7 OpenClinica 4 - Release Notes 2020

OpenClinica 4 Stack 12.2 (Release Date - 20 October 2020)

OpenClinica 4 Stack 12.2 contains targeted fixes to OpenClinica Insight. View the entire **Stack 12.2 changelog here** (login required).

Highlights include:

Changes & Fixes:

- Fixed an issue that could prevent form order from being changed in Study Designer. (**OC-13248**)
- Fixed an issue that prevented archived form versions from being downloaded. (**OC-13112**)
- Updated Event and Form OIDs to be able to be selected and copied from Study Designer cards. (**OC-13153**)
- Fixed an issue that could cause some Event OIDs to be displayed incorrectly in Study Designer. (**OC-13713**)
- Fixed an issue that caused an error when a form was added with the same name as an archived form. (**OC-13090**)
- Fixed an issue that caused the Study Designer scrollbar to behave incorrectly in some cases. (**OC-12896**)
- Improved the UI to make it easier to assign Permission Tags to forms when there are many of them in the study. (**OC-13415**)
- Updated the Archives panel to be more user-friendly. (**OC-13195**)
- Fixed a UI issue with the Participate icon on Form cards. (**OC-13113**)
- Fixed an issue that could cause Study Designer to hang in some cases. (**OC-13623**)

OpenClinica 4 Stack 12.1.1 (Release Date - 09 October 2020)

OpenClinica 4 Stack 12.1.1 contains targeted fixes to OpenClinica Insight. View the entire **Stack 12.1.1 changelog here** (login required).

Highlights include:

Changes & Fixes:

- Fixed an issue with display of public dashboard and pulses in OC Insight. (**OC-13601**, **OC-13616**)
- Fixed an issue where new Study creation could fail if initiated during an Insight refresh in high-volume environments. (**OC-13650**)
- Upgraded Insight user interface to improve security. (**OC-13677**)

Note: Stack 12.1 was reserved and was not deployed to Production environments.

OpenClinica 4 Stack 12.0.4 (Release Date - 29 September 2020)

OpenClinica 4 Stack 12.0.4 contains targeted fixes to OpenClinica. View the entire Stack 12.0.4 changelog here (login required).

Highlights include:

Changes & Fixes:

- Fixed an issue with form rendering that caused note items to be displayed with read-only text fields below them. (**OC-13552**)

OpenClinica 4 Stack 12.0.3 (Release Date - 23 September 2020)

OpenClinica 4 Stack 12.0.3 contains targeted updates to OpenClinica. View the entire Stack 12.0.3 changelog here (login required).

Highlights include:

Changes & Fixes:

- Updated Randomize to allow for future support for multiple randomizations per study. (**OC-13600**)

Note: Stack 12.0.2 was reserved and was not deployed to Production environments.

OpenClinica 4 Stack 12.0.1 (Release Date - 16 September 2020)

OpenClinica 4 Stack 12.0.1 contains targeted fixes to OpenClinica. View the entire Stack 12.0.1 changelog here (login required).

Highlights include:

Changes & Fixes:

- Fixed an issue that prevented Insight from refreshing successfully in some cases. (**OC-13585**)
- Fixed an issue that caused Insight to show incorrect SDV counts in some cases. (**OC-13592**)

OpenClinica 4 Stack 12 (Release Date - 12 September 2020)

OpenClinica 4 Stack 12 contains a variety of enhancements and fixes to OpenClinica. View the entire **Stack 12 changelog here** (login required).

For an overview of this update, view the **Stack 12 Release Announcement here**. Overview videos are also available for the **Status and Signing Updates**, **SDV Updates**, and **Insight Updates**.

Highlights include:

New:

Runtime

- All data has been migrated to a new model for event and form statuses. Instead of a single status describing an event or form, each event and form now has a Workflow status (the data entry status), a Removed status (for events/forms removed for a specific participant), and an Archived status (for events/forms archived in Study Designer). Events also have a Signed status and a Locked status. This model allows for finer control of the status of an event or form as each of these statuses can be in effect independently. For example, an event can be Completed, Signed, and Locked at the same time. If it is unlocked, it will remain Completed and Signed. The UI has been updated throughout the system to show these new statuses together. Workflow status is always included in the UI and separate icons are used to indicated Signed, Locked, and Archived statuses (if applicable). When an event or form is Removed, the Removed status indicator is shown in place of the Workflow status indicator. If a form is currently using a form version that is archived, that is also indicated by an Archived icon next to the form version ID. New action icons have been added to the Participant Details Page for Sign, Lock, and Unlock. These actions can also still be performed from the Update Study Event Page.

The auditing system keeps track of each of these changes distinctly to ensure a clear audit trail. Existing audit records remain unchanged. The signature model also enforces more consistent rules about when an event or participant can be Signed and about which actions and status changes invalidate a signature.

The old status model is still available in ODM casebooks and extracts and in Insight. Support will be maintained for this for at least 3 months to allow for a transition period to the new model for existing questions in Insight and external uses of the ODM.

- Added a new SDV status, Changed Since Verified, to be used for forms that have been automatically un-verified due to a change in their data after verification. The existing Boolean SDV statuses have been renamed to Verified and Not Verified. The SDV Forms table has been updated to reflect these new statuses (with Not Verified forms found by filtering to Ready to Verify). SDV status is now available in the ODM as a form attribute.

