

# 1 Release Notes - OpenClinica 3.17

OpenClinica 3.17 contains a large set of fixes and enhancements. View the entire **3.17 changelog here** (login required).

#### 3.17 - 31-AUG-2023

# **Changes:**

- When a user opens a form using the "View within Record" option from the Notes & Discrepancies page, it will now open in Edit mode if it is editable. Previously forms opened using this option could open in View mode or Edit mode depending on their status, even if they were otherwise editable. (OC-1231)
- Removed forms, when restored, will now return to their previous status. Prior to this release they were restored to the initial data entry status. This resolves an issue reported wherein the removal and restoration of SDV Verified forms could cause the count of SDV Verified forms displayed to exceed the count of completed forms in the study. (OC-2739)
- In studies where the Year of Birth attribute is being collected, this attribute would previously not be included in some extract formats. It will now appear in all extract formats. If not being used, it will appear in those extracts with a value of "Not Used" for all study subjects. (OC-4783)
- Study subjects created via Web Services were previously always attributed to the root user in the audit log. These actions will now be attributed to the user creating the study subject. (OC-7903)
- The "Not Specified" option for subject sex was still being shown in studies that had configured sex as a required field, but was returning an error when selected. This option has been removed from all studies. In studies that require sex this will clarify that requirement. Studies that do not require this field can continue to leave it blank (leaving the field blank and selecting "Not Specified" entered the same value in the data).(OC-21048)

# Fixes and Improvements: Notes and Discrepancies

- Previously the "Notes & Discrepancies Assigned to Me" count displayed on the homepage could show an incorrect count for site users. Now it will always show site users the correct count (OC-828)
- Discrepancy Notes exported in CSV format will now correctly reflect any quotation mark characters included in the text of the notes. Previously the export file included a "\" character in front of quotes. (OC-5701)
- An issue was reported where Discrepancy Notes could in some cases not be saved to items added to forms as part of a version change in records migrated to those new versions. This has been fixed and notes can now be added in migrated CRF records. (OC-7166)
- Discrepancy Notes added to a form hidden at the study-level but not the site-level were previously only visible by a study user in the study-level context. The expected behavior is that the note is visible to study users at the site or study level. This has been resolved (OC-8343)
- There were some limited cases where an attempt to print a subject casebook could be overly sensitive to certain kinds of Discrepancy Notes and fail. This has been resolved and now these casebooks will print regardless of the Discrepancy Notes included. (OC-8827)
- Notes and Discrepancies could sometimes fail to appear for study-level users in the table when at the site level. They will now appear in the table correctly. (OC-13281)

- Discrepancy Notes were sometimes not saving when being added to empty items while in View mode. They will now save as expected. (OC-14064)
- The Enter and Validate Data page could show a red (open) icon when it should show a black (closed) icon for a Query on certain fields. This page now correctly reflects the Query status through the icon. (OC-21017)
- The Notes and Discrepancies table could sometimes show the incorrect status for CRFs. This table will now show the correct status for all CRFs (OC-21268, OC-21393)
- Notes and Discrepancies on items in repeating groups were failing to open if there were special characters in certain fields (e.g., the event name, form name, item group label). These will now appear as expected. (OC-21390)
- Clicking "View within Record" on the Notes and Discrepancies table for a note in a removed subject record was taking the user to the Subject Matrix instead of the CRF as expected. This will now bring the user to the CRF as expected. (OC-21414)

#### **Source Data Verification**

• Some filter combinations in the SDV table were not interacting correctly and displaying too many results. These filters will now show the correct numbers of results. (OC-13310)

