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Clinical Trials Information System (CTIS) List of known issues for Sponsor Users

Release v1.0.38.0 update

Introduction

The purpose of this document is to describe issues known to occur in the sponsor workspace of CTIS. These issues have been identified mainly through use of the CTIS test environments, CTIS training environment (CTIS Sandbox) and CTIS production environment in various activities including e.g. testing, training, organisation model exploration or use in practice. The document also describes workarounds to apply, where possible, should those issues occur.

The document is structured in sections based on CTIS functionalities. The issue is numbered and described followed by an explanation of a workaround. In addition, each item is connected to a number ("[CTCS-xxxxx or SD-xxxxxx]"). This number is unique and is used by EMA to identify and track the issue from reporting to resolution.

EMA aims to publish updates of this document as frequently as necessary once issues are resolved or if new issues would be identified.

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1. Application Creation/Preparation on documents and data

This section contains issues that sponsor users may encounter when creating a new clinical trial application, or substantial or non-substantial modifications or other subsequent actions or while uploading or downloading some documents.

1. **Issue:** When responding to an RFI, the user can upload a supportive document (general section) for which the system incorrectly displays the red statement "document will not be publicly accessible", however this document will be published. When uploading a document to a quality consideration response, the system incorrectly displays the statement "document will be publicly accessible"; this is incorrect as the documents for quality considerations are not published. [CTCS-20567]

   Workaround: The sponsor user should disregard these statements and can confidently upload the document as required.

2. **Issue:** The specific combination of the roles Part I viewer + QIMPD preparer is not working as expected; the user is able to upload documents for different sections in Part I e.g. protocol, IB, synopsis, study design, PIP. [CTCS-22846]

   Workaround: The issue is caused by the combination of these two roles because a user with only one of the roles is not able to perform these additional actions. There is no workaround until the issue is fixed.

3. **Issue:** When a temporary halt is submitted, in the CT summary screen, the end of trial date is updated with the temporary halt date. [CTCS-21083]

   Workaround: There is no workaround until the issue is fixed.

4. **Issue:** When the user drafts a Substantial Modification for which the change is to take place for several trials (multi trials SM application), and the user tries to include more than one trial at the same time, the system displays an error message. [CTCS-23344]

   Workaround: Include the trial for the Multi-Substantial Modification one by one

5. **Issue:** When the user wishes to restart a trial which is halted in one or more Member States concerned and submits a Substantial Modification application with the reason "restart of trial", the system asks for the "anticipated restart trial date" for each Member State concerned, including for those in which the trial is not halted. [CTCS-22793]

   Workaround: To complete the Substantial Modification, the user can provide a fictitious date for the Member States concerned in which the trial is not halted. This fictitious date does not have an impact on the trial in Member States concerned where the trial was not halted.

6. **Issue:** After the initial application is authorised, and a Substantial Modification is created, the draft SM application includes an incorrect header that displays in its title "RFI". [CTCS-21772]

   Workaround: There is no workaround until the issue is fixed.

7. **Issue:** If the user adds the same substance to the application more than once and adds different details for the medical device per each substance, the system saves the medical device information under the first IMP. [CTCS-22802]

   Workaround: The medical device can be defined in the structured data only for the first IMP from the Role until this issue is fixed. The sponsor can provide additional information on the medical device in the documentation provided to the Member State concerned.

8. **Issue:** When Overall Trial Status is "Halted" and a second draft Additional Member State concerned application is added, the translations added to the first Additional Member State concerned application are visible in the draft second Additional Member State concerned application. [CTCS-22653]

   Workaround: There is no workaround until this issue is fixed.

9. **Issue:** In the section "Full trial information", the system does not display the number of subjects per Member State concerned. [CTCS-22593]

   Workaround: The user should view the number of subjects per Member State concerned by clicking on the respective applications.

