

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://bfbdtest.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.

CAR-T Study



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

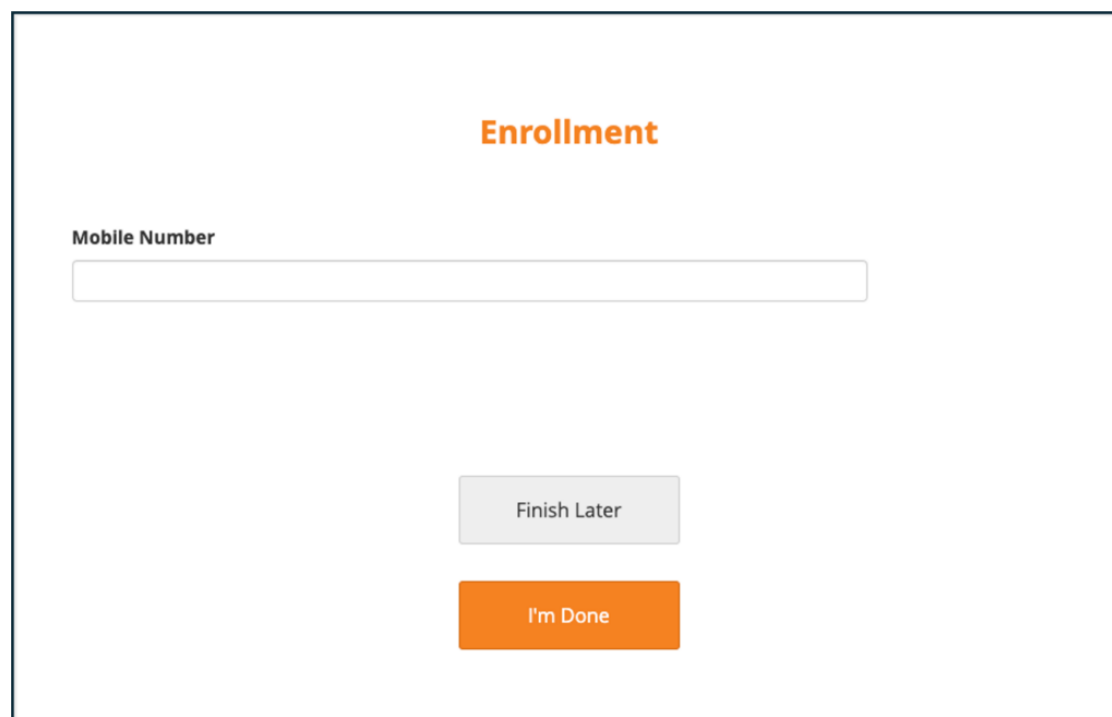
into archived form versions.

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.

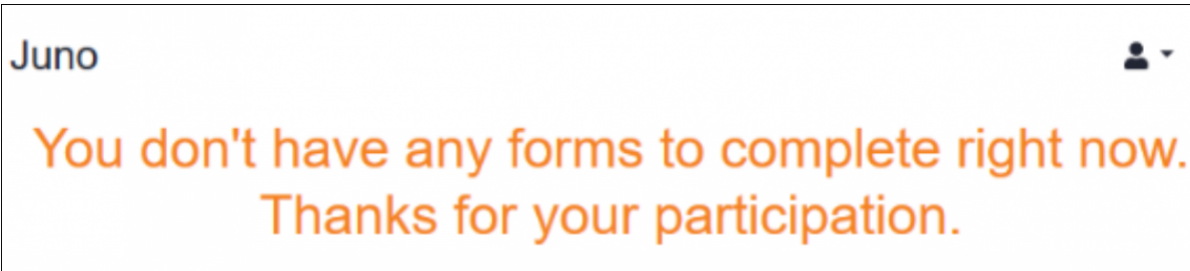
A screenshot of a mobile application screen titled "Enrollment" in orange text at the top center. Below the title, on the left, is the label "Mobile Number" in bold. Underneath this label is a long, empty rectangular text input field. At the bottom center of the screen, there are two buttons: a light gray button labeled "Finish Later" and an orange button labeled "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:



You will

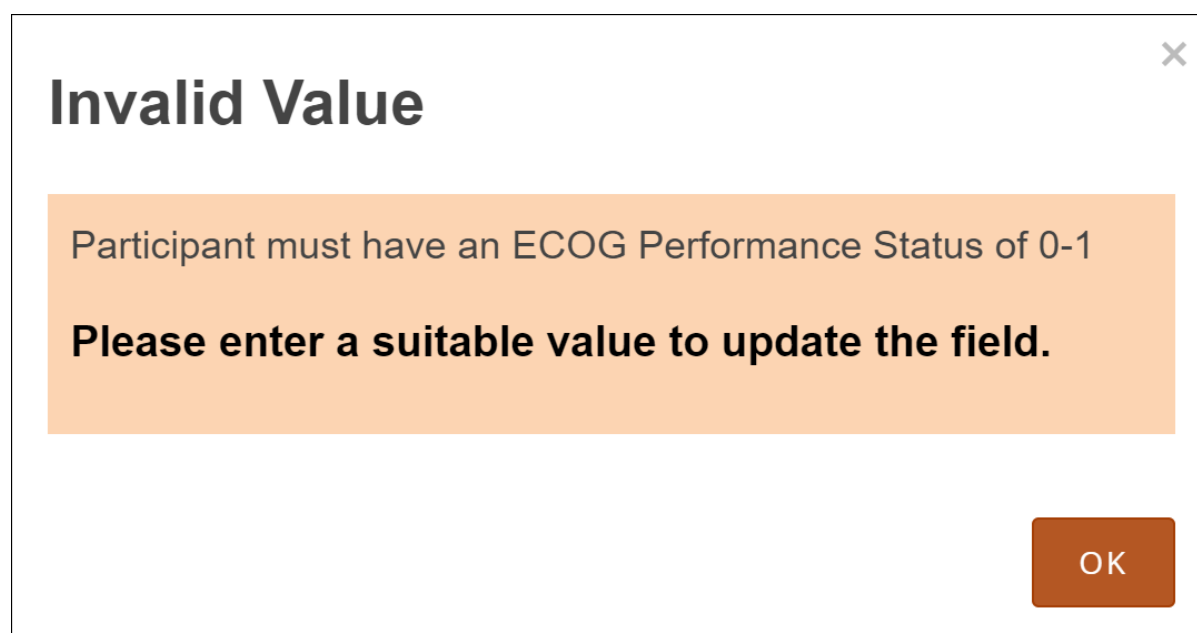
receive a notification if you have more forms to complete at a later date.

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.



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

Approved for publication by Kate Lambert. Signed on 2025-08-08 5:08PM

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