Document Title: External Release Notes		
Product: IBM Clinical Development v2018.7.0	Document Version: 1.0	
Area: Development	Document Type: Template	

Release Notes

IBM Clinical Development v2018.7.0
Release Date: 18 May 2018

OVERVIEW

Purpose:
This document provides an overview of IBM Clinical Development v2018.7.0 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

In an effort to be more transparent about the use of your personal information, a Data Privacy Notification is being included for all users. This will outline how the information we collect about you during the account process is used. This does not apply to information collected in a trial by your sponsor or their vendors.

- Existing Users
  On the first connection (login) after the release, the consent information is provided. Users should review and select 'I agree' or 'I Disagree'. Please note, if 'I Disagree' is selected, the system access is not available.

- New Users
  After completing the third Secret Question/Answer, the consent will be displayed. Users will have the option to select 'I agree' or to choose 'Back' or 'Return to Login'. Unless 'I agree' is selected, the account will not be created.

Additional Notes:

- ePRO Subjects will also be prompted to consent. The process will work the same as regular users (Existing/New) but the consent text has been adjusted for the subject account.
- All consent information and buttons are available in all languages supported by IBM Clinical Development

VERSION DETAILS

The enhancements and features for IBM Clinical Development v2018.7.0 are a direct result of your response to the system.

1. PAYMENT MILESTONE REPORT UPDATE

If your study is using the Payment Milestone report, it currently displays the Study ID, Site ID, Subject ID, Milestone ID, Record Number, Trigger State, and Visit Reference Date in columns. To facilitate your payment process and enhance your potential integration with CTMS, the column Visit Name has been added at the end of the report.

2. BLANK CRF MAY BE BOOKMARKED BY DOMAIN

Depending on the settings for your study, the Blank PDF generated in EDC can now benefit from the 'Bookmark by Domain' option instead of just the standard organization. This has been available on Subject PDF and is now being extended. By Domain indicates that the pages will be grouped by page type, not by their location in the visit or visit schedule. The grouping by visit will also be included.

3. DISPENSE: ABILITY TO ADD UP TO 10 RESUPPLY RUN JOBS

Users with appropriate permissions will now be able to schedule up to 10 resupply run jobs per study. This will help to cover different time zones on global trials. For instance, allowing twice daily scans to accommodate shippers in multiple countries. Recurring jobs should be at least 1 hour apart to enable one request to finish before the next starts.

NOTE: The time for the recurring job definition remains in GMT time.

4. UPDATE STUDY SIGN-UP PDF FOR USER ID DETAILS

Traditionally, the Study Sign-Up PDF was available for study teams to provide to their study users. It contained information about signing up for an IBM Clinical Development account and for requesting access to that study. Feedback indicated that the study users needed further guidance on creating accounts.

With the release of v2018.7.0, the following instructions will be included for the User ID creation:

- IDs cannot contain spaces or special characters such as ` ~!@#$%^&*()+|}{":?><,./;'[]\=
- Do NOT use the Study Name or Passcode provided for your study.
- You will not be able to change your User ID at a later date.
- It may be rejected as it must be unique within the system, if this is the case, please pick another one.

5. ADD SUGGESTIONS OPTION FOR GENERAL USERS

IBM considers feedback and suggestions a vital part of our product management and user experience. General users can access the main suggestion page via the Training/How-To's link and to add ticket requests. Suggestions and feedback can always be submitted via study teams and Support as well.

5. ADD SUGGESTIONS OPTION FOR GENERAL USERS

IMPORTANT: For technical issues or urgent questions, users should contact Support at icdhelp@us.ibm.com rather than use the suggestion site.

6. UPDATED VALIDATION/ERROR CHECKING FOR VISIT SCHEDULE RULES

Rules such as the Payment Milestone Rule, Visit Time Window Rule, and Periodic Send Alert Rule require visit-level context; however, many of the operators/operands in the Advanced Expression Editor are page-level. Incorrect behavior can be seen when these rules have incorrect expressions. To help combat this issue, the system will filter out page-level operators/operand for visit-level rules. Also, the Error Widget will check for invalid operators/operands on the rules and display errors as needed.

7. OCCASIONAL BLANK PAGES IN SUBJECT PDF AND BLANK PDF

Occasional blank pages were seen in both Subject PDF and Blank PDF documents, primarily when the page prior had content to the bottom of the page or when the page was repeating but no records were present. The system has been updated to better manage the PDF generation in these cases and prevent blank pages.

8. SUPPORT FOR IMAGES WITHOUT MODALITY TAG

Previously, when a user uploaded an image without a modality tag, the file was uploaded but an error was displayed. This occurred whether the image was uploaded via the installed Uploader App or the web-based uploader. With the release of v2018.7.0, the system will display the image file name with a question mark (?) at the beginning (where the tag would normally be) instead of displaying the error message. This does not impact the upload functionality.

9. VISIT TIMELINE REPORT UPDATED TO ENFORCE FONTS

When the Target date is displayed on the Visit Timeline Report, it should follow the following rules:

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- The Target Date displayed in black un-bold indicates that the data is not late yet (i.e. within window or pending).
- **The Target Date displayed in black bold indicates that the record is Performed Inside Window**
- The Target Date displayed in red un-bold indicates that the data is late (Overdue)
- **The Target Date displayed in red bold indicates that the record is Performed Outside Window (before Start date or after End Date)**

10. EAM: DELECTED DOSSIER AND EXCLUDED ADJUDICTOR ACTIONS ADDED TO FULL HISTORY

When a new dossier is created or uploaded, the previous version is automatically archived. Once archived, the dossier can be deleted. With this release, archive and delete actions will be captured in the EAM Full History in EDC and the EAM History Report (CSV).

The second change adds information about an Adjudicator who has been 'excluded' for an event to the Full History. Previously, the Full History only contained records for the de-excluded actions. With this release, both excluded and de-excluded actions are captured in both locations.

11. CONFIGURATOR: IBM CUSTOMER NUMBER (ICN) ADDED

As part of the continuing transition to IBM financial and contractual procedures, the IBM Customer Number (ICN) will be added to the main page, checkout page, and PDF generated in the Configurator. This information is to assist customers and IBM staff with processing orders.

12. PERFORMANCE UPDATES

- All Queries Summary Report
  This release contains updates to optimize the data query responsible for providing the query details and comments and thus better manage the

12. PERFORMANCE UPDATES

report. This performance update is applied to both Excel and PDF outputs as well.

- Subject Grid/CRF Display on Large Endpoint Adjudication Studies
  Review of the processes found that the system was checking for permissions across all subjects, not just on the one being accessed. This caused the slowness and was the focus of the update in v2018.7.0. The system has been adjusted to only check permissions as needed for the user's current actions.

- Design Import/Flush
  During the Import Full Study process, the system performs a flush of all current process and design. By adding additional indexing to the project tables and improving the resource management associated with the imports, the system will process faster.

- Data Tracker Study Report
  In large studies, the Data Tracker report can be slow to display or update or can eventually time out if the system resources are overloaded. To alleviate this issue, the request to retrieve the data has been updated to perform better and improve the speed of processing.

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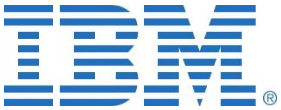
Product: IBM Clinical Development v2018.7.0	Document Version: 1.0	
Area: Development	Document Type: Template	

REVISION HISTORY FOR CONTENT OF THIS DOCUMENT

PRODUCT	REVISION #	AUTHOR/TITLE	CHANGES	CREATED DATE
IBM Clinical Development v2018.7.0	Version 1.0	Emily Malok Instructional Designer	Initial Version.	03 May 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: • 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