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CTIS Release Notes – Release v1.0.33.0

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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

Functional Improvements

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

- Fixed an issue that prevented Sponsor users from adding translations for existing populated data in draft Additional Member State Concern application. The fix allows users to add, delete or re-add translations without errors and save them successfully. For the existing authorized populated data, the user can add translations with the same language per each element, when there is more than one, being also able to save them without error. [135394] [PRB0040434]
- Fixed issue to avoid the system validating part I when submitting a Substantial Modification or Non-Substantial Modification Part II only, Additional Member State Concern application or Assessment Part II Request for Information. Therefore, these applications can now be submitted even if part I is no longer compliant with business validation rules or if there is a Medicinal Product or Substance EV Code that has changed or does not exist in XEVMPD anymore. [SD-737618], [PRB0040426], [SD-711729], [135395]
- Fixed issue to allow the successful completion of the "Authorise" task in an Additional Member State Concern application of a Member State that was previously "Not Authorized" in the Initial application, without getting any error [147503]