10. **Issue:** In the associated clinical trials, when adding a EudraCT trial, the sponsor's name is available in the search box but not when the information is saved in the general tab that contains the list of associated trials. [CTCS-22949]

    Workaround: This information can be consulted in CTIS if the search pop up is opened or directly in the clinical trials register of the EudraCT database (clinicaltrials.eu).

11. **Issue:** In the Part I study design period section, during the drafting of an application, the information related to the roles blinded to the participants' treatment is not displayed properly when the pop-up is opened again. The information is saved but is not visible in the period details pop-up. [CTCS-21055]

    Workaround: The blinded roles to the participants' treatment can be seen on the main screen, and actions can be completed, saved and confirmed on the main screen. Also, the roles are properly saved and displayed in the authority workspace.

12. **Issue:** In the deferrals section after adding years and months when a draft application is saved, when returning to deferrals those fields do not become enabled and the user is unable to correct the values if needed. [CTCS-20652]

    Workaround: Set the deferral as date of decision and try again to set the date and months. That way the deferrals are again editable.

13. **Issue:** In a specific scenario where an additional Member State concerned application is created and the user attempts to submit it without a cover letter, when the user then uploads the cover letter and tries to submit it again, multiple invalid validation errors are displayed. [CTCS-21447]

    Workaround: It is possible to proceed by clicking on the submit button again.

14. **Issue:** When a non-SM Part I only is submitted with updates to documents in an authorised CT, the documents table in Full Trial Information does not show the documents added in Non-SM. [CTCS-22886]

    Workaround: It is possible to consult these documents in the application.

15. **Issue:** When the user verifies that a draft application has all mandatory fields completed by clicking on the "Check" button, the system may not highlight some fields that have not been completed. [SD-635524] [CTCS-21199]

    Workaround: The user should verify manually that the fields for the telephone and the email address have been completed correctly for the third party organisation(s) included in the application. Also, the user should verify that they have provided the scientific and public contact points as these are mandatory fields.

16. **Issue:** When RFIs are raised during any evaluation process (validation, Part I or Part II) for any type of application, a response to RFI due alert is not generated for the sponsor to inform them that there are some days remaining to submit the response to the RFI. [CTCS-19185] [CTCS-18132]

    Workaround: There is no workaround until the issue is fixed.

17. **Issue:** When none of the Member States Concerned authorise a trial, and then one of them reverts the decision to "Authorise with Conditions", this information is not displayed in "Full trial Information" [CTCS-23307]

    Workaround: The user should navigate to the initial application to review the decision on the application.

18. **Issue:** In a draft Initial application part II, the sponsor is provided with a list of document types that includes the ones required to upload the documents to the part II. However, the list also includes three types that refer to documents that can only be uploaded by member states (Part I Disagreement and Revert Decision support documentation). [CTCS-18825]

Workaround: The sponsor user should ignore these document types provided in the list

19. **Issue:** When searching for an ATC code, the search results obtained may not be complete and also, the sorting functionality in the column "ATC code" does not adequately sort the results. [CTCS-22991]

    Workaround: Until the issue is fixed, users are advised not to sort the search results by ATC code.

20. **Issue:** Once an unauthorised product has been added to the clinical trial application in the part I, the user can manually add ATC code associated with the product. However, if they wish to delete or update the ATC code, it is not currently possible. [CTCS-22990] [CTCS-23004]

    Workaround: In order to delete or update the ATC code, the user needs to delete the entire product.

21. **Issue:** When the user wishes to add an active substance, instead of selecting an authorised medicinal product with a specific trade name, in the product section of Part I, the user enters in the search field four letters starting with a capital letter, incorrect results are retrieved. [CTCS-22864]

    Workaround: The user is recommended to enter more than four characters in the search field and/or not use capital letter.

22. **Issue:** When creating a non-substantial modification, if the user navigates to the form section and inserts the "+" character in the field labelled "Non-substantial modification description", after pressing save, the character changes to "+". [CTCS-23710]

    Workaround: The user should refrain from using the character "+" in the description of modification.

