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CTIS Release Notes – Release v1.0.0.5

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1. 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

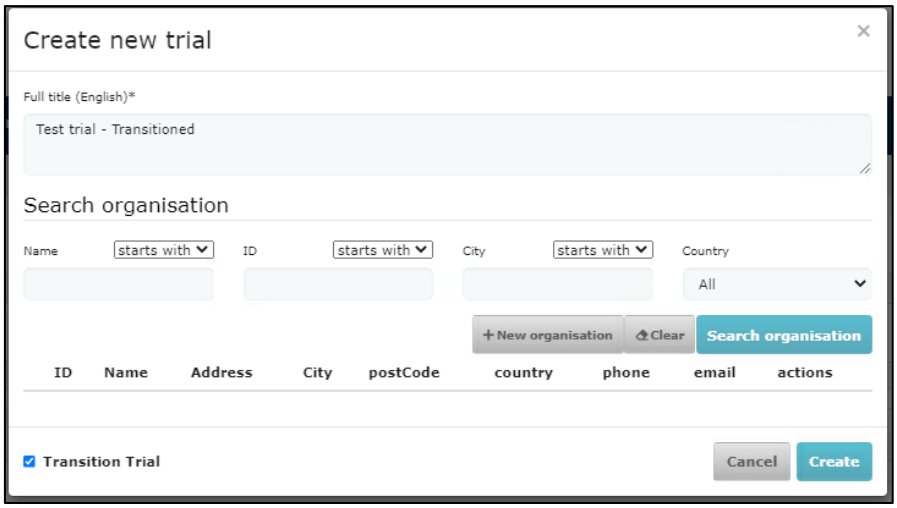
2. Functional Improvements

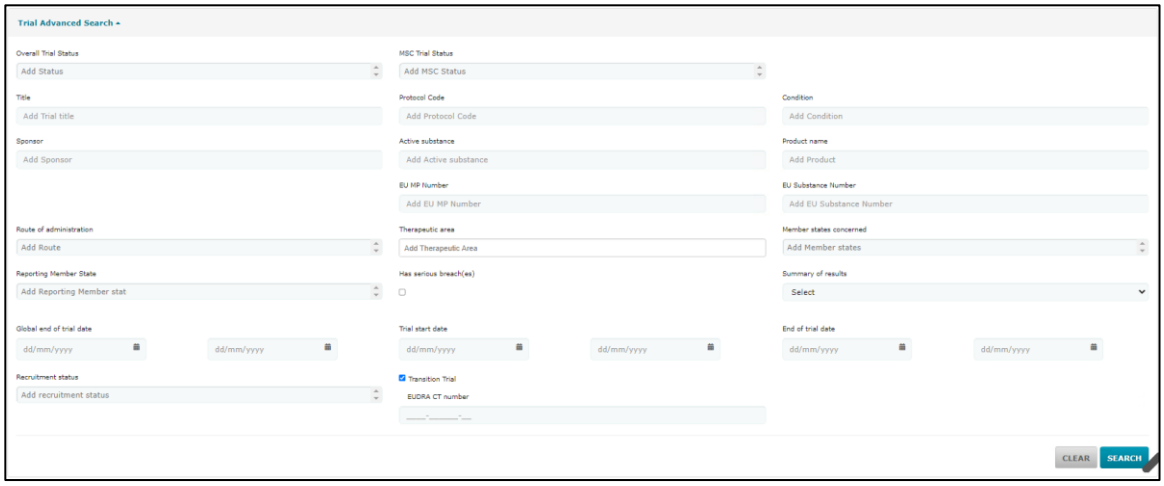
2.1. Improvements on the Application Creation/Preparation of documents and data

- Fixed issues in the mapping and retrieval of the authorised and unauthorised products.
- Improvements in the Products component to search and add unauthorised products – only 2 fields are available, both mandatory for the search:
    - EU Medicinal Product (MP) Number
    - EU Substance Number

- Fixed issue in the product component with not being able to add the same substance for multiple times.
- Fixed issues in the application creation/cancelling when there are parallel applications ongoing:
    - Non-Substantial Modification (NSM) cannot be submitted when there is on-going SM application.
    - After the authorisation of Additional Member State Concerned application, sponsor user will be able to create Substantial Modification (SM) applications.
    - When cancelling the draft Substantial Modification (SM) application, it will no longer be possible to access it via the application URL from the browser.

