







## 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. 
3. To request access to OpenClinica Participate for the Study, in the **Modules** section, click  
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.*  *A request is sent to the team at OpenClinica. Access will be granted once your OpenClinica Participate contract information has been verified. Once approved, the status of the Participate module changes to Active. To deactivate Participate for the Study, simply click  in the Participate Actions column.*
6. Once your Study is activated, complete the Build Study tasks as described in [Build and Modify Study](#), with the following differences:
  1. 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](#).
  2. 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.
  3. 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](#).
    1. **Allow Anonymous Submission** 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.
  - 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.
  - 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.
    - 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:
      - **NOTE:** Offline form support has been discontinued by current web browser distributors. This OpenClinica feature will only work for users using old computer browsers such as Internet Explorer 11 or old mobile versions of Chrome, Safari, or Firefox.
      - 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.
      - The offline feature works on IOS devices (subject to browser requirements above). 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: 
  - "Use Offline" and "Save to homescreen" can be expanded for more information on using offline forms.

Functional approval by Paul Bowen. Signed on 2024-07-02 1:40AM

Approved for publication by Malcolm Jackson. Signed on 2024-07-02 8:03AM

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