09 February 2024
EMA/61503/2024
European Medicines Agency

CTIS Release Notes – Release v1.0.35.0

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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:

- Improvements in the Application Creation/ Preparation of documents and data
- Communication between Sponsor 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 the Part II Conditions. When a user from a Member State Concerned (MSC) raises conditions in Part II, the conditions are no longer displayed in the "Decision" section under the "Evaluation" folder of a different MSC.

- Fixed issue in partial submissions of a Substantial Modification Part I & II with Part II submitted only to a Member State Concern. When the Reporting Member State accepts with conditions the Part I conclusion and claims the Authorise task:

    - The conditions added in the "Submit Part I conclusion" task are now displayed in the "Authorise" task under the "Conditions" header for all Member State Concerned involved in the trial,
    - The Member State Concerned can complete the Authorise task successfully,
    - After the "Authorise" task is completed, the conditions previously added remain in the task [135721].

- Improvement in the Ad-hoc assessments search functionality. The search has been extended to include additional trial statuses (i.e. Not Authorised, Not valid, Lapsed, Expired, Revoked, Withdrawn, Under evaluation), and a new search field "Affected MS" has been added in the advanced search. [125932/CTCS-19099].