


Document Title: External Release Notes		
Product: IBM Clinical Development 2019.2.0.0	Document Version: 1.0	
Area: Development	Document Type: Template	

Release Notes

IBM Clinical Development 2019.2.0.0

Release Date: 22 March 2019

OVERVIEW

Purpose:

This document provides an overview of IBM Clinical Development 2019.2.0.0 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


The following change takes effect with the release of IBM Clinical Development 2019.2.0.0.

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. To keep IBM Clinical Development secure and provide users with a reliable experience, IE v9 and v10 users will no longer be able to access the system. This includes using a v9 or v10 emulator mode in a later version of Internet Explorer.

To fix:

Users will need to upgrade their Internet Explorer to v11 or to Edge to continue to use that browser with IBM Clinical Development. Alternately, they can use current

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- 1. REMOVAL OF SUPPORT FOR INTERNET EXPLORER (IE) V9 AND V10**
versions of Mozilla Firefox or Google Chrome. Other browsers, such as Safari, also work with the system.

VERSION DETAILS

The enhancements and features for IBM Clinical Development 2019.2.0.0 are a direct result of your response to the system.

- 1. ePRO: ALLOW ePRO PAGE TRIGGER BY DATA VALUE/EXPRESSION**

Previously, ePRO pages could be managed by Time Window rules related to number of days from a specific date captured in the CRF pages. This did not meet the needs of all studies. With the release of 2019.2.0.0, an optional "Activate Trigger" has been added to the Page is ePRO rule. This attribute uses the Advanced Expression Editor to define conditions when the ePRO Time Window Rules should be implemented.

How does this work?

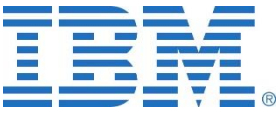
- The trigger will default to TRUE if there is no expression (meaning the Time Window rules are implemented without additional conditions). This enables the existing studies to maintain their current windows/behavior.
- The expression used must evaluate as BOOLEAN (TRUE/FALSE).
- If the trigger is defined and is TRUE for a patient, the time window rules will execute.
- If the trigger is defined and is FALSE or invalid for a patient, the time windows are not created.
- Diary data is not deleted, even if a trigger becomes false. If the trigger becomes false after the window is created, the window would only be deleted if the diary had not been completed or missed.

NOTE: An ePRO cannot be triggered from a repeating page. The Visit-Page must be a static page (can be in a repeating visit).

- 2. ePRO: NEW WEB EXPERIENCE RELEASED**

In order to provide a simpler, clearer method for patients to record diary data (ePRO), a new web experience has been created. Designers will be able to select the legacy format or the new interface in the Design Attributes (Optional) section.

In addition, designers setting up the New Interface can choose to enable drafts when using the 'Question-By-Question' delivery type. Drafts are a copy of the

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2. ePRO: NEW WEB EXPERIENCE RELEASED

patient's responses that are saved in the ePRO but not carried over to the CRF page. These can be re-accessed by the patient at a later time. Draft diaries must be completed within the window in order to be submitted. They will transfer to the CRF when submitted.

When previewing ePRO behavior in the designer, legacy design can view the legacy or new interface. Studies with the new interface can only preview the new interface.

The new interface will display diaries in 5 options:

1. Available: These diaries can be entered. They are either new (not started) or drafts (if enabled) and are within the defined window.
2. Upcoming: These are diaries that will be available later in the day (time has not been reached). This section does not display diaries for future days.
3. Complete: These diaries are submitted and can no longer be edited. They can be viewed.
4. Incomplete: The patient left the diary without saving and no draft was made (either not enabled or not appropriate type). These diaries cannot be viewed or edited.
5. Missed: This section shows the diaries that were not submitted within the window.

A History panel will also be available to review prior patient entries, such as status, time and the responses of completed diaries.


IMPORTANT:

At release, all studies in LIVE, LOCKED, or CLOSED status will remain in the legacy interface. All other studies will be set to the new interface. Designers can manually set to use the legacy interface if needed.

