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

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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. Where a datafix is required, this is indicated in the workaround specifying that the user should contact the EMA CTIS ServiceDesk.

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 (“[ADO-xxxxxx]” or “[PRB-xxxxxxx]”). 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.



Table of contents

1. Access and User Management	3
2. Application Creation/Preparation on documents and data	4
3. Authorisation and supervision of clinical trials	12
4. Communication between Sponsor and Member States	14
5. Publication	15
6. Other Issues	15
7. ADDITIONAL NOTES	17

1. Access and User Management

This section covers known issues related to user account management and access control. It includes problems affecting role-based permissions that may impact user experience and system functionality.

1. **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. [ADO-126268]

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.

2. **Issue:** When a sponsor user requests roles (specific and all trials), the CT Admin for that organisation is not able to approve/assign them. [PRB0040580]

Workaround: The CT Admin can assign the role directly rather than approving the role request. If this doesn't help resolve the issue, please **contact the ServiceDesk** for a resolution.

3. **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.

4. **Issue:** Sponsor/CT Admin users might be able to still see other users as Sponsor Admins in user Administration tab, even after the roles of the latter ones have been removed in IAM. The user whose Sponsor Admin was removed in IAM should have been logged into CTIS, to synch the CTIS view with IAM view. If the user does not log in, the role will be still displayed as assigned to user's account in CTIS. However, the user does not hold the relevant permissions. [ADO-270712]

Workaround: There is no workaround, until the functionality is changed. After the role removal in IAM, the user does not hold any Admin permissions in CTIS.

5. **Issue:** Sponsor users with the ASR_SUBMITTER role only for a specific CT, are able to create an ASR for different CTs of the same organisation. After creating this ASR, the user won't be able to access the ASR, due to not having the ASR_SUBMITTER role for that CT. [PRB0042085]

Workaround: There is no workaround to prevent users from creating ASRs for CTs for which they don't have the ASR_SUBMITTER role. Users can receive access to the submitted ASR by assigning the ASR_SUBMITTER role for the concerned trial

2. 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 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. [ADO-126408]

Workaround: Users are advised to avoid using the multi-trial substantial modification functionality and should create a separate substantial modification per trial.

2. **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". [ADO-126169]

Workaround: There is no workaround until the issue is fixed, however, the Sponsor user will be able to proceed with preparing and submitting the Substantial Modification.

3. **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. [ADO-126257]

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.

4. **Issue:** When the 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. [ADO-126232]

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

5. **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. [ADO-126284]

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

6. **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. [ADO-123136]

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. Other areas that might not be highlighted if certain fields are not properly filled in and prevent users from submitting the application are the three "estimated dates" in the "Trial duration" subsection, in the "Trial information" of Part I and the Characteristics of the added products in the "Products" section of Part I. If everything is complete and you are still unable to submit, please open a ServiceDesk ticket.

7. **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. [ADO-125950]

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

8. **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" [ADO-126402]

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

9. **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. [ADO-126322]

Workaround: Until the issue is fixed, users are advised not to sort the search results by ATC code. If you are unable to complete the search by ATC code, **please open a ServiceDesk ticket.**

10. **Issue:** Once an unauthorised product has been added in Part I of a CTA, 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. [ADO-126325]

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

11. **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 and enters only few characters in the relevant search field, incorrect results are retrieved. [ADO-126276]

Workaround: The user is recommended to enter more than four characters in the search field.

12. **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 “+”. [ADO-126512]

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

13. **Issue:** In the part I section, the user can provide translations 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. [PRB0040555]

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.

14. **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. [ADO-126491]

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

15. **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. [PRB0040498]

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

16. **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 or Part I 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. [ADO-127030]

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.

17. **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”. [ADO-126846]

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

18. **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. [ADO-127070]

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.

19. **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 marked with the (*) symbol, to avoid the communication error with OMS.

20. **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.

21. **Issue:** Different issues when Sponsor user downloads the Clinical Trial in PDF format:

- When an Additional Member State Concerned application is downloaded, a Validation folder might be falsely included. [ADO-129949]
- The Validation conclusion might not be displayed correctly in the download report and according to what RMS has submitted. [ADO-164768]
- Information for the Legal Representative and the Sponsor might be mixed in the download PDF reports. [ADO-178549] [PRB0042387]
- In the End of Recruitment section of the downloaded PDF report, a Start of Recruitment date is populated that is incorrect (same as the End of Recruitment date). The Start of Recruitment date is correctly reflected in the Start of Recruitment section. [PRB0041594]

- In the downloaded PDF, the field for Tacit Decision is marked as 'No' even though a tacit Decision was recorded. [PRB0041678]

Workaround: Structured data in the downloaded pdf cannot be corrected, however, the relevant information can be seen in the application itself. In addition, sponsor users may use the built-in print functionality of their browser to print out parts of the application.

22. **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

23. **Issue:** When a 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.

24. **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.

