8 OpenClinica 4 - Release Notes 2019

OpenClinica 4 Stack 10.2 (Release Date - 17 December, 2019)

OpenClinica 4 Stack 10.2 contains targeted fixes to OpenClinica. View the entire Stack 10.2 changelog here (login required).

Highlights include:

Changes & Fixes:

- Improved form upload performance in Study Designer. Internal tests showed 50% - 75% faster form uploads. (**OC-11811**)
- Fixed an issue where form upload validation updates added in Stack 10 prevented some existing form spreadsheets from being uploaded as new versions of a form due to item group name issues. Stricter validation is now applied only for new forms, not for existing forms. (**OC-11839**)

Note: Stack 10.1 was reserved and was not deployed to Production environments.

OpenClinica 4 Stack 10 (Release Date - 30 October, 2019)

OpenClinica 4 Stack 10 contains a variety of enhancements and fixes to OpenClinica. View the entire Stack 10 changelog here (login required).

For an overview of the update, view the **Stack 10 Release Announcement here**.

Highlights include:

New:

Study Build System

- Added configurable custom columns for the Participant Matrix and Queries Table. Table Design feature in Study Designer allows Data Managers to choose items to display in one or both tables. Non-repeating items can be selected and arranged as needed. All configuration activity is included in the Study Designer Activity Log. Study publish error checking will ensure that the items selected are still valid at the time of publishing. After the study is published, the selected columns will be displayed in the tables. Each row in a table displays the values of the configured items for the corresponding Participant. Each column will have a heading using the Brief Description defined for the item (or the item label if the Brief Description is not defined). Custom columns can be filtered to limit the set of Participants displayed. (**OC-11337**)
- Added ability to upload forms with Brief Descriptions defined for items. Brief Descriptions are optional and can be up to 40 characters long. They will be used as column headings when the item is displayed within certain tables. (**OC-8893**)
- Added ability to upload forms with Long Descriptions defined for items. Long Descriptions are

optional and can be up to 3,999 characters long. They can be used to store data definitions and can be included in extracted datasets. (**OC-11550**)

Runtime

- Added ability to import data into forms that were previously marked as Complete. Any data items that are updated during this process are noted with the system-generated Reason for Change, "Update via Import". (**OC-9838**)

Changes & Fixes:

Study Build System

- Added error checking on Study publish to prevent a Study from being published if a Common Event Form table configuration includes an item that does not exist on any form version. (**OC-10761**)
- Added error checking on form upload to prevent a form from being uploaded if an ItemGroup is used in a different Repeating Group than in a previous version of the form. (**OC-11460**)
- Added error checking on form upload to prevent a form from being uploaded if an ItemGroup has an invalid name. (**OC-11307**)
- Fixed an issue where some form spreadsheet upload errors in Study Designer were being displayed as "Invalid file type" regardless of the actual error. (**OC-10630**)
- Fixed an issue where Study Designer was not displaying form version and events with a Lock icon after being published to Production. (**OC-11461**)
- Updated Study Designer Activity Log entries for configuration of Common Event Form tables to be more user-friendly. (**OC-11405**)
- Updated the Study Designer Navigation Bar to remove labels for some of the buttons to improve the layout on smaller screens. (**OC-11364**)
- Updated the form template in Study Designer to reflect the latest updates in form functionality. (**OC-11611**)

Runtime

- Fixed issue where Removed datasets did not have a Restore button. (**OC-11457**)
- Fixed an issue where the printed version of the Queries Table was missing the Type column. (**OC-9633**)
- Fixed issues where the Participant Matrix might not retain or display the page size correctly. (**OC-11213**, **OC-11201**)
- Fixed an issue where the Add Participant window would sometimes open showing an error message related to the last attempt to add a participant. (**OC-8445**)
- Fixed an issue where in some cases, for the first user to log in after the study was created and published, the Participant Details page would not be displayed correctly. (**OC-10987**)
- Fixed an issue where in rare case opening an existing form after version migration could prevent the user from saving data to the form even after reopening it. (**OC-11566**)
- Fixed an issue where some data for Removed Participants was unexpectedly displayed on the Participant Details page. (**OC-11422**)
- Fixed an issue where Common Event Form Add New buttons on the Participant Details page were enabled for Removed Participants. (**OC-11436**)
- Fixed an issue where having certain characters in a username would prevent a user from being able to edit Event details from the Participant Details page. (**OC-11362**)
- Fixed an issue where Event status was sometimes being displayed inconsistently. (**OC-10939**)
- Fixed an issue where a Participant ID was not treated as a duplicate if it was the same as

another Participant ID except for letter case. (**OC-9834**)
- Fixed an issue where Participant ID search behaved inconsistently depending on the letter case of the value searched for. (**OC-11499**)
- Fixed an issue where Rules were not being triggered after data import in some cases. (**OC-11430**)
- Fixed an issue where importing data into a form with Item OIDs and ItemGroup OIDs that were similar to those in another form caused the import operation to behave unexpectedly. (**OC-11546**)
- Fixed an issue where the wrong error message would be returned if a data import action failed due to an Event not being in the correct status. (**OC-10946**)
- Updated the View Site Details page to be more user-friendly. (**OC-11478**)
- Updated the Bulk Actions Log to have hover text for the action buttons and a confirmation prompt when deleting an item. (**OC-11332**)

Forms

- Improved performance when opening a form. It can now load up to 33% faster depending on form complexity and Participant data volume. (**OC-11143**, **OC-11595**)
- Fixed an issue where cross-form logic did not work as expected in some cases. (**OC-11526**)
- Fixed an issue where the Query Widget Assign To user list was not sorting as expected. (**OC-11268**)

Participate

- Updated messaging on the Participate Dashboard to correctly handle Participants with or without first names entered into the system. (**OC-11403**)

REST API

- Fixed an issue where adding Participants via API was not respecting the Participant enrollment limit. (**OC-11428**)
- Fixed an issue where the Bulk Participant API was showing the wrong error message when it was called with an invalid file. (**OC-11407**)
- Fixed an issue where the Get Participant API was showing the wrong error message when an invalid Participant ID parameter was submitted. (**OC-11398**)
- Fixed an issue where the Get Participant API was providing data for Removed Participants unexpectedly. (**OC-11476**)
- Fixed an issue where the Get Participant API was not returning Site ID as expected. (**OC-11414**)

General

- Added new widget to provide help and announcements. See the orange ? button in the bottom right corner of the screen. (**OC-11555**)

Note: Stack 9.6 and Stack 9.7 were reserved and were not deployed to Production environments.