- Fixed issues with not being able to see the Part II documents in the Initial application.
- Improvements in application creation and trial search to include Transitioned trials.



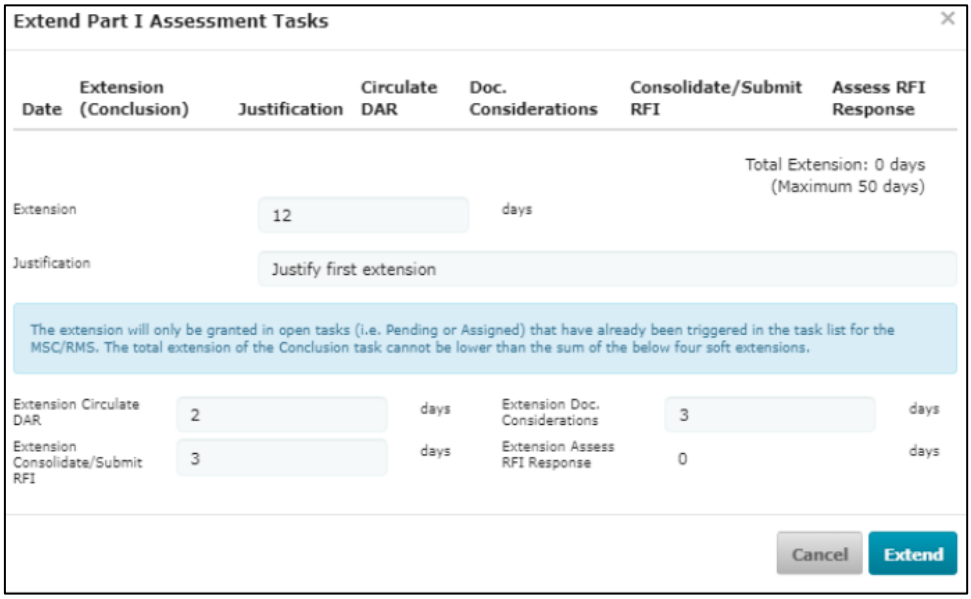


- Improvement in the General Data Protection Regulation (GDPR) related functionalities:
    - When preparing an application, the sponsor user is prompted to upload a document to confirm that data have been (and will be) collected and processed in accordance with Regulation (EU) 2016/679 (repealing Directive 95/46/EEC).
- Fixed issues on visibility of downloadable metadata and documents through the download mechanisms, in line with user permissions.
- Fixed issues with the deferrals that are being lost during the assessment phase of the application:
    - When creating a new application, the sponsor user sets the deferrals in the form section and submits the application. After the submission, the system should retain the deferrals set by sponsor user, the value set should not disappear from the system during the application assessment phase or in any copy or subsequent application.

2.2. Authorisation and supervision of clinical trials

- Fixed issues in the Request for Information (RFI) Response/RFI lapse for different application types:
    - When the due date of an Request for Information (RFI) is reached and sponsor did not respond, it will not be possible to respond anymore, the Request for Information (RFI) will become 'Expired' and the application will be 'Lapsed', and the related hard and soft tasks will be 'Cancelled'.

- Fixed issues in the generation of the task and task overview in the 'task' tab.
- Improvement in the extension of the tasks/tasks display in the timetable.



- Fixed issues with the Reporting Member State (RMS) not being able to add and share assessment comment in Additional Member State Concerned (MSC) Part I.
- Fixed issues with the 'Authorise' task document not being visible to the sponsor in the Additional Member State Concerned (MSC) application, in case more than one application of the same time was submitted.
- Fixed issues with the preparation of considerations in the second Additional Member State Concerned (MSC) application for same Member State Concerned (MSC) after the first one was not 'Authorised' – the relevant users will receive the task and will be able to prepare the considerations.
- Fixed issues when the application status is 'Halted' o 'Suspended'– user will receive the 'Document considerations' tasks when the workflow validation or Part I assessment is triggered.
- Fixed issues and introduced some improvements with the End of trial functionality and the submission of the Summary of results:
    - The 'Early Termination' section will be available for one or all the MSCs that are authorised but not started yet in 'End of Trial' notification.
    - Once a trial has been started and ended for all the Member States Concerned (MSC) that are part of the trial:
        - The sponsor will be able to submit the 'Final' summary of results.
        - The sponsor will also able to submit the 'Final' summary of results for Member States Concerned (MSC) that are not ended but 'Not authorised', 'Revoked', 'Withdrawn', 'Lapsed' or 'Expired'.
    - The anticipated date of the Summary of results section will only be displayed for the 'End of trial' notification when the last Member State Concerned (MSC) that is not 'Ended', 'Expired', 'Not authorised', 'Revoked', 'Withdrawn' or 'Lapsed' is included.
    - Once all the Member States Concerned (MSC) have 'Ended' status, the sponsor will be able to update the information of the Anticipated date for summary of results only

