Release Notes

IBM Clinical Development 2021.7.0.0
Release Date: 22 October 2021

OVERVIEW

Purpose:
This document provides an overview of IBM Clinical Development 2021.7.0.0 released by the IBM Corporation on 22 October 2021.

Background:
IBM Clinical Development 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 several upcoming changes that users need to be aware of and prepare for.

1. **INTERNET EXPLORER v11 IS GOING INTO END-OF-LIFE**

    Microsoft will end support for Internet Explorer (IE) v11 in June 2022. This means they will stop providing defect fixes and security updates. To ensure the security and integrity of IBM Clinical Development, a plan is in place to block IE v11 users from accessing the system starting in the 2nd quarter of 2022.

    There is no immediate impact to users. This is an alert for upcoming changes and more details will follow.

1.   **INTERNET EXPLORER v11 IS GOING INTO END-OF-LIFE**

NEW IN OCTOBER 2021
- **With the 2021.7.0.0 release**, users who access IBM Clinical Development with IE v11 will see an alert. The message content is the same as this alert and is just additional notification of the upcoming change.

WHAT DO I NEED TO DO NOW?
- If you are able to change the browser you use to access IBM Clinical Development, we recommend switching to another supported browser such as Microsoft Edge, Mozilla Firefox, or Google Chrome.
- If you are not able to change your browser, please check with your organization to see if they have plans to change browser versions. Microsoft has publicly announced the end-of-life date and many organizations are already adjusting.
- If your organization does not have plans or is not aware of the change, please alert them to your needs.

2.   **IBM CLINICAL DEVELOPMENT IS UNDERGOING A FACELIFT**

It's time for a new look. IBM Clinical Development will be updated over several months starting in **December 2021**. You will see changes to the page fonts, colors, and icons. The visual changes will not impact the functionality – your access, processes, and tasks will remain the same. More details will be provided as we finalize the release plan and identify when specific elements will change.

3.   **UPDATES TO AUTHENTICATION ON API CALLS**

Currently, the Data Migrator, Monitor Management, and v2 Inventory/Dispense modules use a token authentication. The token method is being updated based on recommendations from the IBM Security team. There is no user-facing change for Monitor Management or v2 Inventory/Dispense.

For studies using the Data Migrator tool directly, there is no impact. The system handles the tokens/authentication.

For studies using the associated Data Migrator APIs (not the integrated module tool):

- 2021.7.0.0 (**October 2021**) will update how the token is passed but users will not need to adjust their programs.

3.   UPDATES TO AUTHENTICATION ON API CALLS

- 2021.8.0.0 (**December 2021**) will finish the update and all tokens must be passed through the Password field. Tokens passed through the Username field will no longer be allowed after this release.

Data Migrator APIs are in the format:
https://data-migrator.clinicaldevelopment.ibm.com/

VERSION DETAILS

The enhancements and features for IBM Clinical Development 2021.7.0.0 are a direct result of your response to the system.

1.   USER ACCOUNT: SIMPLIFICATION OF PROFILES

Some features of the user profile are no longer used and require additional resources that would be better used elsewhere. One of these features is the "Achievements" section where a select list of icons mark milestones such as number of page changes. With the release of 2021.7.0.0, the "Achievements" section will be removed. This was a display only and the removal does not impact any study design, study data, or account permissions.

2.   LANGUAGE SUPPORT: ADD GERMAN (AUSTRIA) DIALECT

IBM Clinical Development supports over 50 languages. With the release of 2021.7.0.0, the Austrian dialect of German is being added to support. This is for system translations only and must be activated in the study design to be available in EDC or for participants in the ePRO/eCOA or eConsent tools. If a translation is not available, the system will display the parent German text (if available) or default to English.

3.   VISIT SCHEDULE RULES: DATA VALUE - AUTO UPDATE FIELD RULE ADDED

Users have requested the ability to pre-populate a field with data generated by an expression. A new visit schedule rule - Data Value - Auto Update Field - is included in the 2021.7.0.0 release.

3.   **VISIT SCHEDULE RULES: DATA VALUE - AUTO UPDATE FIELD RULE ADDED**

Designers will define the visit/page/field to be populated, the expression for the value (using the Advanced Expression Editor), and whether or not system queries should run when the data is added. The rule is triggered by any action to the subject (data change, page status change, subject status change, etc.)

NOTES:
- AutoCalc, Field Attachment, Not Done, and Hidden Fields cannot be populated.
- The target field must be on an existing page (the rule will not create a new repeat record).
- The target field must be shown/enabled if there are page dynamics.
- The rule will add/update the target field whether or not there is other data present.
- If there are multiple rules on the target page, this rule will execute first.
- Once a study has been set Live, a Mid-Study Update (MSU) is required to change the rule configuration.

4.   **VISIT SCHEDULE RULES: UPDATE SUBJECT STATUS OPTIONS ADDED**

Users have requested the ability to add a visit or activate a page based on the subject status. Two new rules are being added in 2021.7.0.0:
1. Update Subject Status - Add Visit
2. Update Subject Status - Activate page

The rule is triggered by a subject status change from the information tab or the Grid/Tree view (i.e. Randomization). Designers are able to specify the initial subject status (one or more), the "To" status (trigger), and the visit or page to activate.

