

2 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_CLOSSES_FORM trigger for Advanced Study Calendaring to trigger rules based on data changes in forms. ([OC-23589](#))
- Updated the USER_CLOSSES_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 unsigned 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 where 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 where initiating a large data import sometimes prevented users from logging into OpenClinica until the import was complete. ([OC-21552](#))
 - Fixed an issue where Tabular Data Imports allowed non-existent dates, for example April 31st, to be imported without error. ([OC-21489](#))
 - Fixed an issue where 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 where 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 a 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 where 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.
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Approved for publication by Paul Bowen. Signed on 2025-05-16 5:11PM

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