

## 5 Launching and Managing Studies

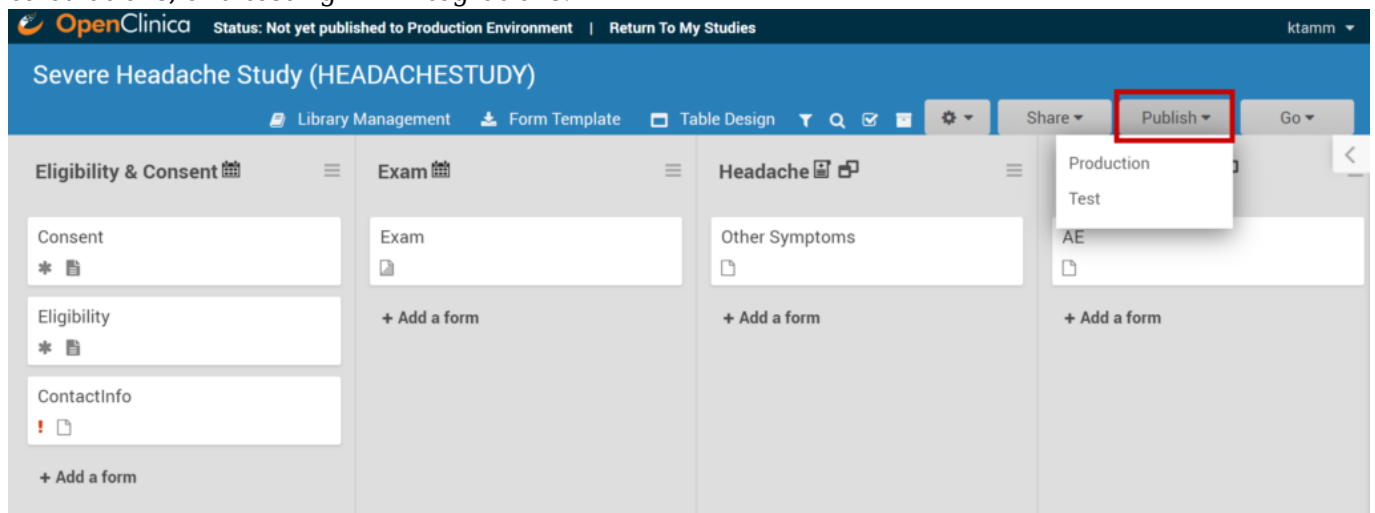
**For Information on Launching and Managing Studies, See the Following Sections:**

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### 5.1 Publishing Your Study

When you are ready to see how your study works in Study Runner, you can publish to **Test**. In addition to letting you use Study Runner features, publishing to **Test** generates OIDs that can be used for edit checks (constraints and required values), cross-form logic, skip logic (relevant fields), calculations, and testing API integrations.



**Warning:** Once you publish your study, you can still change the design of your study as needed without having to change Form version information. In other words, you can update your Form definitions without adding new versions of the Forms. The only Form definition properties that cannot be changed after a Form has been published are as follows:

- You cannot change the data type of an item.
- You cannot move an item into or out of a repeating group.
- You cannot change the **bind::oc:itemgroup** value for an item.

If you need to change any of these Form properties, you can remove the original item and replace it with a new item on the Form. You can still add a new Form without any of these restrictions.

#### To Publish Your Study

1. In **Study Designer**, click the **Publish** header button.
2. Select **Test** or **Production**.
3. Click **Publish** to confirm that you want to publish your study.

You will now see a link to Test and/or Production under the Go button in the main navigation. **Tip!** The first time you publish a study, its status is set to Design. This status does not allow users to add participants or enter data. Be sure to go to the **Share** page and change the study status from 'Design' to 'Available' if you are ready for data entry. It is a best practice to publish to test before production. When you have thoroughly tested your study, you can publish it to **Production**. This should be done only when you feel that you won't need to make any more major changes.

**Warning:** Once you publish a study to **Production**, in addition to the changes above, ANY change to a Form requires you to change the Form version. You cannot:

- Change a Common Event to a Visit Based Event.
- Change a Visit Based Event to a Common Event.
- Change a Repeating Event to a Non-Repeating Event.
- Overwrite a Form version; you must create a new version.

