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CTIS Release Notes – Release v1.0.15.0

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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 and authentication
- Other issues

Functional Improvements

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

- Fixed issue when the title of the clinical trial is updated on a Substantial Modification or Non-Substantial Modification. The new value is now displayed in Sponsor WS, Authority WS and Public Portal, in the following parts of the system:
    - Search result page when the CT is retrieved as a result after using any of the search criteria
    - Summary
    - Full Trial Information
    - Part I (title) for the SM/NSM application
    - Part I (Trial identifiers) for the SM/NSM application
    - Document downloaded using the "Download" button
    - Any other section or document where the title of the document is visible. [CTCS-21821]

B. Authorisation and supervision of clinical trials

- Fixed issue with documents uploaded but not saved by sponsors when responding to RFI, now when a sponsor user uploads a document, it is immediately saved into the system. Also allows sponsor users with proper roles and permissions to see the changes in draft performed by a different user from the same sponsor organisation in the CT. [SD-648490]
- Fixed issue with trial period notifications, it is now possible to submit them after a Non-Substantial modification has been submitted. [SD-615475]

C. Communication between Sponsor and Member States

- Fixed issue with alert "There are 2 days remaining to submit a decision on the trial", now this alert is no longer visible after the MSC has completed the Authorise task. [SD-680324]
- Fixed issue with alert "Express willingness/unwillingness task due", now this alert is hidden after the member states concerned (MSC) has completed the willingness/unwillingness expression task. [SD-680228]
- Fixed issue with alert 'Considerations due (Validation)', now this alert is not triggered to MSCs that are not involved in the trial, in Initial and SM applications. [SD-664839]
- Fixed issue with the redundant alert 'Assess Part I. 12 days after circulating end date passed for application', now this alert is no longer generated 12days after the circulation of the draft assessment report. [SD-670908]

D. User registration and authentication

- Fixed issue with CT admin-specific trial, the user now can assign roles to another user for the same trial(s) under his/her scope. [SD-711303]

E. Other issues

- Fixed issue with logout of users when face an internal server error (500) due to slow response, the users now are not logged out from CTIS. [SD-720782]