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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.