

## 14.4 Participant Data Entry

When a Participant is invited to a study, the Participant receives an email notification or text message that provides access to complete their Participate forms.

### Getting Invited

If you selected **Invite via email**, the Participant receives 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 receives 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://bfbdtest.mytrial.me?accessCode=Dr3z9DDtL>


## To Access/Use Participate:

1. Open the email/SMS text message, and click the **Lets Go** button or link to go to your Participant Dashboard.

**Note:** If this link doesnt open automatically, copy and paste the hyperlink into the search bar of the browser. 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 →

2. Select the Form you want to enter data in. Click the

**Note:** Participants can only enter data into Forms in Events with a status of **Scheduled** or **Data Entry Started**. The Form itself must 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**. The Form itself also cannot have a status of **Archived** or **Removed**. Participants cannot enter data into archived form versions.

2. **Let's Go** button next to the form you want to enter data in.
3. To answer questions, use your mouse, keyboard, and/or touchscreen to select or type responses to each question. Your responses are saved automatically. Click the **Next** and **Back** buttons to navigate within the form. To deselect a response, click the same value again, or click the **Reset** icon, as shown in the image below:

## Quality of Life Survey

Please check the number that best describes your feelings during the past week, including today. Your overall quality of life:

Please check the number that best describes your feelings during the past week, including today. Your level of fatigue, on the average?

In the past 7 days, how would you rate your pain on average?

I am bothered by side effects of treatment

All changes saved.

← Back
Next →

Extreme Distress

No Distress

4. On the last screen, click the Close button. You can resume or or edit the form at any time by clicking the Edit button next to the form on the Participant Dashboard.
5. After you click Close and return to the Participant Dashboard, if you are completely finished and do not intend to make any edits, click **Lets move on** to complete the form. Once you click **Lets move on** button, you cannot edit responses.
6. A message appears to confirm you are finished. Click **Yes, Im Done**.

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 is designed with edit checks (constraints or required fields), Participants must resolve those issues before being able to move to the next page or close the Form.

If a field value is changed, and that change fails a constraint or field requirement, the Participant is notified as follows:

### If the Response was Changed to a Value that Fails a Constraint for that Item:

- The original value remains.
- The constraint message appears.
- The Participant is instructed to enter a suitable value in the field.

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 was Defined as Required:

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

Invalid Value

This field is required

Please enter a suitable value to update the field.

OK

### If the Response was Changed, and that Causes a Constraint, Required, or Field Relevancy Error on Another Item or Group:

The field is highlighted, and the appropriate message appears to indicate the issue (constraint, required, or conflict with a relevant other value). You 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 the Participant first enters data into a Form, the Form status changes from Not Started to Initial Data Entry. Once the Participant clicks **Let's move on**, 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 tries to close the Form, a message appears indicating that data will be lost if they close the Form.

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.

## 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.

Approved for publication by Kerry Tamm. Signed on 2020-11-16 4:22PM

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