23. **Issue:** In the part I section, the user can provide translation to some of the fields populated in English (e.g. endpoint), if the translation is deleted, and then the user tries to add it back in, the language is greyed out as if the translation still exists. [SD-722056]

    Workaround: User needs to click "Confirm" on the popup, open the window again and then the language is no longer greyed out and can be selected.

24. **Issue:** When the user is adding translations in an Additional Member State (AMSC) application to the content labelling document and tries to submit with this section lock, the warning message displayed is not accurate. [CTCS-23636]

    Workaround: After unlocking the section if the user press submit button the AMSC application can be submitted.

25. **Issue:** When Member State concerned (MSC) fails to submit Part II conclusion by the due date deadline and they have a status of "No Conclusion", the Decision timeline is removed from the timetable for that MSC. [SD-723692]

    Workaround: The user can add this MSC and will receive the task as normal once RMS submits the Part I conclusion. Only misleading in the timetable.

26. **Issue:** When creating an Additional Member State Application, the sponsor user is able to delete the Member State concerned just added without the option to add it again. [CTCS-24701]

    Workaround: The user can cancel the additional member state application and create a new one.

27. **Issue:** In the product section, after performing a search, a user might have two results for a product with the same name, MA number, form, strength and active substance but different PRD codes. Currently, these entries are listed separately and not in single one, with the PRD codes separated by a comma. [SD-731875]

    Workaround: There is no workaround until the issue is fixed.

28. **Issue:** In the case of partial submission of a Non-Substantial Modification, non-SM, (submission for one MSC out of two or more MSCs of the trial), in the trial summary page, the details of the 'Application and Non-Substantial Modification' part is not accurate. In the details of the non-SM, in the column 'MSCs', it is displayed not only the MSC for which the trial was submitted, but also that/those for which the non-SM was not submitted. [CTCS-24944]

    Workaround: There is no workaround until the issue is fixed.

29. **Issue:** When a CTA includes an unauthorised (development) product and the sponsor of this CTA tries to submit it, or tries to respond to a Validation RFI, or a Part I assessment RFI, the following error message might be triggered: "The product(s) information has changed in the xEVMPD. Therefore, please update this application to include the new product information". Although, the automated validation rules should highlight the product needing the update in CTIS, another product may be highlighted instead of the development product triggering the error. Moreover, as sponsor user clicks on the padlock button to lock the section and updates the product details, another product may be highlighted. [CTCS-25131]

    Workaround: The sponsor user needs to navigate to the section Part I when clicking on the button "Check" or "Submit" in order to see the correct product record needing an update. If more than one development product are included in the CTA, sponsor users are to update the product for which the substance EV code(s) was recently amended in xEVMPD.

    In order to update the unauthorised product, the sponsor needs to:

    - identify the product requiring an update;

- remove the development product (only the structured data) by clicking on the "bin" icon by the right end side of the product row (e.g. PRDxxx), Sponsor should not click on the "bin" icon located at the product type level (e.g. test));
- search for it using the updated substance EV code and the product EV code;
- add the product in the application; and
- complete the required structured fields pertaining to the newly added product.

30. **Issue:** When trying to resubmit a lapsed Additional Member State Concern application, that contains proof of payment documents "for publication" and "not for publication", an empty red pop-up is displayed, and the operation fails. [SD-734076]

    Workaround: There is no workaround until the issue is fixed. If this issue is encountered, the user should contact the service desk for a resolution.

31. **Issue:** When creating an SM part II only, the statement in the pop-up *"1 or more MSCs must be selected"* must be corrected, as it is only possible for the user to select one Member State Concern at that time, the statement should be *"1 MSCs must be selected"*. [CTCS-24826]

    Workaround: The user should ignore this statement and select one MSC in SM Part II.