The SDV Forms table has been updated with more information such as number of Open Queries per form. If there are any open queries, this value is a link to view those queries. The existing columns have been updated to allow more to be filtered. The new event and form status model has been incorporated into the Form Status and Event Status columns.

Added an Item Details table accessible for each form in the SDV interface. The Data button on each row of the SDV Forms table opens the Item Details table. This allows the user to view a table with

item-level details for each item on a form. This includes current value, number of open queries, and last modified date for each item. There is a filter to toggle between seeing all items and seeing only those items that have been modified since the form was last verified.

- Added ability for Admin users to schedule dataset extracts to run as jobs automatically on a daily, weekly, or monthly basis at a user-defined time. After the scheduled extract job runs, the dataset file is available to download from the Datasets page along with manually created extract files. Added new APIs to allow users to retrieve a list of extract files from scheduled jobs and then retrieve a specific extract file from the server. This new feature is accessed from the Jobs link on the Tasks menu.
- Added support for importing data from flat, tabular data files (XLS, CSV, TXT, SAS) in addition to the existing ODM XML import functionality. A data file is uploaded along with a configuration file that specifies the mapping of the data file to the items on a form. It also includes other options such as the delimiter to use (for .txt files only), the column in the data file that maps to Participant ID, and a Skip Match feature that can prevent the import of duplicate data. This new feature is accessed from the Import Data link on the Tasks menu. This link now leads to a landing page that allows the user to choose between XML Import and Tabular Import.

Changes & Fixes:

Study Build System

- Improved performance of Table Design interface in Study Designer so that it could be opened for large studies without failing. (**OC-11727**)
- Added ability to search the Administration People table by username, email address, first name, or last name. (**OC-9076**)
- Updated the text layout in the Invite New User dialog to make it easier to read. (**OC-12811**)
- Resolved an issue where sites might not be displayed in Study Manager in some cases. (**OC-13371**)
- When searching for an existing user, if the administrator chooses to create a new user, the search term used will now be automatically populated in the username and email address fields of the new user creation form. (**OC-12812**)
- Fixed an issue where the titles for Study environments on the My Studies page were being displayed in a way that made it easy to confuse the statuses for the Production and Test environments. (**OC-12130**)

Runtime

- Added links to each of the main Study Build System pages to the header of Runtime. Now users with access to the Study Build System can go directly from Runtime to the Study Design, Settings, and Share pages for the current Study in one click. (**OC-12802**)
- Updated the Participant Details Page Visits Table filter to search for events based on the entire string, not matching on any word. (**OC-12823**)
- Fixed an issue where a user would see an empty Common Event header on the Participant Details page if they had no access to forms within it due to permission tag assignments. (**OC-12889**)
- Updated the Participant Details Page Casebook checkbox text to make it clear that archived and removed data would be included or excluded together. (**OC-13381**)
- Fixed an issue where Common Event forms could not be removed or restored for Signed Participants. (**OC-12685**)
- Fixed an issue where Common Event forms could not be added for Signed Participants.

(**OC-12715**)
- Updated the event and form context popups on the Participant Matrix to automatically close if a different popup is opened. (**OC-12668**)
- Fixed an issue where the Restore action was not accessible for Removed forms from the Participant Matrix. (**OC-12118**)
- Added Event Start Date to the Participant Matrix context popup for non-repeating events. (**OC-12881**)
- Fixed an issue where column filters would stop working on the Participant Matrix after it had been filtered to show only a single Event. (**OC-13137**)
- Fixed an issue where the Participant Matrix would sometimes show archived events after it had been filtered to show a single event. (**OC-12888**)
- Improved performance of loading the Participant Matrix when custom columns are in use. (**OC-12814**)
- The headers of PDF Casebooks will now include the name of the participant's site. (**OC-12169**)
- Improved the layout of PDF Casebook headers and footers. (**OC-12076**)
- Added an option to the Bulk Actions Log that allows viewing of error messages for failed Casebook generation. (**OC-12107**)
- Fixed an issue where the Bulk Actions Log would display the wrong end time for Casebook generation jobs. (**OC-12370**)
- Added the date and time created to the footer of PDF Casebooks. (**OC-12168**)
- Fixed an issue where PDF Casebook headers would fail to display some information on Events when the study name was too long. (**OC-12106**)
- Text cells in PDF Casebooks will now expand correctly to fit long text entries. (**OC-12474**)
- Fixed an issue where PDF Casebooks for Signed participants would exclude audit log information. (**OC-12680**)
- Fixed an issue where editing large dataset definitions could sometimes lead to some items being omitted. (**OC-12939**)
- Fixed an issue where some form data added after closing a query on an item could be missing from extracts. (**OC-12573**)
- Fixed an issue where queries were not included in extracts if the associated item's value was null. (**OC-12457**)
- Updated the extract job completion notification email to include the study context of the extract job so that the user would always be taken to the correct file when using the link in the email. (**OC-11634**)
- Fixed an issue where adding all items in a large study to a dataset could sometimes lead to some items being omitted. (**OC-12542**)
- Fixed an issue where extracts did not include a given form record if the form had been started but all items were null at the time of the extract. (**OC-13145**)
- Fixed an issue where the logs for a data import could erroneously duplicate the logs of a prior data import. (**OC-12060**)
- Updated the XML Import Template to remove confusing references to a FormLayout Ref OID. (**OC-12977**)
- Added a new landing page to allow access to both the XML and Flat File import pages. (**OC-13104**)
- Fixed an issue where data in an occurrence of a repeating common event could not be updated if those data were originally attempted to be added through a failed import. (**OC-12136**)
- Fixed an issue where attempting to import data of an unsupported type to a field could erroneously update the associated Event's status. (**OC-11814**)
- Updated the XML Import template to reflect the latest updates to the system. (**OC-13041**)
- Updated the SDV Forms table to have separate columns for Form Name and Form Version. (**OC-12252**)

