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CTIS Release Notes – Release v1.0.59.0

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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:

- Application creation/preparation of documents and data
- Other issues identified as indirectly fixed during the validation of this version

Functional Improvements

A. Application creation/preparation of documents and data

- Fixed an issue where the system incorrectly updated the document "submission date" of documents copied from a previous application when creating a new application, even if the documents were not modified or re-uploaded. The system now ensures that only newly uploaded or updated documents have their version and metadata updated, preserving the correct document history. [ADO 278938] [PRB0040493]
- Fixed an issue where sponsor users were unable to partially submit a draft Part II of an Initial Application when the clinical trial included a withdrawn Member State Concerned. The submit button now correctly appears, allowing the sponsor to submit the remaining Part II draft for the active MSC. [ADO 232020] [PRB0042005]

B. Other issues identified as indirectly fixed during the validation of this version

- Fixed an issue where an MSC was not appearing in the list of an application's participating MSCs in the summary page, preventing also the assessment from being completed. If the sponsor withdrew an "End of Trial" notification for an MSC, and then a second "End of Trial" withdrawal occurred in a subsequent application for the same MSC, the MSC now remains visible on both the CT summary page and within the relevant application, and the authorization workflow is correctly generated, preventing the MSC from becoming stuck in the "Under Evaluation" status.