OpenClinica 4 Stack 9.5 (Release Date - 12 September, 2019)

OpenClinica 4 Stack 9.5 contains a variety of enhancements and fixes to OpenClinica. View the

entire Stack 9.5 changelog here (login required).

Highlights include:

Changes & Fixes:

Study Build System

- Fixed an issue where Study Designer was sometimes not showing all forms as Locked after they were published to Production. (**OC-11270**)
- Fixed an issue where hovering over a timestamp in Study Designer was not showing the correct full timestamp. (**OC-11271**)

Runtime

- Fixed an issue where non-repeating events were listed with a StudyEventRepeatKey in extracts. (**OC-10936**)
- Fixed an issue where audit information for repeating events was not grouped correctly in extracts. (**OC-11109**)
- Improved performance of data extracts. (**OC-10302**)
- Updated extracts screen to indicate if an extract is currently running. (**OC-11067**)
- Fixed issue where Site Monitor users were unable to filter the SDV table. (**OC-11205**)
- Fixed issue where SDV table checkboxes and filters were not sticky. (**OC-9337**)
- Updated Data Import page to use the Import API for improved stability. (**OC-11276**)
- Fixed an issue where Event Date was not included in the exported or printed version of the Queries table. (**OC-9724**)
- Fixed an issue where Batch CRF Migration showed an error message if migrating forms at a site where not all form versions were available. (**OC-11353**)
- Fixed an issue where the link to the Bulk Actions Log was not displayed in the Tasks menu if the study did not have a status of Available. (**OC-10930**)
- Fixed an issue where data was not displayed correctly in the Bulk Actions Log if the data contained commas. (**OC-11344**)
- Updated the Bulk Actions Log to initially appear unsorted to preserve the original order of the content of the log. (**OC-11342**)
- Fixed UI issues with the Bulk Actions Log page. (**OC-10985**)
- Fixed an issue on the Enter or Validate Date page where the wrong user might have been shown as the Last Updated By user for a form. (**OC-9671**)
- Fixed an issue where Rules could not be uploaded in some cases. (**OC-11288**)
- Updated the Rules Template to fix an issue where the template could not be uploaded after being filled out. (**OC-11389**)
- Updated the message displayed after Removing or Restoring a Participant to be more user-friendly. (**OC-10792**)
- Updated Participant status display to use consistent capitalization on the Participant Details page. (**OC-10160**)
- Fixed an issue where dropdown menus did not work as expected in IE11. (**OC-11287**)

Forms

- Fixed an issue where forms opened using View Query Only did not show the Item or Query. (**OC-11248**)
- Fixed an issue where forms did not autosave as expected in some cases. (**OC-11235**)
- Fixed an issue where autoqueries were added to forms in rare cases when forms were used in

Review-Only mode. (**OC-11294**)
- Fixed an issue where hard edit checks did not work as expected on date items. (**OC-11301**)
- Fixed an issue where the Query Widget Email checkbox was missing for some items. (**OC-11284**)
- Fixed an issue where the Query Widget would not be displayed in IE11. (**OC-11245**)
- Fixed an issue where complete forms did not load correctly in IE11. (**OC-10854**)
- Fixed an issue where form layout was not as expected in IE11 if VAS items were used. (**OC-11348**)

Participate

- Updated the messages on the Participate dashboard for better handling of Participants without first names entered in the system. (**OC-11320**)
- Fixed an issue where the Participate dashboard did not load correctly in IE11 after editing a form. (**OC-11199**)
- Updated the Reset Access Code checkbox to not be sticky in the Participant Contact window. (**OC-11265**)

Randomize

- Fixed an issue where randomization was not being triggered when a form was marked Complete by a Participant. (**OC-11291**)
- Fixed an issue where randomization was not being triggered in some cases with stratification factors on multiple forms. (**OC-11306**)
- Fixed an issue where an invalid Randomize configuration could prevent users from logging in. (**OC-11237**)
- Improved methods for loading Randomize configurations to improve system stability. (**OC-11290**, **OC-11238**)

REST API

- Refactored Individual and Bulk Add Participant endpoints to resolve defects and improve stability. (**OC-11277**)
- Added Bulk Add Participant endpoints to Swagger page. (**OC-11244**)
- Fixed issue where contact information could not be updated for a Signed Participant. (**OC-11095**)
- Updated Get Participants endpoints to return site name, ID, and OID. (**OC-11208**)

Note: Stack 9.4.1 was reserved and was not deployed to Production environments.

OpenClinica 4 Stack 9.4 (Release Date - 27 August, 2019)

OpenClinica 4 Stack 9.4 contains a targeted fix to OpenClinica. View the entire Stack 9.4 changelog here (login required).

Highlights include:

Changes & Fixes:

- Added support for future Randomize functionality. (**OC-11309**)

Note: Stack 9.3 was reserved and was not deployed to Production environments.

OpenClinica 4 Stack 9.2 (Release Date - 19 August, 2019)

OpenClinica 4 Stack 9.2 contains a targeted fix to OpenClinica. View the entire Stack 9.2 changelog here (login required).

Highlights include:

Changes & Fixes:

- Added support for a site mapping configuration in Randomize to allow for Randomizations to remain consistent over time for all sites. (**OC-11286**)

OpenClinica 4 Stack 9.1 (Release Date - 3 August, 2019)

OpenClinica 4 Stack 9.1 contains a targeted fix to OpenClinica. View the entire Stack 9.1 changelog here (login required).

