Release Notes (OC4)

Warning! This site is no longer being updated and will soon be decommissioned. To access the latest OpenClinica Documentation, **please click here**. Here you can access information about existing OpenClinica releases. **How we work** - We use agile software development practices. This means that while we do keep a "long term" road map, we are always adjusting to deliver high value product(s) for our users. We break up major pieces of functionality into Minimally Releasable Features (MRFs) which we prioritize and work on in order of priority. **How we prioritize** - The product owner gets feedback from all stakeholders (e.g. Enterprise customers, Community Users, Community Developers, Partners, Engineers, etc) and prioritizes based on feedback. **What changes priorities** - The best way to get a feature into OpenClinica is to build it and share your code via GitHub. If it's good we'll get it in right away. Even if you can't write the code, if there is something that you feel passionate about and want to engage with us, please do (the OpenClinica forums are great place to start)! **How often we prioritize -** This is something we do on a perpetual basis (day to day). Although the top priorities are less likely to change (especially the ones currently being worked on), if there is a compelling reason to change them, we can. The further out a feature is the less certain its priority and release date are. Please see Development Roadmap (OC4) for details about upcoming OpenClinica 4 releases.

Approved for publication by Paul Bowen. Signed on 2026-10-15 9:49PM

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1 OpenClinica 4 – Release Notes 2026

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OpenClinica 4 Stack 20.1 (Release Date – 25 April 2026)

OpenClinica 4 Stack 20.1 contains targeted updates to OpenClinica. View the entire **Stack 20.1 changelog here** (login required). For an overview of this update, view the **Stack 20.1 Release Announcement here.** For more details about what this release means to you and your users, view the **Impact Analysis PDF Document here.**

New:

Training is now integrated into the study access workflow OpenClinica now supports both required role-based training for study access and optional in-product training for onboarding. Configurable Required Training and Study Access:

- Data Managers and Administrators can now assign required training by role, making it easier to ensure users complete the appropriate training before entering a study. Required training status is visible in a dedicated column on the **User Roles** page and is also shown on the **Share**

page for improved visibility during study setup and user management.
- When a user is assigned a role with required training, they are redirected to the training page before they can access **Study Runner**.
- After completing all required training, the user is automatically returned to Study Runner, creating a seamless training and access workflow.
- Audit log entries are recorded when a user completes an individual training module and when all required training for an assigned role has been completed, providing seamless traceability for study teams and administrators.
- As part of this new feature rollout, OpenClinica's legacy LMS is being wound down and will be deactivated soon. However, legacy training completion data, including completed courses and completion dates, will be migrated into OpenClinica 4 to preserve historical records. This will also prevent users from being required to retake courses they have already passed.

Optional training content is also integrated into the system via the **Resources beacon** to support easier onboarding and ongoing learning. This allows users to access helpful training materials within the platform even when training is not required for their role, making it easier to get started and build familiarity with study workflows. **Study Designer Form Search** We've introduced the new **Study Designer Form Search** feature to completely streamline form discovery and reuse. This update makes it easier to add existing forms to an event by letting you quickly find and use forms already in your study or from the Library.

Changes and Fixes:

Study Build System

- **Study Manager**
  - Fixed an issue where the People table on the Share page did not allow appropriate sorting. (**OC-26760**)
  - Fixed an issue where performing certain actions in rapid succession could incorrectly create duplicate user metadata records, leading to downstream Insight refresh failures and unexpected behavior in user management. (**OC-23801**)
  - The time zone labelled "GMT0" was removed from the menu of available options when setting a Site's time zone, as it was redundant with the standard GMT time zone and caused issues when used. (**OC-27141**)
  - Fixed an issue where study publishes intermittently failed to correctly log changes in the publish activity logs. (**OC-26372**)
- **Study Designer**
  - Changed default form designer style setting to "Simple-Single Page" to make building your first form more intuitive. (**OC-26544)**
  - Fixed an issue where the "&" character appeared as "&amp" in Form Designer. (**OC-26595**)
  - Fixed issues where Default values did not work properly in Form Designer Preview. (**OC-21176**, **OC-14618**)
  - Fixed an issue where Form Designer was displaying an error when the user tried to preview a form that contained an external list and multi-select in different groups. (**OC-22435**)
  - Removed the "Form Designer" title from the Library Management page and Form Designer itself. (**OC-26957**)
  - Updated "Library Management" button to "Library" in Study Designer. (**OC-26956**)

Study Runner

- **Participant Details Page (PDP)**

    - Fixed an issue that could cause a Common Event record to appear on more than one table page or be missing when the Common Events table was sorted. (**OC-26377**)
    - Removed the following text on Clear Form from Event page for accuracy: "Reason for Change is not captured for this change to the data. Be sure to document the reason for clearing this record elsewhere in your study documentation." Reason for Change is already captured for Clear Form actions. (**OC-26452**)
    - Fixed an issue where archiving a form version for a form in a common event prevented records for forms using that version from being migrated to new versions from the PDP. You are now able to perform version migrations on these forms as expected. (**OC-25907**)
- **Queries**
    - Improved performance of the Queries page. (**OC-15673**, **OC-17272**)
    - Fixed an issue where the discrepancy notes summary table could show incorrect totals. (**OC-27202**)
- **Extract Data**
    - Fixed an issue that was causing an unpredictable order of study metadata in extracts. (**OC-27029**)
- **Investigator Signatures**
    - Signed Participants can now be reassigned to a new site. Previously this was not possible. The signatures will remain in place and the Signed status is retained. (**OC-25036**)
- **Source Data Verification (SDV)**
    - Improved performance of Source Data Verification page. (**OC-26371**)
- **Participate**
    - The button Participants click on their dashboard to complete and submit all the form data in an event and move on has been re-labeled "Submit All". (**OC-26394**)
- **Miscellaneous**
    - Fixed an issue where changing form access from the default level while creating a new Custom User Role could cause a 500 Internal Server Error in Study Runner. (**OC-26988**)

General

- Fixed a rare issue that could prevent a user from logging into OpenClinica. (**OC-24293**)
- Previously when a user logged out of OpenClinica and then left the login page open for an extended time before logging in again, their first attempt to log back in would consistently fail, allowing them to log in on the second attempt. We have corrected this and users will now be able to log in successfully on their first attempt consistently. (**OC-14870**)
- The color scheme has been updated throughout the system to make the OpenClinica interface more modern and user-friendly. (**OC-26767**)

For additional information on purpose, issues addressed, traceability matrix, and deviations please visit the **OpenClinica 4 Stack 20.1 Note to File page here**. **Note:** The Note to File is now being hosted in the OpenClinica Trust Center. In order to view it, you will need to request access.

OpenClinica 4 Stack 20 (Release Date – 31 January 2026)

Stack 20 introduces major updates across OpenClinica.

- View the full **Stack 20 changelog** *(login required)*

- Read the **Stack 20 Release Announcement** for a high-level overview

- See the **Impact Analysis (PDF)** for details about what this release means for your studies and users

- If your existing studies have manual permission tags on contact forms, please see this **Customer Notification** for recommended next steps

New:

Configurable Form Access Permissions

We've enhanced how you control form data access using permission tags. Administrators can now set access levels (Read Only, Review, Edit) for each permission tag by role — offering more flexibility than the previous role-based defaults.

Unified Permission Model

When a manual permission tag is applied to a contact form, Study Runner now uses the access level associated with the manual permission tag to determine access. This allows access to a contact form to be revoked from a CRC/Investigator or to be granted to other roles.

Seamless Migration

Your existing permissions automatically carry forward. Roles that already had specific access configured will keep them in both existing and new studies. You can update access at any time from the **User Roles** page.

Exception: Studies where manual permission tags have been applied to contact forms may need to be updated to achieve the desired level of user access. See the **Customer Notification** for details. (Note that all affected customers have received versions of this notice that include the studies and user roles that need to be reviewed.)

Improved Visibility

You can now easily see which forms have special access rules.

- Contact forms display a new icon in **Study Designer**.

- The **User Roles** page lists tag names and access levels for quick review.

All other permissions—such as closing queries, removing or restoring data, scheduling events, or adding participants—remain managed at the role level.

Changes and Fixes:

Study Build System

- The **Advanced Calendaring** menu now opens a popup instead of a separate page, making it

faster and easier to use. (**OC-23668**)
- Fixed an issue where a site's time zone setting was not reflected across all associated studies. (**OC-23928**)
- Non-Admin users can no longer edit shared site details (Name, City, State, Zip, Country, Time Zone) on the Share page. (**OC-24391**)
- The **State/Province** field when adding/editing sites now enforces a 20-character limit and displays a clear error message if exceeded. (**OC-22338**)
- The **User and Role Audit Log** on the Administration page now requires Start and End Date filters (maximum range: one year) to improve performance and prevent timeouts. (**OC-9499**)

Study Runner

- **Forms**
  - Fixed an issue where forms using cross-form logic to pull in repeating groups only populated the first instance when the form first opened. All occurrences now populate correctly. (**OC-25672**)
- **Queries**
  - Fixed an issue where forms opened in Edit mode instead of Review mode when accessed via **View Query Within Record** in a frozen site. (**OC-26026**)
  - Queries that close automatically (e.g., when a field with an open query becomes hidden via relevant logic) now correctly show as **Closed-Modified**, not **Closed**. This ensures that any applicable constraint or required messages for the item will be shown when the form is opened again. (**OC-24677**)
  - Resolved an issue preventing users from managing queries or annotations in Frozen sites or studies. (**OC-25861)**
- **Extract Data**
  - Fixed an issue where forms containing both a manual permission tag and contact data could block dataset extracts. Extracts now complete successfully. (**OC-11691**)
- **Data Review Tables (DRT)**
  - Filtering by Open Queries within Data Review Tables now works as expected. (**OC-25132**)
  - Closing queries and removing/restoring forms is now correctly restricted for locked sites/studies and sites in Design status. Close Queries remains available for Frozen status. (**OC-25499**)
- **Miscellaneous**
  - Fixed an issue where a removed form could still be opened in Edit mode via Quick Links. Now, consistent with removed events, removed forms opened through Quick Links will display in Read Only mode. (**OC-25603**)
  - Fixed an issue where saving Site Configuration could unintentionally update a form's Advanced Calendaring settings (Visible and Editable). (**OC-25893**)
  - Removed the ability to access CRFs from the **View Events** page for improved consistency. The Participant Matrix and Participant Details page provide direct access to CRFs. (**OC-25344**)
  - Fixed an issue where Edit was shown as an option in the Single Event View of the Participant Matrix even though the user did not have access to the form. (**OC-23575**)

Code

- Fixed a duplication issue that could occur when changing a MedDRA verbatim response immediately after initial entry. (**OC-25928**)
- Fixed an issue where MedDRA table configuration changes may not have been recorded in the **Study Designer Activity Log**. (**OC-26003**)

- MedDRA table links now appear immediately in the **Tasks** menu after the study is published. (**OC-25630**)
- Improved support for enabling MedDRA coding in ongoing studies. When the OpenClinica Code module is activated in an existing study, new verbatim items trigger an asynchronous job to autocode existing data. (**OC-25186**)

Insight

- **Insight** now supports the new form access permission model. Contact data continues to be excluded from Insight. When **Row-Level Security (RLS)** is enabled, other data in contact forms or forms with restricted permission tags is hidden from users who do not have access. (**OC-25045**)
- MedDRA coding data is now included in Insight marts for studies using both modules. (**OC-24847**)

Participate

- Fixed an issue where participants were not always redirected correctly to the Participate dashboard after closing a form. (**OC-24536**)

General

- Security enhancements.

Click **here** to view previous updates.

Approved for publication by Kate Lambert. Signed on 2026-04-27 5:20PM

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2 OpenClinica 4 – Release Notes 2025

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OpenClinica 4 Stack 19.4.1 (Release Date - 29 September 2025)

OpenClinica 4 Stack 19.4.1 contains targeted updates to OpenClinica. View the entire **Stack 19.4.1 changelog here** (login required). For an overview of this update, view the **Stack 19.4.1 Release Announcement here.**

Changes and Fixes:

Study Build System

- Fixed an issue in Study Designer that could lead to slow performance when opening Study

Designer or archiving/unarchiving events or forms in large studies. (**OC-25969**, **OC-25984**)

For additional information on purpose, issues addressed, traceability matrix, and deviations please visit the **OpenClinica 4 Stack 19.4.1 Note to File page here**.

OpenClinica 4 Stack 19.4 (Release Date - 20 September 2025)

OpenClinica 4 Stack 19.4 contains targeted updates to OpenClinica. View the entire **Stack 19.4 changelog here** (login required). For an overview of this update, view the **Stack 19.4 Release Announcement here.** For more details about what this release means to you and your users, view the **Impact Analysis PDF Document here.**

New:

OpenClinica Code

OpenClinica Code is a seamlessly integrated solution that empowers your team to code clinical data with precision and efficiency using the industry-standard MedDRA dictionary. Ensure consistency, accuracy, and compliance directly within your study workflows. Code simplifies your MedDRA adverse event coding while accelerating your path to submission.

- New module allows coding of AEs or other relevant data with the MedDRA dictionary
- Central study-level dashboard for coding and reviewing verbatims, searching MedDRA, adding queries, and exporting coding data
    - Use your MedDRA license to search the dictionary and code directly from OpenClinica
    - Add Queries in bulk or individually directly from the coding interface
    - Review functionality to approve or reject coded terms
    - Download full coding dataset as a CSV file
- Code exact matches to MedDRA LLTs automatically
- Control access with granular user role privileges

Changes and Fixes:

Study Runner

- **Study Calendaring**
    - Fixed a bug where Study Calendaring rules triggered on the closing or completion of a form may not have run consistently. (**OC-25224**, **OC-25920**)
- **Data Transformation Module**
    - Fixed an issue where slower connections could cause page text to fail to load correctly in the Data Transformation Module. (**OC-25299**)

REST API

- Added the ability to use the XML import API to add file attachments to forms.

General

- Security enhancements.

For additional information on purpose, issues addressed, traceability matrix, and deviations please visit the **OpenClinica 4 Stack 19.4 Note to File page here**.

OpenClinica 4 Stack 19.3.1 (Release Date - 10 June 2025)

OpenClinica 4 Stack 19.3.1 contains targeted updates to OpenClinica. View the entire **Stack 19.3 changelog here** (login required). For an overview of this update, view the **Stack 19.3 Release Announcement here**

Changes and Fixes:

Study Build System

- Fixed an issue where non-ASCII characters were not displayed properly after a form was added in Study Designer. (**OC-25077**)

For additional information on purpose, issues addressed, traceability matrix, and deviations please visit the **OpenClinica 4 Stack 19.3.1 Note to File page here**.

OpenClinica 4 Stack 19.3 (Release Date - 07 June 2025)

OpenClinica 4 Stack 19.3 contains targeted updates to OpenClinica. View the entire **Stack 19.3 changelog here** (login required). For an overview of this update, view the **Stack 19.3 Release Announcement here**

New:

Participate

- The Participate module has been internationalized and is now available for use in multiple languages. System content displayed on the Participate Dashboard, within forms opened from Participate, or in Participant invitations is now available to Participants in their preferred browser language. When a Participant is first invited, the site user can select which language to send their invitation in. As of this release, studies can be configured to support Participate in English, German, Spanish, and Canadian French. Note that form content can still be localized into any language using the multi-language features of the form definition

spreadsheet and Participants can manually choose to view forms in language the forms support.

Changes and Fixes:

Study Build System

- Updated the Administration page People table to provide an option to hide or show OpenClinica Support Team users present in the system for support purposes. (**OC-23138**, **OC-23742**)
- Updated the Administration page People table to provide page size control to display 10, 25, or 50 users at once. Previously it could only show 10 users per page. (**OC-23137**, (**OC-23741**)
- Improved performance of study publishing for studies including Common Event Table Configurations. (**OC-24063**)
- Fixed an issue where study publish would fail if the new study definition archived a form version currently set as the default for a site. (**OC-23989**)
- Study Calendaring rule definitions included as part of study publish will now be included in the study metadata artifacts stored as part of each publish. These can be made accessible via SFTP upon request. (**OC-22921**)
- Fixed a display issue where the Publish History table on the Share Page did not correctly render the page number being viewed above page 99. (**OC-21950**)
- Updated the list of available sites when editing a user's site assignments on the Share Page to display in alphabetical order. (**OC-23333**)
- Fixed an issue where several invalid time zones were listed in the time zone dropdown for sites. Study Calendaring rules did not run as expected for Sites with the invalid time zones selected. (**OC-23545**, **OC-24148**)
- Fixed an issue where the Download All button on the Study Calendaring Advanced Calendaring Rules Management page was not working. (**OC-23925**)
- Fixed an issue where accessing the Configure SDV page for a form in Study Designer treated the form as being updated regardless of whether any changes were made. This could decrease performance for the Configure SDV page itself as well as for the next study publish. Additionally, it could lead to the study revision counter being incremented unexpectedly at the next study publish. (**OC-23942**)
- Fixed an issue in Study Designer where the display order of forms could be incorrect after dragging and dropping a form card. (**OC-24496**)
- Fixed an issue where users could create duplicate events in Study Designer using the copy option from the event card context menu. This action will now correctly disallow the creation of multiple event definitions with the same name. (**OC-21805**)
- Fixed an issue where the Study Designer page jumped to the far left when performing actions while the page was scrolled to the right. (**OC-23922**)

Study Runner

- **Participant Details Page (PDP)**
  - Updated behavior when a form could not be opened from the Participant Details Page because it was Not Started and its default version at the site level was invalid. Previously, the form failed to open with no explanation. This case will now show an error message explaining why the form cannot be opened. (**OC-23999**)
  - Fixed an issue where the headers of the Common Events tables on the Participant Details Page could render incorrectly in non-English languages. (**OC-23880**)
  - Fixed an issue where columns in Common Events tables on the Participant Details Page

were extending into the next column if they were displaying items without Brief Descriptions or Labels and the item names were very long. (**OC-23315**)

