7 September 2022
EMA/311078/2022
European Medicines Agency

CTIS Release Notes – Release v1.0.4.0

TABLE OF CONTENTS

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
- User registration and authentication
- Other issues

Functional Improvements

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

- Fixed issue with the re-submission of trials. Resubmit button will be displayed and remain enabled only from the withdrawal of the CTA until the first re-submission following that withdrawal. [SD-622435]

B. User registration, authentication and role matrix

- Fixed issue with NOA Admin user role that will only be able to view/revoke/amend roles for users with roles affiliated to the organization of the NOA Admin that assigned their roles. their specific NOA organisation. [SD-639566]

C. Other issues

- Fixed issues with search in CTIS, as the system now blocks the user from initiating another search till the previous search is completed or cancelled. In addition, also the search process is aborted when the user cancels the search. This fix has been included in the following search areas:
  - Sponsor workspace: "Search Organization", "Search Product" and "Search Associated Trials";
  - Authority Workspace: "GDPR search" and "Inspections search". [SD-622616]