Study ID cannot have more than 30 characters.
6. Click the **Save** button.

To Set a Limit on the Number of Participants:

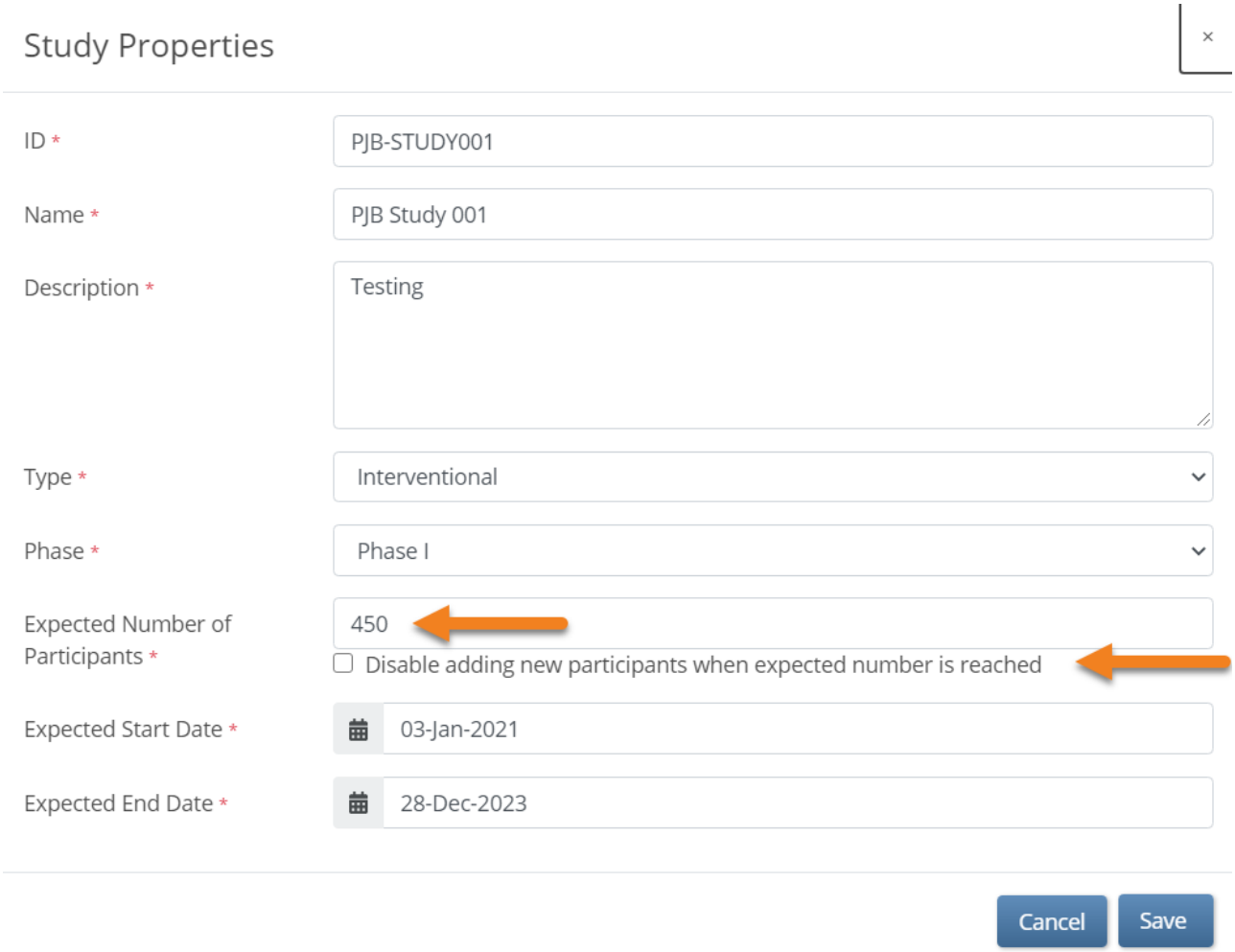
1. On the **My Studies** page, click the **Gear** button  on your study's card and select **Settings.**



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



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

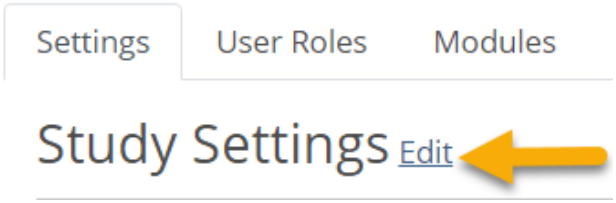


For example, if you enter **100** in the **Expected Number of Participants** field, once the number of study Participants reaches **100**, site users will no longer be able to add Participants.

