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CTIS Release Notes – Release v1.0.6.0

TABLE OF CONTENTS

Introduction	2
Functional Improvements	2
A. Improvements on the Application Creation/Preparation of documents and data 2	
B. Authorisation and supervision of clinical trials	2
C. Communication between Sponsor and Member States	2
D. User registration, authentication and role matrix	3

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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
- Collaboration between Member States and Ad-hoc/safety information
- Communication between sponsors and Member States
- Locking mechanism
- Publication
- User registration and authentication

Functional Improvements

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

- Fixed issue with MSC to which Part II was not yet submitted, now this MSC should be able to retrieve the trial using the field 'Member states concerned' under both Trial and Application Advanced searches. [SD-649226]

B. Authorisation and supervision of clinical trials

- Fixed issue with Member states that are not participating in the CT, those are now able to view/download structured data and documents for trials not of their concern. [CTCS-23361]

C. Communication between Sponsor and Member States

- Fixed issue with subtasks, which are now available to be displayed/viewed/delegated when the parent task is not listed in the same result page. Now the symbol "+" is always displayed in the subtask and if the user clicks in the subtask title or this "+" icon, the system redirects to the subtask page. [SD-668848]
- Fixed issue with subtasks with special character "+" in the name, as this information is now accurate, so the text displayed shows the "+" instead of other characters. [SD-644975]
- Fixed issue with decision reverted notice, now only the correct/updated notice "Decision reverted" is displayed. [SD-696452]

- Fixed issue with Annual Safety Report, as when the Appoint saMS task expires saMS is now elected and "Circulate draft ASR-AR" task is generated. [SD-694171]

D. User registration, authentication and role matrix

- Fixed issue with all authority users, now they can access to service status menu and selecting "Check Service Status". [SD-639843]
- Improvement in the assign role(s) screen, as a new mandatory "email address" field is added to this screen to prevent incorrect assignment of roles to users. The system will validate that both, the username and email address, match what is stored for the user in IAM. [SD-639843]
- Fixed issue with sponsor users, when having a role with scope specific trial, as this sponsor user should only view and access the RFIs and the RFI's notices and alerts related to the specific trial under the role scope. [SD-687869]