

4 OpenClinica 4 - Release Notes 2021

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OpenClinica 4 Stack 15 (Release Date - 20 December 2021) OpenClinica 4

Stack 15 contains new features and updates to OpenClinica. View the entire Stack 15 changelog here (login required). For an overview of this update, view the Stack 15 Release Announcement here. A quick overview of the Participant Details Page changes can be found in this video and this overview document. Highlights include:

New:

Study Build System

- Item-Level SDV: The new Item-Level option for the Source Data Verification (SDV) feature allows Data Managers to specify which items on a form should be verified against source data. Data Managers will define each item as Required, Optional, or Not Applicable for SDV. All new forms added to a study definition after this release will either be configured as using Item-Level SDV or Not Applicable for SDV. All existing forms published to Production prior to this release will continue to utilize legacy Form-Level SDV functionality. Forms created prior to this release but not yet published to production, will be able to be configured to use Item-Level or legacy Form-Level SDV functionality.
- Data Dictionary: The Data Dictionary feature is accessible via a link on each form card in Study Designer. The Data Dictionary gives the user form-specific information including form metadata, form properties, and item metadata such as Item OID, Item Group Name, Item Group OID, Item Type, and Insight Table. Data Managers are no longer required to publish a study to see this information in Study Runner. This allows Data Managers a more detailed look at how a form is represented in OpenClinica and provides easy access to information needed for tasks such as writing cross-form logic expressions or Insight Questions. The data dictionary can be downloaded as a CSV file to view outside of Study Designer.

- Item-Level SDV: For forms configured to use Item-level SDV, a Monitor user can now check off each reviewed item and verify them individually in addition to choosing to verify an entire form with one click. When all SDV Required items on a form have been verified individually, the form status automatically becomes verified. Conversely, if a user verifies a form, the verification cascades down to each SDV Required item on the form. When a value is changed after an item has been verified, the item becomes unverified automatically while other verified items on the form retain their status. If the form has verified status when a verified item on it has a value change, the form moves to Changed Since Verified status.
- Participant Details Page: The redesigned Participant Details Page (PDP) provides a more modern, streamlined view allowing more actions within the page, shorter loading times, and less time spent looking for the next visit or form that needs to be worked on. The old visits table and nested forms table have been replaced by a continuously scrolling section of visit rows with cards for associated forms within each row. After a form has been opened by clicking the form card and then closed, the PDP will show the user the same view as when the form was opened. The information that was previously contained in the table columns (such as statuses and versions) is now displayed on the form cards or available in the vertical ellipsis

menu in the bottom right corner of the form cards (actions). Event details and actions are also presented in this manner in the left-most column of the Visits section. Visits are sorted by start date and the page initially loads directly to the earliest, non-completed visit (highlighted in blue). The visits section now respects the record status filter (top right corner) to align with the existing functionality of the common event sections.

Changes & Fixes:

Study Build System

- Fixed an issue where studies with one Archived environment and one Not Published environment would inappropriately be displayed as Active on the My Studies page. (OC-15817)
- Fixed an issue where the Share page was not sorting Sites alphabetically correctly in some cases. (OC-15549)
- Fixed an issue where changing the name of a form while uploading a new version could result in the version not appearing correctly on the form card. (OC-15452)
- Fixed an issue where including Description or Brief Description in begin group or end group rows in a form template spreadsheet was not producing the expected error message on form upload. (OC-15760)
- Fixed an issue that could prevent new versions of some forms from being uploaded if they were last updated prior to Stack 13's deployment. (OC-16903)

- Relabeled Header in SDV Item Data Table to reflect new options. (OC-15990)
- Removed the "Clear Filter" hyperlink in SDV Item Data Table Header. (OC-16116)
- Updated SDV Item Data Table header row to freeze when scrolling the table vertically.
 (OC-16117)
- Added an info icon for items that aren't viewable on-form in SDV Item Data Table. (OC-16495)
- Updated layout of radio buttons in SDV Item Data table for usability. (OC-16517)
- Fixed an issue where Hidden forms could appear in the SDV Forms table for some users at the site level. (OC-15897)
- Fixed an issue where a verified form was changed to unverified after the form was migrated to a new version. (OC-14089)
- Updated site configuration page to reflect new Item-Level SDV options. (OC-16401)
- Updated the Remove and Restore actions for Common Events on the Participant Details Page to set the same status for the Event Occurrence and Form record inside it. (OC-15628)
- Updated existing Common Event Forms that had previously been Removed and/or Restored to have the same Removed status as their parent Event Occurrence. (OC-16686)
- Fixed an issue where events could be signed from the Participant Details Page when the Study or Site was Frozen or Locked. (OC-16134)
- Fixed an issue that could cause bulk signing of participants from the Participant Matrix to fail in rare cases. (OC-16676)
- When scheduling or updating a visit event, it is now more clearly indicated that an Event Start Date is required but a Start Time is not required. (OC-16624)
- Fixed an issue where SPSS extracts could exclude the CRF Version column inconsistently. (OC-16579)
- Fixed an issue where interacting with a Data Review Table did not prevent a user session from timing out due to inactivity. (OC-16405)
- Participant Audit Log files now have a descriptive, Participant-specific filename when

- downloaded. (OC-16004)
- Imports now allow the scheduling of events with a Start Date including time. (OC-15932)
- Fixed an issue where a Data Review Table could stop working after remaining idle for an extended period. (OC-15853)
- Fixed an issue where a Data Review Table that includes a form with a Permission Tag could be unavailable to a user without that tag even if the Permission Tag is removed from the form.

 (OC-15849)
- Fixed an issue where Data Review Tables became non-editable after the primary form had been archived. (OC-15619)
- Fixed an issue where Reasons for Change added for Form Removal in a Data Review Table were not filtering correctly on the Queries Table. (OC-15405)
- Fixed an issue where the inclusion of a period in a Participant ID could cause Participate contact data to be hidden on the Participant Details Page. (OC-15727)
- Fixed an issue where custom columns in the Participant Matrix or Queries Table could fail to filter if some values included non-ASCII characters. (OC-15195)
- Improved the flow of navigation in Study Runner to be more consistent at returning a user to the page they came from after following a link to another page to perform an action. (OC-12743)

Insight

- Updated to make Insight compatible with the data model used by the Item-level SDV feature. (OC-16007)
- Updated standard SDV questions to cover Item-Level SDV use cases. (OC-16519)
- Added a new table for reporting on parent Queries without other discrepancy notes (OC-12475)
- The Query ID displayed on the Queries page in Study Runner is now in the Insight Queries table. (OC-15292)
- Query Age in Days for parent queries now stops counting after the Query is closed. Query Age
 in Days for child notes now stops counting after another child note is added. (OC-12551)
- Improved refresh stability. (OC-16364)

Randomize

• Improved performance. (OC-16635)

REST API

 Study Event API now supports the inclusion of start time and end time in start date and end date. (OC-14350)

General

• Security enhancements.