- **Participant Matrix**
  - Fixed an issue where unavailable actions were erroneously being displayed for forms in the single event view of the Participant Matrix when the participant was at a Locked site. Note that this was a display issue and the actions could not be taken. (**OC-24053**)
- **Study Calendaring**
  - Fixed an issue where Study Calendaring would intermittently fail to run as expected based on data entered via Public URL forms. This improvement also protects against other potential causes of intermittent Study Calendaring rule failure. (**OC-24325**)
  - Added stability improvements for Study Calendaring to ensure that rules set to run at a specific time of day will be run even if the system is down at their scheduled time. In that case, the rules will be run when the system is back online. (**OC-21878**)
  - Fixed an issue where Study Calendaring rules may not fire correctly based on an event status if the data was imported into a form, rather than being entered into the form itself. (**OC-23681**)
  - Fixed an issue with Study Calendaring where rules referencing repeating events may not run as expected for all event occurrences. (**OC-23969**)
  - Fixed an issue with Study Calendaring where rules referencing repeating item group values may not run as expected for all item group occurrences. (**OC-23970**)
  - Fixed an issue where audit logs for participants using the Study Calendaring module did not contain Epoch or Calendar changes. (**OC-23893**)
- **Queries**
  - Fixed a rare issue where the Queries Page could show Query entries that were from a different study. (**OC-23836**)
- **Extract Data**
  - Update ODM metadata to ease integration with other systems. Site-specific form details for FormLayoutRefID and IsDefaultVersion are now included. New form attribute IsAvailableVersion is also included for sites. This applies to the ODM metadata in Extracts, XML and JSON Casebooks, and Clinical Data API calls. (**OC-22920**)
  - Fixed an issue where items on forms Hidden from Site Users were able to be included in Extract datasets by site users who should not have been able to choose items from those forms. (**OC-22418**)
  - Fixed an issue where items on forms Hidden from Site Users were being included in Extract jobs run by the site users if the dataset had been defined with those items. (**OC-22419**)
- **Data Review Tables (DRT)**
  - Fixed an issue where Data Review Tables viewed at the site level could incorrectly show the open query indicator on an item column value. (**OC-23803**)
  - Fixed an issue where site users were able to access Data Review Tables defined to display data from primary forms that were Hidden from Site Users. Data Review Table access is now appropriately restricted from site users if a Hidden form is used as their primary form or an additional form. (**OC-15925**)
  - Fixed an issue where table pagination settings for Data Review Tables did not persist during the user's session. (**OC-22985**)
  - Added a "Clear All Filters" button to Data Review Tables to allow users to clear all current filters at once. (**OC-21621**)
  - Updated Data Review Tables to allow filtering on numeric and date items based on whether they are 'empty' or 'not empty'. (**OC-23227**, **OC-23229**)
- **Annotated Forms**
  - Fixed an issue where a form containing two items in two different item groups with item

names differentiated only by letter case would cause Annotated Casebook or Annotated Form generation to fail. (**OC-23382**)
    - Fixed an issue where Annotated forms might reflect an outdated iteration of a form version. This scenario could happen in the Test environment when an Annotated form was generated and then the form version was overwritten. This scenario could not happen in the Production environment. (**OC-24155**)
- **Contact Data**
    - Updated null contact data field values to no longer display on Casebook PDFs as "<Masked>". These will now display as blank values. Only non-null values will be displayed as "<Masked>". (**OC-23317**)
    - Updated the masking behavior for the Full DOB contact data field. When masked for unauthorized users, it was previously displayed as "9999-01-01". It is now masked consistently with other contact data fields using the text "<Masked>". (**OC-22314**)
    - Fixed an issue where reassigning a participant to a different site after their contact data had been filled in could sometimes cause an error. (**OC-24448**)
- **Bulk Actions Log**
    - Internationalized the content and filename of the Overall and Site Summary files included in the Archival Casebook job output in the Bulk Actions Log. (**OC-22710**, **OC-22723**)
    - Fixed a bug where the Bulk Actions Log table might not sort jobs correctly if they were run within the same minute. (**OC-24291**)
- **Rules**
    - Fixed an issue where removed participants were still receiving notifications triggered by legacy Rules. (**OC-22896**)
- **Miscellaneous**
    - Fixed an issue where some values in Study Runner were not being localized correctly for non-English languages. (**OC-22341**, **OC-23853**, **OC-23883**, **OC-24357**, **OC-24363**, **OC-24365**, **OC-24436**, **OC-24582**)
    - Fixed an issue where the Lead Investigator set for each site was not displayed in the corresponding fields on the Sites list and View Study pages in Study Runner. Note this value will only be displayed for new sites or existing sites that are edited and saved again from the Share Page. (**OC-21988**)
    - Fixed an issue where a site assigned an OID that included a system reserved word (such as "S_EVAL") would not allow users to access participants at that site. This has been resolved and sites containing these strings in their OID will now work as expected. (**OC-23191**)
    - Improved Study Runner accessibility by adding the language attribute to all pages. (**OC-24067**)

Unite

- Updated Unite Sync to have the option to sync only event schedules and data, but not Participants, between OpenClinica and external studies. This allows Participant creation to be managed by an external process as needed. (**OC-23910**, **OC-23938**)
- Updated Unite Sync to have the option to sync Participants and events between OpenClinica and external studies without also transferring form data records. (**OC-23967**)

Forms

- Improved performance of opening forms when there are many users in the study. This will also prevent a rare issue where the Query list on forms appeared to be out of date. (**OC-23704**)

- Fixed an issue where format-date() function on forms used the user's browser language setting to format the date. Now it will use the form language to format the date. (**OC-22393**)
- Fixed an issue where usernames in the Assign To Query Widget dropdown within forms was not sorting the names correctly in some cases. They will now be sorted in alphabetical order without regard to case. (**OC-23740**)
- Fixed a form layout issue where forms printed as a PDF from within the form (not as part of a PDF Casebook), were cutting off text in the History section for some items if the entries were very long. (**OC-24077**)
- Fixed an issue where the contents of Queries on forms included in PDF Casebooks could sometimes extend into other sections causing a text overlap. (**OC-23805**, **OC-24149**)
- Updated the messaging presented when a user attempts to Edit or Review a form currently open by another user in Edit or Review-Only mode. Previously, the message indicated the other user has the form open for data entry. The new message indicates that the other user has the form open for data entry or query management. (**OC-23906**)

Participate

- Fixed an issue that prevented Participants from opening forms using some versions of Firefox. (**OC-24139**)
- Added ability to send SMS notifications in a FedRAMP-compliant manner. (**OC-23632**)

Consent

- Updated the Consent signature window to be more user-friendly. Text has been updated to be clearer about what the user needs to enter and layout has been updated to help avoid accidental button clicks. (**OC-23934**, **OC-24127**)
- Updated cleared Consent forms to align with general system behavior of opening forms in the default version. Consent forms cleared automatically due to migration to a new version were not necessarily opening in the default version afterward. This conflicted with other functionality in rare cases. This has been resolved and this type of cleared form will now also open in its default version. Since Participants will always start Consent forms in their default version, the appropriate default version must be configured either in Study Designer or for an individual site. (**OC-23868**)
- Fixed an issue where the user shown as having created a Consent form record in the ODM Casebook and Extracts was changing when the form was countersigned by a site user. This field will now always show the user who first created the form record. (**OC-23522**)

REST API

- Fixed an issue where bulk jobs to create or update Participants that were run from the Swagger API testing page could erroneously report an error while executing successfully if the target study was configured to use a non-English language. (**OC-23798**)

General

- Added Spanish and Canadian French localization options for study users and sites users. This applies to Study Runner, forms, the login page, and system notifications. Studies can now be configured to support English, German, Spanish, and Canadian French. (**OC-24078**)

For additional information on purpose, issues addressed, traceability matrix, and deviations please visit the **OpenClinica 4 Stack 19.3 Note to File page here**.

OpenClinica 4 Stack 19.2.5 (Release Date - 03 April 2025)

OpenClinica 4 Stack 19.2.5 contains targeted updates to OpenClinica. View the entire **Stack 19.2.5 changelog here** (login required). For an overview of this update, view the **Stack 19.2.5 Release Announcement here.**

Changes and Fixes:

- Security enhancements.

For additional information on purpose, issues addressed, traceability matrix, and deviations please visit the **OpenClinica 4 Stack 19.2.5 Note to File page here**.

OpenClinica 4 Stack 19.2.4 (Release Date - 29 March 2025)

OpenClinica 4 Stack 19.2.4 contains targeted updates to OpenClinica. View the entire **Stack 19.2.4 changelog here** (login required). For an overview of this update, view the **Stack 19.2.4 Release Announcement here.**

Changes and Fixes:

Form Engine

- Fixed an issue where form display order could change unintentionally during study publish, resulting in some events having their forms listed in an incorrect order in Study Runner. (**OC-24095**)

For additional information on purpose, issues addressed, traceability matrix, and deviations please visit the **OpenClinica 4 Stack 19.2.4 Note to File page here**.

OpenClinica 4 Stack 19.2.3 (Release Date - 07 January 2025)

OpenClinica 4 Stack 19.2.3 contains targeted updates to OpenClinica. View the entire **Stack 19.2.3 changelog here** (login required). For an overview of this update, view the **Stack 19.2.3 Release Announcement here.**

Changes and Fixes:

Form Engine

- Fixed an issue where individual printed form PDFs did not show values entered into date

fields. This issue did not affect PDF Casebooks. (**OC-23945**)
- Fixed an issue where the buttons to Add or Remove occurrences of repeating item groups in forms using the Grid layout were displaying with text labels instead of the intended "+" and "-" labels. (**OC-23960**)
- Fixed an issue where forms configured to use locales other than English (en) or German (de) might present partial translations for some form framework (such as buttons). (**OC-24066**)

For additional information on purpose, issues addressed, traceability matrix, and deviations please visit the **OpenClinica 4 Stack 19.2.3 Note to File page here**.

Note: Stack 19.2.2 was reserved and was not deployed to Production environments.

Click **here** to view previous updates.

Functional approval by Paul Bowen. Signed on 2025-09-29 5:33PM

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3 OpenClinica 4 – Release Notes 2024

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OpenClinica 4 Stack 19.2.1 (Release Date - 19 December 2024)

OpenClinica 4 Stack 19.2.1 contains targeted updates to OpenClinica. View the entire **Stack 19.2.1 changelog here** (login required). For an overview of this update, view the **Stack 19.2.1 Release Announcement here.**

Changes and Fixes:

Study Build System

- Fixed an issue where publishing a study could fail when a form has been configured to use item-level SDV and has items included in Table Design for Data Review Tables, the Queries Table, or the Participant Matrix. (**OC-23937**)
- Fixed an issue where common event form table columns configured on the form card in Study Designer may not have been visible on the Participant Details Page after a study publish that contained no changes to the form. (**OC-23993**)

For additional information on purpose, issues addressed, traceability matrix, and deviations please visit the **OpenClinica 4 Stack 19.2.1 Note to File page here**.

OpenClinica 4 Stack 19.2 (Release Date - 07 December 2024) OpenClinica

4 Stack 19.2 contains targeted updates to OpenClinica. View the entire **Stack 19.2 changelog here** (login required). For an overview of this update, view the **Stack 19.2 Release Announcement here.**

New:

Recruit

- **Recruit:** OpenClinica Recruit is now available on the Modules page. Use Recruit to find eligible participants for your studies.

Unite

- **Unite Sync:** Unlock the power and efficiency of Unite eSource data even if your study was not built using OpenClinica. New integration capabilities allow you to connect OpenClinica Unite to your existing Rave EDC study to pull in EHR data seamlessly. Participants and visits are synced from Rave EDC to OpenClinica. Form data, pulled directly from Epic or Cerner EHR, is pushed back to your existing Rave EDC study. This functionality also enables eSource data collected using OpenClinica's Participate or Consent modules to be synced to Rave EDC in a similar manner.

Changes and Fixes:

Study Build System

- Fixed an issue in Study Designer where creating forms whose names have certain non-alphanumeric characters and editing them in Form Designer resulted in Draft form definitions that could not be added to the study or downloaded. (**OC-17781**)
- Fixed an issue in Study Designer where form definition files that contained the character '#' in their filenames could not be downloaded and the form could not be previewed. (**OC-22815**)
- Fixed an issue where a form added to an event in Study Designer and given the same name as an existing Consent form was not behaving as an Consent form. (**OC-22061**)
- Fixed an issue where Study Designer would not allow a user to upload a new version of a form that changed the form into an Consent form if that form definition were also used in an archived repeating event. Only active events will be considered for this check now. (**OC-22909**)
- Fixed the Data Review Table Description field in Study Designer to allow the description to be cleared for existing Data Review Tables. (**OC-19232**, **OC-21661**)
- Fixed a bug in Study Designer where the Go button to access Study Runner would not be present if the user had a non-Data Manager role in a published study environment and Data Manager role in an unpublished study environment. (**OC-22198**)
- Updated the Data Dictionary interface in Study Designer to allow users to select and copy text so that it can be pasted elsewhere as needed. (**OC-22236**)
- Updated the Configure Item-Level SDV screen in Study Designer so that items that do not exist in any form versions (due to having been removed from all form versions) will no longer be included. (**OC-21745**)
- Improved performance of Study Designer. (**OC-22221**, **OC-22974**, **OC-23267**, **OC-23292**)
- Study publish processing has been optimized. Performance will be improved for publish operations to a study environment after its initial publish. For existing studies, performance will be improved after the first publish to each study environment following this release. (**OC-20869**)
- Fixed a bug where an extra entry including only user information was appearing in the Study

Designer activity log board when the user copied a form from one event to another. (**OC-22789**)

Study Runner

- **Participant Details Page (PDP)**
  - Added user-friendly error messaging to the Participant Details Page to indicate when a Study Calendaring issue has caused evaluation of Study Calendaring rules to be disabled for the Participant. (**OC-23200**)
  - Updated the Participant Details Page to display the SDV status of forms in Common Events. (**OC-21388**)
  - Fixed a bug that caused forms to be opened in Review-Only mode when the View action was used if the form was in Not Started status after being cleared. These forms will now open in Read-Only mode like forms in Not Started status that had never been started. (**OC-22706**)
  - Fixed an issue where forms containing contact data fields would be set to Data Entry Started status if the empty form was opened in View mode before any data were entered. (**OC-23428**)
- **Study Calendaring**
  - Fixed an issue that caused inconsistent behavior for the USER_CLOSES_FORM trigger for Advanced Study Calendaring to trigger rules based on data changes in forms. (**OC-23589**)
  - Updated the USER_CLOSES_FORM trigger in Advanced Study Calendaring to support triggering rules based on data changes on forms in a repeating Common Events. (**OC-23185**)
  - Fixed an issue that could cause Study Calendaring rules to stop triggering for some Participants. (**OC-23866**, **OC-23878**)
  - Fixed an issue where form records created by Advanced Study Calendaring rules were being created in the study default version even if a site default version was set for the Participant's site. (**OC-23424**)
  - Fixed a bug that prevented Advanced Study Calendaring mode from being enabled in some cases. (**OC-22813**)
- **Extract Data**
  - Fixed an issue where Form and Event Descriptions were not included in the CDISC ODM version 1.2 Data Extract format. (**OC-21913**)
- **Data Import**
  - Updated tabular imports to allow ParticipantID to be used as Match Criteria used to identify matching records. This enables tabular imports to be configured to update all items in forms within non-repeating events. (**OC-17267**)
  - Updated the tabular import mapping template to describe usage of ParticipantID as Match Criteria. (**OC-23850**)
  - Fixed an issue where tabular imports configured to skip records in the import file if they matched an existing record based on the specified Match Criteria caused the import to fail if there was a match to a Removed record. (**OC-21639**)
- **Source Data Verification (SDV)**
  - Fixed an issue where a user changing the SDV status of a form record erroneously updated the username displayed on the form card on the Participant Details Page. This card will now correctly show the user who last edited data in the form even if SDV status was updated afterward. (**OC-22936**)
- **Data Review Tables (DRT)**
  - Updated Data Review Table columns containing item data of type decimal or text have

new filter options for "Empty" and "Not Empty" to allow users to filter out records with null values or non-null values for these items. (**OC-14711**, **OC-23228**)
    - Fixed an issue where Data Review Table numeric item column filters provided incorrect results for a filter value of "0". (**OC-22037**)
    - Updated filters on decimal item columns in Data Review Tables to work with up to ten digits. (**OC-15252**)
    - Updated Data Review Tables to make horizontal scroll bars remain visible even when the table was not scrolled all the way to the bottom. (**OC-22247**)
- **Participant Casebooks**
    - Simplified Participant and Archival PDF Casebook headers to avoid potential for the text running off the page. The new headers include only Study OID and Participant OID. (**OC-23297**)
    - Updated the layout of the Participant Casebook Cover Page to be more user-friendly. (**OC-21684**)
- **Annotated Casebooks**
    - Fixed an issue where Annotated Casebook generation failed for forms that included a non-calculate type item with a calculation defined and the label and hint left blank. (**OC-23105**)
- **Bulk Actions Log**
    - Added new job status column for Archival Casebook jobs to the Bulk Actions Log so that users can monitor the progress of long-running jobs. (**OC-21602**, **OC-22344**)
    - Fixed an issue where the log for a large import job was not able to be downloaded from the Bulk Actions Log. (**OC-22072**)
    - Fixed an issue where the top navigation bar on the Bulk Actions Log could be difficult to access in small windows. (**OC-15711**)
- **Rules**
    - Fixed an issue where Legacy Rule Notifications were not being sent to Participants as expected in cases where the study utilized the Consent Module but not the Participate Module. (**OC-23213**)
    - Fixed an issue where the Rule Test interface for Legacy Rules was incorrectly presenting some valid Rules as having errors. (**OC-21619**)
- **Miscellaneous**
    - Added explanatory messages and a save confirmation step to the Site Configuration page in Study Runner to make the existing behavior clearer. The new text notes that saving will lock in all settings for forms at the site and that future Study Designer changes to these forms will not apply to the site. (**OC-23325**)
    - Previously contact data item values could be entered outside of the intended character limits, email address format, or phone number format requirements when entered via the API or invitation by a site user. These constraints were only enforced when entered via a form. The same constraints will now be enforced across all entry methods. (**OC-22873**, **OC-22899**, **OC-23023**)
    - Updated the Study Name in the navigation bar in Study Runner to no longer be a link to the View Study page except when accessed by Data Manager users. (**OC-21636**)

Unite

- Added the ability to automatically pull a patient's Vital Sign data from their EHR record in Epic or Cerner using the Unite module. This new data will be attributed to the EHR source in the Participant's audit log. (**OC-22811**)

Forms

- Fixed an issue where users could paste values into read-only date fields on forms. When this occurred, the pasted value would be saved if the form had been opened in Edit or Review-Only mode. This potentially allowed Monitor users (who can never use Edit mode) or other users who had opted to open a form in View mode to edit date item values unexpectedly. Note that forms opened in Read-Only mode (such as for Locked records or forms opened by Viewer users) were not subject to this issue. (**OC-23583**)
- Previously the Reason For Change fields presented to users in forms leveraged the web browser's built-in functionality to show users a list of previous Reason For Change entries they had used. It was discovered that in rare cases, the web browser could erroneously change form item values when a selection was made due to misapplication of its "autofill" feature. This was only reported in Microsoft Edge. For this reason we have disabled the ability to choose from previous Reason For Change entries. (**OC-23197**)
- Fixed an issue where internal OpenClinica Support users were sometimes appearing in the list of users to whom Queries could be assigned in the Query widget within forms. (**OC-23495**)
- Fixed a bug with select_multiple form items displayed as dropdowns where the count of selected values was displayed incorrectly when re-opening the form after initial data entry was done on the item. (**OC-22333**)
- Fixed an issue where the contact data item Full Date of Birth contained an extra line when appearing in PDF versions of a form. (**OC-22363**)
- Fixed an issue where the form buttons to Add and Remove occurrences of a repeating group were being displayed with English text even when the form was being accessed by a user with non-English localization. (**OC-22334**)

Participate

- Fixed an issue where Consent and Participate forms containing contact data fields opened by the Participant would use the study-level default version even if a site-level default version was configured for the form. (**OC-23332**)
- Fixed an issue where cleared forms opened from the Participant Dashboard would open in the wrong version if the site default version of the form at the Participant's site was changed after the form was cleared. (**OC-23587**)
- Fixed an issue where forms that had been acted on by Advanced Study Calendaring rules to make them visible, editable, or required were not behaving correctly in Participate. These forms could display the wrong button label and allow participants to Move On from the event without completing the forms. (**OC-22420**)
- Fixed an issue where the Participant Dashboard could show the wrong button label for a form if the Participant had opened and closed the form without entering data on it. (**OC-23442**)
- Fixed an issue that could occur with slow internet connection speeds where the Participant Dashboard could briefly load showing the wrong button labels before they were repainted with the correct label text. (**OC-22292**)
- Fixed an issue where embedded Insight dashboards were loading with an error message on the Participant Dashboard. (**OC-22958**)
- In-progress Participate and Consent forms generally attempt to bring the Participant back to the place they left off when they reopen the form. These forms will now open to the beginning of the form if it has been migrated to a new version, cleared, or another user has edited any data on it since the last time the Participant opened it. (**OC-23286**, **OC-23287**)

Consent

- Fixed an issue for an Consent form that had been cleared and then its default version used by the study or site was changed. In this case, the form was using the original version again when it was next opened. Not Started Consent forms will now open in the current default version

after having been cleared. (**OC-23448**)
- Fixed an issue with Consent forms that included only the signature item and no data items where the forms appeared as in-progress on the Participant Dashboard before they had been started. (**OC-23637**)
- Fixed an issue where Participants could erroneously be shown an error message when signing an Consent form after resetting their access code. (**OC-22295**)
- The current consent status of Consent forms, as well as the dates and times of their last Participant signature and countersignature, are now available as dedicated fields in ODM XML extracts and casebooks and accessible in cross-form logic. (**OC-21660**, **OC-23395**)
- Updated Consent forms that are migrated to a new version to also be treated as being Cleared. In addition to having a consent status of "Requires Reconsent," these forms will now also have all data items cleared and will be moved to Not Started status. This ensures reconsent is conducted from the beginning of the form. (**OC-23285**)
- When an Consent form is countersigned, PDFs of the form available on the Participant Dashboard will now include both the original participant-signed copy and the countersigned copy with both signatures. (**OC-21944**)
- Updated Consent countersignature page to allow users to request a signature code for customer instances using SAML authentication. (**OC-21894**)
- Updated the default action for unsigned Consent forms on the Participant Details Page to open the form in View mode rather than Edit mode. (**OC-23336**)

