


Document Title: External Release Notes		
Product: IBM Clinical Development v2018.10.0.0	Document Version: 2.0	
Area: Development	Document Type: Template	

Release Notes

IBM Clinical Development v2018.10.0.0

Release Date: 14 December 2018

OVERVIEW

Purpose:

This document provides an overview of IBM Clinical Development v2018.10.0.0 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 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 early in 2019. 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. More details will be provided as they become available.

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2. 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. The support will be removed early in 2019. A specific date has not been determined yet, but users should review their internal processes to determine any impact. More details will be provided as they become available.

COMING SOON


The following changes are included in IBM Clinical Development v2018.10.0.0 in preparation for a formal debut in 2019.

1. INTRODUCING: SMART REPORTS WITH IBM COGNOS

Leveraging our integration with IBM, we are connecting IBM Clinical Development to the IBM Cognos Analytics platform. This will eventually replace our use of SAS Visual Analytics and will provide a new spectrum of data visualization and analysis tools.

Designers will be able to access through a link on the landing page in IBM Clinical Development. For users of Smart Reports with SAS-VA, they can access both modules via separate links. The new module will include standard data tables, study-defined data tables, and the ability to upload data directly into Cognos. Designers can then use calculations, views, and other tools to combine, define, and transform the data. Reports will be available in the study EDC by role.

As we begin 2019, more information will be coming about Cognos training and access. If you are interested in the new Smart Reports with Cognos module, please contact your Solution Manager or IBM Seller or submit a request through Support. We are excited by this new offering and new benefits of our work as IBM.

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VERSION DETAILS

The enhancements and features for IBM Clinical Development v2018.10.0.0 are a direct result of your response to the system.

1. GENERAL EDC: PROVIDE BOTH PAGE STATUS AND QUERY STATUS ICONS

To enable users to perform their work more efficiently, feedback reported that both the page status and the query status should be shown. Currently, query status is only displayed on the Subject List and Subject View levels when there is a query open. Regular page status icons are restored once the query enters an Answered or Closed status. To clarify statuses, both a page status icon and a query icon (if queries are present) will be displayed. The query icon will default to Open if at least one is in Open status, Answered if none are Open but at least one is in Answered status, and Closed when all queries are in Closed status.


For consistency, this will be applied across the Roll-up View, Subject Grid, Visit Pages navigation, Repeating Page Summary, and EAM locations.

2. SUBJECT VIEW: ENABLE COLLAPSE/EXPAND FOR REPEATING PAGES

While repeating pages can collapse/expand in the left navigation panel when viewing a CRF page, the main Subject Grid lists each repeat record separately. On a study with a large number of repeats, this can make the Grid cumbersome to use. With the release of v2018.10.0.0, a collapse/expand option is being added to repeating pages on the Grid. The new default will be the 'minimized' or collapsed view and a count of records will be included beside the summary page icon.

3. PAGE NAVIGATION: ADD PREVIOUS/NEXT OPTIONS

To facilitate easier movement between pages, 'Next' and 'Previous' links are being added to the top of the CRF pages. The new links will move between pages in the same visit, including repeating records, but not between different visits. The summary page and any existing repeat records are treated as individual static pages for navigation. Please review the user manual for specific details on how the 'Next' and 'Previous' work related to repeating pages.

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4. QUERY MANAGEMENT: MULTIPLE ENHANCEMENTS BASED ON FEEDBACK

In v2018.8.0.0 in August 2018, the query management tools in EDC were updated. Feedback received from users has prompted several updates.

1. The position of the query pop-up has been adjusted so that it does not cover the associated question and data
2. Keyboard navigation for the query dialog has been updated (including the back link, new status, and comments)
3. The ISSUE box has a larger font for easier reading
4. The scroll on the Comments section will automatically display the newest or latest action/comment. The order of comments remains original/first down to latest.
5. The study role of the users is added in the Comment next to the user's name
6. When the query pop-up is accessed from the Query Metrics report, a link has been added to access the CRF page
7. When the query icon is clicked to open and then clicked again without any action, the query pop-up will close

5. QUERY MANAGEMENT: ENABLE DOWNLOAD OF QUERY HISTORY/COMMENT DIALOG


The actions taken and comments provided for a query are captured in the query history, a dialog viewable on the query itself and also included in Page PDF or Subject PDF documents. With the release of v2018.10.0.0, a link is being added to the individual query to download a PDF copy of the query history/comments.