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## 5.2 User Access & Sharing

Once you have built and designed your study, you can share it with users. You can assign different **User Types** and **User Roles** to users to specify their access level within the **Study Build System** and each study environment.

### User Type

When a user is created, that user is assigned a **User Type** and **User Role**. There are two **User Types**: **Admin** and **User**. **Only Admins** have access to the **Administration** page. User Type determines the tasks that the user has permission to perform globally throughout the system. For example, only **Admins** can create studies or view the **Administration** screen.

User Role determines study-level access and specific tasks the user can perform based on the assigned **User Type** in the **Test** or **Production** environments.

For example, a user might have a **User Type** of **Admin** and a **User Role** of **Data Manager** or a **User Type** of **User** and a **User Role** of **Investigator**.

**Available User Types are:**

- **Admin:**
  - Can create studies.
  - Can see all studies.
  - Can assign their own access to any study.
- **User:**
  - Can only view and access assigned studies or sites.

**Best Practice:**

- The **Admin User Type** should be assigned sparingly because administrators have access to all

studies. Most users should be assigned the **User Type** of **User**. **Site users** should never be assigned a **User Type** of **Admin**, as this would give them potential access to all data across all studies and sites in your **Test** and **Production** environments.

- Each user only has one **User Type** but can have different **User Roles** in different studies or sites. For example, one can have a **User Type** of **User**, with a **User Role** of **Data Manager** in one study environment and a **User Role** of **Study Monitor** in another study environment.

## User Roles

Refer to the [User Matrix](#) for a table of permissions available to each of the **OC4 User Roles**.

### User Roles Include:

#### Study-level User Roles:

User Role	Basic Permissions
Data Manager	<ul style="list-style-type: none"> <li>• Add, Remove, Restore, and Reassign Participants</li> <li>• Schedule, View, Add, Remove, Restore, and Lock Events</li> <li>• View, Enter, Edit, Clear, Remove, and Restore Form Data</li> <li>• Add, Update, and Close Queries</li> <li>• Verify and Unverify Forms</li> <li>• Extract and Import Data</li> </ul> <p>*In addition, when the Manage Study permission is enabled:</p> <ul style="list-style-type: none"> <li>• *Edit Study Settings</li> <li>• *Edit Study Design</li> <li>• *Publish a Study</li> <li>• *Add Sites</li> <li>• *Invite Users</li> </ul>
Data Specialist	<ul style="list-style-type: none"> <li>• Add, Remove, Restore, and Sign Participants</li> <li>• Schedule, View, Add, Remove, Restore, and Sign Events</li> <li>• View, Enter, Edit, Clear, Remove, and Restore Form Data</li> <li>• Add and Update Queries</li> <li>• Extract and Import Data</li> </ul>
Data Entry Person	<ul style="list-style-type: none"> <li>• Add and View Participants</li> <li>• Schedule, View, Add, Remove and Restore Events</li> <li>• View, Enter, Edit, Clear, Remove, and Restore Form Data</li> <li>• Add and Update Queries</li> <li>• Import Data</li> </ul>
Monitor	<ul style="list-style-type: none"> <li>• Add, Remove, and Restore Participants</li> <li>• View Events</li> <li>• View Form Data</li> <li>• Add, Update, and Close Queries</li> <li>• Verify and Unverify Forms</li> </ul>
Viewer	<ul style="list-style-type: none"> <li>• View Participants, Events and Form Data</li> </ul> <p>*Viewers have read-only access to Study Runner. They cannot enter or edit data, create queries, perform SDV, or run extracts.</p>

