14 OpenClinica Participate

OpenClinica Participate allows you to design Forms for Participant data entry. These electronic Patient Reported Outcomes (ePRO) Forms are fully integrated in the study. Participants can enter data at scheduled times, and the data is immediately available for review by site and Study-level users.

Participate must be activated by a **Data Manager** before any Participate functionality is available.

Site users with access based on **CRC** or **Investigator** roles can add a Participant to the study and invite the Participant to complete the ePRO Forms.

Participants can access Participate Forms on their own devices (smart phone, tablet, laptop, or desktop computer) and submit them back to the study.

With Participate, you have total control over when Forms are available for each Participant, and the data is captured in real time. This ensures that Participants doesn't pre-fill or back-fill forms. The underlying audit trail contains date-time stamps that prove whether a Participant completed the form(s) in the timeframe required by the study protocol.

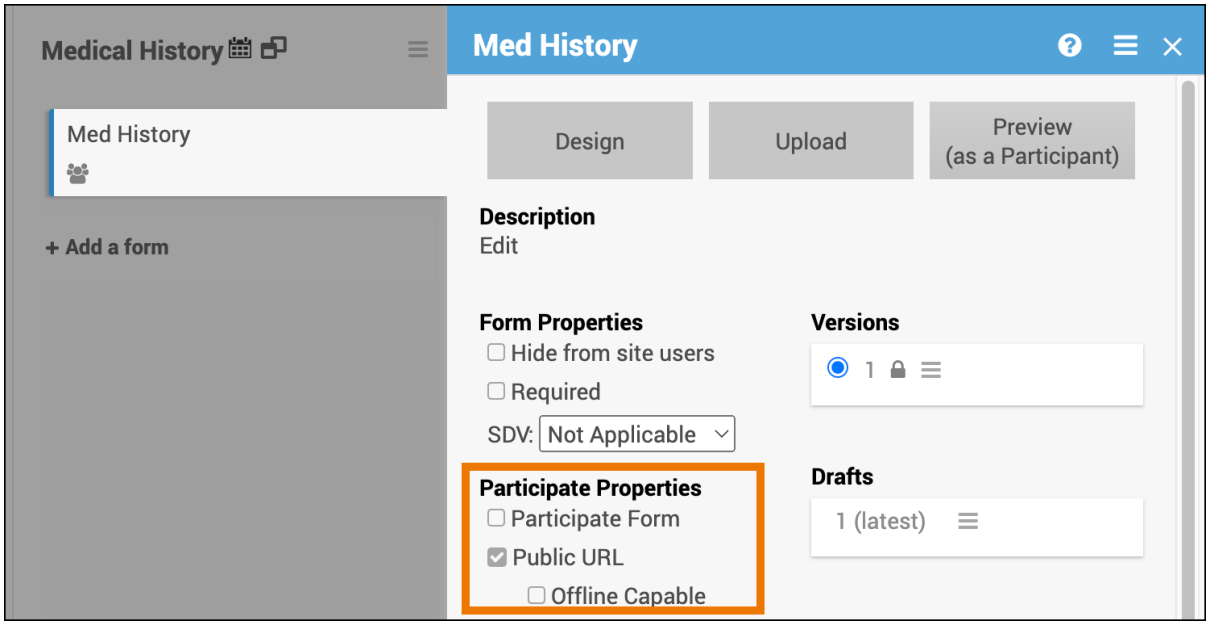
For Information on OpenClinica Participate, See the Following Sections:

14.1 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.

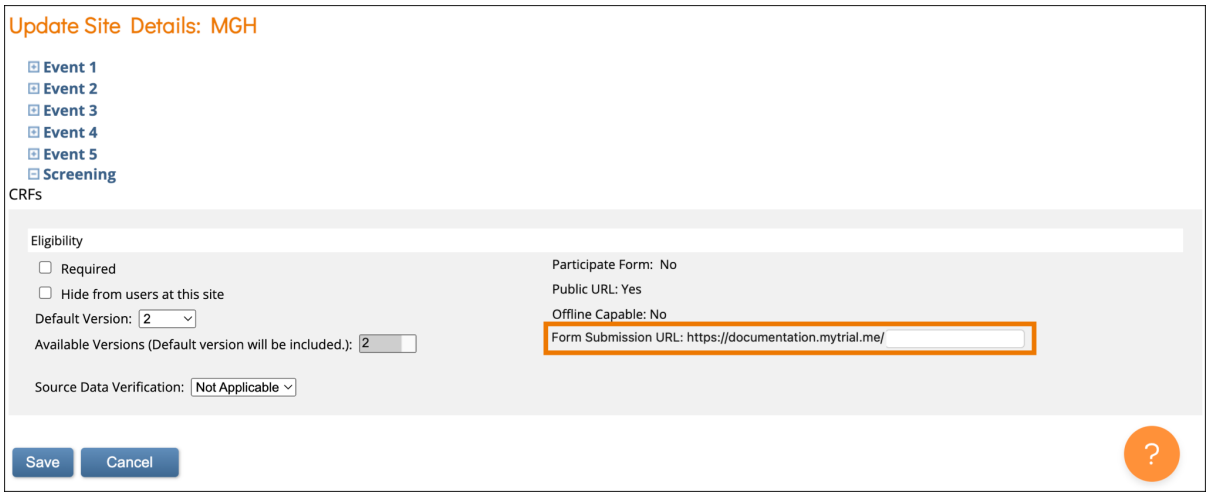
Configure Forms for Offline Mode and Public URL

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.



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.



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.**

Functional approval by Riley Bianchi. Signed on 2023-03-17 12:31PM

Approved for publication by Paul Bowen. Signed on 2023-04-27 11:17PM

14.2 Invite Participants

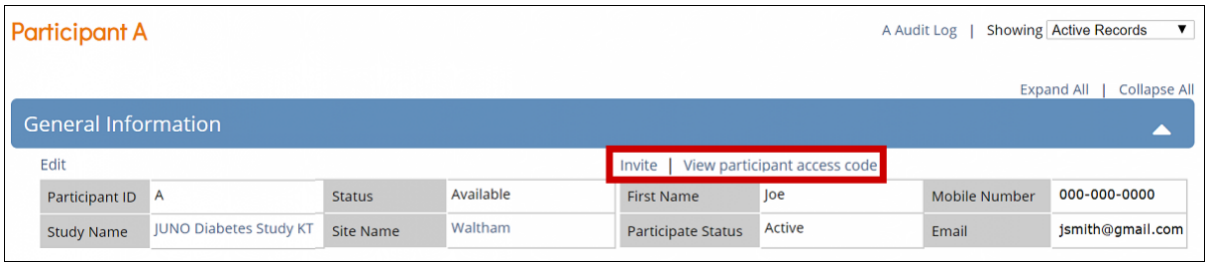
If Participate has been activated for your study, and Participate Forms have been designed, those Forms are available for Participants to complete. Each Participant must first be invited to Participate prior to completing those Forms (with the potential exception of Public URL forms). CRCs and Investigators (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:

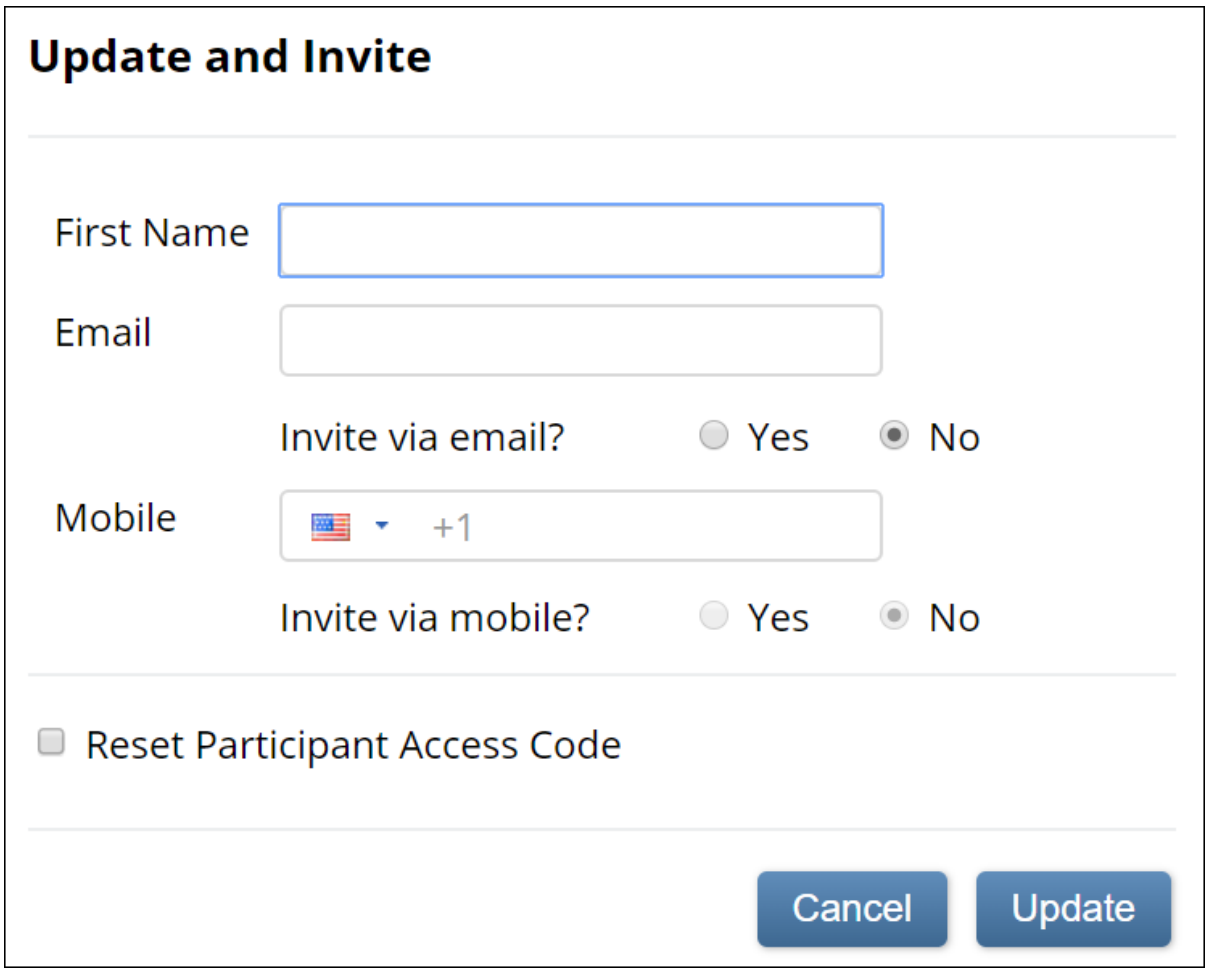
Once the Participant has been added to the study, the Participant Details screen appears for Investigators and CRCs. For site users with appropriate access, the Participant Details screen includes the Invite a participant and View participant **access code** links:



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.

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.



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.

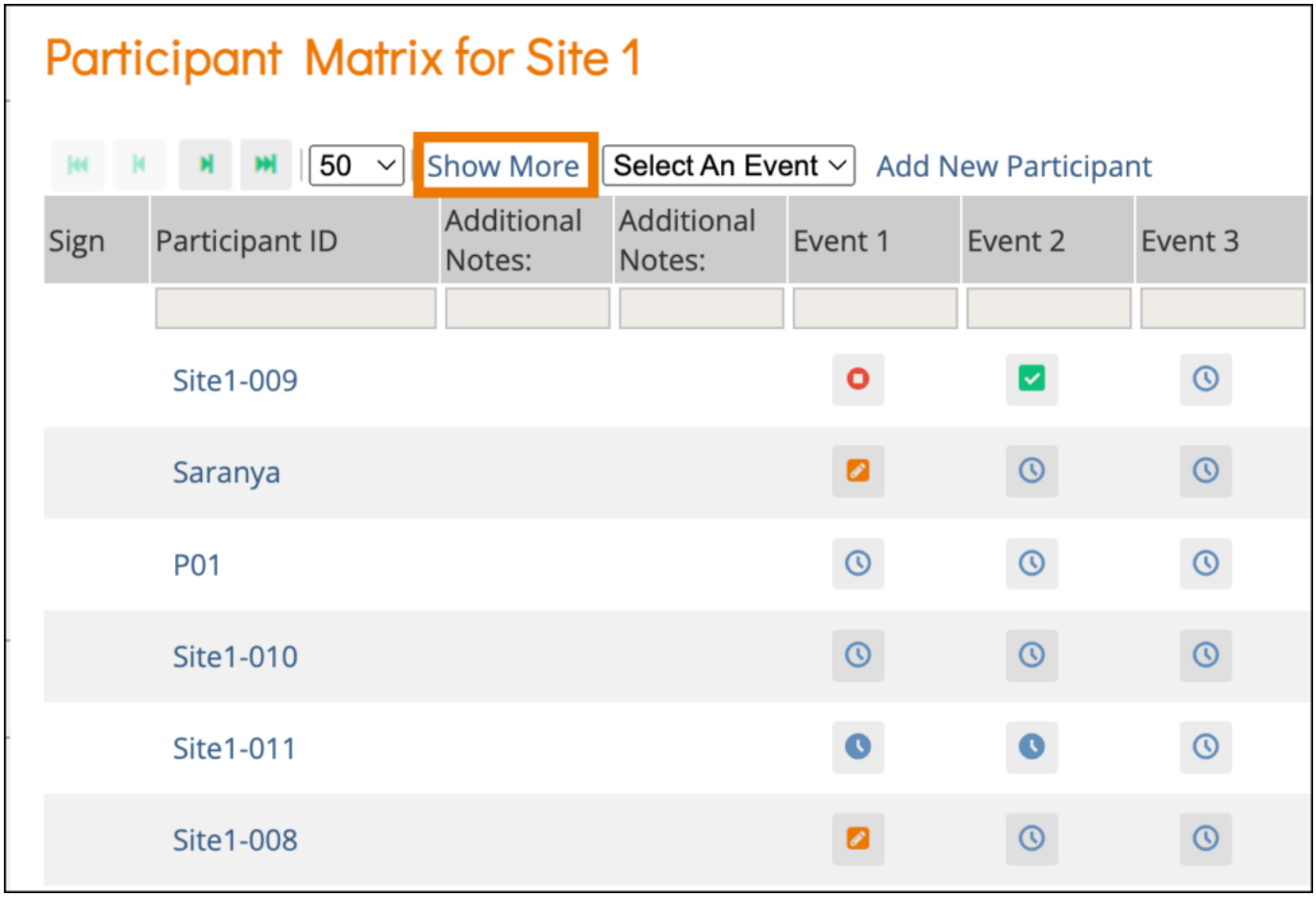
The **Audit Log** includes entries for Participant account creation and updates based on use, but masks all Personally Identifiable Information as appropriate based on User Role. *Note: Fields within Participant-facing or site-facing forms are only treated as PII when specifically identified as Participant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

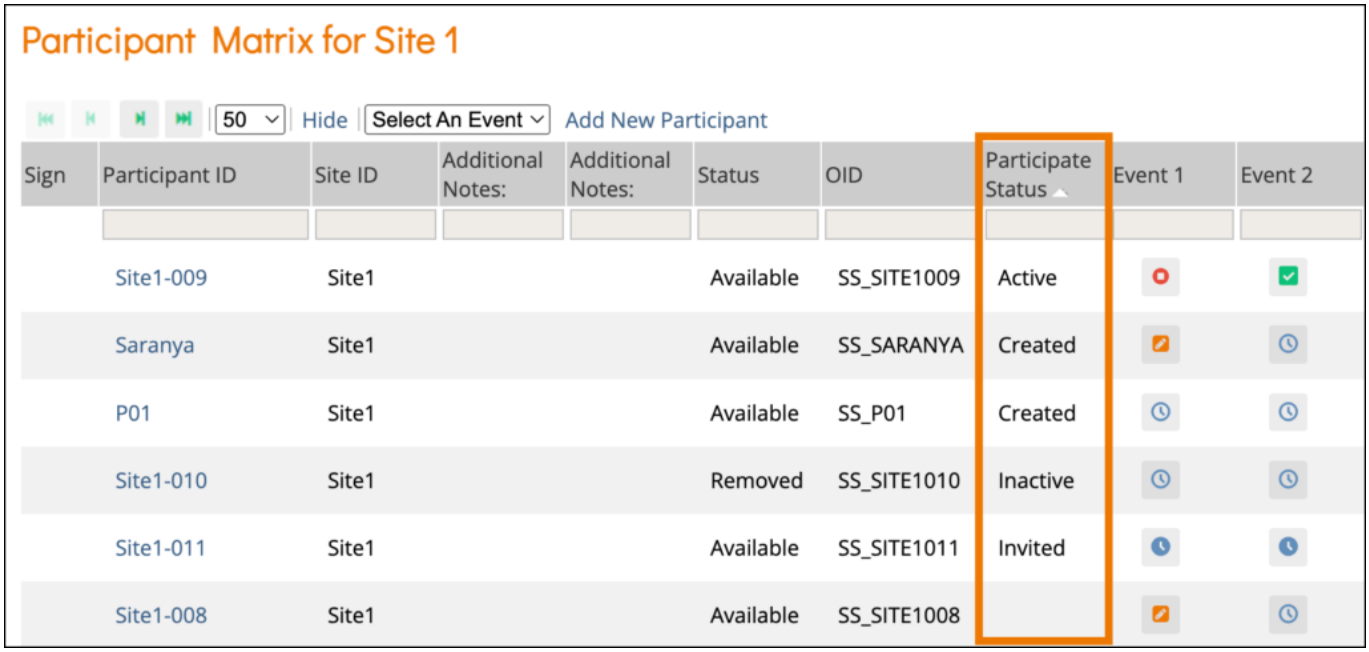
The Participant Status appears on the Participant Details screen and is defined as follows:

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 *No*.
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**.