32. **Issue:** In the summary page, if a medicinal product is associated with a device, the "Yes" indication appears only when the medical device has the CE mark checked. [CTCS-25214]

    Workaround: There is no workaround until the issue is fixed on the summary page, but the user can consult the information in the product section

33. **Issue:** When submitting a Part I only application, in the +info pop up, the record displays Part I & II as if the application included both parts. [SD-736325]

    Workaround: This has no direct impact on the workflow as the application indeed behaves as Part I Only. Please ignore the information on the +info pop up.

34. **Issue:** When uploading multiple documents in all Part II sections with large size 49MB (maximum files size; 50MB), the antivirus service scan should be triggered but the specific warning message for antivirus service is not displayed. This error occurs in all application types. [ADO 126803]

    Workaround: There is no workaround until the issue is fixed.

35. **Issue:** When registering a new Organisation, either in OMS or locally in CTIS, if the Sponsor User does not fill the field "City", an error message appears related with the communication with OMS. This field is mandatory due to a recent change in OMS (although it is not indicated with an asterisk). [ADO 149393]

    Workaround: The field "City" must be filled, even if it is not market with the (*) symbol, to avoid the communication error with OMS.

36. **Issue:** When Sponsor user selects the general download functionality in Summary page of the Clinical Trial and specifically the Corrective Measures, the Justification Documents are not downloaded. [ADO 145209]

    Workaround: If the Sponsor user selects the individual download icon for each of the document that are not generated in the downloaded folder in Sponsor Workspace, the Corrective Measure documents can be downloaded successfully.

37. **Issue:** When selecting the Additional Member State Concerned application to be downloaded, it is not correct to see a Validation folder. [ADO 129949]

    Workaround: There is no workaround until the issue is fixed.

38. **Issue:** When two documents with the same title, language and business version are associated to different medicinal products and the application is withdrawn, then the copy/resubmit operation fails and a red pop-up with the following message is displayed: "Only one document version of a document can be uploaded in draft. Please remove the previous version before uploading a new one.". [PRB0041100]

    Workaround: Please differentiate the document title for each document uploaded in the Product section, following the best practices naming documents: https://www.hma.eu/fileadmin/dateien/HMA_joint/00-_About_HMA/03-Working_Groups/CTCG/2023_04_CTCG_Best_practice_guide_naming_of_documents__version_2.0.pdf

39. **Issue:** When the Sponsor user adds at least two substances with the same EU MP Number and EU Substance Number but with different strengths, if the user tries to remove the substance in the last spot of the list, the system removes the first one. [PRB0041077]

    Workaround: Please add the wrongly removed substance back in.

40. **Issue:** When Sponsor user tries to submit a Part I only application by letting Part II section empty, it will not be submitted due to Part II constraint violations. A red pop-up with error message is displayed: "Submitted application has constraint violations, thus cannot be submitted." This system behaviour is incorrect. [PRB0041121]

    Workaround: Sponsor users can add a mock site with all mandatory Par II fields and then submit the application only for Part I (clearing the check for MSC Part II before the submission, in the confirmation pop-up window).

41. **Issue:** After a Substantial Modification application is submitted, while preparing a response to validation RFI, the Proof of Payment documents already added in the submitted Substantial Modification application disappeared. [PRB0041383]

    Workaround: Please add the document back in before submitting the RFI response.

42. **Issue:** When Sponsor user adds more than one product role, adds products and uploads all mandatory data and documents, then upon clicking on Check validation some errors might occur in one of the Roles and user cannot submit the Clinical Trial. The diagnostic function might indicate mistakenly already mandatory populated fields as empty. The order of the roles might have changed, but the highlighting effects might have not been adjusted accordingly, following the re-arrangement of the roles. The respective fields (to those mistakenly highlighted) might be empty in other roles (with the diagnostic having not identified them as empty. [ADO 126763] [PRB0041]

    Workaround: There is no workaround until the issue is fixed. Please check that the mandatory fields of the other roles have been correctly populated, even if they are not highlighted as empty ones.