#### Site-Level User Roles:

User Role	Basic Permissions
-----------	-------------------

Data Manager	<ul style="list-style-type: none"> <li>• Add, Remove, Restore, and Reassign Participants</li> <li>• Schedule, View, Add, Remove, Restore, and Lock Events</li> <li>• View, Enter, Edit, Clear, Remove, and Restore Form Data</li> <li>• Add, Update, and Close Queries</li> <li>• Verify and Unverify Forms</li> <li>• Extract and Import Data</li> </ul>
Investigator	<ul style="list-style-type: none"> <li>• Add, View, Remove, Restore, and Sign Participants</li> <li>• View, Add, Remove, Restore, and Sign Events</li> <li>• View, Enter, Edit, Remove, and Restore Form Data</li> <li>• Add and Update Queries</li> <li>• Extract and Import Data</li> </ul>
Clinical Research Coordinator	<ul style="list-style-type: none"> <li>• Add and View Participants</li> <li>• View, Add, Remove, and Restore Events</li> <li>• View, Enter, Edit, Clear, Remove, and Restore Form Data</li> <li>• Add and Update Queries</li> <li>• Import Data</li> </ul>
Monitor	<ul style="list-style-type: none"> <li>• View Participants</li> <li>• View Events</li> <li>• View Form Data</li> <li>• Add, Update, and Close Queries</li> <li>• Verify and Unverify Forms</li> <li>• Extract Data</li> </ul>
Viewer	<ul style="list-style-type: none"> <li>• View Participants, Events and Form Data</li> </ul> <p>*Viewers have read-only access to Study Runner. They cannot enter or edit data, create queries, perform SDV, or run extracts.</p>

**Note:** Site-level users can only see Participants at the sites they have been assigned to and cannot see study-level Participants.

## To Access the User Roles screen:

From the **My Studies** screen, click the **Settings** icon on the Study Card, then select **User Roles**.

Settings

User Roles

Modules

User Roles

Create

Role	Description	Access	Actions
Clinical Research Coordinator (Clinical Research Coordinator - SITE)	Site-level role with permission to create, view, edit, and remove records; add and update queries; import data.	<div>Untagged Forms</div>	<div>Edit</div>
Data Entry Person (Data Entry Person - STUDY)	Study-level role with permission to create, view, edit, and remove records; add and update queries; import data.	<div>Untagged Forms</div>	<div>Edit</div>
Data Manager (Data Manager - STUDY)	Study-level role with permission to configure the study, add sites, and invite users; create, view, edit, remove, and SDV records; add, update, and close queries; import and extract data.	<div>Untagged Forms</div> <div>Manage Study</div>	<div>Edit</div>
Data Specialist (Data Specialist - STUDY)	Study-level role with permission to create, view, edit, remove, and sign records; add and update queries; import and extract data.	<div>Untagged Forms</div>	<div>Edit</div>
Investigator (Investigator - SITE)	Site-level role with permission to create, view, edit, remove, and sign records; add and update queries; import and extract data.	<div>Untagged Forms</div>	<div>Edit</div>
Site Data Manager (Data Manager - SITE)	Site-level role with permission to create, view, edit, remove, and SDV records; add, update, and close queries; import and extract data.	<div>Untagged Forms</div>	<div>Edit</div>
Site Monitor (Monitor - SITE)	Site-level role with permission to view and SDV records; add, update, and close queries; extract data.	<div>Untagged Forms</div>	<div>Edit</div>
Site Viewer (Viewer - SITE)	Site-level role with permission to view records; no permission to modify data, add or update queries, or extract data.	<div>Untagged Forms</div>	<div>Edit</div>
Study Monitor (Monitor - STUDY)	Study-level role with permission to view and SDV records; add, update, and close queries; extract data.	<div>Untagged Forms</div>	<div>Edit</div>
Study Viewer (Viewer - STUDY)	Study-level role with permission to view records; no permission to modify data, add or update queries, or extract data.	<div>Untagged Forms</div>	<div>Edit</div>

The **Access** column displays Permission Tags (white background) and General Permissions (green background). This can be updated when creating or editing a user role.

## To Create a New User Role:

1. On the **User Roles** screen, click the **Create** button.
2. The **Create New Role** window appears. Enter information in each field:
  1. Name the **User Role**.
  2. Select a standard **User Role** to base the new **User Role** on. (The base **User Role** provides core permissions of the custom **User Role**.)
  3. Enter a description for the **User Role**. (The default **User Role** description appears to the right/below the **User Role** in the **Based On** field.)
  4. Assign [Permission Tags](#).
3. Click the **Save** button.

