



## 12 OpenClinica Participate

**OpenClinica Participate** enables you to design electronic Patient Reported Outcomes (ePRO) Forms for Participant data entry. These Forms are integrated into the study, and data entered by Participants is immediately available to site- and study-level users.

- **Activation:** A Data Manager must activate Participate before any functionality is available.
- **Participant Management:** Site users with CRC or Investigator roles can add Participants to the study and invite them to complete ePRO Forms.
- **Access:** Participants can complete Forms on their own devices (smartphone, tablet, laptop, or desktop computer).
- **Form Availability:** You control when each Form is available to each Participant. This prevents pre-filling or back-filling of data.
- **Audit Trail:** Each Form submission is date- and time-stamped in the audit trail, providing evidence that the Participant completed the Form(s) within the required protocol timeframe.

For more information, see the following sections:

Approved for publication by Kate Lambert. Signed on 2025-09-19 4:51PM

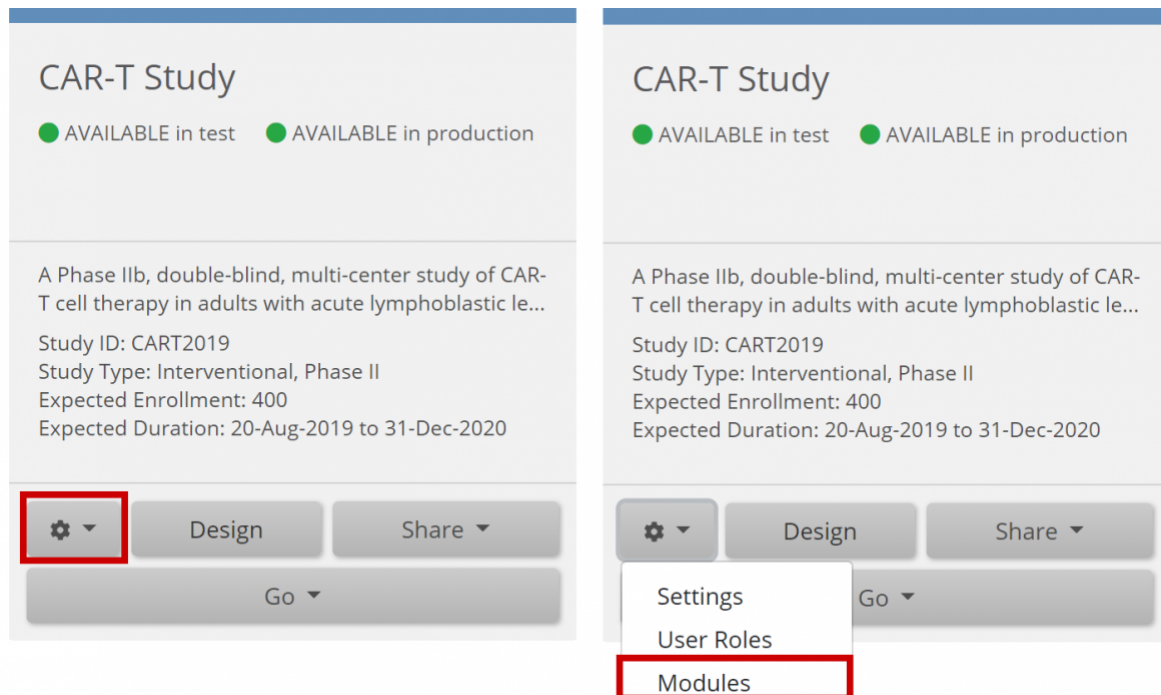
Not valid unless obtained from the OpenClinica document management system on the day of use.

### 12.1 Activate Participate

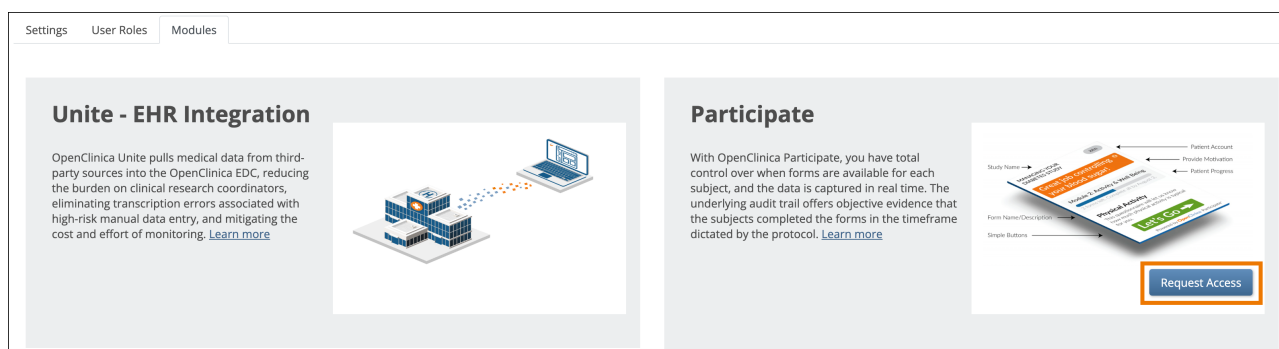
Data Managers can activate Participate. Participate allows participants to enter data into online Forms at scheduled times.

#### To Activate Participate:

1. On the **My Studies** screen, in Study Designer, or the on the **Share** screen, click the **Settings (Gear)** button, and select **Modules**.



2. Click the **Request Access** button on the Participate Module card.



3. Read the instructions in the popup, and provide a subdomain name for your study. The subdomain name can contain letters, numbers, and hyphens (-), but cannot begin or end with a hyphen.

The system checks to ensure that the subdomain is valid and is not already in use (subdomain names are case insensitive, so a subdomain of **Juno** is equal to a subdomain name of **juno** and would therefore be considered already in use). If you do not receive a message indicating that your request was successfully submitted, check the subdomain name you provided and try again.

