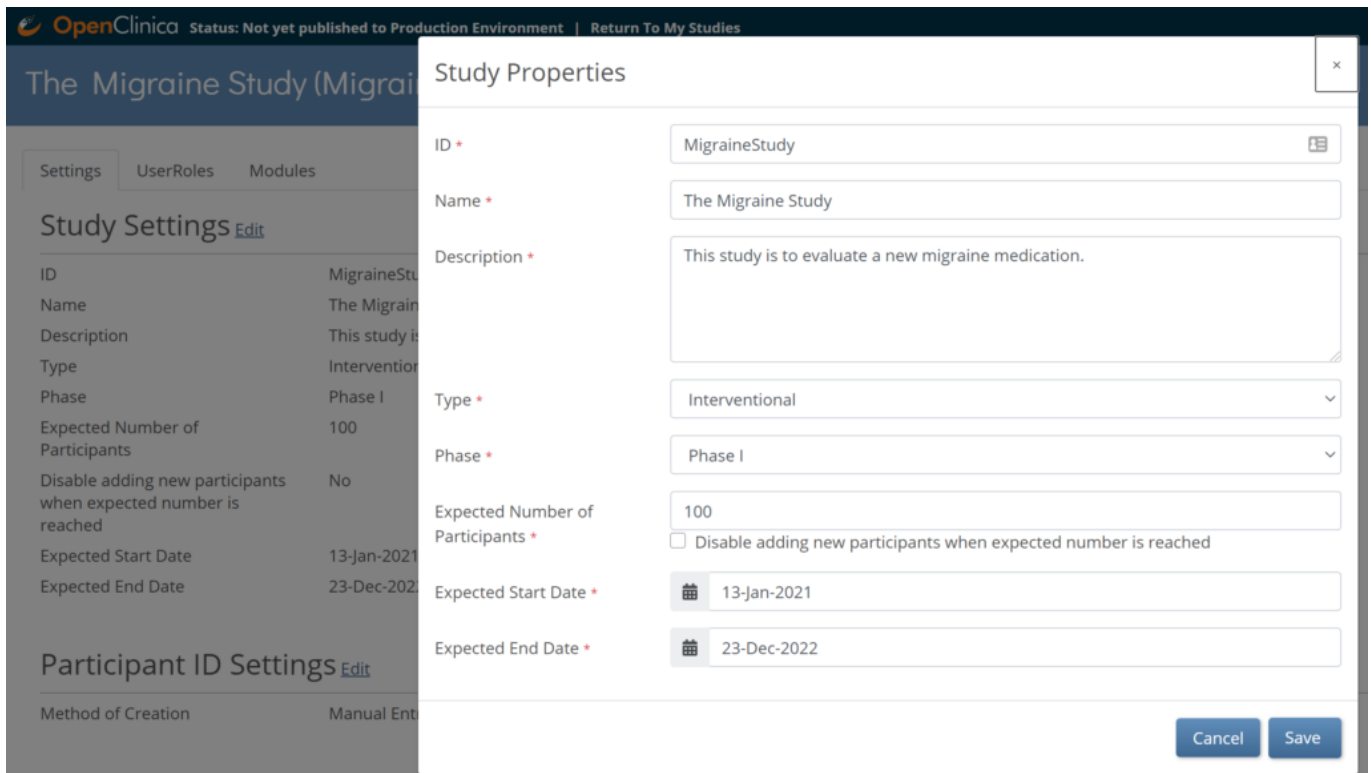


5.2.5 Editing Study Settings

To Edit Study Settings:

1. To the right of **Study Settings**, click **Edit**.
 - a. The Study ID field has a limit of 30 characters.
2. Edit the study settings as needed, and click **Save**.

Note: The changes take effect immediately in both the **Test** and **Production** environments for that study.



The screenshot shows the OpenClinica interface with a modal window titled "Study Properties". The modal contains the following fields and options:

- ID ***: MigraineStudy
- Name ***: The Migraine Study
- Description ***: This study is to evaluate a new migraine medication.
- Type ***: Interventional
- Phase ***: Phase I
- Expected Number of Participants ***: 100
- ☐ Disable adding new participants when expected number is reached
- Expected Start Date ***: 13-Jan-2021
- Expected End Date ***: 23-Dec-2022

At the bottom of the modal are "Cancel" and "Save" buttons. In the background, the "Study Settings" page is visible, showing a table of study details and a "Participant ID Settings" section.

