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CTIS Release Notes – Release v1.0.21.0

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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
- Other issues

Functional Improvements

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

- Fixed issue with age range secondary identifiers, the values are displayed and retained after saved. Also, when downloading the structure data PDF, the 'Age range secondary identifier' is now showing the correct values coming from the workspace. [CTCS-24467] [CTCS-24419]
- Fixed issue with the creation of an SM application, NSM or copy CTA subsequently to a previous authorised SM application containing for publication and not for publication documents in the supporting documentation under the Form section. [CTCS-24592]

B. Authorisation and supervision of clinical trials

- Fixed issue in the Evaluation Assessment overview, the documents uploaded by the authority user per application type (except SM Part I only) in the authorise task are now properly displayed in both Sponsor and Authority workspaces when navigating to Evaluation - Decision - Assessment overview and clicking the + icon. [CTCS-24761]

C. Other issues

- Fixed issue in ASR, in considerations and consolidated considerations now the system displays 15 items per page. [CTCS-24485]
- Fixed issues with organisations created locally in CTIS, when creating/submitting a new Organisation locally in CTIS no email confirmation is sent by the system to the user. [CTCS-24477]

- Fixed issue with notices & alerts for EMA admin, EC admin, Union controller preparer and Union controller submitter. Now the correct notices & alerts are displayed for those roles. [CTCS-23980]