OpenClinica 4 Stack 14.6 (Release Date - 22 November 2021) OpenClinica 4 Stack 14.6 contains targeted updates to OpenClinica. View the entire Stack 14.6 changelog here (login required). Highlights include:

Changes & Fixes:

- Added ability to embed Insight Dashboards into Participate Dashboards to display Participantspecific charts and metrics. (OC-16062)
- Fixed an issue causing SAML Signature Code reset to fail. (OC-16245)
- Improved resilience of Randomize when errors are encountered with importing results. (OC-16137)
- Fixed an issue that could cause notification Rule messages to be sent multiple times. (OC-16365)
- Fixed an issue that prevented Rules from firing based on an event being scheduled via API call. (OC-16205)
- Fixed an issue that could cause invitation links in emails to site users with access at multiple sites to direct the users to the wrong sites. (OC-8868)
- Fixed an issue causing some forms with repeating groups to have an error when being reopened after previously being edited. (OC-16157)
- Fixed an issue that allowed an item to be uploaded as Type select_one on one version of a form and select_one_from_file on another version of the same form. This scenario could lead to errors in subsequent study usage. (OC-15158)
- Improved Study Runner database stability. (OC-16337)
- Improved user role security. (OC-16295)
- Improved API security. (OC-16098)
- Security enhancements. (OC-16123)
- Fixed an issue that could lead to incorrect SMART App user mapping. (OC-16025)
- Fixed an issue that could lead to SMART App lab retrieval failure. (OC-16339)
- Improved messaging for SMART App users experiencing internet connection problems.
 (OC-16046)
- Improved SMART App interface for creating Participants. (OC-16308)

OpenClinica 4 Stack 14.5.1 (Release Date - 05 November 2021)

OpenClinica 4 Stack 14.5.1 contains targeted updates to OpenClinica. View the entire **Stack 14.5.1 changelog here** (login required). Highlights include:

Changes & Fixes:

• Security enhancements. (OC-16466)

OpenClinica 4 Stack 14.5 (Release Date - 25 October 2021) OpenClinica 4 Stack 14.5 contains targeted updates to OpenClinica. View the entire **Stack 14.5 changelog here** (login required). Highlights include:

Changes & Fixes:

 Added Beta Preview option to Study Designer to allow Data Managers to preview forms using the beta version of the upcoming form engine release. Note: Standard form previews remain unchanged. (OC-16235) **here** (login required). Highlights include:

Changes & Fixes:

- Improved Rule execution performance to handle large volumes of RunOnSchedule Rules in studies with many Participants. (OC-16044)
- Fixed an issue that could prevent Study Runner from being used while a Study using Data Review Tables was being published. (OC-16153)

OpenClinica 4 Stack 14.3 (Release Date - 27 September 2021) OpenClinica 4 Stack 14.3 contains targeted fixes to OpenClinica. View the entire Stack 14.3 changelog
here (login required). Highlights include:

Changes & Fixes:

- Fixed an issue in the form engine that could result in failed data submissions in some cases when an item's value changes very quickly from one result to a different result due to a calculation (including a cross-form calculation). In some cases, an item could change from value A to value B while the form was loading and only value A would be saved. This behavior was limited to specific devices. (OC-15872)
- Fixed an issue that caused form items that were populated by triggered calculations but user-editable to be cleared and hidden when they became non-relevant. (OC-15934)

OpenClinica 4 Stack 14.2 (Release Date - 21 September 2021) OpenClinica 4 Stack 14.2 contains targeted fixes to OpenClinica. View the entire **Stack 14.2 changelog here** (login required). Highlights include:

Changes & Fixes:

- Fixed an issue in Data Review Tables that allowed non-Data Manager users to close queries. (OC-15840)
- Fixed an issue that could cause forms to fail to open correctly when there are a very large number of users in a study. (OC-15861)
- Fixed an issue that could allow Hidden forms to be visible to site users via the Enter or Validate Data page. (OC-15848)
- Fixed an issue that prevented the GET clinicaldata API to work only using Participant OID, not Participant ID, in some cases. (OC-15858)
- Fixed an issue that could cause the Participant Details Page to show the wrong form version for a form that is not using the current default version. (OC-15877)
- Fixed an issue that could cause repeating group data to not be displayed on a form if the form was Verified in SDV, then had data changed, and then was viewed in the SDV interface again. (OC-15926)
- Added new Bulk Actions Log Jobs API calls to address issues that prevented calls to the
 previous API calls from working in some cases. The previous API calls are now deprecated.
 (OC-15629)
- Fixed an issue that could prevent data from being saved on forms intermittently in rare cases. (OC-15896)
- Fixed an issue that prevented forms from being displayed correctly if they were in signed events and the forms in the event or signing user's name had certain characters. (OC-15894)

• Fixed an issue that could prevent Rules from firing if they were triggered by the action of other Rules. (OC-15922)

OpenClinica 4 Stack 14.1 (Release Date - 02 September 2021) OpenClinica 4 Stack 14.1 contains targeted fixes to OpenClinica. View the entire Stack 14.1 changelog
here (login required). Highlights include:

Changes & Fixes:

- Fixed an issue that could prevent a user from being able to edit Site information in Study Manager in some cases. (OC-15803)
- Fixed an issue where extracts might not include any data in some cases. (OC-15823)
- Improved performance in Study Runner when clinical data is accessed. (OC-15828)
- Improved performance in Study Runner when forms are opened. (OC-15830)
- Improved Study Runner performance when Data Review Tables are not in use. (OC-15831)

OpenClinica 4 Stack 14 (Release Date - 27 August 2021) OpenClinica 4 Stack 14 contains new features and fixes to OpenClinica. View the entire **Stack 14 changelog here** (login required). For an overview of this update, view the **Stack 14 Release Announcement here**. Highlights include:

New:

• The Data Review Table feature allows Data Managers to configure custom tables of form data in Study Designer and allows other users to view them in Study Runner for the published study. Each custom table includes items from a primary form, and items from one or more non-repeating additional forms. Within each table, users can filter and sort any column, bulk close Queries on any included items, bulk remove forms from the study, and drill into each data point in the source form.