6. QUERY MANAGEMENT: ALLOW RESOLUTION ON DELETED PAGES

When a page is marked deleted, the queries on the page are held in whatever state they were in when the action was completed. This can cause problems for study teams that need to resolve all queries before they close the study. These teams need to ensure that any issue brought up in the query is either resolved or no longer applicable. To assist with this task, queries on pages marked deleted can be edited and updated to a status meaning Closed. New queries cannot be added to the page, so if further cleaning is needed, a new query should be added to a non-deleted page.

7. QUERY MANAGEMENT: REINSTATEMENT OF AN ISSUE AND QUERY TEXT

With the updates to query management in v2018.8.0.0 (Aug 2018), the add query dialog was simplified to only use the Query Type and a Query Text box. This removed

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7. **QUERY MANAGEMENT: REINSTATEMENT OF AN ISSUE AND QUERY TEXT**
the old 'Subject' or 'Issue' label. Feedback indicates that some study teams used the separate 'Issue' label to route queries and identify urgency. To enable this process, an attribute has been added to the Design Attributes (Optional) in the v2018.10.0.0 release. If the attribute is YES, separate 'Issue' and 'Query Text' fields will be provided during the add query dialog and it will be mandatory for all query types.

NOTES:

- If not implemented, the adding a query will only require (a) Query Type and (b) Issue.
- If the query was created when the 'Issue' field was not available and the 'Issue' field is now required, the same details will be used for both Issue and Query Text.
- If the user has the permission to update the non-system query type for an existing query, that user will be able to edit the 'Issue' field if needed. The edit will be captured in the query history.


8. **SOURCE DATA VERIFICATION: MOVE THE 'MARK ALL' OPTION**

When performing Source Data Verification (SDV) or Customizable Field Indicator review, the 'Mark All' option is located at the top right of the page; however, a user reviewing a page usually ends up at the bottom of the page. In addition, the SAVE button is at the bottom of the page. To address this issue, the 'Mark All' box is being moved to the bottom of the page, to the left of the SAVE and CANCEL buttons. Users can still mark individual SDV/CFI boxes during review.

9. **SITE MANAGEMENT: ENSURE CONSISTENT LENGTH BETWEEN DATA ENTRY AND IMPORT**

When entering Site details manually, the Site Name field allowed up to 50 characters. However, when importing a site, the Site Name was limited to 200 characters. The 50 character limit caused issues for several studies, but the import was not always practical. The inconsistency also caused confusion. To resolve the issue, all Site Name input (manual or import) is now 200 characters.

IMPORTANT: This change also increases the character length in the columns in the export table. If column width is used in back-end processes (post-IBM Clinical Development), please review for impact.

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10. LANGUAGE SUPPORT: SUPPORT ADDITIONAL LANGUAGES AND DIALECTS

With the release of IBM Clinical Development v2018.10.0.0, fourteen additional languages are being added to the system. Some of these are considered a dialect or regional/social variation of a language. Where this is the case, an additional backup has been implemented. For 'parent' languages, if a translation is not available, the system defaults to English (US). For 'dialect' languages, if a translation is not available, the system defaults to the 'parent' language (identified below) and then to English (US) if needed.

Language	System Label	Default Parent
Spanish (Argentina)	Español (Argentina)	Spanish
Spanish (Colombia)	Español (Colombia)	Spanish
Spanish (Mexico)	Español (Mexico)	Spanish
Arabic (Egypt)	العربية (مصر)	Arabic (Saudi Arabia)
Arabic (Lebanon)	العربية (لبنان)	Arabic (Saudi Arabia)
Arabic (Kuwait)	العربية (الكويت)	Arabic (Saudi Arabia)
Arabic (United Arab Emirates)	العربية (الإمارات المتحدة)	Arabic (Saudi Arabia)
English (Australia)	English (Australia)	English (UK)
English (Ireland)	English (Ireland)	English (UK)
Portuguese(Brazil)	Português (Brasil)	Portuguese
Spanish (United States)	Español (Estados Unidos)	Spanish
English (Israel)	English (Israel)	English (UK)
Arabic (Israel)	العربية (إسرائيل)	Arabic (Saudi Arabia)
Russian (Israel)	Русский (Израиль)	Russian

11. TRAINING TRACKING: REWORD TRAINING COMPLETION LINK

When a user is assigned training through the Training Tracking module, the link 'Continue to Study' is displayed when they complete their assignments. The link completes the training and marks the user's account. However, because the blue menu tabs are displayed, the 'Continue to Study' link is sometimes overlooked and users access the study directly. Since this can cause errors in applying training completion, the 'Continue to Study' link is being renamed. The new text 'Click here to complete your training program' better indicates the need to click the link before moving into the study tasks.