- Updated the text on bulk action button on the SDV Forms table to "Verify All Checked" for consistency with the other updates. (**OC-13045**)
- Updated the left side panel for the SDV Forms table to be more user-friendly. (**OC-12251**)
- Updated the display in the Event Name column of the SDV Forms table to be more user-friendly for forms in repeating events. (**OC-12254**)
- Updated the Last Updated Date and Event Date columns to be sortable on the SDV Forms table. (**OC-11531**)
- Updated SDV Forms table to have a column for the count of Open Queries and a link to those queries if any exist. (**OC-12205**)
- Fixed an issue where the SDV page would sometimes show a confirmation prompt before telling a user they did not have access to Verify a record. (**OC-9573**)
- Fixed an issue where the SDV page might silently fail an action rather than alert the user that they don't have access to a record. (**OC-11756**)
- Updated signature logic to remove an event signature if a form in the event is removed or restored. (**OC-10309**)
- Updated signature logic so that changing the event to Locked or Unlocked will leave the event's signature in place. (**OC-12655**)
- Updated signature logic so that changing an event's workflow status will remove the event's signature. (**OC-13296**)
- Updated signature logic so that marking an empty form Complete will not remove the signature of the event it is in. (**OC-12656**)
- Updated signature logic so that archiving or unarchiving a form that has been started in an event will remove the signature of the event. (**OC-13188**)
- Updated signature logic so that events and participants are not blocked from being signed due to removed forms (unless they are required), archived forms, archived events, or removed events. (**OC-12761**)
- Updated signature logic for signed Participants to match logic implemented for signed events. (**OC-12654**)
- Updated to allow events that are removed and locked to be able to be unlocked so that they can be updated further as needed. (**OC-13202**)
- Removed the option to Delete Visit-based Events. (**OC-12831**)
- The action to Delete a form record has been renamed to Clear to reflect its functionality of clearing the item data from a participant form record while leaving the record itself intact. (**OC-12821**)
- Clearing a form will update the form Workflow status to Not Started instead of Initial Data Entry. (**OC-12507**)
- Fixed an issue where audit log entries would not make sense when an event was removed. (**OC-9200**)
- Updated the icon key throughout the system to include all the new statuses and actions. (**OC-13037**)
- Updated the event Workflow status dropdown selector on the Update Study Event page to prevent events from being changed between incompatible statuses. (**OC-10027**)
- Fixed an issue where audit log entries were not user-friendly when an event was removed or stopped. (**OC-8416**)
- Fixed an issue where audit log entries were not user-friendly when changing the status of a Locked event. (**OC-11161**)
- Fixed an issue where audit log entries were not user-friendly when restoring a completed event. (**OC-10126**)
- Fixed issues where audit entries were not being added when events were scheduled, forms were removed, or Participants were removed. (**OC-10128**)
- Fixed an issue where restoring a removed Participant was changing the Workflow status of

some forms. (**OC-9686**)
- Fixed an issue where Locked events could be removed from the Participant Matrix. (**OC-13433**)
- Updated signature message shown when viewing forms that are removed or archived but in a signed event to make it clear that the signature does not apply to these forms. (**OC-13392**)
- Updated event status filters on Participant Matrix and View Events page to include Not Signed and Not Locked options. (**OC-13311**)
- Updated Participant Matrix status display for repeating events to show the Workflow status of the event repeat that is furthest from completed status rather than just showing the status of the first event repeat. (**OC-12784**)
- Updated the instructions on the Remove/Restore Event/Form pages to make it clear that these actions will remove signatures. (**OC-13215**)
- Fixed an issue where a form could fail to render, and cross-form references within the form fail to work if item data in the form contained an emoji. (**OC-12044**)
- Fixed an issue where generating an ODM casebook would fail if item data in a record contained an emoji. (**OC-12955**)
- Updated the CRF Details page to more clearly label the Form OID, Version OID, Item Name, and Item OID fields. (**OC-13126**)
- Updated the success message when signing a participant to indicate which participant is being signed. (**OC-12699**)
- Fixed display and text-justification issues on the View Item Details page. (**OC-12813**)
- Fixed an issue where CRC users could sometimes erroneously access the option to migrate a form version, which would fail. (**OC-12979**)
- Updated styling on various pages to account for recent changes in the Chrome web browser that had changed OpenClinica's intended appearance. (**OC-13156**)
- Updated the form metadata page to label some OIDs and attributes of forms more clearly. (**OC-13125**)
- Fixed an issue where the link to access the Bulk Action Log would not be available to Monitors. (**OC-12618**)
- Fixed an issue where the audited event of creating a participant was appearing twice in audit logs. (**OC-11408**)
- Removed the ability to view some deprecated pages. (**OC-13287**)
- Fixed an issue where the name of a participant's site would not appear on the confirmation page when removing them from the study. (**OC-13414**)
- Fixed an issue where locked, frozen, or 'in design' studies could have the option to add new Common Events. (**OC-13306**)
- Improved performance of loading the Enter or Validate Data page. (**OC-12665**)
- Fixed an error that could occur when adding a query to Event Start Date or End Date fields. (**OC-12342**)
- Updated Quicks Links section of the left panel to be expanded by default to make the Queries Assigned to Me link visible. (**OC-10729**)
- CSV exports of Queries will now include both parent and child Queries. (**OC-12155**)
- Fixed an issue where CSV Query exports could have NULL as the status for Closed-Modified Queries instead of their actual statuses. (**OC-13009**)
- The printer-friendly version of the Queries page was omitting Event Name, Event Date, CRF, Item Name, and Item Value. This has been fixed. (**OC-12154**)
- Fixed an issue where item value filters on the Queries table could fail to work. (**OC-12421**)
- Fixed an issue where Item Name filters on the Queries table for Event Start Date or End Date could fail to work. (**OC-11584**)
- Fixed an issue where a Notification Rule could fail to send an email as expected. (**OC-12248**)
- Fixed an issue where users attempting to view Casebooks with the option to include metadata