Highlights include:

Changes & Fixes:

- Fixed an issue where forms opened with errors if they contained items without labels. (**OC-11266**)

OpenClinica 4 Stack 9 (Release Date - 1 August, 2019)

OpenClinica 4 Stack 9 contains a variety of enhancements and fixes to OpenClinica. View the entire Stack 9 changelog here (login required).

For an overview of the update, view the **Stack 9 Release Announcement here**.

Highlights include:

New:

Runtime

- Added Jobs page to provide access to logfiles of asynchronous and bulk operations. Users can see the results (success or failure messages, job-specific output) of operations they have run.
- Added Query ID to Query Manager, Query Notification emails, Participant Casebooks, and ODM extracts.

- Added Annotations to Query Manager.
- Added mobile phone number to the Participant Contact window.

Forms

- Added ability to create multiple queries per item within a form. Each query is opened, updated, and closed independently and can be assigned to different users. Each query is automatically given a study environment-unique ID for easy reference. Updated the Query icon to indicate when an item has multiple open queries.
- Added ability to add annotations to items within a form. Updated the Query icon to indicate whether the item has any annotations.
- Redesigned the Query widget to accommodate multiple queries and annotations. Improved item history display, including ability to display all history or a single query or annotation only. Each entry is now listed with the user it was assigned to and the status the query had at the time of the entry.
- Added ability to define hard required and hard constraint edit checks. Hard edit checks can be used to block invalid data on input and prevent users from navigating forward on the form or marking it complete while there is a hard edit check active.

Participate

- Added ability to define a form to collect Participant contact data. This allows Participants to enter or modify their own contact information for use by the Participate module while still adhering to the access controls already in place for Participant contact data.
- Added ability to send SMS invitation and notification messages to Participants' mobile phone numbers.
- Added ability to generate a new access code for a Participant (in case the previous code was lost).
- Added ability to register a Participant in the Participate module via REST API.

Randomize

- Added new Randomize service to randomize Participants on-demand as their data make them eligible to be randomized. Randomization typically occurs within seconds rather than on a set schedule as with the previous module.

REST API

- Added ability to create and update study events (single or bulk) via REST API.

Changes & Fixes:

Study Build System

- Update page structure in Study Manager to separate the Share Study Page (for managing the Test and Prod environments) from the Configuration page (for managing Settings, User Roles, and Modules). (**OC-9340**)
- Update the Go buttons throughout the Study Build System to only appear for a study if the current user has a role in an environment of the Study that has already been published. Additionally, when the button is clicked, it will only show environments that the current user a role in and have been published. (**OC-10847**, **OC-10848**, **OC-10849**)
- Updated layout of the Share Study page for usability. Study Environment status is shown using icons in the Environment tabs and just below the tabs. Design status is now displayed as In

Design. Publish history has been removed from the top of the display. Full publish history is still displayed at the bottom of the page and is now shown in reverse chronological order. (**OC-10912**)
- Updated layout of My Studies cards to be more user-friendly and consistent. Study Environment status is displayed clearly using icons. Design status is now displayed as In Design. Study name and description will be truncated if too long to allow all cards to be the same size. Button alignment is always consistent for each card regardless of which buttons appear for a user. (**OC-10900**, **OC-10911**)
- Fixed an issue where the login page for Study Designer could be slow if the user had timed out and the window had been unused for a long time. (**OC-11070**)
- Fixed a issue where a non-Admin Data Manager could not remove an Admin user from a study. (**OC-9230**)
- Fixed an issue where in rare cases an Admin user who selects the Administration menu option could be taken to Study Manager. (**OC-10580**)
- Added a link above the People table on the Share Study Page to take the user directly to the User Role Configurations page. (**OC-9348**)
- Improved security of pages in Study Manager to ensure that users cannot access Share Study Pages or Configuration pages for Studies they do not have valid roles in. (**OC-10957**)
- Updated Study Designer Activity Log date filter to use 24 hour time format. (**OC-10627**)
- Fixed an issue where viewing a previous version of a study board in Study Designer would display some forms without versions in rare cases. (**OC-10650**)
- Fixed an issue in Study Designer where activity log entries were not appearing as expected when a form was copied from one event to another. (**OC-10262**)
- Updated error messaging to be more helpful when a study was created with a description exceeding the max length. (**OC-10609**)
- Fixed an issue where error text did not wrap to the next line correctly in Firefox. (**OC-10594**)
- Fixed issues where extraneous errors and warnings were appearing in the browser console when using Study Designer. (**OC-10684**, **OC-10685**)
- Updated the form template in Study Designer to reflect the latest updates in form functionality. (**OC-11228**)

Runtime

- Improved performance when saving data in studies with many Participants. (**OC-11046**)
- Fixed an issue where multiple signatures added to the same event were not listed in the audit log. (**OC-10834**)
- Fixed an issue where system-generated Participant ID did not get created correctly if the Participant Matrix was filtered by event. (**OC-10970**)
- Fixed an issue where a Participant ID with an apostrophe in it prevented an event from being scheduled for the Participant. (**OC-10480**)
- Improved the design of the Participant Details page so that an error in a single form would not prevent the entire page from loading. (**OC-10790**, **OC-10762**)
- Fixed an issue where the Participant Details page would fail to load if a Common Event table was configured to display an item that was no longer on the form. (**OC-10744**)
- Fixed an issue in the Participant Details page where repeatedly archiving and restoring an event between publish operations could cause the event to not be displayed for some Participants. (**OC-10753**)
- Fixed an issue in the Query Manager table where the Date Created was updated with every response to a query. (**OC-10617**)
- Fixed an issue in Query Manager where Event-level queries did not show the correct note text. (**OC-9270**)