Changes & Fixes:

Study Build System

- Improved Study publish performance (OC-15098)
- Updated Site ID and Study ID to not allow a site to have the same ID as its parent study to prevent possible login errors. (OC-14950)
- Updated My Studies page to improve loading performance based on the selection of the Active/Retired Studies filter. (OC-14993)
- Fixed an issue where queries could be automatically closed erroneously during study publish in rare cases. (OC-15467)
- Updated to allow Created and Invited users to be Deactivated. (OC-10890)
- Fixed an issue where a user's status remained as Invited after that user had logged in. (OC-15335)
- Fixed an issue where searching the Share page to invite a user or filter the People or Sites tables would not return any results if certain special characters were included in the search. (OC-8958)
- Fixed an issue where searching for a user to invite to a study would not return any results if certain special characters were included in the search. (OC-8958)

- Fixed an issue where searching the Admin People table would not return any results if certain special characters were included in the search. (OC-15032)
- Fixed an issue where the user is unable to log in by email address if their email address contains a + symbol. (OC-15144)
- Updated system-generated Participant ID templates to prevent use of certain characters that could cause issues in Study Runner: <> & " (OC-13731)
- Fixed an issue where the Go button in the Study Build System would not take the user to the correct study if they had a site-level role in the environment they tried to go to. (OC-11458)
- Fixed an issue where the user may not be able to see all environments they have access to when clicking the "Go" button in Study Designer. (OC-15304)
- Fixed an issue where the user may be prompted to log in twice if logging in directly to a Study Designer URL. (OC-14736)

- Updated the Participant Matrix to load the framework before all content is loaded to improve performance. (OC-14882)
- Improved performance of the Participant Matrix when filtered to a single event. (OC-15737)
- Improved the layout of the Sign column in the Participant Matrix. (OC-15078)
- Fixed an issue where filtering the Participant Matrix to a single event and clicking Show More would display an extra non-relevant column. (OC-14399)
- Fixed an issue with Participant Matrix that could cause selection item column filters to return unexpected results. (OC-15506)
- Fixed an issue where CRF names containing certain special characters could cause an error after the event is signed. (OC-15396)
- Updated the Signature page for improved performance. (OC-15103)
- Fixed an issue where notification emails were not being sent when an event was signed.
 (OC-15281)
- Fixed an issue where the Event Start Date was set for common events imported from an XML Import file. (OC-14559)
- Updated Tabular Data Import logs to report separately on records updated and records that
 were processed but did not change any data (reported as "Rows With No Data Changes").
 (OC-15187)
- Updated Tabular Data Import to improve performance. (OC-15315)
- Updated to allow Investigator users to perform Tabular Data Import. (OC-15403)
- Fixed an issue where scheduled extract jobs were failing after periods of extended inactivity in the system. (OC-15178)
- Fixed an issue where Scheduled Extract Jobs could fail but still send a success notification. (OC-13250)
- Fixed an issue where running a dataset with the same name as an existing dataset would erase a dataset file previously generated for the existing dataset. (OC-11433)
- Fixed an issue where Form Version was not included in some dataset formats when requested by the user. (OC-13929)
- Updated ODM extracts for better handling of deleted repeating groups. Extract formats with OpenClinica extensions now include the attribute, "OpenClinica:Removed='Yes'" along with deleted repeating groups. Extract formats without OpenClinica extensions no longer include deleted repeating groups. (OC-14744)
- Fixed an issue that caused some scheduled extract files to have the prefix "filtered" erroneously. (OC-15657)
- Fixed an issue where the time component of Event Start and End Date were not included in extracts. (OC-13658)

- Fixed an issue where the time component of the Event Start Date was not being displayed on some pages. (OC-14247)
- Fixed an issue that was saving Event Start Date and End Date with "seconds" time component. (OC-14418)
- Fixed an issue with Events not being autocompleted when all Forms are marked Complete by a Participant if the Event Definition contains archived forms. (OC-15213)
- Fixed an issue that caused some data in archived form versions to be unavailable in Casebooks or cross-form logic. (OC-15610)
- Fixed an issue that prevented Participant Last Updated date from being set by a form being marked Complete. (OC-15634)
- Updated Participant Details Page Common Events column header from "Status" to "Form Status". (OC-15067)
- Fixed an issue where Study-level users were unable to see Hidden common event forms. (OC-15132, OC-15133)
- Fixed an issue where some Data Manager users were not seeing the My Studies link in Study Runner as expected. (OC-15105)
- Added Originator column to Queries table to identify the user who first opened a query.
 (OC-12824)
- Updated Query PDF download to include Site ID and Site Name. (OC-14680)
- Fixed an issue where sorting the Queries table would fail if there were a large number of queries. (OC-14800)
- Fixed an issue where filtering the Query ID column on the Queries table could result in an error in some cases. (OC-12576)
- Fixed an issue where the downloaded the Queries table in CSV format may have incorrect formatting if characters like commas, semicolons, or quotation marks are present in the table. (OC-13798)
- Fixed an issue where the Assign To list for queries on Event Start Date or End Date Query does not contain all expected users. (OC-14386)
- Fixed an error when sorting the View Events table by Participant ID. (OC-15167)
- Fixed an error on the View Events Page which was caused by an event type being changed from Common Event to Visit event the event had been published and data had been entered into it. (OC-14828)
- Updated Remove Form and Restore Form pages to require a Reason for Change. (OC-15272)
- Added the missing Cancel button to the Restore Form to Event page. (OC-13351)
- Fixed an issue where enrollment over 100% broke page formatting on the Data Manager Home Page in Study Runner. (OC-14587)
- Fixed an issue where deprecated links could appear on Study Runner error pages.
 (OC-15064)
- Updated the Audit Log "Date" header for Events to "Start Date". (OC-14679)
- Updated Audit Log to include the Source Type, Data Originator, and Data Element Identifier for data that came from an EHR source. (OC-15076, OC-15446)
- Fixed an issue where migrating a form to a different version was causing Quick Access Links for that form record to load without data. (OC-15398, OC-15155)
- Updated form Quick Access Links created by clicking a link on the Queries table to redirect the user to the Participant Details Page when used later. (OC-15137)
- Fixed an issue where a user accessing at the study level temporarily gets changed to site level access after removing or restoring an event. This caused Quick Access links to behave unexpectedly. (OC-15047, OC-15041)
- Fixed an issue where the Reassign From button appeared for CRC users unexpectedly on the Enter or Validate Date Page. (OC-14547)
- Fixed an issue where after logging into Study Runner as a Study-Level user after most recently

having accessed a site would not take the user to their most recent study to start. (OC-11267, OC-13131)

- Updated Study Runner database structure for performance improvement. (OC-13805, OC-13806)
- Refactored Study Runner database calls to improve performance. (OC-13803)
- Update Study Runner configuration to improve performance. (OC-14525)
- Updated error logging capability to allow for easier debugging. (OC-15340)