enabled could encounter an error if the study had rules enabled. (**OC-12679**)
- Fixed an issue where a link to download rules would appear even if the study was not using any rules. (**OC-11957**)

Forms

- Fixed an issue that could allow data to be submitted from forms that loaded with an error. (**OC-12869**)
- Fixed an issue where item history on forms might display a history entry twice when the form is opened. (**OC-12919**)
- Fixed an issue where downloading files that had been uploaded to the server always resulted in a failure message. (**OC-12544**)
- Updated the download button for file items to have descriptive hover text with instructions to use right click and save as to download the file. (**OC-13135**)
- Fixed an issue where repeating groups using the repeat_count parameter did not work correctly if the repeating group were nested in a non-repeating group that had a relevant expression. (**OC-12362**)
- Fixed an issue where select items would show an error message after becoming irrelevant and then being cleared. (**OC-13180**)
- Improved performance of opening forms, especially when opening existing forms that already contain data. (**OC-13141**)
- Updated image map items on forms to respect the sizing parameters defined within the SVG image file. (**OC-12791**)
- Fixed an issue where image upload to annotation widget was failing. (**OC-12013**)
- Fixed an issue where the Query Widget layout was broken for selection items using columns appearance. (**OC-12232**)
- Updated so that bullet points could be rendered in the first line of item label text. (**OC-12498**)
- Updated the Query Widget on forms to only allow Data Manager and Monitor users to reopen closed queries. (**OC-12770**)
- Fixed an issue where the default query assignee when responding to a query was not set as expected. (**OC-9069**)
- Fixed an issue where complete forms with calculated items could prompt the user to enter a Reason for Change when the form was reopened. (**OC-12920**)

Insight

- Updated the Insight user interface, adding a revamped interface and navigation, a new Question Builder with the ability to join tables, custom columns, and improved collection management. (**OC-13361**)
- Updated Insight's Audit Log Event table for compatibility with new Audit Log Event Types in OpenClinica. (**OC-12305**)
- Insight environments with large numbers of studies (around 20 Studies) with large amounts of metadata will see substantial improvements in load times and refresh times. (**OC-12299**)
- Insight's SDV status columns will now contain text values of Verified, Not Verified, Changed Since Verified, or Never Verified, instead of the previous Boolean true/false values. (**OC-12340**)
- The Item table in Insight will now contain the description (bind::oc:description) and brief description (bind::oc:briefdescription) fields as defined in the associated form. (**OC-12858**)
- Fixed an issue where changing URL parameters when loading a form could create an invalid record in the database that may interfere with Insight refreshes. (**OC-12535**)

Participate

- Fixed an issue where events that had been Skipped and were changed to Data Entry Started would not appear on the Participate Dashboard. (**OC-9948**)
- Fixed an issue in Participate notification links where a missing slash caused some older devices to fail to take the participant to the link. (**OC-12934**)
- Updated the country list when assigning participant phone number to include Norway and Finland. (**OC-12787**)
- Updated the SMS messaging service to be able to send messages to participants in any country. (**OC-12819**)
- Updated Participate invitation messages to be split into two messages to ensure that the direct access link was not split between messages on some devices or providers. (**OC-12649**)
- Fixed an issue where participants would see a blank screen if they used the browser Back button from within a form. (**OC-10084**)
- Fixed an issue where a participant's status would be set to invalid if a CRC entered their contact information before they are registered in Participate. (**OC-11101**)

REST API

- Removed access to Get Participant APIs for Monitor users. (**OC-12626**)
- Fixed an issue where the API to create participants in bulk could fail and return an incorrect 'missing Participant ID' error. (**OC-13347**)

General

- Fixed an issue where a user logging in might be taken to a profile page unexpectedly. (**OC-12160**)
- Fixed an issue where users would sometimes see a server error page after login. When this scenario occurs, users will now be taken into the system and shown a user-friendly message. (**OC-11421**, **OC-10721**)
- Fixed an issue where a user could get an error when trying to use the logout link in rare cases. (**OC-11978**)
- Fixed an issue that could cause login to be slow under certain configurations. (**OC-12395**)
- Added security enhancements throughout OpenClinica.

