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CTIS Release Notes – Release v1.0.47.0

Revised the version published on 21 November 2024 to include some missing reference numbers

Table of Contents

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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
- Collaboration between Member States and Ad-hoc/safety information
- Other issues
- Other issues indirectly fixed during the validation of this version

Functional Improvements

A. Authorisation and supervision of clinical trials

- Fixed issue with the request for the start of recruitment extension. When Sponsor user requests an extension via Substantial Modification for the "Start of Recruitment" beyond 2 years and 15 days, once the time reaches the extension due date (i.e. anticipated date indicated in the Substantial Modification to grant the extension) plus 15 days, the clinical trial remains now authorised and only expires if the "Start of Recruitment" is not submitted on this due date (i.e. anticipated date plus 15 days) or if no further SM requesting a new extension is Authorized. [ADO 209905]

- Fixed issue with Sponsor user not being able to restart a halted trial. Sponsor user can now submit the "Restart trial" notification when the current date is equal to the "Restart date" approved in the selected Substantial Modification application by the specific MSC plus 15 days. [ADO 211218]

- Fixed issue when reverting evaluation decisions. When an Authority user reverts the MSC evaluation decision, the updated reverted decision is now correctly displayed in the "Assessment Overview" section within the Evaluation folder, along with any conditions if applicable. [ADO 213404]

- Fixed issue with the RMS decision information in the "Assessment Overview" section. If the RMS submits Part I and/or Part II Conclusion tasks as "Acceptable with conditions" or "Acceptable" but the authorise task remains pending, the decision section displayed when clicking in the "+" button for the RMS row in the "Assessment Overview" table, does not display now any decision information/assessment conditions. [ADO 170798] [PRB0041294]

B. Communication between sponsors and Member States

- Fixed issue when responding to a Validation RFI. When an initial application is partially submitted for all or some of the Member State Concerned, Sponsor user is now able to submit the validation RFI response, after including changes in the application, without having an error message concerning any Part II not submitted. [ADO 204407] [PRB0041437]

- Fixed issue with Notices and Alerts for Member States added after a withdrawal. When a Member State involved in a trial is withdrawn and then re-added through an Additional Member State application, Notices and Alerts are now correctly generated and displayed for that Member State for all application types. [ADO 168668] [PRB0040456]

C. Other Issues

- Fixed issue with Annual Safety Report workflow. After draft Annual Safety Report circulation by the safety MS (saMS), if there are no pending RFIs awaiting response from Sponsor and the "Review ASR" task reaches the due date, the "Finalise Assessment" task can now be completed by the saMS without facing any error message and the status of the Annual Safety Report is correctly displayed as finalised in the Sponsor workspace. [ADO 197906]

- Fixed issue with user permissions. Authority users with certain roles with scope "all" trials and other roles with scope "specific" trial(s) are now able to search and retrieve all Clinical trials, according to their role scope, without having displayed the error message "Permission Denied". [ADO 204410] [PRB0041429]

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

- Fixed issue to prevent the submission of a second part I RFI on the "Submit Part I conclusion" due date. When a 'Submit Part I conclusion' has been extended in the context of an ATMP and the sponsor has replied to a Part I RFI previously submitted on the due date of the extended Part I conclusion, the MS user is not able now to raise a second Part I RFI on the "Submit Part I Conclusion task" due date. [ADO 162092] [PRB0041127]