Insight

- Some API integrations with Insight may require updates to avoid breaking after this release due to a change in the Metabase dataset endpoint that may result in unexpected behavior. After this update, calls that retrieve data in JSON format will default to returning numeric values (bigint field type in Insight's postgres DB) as text values and altering format of date values. There are two options to ensure this change does not affect integrations. (**OC-23842**)
    - Option 1 - Edit integration code to expect these fields as text values and reformat them to be numeric values as needed.
    - Option 2 - Add a new URL query parameter, "format_rows=false" (default if not specified is "true"), to requests that extract query results to force the formats to be retained. This parameter can be added in advance of this release and will have no effect until the release.
    - Any pipeline not updated in one of these ways will break if numeric or date values are being retrieved and integration code is sensitive to field type or format.
- Question downloads from the Insight UI will also default to formatting numeric and date values differently than prior versions (see description for API calls above). When downloading results, press the "Alt" key on your keyboard when you select the download format to preserve original value formats. (**OC-23842**)
- Updated the Insight web user interface. Improvements include API keys for authentication and Dashboard duplication and templating. (**OC-22662**)
- Previously dropdown menus in the Insight Question Builder could be cut off if they extended beyond the current screen size. This has been fixed and the screen will now show the entire menu. (**OC-17115**)

Rest API

- All contact data fields, including the recent additions middle name, hospital number, street address lines 1 and 2, city, state, country, and full date of birth, can now be set and retrieved via API by authorized users. (**OC-22217**, **OC-22224**, **OC-22724**)
- Fixed an issue where the contact data field secondaryID was not being returned in API calls to

retrieve participant info. (**OC-22937**)
- Added an optional parameter "includeConsentInfo" to the API endpoints for retrieving participant info (e.g. contact data and Participate status). This parameter allows users calling these endpoints to retrieve the current consent status of Consent forms as well as the timestamps the Consent forms were last signed and countersigned and the users who performed those actions. (**OC-21886**)
- Updated the clinicaldata API to allow retrieving data using a Form OID in addition to the existing option of using a Form Version OID. In either cases, items from all versions of the form will be returned. (**OC-22533**, **OC-23435**)
- Fixed an issue where calling the clinicaldata API to retrieve data for a form with multiple versions could erroneously return no data in some cases. (**OC-23274**)

General

- Fixed a bug that prevented the optional US Government login screen message from appearing if the user logged out of the system and logged in again without closing their browser window first. (**OC-23201**)
- Added Study Calendaring Scheduling Service to the UpOQ Validation report. (**OC-22274**)
- Security enhancements.

For additional information on purpose, issues addressed, traceability matrix, and deviations please visit the **OpenClinica 4 Stack 19.2 Note to File page here**.

OpenClinica 4 Stack 19.1 (Release Date - 10 August 2024)

OpenClinica 4 Stack 19.1 contains targeted updates to OpenClinica. View the entire **Stack 19.1 changelog here** (login required). For an overview of this update, view the **Stack 19.1 Release Announcement here**.

Changes and Fixes:

Study Build System

- Added support for line breaks in Study Calendaring notification text for email and SMS messages. (**OC-22722**)

Study Runner

- Updated Participant notifications to automatically register Participants and generate access codes for them when notifications that include access code or login URL are being sent to them and they do not yet have access codes. This allows for workflows that do not require site users to manually invite Participants before they can receive automated notifications. This feature works for Study Calendaring notifications configured in Study Build System as well as for legacy Rule notifications configured in Study Runner. For notifications sent at the time a Participant is created via a Public URL form, this automated workflow only supports Study Calendaring notifications. (**OC-22730**)
- Fixed issues that led to intermittent Study Calendaring failures for Participants created via Public URL forms. (**OC-22751**, **OC-22814**)
- Added additional server logging capabilities to improve ability to debug dataset extract issues.

Unite

- Added support for Cerner EHR sites participating in multiple studies. Launching Unite from an EHR system connected to multiple studies (including under multiple sponsors) will direct the

user to select which study they want to access. (**OC-22251**)

Participate

- Fixed an issue where a Public URL form was not able to be submitted if completion of the form caused a legacy Rule to be evaluated and that Rule contained a reference to _CURRENT_DATE. (**OC-22194**)

Rest API

- Fixed a contact data access issue for Site Data Manager users. (**OC-22643**, **OC-22645**) (private tickets - issue affects limited customers)

General

- Updated the authentication server for greater reliability across the OpenClinica platform.

For additional information on purpose, issues addressed, traceability matrix, and deviations please visit the **OpenClinica 4 Stack 19.1 Note to File page here**.

OpenClinica 4 Stack 19.0.3 (Release Date - 11 May 2024)

OpenClinica 4 Stack 19.0.3 contains targeted updates to OpenClinica. View the entire **Stack 19.0.3 changelog here** (login required). For an overview of this update, view the **Stack 19.0.3 Release Announcement here**.

Changes and Fixes:

Study Build System

- Fixed an issue that prevented new form versions from being added if an attempt to add one failed and was not later completed successfully. (**OC-22483**)

Study Runner

- Fixed an issue that caused the Participant Details Page Visits section to fail to load and the study environment to fail to refresh in Insight in the special case where a form was in a cleared state in a different form version from the current default version. In that case, opening the form in Edit mode and Completing it without any data entry or opening it in View mode caused an empty duplicate form database entry to be created. (**OC-22523**, **OC-22765**)
- Fixed an issue that attributed a form version change to a user who viewed a form in the special case where a form was in a cleared state in a different form version from the current default version. In that case, opening the form in View mode caused an audit entry to attribute a form version change to a Viewer or Monitor who viewed the form. (**OC-22695**)
- Added preventive database constraints to ensure duplicate form records are not created in the event of unexpected system behavior in the future. (**OC-22672**)
- Fixed an issue that prevented form version migration on a form record if there was an open query on an item that was not included in the new form version. (**OC-22548**)
- Fixed an issue where Study Calendaring actions did not execute for Participants created by submitting a Public URL form. (**OC-22651**)
- Fixed an issue that prevented Public URL form submission if the form included contact data items. (**OC-22470**)
- Updated Archival Casebooks to include Participants with a status of Signed in all cases. (**OC-22635**)
- Updated Data Transformation Module for pipeline compatibility with AWS Lambda and Python

updates. (**OC-22518**, **OC-22585**)

For additional information on purpose, issues addressed, traceability matrix, and deviations please visit the **OpenClinica 4 Stack 19.0.3 Note to File page here**.

OpenClinica 4 Stack 19.0.1 (Release Date - 16 March 2024)

OpenClinica 4 Stack 19.0.1 contains targeted updates to Study Runner. View the entire **Stack 19.0.1 changelog here** (login required). For an overview of this update, view the **Stack 19.0.1 Release Announcement here**.

Changes and Fixes:

Study Runner

- Fixed an issue that prevented study-level users from extracting data from forms hidden from site-level users. (**OC-22417**)

For additional information on purpose, issues addressed, traceability matrix, and deviations please visit the **OpenClinica 4 Stack 19.0.1 Note to File page here**.

OpenClinica 4 Stack 19 (Release Date - 16 March 2024)

OpenClinica 4 Stack 19 contains broad updates to OpenClinica. View the entire **Stack 19 changelog here** (login required). For an overview of this update, view the **Stack 19 Release Announcement here**. For more details about what this release means to you and your users, view the **Stack 19 Detailed Log here** or the **Impact Analysis PDF Document here.**

New:

Study Calendaring Module

- **Study Visit Windows:** New functionality in Study Designer allows Data Managers to define visit windows for auto-scheduling and auto-closing non-repeating visit-based events. Automatic scheduling and closing of visit events can be triggered based on visit status, time windows, or Participant creation. Time-specific actions will respect the Participant's site's time zone configuration. These calendaring actions are published to Study Runner as part of the study publishing process. This functionality streamlines the scheduling of non-repeating visit-based events from Participant creation to closeout, eliminating the need for manual intervention. It will be extended in future releases and is intended as a replacement for the legacy Rules that are configured directly in Study Runner. Legacy Rules should be removed before publishing similar scheduling actions from Study Designer.
- **Sending Notifications:** New functionality in Study Designer allows Data Managers to define email and SMS notifications for non-repeating visit-based events. These notifications can be sent to Participants or any predefined email addresses. They can be sent upon event creation or completion, as well as before or after the event's start date. Multiple notifications can be set up for an event, each configured to be sent at a specific time of day and respecting the Participant's site's time zone configuration. These notifications are published to Study Runner as part of the study publishing

process. This functionality will be extended in future releases and is intended as a replacement for the legacy Rules that are configured directly in Study Runner. Legacy Rules should be removed before publishing similar notification actions from Study Designer.
- **Site Time Zone:** Added ability for Data Managers to define the site time zone when adding a site or editing a site on the Share page. A new column on the Sites table shows the current time zone setting for each site. This time zone applies to all participants assigned to that site. Currently, the Time Zone feature is used for automated scheduling and closing of events, and notification features. However, the Time Zone feature will be expanded in the future. The default time zone for each new and existing site is UTC.

Study Runner

- **Participant PDF Casebook:** Enhanced Participant PDF Casebooks to include a casebook cover page, table of contents, and a cover page for each form containing study, site, and event information. Additionally, updates were made to the headers and footers of the casebook. The forms in the Participant Casebook are now in chronological order by event start date rather than in study definition order. Finally, study-level users have an option to include forms hidden from the site within the PDF casebook.
- **Archival Casebook:** Added new capability for Admin Data Managers to create Participant PDF Casebooks in bulk at the study-level or site-level using the new Archival Casebooks feature. Archival Casebooks contain a Participant PDF Casebook file for each Participant in the study or site, optionally including removed participants and forms hidden at sites. Each Archival Casebook .zip file contains an overall summary report and site-level summary reports. If a Participant has no form data or the Data Manager does not have permission to view any of the Participant's data, the Participant PDF casebook will contain the message "This participant does not have any forms or the user who generated this does not have permission to view any of the participant's forms." to reflect both scenarios. Archival Casebook jobs appear in the Bulk Actions Log and can be canceled before completion when needed.
    - *Note: This feature is only available to users with Admin user type and Data Manager user role in the study.*
- **Blank Casebook:** New functionality allows Study Runner users to generate a Blank Casebook for a study or site. Each Blank Casebook contains a PDF file with a cover page, table of contents, form cover pages, and a blank copy of each form. The Blank Casebook compiles the study's or site's default version of each active form, collates them by event, and creates a single PDF file for download. Blank Casebook jobs are shown in the Bulk Actions Log.

Participate Module

- **Participant Workflow:** Improved Participate to help ensure data completeness of Participant forms and provide Participants with more options for long forms. The "Let's Move On" option to complete all of Participant's forms in an event and move on to the next event, can now only be accessed if the Participant closes the form via the "I'm done" button (which was previously labeled "Submit"), after completing all required

fields. In case the user needs to exit the form and continue data entry later, we have added a "Finish Later" button to each page of the form. This ensures that if the Participant starts the form but closes it without completing all required fields, they will not be able to submit the form and move on.
- **Form and Event Descriptions:** Form and Event Descriptions added in Study Designer can now be configured to appear in Participate and Consent so that Participants can have more context for their tasks. A checkbox is available in Study Designer, in both event and form cards, to control display of the descriptions to Participants. Form descriptions will now also appear in the CRF metadata table on the View Study page in Study Runner.

Changes and Fixes: Study Build System

- Fixed an issue on the User Roles page in Study Manager where user role lists did not update when a permission tag name was updated in Study Designer. (**OC-9564**)
- Add text to inform the user that usernames cannot be changed once created. The text "(note: this cannot be changed after the user is created)", appears next to the Username field when adding a new user on the Share Page in Study Manager. (**OC-21690**)
- Improved performance of Publish history table on the Share page in Study Manager. (**OC-20817**)
- Fixed an issue where deactivating a user in rare cases did not record the deactivation in the audit log, although the user was correctly deactivated. (**OC-19480**)
- Fixed an issue where creating a new permission tag in Study Designer incremented the study revision number even when the tag was not yet assigned to any forms. In this case there is no change to the study design unless the permission tag is assigned to a form. (**OC-20302**)
- Improved reliability of Study Designer in saving updates made in very large studies. (**OC-21445**)
- Updated Study Designer to allow users to upload form definitions including CSV files greater than 1MB. (**OC-21134**)
- Updated form definition upload in Study Designer to ensure that forms are not treated as containing contact data items inappropriately. Specifically, if a form version is updated and the form no longer has any versions with contact data items, the form will not be treated as containing contact data. (**OC-18719**)
- Fixed an issue where Study Designer became blank when dragging cards to events that are offscreen/out of the user’s current view. (**OC-17763**)
- Fixed alignment and wrapping issues on event cards in Study Designer. (**OC-20288**)
- Improved performance for configuring Data Review Tables in Study Designer for large studies. (**OC-20870**)
- Fixed an issue where form or event names containing a colon (:) could cause item names to be cut off on the Data Review Table configuration interface in Study Designer. (**OC-20878**)
- Updated Study Designer form definition upload to improve validation of Consent form definitions. (**OC-20226**, **OC-20565**, **OC-20321**)
- Updated Study Designer to allow a non-Consent form version to be uploaded as a replacement for an Consent form version if that is the only form version available for

that form. (**OC-21077**)
- Updated Form Designer so Data Managers can configure Consent forms in Form Designer. (**OC-17484**)
- Fixed an issue in Form Designer that prevented users from previewing forms if the form name exceeded 36 characters. (**OC-21279**)
- Fixed an issue preventing users from creating a new collection in the Form Designer Library Management interface. (**OC-21456**)
- Updated the Form Template to reflect changes in Stack 19 (instructions for new contact data items and custom annotations). (**OC-22057**)
- The error message displayed when an attempt to publish fails due to an issue in Consent form configuration will now more clearly indicate the corrective action needed to publish successfully. (**OC-20600**)
- Improved study publishing stability and reliability. (**OC-20597**)
- Improved performance of study publishing. (**OC-21719**, **OC-22110**)
- Fixed an issue where the Study Calendaring Rules Management page did not correctly show the rules configuration dropdown display. (**OC-20643)**

Study Runner

- **Participant Details Page (PDP)**
  - Improved load time for the Participant Details Page Visits section if "Show Active" (the default) or "Show Removed" records is selected for the record filter. (**OC-20912**)
  - Added functionality to the Participant Details Page to allow the Visits section to update dynamically to reflect incremental changes in the records while the page has been open (such as from Calendaring actions firing). (**OC-19905**)
  - Updated form cards in the Visits section of the Participant Details Page to indicate forms configured to be completed by Participants with a new icon. (**OC-20831**)
  - Updated Participant Details Page Visits section default action for Participate forms. When a user clicks the form card the form will open in View Mode by default regardless of form status. (**OC-21234**)
  - Fixed an issue where the count of results in filtered Participant Details Page views included forms hidden from the current user. (**OC-21096**)
  - Fixed an issue on the Participant Details Page where users could schedule a Visit event with an Event End Time, but no Event End Date provided. (**OC-20888**)
  - Fixed an issue where the Participant Details Page did not set the correct default filter in some cases. The correct default filter is "Active Records". (**OC-19818**)
  - Fixed an issue where the Participant Details Page would sometimes load without the most recently used filter settings persisting as expected. (**OC-21173**)
  - Added the ability to verify Common Event forms for SDV directly on the Participant Details Page. (**OC-20917**)
  - Updated Participant Details Page Common Event search functionality to support searches using the character "+". (**OC-19529**)
  - Updated Participant Details Page Common Events table text to correct capitalization and alignment inconsistencies. (**OC-16552**, **OC-17232**)
  - Added an option on the Participant Details Page to download the Participant's CDISC ODM XML casebook rather than view it directly within a browser.

(**OC-21366**)

- **Queries**
  - All system actions, such as system-generated queries, previously attributed to user "root" will now be attributed to "system" when they next occur. This update does not affect audit entries for actions that occurred in the past. (**OC-20683**)
  - Fixed an issue where the Queries Table was missing the Assigned User value for system-generated queries when the user was accessing Study Runner in German. (**OC-20734**)
  - Updated the Queries Table CSV and PDF download functionality to include the "Item Type" column as shown in the browser. (**OC-20683**)
  - Improved performance when downloading the Queries table as a CSV file. (**OC-15113**)
  - Updated the Reason for Change required field asterisk [*] color to red when removing or restoring forms, events, or participants. (**OC-19634**)
- **Extract Data**
  - Fixed an issue where scheduled extract job filenames contained the incorrect job run date if the job had been edited after it was created. (**OC-19826**)
  - Fixed issues where actions to delete and remove jobs worked intermittently (**OC-21192**)
  - Improved performance of data extracts when the study's forms use permission tags. (**OC-20787**)
- **Investigator Signatures**
  - Fixed an issue where republishing a study with archived events that were already archived in Study Runner would cause Participants with those events to be unsigned. Only a publish action that changes an event from active to archived is expected to unsign Participants. (**OC-22103**)
  - Fixed an issue that prevented Investigator users from accessing the Participant audit log via the participant signature page. (**OC-21718**)
  - Updated text on the 'Sign Participant Page' for clarity and usability. (**OC-21711**)
  - Improved performance when bulk signing large numbers of Participants. (**OC-21443**)
- **Source Data Verification (SDV)**
  - Fixed an issue on the Source Data Verification (SDV) page where the page numbers did not match the number of rows if there were hidden forms at a site. (**OC-21172**)
- **Data Review Tables (DRT)**
  - Updated the Participant ID column in Data Review Tables to use the same text sort algorithm as the Participant ID column in the Participant Matrix. (**OC-15309**)
  - Updated Data Review Table functionality to include a participant site column. This column can be filtered and used for sorting. (**OC-15248**, **OC-21632**)
  - Updated the Data Review Table download functionality to include event and form statuses like locked, signed, removed, and archived. These statuses enable users to identify and review specific data based on the event statuses within the table. (**OC-20931**)
  - Improved Data Review Tables (DRT) to allow users to filter for records with open Queries, making it easier to close Queries in bulk directly from the DRT.