43. **Issue:** When the field "plan to share IPD" is blank and the user verifies if the application has all mandatory fields completed by clicking on the "Check" button, the system highlights this field (in Part I) but not the section "Trial information". [ADO 180369]

    Workaround: The user should verify manually that the field "plan to share IPD" has been completed by selecting a value from the dropdown list.

2. Authorisation and supervision of clinical trials

This section contains known issues related to the sponsor's activities for the application where the sponsor interacts with or responds to the Member State assessment of their application.

1. **Issue:** The user cannot associate Active Substance(s) in an unexpected event notification form. [CTCS-22816] [CTCS-23045]

    Workaround: The user can use the free-text field "Other" to enter information about the Active substance(s).

2. **Issue:** The user can create a restart of trial notification for a halted trial due to an issue with the Benefit/Risk and submit it without having received an authorisation to re-start the trial. [CTCS-22403]

    Workaround: The user should not submit a re-start of trial notification if the halt was due to Benefit/Risk before they have received a positive Substantial Modification authorisation to re-start the trial.

3. **Issue:** In an initial application, where the Part II Assessment RFI has lapsed, the overall trial status may still display as "Under evaluation" when in fact the application has lapsed. [CTCS-22748]

    Workaround: The overall trial status will display as lapsed once the Reporting Member State concludes on the Part I assessment. Users are advised to always check the individual Member State concerned trial status.

4. **Issue:** When the CT admin provides the end date of the trial and the projected date for the summary results (which must be within 12 months of the end of the trial) as part of the end of trial notification for a mono-national trial and multinational trial, the system assumes that the results will be provided over 12 months after the end of the trial and requests a justification for the delay. [CTCS-22888]

   Workaround: The user can select the reason "other" and provide the justification that the results are to be provided within 12 months of the end of the trial.

5. **Issue:** When the user updates the 'Notification supporting documentation' document, the updated document is displayed in the previous version of the Unexpected Event notification. [CTCS-22635]

   Workaround: The user should navigate to the previous version to see any updated documentation, until this issue is fixed.

6. **Issue:** At this moment there is no possibility for the member state to disable to winter clock stop during the evaluation of a clinical trial application. [CTCS-11646]

   Workaround: There is no workaround until the issue is fixed

7. **Issue:** When the Sponsor user updates the "Start of Recruitment" or the "Re-start of Recruitment" date, this is not reflected in the main Notifications tab. However, the date can clearly be seen when the user navigates to the notification. [SD-725401]

   Workaround: The date is correctly displayed in the version of the Notification.

8. **Issue:** During the assessment of a clinical trial application, the timetable may show different due dates/status/information than the actual due dates/status on the Tasks page and RFI page. This does not impact the workflow and the actual due date of the task and RFI. [SD-725109]

   Workaround: Users are recommended to comply with the due dates recorded with the individual tasks and RFI. The users can confirm the RFI due date in the Evaluation folder and raise a ticket to confirm any other due dates with the service desk.

9. **Issue:** When the Start of Recruitment Notification is downloaded, the information of the Start of Recruitment date is missing. It is only showing the Submission date as to when the Notification was submitted in the system. [SD-722036]

   Workaround: There is no workaround for the download of the information until the issue is fixed. The information can be consulted in the trial notification page.

10. **Issue:** In the Substantial Modification part I application, the supporting documentation that can be uploaded by the Member State is not visible after Authorise task's completion. [CTCS-24237]

    Workaround: The Member State users need to contact the EMA Service Desk.

11. **Issue:** When the Sponsor user creates a 3rd Country Inspectorate Inspection Notification, without uploading the mandatory document "Report Summary", the progress bar gets stuck and there is no validation error for the missing document. Also, user cannot cancel the notification and if he clicks on "Close", the notification disappears. [ADO 126214]

    Workaround: The Sponsor User must upload the mandatory document and re-submit the notification.

12. **Issue:** In Clinical Trials screen, in the Ad-hoc Assessment tab for the Sponsor user, a banner text is displayed.". This is incorrect once documents from Ad-hoc Assessment section are not published. [ADO 126142]

    Workaround: Please ignore the message as it is misleading and is not aligned with Clinical Trial Regulation.