**Note:** Once you have requested access, the status of the Participate module is set to Pending. While it is in this status, you can start designing Participate Forms, but they are not activated for Participant use until the request is approved and the status is set to Active. Requests are approved by OpenClinica Customer Support based on the current Participate contract with your organization.

Once your Participate request is approved, the status is set to Active, and Participate is fully available for use in the Test and Production environments for that study.

## Participate

With OpenClinica Participate, you have total control over when forms are available for each subject, and the data is captured in real time. The underlying audit trail offers objective evidence that the subjects completed the forms in the timeframe dictated by the protocol. [Learn more](#)

Status:  **Active**

URL for PRODUCTION Environment  
<https://juno.mytrial-dev.me>

URL for TEST Environment  
<https://junotest.mytrial-dev.me>

Deactivate

To deactivate Participate at any time, return to the **Module Management** screen, and click the **Deactivate** button under the Participate module card. If you confirm the deactivation, this removes all Participant access to Forms and reverts all Participate Form settings, but all Participate forms remain accessible to OpenClinica users.

Functional approval by Riley Bianchi. Signed on 2023-04-07 11:41AM

Approved for publication by Paul Bowen. Signed on 2023-04-28 12:16AM

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## 12.2 Design Participate Forms

Once Participate is activated, Data Managers can designate specific forms within visit-based events as Participate Forms.

### Make a Form a Participate Form

To designate a form as a Participate Form:

1. In **Study Designer**, click the form you want a Participant to complete.
2. Select the **Participate Form** checkbox.

When you check the **Participate Form** box, an additional option appears below it:

- **Show Form Description** - Displays the form's description (as defined in the Study Designer form card) beneath the form title on the Participant's **Participate dashboard**.

To display a form description:

1. In **Study Designer**, check **Participate Form**.

2. Check the **Show Form Description** box.
3. (Optional) Hover over the checkbox to view the tooltip:  
*"Will display the form's description on the Participate dashboard."*

□ **Tip:** If the form has no description, the option can still be selected, but nothing will appear on the Participant dashboard.

□ **Note:** If you uncheck **Participate Form**, the **Show Form Description** box will automatically be unchecked and hidden.

□ **Tip:** Participate Forms cannot be used in **Common Events**.

The screenshot shows the 'Medical History' form configuration interface. At the top, there are tabs for 'Design', 'Upload', and 'Preview (as a Participant)'. Below these, the 'Description' section has an 'Edit' link. The 'Form Properties' section includes checkboxes for 'Hide from site users' and 'Required', and a dropdown for 'SDV' set to 'Not Applicable'. The 'Participate Properties' section is highlighted with a red box and contains a checked 'Participate Form' checkbox and an unchecked 'Show Form Description' checkbox. Other sections include 'Versions' (showing 1 version), 'Drafts' (showing None), 'Permission Tag' (with a plus button), 'Data Dictionary' (with a link icon), 'Collaborate' (with an 'OID: F\_GENERAL' label), 'Members' (with a plus button), and 'Labels' (with a green label and a plus button).

□ **Note:**  
Event-level descriptions can also be displayed on the Participant dashboard.  
Data Managers can enable this by checking **"Show Event Description to Participants"** in the **Event Card → Properties** section (available for events that include Participate Forms).

## Track Changes to Participate Settings

All manual and system-generated changes to **Participate Form** and **SDV** settings related to Participate Forms appear in the **Activities** section of the right-hand panel.

To view these changes, click the **expand icon** ( < ).

Changes to the **Show Form Description** setting appear in the **Activities** section:

- “USERNAME marked this form to show the description to participants.”
  - “USERNAME unmarked this form to show the description to participants.”
- 

## Participate Forms and Permission Tags

Permission Tags **do not apply to Participants**.

If a form is designated as a **Participate Form**, Participants will be able to view and complete it regardless of any associated Permission Tags.

However:

- If a Participate Form has a Permission Tag, only OpenClinica user roles with access to that Permission Tag — **and Participants** — can access the form.
- 

## Using Participate Forms

Once Participate is active and the Participant Forms have been published, the forms are ready for Participant use.

Participants can access their forms on a:

- Computer
- Tablet (iPad)
- Smartphone (iPhone)

*Figures below illustrate the Participant Form layout on each device.*

- **Participate Form on computer**

All changes saved.



## Day 1 Questionnaire

Today's date is...

2020-05-04



Today I feel...

- ☐ Very Bad
- ☐ Bad
- ☒ Average
- ☐ Good
- ☐ Very Good

My most recent fasting glucose level was...

85



All changes saved.

Close

Powered by OpenClinica

- **Participate Form on iPad**

## Day 1 Questionnaire

Today's date is...



Today I feel...

- ☐ Very Bad
- ☐ Bad
- ☒ Average
- ☐ Good
- ☐ Very Good

My most recent fasting glucose level was...

Close

Powered by OpenClinica

- **Participate Form on iPhone**





# Day 1 Questionnaire

Today's date is...

2020-05-04



Today I feel...

