

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.

Participant a123 Custom View On x

a123 Audit Log | Showing Active Records

Expand All | Collapse All

General Information

Visits

1 visit added

Sort by Date 1 visit filtered from display

Search form or visit name Add New

Exam (4) 01-Dec-2021 Physical Exam Vital Signs













Exam (2) 23-Nov-2021 Physical Exam Vital Signs

Treatment (1) 02-Nov-2021 *Pre-Treatment Evaluation *Post Treatment Evaluation Vital Signs

Exam (1) 01-Nov-2021 1 form filtered from display Vital Signs

Eligibility & Consent 18-Nov-21 Physical Exam Vital Signs

View Edit Remove Clear Reassign version

Adverse Events					
Adverse Event Add New		Search here <input type="text"/>			
Actions	Adverse Event ↑↓	Event onset date ↑↓	Form Status ↑↓	Last Update ↑↓	Updated By ↑↓
   	Anemia	29-Nov-2021	completed	06-Dec-2021	rbianchi
   	Tinnitus	28-Nov-2021	completed	06-Dec-2021	rbianchi
   	Fatigue	01-Dec-2021	data entry started	06-Dec-2021	rbianchi
Result 1-3 of 3 Show <input type="text" value="10"/> per page < 1 >					

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:

The screenshot shows the 'Physical Exam' form configuration page. On the left sidebar, there's a 'Vital Signs' form and a '+ Add a form' button. The main area has tabs for 'Design', 'Upload', and 'Preview'. Under 'Description', there's an 'Edit' link and a 'Beta Preview' link. The 'Properties' section includes checkboxes for 'Hidden', 'Required', and 'SDV'. The 'SDV' dropdown is open, showing 'Not Applicable', 'Item-Level' (selected), and 'Configure SDV'. The 'Versions' section shows version 1.2 as the latest. The 'Drafts' section shows 1 draft.

After clicking the *Configure SDV* link:

The screenshot shows the 'Configure Item-Level SDV' dialog box. At the top, it displays the form name 'Vital Signs(F_VITALS)', event 'Exam(SE_EXAM)', and study 'Severe Headache Study(S_RGBORTH0)'. Below this is a table of items with their SDV requirements. The 'Update All To:' dropdown is set to 'Required' and the 'Apply' button is highlighted with a red box.

Item Name	Item OID	Item Label	Item Brief Description	Versions	SDV Requirement
VISIT (r)	I_VITAL_VISIT	Visit collected:	Visit number	1	<input type="radio"/> Required <input checked="" type="radio"/> Optional <input type="radio"/> Not Applicable
TEMP (r)	I_VITAL_TEMP	Temperature:	Temperature in Celcius	1	<input type="radio"/> Required <input checked="" type="radio"/> Optional <input type="radio"/> Not Applicable
HR (r)	I_VITAL_HR	Heart Rate:	Heart Rate (BPM)	1	<input type="radio"/> Required <input checked="" type="radio"/> Optional <input type="radio"/> Not Applicable
MAP (r)	I_VITAL_MAP	Mean Arterial Pressure:	Mean Arterial Pressure (mmHg)	1	<input type="radio"/> Required <input checked="" type="radio"/> Optional <input type="radio"/> Not Applicable
SABP (r)	I_VITAL_SABP	Systolic arterial blood pressure:	Systolic arterial blood pressure (mmHg)	1	<input type="radio"/> Required <input checked="" type="radio"/> Optional <input type="radio"/> Not Applicable
DABP (r)	I_VITAL_DABP	Diastolic arterial blood pressure:	Diastolic arterial blood pressure (mmHg)	1	<input type="radio"/> Required <input checked="" type="radio"/> Optional <input type="radio"/> Not Applicable
CVP (r)	I_VITAL_CVP	Central Venous Pressure (if available):	Central Venous Pressure (mmHg)	1	<input type="radio"/> Required <input checked="" type="radio"/> Optional <input type="radio"/> Not Applicable

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.

Source Data Verification for Severe Headache Study

50

Show More

Select: All ShownNone

SDV Status	Participant ID	Site ID	Open Queries	Event Name	Event Date	CRF Name	SDV Requirement	CRF Status	Actions
	a1234								Apply FilterClear Filter
<input type="checkbox"/>	a1234	1	0	Eligibility & Consent	01-Nov-2021	Physical Exam	Item Level		DataVerify
<input type="checkbox"/>	a1234	1	0	Eligibility & Consent	01-Nov-2021	Vital Signs	Item Level		DataVerify
<input type="checkbox"/>	a1234	1	1	Exam (1)	01-Nov-2021	Physical Exam	Item Level		DataVerify
<input type="checkbox"/>	a1234	1	0	Exam (1)	01-Nov-2021	Vital Signs	Item Level		DataVerify
<input checked="" type="checkbox"/>	a1234	1	0	Treatment (1)	02-Nov-2021	Pre-Treatment	Item Level		Data
<input type="checkbox"/>	a12345	1	0	Eligibility & Consent	30-Nov-2021	Physical Exam	Item Level		DataVerify
<input type="checkbox"/>	a12345	1	0	Eligibility & Consent	30-Nov-2021	Vital Signs	Item Level		DataVerify
<input type="checkbox"/>	a12345	1	0	Exam (1)	30-Nov-2021	Physical Exam	Item Level		DataVerify
<input type="checkbox"/>	a12345	1	0	Exam (1)	30-Nov-2021	Vital Signs	Item Level		DataVerify

Results 1 - 9 of 9.