13. **Issue:** When a Start of Recruitment Notification is created and kept in Draft Status, the date might be displayed in the Notifications tab even if it is not submitted, misleading the user to think that the notification has been already submitted (when is not). [ADO 177082]

    Workaround: Users can confirm the information by clicking on the MSC and checking the notifications status.

3. Communication between Sponsor and Member States

This section contains the issues related to the RFI functionality that sponsor users might face when performing the "Change Application" process.

1. **Issue:** When the user changes the application in response to an RFI, more than one version of the 'Content labelling of the IMPs' document can be uploaded. The system should not allow this action and an error message should be displayed stating "Only one document version of a document can be uploaded in draft. Please remove the previous version before uploading a new one." However, this error message may not in fact display. [CTCS-22700]

    Workaround: Sponsor users should only upload the new version that they wish the Member State concerned to review.

2. **Issue:** In the response to an RFI, when the user changes the application and they lock the Member States concerned section, if the user navigates out of the application and navigates back to the Member State concerned tab to unlock the section, the section cannot be unlocked. There is an error message displayed. [SD-645818]

    Workaround: Following the above steps the error will be displayed and the user will not be able to unlock the section. The user needs to wait approximately 45 minutes and log back into the application to be able to unlock the Member State concerned tab without receiving the error message.

3. **Issue:** In the summary tab, under application details, the statement "considerations are pending to be consolidated" appears even though all consolidated considerations are already concluded. [CTCS-20694]

   Workaround: The message disappears when manually refreshing the page. The workflow is not impacted, and it is possible to proceed with CT tasks. It is only the auto-refresh that is not present.

4. **Issue:** When the RFI is sent in Validation phase, in the Conclusion sub-section, it is displayed that the application is valid although the Reporting Member State has not yet submitted the conclusion to the validation and has yet to complete the task. [SD-672772] [CTCS-20643]

   Workaround: The user should ignore this label and proceed as normal.

5. **Issue:** After sharing an Ad-hoc assessment, if any changes are applied and a new RFI is created, the RFI number should be recorded with a sequential number unique to that RFI. However, this is not the case and the RFI number can be the same for distinct RFIs associated with the same ad hoc assessment. [CTCS-23085]

   Workaround: There is no workaround until the issue is fixed.

6. **Issue:** The alert RFI sent to the sponsor is not received [SD-722055]

   Workaround: There is no workaround until the issue is fixed. However, the RFI information can be consulted in the RFI tab.

7. **Issue:** The Sponsor user is unable to respond to a request for opinion related to corrective measure when the request is opened through the Notices & Alerts. [SD-724041]

   Workaround: The user needs to navigate to the RFI tab and opens the request for opinion through this page, then the response box is editable, and the user is able to respond.

8. **Issue:** During an Assess Part I RFI, if an authorised product is removed and added again to the application then its strength and pharmaceutical form may not be displayed but instead a dash "-" is shown on the screen. [SD-733224]

   Workaround: Once the RFI response is submitted, the system shows the information

9. **Issue:** During the change of application in the context of an RFI part II, if the sponsor adds new documents (for publication on not for publication) in the form section but decides later to discard the changes, the documents in this section are still visible like they were already submitted. [CTCS-25142]

   Workaround: There is no workaround until the issue is fixed. Please contact the service desk for a resolution if this issue is encountered.

10. **Issue:** When submitting a new RFI, in some cases the submission date of the RFI is set one year in the future. [SD-712179]

    Workaround: There is no workaround until the issue is fixed. If this issue is encountered, please contact the service desk for a resolution.

