



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

07 December 2022
EMA/311078/2022
European Medicines Agency

CTIS Release Notes – Release v1.0.10.0

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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 public website. Updates may include: improvements to existing features and functionalities, the addition of new features and functionalities and technical improvements, such as on the 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
- User registration, authentication and role matrix
- Other

Functional Improvements

A. Application Creation/Preparation of documents and data

- Fixed issue on sponsor details section, the "status" field is now called "sponsor type". This field will have a dropdown with the options "commercial" and "non-commercial". [SD-703268]
- Fixed issue on deferral settings that were lost when users were modifying the field on population age with an RFI or Substantial Modification part I. [SD-715511]

B. Authorisation and supervision of clinical trials

- Fixed issue with Start of Recruitment, it is now possible to submit this notification (with Start of Recruitment date within 2 years from the clinical trial authorization) during the 15 days after the 2 years from the clinical trial authorization date without the need to provide a substantial modification. [CTCS-21637]
- Fixed issue in filter "My tasks" in authority workspace. A MS user that claims a task will always have it visible from "My task" filter. [SD-709425]

C. Communication between Sponsor and Member States

- Fixed issue with the notice "Response to RFI Submitted" and the task "Assess RFI Response", as they are now generated for all application types (Initial, SM or AMSC) and during all assessment phases. [SD-705036]
- Fixed issue with change application in the context of a RFI Part II, as only the fields related to Part II are validated and not those related to part I (e.g., estimated recruitment start date in EEA). [SD-703271]

D. User registration, authentication and role matrix

- Fixed issue with assigning roles:
 - In the sponsor workspace, Sponsor and CT Administrators with administrator role for different organizations (i.e. different Organisation IDs), which share the same organization name, can now assign roles to users for any of the applicable organisations.
 - A clear warning message is now displayed when an administrator role tries to assign a role to him/herself or to another user with scope "specific trial" when the user has already this role but with scope "all trials". [SD-622436]

E. Other

- Fixed issue with the XML file required for the interface with the WHO ICTRP, as some elements are now fixed (Contact Point for Public Queries, Contact Point for Scientific Queries, Sample Size, Ethics Review, Completion date, Summary Results, IPD sharing statement). [SD-652851]