



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

16 April 2026  
EMA/88831/2026  
European Medicines Agency

## CTIS Release Notes – Release v1.0.60.0

### TABLE OF CONTENTS

<b>Introduction .....</b>	<b>2</b>
<b>Functional Improvements .....</b>	<b>2</b>
<b>A. Access and User Management .....</b>	<b>2</b>
<b>B. Application creation/preparation of documents and data .....</b>	<b>2</b>

---

**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](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://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:

- Access and User Management
- Application creation/preparation of documents and data

## Functional Improvements

### A. Access and User Management

Fixed an issue preventing access to a trial when having Sponsor and Co-sponsor roles for that trial. A user who holds, for the same trial, the CT\_ADMIN role (with all-trial scope) — or any other business role granting view and access rights to the clinical trial — from a Sponsor, and the SPONSOR\_ADMIN role from a Co-Sponsor, can now access the clinical trial via the Clinical Trial search functionality. [ADO 230036] [PRB0041935]

### B. Application creation/preparation of documents and data

- Fixed an issue preventing submission of “Start of Recruitment” for MSCs added via an AMSC application. The sponsor user can submit now the “Start of Recruitment” for a MSC added through an AMSC application within two years plus 15 days from the AMSC decision date. [ADO 267631] [PRB0041979]
- Fixed an issue where, if a sponsor user submitted “Start of Trial”, followed by “Start of Recruitment”, and then a “Temporary Halt notification” due to subject safety reasons and/or a change in the benefit–risk balance, the system would automatically populate an “End of Recruitment” notification. When the “End of Recruitment” notification was subsequently withdrawn, the clinical trial status incorrectly changed to Authorised. The system now ensures that, in this scenario, the clinical trial status correctly remains Halted. [ADO 286971] [PRB0042563]
- Fixed an issue where an updated or withdrawn “Restart of Recruitment” date was not reflected in the Notifications table. The system now ensures that updated or withdrawn “Restart of Recruitment” date is correctly displayed in the “Trial & Recruitment Periods” table under the Notifications tab of the relevant clinical trial. [ADO 286964] [PRB0040581]