


Document Title: External Release Notes		
Product: IBM Clinical Development v2018.8.0.0	Document Version: 1.0	
Area: Development	Document Type: Template	

Release Notes

IBM Clinical Development v2018.8.0.0

Release Date: 17 August 2018

OVERVIEW

Purpose:

This document provides an overview of IBM Clinical Development v2018.8.0.0 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.

VERSION DETAILS

The enhancements and features for IBM Clinical Development v2018.8.0.0 are a direct result of your response to the system.

1. **PAGE STATUS: ABILITY TO EXCLUDE PAGES FROM REGULAR WORKFLOW**

Customer feedback indicated that there is a need to manage different page status workflows in some studies. Previously, designers used combinations of multiple roles and multiple page/field role permissions to handle this. With the release of v2018.8.0.0, designers will now be able to exclude individual pages from a specific role-status update. For example, if the Investigator needs to review the Lab Results page after the Coordinator enters it, the Coordinator may be blocked from updating the page from 'Entered' to 'Finished'.

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2. PAGE STATUS: AUTOMATIC UPDATE BASED ON SDV COMPLETION

To increase efficiencies, designers can now set the system to automatically update a page status once SDV is completed. By checking the attribute “Set to on SDV Completion?” for a page status, the update will occur when all relevant SDV flags are checked and there are no Open queries. The page status will be reverted if SDV is removed (either manually or due to a data update) unless this attribute is applied to the first page status after ‘No Data’.

3. VISIT SCHEDULE RULES: RULE MANAGEMENT UPDATES

The Visit Schedule Rules have three updates to assist designers with management on their studies. The first is that the latest revision will be displayed by default on the rules page. Designers still have the option to access other revisions by choosing the Rules link from the Revision or other Visit Schedule pages or by choosing the revision from the View dropdown. Second, the Add box has been moved to the top of the screen for easier access. Last, the batch function that previously allowed for multiple delete has been updated to allow multiple activate or multiple inactivate.

4. MID-STUDY UPDATE: BATCH EXECUTE CALCULATIONS


AutoCalc fields are only calculated when their page is saved, so recalculating when a remote value is changed or when a mid-study update is applied means that users must manually resave pages. To assist, an option has been added to the Study Updates to batch update the AutoCalc fields.

5. LANGUAGE SUPPORT: GENERATE A SUBJECT PDF IN NON-ENGLISH LANGUAGE

IBM Clinical Development supports over 30 languages and study designers can provide corresponding study-specific translations for their users. Despite this, the Subject PDF was only available in English.

With the release of v2018.8.0.0, Subject PDFs can be generated in non-English languages:

- In EDC, the Subject PDF will be generated in the language selected by the user to access the study. A limited number of elements may not be translated – for example, the reason within the Audit Trail if entered in English or entered as a system comment.
- In the Designer, the Subject PDF has an additional attribute for the selection of language. The dropdown for this includes all active languages in the study.

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5. LANGUAGE SUPPORT: GENERATE A SUBJECT PDF IN NON-ENGLISH LANGUAGE

NOTE: If the language selected is not available for any element or is not active for the study, the Subject PDF will be generated in English.

6. SUBJECT LIST: ADD DOES NOT EQUAL (<>) TO SUBJECT STATUS FILTER OPTIONS

On the Subject List, filters are available to locate specific subjects. Among these, the 'does not equal' (<>) operator is available for Site Name and for numeric or date values. With the release of v2018.8.0.0, this filter option is also available for Subject Status. The filter is still 'case-sensitive' for all criteria.

7. QUERY MANAGEMENT: UPDATED STAT TICKER AND HOME PAGE ACCESS


With the release of version 2018.8.0.0, users will now be able to view and access queries from the EDC Home page. The Stat Ticker has been updated to group queries by type and to display the time period and patients at the left. If the user has access to a query metrics report, they can click any value on the ticker and open the report pre-filtered to their selection.

8. QUERY MANAGEMENT: UPDATED QUERY METRICS REPORT

The Query Metrics report has been updated and streamlined. The specific content is determined by the study design, but options have been simplified to include search by free text, filter by type/status (with multiple selection), and filter by Site. Downloaded copies will reflect the filters (but not the sort or search). Users can access individual queries via a pop-up dialog to review or update. Depending on permissions, users can also select one or more queries and update the status in bulk.

9. QUERY MANAGEMENT: IMPROVED MANAGEMENT VIA POP-UP DIALOGS

Traditionally, query management was done on separate query screens. This meant users were unable to view the CRF data while answering or resolving the query. To address this issue, version 2018.8.0.0 moves the query management to a pop-up dialog. The new dialog is displayed to the side of the CRF page, so data is visible, and the pop-up has been simplified to emphasize what action is needed. Users will see a dropdown box of status options based on their permissions and a corresponding comment box. Prior actions and comments are displayed in a chat or conversation

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9. QUERY MANAGEMENT: IMPROVED MANAGEMENT VIA POP-UP DIALOGS
 style above the dropdown. These changes apply to all query types and for both adding queries and editing them.

