Document Title: External Release Notes		
Product: IBM Clinical Development 2021.6.0.0	Document Version: 1.0	
Area: Research & Development	Document Type: Record	

Release Notes

IBM Clinical Development 2021.6.0.0
Release Date: 17 September 2021

OVERVIEW

Purpose:
This document provides an overview of IBM Clinical Development 2021.6.0.0 released by the IBM Corporation on 17 September 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 two upcoming change that users need to be aware of and prepare for.

1. **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 the 3rd quarter of 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.

2. 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.

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.

VERSION DETAILS

The enhancements and features for IBM Clinical Development 2021.6.0.0 are a direct result of your response to the system.

1. LOGIN: UPDATE THE INVALID USER ID, EMAIL OR PASSWORD MESSAGE

When a user enters an incorrect User ID/Email or Password on the login page, a message is displayed in red. The account will be locked after 5 of these attempts and the message suggests that users access "Forgot your password?" before they lock the account. Since locked accounts require the user to contact IBM Support, this adds extra steps and potential delays to their access.

To help users avoid this, a link to the wizard will be included in the error message starting with the 2021.6.0.0 release. Users can click the link to open the wizard and get a User ID reminder or password reset.

2. STUDY REPORTS: ADD 'DOES NOT CONTAIN' TO ADVANCED SEARCH

Study Reports include a Search field and then an expandable Advanced Search with additional filter options. The traditional filters are Greater Than (>), Greater Than or Equals (≥), Less Than (<), Less Than or Equals (≤), Equals (=), Does not equal (≠), and Contains. With the 2021.6.0.0 release, the 'Does Not Contain' operator is being added.

This is available for these report types:

- Adjudication Tracker
- Translation Tasks Listing
- EAM Full History
- Data Audit Trail
- ePRO Compliance Report
- Medical Coding
- EAM Billable Events
- Findings Report
- Page Status Report
- Query Metrics
- SDV/CFI Progress
- Subject Status Report
- Visit Timeline
- Lab Normals Report
- Data Tracker

NOTES: The new operator is also available in the following modules:

- For the Medical Coding Item Detail dictionary search, the "Advanced Search" filtering tool uses the same operators.
- Endpoint Adjudication Event Detail tables also use the filter tools.

3. ADVANCED EXPRESSION EDITOR: NEW "FREQUENCY" OPERATOR ADDED

With the release of 2021.6.0.0, a new operator is being added to the Advanced Expression Editor (AEE). Frequency returns the number of occurrences of a specific term/text. This can be used in an expression to identify counts or compare the number of a specific response. The operator uses a MapToField operator to set the first argument and then allows the designer to specify the value to be counted. The value to be counted can be a constant or datapoint/field value.

4. ADVANCED EXPRESSION EDITOR: CUSTOMIZE MODE FOR ROUND OPERATOR

The ROUND operator allows a designer to designate that an output be rounded to a set precision. The ROUND operator currently uses "banking" rounding (also called "half-even") -- rather than rounding 0.5 and higher values up and 0.4 and lower values down, this type of rounding will round odd numbers up and even numbers

4. ADVANCED EXPRESSION EDITOR: CUSTOMIZE MODE FOR ROUND OPERATOR

down. This means that an output of 7.5 and 8.5 would both round to 8. This does not work for all studies.

With the release of 2021.6.0.0, a "rounding mode" option is being added to the ROUND operator. This mode has the following options:

1. Default (Current behavior, HALF_EVEN)
2. HALF_UP (Round towards "nearest neighbor", rounding up if the discarded fraction is >= 0.5)
3. HALF_DOWN (Round towards "nearest neighbor", rounding up if the discarded fraction is > 0.5 but down if the fraction is <= 0.5)

NOTE: Existing expressions will use the Default mode to maintain current behavior. Designers would need to update the expression to use either the UP or DOWN mode.

5. ADVANCED EXPRESSION EDITOR: ADD OPERATOR FOR PARTIAL DATE CALCULATIONS

Partial Date fields are a valuable part of data capture due to the way data is captured or legal/privacy restrictions. Previously, Partial Dates were excluded from many Advanced Expression Editor (AEE) expressions because of the missing data -- how does the system compensate if one date has more information than the other? To assist with this, a new operator is being added with the 2021.6.0.0 release.