(**OC-20021**)
    - Increased the maximum number of rows that can be displayed on a single page in a Data Review Table (DRT), allowing bulk actions to be performed on more records at once. (**OC-20022**)
    - Data Review Tables (DRT) now have a "Select All" checkbox on each column to allow bulk selection of all instances of a particular item. This enables bulk closing of Queries for that item. (**OC-20023**)
    - Fixed an issue in Data Review Tables where deselecting the checkbox for the only item cell in a row did not also fully deselect the row-level checkbox. (**OC-20554**)
    - Fixed an issue where filtering items in the data review table did not work as expected when filtering a column with multiple special characters (**OC-19629**)
    - Updated Data Review Tables to include labels for select_one and select_multiple items in addition to their database values when downloading the table. For example, if you have an item show on the form as "Yes" with a stored value of "Y", both values will show in the downloaded file. (**OC-21618**)
    - Fixed an issue were clicking on links for form items in a Data Review Table did not work if the Data Review Table contained multiple common event forms. (**OC-16743**)
    - Fixed an issue where Data Review Table links to secondary form items that were in Common Events did not open the source form as expected. (**OC-20668**)
    - Fixed an issue where queries were missing from Data Review Tables in rare cases. (**OC-20607**)
    - Fixed an issue where unwanted and non-functional check boxes appeared on Data Review Tables in certain scenarios. (**OC-20863**)
- **Annotated Casebooks**
    - Fixed an issue where line breaks within Required, Relevant, Calculation, Default and other form item attributes that contain logical expressions broke Annotated CRF formatting. (**OC-20918**)
    - Added the title "Annotated Casebook" to Annotated Casebooks' title pages to help differentiate them from Blank Casebooks and Participant Casebooks. (**OC-20270**)
    - Added option to generate Annotated Casebook for a specific site. (**OC-20518**)
    - Applied standard file naming format to Annotated Casebook job files. Previously the file name started with Study Name and now uses Study ID instead. (**OC-21625**)
- **Bulk Actions Log**
    - Updated the Bulk Actions Log column header "Completion Time" to be renamed as "End Time" to reflect that some jobs may end in failure. (**OC-21005**)
    - Fixed an issue on the Bulk Actions Log where Participant PDF Casebooks or Annotated Casebooks that had failed to generate successfully would sometimes not allow the user to download or view the error log. (**OC-20458**, **OC-20461**)
    - Updated error messaging for failed jobs on the Bulk Actions Log to display the error message from the server, followed by "Contact your administrator if this persists." (**OC-20481**)
    - For data import jobs that also include running form logic, Data Managers can

now see BACKGROUND_FORM_PROCESSING jobs in the Bulk Actions Log regardless of which user initiated the data import job. This provides greater visibility into the status of data import jobs. (**OC-21742**)

- **Data Transformation Module (DTM)**
  - The Data Transformation Module Queue now allows filtering and sorting by file type. (**OC-20799**)
  - Files with no extension in their name will now appear with a "File Type" of "None" in the Data Transformation Module Queue. Previously they were labelled as "txt" files. (**OC-20802**)
  - Data Transformation Module import jobs that fail due to mapping file errors now produce an appropriate error message based on the import error returned. (**OC-20832**)
  - The name of the current mapping file used by each pipeline is now shown in the Transform menu when selecting a Data Transformation Module pipeline. (**OC-20833**)
  - The Data Transformation Module now provides the option to automatically extract the contents of .zip files and other types of file archives upon upload to the Queue. (**OC-20925**)
  - All email notifications generated by the Data Transformation will now include an indication of whether they are being sent by the Production or Test environment of the study. (**OC-21694**, **OC-20372**)
  - Study Viewers can now download the Data Transformation Queue table. (**OC-20404**)
  - Fixed an issue where a Site Data Manager actively using the Data Transform Module could be logged out of Study Runner if their user role were changed. (**OC-20760**)
- **Rules**
  - Fixed an issue where Study Runner permitted users to upload invalid Notifications Action Rules based on item data changes instead of event level attribute changes. (**OC-17142**)
  - Fixed an issue where Notification Action rules failed to execute when the target event's status changed. (**OC-21440**)
- **Miscellaneous**
  - Fixed an issue where, after using OpenClinica for over 4 hours in a single login session, users would receive errors on some Study Runner pages until they logged out and then logged back in. (**OC-18069**)
  - Fixed an issue where Participant IDs containing a "." caused some of the expected Event action options to be missing from the Participant Matrix single event view. (**OC-19949**)
  - Fixed an issue affecting Locked and Frozen sites where the wrong action icon was displayed for events on the Participant Matrix. (**OC-20149**)
  - Fixed an issue were initiating a large data import sometimes prevented users from logging into OpenClinica until the import was complete. (**OC-21552**)
  - Fixed an issue were Tabular Data Imports allowed non-existent dates, for example April 31st, to be imported without error. (**OC-21489**)
  - Fixed an issue were importing data for Participants with an ID containing "\" or

"/" failed. (**OC-20448**)
    - Fixed an issue where removing an Event was not updating the Last Modified date/time for a Participant. (**OC-20960**)
    - Added a timestamp to the Participant Audit Log filename. (**OC-16799**)
    - In studies where non-English language settings are enabled, language translations have been added or updated including for participant invitations, the user login page, Consent text, the Consent counter-signature page, and form statuses in the audit log. (**OC-19528**, **OC-19898**, **OC-20070**, **OC-20204**, **OC-20205**, **OC-20206**, **OC-21347**, **OC-21558**)
    - Reorganized links in Data Manager's Tasks Menu. Under the Monitoring and Managing Data Tasks section, when accessing a specific site, the order was changed to be consistent with the study-level display. (**OC-20018**)

Unite

- Fixed an issue to make launching OpenClinica Unite more robust. (**OC-21437**, **OC-21411**)
- Fixed an issue where "Last Pulled" relative time for resources was not updating on screen in Unite. (**OC-22145**)
- Fixed a UI bug with the Medication Start Date item for Unite. (**OC-21578**)
- Fixed a bug with Gender at Birth data pull for the Unite Demographics feature. (**OC-21548**)
- Updated Unite data pulls for Demographics, Medications, Medication Start Date, and Gender at Birth value to be compatible with the newer FHIR versions. (**OC-20786**, **OC-19930**, **OC-20786**)
- Fixed an issue that prevented very large Participant datasets from being pulled from an EHR to OpenClinica using Unite. (**OC-21334**)
- Added the ability to retrieve data for Conditions, Immunizations, and Procedures using OpenClinica Share (iOS app). (**OC-19978**, **OC-20042**, **OC-19752**)

Forms

- Fixed an issue where forms could pull in incorrect cross-form values in rare cases of simultaneous usage of the same form for different Participants. (**OC-21989**)
- Fixed an issue were generating PDF forms with Visual Analogue Scale (VAS) items did not show the central line or tick marks in the PDF as they were displayed on the screen. (**OC-20423**)
- Fixed an issue where a user opening a form in Review-Only Mode and adding or responding to a query caused the text "You're in review-only mode" to disappear. (**OC-20784**)
- Fixed an issue with Queries rendering incorrectly within forms when the query text contained special characters such as / or '. (**OC-20246**, **OC-21847**)
- Fixed an issue where form definitions with filenames containing the letters "api", including in external list or media files, could not be opened correctly. (**OC-16598**, **OC-17116**)
- Improved performance of running all background form logic and form PDF actions. (**OC-21352**)

Participate

- Fixed an issue where an erroneous US Government access message was shown to Participants logging in for customers with SAML authentication enabled for site-level and study-level users. (**OC-21628**)
- Updated secure PII handling to support new contact data items: Street Address 1, Street Address 2, City, State, Postal Code, Country, Middle Name, Date of Birth, and Hospital Identification Number. When configured appropriately within forms, these fields are securely stored in a separate encrypted database table that is accessible only to CRC and Investigator users. (**OC-20552**, **OC-21891**, **OC-21898**, **OC-21883**)

Consent

- Updated Participant Details Page General Information section to dynamically reflect Consent status changes. (**OC-20658**, **OC-20843**)
- Updated Participant Matrix column name from Participate Status to Invitation Status when Consent is active but Participate is not active. (**OC-21159**)
- Fixed an issue on the Consent Countersign Form page where the query count listed for the form was incorrect. (**OC-20697**)
- Updated the text used to mask PII in Participant Consent signatures to "<Masked>" for consistency with other Study Runner functionality. (**OC-20849**)
- The PDF copy of an Consent form generated when a Participant signs it will now be available for download on the Participant's Dashboard automatically without requiring a manual page reload. (**OC-21067**)
- Added "version" label for Consent PDFs listed on the participant's dashboard to make it clear to the participant what the version number is referring to. (**OC-20323**)
- Updated error messages that could appear when a Participant attempted to reset their Access Code for Consent to remain visible until cleared manually instead of disappearing after a short time. (**OC-21997**)
- Updated text for resending Access Codes to participants via SMS to support easier copy/paste of the Access Code across all mobile operating systems. (**OC-21550**)

Insight

- Added an opt-in feature to enable fully integrated user role and permission tag-based data access in Insight. (**OC-11852**)
- Updated Insight to correctly maintain users' first and last names in Insight when using Single-Sign On with Study Runner. (**OC-10416**)
- Added an optional link to Insight to the Tasks Menu in Study Runner. The presence of this link can be configured per user role for each study. (**OC-18828**, **OC-21196**)
- Fixed an issue where attempts to download an Insight Question's results could fail if the user accessed the Question via a link from a Dashboard but lacked Unrestricted access to the study's data mart in the Insight permission settings. (**OC-21868**)
- Fixed an issue in Insight where columns could not be reordered in questions with large numbers of groupings and hidden columns. (**OC-22086**)
- Updated Insight UI to include the ability to break dashboards out into multiple tabs. (**OC-21868**)
- Updated Insight UI to include the ability to add automatically formatted links to Dashboards. (**OC-21301**)
- Updated Insight UI to include the ability to download entire Dashboards or individual charts/tables as PDF or PNG files. (**OC-21301**)

REST API

- Fixed an issue where API tokens issued to users did not immediately become invalid when the user was removed from the study. (**OC-20676**)
- Fixed an issue where users were unable to use the PDF Casebook API unless they were not logged into the same study in their browser. (**OC-21665**)
- Added Participant API endpoint to retrieve data for a single participant even when Participate Module is not being used. (**OC-20812**)
- Fixed an issue were creating the first Participant for a new site via API in a study using system-generate Participant IDs would skip the expected first Participant ID. (**OC-21801**)
- Fixed an issue where Participant contact data added via API could be misattributed in the audit log to the user who had created the participant. (**OC-22265**)

General

- Added help icons linking the user to context-specific pages of OpenClinica's documentation site throughout the OpenClinica user interface, such as Study Runner, Study Designer, and other pages. Note that some of the new documentation pages will be placeholders until new content is published. (**OC-20788**, **OC-20789**, **OC-20791**, **OC-20792**)
- Added announcement icon to user login page so that users can access system announcements prior to logging in. (**OC-20759**)
- Added user-friendly error messaging for users when SAML login fails due to customer certificate expiration. (**OC-20761**)
- Security enhancements.

Click **here** to view previous updates.

Approved for publication by Paul Bowen. Signed on 2025-05-16 5:11PM

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4 OpenClinica 4 – Release Notes 2023

Login is required to view issue links on this page. Some issues may not be accessible to all users.

OpenClinica 4 Stack 18.1.2 (Release Date - 02 August 2023) OpenClinica 4 Stack 18.1.2 contains targeted updates to Insight. View the entire **Stack 18.1.2 changelog here** (login required). For an overview of this update, view the **Stack 18.1.2 Release Announcement here.** Overview information and detail breakdowns can be found in **18.1.2 Detailed Log here**.

Changes and Fixes:

- **Insight**
  - Security enhancements for Insight. No functional impact and no end user actions needed.

For additional information on purpose, issues addressed, traceability matrix, and deviations please visit the **OpenClinica 4 Stack 18.1.2 Note to File page here**.

OpenClinica 4 Stack 18.1.1 (Release Date - 22 July 2023)

OpenClinica 4 Stack 18.1.1 contains targeted updates to OpenClinica. View the entire **Stack 18.1.1 changelog here** (login required). For an overview of this update, view the **Stack 18.1.1 Release Announcement here.** Screenshots, overview information, detail breakdowns, and expected behavior can be found in both the **Stack 18.1.1 Impact Analysis here** and the **18.1.1 Detailed Log here**.

Changes and Fixes:

- Fixed an issue where files uploaded to the Data Transformation Module containing multiple periods were, when downloaded, having the site name appended to the filename in the wrong place. (**OC-21140**)
- Fixed an issue preventing certain user roles from seeing eConsent statuses on the Participant Matrix when an eConsent form contained participant contact data. (**OC-20879**)
- Fixed an issue where duplicate eConsent Status columns were added to the Participant Matrix. Fixed an issue where duplicate eConsent Status rows were added to the Participant Details Page. This occurred after a Data Manager saved any site configurations. (**OC-21075**)
- Fixed an issue with the Study Audit Log Page where the view button hover text always displayed as "View" rather than using the user's OpenClinica study language. (**OC-20899**
- Fixed an issue with Data Transformation Module download button hover text always displayed as "Download" rather than using the user's OpenClinica study language. (**OC-20900)**
- Fixed an issue where an extract job or extract dataset result table always displayed "Status" information in English rather than using the user's OpenClinica study language. **(OC-20903)**
- Fixed an issue with Data Review Table download button hover text always displayed as "Download current view" rather than using the user's OpenClinica study language. (**OC-20904**)
- Fixed an issue where downloaded Data Review Table files contained column headers in English rather than using the user's OpenClinica study language. (**OC-20905**)
- Fixed an issue where users experienced an error message when previewing forms in Form Designer. (**OC-20919**)
- Fixed an issue where certain item group names for forms were missing from the study metadata page in Study Runner. (**OC-20956**)
- Resolved an issue where participant IDs were not shown on the View Events page. (**OC-21065**)
- Fixed a data extract formatting issue with OpenClinica Extension ODM nodes, specifically OpenClinica:StudyDetails XML node. (**OC-21079**)
- Resolved an issue where calendaring rules were not firing due to a lock on the participant's calendar. (**OC-21124**)
- Fixed an issue where filtering on the SDV table could show incorrect results if there was a form that appeared in multiple events with different SDV settings. (**OC-20897**)
- Fixed a Participate issue where the Dashboard would not show any forms when a Participant's next forms to complete were in a visit containing many forms. (**OC-21194)**
- Fixed a CRF version migration issue where the data incorrectly displayed on the "Confirm CRF Migration" page data mapping table. (**OC-19330)**
- Security enhancements.

For additional information on purpose, issues addressed, traceability matrix, and deviations please visit the **OpenClnica 4 Stack 18 Note to File - Stack 18.1.1 page here**.

OpenClinica 4 Stack 18.1 (Release Date - 01 May 2023)

OpenClinica 4 Stack 18.1 contains targeted updates to OpenClinica. View the entire **Stack 18.1 changelog here** (login required).

Changes and Fixes:

- Fixed an issue causing slow Participant Details Page Visits section loading for studies with large query volumes and/or events with many forms. (**OC-20910**)
- Fixed an issue preventing Unite from launching in some studies. (**OC-20911**)

OpenClinica 4 Stack 18 (Release Date - 29 April 2023)

OpenClinica 4 Stack 18 contains targeted updates to OpenClinica. View the entire **Stack 18 changelog here** (login required). For an overview of this update, view the **Stack 18 Release Announcement here**. For more details about what this release means to you and your users, view the **Stack 18 Impact Assessment here**.

New:

Study Runner

- **Annotated Case Report Forms (aCRFs):** Allows Data Managers to create individual blank annotated form PDFs and blank annotated Casebook PDFs which contain all forms in the study. Any form published to Study Runner can be downloaded as a PDF with annotations describing the form definition. This supports annotated forms needed for review during study design and as part of data submission or analysis after data collection. Individual annotated forms can be created from the CRFs page and annotated Casebooks can be created from a new page in Study Runner.

eConsent Module

- **eConsent:** This new module allows Participants to sign Informed Consent forms with 21 CFR Part 11-compliant signatures. Investigators and CRCs can add 21 CFR Part 11-compliant countersignatures from the Participant Details Page. Provides new tools for tracking the consent status of participants and an audit trail of all informed consent activity. PDF copies of signed eConsent forms can be downloaded by Participants as needed.

Study Calendaring Module

- **Study Calendaring:** This new module provides new ability to use Form Action, Event Action, and Participant Action rules to automate Participant Calendars. The Participant Details Page is updated dynamically to reflect the results of the rules as they run. This allows study designers to make Forms editable, visible, and/or required based upon changes to Event data, Form data, and/or Item data in the study. In addition, Events can be scheduled, locked, or have their statuses change based on a data change. This functionality can be based on breaking your study into epochs, representing time periods within the study such as "Screening", "Treatment", and "Follow-up", and calendars representing different study arms or cohorts. This feature is available as a pilot with Stack 18, but is planned for general availability for Stack 19.

Changes and Fixes: Study Build System

- Updated the Modules page to display the Unite - EHR Integration module with a Learn More link. Unite is available for clients to request, but will need to be configured for each study. (**OC-17935**)
- Added new messaging to the Share, User Roles, and Administration pages to describe how changes to user roles and permissions are processed for users currently logged into Study Runner. (**OC-20220**, **OC-20393**, **OC-20367**)
- Updated the Form Property label on the Study Designer Form Card from “Hidden” to “Hide from site users” to better align with the functionality. (**OC-18460**)
- Updated the Data Dictionary to filter out items that are not present on any form version by default. (**OC-19409**)
- Updated the Data Dictionary to show Form Properties, Participate Properties (if Participate is configured for the study), and Calendaring (if Study Calendaring is configured for the study) in the form-level header. (**OC-18404**)
- Updated the header in the Data Dictionary to avoid unnecessary scrolling. (**OC-17035**)
- Fixed an issue that caused the Data Dictionary to split item labels that have commas into two separate columns and displayed quotes incorrectly in the Label field when downloading content. (**OC-17306**, **OC-19628**)
- Fixed an issue that caused the Data Dictionary to display blank column versions on the user interface even though they would correctly display when downloaded. (**OC-19726**)
- Fixed an issue that prevented Form order changes to persist in Study Designer. (**OC-17357**)
- Added Accessibility Statement links to the User Menu in Study Manager and Study Designer. (**OC-16629**, **OC-16628**)
- Fixed a server issue due to Study Designer not receiving final publish completion confirmation. (**OC-20146**)
- Fixed an issue that prevented some users from being able to access Form Designer due to an error that made it appear as though users had duplicate usernames. (**OC-20038**)
- Fixed an issue that caused an error when trying to add a new question to the Library in Form Designer. (**OC-20287**)
- Fixed a bug that was incrementing study revisions in Study Designer in some cases even when no study design changes were made. (**OC-17490**)
- Improved performance of Study Designer for large studies. (**OC-19580**)

Study Runner

- Fixed an issue that caused an error when attempting to sign a form in a non-repeating common event that had more than one event occurrence (such as an event containing two forms). (**OC-20675**)
- Removed access to the Enter or Validate Data For CRFs in Event page in Study Runner. Now, when a user clicks an event action button on the Participant Matrix, it will take the user to the corresponding event on the Participant Details Page. (**OC-17688**)
- Updated the Participant Details Page to load on the All Records view when clicking View for a Removed Event from the Participant Matrix. The Participant Details Page will load with the Active Records view when clicking the View button on the Participant Matrix for an Event that is not Removed. (**OC-18239**)
- When opening the Participant Details Page from the Participant Matrix through a referenced event, the search bar will automatically be cleared on the page load. (**OC-20060)**
- Updated Participant IDs in the Data Review Table to act as links to their associated Participant Details Page. (**OC-18575**)
- Added the Verify action to the Form card action menu on the Participant Details page to allow Data Managers and Monitors to verify forms without going to the SDV page. (**OC-17256**)
- Updated the Form cards on the Participant Details page to include an icon for the Source Data

Verification (SDV) status of the record. (**OC-18352**)
- Added a Query bubble icon to form cards on the Participant Details Page for forms that have open queries assigned to any items in the form. (**OC-17257**)
- Fixed an issue that prevented Common Events to load on the Participant Details Page when certain UTF-8 characters were in Visit Event names. (**OC-16970**)
- Fixed an issue that caused the View form menu item to not display on the Participant Details Page within Locked or Frozen studies. (**OC-20029**)
- Fixed an issue that allowed Study Viewer roles to edit the Participant ID on the Participant Details Page for studies using Manually Generated Participant IDs. (**OC-20096**)
- Fixed an issue where the Reassign menu option could inappropriately appear for Archived forms on the Participant Details Page. (**OC-18661**)
- Updated the way study user roles and permissions are loaded during a user's session to enhance security, improve page load times, and create consistency across the application. (**OC-19166**)
- Fixed an issue that caused Event actions to be listed in the Participant Details Page menu when the study was in Design status. (**OC-19055**)
- Fixed an issue that prevented display of Common Events on the Participant Details Page if a form in the event contained a comma in a choice name for a select_one item. (**OC-19758**)
- Fixed bug that brought user to Participant Details Page after removing or restoring an event from the Participant Matrix (**OC-16748**)
- Fixed an issue causing the highlighting of recently accessed forms to disappear from the Participant Details Page earlier than expected.(**OC-16752**)
- Fixed an issue where a Removed form that was also Hidden from the current user would cause the Participant Details Page to display a message indicating some forms were hidden in the active view. (**OC-18341**)
- Fixed an issue that caused date filters to return incorrect results in the Common Events table on the Participant Details Page when there was a difference between the user's time zone and the system time zone. (**OC-19988**)
- Fixed an issue where embedded Insight reports on the Participant Details Page could sometimes cause an error when loading the page. (**OC-18525**)
- Fixed styling of embedded Insight reports in Study Runner. (**OC-13255**)
- The Save button on the Site Configuration Page will now become disabled while a previous Save is still in progress. (**OC-18596**)
- Updated the text on the Site Configurations page from "Hide CRF" to "Hide from users at this site" to better align with the functionality. (**OC-18540**)
- Fixed an issue that could cause duplicate database entries to be created when selecting several form versions as available versions on the Site Settings page for forms with a large number of available versions. (**OC-20075**)
- Updated the visibility of jobs in the Bulk Actions Log page to allow Data Managers to see all jobs that do not display clinical data in their results regardless of who ran them. (**OC-16345**, **OC-19005**, **OC-19004**, **OC-19003**, **OC-19002**, **OC-19001**, **OC-19000**)
- Updated the date format on the Bulk Actions Log page to be consistent with the date format throughout OpenClinica. The date format was Mon-DD-YYYY and was updated to be DD-Mon-YYYY. (**OC-19740**)
- Added tooltip hovertext to the Action buttons on the Bulk Actions Log page. (**OC-13756**)
- Updated Tabular Imports to allow the import of blank values. (**OC-15472**, **OC-17281**)
- Updated Tabular Imports to allow the use of the Update match action using EventRepeatKey in repeating common events. (**OC-18178**)
- Updated the Submit button on the Import CRF Data page to be disabled and unclickable unless a file is selected. (**OC-13718**)
- Reformatted the time stamp in the XML import log to include a time zone indicator.

