7 November 2025
EMA/336410/2025
European Medicines Agency

CTIS Release Notes – Release v1.0.55.0

Table of Contents

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
- Publication

Functional Improvements

A. Application creation/preparation of documents and data

- An improvement has been implemented to allow sponsor users the re-submission of an Initial Application (IN) or Substantial Modification (SM) application with status "Not Valid". Sponsor users can now click the "Resubmit" button, within a submitted IN or SM application to initiate resubmission, redirecting users to a new pre-filled initial application in draft under the CT number of the initial but with the final two digits increased sequentially (YYYY-NNNNN-XX-**00)** per resubmission, or to a new pre-filled SM in draft under the same CT number. [ADO 260919]

- An improvement has been implemented to enable sponsor users to update a broader set of fields and documents within non-substantial modification applications (NSM), aligning the system behaviour with real-world trial amendment practices. The enhancement ensures that users can: 1. Edit and upload documents across multiple sections of the application; 2. Reflect changes in both Part I and Part II, depending on the NSM scope selected; 3. Maintain system validation integrity while allowing flexibility in data updates. Please refer to section 4.8 of the sponsor's handbook to understand the structured data and documents that can now be modified through a NSM. [ADO 125869]

B. Publication

- An improvement has been implemented for public users to view any changes made to a clinical trial application through a Non-Substantial Modification (NSM), including the publication of Part I documents submitted in NSM of historical trials. [ADO 164150]