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CTIS Release Notes – Release v1.0.42.0

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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

Functional Improvements

A. Application Creation/Preparation of documents and data

- Improvement for sponsor users to be able to indicate if a trial is a transitional trial, not only at the time of its creation but also when drafting the initial application or after resubmission. The sponsor user with the right permissions (CT Admin or Application Submitter) is able to see and edit the "Transition Trial" sub-section displayed now in the Form section, regardless of whether the box is checked or not, to declare it or not as a transitional trial. [ADO 126724]

- Improvement in the system to allow the change of sponsor through a specific single Substantial Modification entitled "Part I only - Change of Sponsor". Now, when selecting the creation of this specific Substantial Modification, the sponsor user can only edit specific information in the "Form" section, the structure fields for substantial modification reason and scope display predefined values and the structured data fields in the Part I- Sponsor section can be modified, including the sponsor the Org ID as well as contact points. [ADO 134886]

B. Authorisation and supervision of clinical trials

- Fixed issue with Start of Recruitment date. The Start of Recruitment date is now only displayed in the Notifications tab if the start of recruitment notification has been submitted. [ADO 177082] [PRB0041185]

- Fixed issue with the "finalize assessment" task for Annual Safety Report (ASR). Now, when the saMS user fianlise the ASR Assessment, the task 'Finalise assessment' is displayed as completed in the task list. [ADO 182197] [PRB0040818]

- Fixed issue with Member State Concerned (MSC) not being displayed in the Annual Safety Report. When one of MSC or the Reference Member State (RMS) does not authorise the Initial application and afterwards authorises it through an Additional MSC application, when an ASR is created, the previous MSC/RMS is now correctly displayed in the MSC section inside the ASR [ADO 162094] [PRB0041075]

C. Communication between sponsors and Member States

- Fixed issue with "Change Application" functionality. When a Sponsor responds to a validation RFI and intends to change the application to a clinical trial that has been restarted through a Substantial Modification after a temporary halt due to safety, the draft version of the RFI response is now successfully created and submitted without error in subsequent substantial modifications. [ADO 162095] [PRB0041142]

D. Other Issues

- Improvement to trigger the population of the "Anticipated date of summary of results" when the overall status of a clinical trial changes to "Revoked" after a Corrective measure is applied. A new section entitled "Revocation" is displayed in both Sponsor and Authority workspaces, which contains the following fields/button:
    - The field "Revocation EEA", which will be automatically populated with the date of revocation in the last MSC;
    - The field "Anticipated date of summary of results from Revocation", which will be populated with a date set to a) 12 months after the revocation of the trial in the last MSC for adult trials or b) 6 months for paediatric trials;
    - The "Update results date" button, for the sponsor user to update the 'Anticipated date for summary of results from Revocation', if required.