Release Notes (OC3)

Below you can access information about OpenClinica 3 releases. For OpenClinica 4, see here. Read about OpenClinica 3 vs 4 on GitHub.

Functional approval by Malcolm Jackson. Signed on 2020-11-03 1:22PM

Approved for publication by Daoxu Ye. Signed on 2020-11-03 2:16PM

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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-22346, OC-23036, OC-23080)
- 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)

3.17.3 - 12-NOV-2025 (Changelog)

- Events in "Removed" status could erroneously be edited: Users could mistakenly change an event marked as "Removed" to another status (like "Stopped" or "Data Entry Started") if they viewed and then edited the event directly. This has been fixed and the ability to directly edit the status of Removed events has been removed. (OC-25226)
- When events in a status of "Stopped" or "Skipped" were removed, an audit log entry for the status change was not recorded. This has been fixed and future removals of events in these statuses will be appropriately logged as expected. (OC-25225)
- HTML casebooks were not displaying signature attestations as expected for events that were locked after being signed. This has been fixed and new casebooks will now correctly display all signature attestations. (OC-25477)
- In cases where events have been signed more than once, the HTML casebook was displaying the attestation of the first signature, instead of the most recent signature. Now the attestation from the most recent signature will be displayed. (OC-26159)

Other Links

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

Functional approval by Malcolm Jackson. Signed on 2025-11-13 10:44AM

Approved for publication by Paul Bowen. Signed on 2025-11-13 11:54AM

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2 Release Notes - OpenClinica 3.16

OpenClinica 3.16 contains a variety of enhancements and fixes to OpenClinica. View the entire **3.16 changelog here** (login required).

Highlights include:

3.16 - 03-NOV-2020

Changes & Fixes:

- Fixed an issue where a form could still appear as available at the site level after removing it from an event definition at the study level. (**OC-2188**)
- Fixed an issue where a large volume of removed rules targeting the same objects as active rules could cause performance issues when opening forms. (**OC-12523**)
- Fixed an issue where rules could take too long to run, potentially causing failures. (**OC-12424**)
- Enhanced OC3 security.
- ... and several other improvements

Removed

- None

Patches

3.16.1 - 03-MAR-2021 (Changelog)

- Updated version of OCForm form engine used by Participate module to resolve an issue encountered in using older browsers to complete offline forms. (**OC-14595**)

3.16.2 – 30-APR-2022 (Changelog)

- Enhanced OC3 security.

Other Links

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

Functional approval by Paul Bowen. Signed on 2023-08-31 12:29AM

Approved for publication by Brooke Davis. Signed on 2023-08-31 11:12AM

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3 Release Notes - OpenClinica 3.15

OpenClinica 3.15 contains a variety of enhancements and fixes to both OpenClinica and OpenClinica Participate. View the entire 3.15 changelog here (login required).

Highlights include:

3.15 - 19-FEB-2020

New

- Study Subject ID on the Participant Matrix is a link to the View Subject page. (**OC-6790**)

Changes & Fixes:

- New studies can be created using IE 11. (**OC-9823**)
- Fixed issue with Job Log messages not being rendered correctly. (**OC-9075**)
- Fixed issue with study metadata rendering some characters incorrectly. (**OC-9066**)
- Fixed issue with Subject Casebooks when items have similar names. (**OC-9036**)
- Fixed issue with Rules not working with multi-select items as expected. (**OC-8975**)
- Fixed typo in XML schema that caused an API error. (**OC-8901**)
- Fixed issue where text values could be treated as partial dates. (**OC-8752**)
- Updated default end date for new datasets to ensure it is in the future. (**OC-8368**)
- SAS extracts do not truncate text at 255 characters. (**OC-7439**)
- Emojis in text items will not prevent extracting data. (**OC-7263**)
- File upload size limit is increased to 100 MB. (**OC-6779**)
- Fixed issue with version migration user in audit logs. (**OC-6711**)
- Fixed issue with extracting Study Subjects whose Enrollment Dates were removed. (**OC-6322**)
- Fixed issue with Data Mart response text limit of 255 characters. (**OC-5755**)
- Fixed issue with editing sites after changing to a different study. (**OC-5601**)
- Fixed issue with accessing datasets after changing to a different study. (**OC-5599**)
- HTML Tags in Repeating Group Items are rendered correctly in Double Data Entry. (**OC-3272**)
- Removed sites no longer appear in the Change Study/Site list. (**OC-2447**)

- Fixed issue with SDV Requirement filters not working for Site Monitor users. (**OC-1887**)
- Fixed issue with viewing event definitions after changing to a different study. (**OC-1849**)
- ... and several other improvements

Removed

- None

Patches

3.15.2 - 17-APR-2020 (Changelog Part 1, Part 2)

- New Feature: Study Subject OIDs will now be included in responses from the "listAllByStudy" SOAP webservice endpoint. (**OC-12548**)
- Fixed issue causing "\" to be interpreted literally when entering data into form fields, instead of their intended function as escape characters. (**OC-12543**, **OC-12547**)
- Fixed issue that prevented some non-admin users from entering data into forms at the site level. (**OC-12586**)
- Fixed issue causing entries with special characters to be displayed incorrectly in the ODM audit log. (**OC-12633**)
- Fixed issue where multiple users switching back and forth on the same browser without closing their tabs could lead to unexpected results. (OC-12286)

Note: 3.15.1 was an internal release. Its fixes are first included generally in 3.15.2.

3.15.3 - 14-MAY-2020 (Changelog)

- Fixed issue that could prevent successful data entry in site-specific form version. (OC-12744)

3.15.4 - 19-MAY-2020 (Changelog)

- Updated version of OCForm form engine used by Participate module to support continued use of offline form functionality with recent updates to web browsers. (OC-12647)

3.15.5 - 8-JUN-2020 (Changelog)

- Resolved an issue where single-quote characters in response text were interpreted incorrectly. (OC-12778)
- Resolved an issue where single-quote characters were causing some form item text functionality to break. (OC-12835)

3.15.6 - 19-JUN-2020 (Changelog)

- Updated version of OCForm form engine used by Participate module to resolve issues with Participate form display in some browsers. (OC-12951)

3.15.7 - 09-JUL-2020 (Changelog)

- Resolved issue where the use of single-quote characters instead of double-quote characters in JavaScript included in form templates caused an error when uploading the template to create a CRF. (OC-12973)
- Updated the instructions in the form template to provide more accurate information about which fields accept spaces. Form template is now version 3.10. (OC-716)

Other Links

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

Functional approval by Malcolm Jackson. Signed on 2020-11-03 2:09PM

Approved for publication by Daoxu Ye. Signed on 2020-11-03 2:23PM

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4 Release Notes - OpenClinica 3.14