Verify All Checked

Participant ID: a12345	Event Name: Exam
Site ID: 1	Event Start Date: 30-Nov-2021
Form Name: Vital Signs	SDV Form Requirement: Item Level
Form Status: data entry complete	SDV Form Status: Ready to verify

☒ Show all items

☐ Show all SDV items

☐ Show items needing verification

<input checked="" type="checkbox"/>	Brief Description (Item Name)	Value	SDV Requirement	Last Verified (UTC)	Open Queries	Last Modified (UTC)	Modified By	Actions
<input checked="" type="checkbox"/>	Visit number (VISIT) (1)	Baseline	Required		0	06-Dec-2021 14:15	Riley Bianchi	
<input checked="" type="checkbox"/>	Temperature in Celcius (TEMP) (1)	36	Required		0	06-Dec-2021 14:15	Riley Bianchi	
<input checked="" type="checkbox"/>	Heart Rate (BPM) (HR) (1)	98	Required		0	06-Dec-2021 14:15	Riley Bianchi	
<input checked="" type="checkbox"/>	Mean Arterial Pressure (mmHg) (MAP) (1)	76	Required		0	06-Dec-2021 14:15	Riley Bianchi	
<input checked="" type="checkbox"/>	Systolic arterial blood pressure (mmHg) (SABP) (1)	110	Required		0	06-Dec-2021 14:15	Riley Bianchi	
<input checked="" type="checkbox"/>	Diastolic arterial blood pressure (mmHg) (DABP) (1)	60	Required		0	06-Dec-2021 14:16	Riley Bianchi	

Verify All Checked

Close

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.

The screenshot shows the 'Vital Signs' form configuration window. On the left, a sidebar lists 'Physical Exam' and 'Vital Signs' (selected). The main area has tabs for 'Design', 'Upload', and 'Preview'. The 'Design' tab is active, showing a 'Description' section with an 'Edit' link and a 'Beta Preview' link. Below this are 'Properties' (Hidden, Required, Participate Form) and 'Versions' (1). A 'Drafts' section shows '1 (latest)'. The 'SDV' is set to 'Item-Level' with a 'Configure SDV' link. The 'OID' is 'F_VITALS'. A 'Permission Tag' section has a '+' button. A red box highlights a 'Data Dictionary' link at the bottom right.

Form: Vital Signs(F_VITALS)
Event: Exam(SE_EXAM)
Study: Severe Headache Study(S_RGBORTH0)

Properties
☐ Hidden
☐ Required
☒ Participate Form
SDV: Item-Level

Versions
1

Item Name	Item OID	Item Label	Item Brief Description	Item Group Name	Item Group OID	Item Type	Versions	Insight Table	SDV Requirement
VISIT (r)	L_VITAL_VISIT	Visit collected:	Visit number	group1	IG_VITAL_GROUP1	select_one	1	Vital Signs - group1	Required
TEMP (r)	L_VITAL_TEMP	Temperature:	Temperature in Celcius	group1	IG_VITAL_GROUP1	integer	1	Vital Signs - group1	Required
HR (r)	L_VITAL_HR	Heart Rate:	Heart Rate (BPM)	group1	IG_VITAL_GROUP1	integer	1	Vital Signs - group1	Required
MAP (r)	L_VITAL_MAP	Mean Arterial Pressure:	Mean Arterial Pressure (mmHg)	group1	IG_VITAL_GROUP1	integer	1	Vital Signs - group1	Required
SABP (r)	L_VITAL_SABP	Systolic arterial blood pressure:	Systolic arterial blood pressure (mmHg)	group1	IG_VITAL_GROUP1	integer	1	Vital Signs - group1	Required
DABP (r)	L_VITAL_DABP	Diastolic arterial blood pressure:	Diastolic arterial blood pressure (mmHg)	group1	IG_VITAL_GROUP1	integer	1	Vital Signs - group1	Required
CVP (r)	L_VITAL_CVP	Central Venous Pressure (if available):	Central Venous Pressure (mmHg)	group1	IG_VITAL_GROUP1	integer	1	Vital Signs - group1	Required

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](#).