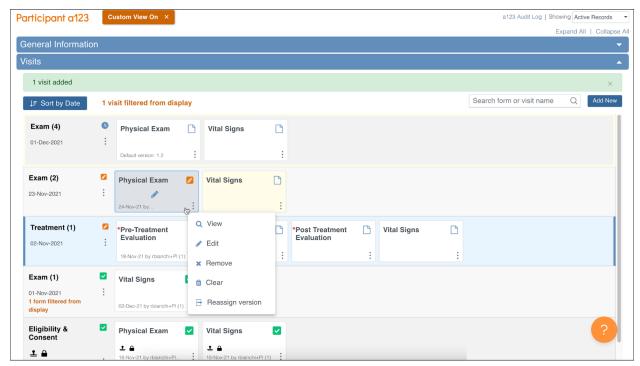
Stack 15 OpenClinica Features

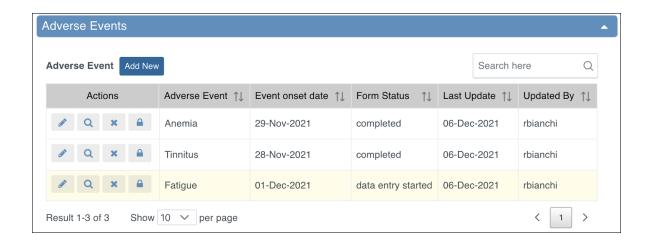
Scheduled Release - December 20th

This release will be deployed from 8:00 PM - 12:00 AM EST (UTC-5). Please note, the OpenClinica system will be down during this time.

Participant Details Page (PDP)

The redesigned Participant Details Page (PDP) provides a more modern, streamlined view allowing more actions within the page, faster loading times, and easier navigation. The visits table and nested table of forms were replaced with rows of visit events (with visit details on the left) and associated form cards going across the row. Form information and actions that were previously in the nested table columns (including statuses and versions) are now displayed directly on the form cards or available in the vertical ellipsis menu (actions). Visit actions are accessed by clicking the ellipsis menu in the left column (below the visit status). Visits are sorted by start date and the page will load directly to the earliest, non-completed visit event. Scrolling up or down in the visits section will load additional visits without page navigation.





Additional features:

- 1. Clicking a form card will open the form. The most recently opened form (Visit or Common Event) will display with a yellow background, bookmarking where you left off.
- 2. Add a new visit without the entire page needing to reload. New visits will have a yellow border around them indicating they are new. Non-repeating visits will no longer display in the options menu once they have been scheduled.
- 3. A red asterisk displays on the required form cards (previously, there was no indicator).
- 4. Forms that a user does not have access to will not be included on the page.
- 5. Removed and Archived Visits will be filtered out by default, aligning with the existing behavior for Common Events. These records can be displayed by using the filter in the top right corner of the page (All Records/Active Records/Removed Records).
- 6. Common Event actions have been moved from the right column to the left column of each Common Event table.

A quick overview of the PDP changes can be found in this video and this overview document.

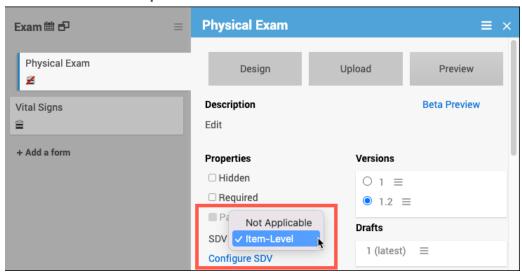
Item-Level SDV:

Study Designer: Item-Level Source Data Verification (SDV) allows Data Managers to specify which items on a form should be verified by setting each item as *Required*, *Optional*, or *Not Applicable* for SDV.

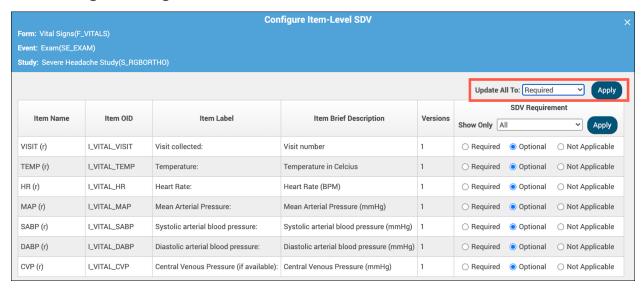
Not all forms will have all SDV Requirements available. The SDV options available are related to when the form was created and published to Production in relation to the Stack 15 release:

- Form already created and published to Production: Not Applicable, Not Required, Partial Required, 100% Required
- Form already created, but not yet published to Production: *Not Applicable, Not Required, Partial Required, 100% Required, Item-Level*
- Form created after Stack 15 is released: Not Applicable, Item-Level

New Item-Level SDV options:

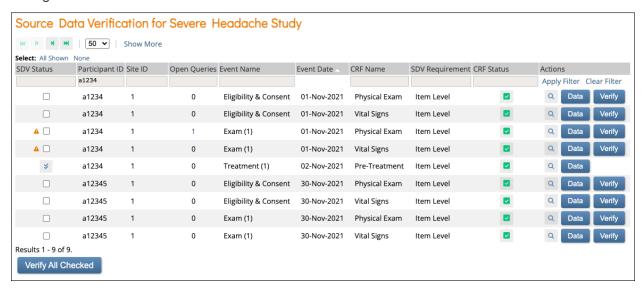


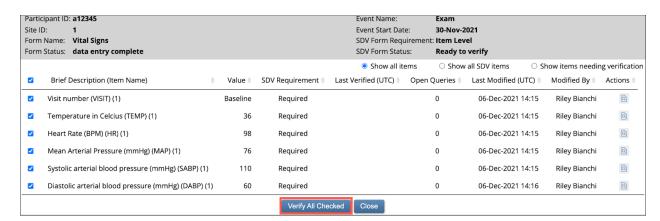
After clicking the Configure SDV link:



Study Runner: For forms configured to use Item-level SDV, a Monitor user can now check off each reviewed item and verify them individually (in addition to choosing to verify an entire form with one click). When all SDV Required items on a form have been verified individually, the form status automatically becomes Verified. Conversely, if a user verifies a form, the verification cascades down to each SDV Required item on the form. When a value is changed after an item has been verified, the item becomes unverified automatically while other verified items on the form retain their status. If the form has verified status when a verified item on it has a value change, the form moves to

Changed Since Verified status.

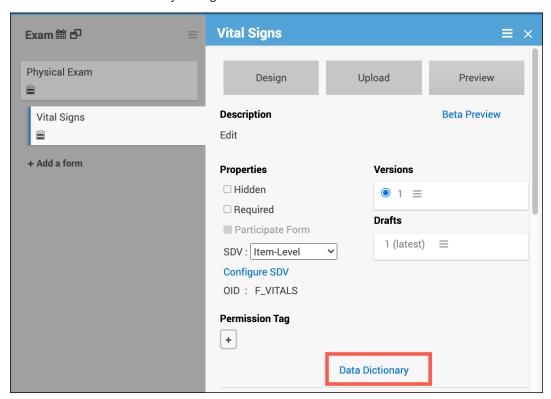


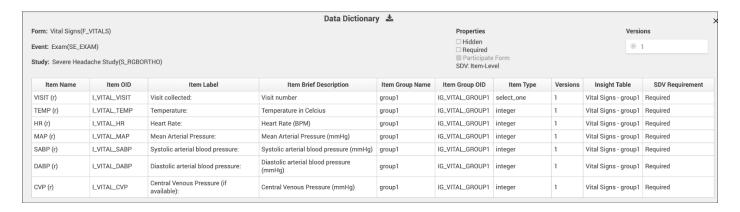


Data Dictionary

The Data Dictionary provides a detailed look at how a form is represented in OpenClinica. This allows users to view information needed for tasks such as writing cross-form logic expressions or Insight Questions and can be accessed before the form has been published. It is accessible via a link on each form card in Study Designer. The Data Dictionary gives the user form-specific information including form metadata, form properties, and item metadata such as Item OID, Item Group Name, Item Group OID, Item Type, and Insight Table. It can also be downloaded as a CSV

file to view outside of Study Designer.





Remove/Restore Common Events and Forms:

When a Common Event is removed or restored, it will now update the corresponding form record accordingly. This was first introduced in Stack 14 for actions performed from Data Review Tables. Now, it will also function the same way for actions performed from the Participant Details Page. Previously, the event record was updated but the form record was not updated. Since Common Events have one form record for each Event record, the new model ensures that status is clear whether looking at event status or form status. Existing form statuses will be updated, if needed, as part of the deployment for consistency across all records.

Performance Improvements, Enhancements, and Bug Fixes:

General performance improvements, enhancements, and bug fixes have been added to OpenClinica.

See full release notes for Stack 15 here.