OpenClinica 4 Stack 11.7 (Release Date - 10 July 2020)

OpenClinica 4 Stack 11.7 contains targeted fixes to OpenClinica. View the entire Stack 11.7 Changelog here (login required).

For an overview of the update, view the **Stack 11.7 Release Announcement here**.

Highlights include:

New:

Study Build System

- Added Content Library to Form Designer. This allows administrators to create, edit, and

manage a shared library of items, item groups, and entire forms across all of their studies. Other users within their customer domain can drag library content into their forms during form editing.

Changes & Fixes:

Study Build System

- Added Form and Event OIDs to the Form/Event cards in Study Designer prior to publication to support the creation of rules and cross-form logic. (**OC-12557**)
- Added Select All/Unselect All options to Multi-Selection interface in Study Designer. (**OC-9802**)
- Updated the downloaded version of the Study Designer Activity Log to include publish activity. (**OC-12278**)
- Fixed issues with uploading large media files in Study Designer. Study Designer now supports combined file sizes of up to 50 MB per form version or draft. (**OC-12280**, **OC-12285**)
- Copying a form from a Common Event to a Visit-based Event with a table configuration will no longer copy the table configuration (which could lead to subsequent unexpected behavior). (**OC-12284**)
- Updated Activity Log entry when a user first access a Study in in Study Designer to more clearly describe the activity. (**OC-12302**)
- Added support to drag-and-drop multiple items at once in Form Designer. (**OC-12899**)
- Added a bulk delete action to Form Designer. (**OC-12581**)
- Added a bulk duplicate action to Form Designer. (**OC-12582**)
- Increased the size of Form Designer and Form Designer Preview windows to provide more working space. (**OC-12772**, **OC-12773**)
- Fixed an issue in Form Designer Preview that showed labels in all uppercase letters for Grid forms. (**OC-12580**)
- Updated item appearance configuration to separate primary appearance and column width for Grid forms. (**OC-12722**)
- Added Parent Group Width to item appearance configuration for Grid forms to provide context for the item width configuration. (**OC-12840**)
- Updated group appearance configuration to match the updated item appearance configuration. (**OC-12841**)
- Updated error message when an improperly designed form with multiple languages is opened so that the user will know how to address the issue. Multiple language forms can be loaded in Form Designer as long as all user-facing content columns specify which language they are used for. (**OC-11938**)
- Added the ability to define items with external file response lists (i.e., select_one_from_file type items) in Form Designer and load forms containing these items. (**OC-12064**)
- Fixed issues occurring with autopopulation of Item Group when using nested Layout Groups in Form Designer. (**OC-12190**, **OC-12277**)
- Fixed issues associated with opening or editing forms with UTF-8 characters in Form Designer. (**OC-12314**, **OC-12378**)
- Fixed an issue that could occur in Form Designer when using Firefox that caused some changes to item settings to fail to save. (**OC-12316**)
- Fixed an issue where Form Designer was inappropriately allowing the user to select "contactdata" or "clinicaldata" for "Use External Value" for item types that did not support these configurations. (**OC-12358**)
- Fixed an issue where "clinicaldata" items were incorrectly displaying an error message for not having an Item Group defined. (**OC-12598**)

- Removed non-applicable Required configuration option from Note type items. (**OC-12721**)
- Removed non-applicable Accepted Files configuration option from File type items. (**OC-13035**)
- Improved Form Designer usability by having the interface shift focus to the response choice's label field after adding a new response choice. (**OC-12383**)
- Form Designer will now correctly flag a draft as having unsaved changes if the response choice values have been changed for Select One or Select Multiple type items. (**OC-12387**)
- Updated spreadsheet downloads for forms edited in Form Designer to include all columns found in the Form Template. (**OC-12412**)

Note: Stack 11.6 and Stack 11.6.1 were reserved and were not deployed to Production environments.

OpenClinica 4 Stack 11.5.1 (Release Date - 23 June 2020)

OpenClinica 4 Stack 11.5.1 contains targeted fixes to OpenClinica. View the entire Stack 11.5.1 Changelog here (login required).

Highlights include:

Changes & Fixes:

- Updated system user handling to support future development efforts. (**OC-13000**)

OpenClinica 4 Stack 11.5 (Release Date - 12 March 2020)

OpenClinica 4 Stack 11.5 contains targeted fixes to OpenClinica. View the entire Stack 11.5 changelog here (login required).

For an overview of the update, view the **Stack 11.5 Release Announcement here**.