ToCompleteDate will create a "complete date" from the response in a Partial Date field by using a Min/Max attribute. The "MIN" attribute will use the minimum possible value for the missing component(s). For example, if Unknown Day, this would be 01. The "MAX" attribute will use the maximum possible value for the missing component(s). This value will depend on the known parts. For example, if Unknown Day in February, the MAX is 28, but in March, the MAX is 31.

6. v1 INVENTORY/DISPENSING: EXPAND DISPENSE FACTOR COLUMNS TO ALLOW LARGER EXPRESSIONS

Earlier this year (2021.4.0.0), the Dispense Factor as increased from 1,000 to 4,000 characters so larger expressions could be entered to meet study needs. Unfortunately, there were studies that still surpassed the 4000 character limit. With the 2021.6.0.0 release, the Dispense Factor will be updated to a CLOB type with a limit of 76,000 characters.

7. MEDICAL CODING: INCLUDE HISTORY IN EXPORT

Traditionally, the history of coding for a particular verbatim was only available on screen. This meant that the information would not be included in exports and could not be used in reports generated from export data tables.

To support using the history, two changes are being made in the 2021.6.0.0 release:

1. Designers will see a new Design Attribute (Optional) to 'Include Medical Coding Audit Trail Tables in the Data Export'.
2. When the attribute is set to YES and 'Include Audit Trail Tables' is YES for the export, the following tables will be included in V2 Data Exports (any format):
    - DAT_MC_MEDDRA_TR
    - DAT_MC_WHO_DRUG_TR
    - DAT_MC_IYAKUHINMEI_DATA_FILE_TR

NOTES:

- The verbatim must be in Approved status to be included in the Audit Trail. This is consistent with the requirement for including the coding in the data export.
- Due to the potential size of these tables, IBM does not recommended that you include the audit trail tables in all your data exports. This may slow the generation and/or file transfer.

8. eCOA/ePRO: ENABLE PATIENT IN-OFFICE ACCOUNT

With some studies, participants will access their diary while in the office (at their healthcare provider site) and not remotely/at home. This may be used to assist participants who are not as comfortable with technology, do not have their own devices, or due to local restrictions. This also means there may be shared devices.

To best protect the access and data for participants at the site, an "In-Office" account type has been added to IBM Clinical Development.

WHAT IS DIFFERENT FOR AN IN-OFFICE ACCOUNT?

- An in-office account can be created without an email address. This is to accommodate participants without email or in locations that limit the personal information.
- The display is simplified to just the functions required. This means that User Preferences are not available.

8. eCOA/ePRO: ENABLE PATIENT IN-OFFICE ACCOUNT

- The log-out is more prominent to ensure that participants exit the system completely and other users on a shared device cannot access their data.
- An In-Office account may be converted to a Remote (Traditional) account. A Remote account cannot be converted to an In-Office account.

NOTE: eConsent cannot be accessed with an in-office account (if this is being used on the study).

9. eCOA/ePRO: INTEGRATE THE WEB VIEWER INTO MY CLINICAL DIARY MOBILE FOR iOS (APPLE) DEVICES

With the 2021.6.0.0, a new option is available for studies using eCOA/ePRO with the iOS mobile App: "Use responsive web page viewer in native mobile app?". If turned ON, the NWA/New Web Interface can be used within the My Clinical Diary App.

- WHAT IS THE WEB INTERFACE VERSUS MY CLINICAL DIARY MOBILE APP FOR iOS?

  Participants who use the web interface will access their diaries using an internet browser and the same login page that you use. The system will adjust the display so they can do this on a variety of devices (laptop, tablet, phone).

  Participants who use the My Clinical Diary Mobile App for iOS will download the App from the Apple store and install it on their device. They will log in to the App and it will synchronize with IBM Clinical Development to provide their diaries and send their data back to the core system.

- WHY TURN ON THE NEW WEB INTERFACE?

  The My Clinical Diary App only supports eCOA/ePRO use (patient diaries). The NWA interface enables both eCOA and eConsent. Turning the NWA on for the My Clinical Diary Mobile of iOS will enable participants to access eConsent on their Apple Device.

- DOES THIS CHANGE THE WAY THE eCOA/ePRO WORKS?

