

8.1 Activate and Build OpenClinica Participate for your Study

To activate OpenClinica Participate and build a Study for use by Participants:

1. Once the [Study is created](#), select **Tasks > Build Study**.
2. In the **Modules** section of the Build Study window, note that the Status for the Participate Module is set to Disabled.

Modules	Status	URL	Actions
Participate	Disabled		+

3. To request access to OpenClinica Participate for the Study, in the **Modules** section, [+](#) click .

The following window displays:

Please enter your preferred subdomain below: ?

https:// .mystudy.me

https://exampleurl.mystudy.me

[Request Access](#) [Cancel](#)

4. Enter your preferred subdomain for the Participate Study.

A subdomain is part of a web address (URL) and is required to create a web address for your Study.

OpenClinica provides the secure access (https://) and .mystudy.me domain portions of the URL, but

you must provide a unique subdomain name for accessing this particular Study. For example, for the

JUNO diabetes study, we entered the subdomain JUNO, for a complete web address of https://JUNO.mystudy.me.

5. Once you have provided a unique subdomain, click **Request Access**.

The Build Study page displays, and the status for Participate is set to Pending.

Modules	Status	URL	Actions
Participate	Pending	https://JUNO.mystudy.me	X

A request is sent to the team at OpenClinica. For your TEST environment, access will be granted unconditionally.

For your PRODUCTION environment, access will be granted once your OpenClinica Participate contract information has been verified.

Once approved, the status of the Participate module changes to Active as follows:

Modules	Status	URL	Actions
Participate	Active	https://JUNO.mystudy.me	

The Study is activated for OpenClinica Participate. To deactivate Participate for the Study, simply click in the Participate Actions column.

- Once your Study is activated, complete the Build Study tasks as described in [Build and Modify Study](#), with the following differences:
 - When creating CRFs, be sure to reference the popup help and instructions worksheet of the OpenClinica CRF Template for information regarding Participant forms. Information specific to Participate functionality is also summarized in the section of documentation called [OpenClinica Participate Forms](#).
 - When creating Rules, it is useful to include a NotificationAction rule to remind Participants of upcoming forms that are due. For information on NotificationAction rules, see [Rule Actions](#) and scroll down to the NotificationAction topic.
 - When creating the Event Definitions, for any form that you would like a Participant to complete, just check the **Participant Form** box.

Note: To provide access to Participants, each Participant must be enrolled and have at least one Event scheduled that includes at least one Participant form. For more information on these tasks, see [Add Subject](#) and [Connect Participants](#).

CRFs

Add a New CRF

DEMOG

☒ Required:
 ☐ Double Data Entry:
 ☐ Password Required:
 Default Version: 1

☐ Hide CRF:
 Source Data Verification:

☐ Participant Form:

Null Values:

<input type="checkbox"/> NI	<input type="checkbox"/> NA	<input type="checkbox"/> UNK	<input type="checkbox"/> NASK
<input type="checkbox"/> ASKU	<input type="checkbox"/> NAV	<input type="checkbox"/> OTH	<input type="checkbox"/> PINF
<input type="checkbox"/> NINF	<input type="checkbox"/> MSK	<input type="checkbox"/> NP	<input type="checkbox"/> NPE

Eating Habits Questionnaire

☒ Required:
 ☐ Double Data Entry:
 ☐ Password Required:
 Default Version: V1.2

☐ Hide CRF:
 Source Data Verification:

☒ Participant Form:
 ☐ Allow Anonymous Submission:

Null Values:

<input type="checkbox"/> NI	<input type="checkbox"/> NA	<input type="checkbox"/> UNK	<input type="checkbox"/> NASK
<input type="checkbox"/> ASKU	<input type="checkbox"/> NAV	<input type="checkbox"/> OTH	<input type="checkbox"/> PINF
<input type="checkbox"/> NINF	<input type="checkbox"/> MSK	<input type="checkbox"/> NP	<input type="checkbox"/> NPE

1. Allow Anonymous Submission

Starting with OpenClinica 3.7, you have the option of setting up a Study that allows anonymous submission of Participant Forms. This allows for broad-reaching, survey-based data collection. If you create a Study for survey-based data collection, the data that is submitted is captured anonymously and stored in the Study using OpenClinica-generated, unique "Subject" IDs. A Study should be created for EITHER a clinical trial that includes Subject-specific, informed consent-based data OR for a general survey that allows for information to be collected anonymously. It is not recommended that you mix anonymous submission Forms with Subject-specific data collection Forms.

To set up a Study Event Form for anonymous data collection:

1. Check the **Participant Form** checkbox.
The Allow Anonymous Submission checkbox displays.
2. Check the **Allow Anonymous Submission** checkbox.
The Submission URL field displays.
3. Provide a URL as follows:
 - The URL must be unique for the Study and cannot contain spaces.
 - You can optionally provide Site-level URL(s) by editing the Event definition for the Site(s)
 - Site-level URLs must be unique within the Study
 - If you do not specify a Site-level URL, the submission defaults to the Study URL and the data submitted is entered at the Study-level as opposed to the Site-level.
 - You can provide the URL to the general public (e.g., via advertisement) and people can access that URL to complete the Form(s) and submit their data anonymously.