Create New Role

Name \*

New Specialist Role

Based On \*

Data Specialist

Description \*

New role based off of Data Specialist role.

Form Permission Tags

Access

Admins	<input type="checkbox"/>
Untagged Forms	<input checked="" type="checkbox"/>

Cancel

Save

**Note:** When a **User Role** is saved, it becomes available to users in both **Test** and **Production** environments for the current study.

## To Edit a User Role:

1. On the **User Roles** screen, click the **Edit** button to the right of the role you want to edit. The **Edit Role** screen appears.
2. Edit information in one or more of the following fields:
  1. **Name**
  2. **Based On**
  3. **Description**
  4. [Permission Tags](#)
  5. General Permissions (when applicable)
3. Click the **Save** button.

×

Edit Role

Name \*

Data Manager

Based On \*

Data Manager

Description \*

Study-level role with permission to configure the study, add sites, and invite users; create, view, edit, remove, and SDV records; add, update, and close queries; import and extract data.

Form Permission Tags ↕

Admins

Untagged Forms

Access

☐

☒

General Permissions

Manage Study

Access

☒

Cancel

Save

## General Permissions

General Permissions is a section that allows you to customize the permissions for a user role. This section varies by role and only appears for some roles. For example, when selecting *"Data Manager"* in the **Based On** field, the General Permissions section is available and shows the **Manage Study** permission. General Permissions can be selected or deselected as needed to grant or restrict access to OpenClinica features for the role being configured. The **Manage Study** permission will be available for all user roles that are "based on Data Manager" and can be configured from the Edit Role window within the User Roles page. If checked, this permission will grant access to Study Manager and Study Designer. All roles based on Data Manager will have this permission enabled by default.

## Keep the Following in Mind:

- **User Roles** are defined per study.
- Custom **User Roles** have the same access as the **User Roles** they were based on.
- Changes to **User Roles** take effect upon saving and it is not necessary to re-publish the study.
  - Changes to roles assigned to users, user role definitions, and permission tags assigned to user roles take effect for users based on whether they are logged in at the time of the change.
  - For users who are not logged in at the time of the change, they will see the changes at

- their next login.
- For users who are logged in at the time the change was made, the change will be active in their session when they do any of the following:
    - Click the Go button from Study Designer
    - Access the Change Study page in Study Runner
    - Navigate to any other Study Runner page (may not take effect for up to five minutes from when the change was saved)
    - Log Out and Log In
  - If you want a user to have access in one environment but not another, you must use a different **User Role** in each environment. For example, the **User Roles** might be **Clinical Research Coordinator 1** in **Test** and **Clinical Research Coordinator 2** in **Production**. In this case, **Clinical Research Coordinator 1** in **Test** might have access to a Form, but **Clinical Research Coordinator 2** in **Production** might not have access to that Form (based on the permission tags assigned to it).

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## 5.2.1 Using the Share Screen

**Share** screen features allow you to add sites and invite users to access your study.

You can access the **Share** screen from either the **My Studies** screen, **Study Designer**, or the **Settings** screen.

The **Share** button is on the bottom of the study card on the **My Studies** screen. Select **Test** or **Production** to share your study.

# New Cancer Drug

AVAILABLE in test

⊘

UNPUBLISHED in production

This study tests a newly developed drug that is intended to shrink malignant tumors.

Study ID: NewCancerDrug  
Study Type: Interventional, Phase I  
Expected Enrollment: 100  
Expected Duration: 26-Aug-2019 to 30-Aug-2020

⚙️

Design

Share

Go

The **Share** button is also in the header bar in **Study Designer**. Select **Test** or **Production** to share your study.

OpenClinica

Status: Not yet published to Production Environment | Return To My Studies

sjones

New Cancer Drug (NewCancerDrug)

Form Template

Table Design

⌵

🔍

✉️

⚙️

Share

Publish

Go

Screening Visit

VS Screening

Eligibility

C-DASH

Demographics

Contact Info

+ Add a form

Baseline Visit

+ Add a form

Adverse Event

Adverse Event

+ Add a form

+ Add an event

Production

Test



# 5.2.2 Adding Sites

Before you invite users to your study, add at least one site. This applies even if your study is only collecting data from a single site.