OpenClinica 3.14 contains a variety of enhancements and fixes to both OpenClinica and OpenClinica Participate. View the entire **3.14 changelog here** (login required). Highlights include:

New

- Ability to request to start new studies in OC4(**OC-8540**)
- Brazil is now an option to send SMS through OC Participate(**OC-7945**)

Changes & Fixes:

- Email address containing hyphen can be used to create email action rules in rule designer(**OC-2795**)
- CRF data entry performance improvements(**OC-8124**)
- Multi-select Response Text starting with a numeric value can now be extracted(**OC-2868**)
- Constraints have been added to prevent duplicate event CRF creation(**OC-7394**)
- Updates to SAS FORMAT file(**OC-7816**)
- Locked studies will no longer allow SDV status changes(**OC-8284**)
- CRF version migration is prevented after data import if Data Entry did not begin prior to the import(**OC-8739**)
- ... and several other improvements

Removed

- None

Other Links

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

Patches

3.14.1 – 30-APR-2022 (Changelog)

- Enhanced OC3 security.

Functional approval by Riley Bianchi. Signed on 2022-04-26 3:42PM

Approved for publication by Paul Bowen. Signed on 2022-04-26 11:17PM

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5 Release Notes - OpenClinica 3.13

OpenClinica 3.13 contains a variety of enhancements and fixes to both OpenClinica and OpenClinica Participate. View the entire **3.13 changelog here** (login required). Highlights include:

New

- Single Sign On for CRCs between OpenClinica and Participate using OAuth2. Participate now also works for LDAP-based user accounts.

Changes & Fixes:

- File uploaded in a repeating group row no longer gets duplicated on subsequent rows (**OC-7162**)
- Fixed question numbering bug in OC Randomize API (**OC-7762**)
- ... and several other improvements

Removed

- None

Other Links

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

Patches

3.13.1 – 30-APR-2022 (Changelog)

- Enhanced OC3 security.

Functional approval by Riley Bianchi. Signed on 2022-04-26 3:43PM

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6 Release Notes - OpenClinica 3.12

OpenClinica 3.12 contains a variety of enhancements and fixes to both OpenClinica and OpenClinica Participate. View the entire 3.12 changelog here (login required).

Highlights include:

New

- Support for batch CRF Migration (OC-7092)
- Item OIDs alone are sufficient in the rule expression to compare items across different repeating groups within the same CRF(OC-7395)
- APIs to report OpenClinica configuration

Changes & Fixes:

- Select all items in a study link now retrieves the correct number of data items(OC-3437)
- Hidden required fields will no longer prevent CRFs from being marking complete(OC-7292)
- Fixes to the creation of discrepancy notes when the rule message is longer than 255 characters(OC-5891)
- Item group OID is not required in the rule expression when the item(s) in the expresssion belong to the same repeating group as the item in the target(OC-7360)
- Blank rows created in item data during import when non-repeating groups were followed after repeating groups with ordinal greater than 1(OC-7431)
- ... and over 30 more improvements

Removed

- Old audit log records will not be corrected for those affected by the SDV bug introduced in 3.6 release version and fixed in 3.8 version.

Patches

3.12.1 - 10-NOV-2016 (changelog)

- Fixes issues related to Data Import via SOAP Web Services triggering eventAction Rules (OC-7446), scheduling of events via SOAP Web Services triggering eventAction Rules (OC-7469) and with uneccesary white space in the header of Participant Forms when displayed in mobile devices (OC-7476).

3.12.2 - 23-NOV-2016 (changelog)

- Fixes issues with eventAction not running when set to runOnSchedule (OC-7560),

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- OpenClinica Reference Guide
- Installation guides

Approved for publication by Cal Collins. Signed on 2017-03-02 8:50AM

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7 Release Notes - OpenClinica 3.11

OpenClinica 3.11 contains a variety of enhancements and fixes to both OpenClinica and OpenClinica Participate. View the entire 3.11 changelog here (login required).

A summary of highlights include:

New

- Support for SAS extract format (OC-6962)
- Ability to set the default CRF version at the Site Level for participate forms (OC-7029)
- Option to view the access code after connecting a participant (OC-7118)

Changes & Fixes:

- Fixes to CRF version migration feature:
  - Show/HideAction rules were not behaving properly after CRF version migration (OC-5918)
  - Hidden required fields prevent the CRF from being marked compete after CRF version migration (OC-3465)
  - OC does not record the correct user for CRF version migration in the audit log (OC-6711)
  - No properties for new items after CRF version migration (OC-7119)
- 404 error message while exporting Notes & discrepancies (OC-6433)
- Fixed the Data Mart xslt to make it compatible with PostgreSQL 9.5 (OC-7161)
- Rule designer opens the wrong rule from the view rule page (OC-6840)
- Removing (Pausing) an export job results in the job still running at the scheduled time (OC-6879)
- Opening a participant form in data entry mode no longer makes it invalid for data entry by Participant (OC-7137)

Removed

- Removed the sort link from the manage event definition page (OC-7100)

Other Links

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

Approved for publication by Iryna Galchuk. Signed on 2016-09-30 10:45AM

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8 Release Notes - OpenClinica 3.10

OpenClinica 3.10 contains a variety of enhancements and fixes (50 in total) to both OpenClinica and OpenClinica Participate. View the entire 3.10 changelog here (login required).

A summary of highlights include:

New

- Participate supports offline forms (offline surveys) ?
- Participate supports image capture (photos as responses) ?
- Upgrade database to Postgres 9.5?

Changes & Fixes:

- Long time to load Notes and Discrepancies in OC 3.9 (performance fix on page load) (OC-6980)?
- Fix to Rules run on parameter to allow rules to run only during the second pass of data entry if so indicated (OC-3333)?
- Fix to data entry lock issue preventing a CRF from being released if another user had timed out of their session while previously accessing that form (OC-6906)?
- Fix Participate form layout and submission button issues in IE 11 (OC-6880)?
- Fixed representation and storage of escape characters in extract and print modules (OC-6981)

Patches

3.10.1 - 30-MAR-2016 (changelog)

- Improved support for IE11 (OC-7109) and for offline forms on iOS (OC-7086, OC-7058) in Participate

Other Links

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

Approved for publication by Ben Baumann. Signed on 2016-05-21 9:59AM

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9 Release Notes - OpenClinica 3.9

OpenClinica 3.9 contains a variety of fixes and enhancements to both OpenClinica and OpenClinica

Participate. Highlights are below. View the entire 3.9 changelog here (login required).