- Updated Query Manager's View Query Within Record button to be more user-friendly. (**OC-10688**)
- Updated system-generated autoqueries created on deleting or removing a form or event to consistently set the status of autoclosed queries. (**OC-9549**)
- Fixed an issue where Monitor users saw a non-functional Edit link on the View Event page. This link is no longer present. (**OC-10556**)
- Fixed an issue where the SDV Page's SDV All Checked action did not work as expected. (**OC-10558**)
- Updated SAS extracts to export full text values rather than truncate them to 255 characters. (**OC-10259**)
- Fixed an issue where in rare cases a user with site-level access could log into a site they had been removed from. (**OC-10897**)
- Added ability to generate a Participant casebook with or without metadata and with or without data from archived forms.
- Updated Remove and Delete form pages to show the correct form version. (**OC-9872**)
- Fixed an issue where Remove Participant and Restore Participant would trigger an error page. (**OC-10488**)
- Fixed an issue where certain rare cases causes event start and event complete audit records to not store the user associated with the action. (**OC-10430**, **OC-10679**)
- Fixed an issue where the default table size of 50 records was not being maintained as expected. (**OC-10407**)
- Added support in Notification Action Rules to include the following variables - Participant ID, Study ID, Site ID, Site Name. (**OC-9687**)
- Updated Rules page to remove non-applicable Run button. (**OC-10175**)
- Updated Rules page to remove non-applicable Test Rules link. (**OC-11124**)
- Added a link for Download Rules Template to the Rules page. (**OC-11124**)
- Fixed button text on the Update Participant ID window. (**OC-10757**)
- Updated Participant Contact Info window title. (**OC-10565**)

Forms

- Updated form rendering to block forms which have loading errors (for example, where the form can't be parsed properly and loads with a popup showing an error message, not where there are constraints active) from submitting data back to the server to prevent malfunctioning forms from creating bad data. This invalid form state can also be recognized by the absence of a Close button on these forms. (**OC-11069**)
- Updated Relevant error behavior to match new hard constraint edit check behavior. Users can only close a form with an active relevant error by adding a manual query or autoquery, but the user is able to leave both complete and incomplete forms in this state. (**OC-10990**)
- Fixed an issue where irrelevant VAS items were still displayed even when they had null values. (**OC-10867**)
- Fixed an issue where audio files embedded in forms would not play on iOS devices. (**OC-10079**)
- Fixed an issue where read-only calculated items could allow user input on iOS devices. (**OC-10982**)
- Fixed an issue that sometimes caused item label text to overlap with the Query icon. (**OC-8687**)
- Updated form definitions to support the latest ODK standard for XForm appearances for select_one and select_multiple items. (**OC-10845**)
- Improved readability of printed forms. (**OC-11018**)
- Updated printed forms to show the item name after its label at the top of its History box.

(**OC-11086**)

Participate

- Fixed an issue where the Participate Access Code Viewed event was logged before the CRC or Investigator user actually exposed the Access code value. (**OC-10878**)
- Added messaging to inform the user if a Participant invitation email or SMS message is not sent successfully. (**OC-10758**)
- Fixed an issue where the Participant Contact table did not always appear with consistent sizing. (**OC-10601**)
- Improved Participate support for forms with UTF-8 characters. (**OC-9938**)
- Improved Participate support for IE11. (**OC-10073**, **OC-10541**)
- Added Participant's first name to motivational messages displayed after a form is entered. (**OC-11139**)
- Added Participant's first name to the top right user menu. (**OC-10019**)

REST API

- Refactored XML Import API to improve stability and performance. (**OC-10767**)
- Updated XML Import API to run asynchronously and send output to the Jobs page. (**OC-10726**)

General

- Updated Authentication system to support audited account locking based on a configurable number of invalid login attempts. (**OC-9955**)
- Added support for SAML integration for logins. Note that this is not currently compatible with signing Participants or Events. (**OC-10921**)
- Updated the Support link to open the Support page consistently across all applications. (**OC-9039**)
- Proactively fixed potential security vulnerabilities. (**OC-10992**)

OpenClinica 4 Stack 8.8 (Release Date - 18 July, 2019)

OpenClinica 4 Stack 8.8 contains a targeted fix to OpenClinica. View the entire Stack 8.8 changelog here (login required).

Highlights include:

Changes & Fixes:

- Fixed an issue where existing forms would fail to load in some cases when the server response was slow. (**OC-11141**)

Note: Stack 8.6 and Stack 8.7 were reserved and were not deployed to Production environments.

OpenClinica 4 Stack 8.5 (Release Date - 3 June, 2019)

OpenClinica 4 Stack 8.5 contains targeted fixes to OpenClinica. View the entire Stack 8.5 changelog here (login required).

Highlights include:

Changes & Fixes:

- Fixed an issue where the Participate Dashboard would intermittently fail to load. (**OC-10665**)
- Fixed an issue where certain older browsers were not able to load Participate as expected. (**OC-10865**)
- Fixed an issue where attempting login to Participate with a login page that had been open for an extended period would show an Invalid Access Code message even though the login attempt was not processed fully. (**OC-10856**)
- Fixed an issue where Participate shortcuts used the wrong icon on mobile devices. (**OC-10830**)

Note: Stack 8.4 was reserved and was not deployed to Production environments.

OpenClinica 4 Stack 8.3 (Release Date - 14 May, 2019)

OpenClinica 4 Stack 8.3 contains targeted fixes to OpenClinica. View the entire Stack 8.3 changelog here (login required).