## To Add a Site:

1. On the **Share** screen, scroll down to **Sites**, and click the **Add** button.

Sites												Add
Name	ID	Lead Investigator	IRB Approval Date	Expected Start Date	Expected Number of Participants	Site Location	Time Zone	Primary Contact	Created (UTC)	Updated (UTC)	Status	Actions
MGH	123	doctor@openclinica.com	08-Apr-2024	29-Apr-2024	300	Boston, MA	US/Eastern		23-Feb-2024 19:15	15-Apr-2024 19:03	Available	Edit

2. On the **Add Site** screen, begin to type the site name.
  1. If the site already exists in another environment, select that site from the list. Fields are prefilled with site information.
  2. If you need to make a new site, type the name of the site, and enter information in the appropriate fields.
    - i. Although the *Expected Number of Participants* field is required, this will not limit the number of participants at the site. Limiting the number of participants can only be done at the Study level. View the [Create a Study](#) page for detail on limiting participants in a study.

**Note:** Sites are global, meaning if you use a site in **Study A** you don't need to recreate that site for **Study B**. When adding an existing site to a study, values appear in the **Site Name**, **Time Zone**, **City**, **State/Province**, **Zip**, and **Country** fields automatically.

3. Click the **Save** button.

Add site to your study (TEST Environment)

Site Name \*

Site ID \*

Lead Investigator \*

IRB Approval Date

DD-MMM-YYYY

Expected Start Date

DD-MMM-YYYY

Expected Number of Participants \*

Status \*

Site Location

Time Zone \*

Choose...

Time zones are displayed as: Region/Major City (Offset from UTC)  
Type to search for a time zone

City

State/Province

Zip

Country

Type to search...

Primary Contact Info

Name

Phone

Email

Cancel
Save

Within Study Runner, additional site specific CRF settings can be configured on the **Site Details** page after publishing.

1. Select **Sites** within the **Tasks** menu.
2. Click the **Edit** pencil icon within the **Actions** column for the Site.
3. Select the **Event** to edit. From here, you can edit the the CRF settings for the site including the SDV requirement, Default Version, and Form Submission URL (if using Participate Public URL).

## 5.2.3 Inviting Users

### To Invite a User:

1. Click the **Share** button under the Study Card of your study on the **My Studies** screen or in the header of the **Settings** screen or **Study Designer**.
2. Select your study environment (**Test** or **Production**).
3. Under the **People** header, on the right, click the **Invite** button.
4. Begin typing, and click **Invite a new user**, or select an existing user from the drop-down list.
  1. If you select **Invite a new user**, the **Add User** screen appears, and you can enter values for each field. Then click the **Create User** button.