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12. V1 DISPENSE: ENABLE THE ADVANCED EXPRESSION EDITOR FOR FACTOR DEFINITION

Feedback indicates that some studies require advanced expressions for their dispense factors and these cannot be created with the current factor tools. To support these studies, the Advanced Expression Editor is being enabled for the Dispense module. The advanced expressions can be used alone or can be used in conjunction with factors defined using the traditional tools. The advanced expressions also allow the factor to include details on the current dispense page (even if it is a repeating page record).

13. V1 DISPENSE: SHIPPER-TO-SHIPPER BATCH ASSIGNMENTS

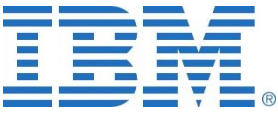
Previously, when tracking a Shipper-To-Shipper order, the receiving shipper is checked for batches with the same item type and expiration date to assign the kits to. However, some studies have multiple batches with the same kit type and expiration date, so the check is not sufficient. With the release of v2018.10.0.0, the system will identify the common origin of a batch by internal identifiers (which cannot be changed by users). The transferred items will be assigned to the batch with the same origin, not just the same type and expiration.

14. EAM: SORT USER LISTS BY LAST NAME

Currently, the list of Event Assignee and Adjudicators for an event are in random order. This can make it difficult to find the specific user needed and can inadvertently cause errors. To assist users, the dropdown lists will now be sorted by the last name of the user (users are listed as last name, first name). Also, a search field is included at the top of the dropdown list to enable quicker selection. Just begin typing the name to filter the dropdown options.

15. EAM: ADD MEDICAL REVIEWER TO EVENT PREPARATION PROCESS

Often, a Medical Review of the subject information is performed prior to the beginning of the Adjudication process. If CRF pages are involved, they can be designated as Medical Reviewer, but the tracking of which reviewer is assigned has been done outside the system. To integrate this process into the Endpoint Adjudication module, a new role has been added (the 'Medical Reviewer' role permission). If the team chooses to use the role, the designer can mark 'Enable Medical Reviewers Assignment' on the coordinating rule(s). In the module tab in EDC, the reviewer is designated on the main event box below the Assigned To

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- 15. EAM: ADD MEDICAL REVIEWER TO EVENT PREPARATION PROCESS**
dropdown for the coordinator. The reviewer will be displayed on the summary tables and be accessible via the 'Assigned to Me' lists.


NOTE: There is no restriction to accessing events based on the Medical Reviewer assignment.

- 16. DATA MIGRATOR: ADD SUPPORT FOR JSON PARSING**

Feedback indicates that some studies will implement JSON file imports and would like to utilize the Data Migrator features to process them. JSON (JavaScript Object Notation) is a format for structuring data for transmission instead of using a Delimited format. To accommodate this, v2018.10.0.0 adds several new attributes for Mapping Configurations and File Sets including support for UTF-8 w/ BOM encoding.

- 17. CONFIGURATOR: ADD WARNINGS FOR CUSTOMERS**

The Planned Study detail and Configurator have been updated to post a message when a Master Service Agreement has expired and a new one is required. This will assist users with accessing the Configurator when needed and obtaining accurate quotes.

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REVISION HISTORY FOR CONTENT OF THIS DOCUMENT

PRODUCT	REVISION #	AUTHOR/TITLE	CHANGES	CREATED DATE
IBM Clinical Development v2018.10.0.0	Version 1.0	Emily Malok Instructional Designer	Initial Version.	20 Nov 2018
IBM Clinical Development v2018.10.0.0	Version 2.0	Emily Malok Instructional Designer	Updated #4 to clarify changes to query management (Comment section display).	11 Dec 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