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.

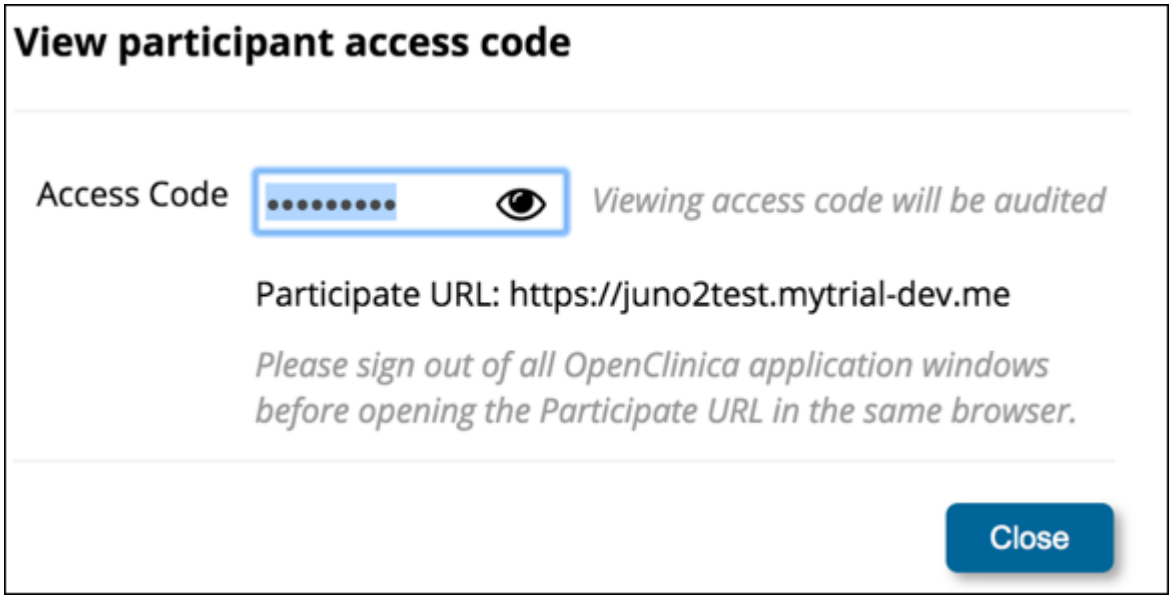
CRCs and Investigators have access to view Participant access codes as long as the Participant has a status of Created, Invited, or Active.

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.



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.

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.

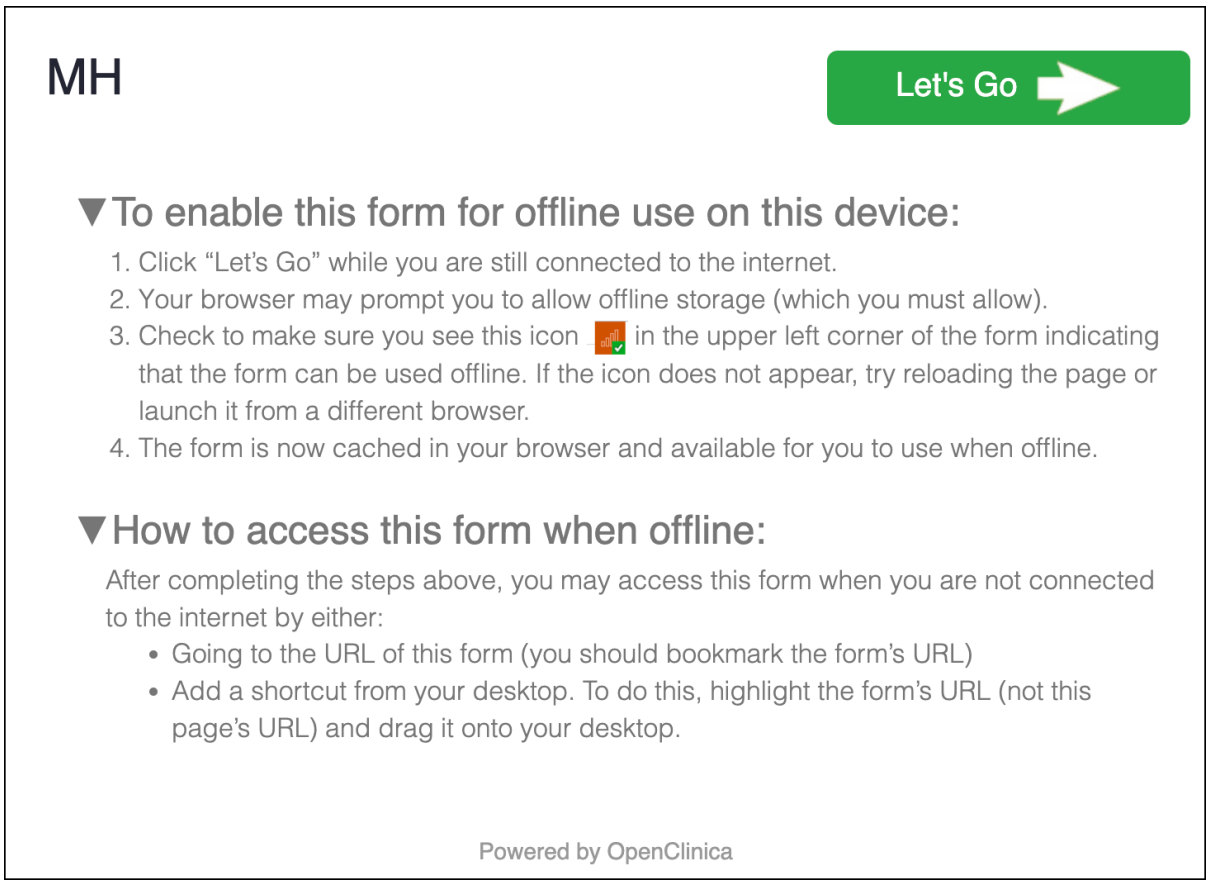
14.3 Using Offline Data Capture

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

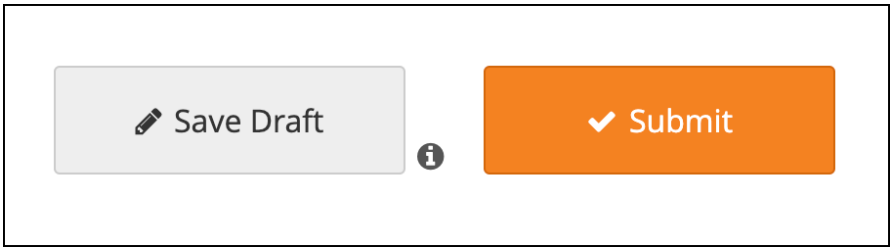
After a form has been configured for Offline Data Capture, it needs to be set up on the device where the data will be captured so it can be used while offline. The URL that was created on the Site Configuration page is what will be used to access the form.

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).



