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## CTIS Release Notes – Release v1.0.29.0

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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
- Others issues

## Functional Improvements

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

- Fixed issues with the creation of a clinical trial, when the organisation searched and to be selected contains in the address just the character "-", the sponsor user can now select it as a valid organization. [SD-721095/ PRB0040462/ 127169]
- Fixed issue when the strength of a medicinal product is expressed as a fraction, and the figure in the denominator is 1, the information is now correctly displayed including the denominator (e.g. 15mg/1ml instead of 15mg). [SD-729644/ PRB0040633/ 127182]
- Fixed issue with the ATC search, for the timeouts that are keeping ATC searches out of order and for simplifying the ATC search functionality by retrieving from and above the ATC code level used in the search (i.e. add an ATC code Level 4 and find Level 4 and 5 codes). [SD-725135/ PRB0040430/ 127186]
- Fixed issue with the resubmission of an application with status "Not authorised", "Lapsed" or "Withdrawn", if the sponsor user clicks twice the resubmit button the error message "The resubmission is already in progress" is now displayed, preventing the creation of more than one draft of the resubmitted application. [SD-726829/ PRB0040453/ 129615]

### B. Authorisation and supervision of clinical trials

- Fixed issue with the creation of an Additional MSC for the RMS country when Initial application status was "Not authorised", "Lapsed" or "Withdrawn", this country (RMS) is now able to authorise the Additional MSC application. The other MSC are also able to see the tasks of the trial in the tasks tab. [CTCS-25232/ 127760]

## C. Communication between sponsor and member states

- Fixed issue with the creation of an RFI by the RMS in the following scenarios:
  - If the RMS status is "Lapsed", the RMS has now the button "create RFI" enabled (according to their roles permissions) and can create and submit the Part I assessment RFI for an Initial application.
  - If the RMS status is "Not authorised", "Lapsed" or "Withdrawn", the RMS has now the button "create RFI" enabled (according to their roles permissions) and can create and submit the Validation or Part I assessment RFI for SM Part I & II and SM Part I only application.
  - If the RMS's Part II has not yet been submitted in the Initial or in an SM Part I & II application, the RMS have the button "create RFI" enabled (according to their roles permissions) and can create and submit the Validation or Part I assessment RFI. [SD-736820/ PRB0040414/ 133283]
  - If the RMS status is "Not authorised", "Lapsed" or "Withdraw", the RMS has now the button "create RFI" enabled (according to their roles permissions) and can create and submit the Part I assessment RFI if a consideration is raised by an Additional MSC. [SD-732447/ PRB0040419/ 127205]
- Fixed issue for the Member State user, who is now able to comment the RFI response regardless of whether the RMS has already authorised the application, having the assessment comment box available according to role permission. [SD-722940/ PRB0040492/127147]

## D. User registration and authentication

- Fixed issue with the "user administration tab" in the sponsor workspace, when using the amend button to add, delete or change the "Authorise from" and "Authorise to" dates in a role, if the sponsor user clicks on the "Cancel" button or the "X" to close the pop-up window, the changes are now not saved and the previous values are correctly displayed in the search results list. [CTCS-24483/ 129623]

## E. Other issues

- Fixed issue with documents with special characters in the document title, now those can be downloaded. [SD-682890/ PRB0040451/ 133599]
- Fixed issue for sponsor and authority users, when downloading a Part I structure data information that contains in the free text of the dossier the control characters "STX- Start of Text" and "SOH- Start of Heading", the users can now download and open the PDF properly with the corresponding Part I structure data information. [SD-719049/PRB0040458/130171]
- Fixed issue related with application edition load, now if the sponsor tries to submit an application it should be able to proceed. To correct this, the pagination

mechanism (10 items per page) has been applied to the sections that display the document, located in Part I and Part II (in Summary inside the application and in Full Trial Information tab). [SD-729198/PRB0040641/127159]

- Improvement on WHO XML file with the fields that contains a URL. [CTCS-25073/126989]