3. ePRO: DEFINING A PREFERRED LANGUAGE FOR SUBJECTS DURING ACTIVATION

To support patients using a non-English language and assist in implementing ePRO notifications in the local language, a new attribute will be collected during ePRO activation. This attribute (Language) will be required and is a dropdown of the active languages on the study. The value will be stored as the 'preferred language' for the patient.

What happens...

Document Title: External Release Notes		
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3. ePRO: DEFINING A PREFERRED LANGUAGE FOR SUBJECTS DURING ACTIVATION

...If a user wants to change the language? Users can update their preferred language on the Settings when they are logged in.

...If the preferred language is not available for a specific diary or element? The fallback language (if available) will be used or the element will be displayed in English. The diaries will not be blocked.

...If a user doesn't have a preferred language (i.e. existing user)? Their ePRO will remain the same. If they update their settings, they will be required to specific a preferred language, since it is a required field.

...If a user chooses a different language on the Login screen? If a preferred language is saved, it will be the display language, regardless of any selection on the Login screen.

NOTE: When a patient accesses the ePRO for the first time, the "Consent" dialog is displayed. This will be displayed based on the language selected on the login page.

4. ePRO: ENABLING LOCAL LANGUAGE FOR ePRO NOTIFICATIONS


As more patients access IBM Clinical Development in non-English languages, the notifications need to be available in their local language so all communication is clear. To implement this, the first step is to define the language for the patient. This is now done during activation (see enhancement above).

With the release of 2019.2.0.0, the following changes have been made:

- The Email Subject Line and Email Body attributes of the ePRO Time Window Rule is now available for translations.
- The translations will be used for both email notifications and push notifications.
- The notification uses the same fallback and default to English processes.

The impacted emails are:

- Study Access Request Received
- Study Access Updated: [STUDY_NAME]: [USER_FULL_NAME]
- User Settings Updated [USER_FULL_NAME]: [ACTION]:
- User Settings Updated: [USER_FULL_NAME]
- Verify your account
- Email address change detected
- Password Reset: [USER_FULL_NAME]
- User ID Information: [USER_FULL_NAME]
- ePRO Reminder

Document Title: External Release Notes		
Product: IBM Clinical Development 2019.2.0.0	Document Version: 1.0	
Area: Development	Document Type: Template	

5. SYSTEM QUERIES: RE-TRIGGER QUERY WHEN DATA IS CHANGED

Traditionally, a system query will fire when data meets specific criteria and then be manually closed or close automatically when the data is changed to be acceptable. If a user later changes the data again, only a query that was closed by the system will re-open. If a query was manually closed, the query does not re-fire because no automation is allowed after a user intervenes. Users requested that the manually closed queries also re-fire if needed, since not firing can lead to errors in data and extra work to monitor/resolve.

With the release of 2019.2.0.0, the system has been updated to allow re-opening. This is controlled by a new attribute on the Design Attributes (Optional).

When the attribute is YES:

1. System query has been answered or closed by any method
2. The data associated with the query is updated to trigger the query
3. The existing system query will move back to Open status

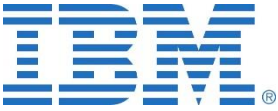
NOTE: When this is first implemented, there may be a large number of queries that revert to Open status, depending on the data in the study.

6. PROCESS: CUSTOMIZABLE eSIGNATURE STATEMENTS ENABLED

Users have reported that they use the eSignature process for multiple roles and purposes, so a single eSignature statement becomes a limitation to their study designs.

To implement multiple statements, the following changes have been made:

- The standard statement will still be collected on the Design Attributes (Required) and this will be used if no customized statements are defined.
- The customized statements will be defined on the page status. Since page status permissions are role-based, the statement can be applied based on the role of the user.
- A new column (Customized eSignature Statement) will be displayed in the Current Page Statuses that shows a checkbox for enabled and a text link Details to access the definition.
- The customized statements can be translated as with other study design.
- The customized statements can be combined with the Exclude Pages functionality.