(**OC-14293**)

- Canceling an XML import will now redirect the user back to the import page. (**OC-19226**)
- Fixed an issue that caused invalid date values on SPSS Extracts for date values that were entered and then changed to null. (**OC-19787**)
- Reorganized the links to relevant Data Review Table entries that appear in Bulk Actions Logs for better clarity and readability. (**OC-19123**)
- Updated the Data Review Table formatting by setting the maximum height for review table cells and freezing the Participant ID column. (**OC-15223**, **OC-14854**)
- Updated the date format on the Data Review Table to be more consistent with the date format used throughout the system (DD-Mon-YYYY). (**OC-16483**)
- Changed the sort behavior on the Data Review Table for columns with multi-select values to sort by their response option text rather than response values. (**OC-15416**)
- Fixed an issue that could cause the date picker on the Data Review Table to open in a way that prevented users from having the option of entering a date manually. (**OC-15579**)
- Fixed an issue that required some users to clear their browser cache before certain UI updates released as part of OpenClinica releases took effect for those users. (**OC-19162**)
- Updated the Data Review Table to include Removed/Not Removed as filter options within the Form Status and Event Status columns. (**OC-15652**)
- Added a Download button to the Data Review Tables to allow users to download the table to review in another setting. (**OC-18076**)
- Fixed an issue that caused query bubble icons to display incorrectly on the Data Review Table when multiple queries were on different items. (**OC-15725**)
- Fixed an issue that caused the horizontal scrollbar to not appear when a filtered view of a Data Review Table displayed no results. (**OC-19212**)
- Fixed an issue that could cause the Data Review Table to display inappropriately if the sort was enabled on a column item and that item was removed from the Data Review Table configuration. (**OC-19340**)
- Fixed an issue that caused checkboxes to display on the Data Review Tables for Monitors even though the Monitors were unable to complete any action. (**OC-18496**)
- Fixed an issue where Data Review Tables without data were showing an inappropriate error in browser consoles. (**OC-19105**)
- Updated the Queries table to include only the “View Query within record” link for all Reasons for Change on the table. (**OC-17265**)
- Fixed an issue that prevented queries from automatically closing when a form with a Permission Tag is archived. (**OC-18570**)
- Fixed an issue that caused the Reason for Change entry to be omitted for Remove, Clear, and Restore form actions when the Queries Table is downloaded in CSV format. (**OC-19601**)
- Fixed an issue that prevented some queries from being auto-closed after the associated form was removed. (**OC-20013**)
- Fixed an issue where having a Query on an empty Event End Date field could cause an error. (**OC-18822**)
- Fixed an issue where the old and new values of item-level SDV status changes could appear as question marks in the Audit Log. (**OC-18297**)
- Updated the behavior when a form is cleared and then edited in a different version what it had been set to. The form version in the database will now be changed when the form is opened regardless of when data is entered. (**OC-20636**)
- Fixed an issue that caused Common Event status filters to return results for the expected German text and also the English equivalent when Study Runner is being displayed in German. (**OC-19992**)
- Added missing German translations in Study Runner. (**OC-19718**, **OC-19971**, **OC-19973**, **OC-20011**, **OC-20227**, **OC-20061**, **OC-19808**)

- Internationalization changes. (**OC-20036**, **OC-19367**, **OC-20016**, **OC-19921**, **OC-19900**, **OC-20212**)
- Fixed an issue where contact module information was masked for CRC and Investigator. (**OC-19887**)
- Fixed an issue that allowed the display of the "Add another occurrence" in the menu for repeating events on the Participant Matrix for Removed Participants. (**OC-19014**)
- Updated the Data Transformation Module to correctly display links to job results pages for all users who now have access to those job records. (**OC-19043**)
- Updated the Data Transformation Module to allow persistent highlighting on the row with the action most recently taken. (**OC-17799**)
- Added the option for users to add a description to files at upload in the Data Transformation Module. (**OC-17324**)
- Fixed an issue where the Data Transformation Module did not display an error when a file upload to the queue failed. (**OC-18393**)
- Added the ability to download an aggregated activity log that includes all of the actions performed on multiple files in the Data Transformation Module. (**OC-18070**)
- Added units to the header of the file size column on the Data Transformation Queue. (**OC-17710**)
- Added a divider between locked and scrolling columns on the Data Transformation Queue. (**OC-18139**)
- Fixed an issue where date item values displayed in the audit log could have a different format than when displayed in the form. (**OC-19541**)
- Added the ability to download the Data Transformation Queue table. (**OC-19190**)
- Added the ability to Restore/Reject files in bulk from the Data Transformation Module. (**OC-18149**)
- Fixed an issue causing inconsistent display of filter options in the Data Transformation Queue. (**OC-20111**)
- Changed the "View Log" button in the Data Transformation Module to create a popup. (**OC-18110**)
- Updated the downloadable filename from the Data Transformation Module to include the site name. (**OC-19875**)
- The field to enter a description when uploading a file to the Data Transformation Module now correctly displays transparent placeholder text. (**OC-19099**)
- Fixed an issue where a Site Data Manager was unable to filter by site in the Data Transformation Module. (**OC-20379**)
- Fixed an issue where Data Transformation Module file uploads were failing in some cases due to email connectivity issues. (**OC-20378**)
- Data Transformation Module dialogs will now only display error messages if the user attempts to confirm their pending action. (**OC-18884**)
- Clicking "Go Back" from the Bulk Actions Log when viewing a Data Transformation Module-related job now returns the user to the Data Transformation Module page, rather than the main Bulk Actions Log page. (**OC-18673**)
- Updated the Tasks menu to allow it to collapse when it is no longer being hovered over. Previously, the Tasks menu would remain open indefinitely when viewing certain pages. (**OC-12188**, **OC-19104**)
- Fixed an issue that caused an inconsistency in color of the asterisk [*] indicating Required fields on some pages in Study Runner. The asterisk would show in black on some pages, but it has been updated to display correctly in red on the following pages: Update Study Event, Create Dataset, Create Scheduled Job, End Date: Add Query, Start Date: Add Query, Remove Event from Study, Remove Form from Event, Clear Form from Event, Restore Form to Event, Remove Participant from Study, Restore Participant to Study. (**OC-19634**)

- Fixed an issue that caused events to remain Signed when the Event Status was updated. (**OC-20069**)
- Fixed an issue allowing Run on Schedule Rules to still fire and send notifications for Removed Participants. (**OC-13430**)
- Fixed an issue where a rule that did not explicitly list all possible event workflow statuses in the RunOnStatus node of the rule definition could unexpectedly fail to fire. (**OC-19029**)
- Fixed an issue preventing all rules in study from being included in the rules download. (**OC-14536**)
- Fixed an issue causing rules to fire when the target for the rule was removed. (**OC-18033**)
- Fixed an issue that allowed Participants at Locked or Frozen Sites to be signed by Data Specialist users accessing at the Study Level. (**OC-18533**)
- Fixed an issue that prevented Casebook PDFs from displaying the images for Signature and Drawing item types. (**OC-18829**)
- Fixed an issue where the PDF Casebook could be missing some repeating groups entries on a form if there were deleted entries and the form definition used repeat_count. (**OC-19831**)
- Added an update to prevent PDF Casebooks with very large forms from failing due to timing out. (**OC-20613**)
- Fixed an issue where canceling an individual form version migration action could return to the user to the wrong page. (**OC-19009**)
- Fixed an issue that prevented the restoration of a participant from the Participant Matrix while in the Single Event view. (**OC-19007**)
- Improved performance of View Events page for large studies. (**OC-18664**)
- Fixed an issue that could cause Scheduled Extract Jobs to fail to run based on the status of the user who is configured to be notified when the job runs. (**OC-20052**)
- Updated Scheduled Extract Jobs table sorting to persist after actions are performed. (**OC-12833**)
- Improved loading times for the View Events page in studies with many events. (**OC-18664**)
- Fixed an issue where a form version could be made a default form version at a site without that form version being available to users, which prevented users from accessing the form. (**OC-19708**)
- Fixed an issue where the preserved files from past runs of scheduled extract jobs could sometimes fail to delete properly if they included forms using permission tags. (**OC-20542**)

Forms

- Updated the form Complete button to give users the option to add automatic queries for standard soft constraint and required edit checks when a form is marked Complete. (**OC-12769**)
- Updated previously cleared forms to populate item default values the first time a cleared form is edited again. (**OC-14456**)
- Fixed an issue that allowed forms to be opened in Review-only mode instead of Read-only mode when a study was still in the Design status. (**OC-14919**)
- Fixed an issue that allowed Participants to complete a form with a blank signature widget item even though the item was defined as required. (**OC-19319**)
- Fixed an issue that caused Select items with a choice filter in repeating groups to show incorrect values in View mode. (**OC-16586**)
- Fixed an issue that caused an error when opening a form in a View mode for forms with a repeating group that uses repeat count and had deleted repeating group entries. (**OC-18086**)
- Fixed an issue where tabbing out of a date field in a form could result in the value being set inappropriately. (**OC-19442**)
- Fixed an issue that only allowed users to select increments of 10 when using a visual analog

scale item with appearance “analog-scale vertical show-scale”. (**OC-19690**)
- Fixed an issue that was preventing the progress bar to persist once in offline mode. (**OC-18091**)
- Fixed an issue preventing the opening of forms with data that were previously in a non-repeating event and are now in a repeating event. (**OC-18122**)

Participate

- Fixed an issue that prevented Participants from editing forms if they were reassigned to a new site and their old site was Locked. (**OC-19447**)
- Added Accessibility Statement and Privacy Policy links to the User Menu in Participate. (**OC-16630**)

REST API

- Clarified the API parameter description to the swagger GET API Participant call to give the user more information. (**OC-19693**)
- Improved performance of the Bulk Study Event API call that could cause it to prevent user access to Study Runner. (**OC-19985**)

Insight

- Updated Insight user interface to provide an improved navigation experience for users and admins. (**OC-20279**)
- Fixed a variety of issues related to Insight email notifications containing data in a different format than the Insight user interface. (**OC-20279**)
- Updated Insight to include compatibility with eConsent by including the new statuses, event types, and a new standard question. (**OC-18959**, **OC-20340**)

General

- Updated the white icon on the orange help widget from a question mark to a broadcast icon. (**OC-20114**)
- Security enhancements.

OpenClinica 4 Stack 17.4.1 (Release Date – 09 March 2023)

OpenClinica 4 Stack 17.4.1 contains targeted updates to OpenClinica. View the entire **Stack 17.4.1 changelog here** (login required).

Changes and Fixes:

- Fixed an issue that caused Visit Events to be scheduled for the wrong day if they were added from the Participant Details Page during February for the 29th, 30th, or 31st day of another month or during April, June, September, or November for the 31st day of another month. (**OC-20351**)
- Fixed an issue that could cause Casebook PDF failures for forms with very large data sets due to a timeout issue. (**OC-20464**)

OpenClinica 4 Stack 17.4 (Release Date - 21 January 2023)

OpenClinica 4 Stack 17.4 contains targeted updates to OpenClinica. View the entire **Stack 17.4 changelog here** (login required).

New:

Study Runner

- **Internationalization:** Study Runner and Forms opened from Study Runner can now be displayed in different languages based on study configuration and a user's browser locale settings. Initially, English (en) and German (de) are the supported languages.

Unite

- **Additional Data Domains:** Participant Immunizations, Encounters, Conditions, and Procedures data can now be sent from the Cerner EHR to OpenClinica using Unite. This expands the existing ability to send patient EHR data including Labs, Medications, and Demographics to OpenClinica.

General

- **Qualification Report**: The most recent UpOQ report can now be downloaded from within OpenClinica using a button on the Administration page. The report layout and style have been updated to present the information in a cleaner, more concise format. For customers using Insight, Insight UpOQ reports will continue to be provided separately.

Changes and Fixes:

Study Runner

- Fixed an issue that caused Common Event form table search on the Participant Details Page to return unexpected results for some text in the Form Status column. (**OC-19515**)
- Fixed an issue that caused version reassignment for non-repeating Common Event forms to fail from the Participant Details Page. (**OC-19583**)
- Fixed an issue that allowed the Common Event Add New button on the Participant Details Page to remain active after being clicked. This could result in duplicate form records being created. (**OC-19101**)
- Fixed an issue on the Participant Details Page causing form tables for Archived Common Events to not be displayed in some cases when the record filter is changed while using the page. (**OC-19512**)
- Fixed an issue on the Participant Details Page that caused Common Event form tables to highlight an incorrect row after adding a form while the record filter was set to show Removed records. (**OC-19537**)
- Fixed an issue that prevented a Common Event section from loading correctly on the Participant Details Page if a Common Event form table was configured to show a column for a select_multiple item which had more than 50 choices. (**OC-19547**)
- Fixed an issue that caused Common Event form table search on the Participant Details Page to return no results if the search term contained a leading or trailing space. (**OC-19517**)
- Improved performance of generating PDF Casebooks for Participants with any forms. (**OC-19647**)
- Fixed an issue which caused access to some forms to be restricted as if they contained contact data even when they did not. (**OC-19540**)
- Fixed an issue that allowed Site-level Data Managers to see the list of all Sites in the study when viewing the Study metadata in Study Runner. (**OC-19507**)
- Changed the job run frequency option on the Scheduled Extract Jobs pages from "Monthly" to "Every 4 Weeks" to describe the existing functionality more accurately. (**OC-19361**)
- Fixed an issue where Scheduled Extract Jobs set to trigger daily could sometimes stop

triggering after the first day. (**OC-19810**)
- Fixed an issue that allowed a user to open a form in edit mode from Data Review Tables when the version the form was using was archived. (**OC-19344**)
- Fixed an issue that prevented some data from archived forms from being displayed on Data Review Tables. (**OC-19483**)
- Added additional options to the Data Transformation Module filters for the Pipeline, Uploaded By, Transformed By, and Imported By columns. (**OC-19196**)
- Data Transformation Module file upload notification emails are now sent to Study Monitors as well as to Data Managers. (**OC-19125**)
- Updated the Data Transformation Module permissions to permit Site-level Data Managers to use the same functionality as Study Data Manager, but only for files at their own site. (**OC-19482**)

General

- Security enhancements.

Click **here** to view previous updates.

Functional approval by Paul Bowen. Signed on 2024-12-07 11:57AM

Approved for publication by Brooke Davis. Signed on 2024-12-07 11:59AM

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OpenClinica 4 Stack 17.3 (Release Date - 19 November 2022)

OpenClinica 4 Stack 17.3 contains targeted updates to OpenClinica. View the entire **Stack 17.3 changelog here** (login required). For an overview of this update, view the **Stack 17.3 Release Announcement here**.

New:

Study Build System

- **Site-Level Data Manager Role:** Data Manager access can now be set at the Site level. Previously, there was only one Data Manager role at the Study level, but now an additional role is available for Site-level access. Existing Data Manager roles (including any study-specific roles based on the Data Manager role) will continue to have Study-level access. Users assigned to the Site Data Manager role will not have access to manage the study but will have all access in Study Runner that an existing Study Data Manager has while accessing at a specific site.

Unite

- **Additional Data Domains:** Participant Immunizations, Encounters, Conditions, and Procedures data can now be sent from the Epic EHR to OpenClinica using Unite. This expands the existing ability to send patient EHR data including Labs, Medications, and Demographics to OpenClinica.

Changes and Fixes:

Study Build System

- Fixed an issue that could cause user creation to timeout in some cases. (**OC-18988**)
- Fixed an issue that could cause timeout error when attempting to publish a large study. (**OC-19155**)
- Fixed an issue causing a publishing error when form item names were too long. (**OC-18734**)
- Fixed an issue that prevented items from being reordered in Data Review Tables being configured in Study Designer for items on archived form versions. (**OC-16859**)
- Fixed an issue causing intermittent slow loading and processing in Study Designer. (**OC-18852**)
- Fixed an issue causing files downloaded from a form card in Study Designer to have filename “undefined” if the original filename contained parentheses. (**OC-19059**)
- Fixed an issue causing the Study Designer Activity Log to incorrectly display multiple publish actions at the same time. (**OC-19252**)
- Fixed an issue causing the Study Designer Activity Log to record incorrect users to be listed for some actions during concurrent usage. (**OC-19421**)

Study Runner

- Added general optimizations to improve performance throughout Study Runner. (**OC-18924**)
- Added performance improvements for database access under heavy load. (**OC-19042**)
- Added performance improvements for batch form version migration. (**OC-18893**)
- Added performance improvements to the Common Events section of the Participant Details Page. Initial page load and form table load will be faster for Participants in large studies or with many common event forms.
- The Actions column in the Common Events section was converted from buttons to a drop-down kebab menu to better match the Visits section of the Participant Details Page and allow more room for other columns in Common Events Form tables.
- Archived Common Events and Archived Common Event Forms are no longer displayed on the Participant Details Page when the Active Records filter is selected.
- Active Common Events that do not contain any Archived Forms or Removed Form records will no longer be displayed on the Participant Details Page when the Removed Records filter is selected. Active Common Event Forms that do not contain any Removed Form records will no longer be displayed on the Participant Details Page when the Removed Records filter is selected.
- Fixed an issue that that caused some text item values that were formatted like dates to be displayed as different strings in Common Events Form tables on the Participant Details Page. If text was entered like date format YYYY-MM-DD (such as "2022-11-19"), it would be displayed as if converted to date format DD-MMM-YYYY (such as "19-Nov-2022") in Common Events Form tables. Now, text items will be displayed exactly as they were entered even if they resemble date values. (**OC-19488**)
- Fixed an issue that prevented Common Events from being Locked on the Participant Details

Page for Participants with Signed status. (**OC-18423**)
- Fixed an issue that could cause forms to appear out of order on the Participant Details Page for Participants at sites which had site configurations defined. Now, the forms will appear in the same order they are set to in Study Designer. (**OC-18972**)
- Fixed an issue causing Common Events to not be displayed on the Participant Details Page correctly in some cases for a Removed participant. (**OC-18344**)
- Fixed an issue causing Archived Common Event forms with data added before archiving to be displayed when the default Active Records filter is applied on the Participant Details Page. (**OC-18536**)
- Fixed an issue which caused access to some forms to be restricted as if they contained contact data even when they did not. (**OC-18732**)
- Added accessibility statement link to the user menu in Study Runner. (**OC-16627**)
- Updated the Tasks menu for Data Managers to include a link to Source Data Verification when logged in at the Site level. Previously, this was only available when logged in at the Study level. (**OC-18814**)
- Fixed an issue that allowed users to Clear a form and skip entering a Reason for Change. (**OC-18947**)
- Fixed an issue that could cause the Audit Log to display an incorrect user for the Initial Entry of the Event End Date if the first value was entered after the event was scheduled. (**OC-19401**)
- Fixed an issue that could cause an error when getting the Audit Log for a very newly created participant. (**OC-17446**)
- Fixed an issue causing an error when trying to open the Audit Log for some participants with large data records. (**OC-18566**)
- Updated Data Transformation Module Transform menu to list pipelines sorted in alphabetical order. (**OC-18882**)
- Fixed an issue causing an error when Investigators would select a Participant link from the Sign Participants page when signing participants in bulk. (**OC-18962**)
- Added help text to the download queries window to help users know that the file is currently being generated. The Download notes button will also be disabled upon clicking to prevent duplicate actions from being initiated. (**OC-18965**)

Forms

- Improved performance when opening forms containing large data volumes under heavy load. (**OC-19022**)
- Improved form engine performance when generating PDFs. (**OC-18795**)
- Fixed an issue that caused some PDF Casebook jobs to remain as in “IN_PROGRESS” when they should have “FAILED” for the Job Status. (**OC-18856**)
- Fixed an issue that could cause files saved to forms (uploaded files or drawn images) to be overwritten on rare occasions because the file names were not unique across forms. Files saved to forms will now have Participant OID and a more detailed timestamp appended to their names to ensure no duplicates exist. (**OC-18913**)

Insight

- Added the OpenQueries form attribute to Insight to match what is include in the ODM and cross-form data. (**OC-18737**)

General

- Security enhancements.