Forms

- Fixed an issue where adding a query to some required form items might not suppress the required item error message as expected and could prevent marking the form Complete. (OC-15428)
- Fixed an issue where calculated items with relevant logic could be calculated or displayed incorrectly after becoming non-relevant. (OC-14968)
- Fixed an issue where printing a form containing a multiline text item with more than two lines of text was causing the remainder of the text to be truncated from the printed version. (OC-14990)
- Fixed an issue where View Query Within Record would not open the form directly to the intended Query unless the Query was on the first page of the form. (OC-15135)
- Fixed an issue where viewing a form from the Item Details Table in the SDV interface did not open the form to that item as expected. (OC-15093)
- Fixed an issue that could result in form upload treating certain item names as reserved words unexpectedly. (OC-14540)
- Fixed an issue where a form was not able to be added to the study if it only contained calculate and/or note items. (OC-14599)

Participate

• Fixed an issue where the Participate Dashboard "Complete By" date could be off from the event Start Date by 1 day. (OC-15278)

Insight

- Updated Insight to ensure all current user roles are reflected in it (including Invited users and users' whose roles have changed). Note that previous user roles are not included. (OC-15000)
- Updated Insight to Include organization name and phone number for users. (OC-15001)
- Fixed an issue where joining tables in Insight questions could cause an error. (OC-15235)
- Improved performance of Insight for instances with many marts. (OC-15484)
- Removed the deprecated signature_required column from the event_definition_crf table in Insight. (OC-14528)
- Updated Insight to apply % formatting for percentage value columns in Standard Question. (OC-14987)
- Updated Insight to include a standard question for Cumulative Enrollment by Site. (OC-15226, OC-15493)
- Updated Insight for compatibility with Study Runner database changes. (OC-15238)

REST API

- Fixed an issue where it was not possible to unlock an event via the API. (OC-14012)
- Updated Participant Creation APIs to prevent use of certain characters that could cause issues in Study Runner: <> & " '(OC-14043)

OpenClinica 4 Stack 13.3.1 (Release Date - 04 June 2021) OpenClinica 4 Stack 13.3.1 contains targeted fixes to OpenClinica. View the entire **Stack 13.3.1 changelog here** (login required). Highlights include:

Changes & Fixes:

• Fixed an issue that prevented newly uploaded forms containing cross-form logic using item references from working as expected. (OC-14928)

OpenClinica 4 Stack 13.3 (Release Date - 27 May 2021) OpenClinica 4 Stack 13.3 contains targeted fixes to OpenClinica. View the entire **Stack 13.3 changelog here** (login required). For an overview of this update, view the **Stack 13.3 Release Announcement here**. Highlights include:

New:

Study Build System

• Study environments can now be archived via a new status (Archived). A study environment (production or test) can be set to a status of archived on the Share page using the same menu currently used to set other study statuses (e.g. Available, Frozen, Locked, etc.). An archived study environment is inaccessible in Study Runner, can't be published to, and Notification Rules, Jobs, and Insight refresh will cease to function for it. Studies with both environments archived will be considered retired and will no longer appear on the default view of the My Studies page. Study environments can be unarchived and this will cause them to resume their normal functionality.

Study Runner

- Data Specialists and Investigators can now select multiple participants on the Participant Matrix via checkbox, or 'Select All', and sign them in bulk. The logic for determining whether a participant record can be signed is not changed as part of this release.
- The Quick Access panel on the left side bar now includes a list of the user's most recently accessed participants and forms in their current study or site. Participant links are shown as Participant ID and will open the Participant Details Page for that participant. Form links are shown as event name (and event ordinal) along with form name and will open that form record again in the same manner as it was opened the last time. The order of the links will update dynamically as participants and forms are accessed. This will only track recently accessed forms and participants within the user's current login session.

Changes & Fixes:

Study Build System

- Users will now be prompted to confirm their action when publishing a new study to the Production environment for the first time. (OC-14862)
- Fixed an issue where searching for a site could show no results when including a space in the search terms. (OC-14954)
- Updated Study ID and Site ID input to prevent use of certain characters that could cause

- issues in Study Runner: < > & " '. (OC-13730)
- Updated the Share Page to allow searching within the People table. (OC-11875)
- Fixed an issue where the Administration People table would fail to load if user roles had been changed from study level to site level and user assigned to these roles did not have an sites associated with them. (OC-15035)
- Updated People table search to allow Enter to initiate the search rather than using the search button manually. (OC-13257)
- Fixed an issue where usernames could be created with spaces at the beginning or end and it could cause future login or signing issues. (OC-13934)
- Fixed an issue that allowed a user to be created with the same username as another user's email address. (OC-13742)
- Fixed an issue where Site updated date was only updated when the Site status was changed. (OC-12945)

Study Runner

- The standard OpenClinica signature attestation has been updated. Event signatures now explicitly list the forms within the event that the signature covers, excluding forms not accessible to the signing user and forms not started. (OC-15054, OC-15091)
- Fixed an issue where one user could trigger a concurrency lock on a form that prevents them from reopening the form. (OC-14791)
- Fixed an issue where the "add another form" feature in repeating common events could create empty event occurrences. (OC-14837)
- Improved scheduled extract job performance to resolve some cases where the extract could fail. (OC-12988)
- Fixed an issue where some site-specific configurations were not being correctly applied when adding new common event forms at some sites. (OC-14838)
- Fixed an issue where the Visits table of a participant details page could fail to sort correctly when trying to sort by status. (OC-14846)
- Fixed an issue where Data Managers would not see the Design link in Study Runner if they were assigned a different role in one of the environments of their study. (OC-14896)
- Improved performance of Queries download feature. (OC-14900)
- Fixed an issue where Participant IDs could fail to appear in printed View Events pages if filters were applied prior to printing. (OC-14937)
- Fixed an issue where uploading a rule that inappropriately referenced the same object as an existing rule did not resolve correctly. Uploading a rule in this case will now fail with an appropriate error message. (OC-15025)

REST API

- The date SDV was last modified for each participant is now included in the Get Participant API. (OC-14898)
- Fixed an issue where calling the study API to create many events at one time could inappropriately return an error. (OC-14957)
- Fixed an issue where calling the API to get a participant casebook could sometimes fail.
 (OC-14949)

Insight

- Fixed an issue where an archived form could inappropriately appear in Insight if it was present in an archived event. (OC-14907)
- Fixed an issue where archived forms that were also present in other archived events could

