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CTIS Release Notes – Release v1.0.32.0

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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
- User registration and authentication
- Others
- Other issues indirectly fixed during the validation of this version

Functional Improvements

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

- Fixed issue with the number of subjects in "Full trial information" tab, now the latest authorized information is displayed after the number of subjects is updated in the context of all types of Substantial Modifications. [126682/CTCS-24471]
- Fixed issue with "Authorisation number of Manufacturing and Import" in the Medicinal Product section "Compliance with (GMP)" in the context of the RFI response or creation of Substantial modification containing Part I. This field is now editable, and the number previously added in an authorised application is not deleted in the context of an RFI response. Also, highlighted changes do not appear in this field if changes have not been made yet. [133620/126042/ SD-729320]
- Fixed issue with supporting documents for publication and not for publication in RFI pop-up, when the sponsor user uploads a document while responding an RFI, for the document "not for publication" the label is now displayed correctly. [127751/CTCS-24763]
- Fixed issue to submit a Part II for a partially submitted application, when the submit Part I hard task is not completed yet, having the sponsor user now only available the buttons "Withdraw", "Copy" and "Check". Once the MS completes the Part I conclusion hard task, the sponsor is then able to proceed with the submission of the Part II. [135385]

B. Authorisation and supervision of clinical trials

- Fixed issue in Additional Member State Concerned (AMSC) applications to help the user to decide whether the completion of the "Authorise" task should be completed or not in the case there are pending Part I RFIs to be responded by the sponsor. In case the AMSC has raised considerations for part I and tries to complete the "Authorise" task (no RFI has been submitted yet), a new message is displayed to inform the user that there are pending tasks to be completed by the RMS (Consolidate considerations and/ or Submit RFI tasks) alerting the user to wait for

those tasks to be completed but without preventing to complete the "Authorise" task if the user decides to do so. [126448/126029]

- Fixed issue with Part I Draft Assessment Report (DAR) templates, the user is now able to generate and download the document with no error displayed. [135390/PRB0040490]
- Fixed issue with the extension of the "Start of the recruitment" approved via Substantial Modification (SM), the user is now able to select a date within the extension period until the "Anticipated Start of Recruitment Date" approved in the SM and is also able to submit this notification in the same extension period plus 15 days. [133179/130652]
- Fixed issue with the application of the clock stop for the resubmission of subsequent applications to the initial, now all hard and soft tasks are extended considering the winter clock stop. [127178/126776]
- Fixed issue with the withdrawal of a Member State Concerned (MSC), in the context of a Substantial Modification Part I & II, after the "Authorise" task has been generated. The ongoing tasks now change to "cancelled" status after the withdrawal and future tasks for that withdrawn MSC are not generated. Also, the status remains "Withdrawn" after the projected due date for the decision has passed. [126814]
- Fixed issue with Part II conclusion task expiration, the conclusion field will no longer be populated with the saved option that was entered before the task expiration and instead displays now "No conclusion". Additionally, the information saved is not visible from the sponsor workspace until it is submitted. [135385]
- Fixed issue with Part I or Part II hard tasks expired, the decision displays now "No conclusion" and in the case conditions were added on the task, they are not displayed in the evaluation–assessment overview. [126980]
- Fixed several issues when using the filters in the advance search of the task tab. [135404/ PRB0040416]
- Restore access to non-MSC to view and download documents for trials for which they are not concerned. [135528]
- Fixed issues with notices and alerts when a Member State Concern is withdrawn. [126774/CTCS-24702]
- Fixed issue in the ad hoc assessment, IMP number is now correctly displayed after ad hoc is saved and completed. [135403/PRB0040612]
- Fixed issue with ASR search in the tasks tab, now filters are working correctly. [133600/PRB0040510]
- Fixed different issues in the ASR- saMS selection functionality:

    - In the "Appoint saMS" task, the MS of the candidate saMS is now correctly displayed in the drop-down menu and the "saMS selection" section is correctly populated in the Authority WS.

    - When an ASR has multiple MSC and if only one MSC express willingness in the task "Express willingness/ unwillingness" and for at least one MSC the task has expired, the willing MSC becomes saMS automatically (without receiving the

task “Appoint saMS”) and the normal saMS workflow starts for this MSC. [135405]

C. User registration and authentication

- Fixed issue with permissions for users with NOA admin role for an “specific clinical trial” combined with a business role for a different “specific clinical trial”, who now can manage users in line with the scope of its roles. [126806/CTCS-24745]

D. Other issues

- Fixed issues with GDPR functionality, the document is successfully replaced keeping the original metadata and replaced in the download folder. [1270947]

E. Other issues indirectly fixed during the validation of this version

- Fixed issue in an Org-Centric Organisation, CT Admin “Specific CT” scope can now resubmit that specific Initial CTA. Upon resubmitting, the system automatically grants them CT Admin “Specific CT” scope to the resubmitted CTA. [133623]
- Fixed issues with GDPR functionality, the system now completes the replacement successfully. [135388]