# **Forms and Data Entry**

- Items with a data type of "real" were incorrectly accepting some values containing certain letters. These items will no longer accept invalid values. (OC-12587)
- Uploading a new version of a form that included quote characters in item labels immediately after uploading a prior version was resulting in an error. This has been fixed and these forms in this scenario will now upload as expected. (OC-12863)
- Forms with large (>300 items) repeating groups could sometimes fail to save all updated items. These will now save as expected even when including large numbers or items (OC-12895)
- Attempts to change form definitions will now correctly show a warning when a user attempts
  to change the value of a response option for an item that already exists in the database.
  (OC-15058)
- When performing an import that migrated records to a new form version, records could sometimes be marked complete regardless of the status specified in the import. Now any import will have its specified status respected. This was fixed in both the GUI and Web Services import pathways. (OC-21355, OC-21406)
- In cases where a form was created via import, and a record of that form already existed using a different form version, a duplicate record was being erroneously created. The expected behavior is that this action will migrate the existing record to the version used in the import. This has been resolved for all import pathways (Manual, scheduled, and via Web Services) (OC-8239, OC-8254, OC-8255)
- Imports could sometimes fail because the data files were being validated against the first form version defined instead of the version specified in the import. Imports will now validate against the specified CRF version. (OC-14979)

#### **Web Services**

- SOAP Web Services will now work as expected when the Protocol name metadata field contains a space. Previously this could cause some calls to fail. (OC-21212)
- Subjects created via Web Services were previously ignoring the "Secondary Label Viewable" setting and showing this field regardless. Now it will be hidden as expected if the setting is turned off, regardless of how the participant was created. (OC-21314)

#### **Extracts**

- ODM extracts were exporting Unicode characters as "?" instead of their appropriate Unicode XML designation. These characters now export correctly. (OC-13705)
- Certain special characters were causing XML extracts to fail. This has been fixed and extracts will no longer fail due to the presence of certain characters in the data. (OC-14727)
- Extracts could occasionally include multiple instances of a CRF attribute value within the relevant column. The issue that could cause this has been resolved and extracts will now include only one instance of any CRF attribute value. (OC-20790)
- Extract jobs were failing if the dataset contained multi-byte UTF-8 characters. This has been fixed and these will now export as expected. (OC-21102)
- Extracts of datasets containing emojis sometimes contained additional instances of the emoji characters. The number of emojis in the dataset will now be correctly reflected in the exported file. (OC-21103)
- Files created by scheduled extracts will now include the timestamp of the job's execution in the filename to guarantee uniqueness. Previously the name included the time that the job was saved. (OC-4087)
- Excel extracts that included data containing an opening quote but not a closing quote character were not dividing their contents into columns correctly. These extract files will now appear as expected. (OC-12795)

## **Subject Matrix**

- The Subject Matrix would previously show extra results when a CRF status filter was applied while using the single Event view option. It will now only show CRFs of the selected status when such a filter is applied on this view. (OC-2084, OC-21364)
- The Subject Matrix will now preserve changes made to the number of rows displayed when
  navigating to other pages and returning, rather than reverting to the default row settings.
  (OC-11023)

#### **Miscellaneous**

- There were some cases where a user erroneously had the ability to edit auto-generated and non-editable study subject IDs. This has been fixed and no users can now edit non-editable IDs. (OC-7411, OC-18040)
- When a form with data entry performed was migrated to a new version, the View Subject Page was previously showing the user who performed the migration as the user who completed data entry. This has been fixed and the user who completed data entry will now be correctly shown on the View Subject page. (OC-10569)
- The audit log in the database now correctly logs user removals. Previously removing a user did not update the audit log in the database. The removal of users is still not displayed in the GUI study audit log since it is not a change to study data. (OC-11670)
- Passwords that included certain characters could not previously be used to complete CRFs that were configured to require passwords. This has been fixed and all valid passwords can now be used to complete CRFs. (OC-12161)
- The Double Data Entry workflow was previously showing the wrong action tooltips and CRF statuses to users for CRFs that were being re-completed after being deleted. These issues have been resolved and forms enabled for DDE will now show the correct CRF statuses and action tooltips regardless of whether they've been previously deleted. (OC-12177)
- Site users were not able to download files uploaded to CRFs by participants moved to their site from another, if the files had been uploaded while the subject was at the other site. The expected behavior is that these files are available to site users based on their and the subject's current site, and this issue has been resolved. (OC-12392)
- Some pages were not respecting the setting to hide the Secondary ID field in studies correctly

and showing the field when it was disabled. This has been fixed and this field will no longer appear or be editable in studies with it disabled. (OC-12575)