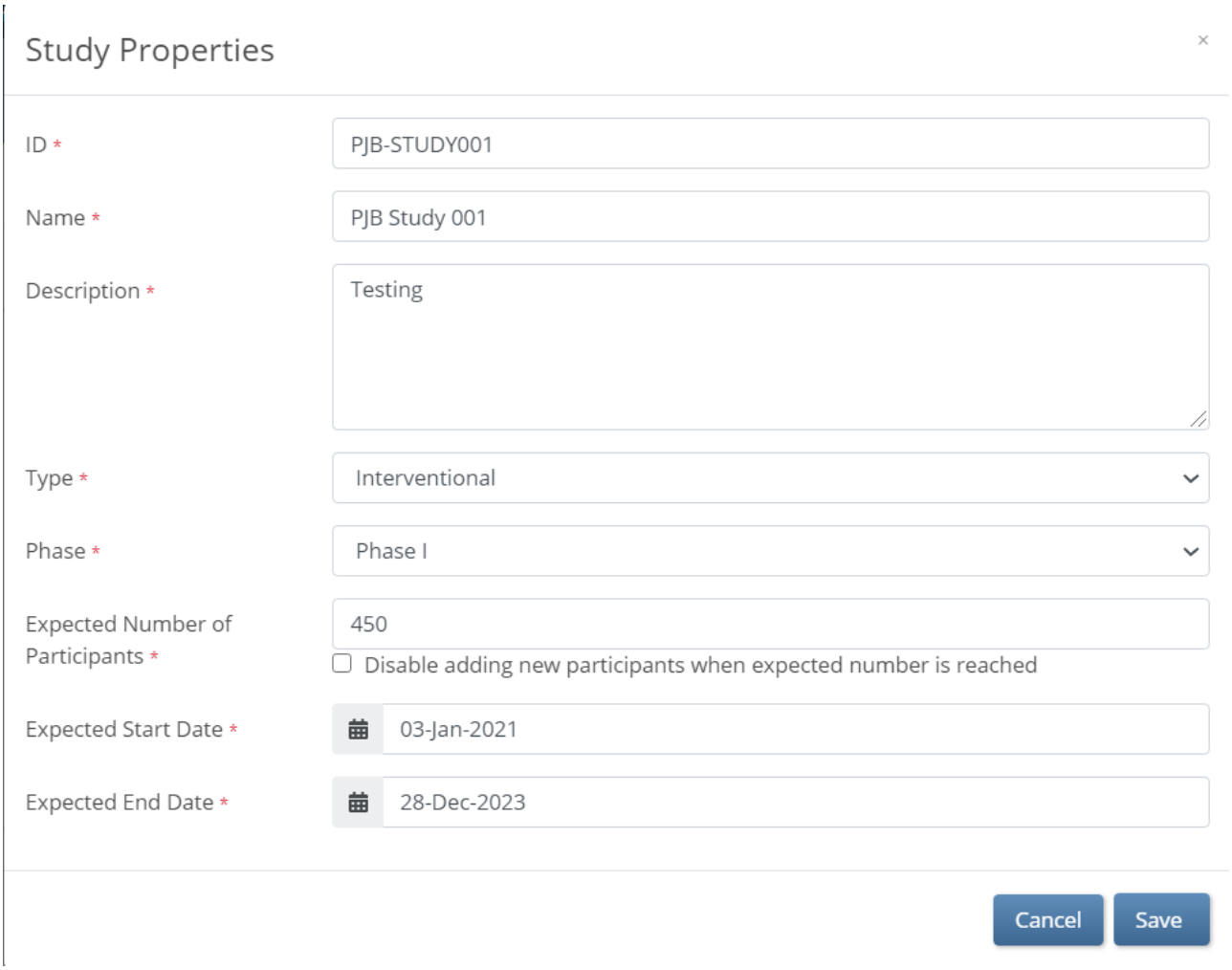
Note: *The total number of Participants includes Participants with a* ***Status*** *of* ***Available*** *or* ***Signed****. Participants with a status of* ***removed*** *are not included in the total number. You can view the current number or percentage of Participants in each* ***Status*** *in the* ***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).



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 /]

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

Not valid unless obtained from the OpenClinica document management system on the day of use.