8 OpenClinica Participate

Welcome! Here you'll find some helpful information to get your Study Subjects ***really*** participating in your Study by allowing them to use their own internet-connected devices to provide data directly into OpenClinica Forms. This allows for more accurate and timely responses promoting a higher level of Subject compliance. It also means that clinic staff can spend more quality time with Study Participants, and less time on administration.

Starting with OpenClinica 3.7, you also have the option of setting up a Study that allows anonymous submission of Participant Forms. This allows for broad-reaching, survey-based data collection.

Here's a video that provides a very high-level, conceptual overview of OpenClinica Participate being used in a consent-based clinical trial:

With OpenClinica Participate, you have total control over when forms are available for each subject, and the data is captured in real time. This means there is no option for subjects to pre-fill or back-fill forms. The underlying audit trail offers objective evidence that the subjects completed the forms in the timeframe dictated by the protocol.

OpenClinica Participate (OCP) works with electronic case report forms (eCRFs) designed in OpenClinica. You can design the form once and use it in OpenClinica and/or Participate as needed. To accommodate OCP functionality, the following updates have been made to the OpenClinica Study Build process:

- The OpenClinica CRF Template has been updated with additional help text and more guided instructions.
- There is an additional option to identify Participant Forms when creating Study Event Definitions.
- There is an additional option for Participant Forms to allow for anonymous submission.
- There is an option on the Build Study page that allows you to request activating Participate for your Study.

For Studies collecting data for a clinical trial, Participants must be enrolled in OpenClinica with at least one Event scheduled that contains at least one Participate form. For Studies collecting general survey information, OpenClinica generates a unique identifier and populates an Event automatically when a Form is submitted.

To activate your Study for use with OCP or to find out more about Study build considerations, see the topics below.

As always, we appreciate your feedback and contributions.

cleaner data capture so study coordinators can spend more time with their study participants and potentially enjoy higher patient compliance. - See more at: http://social.eyeforpharma.com/digital/using-electronic-patient-reported-outcomes-epro-first-time-lessons-learned#sthash.rjjxm9qX.dpuf
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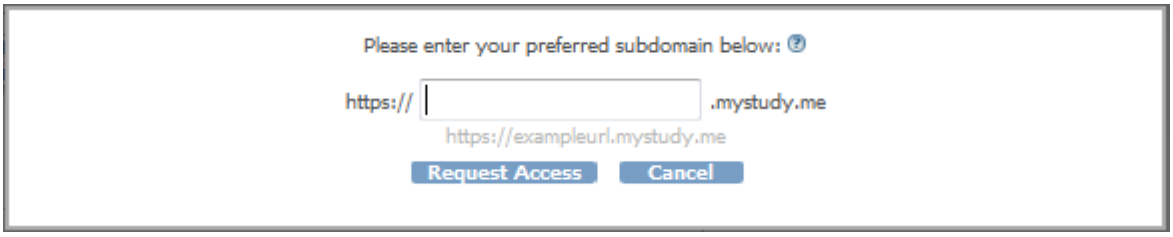
8.1 Activate and Build OpenClinica Participate for your Study

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:



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:

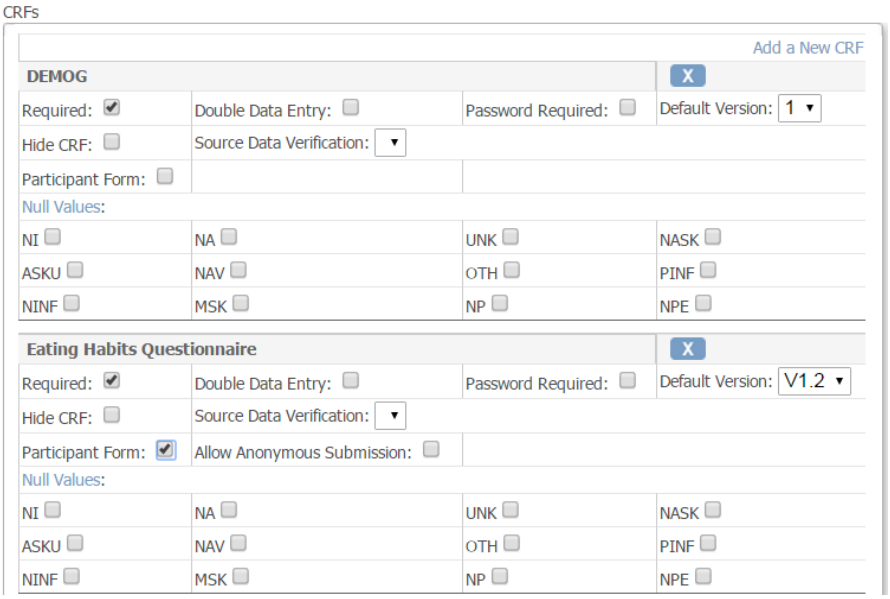
	Modules	Status	URL	Actions
	Participate	Active	https://JUNO.mystudy.me	X

