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CTIS Release Notes – Release v1.0.26.0

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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
- Communication between sponsors and Member States
- User registration, authentication and roles
- Other issues indirectly fixed during the validation of this version

Functional Improvements

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

- Fixed issue with full trial information, the "Member State" drop-down list displays now all the MSC for selection and retrieval of their latest authorized MSC information. [CTCS-24468]

B. Authorisation and supervision of clinical trials

- Fixed issue with notice "Considerations due" (Validation), now is received only by the MSC that can document considerations, regardless of whether considerations were raised or not. [CTCS-24585]
- Fixed issue with the "Supporting information documents" under the "Form" section in SMs, in the "All document" table the submission date is now filled in with the correct date. [CTCS-25091]
- Fixed issue when consultation with experts after RFI creation, now the submit part I conclusion hard task and authorise task are generated with the correct creation date and due date. [CTCS-24067]
- Fixed issue with "Submit Part I Conclusion" task's due date, after RFI for Part I submission, the task is now calculated considering the Consultation with Experts extension. [CTCS-24890]

C. Communication between sponsor and Member states

- Fixed issue in ASR, the authority users are now able to assess the RFI response and submit their comments successfully. [CTCS-24319]

D. User registration, authentication, and roles

- Fixed issue with "Sponsor Admin" role, the user is now able to assign "CT admin" role to a user for two different organisations (i.e. different Organisation IDs) which share the same name, simultaneously or one by one. [CTCS-24387]

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

- Fixed issue in the task "Re-express willingness/unwillingness" and "Agree RMS", the system does not display "tacit unwilling" for some MSC before the due date. [SD-729457]

- Fixed issue with the decision dropdown values in the "Authorize" task of the AMS Application, which are now shown correctly when the Part II conclusion is acceptable with conditions. [CTCS-24633]

- Fixed issue with "Authorise" task, now is generated for the MSC which was Lapsed/Not Authorised/Withdrawn in the initial application and the MSC user is now able to complete it without any problem. [CTCS-24815]