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CTIS Release Notes – Release v1.0.7.0 & v1.0.8.0

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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 with "Daily and Total" unit measures, now the drop-down list is aligned with EudraCT and the values ordered alphabetically. [SD-675810] [CTCS-24015]

- Fixed issue with RFI, preventing the lapsing of the clinical trial application due to the expiration of a second RFI raised in the assessment Part I phase and not responded within 47 natural days of the validation conclusion of that application. [SD-703910]

- Fixed issue with RFI, preventing the lapsing of the clinical trial application due to the expiration of a second RFI raised in the Validation phase and not responded within 23 natural days of the submission of that application. [SD-703898]

- Fixed issue with RFI modal (date picker), as the calendar displays now 10 natural days maximum for the selection of due date response for an RFI raised in the Validation phase. In case the RFI due date falls in a weekend, the due date will then be moved to the next working day. In addtion, the latest selected due date response cannot be never later than the Submit Validation Conclusion task due date. [SD-703898]

- Fixed issue with RFI modal (date picker), as the calendar due date response displays now 12 natural days maximum for an RFI being raised in the assessment phase. In case the RFI due date falls in a weekend, the due date will then be moved to the next working day. In addition, the latest selected due date response cannot be never later than the Submit Part I Conclusion task due date. [SD-707720]

B. Authorisation and supervision of clinical trials

- Fixed issue that allows the submission of the restart of trial notification after a Temporary Halt due to risk/benefit reasons once a Substantial Modification has been authorised or authorised with conditions. [SD-622437]

C. User registration, authentication and role matrix

- Fixed issue with EMA admin, the system does not allow now to assign roles for different member states to the same user. [CTCS-23356]
- Fixed issue role "MS admin", now it appears in the list of roles under the profile of users that only have that user role. [CTCS-23355].