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

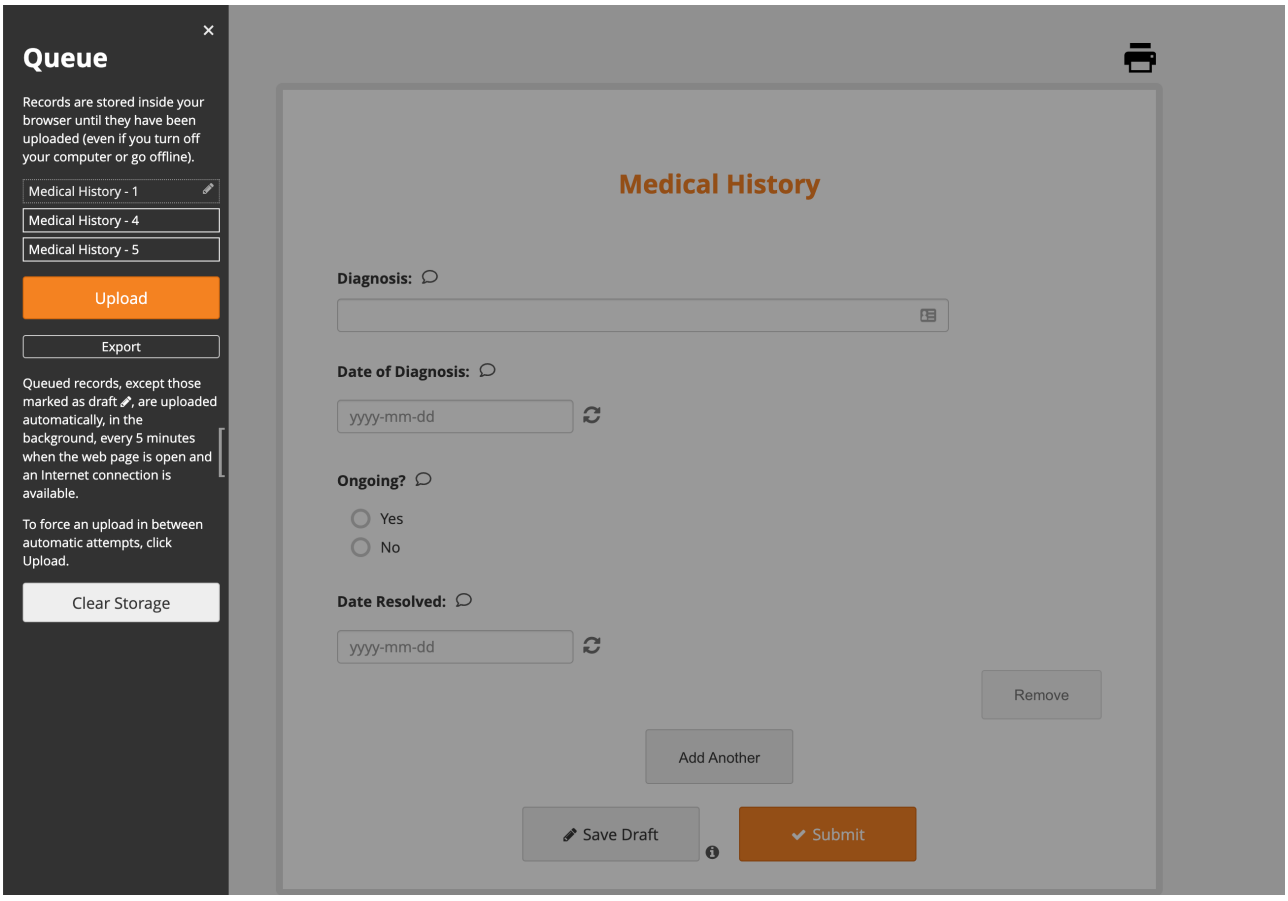
1. Click the form's saved bookmark on your web browser or open the shortcut from the desktop.
2. Enter form data as normal and click **Submit** when done, or **Save Draft** to return to finish the form later.
    a. **Submit** - Queues records to be submitted automatically. The queue is processed in 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 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.



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.

Functional approval by Riley Bianchi. Signed on 2022-06-27 1:10PM

Approved for publication by Paul Bowen. Signed on 2022-06-27 1:16PM

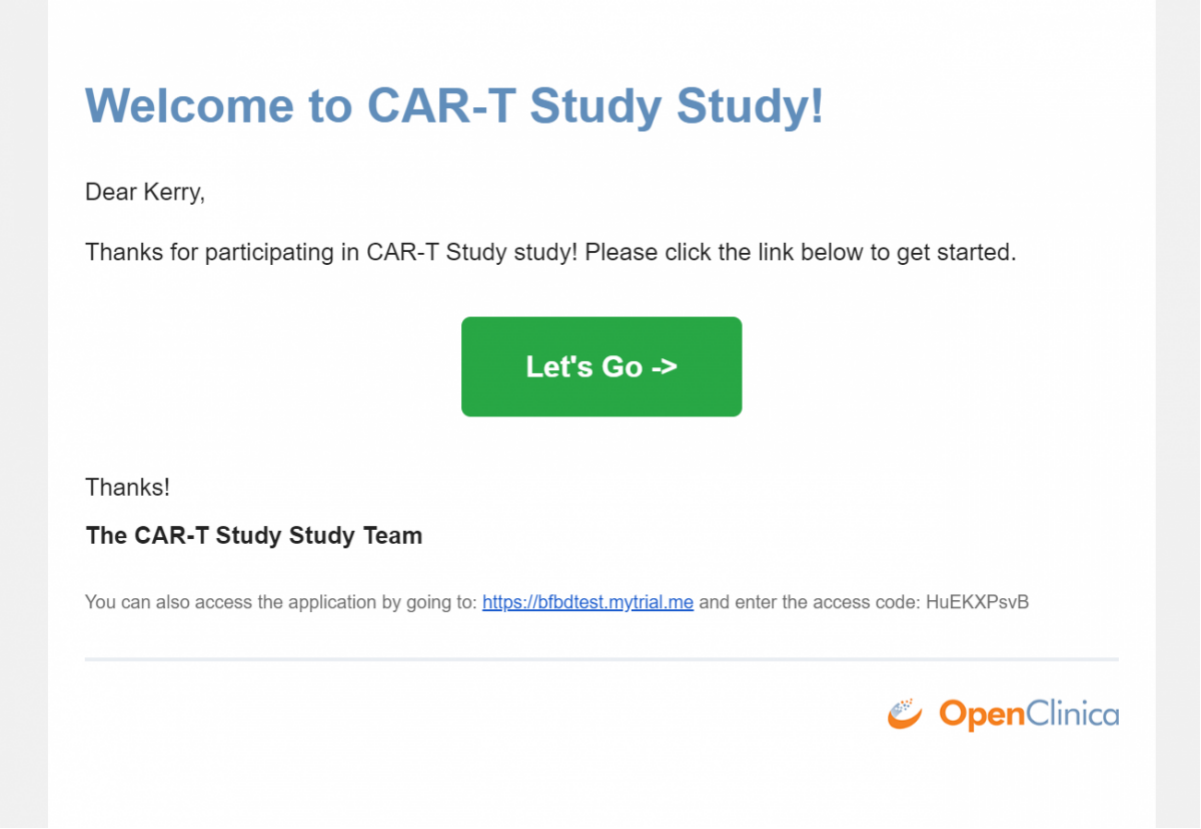
Not valid unless obtained from the OpenClinica document management system on the day of use.

14.4 Participant Data Entry

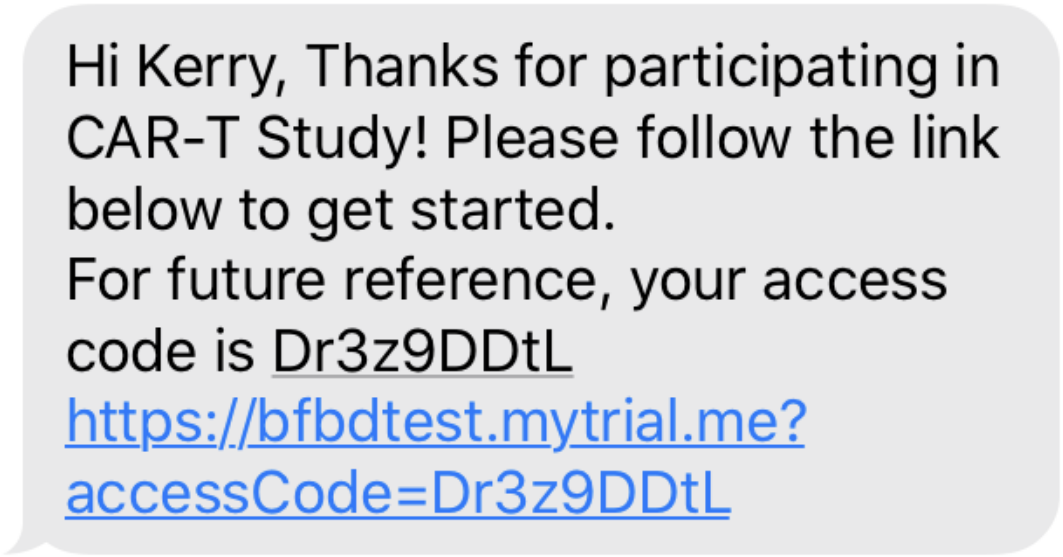
When a Participant is invited to a study, the Participant receives an email notification or text message that provides access to complete their Participate forms.