- inappropriately appear in Insight. (OC-14907)
- Fixed an issue in Insight where a pulse using a question built by joining a saved question to a different table would fail to be sent. (OC-15062)
- Fixed an issue where resetting an Insight password could be difficult on screens with low resolution. (OC-14452)
- Fixed an issue where setting up an Insight dashboard to drill through to a custom URL and then editing the question would cause the dashboard to cease functioning. (OC-14434)
- Fixed visual issues with the menus used to show or hide columns in the Insight custom question builder. (OC-14609, OC-14610)

General

• Security enhancements

OpenClinica 4 Stack 13.2.2 (Release Date - 05 May 2021) OpenClinica 4 Stack 13.2.2 contains targeted fixes to OpenClinica. View the entire **Stack 13.2.2 changelog here** (login required). Highlights include:

Changes & Fixes:

• Fixed an issue that excluded data from Signed Participants in data extracts. (OC-15011)

OpenClinica 4 Stack 13.2.1 (Release Date - 04 May 2021) OpenClinica 4 Stack 13.2.1 contains targeted fixes to OpenClinica. View the entire **Stack 13.2.1 changelog here** (login required). Highlights include:

Changes & Fixes:

- Fixed an issue that prevented cross-form values from being loaded in some cases. (OC-14836)
- Fixed an issue that included data from removed Participants in data extracts unexpectedly. (OC-14856)
- Fixed an issue that caused flat file data import to work incorrectly when the first column in a data row was empty. (OC-14858)
- Fixed an issue that prevented selection item code choices from displaying item values in their labels if the choices used choice filters. (OC-14458)
- Increased the size of the Calculation and Default text boxes in Form Designer to accommodate large expressions more easily. (OC-14435)
- Updated the Form Designer item label area to be displayed in an appropriate size more consistently. (OC-14801, OC-14612)
- Fixed an issue in Form Designer that did not truncate system-generated item names to the maximum length correctly in some cases. (OC-14611)
- Fixed an issue in Form Designer that caused item label text to be displayed outside of the label box in some cases. (OC-14759)
- Technical improvements for the authentication system to support future enhancements. (OC-14932)

OpenClinica 4 Stack 13.2 (Release Date - 08 April 2021) OpenClinica 4 Stack 13.2 contains targeted fixes to OpenClinica. View the entire **Stack 13.2 changelog here** (login

Changes & Fixes:

- Improved Study Runner performance. (OC-14637)
- Improved performance of the Participant Matrix when Custom Columns are in use. (OC-12974)
- Improved performance of the Participant Matrix for users with signing permission. (OC-14584)
- Improved performance of the Participant Matrix when filtered to a single event. (OC-14548)
- Fixed an issue with the Participant Matrix not loading correctly after cancelling an action. (OC-14510)
- Fixed an issue with the Participant Matrix displaying started forms as Not Started.
 (OC-14604)
- Fixed an issue with Custom Columns on the Participant Matrix not sorting null values consistently. (OC-14779)
- Fixed an issue that could cause signing Participants to fail in some cases. (OC-14808)
- Fixed an issue with study publishing failing if an event with an open Start Date or End Date Query is being archived. (OC-14582)
- Fixed an issue with system-generated IDs not being created correctly in some cases. (OC-14549)
- Fixed an issue with Rules not firing based on the current date as expected in some cases. (OC-14597)
- Update Tabular import to allow mapping the Participant ID column to an item on the form. (OC-14111)
- Fixed an issue with import that caused query updates to unsign Events. (OC-14622)
- Fixed an issue with Form Last Updated Date not reflecting updates made via data import. (OC-14696)
- Fixed an issue with importing data into select one from file items. (OC-14786)
- Fixed an issue with Events not being autocompleted when all Forms are marked Complete if the Event Definition contains archived forms. (OC-14661)
- Fixed an issue with users sometimes being prompted to login again after successful login to Study Runner. (OC-14685)
- Fixed an issue with inactivity timeout sometimes not working as expected when a computer is put into sleep mode during a session. (OC-14554)
- Improved form loading performance. (OC-14721)
- Fixed an issue with the View Queries Only link not working for Queries on items that do not have labels. (OC-14361)
- Fixed an issue with Add Another form feature not working as expected. (OC-14567, OC-14608)
- Fixed an issue with forms using pages theme that could result in non-relevant items containing data being displayed on every page. (OC-14682)
- Fixed an issue with single select items on forms not printing correctly. (OC-14558)
- Fixed an issue with blank forms not respecting page breaks when printed. (OC-14564)
- Fixed an issue with Query Widget History not including labels for some selection items within the form editing session. (OC-14577)
- Fixed an issue with Query Widget History not updating within the form editing session if one of the selections became filtered out by a choice filter. (OC-14686)
- Fixed an issue with using View Query Within Record link for an image map item. (OC-13530)
- Updated system modules to provide improved security.

OpenClinica 4 Stack 13.1.1 (Release Date - 23 March 2021) OpenClinica 4 Stack 13.1.1 contains targeted fixes to OpenClinica. View the entire **Stack 13.1.1 changelog here** (login required). Highlights include:

Changes & Fixes:

- Improved performance for uploading a form version or adding a draft to a study. (OC-14645)
- Fixed an issue that prevented forms from being added to a study if an item has a hint but no label. (OC-14614)
- Fixed an issue with downloading a form version definition containing a large CSV file attachment that could result in the CSV file being corrupted. (OC-14490)
- Fixed an issue with attempting to add a line break to an Event name that could cause Study Designer to hang. (OC-14442)
- Fixed an issue that prevented users from using the Design button on a Form card after unarchiving the Form. (OC-14517)
- Updated Study Designer to disallow Form names from starting with "F_" and Event names from starting with "SE" to prevent subsequent publishing errors. (OC-14472)
- Fixed an issue that caused some Study Designer icons to be displayed incorrectly on some Mac browsers. (OC-14397)
- Fixed an issue for relevant or constraint logic defined using the logic builder Form Designer. (OC-14674)
- Fixed an issue that could cause Form Designer to hang when opening an invalid multilanguage form. (OC-14467)
- Updated Form Designer to include hover text showing item type for existing items. (OC-13897)
- Updated Form Designer to use different styling for item labels and the item label hint text displayed when a label is empty. (OC-14516)
- Updated Form Designer to support multiple line item labels and display item names directly on item tiles. (OC-12846)

OpenClinica 4 Stack 13.0.4 (Release Date - 6 March 2021) OpenClinica 4 Stack 13.0.4 contains targeted fixes to OpenClinica. View the entire **Stack 13.0.4 changelog here** (login required). Highlights include:

Changes & Fixes:

- Fixed an issue where forms using the jr:choice-name() function would load with an error in some cases. (OC-14568)
- Fixed an issue where repeating groups with relevant logic at the group level might cause the entire group to be hidden when the group is non-relevant and only instances after the first contain data. (OC-14575)
- Fixed an issue where a triggered calculation using an item in a repeating group to trigger an item out of the repeating group could fail to work properly. (OC-14466)
- Fixed an issue where Select One items in repeating groups might not be hidden when they become non-relevant. (OC-14563)
- Fixed an issue where pages style forms could allow opening the Query Widget for non-relevant items without allowing it to be closed easily. (OC-14576)

OpenClinica 4 Stack 13.0.3 (Release Date - 24 February 2021) OpenClinica 4 Stack 13.0.3 contains targeted fixes to OpenClinica. View the entire **Stack 13.0.3 changelog here** (login required). Highlights include:

Changes & Fixes:

• Fixed an issue where calculated items were not being cleared of data correctly when changes to other data in the form made them no longer relevant during form load. (OC-14542)

OpenClinica 4 Stack 13.0.2 (Release Date - 19 February 2021) OpenClinica 4 Stack 13.0.2 contains targeted fixes, enhancements, and new features to OpenClinica. View the entire **Stack 13.0.2 changelog here** (login required). Highlights include:

Changes & Fixes:

- Details of archived forms are no longer included during study publish. (OC-14523)
- Fixed an issue where some forms could fail to load correctly after publishing a study to restore archived events. (OC-14085)
- Fixed an issue that could cause the reuse of form OIDs when form names were changed and new forms were added with similar names. (OC-14514)
- Fixed an issue where archived forms were appearing in some Common Events on the Participant Details page. (OC-14519)
- Fixed an issue that could cause new common event forms to not appear on the Participant Details page. (OC-14520)
- Improved Participant Matrix performance. (OC-14518, OC-14522, OC-14531)
- Fixed an issue that was causing session time out to work incorrectly in some cases. (0C-14532)

OpenClinica 4 Stack 13 (Release Date - 13 February 2021) OpenClinica 4 Stack 13 contains targeted fixes, enhancements, and new features to OpenClinica. View the entire **Stack 13 changelog here** (login required). For an overview of this update, view the **Stack 13 Release Announcement here**. Highlights include:

New:

Study Build System

- Added Study Viewer and Site Viewer user roles to all studies. These roles have permission to view events and forms, but not change data or manage queries. They also do not have permission to use data extracts. Custom roles can be created based on these roles as needed and permission tags can be assigned to them to manage form-specific access.
- Added support for additional form logic options. All options support cross-form logic.

Defaults can now be defined to set item values at form creation (or when adding a new repeating group instance for items in repeating groups). They can be static values or calculated values (i.e., Dynamic Defaults). Items with defaults can be user-editable or read-only. Defaults can be used in conjunction with standard calculations or triggered calculations for an item (if needed). Triggered calculations can now be defined to set items to a calculated value when a trigger item's value

changes. They do not have any effect except when the trigger item's value changes. Items with triggered calculations can be user-editable or read-only. They can be used in conjunction with defaults (if needed). With these new features, there are now three options for system-generated form item values. Standard calculations always keep the calculated value in sync with the other items on the form and they are re-evaluated every time the form is opened. Items using these must be read-only. Triggered calculations only update the calculated value when the trigger item's value changes (regardless of any changes to items used in the calculation). Defaults update item values only when the form is first created and when a new repeating group instance is added.

Study Runner

- XML imports now allow the import of Queries, Annotations, historical signature attestations, and the setting of SDV statuses. Using an XML import, you can now add Queries to items or update and close existing Queries in bulk, as well as add Annotations, set form SDV statuses to verified or not verified, and set the Signed status of Study Events to Signed while adding a signature attestation to the audit log. These can be done as part of an import of clinical data or imported independently without associated item data.
- Tabular imports have been expanded with new features available in the mapping file. The SkipMatch feature of tabular imports has been expanded to allow choosing whether to skip the import of a row based on matching against a set of criteria or to update existing records when matches are found. Previously only new records could be added as part of a tabular import. To support matching and updating specific occurrences of repeating events, the start date and repeat key of repeating events can be included as optional columns in the tabular file. Using the start date, new instances of visit events can also now be scheduled as part of the tabular import. The post-import status of forms can now be configured. The Reason for Change to use if the import changes data on complete forms can also be configured. Finally, these imports can now be configured to ignore columns in the import file that are not explicitly mapped to items so that data files do not need to be modified to remove unmapped columns.
- Added support for users to navigate directly from one repeating common event form to the next occurrence of that form. This allows data entry users who are adding new forms to choose to open the next form automatically without having to return to Study Runner and click the link for the form they want to open. This feature is only available during initial data entry for these forms, not for subsequent editing or viewing of the forms. It can be enabled per form using the Allow Add Another checkbox on the form card in Study Designer for each repeating common event form.

Changes & Fixes:

Study Build System

- Added link to create a new study to the top of the My Studies page. (OC-12236)
- Updated the My Studies page to have a more intuitive sorting. (OC-11220)
- Fixed an issue that could result in duplicate participant IDs within a study. (OC-10552)
- Removed typo in User Roles tab label. (OC-14205)
- Fixed an issue where reusing site identifiers could cause errors when some users attempted to login. (OC-13321)
- When publishing an overwritten form version, referenced files will now be cleared as expected. (OC-12972)
- Fixed an issue where the wrong error message would be displayed for certain types of form issues when uploading a completed form definition spreadsheet. (OC-13997)
- Added the ability to tag other Study Designer users in comments added to Study Designer cards. (OC-12931)