- ☐ Very Bad
- ☐ Bad
- ☒ Average
- ☐ Good
- ☐ Very Good

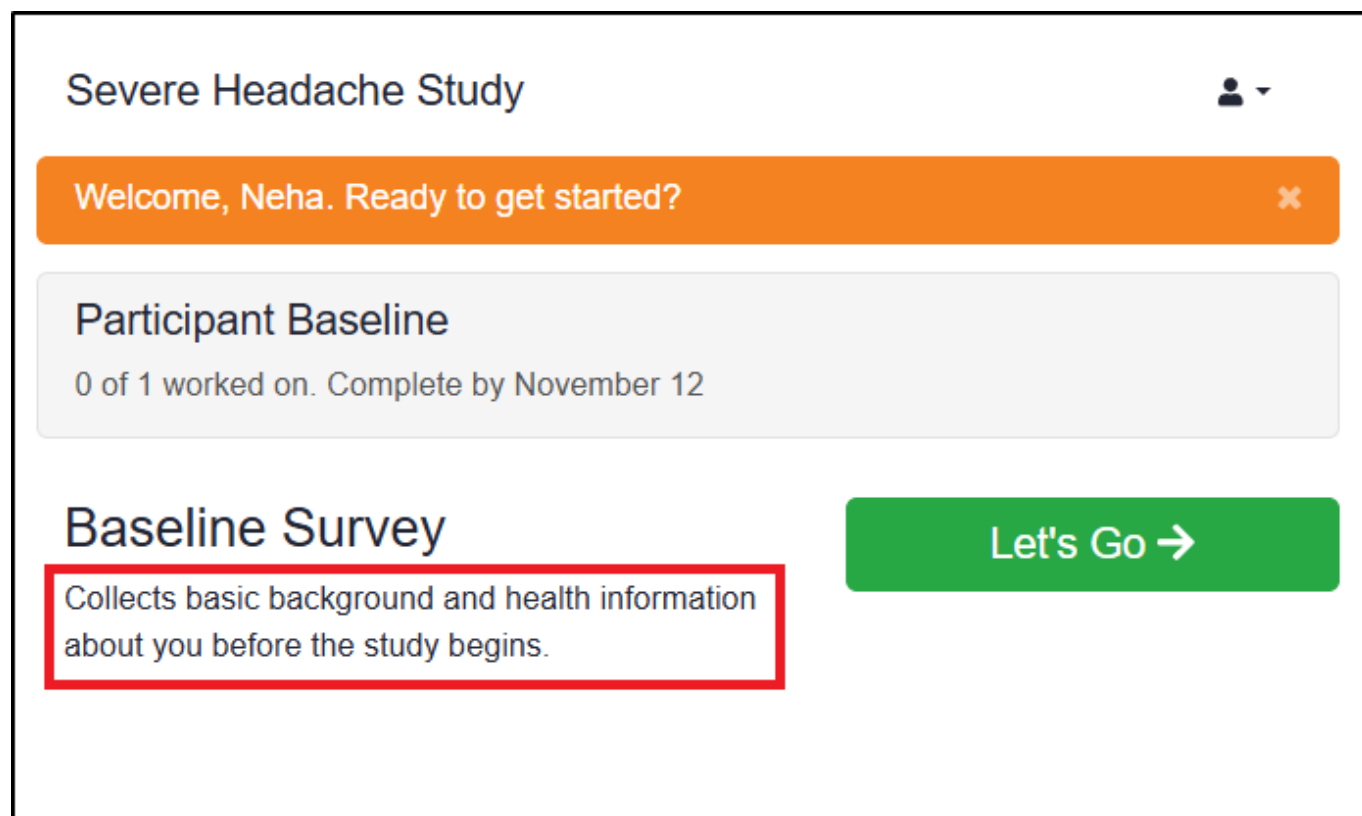
My most recent fasting glucose level was...

85

Close

Powered by OpenClinica

If **Show Form Description** is enabled, the form's description appears in smaller text below the form title on the Participant's **Participate dashboard**.



The screenshot shows a web interface for a study titled "Severe Headache Study". At the top right is a user profile icon. Below the title is an orange banner with the text "Welcome, Neha. Ready to get started?" and a close button. Underneath is a grey box labeled "Participant Baseline" with the text "0 of 1 worked on. Complete by November 12". The main section is titled "Baseline Survey" and contains a red-bordered box with the text "Collects basic background and health information about you before the study begins." To the right of this box is a green button that says "Let's Go →".

□ **Note:** If an event's **Show Event Description to Participants** option is enabled, the event's description appears in smaller text below the event title on the Participant dashboard.

## Add Participant Contact Information to a Form

You can include contact information fields directly within a form. This feature supplements the Participant Details screen and allows collection, display, and updates of contact information within a form.

These data are stored separately from other form data to enforce role-based access controls. For more information on contact data and external values, refer to [Understanding Contact Data](#).

Approved for publication by Kate Lambert. Signed on 2025-12-12 12:14PM

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## 12.3 Configure Forms for Offline Mode and Public URL

**Definition:**

- **Public Participant Surveys (Public URL):** Allows participants to self-register for a study. Configure forms to allow Public URL within Study Designer and then create the form URL within the Site Configurations page in Study Runner. This URL can be shared in a public forum, such as a subway advertisement, social media post, etc., which can help attract potential participants. Each form submitted through this feature will create a new participant in the study. This feature allows the study to be accessed by a wide audience for easier recruitment.

- **Offline Data Capture (Offline Capable):** Allows research staff to enter form data even if they do not have internet service available. Configure forms by selecting Public URL and Offline Capable in Study Designer and then create the form URL within the Site Configurations page in Study Runner. Form data entered while offline will automatically be uploaded to OpenClinica when the user's device is back online. The form will need to be cached on the device while online prior to the user going into an offline environment. This allows data to be gathered in remote locations that do not have access to the internet. Offline data capture uses a dedicated form URL that can be configured within the Site Configurations page in Study Runner.

**Potential Uses:**

- **Public Participant Surveys (Public URL)** allows the URL for the form to be shared in a public forum, such as a subway advertisement, social media, emails, etc. The Public URL could be used to help attract potential participants.

- **Offline Data Capture (Offline Capable)** allows research staff to enter form data from remote places that do not have access to the internet.

**Considerations:**

- Offline and Public URL forms are part of the [Participate](#) module. When designing a study, the Participate module needs to be requested first before seeing the **Participate Properties** section in the Form card. The Participate module will need to be activated before the Public URL will be available.

- When data is submitted using a Public URL form or an Offline Capable form, the user will display as "**PublicURL**" on the Audit Log. This user name will appear for *Participant creation, Event creation, Form creation, Queries added, Item creation/values set*, as well as in the *Last Updated By/Created By* user on the Participant Details Page.

## Configure Forms for Offline Mode and Public URL

1. Open the Form card in the Study Build System to edit the the form and select the **Participate Properties** to enable.
  - a. **Public URL** must be enabled in order for **Offline Capable** to appear as an option.
  - b. If the **Participate Properties** section does not appear on the form card, you will need to enable the [Participate](#) module before proceeding.

