

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.

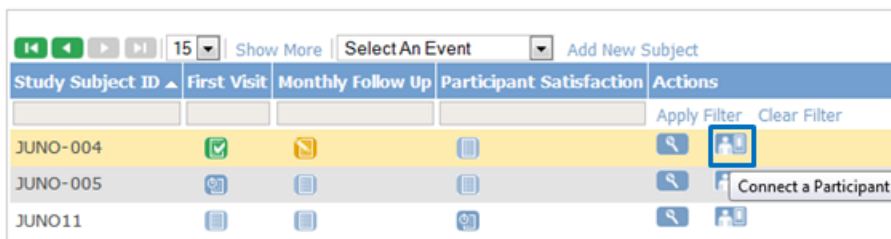
To Connect a Participant

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:

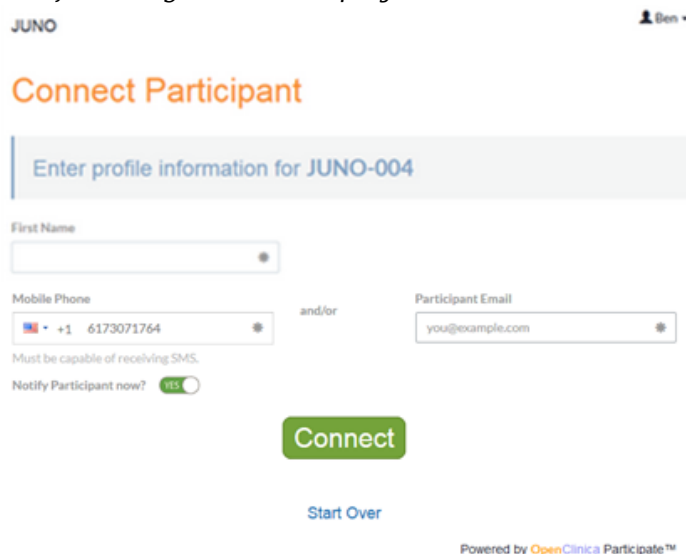
1. In OpenClinica, on the menu bar at the top of the screen click **Subject Matrix**. Then, for the Subject you'd like to connect to Participate, in the **Actions** column, click the **Connect a Participant** icon.

Subject Matrix for Site A



Study Subject ID	First Visit	Monthly Follow Up	Participant Satisfaction	Actions
JUNO-004				
JUNO-005				
JUNO11				

The following window displays:



JUNO Ben ▾

Connect Participant

Enter profile information for JUNO-004

First Name

Mobile Phone and/or Participant Email

Must be capable of receiving SMS.

Notify Participant now?

Connect

[Start Over](#)

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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.

Congratulations

A new access code has been generated and **0042** is now connected. Choose 'Show Access Code' if you need to help them log in or access Participate directly. This action will be audited. Choose 'Connect Another' to register the next participant.

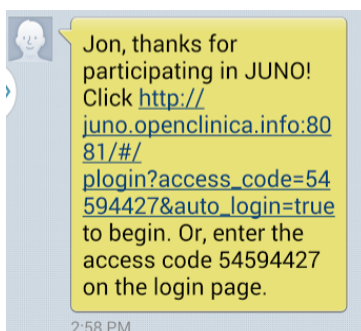
Show Access Code

Connect Another

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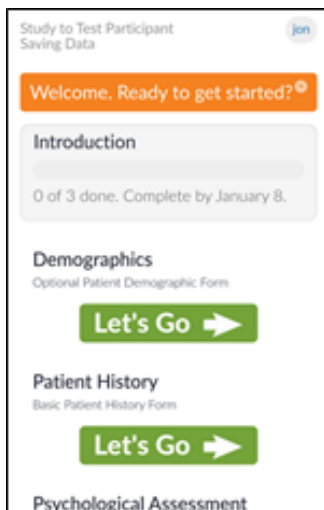
6. If you need to assist the Participant in logging in, or are using a shared, site-based device, click **Show Access Code** and present the Participant with the code. Note that the audit trail records the date/time that you viewed the code. Otherwise, continue with step 8, below.
7. To connect another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

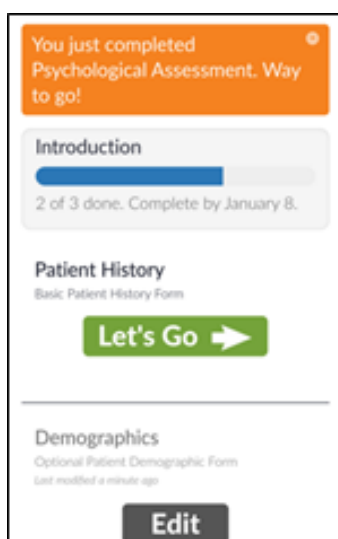
When the Participant clicks the link or logs in using the Access Code, OCP displays a list of forms that the Participant is scheduled to complete. OpenClinica also captures the Participant's local date-time so that Notifications will be sent at the appropriate time for the Participant, and so that Rules 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.

Approved for publication by Laura Keita. Signed on 2019-01-20 8:15AM

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