- OC3 supports multiple roles per user, but only one role within each study/site context. Previously users with multiple roles could sometimes be erroneously treated as if they were one role when in the context of their other role. This has been fixed and all multi-role users will now behave correctly in all contexts. (OC-12658)
- Previously it was possible under some circumstances to change a repeating study event to a non-repeating study event after there were already multiple occurrences of the event. This loophole has been closed and these events can longer be changed to non-repeating. This action now has an associated appropriate error message. (OC-12780)
- Attempts to save a job with a duplicate name were failing without displaying an appropriate error message. An error message has now been added. (OC-12788)
- Authentication was failing unexpectedly when trying to log in after deleting the session cookie. Logging in immediately after doing this will now work as expected. (OC-12915)
- There was a rare issue in which creating new events could sometimes result in duplicates if the transaction was initiated multiple times simultaneously. This has been fixed and a new transaction will not be initiated until the earlier one is completed (OC-13663)
- Fixed an issue where CRF version migrations could fail under some circumstances. (OC-13812)
- The RSS feed on the OC3 login page will now display contact information to set up your own custom feed instead of an error indicating there is no news to display in cases where there is not already a custom feed. Custom feeds are unchanged. (OC-15012)
- Fixed an issue that could prevent some external automated tools from correctly authenticating. (OC-15097)
- Rules configured to send notifications when there were new occurrences of a repeating event could erroneously trigger a notification for all past occurrences when the conditions were met. This has been fixed and such rules will now send only one notification, corresponding to the new occurrence, as expected. (OC-18491)
- There is now a link to the OpenClinica documentation site on the Create CRF page. (OC-20996)
- Study level users can now appropriately navigate to a site's details page from a site-level subject's details page. Previously these users could be erroneously treated as site users and denied access to the page. (OC-21003)
- Fixed an issue that could result in date filters applied to the View All Events page showing no results. (OC-21016)
- Usernames are intended to support a maximum limit of 64 characters. Previously they were being rejected at 63 characters. The correct limit is now being enforced. (OC-21311)
- The search field for CRFs on the Administer CRFs page was giving an error if a parenthesis was entered. This will now search as expected with a parenthesis character. (OC-21374)
- When creating a new user in a study configured for LDAP SSO, the user's information was not being automatically populated from the LDAP information. This will now autopopulate as expected when picking the user from the LDAP list. (OC-21377)
- The Privacy Policy link visible in the OC3 footer now links correctly to the policy. (OC-20995)
- Updated configurations to improve performance. (OC-21281)
- Updated libraries in a variety of system areas to enhance security and maintain compatibility with the latest technologies.
- Improved security throughout the system.

### 3.17.1 - 01-FEB-2024 (Changelog)

• It was discovered that in 3.17, when a show/hide rule was employed to conditionally show the

group or occurrences of the group in a form containing repeating groups, and the rule's destination property did not target the item group specifically, occurrences of the repeating group beyond the first were being inappropriately hidden when the form was opened in edit mode. 3.17.1 addresses this issue and now those groups will appear as expected when such a rule executes. (OC-21848)

## 3.17.2 - 08-AUG-2024 (Changelog)

- The audit log in 3.17 sometimes displayed audited events to users out of chronological order due to a change in sorting as applied by the database version upgraded to in 3.17. 3.17.2 adds explicit sorting to all audit logs as displayed to the user at all levels of the data model (e.g. participant, study event, form, item data) ensuring they are displayed in chronological order. (OC-22919, OC-23346, OC-2336, OC-23380)
- Fixed an issue where certain characters in regular expressions included in forms were being erroneously changed when saved to the database, interfering with the expression's function. (OC-22916)

# **Other Links**

- **Download** (OpenClinica.com login required to download)
- OpenClinica Reference Guide
- Installation guides

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