Getting Invited

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



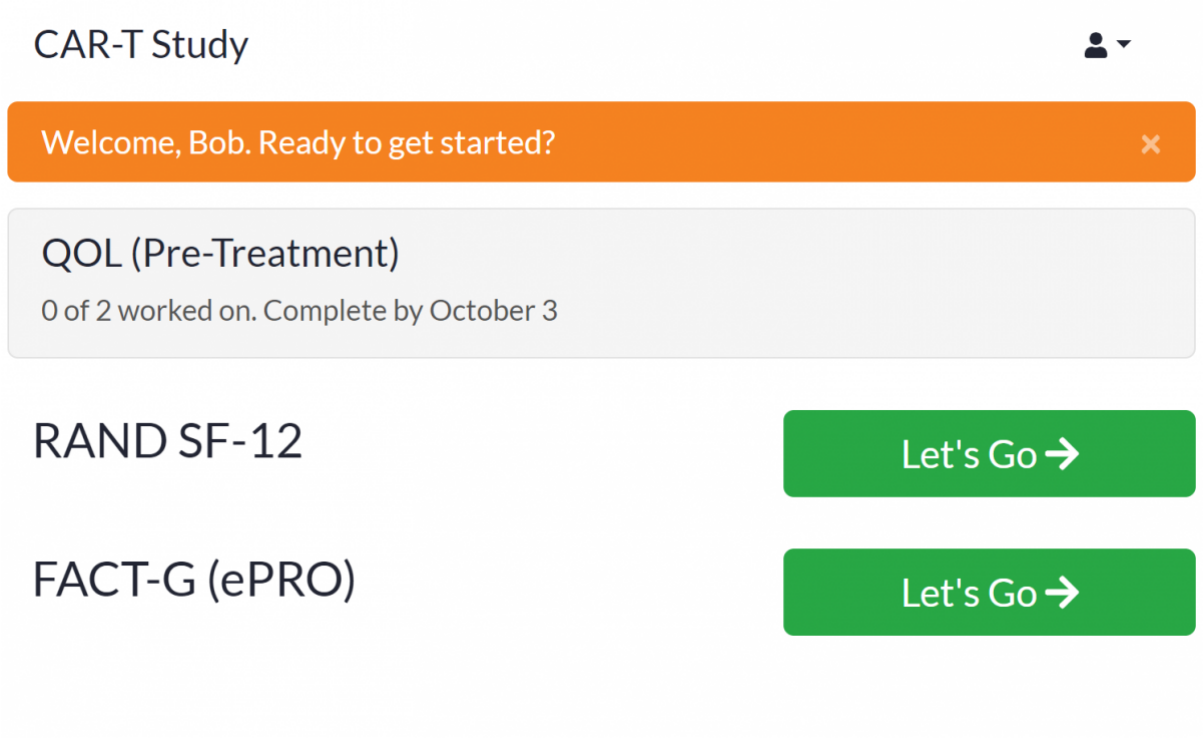
If you selected **Invite via Mobile**, the Participant receives the following SMS text message:



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.*



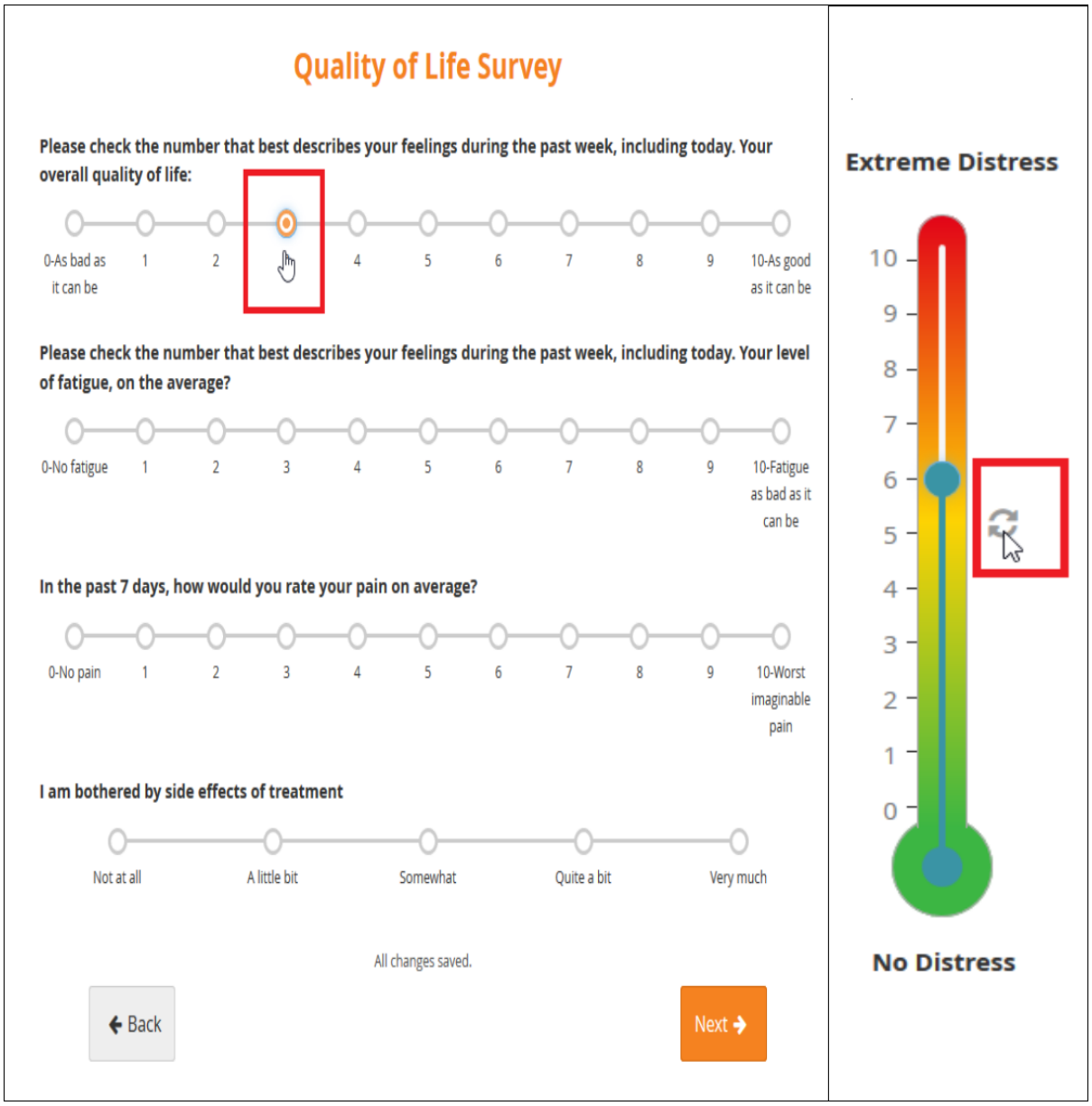
2. Select the Form you want to enter data in.Click the

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*

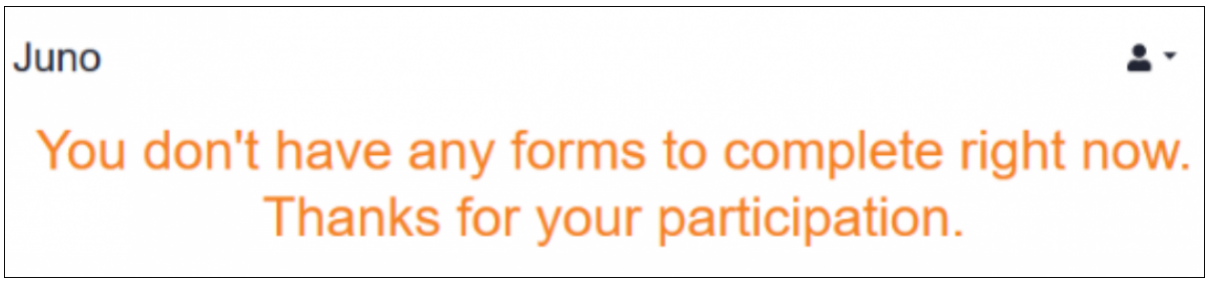
into archived form versions.

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:



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:



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

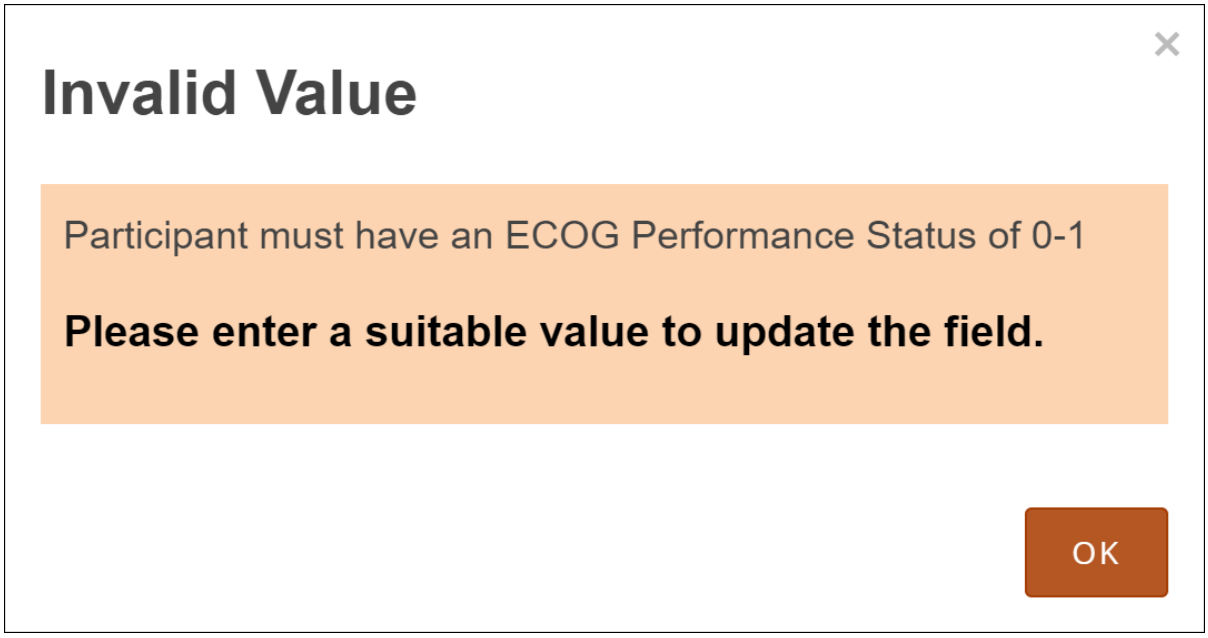
Constraints and Required Fields on Participate Forms

