EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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CTIS Release Notes – Release v1.0.14.0

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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
- Other issues

Functional Improvements

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

- Fixed issue, allowing the creation of multiple draft Substantial Modification (SM) Part II at the same time (one draft SM Part II per MSC) and enabling the submission and evaluation of these distinct SMs Part II carried out by each individual MSC. [SD-716272]
- Fixed issue with documents added for translation in an additional Member State application during change application Part I, as part of an RFI response, which are now visible in both workspaces. [SD-716032]
- Fixed issue for authorised medicinal products, the active substance details, including the substance name and its EV code available on XEVMPD, will be populated in CTIS. [CTCS-22890]
- Fixed issue allowing users to download documents containing special characters in their name. [SD-709426]
- Fixed issue in a specific scenario when an SM part I only is authorised in one MSC and still ongoing in any other, when creating an Additional Member State concern application, this application cannot now be submitted. [CTCS-24410]

B. Authorisation and supervision of clinical trials

- Fixed issue with "Part I Disagreement", the Member State Concern (MSC) is now able to issue a "Part I Disagreement" after the RMS submits a positive decision and whenever the "Authorise" task is still pending for that MSC [CTCS-22932]
- Fixed issue with the download button in validation phase, now it is present under the "Consolidated Considerations" screen after submission of validation conclusion. [SD-714751]

- Fixed issue, as the "Considerations", "Consolidated Considerations" and "Request for information (RFI)" tables are now always rendering 15 items per page. [SD-717939]
- Fixed issue with the due dates of "Consolidate Considerations" and "Submit RFI" tasks, which are calculated now using Central European Time (CET) and the deadline for expiry of both tasks is 23:59:59 CET on the set due date. [SD-666400]
- Fixed issue when authorizing an SM Part I & Part II, the conditions displayed for part II decision are now related to my MSC. Each MSC has their own conditions separately in their own decision. [CTCS-22627]
- Fixed issue in all applications, with the decision date recorded for tacit decision (whether "Authorised", "Authorised with Conditions" or "Not Authorised"), matching the due date of the "Authorise task". The tacit decision occurs in the same second as the expiry of the Authorise task i.e. 23.59.59 on the due date. [CTCS-23028]
- Fixed issue in Additional Member State Concern application, the "Part I Disagreement" section only displays information related to that application. [CTCS-19101]
- Fixed issue with "authorise" task, the decision field needs to be populated for the user to be able to complete the task. [CTCS-24009]

C. Communication between Sponsor and Member States

- Fixed issue with comments in Assess RFI response, in Validation and Part I, are showing now the correct MSC name. [SD-713247]
- Fixed issue related to the number of subjects changed in an application as a response to an RFI, as when the information is saved through the "save button or the "padlock" release but not submitted, the changes are now not visible in the authority workspace and API.
- Fixes issue with responses to RFI saved but not submitted, which are now not visible in the authority workspace and API. [CTCS-22871] [CTCS-23046]
- Fixed issue with the alert "response to RFI due", when an RFI is created in the assessment part I of an additional Member State Concerned application, the user can see now the correct "received date", "evaluation process" and "source type" in the alert. [SD-701288]

D. Other issues

- Fixed issue with the log out of users, when the user visits the public portal they are not now log out of the Sponsor and Authority workspace. [SD-720779]
- Fixed the behaviour with the "x" button in the pop-up windows in the system, closing now successfully the window instead of triggering a cancelation action. [SD-683686]

- Fixed issue with MS API user, when calling the notifications endpoint *GET/clinicalTrials/{clinicaltrialId}/notification*, with multiples pages, the user can now retrieve the correct values. [CTCS-21121]
- Fixed issue with MS API performance, the service performance was improved. [SD-708822] [SD-716412]
- Fixed issue with MS API pagination, when calling the GET/clinicalTrials´ endpoint the last page indicated in the Metadata as ´lastPage´ is now the last one that retrieves entries. [CTCS-20541]
- Fixed issues with Scientific Advice documents and Assessment reports, now these documents are published according to the deferrals selected. [CTCS-23760]
- Fixed issue with "IMPD Safety and Efficacy" sections and "Investigator Brochure", this is now published according to the sponsor deferrals settings. [CTCS-23888]