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CTIS Release Notes – Release v1.0.38.0

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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
- Collaboration between Member States and Ad-hoc/safety information
- Communication between sponsors and Member States

Functional Improvements

A. Application Creation/Preparation of documents and data

- New functionality to allow the sponsor user to record in the system in a structured way if there is a plan (and its description) to share deidentified Individual Participants Data (IPD). This information can be updated via Non-Substantial Modification and Substantial Modification with Part I in scope and as a response to a Validation/Part I Request for Information. This information is displayed in Part I (subsection Trial Information) [ADO 125833]

- New functionality to allow sponsor user to change the sponsor details via Non-Substantial Modification (NSM) with Part I in scope. In Part I (sponsor section), now it is possible to update the sponsor details into the dossier, by clicking on the new "Edit" button and retrieving the updated information of the organisation (from OMS). While NSM is in draft, the "Organisation ID" of the sponsor is displayed in a new field. Notice that any change made is not effective until the NSM is submitted. Once the NSM is submitted, the changes are reflected in all relevant parts of the CTA Dossier, Full trial information and new Notices & Alerts, RFI, ASR, Inspection records and public portal. [ADO 126215]

- Fixed issue in Non-Substantial Modification Part I only, when the number of subjects is updated and the changes are saved by clicking on the "Save" button, without having unlocked the Member State Concerned section. Now, if the number of subjects is updated, the Member State Concerned is not duplicated, not even in Part II section. Also, if the number of subjects is updated, when creating a subsequent Substantial Modification Part I only application, the same issue described above is fixed. [ADO 142251/PRB0040991]

- Fixed issue with the submission of a Non-Substantial Modification Part I&II or Part II only, if the user chooses to not submit Part II for one or more of the listed Member States Concerned, then Part II of those MSC will not be submitted and a draft (NSM Part II) is created instead. [ADO 147690/PRB0040700]

B. Collaboration between Member States and Ad-hoc/safety information

- Fixed issue in the authority workspace when downloading the temporary halt notification from the "Notifications" option. [ADO 151618/PRB0041003]

C. Communication between Sponsor and Member States

- Fixed issue when there is more than one document in content labeling of the IMPs. Now, when performing a change in the context of a Request for Information (any phase) or submission of any type of application, the links to products are not mixed. [ADO 135392]

- Fixed issue when the roles Q-IMPD Preparer is combined with a CT Admin role. This user can see all the corresponding Requests for Information and their considerations (quality and non-quality). [ADO151609/PRB0040844]