

1 OpenClinica 4 - Release Notes 2022

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The Stack 17 release notes are in draft form and subject to change until Stack 17 is deployed.

DRAFT OpenClinica 4 Stack 17 (Scheduled Release Date - 23 July 2022) OpenClinica 4 Stack 17 contains targeted updates to OpenClinica. View the entire [Stack 17 changelog here](#) (login required). For an overview of this update, view the [Stack 17 Release Announcement here](#).

Highlights Include:

New:

Study Runner

- **Data Transformation Module (DTM):** The Data Transformation Module was created to take existing files or data types that are not compatible with OpenClinica and transform them into files that can be used by OpenClinica. Files that are normally unable to be imported can be uploaded, transformed by running a custom script, and then imported. For example, a raw data file taken directly from an instrument could be transformed into a tabular file that could be imported into OpenClinica.

Unite

- **Cerner EHR Integration:** The Unite module can now be used with Cerner EHR. This allows a Participant Details Page to be opened from within a Cerner EHR. Data can be pulled from the EHR to OpenClinica. Additionally, Participant-specific reports are visible and visits can be managed from within the Cerner EHR environment. Forms cannot be opened directly in this view due to legacy browser incompatibility with Cerner EHR.
- **Apple Health Integration:** The Unite module can now be used to receive data from Participant medical records via Apple Health. Participants can be invited to connect to Apple Health from the Participant Details Page. Participants who are invited can download the OpenClinica iOS app from the Apple App Store to participate. Participants are directed to link Apple Health to the medical records maintained by their providers. After initial setup, Participants will receive notifications to transmit data from Apple Health to OpenClinica with one tap in the OpenClinica iOS app.

Participate

- **Public Participant Surveys:** Allows participants to self-register for a study. Configure forms to allow Public URL within Study Designer and then create the form URL within the Site Configurations page in Study Runner. This URL can be shared in a public forum, such as a subway advertisement, social media post, etc., which can help attract potential participants. Each form submitted through this feature will create a new participant in the study. This feature allows the study to be accessed by a wide audience for easier recruitment.
- **Offline Data Capture:** Allows research staff to enter form data even if they do not have internet service available. Configure forms by selecting Public URL and Offline Capable in Study Designer and then create the form URL within the Site Configurations page in Study Runner. Form data entered while offline will be uploaded to OpenClinica when the user's device is back online. The form will need to be cached on the device while online prior to the user going into an offline environment. This allows data to be gathered in remote locations

that do not have access to the internet. Offline data capture uses a dedicated form URL that can be configured within the Site Configurations page in Study Runner.

Changes & Fixes:

Study Build System

- Fixed an issue that could prevent a user from having another site added to their permission if the study has a large number of sites. ([OC-17249](#), [OC-17418](#))
- Fixed an issue for customers with Single Sign-On enabled that could prevent user email addresses from being updated in Study Manager if the user had never previously logged in. ([OC-17373](#))
- Internal OpenClinica Team users are no longer listed on the Administration page or Share page. Note that they are still included in the Audit Log. ([OC-16990](#), [OC-17060](#))
- Updated Study Manager to prevent users from being created with the reserved username "system". ([OC-16850](#))
- Fixed an issue that allowed Study ID of longer than 30 characters to be entered only to fail with an unhelpful error message. This is now restricted to 30 characters maximum. ([OC-11980](#), [OC-15470](#))
- Fixed an issue that could cause a Site ID to be blocked from use in a Study unexpectedly. ([OC-18044](#))
- Fixed an issue that allowed Studies and Sites to be assigned the same IDs in some cases. ([OC-17943](#))
- Fixed an issue where the System-Generated Participant ID template included leading or trailing spaces in some cases. ([OC-15839](#))
- Fixed an issue where users accessing Study Designer and turning their computers off without logging out might not be logged out due to inactivity as expected. ([OC-17835](#))
- Updated form definition upload validation in Study Designer to reflect the latest changes in the Form Engine. ([OC-15783](#))
- Updated Study Designer Form Card properties layout to be more user friendly and include the new Public URL and Offline Capable settings. The Participate Module properties will now only be displayed for Studies where the Participate module has been requested. ([OC-16561](#), [OC-17440](#))
- Added a help icon to Study Designer Form Cards to link to helpful resources in the User Guide. ([OC-17277](#))
- Fixed an issue where form definitions (including media and external list files) would have underscore characters removed from filenames when downloaded from Study Designer. ([OC-16926](#))
- Updated Form template to reflect changes in Stack 17 (instructions for setting bind::oc:external to use identifier). ([OC-17182](#))
- Fixed an issue in Study Designer that could cause copies of existing Contact Data Forms to not have the appropriate permissions to limit access to those forms in the published study. ([OC-16929](#))
- Fixed an issue where users could be prevented from downloading forms from Study Designer if their filenames contained special characters. ([OC-16982](#))
- Fixed an issue in Study Designer where Event Names with special characters might not work as expected. ([OC-15893](#))
- Fixed an issue where users could be prevented from downloading forms from Study Designer or opening them in Form Designer if the forms had been edited in Form Designer and the form version contained special characters. ([OC-17007](#))
- Fixed an issue that caused an unnecessary column to be included when a form definition was