Highlights include:

New:

Runtime

- Added columns for Form and Form Version to SAS Extracts. (**OC-9723**)

Participate

- Added a QR code version of the Participant Access Code to the Participant Details page to make in-clinic Participate usage easier without requiring the copying or typing of the Participate URL or the Access Code. (**OC-12000**)

Changes & Fixes:

Study Build System

- Fixed issues where users with specific characters in their usernames were unable to access Form Designer as expected. (**OC-12377**, **OC-12373**)
- Fixed an issue that caused Form Designer to fail to load as expected in customer subdomains containing specific characters. (**OC-12375**)
- Fixed an issue that could cause newly created users' access to Form Designer to be delayed. (**OC-12401**)
- Fixed an issue that could cause Form Designer to display an error page when users tried to access it. (**OC-12374**)
- Fixed an issue that could cause publishing a Study to fail if it contained a form in a Visit Event that had been copied from a Common Event. (**OC-12231**)
- Updated Study publish error messaging to be inclusive of forms created in Form Designer and via spreadsheet upload. (**OC-12129**)
- Added validation to prevent the addition of a form to a Study if it contains items with names longer than 40 characters. (**OC-12357**)
- Added validation to ensure that forms added to a Study do not contain items of a type other than calculate with the Use External Value field set to "clinicaldata", as including such items can cause errors when entering data. (**OC-12353**)
- Added validation to prevent the addition of a form to a Study if it specifies conditional logic in the Read Only field for any items. The system will now correctly reflect that conditionally read-only fields are not currently supported. (**OC-12324**)
- Added validation to prevent the addition of a form to a Study if it includes items with the same name as an item group used in a repeating group, which can cause issues with data entry. (**OC-12170**)

Runtime

- Fixed an issue where forms in Locked sites were able to be opened in Review-only mode instead of Read-only mode. (**OC-12275**)
- Fixed an issue that could allow Study-level users to add data to Locked sites. (**OC-12332**)
- Fixed an issue where some users where able to "Delete" Locked Event CRFs in certain cases. (**OC-12334**)
- Fixed an issue that could cause a Signed Event to become un-signed when a form within it was opened in Edit mode and then closed with no changes. Only editing data or marking a new form Complete will un-sign the event. (**OC-12265**)
- Fixed an issue with SAS Extracts where an error in output files required manual editing to allow the files to be loaded into SAS. (**OC-11593**)
- The Queries page now correctly displays status values associated with Event CRFs, rather than with Participants. (**OC-12159**)
- Fixed an issue that could cause CSV exports of the Queries page to include the wrong Item Names. (**OC-11703**)
- Fixed an issue that prevented the printing of PDF Casebooks for Locked Studies. (**OC-12281**)
- Fixed an issue that could cause Site User attempts to print PDF Casebooks to fail. (**OC-12341**)
- Fixed a few issues with PDF Casebook printing that could occur if the associated Participant ID contains an apostrophe. (**OC-12307**, **OC-12336**)
- Updated PDF Casebooks to mask all contact information fields even for CRC and Investigator users. (**OC-12268**)
- Fixed an issue where the contents of adjacent long text fields in printed PDF Casebooks would

overlap. (**OC-12196**)
- Improved performance of PDF Casebook printing when the forms contain video, audio, or other non-printable files. (**OC-12110**)
- Added additional logging on notification action rules to aid in troubleshooting. (**OC-12338**)

Forms

- Fixed an issue where date fields defined as partial dates (e.g. year only or month-year only) were displaying as full dates when displayed as Read-only. (**OC-12266**)
- Fixed an issue where printed forms were duplicating the text of hyperlinks in text fields. (**OC-12208**)

Participate

- Fixed an issue with Participate that could cause an error page to display when attempting to log back in after a session timeout. (**OC-12026**)
- Fixed an issue that could cause the generation of a new Participate access code to fail to be recorded in the audit log. (**OC-12216**)
- Confirmation dialog was added to the "Let's Move On" option in Participate, to decrease the chance that participants will move on from an event before they are ready. (**OC-12388**)
- Text was updated on the Participate dashboard, and the progress bar was removed to improve usability. (**OC-12365**)

REST API

- Removed a potential block on using the Participant API. (**OC-12367**)

General

- The dialog to update a user password through the Profile page will now display the requirements new passwords must meet if an invalid new password is entered. (**OC-10230**)
- Improved compatibility of some OpenClinica modules with upcoming security features for the Chrome browser. (**OC-12214**)

OpenClinica 4 Stack 11.4 (Release Date - 18 February 2020)

OpenClinica 4 Stack 11.4 contains targeted fixes to OpenClinica. View the entire Stack 11.4 changelog here (login required).

Highlights include:

New:

- Added the ability to create new forms and edit existing forms using a drag-and-drop Form Designer. Allows setting a form style and version; adding, editing, deleting, or grouping questions; changing the order of questions; previewing forms in real time; saving the form as a draft; and adding the draft form to the study. It allows adding questions to a library and copying questions from the library as needed. Form Designer can be used instead of or in conjunction with uploading Form Definition spreadsheets.

Changes & Fixes:

- Improved stability of uploading large media file attachments with Form spreadsheets. (**OC-12151**)
- Updated the Table Design search interface to improve item search usability. (**OC-11612**)
- Fixed issue where Table Design interface might not load for some studies. (**OC-12230**)
- Added Study Publish activity to Study Designer Activity Log. (**OC-10889**)

Note: Stack 11.3 was reserved and was not deployed to Production environments.

OpenClinica 4 Stack 11.2 (Release Date - 2 February 2020)

OpenClinica 4 Stack 11.2 contains targeted fixes to OpenClinica. View the entire Stack 11.2 changelog here (login required).