Highlights include:

Changes & Fixes:

- Fixed an issue where View Query Within Record for an item that was hidden on the form did not show the expected message in some cases. (**OC-10660**)
- Fixed an issue where a calculated item that was made irrelevant (i.e., hidden) and then relevant again (i.e., shown) had an extra entry for a value change from null to null in the History widget. (**OC-10699**)
- Fixed an issue where only the first page of multi-page forms could be printed. (**OC-10687**)
- Fixed an issue where the asterisk indicating an item is required did not disappear when a value was entered for the item. (**OC-10728**)
- Fixed an issue where forms with repeating groups using relevant expressions and including calculated values showed a relevant error when the repeating group was irrelevant and all non-calculated items in the repeating group were empty. (**OC-10667**)
- Fixed an issue where forms with repeating groups using dynamic repeat count (i.e., repeat count set as the value of an item on the form) and relevant expressions showed a relevant error when the repeating group was irrelevant and all items in the repeating group were empty. (**OC-10746**)
- Fixed an issue where forms with repeating groups using the repeat count parameter opened with an error in Safari. (**OC-10696**)
- Fixed issue where leading or trailing spaces in a date value caused the value to be treated as invalid and saved as null. The extra whitespace is now stripped and the date value saved if the value is otherwise a valid date. (**OC-10651**)
- Fixed an issue where date values calculated using the "date(string value)" function sometimes

produced unexpected values depending on whether the date calculation generated a date in Daylight Saving Time or Standard Time. (**OC-10668**)
- Fixed an issue where the reset/clear button that appears for date items could be displayed in the wrong column on Grid Theme forms viewed in Firefox. (**OC-10711**)
- Fixed an issue where VAS items configured to be required that were used in Participate forms showed an error message upon making the first value selection. (**OC-10795**)
- Fixed issues where VAS items were sometimes unable to accept input on iOS and Android devices. (**OC-10676**, **OC-10700**)
- Fixed issues with the Drawing Widget where the Undo and Reset buttons did not work. (**OC-10075**, **OC-10205**)

Note: Stack 8.2 was reserved and was not deployed to Production environments.

OpenClinica 4 Stack 8.1 (Release Date - 29 April, 2019)

OpenClinica 4 Stack 8.1 contains targeted fixes to OpenClinica. View the entire Stack 8.1 changelog here (login required).

Highlights include:

Changes & Fixes:

- Fixed an issue with the Randomize module where randomization values were not being inserted into forms as expected.

OpenClinica 4 Stack 8 (Release Date - 18 April, 2019)

OpenClinica 4 Stack 8 contains a variety of enhancements and fixes to OpenClinica. View the entire Stack 8 changelog here (login required).

For an overview of the update, view the **Stack 8 Release Announcement here**.

Highlights include:

New:

Study Build System

- Added the ability to see the previous study definitions in Study Designer. Each publish event listed on the Share Study Page has a link to "View Study Design". Clicking this link opens the study in Study Designer as it existed at the time of the publish. This allows the user to see what events, forms, and form versions were present in the study definition at that time. The study definition is presented in a read-only manner when this feature is in use. The user can click the "View Current" link in the header bar to return to the current study definition and resume making any necessary changes. (**OC-10339**)
- Added Date Filters to the Activity Log in Study Designer. All Study Designer activity is shown by default. The user can enter a start date/time and/or an end date/time to narrow the

activities shown. This can be used to see the activity between two specific dates or skip past recent activity more easily. (**OC-10263**)

Changes & Fixes:

Study Build System

- Improved performance of publishing a study (especially when large volumes of data are present). (**OC-10341**)
- Added Gear icon button to the study cards on the My Studies page to allow quicker access to the Settings, Modules, and User Roles configurations for the study. (**OC-9473**)
- Updated the Sites table on the Share Study page to include sorting and pagination. (**OC-8965**)
- Updated the error message to be more user-friendly when a Data Manager or Admin user attempts to add a duplicate user to the system. (**OC-10261**)
- Fixed an issue on the Share Study page where attempting to invite a new user whose username and/or email are the same as an existing user's except for the case might not be rejected as a duplicate user. (**OC-10525**, **OC-10290**)
- Updated the Share Study page Status section message about the study publish status to include the name of the environment the study was published to. (**OC-10338**)
- Fixed an issue that was sometimes causing a blank screen to be displayed when accessing OpenClinica. (**OC-10462**)
- Updated Study Manager to show an error page when a user attempts to access a non-existent customer URL (instead of failing silently). (**OC-10401**)
- Updated Study Designer to show an error page when a user attempt to access a non-existent customer URL (instead of failing silently). (**OC-10400**)
- Added logic to Study Publishing to ensure that duplicate events do not get created internally. (**OC-10521**)
- Fixed an issue in Study Designer where only the 40 most recent activities were loaded into the Activity Log. (**OC-10297**)
- Fixed an issue in Study Designer that was causing form cards to show the incorrect SDV setting for the form in certain cases. (**OC-10362**)
- Fixed an issue in Study Designer that was causing Form Previews to show the wrong form version info in the heading of the frame that contains the Form Preview. (**OC-10418**)
- Fixed an issue in Study Designer that was causing the Tab key to trigger an error in certain cases. (**OC-10268**)
- Updated the form template in Study Designer to reflect the latest updates in form functionality. (**OC-10531**)

Runtime

- Improved performance of the Participant Matrix (especially when large volumes of data are present). (**OC-10349**)
- Improved performance of the Data Manager homepage (especially when large volumes of data are present). (**OC-10359**)
- Improved performance of extracts (especially when large volumes of data are present) (**OC-10350**)
- Improved performance of data import (especially when large volumes of data are present) (**OC-10273**)
- Improved performance of the Participant Audit Log (especially when large volumes of data are present). (**OC-10420**)
- Improved performance of the Participant Details page (especially when large volumes of data

