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# CTIS Release Notes – Release v1.0.3.2

## TABLE OF CONTENTS



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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 issues in the product section of application creation:
    - All the substance names and the 'EU substance number', listed in a draft application, are now displayed within the application in the "Full trial information" tab after its submission. [SD-641374]
- Fixed issue with section "Source of monetary support or material support", delete button is now working. [SD-627236]
- Fixed issue with the "Estimated recruitment start date" field of the Part I section, the sponsor user is now able to select a date in the past when the trial is transitional. This applies to Initial, Substantial Modification applications and non-Substantial Modifications. [SD-638820]
- Fixed issue with downloaded "Withdraw details" document, now all the required information (date, justification) is according to the CTIS information per Member State Concerned. Also, the message for withdrawal displayed when navigating to the application has all the withdrawn MSCs and an indication to consult the withdrawn details document. [SD-637667]
- Fixed issue with document upload pop-ups in both workspaces, where the language drop-down was updated with a more specific list of official EU languages, following the existing sorting of alphabetic order, and the option "other" was added. [SD-634288]

## B. Authorisation and supervision of clinical trials

- Fixed issue in which a clinical trial application lapsing in one Member State concerned incorrectly prevented the Member States Concerned to continue their activities under the evaluation workflow and their respective tasks. [SD-677589]

## C. Communication between Sponsor and Member States

- Fixed issue with RFI due dates, that could be set in the past when manually typed by the users after closing the calendar date picker. Now this fix prevents the expiration of the RFI and as consequence the lapse of the concerned clinical trial application. [SD-676216]

## D. User registration, authentication and role matrix

- Fixed issue when importing organisations in CTIS from OMS with the special character "&". [SD-622432]
- Fixed issue to ensure correct role assignment by the Administrator roles when the users have a very similar username. [SD-622433]
- Fixed issue with the "Users" tab in the summary clinical trial screen, as now it only displays users that have that clinical trial in the scope of their user role(s). [SD-636994]