Release Notes

Merge eClinicalOS v2016.9.0
Release Date: 18 November 2016

OVERVIEW

Purpose:
This document provides an overview of Merge eClinicalOS v2016.9.0 released by Merge Healthcare's eClinical division.

Background:
Merge eClinicalOS is a Software as a Service (SaaS) application available for clients to design, deploy, and manage their clinical trials. It provides design tools for each aspect of the design and management process and provides an EDC interface for end-user data collection. It also provides additional tools such as ePRO access, Randomization, Dispense/Shipping Management, Endpoint Adjudication, Medical Coding, and Laboratory Normal collection to help manage different aspects of the trial.

Documentation:
User manuals for all features in the system are available online within eClinicalOS by clicking Online Help from the landing page or User Manuals from the help links in the header.

VERSION DETAILS

The enhancements and features for eClinicalOS v2016.9.0 are a direct result of your response to the system.

1. 'MONITORING LEVEL' MODULE NOW REQUIRES 'ALL SITES' ACCESS

IMPORTANT: In order to ensure that Monitoring Levels access is provided to roles that can manage all site and subject levels, restrictions for access to the module have been added. 'All Sites' access must be attached to role users in addition to the permission 'Can Manage Monitoring Levels' in order for the role to access Monitoring Levels.

2. IMPORT STUDY REPORTS

Previously, Study Reports could be imported with either a Full Study import or a Build import. However, the ability to import Study Reports after a study has been configured adds considerable convenience when the reports are many or detailed, and if an MSU occurs, reports that have already been validated on the MSU test

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copy can be imported instead of manually rebuilt in the Live study, preserving QA processes.

NOTE: These enhancements are for the Study Reports available under the Build menu in the designer. They are not associated with the Smart Reports module.

2.1 Study Standard Reports

A feature has been added to allow study-to-study import of Standard Study Reports. After choosing the study to import from, the reports available for import are listed in a table with the following details: report ID, Report Name, Type, Description/Notes, Roles View, Sites View, Landing Page, Active, Subject PDF, Mobile Enabled, and Duplicated. One or more reports can be imported using checkboxes in the table.

2.2 Study Define Reports

The tool for importing Standard Study Reports was also expanded to include Study Define reports, with some restrictions. After choosing the team and study to import from, the reports available for import are listed in a table with the following details: report ID, Report Name, Type, Description/Notes, Roles View, Sites View, Landing Page, Active, Subject PDF, Mobile Enabled, and Duplicated. One or more reports can be imported using checkboxes in the table.

For Study Define reports, Merge advises that you ensure the build items detailed in the report and the enabled optional modules between the target and source studies match; however, the import process catches these discrepancies and lists them in the Error Widget so they can be addressed. For example, if a Table/Column, Remote Value, Medical Coding Dictionary, or a Visit definition is defined in the report but does not exist in the target study, the incorrect or missing value will be imported in the study definition, but an error will be added to the Widget. The same process would occur if the EAM module is turned off in the target study but an Adjudication Tracker report has been imported.

The following reports cannot be imported:
- Study Define: File/Document Posting

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- Study Define: Scheduling Listing
- Study Define: Scheduling Listing w/Detail
- Study Define: Subject Status Changes over Time (Mobile Only)

3. FULL STUDY IMPORT SUPPORT FOR DISPENSE V2 MODULE

In the past, when you attempted to Import Full Study using a source study with V2 Inventory/Dispensing Management, you would receive an error if the target study was not set for Inventory/Dispensing or had the V1 version of the module enabled. This was not the same behavior as when importing a source study with V1 Inventory/Dispensing. The system has been updated to be consistent and allow the following behavior:

- If the source study has either version of Inventory/Dispensing Management turned on, an Import Full Study will overwrite the target study information. This includes targets with no dispense set, V1 Dispense set up, and V2 Dispense set up. The system will import each Dispense design element from the source (attributes, role permissions, Optional Module, etc.).

