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CTIS Release Notes – Release v1.0.18.0

TABLE OF CONTENTS

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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

Functional Improvements

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

- Fixed issue with document AMPD-Full, in the UI the label is corrected now to not for publication. [SD-715308]
- Improvement in the number of draft substantial modifications allowed to be created at a time. Now, the system allows the creation of one draft SM part I and a maximum of one SM part II in draft per MSC. [SD-713781]

B. Authorisation and supervision of clinical trials

- Fixed issue with Supporting documentation in the Authorise task. When the user uploads one or more documents for publication and/or not for publication and completes the task, the document is visible in both workspaces and remains visible when opening the completed task but it is not visible in any other Authorise task of subsequent applications. It is also not visible for the other MSC involved in the CT. [CTCS-23507]
- Fixed issue in an Additional MS application with a third RFI raised in Part I, if the due date is the same as the authorise task it will remain pending and does not expire until its due date. [CTCS-24062]
- Fixed issue with the withdrawal of an MSC (in any application), the ongoing tasks for the MSC are now cancelled, no further tasks are generated and the MSC remains as withdrawn after the projected due date for the decision has passed. [CTCS-24616]
- Fixed issue, with the creation of Corrective measures. Now the MSC who didn't authorize the IN application but was added later on with Additional MSC Application is able to create a corrective measure. [CTCS-22827]

C. Communication between Sponsor and Member States

- Fixed issue with most of the Supporting and General documents in the RFI section in any application type and any phase. When the users upload these documents the correct indication for publication or not for publication is displayed. Users can upload several documents in the corresponding placeholder and editing/deleting a document does not cause that previous uploaded documents disappear. [CTCS-23637]
- Fixed issue when the user submits a second RFI in Part II, now the calendar is not greyed out and the user can select the correct dates in the date picker. [SD-715219]

D. User registration and authentication

- Fixed issue with "CT Admin" and/or "Application Submitter" roles for a specific trial (regardless of the assignment approach i.e. CT centric or Organisation centric). Now users with these roles can create all types of SM, NSM and AMSC. [SD-684187]