Highlights include:

Changes & Fixes:

- Fixed an issue where complete forms with cascading select items could prompt users to enter Reason for Change when the cascading select item values had not changed. (**OC-12199**)
- Fixed an issue that could cause Grid forms within PDF Casebooks to have inconsistent formatting. (**OC-12074**)

OpenClinica 4 Stack 11.1 (Release Date - 31 January 2020)

OpenClinica 4 Stack 11.1 contains targeted fixes to OpenClinica. View the entire Stack 11.1 changelog here (login required).

Highlights include:

Changes & Fixes:

- Fixed an issue that could prevent site users from accessing forms they had privileges for based on Permission Tags. (**OC-12203**)

OpenClinica 4 Stack 11 (Release Date - 29 January 2020)

OpenClinica 4 Stack 11 contains a variety of enhancements and fixes to OpenClinica. View the entire **Stack 11 changelog here** (login required).

For an overview of the update, view the **Stack 11 Release Announcement here**.

Highlights include:

New:

Runtime

- Added the ability to generate printable Participant Casebooks. There is a link at the bottom of the Participant Details page to generate a PDF Casebook including all the Participant's Forms that have data (including history and queries).
- Added the ability to use random numbers in system-generated Participant IDs. Updated Site ID to be optional in system-generated IDs.

General

- Added support for Multi-Factor Authentication, which can now be enabled for all studies at the customer-level. With this enabled, all non-Participant users logging into OpenClinica are required to provide a dynamic access code.

Changes & Fixes:

Study Build System

- Fixed an issue that could cause an error when publishing a study that contained Form versions including items with names that had been used in other Form versions but had been removed from the other Form versions when those versions were overwritten. (**OC-9428**)
- Fixed an issue where a study would fail to publish if new Form versions changed the case of item or item group names. (**OC-10602**)
- Fixed an issue that was sometimes allowing Forms with duplicate item or itemgroup OIDs to be created, which could prevent the study from publishing. (**OC-11845**)
- Improved the study publication workflow by preventing publication of a study environment while a previous attempt to publish that study environment is still being processed, which could result in errors and decreased performance. (**OC-10523**)
- Fixed an issue that could cause failed attempts to publish a study to induce errors in future attempts to publish the study. (**OC-11929**)
- Fixed an issue where a study could fail to publish if it contained an archived Event that included a Form without a Form version defined for it. (**OC-11718**)
- Fixed an issue where having an archived Common Event in a study that includes an overwritten Form version could cause the study to fail to publish. (**OC-11676**)
- Fixed an issue where configuring custom columns in the Participant Matrix or Queries table to display items from a Form and then updating that Form to a version that does not include the items configured for the custom columns could prevent the study from publishing. (**OC-11675**)
- Added a link to the Publish History section at the top of the Share Study page. (**OC-11122**)
- Added help text to the interface for configuring system-generated Participant IDs. (**OC-12024**)
- Study names and descriptions can now correctly include up to 255 characters. (**OC-11024**)
- Improved performance on the Study Settings page. It will now immediately reflect updates made to Study Type and Phase. (**OC-11704**)
- Fixed an issue that could cause the Modules configuration page to display incorrectly. (**OC-11197**)
- Added the ability to export the Activity Log from Study Designer, enabling Data Managers to

examine a record of all the changes that have been made to a study design. (**OC-10777**)
- Fixed an issue that could sometimes cause the Activity Log to fail to load fully in Study Designer. (**OC-11686**)
- Updated the error message displayed when an invalid itemgroup is included in an uploaded Form Template to be more user-friendly. (**OC-11625**)
- Fixed an issue that could cause changes to Form order in Study Designer to revert on future loads of Study Designer. (**OC-11806**)
- The Go button in Study Designer will no longer display environments the user does not have access to. (**OC-12105**)
- Updated the examples provided in the Study Designer Table Design interface to aid in custom column configuration. (**OC-11620**)
- Fixed an issue with when copying Participate forms to Common Events in Study Designer. (**OC-11991**)
- Updated the Form Template in Study Designer to support new Stack 11 features. (**OC-12113**)

Runtime

- Data Managers can now edit system-generated Participant IDs without changing the study settings. (**OC-9676**)
- Removed mouse-over context menus for Events and Forms from the Participant Matrix to improve usability and enable usage on touch-screen displays. (**OC-11512**, **OC-11795**)
- Made custom columns in the Participant Matrix sortable. (**OC-11482**)
- Made custom columns in the Queries table sortable. (**OC-11556**)
- Item brief descriptions will now be displayed as column headers in CRF Summary tables for Common Events on the Participant Details page. (**OC-8892**)
- Updated the database underlying the Participant Matrix and Queries table to better support custom columns. (**OC-11725**)
- Improved the way the Add New Participant dialog behaves to reduce confusion when creating Participant IDs. (**OC-11588**)
- Removing a Participant from the study now automatically closes all queries associated with that Participant. (**OC-9585**)
- Migrating a Form to a version that does not include an item now automatically closes all queries associated with that item. (**OC-11580**)
- Fixed an issue that could cause the View within Record display for viewing a query in context within a Form to appear empty. (**OC-11601**)
- Fixed an issue where removing a record associated with a Participant could sometimes interfere with the ability to later sign off on that Participant. (**OC-11450**)
- Added Participant ID to the confirmation message when reassigning Participants. (**OC-9471**)
- Users should see performance improvements of up to 60% on the View / Enter Data page for an Event. (**OC-11751**)
- Removed irrelevant action options for removed Forms from the View / Enter Data page for an Event. (**OC-9647**)
- Fixed an error that could occur when trying to open a Form in a Study that is in Design status. (**OC-11882**)
- Added the Item Label and Brief Description to query notifications. (**OC-9605**)
- Updated the link included in query notification emails to appropriately filter the Query table after it is clicked. (**OC-11250**)
- Removed the Add New button for removed Participants from the Common Events page, since removed Participants should not have new Common Events added. (**OC-11308**)
- Fixed an issue that could make it impossible to edit items within a Dataset from the View Datasets menu. (**OC-11678**)