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:

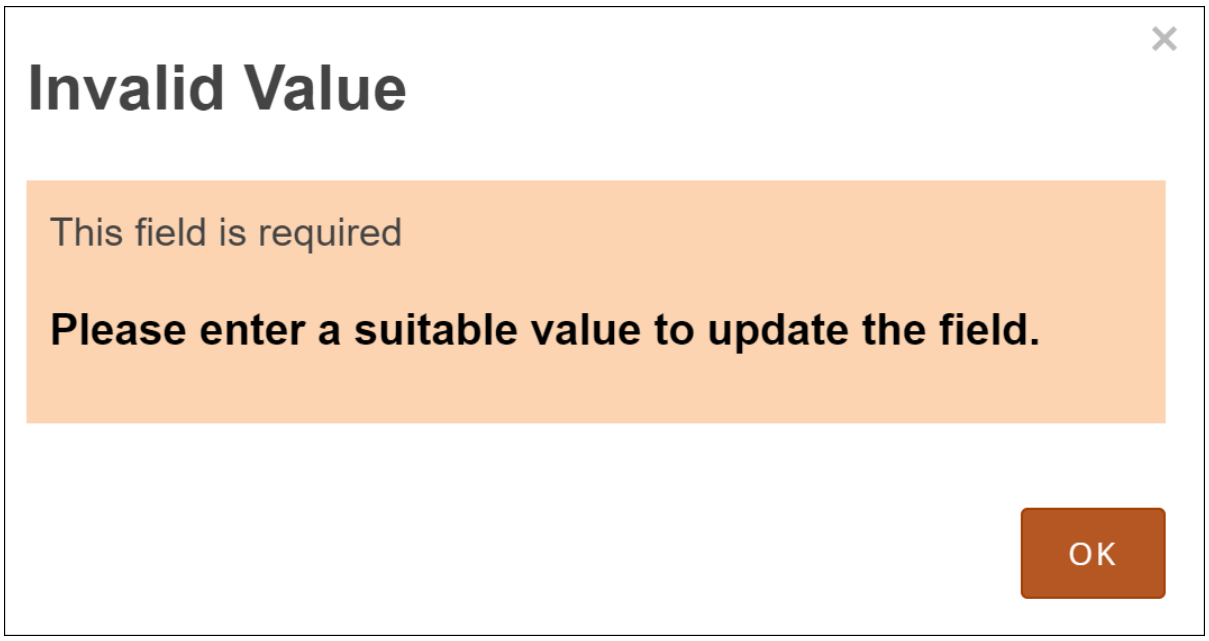
If the Response was Changed to a Value that Fails a Constraint for that Item:

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



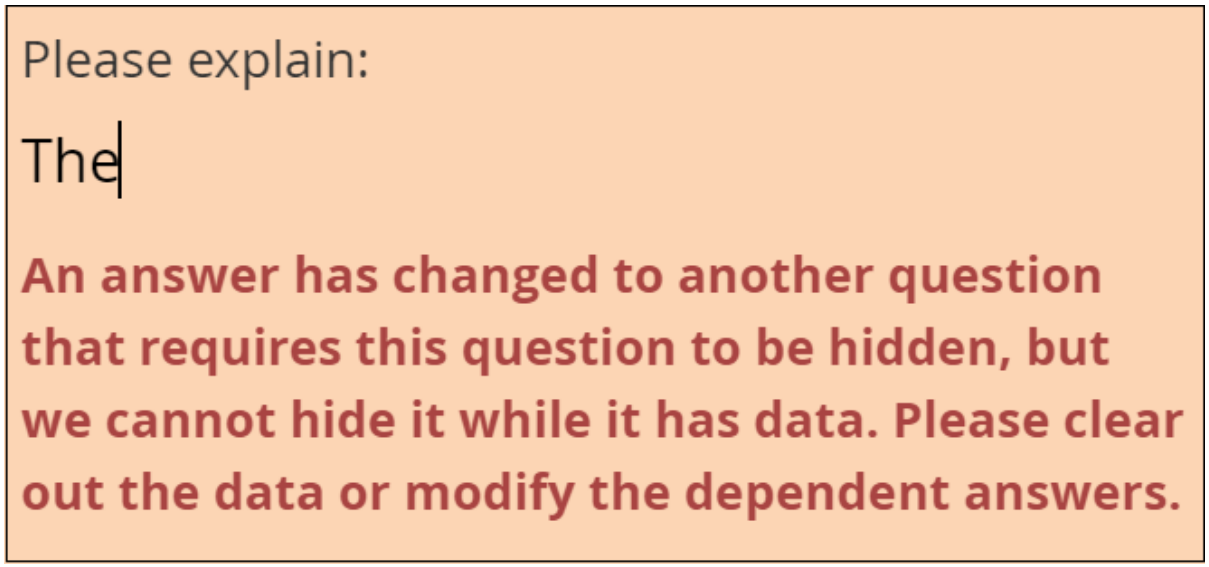
If the Response was Removed, and the Item was Defined as Required:

- 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.



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.



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.

14.5 Participate and the Audit Log

When Participants enter data in a form from the Participant Dashboard, the data that is entered is tracked in the Audit Log and the Participant is listed as the user who performed the action. No personally identifiable information is presented 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 Test environment, Participant OHIO-1705 is identified as: **S_JUNO.TEST.SS_OHIO1705** 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 Event CRF Status
  - When a Participant selects **Let's Move On**, the Event CRF 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

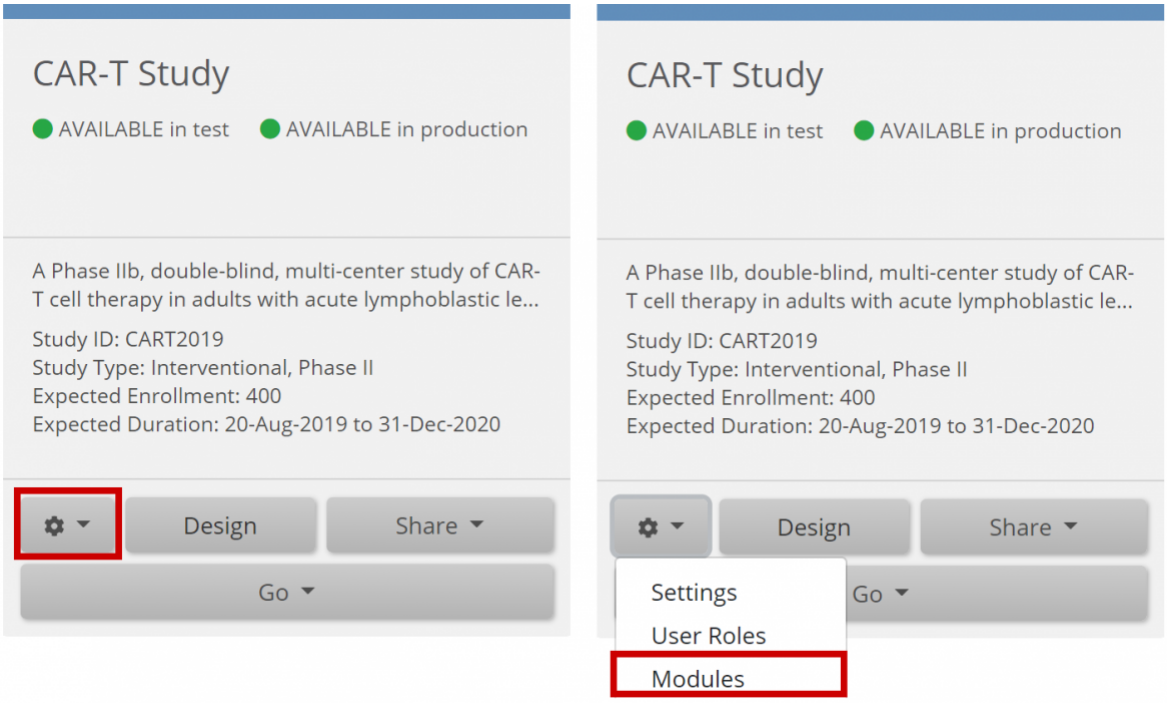
Audit Event	Date/Time of Server	User	Value Type	Old	New
Event CRF marked complete	05-Mar-2020 00:11:05	S_JUNO.TEST.SS_OHIO1705	Status	available	unavailable
Item data value updated	05-Mar-2020 00:10:36	S_JUNO.TEST.SS_OHIO1705	WHITE (1)		2
Item data value updated	05-Mar-2020 00:10:29	S_JUNO.TEST.SS_OHIO1705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