using the 'Update result date' button in EEA and Global section, even if there are no Recruitment periods submitted.

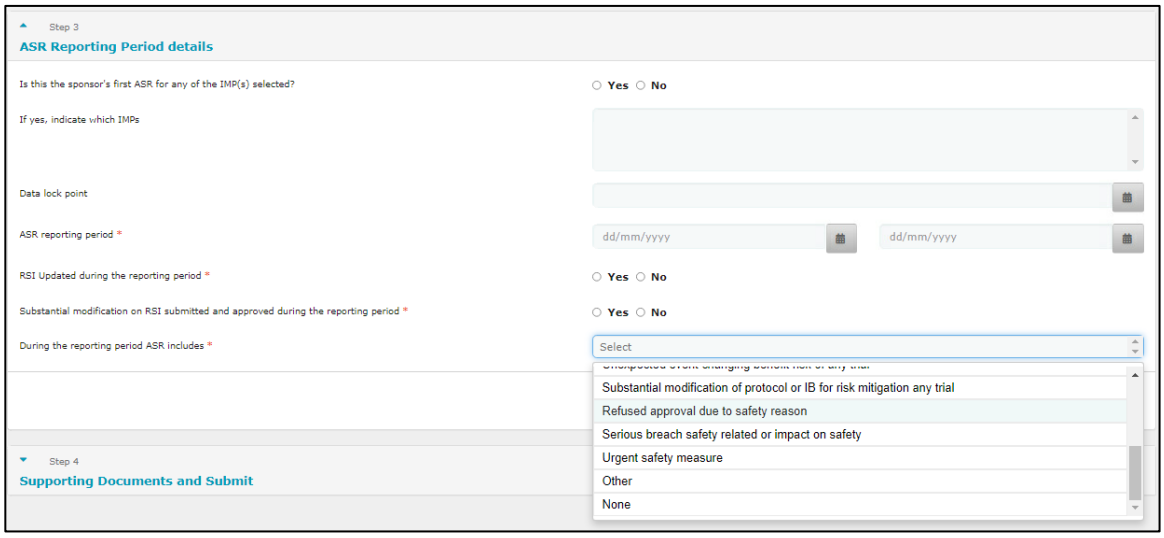
    - The Summary of results, Layperson summary and Clinical Study Report (CSR) information will be published according to the deferral rules set for the trial.

- Fixed issues with the Restart of the trial Substantial Modification (SM) for 'Halted' trials:
    - When creating the Substantial Modification with reason 'Restart trial':
        - The Member States Concerned (MSC) in 'Halted' status will be available to select in the Substantial Modification (SM).
        - The Anticipated trial restart date field will be displayed for all Member States Concerned (MSC) selected in case the Substantial Modification (SM) contains a Part II and only for the selected Member States Concerned (MSC) in case the Substantial Modification (SM) is for Part II only.
    - After the Substantial Modification (SM) is completed and the Member States Concerned (MSC) involved have authorised it, when creating a Restart of trial notification:
        - The user will be able to select the Substantial Modification (SM) where the Anticipated trial restart date was authorised by the Member State Concerned (MSC).
    - When the notification is saved instead of submitted and later edited:
        - The user will be able to select again the Substantial Modification (SM) where the Anticipated trial restart date was authorised by the Member State Concerned (MSC) before submitting.
- Fixed issues in the (intended) Disagreement functionalities:
    - A Member State Concerned (MSC) will be able to issue disagreement after another MSC had issued disagreement and that has been withdrawn by the sponsor.
    - The disagreement information will be correctly downloaded for each of the Member States Concerned (MSC) in the trial.
    - The Justification for the disagreement information will be correctly stored for each Member State Concerned (MSC) that has disagreed.
    - A Member State Concerned (MSC) will be able to issue a disagreement during the assessment of Substantial Modification (SM) Part I and Part II.