10. DOCUMENT FILES: LIST OF ACCEPTABLE FILE EXTENSIONS FOR MARKUP AND ENDPOINT ADJUDICATION

The Document Markup tools (Page/Field/Event Attachments) and Endpoint Adjudication Dossiers allow for upload and manipulation of document files. Some file types are not allowed due to tool limitations, system security, or other issues. The following file extension types are supported:

BMP	CSV	DOC	DOCX	EML	GIF	HTM
HTML	JPEG	JPG	ODG	ODS	ODT	PAGES
PDF	PNG	PPT	PPTX	RTF	TIF	TIFF
TXT	XLS	XLSX	XML			

11. SITE DOCUMENTS: EMAIL ALERT ON UPLOAD


Site Documents are an optional tool to collect files and documents at the site level, rather than for an individual subject. Depending on the purpose, an email notification may be valuable to alert study team members when a document is uploaded. With the release of v2018.8.0.0, Study Designers can identify roles that should receive an email notification.

NOTES:

- Notifications will be based on site permissions.
- If the file uploaded is flagged as ‘Unblinding’, the alert will not be sent to blinded role users.

12. TRAINING TRACKING: ABILITY TO WAIVE TRAINING FOR INDIVIDUAL USERS

The Training Tracking module enables study teams to assign training to users based on Role and/or Site on a study. However, if a user participates in more than one study, they may be assigned the same training multiple times. With the release of v2018.8.0.0, study teams will be able to ‘waive’ completion of training for an individual user on a study. On the Update User screen, a designer can click ‘Waive Training’ beside Trainings Completed and confirm. This will mark the user as Completed.

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13. RANDOMIZATION: INCLUSION OF RANDOMIZATION DATE ON RAND LIST

A recent system change updated all randomization records, causing all the Last Modified Dates to reflect the date of the system change, not any associated Randomization Dates. With the release of v2018.8.0.0, a new Randomization Date column has been added to the List so that both the Rand Date and the Last Modified Date are displayed

14. RANDOMIZATION: INCLUSION OF RANDOMIZATION DATE ON DAT_RAND TABLE

A recent system change updated all randomization records, causing all the Last Modified Dates to reflect the date of the system change, not any associated Randomization Dates. With the release of v2018.8.0.0, the Randomization Date is being added to the DAT_RAND table as the RANDDT variable. The new column is located between SUBNUM and STRATAID. Randomization dates that occurred prior to this release will be taken from the audit trail.


IMPORTANT: This will impact all data exports with the DAT_RAND table and therefore may impact any external programs that rely on the column order.

15. V1 DISPENSE: RE-ASSOCIATE CANCELLED ITEMS TO ORIGINAL SHIPPING DETAILS

Previously, if an item was assigned to a shipment that was then cancelled, the shipment number and 'To' fields on the item page were left 'blank'. This could impact filtering items based on shippers or shipments if the item was previously shipped (i.e. manufacturer to local depot). With the release of v2018.8.0.0, if an item was previously shipped and then added to a shipment that was cancelled, the item will display the original shipping information. If the item was not previously shipped, the shipment number and 'To' fields will be blank.

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item will display the original shipping information. If the item was not previously shipped, the shipment number and 'To' fields will be blank.

17. MONITOR MANAGEMENT: PROVIDE EXPORT FILES

Traditionally, Monitoring Management details are only visible within the system and there is no option to download the information. With the release of v2018.8.0.0, the Monitor Management Export (Excel) report is being added to the Study Documents/Exports list. This generates a multi-tab file of information about the Monitoring Visit and Visit Documentation, including audit trails.

18. DICOM: ACCEPT THIRD-PARTY IMAGES


Some medical images used by study sites are not fully compliant with DICOM. Because of this, users were unable to upload the files to IBM Clinical Development. The system is being updated to 'fix' the non-compliant issue to allow for upload. The change is for the web-based upload process only. Due to the way files are processed, the legacy uploader could not be changed and should not be used for non-compliant images.

19. ADMIN: ENHANCE TEAM MANAGEMENT FUNCTIONALITY

Team Management has been primarily handled through IBM staff - either Support, your IBM Seller, or your Solution Manager. Many customers have requested more access to management, to better control their resources and remove access when designers no longer require it. IBM Clinical Development v2018.8.0.0 includes several enhancements to facilitate this.

All management options require the 'Team - Administer' permission on the user account. This permission can only be applied by IBM and requires approval from the user's organization. Users with the 'permission are able to access the View Team Details page (link available on the Team Studies home page) and see the users currently assigned to the team. Team-level users can be added using to the team via their user ID. General Users cannot be updated to a Designer or other team-level role and added to the team in one step.


A new 'Remove' option is being added to the user section. This will appear as an [X] button beside the user and provide three options when clicked:

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- 19. ADMIN: ENHANCE TEAM MANAGEMENT FUNCTIONALITY**
- Remove: Removes the user from the team only
 - Remove and Disable: Removes the user from the team and disables their access to studies on the team
 - Cancel

20. ADMIN: TEAM USER MANAGEMENT REPORT

As part of the Team Administration enhancements, a new User Management Summary report is being added to the Team Reports tab. This report will enable users to view all non-subject access records to studies on the teams they have access to, including sort and filter, and activate or deactivate the study users in batch. The report can also be downloaded in Excel format. Access requires the 'Team - Administer' permission on the user account. This permission can only be applied by IBM and requires approval from the user's organization.

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REVISION HISTORY FOR CONTENT OF THIS DOCUMENT

PRODUCT	REVISION #	AUTHOR/TITLE	CHANGES	CREATED DATE
IBM Clinical Development v2018.8.0.0	Version 1.0	Emily Malok Instructional Designer	Initial Version.	01 Aug 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