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CTIS Release Notes – Release v1.0.53.0

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Introduction

This document outlines the latest updates to the CTIS system, including the secure Sponsor and Authority workspaces, and to the Clinical Trials website. Updates may include improvements to existing features and functionality, the addition of new features and functionality and technical improvements, such as improvements to system performance.

In this release, improvements have been made for:

- Access and User Management
- Application creation/preparation of documents and data
- Other issues

Functional Improvements

A. Access and User Management

- Fixed an issue where sponsor users with Part II-only roles (Viewer or Preparer) encountered a "permission denied" error when attempting to access an application with a pending Part I RFI directly from the Clinical Trial Summary page. This error prevented access to the application's Part II dossier via that route, although the dossier remained accessible through the RFI tab. Sponsor users with Part II-only roles (Viewer or Preparer) can now access the Part II dossier from the Clinical Trial Summary page when a Part I RFI is pending. [ADO 241347] [PRB0040569]

B. Application creation/preparation of documents and data

- Fixed issue where sponsor users could not submit a Start/End of Trial or Start/End of Recruitment notification in CTIS if the date fell between the trial's initial authorisation date and the submission date of a subsequent Non-Substantial Modification (NSM). The system previously blocked these dates, only allowing notifications with dates after the NSM submission. [ADO 240672] [PRB0040515]
- Fixed issue where alerts for the submission of the layperson's summary and summary of results were generated prematurely based on the first end-of-trial date from a single MSC. Alerts are now issued at three intervals: three months, one month, and five days prior to the submission deadline based on the sponsor's anticipated summary of results date. [ADO 241343] [PRB0041327]
- Fixed issue where updating a content labelling document through a substantial modification application did not replace the existing file. Instead, the updated document was added alongside the original, both showing the same system version number, causing confusion as the system treated the update as a new, separate document rather than a versioned replacement. [ADO 225723] [PRB0040518]

C. Other issues

- Fixed issue where, during the creation of an ASR for certain clinical trials created after May 27th, 2022, the primary sponsor was either missing or not visible in the UI. This resulted in some trials showing no sponsor at all and others having the sponsor present in the database but hidden from UI, which could lead to further submissions being created without a sponsor. [ADO 219438] [PRB0041822]