  This does not change anything about the diaries or their windows, etc. This would simply allow users to access both eConsent and their diaries in the App.

9. eCOA/ePRO: INTEGRATE THE WEB VIEWER INTO MY CLINICAL DIARY MOBILE FOR iOS (APPLE) DEVICES

When they sign into the App, they will see the Patient Portal, just like if they used a browser and the traditional login page.

- IS eCONSENT ONLY AVAILABLE USING THIS METHOD?

eConsent and New Web Interface diaries can be accessed directly on mobile devices using a browser and the main IBM Clinical Development website. My Clinical Diary traditionally provided access to diaries for iOS and Android devices through an App, since some participants find this easier than a browser. In parallel with this release, the iOS App is being updated to enable the New Web Interface. The Android App is scheduled for release later this year.

NOTE: The first release will be for participants only. Agents will be able to use the My Clinical Diary Remote App for iOS, but will not be able to use the NWA interface in the App until a future release.

10. eCOA/eCONSENT: LIMITATIONS ON AGENT ACCOUNTS

Agents (LAR, Caregiver) can be associated with one or more participants once their account has been created. Their information, however, resides within the study where they are activated. To prevent issues with access and data, agent accounts from one study cannot be associated to a participant in another study. The agent would need separate accounts in each study. This also means the agent will not be able to access all participants in one login if they are spread across multiple studies.

11. ENDPOINT ADJUDICATION: ENHANCE EVENT AGING VIEWS AND CALCULATIONS

Traditionally, the Event Aging calculation is the number of days between the event creation and current date OR the number of days between the event creation and the LATEST final outcome generated. This does not meet the needs of all studies. In addition, Event Aging can only be viewed on a study report.

11. ENDPOINT ADJUDICATION: ENHANCE EVENT AGING VIEWS AND CALCULATIONS

The 2021.6.0.0 release includes two changes to make Event Aging more engaging for study users.

1. A new Design Attribute (Optional) has been added to allow designers to set the calculation to be the LATEST or the FIRST outcome generated. This attribute will be used for all Aging displays (on-screen, reports).
2. The Event Aging will be added to the Visit navigation box at the left of the CRF page.

12. ENDPOINT ADJUDICATION: IMPROVE FILTERING AND MONITORING OF QC EVENTS

For studies using Endpoint Adjudication (EAM), an optional QC process will duplicate events for a second review and confirmation.

Several changes are included in 2021.6.0.0 to help users manage the process:

1. Quick filters are being added to include/exclude QC Events from the EAM Event View.
2. If a user has the 'Can Manage QC' role permission, they will see additional columns on the Event View for Quality Control Status and Quality Control Result. For this user, additional quick filters are available to Display only QC Events or Display only QC Events associated to their Source Events.
3. A new column is also being added to identify the source EAM # on the QC event to allow users to easily map the source and duplicate pairs.

13. ENDPOINT ADJUDICATION: ENABLE "PHASE ONE ADJUDICATION IN PROGRESS" NOTIFICATIONS FOR QC EVENTS

Traditionally, the QC Process for Endpoint Adjudication (EAM) did not send notifications for the status "Phase One Adjudication In Progress". With the release of 2021.6.0.0, this will be enabled. Designers will be able to use the "Disable email notification for 'QC event'" attribute to disable the notifications if needed.

14. ENDPOINT ADJUDICATION: REFINEMENT FOR THE QC NOTIFICATIONS

Previously, an option was added to disable notifications for the Endpoint Adjudication (EAM) QC events. This was to prevent confusing or frustrating users on the source event who do not participate in the QC. However, this blocked all notifications on the QC event and QC participants didn't get the alerts needed to do their jobs.

With the release of 2021.6.0.0, designers will have more options to control the QC notifications.

- If the "Disable email notification for 'QC event'" is unchecked, the same email notifications will be sent for the QC event as the original event.
- If the "Disable email notification for 'QC event'" is checked, a new attribute "QC notifications disabled, except for the following notification types" is displayed. This new attribute allows designers to specify if the 'Phase One Adjudication In Progress' and/or 'Phase One Adjudicator Assigned / Updated' notifications should be sent for the QC event.

