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SCIENCE MEDICINES HEALTH

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CTIS Release Notes – Release v1.0.20.0

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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:

- Authorisation and supervision of clinical trials
- Communication between sponsors and Member States
- User registration, authentication and role matrix
- ASR creation and search

Functional Improvements

A. Authorisation and supervision of clinical trials

- Fixed issue with authority users that have roles for specific clinical trial, who are now able to view all trials when performing a search in the Clinical Trials tab. [CTCS-24638]

B. Communication between Sponsor and Member States

- Fixed issue in the specific scenario when an Additional MSC application is submitted and authorised for a previous MSC that was lapsed, not authorised or withdrawn in the initial application, during the assessment of a subsequent SM Part I&II or SM Part II, now the user can create an RFI for Part II for that MSC. [CTCS-24411]

C. User registration, authentication and role matrix

- Fixed issue with EMA admin role assignment. Now EMA admin user cannot assign a NOA role to an MS admin user using the organisation of a different MS admin. [CTCS-24589]

D. ASR creation and search

- Fixed issue in ASR form, when the user searches an ASR by product name, now the autosuggestion is working with a list of products that start with (or match) the product inserted. [CTCS-24689]
- Fixed issue when sponsor is creating a new ASR, now in the search form when adding a valid product ID, the search is working, and information is displayed. [CTCS- 24687]