Note: Removing an Event does not remove URL access. If an Event with an anonymous form is removed, you must also edit that Event CRF to remove the URL. To do this, view and edit the Event, locate the appropriate Form, and clear the "Participant Form" box.

Eating Habits Survey				X
Required: <input checked="" type="checkbox"/>	Double Data Entry: <input type="checkbox"/>	Password Required: <input type="checkbox"/>	Default Version: Version 1 ▾	
Hide CRF: <input type="checkbox"/>	Source Data Verification: Not Required ▾			
Participant Form: Allow Anonymous <input checked="" type="checkbox"/>		Submission URL: http://JusTrain.openclinica.info:8081/		
Submission: <input checked="" type="checkbox"/>		<input type="text" value="US_diet"/>		
Null Values:				
NI <input type="checkbox"/>	NA <input type="checkbox"/>	UNK <input type="checkbox"/>	NASK <input type="checkbox"/>	
ASKU <input type="checkbox"/>	NAV <input type="checkbox"/>	OTH <input type="checkbox"/>	PINF <input type="checkbox"/>	
NINF <input type="checkbox"/>	MSK <input type="checkbox"/>	NP <input type="checkbox"/>	NPE <input type="checkbox"/>	

- For studies that allow for anonymous submissions, a unique Subject identifier is created automatically for the submitter of the Form(s) and the Event is automatically scheduled when the Form is submitted.
- Starting in version 3.10 of OpenClinica, if the Event for the Anonymous Submission form is a repeating Event, you also have the option of designating the form as an offline form. Offline forms allow Participants to download the designated form(s) and then disconnect from the internet. The form(s) can be completed offline and then are automatically submitted to your OpenClinica study when an internet connection is established again. This option is currently only available for repeating Events.

Physical Activity Log			X
Required: <input checked="" type="checkbox"/>	Double Data Entry: <input type="checkbox"/>	Password Required: <input type="checkbox"/>	Default Version: 1 ▼
Hide CRF: <input type="checkbox"/>	Source Data Verification: Not Required ▼		
Participant Form: <input checked="" type="checkbox"/>	Allow Anonymous: <input type="checkbox"/>	Submission URL: http://juno.openclinica.info:8081/	
	Submission: <input checked="" type="checkbox"/>	Daily_Activity	
		Offline: <input checked="" type="checkbox"/>	
Null Values:			
NI <input type="checkbox"/>	NA <input type="checkbox"/>	UNK <input type="checkbox"/>	NASK <input type="checkbox"/>
ASKU <input type="checkbox"/>	NAV <input type="checkbox"/>	OTH <input type="checkbox"/>	PINF <input type="checkbox"/>
NINF <input type="checkbox"/>	MSK <input type="checkbox"/>	NP <input type="checkbox"/>	NPE <input type="checkbox"/>

- It is also possible to submit anonymous offline forms for Subject-specific data in your Study. This involves incorporating a reserved variable for Subject ID into your form. When submitted, OpenClinica stores the entered data with the specified Subject's record, or creates the Subject if the ID does not already exist. Please contact your OpenClinica support team for more information about how to implement this feature.
- Please note the following regarding the use of offline forms:
 - Data entered in offline mode is not encrypted when entered or stored. It is encrypted during transfer once an internet connection is re-established and the data is uploaded to OpenClinica.
 - There may have behavioral differences between browsers.
 - With the release of 3.10.1, the offline feature works on IOS devices. For example, an iPad can be used to capture form fields and images while offline as follows:
 - While online, open the form.
 - **Keep the form open** and go offline.
If you inadvertently close the form, you'll have to go online, open the form, and then go offline before continuing.
 - Enter data and/or add photos as appropriate for the form.
 - Submit the data.
 - The next time you go online, upload the submitted forms.
 - When users connect to an anonymous offline form, a screen similar to the following displays:

Eating Habits Questionnaire

Let's Go ➔

► Use Offline

► Save to homescreen

Powered by OpenClinica Participate™

- "Use Offline" and "Save to homescreen" can be expanded for more information on using offline forms.

▼ Use Offline

This form may be used offline. Click "Let's Go" to load the form at least once before you go offline. Your browser may prompt you to allow offline storage. You must ok this for offline use to function.

▼ Save to homescreen

After enabling offline use, you can access this form when you are not connected to the internet. To do so just return to this URL. You can bookmark it in your browser. On most mobile devices you can also save an icon to your homescreen.

For Safari : tap the **Share** button (the rectangle with an arrow pointing upward) on the browser's toolbar. It's on the bar at the top of the screen on an iPad, and on the bar at the bottom of the screen on an iPhone or iPod Touch. Tap the **Add to Home Screen** icon in the Share menu.

For Chrome : tap the **Menu** button and tap **Add to Home Screen**. You'll be able to enter a name for the shortcut and then Chrome will add it to your home screen.

Functional approval by Laura Keita. Signed on 2017-10-11 2:27PM

Approved for publication by Ben Baumann. Signed on 2017-10-11 2:34PM

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