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CTIS Release Notes – Release v1.0.40.0

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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
- Publication

Functional Improvements

A. Application Creation/Preparation of documents and data

- Improvement of the technical validation of the clinical trial applications to be aligned with the [revised transparency rules](#). When creating an Initial, Substantial Modification, Additional Member State or non-Substantial Modification application, the system must check and highlight in red the missing mandatory documents according to the revised transparency rules. [ADO 134146]
- Improvement concerning documents uploaded in applications, regardless of their status, submitted before the cut-off date of the implementation of the [revised transparency rules](#) and to comply with these requirements after this date:
 - For the documents that are published and will remain published under the revised transparency rules, the system remains AS-IS.
 - For the documents that are currently not published and will remain not published under the revised transparency rules, the system also remains AS-IS. Those documents, when uploaded after the cut-off date, will display a red informative text "This document will not be publicly accessible." (e.g.: quality related documents, DAR, Financial arrangements, etc.).
 - For the previously published documents that will no longer be published under the revised transparency rules, they will be hidden for publication version or converted (e.g. if only the document "for publication" was uploaded, it will be converted to the "not for publication" document and the label "not for publication" will not be displayed now). In addition, when downloading the documents of an application from the general 'Download', both from Sponsor and Authority WS, the hidden documents from the user interface are not downloaded. [ADO 134144]
- Improvement concerning the "upload document" functionality for new applications to be submitted after the cut-off date of the implementation of the [revised transparency rules](#):
 - For documents to be published under the revised transparency rules, the system remains AS-IS, having the option to upload a "for publication" document (as mandatory document) and the "not for publication" one (as optional document). The label "for publication" and "not for publication" will remain AS-IS.

- For the documents that are not published under the revised transparency rules, the system will only allow to upload a "not for publication" version. Those documents, when uploaded after the cut-off date, will display a red informative text "This document will not be publicly accessible." (e.g.: quality related documents, DAR, Financial arrangements, etc.) and the label "not for publication" will not be now displayed. [ADO 134143]
- Improvements concerning deferral information to be aligned with the [revised transparency rules](#). For new and already existing clinical trial applications, deferral information is hidden in the user interface (e.g.: setting deferrals in a CTA Form section; screen allowing RMS/MSC to set deferrals when performing the "Authorise" task; under the "Evaluation" section and "Decision" folder; under Amend functionality screen, etc.). [ADO 134141]
- Improvements in the MS API, to be aligned with the revised Transparency Rules:
 - When the MS API user uploads the following documents through the MS API, the document is uploaded properly in the Workspace and the type is "not for publication":
 - "Part I assessment report except quality – Final" using the endpoint `"/clinicalTrials/{clinicalTrialId}/applications/{applicationId}/part1/documents/"`;
 - "Part II Assessment Report – Final" using the endpoint `"/clinicalTrials/{clinicalTrialId}/applications/{applicationId}/parts2/{part2Id}/documents/"`;
 - The deferrals related endpoints were removed and are no longer available;
 - When using any endpoint that retrieves documents, MS API user does not retrieve the documents that are not visible in the user interface. [ADO 134145]
- Improvement implemented in the "assessment outcome" option for sponsor notifications in the Authority Workspace. There is now an additional option "No ad hoc required" to trigger the publication of a notification without the need to have it linked to an Ad hoc assessment. This new feature also allows to provide the summary of assessment and outcome in a free text field and upload a document [ADO 125645]

B. Publication

A new version of the CTIS public portal has been released, to allow the implementation of changes foreseen in the [revised transparency rules](#). For a description of the changes, refer to [Annex I](#) of the [Guidance document](#).