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CTIS Release Notes – Release v1.0.57.0

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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

Functional Improvements

A. Access and User Management

- Fixed an issue where authority users with a large number of trial-specific roles were unable to view CT-related tasks in the "Tasks" tab due to long load times or timeouts. This occurred when listing all the CT and ASR tasks for users with over 1,000 roles. The task search and the loading performance has been improved, allowing tasks to be displayed within a reasonable timeframe and enabling users to successfully refine results using search criteria. [ADO 262745] [PRB0041286]

B. Application creation/preparation of documents and data

- Fixed an issue where sponsor users were unable to submit a new multinational Substantial Modification (SM) due to an incorrect message indicating an ongoing SM under evaluation. This occurred in the scenario where a previous SM with an RFI had been responded to by the sponsor, but a lapsed or withdrawn RMS/MSC was still incorrectly considered under evaluation for that previous SM. The system now correctly changes the evaluation status, allowing new SMs to be submitted without error. [ADO 270807] [PRB0041434]
- Fixed an issue where sponsor users were unable to create or update Serious Breach, Unexpected Event, Urgent Safety Measure, or Third Country Inspectorate Inspections notifications when a clinical trial was halted. The system now correctly allows sponsors to create or update the event notifications when the clinical trial is halted. [ADO 267540] [PRB0042540]