


Document Title: External Release Notes		
Product: IBM Clinical Development v2018.7.2.0	Document Version: 1.0	
Area: Development	Document Type: Template	

Release Notes

IBM Clinical Development v2018.7.2.0

Release Date: 19 June 2018

OVERVIEW

Purpose:

This document provides an overview of IBM Clinical Development v2018.7.2.0 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 ALERT

Starting in June 2018, the version identifier for IBM Clinical Development will be changed. The previous format YYYY.A.B did not allow for easy identification of a scheduled major, minor or patch release type, since all were grouped in the 'A' sequence. This led to concerns from customers. Future releases will follow the format YYYY.A.B.C, where the 'A' sequence is scheduled major releases, the 'B' is scheduled minor or patch releases, and the 'C' sequence is unscheduled releases. This does not impact version content and the validation, release, and rollout processes for each version remain the same. This version – 2018.7.2.0 – is the first minor release related to version 2018.7.0; however, a previous unscheduled patch was recorded as 2018.7.1, so the 'B' sequence was updated to '2'.

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VERSION DETAILS

The enhancements and features for IBM Clinical Development v2018.7.2.0 are a direct result of your response to the system.

1. LANGUAGE SUPPORT: ADDITION OF CHINESE (TRADITIONAL), CATALAN, AND ARABIC

Starting with the release of v2018.7.2.0, Chinese (Traditional), Catalan, and Arabic are being added to the languages available within IBM Clinical Development. As with all language support, the languages can be used:

- General User Landing Page system labels are displayed in language selected
- EDC users will see system labels in language selected if language is active on study design
- EDC users can see study-specific information in language selected if language is active and information has been provided in study design
- Designers will see language selected on My Profile and in any study EDC-related access
- The team level landing page and designer remain in English, regardless of the user's language selection

2. GO LIVE: ORDER DATES INCLUDED IN PROCESS

Order Date, the date a quote is created, will now be taken into account when a user attempts to execute the quote or associate it to a study for Go Live.


For Usage Based orders, an order can be used for Go Live if...

- The Rate Card is active and the order is less than 365 days old
 - The Rate Card is inactive and the order is less than 365 days old
- ...whether or not a study has already been associated to the quote/order.

For Subscription orders, a Rate Card must be active, but there is no Order Date or association requirement. The Order cannot be closed, however.

3. PERFORMANCE: MEDICAL CODING AND V2 DATA EXPORTS

The prior release of IBM Clinical Development v2017.8.0 (August 2017) included a fix to adjust the query used to capture medical coding data into the coding tables in V2 Data Exports. This fix was necessary because of Oracle issues which caused export failures. With the recent update to Oracle (April 2018), the root issue was

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3. PERFORMANCE: MEDICAL CODING AND V2 DATA EXPORTS
corrected and now the fix is causing intermittent export issues. The 2017.8.0 fix is being reverted to restore original behavior and enable successful generation of exports with Medical Coding data.

4. CONFIGURATOR: UPDATE DESCRIPTIONS AND INSTRUCTIONS
Previous releases updated the Configurator options to reflect current offerings and contract services. Some of these options did not provide enough information for users to accurately select or estimate their needs. The following areas are being updated:

MAIN


- Build It Yourself
- Have Us Build It

MODULES

- Safety Reports?
- Smart Reports?
- Training Video?
- Additional Languages?
- File Uploads?
- Data Imports/Application Programming Interface ("API")?
- Advanced Monitoring?
- Study Manager?
- Training Material?
- Number of non-English (US) languages that will be enabled
- Medical Imaging Exams (DICOM)?
- PDF Generation?
- Training Tracking?
- Trial Testing?
- Available Languages
- Subject Diaries / Electronic Patient Reported Outcomes (ePRO)?

TRAINING/SERVICES

- Choose Training Type:
- Number of Training Days
- Randomization Training
- Lab Normals Training
- How many certifications will you require?
- Study Testing Training
- Cohorts Training
- Advanced Expression Editor Training
- Number of trainees
- Dispense Training
- Medical Coding Training
- EAM Training

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- 4. CONFIGURATOR: UPDATE DESCRIPTIONS AND INSTRUCTIONS**
- Safety Reporting Training
 - End User Training
 - Training - Additional Day
 - ePRO Training
 - Advanced Reporting Training
 - Training - Additional Instructor
 - Mid Study Update Training
 - Data Migration Training

5. CONFIGURATOR: INCLUDE EAM EVENT CHARGES FOR IBM PA CONTRACTS

Starting with the release of v2018.7.2.0, IBM Passport Advantage (PA) contracts will be able to quote Endpoint Adjudication use for a study. The quote will include the module fee and a per event calculation. This will require users to provide the estimated number of events in the Configurator. This change will also be included in checkout and PDF outputs.

6. DATA EXPORTS: UPDATE LIBRARY TO COORDINATE WITH SFTP SERVERS

Some SFTP transfers stopped working previously due to issues with server agreements on encryption. Insecure algorithms used for encryption are blocked to protect IBM Clinical Development, but other valid algorithms were being blocked because the definitions in the system were outdated. Some users were able to work around the block by updating their servers but this did not work for all studies. With the release of v2018.7.2.0, the IBM Clinical Development library is being updated. This will enable additional algorithms and resolve the issue for customer with valid transfer information.

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REVISION HISTORY FOR CONTENT OF THIS DOCUMENT

PRODUCT	REVISION #	AUTHOR/TITLE	CHANGES	CREATED DATE
IBM Clinical Development v2018.7.2.0	Version 1.0	Emily Malok Instructional Designer	Initial Version.	08 Jun 2018

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: <ul style="list-style-type: none"> 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