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SCIENCE MEDICINES HEALTH

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CTIS Release Notes – Release v1.0.44.0

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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
- Other issues
- Other issues indirectly fixed during the validation of this version

Functional Improvements

A. Application Creation/Preparation of documents and data

- Fixed issue with Member State Concerned with an "Ended" status. Now, when the Sponsor creates a Substantial Modification application Part I&II or Part I only, a MSC with an "Ended" status will not be part of the Substantial Modification application and therefore, will not receive any task. [ADO 168669] [PRB0041244]

- Fixed issue when the optional field "Plan description" is not populated. When a Sponsor user creates a new clinical trial, this field will now not be highlighted after validating the application using the "Check" button. [ADO 196750]

- Fixed issue with "Authorisation number of manufacturing and import" field. Now, the field is displayed correctly, being presented one number per document and another one for the section. [ADO 201734]

- Fixed issue with the download of the Corrective measure PDF file. The downloaded file correctly displays now the field "Anticipated date of summary of result from revocation". [ADO 196908]

- Fixed issue with save functionality for trials that were created before the implementation of the revised transparency rules in the workspaces and for which certain documents were soft-deleted and at least one product was linked to a document of type content labelling. Now, after a certain number of save operations, Sponsor user is still able to save a draft application or the draft for the response of an RFI, without facing any error message. [ADO194250] [PRB0041597]

B. Authorisation and supervision of clinical trials

- Fixed issue to allow the change of sponsor for tacit clinical trial authorizations. Now, when a Substantial Modification "Part I only - Change of Sponsor" is tacitly authorised, Sponsor is changed to the new one for the concerned trial. [ADO 189746]

- Fixed issue with Sponsor user not being able to restart a halted trial. Now, Sponsor user is able to link an "Authorised" Substantial Modification, which is a mandatory field, to restart the halted trial inside the extension period, regardless of whether the Temporary halt is due to a benefit/risk reason or not. [ADO 186841]

- Fixed issue with Substantial Modification Part II only application status. Now, after the submission of an acceptable "Validation Decision" and "Part II Conclusion", if the "Authorise" task expires, the Substantial Modification Part II only application status correctly displays "Authorised" instead of "Under Evaluation" in the Sponsor workspace. [ADO 196790]

C. Communication between sponsors and Member States

- Fixed issue with the field "Authorisation number of manufacturing and import" being highlighted to all products. Now, when Sponsor user updates the mentioned field, in the context of a response to a Validation/Part I assessment RFI, the field is shown as updated (highlighted) only for the updated product in both workspaces. [ADO 149863]

- Fixed issue with "Part I conclusion" being displayed in the "Authorise" task of an "Authorised" Substantial Modification Part II only. Now, if the Sponsor user creates a Substantial Modification Part II only, which is then authorised, when the MSC user navigates again to the "Authorise" task in the Authority workspace, only the Part II conclusion information will be displayed. [ADO 186775] [PRB0041512]

D. Other Issues

- Fixed issue with role assignment by administrator users with "Trial specific" scope. These administrator users cannot assign now roles with scope "All trials" . [ADO 196171] [PRB0041610]

- Fixed issue with clinical trials search in the "Clinical Study Reports" tab. Now, when creating a new CSR, the search for clinical trials is working properly and all available clinical trials are displayed, also for clinical trials with NSM in draft status or cancelled. [ADO 193263]

- Fixed issue with role revocation. Now, when Sponsor user tries to revoke a role through the "User administration" tab, no error message is displayed. [ADO 197782]

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

- Fixed issue with "Submit Validation" task for a Substantial Modification Part II only application. Now, when the "Submit Validation" task expires, the application is tacitly validated and the assessment workflow continues. [ADO 186770] [PRB0041520]