The screenshot shows the 'Med History' form configuration page. On the left is a sidebar with 'Medical History' and a '+ Add a form' button. The main area has tabs for 'Design', 'Upload', and 'Preview (as a Participant)'. Below these are sections for 'Description', 'Form Properties', 'Participate Properties', 'Versions', and 'Drafts'. The 'Participate Properties' section is highlighted with an orange border and contains the following options:

- ☐ Participate Form
- ☒ Public URL
- ☐ Offline Capable

Other visible settings include 'SDV: Not Applicable' and 'Versions: 1'.

**Note:** It is not recommended to select **Participate Form** in addition to **Public URL** as this would also allow Participants to access the form through the Participate Dashboard. After publishing the study, the URL used for this form for each site will need to be created on the Site Configuration page in Study Runner.

2. Within Study Runner, use the **Tasks** menu to select **Sites**.
  - a. Click the **Pencil** icon to edit the Site, then expand the Event to find the **Form Submission URL** field.
  - b. Enter the unique ending of the URL for this form.
  - c. Repeat these steps until each Public URL form and Offline Capable form in each Event has been updated for each site that will be using these forms.

The screenshot shows the 'Update Site Details: Best Hospital' dialog. It has tabs for 'PublicURL', 'Baseline', 'Cycle 1', and 'Cycle 2'. The 'PublicURL' tab is active. The dialog contains various settings for the site, including 'Contact', 'Required', 'Hide from users at this site', 'Default Version', 'Available Versions', 'Source Data Verification', 'Participate Form', 'Public URL', 'Offline Capable', and 'Form Submission URL'. The 'Form Submission URL' field is highlighted with an orange border and contains the text 'https://katetesttest.mytrial-dev.me/ abc123'. At the bottom, there are 'Save' and 'Cancel' buttons and a note: 'Clicking **Save** will lock in all settings for all forms at this site. Changes made in Study Designer will no longer affect this site.'

**Note:** Once the Public URL is created for the site, all settings for existing forms will be locked in for the site, and will no longer be modified when changes are made to default settings within Study Designer. For Offline Data Capture, the form will need to be set up on the device that will be used

prior to going offline. For specific details on the device setup, see **Using Offline Data Capture**.

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## 12.4 Invite Participants

If Participate has been activated for your study, and Participate Forms have been designed, those Forms are available for Participants to complete. Each Participant must first be invited to Participate prior to completing those Forms (with the potential exception of Public URL forms). CRCs and Investigators (and any custom roles that are based on those roles) have access to invite Participants. **Note:** *In order to add participants, you must have at least one site associated with your study. You can create a site by clicking **Add New** on the **Share** screen.*

### Add a Participant to a Participate Study:

Once the Participant has been added to the study, the Participant Details screen appears for Investigators and CRCs. For site users with appropriate access, the Participant Details screen includes the Invite a participant and View participant **access code** links:

Participant A

A Audit Log | Showing Active Records

Expand All | Collapse All

General Information

Edit

Invite | View participant access code

Participant ID	A	Status	Available	First Name	Joe	Mobile Number	000-000-0000
Study Name	JUNO Diabetes Study KT	Site Name	Waltham	Participate Status	Active	Email	jsmith@gmail.com

### Invite a Participant to Complete Participate Forms:

1. In the **General Information** section of the Participant Details screen, click **Invite**.
2. Create a Participant account:
  1. For use on a device used in-clinic: All Participate fields are optional.
  2. For use by Participant on personal device: Enter the First Name and Email or Mobile, and select Yes on either *Invite via email* or *Invite via mobile* (or both).
3. Click **Update** to create the account and Participant access code.
  1. Note that the invitation is sent in the study default language or a supported language. For more information about supported languages, see [Language Support](#).
  1. The initial invitation is sent using the site user's selection, whether it is the default language or a supported language.
  2. Once the Participant has logged in, if another invitation is triggered, it will be sent:
    1. in the language the Participant has previously logged in with if it is a

- supported language.
2. in the default language if the language the Participant has previously logged in with is not a supported language.

You can return to the **Participant Details** screen to send or resend an invitation at any time. If you click the checkbox for **Reset Participant Access Code**, a new Participant access code generates, and the previous code becomes inactive.

## Update and Invite

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First Name


Email

Invite via email?

☐ Yes

☒ No

Mobile

 ▼

+1

Invite via mobile?

☐ Yes

☒ No

☐ Reset Participant Access Code

Cancel

Update

## OpenClinica Enforces the Following Limits for Each Field:

- **First Name** is limited to 35 characters.
- **Email** is limited to 255 characters.
- **Mobile** is limited to 17 characters, including the country code.

To ensure privacy and security, all Participant Personal Identifying Information (PII) entered via the above window is encrypted in the database. The unencrypted information is only visible to CRC-based roles and Investigator-based roles, and only on the **Participant Details** screen. *Note: Fields within Participant-facing or site-facing forms are only treated as PII when specifically identified as Participant Contact Information in the form definition as described in [Design Participate Forms](#).*

Once the information has been updated, the Participant's contact information appears on the **Participant Details** screen.

The **Audit Log** includes entries for Participant account creation and updates based on use, but masks all Personally Identifiable Information as appropriate based on User Role. *Note: Fields within Participant-facing or site-facing forms are only treated as PII when specifically identified as*

Participant Contact Information in the form definition as described in [Design Participate Forms](#).

The Participant Status appears on the Participant Details screen and is defined as follows:

Status	Definition
Created	The Participant account was created, but the invitation has not yet been sent, and the Participant has not yet accessed Participate. Both Invite via email and Invite via mobile were set to <i>No</i> .
Invited	The Participant account was created. An invitation was sent via email and/or mobile, but the Participant has not yet accepted the invitation.
Active	The Participant has successfully accessed Participate and can complete forms.
Inactive	The Participant has been removed from the study. (Data Managers and Investigators can remove Participants. Any data associated with removed Participants can be viewed but cannot be edited or extracted from the database.