OpenClinica 4 Stack 17.2 (Release Date - 27 August 2022)

OpenClinica 4 Stack 17.2 contains targeted updates to OpenClinica. View the entire **Stack 17.2 changelog here** (login required).

New:

Unite

- **iOS Background Data Refresh**: The iOS app now supports sending Lab and Medication data to OpenClinica studies in the background. Once a Participant has accepted an invitation to connect to a study and has also connected Apple Health to their medical records, the app can begin sending data to the study regularly while the Participant remains active on the study protocol. This eliminates the previous need for the user to initiate subsequent data submissions manually.

Participate

- **Embedded Content Frame**: Participate Dashboards can now be configured to include an embedded web page to display content to Participants. This allows study information (news, contact info, etc.) to be communicated easily to Participants who are accessing Participate to fill out forms. This feature can also be used in conjunction with embedding Insight dashboards within Participate (which can display Participant-specific or aggregate data reports).

Changes and Fixes:

Study Runner

- Fixed browser caching issue that could prevent the Participant Details Page, Data Review Tables page, or Data Transformation Module page from being displayed correctly on some devices after a new release of OpenClinica. (**OC-18513**)
- Fixed an issue with the Add New button appearing for Common Events on the Participant Details Page for Removed Participants. (**OC-18410**)
- Fixed an issue causing the Casebooks to render non-ASCII characters incorrectly in some cases. (**OC-18538**)
- Fixed an issue with the preview pane in the Data Transformation Module that caused data containing commas to be displayed incorrectly. (**OC-18672**)

Forms

- Fixed an issue that prevented data from Hidden forms from being accessed using cross-form logic. (**OC-18669**)

Unite

- Updated the iOS app error message for participants who attempt to send their data in the OpenClinica app without having their medical records connected to their Apple Health app. (**OC-17663**)
- Updated the iOS app instructions about authorizing access to medical records to be more user-

friendly. (**OC-18556**)

General

- Security enhancements. (**OC-18787**)

OpenClinica 4 Stack 17.1 (Release Date - 06 August 2022)

OpenClinica 4 Stack 17.1 contains targeted updates to OpenClinica. View the entire **Stack 17 changelog here** (login required). For an overview of this update, view the **Stack 17.1 Release Announcement here**.

New:

Study Build System

- **Manage Study Role Configuration:** Data Manager access to the Study Build System can now be controlled through the new Manage Study permission. This permission will be available for all user roles with base role Data Manager and can be configured from the Edit Role window within the User Roles page. This will allow user roles to permit access to Study Runner with Data Manager permissions but grant or restrict access to manage the study in Study Manager and Study Designer based on the Manage Study permission. All existing roles based on Data Manager have this permission enabled as part of this release to maintain continuity with previous behavior. All new roles based on Data Manager will also have this permission enabled by default.

Changes and Fixes:

Study Build System

- Updated the validation criteria for user email addresses to allow apostrophes to be included. (**OC-15394**)

Study Runner

- Improved performance of running data extracts. (**OC-18191**)
- Updated data extracts defined at a site to always include data only for that site regardless of whether they are run by a study-level or site-level user. (**OC-18331**)
- Fixed an issue where Hidden forms could appear in casebooks and extracts for some users at the site level. (**OC-15885**)
- Fixed an issue that caused extracts to fail in some cases for studies containing multiple forms in a non-repeating common event. (**OC-18456**)
- Fixed broken Participant links in the Study Audit Log. (**OC-18512**)

Forms

- Improved performance of opening forms that use cross-form logic. (**OC-18571**, **OC-18548**)

OpenClinica 4 Stack 17.0.3 (Release Date – 27 July 2022)

OpenClinica 4 Stack 17.0.3 contains targeted updates to OpenClinica. View the entire **Stack 17.0.3 changelog here** (login required).

Highlights Include:

Changes and Fixes:

General

- Fixed an issue causing some forms using cross-from logic to load slowly. (**OC-18526**)
- Fixed an issue causing the Participant Details Page to intermittently load only partially and with multiple error messages. (**OC-18543**)

OpenClinica 4 Stack 17.0.2 (Release Date - 25 July 2022)

OpenClinica 4 Stack 17.0.2 contains targeted updates to OpenClinica. View the entire **Stack 17.0.2 changelog here** (login required).

Highlights Include:

Changes and Fixes:

General

- Performance updates for the Participant Matrix. (**OC-18511**)

OpenClinica 4 Stack 17 (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 Manager and turning their computers off without logging out might not be logged out due to inactivity as expected. (**OC-17123**)
- 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**)
- Removed the ability to upload Rules while accessing from a site since Rules had not run on a site-specific basis. (**OC-15648**)
- 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-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**)

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**)

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**)

Click **here** to view previous updates

Functional approval by Paul Bowen. Signed on 2022-11-19 10:03AM

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6 OpenClinica 4 - Release Notes 2021

Login is required to view issue links on this page. Some issues may not be accessible to all users.

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.

Study Runner

- **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**)

Study Runner

- 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 Participant-specific 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**)

OpenClinica 4 Stack 14.4 (Release Date - 13 October 2021)

OpenClinica 4 Stack 14.4 contains targeted fixes to OpenClinica. View the entire **Stack 14.4 changelog**

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**)

Study Runner

- 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

required). Highlights include:

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 multi-language 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. (**OC-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**)

Study Runner

- 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-13558**, **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**)

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

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

Highlights include:

Changes & Fixes:

- Fixed an issue that could prevent form order from being changed in Study Designer. (**OC-13248**)
- Fixed an issue that prevented archived form versions from being downloaded. (**OC-13112**)
- Updated Event and Form OIDs to be able to be selected and copied from Study Designer cards. (**OC-13153**)
- Fixed an issue that could cause some Event OIDs to be displayed incorrectly in Study Designer. (**OC-13713**)
- Fixed an issue that caused an error when a form was added with the same name as an archived form. (**OC-13090**)
- Fixed an issue that caused the Study Designer scrollbar to behave incorrectly in some cases. (**OC-12896**)

- Improved the UI to make it easier to assign Permission Tags to forms when there are many of them in the study. (**OC-13415**)
- Updated the Archives panel to be more user-friendly. (**OC-13195**)
- Fixed a UI issue with the Participate icon on Form cards. (**OC-13113**)
- Fixed an issue that could cause Study Designer to hang in some cases. (**OC-13623**)

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

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

Highlights include:

Changes & Fixes:

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

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

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

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

Highlights include:

Changes & Fixes:

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

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

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

Highlights include:

Changes & Fixes:

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

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

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

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

Highlights include:

Changes & Fixes:

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

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

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

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

Highlights include:

New:

Runtime

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

icon next to the form version ID. New action icons have been added to the Participant Details Page for Sign, Lock, and Unlock. These actions can also still be performed from the Update Study Event Page.

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

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

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

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

Added an Item Details table accessible for each form in the SDV interface. The Data button on each row of the SDV Forms table opens the Item Details table. This allows the user to view a table with item-level details for each item on a form. This includes current value, number of open queries, and last modified date for each item. There is a filter to toggle between seeing all items and seeing only those items that have been modified since the form was last verified.

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

Changes & Fixes:

Study Build System

- Improved performance of Table Design interface in Study Designer so that it could be opened for large studies without failing. (**OC-11727**)
- Added ability to search the Administration People table by username, email address, first

name, or last name. (**OC-9076**)
- Updated the text layout in the Invite New User dialog to make it easier to read. (**OC-12811**)
- Resolved an issue where sites might not be displayed in Study Manager in some cases. (**OC-13371**)
- When searching for an existing user, if the administrator chooses to create a new user, the search term used will now be automatically populated in the username and email address fields of the new user creation form. (**OC-12812**)
- Fixed an issue where the titles for Study environments on the My Studies page were being displayed in a way that made it easy to confuse the statuses for the Production and Test environments. (**OC-12130**)

Runtime

- Added links to each of the main Study Build System pages to the header of Runtime. Now users with access to the Study Build System can go directly from Runtime to the Study Design, Settings, and Share pages for the current Study in one click. (**OC-12802**)
- Updated the Participant Details Page Visits Table filter to search for events based on the entire string, not matching on any word. (**OC-12823**)
- Fixed an issue where a user would see an empty Common Event header on the Participant Details page if they had no access to forms within it due to permission tag assignments. (**OC-12889**)
- Updated the Participant Details Page Casebook checkbox text to make it clear that archived and removed data would be included or excluded together. (**OC-13381**)
- Fixed an issue where Common Event forms could not be removed or restored for Signed Participants. (**OC-12685**)
- Fixed an issue where Common Event forms could not be added for Signed Participants. (**OC-12715**)
- Updated the event and form context popups on the Participant Matrix to automatically close if a different popup is opened. (**OC-12668**)
- Fixed an issue where the Restore action was not accessible for Removed forms from the Participant Matrix. (**OC-12118**)
- Added Event Start Date to the Participant Matrix context popup for non-repeating events. (**OC-12881**)
- Fixed an issue where column filters would stop working on the Participant Matrix after it had been filtered to show only a single Event. (**OC-13137**)
- Fixed an issue where the Participant Matrix would sometimes show archived events after it had been filtered to show a single event. (**OC-12888**)
- Improved performance of loading the Participant Matrix when custom columns are in use. (**OC-12814**)
- The headers of PDF Casebooks will now include the name of the participant's site. (**OC-12169**)
- Improved the layout of PDF Casebook headers and footers. (**OC-12076**)
- Added an option to the Bulk Actions Log that allows viewing of error messages for failed Casebook generation. (**OC-12107**)
- Fixed an issue where the Bulk Actions Log would display the wrong end time for Casebook generation jobs. (**OC-12370**)
- Added the date and time created to the footer of PDF Casebooks. (**OC-12168**)
- Fixed an issue where PDF Casebook headers would fail to display some information on Events when the study name was too long. (**OC-12106**)
- Text cells in PDF Casebooks will now expand correctly to fit long text entries. (**OC-12474**)
- Fixed an issue where PDF Casebooks for Signed participants would exclude audit log information. (**OC-12680**)

- Fixed an issue where editing large dataset definitions could sometimes lead to some items being omitted. (**OC-12939**)
- Fixed an issue where some form data added after closing a query on an item could be missing from extracts. (**OC-12573**)
- Fixed an issue where queries were not included in extracts if the associated item's value was null. (**OC-12457**)
- Updated the extract job completion notification email to include the study context of the extract job so that the user would always be taken to the correct file when using the link in the email. (**OC-11634**)
- Fixed an issue where adding all items in a large study to a dataset could sometimes lead to some items being omitted. (**OC-12542**)
- Fixed an issue where extracts did not include a given form record if the form had been started but all items were null at the time of the extract. (**OC-13145**)
- Fixed an issue where the logs for a data import could erroneously duplicate the logs of a prior data import. (**OC-12060**)
- Updated the XML Import Template to remove confusing references to a FormLayout Ref OID. (**OC-12977**)
- Added a new landing page to allow access to both the XML and Flat File import pages. (**OC-13104**)
- Fixed an issue where data in an occurrence of a repeating common event could not be updated if those data were originally attempted to be added through a failed import. (**OC-12136**)
- Fixed an issue where attempting to import data of an unsupported type to a field could erroneously update the associated Event's status. (**OC-11814**)
- Updated the XML Import template to reflect the latest updates to the system. (**OC-13041**)
- Updated the SDV Forms table to have separate columns for Form Name and Form Version. (**OC-12252**)
- Updated the text on bulk action button on the SDV Forms table to "Verify All Checked" for consistency with the other updates. (**OC-13045**)
- Updated the left side panel for the SDV Forms table to be more user-friendly. (**OC-12251**)
- Updated the display in the Event Name column of the SDV Forms table to be more user-friendly for forms in repeating events. (**OC-12254**)
- Updated the Last Updated Date and Event Date columns to be sortable on the SDV Forms table. (**OC-11531**)
- Updated SDV Forms table to have a column for the count of Open Queries and a link to those queries if any exist. (**OC-12205**)
- Fixed an issue where the SDV page would sometimes show a confirmation prompt before telling a user they did not have access to Verify a record. (**OC-9573**)
- Fixed an issue where the SDV page might silently fail an action rather than alert the user that they don't have access to a record. (**OC-11756**)
- Updated signature logic to remove an event signature if a form in the event is removed or restored. (**OC-10309**)
- Updated signature logic so that changing the event to Locked or Unlocked will leave the event's signature in place. (**OC-12655**)
- Updated signature logic so that changing an event's workflow status will remove the event's signature. (**OC-13296**)
- Updated signature logic so that marking an empty form Complete will not remove the signature of the event it is in. (**OC-12656**)
- Updated signature logic so that archiving or unarchiving a form that has been started in an event will remove the signature of the event. (**OC-13188**)
- Updated signature logic so that events and participants are not blocked from being signed due to removed forms (unless they are required), archived forms, archived events, or removed

events. (**OC-12761**)
- Updated signature logic for signed Participants to match logic implemented for signed events. (**OC-12654**)
- Updated to allow events that are removed and locked to be able to be unlocked so that they can be updated further as needed. (**OC-13202**)
- Removed the option to Delete Visit-based Events. (**OC-12831**)
- The action to Delete a form record has been renamed to Clear to reflect its functionality of clearing the item data from a participant form record while leaving the record itself intact. (**OC-12821**)
- Clearing a form will update the form Workflow status to Not Started instead of Initial Data Entry. (**OC-12507**)
- Fixed an issue where audit log entries would not make sense when an event was removed. (**OC-9200**)
- Updated the icon key throughout the system to include all the new statuses and actions. (**OC-13037**)
- Updated the event Workflow status dropdown selector on the Update Study Event page to prevent events from being changed between incompatible statuses. (**OC-10027**)
- Fixed an issue where audit log entries were not user-friendly when an event was removed or stopped. (**OC-8416**)
- Fixed an issue where audit log entries were not user-friendly when changing the status of a Locked event. (**OC-11161**)
- Fixed an issue where audit log entries were not user-friendly when restoring a completed event. (**OC-10126**)
- Fixed issues where audit entries were not being added when events were scheduled, forms were removed, or Participants were removed. (**OC-10128**)
- Fixed an issue where restoring a removed Participant was changing the Workflow status of some forms. (**OC-9686**)
- Fixed an issue where Locked events could be removed from the Participant Matrix. (**OC-13433**)
- Updated signature message shown when viewing forms that are removed or archived but in a signed event to make it clear that the signature does not apply to these forms. (**OC-13392**)
- Updated event status filters on Participant Matrix and View Events page to include Not Signed and Not Locked options. (**OC-13311**)
- Updated Participant Matrix status display for repeating events to show the Workflow status of the event repeat that is furthest from completed status rather than just showing the status of the first event repeat. (**OC-12784**)
- Updated the instructions on the Remove/Restore Event/Form pages to make it clear that these actions will remove signatures. (**OC-13215**)
- Fixed an issue where a form could fail to render, and cross-form references within the form fail to work if item data in the form contained an emoji. (**OC-12044**)
- Fixed an issue where generating an ODM casebook would fail if item data in a record contained an emoji. (**OC-12955**)
- Updated the CRF Details page to more clearly label the Form OID, Version OID, Item Name, and Item OID fields. (**OC-13126**)
- Updated the success message when signing a participant to indicate which participant is being signed. (**OC-12699**)
- Fixed display and text-justification issues on the View Item Details page. (**OC-12813**)
- Fixed an issue where CRC users could sometimes erroneously access the option to migrate a form version, which would fail. (**OC-12979**)
- Updated styling on various pages to account for recent changes in the Chrome web browser that had changed OpenClinica's intended appearance. (**OC-13156**)

- Updated the form metadata page to label some OIDs and attributes of forms more clearly. (**OC-13125**)
- Fixed an issue where the link to access the Bulk Action Log would not be available to Monitors. (**OC-12618**)
- Fixed an issue where the audited event of creating a participant was appearing twice in audit logs. (**OC-11408**)
- Removed the ability to view some deprecated pages. (**OC-13287**)
- Fixed an issue where the name of a participant's site would not appear on the confirmation page when removing them from the study. (**OC-13414**)
- Fixed an issue where locked, frozen, or 'in design' studies could have the option to add new Common Events. (**OC-13306**)
- Improved performance of loading the Enter or Validate Data page. (**OC-12665**)
- Fixed an error that could occur when adding a query to Event Start Date or End Date fields. (**OC-12342**)
- Updated Quicks Links section of the left panel to be expanded by default to make the Queries Assigned to Me link visible. (**OC-10729**)
- CSV exports of Queries will now include both parent and child Queries. (**OC-12155**)
- Fixed an issue where CSV Query exports could have NULL as the status for Closed-Modified Queries instead of their actual statuses. (**OC-13009**)
- The printer-friendly version of the Queries page was omitting Event Name, Event Date, CRF, Item Name, and Item Value. This has been fixed. (**OC-12154**)
- Fixed an issue where item value filters on the Queries table could fail to work. (**OC-12421**)
- Fixed an issue where Item Name filters on the Queries table for Event Start Date or End Date could fail to work. (**OC-11584**)
- Fixed an issue where a Notification Rule could fail to send an email as expected. (**OC-12248**)
- Fixed an issue where users attempting to view Casebooks with the option to include metadata enabled could encounter an error if the study had rules enabled. (**OC-12679**)
- Fixed an issue where a link to download rules would appear even if the study was not using any rules. (**OC-11957**)

Forms

- Fixed an issue that could allow data to be submitted from forms that loaded with an error. (**OC-12869**)
- Fixed an issue where item history on forms might display a history entry twice when the form is opened. (**OC-12919**)
- Fixed an issue where downloading files that had been uploaded to the server always resulted in a failure message. (**OC-12544**)
- Updated the download button for file items to have descriptive hover text with instructions to use right click and save as to download the file. (**OC-13135**)
- Fixed an issue where repeating groups using the repeat_count parameter did not work correctly if the repeating group were nested in a non-repeating group that had a relevant expression. (**OC-12362**)
- Fixed an issue where select items would show an error message after becoming irrelevant and then being cleared. (**OC-13180**)
- Improved performance of opening forms, especially when opening existing forms that already contain data. (**OC-13141**)
- Updated image map items on forms to respect the sizing parameters defined within the SVG image file. (**OC-12791**)
- Fixed an issue where image upload to annotation widget was failing. (**OC-12013**)
- Fixed an issue where the Query Widget layout was broken for selection items using columns

appearance. (**OC-12232**)
- Updated so that bullet points could be rendered in the first line of item label text. (**OC-12498**)
- Updated the Query Widget on forms to only allow Data Manager and Monitor users to reopen closed queries. (**OC-12770**)
- Fixed an issue where the default query assignee when responding to a query was not set as expected. (**OC-9069**)
- Fixed an issue where complete forms with calculated items could prompt the user to enter a Reason for Change when the form was reopened. (**OC-12920**)

Insight

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

Participate

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

REST API

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

General

- Fixed an issue where a user logging in might be taken to a profile page unexpectedly.