are present). (**OC-10301**, **OC-10376**)
- Updated the Participant Details page to load all Common Events collapse by default to improve performance. (**OC-10332**, **OC-10378**, **OC-10397**)
- Updated Participant Details Page Common Events tables to display item names instead of item OIDs for items that do not have labels (such as calculate items). (**OC-10388**)
- Updated the Participant ID search box in the top left corner to be more user-friendly. (**OC-10329**)
- Updated the signature page to allow users to sign participants and events case-insensitively with their username. (**OC-10381**)
- Fixed an issue where removing or deleting a Participant's form from the Participant Matrix might not take the user back to the Participant Matrix when the action is finished. (**OC-9506**)
- Updated the message displayed when a Participant's form is deleted to remove deprecated terminology. (**OC-9621**)
- Fixed an issue where reassigning a Participant to a different site could lead to incorrect system-generated Participant IDs at the sites being created afterwards. (**OC-9644**)
- Fixed an issue with the View Query Only link in Query Manager where the display might be incorrect if the selected query's form had calculated values or cross-form logic. (**OC-9266**)
- Fixed an issue where some user roles were not able to download the Data Import template. (**OC-9409**)
- Updated data import to support import up to 3999 characters into text items to match the new UI behavior. (**OC-10533**)
- Updated data import to allow importing data into external code list items (i.e., select_one_from_file items). (**OC-10405**)
- Fixed an issue in data import where data could not be imported into existing non-repeating common event forms. (**OC-10365**)
- Updated the View CRF Details page to remove the deprecated link to "Run All Rules for this CRF". (**OC-9714**)
- Fixed an issue where uploading multiple Rules could cause an error. (**OC-10346**)
- Fixed an issue where Notification Action Rules could trigger multiple email notifications when only one is expected. (**OC-10279**)
- Fixed an issue related to running Notification Action Rules on a schedule. (**OC-10343**)
- Fixed an issue related to running Event Action Rules on a schedule. (**OC-10300**)

Forms

- Updated text items to support 3999 characters instead of 2000 characters. (**OC-10127**)
- Update text items to disallow users from typing or pasting more characters than the system supports in order ensure that the text shown can be saved successfully. (**OC-8595**)
- Fixed an issue where multi-language forms would display text inconsistently in repeating groups. (**OC-10181**)
- Fixed an issue where dynamic code text (i.e., choice options that display a value from another item) would be displayed inconsistently in repeating groups. (**OC-10448**)
- Fixed an issue with the display of likert select_one items. (**OC-10245**)
- Added support for forms with 20x larger data and query volumes. (**OC-10587**)
- Updated the error message displayed on the form to be more user-friendly when an item or group should be hidden but can't be because it currently has data. (**OC-10526**)
- Updated the form printing options window to be more user-friendly. (**OC-10011**)
- Fixed an issue where forms opened in Review-Only mode displayed a non-functional Clear icon for file upload items. (**OC-10524**)
- Fixed an issue where a specific error condition could cause a form to fail to save data but not notify the user of the failure. (**OC-10567**)

- Added more robust security for internal calls used to open forms.

Participate

- Fixed an issue with Participate forms where an item that had a constraint and was also required might not display the expected error message when one of these conditions was triggered. In rare cases, this caused the browser to get into an unstable state. (**OC-10519**)
- Added auditing of Participant contact information. Contact info is audited and encrypted in the internal audit log. It is only decrypted in the user-facing audit log for privileged users (Clinical Research Coordinator and Investigator roles). It remains masked in the casebook and extracts for all users. (**OC-9858**, **OC-10321**)
- Updated the layout of the Participant Details page so that the Participant Contact Information table is aligned with the Participant ID table. (**OC-10227**)
- Updated the layout of the Invite Participant and View Contact Information windows. (**OC-10165**, **OC-10185**)
- Added help text to show the maximum lengths for the input areas in the Invite Participant window. (**OC-10492**)
- Updated error handling for invalid phone numbers entered into the Invite Participant window. (**OC-10116**)
- Changed the Participant Access code display to use a font that is more clearly distinguishable for all characters. (**OC-10555**)
- Updated the text and workflow of the Participate Module settings interface to be more user-friendly. (**OC-10192**, **OC-10194**)
- Updated the interface for Participate-related features in Study Designer to be more user-friendly. (**OC-10191**)
- Added the ability to extract participant access codes in bulk via API (for use in cases such as physically mailing the codes to Participants). (**OC-9684**)

REST API

- Updated the showArchived parameter. It now defaults to no and only includes archived data when its value is "y". (**OC-9725**)
- Added the includeMetadata parameter. It defaults to no and only includes metadata when its value is "y". (**OC-9749**)

General

- Updated login functionality to allow users to log into the system case-insensitively with either username or email address. (**OC-10295**, **OC-10044**)
- Updated workflow for unknown users logging in. If the username/email address entered does not belong to a valid system user, the user will see a generic invalid login message and a failed login attempt will be added to the user audit log. Previously, these users saw the same message as valid users who had not logged into the system since before the authentication model was changed when Stack 7 was deployed in January. (**OC-10176**)
- Updated the text to be more user-friendly when a user attempts to log in with an expired password. (**OC-10236**)
- Fixed an issue where attempting login when multiple OpenClinica browser tabs are open might cause a "No Matching State" error. (**OC-10232**)
- Fixed an issue where accepting the invitation for a new Data Manager user while still logged in as a different Data Manager user could produce inconsistent results. (**OC-10333**)
- Fixed an issue where switching between different customer environments could produce inconsistent results. (**OC-10465**)

- Increased internal system timeout settings to allow publish, import, and other operations to run for up to an hour before timing out. (**OC-10353**)
- Fixed an issue where password changes made via the My Profile page were not being included in the user audit log. (**OC-10294**)
- Fixed an issue where changing the user's profile info or password via the My Profile page might not show the user the appropriate success or failure message. (**OC-10503**)
- Fixed issues that were causing duplicate user login events to be recorded when moving between applications and during continued system usage. (**OC-10292**, **OC-10340**, **OC-10363**)
- Added more robust safeguards to system security to prevent attacks based on cookies, cross-site scripting, and frame injection.

OpenClinica 4 Stack 7.0.4 (Release Date - 12 April, 2019)

OpenClinica 4 Stack 7.0.4 contains targeted fixes to OpenClinica. View the entire Stack 7.0.4 changelog here (login required).

Highlights include:

Changes & Fixes:

- Fixed an issue with the Randomize module where randomization might unexpectedly be triggered for a Participant who had data entered for all stratification factors but then one of the values was deleted before the randomization form was marked Complete.