The Participate status is also visible in the Participant Matrix. To view the Participate status, click **Show More**.

Participant Matrix for Site 1						
<div><div><div><div></div></div><div><div></div></div><div><div></div></div><div><div></div></div></div><div>50 ▾</div><div>Show More</div><div>Select An Event ▾</div><div>Add New Participant</div></div>						
Sign	Participant ID	Additional Notes:	Additional Notes:	Event 1	Event 2	Event 3
	Site1-009					
	Saranya					
	P01					
	Site1-010					
	Site1-011					
	Site1-008					

## Participant Matrix for Site 1

50

Hide

Select An Event

Add New Participant

Sign	Participant ID	Site ID	Additional Notes:	Additional Notes:	Status	OID	Participate Status ▲	Event 1	Event 2
	Site1-009	Site1			Available	SS_SITE1009	Active		
	Saranya	Site1			Available	SS_SARANYA	Created		
	P01	Site1			Available	SS_P01	Created		
	Site1-010	Site1			Removed	SS_SITE1010	Inactive		
	Site1-011	Site1			Available	SS_SITE1011	Invited		
	Site1-008	Site1			Available	SS_SITE1008			

Schedule Events as appropriate for the Participant. Participants only have access to forms that are in events with a status of *Scheduled* or *Data Entry Started*.

Forms that have been identified as Participate Forms can be completed by Active Participants as well as CRCs and Investigators. When the Participant enters data into a Participate Form, that Form data is immediately available in OpenClinica for review.

## Invite Participant Errors

OpenClinica generates the following errors if you attempt to invite a Participant with an invalid email or phone number.

- Invalid email address: If the Participant's email address is invalid, *Invalid email address* appears under the Email field, and you cannot click **Update**.
- Invalid mobile number: If the Participant's mobile number is invalid, and you select **Yes** only for *Invite via mobile*, the message, *Oops! Mobile invitation to the participant could not be sent. Please ensure mobile number is correct, or try again later*, appears.
- Invalid email address and mobile number: If you select **Yes** for both *Invite via e-mail address* and *Invite via mobile*, a message regarding the success/failure of both email and mobile appears.

**Note:** When you invite a Participant to a study, the system is actually creating a user with a User Type of Participant. Though they are defined as "users," they are not listed on any of the user listings or extracts. Specifically:

- If you click the **Tasks** menu and select *View Study*, users with a User Type of Participant are not listed in the User table.
- If you download the study metadata, Participant users are not included in the XML.
- If you download a casebook in XML or JSON format, Participant User Types are not included in the results.
- Participant users are not available in the user search boxes (For example, when assigning a query).
- Participant users are not listed on the Share screen (available to Data Managers and Administrators).



- Participant users are not displayed in the Central User Administration screen (available to Administrators only).
- The Audit Log does not contain any identifiable information about Participants.
- Extracts do not include identifiable information about Participants.
- XML extracts do not include Participant User Types.

## View Participant Access Code

For Studies that have been designed to collect Participant data in-clinic rather than on individual Participant devices, CRCs and Investigators might need to view the Participant access code in order to allow the participant to enter data on a clinic-provided device.

CRCs and Investigators have access to view Participant access codes as long as the Participant has a status of Created, Invited, or Active.

**Note:** Viewing the Participant access code should only be done if it is defined as a permitted action in the Study Protocol. Though the action of viewing the code is tracked in the audit log, once that code has been viewed, anyone with that code could enter data as the Participant. There is no way to distinguish in the audit log whether the data was actually entered by the Participant or by the CRC or Investigator who viewed the access code.

**If you have any questions regarding whether you should view the access code or not, please check with your Study Monitor or Data Manager prior to viewing the code.**

Once you have taken the above note into full account, to view the access code:


1. In the General Information section of the Participant Details screen, click the View participant access code link.

### View participant access code

---

Access Code

.....



Viewing access code will be audited

Participate URL: <https://juno2test.mytrial-dev.me>

Please sign out of all OpenClinica application windows  
before opening the Participate URL in the same browser.

---

Close

2. If you are certain that viewing the code is permitted in your study, to view the code, click the Eye icon.

To copy the code, click the Copy Access Code to Clipboard button. Once you have viewed the code, a QR code appears.

## View participant access code

Access Code

Copy Access Code to clipboard



Participate URL: <https://trainingtest.mytrial-staging.me>

*Please sign out of all OpenClinica application windows  
before opening the Participate URL in the same browser.*

Close

## Remove a Participant from a Participate Study

Remove a Participant from a Participate study by clicking the Remove button on the Participant Details screen:

- The Participant status in the Participant Matrix is set to Inactive.
- The Participant status in the General Information section of the Participant Details screen is set to Removed, and the contact information and links are removed from the screen.
- The Participant's access code is deactivated and that Participant tries to access Participate, an authentication error appears.

If the Participant is restored, the statuses, access, and participant details are restored to their previous settings.

Approved for publication by Kate Lambert. Signed on 2025-06-05 5:13PM

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## 12.5 Participant Data Entry

When a Participant is invited to a study, they will receive an email notification or text message that provides access to complete their Participate forms. If the Participant's browser locale matches a supported language in the study, they will see the Participate UI in that language. Otherwise, the UI will display in the study's default language. For more information, refer to [Language Support](#).

# Participant Invitation and Access

## Getting Invited

If you selected **Invite via email**, the Participant will receive the following email:

### Welcome to CAR-T Study Study!

Dear Kerry,

Thanks for participating in CAR-T Study study! Please click the link below to get started.

Let's Go ->

Thanks!

The CAR-T Study Study Team

You can also access the application by going to: <https://bfbdttest.mytrial.me> and enter the access code: HuEKXPsvB



If you selected **Invite via Mobile**, the Participant will receive the following SMS text message:

Hi Kerry, Thanks for participating in CAR-T Study! Please follow the link below to get started.