## Add User

Username \*

First Name \*

Last Name \*

Phone \*

E-mail \*

Organization \*

User Type \*

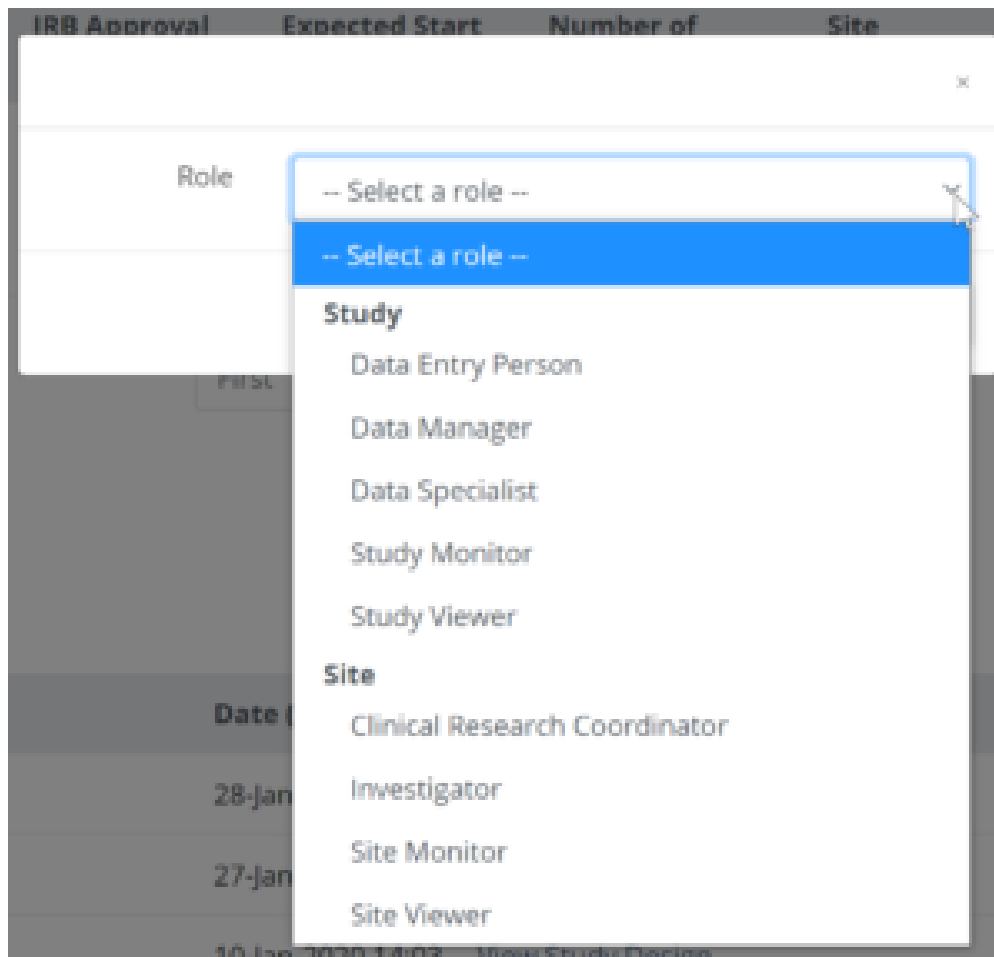
Back

Create User

2. If you select an existing user from the drop-down list, the system sends a new email invitation.

**Note:** The username and email of each user in the system must be unique.

4. When prompted, select a role for the user from the list of available roles:



**Note:** To provide access to another site, for example for a Monitor who is responsible for monitoring two sites, click in the **Site** box again and select additional site(s) as needed.

- When finished granting the appropriate access, click **Invite**. An email is sent to the user, and they are listed in the **People** table on the **Share** screen.

### Before a User can Access a Study, They Must Create a Password that Meets the Following Criteria:

- Must be at least **8** characters in length
- Must contain at least one of each of the following types of characters:
  - Lower case letters (**a-z**)
  - Upper case letters (**A-Z**)
  - Numbers (**0-9**)
  - Special characters (**!@#\$%^&\***)

## 5.2.4 Publish History

The **Share** screen tracks the publication history for each environment (**Test** and **Production**). Scroll to the bottom of the **Share** screen to see the publication history.

### To View a Previously Published Version of the Study:

Click the **View Study Design** link to the right of the version you'd like to view.

## Publish History

Revision	User	Date (UTC)	
10	Kerry Tamm	28-Jan-2020 16:18	<a href="#">View Study Design</a>
9	Kerry Tamm	27-Jan-2020 17:29	<a href="#">View Study Design</a>
8	Kerry Tamm	16-Jan-2020 14:03	<a href="#">View Study Design</a>
7	Kerry Tamm	16-Jan-2020 13:57	<a href="#">View Study Design</a>
6	Kerry Tamm	08-Jan-2020 17:10	<a href="#">View Study Design</a>
5	Kerry Tamm	08-Jan-2020 17:03	<a href="#">View Study Design</a>
4	Kerry Tamm	29-Aug-2019 15:06	<a href="#">View Study Design</a>
3	Kerry Tamm	27-Aug-2019 19:20	<a href="#">View Study Design</a>
2	Kerry Tamm	27-Aug-2019 18:41	<a href="#">View Study Design</a>
1	Kerry Tamm	27-Aug-2019 13:39	<a href="#">View Study Design</a>

A read-only version of the previously published study design displays:

The screenshot shows the OpenClinics interface for a study titled "New Cancer Drug (NTPNewCancerDrug)". The header indicates the status is "Not yet published to Production Environment" and provides a link to "Return to My Studies". The main content area displays a read-only version of Revision 10, published on 28-Jan-2020 11:18. The interface is divided into several sections: Screening Visit, Baseline Visit, Checkup, and Adverse Events. Each section contains various form elements like checkboxes and text boxes. On the right side, there is a sidebar with options for Members, Permission Tags, Labels, Filter Activity, and a list of recent activities, including published and edited versions of the study design.

