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CTIS Release Notes – Release v1.0.52.0

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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:

- Authorisation and supervision of clinical trials
- Other issues

Functional Improvements

A. Authorisation and supervision of clinical trials

- Fixed issue to prevent unexpected task cancellation/expiration and application lapsing. The system now handles timeline adjustments and task dependencies during the evaluation workflow of an initial mononational application, preventing the lapse of the initial application, the cancelation of the 'Submit Part I conclusion' task and expiration of the 'Assess Part I RFI' task. [ADO 170791] [PRB0041249]

- Fixed issue where 'Submit Part I Conclusion' and 'Submit Part II Conclusion' tasks expire before their respective due dates in SM. In cases where validation expires and, as consequence, a tacit validation is triggered, the tasks "Submit Part I conclusion" and "Submit Part II conclusion" now expire after their due date, as expected. [ADO 222559] [PRB0041889]

- Fixed issue to enable the submission of Substantial Modifications. After a tacit authorisation for a Part II-Only or Part-I Only SMs in multinational clinical trials, the system fails to update the application status in the back-end of the system, showing there "under evaluation". This status now updates correctly, so subsequent SM submissions can proceed as expected with no error message referring to an application under evaluation. [ADO 226958] [PRB0041879]

B. Other issues

- Fixed issue with the search feature of the GDPR tool. The EMA Admin role can now search and retrieve documents in CTIS for their deletion or update using the GDPR functionality, preventing standard data fixes upon Service Desk requests, where applicable.   [ADO 247078] [PRB0042150]