4. BLOCK V1 DISPENSE ITEM MOVES: 'AT SITE' AND 'AVAILABLE AT SHIPPER'

With this release, the status changes for V1 Dispense items has been restricted so that a change cannot be made from 'At Site' to 'Available at Shipper,' or from 'Available at Shipper' to 'At Site.' If items are returned to a shipper to be used again for another site, the status can be changed to 'On Hold' and then 'Available at Shipper' once the item has been returned. As a reminder, a message has been added to the bottom of the Dispense Items page to indicate the list of restricted moves.

5. ADJUDICATION TRACKER REPORT AT THE SUBJECT LEVEL

With the release of eClinicalOS v2016.9.0, the Adjudication Tracker Report can now be configured to show at the subject level. The report has been improved to pull in the same data but for the subject selected, and to have the same ordering and tools, exports, and filters as the study level version.

6. DATA TRACKER REPORT - USING EAM WITH THE 'TRIGGERED FROM' SCENARIO

Previously, the EAM # and Status were not displayed properly in the Data Tracker Report if the Adjudication Forms were contained in a visit added by a rule that was triggered by a page in a separate visit. The system has been updated to pull the

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correct EAM information and display it according to the report context that is defined and the manner used to trigger the EAM.

- Displayed if:
  The report context is on a repeating visit containing the adjudication forms or any repeating pages of the visit AND the adjudication forms are in the same visit or different visit as the trigger value page.
  OR
  The report context is on a repeating page that triggered the EAM visit AND the adjudication forms are in a different visit as the trigger value page.

- Not Displayed if:
  The page that triggered the EAM visit is a non-repeating page in a repeating visit, or the report context is just linked to an EAM visit page.

7. SFTP CONNECTION TEST BUTTON

A new button to test an SFTP connection has been added with this release. From Closeout > Study Documents / Exports, after selecting the export type, if SFTP is set up in your study the connection can be tested by clicking the 'test SFTP Connection' button. The test process will run and either provide a success message or a failure message. The test button has also been added to the Study Recurring Jobs Summary screen in the 'Current Recurring Jobs' summary.

8. LANGUAGE SUPPORT FOR EPRO MOBILE APP

To prepare for language translations in MY CLINICAL DIARY, eClinicalOS APIs that communicate with the ePRO Mobile App have been updated to support multiple languages. Because the system talks to the App, translation support is started in eClinicalOS core where the user language choices are also captured. This enables the subject to enter their diary in their preferred language which increases the accuracy of their entry via the App.

9. SMART REPORTS UPDATES

Smart Reports is an optional module that was integrated with eClinicalOS in previous releases. With this release, Lab Normals data has been made available for use in Smart Reports (if the study is using Lab Normals and Smart Reports). The data for Lab Normals is the same that users see in their DAT_LBSN, DAT_LBS, and DAT_LBSR data exports.

10. AUTH0 SINGLE SIGN ON UPGRADE

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With this release, the eClinicalOS Auth0 single-sign-on service will be upgraded to meet product changes and enhancements. Auth0 is a software that enables single-sign-on and token based security authentication for eClinicalOS. It enables us to provide you with secure access to the system as well as other integrations to eClinicalOS such as ZenDesk. We can set levels of security, view analytics for the system performance, and better protect your data. You also get the ability to have one username/password and access eClinicalOS and its various integrated tools all in the single login.

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REVISION HISTORY FOR CONTENT OF THIS DOCUMENT

PRODUCT	REVISION #	AUTHOR/TITLE	CHANGES	CREATED DATE
eClinicalOS v2016.9.0	Version 1.0	Angela Reedy Documentation Specialist	Initial Version.	26 Oct 2016

REVISION HISTORY FOR THIS TEMPLATE

TEMPLATE #	REVISION #	AUTHOR/TITLE	CHANGES	CREATED DATE
QA-1338	Version 01	Emily Malok Instructional Designer	Initial version.	09 Jul 2014
QA-1356-T3	Version 02	Emily Malok Instructional Designer	• Changed Template ID for new format • Updated Template design • Adjusted template to better describe eCOS examples versus required sections	13 Feb 2015

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