- viewed in XLS format after editing it in Form Designer. ([OC-17323](#))
- Fixed an issue where users were not able to delete questions within Form Designer in some cases. ([OC-15561](#))
- Fixed an issue where users were prevented from previewing forms in Form Designer if the forms used external code lists or pulldata() functions. ([OC-17741](#))
- Fixed an issue in Form Designer where relevant logic entered outside of the wizard might not be saved correctly in some cases. ([OC-17386](#))
- Fixed an issue in Form Designer where expressions using the today() function were changed to date('today()'). ([OC-16142](#))
- Fixed an issue in Form Designer where selection choice values were incorrect in some cases when the system managed them to prevent duplicate values. ([OC-15243](#))
- Added Automatic Repeat Count field to repeating group settings in Form Designer to allow configuration of the repeat_count parameter previously only available using the form template. ([OC-15046](#))
- Added the ability to duplicate individual groups and bulk duplicate items and groups together in Form Designer. ([OC-12838](#), [OC-12839](#))
- Added the ability to add individual groups as well as bulk items and groups to the Library in Form Designer. ([OC-12842](#), [OC-12843](#), [OC-12844](#))
- Updated the Form Designer Library Management interface to show library items' labels more easily. ([OC-12571](#))

Study Runner

- The Participant Details Page can be configured to display embedded Participant-specific Insight reports. ([OC-16971](#))
- The Participant Details Page can be configured to display embedded Item Summary Reports. ([OC-17016](#))
- Fixed an issue that prevented the Participant Details Page from loading correctly when an ad blocker was enabled in the user's browser. ([OC-16473](#))
- Updated the Edit Participant ID popup on the Participant Details Page to trigger the Update button when the user types the Enter key. ([OC-16827](#))
- Updated the calendar pop-up in the Participant Details Page to allow the selection of all dates visible in that display. ([OC-16721](#))
- Fixed an issue that prevented forms that had been started and then cleared from later being restarted in the default version or other version selected by the user on the Participant Details Page. ([OC-16452](#), [OC-17785](#))
- Fixed an issue where the Add New button could be present on the Participant Details Page unexpectedly when a Study or Site was in Locked or Frozen status. ([OC-17137](#), [OC-17994](#))
- Fixed an issue where Clear and Remove might appear on the Form Actions menu on the Participant Details Page when the Site is Locked or Frozen. ([OC-18131](#))
- Fixed an issue where Participant Details Page filters were being reset after an Event was removed or the Edit Event window was closed. ([OC-17108](#), [OC-16894](#))
- Fixed an issue where error messages on the Participant Details Page Add New popup could be displayed in the background on the main page. ([OC-16891](#))
- Made minor improvements to text on the Participant Details Page. ([OC-16762](#))
- Updated the confirmation message after adding a New Visit to disappear from the Participant Details Page once another action has been taken. ([OC-16462](#))
- Forms with a Completed status will open in View mode by default from the Participant Details page. They can still be opened in Edit mode using the Form Actions menu. ([OC-17876](#))
- Fixed an issue with the Participant Details Page that could cause the page to scroll unexpectedly when the last Common Event section is closed. ([OC-16956](#))