   The Study is activated for OpenClinica Participate. To deactivate Participate for the Study, simply click X *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**
   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:

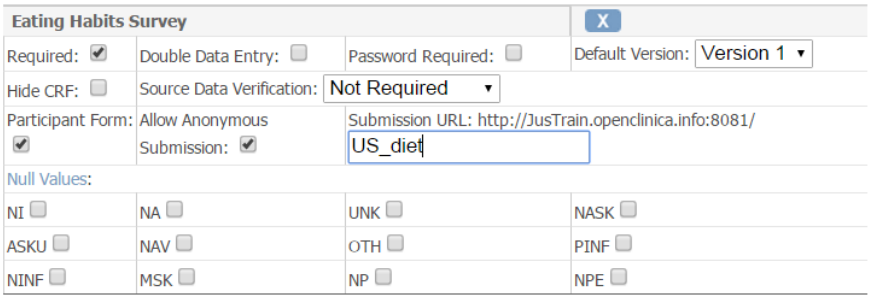
   1. Check the **Participant Form** checkbox.
      The Allow Anonymous Submission checkbox displays.

   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.

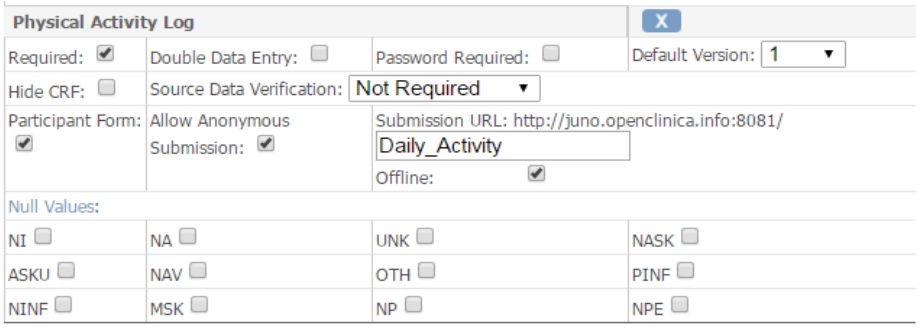
        Note: Removing an Event does not remove URL access. If an Event with an anonymous form is removed, you must also edit that Event

CRF to remove the URL. To do this, view and edit the Event, locate the appropriate Form, and clear the "Participant Form" box.



- 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.

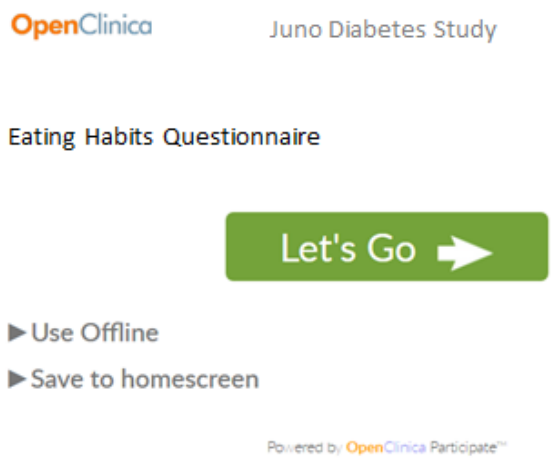
- Starting in version 3.10 of OpenClinica, if the Event for the Anonymous Submission form is a repeating Event, you also have the option of designating the form as an offline form. Offline forms allow Participants to download the designated form(s) and then disconnect from the internet. The form(s) can 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.



