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CTIS Release Notes – Release v1.0.5.0

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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
- Collaboration between Member States and Ad-hoc/safety information
- Communication between sponsors and Member States
- Locking mechanism
- Publication
- User registration and authentication

Functional Improvements

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

- Fixed issue in Part I document 'Content labelling of IMP's' linked to a product, which can now be deleted for Initial and Substantial Modification applications containing Part I, as well as in the context of RFI's changes. [SD-622754]
- Fixed issue in Part I document 'Content labelling of IMP's' in Substantial Modifications containing Part I, which appears linked now to the correct product [CTCS-22491]
- Fixed issue in draft application, with cancellation application pop-up warning. When the user clicks 'x' in the upper corner, the pop-up closes, and the draft application is not cancelled now, remaining in draft as expected. [SD-644779]

B. Authorisation and supervision of clinical trials

- Fixed two issues with deferrals. When the sponsor updates the deferrals through an RFI, this information is visible in the evaluation-assessment overview table of both workspaces only after the sponsor submits the response. In addition, deferrals are now only displayed in the evaluation-overview table of both workspaces once the member state authorises the trial. [CTCS-22808]

C. Communication between Sponsor and Member States

- Fixed issue with notices & alerts for CT admin role with scope specific trial. Those users are now receiving only the notices & alerts for that specific trial. [SD-620086]
- Fixed issue for Authority users with role(s) with scope specific trial, as they can only view the clinical trials as well as receive notices/alerts only for the clinical trial(s) under the scope of their assigned role. [SD-643623]
- Fixed issue with Agree RMS due date calculation. In a multi-national Initial Application, only the longest MSC calendar will determine the task's due date related to the timers of day 3, day 6 and day 7. [SD-646658]

D. User registration, authentication and role matrix

- Fixed issue with 'Organisation name' and 'Organisation ID' in the search functionality for requesting a role, as the fields are now read-only, and the user can't edit those fields after adding an organization selected from the search results [SD-644443]
- Fixed issue with 'Organisation name' dropdown values generated when the user is an administrator for more than one organization, as when assigning a role to a user with scope specific trials, the values remain now in the dropdown list [SD-624869]
- Fixed issue with role Assessor Part II Preparer, this role is now able to delete, comment and share consolidated considerations in Part II consolidated considerations tab. [CTCS-23712]