OpenClinica 4 Stack 7.0.3 (Release Date - 12 March, 2019)

OpenClinica 4 Stack 7.0.3 contains targeted fixes to OpenClinica. View the entire Stack 7.0.3 changelog here (login required).

Highlights include:

Changes & Fixes:

- Fixed an issue where some form previews would not load in Study Designer.

OpenClinica 4 Stack 7.0.2 (Release Date - 28 February, 2019)

OpenClinica 4 Stack 7.0.2 contains targeted fixes to OpenClinica. View the entire Stack 7.0.2 changelog here (login required).

Highlights include:

Changes & Fixes:

- Updated Form Previews in Study Designer to enhance the security of form definitions.

OpenClinica 4 Stack 7.0.1 (Release Date - 11 February, 2019)

OpenClinica 4 Stack 7.0.1 contains targeted fixes to OpenClinica. View the entire Stack 7.0.1 changelog here (login required).

Highlights include:

Changes & Fixes:

- Fixed an issue where user activity such as login/logout was not being captured in the audit log in some cases.
- Fixed an issue where study publish operations taking longer than one minute to complete were causing the publish window to be unresponsive when the publish operation completed.

OpenClinica 4 Stack 7 (Release Date - 31 January, 2019)

OpenClinica 4 Stack 7 contains a variety of enhancements and fixes to OpenClinica. View the entire Stack 7 changelog here (login required).

For an overview of the update, view the **Stack 7 Release Announcement here**.

Highlights include:

New:

Participate

- Added Participate module to allow ePRO data to be captured as part of a study. Participate is an optional module that can be requested for a study via the new Modules page.
- Once it is enabled, individual forms can be marked as Participate forms in Study Designer. These forms can then be previewed as Participate forms to see how they will look to participants. Any form in a visit-based event can be marked as a Participate form.
- Participants' user accounts for Participate can be created with or without capturing any PII. When a participant user account is created with PII including email address then an invitation email can optionally be sent to the participant to notify them of how to access the study. Only users in site-level roles based on Clinical Research Coordinator (CRC) or Investigator can enter, view, or edit the participant PII needed to invite participants to the study. Any data captured directly by a participant via Participate is audited and attributed to the participant's account. Data can also be entered to Participate forms by users logged in as study-level or site-

level user roles with data entry permission. In that case, the data entry will be attributed to the user who entered it.
- Participants can access the Participate application either via the direct access link sent in the invitation email sent to them when they are invited to the study or by going to the study's Participate URL and manually entering the access code included in the email. Once authenticated, the Participant will see the forms that are available for them to enter data in. A Participate form becomes available to the participant when the event it is in is Scheduled. It remains available to enter or edit as long as the event has Scheduled or Data Entry Started status and the form has Not Started or Data Entry Started status. Once a participant has finished entering data on their forms, their dashboard will give them the option of moving on and this will mark the Participate forms as complete. If the participant has no forms available to enter, an appropriate message will be shown to the participant on their dashboard.
- Participants will be able to enter form data using a computer or mobile device. Data will be auto-saved as it is entered to protect against data loss. Any edit checks programmed into the form will be strictly enforced when a Participant is entering data. Participants will not be able to finish data entry while there are any errors on the form. Participants will not have access to view or enter queries or view item history while on the form or from the Participate dashboard.

Study Build System

- Added Modules page to allow users to request access to the following optional modules for a study: Participate, Randomize, and Insight.

Forms

- Added support for external CSV code lists for single-select items. These external lists can be used with items of type select_one_from_file. They allow code lists to be used that exceed the system limitations for lists defined directly within the form's Excel file.

Changes & Fixes:

Study Build System

- Improved performance of loading Study Manager for the first time after login.
- Fixed an issue where entering a custom role description longer than 255 characters caused an internal server error message to be displayed. The description field no longer accepts more than 255 characters.
- Fixed an issue where publishing a study would fail when a user in that study had a name that contained an apostrophe.
- Fixed an issue where users would not be automatically logged out of Study Manager in certain cases where they closed their computer while still logged in.
- Fixed an issue where certain users were unable to be edited or removed in cases where a study had many users.
- Fixed an issue where user logout events were not being included in the User Audit Log.
- Updated permissions to disallow Admin users who are not Data Managers in a study from adding or editing sites in that study.
- Fixed an issue where Data Managers for a study who changed their role to something else and then back to Data Manager were unable to access Study Designer for that study.
- Fixed an issue where certain Data Managers were unable to access Study Designer.
- Fixed an issue where uploading forms with attached files totaling above 10 MB was causing the upload to fail and Study Designer to become unstable until the user left and came back in.

- Updated Study Designer to support previewing forms with external files including embedded video and audio files and external CSV code lists. Image files were already supported.
- Fixed an issue in Study Designer where the study publish status message in the title bar was sometimes showing the status of a different study.
- Updated Study Designer to prevent uploaded forms from using the same name for an Item and the Group it is in. Forms in this state could have had been unable to save data to the Item in this case.
- Updated Study Designer to prevent Items of type Calculate from being defined as Read-Only or have Constraint or Required logic. A form with an Item in this state could have shown an unexpected error message on the Group containing the Item in this case.
- Fixed an issue in Study Designer where typing the Home key would cause an Application Offline message to appear and Study Designer to become unstable until the user left and came back in.
- Updated Study Designer to allow the Multi-Selection feature to be used to add or remove Permission Tags to forms.
- Updated form cards to have a scroll bar on the versions list in case a form has many versions available.
- Fixed an issue that was preventing the common event form Fields to Display list from scrolling in certain cases.
- Fixed an issue where Study Designer form tiles within an event would sometimes scroll unexpectedly.
- Updated audit text for form SDV setting changes to better reflect that the change only applied to the form within that specific event.
- Fixed an issue where the title bar would sometimes not show the study status when the user navigated directly from Study Designer to the Settings or User Roles pages.
- Updated Study Designer Multi-Selection button to be able to be toggled off by clicking anywhere within the button rather than only on the small X.
- Removed extraneous links for Remove from Form and Update Profile that appeared if you clicked on users on a form card.
- Updated the Form Template in Study Designer to reflect functionality changes in this release and clarify instructions.
- Fixed an issue where the help text in the title bar would sometimes overlap the study status text.

