



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## CTIS Release Notes – Release v1.0.25.0

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

## Functional Improvements

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

- Fixed issue in partial initial applications submission (part I only for at least one MSC) where different documents in the "Form" section were still open for editing after submission. The system now allows the addition of further documents in the section but does not allow the removal/edition/update of already submitted documents. [SD-722454]
- Fixed issues with the resubmission of an already withdrawn Additional MSC application containing the proof of payment document, the sponsor user can now proceed without retrieving any error. [CTCS-24584]
- Fixed issue with AR templates, now the information that is auto populated to the assessment report templates is accurate in sections 5.4.15.3 (DSMB), 5.4.15.2 (RSI), 5.4.7 (vulnerable populations), 5.4.5/5.4.6 (Inclusion and exclusion criteria), 5.4.2/5.4.3 (Objectives and endpoints). Also, the versions of the documents recorded are correct. [SD-722057]

### B. Authorisation and supervision of clinical trials

- Fixed issue with consultation with experts, the Member State user is now able, after a Part I soft task is complete, to extend Part I hard task and other soft tasks that are still pending or assigned. [SD-720411]
- Fixed issue with notification documents after an update, no red pop-up with a warning message is displayed, and the documents are correctly updated and displayed. [CTCS-25146]

## **C. Publication**

- Fixed issue with “contact point for union” information, now when a public user downloads the data from Public Portal the whole section “Contact Point for the Union” information is not appearing in the PDF. [SD-732530]

## **D. Other issues**

- Fixed issue with GDPR functionality, now the system successfully completes the replacement of documents. [SD-723197]
- Improvement on GDPR sorting and filtering functionality. Now the EMA Admin users with access to this functionality have more fields to search and filter to quickly find the information needed. [CTCS-24634]
- Enhancement in the WHO API to improve the process of data extraction from the CTIS public portal. [SD-722338]

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

- Fixed issue with GDPR functionality, now the “Decision Supporting” document is returned in the results list after the search. [SD-724127]