14.6 Activate Participate

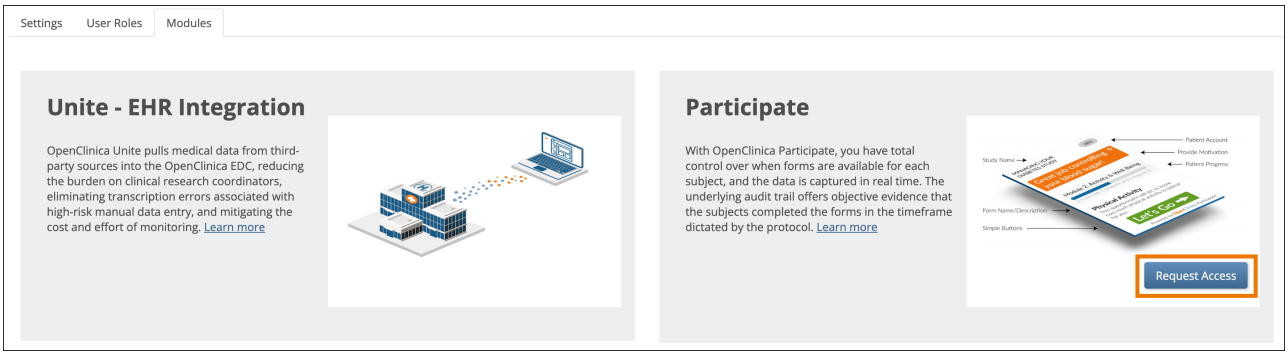
Data Managers can activate Participate. Participate allows participants to enter data into online Forms at scheduled times.

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.



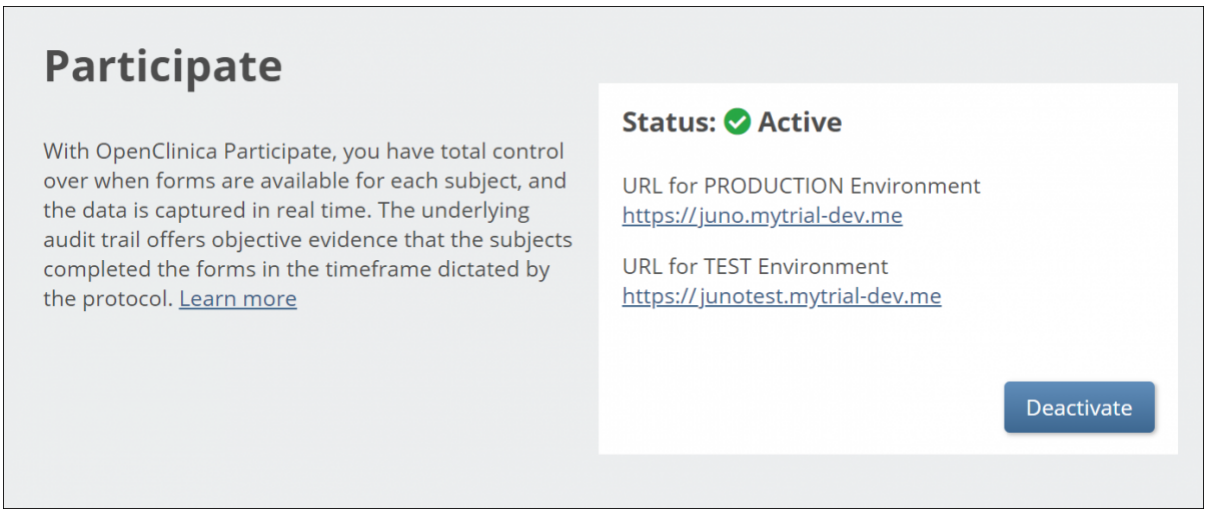
3. Read the instructions in the popup, and provide a subdomain name for your study. The subdomain name can contain letters, numbers, and hyphens (-), but cannot begin or end with a hyphen.

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.



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

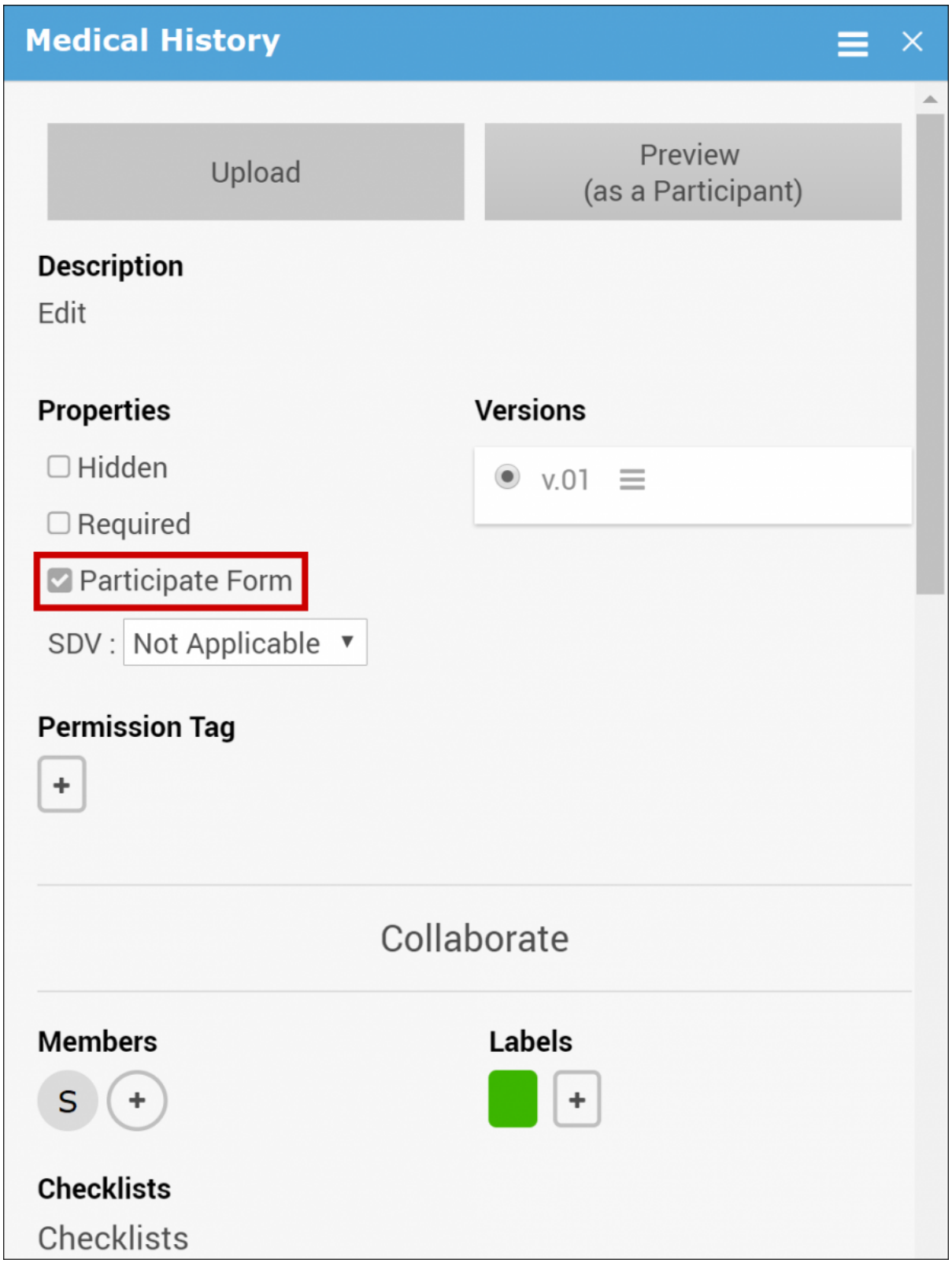
Not valid unless obtained from the OpenClinica document management system on the day of use.

14.7 Design Participate Forms

Once Participate has been activated, Data Managers can designate Forms within Visit-Based Events as Participate Forms. Participate Forms are not available for use in Common Events.

To Make a Form a Participate Form:

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



Tracking Changes to Participate Settings

All manual and systematic changes to Participate Form and SDV settings related to Participate Forms appear in the **Activities** section of the panel on the right that can be expanded by clicking **<**.

Participate Forms and Permission Tags

Permission Tags do not apply to Participants. If a Form is designated as a Participate Form, Participants are able to see that Form, regardless of the Permission Tag to which it is attached.