- Fixed an issue where the popup to Discard a form draft in Study Designer could fail to render. (OC-13889)
- Fixed an issue that could cause an extra character to be inserted into form names when using Study Designer. (OC-14166)
- Added an error message to display when a form containing only calculate items is added to a study. (OC-12101)
- Removed items that exist only in archived form versions from the configuration menus for adding custom columns to the Queries table and Participant Matrix. (OC-13726)
- Improved form card performance in Study Designer. (OC-14190)
- Added error checking on form upload to reflect that 'data' is a reserved word in form design and cannot be used as an item or item group name. (OC-14202, OC-14152)
- Validating a form preview will now always correctly indicate when there is a non-strict error that needs to be resolved. (OC-14076)
- Improved efficiency of form preview feature. (OC-13107)
- Fixed an internal form definition structure issue. (OC-12853)
- Updated form engine validator to enable support for new features. (OC-9114)
- Updated Form Template to include Stack 13 features. (OC-13431)
- Clarified label of Appearance in Form Designer. (OC-14203)
- Fixed an issue that could cause Form Designer to unexpectedly change relevant logic.
 (OC-14370)
- Updated Form Designer to allow items to have empty labels to use them as background calculations. (OC-14016, OC-14018)
- Fixed an issue where Form Designer would sometimes hang on load. (OC-13977)
- Made conditional expressions required in form designer if conditional is selected. (OC-12458)
- Added integer item appearance options to Form Designer. (OC-13776)
- Added support for contact data in the Use External Value field in Form Designer. (OC-12287, OC-13750)
- Fixed an issue where users whose usernames were email addresses could not access Form Designer. (OC-13642)
- Added clarity to the error message displayed when Form Designer is unable to save.
 (OC-13701)
- Fixed an issue where building a form with an external list item type in Form Designer could cause the form draft to become non-downloadable. (OC-13697)
- Updated Form Designer to truncate the auto-populated values for item names at the maximum length of this field to avoid errors. (OC-13441)
- Removed Beta designation from Form Designer UI. (OC-13133)
- Added ability to preview forms with External List items in Form Designer. (OC-12627)
- Added ability to preview forms with cross-form logic in Form Designer. (OC-13132)
- Updated Form Designer Library List to include column for Version. (OC-13123)
- Updated Form Designer Library so that uploaded content will now be saved as templates instead of blocks. (OC-13122)
- Updated Form Designer Logic Item selectors to include items from the entire form rather than just items from earlier on the form. (OC-13309)
- Updated Form Designer Logic Item selectors to include the item name as well as its label.
 (OC-13308)
- Fixed an issue that could prevent further editing of a form in Form Designer after a large media file was attached to the form definition. (OC-13106)
- Added the ability to cancel a drag and drop action by pressing ESC to Form Designer.
 (OC-13031)
- Fixed an issue that could present invalid error messages when a newly created user used Form Designer for the first time. (OC-13004)

• Fixed an issue that could cause problems with Form Designer's handling of multi-language media columns. (OC-13108)

- Improved performance in the Participant Matrix. (OC-13591, OC-14406)
- Fixed an issue that could cause a link to a completed form to work incorrectly when the Participant Matrix was filtered by an event. (OC-14407)
- Fixed an issue where forms could be incorrectly displayed as editable in the Participant Matrix. (OC-13466)
- Updated the Participant Matrix Event and Form links to be independent of user type and match the links on the Participant Details Page. (OC-13447)
- Fixed an issue where options on the Participant Matrix were not being correctly adjusted based on user privileges. **OC-13200**)
- Updated Status attribute to display on same line as workflow status on Participant Matrix. (OC-13199)
- Updated labels for Participant Matrix form actions. (OC-14468)
- Fixed an issue that could cause the signed status icon to fail to display on the Participant Matrix for repeating visit events after one occurrence of the event was removed. (OC-14167)
- Updated which characters can be used in participant IDs. Greater than, less than, double quotes, single quotes, and ampersands can no longer be used in participant IDs. (OC-13732)
- Changes to data related to a participant including item data, event status, and form status, will now update the Last Modified Date and Last Modified By fields of the associated participant.

 Queries and SDV status are excluded from this.
 - (OC-12023, OC-13184, OC-13332, OC-13553, OC-13554, OC-13555, OC-13556, OC-135 58, OC-13577, OC-13578, OC-13665)
- Fixed some cases of an issue that could cause an error when multiple export jobs are scheduled concurrently. (OC-14481)
- SAS extracts will now include site ID and form status. (OC-9109)
- Fixed an issue that could cause CRFs not to appear in the header of Tab Delimited Text Extracts when used in multiple events. (OC-12585)
- Significantly improved extract job performance. Time required for benchmark extracts reduced by several orders of magnitude. (OC-13851)
- Updated the dataset creation feature to always list all versions for items in more than one form version. (OC-9830)
- Fixed an issue where some extract formats would not include form version information.
 (OC-9777)
- Data specialists and Investigators can now remove data sets they have created. (OC-14136)
- Fixed an issue that could sometimes cause concurrent scheduled jobs to fail. (OC-13259)
- Fixed an issue where applying a sort or filter on the table of job runs on the scheduled job detail page caused the page to fail to render correctly. (OC-12800, OC-12796)
- Fixed an issue with migrating Event CRFs in bulk to different CRF versions. (OC-14133)
- Fixed an issue that could prevent form version migration when the SDV status was set to Verified. (OC-13741)
- Migrating a record to a different CRF version will no longer unsign the record. (OC-14277)
- Fixed an issue in which migrating the version of a CRF could in some cases result in performance issues. (OC-14254)
- Updated the Bulk Actions Log link label for Monitor users (OC-13780)
- Improved accuracy of tabular import error messaging. (OC-14305)
- Fixed an issue where importing tabular data into a form with an invalid or inactive form version OID could cause errors when attempting to enter data in the form manually or errors

- in the import. (OC-13630, OC-13595)
- Fixed an issue where importing data into an event manually marked complete could cause the event status to change if unstarted forms were present in the event. (OC-14192)
- Fixed an issue where tabular data could sometimes be imported for participants at unavailable sites. (OC-13346)
- Fixed an issue where the ampersand character could cause XML imports to fail if included in item data. (OC-14160)
- Added error message to correctly identify when a tabular import mapping file attempts to map data that are not present in the data file. (OC-14147)
- When a time is not specified for Event Start Date, it should now correctly have no associated time, rather than showing a time of noon. (OC-13445)
- Fixed an issue where a form's concurrency lock could fail to be released if opened from certain pages. (OC-14068)
- Query Notification Emails will now always link the user to the correct study. (OC-11033)
- Fixed an issue where custom columns on the Queries table could cause a CSV download of the Queries table to be formatted incorrectly. (OC-14065)
- Fixed an issue that could cause some Event Queries to be non-editable in certain browsers. (OC-13116)
- Queries can now be assigned to invited users of the study prior to their initial login.
 (OC-13815)
- Fixed an issue where pipe characters in item data was sometimes being interpreted inappropriately as a delimiter in tabular imports. (OC-14048)
- Fixed an issue where the use of rules in a study could cause errors in tabular imports. (OC-14006)
- Fixed an issue where a user account creation glitch could cause some pages to display errors. (OC-13931)
- Fixed an issue where the user would sometimes encounter an error when clicking the link to view a participant from the Participant Matrix. (OC-13903)
- Fixed an issue where the order of forms in Study Designer was not being respected on the Enter or Validate Data page in Study Runner. (OC-13871)
- Fixed an issue that could cause changes made to site-level form configurations to fail to save. (OC-13700)
- Fixed an issue that could cause inappropriate insufficient privilege errors when editing a form after updating settings related to site form versions. (OC-13463)
- Fixed an issue that allowed participants with only removed or archived events to be signed.
 (OC-13621)
- Fixed an issue where headers for Archived Common Events could be displayed for Participants who have no data in those events. (OC-13559)
- Fixed an issue that could allow event statuses to be set to completed after required forms had been removed. (OC-13475)
- Fixed an issue where the Restore Participants page was incorrectly showing the site value as the study value for participants assigned to a site. (OC-13439)
- Updated the Sign Participants page to remove unused fields. (OC-13429)
- Removing a required form from a Complete event will now update the event status out of Complete. (OC-13419)
- Starting data entry on a new form in a Complete event will now update the event's status out of Complete. (OC-13418)
- Added the Audit Log Event Type Event CRF Cleared to replace the deprecated audit type Event CRF Deleted. (OC-13384)
- Fixed an issue where the Sign Events page was missing event status icons. (OC-13292)
- Updated to allow Data Specialists and Investigators to Sign Events and Participants using