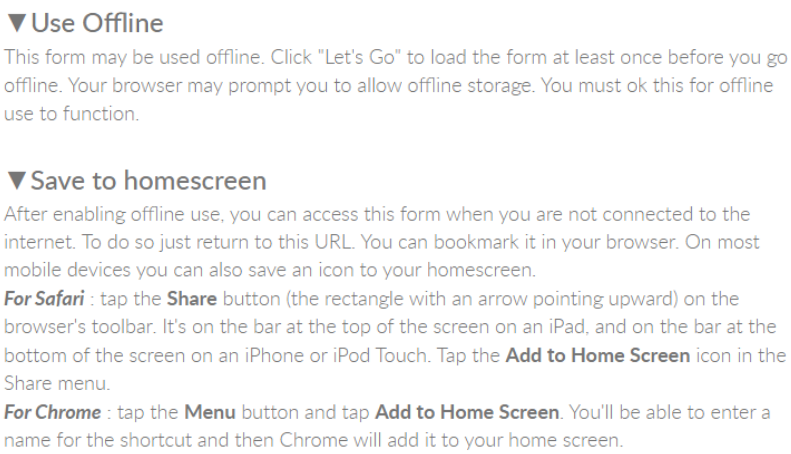
  - It is also possible to submit anonymous offline forms for Subject-specific data in your Study. This involves incorporating a reserved variable for Subject ID into your form. When submitted, OpenClinica stores the entered data with the specified Subject's record, or creates the Subject if the ID does 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:



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



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

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8.2 Configure a Study for OpenClinica Participate

When setting up an OpenClinica Study for use by study Participants, it can be helpful to keep in mind some form design considerations and best practice recommendations. Click the topics listed below for more information.

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8.2.1 OpenClinica Participate Forms

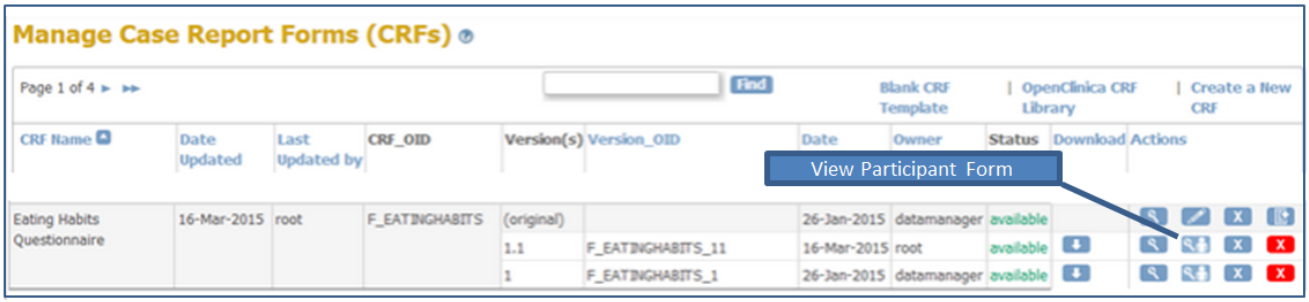
One of the advantages of OpenClinica Participate is that you can design your CRFs once then use them in either OpenClinica and/or Participate as needed. Any Study may comprise a combination of OpenClinica forms and Particpate forms to best fit the design and goals of your Study. Use the same CRF template and instructions for creating all of your forms, though there are minor differences in how Participate forms are displayed and function.

In particular, the following OpenClinica features function differently in Participate forms:

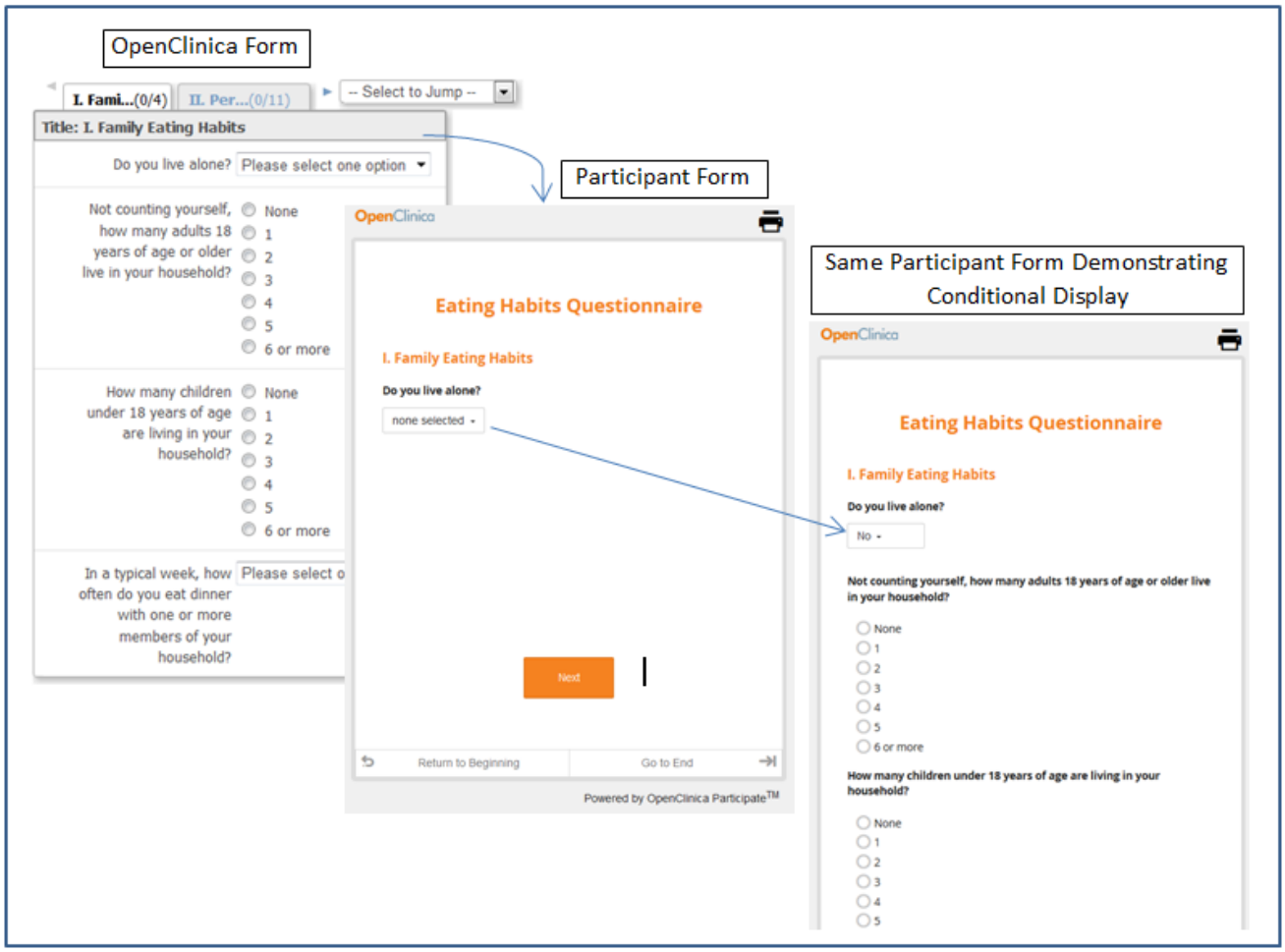
Template Worksheet	**Column Title**	**Participate Form Functionality**
CRF	CRF Version	Does not display in Participate forms.
Sections	Section label	Does not display in Participate forms.
Groups	Group Repeat Max	Cannot set a maximum number of repeats for Participate forms.
	Group Label	Does not display in Participate forms.
	Group Display Status	Has no effect in Participate forms.

Items	Units	Does not display in Participate forms, hence it is a good idea to write it in left item text itself (e.g Temperature (in F)) or collect units in a separate item.
	Right item text	Does not display in Participate forms.
	Column Number	Has no effect in Participate forms.
	Question number	Does not display in Participate forms.
	Response Type	Calculations and File do not work in Participate Forms.
	Response Layout	The layout of responses will automatically adjust on Participate forms based on the size of the data entry device being used (e.g., SmartPhone, Tablet, or Laptop).
	Default Value	Not supported in Participate forms.
	Data Type	Data type of REAL, PDATE, and FILE are not supported in Participate forms.
	Validation	Not supported in Participate forms; must use Rules to perform data validation checks. Regular expressions are not supported in Participate forms.
	Validation Error Message	Not supported in Participate forms.
	Simple Conditional Display	Not supported in Participate forms. Item Display Status can be used, but to conditionally show or hide an Item, write a Rule using a ShowAction or HideAction as needed.

From within OpenClinica, you can display a form as it will appear to Participants. Go to **Tasks > Monitor and Manage Data > CRFs** and click the **View Participant Form** icon :



The following image shows the same form represented in OpenClinica and in Participate, and illustrates the use of show/hide functionality on the Participate form.



Participant Form Customizations

OpenClinica can customize your Participant forms to display your organization's custom logo, to include a configurable VAS scale, or to allow Participants to upload images. Please contact your OpenClinica support team for information about custom forms.

