22 March 2024
EMA/135407/2024
European Medicines Agency

CTIS Release Notes – Release v1.0.36.0

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

Functional Improvements

A. Authorisation and supervision of clinical trials

- Fixed issue with buttons/icons missing for soft tasks in Substantial Modification for Member States added via Additional Member State application. The soft tasks buttons ("Assign", "Assign to me" and "Create sub task") are now correctly displayed for these Additional Member States, even if the trial status for the Additional Member State is suspended or halted. [153770/PRB0040757]

B. Collaboration between Member States and Ad-hoc/safety information

- Fixed issue with Ad-hoc assessment. After creating, sharing and searching for an Ad-hoc assessment, the authority user is now able to update it and save it with no error message displayed. [132817/PRB0040981]
- Fixed issue with the task "Submit RFI", which is now generated for the Reporting Member State in the task list in the following scenarios:
    - After sharing consolidated Part I considerations, in the context of an Additional Member State Concerned, when a Request for Information in Part II is created before creating and sharing the Part I considerations;
    - After sharing consolidated Part II considerations, in the context of Substantial Modification Part I & II, when a Request for Information is submitted for Part I in advance to the documentation of considerations for Part II. [151617, /CTCS-23305/PRB0040742]

C. Communication between Sponsor and Member States

- Fixed issue with the "Validation conclusion" information in the evaluation section, which will not be available from the Sponsor workspace while it is saved in the Authority workspace and then only displayed once the validation decision is submitted by the Member State Concerned. [153769/PRB0040835]

- Fixed issue with Annual Safety Report (ASR), enabling the submission of ASRs for clinical trials linked to Investigational medicinal products (IMP) containing more than 23 substances. [160063/PRB0041169]

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

- Fixed issue with the trial sites. They are now correctly displayed in the User Interface for a saved/submitted clinical trial application and can be downloaded in both Sponsor and Authority workspaces. [137908/PRB0040899]