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SCIENCE MEDICINES HEALTH

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CTIS Release Notes – Release v1.0.34.2

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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:

- Improvements in the Application Creation/ Preparation of documents and data
- Authorisation and supervision of clinical trials
- Publication
- Other issues indirectly fixed during the validation of this version

Functional Improvements

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

- Fixed issue in the download output of a "Start of Recruitment" notification in both Sponsor and Authority workspaces. A new field named "Start of recruitment date" has been added to this document, which now is populated with this date as entered by the user in the user interface when creating, editing, submitting or updating the "Start of recruitment" notification. [135396].

B. Authorisation and supervision of clinical trials

- Fixed issue with the status of a Member State Concerned where the "Start of Recruitment" notification has not been submitted within the 2 years of authorisation as required by the Clinical Trials Regulation (2 natural calendar years + 15 days), being correctly displayed now as "Expired" in both Sponsor and Authority workspaces. [135402/CTCS-21657].
- Fixed issue with the trigger of the soft tasks "Document considerations" and "Assess RFI", for Substantial Modification applications Part I & II and Part I only, during the Validation, Assessment part I and Assessment part II phases, when the Member State Concerned has the status "Suspended".

C. Publication

- Fixed issue in the Public Portal when a public user downloads Clinical Trial information. Now the "Start of Recruitment" information appears in the Summary PDF, under the "Trial information" section. [126971/CTCS-25012].

D. Other issues indirectly fixed during the validation of this version

- Fixed issue in multinational trials allowing the Reporting Member State, who did not authorize the "Initial" clinical trial application, to create and share considerations in Validation and Assessment Part I for Substantial Modifications Part I & II and Part I only. The Reporting Member State has now enabled the triggered soft task "Document considerations". [126079/ CTCS-20572].