CTIS Release Notes – Release v1.0.12.0

TABLE OF CONTENTS

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
- Others

Functional Improvements

A. Application Creation/Preparation of documents and data

- Fixed issue with the deletion of a MSC from a draft clinical trial, now it is possible for the Sponsor users to delete a MSC from a draft clinical trial. [SD-715885]

- Fixed issue with the deletion of "for publication" documents when they have a "not for publication" document linked. Now the deletion of the "for publication" one is not allowed in this case, unless the linked "not for publication" document is deleted in the first place. [SD-622438]

- Fixed issue as consequence of previous fix, that allows sponsor user to create an SM or NSM without a red pop-up error displayed. [SD-710498]

- Fixed issue with the information from the "Sponsor type" field in the "Legal representative" section. [CTCS-24205]

- Fixed issue with the "proof of payment" document, now the document remains when the Sponsor user responds to an RFI using the "change application" button. [CTCS-21401]

B. Authorisation and supervision of clinical trials

- Fixed issue with the Considerations and Consolidated Considerations sorting mechanism. The sorting is ascendant or descendant according to arithmetic order when using the number attributed or the date columns and alphabetic order when using wording. [SD-715028]

C. Communication between Sponsor and Member States

- Fixed issue to allow Sponsor users to have enabled/present the padlock to 'Change application' in a pending Part II RFI of a CTA under evaluation, regardless of the CTA status in any other MSC involved in that CTA. [CTCS-22790; SD-716264]

- Fixed issue with the visibility in the Authority WS and MS API of the RFI responses saved but not submitted by the Sponsor, now only submitted responses become visible for the Authority and MS API users. [CTCS-22871]

D. User registration, authentication, and role matrix

- Fix issue that allows an administrator user to assign roles to a blank user, even if this blank user was previously assigned with roles that were further revoked by an administrator of a different organization. [CTCS-23979]

E. Others

- Fixed issue with GDPR feature, now it can be used to replace documents uploaded not only by Sponsor users but also by Authority users. [SD-716265]

- Fixed issue with the presentation of different tasks in the Timetable, now the tasks Submit RFI response (projected) appears with the correct values and there is no gap between Submit RFI (projected) task and Submit RFI Response (projected). [SD-708655]