For future reference, your access code is Dr3z9DDtL

<https://bfbdttest.mytrial.me?accessCode=Dr3z9DDtL>

## To Access/Use Participate:

1. Open the email/SMS text message
2. Click the **Let's Go** button or link to go to your Participant Dashboard.

□ **Note:** If the link doesn't open automatically, copy and paste the hyperlink into the browser's address bar. Google Chrome or Mozilla Firefox are recommended.

Welcome, Bob. Ready to get started?



## QOL (Pre-Treatment)

0 of 2 worked on. Complete by October 3

RAND SF-12

Let's Go →

FACT-G (ePRO)

Let's Go →

## Form Access and Eligibility

Participants can only enter data into Forms in Events with a status of **Scheduled** or **Data Entry Started**. The Form itself must also have a status of **Not Started** or **Data Entry Started** to be eligible for data entry.

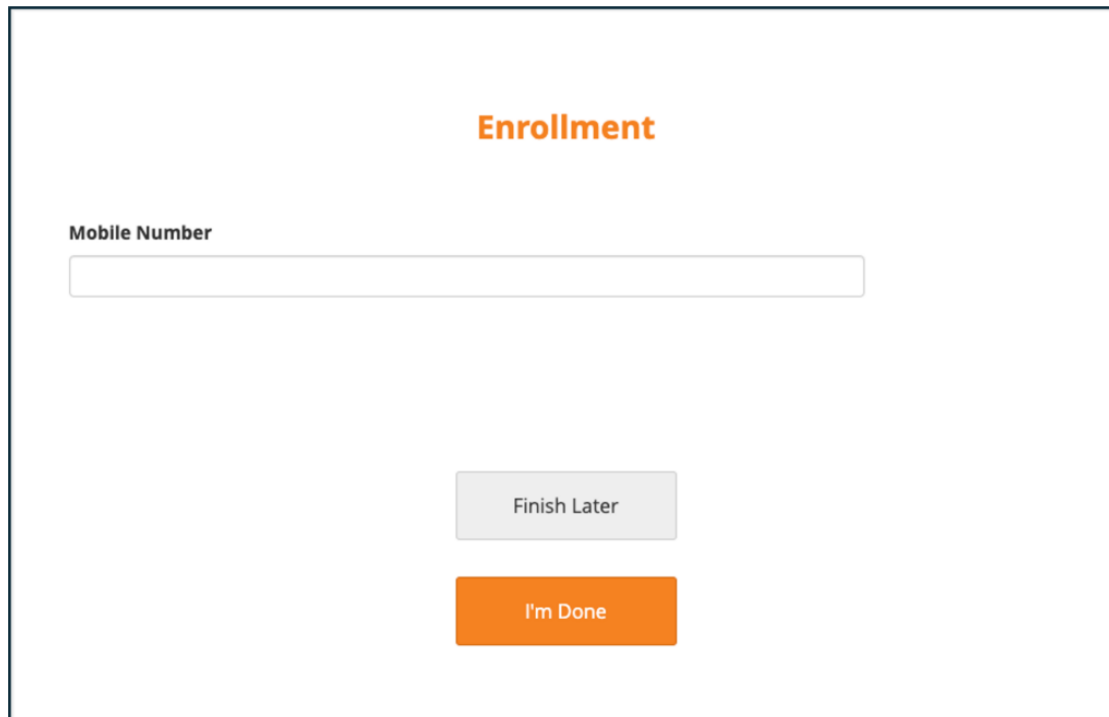
Participants cannot enter data into forms in Events with a status of **Locked**, **Archived**, or **Removed**. Additionally, the Form itself cannot have a status of **Archived** or **Removed**, nor can data be entered into archived form versions.

### Selecting a Form:

1. Select the Form you want to enter data in.
2. Click the **Let's Go** button next to the form to start data entry.

To answer questions, use your mouse, keyboard, and/or touchscreen to select or type responses. Responses are saved automatically. Use the **Next** and **Back** buttons to navigate within the form. To deselect a response, click the same value again, or click the **Reset** icon.

On the last screen, click the **I'm Done** button to complete the form. If you need to finish later, click **Finish Later**. You can resume or edit the form at any time by clicking the **Review** button next to the form on the Participant Dashboard.



**Enrollment**

Mobile Number

[Finish Later](#)

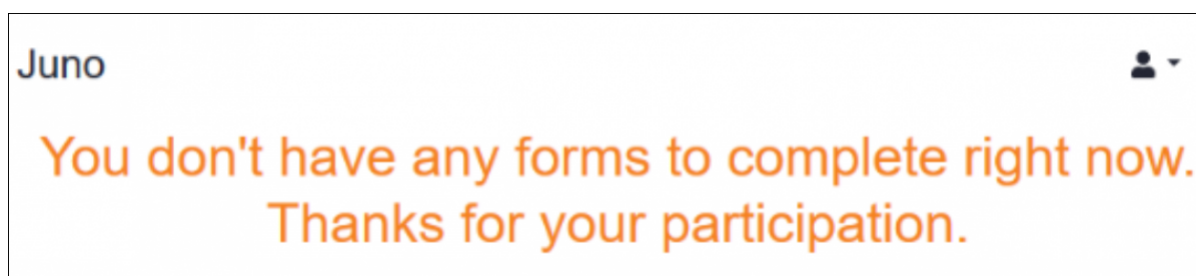
[I'm Done](#)

□ **Note:** When you reopen a form through your **Participate Dashboard**, the system will take you to the last question you edited. However, if the form has been edited by another user or if changes have been made to the form's questions since your last visit, the system will open the form at the beginning, on the first page.

Once you click **I'm Done** for all forms within a visit, the **Let's Move On** button will appear on the Participant Dashboard. If you are completely finished and do not intend to make any edits, click **Let's Move On** to complete the event. Once you click **Let's Move On**, you cannot edit your responses.

