OpenClinica 4: New Features

Scheduled for September 13, 2018 Release

New for Site Users

Adding a Participant

Data Managers have the option to set up studies to auto-generate the Participant ID. If your study was set up with this new feature, the Add Participant page appears as follows:
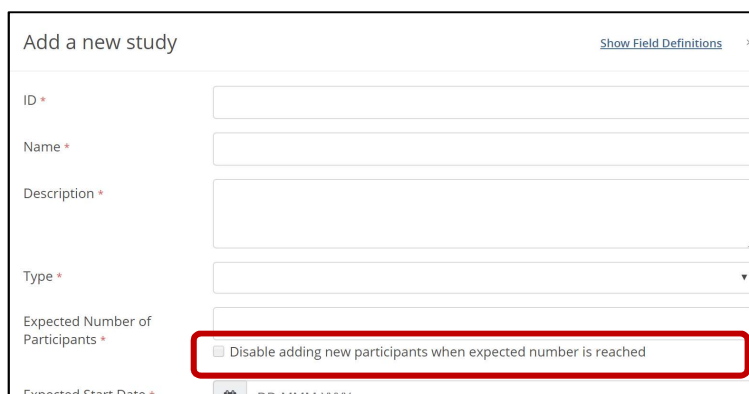

Simply click **Add** and the Participant ID is automatically generated for you.

New for Data Managers

Participant Limit

In addition to specifying the expected number of Participants, Data Managers can restrict users from adding participants once that limit for the study is reached - just check the **Disable adding new participants when expected number is reached** box when you add a new study. Data Managers can modify study settings at any time by editing the study settings.

Participant ID Settings

The Study Settings tab now includes options for generating the Participant ID. The IDs can be set to be entered manually or to be system generated. If they're system generated, Data Managers can customize the format of the ID based on an ID template. Go to **Share→Test→Settings→Participant ID Settings→**Edit to define how the ID is entered and, if system-generated, to specify the format of the ID. A standard template is provided, but it can be modified.

If you choose System-generated, you must specify the template for the system-generated ID. The standard template that is provided breaks down as follows:

$${siteId}-${siteParticipantCount+1)?string["000"]}$$

Required	A static – (dash) character. This can be modified or removed.	Required	Indicates the minimum length for the Participant count results. If there are fewer than three characters in the ID, leading 0s are added. The number of 0s can be modified by adding or removing 0s as needed to meet your minimum Participant ID length requirements.
Unique Site ID for the current site where the Participant is being added.		Adds 1 to the current count of Participants for the current Site. **This number can be modified to change the starting ID number.** e.g., +100 would generate 101, 102, 103, etc.	

Assuming there is a study with three sites: AAA, BBB, and CCC, using the above template the Participant IDs would be assigned as follows:

- When Site AAA adds Participants, the Participant IDs will be: AAA-001, AAA-002, AAA-003, etc.
- When Site BBB adds Participants, the Participant IDs will be: BBB-001, BBB-002, BBB-003, etc.
- When Site CCC adds Participants, the Participant IDs will be: CCC-001, CCC-002, CCC-003, etc.

Things to note about the template:

- ${siteId} and ${siteParticipantCount} are both required but can be in any order.
- The maximum length permitted is 255 characters.
- Static text can be added to any portion of the template, but slash and backslash are not allowed.
  For example:
      StudyXYZ:${siteID}-${siteParticipantCount+1}?string["000"]}
  would generate the following Participant ID for site AAA:
      StudyXYZ:AAA-001
- The increment number can be changed as needed.
  For example:
      ${siteID}-${siteParticipantCount**+100**}?string["000"]}
  would generate the following Participant IDs for site AAA:
      AAA-101
      AAA-102
      AAA-103
      etc.
- The minimum length can be modified as needed.
  For example:
      ${siteID}-${siteParticipantCount+1}?string["**0000**"]}
  would generate the following Participant IDs for site AAA:
      AAA-0001
      AAA-0002
      …
      AAA-1000
      …
      AAA-9999
      AAA-10000
  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 (e.g., length>255 characters or invalid characters (slash or backslash) were used), the system uses a default template of ${siteOID} followed by a dash and a six-digit random number.

## Configurable Roles and Permissions

Data Managers can define and assign "tags" to forms when designing a study. These tags can then be assigned to roles in the Share/User Roles tab. This allows you to restrict access to forms for specific roles. This process involves three steps:

1. **Design**: Define the tags and assign them to forms (limit of one tag per form)
2. **Share**: Edit User Role(s) as needed to allow access to tagged forms as needed
3. **Go**: Subject Details, Extracts, SDV, Queries, and the Audit Log are all filtered to only show you data for forms that you have been granted permission to see.
   a. For example, if you only have access to see the Labs form, then that is the only form that will be available to you.
      i. Though you can still "select all items in the study" during extract, the results will only include the Lab form data.
      ii. If there are queries on Labs, Vital Signs, and Demographics, you will only see queries associated with Labs.
      iii. If you try to view or edit a form OTHER than the Lab form, a message displays that indicates you don't have access to that form.
      iv. If you view the Audit Log for a participant, you will see the details for the Lab form. Though you will see rows that indicate activity in other forms, the data values display as **<Masked>**.

Let's step through the process of assigning the Labs tag to a form in Design, and then we'll assign that tag to users. As part of that process, we'll also define a new user role of "Lab Reviewer."

