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CTIS Release Notes – Release v1.0.2.0

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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
- Collaboration between Member States and Ad-hoc/safety information
- Communication between sponsors and Member States
- Locking mechanism
- Publication
- Member State API
- User registration and authentication

Functional Improvements

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

- Fixed issues when creating an initial clinical trial application:
    - When completing a partial submission, the sponsor user will be able to update the number of subjects field only for the Member State Concern which the Part II has not been submitted yet.
    - The sponsor user can add the "Proof of payment" for each Member State Concern and the document will be uploaded properly for each of them.
    - When preparing an initial application, if the user clicks on "low intervention trial" and adds a justification and then unselects the "low intervention trial" button, a warning was displayed in Part I when checking the initial application. In the warning, the "trial information" section was highlighted. The bug fix now disables this incorrect warning and the highlight in the "trial information" section.

- Fixed issues in the product section of application creation:
    - The sponsor user will be able to select the ''Excluded MSC '' for the product they are adding to the trial.
    - The sponsor user can search by registered active substance when adding a new "Product Role" and to retrieve new or existing active substances registered in the medicinal product dictionary.
    - The sponsor user can search by unauthorised product when adding a new "Product Role" and to retrieve those with no error message.

- Fixed issues related to Substantial Modification (SM) application:
    - The sponsor user can submit a SM that has "all" documents uploaded.
    - The sponsor user cannot submit a Part I SM until all the Member States Concern issue their decision on the initial application.
    - The sponsor user cannot submit a Part I SM while there is still an ongoing initial application.
    - The sponsor user can create a draft Part I SM after an initial application has been authorised, and after an "Additional MSC" application has also been authorised.

- Improvements for multi-SM applications
    - The sponsor user can now make an update in a document related to a product for more than one trial at the same time, if the trials are included one by one instead of in bulk.

- Fixed issue in "Full trial information" as the switch between "Non-SM" and "latest authorised CTA" appears correctly now in Part II for a "Non-SM" with Part II changes instead of part I.

B. Authorisation and supervision of clinical trials

- Fixed issue with the visibility of the Authorisation date:
    - If Member State Concern do not actively complete the "Authorise task", the system will issue a tacit decision. The decision and the date of the decision will be displayed in the corresponding sections of the trial. The "Authorise task" will change to "Expired" status and no button will be displayed for any action.
- Fixed issues with the "Authorise task" document not being visible to the sponsor in the "Decision" and "Assessment overview" sections, which are available under the "Evaluation" area, in relation to different SM types.
- Fixed issues with Revert decision button in the SM applications:
    - A Member State Concern (not the Reporting Member State) will now be able to revert the decision by clicking on the "Revert" button under the "Evaluation area– Part I disagreement" section after creating a disagreement for Part I inside a SM and later giving a negative decision (i.e. not authorize).
- Fixed issues with Notices and Alerts:
    - When "Submit validation decision" hard task expires then the CTA is tacitly validated and the notice "Validation Conclusion recorded" is sent to all stakeholders
    - The Reporter Member State (RMS) or the Member State Concern can go to the "Notices and Alerts" tab and click on the title of the "Consolidated Considerations" notice for validation in order to directly navigate to the consolidated considerations inside the application.

- The users with the role EMA Admin and EC Admin receive properly now the "Notices and Alerts", according to the role matrix permissions.
- An alert with the title "Agree RMS task due" is sent and is properly displayed for the Member State Concern users with the message: "There is 1 day remaining to agree on which MSC should be the RMS" when there is only 1 day remaining for the Member State Concern to agree the RMS.
- The Member State Concern user receives "RFI sent to sponsor" and "Consolidated consideration shared" notices even when Part II is not submitted yet for that MS.

