


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

Technical Notes

IBM Clinical Development Maintenance

Date: 03 December 2021

OVERVIEW

Purpose:

This document provides an overview of the changes to IBM Clinical Development during the Maintenance period on 03 December 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. LEGACY FORMAT DICOM UPLOADER WILL BE SUNSET IN DECEMBER 2021

The legacy format uploader for DICOM is limited to Internet Explorer and requires installation and/or a plug-in. In addition, the underlying software has aged and requires more preparation and testing to update. Because of these factors, the decision was made to sunset the tool.

A web uploader tool was introduced in 2019 and is fully integrated into the system. **In the December release** (2021.8.0.0 on 10 Dec 2021), the legacy uploader tool will be removed from the system.

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1. LEGACY FORMAT DICOM UPLOADER WILL BE SUNSET IN DECEMBER 2021

The web uploader tool and iConnect viewer functionality will remain unchanged and available for studies.

2. 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):

- Starting with 2021.8.0.0 (**December 2021**), 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/>

Noted In:

- Data Migrator Module > Technical FAQ
- Imports and API Module > What API Tools are available?

3. 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 early 2022. The start date has been delayed to incorporate feedback from research participants. 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.

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4. 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. As of October 2021, 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.

5. SUNSET ACTIVITIES FOR IBM CLINICAL DEVELOPMENT MODULES

Several modules in IBM Clinical Development have limited use and will be discontinued in a future release:

1. **V1 Data Exports:** This has been replaced by the V2 Data Exports and is currently not being updated. IBM recommends that users review the V2 Data Exports and plan their migration to the updated tools. No final removal date has been set.
2. **StudyConnect Mobile App for iOS:** This App is no longer available in the Apple Store. Existing users will be able to continue using the App until their study closes. We are working with existing customers on future options and a final removal date.
3. **Study Manager:** This module has limited use and IBM is looking at other options for assisting teams with clinical trial documents. In 2022, users will not be able to enable the module on new studies. Existing studies are not impacted at this time. We are working to identify customers that are using the module and assessing their needs. No final removal date has been set.


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CHANGES PERFORMED DURING MAINTENANCE

Periodic security patches and updates are required for the core IBM Clinical Development system and its support software and components. Where possible, these patches are applied with system releases or without downtime for the core system. Some patches will require the system to restart or be taken down to preserve data security and integrity.

During the maintenance window on 03 December 2021, routine operating system patches and security updates will be applied.

There are no changes to the core product or its functionality.

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REVISION HISTORY FOR CONTENT OF THIS DOCUMENT

Doc #	REVISION #	AUTHOR/TITLE	CHANGES	CREATED DATE
IBM Clinical Development Maintenance	Version 1.0	Emily Malok Instructional Designer	Initial version.	19 Nov 2021