- Updated the Participant Details Page to show a loading message while the Visits section is still being loaded. ([OC-16813](#))
- Fixed an issue that caused the Participant Details Page Visits section to reload when a Common Event section was collapsed. ([OC-16936](#))
- Fixed an issue that could cause the Participant Details Page Visits section to not load if events had been changed from Common Events to Visits Events and did not have Start Dates. ([OC-17031](#))
- Fixed an issue where loading the Participant Details Page with non-default filters could cause page load to take twice as long as expected. ([OC-17071](#))
- Fixed an issue that caused the newly added Visits to be misaligned on the Participant Details Page in some cases. ([OC-16558](#))
- Fixed an issue that caused a Common Event section header to be displayed on the Participant Details Page in some cases when forms in the event were hidden for site. ([OC-17009](#))
- Fixed an issue where the Participants Details Page could flicker when Common Event sections were being loaded. ([OC-16828](#))
- Updated Participant Details Page Common Event headers truncate long text and show an ellipsis rather than expanding to show all text in the header. ([OC-16921](#))
- Added a visual indicator when opening a form from the Participant Details Page to show that the system is working prior to the form engine initiating. ([OC-16949](#))
- Fixed an issue where refreshing the browser window while viewing a form could sometimes return the user to the Participant Details Page. ([OC-16761](#))
- ODM Casebooks and Extracts now include a Query status flag (OpenClinica:OpenQueries) at the form level to indicate if the form has open queries. This flag can also be referenced in cross-form logic. ([OC-16879](#))
- Site Name and Site ID for each query are now included in CSV downloads from the Queries page. ([OC-16144](#))
- Monitor users can now access Data Review Tables. They can close queries on the tables in bulk as needed. ([OC-15841](#))
- Fixed an issue where filtering the Queries table by Date Created or Date Updated caused an error. ([OC-17125](#))
- Fixed an issue where removing a form did not close all open queries on that form. ([OC-15724](#))
- A Reason for Change is now required when removing or restoring participants, removing or restoring events, or clearing a form. ([OC-15143](#), [OC-16392](#), [OC-16705](#))
- All active signatures will now be displayed on forms in Signed events rather than just the most recent signature. This only applies to signatures added going forward. ([OC-17424](#))
- Studies and sites on the Change Study page are now sorted alphabetically by name so they can be found more easily. ([OC-17003](#))
- Extracts can be run in Tab-delimited and Excel formats with headers and data in separate files to allow easier data analysis. ([OC-13010](#))
- Fixed an issue where an import job using the option to run form logic after import was reporting that it was complete prior to the form processing finishing. ([OC-17897](#))
- Fixed an issue where deleted repeating group occurrences were included in SAS extracts. ([OC-15547](#))
- Updated the Site Configuration page interface to be more user-friendly and support the addition of Public URL forms. ([OC-17438](#), [OC-17240](#))
- Added a new tabular import status: Complete with Errors. This occurs when a file is imported successfully overall but at least one record fails individually. Previously this case produced an import status of Complete. ([OC-16459](#))
- The Tabular Import template was updated to reflect changes in Stack 17. ([OC-16807](#))
- Added SDV info hover text to let users know why rows are grayed out in the SDV Items Details table. ([OC-16709](#))