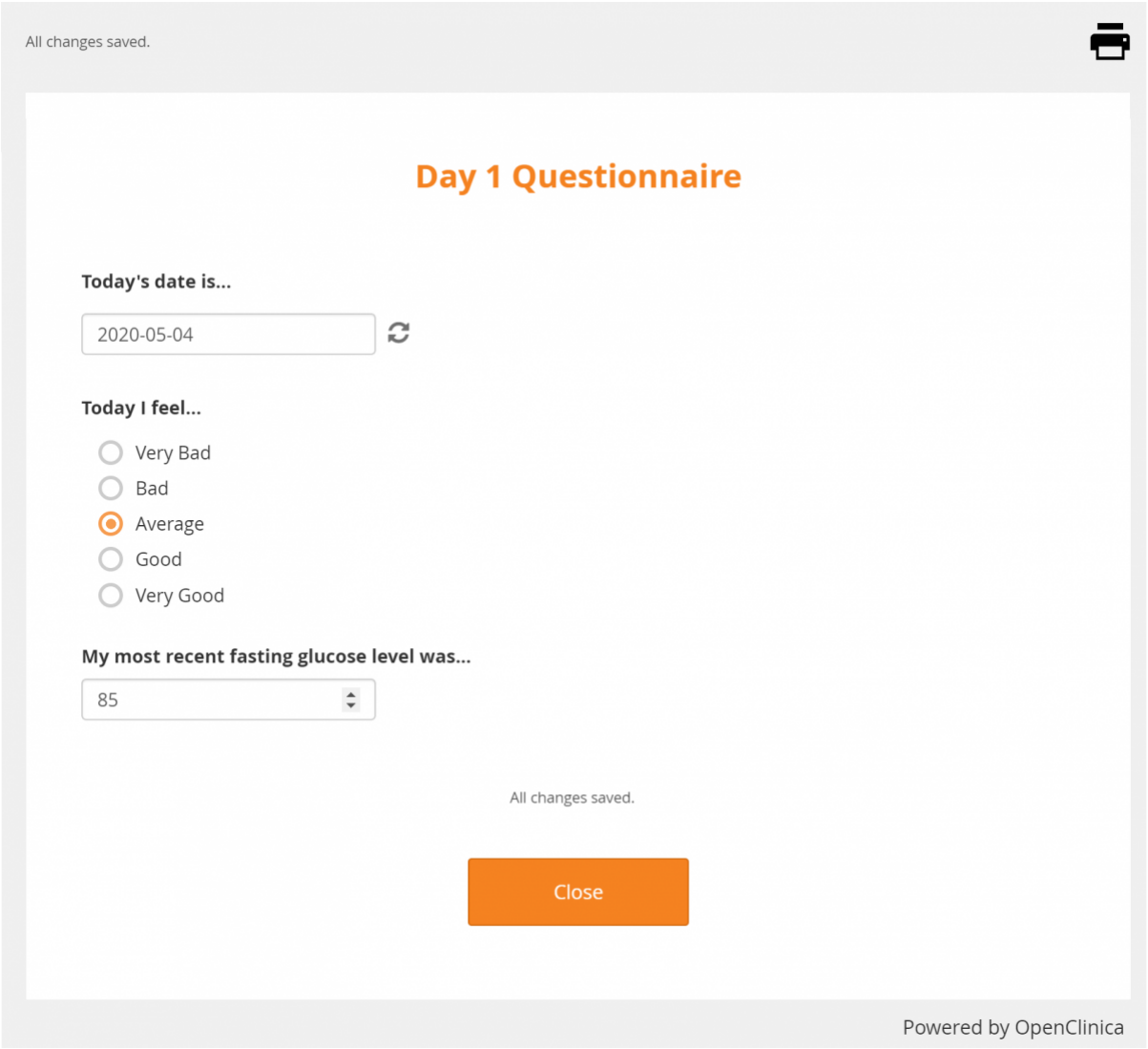
If a Participate Form has a Permission Tag attached to it, only OpenClinica user roles that have been granted access to that Permission Tag (as well as Participants) are able to access that Form.

Using Participate Forms

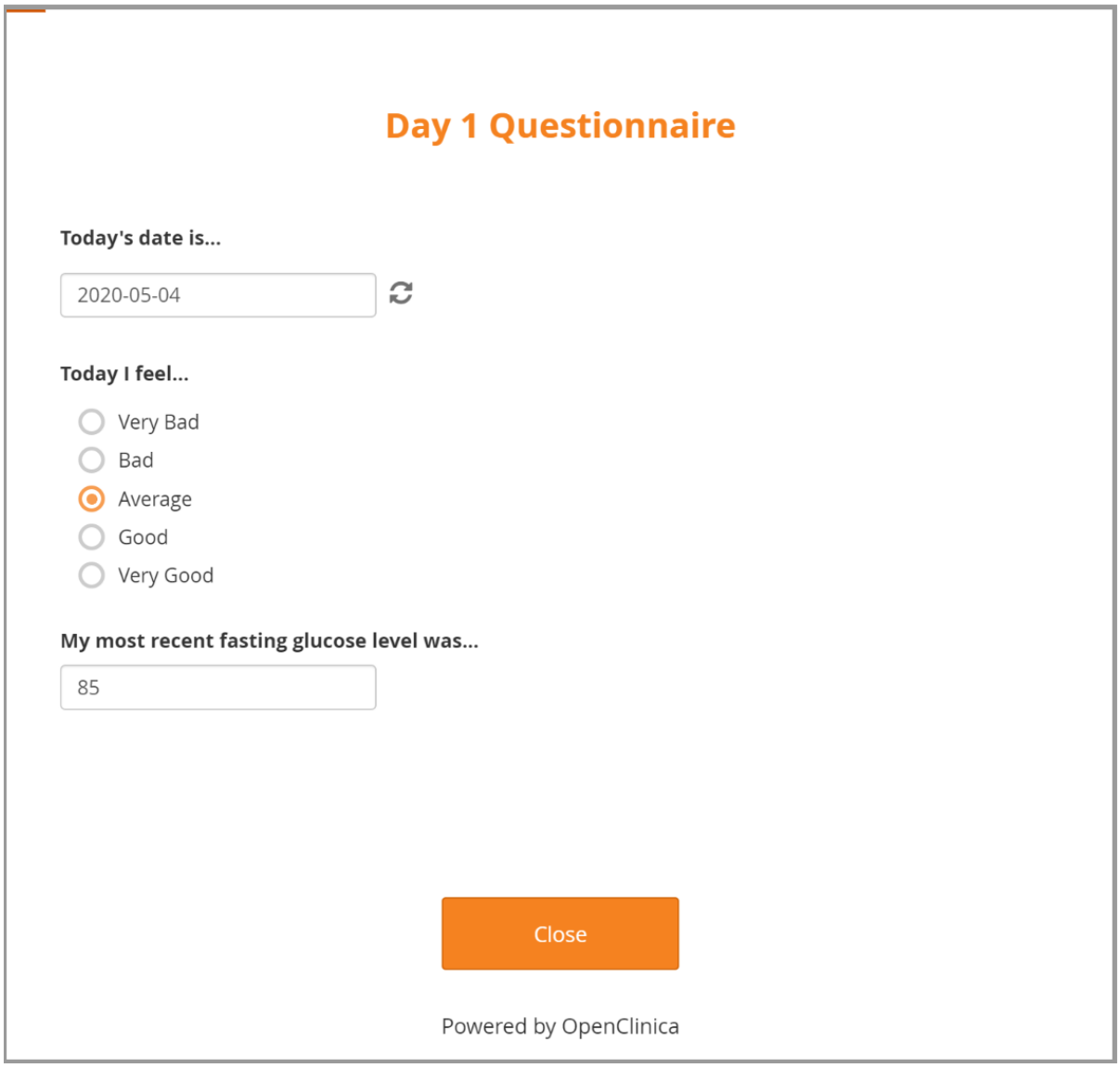
Once Participate is active and Participant Forms have been published, the Participant Form is available for use.

Participate forms can be accessed on a Participants computer, tablet, or smartphone.

Below are Images of a Form on Each Device:



Computer


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

iPad

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

iPhone

Participant Contact Information

Reference the following instructions when inserting Participant contact information fields directly into form. This feature is intended to supplement collection of contact information through the **Participant Details** screen. It allows this data to be captured, displayed, and updated directly on a form, including by Participants accessing the form using the Participate module. Contact data collected on a form is not stored with the rest of the form data but rather with the contact information to enforce access limits by user role.

1. Create a text item in your form.
2. in the **bind::oc:external** cell for that newly added item, select **contactdata** from the drop-down list.
3. Add a column called **instance::oc:contactdata**. Enter one of the following values:
    - **firstname** - to collect first name
    - **lastname** - to collect last name
    - **email** - to collect email address
    - **mobilenumber** - to collect mobile phone number
    - **secondaryid** - to collect an alternate ID
4. The constraint, constraint message, and constraint type will automatically be set by the system to ensure data collected meets system requirements.
5. The item must not have a value entered in the **bind::oc:itemgroup** column.
6. You can define any **label**, **hint**, **relevant**, and **required** fields that you want for the item.

Note:

Only Clinical Research Coordinator, Investigator, and Participant users will be able to open a form using a contactdata item or see data from it in extracts.

It is recommended that **contactdata** items and other data items not be mixed on the same form due to these access limitations.

Mobile phone number is stored internally along with country code (for example **+123 456789012345**). Once a value has been collected, on either the form or from the **Participant Details** screen, it will be displayed in that format with country code (including **+1** before US phone numbers). The form will permit phone number entry in either the **+**, country code, space, and number format or as strictly a 10-digit number that is assumed to be for country code **+1**.