8.2.2 Best Practices

Here are some recommended best practices for designing studies and forms that use OpenClinica Participate:

- Reference the tooltips and instruction worksheet of the CRF Template as you create your forms. Best practices, tips, and usage information are provided for each attribute on the template.
- Keep your forms at a length that is practical for a Participant to work with on a mobile device. OpenClinica does not save data locally on Participant devices, so shorter forms can help eliminate the potential for data loss.
- If you do not want a Participant to see forms for future Events on his/her device, schedule each Event just prior to when you want the form to be completed and connect the Participant prior to when you want them to complete the form. This way, only the forms relevant to the scheduled Event are displayed. If you schedule multiple Events in advance, all forms for all those Events are available to the Participant when the Participant is connected. Scheduling one event at a time eliminates the chance that a Participant completes a form prior to the expected completion date.

8.3 Connect Participants

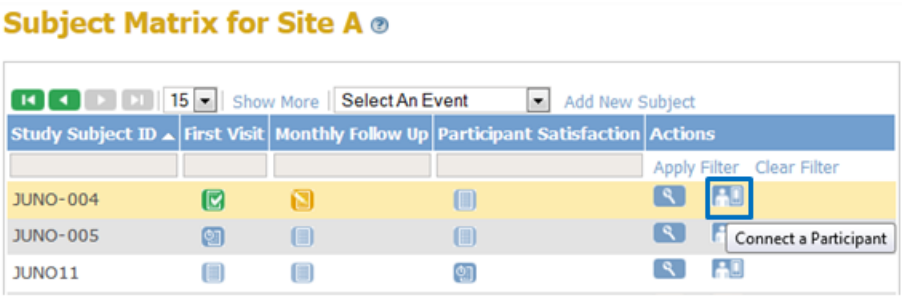
OpenClinica is used to enroll Participants, and to schedule Events that contain Participant forms. Then a user with a role of CRC or Data Entry Person can Connect each Participant to OpenClinica using the Study URL that was created when the Study was Built and Activated for Participate. Follow the steps below to Connect Participants.

To Connect a Participant

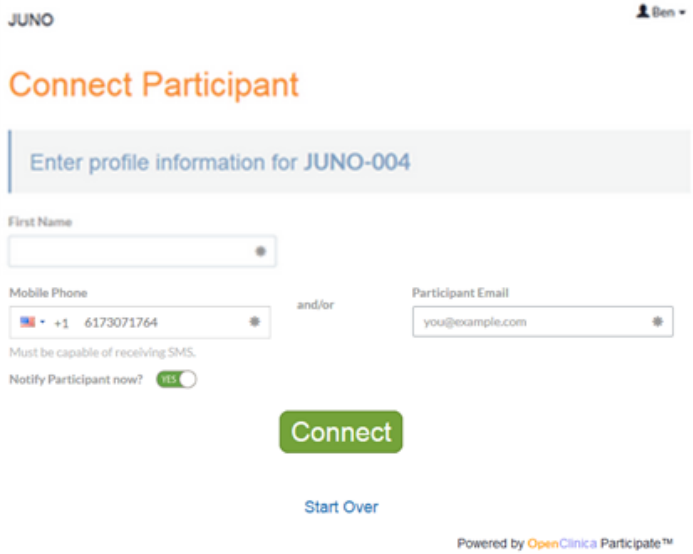
Once the Subject/Participant has been enrolled in OpenClinica and an Event with at least one Participate form has been scheduled for that Subject:

CRC or Data Entry Person:

1. In OpenClinica, on the menu bar at the top of the screen click **Subject Matrix**. Then, for the Subject you'd like to connect to Participate, in the **Actions** column, click the **Connect a Participant** icon.



The following window displays:



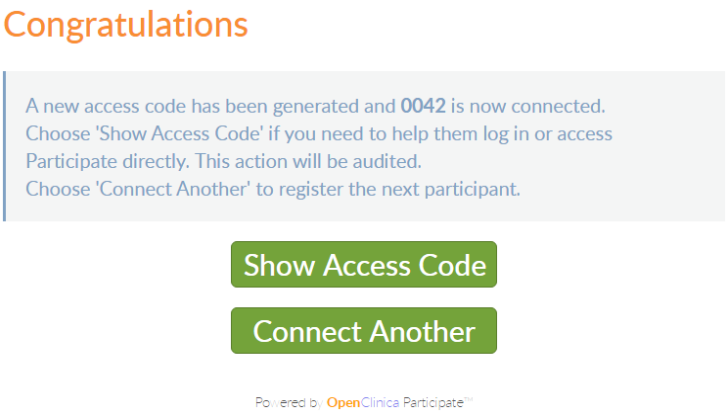
2. Type the Participant's first name, and then enter the Participant's mobile phone number and/or email address where s/he will receive a link to the Participate Form(s).

