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CTIS Release Notes – Release v1.0.13.0

TABLE OF CONTENTS

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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
- Communication between sponsors and Member States
- Other issues

Functional Improvements

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

- Fixed issue with the submission of an Additional Member State Concerned (AMSC):
  - It is now possible to submit an AMSC for an MScs that issued a negative decision or was withdrawn or lapsed, in the Initial Application.
  - It is not possible to submit an AMSC when an SM Part I or SM Part I & II are ongoing in any MSC.
  - It is possible to submit an AMSC when an SM Part I or SM Part I & II or SM Part II lapses or is withdrawn (keeping the rule that the new MSC is neither ongoing in any application nor authorized).
  - It is possible to have more than one AMSC submitted at the same time as long as each has a different MSC. [CTCS-22901]
- Fixed issues when creating a transitional trial: the user cannot submit an initial application that does not contain a valid EudraCT number. [CTCS-22853]
- Fixed issue with sponsor user, when unlocking the products section and clicking directly on the IMPD safety and efficacy section, the justification field now is not present if a document has been previously uploaded in the IMPD-Q section or vice-versa. [CTCS-16123]
- Fixed issue with age range between 18-64 years in the MS API, which is now present in the CT_AGE_RANGE table. [SD-660736] [SD-696112]
- Fixed issue with the mix up/not copy of certain product related documents when changing an application as part of the response to an RFI raised in the context of an Additional MSC application or Substantial Modification. [SD-719683]

B. Authorisation and supervision of clinical trials

- Fixed issue with proof of payment document, now the sponsor user is able in all evaluation phases, after changing an application as part of an RFI, to upload or remove this document. [SD-639285] [SD-715203] [CTCS-23648]

C. Communication between Sponsor and Member States

- Fixed issue in the authority workspace, on an Initial application, all the Member States concerned by the application process of the RFI are now receiving the notice 'RFI sent to sponsor', 'Consolidated consideration and 'Response to RFI submitted' shared', even the MSCs that are still pending to receive the Part II from the sponsor. [SD-717997] [CTCS-23327]
- Fixed issue when raising considerations, sharing consolidated considerations or preparing the considerations to be included in an RFI, if the user selects the tick-box to 'select all', now "all" of them will be selected regardless the number of pages needed for listing those. [SD-713926] [SD-658027]

D. Other issues

- Fixed issue with MS API user, now in the endpoint *clinicalTrials/{clinicalTrialId}/applications/{applicationId}/parts2/{part2Id}*, the user is able to retrieve all trial sites information under Part II. [CTCS-21126]