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## CTIS Release Notes – Release v1.0.58.0

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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

## Functional Improvements

### A. Application creation/preparation of documents and data

- An improvement has been implemented to prevent the expiration of Clinical Trials in case the sponsor requests an extension of "Start Recruitment" or "Restart trial" beyond the two-year limit, by introducing mandatory date fields within the selected Substantial Modification (SM) reason for extension and requiring the completion of at least one relevant date (Recruitment Start Date and/or Restart Trial Date) for one or more Member States Concerned (MSCs). [ADO 260165]
- Fixed an issue where sponsor users were unable to correctly change the primary sponsor of a clinical trial via a SM Part I when the trial included one or more MSCs with status "Ended" or "Revoked". The sponsor change is now correctly applied at the clinical trial level, ensuring the new sponsor is reflected in CT Search, CT Summary, and Full Trial Information, and that access and roles associated with the previous sponsor are correctly revoked. [ADO 251576] [PRB0042050]

### B. Other issues

- Fixed an issue where for certain trials, the timetable displayed incorrectly the due date for Part I conclusion task, diverting from the accurately calculated due date in "Tasks" tab (authority workspace). The Part I conclusion was wrongly extended by a period of 28-40 days in the "Timetable" due to RFI phase being counted twice. The timetable now reflects the correct expected due date and in line with that depicted on the "Tasks" tab. [ADO 266621] [PRB0040454]