28 September 2023
EMA/426786/2023
European Medicines Agency

# CTIS Release Notes – Release v1.0.28.0

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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:

- Application creation/preparation of documents and data
- Authorisation and supervision of clinical trials
- User authentication, registration and roles
- Other issues indirectly fixed during the validation of this version

## Functional Improvements

### A. Improvements in the Application Creation/Preparation of documents and data

- Fixed issue related to the addition of translations in Part I, allowing 4000 characters for "Full title", "Public title", "Medical condition", "Main objective", "Secondary objective", "Principal inclusion criteria", and "Principal exclusion criteria" and 500 characters for "Primary and Secondary endpoints", being able to save those translations without error. [SD-724638/PRB0040509]
- Fixed issue with EudraCT search for transition trials, the sponsor user will be able to find and select a clinical trial available in EudraCT when searching with its EudraCT number in the "Form" section. [PRB0040649]

### B. Authorisation and supervision of clinical trials

- Fixed different issues in the "Decision" and "Evaluation" documents that can be downloaded in CTIS [SD-681062/PRB0040609]:
    - The "Submission date" in the "Disagreement with Part I" section is not populated now when the MSC has not disagreed with Part I.
    - The "Reporting date" has been renamed to "Decision date" in the Decision document and "Conclusion reporting date" in the Evaluation document for Part I and II.
    - When in an MSC there is "No conclusion", the "Conclusion" date is populated with the correct "no conclusion" date.
- Fixed issue with the extension of the "Authorise" task in the context of an AMS application. Now this task is correctly extended if an RFI is raised in Part I, even if the Submit Part II Conclusion task has already been completed. [CTCS-24786]
- Fixed issue with the extension of the "Start of Recruitment" authorised via SM, allowing the user to select now a date inside the extension period. [CTCS-24207]

- Fixed issue for the AMS application, which does not lapse unless the Sponsor has not responded to a Part I or Part II RFI by the due date deadline [SD-721468/PRB0040593]
- Fixed different issues with the "RFI response" date picker in different applications and phases:
    - For all application types, when a CT is created before the clock stop and regardless of being submitted before or after the clock stop, the date picker for the "RFI response" for the 1st RFI in in the Part II assessment allows for a maximum of 12 natural days selection not falling on a weekend;
    - In an SM Part II only application, the date picker for the "RFI response" for the 2nd RFI in the Part II assessment allows for a maximum 12 natural days not falling on a weekend but cannot exceed the due date of the hard task "Submit Part II conclusion";
    - In an IN application when a CT is submitted on a different day of its creation, it is possible to create the 1st RFI in the due date of the "Submit Part II conclusion" task and the date picker also allows for a maximum 12 natural days not falling on a weekend. [CTCS-24760/SD-728743/ PRB0040429]

## C. User registration, authentication, and roles

- Fixed issue with the Validator Part II submitter role, allowing this user to consolidate considerations and send RFIs in the Validation phase of an SM part II-only application. [SD-725004/PRB0040617]
- Fixed issue when a role is assigned, revoked, rejected or amended, the user (sponsor or authority) will receive a role confirmation email. [SD-671034/ PRB0040478]
- Fixed different issues related to re-submission permissions:
    - In an Org-Centrica approach, the CT Admin with scope "specific CT" is now able to resubmit the initial application for that trial, and automatically gets the same role and scope for the resubmitted CTA;
    - In either Org or CT- Centric approach, the Application Submitter cannot resubmit an initial CTA regardless of the role scope i.e. "Specific CT" or "All trials". [SD-734516/PRB0040502]

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

- Fixed issue when the RMS manually extends the hard task "Submit Part I conclusion", the date picker for the "RFI response" for the 1st RFI allows for a maximum of 12 natural days selection not falling on a weekend. The same applies in case of subsequent RFIs but in this case the date selected cannot exceed the due date of the extended task "Submit Part I conclusion". [SD-732949/PRB0040477]