Runtime

- Improved performance of loading the Participant Details page for Participants with many forms.
- Fixed an issue where the Participant Details page would display a Visits section in studies with only common events in certain cases where events had been archived from the study definition.
- Fixed an issue where changing the order of forms within an event was not being reflected in Runtime once the study was published. Note that on the Participant Details page, forms are still sorted first with forms that have not been started and then with forms that have been started. With this update, the list of not started forms will match the order the forms had in Study Designer at the time of publish.
- Updated the default length of most tables to display 50 records upon load.
- Updated so that a Signed Participant is automatically reverted to Available if a new event is scheduled for them.
- Updated so that a Signed Participant is automatically reverted to Available if a new form is opened and marked as complete without entering any data into it.

- Updated so that a Signed Event is automatically reverted to Completed if a new form is opened and marked as complete without entering any data into it.
- Fixed an issue where the Add Participant link didn't immediately respond to the new study when changing between a study that had exceeded the Participant Enrollment Limit and one that had not exceeded the limit or had no limit. Previously, the link wasn't responsive until the user navigated the new study further after switching studies.
- Fixed an issue with the SDV Status filter not working correctly in the SDV table.
- Fixed an issue where using the Query Manager to open an event-level query was opening the wrong record in certain cases.
- Fixed an issue where the View Site and Edit Site pages were causing errors in certain cases.
- Fixed an issue where form Created By was not being updated in internal tables when data was first entered into a form in certain cases. This did not impact the audit trail.
- Fixed an issue where event Date Completed was not being updated in internal tables when an event was completed in certain cases. This did not impact the audit trail.
- Fixed an issue where forms in Skipped and Stopped events were able to be edited in some cases. These forms are now only editable when the event is moved out of Skipped or Stopped status.
- Fixed an issue where a participant's status was not updated to Removed when the Participant was removed.
- Fixed an issue where restoring a Removed site-level Participant was causing an error.
- Fixed an issue where certain site users were unable to view their Profile page in some cases.
- Fixed an issue where the API to retrieve Participant IDs would permit users authenticated at the site level to receive IDs for Participants at other sites. No clinical data was accessible outside of the user's site.
- Fixed an issue where an import file with duplicate common event forms was not being rejected as expected.
- Fixed an issue where an import file with invalid common event form data was causing the common event repeat key to increment even though no new record was created by the import.
- Fixed an issue where an unexpected error message was shown if an import data file was missing event repeat key. For common events, a user-friendly error message is now shown in this case. For visit-based events, the import will proceed with the empty repeat key treated as the value 1.
- Updated the buttons in the navigation bar to be clickable within the entire button rather than just on the button text.

Forms

- Improved form loading performance for forms that do not read in cross-form data.
- Fixed an issue where the first form started in an event was not able to read in event-level data (such as Start Date or Repeat Key) using the cross-form data feature.
- Fixed an issue where repeating groups with relevant expressions were being hidden when the first repeat of the group was completely blank but other repeats contained data. In this case, the data in the other repeats was hidden from view while the group was irrelevant, but the data was not cleared.
- Fixed an issue where certain forms with calculations within repeating groups were opening with unexpected error messages.
- Fixed an issue where multiple page forms with nested groups with relevant expressions may not show the user the Next button when the form is first opened.
- Fixed an issue where calculated items in groups with relevant expressions may not be hidden when expected.
- Fixed an issue where calculated items with open queries that became irrelevant might not

have their auto-closed query entries records. The queries were still being auto-closed in this case.
- Fixed an issue where entering an all-space value in a text item was appearing as a distinct change to spaces in the item history when viewed within the form session. Since an all-space value is considered as null, the history now treats this as a null value within the form session and after leaving and then returning to the form.
- Fixed an issue where multiline text items and select multiple items that were required were not showing the red asterisk as expected in certain cases.
- Fixed an issue where Likert items were not rendered as expected when code text was long for some options.
- Fixed an issue where opening a form directly to a specific query from the Query Manager was not showing the correct message if the item the query belonged to was currently hidden.
- Fixed an issue where using Query Manager to open a query on a form that contained no other data was causing an error.
- Fixed an issue that prevented large (greater than 10 MB) files from being uploaded within forms. Files up to 95 MB are now accepted.
- Fixed an issue where annotation widgets were not rendering as expected in read-only and review-only modes.
- Fixed an issue where printing a form in Safari, Firefox, or Internet Explorer 11 was not producing the expected results in some cases.
- Fixed an issue with forms opened in Firefox where Queries could not be added to items in certain cases.
- Fixed an issue where certain forms were unable to be opened in Internet Explorer 11.
- Fixed an issue where an error would be triggered in Internet Explorer 11 when a form was opened in certain cases.

Randomize

- Added configuration options to support defining site-specific randomization rules for sites in the Test study environment and then using the same configuration without changes if those same sites are added to the Production study environment.

General

- Updated authentication methods. The new model provides greater overall configuration options, including password expiration (which is set to 180 days). Due to the change in authentication model, existing users will be required to set a new password the first time they access the system after this version is released. A password reset email will be sent to the user on their first login attempt. Passwords are required to be at least 8 characters long and include 1 each from the following groups: lowercase letters, uppercase letters, digits, and special characters.
- Session inactivity timeout has been updated to 1 hour for all components of OpenClinica.
- Added support for more data centers so that customers have more options for where their data is stored.
- Added support for SSL connections to the Postgres database.

Click here to view previous updates

Functional approval by Paul Bowen. Signed on 2019-12-17 4:41PM

Approved for publication by . Signed on 2019-12-17 5:05PM

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