New

- Participants can edit forms
- New module to add randomization capabilities to studies
- Randomization rules can be configured to include stratification factors from subject attributes or CRF values

Changes and Fixes

- Data Entry: CRFs locked for data entry will be released if the session times out
- Rules: Rule character limitation extended from 1025 to 2040
- Rules: It is now possible to use the fully qualified path (e.g. SE_OID.CRF_OID.IG_OID.I_OID) in the expression and it will evaluate to a result when run (where formerly the relative path had to be used to run)
- Rules: Increased max character limitations in Notification rule actions to allow for longer subject lines (to 1024 chars) and bodies (to 2000 chars)
- Support: Changed the support link in the UI to point to the new OpenClinica support portal: https://www.openclinica.com/support
- Schedule Event: A uniqueness constraint has been applied so that it is not possible to have a duplicate event

Removed

- Removed the "Report Issue" link (subsumed with new support portal)

Patches

3.9.1

- Fix applied for Discrepancy Notes taking a long time to load

Other Links

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

Approved for publication by Ben Baumann. Signed on 2016-03-29 2:20PM

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10 Release Notes - OpenClinica 3.8

OpenClinica 3.8 contains a variety of fixes and enhancements to both OpenClinica and OpenClinica Participate. Highlights are below. View the entire 3.8 changelog here (login required).

New

- Capture data in Participate using configurable visual analog scales (VAS).
- Intelligent parsing of Participant phone numbers (used to send text message notifications/reminders) submitted in varying formats
- Display "Add Another" and "Remove" as buttons for Participants to add/remove repeating data structures
- Display a custom study-specific logo on Participate dashboard
- Better support for designing Participate forms using OpenRosa XForms.
- Display media (images, video, audio) within OpenClinica Participate forms when using XForms.
- API methods to ennhance CTMS integration abilities:
    - REST call to create studies
    - REST call to create event definitions
    - REST call to create sites
    - Overhauled API documentation, and made interactive

Changes and Fixes

- Fixed audit log not displaying correct user when SDV status is changed
- Fix to filters in manage rules table to search by RunOnSchedule attribute
- Fix problem with date validation in internationalized calendars
- Fixes to various Participate login/session related issues
- Fix to bug that allowed multiple occurrences of a non-repeating event to be scheduled under certain circumstances

Other Links

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

Approved for publication by Alicia Goodwin. Signed on 2016-02-22 2:46PM

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

11 Release Notes - OpenClinica 3.7

OpenClinica version 3.7 provides bug fixes, and enhancements. A lot of work also went into Particpate including anonymous form submission. Visit our Particpate product page to learn more

about this great patient engagement and ePRO module.

3.7 Changes and Fixes

Feature Name	Description
File upload in CRFs	OC-6625 File Upload, only when outside of GRID on a section which has a GRID, does not place the file in the backend on Replace
File upload in CRFs	OC-2893 Attached files are not accessible when the items in the CRF are modified from a different level(study/site) during admin editing
File upload in CRFs	OC-1996 Replacing and Removing Attached Files in Repeating Groups
Simple Conditional Display	OC-6558 Skip logic not working in Administrative Editing when form status is completed
Manage / Upload CRF	OC-3285 "Create a new CRF" page looks strange
Source Data Verification Dashboard	OC-1888 Event date in SDV screen is date Event created, instead of Event-start-date
Collect subject DOB	OC-4540 Year of birth not changeable when PersonID "not used"

Minor Releases

3.7.1 Changes and Fixes

Feature Name	Description
Participant Access codes	FIX: Access codes were not being consistently generated for Participants and a fix has been issues.

3.7.2 Changes and Fixes

Feature Name	Description
Collecting dates in local formats	OpenClinica supports the use of data collection with different localizations, including date localization. In 3.7 an issue was introduced where non-US dates were being incorrectly validated and could not be entered if the users browser language preference was not set to en_us AND local properties files were not included in the application. A fix has been issues.

Other Links

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

Approved for publication by Alicia Goodwin. Signed on 2015-11-20 3:17PM

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

12 Release Notes - OpenClinica 3.6

OpenClinica version 3.6 provides new features, bug fixes, and enhancements

Click **here** for the complete change log.

New

Feature Name (Click to view related stories)	Description
OC-6193 REST WS Call to get all records from a site or study (XML / JSON)	The ability to get clinical data records for all subjects via a REST WS call in XML or JSON format
OC-3865 Behavior and status of event CRFs before and after import	When importing data it must be possible to have the status of the event CRF go to either Started or Completed. It must also be possible to skip records based on their current status (for example, do not update a record which has a status of Completed).
OC-6323 Email Based authentication for participants	The ability to generate notification to the Patient via email so that they can connect to Participate
OC-6290 Notification Action	A notification action that can support messaging and variables as part of the action to send notification(s) to Participants or a specific email address. Can support different modes of delivery (currently SMS and email)
OC-6325 Run rules in batched on a schedule	Ability to have Notification Actions run in batch on a schedule so that they do not have to be user triggered but will run regularly and generate notifications according to the rules
OC-6393 Notification Action logic	Expressions can execute against Event Start Date and can use + / - with integer values, support use of _CURRENT_DATE and can use conditional and relational operators when comparing start_date. Use of Items are not yet supported for this logic.
OC-6400 Rule Management updates	Updating the Manage Rules interfaces and Rule Designer to support the new rule action, Notification Action

Changes and Fixes

Feature Name (Click to view related stories)	Description
OC-6191 Deleting an Event CRF clears the form for Re-entry	Deleting an Event CRF must set all of its values to blank and must reset all of the in-form logic (for required fields, validations and rules) so that the form can be re-entered.

Removed

Feature	Description
N/A	

Other Links

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

Approved for publication by Ben Baumann. Signed on 2015-09-30 4:07PM

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

13 Release Notes - OpenClinica 3.5

OpenClinica version 3.5 provides new features, bug fixes, and performance enhacemenets.

Click **here** for the complete change log.

New

Feature	Description
OC-5741	Support Integration with OpenClinica Participate
OC-6091	Initial (partial) support for the Open Rosa APIs In OpenClinica

Changes and Fixes

Feature	Description
OC-5971	Fix CRF Header in data entry (reverse proxy environment)
OC-6101	Disable "Save" in CRF until page renders

Removed

Feature	Description
N/A	

Other Links

- Download (OpenClinica.com login required to download)
- OpenClinica Reference Guide
- Installation guides
- If you originally started using OpenClinica with version 2.5 or earlier, your database schema needs attention. Be sure to follow the instructions in issue #15256 and review issue #13424.

