



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 May 2026
EMA/105033/2026
European Medicines Agency

CTIS Release Notes – Release v1.0.61.0

TABLE OF CONTENTS

| | |
|---|----------|
| Introduction | 2 |
| Functional Improvements | 2 |
| A. Application creation/preparation of documents and data | 2 |
| B. Authorisation and supervision of clinical trials | 2 |
| C. Communication between sponsors and Member States | 2 |
| D. Other issues indirectly fixed during the validation of this version | 3 |

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



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 indirectly fixed during the validation of this version

Functional Improvements

A. Application creation/preparation of documents and data

- Fixed an issue where the system did not correctly clone Part I, resulting in outdated Part I content being carried forward into new applications. As a sponsor user, when creating a new SM, NSM, AMSC, or Change of Sponsor application, the system clones now Part I from the latest authorised application that had Part I in scope and clones Part II per MSC from the latest authorised application that had Part II in scope for that MSC. [ADO 296078] [PRB0042683]

B. Authorisation and supervision of clinical trials

- Fixed an issue where soft tasks action buttons were missing or assigned subtasks could not be completed during the Validation or Part I assessment of a SM Part I or SM Part I& II when the trial status for the RMS was "Ended". The system now ensures that these action buttons are always available, regardless of the RMS trial status. [ADO 267625] [PRB0041660]

C. Communication between sponsors and Member States

Fixed an issue where the "Change Application" button disappeared after being clicked twice while drafting an RFI response (Part I or Part II). After selecting "Discard Changes," the "Change Application" button was no longer available. The button now remains visible and accessible until the RFI response is submitted. ADO 292751] [PRB0041433]

- Fixed an issue encountered when changing an application as part of a validation RFI response in an SM application, where the originally submitted Proof of Payment (PoP) document in the Form section was not visible. The system ensures that PoP document uploaded and submitted with the original application is now correctly displayed in the "Proof of Payment" section under the "Form" tab within the SM application. [ADO 292744] [PRB0041383]
- Fixed an issue where the RMS did not receive a notification for the submission of an SM containing Part I (SM Part I or SM Part I & II) if the trial had already ended in that RMS. The system now always sends the SM submission notification to the RMS, regardless of the RMS trial status (ended, not authorised, revoked, withdrawn, or expired). [ADO 285886] [PRB0042134]

D. Other issues indirectly fixed during the validation of this version

- Fixed an issue where the system did not generate the "Assess RFI Response" soft task when the clinical trial was in a "Halted" status. The system now ensures that the "Assess RFI Response" soft task is correctly displayed for authority users in an SM. [ADO 296066] PRB0041984]
- Fixed an issue where submitting an additional MSC to a clinical trial was blocked due to a validation error on the "Estimated end of trial date in EEA". The sponsor user is now able to submit the additional MSC application even if this date is flagged with an error indicating it must be in the future. [ADO 309316] PRB0043053]