


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: 22 January 2021

OVERVIEW

Purpose:

This document provides an overview of the changes to IBM Clinical Development during the Maintenance period on 22 January 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 should be aware of and prepare for.

1. CHANGES TO THE IBM CLINICAL DEVELOPMENT WEB ADDRESS

Traditionally, users have accessed IBM Clinical Development (ICD) through the **secure.eclinicalos.com** web address (URL). In the first quarter of 2021, users will also be able to access the system via **secure.clinicaldevelopment.ibm.com**. More details about exact release will be communicated soon. The legacy URL will be redirected for 2 subsequent years; however, it is recommended that users switch to the new URL.

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

2. UPDATE FROM THE 2020.7.0.0 RELEASE REGARDING DATA MIGRATOR


In the 2020.7.0 release, the Data Migrator sFTP job was upgraded to support only the most up to date security Ciphers and Algorithms. Listed below are the currently supported protocols. Any protocols NOT listed below are not supported and will be blocked by the Data Migrator sFTP fetch job. This list applies ONLY to the Data Migrator tool. Please reach out to your IBM representative if you have any additional questions.

- **Key Exchange Algorithms (kex):**
 - ecdh-sha2-nistp521
 - ecdh-sha2-nistp384
 - ecdh-sha2-nistp256
 - diffie-hellman-group-exchange-sha256
 - diffie-hellman-group14-sha1
- **Encryption Ciphers:**
 - aes256-ctr
 - aes192-ctr
 - aes128-ctr
- **Host Key Algorithms:**
 - ecdsa-sha2-nistp521-cert-v01@openssh.com
 - ecdsa-sha2-nistp384-cert-v01@openssh.com
 - ecdsa-sha2-nistp256-cert-v01@openssh.com
 - ecdsa-sha2-nistp521
 - ecdsa-sha2-nistp384
 - ecdsa-sha2-nistp256
 - ssh-rsa-cert-v01@openssh.com
 - ssh-rsa

3. TWO OPTIONAL MODULES TO BE DEPRECIATED

1. STUDY CONNECT MOBILE APP

With this release, a notice will be added indicating that the Study Connect iOS Mobile App will be deprecated and that it is no longer available for download from the Apple Store. This message will appear in the Design Attributes Optional area where the module is activated and within the mobile app itself. Those who have the app downloaded may continue to have access at this time, but it will be removed in future (date not determined).

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

3. TWO OPTIONAL MODULES TO BE DEPRECIATED
 2. V1 DATA EXPORTS


With this release, a notice will be added in Design Attributes Optional indicating that the V1 version of Data Exports are being deprecated. Previously, the V1 Data Exports only received minimal enhancement and defect fixes. Study teams should update to the V2 Data Exports to maintain access (default). V2 Exports contain the most up-to-date features. The V1 Data Exports will remain available with this release, but will be removed in future (date not determined).

CHANGES PERFORMED DURING MAINTENANCE

Periodic security patches 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 22 January 2021, routine operating system patches and security updates will be applied.

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

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

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.	08 Jan 2021

REVISION HISTORY FOR THIS TEMPLATE

TEMPLATE #	REVISION #	AUTHOR/TITLE	CHANGES	CREATED DATE
QA-1356-T9	Version 1.0	Emily Malok Instructional Designer	Initial version. This was split from the original QA-1356-T6 to handle the special requirements of an unscheduled patch.	26 Mar 2020
QA-1356-T9	Version 2.0	Emily Malok Instructional Designer	Not Used. Iterated to bring template up to the same version as the SOP (changed guidelines)	26 Mar 2020
QA-1356-T9	Version 3.0	Emily Malok Instructional Designer	Not Used. Iterated to bring template up to the same version as the SOP (changed guidelines)	26 Mar 2020
QA-1356-T9	Version 4.0	Emily Malok Instructional Designer	Not Used. Iterated to bring template up to the same version as the SOP (changed guidelines)	26 Mar 2020
QA-1356-T9	Version 5.0	Emily Malok Instructional Designer	Not Used. Iterated to bring template up to the same version as the SOP (changed guidelines)	26 Mar 2020
QA-1356-T9	Version 6.0	Emily Malok Instructional Designer	Not Used. Iterated to bring template up to the same version as the SOP (changed guidelines)	26 Mar 2020
QA-1356-T9	Version 7.0	Emily Malok Instructional Designer	Not Used. Iterated to bring template up to the same version as the SOP (changed guidelines)	26 Mar 2020