3. **Note**: To provide a mobile phone number:
   - Click the flag drop-down and select the appropriate country. Then type the phone number in the appropriate format for that country. If the country you need is not listed, please contact OpenClinica and submit a request to add a country.
   - You must enter a valid mobile telephone that can receive SMS text messages.

4. By default, the Participant will be notified by the means you indicated. If you prefer to notify the Participant by another means or at a later date/time, click the **Notify Participant now** button to turn off immediate, automatic notification.

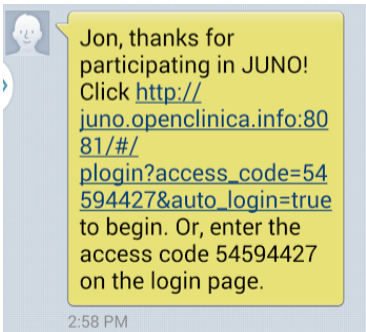
5. Click **Connect**.

   The following message displays.

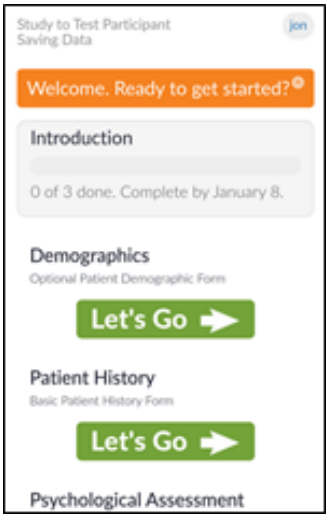


6. If you need to assist the Participant in logging in, or are using a shared, site-based device, click **Show Access Code** and present the Participant with the code. Note that the audit trail records the date/time that you viewed the code. Otherwise, continue with step 8, below.
7. To connect another Participant, click **Connect Another** and repeat the above steps.

   The Participant is Connected and, if "Notify Participant now" is set to "Yes," they will receive an SMS message on the mobile telephone number provided and/or an email message at the email address provided. The SMS message will be similar to the following, though each message has a unique link and unique access code. If there are any connection issues, connect the Participant again using the steps above. This will provide a new link and access code.



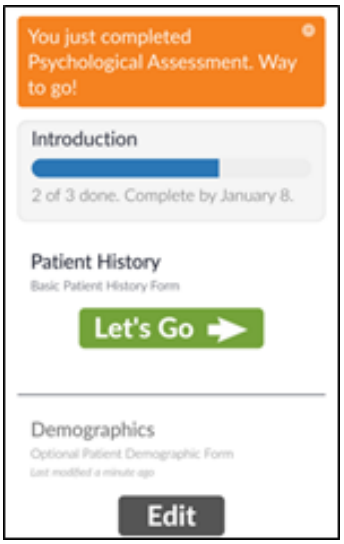
   The message includes a link to the Study URL.
   When the Participant clicks the link or logs in using the Access Code, OCP displays a list of forms that the Participant is scheduled to complete. OpenClinica also captures the Participant's local date-time so that Notifications will be sent at the appropriate time for the Participant, and so that Rules can be executed on a schedule based on the Participant's local date-time. For more information see Rules.

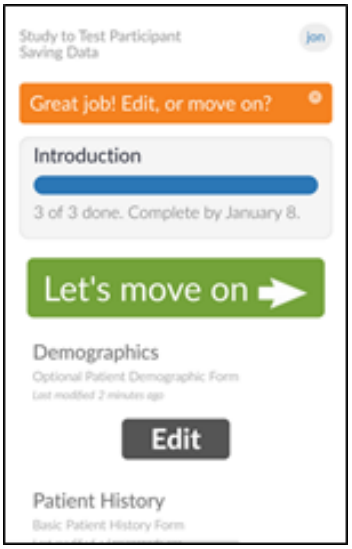


Note: *All forms that have been scheduled for the Participant are listed and available regardless of expected completion date.*

Once the Participant enters data in the form(s) and clicks Submit, the data is immediately available for review in OpenClinica.

