EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 November 2022
EMA/311078/2022
European Medicines Agency

CTIS Release Notes – Release v1.0.9.0

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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
- Communication between sponsors and Member States
- User registration and authentication

Functional Improvements

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

- Fixed issue with upload of documents, now is allowed to upload documents with a maximum size of 50MB. [SD-624973]
- Fixed issue with "Timetable" when users are in different time zones, now the submission date is shown on the same date as the clinical trial application was submitted. [SD-656248]
- Fixed issue with IMPD documents of Comparator role, when more than one product is present. The user can now perform the "Change application" action as part of an RFI response in any evaluation phase, and the documents, "IMPD Quality" and "IMPD Safety and Efficacy", remain in the relevant section and not mixed anymore. [SD-696045]
- Fixed issue with products with "Excluded MSC", the user is now able to delete this product and role. [SD-625208]
- Fixed issue in the summary tab with unauthorised products, now the active substance name field is displayed on this screen. [SD-653870]
- Fixed issue with deferrals lost:
    - When changing a Clinical trial application to a paediatric age, only "Main characteristics", "Notifications", "Clinical trial results summary for an intermediate data analysis" and "Clinical trial results summary and layperson summary" should be reset to default values;
    - When accessing a paediatric trial, if the user changes any section on Part I or uses the check functionality (without opening the Form part) the deferrals values are kept;
    - To have the same behaviour as other sections, in a draft application if the user adds values to deferrals and does not save before changing to other section those values are kept. [SD-707978]

B. Authorisation and supervision of clinical trials

- Fixed issue with subtasks assignment, the CT Coordinator is always able to delegate created subtasks to another user. [CTCS-23876] [SD-713865]

C. Communication between Sponsor and Member States

- Fixed issue with users with a role with scope specific trial, who are now able to see only the Notices & Alerts/Request for information for the specific trials under the scope of their role.[CTCS-23800]

D. User registration, authentication and role matrix

- Fixed issues with organisations with special characters, now when the search is performed the organisation name is shown properly. [SD- 666566]
- Fixed issue with CT Admin Specific trial scope, this user is now not able to create trials on an Org-Centric sponsor.[SD-636465]
- Fixed issue with Employer name, the user can update his Employer Name successfully and the Name is also displayed correctly. [CTCS-23948]