- Fixed issue with "+INFO" button:
  - Part I disagreement label is now displayed correctly for sponsor users and for Member State users in the "+ INFO" pop-up (summary overview) and in the "Assessment overview" table (evaluation area).
- Fixed issue with displayed information:
  - The sponsor and Member State users are now able to see in the "Full Trial Information" the correct value in total number of subjects according to the latest authorised data.
  - The sponsor and MS users are now able to see in the Full Trial Information all the translations coming from the latest authorised "Additional MSC" applications.
- Fixed issue with the calculation of the "Agree RMS" task and presentation in the timetable:
  - The task 'Agree RMS' is calculated and presented correctly for multinational clinical trials with multiple Member State Concern calendars in the case where a consideration is raised before the RMS is selected and users from the Member State Concern do not actively complete the "RMS selection" hard tasks.

C. Improvement on the Collaboration between Member States and Ad-hoc/safety information

- Fixed issues with 'Task overview' section:
  - In an application with several Member States, the "Task overview" section in the "Evaluation" area will now display the respective completion date for each of the Member State Concern tasks.

D. Communication between Sponsor and Member States

- Fixed issue with the Corrective Measures (CM):
  - The Member State Concern user can view the submitted CM in read only mode but cannot edit/update it when clicking the alert "Opinion Submitted" of the CM
- Fixed issue with Request for information (RFI) submission:

- The Member State Concern user can remove and edit a supporting document when submitting a new RFI.
- The MSC user can now submit a Part II RFI in an "Additional MSC" application, after an initial application is halted in one of the MSC and another two "Additional MSC" applications were submitted for the same trial.
- When an RFI is submitted and the sponsor clicks on "Change application" button, until the sponsor submits the response to the RFI, the changes made are not shown under the "Full Trial Information" and under the current initial application.

- Fixed issues with RFI response:
  - When changing the deferrals during a RFI response, the deferrals will be visible in the authority workspace only after the submission of the RFI.
  - When providing a response to an RFI, the user can now update the document "Agreement from another sponsor"
  - The sponsor user can upload documents (general documentation and quality-related), which contain comments with special characters, during the response to an RFI.
  - The sponsor can remove and edit a supporting document when replying to an RFI.

E. Locking mechanism

- Fixed issues with locks:
  - The sponsor and authority users can now properly use the lock mechanism, even when they are working with more than one user on the same trial at the same time.
- Improvements in locks and user logout:
  - When the user locks a section and does not take an action for 25 minutes, the system will not do auto-refresh up to 45 minutes inactivity.

F. Publication

- Fixed issue with decision date publication per Member State Concern in Public Portal
- Fixed issues on published data
  - The public user can see all product information properly, as it appears in the workspaces.
  - The public user can see the MedDRA information.
  - The public user can see the therapeutic area information properly.
  - The public user can see the information regarding the countries outside of the EEA.

- The public user can see in the Summary view and in the trial information the Member State Concern country information.
- The public user can see the supportive document of the decision of the Member State Concern

G. Member State API

- Fixed issue with MS API not being able to retrieve all applications when a clinical trial has more than one application for a member state.

H. User registration, authentication and role matrix

- Fixed issue with NOA Admin being able now to assign roles with scope specific trials to other users within the NOA organization.
- Fixed issues with user roles:
  - Supervisor submitter is no longer able to update a "Corrective Measure" as this user role does not have the permission for this action in the role matrix.
  - Assessor Part II Submitter role is now able to view the "Clock Stop agreement" document in timetable.
  - Validator Part II Submitter can now participate in the discussion of a Validation RFI.
- Fixed issue with EMA Admin being able to assign Member State and Sponsor roles to the same user.

I. View/search/download CT Related Information

- Fixed issue with downloading documents from applications:
  - The sponsor user will not be able to see the "Draft Assessment Reports" for Part I and Part II when using the download functionality. This has been corrected for initial and additional Member State Concern applications.
  - The Member States are not able to view/download the documents of the trials where they are not Member State Concern .
- Fixed issues with the search functionality of the clinical trials:
  - The sponsor user can use the "Advanced Search" criteria for looking for clinical trials using the following filters, which work properly now:
    - The filters "End of Trial from-to" are working properly
    - The filter "Has serious breach" is working properly.
- Fixed issues with SM, as mandatory documents (cover letter and modification description) are now shown in the authority workspace.
- Fixed issue in "Full trial Information", after selecting the Member State Concern in the dropdown, the header is now updated showing the correct CTA type and identifier of the application for the Member State Concern .