Document Title: External Release Notes		
Product: IBM Clinical Development 2019.2.0.0	Document Version: 1.0	
Area: Development	Document Type: Template	

7. ENDPOINT ADJUDICATION: REMOTE VALUE DISPLAY FROM TRIGGER PAGE

Users reported the need to display information from the trigger page in the Endpoint Adjudication visit. Having users re-enter the details can lead to data entry errors and requires more data review. Since the trigger page is often repeating, this can limit the options to display the data.

With the release of 2019.2.0.0, the remote value control type is being adjusted for use with the Endpoint Adjudication (EAM) module. Designers can set up the remote value on a page in the EAM visit and define a source page field from the trigger page. When this is evaluated in EDC/Study Connect, the remote value is pulled from the trigger page associated with that EAM visit (as defined in the Visit Schedule rule), ignoring other repeats.

8. GENERAL: LOGIN PAGE HELP SECTION UPDATES


Currently, the Help Section (Need Help?) at the top right of the login page has options available in English. With the release of 2019.2.0.0, these will be translated and available in the language selected for the login. To assist with this, some minor UI changes have been made so that the language support and English remain consistent.

In addition, the Support website has been updated to connect to <https://developer.ibm.com/watsonhealth/ibm-clinical-development-support/>. The HOME link has been removed (obsolete) and the 'Helpful Videos' section has been renamed to just Videos.

NOTE: The footer with IBM Privacy and Copyright notices will not be translated.

9. LANGUAGE SUPPORT: IMPROVED ALERTS REGARDING LOGIN LANGUAGE AND STUDY LANGUAGE

Language support is provided at multiple levels. If the user is a general user and a non-English language is selected at login, the landing page and general system areas are displayed in the chosen language. Team landing pages are always displayed in English, but elements such as My Profile for team users can be displayed in the chosen language.

Document Title: External Release Notes		
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Area: Development	Document Type: Template	

9. LANGUAGE SUPPORT: IMPROVED ALERTS REGARDING LOGIN LANGUAGE AND STUDY LANGUAGE

If the study also has the language active, the system areas in the EDC/Study Connect will be displayed in the chosen language. If the study does not have the language active, the EDC/Study Connect will remain in English. The designer will always be in English.

Previously, a 'fallback' language was implemented to support dialects in ePRO studies. This is the parent language and would be used when the dialect translations are not available. If the parent language is also not available, then the system defaults to English.

With the release of 2019.2.0.0, the following improvements have been added:

1. If the platform and CRF are using the fallback language (login language is not active or not available), a message at the top of the screen indicates what language has been selected. It also includes a hyperlink to allow the user to change the language. The link displays a popup with the listing of language available for this particular study.
2. If the fallback language is not active/available, a message at the top of the screen indicate English has been selected (current behavior). After the release, a hyperlink will allow users to change the language if needed. The link displays a popup with the listing of language available for this particular study.


NOTE: The message and link to change is only displayed during the first connection to the EDC/Study Connect in that session. If the user moves to other tabs, the message is removed.

10. GO LIVE: PREVENT LIVE DEPLOYMENT IF CUSTOMER MSA/CSA HAS EXPIRED

An MSA is considered expired if the Customer MSA expiration date has passed or if the Customer MSA Date and IBM Agreement Start Date (CSA) are missing. These customers do not have an active contract to use IBM Clinical Development. Previously, this was not well-defined and did not have clear messaging in the system.

With the release of 2019.2.0.0, the following restrictions will occur if the MSA is expired:

- A user will not be able to use Go Live to deploy the study for live conduct.
- A user will not be able to access the Configurator to generate or review quotes.

Document Title: External Release Notes		
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Area: Development	Document Type: Template	

10. GO LIVE: PREVENT LIVE DEPLOYMENT IF CUSTOMER MSA/CSA HAS EXPIRED

- A user will not be able to execute an existing quote.

The following message will be displayed to the user when they attempt to perform one of these actions:

The [Customer Name] charge agreement is no longer valid due to the expiration of the governing Master Services Agreement. Please contact your Sales Representative to initiate a new Cloud Services Agreement.