11. **Issue:** When the sponsor user tries to reply to an RFI part II for a trial containing a development product (with Part I RFI already concluded), or tries to submit a Part II SM, or an Additional MSC application or a non-SM Part II, an error may be triggered asking for the product information to be updated. The sponsor user cannot update the information because Part I is not editable and therefore cannot submit the response to the RFI Part II. [SD-737618]

    Workaround: There is no workaround until the issue is fixed. Please contact the service desk for a resolution if this issue is encountered.

4. Locking mechanism

This section contains the known issues related to the lock mechanism and the problems with data/document refresh while there are parallel users working at the same time.

N/A

5. Publication

This section describes the known issues related to the CTIS Public Portal and publication processes of trial-related information.

1. **Issue:** The supportive documentation submitted by the sponsor within the overall section of the RFI may not be published as per the system specifications. [CTCS-22012]

   Workaround: There is no workaround until the issue is fixed.

2. **Issue:** For all trials including several Member States concerned, the Reporting Member State is not identified in the public website. [CTCS-22892]

   Workaround: There is no workaround until the issue is fixed. Trial details for all Member States concerned and the reporting Member State are displayed on the public website, only the identification of which Member State is the reporting Member State is not displayed.

3. **Issue:** From 15.7.2022 information related to a limited set of clinical trials was prematurely published on the public website of the EU Clinical Trial Information System (CTIS) portal.

Based on available findings, it has been confirmed that information on requests for information or the reports related to Part I or Part II assessment were inadvertently made available on the public portal which is not in accordance with the established transparency rules. These documents were published earlier than the deferral rules allowed it. link

It has been confirmed that the protocol, the investigator brochure and Investigational Medicinal Product Dossier (IMPD) were not published, which is in accordance with the established deferral transparency rules. link

Mitigation action was taken on 9 August 2022 to suspend access to the published trials on the public website of the EU CTIS portal. As a consequence, external users were not able to view or search for public trials.

The CTIS public website is now available again, following verification by EMA that only the correct information is accessible via the public domain for all trials with deferrals. The disclosure rules have now been correctly applied to previously affected trials, preventing publication of RFIs, RFI responses and assessment reports.

A mitigation measure has also been put in place to prevent publication of clinical trials with deferrals.

As a consequence, clinical trials with any type of deferrals with a decision issued mid-August onwards are not available in the public domain.

This is a temporary measure until the functionality of the deferral mechanism is restored.

It is still possible for sponsors and EU/EEA Member States to apply deferrals to clinical trials data, which will be published in due course once the issue is resolved.

6. Other Issues

This section includes the known issues that do not fall under the above categories.

1. **Issue:** When a user creates a trial without using an organisation retrieved by OMS (indicated with valid IDs, OR**G**-), but instead, using an organisation that is registered locally in CTIS (with a temporary not validated ID, OR**Q**-), the user cannot assign roles to other users. Even if the respective request (a change request is submitted to OMS, once user creates the organisation in CTIS and a temporary ID is assigned to it) is approved by OMS team, user's CT Admin role will be under temporary OR**Q**-ID and will not be able to assign roles to other users [CTCS-22792] [ADO 126253]

   Workaround: It is strongly recommended that the user creates the new organisation in the Organisation Management System (OMS), following the guidelines as those described in document **E - OMS Change Requests**, found in OMS document repository, before using it to create a trial. If the organisation is created through CTIS, the user (with the CT Admin role) will need to have the Sponsor Admin role for the validated OR**G**-ID (providing that the request to OMS had been approved) or the CT Admin role (associated with valid OR**G**-ID), assigned to them by the Sponsor Admin of their organisation.

2. **Issue:** The "search for organisation" feature, which is an integration with the Organisation Management System (OMS), **does not support non-Latin characters**. [CTCS-22798]

   Workaround: The users should search using the organisation ID code. Alternatively, the search can also be done using Latin characters only.

3. **Issue:** The user is not able to remove a location associated with an organisation by accessing the relevant functionality in CTIS. [CTCS-22595]

   Workaround: It is recommended to request any organisation change directly in the Organisation Management System (OMS).

4. **Issue:** When the user receives an email from CTIS, the EMA phone number and address are outdated [CTCS-22925].