For Developers

- Component Data Model (with class diagrams)
- Data Model
- Source Code

Approved for publication by Alicia Goodwin. Signed on 2015-04-22 1:57PM

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

14 Release Notes - OpenClinica 3.4.1

OpenClinica version 3.4.1 provides bug fixes, and performance enhacemenets.

New

Feature	Description
N/A	

Changes and Fixes

Feature	Description
RSS Feed on login page	By default the RSS feed is a live feed from the OpenClinica blog

Removed

Feature	Description
N/A	

Other Links

- Download (OpenClinica.com login required to download)
- OpenClinica Reference Guide
- Installation guides
- If you originally started using OpenClinica with version 2.5 or earlier, your database schema

needs attention. Be sure to follow the instructions in issue #15256 and review issue #13424.

Known Issues

Below is a list of known issues in the 3.4.1 version of OpenClinica.

For Developers

- Component Data Model (with class diagrams)
- Data Model
- Source Code

Approved for publication by Alicia Goodwin. Signed on 2015-07-24 2:54PM

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

15 Release Notes - OpenClinica 3.4

OpenClinica version 3.4 provides new features, bug fixes, and performance enhacemenets.

Click **here** for the complete change log.

New

Feature	Description
Role for site data entry	It is now possible to have a data entry role that is restricted to a site which is not a Clinical Research Coordinator.
REST API for ODM using SSID	OIDs are OpenClinica identifiers which other systems may not be aware of. For easier integration of systems, we are exposing Study Subject ID for use in the REST API calls for clinical data.
Token for StudySubjectOID	OpenClinica CRFs support use of tokens as variables which could be used in many ways but perhaps are most useful in URLs or in scripts (e.g. Java-script). We have added a new token which will substitute the variable with the given study subjects StudySubject OID; ${studySubjectOID}.

Changes and Fixes

Feature	Description
Normalize Date/Time stamps	Dates are captured for many entities throughout the system but were captured in different formats. In some places the date was being rendered as the database server time while in others were rendered as the application server date. All dates related to data capture are now captured as date+time+offset.
Restoring CRF version doesn't bring back removed data	If a user had access to a Global CRF which had been used for data entry and they removed the CRF, if it was restored, the item data were not being restored.

Performance issue due to unnecessary repeated generation of JavaScript	Unnecessary generation of repeated javascript could cause slower performance. This has been fixed.
Update CRF Template to include corrections and additional guidance to the Instructions worksheet	CRF Template Instructions contain more detail on best practices for building CRF with use of Groups.
Display a message to the user if OpenClinica is accessed from a non-supported browser or browser version	If a user accesses OpenClinica from a browser which is not officially supported, a warning message will appear on the login screen.
PrintCRF Left Item Text HTML will not render	If HTML was used in LEFT_ITEM_TEXT it was printing the tags but will now be passed through (e.g. formatting will display correctly) in the printed views.
Cannot insert a value using rule into a PDATE field from another PDATE field	If a rule was created to insert from one PDATE into another it was not working correctly. This has been fixed.

Removed

Feature	Description
N/A	

Other Links

- Download (OpenClinica.com login required to download)
- OpenClinica Reference Guide
- Installation guides
- If you originally started using OpenClinica with version 2.5 or earlier, your database schema needs attention. Be sure to follow the instructions in issue #15256 and review issue #13424.

Known Issues

Below is a list of known issues in the 3.3 version of OpenClinica.

For Developers

- Component Data Model (with class diagrams)
- Data Model
- Source Code

Approved for publication by Alicia Goodwin. Signed on 2014-12-23 7:31AM

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

16 Release Notes - OpenClinica 3.3

OpenClinica version 3.3 provides new features, bug fixes, and performance enhacemenets.

Click **here** for the complete change log.

New

Feature	Description
Schedule Next Event	Study designers can build rules to automatically schedule events using Event Start Date and Event Status. When users schedule events and perform data entry, the next event or events can be automatically scheduled.
Parameterized links	Using Tokens (substitution variables) for study objects (such as Study Name, Event Name, CRF Name, Study Subject, etc). users can designer a form that will dynamically use the value of these variables either for representation on the form, to build a dynamic URL or for use in jquery.

Changes and Fixes

Feature	Description
Long duration of saving CRFs with dynamic items	Long save times were experienced with complex CRFs including dynamic items. Indeces were added to improve performance times.

Removed

Feature	Description
N/A	

Other Links

- Download (OpenClinica.com login required to download)
- OpenClinica Reference Guide
- Installation guides
- If you originally started using OpenClinica with version 2.5 or earlier, your database schema needs attention. Be sure to follow the instructions in issue #15256 and review issue #13424.

Known Issues

Below is a list of known issues in the 3.3 version of OpenClinica.

- Print CRF Left ITem Text HTML will not render

For Developers

- Component Data Model (with class diagrams)
- Data Model

- Source Code

Approved for publication by Alicia Goodwin. Signed on 2014-10-10 2:01PM

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

17 Release Notes - OpenClinica 3.2

OpenClinica 3.2 provides Subject Casebooks for archival purposes with full audit history and Discrepancy Note information. OpenClinica 3.2 also supports more REST APIs for getting and filtering clinical data, updated stack requirements and has vastly improved automated test coverage (almost entirely automated).

Click **here** for the complete change log.

New

Feature	Description
Printable Subject Casebooks	Print full Subject Casebooks including all provenance data (full audit trails and discrepancy notes).
Stack upgrade (updated version of Tomcat and JavaJDK)	OpenClinica 3.2 can now run on Tomcat 7 and Java 7 (Tomcat 6 and Java 6 are still supported).
Excel download of Audit logs	Download the audit log to excel from the audit log window.
Performance enhancements for Extract Data	Adding indecises has greatly improved performance of extracts (~ 4 - 10x faster based on test results).

Changes and Fixes

Feature	Description
i18n enhancements and fixes	
Add ordinal (occurrence) to discrepancy note download to CSV	Download of Notes & Discrepancies to Excel now contains ordinals for repeating Events and items in a grid.
Fixes to web services	

Removed

Feature	Description
Support for Oracle (OpenClinica will no longer be supported on an Oracle database)	

Other Links

- Download (OpenClinica.com login required to download)

- OpenClinica Reference Guide
- Installation guides
- If you originally started using OpenClinica with version 2.5 or earlier, your database schema needs attention. Be sure to follow the instructions in issue #15256 and review issue #13424.

Known Issues

Below is a list of known issues in the 3.2 version of OpenClinica.