- Fixed an issue where the wrong message was appearing on the SDV Item Details table for items on Forms configured to use Form-Level SDV. ([OC-16885](#))
- Fixed an issue where the wrong SDV icon was appearing on the SDV Item Details table. ([OC-16912](#))
- Fixed an issue where an alert showed up erroneously on the SDV Item Details table based on selections made on the SDV Forms table. ([OC-16896](#))
- Fixed an issue where blank repeating groups were not appearing on the SDV Item Details table. ([OC-16727](#))
- Fixed an issue where Last SDV Changed Date was not updating in some cases. ([OC-18224](#))
- Updated the SDV Item Details table to allow opening forms directly to items in the table even if they have null values. ([OC-16740](#))
- Updated user interface alignment on the SDV Item Details table in some cases. ([OC-16920](#))
- Fixed an issue where concurrent batch form version migration and data entry created invalid database entries. ([OC-16955](#))
- Fixed an issue where the default form version was not being displayed correctly on the View Event Definition page. ([OC-15991](#))
- Fixed an issue where Data Managers were missing navigation links to the Study Build System in some cases. ([OC-15514](#))
- Fixed an issue where an audit entry was not generated when an Event Start Date or End Date was first entered. ([OC-14141](#))
- Improved performance of signing participants with large records. ([OC-17992](#))
- Fixed an issue where Hidden forms could appear in ODM records for some users at the site level. ([OC-15885](#), [OC-15883](#))
- Updated the SDV Item Details table for Form-level SDV forms so that items that have never had data entered will not have value listed for Modified Date or Modified By. ([OC-16797](#))
- Improved the performance of data import jobs using the option to run form logic after import when there are errors opening some of the forms. ([OC-17881](#))
- Updated Verified Item-Level SDV forms to be changed to Changed Since Verified status when a new repeating group entry is added to the form and it contains an item that is configured to be required for SDV. ([OC-16922](#))

Forms

- Fixed an issue where triggered calculations for items of type calculate did not work. ([OC-16162](#))
- Improved performance of opening large forms with many data items (including many repeating group occurrences). ([OC-16476](#))
- Fixed an issue where adding queries within forms could fail. ([OC-17231](#))
- Fixed an issue where iOS devices could not play videos embedded in form definition or upload as item data within forms. ([OC-11658](#), [OC-11121](#))
- Fixed an issue where the signature canvas was appearing in the wrong location on iPhones in some cases. ([OC-18128](#))
- Internal OpenClinica Team users are no longer listed in the Assign To dropdown in the Form Query Widget. ([OC-17061](#))
- Fixed an issue where languages were not switching correctly within forms. ([OC-17309](#))

Insight

- Updated Insight user interface to provide an improved navigation experience for users and admins. ([OC-16957](#))
- Updated Dashboard subscriptions to provide charts in Question results emails that appear

- more consistent with their appearance in Insight. ([OC-16957](#))
- A new standard question was added to Insight for “Average Days to Close a Query.” ([OC-15347](#))
- The Insight “Participants” and “Event Definition CRFs” tables were updated to reflect changes in Stack 17. ([OC-17110](#), [OC-17329](#))
- Fixed an issue that could cause Insight refresh failures in rare cases when the name of a custom role in a study was the same as the name of a default role which had no custom roles associated with it. ([OC-16609](#))
- Improved memory usage performance during refreshes. ([OC-17342](#))
- Fixed an issue in Insight where custom column titles were not persisting when Question results were downloaded. ([OC-16962](#))
- Fixed an issue with Insight Excel downloads that caused the files to be formatted as CSV files unexpectedly. ([OC-13637](#))
- Fixed an issue in Insight that prevented subcollections from being listed on the Collection Permissions page intermittently. ([OC-15497](#))

REST API

- Improved performance of bulk participant creation API. ([OC-18011](#))
- Updated the scheduled jobs APIs to allow access by user type User. Previously, only user type Admin users could access these files via API. ([OC-14598](#))
- Updated the error message and response code for expired passwords from the Authentication API to help users understand the error that occurred. ([OC-12045](#)), ([OC-18275](#))
- Updated Participant API calls to permit creation of Participants even when the study is configured to use system-generated Participant IDs. ([OC-17879](#))

