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SCIENCE MEDICINES HEALTH

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## CTIS Release Notes – Release v1.0.19.0

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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
- Communication between sponsors and Member States
- User registration, authentication, and role matrix

## Functional Improvements

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

- Fixed issue with the specific scenario, if the sponsor user submits an Additional Member State Concerned application to re-add a Member State Concerned that did not authorise the trial in the first place, this Member State Concerned will now have available the locker in the "Submit Part II Conclusion" task to be able to proceed with its completion. [CTCS-22720]
- Fixed issue when the sponsor user removes a product and save it, the section "all documents" reflects the removal and it is now updated with the last saved information. [SD-698821]

### B. Authorisation and supervision of clinical trials

- Fixed issue with all SM application types, in the Validation phase, the due date of the "Submit validation decision" task is now correctly displayed. [CTCS-23931]

### C. Communication between Sponsor and Member States

- Fixed issue for Additional MSC application, the "Authorise" task is now extended when an RFI has been issued for the Part I phase after the "Submit part II conclusion" has been completed for this application. [CTCS-19354]

### D. User registration, authentication, and role matrix

- Fixed issue with MS validator and assessor preparer roles with quality restricted rights, which are now able to create/edit/delete quality "Part I considerations" non-IMPdq related. [CTCS-20798]