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Release Notes

IBM Clinical Development 2019.1.1.0
Release Date: 15 February 2019

OVERVIEW

Purpose:
This document provides an overview of IBM Clinical Development 2019.1.1.0 released by the IBM Corporation.

Background:
IBM Clinical Development (formerly 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 IBM Clinical Development by clicking Online Help from the landing page or User Manuals from the help links in the header.

IMPORTANT ALERTS

There are two upcoming changes that users need to be aware of and prepare for.

1. REMOVAL OF SUPPORT FOR SSL V3, TLS V1.0, AND TLS V1.1

The use of old transport protocols introduces a security risk to IBM Clinical Development. Support for these encryption methods has been removed from many common software tools and others have scheduled an end date. IBM has maintained older protocols to give customers the opportunity to upgrade their own systems. ***Due to increased customer concerns and the release of the DICOM enhancements with 2019.1.1.0, support for the old protocols will be removed on 28 Feb 2019.*** Please contact your Account Manager, Seller, or Support as soon as possible if there are concerns.

2. REMOVAL OF SUPPORT FOR INTERNET EXPLORER (IE) V9 AND V10

Microsoft has stopped supporting versions of Internet Explorer (IE) prior to v11 and no longer provides security patches or fixes for these versions. IBM has maintained support for these versions to give customers the opportunity to upgrade their browsers. ***Support will be removed in March 2019 with the release of 2019.2.0.0.*** A specific date has not been determined yet, but IE v9 and v10 users will be unable to access IBM Clinical Development once support is removed. Users should update their IE version or switch to an alternate browser.

VERSION DETAILS

The enhancements and features for IBM Clinical Development 2019.1.1.0 are a direct result of your response to the system.

1. SUBJECT PDF: CHANGE IN DEFAULT FOR NEW STUDIES

Starting with the release of 2019.1.1.0, the 'Enable Customized Subject PDF' attribute on Design Attributes (Optional) will be set to YES by default. Previously, the default value would be NO if the attribute was blank. Users must manually update the attribute if they do not want to use the customized tool.

NOTE: Customized Subject PDF will now be provided at no cost for all customers. Current organizations rate cards/price books will be updated in IBM Clinical Development as needed.

2. SUBJECT PDF: IMPROVEMENTS MADE TO INTERFACE AND OUTPUT

Under the Customized Subject PDF on the Design Attributes (Optional), a new attribute allows you to include/exclude the Page Summary section on generated PDFs. This is the panel to the right of the CRF image that shows status, last modified, and query metrics. This attribute will impact the Subject PDF from both Designer/EDC, the page PDF download, and the EAM Dossier when it contains CRF pages.

In the configuration of the Subject PDF, the attribute sections will be collapse by default. Users can access the Content options or Display Options as needed or just select the template and generate. There are also new attributes available for studies with the Customized Subject PDF ON:

2. SUBJECT PDF: IMPROVEMENTS MADE TO INTERFACE AND OUTPUT

1. Other Summaries - This enables you to display or hide the 'Subject Information', 'Page Links', and 'Page Attachments' summaries located in the initial Summary section of the PDF. By default, this is checked (displayed).
2. EAM History (with EAM only - see separate description under EAM)
3. PDF by Event (with EAM only - see separate description under EAM)

3. ENDPOINT ADJUDICATION: 'PDF BY EVENT' OPTION IN SUBJECT PDF

For studies using Endpoint Adjudication, a new attribute 'PDF by Event' is available on the Subject PRF to generate documents. This will generate a PDF by occurrence of a repeating visit relative to an EAM event (i.e. visits only included if they trigger an EAM rule or are the EAM visit). Once the subject population is defined, users can also specify the event status/statuses to be included.

NOTES:

- Designers must select YES for the 'Enable Customized Subject PDF' attribute on Design Attributes (Optional) to use this new Subject PDF option.
- The 'Include File Attachments' will be disabled (default checked) when using this attribute.

4. ENDPOINT ADJUDICATION: 'EAM HISTORY' OPTION IN SUBJECT PDF

For studies using Endpoint Adjudication, a new attribute 'EAM History' is available on the Subject PRF to generate documents. This will include the EAM # summary in the EAM visit in the Subject PDF. It is checked (displayed) by default.

NOTES:

- Designers must select YES for the 'Enable Customized Subject PDF' attribute on Design Attributes (Optional) to use this new Subject PDF option.

5. DICOM/IMAGING: UPLOADER UPDATED

The DICOM/Imaging module has two options for uploading images -- a legacy Uploader tool that must be installed on the user's system and a web-based application. The legacy Uploader is commonly used when additional anonymization is needed since it has expanded tools. The legacy Uploader is not compliant with the TLS changes being applied to the system in IBM Clinical Development 2019.2.0.0. To address this issue, the Uploader has been updated to handle supported TLS versions.

6. PERFORMANCE: TEAM ADMINISTRATION CHANGE

To facilitate proper assignment of resources and servers, the system was updated to no longer require old configuration properties when creating new teams in Admin. There is no visible change to users.

7. PERFORMANCE: DATA MIGRATOR HEALTH CHECK UPDATE

The previous design of the Data Migrator Health Check did more than just confirm that the module was running. While this is comprehensive and can be valuable, it also uses a large amount of resources. Over time, this can also cause slowness and delays in the module. The health check is updated to use a tiered approach, where the basic is default and IBM staff can expand the check if needed for a particular situation.

8. PERFORMANCE: ADD INDEX TO SUPPORT VISIT DOMAIN KEYS

The system must do a look-up when handling study designs with Visit Domain Keys (custom ID for repeating visits and pages). This uses a legacy process and requires more resources than it should. To help optimize the look-up and better manage resources, an index has been added. This will improve performance.

9. COGNOS: INCLUDE DASHBOARD REPORTS, ACTIVE REPORTS, AND STORIES

When Smart Reports with Cognos is active for a study and reports are available, users with permissions can access the reports in the study EDC on the reports page. This enhancement is to include not just general reports but dashboard reports, active reports, and stories as well. This provides added support for data review.

REVISION HISTORY FOR CONTENT OF THIS DOCUMENT

PRODUCT	REVISION #	AUTHOR/TITLE	CHANGES	CREATED DATE
IBM Clinical Development 2019.1.1.0	Version 1.0	Emily Malok Instructional Designer	Initial Version.	31 Jan 2019

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	Updated: • Changed Template ID for new format • Updated Template design Adjusted template to better describe eCOS examples versus required sections	13 Feb 2015
QA-1356-T3	Version 03	Emily Malok Instructional Designer	Not Used. Iterated to bring template up to the same version as the SOP (changed guidelines)	19 May 2017
QA-1356-T3	Version 04	Emily Malok Instructional Designer	Updated the company name and branding for the product	19 May 2017
QA-1356-T3	Version 05	Emily Malok Instructional Designer	Updated revision due to update of associated SOP	22 Dec 2017
QA-1356-T3	Version 06	Emily Malok Instructional Designer	Updated revision due to update of associated SOP	30 May 2018