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Product: IBM Clinical Development 2019.4.0.0	Document Version: 1.0	
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Release Notes

IBM Clinical Development 2019.4.0.0
Release Date: 23 August 2019

OVERVIEW

Purpose:
This document provides an overview of IBM Clinical Development 2019.4.0.0 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.

VERSION DETAILS

The enhancements and features for IBM Clinical Development 2019.4.0.0 are a direct result of your response to the system.

1. DESIGNER: EXPAND CODELIST CODE/DISPLAY LIMITS

Traditionally, Codelist design allowed a 10 character code and 100 character display text. This limit was applied across all codelists, regardless of the method used to create the codelist. Based on user requests, this is being extend. In the IBM Clinical Development 2019.4.0.0 release, the code will allow up to 20 characters and the display text will allow up to 500 characters. The error messages for these limits have also been updated.

2. MEDICAL CODING: IMPLEMENTING THE 'ASK WATSON' INTERFACE

With the release of IBM Clinical Development 2019.4.0.0, we are enabling IBM Watson for the first time. The 'Ask Watson' interface is been connected to the Medical Coding module to assist with identification of MedDRA coding. The tool uses machine learning to provide low level term suggestions based on the verbatims captured in EDC.

IMPORTANT: Access to the Watson-enabled interface at release is blocked. Use of the Watson cognitive features are not accessible in non-production environments and may require an updated IBM Clinical Development contract. Please contact your Client Success Manager or IBM Seller to request more details or a demonstration.

NOTE: WHO Drug suggestions are planned for a future release.

3. ePRO: SITE ENABLEMENT UPDATES

To enable site users to support ePRO patients, two new features have been added in IBM Clinical Development 2019.4.0.0. The first is access to the preferred language for the patient after the activation is complete. Site users will be able to see the current setting and update if needed. The current language selection will also be visible in the study User Management and in Admin for IBM Support. The second change involves a preview for available diaries. A link is now available on the patient record to allow the site user to review a read-only copy of an available diary to assist the patient.

4. ePRO: DISABLE HISTORICAL DIARY VIEWS FOR SUBJECTS

Traditionally, patients are able to view their previously entered diaries in IBM Clinical Development. Some study teams have indicated that they need to block the history from their ePRO patients. This ability has been added in 2019.4.0.0 as a new attribute on the ePRO section of the Design Attributes (Optional). The new attribute is available for both Legacy web or New reactive web formats.

5. ePRO: UPDATES TO THE ERROR WIDGET FOR ePRO ISSUES

With the release of 2019.4.0.0, if a control type is not supported in ePRO but is included in a page design that is designated as 'Page is ePRO', a warning will be displayed.

5. ePRO: UPDATES TO THE ERROR WIDGET FOR ePRO ISSUES

The message will read: ''WARNING: The unsupported control type 'CONTROL_TYPE' is in use on an ePRO page. Please review the page design for any use of this control type." Blocked Control Types include: Not Done, Auto Calc Fields, Row Start/End, Remote Value, Lab Selection, Field Attachment, and Many Select.

6. COGNOS: ENABLE CROSS-STUDY REPORTING

With the release of IBM Clinical Development 2019.4.0.0, designers will be able to create reports across multiple studies that are 'Smart Reports v2 Enabled'. Views must contain the same number of fields and the same field types and then a union query is used to combine the data. All users, designer or end user, must have access to all studies involved.

7. CONFIGURATOR: IMPROVE DESCRIPTIONS AND LABELS

To improve clarity, the Configurator has been updated in three areas:

1. The "Data Entry > How many forms..." section has been updated to clarify what is included in the data points counts and how page estimates should be done
2. The description for the Site section will be renamed to "Clinical data to be entered" (removing the "by site users")
3. The description for the Subject section will be renamed to "Subject Questionnaires"

8. ADMINISTRATION: UPDATES TO ARCHIVE/RESTORE TOOLS

The Archive/Restore Tool has been updated with the IBM Clinical Development 2019.4.0.0 release, but is not yet ready for use across most studies. The tool was erroneously noted in the 2019.3.1.0 release as a general access tool; however, the initial release was for a limited definition and evaluation. Development is ongoing with a final customer tool expected later this year. Full details about the functionality and how to obtain access will be provided with that release.

9. ADMINISTRATION: MULTIPLE CHANGES TO IMPROVE THE SYSTEM PERFORMANCE

To improve user's experience and reduce delays, several performance enhancements have been included in the IBM Clinical Development 2019.4.0.0 release. These include:

- Faster Display of the Study/Design Attributes, Page Design, Icons, and Language Support (Translations) sections
- Faster Display of CRF pages for non-Dispense studies
- Faster processing of Cross-Page queries
- Improve SDV/CFI Progress report display

REVISION HISTORY FOR CONTENT OF THIS DOCUMENT

PRODUCT	REVISION #	AUTHOR/TITLE	CHANGES	CREATED DATE
IBM Clinical Development 2019.4.0.0	Version 1.0	Emily Malok Instructional Designer	Initial Version.	07 Aug 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: • 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