- Print CRF Left Item Text HTML will not render

For Developers

- Component Data Model (with class diagrams)
- Data Model
- Source Code

Approved for publication by Alicia Goodwin. Signed on 2014-06-20 1:46PM

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

18 Release Notes - OpenClinica 3.1.4.1

OpenClinica 3.1.4.1 addresses three issues discovered in 3.1.4. This is a minor maintenance release. No other changes have been made between versions 3.1.4 and 3.1.4.1. For additional information on this release, including known issues, please refer to the 3.1.4 Release Notes. It is recommended that all OpenClinica users upgrade. View the complete changelog in the JIRA bug tracker here.

Changes and Fixes

Change/Fix		Description
OC-2878	Rules Designer gives "NullPointerException" when trying to save some rules in 3.1.3.1	This fix addressed an issue when the transactional annotation was removed from a piece of code for updating a rule from rule designer. This resulted in a partial transaction and the rule OID was used a null. The fix was to put the transactional annotation back, i.e treat the block as a transaction.
OC-2658	The left navigation pane (study event structure) is not available from Enter for data page	This is a fix for the navigation pane which is not showing on the "Enter" or "Validate" data page

OC-3349	PrintCRF single option lists are not showing up	Minor Print CRF fix to correctly display single-option multi-select field

Removed

- None

Other Links

- Download (OpenClinica.com login required to download)
- 3.1.4 Release Notes
- OpenClinica Reference Guide
- Installation
- If you originally started using OpenClinica with version 2.5 or earlier, your database schema needs attention. Be sure to follow the instructions in issue #15256 and review issue #13424.

Known Issues

Below is a list of known issues in the 3.1.4 version of OpenClinica.

- *Internet Explorer V7 copies data from a previous row in a repeating group to the newly added row.* There is a known issue with IE7 which we are not going to fix specifically, but for the next release we will look at what it would take for us to rewrite data entry **17301**

- User is able to upload a CRF with erroneous changes which can lead to issues in the data structure. When a user uploads a CRF version there are some changes which are acceptable (these changes are mostly around visual presentation) and some changes which the system should not allow to change between versions (these changes affect data structure, etc.) which OpenClinica should verify at the time of upload. A user should be able to change their RESPONSE_TYPE for the following scenarios:
  - radio / single-select
  - text / textarea
  - checkbox / multi-select
  The system should NOT allow a user to change from (radio/single-select) / (checkbox/multi-select). This is not currently being checked. If a user does make this change between versions it can affect the ODM and could cause issues with any ODM-dependant programs (e.g. data extractions, printed CRFs). This will be checked in a future version of OpenClinica.

- When Editing the Study level parameter, the site level parameter is hidden. There is a workaround in place **SR-119**

- In different versions of CRFs, if QUESTION_NUMBER changes from one version to the next, it will always reflect the most recent number between versions of CRFs since it only stores one value at a time. So, if a user changed a QUESTION_NUMBER from "1" to "2" between v1 and v2 respectively, then printed v1 again, the ODM would show the v2 value. **SR-95**

- *Password Settings not preserved on upgrade from pre-3.1.3 version:* OpenClinica now allows an administrator to configure the password policy for your OpenClinica system via a page in

the user interface. However the previous settings from your datainfo.properties file for password expiration and change initial password required will not be preserved upon upgrade. You should go into the admin UI and re-set the password settings to the desired settings post-upgrade, then re-start Tomcat.

- *Hiding Fields on Items in Repeating Groups* - Due to issues with the implementation of hidden fields in Repeating Groups, we do not recommend hiding individual fields within a repeating group of items in a CRF. Usage of the hidden items in repeating groups works as expected in initial data entry phase, but is problematic after a CRF is marked complete. If hidden Items in Repeating Groups do not get displayed after the CRF is completed, unexpected behavior may occur. The following issues fall under this category: 12052, 12058, 12095, 12102, 12109, 12098, 12074.
- *Data Entry in Repeating Groups* - During the administrative editing phase; entering Discrepancy Note(s) on the last added row of a Repeating Group will cause the Discrepancy Note(s) to be saved to the first row. Also, saving data on the last row of the displayed Repeating Group that is a part of Rules target triggers an alert that prevents user from going to the next section. The following issues fall under this category: 12108, 12091, 12174.
- *Population of Group-calculation Fields* - Group-calculation values are not populated immediately upon saving a CRF section with the group-calculation inputs. It is not until you hit Save on the subsequent section that contains the the group-calculation field that the field updates correctly. This behavior can cause problems if you are have a rule targeted on the group-calculation item, since the rule may evaluate before the group-calculation value is populated. This issue does not exist in 3.1.2. 16551.
- *Internal CRF Navigation Broken when using RESTful URLs* - If you use the RESTful URL for a multi-section CRF, then click the tab of another section after you get there, or if you use the drop down to navigate, the link is broken and you will get an error, "404: Page not found [Invalid case report form OID]". Refer to issue 16174.
- *Data Import with Partial Dates* - When importing data values for items of type 'Partial Date', OpenClinica will not import partial date data values formatted in the expected manner YYYY-MM-DD. The data type must be provided as DD-MMM-YYYY format in the XML. Refer to issue 11617.
- *Filtering on Administer Subject page* - The search filter criteria (such as Person Identification Number) on the Administer Subjects page does not return Subjects that meet the requested criteria. For the time being it is recommended that users utilize column sorting on the Administer Subject page in order to locate records. Refer to issue 11966.
- *Extract Data Problems* - There are a number of minor known Extract related problems. Currently, data extracts may fail if certain characters (such as "*" or "?") are included as a part of dataset name. Also, certain characters, if present as data values in a CRF, will be extracted incorrectly. Issues that fall under this classification are 11874,11409, 11387, 11389. Other miscellaneous Extract-related issues include: 11419, 11961, 14158 (affects OpenClinica Enterprise Datamart only), 12422.
- *Filter issues on the Subject Matrix > View by Event page* - On the Subject Matrix > View by Event page, only the "initial data entry" status filter is functional. Filtering by other statuses will not work. Issue 12336.
- *Unexpected Error page for 'Go Back to Site'* - When selecting 'Go Back to Site' link after editing Site information, you may get an unexpected error page. The workaround is to click "Exit" rather than "Go Back to Site List". Issue 12228.
- *Duplicate Alert Message for Restore CRF* - Restoring an event CRF causes a duplicate notification message. Issue 12237.
- *Leaving Data Entry Unlocks all CRFs that were locked for a User Session* - The logic that unlocks a CRF when the user leaves the data entry page for a given CRF will release any other CRF locks this user may hold. Issue 13950.