- SPSS Data Extracts will now include variable labels. (**OC-11447**)
- SAS extracts now include item descriptions. (**OC-11748**)
- Fixed an issue that could cause the extract list to fail to include the correct Dataset Format for previously run extracts. (**OC-11419**)
- Reordered the options to View and Create Datasets on the Tasks menu so that they are consistent for all users. (**OC-11832**)
- Fixed issues related to errors arising from removing a Monitor's Form-specific permissions while they are accessing the SDV page. (**OC-11749**, **OC-12139**)
- Fixed an issue that could cause the Add New Visit Event button to disappear from the Participant Details page in cases where events included Forms that were restricted with Permission Tags. (**OC-11536**)
- Removed the Add New button from the Participant Details page for Non-Repeating Common Events if there is already a Form present for that Event. (**OC-11633**)
- Improved usability on the Participant Details page by updating hover text to be more accurate. (**OC-11709**)
- Update the Participant Matrix to include the appropriate set of options for all Forms based on their statuses. (**OC-9482**)
- Improved usability of the Bulk Actions Log page with updated help text. (**OC-12073**)
- Removed the option to download Rule files from studies with no available Rules to download. (**OC-11135**)
- Fixed an issue with multiple studies that contain Events of the name that could interfere with Rules referencing one of those Events. (**OC-12099**)
- When importing data into complete Forms, users can now supply a Reason For Change for all items in the Form automatically by including it in their import file. (**OC-10918**)
- Added informative error messages when imports are attempted with files that are invalid due to missing or invalid Study IDs. (**OC-11453**)
- It is now possible to import data for a signed Participant, consistent with how data can be entered for such Participants manually via the Form UI. (**OC-11596**, **OC-11632**)
- Fixed an issue where creating Non-Repeating Common Events via an XML import could result in multiple instances of the Event being created. (**OC-11805**)
- Updated the import template to support new Stack 11 features. (**OC-11747**)

Forms

- Significant performance improvements (up to 80% or more) in forms using cross-form logic can now be achieved by configuring the Form to have access to only those Events relevant to the logic on the Form. Previously the Form had access to all Events whether or not they included relevant items, which could impact performance. (**OC-10066**)
- Activity by the user within a Form will now correctly reset the timer for an automatic timeout, preventing the user from being logged out while working on the form. 1 hour of inactivity will cause them to be logged out. (**OC-10099**)
- Added ability for Data Managers to define item-specific Required Messages on forms. (**OC-11917**)
- Improved help for date calculations using Event Start Date to provide best practice that will prevent calculation errors for users of Internet Explorer. (**OC-11659**)
- Improved line-break behavior of radio button and checkbox items in Forms. (**OC-11575**)
- Fixed an issue related to Form page navigation in some Forms with Repeating Groups. (**OC-12145**)
- Fixed an issue that could prevent the Assign To list in the Query widget from populating. (**OC-11723**)
- When printing forms with Show History enabled, they will now show history for all items that

have any history (current or previous non-null value, queries, etc.) even if the items are currently hidden on the Form. (**OC-11673**)
- Fixed an issue in which printed Forms were breaking text in the middle of an item or history section. They now format text more appropriately, breaking pages between items or history sections. (**OC-11750**)
- Resolved an issue that could result in calculated fields not being correctly represented in the Query Widget History section before the form was reopened. (**OC-11829**)

Participate

- Fixed some issues related to scrolling on Participate Forms. (**OC-9901**, **OC-9902**)
- Added a Copy button to the Participant Details page where Participant access codes are generated to allow CRCs to more easily help Participants start data entry for in-clinic usage. (**OC-11480**)
- Updated Participate access codes to avoid including characters that can be easily confused for each other so that Participants are less likely to mistype their access code. (**OC-11627**)
- Fixed an issue that could result in the Participate Invite table on the Participant Details page not being displayed shortly after the activation of the Participate module. (**OC-11982**)

REST API

- Updated the GET Participants API to allow for data retrieval from locked studies. (**OC-11590**)
- Fixed an issue in which the GET Participants API could return data with incorrect timestamps. (**OC-11757**)
- Implemented significant performance improvements in the API call to get Participant access codes in bulk. (**OC-11788**)
- Added default pagination to the API that provides Participant access codes for improved performance. (**OC-11745**)
- Fixed an issue that could cause some API calls to fail. (**OC-11767**)

General

- Improved the behavior that occurs when navigating away from the Profile page to make it more intuitive. (**OC-10042**)
- Proactively fixed potential security vulnerabilities.
- Updated the Help system to support more targeted display of content specific to the user's context rather than one set of content for all users, improving the value of this resource. (**OC-12015**)

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