Design:

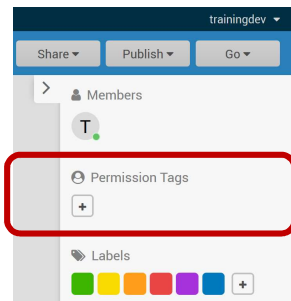1. Assign a "Lab" tag and attach that tag to the Lab form.
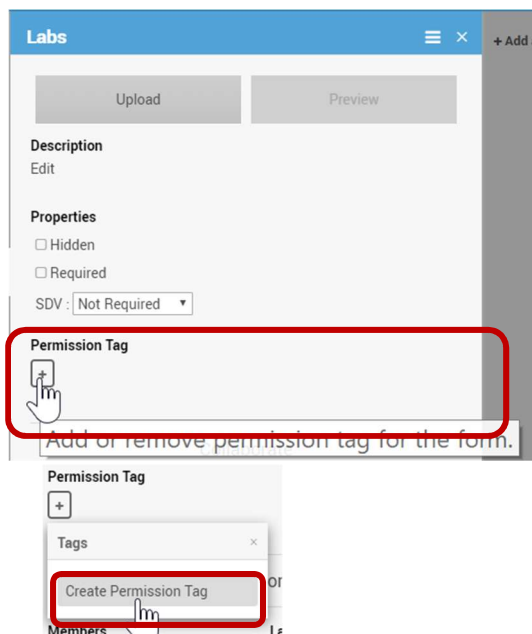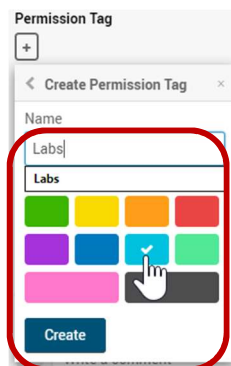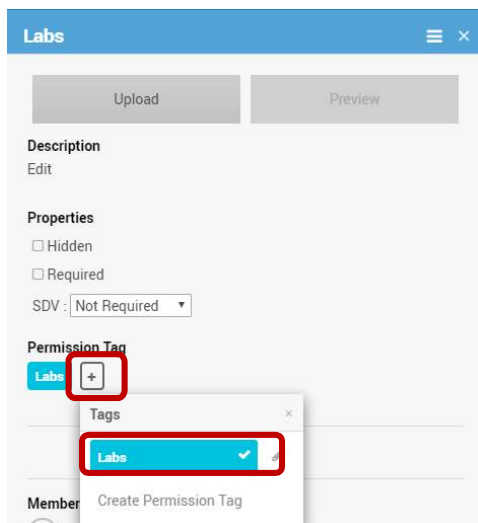
Optionally, Tags can be built outside of forms using the Permission Tags section of the Members panel on the right of the Design page:

a. Provide a Name for the tag, select a color, and click **Create**:

b. For any given form, add the permission tag. To continue our example, we'll add the Labs tag to the Labs form:

Once assigned, the form card includes an icon that indicates a tag has been assigned:

Once created, a tag can be attached to as many forms as needed, though only one tag can be assigned per form.

If you add a tag to a form, then copy that form to another event, the tag is copied along with the form, but can be removed from a specific event, if necessary.

Share:

1. To assign access to tagged forms to specific user roles, or to customize user roles, go to
Share→Test→User Roles
Though we specify the Test environment here, all Settings and User Role specifications apply to Test and Production environments.

The standard seven user roles are listed; each role has access to all untagged forms, no access to tagged forms, and can be edited to give specific access to tags (all users will have access to untagged forms).

2. To edit role access to tagged forms, click **Edit** for the role you want to change:

The Edit Role page displays:

Rename the role if you want.	
The default role description displays to the right of the source role.	
Edit the Description as needed.	
Check the box to provide access to Labs. All users will have access to untagged forms. If you want a user to ONLY have access to Labs, add a different tag to all the other forms and don't grant access to that tag to the "labs only" user.	

Data Managers also have the option of creating an entirely new Role.

On the **User Roles** tab, click **Create**:

The Create New Role form displays:

Create New Role	✕
Role *	[ ]	Name the role.
Based On *	-- Select a role -- ▼	Select the standard role on which the new role is based.
Description *	[ ]	Provide a description for the new role.

Permission Tag ⬦	Access
Labs	☐
Untagged Forms	☑

Select the appropriate tags. *All users have access to Untagged Forms.*

Cancel Save

Save the new role. *This role is now available to assign to users in the Test AND Production environments for this study.*

Things to note about roles:

- Roles are defined per study
- By default, adding a Tag to a form REMOVES access to that form for all users; you must edit the User Roles and check the **Allow** box to grant access to those forms for each role
- If you want a user to have access to a form in Test, but not in Production, define two roles and assign them the appropriate role in each environment
- Changes to Roles take effect immediately – there is no need to re-publish the study
- Current access is either granted or denied. There is a plan to add specific, granular access to roles (read, write, etc.) in the future.

Web Services

Web services have been added to allow the following:

- Get a list of Study Participant IDs
  - This list is available for the overall Study or on a site-specific basis
- Add a Participant
  - You can add a Participant via Web Services by entering the Participant ID
- Add Participants in bulk
  - Participants can be added in bulk at the Study or Site level using a CSV file of unique Participant IDs

These are available to Administrators only. From the user menu, select **Administration**, then **Web Services Information**. This opens a new tab that provides documentation and allows you to call Web Services from within the documentation.