Though no changes can be made to this version of the study, you can:

- View form and event settings
- Download form versions,
- Preview forms

etc. The header clearly indicates this is a read-only version, and includes a link to quickly access the current version of the study, which is fully editable. **Note:** Some Form attributes (checklists, tags, and labels) show the values that they have in the current design, regardless of their state in the previously published version. In the **Test** environment, if a Form version was overwritten after a previous publication, only the newest version of that Form is available for preview and download. This is not a concern in the **Production** environment, since Form versions cannot be overwritten.

## 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 dialog titled "Study Properties" open over the "Study Settings" page. The background page shows a table of study settings for "The Migraine Study (Migraine)". The "Study Properties" dialog contains the following fields:

- 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 right of the dialog are "Cancel" and "Save" buttons.

### 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 \*

[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']}`

<b>Optional</b> Unique site ID for the current site where the Participant is being added.	<b>Optional</b> A static dash (-) character. Can be replaced by different character(s) or removed.	<b>Required</b> 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).	<b>Optional</b> 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.
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## 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**.

## 5.2.6 Using Multifactor Authentication

You can enable multi-factor authentication (MFA) for your OpenClinica domain with an API or contact the **OpenClinica Customer Service** team.

When you enable multi-factor authentication, users are prompted to:

1. Download either the **FreeOTP** app or the **Google Authenticator** app to your smartphone.
2. Scan a barcode.
3. Enter the access code from their device.

### Initial User Sign-up:

**You are required to set-up multi-factor authentication.**

This extra security measure keeps your account safe if someone discovers your username and password. To get started, please follow the steps below. Then, each time you log in you will need to access the authentication app and enter the code it displays.

**Step 1:** Install one of the following applications on your mobile device:


- Google Authenticator (recommended) - ([Android](#) - [iOS](#))
- FreeOTP - ([Android](#) - [iOS](#))

**Step 2:** Open the application and scan the barcode:



[Unable to scan?](#)

**Step 3:** Enter the one-time code provided by the application in the box below and click Log In to finish the setup.



LOG IN >

### Subsequent Logins:



Use your mobile device to open the authentication app that you previously configured to access this site and enter the code it displays.



One-time code

CANCEL

LOG IN >

**Note:** Once you have enabled multi-factor authentication, you no longer need to scan a barcode. Only username, password, and an access code are required to sign in. The barcode should be treated as your password and should not be shared with anyone (including via screenshare).

### If This Feature is Enabled:

- All Study and Site Users are required to login with username, password, and an additional code.
- **Data Specialists** and **Investigators** will still sign participant records with only their username and password.
- Participant users logging into **Participate** are still only required to enter access codes.
- You cannot enable multi-factor authentication for a specific study, site, or user. It must be enabled per OpenClinica domain.

### Additional Information:

#### **There is no link between a user's authenticator app/device and the authentication server:**

Authenticator apps do not communicate with a server in any capacity. If a user deletes an MFA entry in their app, the server is not informed in any way and the user will still be expected to enter their One Time Password (OTP) upon login.

**Troubleshoot syncing the device clock to the server time:** We suggest the user compare their MFA device time to something official (e.g. <https://www.time.gov/>) - ensure that the users understand that MFA is sensitive down to the second. Some mobile devices fetch the time from their local Wi-Fi device and may be inaccurate.

**If a user loses their MFA device or authenticator entries:** they will have to make a request to the support team to reset their MFA credentials, which will prompt them to re-configure MFA and give them a new QR code to scan.

**Note:** Our current implementation of MFA/OTP requires a second device such as a phone or tablet running iOS or Android and using one of the apps listed above.