New for All Users

OpenClinica Participate ™ Available for OC4

Participate, OpenClinica's module for ePRO and patient engagement, is available on OC4.
See 'New for Site Users' and 'New for Data Managers' below for information on OC4 Participate.

Enhancements to Security and Authentication

As part of our effort to ensure best-in-class security, OpenClinica has updated its user authentication technology. As a result of this change, upon first login to the Stack 7 release, users will be prompted to reset their password.

New for Site Users

The following features are available only if Participate, OpenClinica's ePro module, has been activated for your study. If you do not see the options listed below, then Participate has not been activated for your study and these features are not displayed.

Invite Participants

Investigators and Clinical Research Coordinators (CRCs) can invite study participants to complete forms that have been defined for Participants to complete (e.g., daily diaries, questionnaires, etc.). Investigators and Clinical Research Coordinators (CRCs) can also view participant access details. These options are displayed on the Participant Details page:

View Access Details

Investigators and CRCs have access to view the Participant's access code. This is sometimes used when Participants are completing forms in the clinic rather than on a personal device.

Note: Access codes should only be viewed if this is defined as an allowable action per your study protocol.

View Participate Status

The status of each Participant is available in the Participant Matrix. Click **Show More**, and the Participate Status column is displayed. To filter the list for a particular status, click the gray filter box and select the relevant status.

The statuses are defined as follows:

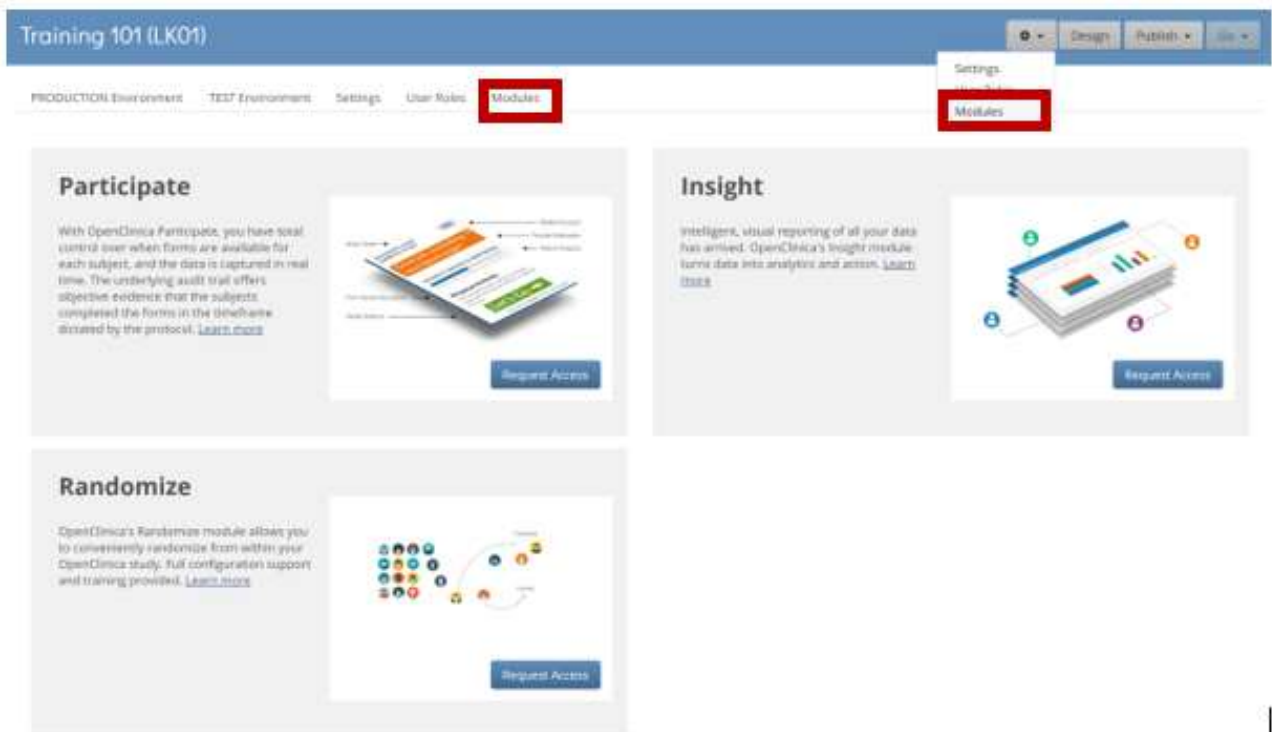| Status	Definition
Active	The Participant has accepted the invitation to participate in the study.
Inactive	The Participant has been removed from the study.
Created	The Participant account has been created, but the invitation to participate has not yet been sent.
Invited	The Participant account has been created and the invitation has been sent, but the Participant has not yet accepted the invitation.

New for Data Managers

Module Management

Manage the add-on modules you use or would like to use for your studies. It's as easy as 1-2-3!

1. Access the **Modules** tab from the **Share** page or from the Modules selection on the gear icon.

2. Determine which module(s) you'd like to activate. Available modules are displayed with descriptions of their functionality.

3. Click **Request Access** to begin the activation process for the specific module or modules that you'd like to use.

The current modules available are:

- **Participate** Design and collect ePro forms in OpenClinica.
- **Randomize** Randomize participants from within your OpenClinica study.
- **Insight** Just-in-time, intelligent, visual reporting. Get listings, graphs, and/or charts of your data with just a few mouse clicks. Schedule automatic delivery of the output to those who need to see it.

Participate Form Features

If Participate is activated, additional features are available for any form in the Design workspace.

- **Properties**: Check the Participate Form box to identify this form as one to be completed by a study participant.

- **Preview**: If a form is identified as a Participant Form:
  - The Preview button changes to allow you to preview the form as a participant.
  - The Version Options allow you to view the form as a Participant or as a study-level user (Preview).

- **Constraints and Queries**
  - Any constraints or required items that are built into Participate Forms are automatically defined as "hard checks." This means that the value must be corrected before the participant can submit the form or move to the next page of the form.
  - Queries are not an option in Participate Forms; the query bubble does not display on these forms.

Reference External Long Lists

For choice lists that are longer than 4,000 characters (or for any choice list), you can reference an external .csv file that contains the list choices (i.e., "label" and "name" in the choices worksheet). This allows you to maintain the choices outside of the OpenClinica form template. Just be sure to upload the external file along with the form template for the list to be available.

Form Template Updates

To accommodate external long lists (mentioned above), a new item type (select_one_from_file) has been added. Use this whenever referencing an external set of choices.

The syntax of the cross-checking examples has been updated to speed up the processing of cross-checks.

A Participant ID lookup example has been added to the cross-checking examples. This allows you to dynamically access the current Participant ID.

Bug Fixes

Several bug fixes have been included in the Stack release.

As always, check the release notes and documentation for more details on all updates.