General

- Removed support for Internet Explorer 11 (IE11). OpenClinica should be accessed using Chrome, Edge, Firefox, or Safari.
- Added security enhancements. ([OC-17253](#), [OC-17353](#), [OC-17510](#), [OC-17317](#))

OpenClinica 4 Stack 16.2 (Release Date - 14 April 2022) OpenClinica 4 Stack 16.2 contains targeted updates to OpenClinica. View the entire [Stack 16.2 changelog here](#) (login required). Highlights Include:

Changes and Fixes:

General

- Minor authentication updates to support future integrations. ([OC-17755](#), [OC-17759](#))

OpenClinica 4 Stack 16.1.0.1 (Release Date - 01 April 2022) OpenClinica 4 Stack 16.1.0.1 contains targeted updates to OpenClinica. View the entire [Stack 16.1.0.1 changelog here](#) (login required). Highlights Include:

Changes and Fixes:

General

- Security updates. ([OC-17725](#))
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OpenClinica 4 Stack 16.1 (Release Date - 28 March 2022) OpenClinica 4 Stack 16.1 contains targeted updates to OpenClinica. View the entire [Stack 16.1 changelog here](#) (login required). Highlights Include:

Changes and Fixes:

General

- Minor authentication updates to support future integrations. ([OC-17321](#))
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OpenClinica 4 Stack 16 (Release Date - 24 February 2022) OpenClinica 4 Stack 16 contains targeted updates to OpenClinica. View the entire [Stack 16 changelog here](#) (login required). For an overview of this update, view the [Stack 16 Release Announcement here](#). Highlights Include:

New:

Forms

- The form engine has been redesigned to take advantage of performance efficiencies available in modern web browsers. Forms opened in Chrome, Edge, Firefox, Safari, mobile Chrome (Android), or mobile Safari (iOS) will leverage the optimizations within those browsers to load more quickly and to respond to user actions more quickly once in the form. This will be most pronounced in slower forms, especially in larger forms that have a substantial set of logic defined (such as relevant logic), forms with many repeating group occurrences, and forms that read in values from a large set of cross-form data. Form load times have been found to be cut by 75% to 95% (or more) in these slower forms. Smaller, less complex forms that are already relatively fast will also have improved performance, but they will generally be faster by a smaller degree. Note that this update does not impact Internet Explorer 11. IE11 still uses the older processing mechanisms and will be much slower than newer browsers. ([OC-14747](#))

Changes & Fixes:

Study Build System

- Updated form upload validation to utilize the improvements made to the form engine. ([OC-14829](#))
- Fixed an issue that prevented forms from being uploaded if they used the pad2() function. ([OC-14868](#))
- Fixed an issue that prevented forms from being uploaded if they used the digest() function. ([OC-14827](#))
- Fixed an issue that prevented forms from being uploaded if they used the if() function nested in the count-selected() function. ([OC-16290](#))
- Removed the Beta Preview link from Study Designer. ([OC-17226](#))

Forms

- Form definitions that specify multiple languages will now be loaded in the user's browser language (if available in the form definition). To specify a particular language, form definition columns should be defined like "label::English (en)". This will appear as "English" in the language selector on the form. If the user's browser is set to the "en" locale, the form engine will default to showing "en" translations on initial load. If the primary browser locale is not used within the form definition, other locales configured in the browser settings would be considered next. Only top-level languages are supported (for example, "en" but not "en-us"). ([OC-12461](#))
- Fixed an issue that caused the format-date() and format-date-time() functions to return unexpected results if they were supplied integer values (rather than date values). ([OC-16221](#))
- Fixed an issue that could cause cross-form logic to return an unexpected result if it referenced an attribute in a specific node and that attribute was not present in that node. ([OC-16037](#))
- Fixed an issue that prevented items using choice filters from working correctly if they used relevant logic and were in repeating groups. ([OC-15958](#))
- Fixed an issue that prevented items using dynamic choice labels (i.e., item values piped into choice labels) from working correctly if they were based on item values from a repeating group. ([OC-16293](#))
- Fixed an issue that could cause forms opened to their last item via the View Query Within Record link to not open directly to the Query Widget for that item as expected. ([OC-15175](#))

