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CTIS Release Notes – Release v1.0.23.0

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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
- 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 the submission date in the "All Documents" list in both sponsor and authority workspace, the documents display the submission date of the clinical trial application in which they were submitted. [SD-722317]
- Fixed issue with the creation of any application type when in the IN application there is at least one unauthorised product that has changed or is not in xEVMPD anymore, now a message is displayed to the user informing that the unauthorized product information has changed in xEVMPD and needs to be updated in the application to be able to proceed with the application submission. [SD-711729]
- Fixed issue in sponsor workspace, in the case of a partially submitted trial where the 'submit part I' hard task is not yet completed, the user has now only access to the 'Withdraw', 'Copy' and 'Check' buttons. Once the member state concern completes the Part I conclusion hard task, the sponsor can proceed with the submission of Part II. [CTCS-24637]

B. Authorisation and supervision of clinical trials

- Fixed issue for sponsor and authority users with defined access rights, now they can see the publication timepoint for "RFIs sent to Sponsor" and for "Assessment Reports and conditions" in the Decision section of the Assessment Overview under the Evaluation area in line with the selection done by the MSC/RMS when completing the decision task. Also, on the download data, the deferrals recorded from the MSC/RMS are now displayed. [SD-717813]
- Fixed issue in the authority workspace, in the scenario when a user in the Part II conclusion task adds a final decision option and saves it using the save button or lock (and NOT submitted), in case the timer passes and the task is expired, the conclusion field now is not populated with the saved option but instead is populated with the correct indication "no conclusion". The fix is applicable to all relevant application types and their corresponding sections in i) the evaluation folder, ii) the

'+Info' button, iii) the Assessment overview table and iv) CT download [SD-722091]

- Fixed issue in the sponsor workspace, now the users are not seeing 'Acceptable with condition' or 'Not acceptable' when these options are saved but not yet submitted by the Member State Concern. This issue is related to Part I and Part II conclusions of relevant application types and their corresponding sections in i) the evaluation folder, ii) the '+Info' button, iii) the Assessment overview table and iv) CT download [SD-724106]

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

- Fixed issue with documents submitted in the context of an SM part I and II, which are now displayed, instead of missing, and no empty error message appears when expanding the "All documents" section. The documents are correctly visible in both sponsor and authority workspace. [SD-722047]