When the Participant submits a form, the form moves to the bottom of the Participant's list of forms, and is available for editing. Once all forms for an Event have been completed, the Participant can continue to edit the form(s) or click "Let's Move On" to finalize the form(s) and complete the visit. Once the Participant has moved on, forms for that previous Event are no longer available for editing.





Encryption

A Participant's Personally Identifiable Information (PII) captured during the connect process (first name, email and/or mobile phone number) is stored in encrypted form in your OpenClinica database. Users with access to subject casebooks or audit trails may see encrypted text in the audit trail on those pages, however they will not be able to decrypt it. The information is only decrypted when used by Participate to send a message, display the dashboard, or update the information.

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8.4 What if a Participant Can't Connect?

OpenClinica Participate is designed to be easy-to-use and reliable for study participants. However, it is dependent on a few things like email, text messaging, and Internet access working correctly. Sometimes your participants may run into glitches. Here's a brief guide to help them.

"I never received the message!"

Activation and notification messages are sent as emails and/or text messages. Depending on the method, here are a few things that could correct problems or help the participant work around any issues.

Text Message:

- Confirm the participant's phone number is correct and that s/he is able to receive text messages at that number.
- Make sure the phone number is in the list of supported countries (available in the dropdown box on the connect participant page).
- Confirm there is a cellular signal.
- If you think you fixed the problem but the previously sent text message does not arrive, resend the activation message by reconnecting the participant. However, make sure to wait a few minutes first, since doing this will make the links in prior messages invalid (because doing so resets the activation code).
- If all of the above are correct but it still doesn't work, try connecting the participant via email or by using a different phone number.

Email:

- Confirm the participant's email is correct.
- Confirm that the participant's device/computer is connected to the Internet (i.e., able to receive emails).
- Have the participant check his/her Spam/Trash folder. Also, ask if emails from unknown senders are likely to be blocked (such as by a corporate firewall). If this is the case, have the participant contact the network administrator or try a different email address.
- If you think you fixed the problem but the previously sent email does not arrive, you can resend the activation email by reconnecting the participant. However, make sure to wait a few minutes first, since doing this will make the links in prior emails invalid (because it resets the activation code).
- If all of the above are okay but it still doesn't work, ask if s/he has another email address and try connecting via that.
- As a last resort, you can reconnect the participant using your own email or phone number as the contact info. Then provide the participant with the URL (e.g. https://[YOURSTUDY].mystudy.me/#/plogin) and the activation code directly. Make sure this is allowable within your study's data validation and privacy guidelines, and is noted as a process deviation. Change the contact info back to the participant's so you do not receive future

messages.

"I got a message but the link doesn't work!"

After receiving the activation message or a notification/reminder, the participant should be able to click on the link and access the participant dashboard. If there is a problem with this, try to find out more about what is happening:

- "*Clicking on the link in the text gives me a warning message*." Some phones will pop up a warning message when clicking on a link within a text message. The participant should simply tap 'OK' or 'Continue' and the dashboard should load normally.
- "*I get a 'Page not found' or 'Cannot connect' error.*" This usually means there is no connection to the internet. Participate requires an active internet connection to work. To confirm the connection is working, try loading another website (Google, Yahoo, CNN, etc.); if it does not load, the participant needs to fix the internet connection or try another device that is connected to the internet. In some cases, the network that the device is connected to may block unknown websites (especially if on a corporate network). If this is suspected, contact the network administrator to get the mystudy.me domain added to the whitelist, or try from another network.
- "*The link doesn't take me anywhere.*" Participate requires the use of a smartphone, tablet, or computer with a modern web browser. Non-smartphones will not work, nor will very old browsers. Try a different device.
- In rare cases, the participant may see a 'Loading' page that never loads anything. We're working on fixing this as soon as we can. In the meantime, have the participant try accessing the system from another browser or device.

"I got to the application but I can't do anything?"

The Participate dashboard displays the study name at the top, a notification/welcome message, and a set of activities (aka forms) to complete with big green "Let's go" buttons next to each. If the participant does not see these on the dashboard, it could be one of a few problems:

- If instead of the dashboard, the following message displays: "You have no forms to complete right now," then the participant's forms are up-to-date. S/he can come back a later time to complete any forms that have been scheduled. The study can be designed to automatically send a reminder message to inform participants of upcoming events or forms that are due.
- "The page is messed up/broken." The participant's device must be a smartphone, tablet, or computer with a modern web browser, and Javascript and cookies should be enabled. Non-smartphones will not work, nor will very old browsers. We recommend recent (released in the past 1-2 years) versions of Firefox, Chrome, and Safari.

