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CTIS Release Notes – Release v1.0.48.0

Revised the version published with date of 4 February 2025 to include the missing problem PRB0041717

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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
- Authorisation and supervision of clinical trials
- Communication between sponsors and Member States
- Other issues indirectly fixed during the validation of this version

Functional Improvements

A. Access and User Management

- Fixed issue related to roles with Part I permissions only. Sponsor users with this type of roles are now able to access an initial application, from summary page, when there is a Part II draft RFI response. [ADO 204402] [PRB0041596]

- Fixed issue with MS roles with scope "specific" trial. When the sponsor submits a Non-Substantial Modification application, the affiliated organization for the MSs roles with scope "specific" trial" remains unchanged. [ADO 225176] [PRB0041921]

B. Application creation/preparation of documents and data

- Fixed issue with trial sites information. Trial sites added in an application containing Part II will be now saved automatically. This will prevent cases where they disappeared after submission due to a time out of the user session during the drafting of an application or of an RFI response. [ADO 188919] [PRB0040899]

C. Authorisation and supervision of clinical trials

- Fixed issue with due date of "SM document considerations for validations" task. When a Substantial Modification Part I or Part I&II is submitted, the due date of this specific task, which is triggered for both RMS and MSCs, is now correctly taking as reference the RMS calendar involved in the Clinical Trial. For SM part II only, the due date task takes as reference each MSC calendar. [ADO 206079] [PRB0041653]

- Fixed issue with Sponsor user not being able to submit "End of Trial" notification. When a Clinical Trial is authorized, Sponsor user can now submit this notification without facing any error message. [ADO 223968] [PRB0041905]

- Fixed issue with soft tasks buttons not being displayed. When an RMS is withdrawn from an initial application, the soft tasks buttons related to the

"Validation" and "Part I assessment" for any subsequent Substantial Modification application type, are now correctly displayed for the Authority user to perform the required action i.e. assign to/assign to me/create subtask. [ADO 206310] [PRB0041717]

D. Communication between sponsors and Member States

- Fixed issue with Additional Member States Concerned application, submitted after Substantial Modification(s), getting lapsed. If the RMS submits an assessment Part I RFI, now the AMS application does not get lapsed on the Part II conclusion due date. [ADO 186769] [PRB0041493]

E. Other issues indirectly fixed during the validation of this version

- Fixed issue with the "Organisation" name not being displayed while assigning roles. When a Member State administrator user tries to assign a new role, the field Organisation name is now correctly displayed. [ADO 126595]

- Fixed issue with "Check" button not being active. When a Sponsor user includes changes as part of a Validation RFI in an initial application, this button is now correctly displayed, active and the user can perform the technical validation for that response. [ADO 164998]