- *Unexpected Error page* - When selecting 'Go Back to Site' link after editing Site information, you may get an unexpected error page. The workaround is to click "Exit" rather than "Go Back to Site List". Issue 12228.
- *Duplicate Alert Message for Restore CRF* - Restoring an Event CRF causes a duplicate notification message. Issue 12237.
- *Outlook Emails with Links to Datasets* - OpenClinica supports email notifications when data sets have completed running. The user may experience an error when clicking on the link to download the file if (a) the email is accessed in Microsoft Outlook, (b) the default browser for the user is Internet Explorer, and (c) the user is currently logged into OpenClinica. If the error is encountered, the user should navigate to the dataset from the OpenClinica home page and download the file from the application.
- *Site Unique Protocol IDs* - Site Protocol IDs must be unique across a Study and can not share the Study unique protocol ID. This is neccessary to allow the web service of registering a Subject and scheduling an Event to work properly.
- Rules / Dynamic Logic - Rules containing the absolute full target path may sometimes cause the rule to fail. This issue is mitigated by uploading the CRF Item OID instead of the full path. Refer to issue 11803 for more information.
- Discrepancy Note Tooltips when Viewing CRFs with Repeating Groups - There is new functionality in 3.1 for the Discrepancy Note tooltip where information about the Item name is displayed, a summary of the Discrepancy Notes on the item and whether an audit log history exists for a particular Item. This does not work 100% accurately when a Repeating Item has a Discrepancy Note assigned to it. It will not show the summary of the Discrepancy Note information or the fact an audit log exists. It will show the Item name for the Item at all times. Please refer to issue 9345 for more information.
- Password Required to Mark CRF Complete - During the creation of an Event definition, the user can define whether the system will require a user to enter their password before marking a CRF complete. If this feature is enabled, the user will see a popup box to enter their password after choosing the Mark CRF Complete checkbox.
  However if the user hits the 'Enter' key on their keyboard without entering a password, the form will be saved without a password being entered. Please see issue 9340 for more information.
- Validation Messages for Calculations - If a user encounters a validation error message pointing to an Item defined as a calculation, they will not be able to click on the message to be brought to the field. Due to the fact the user can not edit calculated fields, the application will not direct them to field. Instead they must scroll down the page to find the red exclamation point (!) for the calculated value and provide the Discrepancy Note. This issue exists with OpenClinica 3.1.3 as well. Issue#: 13529 is associated with this.

For Developers

- Component Data Model (with class diagrams)
- Data Model
- Source Code

Approved for publication by Cal Collins. Signed on 2014-04-01 10:25PM

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

19 Release Notes - OpenClinica 3.1.4

OpenClinica 3.1.4 provides some notable improvements to Printntable unpolulated CRFs, RESFTful APIs, LDAP Authentication, Notes & Discrepencies fixes, jquery libraries updates to address the FireFox 20+ bug, and improved automated testing coverage.

Click **here** for the complete change log.

New

Feature	Description
Print CRF Next generation of Print CRF for Global unpopulated forms - In this case, "Global" refers to CRFs uploaded and available on OpenClinica (which may/may not be associated with a Study) which are available through "Administer Case Report Forms" & "Manage Case Report Forms" and are accessible to Administrators, Data Managers, & Study Director user roles.	Print CRF layout/formatting: *Headers/Footers, ordering, formatting grids, portrait/landscape print support, Support of non ASCII Characters, page layout formatting, support hidden items in unpopulated CRFs,* Site ODM Improvements RESTful architecture for access to metadata and Print CRFs for Study/Site and unpopulated global CRFs
LDAP Integration	OpenClinica can be configured to authenticate users against an LDAP/Active Directory server to support single user accounts across the multiple applications and systems used in the organization.
Automated Testing Support	Automated Testing suites covering all features of 3.1.4

Changes and Fixes

Change/Fix	Description
Enterprise Data Mart updates	Addresses column and table naming conventions; control of width with truncation and new mapping table.
Javascript libraries update (Firefox 20+ bug)	Updates to the javascript libraries so that OpenClinica can run on more browsers and versions of browsers (primary fix for Firefox update 20+)
Duplicate Discrepency Note fix	Fixed discrepancy notes rendering. Addressed a niche issue where duplicates may be displayed on CRFs which were hidden from a site. For more information click the link to see the Jira ticket
Updates and enhancements to Metadata ODM 1.3 Full with OpenClinica extensions	The metadata is now more robust; work was done to support the new model for Print CRF.

Removed

- None

Other Links

- Download (OpenClinica.com login required to download)
- OpenClinica Reference Guide
- Installation
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Known Issues

Below is a list of known issues in the 3.1.4 version of OpenClinica.

- *Internet Explorer V7 copies data from a previous row in a repeating group to the newly added row.* There is a known issue with IE7 which we are not going to fix specifically, but for the next release we will look at what it would take for us to rewrite data entry **17301**

- User is able to upload a CRF with erroneous changes which can lead to issues in the data structure. When a user uploads a CRF version there are some changes which are acceptable (these changes are mostly around visual presentation) and some changes which the system should not allow to change between versions (these changes affect data structure, etc.) which OpenClinica should verify at the time of upload. A user should be able to change their RESPONSE_TYPE for the following scenarios:
  - radio / single-select
  - text / textarea
  - checkbox / multi-select
  The system should NOT allow a user to change from (radio/single-select) / (checkbox/multi-select). This is not currently being checked. If a user does make this change between versions it can affect the ODM and could cause issues with any ODM-dependant programs (e.g. data extractions, printed CRFs). This will be checked in a future version of OpenClinica.

- When Editing the Study level parameter, the site level parameter is hidden. There is a workaround in place **SR-119**

- In different versions of CRFs, if QUESTION_NUMBER changes from one version to the next, it will always reflect the most recent number between versions of CRFs since it only stores one value at a time. So, if a user changed a QUESTION_NUMBER from "1" to "2" between v1 and v2 respectively, then printed v1 again, the ODM would show the v2 value. **SR-95**

- *Password Settings not preserved on upgrade from pre-3.1.3 version:* OpenClinica now allows an administrator to configure the password policy for your OpenClinica system via a page in the user interface. However the previous settings from your datainfo.properties file for password expiration and change initial password required will not be preserved upon upgrade. You should go into the admin UI and re-set the password settings to the desired settings post-upgrade, then re-start Tomcat.

