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CTIS Release Notes – Release v1.0.27.0

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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 issues with CTIS local organisations creation:
 - Upon creation of a new Organisation in "draft" and before submission, an edit pencil is now available to edit again the draft, as required. [CTCS-24476]
 - When the submitted Organisation is opened for updating, all the previous data is retained as it was when submitted except the "contact email", "contact phone" and "Comments" - these should be blank for each update. [CTCS-24474]
 - The form is updated successfully with the changes made only when the user clicks "Update" and confirms; when the user clicks "Cancel" or "X" in the confirmation pop up window of the "Update" form instead, any changes are discarded and the data that was previously submitted is restored. [CTCS-24475]
 - The attachment section inside the Form is removed. [CTCS-24473]
- Fixed issue with Q-IMPD Preparer role, which is now able to upload quality documents in a draft version of a clinical trial application without retrieving an error message. [CTCS-25157]
- Fixed issue with a CT Admin role with scope "specific" CT combined with other non-quality related business roles with "specific" scope but for other trials, which has now access only to the FAR Part I-Quality for the trial under the scope of the CT Admin role. [PRB0040468]

B. Authorisation and supervision of clinical trials

- Fixed issue with the task "Assess RFI Response", which does not expire now before its due date during the assessment Part I of substantial modification applications. [SD-729085] [PRB0040513]

C. Other issues

- Fixed issue allowing to search, select and add organizations located in United Kingdom (Northern Ireland) with no strange characters or error message displayed. [SD-662778] [PRB0040589]
- Fixed issue with the two-factor authentication (2FA) and the impact on the Notices and alert count, the counting is now correct after the fix. [PRB0040460]