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CTIS Release Notes – Release v1.0.11.0

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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 functionalities, the addition of new features and functionalities and technical improvements, such as improvements to system performance.

In this release, improvements have been made for:

- Application creation/preparation of documents and data
- Communication between sponsors and Member States
- Locking mechanism
- Other issues

Functional Improvements

A. Application Creation/Preparation of documents and data

- Fixed issue with documents 'Agreement from another Sponsor' and 'PIP Opinion', which are now visible in the Authority workspace when uploaded by Sponsor, regardless of whether they are for publication or not for publication. [CTCS-22694]
- Fixed the exception error displayed in the GDPR feature when documents without specified Date were erased and replaced. No document can be uploaded/updated in CTIS having the field Date empty. [SD-684284]

B. Communication between Sponsor and Member States

- Fixed issue with RMS/MSC, they are now able to raise the first validation RFI on day 10 or day 6 for an initial application or substantial modification respectively. [SD-715928]
- Fixed issue with RMS/MSC, they are now able to raise the first part I assessment RFI on day 45 or 38 or day 47 for an initial application, a substantial modification or an additional MSC application, respectively. [SD-715928]
- Fixed issue with RMS/MSC raising the first RFI, they can now add, if required, the maximum number of days (10 and 12 respectively in validation and part I) for the sponsor to respond. [SD-715928]
- Fixed issues with notices from other organisations, which will no longer be received by the sponsor users that do not participate in the trial. [CTCS-20715]

C. Locking Mechanism

- Fixed issue with the lock mechanism when multiple users are working on a clinical trial application. [CTCS-23347]

D. Other issues

- Fixed issue with MS API, when a trial is authorized with conditions in Part II, now the conditions provided in Part II conclusion are displayed in API. [SD-623516]
- Fixed issue with the ability to create Organisations locally in CTIS without the need to be registered in OMS in the following five parts of the system:
 - Part I: Sponsor section- "Third-party organisations"
 - Part II: "Investigational Trial sites"
 - Serious Breach Notification: "Details of the site where the serious breach occurred"
 - Third Country inspectorate Notification: "Third country inspection site"
 - MS Inspections: "Inspected site"

Organisations created locally in CTIS will behave and function in the same way as the ones sourced from OMS. [SD-632273]