OpenClinica 4 Stack 15.1 (Release Date - 31 January 2022) OpenClinica 4 Stack 15.1 contains targeted updates to OpenClinica. View the entire [Stack 15.1 changelog here](#) (login required). Highlights Include:

Changes & Fixes:

Study Build System

- Fixed an issue where the Study Revision was incrementing when no changes had been made in Study Designer. ([OC-17117](#))
- Fixed an issue where the system was erroneously preventing user accounts from being updated in some cases if there had been a previous error when adding a new user. ([OC-16577](#))

Study Runner

- Fixed an issue where signing a participant was not including the signature in the Casebook or the Audit Log. ([OC-16293](#))
- Fixed an issue where the tabular import was failing to update existing records when a time value was included as part of event Start Date in the import file. ([OC-16838](#))
- Fixed an issue where the log for tabular imports could display incorrect summary information. ([OC-16161](#))
- Improved performance of downloading queries. ([OC-16933](#))
- Fixed an issue where Query IDs could be duplicated in some cases when many queries were added at the same time. ([OC-16817](#))
- Fixed an issue where Queries might not be visible to study-level users as expected when viewing forms hidden to site users. ([OC-15935](#))
- Fixed an issue where users were able to perform unexpected actions directly from the

- Participant Matrix when a study or site was locked or frozen. ([OC-16806](#))
- Fixed an issue where site users were sometimes able to see hidden forms when viewing the Participant Matrix in single-event view. ([OC-15884](#))
 - Fixed an issue where sorting the Participant Matrix could cause some participants to fail to appear in the sorted view. ([OC-16393](#))
 - Fixed an issue that could direct a user to the wrong page when a form was closed. ([OC-17055](#))
 - Fixed an issue where the Participant Details Page Participant Invitation popup window would not allow invitations to be sent via email if the Participant's email address was already populated when the popup window was opened. ([OC-16856](#))
 - Fixed an issue that could prevent the Participant Details Page from loading in rare cases after a form has been cleared. ([OC-17014](#))
 - Fixed an issue that could prevent some forms from appearing on the Participant Details Page if they were hidden at other sites. ([OC-16963](#))
 - Fixed an issue on the Participant Details Page where a Visit name could be displayed as an ellipsis. ([OC-17021](#), [OC-17015](#))
 - Fixed an issue where configuring the Participant Details Page Visits section to show visit-specific data could cause the page to fail to load. ([OC-16947](#))
 - Fixed an issue where the Visits section of the Participant Details Page would still be displayed even if the study had no Visit events defined. ([OC-16722](#))
 - Updated loading error messaging for the Participant Details Page Visits section. ([OC-16718](#))
 - Updated the Add New Visit dropdown selector on the Participant Details Page to display Visits in the order they appear in Study Designer. ([OC-16625](#))
 - Fixed an issue where the Participant Details Page Visits section could return no search results if certain special characters were included in the search string. ([OC-15810](#))
 - Fixed an issue with Common Events not loading on the Participant Details Page when the study has many single-select or multi-select items with very similar item names. ([OC-17087](#))
 - Updated the Participant Details Page Common Event form table UI to be more user-friendly. ([OC-17002](#), [OC-16832](#))
 - Fixed an issue with sort by date not working for Common Events on the Participant Details Page. ([OC-16954](#))
 - Fixed an issue where archived Common Event forms were displayed on the Participant Details Page unexpectedly in some cases. ([OC-16946](#))
 - Fixed issues with Participant Details Page load when a Common Event contains a form that collects Contact Data. ([OC-16931](#), [OC-16924](#))

General

- Security Enhancements ([OC-16953](#), [OC-15522](#))

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Approved for publication by Paul Bowen. Signed on 2022-06-24 11:27AM

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