If you cannot resolve the problem or for further help troubleshooting, please contact OpenClinica support.

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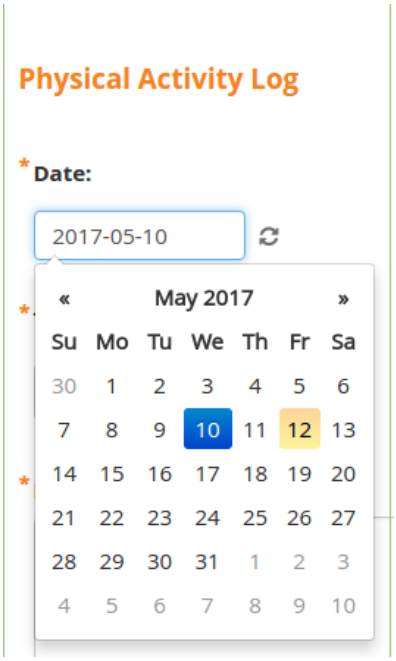
8.5 Date Pickers

Participate forms are built using responsive design, which means they automatically adjust and optimize their layout for the device and browser being used. This can include different date picker interfaces depending on the type of mobile device or PC you have and which browser you are using.

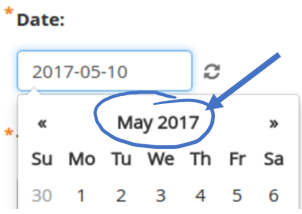
The most common date picker allows you to easily select a date in current or adjacent months.

To browse and choose an older date:

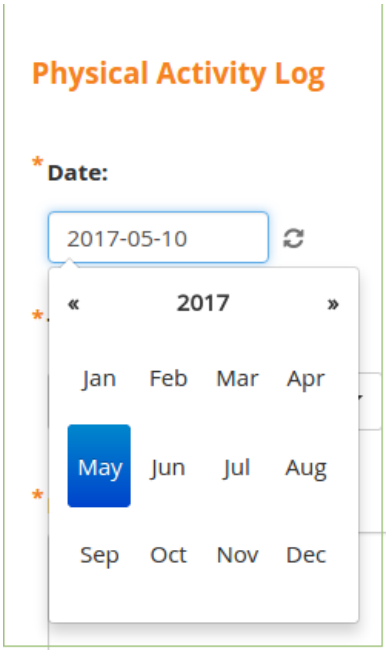
1. Press the date field to open the date picker:



2. To browse by month, press the month name at the top of the calendar:

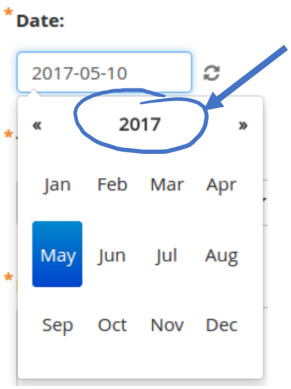


All months for the current year display:

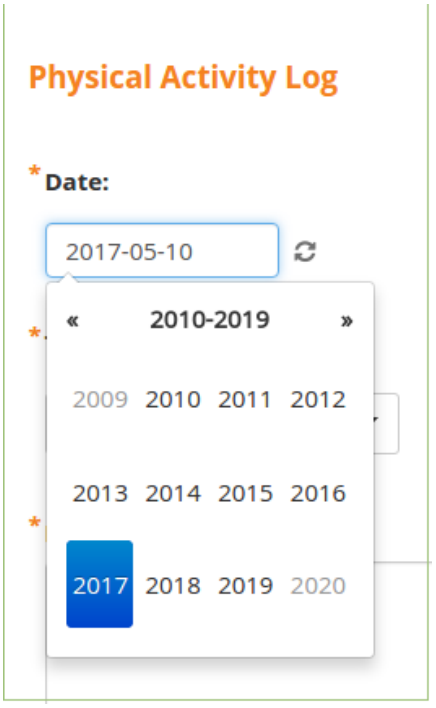


3. Press the appropriate month for the date in question.

4. To change the year, use the left and right arrows on the display as needed. If you need to go back a number of years, press on the year at the top of the display:



The browser displays a list of years.



5. Locate and select the appropriate year. If necessary, use the arrows to scroll through groups of years.

Functional approval by Laura Keita. Signed on 2017-05-12 3:39PM

Approved for publication by Cal Collins. Signed on 2017-05-15 8:24AM

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