- signature codes when SAML SSO is in use. (OC-14015, OC-14019)
- Fixed an issue where archiving a form with a changed name and then creating a new form with the original name of the archived form could cause the View CRF page to display incorrectly. (OC-13238)
- Fixed an issue where the SDV Detailed View was missing items from older version of forms. (OC-13166)
- Imported data will now correctly set SDV status to Unverified if data in verified forms change.
 (OC-13490)
- Fixed an issue where the SDV Item-level Details table would not handle commas correctly, causing some data to be displayed inappropriately in the table. All delimiters will now be processed correctly by this table. (OC-14082, OC-14092)
- Fixed an issue where the SDV table would not correctly show all instances of a repeating event when some contained only a single item with data. (OC-13842)
- Updated "Clear Event CRF" (formerly delete) confirmation page. (OC-12832)
- Updated the Participants Details page to hide the header for an event if all forms within the event are hidden. (OC-12131)
- Fixed issue that could cause Event Action Rules to fail. (OC-13906)
- Performance improvements for Rules. (OC-14151) ode maintenance improvements in Study Runner. (OC-14102, OC-13268)

Forms

- Field histories viewed on a form now display the value and the label associated with each change. (OC-7954, OC-14049)
- View Query Only form view will no longer display with a collapsible group label. (OC-9021)
- Added a message that will appear when viewing forms in Removed or Archived events, indicating the form is in such an event. (OC-14059, OC-13393)
- Fixed an issue where a Query could fail to auto-close correctly if the associated item was not appearing as relevant when the form was initially opened. (OC-13902)
- Fixed an issue where changing data in a completed form and then closing it without providing the required Reason for Change would automatically log a Reason for Change instead of a Query. (OC-13804)
- Updated the message indicating the maximum size for uploaded files to be more exact. (OC-13768)
- Fixed an issue that could interfere with the successful running of cross-form logic. (OC-13744)
- Fixed a layout issue that could arise in printed PDF casebooks in Firefox. (OC-13561)
- Fixed an issue where when copying and pasting data of the wrong type into a field, no change in the data was saved in the form. (OC-13531)
- Fixed an issue where no error message was being displayed when a form is opened with an external file that is missing. (OC-13479)
- Fixed an issue where multiple consecutive analog scale items could cause the form to render incorrectly. (OC-13436)
- Fixed an issue where form labels starting with a digit and period would be indented unexpectedly. (OC-13400)
- Fixed an issue where image maps in printed PDF casebooks could sometimes display incorrectly. (OC-13222)
- Clarified message provided when uploaded form contains item groups that begin with unsupported characters. (OC-13165)
- Fixed an issue where certain invalid form uploads would fail with an invalid file type error

- instead of correct error messages. (OC-13138)
- Updated Vertical VAS to have option to display numeric labels every 10 units to match the requirements of certain validated instruments. (OC-13127)
- Fixed an issue where the choice filter would not work if the filter evaluation was done before the item became relevant. (OC-12885)
- Fixed an issue where a loading page could be displayed indefinitely when closing a form. (OC-11467)
- Added support for the pad2() function to pad a number to 2 digits. (OC-11206)

Participate

- When a participant edits a form already in progress, they will now be taken to the point of the form where they last left off. (OC-12389)
- Fixed an issue that could cause calculation items based on a date to display incorrectly on some systems.(OC-14184)
- Performance of Participate dashboard will be significantly improved when participants have many forms visible. (OC-14052)
- Fixed an issue where a participant would be unable to move on to the next form after reopening a contact form containing data. (OC-13517, OC-11179)
- Fixed an issue that could cause the Invite Participant dialog to start defaulting to select invitation by mobile. (OC-12942)
- Expanded Participate mobile number country selector to include all countries. (OC-12872)
- Code refactoring to improve performance. (OC-14252)

Randomize

- Added support for multiple randomizations per study. (OC-13184)
- Improved stability for randomizations. (OC-12527)

REST API

- Updated the API to create Event CRFs for associated forms when events are scheduled via this method. (OC-13995)
- Added new endpoints for tabular and XML import APIs. The prior endpoint is still operational but will be deprecated in the future. (OC-13755, OC-13657)
- Updated the scheduled job API to appropriately restrict access to the correct site/study admin users. (OC-13546)
- Updated the scheduled job API to give the correct error code responses and improved messaging in the response bodies in certain cases. (OC-13488)
- Fixed an issue where it was not possible to lock an event via the API. (OC-13368)

Insight

- Fixed an issue where Insight refreshes could begin to fail if previously published forms or events containing them were archived in Study Designer. (OC-13357)
- Added support for new Viewer role to Insight. (OC-14307)
- Updated the labels recorded in Insight for several Audit Log Event Types to match what is displayed in the OpenClinica Audit Log interface. (OC-13690)
- Updated Insight to address possible refresh issues. (OC-13359, OC-13358)

General

• Fixed an issue that could cause a new user's status to not be updated appropriately in

environments with SAML SSO enabled. (OC-14259)

- Code maintenance improvements for authentication. (OC-14330)
- Runtime is now called Study Runner in Qualification Reports. (OC-13779)
- Fixed an issue that was requiring users to login twice on their next login following a session timeout. (OC-11106)
- Fixed an issue that could inappropriately log users out when navigating between Study Runner or Study Designer and the Study Manager. (OC-11087)
- Security enhancements.

OpenClinica 4 Stack 12.5 (Release Date - 20 January 2021) OpenClinica 4 Stack 12.5 contains targeted fixes to OpenClinica. View the entire **Stack 12.5 changelog here** (login required). Highlights include:

Changes & Fixes:

• Updated authentication service to support a custom logout extension. (OC-14142)

Click here to view previous updates

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