NOTES:
- These rules do not require an MSU to update.
- For Add Visit, the visit must be defined as "By Rule Only" add type.
- For Activate Page, the page must be marked "By Rule Only" in the visit.
- Repeating visits or pages will be added as long as the maximum repeat value has not been met.

5.   **ADVANCED SDV: ENABLE SOURCE DOCUMENT MANAGEMENT**

In the current environment, having the option to perform tasks like Source Document Verification (SDV) remotely is necessary. To assist customers moving in that direction, a new Remote SDV Document Management option is being added in 2021.7.0.0.

When enabled by role permissions, users will be able to upload and manage source documents at the patient level. The document upload is similar to other attachments, but this tool allows for multiple documents to be uploaded at once. The document viewer with markup is also available if redaction is needed. The document manager users will be able to publish "cleaned" documents to other users with SDV permissions.

6.   **SMART REPORTS WITH COGNOS: NEW DATASETS FOR EPRO MODULE**

Customers have requested a better way to monitor incomplete or missed diaries. To enable this in Smart Reports with Cognos, the 2021.7.0.0 release contains updates to ePRO Data.

DAT_EPRO is already available in Cognos; however, additional columns are being included to support incomplete diaries. These are: STUDYID, LASTMODBYID, RESUMABLE, and WINDOWID.

A new table (DAT_EPRO_WINDOWS) is being added to provide information about missed diaries. This table includes WINDOWID, PROJID, SUBID, VISITID, VISITSEQ, PAGEID, WINDOW_OPEN_DATETIME, and WINDOW_CLOSED_DATETIME.

NOTE: The DAT_EPRO for existing ePRO studies will be reloaded to include the new data.

7.   **API MAPPER: ENABLE DOWNLOAD OF THE EXPORT LOG**

In the last release, an export log was added to the Data Migrator to provide information about API Exports. With the 2021.7.0.0 release, users will be able to download a CSV copy of the log. The CSV copy will include the Status, Date, Mapping Configuration Name, and any Message. The file name will be in the format "PushExportLog-{StudyName}-{timestamp}.csv.

8. **API MAPPER: UPDATE LOG TO SEPARATE CSV GENERATION AND FILE TRANSFER**

API Mapper users are able to set up a CSV file generation instead of push over the API to a remote location. This CSV file can be posted to the Study Documents/Exports and/or transferred via sFTP to another location. Previously, if the CSV was generated and posted but the transfer failed, the log would show success. With the 2021.7.0.0 release, the log will show both tasks and their outcome - the push job export (CSV generation) and the data transfer.

IMPORTANT: The data transfer information will only be available in the log for exports that occur after the release.

9. **eCOA/ePRO: UPDATE TO eOBSRO/AGENT PORTAL FOR MULTIPLE PATIENTS**

Traditionally, an Agent associated with multiple patients would access their portal and the lowest value Patient ID would be the default. This can cause errors if the Agent doesn't remember to check which patient is selected. With the release of 2021.7.0.0, the default is being removed.

When an Agent associated to multiple patients logs in, the subject selection dropdown will be blank and the instructions on screen will remind them to pick the subject to work on.

If an Agent is only associated with a single patient, there are no changes. When this Agent logs in, they will have the patient selected.

This change does not impact the associations between Agent and patient, the Agent's account, or the diaries themselves.

10. **eCOA/ePRO: DISPLAY SUBJECT ID ON DIARIES FOR AGENTS**

Traditionally, an Agent can see the Patient ID before accessing the diary, but not while the diary is displayed. To help Agents focus on which patient they are updating, the ID will now be displayed in the header during diary entry. This change applies to Agents associated with one or more patients.

This change does not impact the associations between Agent and patient, the Agent's account, or the diary content. Participants will not see the ID during their diary entry.

11.   eCOA/ePRO: IDENTIFY SUBMISSION METHOD FOR IN-OFFICE/ONE-TIME LOGINS

The September 2021 release include a new method of capturing patient diaries - the In-Office/One-Time account. With 2021.7.0.0, "Web App (OTL)" is being added to the submission method for the eCOA/ePRO Summary and Reports.

The traditional submission methods will remain available:
- Legacy ePROs are entered as "Web"
- The new web interface show as "Web App"
- The My Clinical Diary Mobile apps show as "Native App"

12.   eCOA/ePRO: UPDATES TO THE IN-OFFICE/ONE-TIME LOGIN LABELS AND INSTRUCTIONS

The "In-Office" type of participant account was added in the last release. However, feedback indicates that the label is misleading and inconsistent with the link on the login page, so the label is being updated to "One-Time Login" with the 2021.7.0.0 release. Users may also see this abbreviated as "OTL".

