2 OpenClinica 4 - Release Notes 2025

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

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

Approved for publication by Jigyasa Gupta. Signed on 2025-09-29 7:10PM

Not valid unless obtained from the OpenClinica document management system on the day of use.