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

- Fixed issues with the comments in the Discussion not being displayed in a chronological order in the Reporting Member State (RMS) Selection process.
- Fixed issues in the Annual Safety Reporting (ASR)/Ad-hoc discussion forum section to being able to comment.
- Fixed the issues with the ability to view/assess the response in Ad-hoc Request for Information (RFI) response:
    - Ad-hoc Request for Information (RFI) response and Discussion forum will be visible to Affected Member States and Non-Member States Concerned (nMSC).
    - Member States Concerned (MSC) will not receive the notice that the Ad-hoc Request for Information (RFI) was not responded even after the response had been sent on the due date.

- Improvement in the 'During the reporting period Annual Safety Reporting (ASR)' includes dropdown list – new values are added 'None', and 'Other'.



2.4. Communication between Sponsor and Member States

- Fixed issues in the Corrective Measure functionality:
    - Sponsors will not view the draft Corrective Measure form.
    - Preventing the update of the form after the submission.
    - Corrective measure cannot be applied without request for opinion.
- Fixed issues with non-consolidated considerations being included in Requests for Information (RFIs).

2.5. Locking mechanism

- Fixed issues with the ability for different users to work in parallel in the Corrective Measure Discussion Forum.
- Fixed issues with the ability for users from different countries to work in parallel in the response to Part II Request for Information (RFIs).
- Improvements in locks and user logout:
    - Pop-up message is prompted when the user closes the browser tab, warning them that unsaved data may be lost. The pop-up will offer the option to stay on the page, not log out and save data or to leave the page and log out, losing the data input.
    - When a section is locked for more than 45 minutes or when the browser is closed without closing the application tab first:
        - The section locked by the user is unlocked for other users to work on.
        - A pop-up message is prompted after the user logs in again informing that the session was closed unexpectedly and that unsaved changes are lost.

2.6. Publication

- Fixed issues with the Basic and Advanced Search in the Public Portal:

- Basic search: the issues when searching a Clinical Trial (CT) with '&' and '+' in the title are fixed.

- Advanced search:
  - The issues with the checkbox options to search for specific events or results (clinical trial results, clinical study report, low intervention trial, serious breach, unexpected event, urgent safety measure, inspection) are fixed.
  - The issues with the search combining Member State and Trial status are fixed.
  - The issues with the search with Yes/No options for the field 'Does this product have an orphan drug' are fixed.

- Fixed issues with structured data and documents missing in the Public Portal when they should have been published.
- Fixed issue with documents that were duplicated or not always available for download in the Public Portal.
- Fixed issues with the publication of 'Unexpected event', (substantiated/unsubstantiated) 'Serious breach' and 'Urgent Safety Measure' notifications after they were assessed.
- Fixed issue with the publication of Inspections after they were completed and submitted.
- Fixed issues on visibility of downloadable metadata and documents through the download mechanisms.

2.7. Member State API

- Fixed issue with the distinction between Substantial Modification (SM) Part I & II vs Substantial Modification (SM) Part II only in Member State API.
- Fixed issue with the download of Quality information by non-quality roles in Member State API: non-quality roles were able to download it in Member State API and this is fixed.
- Fixed issues with the retrieval of Part I Trial details and Products information and the cumulative list of Member States Concerned (MSCs) via the Member State API.
- Fixed issue with documents that were duplicated or not always available for download in the Member State API.

2.8. User registration and authentication

- Fixed issues with National Organisation Administrator (NOA) Admin user being able to see tasks beyond their business roles.
- Fixed issue with National Organisation Administrator (NOA) Admin user being able to assign roles beyond their National Organisation Administrator (NOA) organisation.

2.9. Other Improvements

- Fixed instability issues with the user session in Member State and Sponsor workspace while using the Public Portal in the same browser.
- Fixed instability issues with information visibility and persistence after saving and/or logging out.
- Fixed instability issues with user concurrence.
- Fixed confidentiality issue with username exposed in 'Task completed' alerts.

- Fixed security issue that allowed any authority user to access a draft application by typing the URL in the browser.