A confirmation message will appear to verify that you are finished. Click **Yes, I'm Done** to complete the process.

When you have completed all forms, the following appears:



Juno

**You don't have any forms to complete right now.  
Thanks for your participation.**

You will receive a notification if you have more forms to complete at a later date.

## Constraints and Required Fields on Participate Forms

If a Participate Form has edit checks (constraints or required fields), Participants must resolve these issues before they can proceed to the next page or close the Form.

**If a field value is changed, and the change fails a constraint or field**

### requirement:

- The original value remains.
- The constraint message appears.
- The Participant is instructed to enter a valid value.

×

## Invalid Value

Participant must have an ECOG Performance Status of 0-1

**Please enter a suitable value to update the field.**

OK

### If the Response was Removed and the Item is Required:

- The original value remains.
- A message indicating that the field is required appears.
- The Participant is instructed to enter a valid value.

×

## Invalid Value

This field is required

**Please enter a suitable value to update the field.**

OK

### If a Response is Changed and Causes an Error with Another Item or Group:

- The affected field is highlighted, and the appropriate message appears to indicate the issue.  
The Participant can enter data in the field or modify the dependent answers.

Please explain:

The

**An answer has changed to another question that requires this question to be hidden, but we cannot hide it while it has data. Please clear out the data or modify the dependent answers.**

## Participant Form and Event Statuses

As Participants enter data into Forms, the status of those Forms changes. Once all Forms for an Event are completed, and the Participant clicks **Let's move on**, the Event status changes. These changes occur as follows:

- As Participants enter data into Forms, the status of those Forms and the associated Events change.
  - When data is first entered into a Form, the Form status changes from **Not Started** to **Initial Data Entry**.
  - Once the **Let's Move On** button is clicked, the Form status changes to **Completed**.
  - If this is the only Form in the Event, the event status also changes to **Completed**.
  - If there are also non-Participate Forms in the Event:
    - If a non-Participate Form has a status of **Initial Data Entry**, the Event status remains **Data entry started**.
    - If the non-Participate Form has a status of **Completed**, the Event status is set to **Completed**.

## Participant Forms and Loss of Internet Connection

If a Participant is in the process of completing a Participate form and loses internet access but continues to enter data, a **Failure to save data** message appears.

If the Participant is still offline and attempts to close the Form, a message will appear indicating that data will be lost if the Form is closed.

Any data entered prior to losing the internet connection is saved successfully, however, and the Form is listed in the **Edit** section on the Participant Dashboard.

If the Participant was on the Participant Dashboard when he or she was disconnected from the internet, and the Participant clicks **Let's move on**, no action occurs. The Participant can continue once an internet connection is re-established and he or she returns to the Participant Dashboard.

# Participant Details Page

**Participate forms** appear in the **Participant Details Page (PDP)**, indicated by an icon, allowing the participant to access the form for data entry or review.



## □ Notes:

- The icon automatically disappears if the form is unmarked as **Participate** and republished.
- If the **Participate module** is deactivated, the icon is removed from all forms.
- **eConsent** and **offline-capable forms** do not display this icon, even if they are **Participate-enabled**.

For all **Participate-enabled forms**, clicking the form card on the **Participant Details Page (PDP)** will always open the form in **View mode** only—regardless of the user's role or the form's workflow status. This design helps prevent accidental changes to data entered by participants themselves.

## Participate and Audit Log

When Participants enter data into a Form from the Participant Dashboard, the data is tracked in the Audit Log, and the Participant is listed as the user who performed the action. No Personally Identifiable Information (PII) appears in the audit log. The Participant is identified with a user identifier structured as follows:

**StudyOID.environment.TEST or PROD.SS\_OID**

For example, in a Study named **Juno**, in the Production environment, Participant **HT1003** is identified as:

**S\_JUNO.PROD.SS\_HT1003**

All actions performed by the Participant are recorded in the Audit Log.

### These Actions Include:

- Entering data
- Changing Event status
- When a Participant starts entering data into a form, the Event status changes to **Data entry started**.
- Changing Form status
- When a Participant selects **Let's Move On**, the Form status changes to complete.



## In the Following Example, in the Juno Study:

- A CRC invited a Participant and scheduled an event containing a Participate form
- A Study Participant (with a coded identifier of **S\_JUNO.TEST.SS\_OHIO1705**) started data entry for the Event
  - Each value entered is logged and attributed to the Participant
  - The Event Status change is logged and attributed to the Participant
  - The Event CRF status change is logged and attributed to the Participant

Audit Event	Date/Time of Server	User	Value Type	Old	New	Details
Study Event data entry started	05-Mar-2020 00:10:19	S_JUNO.TEST.SS_OHIO1705	Status	scheduled	data_entry_started	

Name	Version	Date Interviewed	Interviewer Name	Owner
Demographics	v3.0			S_JUNO.TEST.SS_OHIO1705

Audit Event	Date/Time of Server	User	Value Type	Old	New
Event CRF marked complete	05-Mar-2020 00:11:05	S_JUNO.TEST.SS_OHIO1705	Status	available	unavailable
Item data value updated	05-Mar-2020 00:10:36	S_JUNO.TEST.SS_OHIO1705	WHITE (1)		2
Item data value updated	05-Mar-2020 00:10:29	S_JUNO.TEST.SS_OHIO1705	RACE (1)		5
Item data value updated	05-Mar-2020 00:10:23	S_JUNO.TEST.SS_OHIO1705	ETHNIC (1)		3
Item data value updated	05-Mar-2020 00:10:19	S_JUNO.TEST.SS_OHIO1705	SEX (1)		0
Event CRF Started	05-Mar-2020 00:10:19	S_JUNO.TEST.SS_OHIO1705	Status	unavailable	available

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## 12.6 Using Offline Data Capture

### Definition:

• **Offline Data Capture (Offline Capable forms):** Allows research staff to enter form data even if they do not have internet service available. Configure forms by selecting Public URL and Offline Capable in Study Designer and then create the form URL within the Site Configurations page in Study Runner. Form data entered while offline will be uploaded to OpenClinica when the user's device is back online. The form will need to be cached on the device while online prior to the user going into an offline environment. This allows data to be gathered in remote locations that do not have access to the internet. Offline data capture uses a dedicated form URL that can be configured within the Site Configurations page in Study Runner.

