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# CTIS Release Notes – Release v1.0.39.0

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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

## Functional Improvements

### A. Application Creation/Preparation of documents and data

- Fixed issue with the submission of Part I only application, when there are requirements not fulfilled for Part II. Now, the user can submit the Part I only application if validation requirements have been fulfilled for Part I but not for Part II. [ADO 162093] [PRB0041121]

- Fixed issue when creating a new draft application which has two or more Product Role Groups with the same name. Documents are not being duplicated now between the different Product Role Groups, which share the same product name, when creating a draft of a subsequent application. [ADO 175978] [PRB0040682] [PRB0041259]

- Fixed issue when using the Delete/Edit functionality after adding multiple documents at the same time. Now the selected action (e.g. delete/edit) is performed only to the document that the user selects. [ADO 140960]

- Fixed issues when trying to delete and replace documents, when using the GDPR functionality, from the system Part RFI, Ad-hoc assessment, Inspections and ASR. Also, the new and replaced documents are appearing correctly in the download folder. [ADO 127094]

### B. Authorisation and supervision of clinical trials

- Fixed issue for Supervisor Submitter and Supervisor Preparer roles. The user with these roles (for all or specific trials scope) can navigate through all sections within a Clinical Trial Application, including the Evaluation folder, without facing any red error message. [ADO 136837]

- Fixed issue with the alert "There are 2 days remaining to submit a decision on the trial" in Substantial Modification applications (all types). This alert is now received by all Member States Concerned, who need to submit a decision on the application, while the "Authorise" task remains pending. [ADO 126728]

## C. Collaboration between Member States and Ad-hoc/safety information

- Fixed issues in Ad-hoc assessment workflow:
    - When an Ad-hoc assessment is linked to an event notification (Serious breach, Unexpected event or Urgent safety measure) previously created, the Sponsor user receives the alert "Assessment of additional information" only after the assessing Member State Concerned submits the outcome of the Ad-hoc assessment. For this alert, the columns "IMP" and "Sponsor" are now populated and display the correct information;
    - When the Sponsor user clicks on this alert's title, he is redirected to the Notifications tab;
    - When the Authority user submits the assessment conclusion and navigates to the "Notices and Alerts" tab, in the 'Notification assessment outcome submitted' notice, the columns 'IMP' and 'Sponsor' are populated and display the correct information. [ADO 127056]