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- *Population of Group-calculation Fields* - Group-calculation values are not populated immediately upon saving a CRF section with the group-calculation inputs. It is not until you hit Save on the subsequent section that contains the the group-calculation field that the field updates correctly. This behavior can cause problems if you are have a rule targeted on the group-calculation item, since the rule may evaluate before the group-calculation value is populated. This issue does not exist in 3.1.2. 16551.
- *Internal CRF Navigation Broken when using RESTful URLs* - If you use the RESTful URL for a multi-section CRF, then click the tab of another section after you get there, or if you use the drop down to navigate, the link is broken and you will get an error, "404: Page not found [Invalid case report form OID]". Refer to issue 16174.
- *Data Import with Partial Dates* - When importing data values for items of type 'Partial Date', OpenClinica will not import partial date data values formatted in the expected manner YYYY-MM-DD. The data type must be provided as DD-MMM-YYYY format in the XML. Refer to issue 11617.
- *Filtering on Administer Subject page* - The search filter criteria (such as Person Identification Number) on the Administer Subjects page does not return Subjects that meet the requested criteria. For the time being it is recommended that users utilize column sorting on the Administer Subject page in order to locate records. Refer to issue 11966.
- *Extract Data Problems* - There are a number of minor known Extract related problems. Currently, data extracts may fail if certain characters (such as "*" or "?") are included as a part of dataset name. Also, certain characters, if present as data values in a CRF, will be extracted incorrectly. Issues that fall under this classification are 11874,11409, 11387, 11389. Other miscellaneous Extract-related issues include: 11419, 11961, 14158 (affects OpenClinica Enterprise Datamart only), 12422.
- *Filter issues on the Subject Matrix > View by Event page* - On the Subject Matrix > View by Event page, only the "initial data entry" status filter is functional. Filtering by other statuses will not work. Issue 12336.
- *Unexpected Error page for 'Go Back to Site'* - When selecting 'Go Back to Site' link after editing Site information, you may get an unexpected error page. The workaround is to click "Exit" rather than "Go Back to Site List". Issue 12228.
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- *Outlook Emails with Links to Datasets* - OpenClinica supports email notifications when data sets have completed running. The user may experience an error when clicking on the link to download the file if (a) the email is accessed in Microsoft Outlook, (b) the default browser for the user is Internet Explorer, and (c) the user is currently logged into OpenClinica. If the error is encountered, the user should navigate to the dataset from the OpenClinica home page and download the file from the application.
- *Site Unique Protocol IDs* - Site Protocol IDs must be unique across a Study and can not share the Study unique protocol ID. This is neccessary to allow the web service of registering a Subject and scheduling an Event to work properly.
- Rules / Dynamic Logic - Rules containing the absolute full target path may sometimes cause the rule to fail. This issue is mitigated by uploading the CRF Item OID instead of the full path. Refer to issue 11803 for more information.
- Discrepancy Note Tooltips when Viewing CRFs with Repeating Groups - There is new functionality in 3.1 for the Discrepancy Note tooltip where information about the Item name is displayed, a summary of the Discrepancy Notes on the item and whether an audit log history exists for a particular Item. This does not work 100% accurately when a Repeating Item has a Discrepancy Note assigned to it. It will not show the summary of the Discrepancy Note information or the fact an audit log exists. It will show the Item name for the Item at all times. Please refer to issue 9345 for more information.
- Password Required to Mark CRF Complete - During the creation of an Event definition, the user can define whether the system will require a user to enter their password before marking a CRF complete. If this feature is enabled, the user will see a popup box to enter their password after choosing the Mark CRF Complete checkbox.
  However if the user hits the 'Enter' key on their keyboard without entering a password, the form will be saved without a password being entered. Please see issue 9340 for more information.
- Validation Messages for Calculations - If a user encounters a validation error message pointing to an Item defined as a calculation, they will not be able to click on the message to be brought to the field. Due to the fact the user can not edit calculated fields, the application will not direct them to field. Instead they must scroll down the page to find the red exclamation point (!) for the calculated value and provide the Discrepancy Note. This issue exists with OpenClinica 3.1.3 as well. Issue#: 13529 is associated with this.

For Developers

- Component Data Model (with class diagrams)
- Data Model
- Source Code

This page is not approved for publication.

20 Release Notes - OpenClinica 3.1.3.1

OpenClinica 3.1.3.1 addresses two data entry edit check issues discovered in 3.1.3. This is a patch

release targeted to fix two issues (16415, 16479) that worked correctly in 3.1.2 and can block data entry in certain cases. No other changes have been made between versions 3.1.3 and 3.1.3.1. For additional information on this release, including known issues, please refer to the 3.1.3 Release Notes. It is highly recommended that all OpenClinica users upgrade as soon as possible. View the complete changelog.

Changes and Fixes

- Fix errors in Validation/Edit Check logic. During Initial Data Entry, the version 3.1.3 system prevents saving data in CRF Sections containing blank required fields or fields containing Simple Validation Checks with non-conforming data even after creating a Discrepancy Note (DN). This phenomenon happens for both repeating and non-repeating Items during Initial Data Entry. For more details refer to issue 16415.
- Fix errors in Rule logic. In 3.1.3, cross-form rules for the do not work properly if written for the same CRF item across different event definitions. For more details refer to issue 16479.

Other Links

- Download (OpenClinica.com login required to download)
- 3.1.3 Release Notes
- OpenClinica Reference Guide
- Community Edition installation instructions
- If you originally started using OpenClinica with version 2.5 or earlier, your database schema needs attention. Be sure to follow the instructions in issue #15256 and review issue #13424.

This page is not approved for publication.

21 Release Notes - OpenClinica 3.1.3

OpenClinica 3.1.3 addresses a large number of issues discovered with 3.1, 3.1.1, and 3.1.2. There are well over 100 changes included in this release. It is highly recommended that all OpenClinica users upgrade as soon as possible. The most notable fixes and improvements are summarized below (or, view the complete changelog).

New

- Support CRF Version migration for individual Event CRFs (#13508)
- Rules can be run at data import and when loading data via web services (#12344)
- Option to require strong passwords (#14506)
- Reference a CRF via an ODM-based URL (#12343)

Changes and Fixes

- Overhaul of OpenClinica's internationalization/localization support to fix defects and increase ease of use. (#13713)
- Fixes to problems with data entry/editing in Repeating Groups (#13135)
- Improved performance for CRF data entry/editing, the View Study Subject page, and the Notes and Discrepancies page (requires changes to Tomcat memory settings) (#12079, #14508, #13347)
- Fixes and improvements to SPSS output format (#13051)
- Improved server stability (#13714)
- Fixes to nested simple conditional displays in CRFs (#12827)
- Fixes to missing database constraints for OpenClinica installations upgraded from 2.5 or earlier (#15256)

Removed

- Ability to use greater than/less than operators to filter by Discrepancy Note age/days open. The function was not working correctly, will be added back in a future release.
- Ability to cancel a Job that has already started running. The function was not working correctly. Queued Jobs can still be cancelled.