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

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

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

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

Highlights include:

New:

Study Build System

- Added Content Library to Form Designer. This allows administrators to create, edit, and manage a shared library of items, item groups, and entire forms across all of their studies. Other users within their customer domain can drag library content into their forms during form editing.

Changes & Fixes:

Study Build System

- Added Form and Event OIDs to the Form/Event cards in Study Designer prior to publication to support the creation of rules and cross-form logic. (**OC-12557**)
- Added Select All/Unselect All options to Multi-Selection interface in Study Designer. (**OC-9802**)
- Updated the downloaded version of the Study Designer Activity Log to include publish activity. (**OC-12278**)
- Fixed issues with uploading large media files in Study Designer. Study Designer now supports combined file sizes of up to 50 MB per form version or draft. (**OC-12280**, **OC-12285**)
- Copying a form from a Common Event to a Visit-based Event with a table configuration will no longer copy the table configuration (which could lead to subsequent unexpected behavior). (**OC-12284**)
- Updated Activity Log entry when a user first access a Study in in Study Designer to more clearly describe the activity. (**OC-12302**)
- Added support to drag-and-drop multiple items at once in Form Designer. (**OC-12899**)
- Added a bulk delete action to Form Designer. (**OC-12581**)
- Added a bulk duplicate action to Form Designer. (**OC-12582**)
- Increased the size of Form Designer and Form Designer Preview windows to provide more

working space. (**OC-12772**, **OC-12773**)
- Fixed an issue in Form Designer Preview that showed labels in all uppercase letters for Grid forms. (**OC-12580**)
- Updated item appearance configuration to separate primary appearance and column width for Grid forms. (**OC-12722**)
- Added Parent Group Width to item appearance configuration for Grid forms to provide context for the item width configuration. (**OC-12840**)
- Updated group appearance configuration to match the updated item appearance configuration. (**OC-12841**)
- Updated error message when an improperly designed form with multiple languages is opened so that the user will know how to address the issue. Multiple language forms can be loaded in Form Designer as long as all user-facing content columns specify which language they are used for. (**OC-11938**)
- Added the ability to define items with external file response lists (i.e., select_one_from_file type items) in Form Designer and load forms containing these items. (**OC-12064**)
- Fixed issues occurring with autopopulation of Item Group when using nested Layout Groups in Form Designer. (**OC-12190**, **OC-12277**)
- Fixed issues associated with opening or editing forms with UTF-8 characters in Form Designer. (**OC-12314**, **OC-12378**)
- Fixed an issue that could occur in Form Designer when using Firefox that caused some changes to item settings to fail to save. (**OC-12316**)
- Fixed an issue where Form Designer was inappropriately allowing the user to select "contactdata" or "clinicaldata" for "Use External Value" for item types that did not support these configurations. (**OC-12358**)
- Fixed an issue where "clinicaldata" items were incorrectly displaying an error message for not having an Item Group defined. (**OC-12598**)
- Removed non-applicable Required configuration option from Note type items. (**OC-12721**)
- Removed non-applicable Accepted Files configuration option from File type items. (**OC-13035**)
- Improved Form Designer usability by having the interface shift focus to the response choice's label field after adding a new response choice. (**OC-12383**)
- Form Designer will now correctly flag a draft as having unsaved changes if the response choice values have been changed for Select One or Select Multiple type items. (**OC-12387**)
- Updated spreadsheet downloads for forms edited in Form Designer to include all columns found in the Form Template. (**OC-12412**)

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

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

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

Highlights include:

Changes & Fixes:

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

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

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

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

Highlights include:

New:

Runtime

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

Participate

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

Changes & Fixes:

Study Build System

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

Runtime

- Fixed an issue where forms in Locked sites were able to be opened in Review-only mode instead of Read-only mode. (**OC-12275**)
- Fixed an issue that could allow Study-level users to add data to Locked sites. (**OC-12332**)
- Fixed an issue where some users where able to "Delete" Locked Event CRFs in certain cases. (**OC-12334**)
- Fixed an issue that could cause a Signed Event to become un-signed when a form within it was opened in Edit mode and then closed with no changes. Only editing data or marking a new form Complete will un-sign the event. (**OC-12265**)
- Fixed an issue with SAS Extracts where an error in output files required manual editing to allow the files to be loaded into SAS. (**OC-11593**)
- The Queries page now correctly displays status values associated with Event CRFs, rather than with Participants. (**OC-12159**)
- Fixed an issue that could cause CSV exports of the Queries page to include the wrong Item Names. (**OC-11703**)
- Fixed an issue that prevented the printing of PDF Casebooks for Locked Studies. (**OC-12281**)
- Fixed an issue that could cause Site User attempts to print PDF Casebooks to fail. (**OC-12341**)
- Fixed a few issues with PDF Casebook printing that could occur if the associated Participant ID contains an apostrophe. (**OC-12307**, **OC-12336**)
- Updated PDF Casebooks to mask all contact information fields even for CRC and Investigator users. (**OC-12268**)
- Fixed an issue where the contents of adjacent long text fields in printed PDF Casebooks would overlap. (**OC-12196**)
- Improved performance of PDF Casebook printing when the forms contain video, audio, or other non-printable files. (**OC-12110**)
- Added additional logging on notification action rules to aid in troubleshooting. (**OC-12338**)

Forms

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

Participate

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

REST API

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

General

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

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

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

Highlights include:

New:

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

Changes & Fixes:

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

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

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

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

Highlights include:

Changes & Fixes:

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

formatting. (**OC-12074**)

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

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

Highlights include:

Changes & Fixes:

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

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

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

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

Highlights include:

New:

Runtime

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

General

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

Changes & Fixes:

Study Build System

- Fixed an issue that could cause an error when publishing a study that contained Form versions including items with names that had been used in other Form versions but had been removed from the other Form versions when those versions were overwritten. (**OC-9428**)

- Fixed an issue where a study would fail to publish if new Form versions changed the case of item or item group names. (**OC-10602**)
- Fixed an issue that was sometimes allowing Forms with duplicate item or itemgroup OIDs to be created, which could prevent the study from publishing. (**OC-11845**)
- Improved the study publication workflow by preventing publication of a study environment while a previous attempt to publish that study environment is still being processed, which could result in errors and decreased performance. (**OC-10523**)
- Fixed an issue that could cause failed attempts to publish a study to induce errors in future attempts to publish the study. (**OC-11929**)
- Fixed an issue where a study could fail to publish if it contained an archived Event that included a Form without a Form version defined for it. (**OC-11718**)
- Fixed an issue where having an archived Common Event in a study that includes an overwritten Form version could cause the study to fail to publish. (**OC-11676**)
- Fixed an issue where configuring custom columns in the Participant Matrix or Queries table to display items from a Form and then updating that Form to a version that does not include the items configured for the custom columns could prevent the study from publishing. (**OC-11675**)
- Added a link to the Publish History section at the top of the Share Study page. (**OC-11122**)
- Added help text to the interface for configuring system-generated Participant IDs. (**OC-12024**)
- Study names and descriptions can now correctly include up to 255 characters. (**OC-11024**)
- Improved performance on the Study Settings page. It will now immediately reflect updates made to Study Type and Phase. (**OC-11704**)
- Fixed an issue that could cause the Modules configuration page to display incorrectly. (**OC-11197**)
- Added the ability to export the Activity Log from Study Designer, enabling Data Managers to examine a record of all the changes that have been made to a study design. (**OC-10777**)
- Fixed an issue that could sometimes cause the Activity Log to fail to load fully in Study Designer. (**OC-11686**)
- Updated the error message displayed when an invalid itemgroup is included in an uploaded Form Template to be more user-friendly. (**OC-11625**)
- Fixed an issue that could cause changes to Form order in Study Designer to revert on future loads of Study Designer. (**OC-11806**)
- The Go button in Study Designer will no longer display environments the user does not have access to. (**OC-12105**)
- Updated the examples provided in the Study Designer Table Design interface to aid in custom column configuration. (**OC-11620**)
- Fixed an issue with when copying Participate forms to Common Events in Study Designer. (**OC-11991**)
- Updated the Form Template in Study Designer to support new Stack 11 features. (**OC-12113**)

Runtime

- Data Managers can now edit system-generated Participant IDs without changing the study settings. (**OC-9676**)
- Removed mouse-over context menus for Events and Forms from the Participant Matrix to improve usability and enable usage on touch-screen displays. (**OC-11512**, **OC-11795**)
- Made custom columns in the Participant Matrix sortable. (**OC-11482**)
- Made custom columns in the Queries table sortable. (**OC-11556**)
- Item brief descriptions will now be displayed as column headers in CRF Summary tables for Common Events on the Participant Details page. (**OC-8892**)
- Updated the database underlying the Participant Matrix and Queries table to better support

custom columns. (**OC-11725**)
- Improved the way the Add New Participant dialog behaves to reduce confusion when creating Participant IDs. (**OC-11588**)
- Removing a Participant from the study now automatically closes all queries associated with that Participant. (**OC-9585**)
- Migrating a Form to a version that does not include an item now automatically closes all queries associated with that item. (**OC-11580**)
- Fixed an issue that could cause the View within Record display for viewing a query in context within a Form to appear empty. (**OC-11601**)
- Fixed an issue where removing a record associated with a Participant could sometimes interfere with the ability to later sign off on that Participant. (**OC-11450**)
- Added Participant ID to the confirmation message when reassigning Participants. (**OC-9471**)
- Users should see performance improvements of up to 60% on the View / Enter Data page for an Event. (**OC-11751**)
- Removed irrelevant action options for removed Forms from the View / Enter Data page for an Event. (**OC-9647**)
- Fixed an error that could occur when trying to open a Form in a Study that is in Design status. (**OC-11882**)
- Added the Item Label and Brief Description to query notifications. (**OC-9605**)
- Updated the link included in query notification emails to appropriately filter the Query table after it is clicked. (**OC-11250**)
- Removed the Add New button for removed Participants from the Common Events page, since removed Participants should not have new Common Events added. (**OC-11308**)
- Fixed an issue that could make it impossible to edit items within a Dataset from the View Datasets menu. (**OC-11678**)
- SPSS Data Extracts will now include variable labels. (**OC-11447**)
- SAS extracts now include item descriptions. (**OC-11748**)
- Fixed an issue that could cause the extract list to fail to include the correct Dataset Format for previously run extracts. (**OC-11419**)
- Reordered the options to View and Create Datasets on the Tasks menu so that they are consistent for all users. (**OC-11832**)
- Fixed issues related to errors arising from removing a Monitor's Form-specific permissions while they are accessing the SDV page. (**OC-11749**, **OC-12139**)
- Fixed an issue that could cause the Add New Visit Event button to disappear from the Participant Details page in cases where events included Forms that were restricted with Permission Tags. (**OC-11536**)
- Removed the Add New button from the Participant Details page for Non-Repeating Common Events if there is already a Form present for that Event. (**OC-11633**)
- Improved usability on the Participant Details page by updating hover text to be more accurate. (**OC-11709**)
- Update the Participant Matrix to include the appropriate set of options for all Forms based on their statuses. (**OC-9482**)
- Improved usability of the Bulk Actions Log page with updated help text. (**OC-12073**)
- Removed the option to download Rule files from studies with no available Rules to download. (**OC-11135**)
- Fixed an issue with multiple studies that contain Events of the name that could interfere with Rules referencing one of those Events. (**OC-12099**)
- When importing data into complete Forms, users can now supply a Reason For Change for all items in the Form automatically by including it in their import file. (**OC-10918**)
- Added informative error messages when imports are attempted with files that are invalid due to missing or invalid Study IDs. (**OC-11453**)

- It is now possible to import data for a signed Participant, consistent with how data can be entered for such Participants manually via the Form UI. (**OC-11596**, **OC-11632**)
- Fixed an issue where creating Non-Repeating Common Events via an XML import could result in multiple instances of the Event being created. (**OC-11805**)
- Updated the import template to support new Stack 11 features. (**OC-11747**)

Forms

- Significant performance improvements (up to 80% or more) in forms using cross-form logic can now be achieved by configuring the Form to have access to only those Events relevant to the logic on the Form. Previously the Form had access to all Events whether or not they included relevant items, which could impact performance. (**OC-10066**)
- Activity by the user within a Form will now correctly reset the timer for an automatic timeout, preventing the user from being logged out while working on the form. 1 hour of inactivity will cause them to be logged out. (**OC-10099**)
- Added ability for Data Managers to define item-specific Required Messages on forms. (**OC-11917**)
- Improved help for date calculations using Event Start Date to provide best practice that will prevent calculation errors for users of Internet Explorer. (**OC-11659**)
- Improved line-break behavior of radio button and checkbox items in Forms. (**OC-11575**)
- Fixed an issue related to Form page navigation in some Forms with Repeating Groups. (**OC-12145**)
- Fixed an issue that could prevent the Assign To list in the Query widget from populating. (**OC-11723**)
- When printing forms with Show History enabled, they will now show history for all items that have any history (current or previous non-null value, queries, etc.) even if the items are currently hidden on the Form. (**OC-11673**)
- Fixed an issue in which printed Forms were breaking text in the middle of an item or history section. They now format text more appropriately, breaking pages between items or history sections. (**OC-11750**)
- Resolved an issue that could result in calculated fields not being correctly represented in the Query Widget History section before the form was reopened. (**OC-11829**)

Participate

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

REST API

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

performance. (**OC-11745**)
- Fixed an issue that could cause some API calls to fail. (**OC-11767**)

General

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

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Functional approval by Paul Bowen. Signed on 2020-10-20 7:46PM

Approved for publication by Brooke Davis. Signed on 2020-10-20 8:09PM

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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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9 Release Notes - OpenClinica Insight - 2019

OpenClinica Insight Release 1 (v0.1.16) (Release Date - 23 April, 2019)

OpenClinica Insight v0.1.16 allows you to reference data in the user accounts table and includes some minor enhancements.

Highlights of this release include:

New:

- Participant OID is now available in the OC4 insight data warehouse. The following tables have been updated for this change: Participants, Events, Event CRFs, Item Data, Queries, Audit Log, Missing Forms, Participant Matrix, and all Item Group (form data) tables.
- The following user account tables have been added to the Insight study database:
    - **User Accounts**:
      This table contains a list of all user accounts that have (or ever had) a study- or site-level role in the given study environment.
    - **User Roles**:
      This table contains all standard and customized user roles defined and available for user accounts in the given study environment.
    - **User Account Role**:
      This table contains the mapping of each user account with the corresponding assigned user role in the study environment.
    - **User Types**: This table contains the user types possible for all user accounts. For example: Admin, User, Technical Administrator (reserved), and Participant (reserved).

Changes & Fixes:

- Refresh time improvements

Functional approval by . Signed on 2019-04-17 1:01PM

Approved for publication by Laura Keita. Signed on 2019-04-23 2:51PM

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10 OpenClinica 4 - Release Notes 2018

OpenClinica 4 Stack 6.1 (Release Date - 26 October, 2018) OpenClinica 4 Stack 6.1 contains a variety of minor enhancements and fixes to OpenClinica. View the entire Stack 6.1 changelog here (login required). Highlights include:

New:

- Added support for Randomize module. This module allows study-specific participant randomization algorithms to be used.

Changes & Fixes:

- Fixed an issue where SAS dataset extracts were grouping data incorrectly in some cases.
- Fixed an issue where system-generated Participant IDs were not created according to the ID template in multi-user scenarios.
- Fixed an issue where the on-form Query Widget Assign To dropdown did not contain all

expected users.
- Updated Clinical Data API to support XML format.

OpenClinica 4 Stack 6 (Release Date - 13 September, 2018) OpenClinica 4 Stack 6 contains a variety of enhancements and fixes to OpenClinica. View the entire Stack 6 changelog here (login required). For an overview of the update, view the **Stack 6 Release Announcement here**. Highlights include:

New:

Study Build System

- Added ability to create custom roles with permission enabled per form. Added a User Roles page to configure User Roles per study. Each custom role can be configured to have a unique name, a description, and a base role. The base role determines what actions the custom role can perform (for example, events can be signed by custom roles based on Data Specialist or Investigator, SDV can be performed by roles based on Monitor, etc.).
- Up to one permission tag can optionally be added to each form in Study Designer. All forms are untagged by default. Once a permission tag has been created, it can be enabled per custom user role on the User Roles page. By default, all custom user roles have access to only untagged forms. If a permission tag is enabled for a custom role, then users in that custom role will also have access to all forms that have that permission tag.
- Permission Tags are used to restrict access to clinical data on forms by user role in Runtime. Users will not have access to form data if the form is tagged and the users' role does not have the tag enabled. Note that a form that is defined to pull in cross-form data will pull in data regardless of the viewing user's role. For this reason, the study designer must be careful if a form is designed to pull in data from another form with a different permission tag.
- Changes to form permission tags are included in the Study Designer Activity Log.
- Changes to custom roles are included in the User and Role Audit Log accessible from the Administration page.
- Added Participant ID configuration at the study level (accessible via the Study Settings page). IDs can be configured to be entered manually or system-generated automatically. If the ID is system-generated, an ID template can be configured. The Template supports settings Participant IDs based on the current participant count in the study and including the Site ID (or Study ID, for study-level participants) and optional study-defined separators or other text. For example, a study could be configured to automatically generate the ID "Site123-0025" for the 25th Participant added at the Site with ID "Site123". The Participant ID configuration can be modified during the life of the study as needed.
- Added Participant Limit configuration at the study level (accessible via the Study Settings page). If desired, a study can be configured to use the "Expected Number of Participants" as a hard limit on adding new participants. If this option is used, Participants will not be able to be added to the study if the Expected Number of Participants has been reached (excluding Removed Participants). This includes participants created within a site or at the study level. If this option is not used, then there will be no limit to the number of participants that can be created.
- Added link to Swagger UI to the Administration page. This allows users to view and test system APIs.