Adding and Editing Participant IDs

Participant IDs can be created with:

- **Manual Entry:** The user must enter the ID for each Participant.
- **System-generated:** The system will auto-generate the ID based on an ID Template that you specify.

To Change the Method of Creation to Allow Automatic Entry:

1. From the **My Studies** screen, click the **Settings (gear)** icon under the study name, and select **Settings**.
2. Click the **Edit** link next to the **Participant ID Settings** header.
3. Click the radio button next to **System-generated**.

Note: If **Method of Creation** is set to **System-generated**, only Data Managers can edit the

Participant ID. Data Managers can always edit IDs, even ones that are system-generated.

Participant ID Settings

Method of Creation *

☐ Manual Entry

☒ System-generated

ID Template *

`${siteId}-${(siteParticipantCount+1)?string['000']}`

[View Examples](#)

Cancel

Save

System Generated IDs

If you choose **System-generated**, you must specify the template for the system-generated ID.

Example 1: `${siteId}-${(siteParticipantCount+1)?string['000']}`

Example 2: `${(helper.random(5))?string['00000']}`

Optional
Unique site ID for the current site where the Participant is being added.

Optional
A static dash (-) character. Can be replaced by different character(s) or removed.

Required
Must use either the Participant Count Method or the Random Number Method.

Participant Count Method adds 1 to the current count of Participants. The number can be modified to change the starting ID (e.g. +101 would generate 101, 102, 103, etc.)

Random Number Method uses a number from 1-9 to determine the number of digits in the generated ID (including leading zeros).

Optional
Adds leading zeros to the result value (up to the number of digits indicated by the number of zeros).

If using Random Number Method, the number of zeros must be the same as the number of digits indicated by the random number.

You Can Generate Participant IDs by the Following Methods:

- **The Participant Count Method:** Generate Participant IDs sequentially.
- **The Random Number Method:** Generate Participant IDs using random numbers.

You Can Build Your ID Template Using One or More of the Following Components:

1. **\${siteId}**: The unique identifier for the site the Participant is being added to.
2. **\${siteParticipantCount}**: The current number of Participants at the site. This is generally used like **\${(siteParticipantCount+1)}** to have the ID increment the Participant count for each new Participant added.
3. **\${helper.random(n)}**: Generates a random number with up to n digits each time a Participant ID is generated.
4. **?string[000]**: Added to the resulting values to pad them with leading zeros to equal the number of digits specified, for example, **\${(siteParticipantCount+1)?string[000]}** or

`${(helper.random(5))?string[00000]}`.

5. Prefixes, suffixes, separators - Include other text (such as - or a Study-specific prefix) to include standard content in each ID.

Note: Each ID Template must include #2 or #3.

Examples: The Participant Count Method template, **`${siteId}-${(siteParticipantCount+1)?string[000]}`**, for site University Hospital (**Site ID = UH**) would

produce the IDs, **UH-001**, **UH-002**, **UH-003**, etc. For site Central Hospital (**Site ID = CH**) would produce **CH-001**, **CH-002**, **CH-003**, etc.

The Random Number Method template, **`P-${(helper.random(5))?string[00000]}`**, would produce IDs with a fixed prefix of **P-** followed by a 5-digit random number (including leading zeros), for example **P-00362**, **P-82394**, **P-35070**.

Notes About the Template:

- The template cannot exceed **255** characters, and the resulting Participant ID cannot exceed **30** characters.
- **`${siteId}`** and **`${siteParticipantCount}`** are both required but can be in any order.
- Static text can be added to any portion of the template, but cannot include the following characters:
 - Slash (/)
 - Backslash (\)
 - Less Than (<)
 - Greater Than (>)
 - Ampersand (&)
 - Quotation Marks {"}
 - Apostrophe (')

Best Practice: There is no restriction for going beyond the minimum, but it is best practice to set up the minimum length to match the length of the maximum number of expected Participants.

If the template is invalid for any reason, the system uses a default template of **`${siteOID}`** followed by a **dash** and a **six-digit random number**.

Functional approval by Riley Bianchi. Signed on 2022-07-15 10:01AM

Approved for publication by Paul Bowen. Signed on 2023-01-19 1:02AM

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