15. API MAPPER: ADD EXPORTS LOG FOR REAL-TIME/SCHEDULED PUSHES

Currently, users do not see the result of scheduled pushes and rely on the external user/vendor to alert them if there are issues. To enable users to better monitor their jobs, an exports log is being added to the Data Migrator/API Mapper tool.

On the main module page, a new icon has been added to the right for the exports.

The circle highlight will show the number of new records.

Clicking this icon opens a pop-up with a list of the real-time and scheduled push configurations. The log also contains a result icon, the date/time, a message, and a link to the details as needed. A link to jump to the mapping definitions will also be included. The log will be displayed with five (5) configurations per page and can be downloaded in Excel.

IMPORTANT: The log will only show export jobs executed after the release of 2021.6.0.0. It will not contain historical jobs but would contain new exports for existing configurations.

16. API SERVICES: NEW API ENDPOINT TO LIST AGENTS IN A STUDY

With the release of 2021.6.0.0, a new endpoint is being added to report all Agent users associated with study participants. An optional "type" parameter can be used to filter by eObsRO (eCOA) or LAR (eConsent). The list of agents only includes those visible to the requesting user (role permissions, site permissions).

17. OPTUM: ADD SF12 QUESTIONNAIRE

Traditionally, the integration with Optum include the SF36 and SF36-Acute questionnaires. The integration enables the responses in IBM Clinical Development to be sent to Optum, who evaluates and returns the results back electronically. If studies need a different questionnaire, the integration needs to be update to provide the responses in the correct format for Optum.

SF36 is a standard quality of life (QOL) survey. SF12 is a shorter adaptation that captures differences in QOL among patients with specific conditions. The 2021.6.0.0 release will enable the SF12 questionnaire for use with the integration.

18. eCONSENT: UPDATES TO PACKET CONTENT HISTORY FOR SPONSOR/CRO USERS

When uploading a PDF for content, the activity should be clearly defined in the packet history. To better identify the action, a PDF upload will be labeled "Edited/Draft" in the history instead of the traditional "Draft". In addition, the file name will be displayed for tracking purposes.

19. eCONSENT: UPDATES TO PRINT-TO-SIGN HISTORY AT THE SUBJECT LEVEL

To further support print-to-sign and the audit of personally identifiable information (PII), downloads of files from the history will also be tracked. When a packet is uploaded to a subject, the file is available via a link in the history. This file may contain PII and access needs to be captured.

20. eCONSENT: UPDATE TOTALS TO VISUAL CHARTS

Traditionally, the study eConsent metrics for both Sponsor/CRO users and Site users were displayed in table format. With the release of 2021.6.0.0, these will be update to gauge charts. This will provide a quick visual display of the current counts and a "delta" will indicate the change over the past day (up/down). The option to collapse/expand metrics will remain available.

21. eCONSENT: PACKET EXPORTS RE-LABELED TO DOWNLOADS

Previously, saving a copy of a packet was either done by an export icon or by clicking a text link "Export". This terminology can be misleading or confusing to site users and study participants. To improve this, "export" will be replaced with "download".

The following icon will be used for downloads: 

Text links will be updated to read "Download a copy".

22. CONFIGURATOR/FINANCE: UPDATES FOR eCOA/ePRO AND IMPORTS/API MODULES

The ePRO Module was updated in December 2020 to include eCOA functionality (allow for diary completion by a legal representative or caregiver). As part of the update, design attributes were added or changed.

To better capture the module in quotes and for invoices, the following changes have been included in 2021.6.0.0:

1. The module naming in Configurator and Finance tools will be "ePRO/eCOA". This will also be seen in messages/warnings in the Design Attributes (Optional), Error Widget, and Go Live areas.
2. Usage will be updated to check the "Study using eCOA" attribute instead of the "Study Using ePRO" attribute. This will capture studies that do not use ePRO but do use the eObsRO (Agent) portion.

The "Imports/API" label was used previously to describe data that was entered into IBM Clinical development through electronic transfer, not through data entry. This is being renamed to "Imported Data Points" for clarity, since it is the data points that are related to the cost.

REVISION HISTORY FOR CONTENT OF THIS DOCUMENT

PRODUCT	REVISION #	AUTHOR/TITLE	CHANGES	CREATED DATE
IBM Clinical Development 2021.6.0.0	Version 1.0	Emily Malok Instructional Designer	Initial Version.	27 Aug 2021