

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

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.

LDAP Integration

Automated Testing Support

Description

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

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 suites covering all features of 3.1.4

Changes and Fixes

Change/Fix

Enterprise Data Mart updates

<u>Javascript libraries update</u> (<u>Firefox 20+ bug</u>)

Duplicate Discrepency Note fix

Description

Addresses column and table naming conventions; control of width with truncation and new mapping table.

Updates to the javascript libraries so that OpenClinica can run on more browsers and versions of browsers (primary fix for Firefox update 20+)

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

<u>Updates and enhancements to</u> <u>Metadata ODM 1.3 Full with</u> <u>OpenClinica extensions</u>

The metadata is now more robust; work was done to support the new model for Print CRF.

Removed

None

Other Links

- <u>Download</u> (OpenClinica.com login required to download)
- OpenClinica Reference Guide
- <u>Installation</u>
- 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 <u>SR-119</u>
- 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 postupgrade, 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. <u>16551</u>.
- 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 <u>13950</u>.
- *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 <u>12237</u>.
- 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 <u>9340</u> 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.