Other Links

- Download (OpenClinica.com login required to download)
- OpenClinica Reference Guide
- Community Edition installation instructions
- If you originally started using OpenClinica with version 2.5 or earlier, your database schema needs attention. Be sure to follow the instructions in issue #15256 and review issue #13424.

Known Issues

Below is a list of known issues in the 3.1.3 version of OpenClinica.

- *Validation/Edit Checks:* During Initial Data Entry, the system-3.1.3- prevents saving data in CRF Sections containing blank required fields or fields containing Simple Validation Checks with non-conforming data even after creating a Discrepancy Note(DN). This phenomenon happens for both repeating and non-repeating Items. However, this issue is not observed for Double Data entry and Admin Editing modes. A mitigation | workaround is to use Rules instead of Simple Validation Checks or have users enter a Null Value code to circumvent the validation (this requires that the Event Defintion CRF have Null Values configured). For more details refer to Issue 16415.
- *Password Settings not preserved on upgrade from pre-3.1.3 version:* OpenClinica now allows an administrator to configure the password policy for your OpenClinica system via a page in the user interface. However the previous settings from your datainfo.properties file for password expiration and change initial password required will not be preserved upon upgrade. You should go into the admin UI and re-set the password settings to the desired settings post-upgrade, then re-start Tomcat.
- *Hiding Fields on Items in Repeating Groups* - Due to issues with the implementation of hidden fields in Repeating Groups, we do not recommend hiding individual fields within a repeating group of items in a CRF. Usage of the hidden items in repeating groups works as expected in

initial data entry phase, but is problematic after a CRF is marked complete. If hidden Items in Repeating Groups do not get displayed after the CRF is completed, unexpected behavior may occur. The following issues fall under this category: 12052, 12058, 12095, 12102, 12109, 12098, 12074.

- *Data Entry in Repeating Groups* - During the administrative editing phase; entering Discrepancy Note(s) on the last added row of a Repeating Group will cause the Discrepancy Note(s) to be saved to the first row. Also, saving data on the last row of the displayed Repeating Group that is a part of Rules target triggers an alert that prevents user from going to the next section. The following issues fall under this category: 12108, 12091, 12174.
- *Population of Group-calculation Fields* - Group-calculation values are not populated immediately upon saving a CRF section with the group-calculation inputs. It is not until you hit Save on the subsequent section that contains the the group-calculation field that the field updates correctly. This behavior can cause problems if you are have a rule targeted on the group-calculation item, since the rule may evaluate before the group-calculation value is populated. This issue does not exist in 3.1.2. 16551.
- *Internal CRF Navigation Broken when using RESTful URLs* - If you use the RESTful URL for a multi-section CRF, then click the tab of another section after you get there, or if you use the drop down to navigate, the link is broken and you will get an error, "404: Page not found [Invalid case report form OID]". Refer to issue 16174.
- *Data Import with Partial Dates* - When importing data values for items of type 'Partial Date', OpenClinica will not import partial date data values formatted in the expected manner YYYY-MM-DD. The data type must be provided as DD-MMM-YYYY format in the XML. Refer to issue 11617.
- *Filtering on Administer Subject page* - The search filter criteria (such as Person Identification Number) on the Administer Subjects page does not return Subjects that meet the requested criteria. For the time being it is recommended that users utilize column sorting on the Administer Subject page in order to locate records. Refer to issue 11966.
- *Extract Data Problems* - There are a number of minor known Extract related problems. Currently, data extracts may fail if certain characters (such as "*" or "?") are included as a part of dataset name. Also, certain characters, if present as data values in a CRF, will be extracted incorrectly. Issues that fall under this classification are 11874, 11409, 11387, 11389. Other miscellaneous Extract-related issues include: 11419, 11961, 14158 (affects OpenClinica Enterprise Datamart only), 12422.
- *Filter issues on the Subject Matrix > View by Event page* - On the Subject Matrix > View by Event page, only the "initial data entry" status filter is functional. Filtering by other statuses will not work. Issue 12336.
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For Developers

- Component Data Model (with class diagrams)
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Release Notes 3.1.3 Presentation

The Release Notes 3.1.3 presentation slides link is as follows:

OpenClinica 3.1.3 release notes on Prezi

This page is not approved for publication.

22 Release Notes - Older Releases

OpenClinica 3.1.2

28-Dec-2011

OpenClinica 3.1.2 is an important maintenance release of OpenClinica 3.1 and it is highly recommended you upgrade as soon as possible. 3.1.2 addresses a large number of issues discovered with 3.1 and 3.1.1. The most notable improvements include:

Fixes to Extract Data issues tied to extract job completion, data format/accuracy

Increased data capture performance (especially for very large CRFs with lots of rules)

Show/Hide improvements allowing use of simple conditionals with rule-based show/hide on CRF items, and numerous other fixes

Addition of filter/sort persistence on SDV, so when you leave the page and return your filter sort settings will persist.

Addition of audit entry upon entry of initial value to an item

The web application and the web services modules of OpenClinica are in separate war files.

Features and Issues Addressed - https://issuetracker.openclinica.com/changelog_page.php?version_id=54

OpenClinica 3.1

10-Jun-2011

This release of OpenClinica addresses issues in OpenClinica 3.0.x and includes many new features and functionality. Please see http://clinicalresearch.wordpress.com/2010/06/09/openclinica-3-1-project-%E2%80%9Camethyst%E2%80%9D-preview/ and http://clinicalresearch.wordpress.com/2010/10/26/new-capabilities-added-to-openclinica-version-3-1/ for some information on the new features.

A list of all the issues addressed in the 3.1 release can be found at https://issuetracker.openclinica.com/changelog_page.php?project_id=84

OpenClinica 3.0.4.1

17-Jan-2011

All issues addressed can be found at https://issuetracker.openclinica.com/changelog_page.php?project_id=82

In particular, this releases resolves problems with Partial Dates with a full date value getting saved to the database incorrectly as well as upgrading 3.0.3 to 3.0.4 with Oracle when the same RULE OID is present 3 or more times.

OpenClinica 3.0.4

03-Sep-2010

All issues addressed can be found at
https://issuetracker.openclinica.com/changelog_page.php?project_id=82

OpenClinica 3.0.3

24-May-2010

All issues addressed can be found at
https://issuetracker.openclinica.com/changelog_page.php?project_id=82

OpenClinica 3.0.2

11-Mar-2010

All issues addressed can be found at
https://issuetracker.openclinica.com/changelog_page.php?project_id=82

Approved for publication by Cal Collins. Signed on 2014-06-26 12:12PM

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