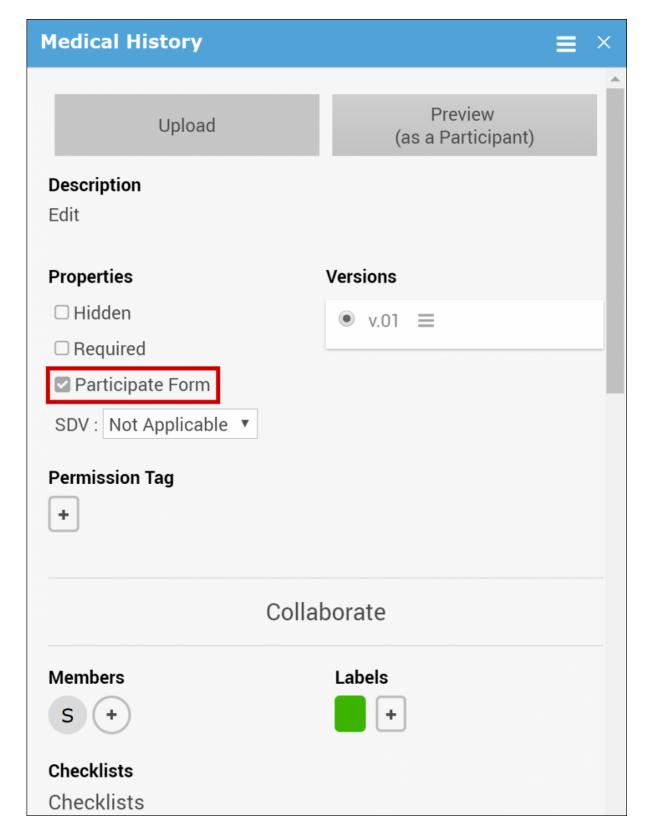


12.7 Design Participate Forms

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.

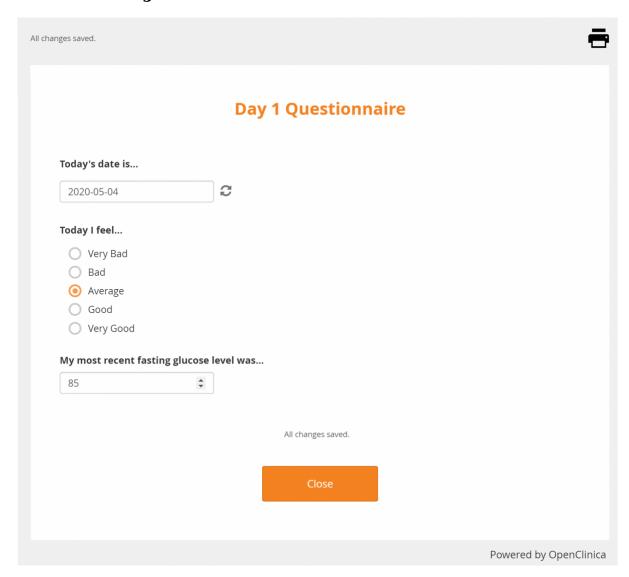
If a Participate Form has a Permission Tag attached to it, only OpenClinica user roles that have been granted access to that Permission Tag (as well as Participants) are able to access that Form.

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 | C | |
| Today I feel | | |
| O Very Bad | | |
| Bad | | |
| Average | | |
| Good | | |
| O Very Good | | |
| My most recent fasting g | zlucose level was | |
| 85 | , | |
| 03 | | |
| | | |
| | | |
| | | |
| | | |
| | Close | |

iPad

| Good Very Good most recent fasting glucose level was | 2020-05-04 | C |
|---|----------------------------|----------------|
| Bad Average Good Very Good most recent fasting glucose level was | day I feel | |
| Average Good Very Good most recent fasting glucose level was | O Very Bad | |
| Good Very Good most recent fasting glucose level was | Bad | |
| Very Good most recent fasting glucose level was | Average | |
| most recent fasting glucose level was | Good | |
| | O Very Good | |
| | ly most recent fasting glu | cose level was |
| | | |
| | | |

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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.

Approved for publication by Kerry Tamm. Signed on 2021-01-19 11:52AM

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