11. STUDY REPORTS: IMPROVE ERROR MESSAGING FOR MEDICAL CODING REPORT

When a medical coding report already exists and the medical coding definition on the page is changed, an error needs to be displayed in the Widget to alert designers. Previously the error message was "Dict not found: 0", which was not clear to users and did not appropriately describe the issue. This message has been updated to "Bad configuration: No Medical Coding Dictionary found on control TAB.COL" so that users are able to locate and fix the issue.


12. CONFIGURATOR: UPDATE TRAINING OPTIONS TO INCLUDE MODULES

Previously, users could select Optional Module training to include in their General (Core) Training or their Mentor Build Training. This would enable them to get a full picture of the costs associated with their needs. However, this blocked existing customers from being able to request just the optional module training.

With the release of 2019.2.0.0, a new training option will be included. When "Only Solution Options Training" is chosen, users will provide the number of trainees, the number of certifications, and then select just the module(s) they need. A "None" option has also been added in case users select training and then change their mind.

13. CONFIGURATOR: UPDATES TO SAFETY REPORTING MODULE

Previously, studies using the Safety Reporting module were billed a fee for using the module and then a daily fee based on the number of reports. With the release of 2019.2.0.0, the daily fee will no longer be based on the number of reports. This change includes the removal of the 'How many safety reports will be generated' question from the configurator and an update to the quote checkout.

Document Title: External Release Notes		
Product: IBM Clinical Development 2019.2.0.0	Document Version: 1.0	
Area: Development	Document Type: Template	

14. COGNOS: UPDATES TO PERMISSIONS AND ACCESS

In an effort to improve performance and support single-sign-on access, the server management is being updated. In addition, several configuration changes are being applied to the server and Cognos side. These changes will improve user experienced when they have access to multiple projects and enable further scalability of the Smart Reports module.

15. COGNOS: INCLUSION OF TRAINING INFORMATION IN DAT_USER

The DAT_USER dataset has been updated to include information from the Training Tracking module. The following fields have been added:

- Training Completed (Y/N)
- Training Completed Date
- Training Revoked (Y/N)
- Training Revoked Date


Only the date corresponding to the current status of the training will be provided (i.e. if currently revoked, Completed Date is null). If the training is incomplete the both Completed and Revoked will be 'N' and the dates will be blank.

16. COGNOS: MULTIPLE PERFORMANCE AND PROCESSING UPDATES

Multiple updates are being made to the central tables and environments that support the Smart Reports with Cognos module. This includes changes to tracking tables, updates to triggers, code cleanup, and query updates. These changes will make the processing more efficient and improve performance as this module is rolled out to customers.

17. PERFORMANCE: IMPROVE SYSTEM QUERY COUNTS

When the system performs actions such as displaying the Build menu or the selected design area, a count of system queries is performed in the background. The project id for system queries is not indexed and this slows the system. With 2019.2.0.0, an index is being added to improve the speed of loading the designer menu and related screens.

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18. PERFORMANCE: SLOW QUERY DURING REVISION MOVES


When doing a Revision Move Jump or when displaying the details for a jump, the system reviews the codelist values associated with the revisions. The query used to access the details is old and needed to be optimized. With the release of 2019.2.0.0, the query has been updated to work faster and more efficiently.

19. PERFORMANCE: SLOW CSV EXPORT OR SUBJECT PDF GENERATION

In some circumstances, the generation and delivery of a CSV Export or Subject PDF can be slow. This relates to the resource management, but the team felt it could be improved, if not completely alleviated. The buffering was expanded to reduce any lags in the process.

20. PERFORMANCE: DESIGNER PAGE LOAD IMPROVEMENTS

To improve the display of pages in the designer, back-end support has been optimized to reuse resources and definitions. This will speed up the display for users. There is no change to the function of the designer pages or to the process of using them to design a study.

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REVISION HISTORY FOR CONTENT OF THIS DOCUMENT

PRODUCT	REVISION #	AUTHOR/TITLE	CHANGES	CREATED DATE
IBM Clinical Development 2019.2.0.0	Version 1.0	Emily Malok Instructional Designer	Initial Version.	08 Mar 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: <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