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CTIS Release Notes – Release v1.0.16.0

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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
- Other issues

Functional Improvements

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

- Fixed issue with the document(s) attached per Auxiliary role in the submission of initial and substantial modification applications. The document is now under the correct Auxiliary role to which it was attached and in the same order that it was submitted. [SD-712518]
- Fixed some of the issues with ATC codes search, when the user searches ATC level 3, is now able to find levels 4 and 5 and vice versa, meaning when it searches by level 5, it can also find the corresponding levels 3 and 4. [SD-637419]
- Fixed issue when searching for products with more than 35 substances, the search is now possible, and the user should not experience any irregular delays/timeouts/internal errors. [SD-617619]
- Fixed issue with the creation of an SM application, NSM or copy CTA subsequently to a previous authorised SM application containing for publication and not for publication documents for i) cover letter and ii) modification description. [CTCS-24401]
- Fixed issue in the Structured Data Download Document:
 - The information displayed in the sections "IMPD Quality" and "IMPD Safety and Efficacy" is now accurate, in line with the information displayed in CTIS
 - The information displayed in the section "Contact Point for the Union", is now accurate, in line with the information displayed in CTIS
 - When public user downloads the data from Public Portal, the sections "IMPD Quality" and "IMPD Safety and Efficacy" in the downloaded PDF displays accurate information, in line with the information displayed at that moment in the Public Portal. [SD-713050] [SD-722348]

B. Authorisation and supervision of clinical trials

- Fixed issue with start of recruitment date, which can only be selected within the period of 2 years after the authorization date. [CTCS-24227]

C. Communication between Sponsor and Member States

- Fixed issue with the validation of the "estimated start of recruitment date" in the past when responding to a Validation RFI. When the sponsor user responds to an RFI in the validation phase and the "estimated start of recruitment date" is in the past, now the system highlights this date when the application is checked before submission, however this does not prevent the submission of the application. [CTCS-24225]
- Fixed issue upon RFI Response by Sponsor in SM Part II only, the notice "Response to RFI Submitted" and the task "Assess RFI Response" is now generated. [CTCS-24228]
- Fixed issue with alerts when initial applications are withdrawn in all Member States. Alerts are no longer generated for any of the Member States. [SD-680127]
- Fixed issue with alert "Response to RFI due", this alert is now no longer visible after the sponsor has responded to the RFI. [SD-689468]

D. User registration and authentication

- Fixed issue with the role combination of MS Admin and MS National Admin, which can now only view and manage users (assign/ revoke/ amend) affiliated with the MS Admin organization. [SD-715236]
- An sponsor user with a CT Admin role with specific trial(s), which is combined with same/other sponsor organizations business roles with scope "all" or "specific" trials, will be able to manage user(s) (i.e. view, assign, amend , revoke, approve role requests) only for the trial(s) under the scope of the 'CT Admin' role [CTCS-23851] [CTCS-23867].

E. Other issues

- Fixed issue with organisation with special characters:
 - When searching in trial advance search, the special character "'" (apostrophe), is properly displayed in the search results.
 - When confirming a role for an organisation with the special character "&", the complete and correct name of the organisation is displayed in the "Confirm role (s)" pop-up.

- When the sponsor and authority user amend a role under the user administration tab, the special character "" is properly displayed in the organisation name.
- The Sponsor names containing the special character "" is properly displayed when the user navigates to Part I via the application and Full Trial information.
- In the Public Portal where the Sponsor/co-Sponsor names contain the special characters " ' " and "&", both Sponsor/co-Sponsor names are properly displayed in the Summary and the Full Trial information. [CTCS-24206]
- Fixed issue for MS API user trying to retrieve a partial submitted trial, when calling the clinical trial application endpoint *GET/clinicalTrials?ms=msc*, the user can now retrieve the information about the clinical trial. [CTCS-23891]