### Potential Uses:


• **Offline Data Capture (Offline Capable forms)** allows research staff to enter form data from remote places that do not have access to the internet.

### Considerations:


• Offline forms are only available with the **Participate** module. After the Participate module is active, the form will need to be configured for Offline Mode (see **Configure Forms for Offline Mode and Public URL** for details).

## Device Setup for Offline Forms


After a form has been configured for Offline Data Capture, it needs to be set up on the device where the data will be captured so it can be used while offline. The URL that was created on the Site Configuration page is what will be used to access the form.

1. From the device that will be used for Offline Data Capture, first open the form while online by going to the form's URL.
2. Click **"Let's Go"** while you are still connected to the internet.
  - a. If your browser prompts you to allow offline storage, you must allow this for the form to work offline.
3. Check to make sure you see this icon  in the upper left corner of the form. This icon indicates that the form is cached in your browser and available for you to use on this device while offline.
  - a. If the icon does not appear, try reloading the browser page. If it still does not appear, try using a different browser.
4. After confirming that the icon is visible on the form, add a bookmark or shortcut to the URL on the device to access the form when offline. This can be done in one or both of the following ways.
  - a. Bookmark the form's URL.
  - b. Add a shortcut to your desktop (highlight the form's URL, then drag and drop it onto your desktop).

MH

Let's Go 

▼ To enable this form for offline use on this device:

1. Click "Let's Go" while you are still connected to the internet.
2. Your browser may prompt you to allow offline storage (which you must allow).
3. Check to make sure you see this icon  in the upper left corner of the form indicating that the form can be used offline. If the icon does not appear, try reloading the page or launch it from a different browser.
4. The form is now cached in your browser and available for you to use when offline.

▼ How to access this form when offline:

After completing the steps above, you may access this form when you are not connected to the internet by either:

- Going to the URL of this form (you should bookmark the form's URL)
- Add a shortcut from your desktop. To do this, highlight the form's URL (not this page's URL) and drag it onto your desktop.

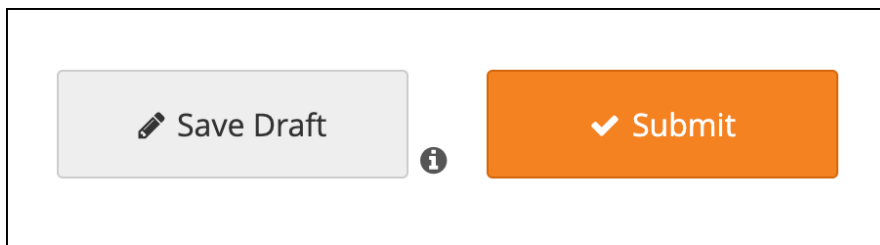
Powered by OpenClinica

## Use the Form for Offline Data Capture (After Device Setup)

1. Click the form's saved bookmark on your web browser or open the shortcut from the desktop.
2. Enter form data as normal and click **Submit** when done, or **Save Draft** to return to finish the

form later.

- a. **Submit** - Queues records to be submitted automatically. The queue is processed in the background every 5 minutes when the web page is open and an Internet connection is available.
  - b. **Save Draft** - Stores records within the current browser to allow the user to return to finish later. Drafts data will not be submitted. The user can close this browser without losing the stored record. Draft records can be accessed by reopening the page and clicking the button on the left of the screen.
3. The form will either create a new participant or link the form to an existing participant.
    - a. If the form has a Participant ID field and it is populated with an existing Participant's ID, the system will add the form to the existing participant's record.
    - b. A new participant will be created if the Participant ID field does not exist on the form or if the data entered in the Participant ID field does not match an existing participant (including if the field is left blank).
  4. Records are automatically stored and queued in your browser until an Internet connection is available. It is recommended that you keep a tab open for each form until the device is back online and the queued records are successfully uploaded.



When data is submitted using a Public URL or an Offline Capable form, the user will display as "**PublicURL**" on the Audit Log. This username will appear for *Participant creation, Event creation, Form creation, Queries added, Item value change*, as well as in the *Last Updated By/Created By* user on the Participant Details Page.

## Manage the Queue

1. In the upper left corner of the Form webpage, click the number in the white box to open the Queue. This box indicates the number of form records in the queue.
2. The form records will display in the queue with drafts indicated by the pencil icon. To edit a draft, click the pencil icon next to the draft you want to edit.
3. Queued records (except those marked as draft) are uploaded automatically in the background every 5 minutes when the web page is open and an Internet connection is available. The automatic upload will occur for every open tab even if the window is minimized.
  - a. To manually upload the records prior to the automatic upload, click **Upload**.
4. After a record has been successfully submitted, it will be removed from the queue.
  - a. You can safely close down your browser and device with items in the queue, they will still be there next time you load the form.
5. Use the **Export** option to export the records in a .zip file as a backup on the device.

Queue

Records are stored inside your browser until they have been uploaded (even if you turn off your computer or go offline).

Medical History - 1

Medical History - 4

Medical History - 5

Upload

Export

Queued records, except those marked as draft, are uploaded automatically, in the background, every 5 minutes when the web page is open and an Internet connection is available.

To force an upload in between automatic attempts, click Upload.

Clear Storage

Medical History

Diagnosis:

Date of Diagnosis:

Ongoing?

Date Resolved:

Remove

Add Another

Save Draft

Submit

**Clear Storage** - This will delete all of the queued form records and all of the cached form definitions from the browser storage. The data will be lost forever and the forms will not be usable until you are back online. Use this only if your browser storage seems corrupt. Similarly, if you clear your browser cache/history, all draft and non-submitted final records will be permanently deleted.

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