Runtime

- If the study has permission tags defined for any forms, users will only be able to access tagged

forms if the users' roles have these permission tags enabled. All users have access to untagged forms. If a user has access to a form based on the form and role permission tags, the user will have the ability to perform all of the functions on the form that the user's base role is permitted to do (for example, roles based on Monitors can SDV forms).
- If a user does not have permission to access a form, they will not be permitted to open the form in edit mode, review-only mode, or read-only mode, they will not permitted to view queries on the form, they will not be permitted to SDV the form, extract the form clinical data in a dataset or participant casebook, view common event tables for the form on the Participant Details page, or otherwise view clinical data for the form. The user will still be permitted to view a blank copy of the form or the metadata for the form.
- If the user does not have permission to access a form, the form will not be listed in the SDV table and queries on items in the form will not be listed in the Query Manager table. The user will still be able to see the status of Visit-Based event forms in the Participant Matrix, Participant Details page, or Enter or Validate Data page, however, the user will not be permitted to open, remove, delete, or reassign the version of the form.
- All users will be permitted to define a dataset extract to include any forms in the study. However, when the extract is generated, only data from forms the user is permitted to access will be included in the dataset file. When a dataset is generated and the resulting file does not contain all data defined to be part of the dataset definition due to form permissions, the resulting filename will start with "filtered". Additionally. once a dataset file is generated, only users who have permission to access all forms that are contained in the dataset file will be permitted to download or delete the dataset file. If a user does not have permission to download an existing dataset file, they will be permitted to run the dataset again to create a new file that contains only data from forms that the user is permitted to access.
- When a user views the Audit Log for a Participant, entries will be shown for all data changes. However, if the user does not have permission to access a form, the old value and new value will be masked.
- If the user clicks a link for an action they are not allowed to perform due to permission tags, the user will see either a popup message or new page showing a message about the lack of permissions.
- If the study is configured to use system-generated Participant IDs, when adding a new Participant, the user will not be able to enter a Participant ID. It will be generated when the Participant is created.
- If the study is configured to use system-generated Participant IDs, existing Participant IDs cannot be modified.
- The Participant ID configuration has been added to the View Study page.
- If the study is configured to limit the participants and the maximum number has been reached, the Add Participant links in Runtime will not be displayed for any users.
- If a user loads a page with the Add Participant link and another user adds a participant to reach the cap, when the first user clicks the Add Participant link a message will be displayed that the limit has been reached and a participant cannot be added.
- The Participant Limit configuration has been added to the View Study page.
- Fixed issue where Site ID changes from Study Manager did not get displayed in Runtime.
- Added a REST API to add a single participant.
- Added a REST API to get the list of existing participants.
- Added a REST API to import data.
- Added a new feature (available via REST API) to bulk create participants by including a file containing the participant IDs to be created.
- Added ability to import data into new forms in common events.

Changes & Fixes:

Study Build System

- All studies were automatically updated to replace the existing 7 standard roles with 7 equivalent custom roles. All roles are the same except study-level Monitor is now called "Study Monitor" and site-level Monitor is now called "Site Monitor". All existing users continue to have the same permissions as before.
- Study Designer has been updated with improved filtering by Label and Member (and Permission Tag filtering has been added).
- Added a Gear Icon navigation button to Study Designer and the Share Study page to enable quick access to the Study Settings and User Role pages.
- Fixed an issue where publishing a study was failing in certain cases when two forms had similar names (the same first five non-space characters) and the forms had items or item groups with the same name and the second form was overwritten after it had been published.
- Fixed an issue where adding a Site to a study as a new site when it already exists in a different study could result in the study being created in Runtime but appearing to fail in Study Manager. This case now causes the operation to fail and instructs the user to try again.
- Fixed an issue where inviting an existing user to a new study was resetting their status to invited.
- Fixed an issue where renaming a form that is used in multiple events could trigger an error message.
- Fixed an issue where users might not be logged out of Study Manager in certain cases when their computers went into sleep mode.
- Fixed an issue in Study Designer that caused performance to degrade over time.
- Updated Share Study page column title from Version to Revision to match the terminology elsewhere in the system.
- Updated Share Study Page to show Date and Time of each publish operation rather than just the Date.
- Removed configurations for deprecated fields Person ID, Sex, and Date of Birth from the Study Settings page.

Runtime

- The User Menu in the top right corner of the screen and the Change Study page have been updated to show the current user's custom role name.
- The Monitor user at the study-level is now called "Study Monitor". The Monitor user at the site-level is now called "Site Monitor".
- Updated Query Manager table to persist filtering and sorting when the user opens a form from the table and returns to the table after closing the form.
- Updated the Query Manager table to default to sorting by Days Since Updated, then Site ID, and then Participant ID.
- Added Quick Links section to the left panel with a link to "Queries Assigned to Me".
- Fixed an issue where adding a query to a form was changing its status from Complete to Data Entry Started.
- Fixed an issue that was causing Reasons for Change to be set to Closed status if the form they were on was archived, removed, or deleted. Now these remain with Not Applicable status as expected.
- Fixed an issue where queries which were auto-closed due to the form they were on being archived, removed, or deleted not showing the auto-closure text in the Query Manager table.
- Updated the Participant Audit Log to refer to the "Participant" rather than the "Subject" for

consistency with the rest of Runtime.
- Fixed an issue that displayed the wrong username in the message displayed when a user attempted to delete a form that was locked for use by another user.
- Fixed an issue where a participant was incorrectly marked as signed if they only had one event started and it was signed.
- Fixed an issue where changing data for a signed participant did not automatically un-sign the participant.
- Fixed an issue in the data import template where "complete" status was incorrectly listed as "completed".
- Fixed an issue in rare cases where the Participant ID link in the Participant Matrix might link to a different participant's details page.
- Fixed an issue where Admin users who were not Data Managers could lock events. Locking permission is now available only to Data Managers.
- Fixed an issue where an archived form could be deleted. This scenario was putting the form in an unstable state.
- Fixed an issue where the Participant Details page couldn't be loaded immediately after publishing a study.
- Removed deprecated fields Person ID, Sex, Secondary ID, Enrollment Date, and Date of Birth from throughout Runtime.
- Removed Filter by Enrollment screen from the dataset definition workflow.
- Updated the Add Participant and Edit Participant windows to standardize the UI.
- Updated UI on Reassign Participant, Remove Participant, Restore Participant, View Study, and View Site pages.

Forms

- Fixed an issue where entering only spaces into a required text item would satisfy the requirement and not show an error that the field was required.
- Added support for forms with item type text and appearance "url". This item can be populated with a URL by a calculation and the resulting link will be displayed prominently after the item label.
- Fixed issue where the Close and Complete buttons moved down slightly when data was saved to a form for the first time in a session. This caused some clicks to miss the buttons when they moved.
- Fixed an issue where a user opened a form using the View Query Within Record link in the Query Manager table and the item the query belonged to was either hidden or removed from the form. In this case, it was not displaying a message about this circumstance to the user.
- Fixed an issue where the Query Widget's Assign To list was not always populated with the current list of users and did not necessarily reflect the latest role updates or name changes to the users.
- Fixed an issue where the formatting of the timestamp in the Query Widget was not padded correctly for day values less than 10.
- Fixed issue where file upload items did not have download buttons in IE11.
- Fixed issue here the Query Widget did not render correctly in IE11.
- Fixed issue where form width was unstable in IE11.

OpenClinica 4 Stack 5.1 (Release Date - 5 July, 2018) OpenClinica 4 Stack 5.1 contains a variety of minor enhancements and fixes to OpenClinica. View the entire Stack 5.1 changelog here (login required). Highlights include:

Changes & Fixes:

- Updated the General Information section of the Participant Details Page to remove the following fields - OID, Person ID, Secondary ID, Sex, Date of Birth, and Enrollment Date.
- Fixed an issue where opening a form using the View Query Within Record link from the Query Manager page was causing an error message to be displayed if the form being accessed was in a Locked Event.
- Fixed an issue where the timestamps shown in the History section of the on-form Query Widget were not displaying the correct date and time in some cases.

Removed:

- Updated the Add Participant and Update Participant pages to remove all fields except Participant ID. The following Participant data fields have been removed - Person ID, Secondary ID, Sex, Date of Birth, and Enrollment Date. If this data is needed for a study, the appropriate fields should be added to a standard Visit-Based Event Form or Common Event Form.
- Updated the Add Participant and Update Participant pages to remove the fields that allowed a user to schedule the new Participant's first Event. After the new Participant is created, the user can schedule an Event as needed from the Participant Matrix, Participant Details Page, or Schedule Event link.

OpenClinica 4 Stack 5 (Release Date - 28 June, 2018) OpenClinica 4 Stack 5 contains a variety of enhancements and fixes to OpenClinica. View the entire Stack 5 changelog here (login required). For an overview of the update, view the **Stack 5 Release Announcement here**. Highlights include:

New:

Runtime

- Concurrency Locking functionality has been added to prevent concurrent data entry into the same record by different users. When a user opens a form in edit mode or review-only mode (i.e., queries only mode), they will acquire a lock on it. Any other user attempting to open the locked form will automatically open it in read-only mode. Additionally, locked forms cannot be deleted, removed, or reassigned by other users. If a user is prevented from performing an action due to another user having a lock on a form, a message will tell the user who currently has a lock on the form. The user's lock on the form will be released when the user closes the form via the Close or Complete buttons or when the user's session expires due to inactivity.
- Updated the Participant Details page to make the page view settings persist during a user's session. Filtering, sorting, etc., of the Common Event tables will persist when the user navigates back to this page. Page view Persistence is Participant-specific. The page view can be reset at any time by clicking the "Customer View On" button. It will reset automatically when the user logs out or changes to a different study.
- Added ability for all user roles (except Monitors) to remove and restore events and forms.
- Improved external API coverage and added a user access token system for using the APIs.

Study Build System

- Added a feature to download the Excel form definition for an archived form version in Study Designer. This is accessible from the Archives.

Forms

- When a form is being printed using the on-form Print button, the user is now prompted to choose whether to include item history. If history is not included, the printed version of the form will contain only the data items on the form. If history is included, the print form will include the data items on the form and the history of each item (for example: value changes, queries, and reasons for change).

General

- A link to the Privacy Policy has been added to the user menu for all users across Runtime and the Study Build System.

Changes & Fixes:

Runtime

- The terms 'Subject' and 'Study Subject' have been replaced with 'Participant' throughout OpenClinica. The Subject Matrix is now the Participant Matrix, Add Subject is now Add Participant, etc.
- Fixed an issue where the SDV interface was not displaying the correct form version information after a form was migrated to a different version.
- Fixed an issue where a user attempting to navigate from Runtime to the My Studies, My Profile, or Administration pages would sometimes be bounced back to Runtime.
- Fixed an issue where some users were redirected to their home screen when they attempted to edit their information on the My Profile page.
- Fixed an issue where Data Managers would sometimes get redirected to the Change Study page after leaving the My Profile page.
- Fixed an issue that was preventing a success email from being sent to a user when their extract finished generating.
- Fixed an issue where Query notification emails showed the incorrect "updated by" user.
- Fixed an issue that was causing repeating events to be displayed in the Participant Matrix with their creation date rather than their Start Date.
- Fixed an issue that was not allowing forms in a Stopped event to be edited. If a form in a stopped event is edited now, the event is automatically changed back to Data Entry Started status.
- Fixed an issue where updating an event's status from Stopped to Data Entry Started was sometimes changing the status of forms in the event from Data Entry Started to Complete.
- Fixed an issue where form data could be imported for multiple versions for the same form in the same event for the same Participant.
- Fixed an issue where the ending form status defined in the import data file was not being respected during the import process.
- Fixed an issue that allowed non-Data Managers to access the locking interface for Common events.
- Fixed an issue where a user was able to delete a form in a locked event.
- Fixed an issue that caused an Edit button to be displayed for "Not Started" forms within locked events.
- Fixed an issue that caused Common Event forms defined as hidden to be hidden from study-level users. These forms are now correctly hidden from only site-level users.
- Fixed an issue where an existing form in a Common Event remained editable for a Participant even after the form was archived.
- Fixed an issue where an existing form in a Common Event remained editable for a Participant

even after the Participant was removed.
- Fixed the label of Site ID in several pages where it was mis-labeled.
- Updated the icon key to be consistent for all user roles and to include missing actions/status.
- Updated the icon key and Participant Matrix/Participant Detail page to differentiate between the icons for Signed (status) and Sign (action).

Study Build System

- Fixed an issue where publishing a large study would fail after 5 minutes. The publish timeout is now 1 hour to allow for very large studies to be published.
- Fixed an issue where publishing a study fails when certain forms have been archived.
- Fixed an issue where form upload would fail if there was already another version of the form and the version names of the forms were very similar (for example, the same except for non-alphanumeric characters).
- Added validation to prevent uploading/publishing forms that exceed the system maximum length of a code list of 4,000 characters. If a single form version exceeds this limit an error message will be displayed at form upload time. If the limit is not exceeded by a single version of a form but is exceeded collectively by the combination of all versions of a form, an error message will be displayed at study publish time.
- Fixed an issue where user logins were sometimes not being recorded consistently.
- Fixed an issue where updating a user's role or type was not updating the "Updated" column in the User tables on the Share Study and Administration pages.
- Fixed an issue where a user logging into the system was incorrectly updating the "Updated" column in the User tables on the Share Study and Administration pages.
- Fixed an issue where inviting an existing user to a new study would change the user's status to "Invited".
- Fixed an issue where in certain circumstances a user could log into a study they had recently been removed from.
- Fixed an issue where forms would sometimes not be able to be reordered in Study Designer.
- Updated the Form Template in Study Designer to reflect functionality changes in this release.

Forms

- External data read capability has been expanded to allow the current form user's username and user role to be loaded into a form. This can then be used in logic on the form (for example, to make a note item visible to only users in a specific role).
- External data read capability has been enhanced to retrieve external data when a form is opened in read-only or review-only modes. If the external data is displayed on the form (such as in an item label), it will now be displayed in those modes. Note that calculations will only be evaluated and displayed/submitted for forms opened in edit mode.
- The on-form Query Widget has been updated to include the full timestamp of each item in the History section (instead of just a relative timestamp).
- Fixed layout issues that caused incorrect "Required" error message placement for certain item type/appearance type configurations.
- Fixed an issue where forms were not displaying correctly on smaller screens (such as on tablets or phones).

OpenClinica 4 Stack 4.1 (Release Date - 9 May, 2018) OpenClinica 4 Stack 4.1 contains a variety of minor enhancements and fixes to OpenClinica. View the entire Stack 4.1 changelog here (login required). Highlights include:

New:

- The on-form Print icon has been restored. Existing forms and blank forms can be printed.

Changes & Fixes:

- Improved study publish performance. Publishing a study typically takes less than half as long as it did before this release.
- Improved performance of Study Designer as additional forms are added to a study.
- When an item of type "file" is added to a form, it will automatically accept files of any type without requiring additional configurations.
- Updated mail server configuration to reduce the likelihood that user invitation emails will be flagged as spam.
- Fixed an issue where the "clear" button to remove files that were uploaded to a form was not removing the uploaded files as expected.
- Fixed issues where manually typed or pasted dates that were in the wrong format were not rejected as expected.
- Fixed form layout/spacing issues with the Query icon and multi-line label text.

OpenClinica 4 Stack 4 (Release Date - 17 April, 2018) OpenClinica 4 Stack 4 contains a variety of enhancements and fixes to OpenClinica. View the entire **Stack 4 changelog here** (login required). Highlights include:

New:

- Added support for non-visit-based events (known as "Common Events"). Repeating Common Events can be used to achieve repeating form functionality for use cases such as Adverse Events or Concomitant Medications. Non-repeating Common Events can be used for single-entry forms such as Early Termination.
- Redesigned Subject Details page to support both visit-based events and common events and make the UI more user-friendly. Each Common Event is displayed in a separate collapsible section. Common Events can be configured to display form data as part of the table view on the Subject Details page. Common Events tables have new sorting, filtering, and pagination functionality.
- Added customer-wide People table to the Administration page. This includes a Deactivate option to remove user access at the customer level. (Note that user access can also still be removed per study.)
- Added new file types for file upload items on forms. The following items are now supported (in addition to image): audio, video, and file (for generic files).
- Three drawing items are now supported - draw (for drawing on blank canvas in multiple colors), annotate (for uploading an image and then drawing on it in multiple colors), and signature (for collecting a black and white signature). Each of these are saved as image files.

Changes & Fixes:

- On the Subject Matrix, each Subject ID is a link to go to the Subject Details page for that subject. This is helpful if the Subject Matrix is very wide.
- Improved cross-form logic performance by making only subject clinical data accessible (not study metadata).
- Uploaded files and drawings can now be downloaded directly from a form. The UI for uploading/removing files has been improved to prevent accidental file removal.

- When inviting users to a study, you can search for existing users by name, username, or email address.
- Updated the Share Page People table in Study Build System to have more user-friendly pagination and to make most columns sortable. Date columns now show both date and time. User Status is now included in the table.
- When uploading a form, style "no-text-transform" is automatically applied to the form so that it doesn't need to be specified manually. This ensures that forms display label text case-sensitively.
- When uploading a form, appearance "no-collapse" is automatically applied to each group so that it doesn't need to be specified manually. This ensures that the form user does not accidentally collapse a group and hide data unintentionally.
- Improved performance and functionality support for Internet Explorer and Edge browsers.

Removed:

- Removed Print icon from on-form view.

OpenClinica 4 Stack 3 (Release Date - 15 February, 2018) OpenClinica 4 Stack 3 contains a variety of enhancements and fixes to OpenClinica. View the entire **Stack 3 changelog here** (login required). Highlights include:

New:

- Added support for Cross-Form logic. External Values can be pulled into a form for use in calculations, constraints, hide/show, conditional required, and display piping.
- User invitations can be resent from the Study Build System.
- Reason for Change entries can be viewed from the Query Manager.

Changes & Fixes:

- Single Sign-on enhancements
- Improved appearance of embedded documentation.

Click **here** to view previous updates

Functional approval by Kerry Tamm. Signed on 2019-11-04 1:07PM

Approved for publication by Paul Bowen. Signed on 2025-12-08 11:19AM

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11 Release Notes - OpenClinica Insight - 2018

OpenClinica Insight Release 1.1 (v0.1.14) (Release Date - 4 December, 2018)

OpenClinica Insight v0.1.14 contains a couple of defect fixes that were communicated as part of Insight release 1.

Highlights include:

New:

- None

Changes & Fixes:

- Issue related to incorrect CRF version in various item group tables has been resolved. You should have the correct CRF version information in all item group tables (clinical data tables)
- Issue with the SDV tables, where incorrect could were showing up for the common event forms that are SDVed or need to be SDVed, has been resolved

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OpenClinica Insight Release 1 (v0.1.13) (Release Date - 25 October, 2018)

OpenClinica Insight Release 1 is our first production release of Insight for OpenClinica 4 studies.

Highlights include:

New:

- Deploy OpenClinica Insight reporting environment with connection to clinical data from OpenClinica 4 studies
- Update database metadata to synchronize with OpenClinica 4 database (e.g. columns, names, constraints, references, etc.)
- Update metabase data reference information to match OpenClinica 4 data
- Allow Study's Test and Prod together on the same Insight instance
- Include/update SQL templates for OC4 source database preparation
- Revise config format to not require manually duplicated / edited config info

Open Issues:

- CRF Version in the data tables is incorrect when there are more than one active versions for a given CRF
- SDV cmpletion count is incorrect for the common event CRFs
- Completed timestamp in Event CRF table is not populated sometimes
- Event CRF display order is not populated in Event CRF table

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Functional approval by . Signed on 2019-02-11 11:03AM

Approved for publication by Laura Keita. Signed on 2019-02-11 1:42PM

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OpenClinica 4 Stack 2 (Release Date - 18 December, 2017)

OpenClinica 4 Stack 2 contains a variety of enhancements and fixes to OpenClinica, and is the first fully validated release of OpenClinica 4. View the entire Stack 2 changelog here (login required).

Highlights include:

New:

- Reason For Change is required when data chnages are made to complete forms
- User account audit log can be downloaded from Study Build System
- SDV can be configured per form
- Documentation/tutorials embedded in the application

Changes & Fixes:

- Single Sign-on enhancements

Other Links:

- Blog post series introducing the new OpenClinica

OpenClinica 4 Stack 1 (Release Date - 1 October, 2017)

OpenClinica 4 Stack 1 is a major redesign of OpenClinica and contains hundreds of enhancements and fixes to OpenClinica. View the entire Stack 1 changelog here (login required).

More information on OC4 is available on the OpenClinica blog: Part 1, Part 2, Part 3

Highlights include:

New:

- New Study Build System with drag-and-drop design and publish to test and production from one design
- New form engine with improved look-and-feel, mobile friendliness, autosave, multimedia capabilities, real-time skip logic, edit checks, and calculations

Changes & Fixes:

- Improved study UI
- Cleaner Extract formats for CRFs with multiple versions

- Multiple modules working in a microservices model as opposed to a single Java application/WAR file
- Separate database schemas for each study

Removed:

- Double Data Entry

Functional approval by Paul Bowen. Signed on 2018-06-27 7:28PM

Approved for publication by Jim Bonica. Signed on 2018-06-28 4:39PM

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