The change is visible in the following locations:
1. The Design Attribute (Optional) attribute that turns the feature ON/OFF is now labeled "Enable in-office subject accounts and one-time logins".
2. The section for generating the login is now labeled "Patient 071001: In-office account and one-time logins".
3. The link to generate a code is now labeled "Generate one-time login code".
4. The message generated with the code will now say "One-time login passcode for subject: 0000-000000".

NOTE: The login page will continue to show "Switch to One-Time Login" for the link.

IMPORTANT: This is a visual/label change only and does not change the functionality or how users access their accounts.

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13.   **eCOA/ePRO: UPDATES TO CONTROL USE FOR ePRO WEB INTERFACE IN THE MOBILE APPS**

After the last release, study teams are able to use the new web interface instead of the default My Clinical Diary Mobile interface for the App. Traditionally, the new web interface allowed field attachments but the mobile apps did not. Because the new feature embeds the new web interface into the App, field attachment questions will appear but will not work.

Starting with the 2021.7.0.0 release, a blocking error will display when the attribute "Use responsive web page viewer in native mobile app" is set to YES and a field attachment is included in a page designated as ePRO. The field attachment can be used if the Mobile Apps are not going to be used.

14.   **eCONSENT: IMPROVED PACKET LOCK FUNCTIONALITY**

When a Sponsor/CRO user is accessing a packet, the packet is "locked" so that there is not a conflict caused by multiple users making changes. The Lock process is being updated to better reflect the status:
- The Lock icon will be clearly visible on the table of packets when a packet is locked.
- If a user hovers over the icon, a pop-up will show the user who has locked the packet.
- The lock is automatically removed when the user exists the eConsent module, logs out of IBM Clinical Development, or is timed out.
- If a user makes a change and returns to the main eConsent page, the lock may not be removed immediately. In this case, the hover will also provide instructions on removing the lock (re-open and re-close).

15.   **eCONSENT: ENABLE AUTO-ASSIGNMENT OF PACKETS**

Starting with the release of 2021.7.0.0, Sponsor/CRO users can designate a packet for auto-assignment when they are creating/updating it. If the packet is set to YES, the packet will be automatically assigned to the subject when the subject is added.

All assignments will be captured in the history, with text that indicates whether the assignment was automatic or manual. In addition, labels for the packet will indicate Auto-Assignment beside the status for quick identification.

15.   **eCONSENT: ENABLE AUTO-ASSIGNMENT OF PACKETS**

IMPORTANT: This does not assign packets to existing subjects. This will not apply to amendments (will not automatically assign to subjects who had the previous packet version).

16.   **eCONSENT: IMPROVED LANGUAGE SUPPORT ON SIGNED PACKET DOWNLOADS**

For Site, Participant, and Agent eConsent users, 2021.7.0.0 includes 3 changes to the download (export) for language support.
1. The Participants and Agents "Electronically signed by" label is being replaced by "Consent given by".
2. The Site User "Electronically signed by" label is being replaced by "Countersignature given by".
3. The system generated content will be translated into the user's language (as identified by the language setting on their study access). The study-specific content is translated if a translated version is available.

This does not change the content of a packet (other than language displayed) or the status/decision made.

17.   **eCONSENT: UPDATES TO HEADER WITH ePRO WEB INTERFACE IN THE MOBILE APPS**

After the last release, study teams are now able to use the new web interface instead of the default My Clinical Diary Mobile interface for the App. Traditionally, the new web interface has a profile icon and help icon in the header. The profile icon allows users to log out and the help opens support information. The Mobile App has alternate methods for log out and support, so these icons are not needed.

With the release of 2021.7.0.0, the embedded web interface will not have the profile or help icon in the header. App users will use the App functionality.

18.   **FILE TRANSFERS: ENABLE EN-MASSE PASSWORD CHANGES**

There are times when the file transfer passwords need to be updated and if one is missed, that job may fail to transfer and interrupt a workflow. For example, file transfers can occur with Data Exports, Data Migrator/API Mapper jobs, Safety Reports, and Payment Milestones, so multiple locations could need update.

18.   FILE TRANSFERS: ENABLE EN-MASSE PASSWORD CHANGES

To improve the process for file transfer passwords, the following changes have been included in 2021.7.0.0:

1. A new button "File Transfer Accounts" has been added to the Study Documents/Exports page on the Closeout menu.
2. Clicking the "File Transfer Accounts" button opens a new screen that allows the user to select an account, provide a new username and new password (with confirmation).
3. Once submitted, a log is displayed that shows the locations/jobs where the password was changed.

NOTES:
- This option only changes passwords within the study. Each study must be done individually.
- The "Account" dropdown is populated with the accounts stored for Data Exports, Data Migrator/API Mapper jobs, Safety Reports, and Payment Milestones (as applicable).
- The password change only requires Study Designer access to the study, regardless of where the password change is needed. Users do not need to have access to the Data Migrator directly (the tool will do that).

REVISION HISTORY FOR CONTENT OF THIS DOCUMENT

PRODUCT	REVISION #	AUTHOR/TITLE	CHANGES	CREATED DATE
IBM Clinical Development 2021.7.0.0	Version 1.0	Emily Malok Instructional Designer	Initial Version.	11 Oct 2021