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CTIS Release Notes – Release v1.0.22.0

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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
- User registration, authentication and roles
- Other issues identified indirectly fixed during the validation of this version

Functional Improvements

A. Authorisation and supervision of clinical trials

- Fixed issue in multinational trials for the "Start of recruitment" notification. The user can now select for each MSC a "Start of recruitment" date in the past by considering the "Start of trial" of that MSC. The calendar date picker is now dependent only on the "Start of trial" date on that specific MSC. This also applies when editing a draft or updating a submitted "Start of the recruitment" notification. In the case that more than one MSCs are multi-selected to submit the "Start of recruitment" date, the system will check that the "Start of trial" date of all selected MSCs is the same, otherwise the "Start of recruitment" button will be disabled. [SD-729749] [SD-722445]
- Fixed issue in transitional trials for the "Start of recruitment" notification. The user can now select for each MSC a "Start of recruitment" date in the past by considering the "Start of trial" of that MSC. The calendar date picker is now dependent only on the "Start of trial" date on that specific MSC. This also applies when editing a draft or updating a submitted "Start of the recruitment" notification. In the case that more than one MSCs are multi-selected to submit the "Start of recruitment" date, the system will check that the "Start of trial" date of all selected MSCs is the same, otherwise the "Start of recruitment" button will be disabled. [SD-709867] [SD-731212]

B. User registration, authentication, and roles

- Fixed issue to allow the assignment of roles to users despite the ORG name selected contains the special characters "&" and "." or Greek letters [SD-730685] [SD-718611]

C. Other issues identified as indirectly fixed during the validation of this version

- Fixed issue within the initial application that has more than one Part II RFIs, if at least one RFI is responded to, but any other RFI is not responded to, now the pending RFIs automatically do not expire and as consequence the application for that specific MSC will not change to lapsed before the due date set by the submitter for the pending RFIs. [SD-724622]
- Fixed issue when a member state user merge, accept, not include, or adapt considerations, only those consolidated ones and selected from the consolidated considerations tab will be included in the RFI to be sent to the sponsor. [SD-722366]