   Workaround: There is no workaround until the issue is fixed.

5. **Issue:** In the Notice & Alert dashboard advanced search, in the field "Title of the Notice/Alert" the predictive search is not returning dedicated workspace specific notices and alerts. [CTCS-19133]

   Workaround: There is no workaround until the issue is fixed.

6. **Issue:** Sponsor and Authority users navigate to Notices & Alerts Tab and search for the "Validation conclusion recorded" notice for Substantial Modification, then click on the notice and the user is not redirected to the correct section. [CTCS-23319]

   Workaround: The information can be consulted in the Evaluation section.

7. **Issue:** When a sponsor user requests roles (specific and all trials), the CT Admin for that organisation is not able to approve/assign them. [SD-708662]

   Workaround: If this issue is encountered, please contact the service desk for a resolution.

8. **Issue:** When the user performs a search by email in the user administration advance search, no results are returned. [CTCS-23778]

   Workaround: The user can use other fields to perform the search e.g. username.

9. **Issue:** When a role is requested, the sponsor admin user cannot change the dates in the "authorise date" field when approving the role. [CTCS-21463]

   Workaround: The administrator can approve the role and then use the amend to change the dates.

10. **Issue:** When a role has expired, and the sponsor admin user re-assigns it again, upon confirmation if the action, the following error message is triggered "This role has been already assigned to the user". However, if the user refreshes the page the role is indeed re-assigned to the user. [CTCS-23893]

    Workaround: The users should always refresh the page to view/confirm if the message is valid.

11. **Issue:** In the request roles pop-up, the field organisation name may be truncated if it contains too many characters, the full name of the organisation for which the sponsor user is requesting a role is not displayed correctly if it contains too many characters. [CTCS-23442]

    Workaround: Even if the name of the organisation is not rendered correctly, the Sponsor user can still request a role.

12. **Issue:** When trying to open a Clinical trial that the user did not create, a message Permission for viewing summary of results denied is displayed and blocks the user from opening a CT. [CTCS-24712]

    Workaround: This is related to the cache. Try again after a couple of minutes. If the issue persists, please contact the Service desk.

13. **Issue:** The users with roles Part I Preparer (exc - Q-IMPD) and Q-IMPD Preparer do not receive an alert after the sponsor RFI response in the validation phase. [CTCS-23756]

    Workaround: There is no workaround until the issue is fixed.

14. **Issue:** In an Organisation centric approach, Application Submitter and CT Admin with CT-specific scope seem to be able to resubmit CTs. However, they can create a draft application to which they do not have access. CT Admin with All trials scope should be able to resubmit CT and access the draft application. [SD-730405]

    Workaround: There is no workaround until the issue is fixed.

15. **Issue:** In few cases, for the ASR the notices related to RFI are not received. [SD-736448] [PRB0040553]

    Workaround: The user can consult the information in the RFI tab.

16. **Issue:** The alerts "Submission of the laypersons summary of results due" and "Submission of the summary of results due", sent to Sponsor user, are triggered early with wrong due date. CTIS mistakenly takes the first End trial notification submitted (instead of the last MS') as the reference starting point to calculate the due date of the result submission related actions, thus resulting in earlier submission of aforementioned alerts. [PRB0041327]

    Workaround: There is no workaround until the issue is fixed.

17. **Issue:** Sponsor user with role "ASR Submitter" for a specific trial, which creates an Annual Safety Report, does not receive the notice "RFI sent to sponsor" from Notices and Alerts tab, when the Member State Concerned creates a Request For Information. For a user with "Application Submitter" and "CT Admin" roles for a specific trial, the user does not receive the notice "Ad-Hoc Assessment RFI submitted". In addition, Sponsor user with the appropriate roles but for the specific trials does not receive RFI results for Ad-Hoc assessments and ASR's under RFI tab. [PRB0041258]

    Workaround: There is no workaround until the issue is fixed.