25. **Issue:** When a Sponsor user adds more than one product but does not complete all mandatory data/documents, upon clicking on 'Check validation' some fields might be marked in red despite the field being completed. The order of the Products might have changed, but the highlighting effects might have not been adjusted accordingly, following the re-arrangement of the Products. The fields highlighted in red might be empty in other Products (with the diagnostic having not identified them as empty). [ADO-126763] [PRB0041387]

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

26. **Issue:** When a Sponsor user tries to save multiple trial sites entries with the padlock icon, a red error message appears with internal error. [ADO-167757]

Workaround: Please add the multiple trial sites at the same time and then click the "Save" button (don't use the padlock icon for save action). As an alternative, if a Sponsor user wants to use the padlock icon, he must add the multiple trial sites one-by-one and click padlock icon each time after adding each entry.

27. **Issue:** Application Submitter role is not allowed to view the FAR Part II. [PRB0040410]

Workaround: Please assign the Viewer Part II role to the affected user OR another user with CT Admin can download it and share with this user.

28. **Issue:** When a Sponsor user creates an Initial or Substantial Modification application and adds Principal Inclusion Criteria, Exclusion Criteria, Primary and Secondary Objectives and translations with characters between 2000 and 4000, after saving, some text is missing. [PRB0041687]

Workaround: Please, limit the characters to 2000 for the mentioned fields.

29. **Issue:** When a Sponsor user tries to resubmit an expired Clinical Trial, the resubmit button is not displayed, whether is Trial-Centric or Org-Centric approach. [PRB0041766]

Workaround: Until an improvement allows resubmission of expired trials (overall status), users could create a trial from scratch and associate it with the original (expired) trial by adding reference to the latter in the "Associated trial" subsection of Part I. By using the copy functionality in the Expired CTA, a new trial will be created and the original EU CT number will be automatically added in the Associated Trials section of the new trial.

30. **Issue:** When a Sponsor user creates a second Substantial Modification Part II only application and selects as reason "Extension to start recruitment beyond 2 years", he cannot select from the calendar as "Recruitment start date" a date with a minimum date after 2 years from the decision date of Initial application as the system will only allow a date of at least 2 years after the latest authorised application. [PRB0041826]

Workaround: The sponsor can select a later date and provide an explanation in the cover letter. Alternatively, if needed, Sponsors can **open a ServiceDesk ticket to apply a datafix**. Please also note that the mandatory date validation is not working and the SM can be submitted without Recruitment date in case of 'Substantial modification reason' as 'Extension to start trial recruitment beyond 2 years'. Please make sure to select a date, even if the system does not mark it as mandatory.

31. **Issue:** When Checking 'Vulnerable population' in *Part 1 – Trial information – Population of trial subjects*, and selecting one or more 'Recruitment population group' options, followed by unchecking 'Vulnerable population', the previously selected Recruitment population group items are incorrectly still visible in the 'Population type' field in the Summary page of the trial. [PRB0041931]

Workaround: Before unselecting the 'Vulnerable population' checkbox, first remove all selected 'Recruitment population type' options.

32. **Issue:** When users use angle brackets (< >) characters in structured data fields, the system eliminates the text inside these characters. [ADO-219293] [PRB0041854]

Workaround: Please avoid the use of angle brackets characters. As a suggestion, please use other types of brackets, e.g., (); {}; [].

33. **Issue:** For submitted trials, when sponsor users create new application drafts to respond to RFIs or to submit new applications, or non-SMs, the cloned documents from previous versions might be listed in the section 'ALL DOCUMENTS'. The problem might appear in both workspaces (Sponsor and Authority). [PRB0041274]

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

34. **Issue:** When trying to update the number of subjects in response to an RFI, an error message (HTTP 404 Not Found) is shown after clicking on the padlock button to open the MSc section. [PRB0040432]

Workaround: Navigate to the RFI tab and click on the relevant RFI ID (NOT the CT hyperlink). Click the padlock to open the RFI. If there are existing changes and you see "Discard Changes" click on "MSCs" from the left panel. If there are no existing changes and you see "Change application", click on the "Change application" button and then click on "MSCs" from the left panel. Click on the padlock to edit the number of subjects.

35. **Issue:** When creating a draft SM, the number of planned subjects per MSc does not match the latest authorised application but is copied from the initial application. [PRB0040432]

Workaround: If this issue occurs, please update the number of planned subjects before submitting the SM.

36. **Issue:** A Proof of Payment document cannot be uploaded in a Substantial Modification if the trial has been temporarily halted due to the risk-benefit balance. [PRB0040998]

Workaround: If this issue occurs, please upload the Proof of Payment document under the Cover Letter section.

37. **Issue:** When responding to a Part I or Part II RFI, if the *Change Application* button is clicked twice, two draft RFI responses will be created and the Sponsor cannot respond to the RFI. [PRB0041433]

Workaround: If this issue is encountered, the user should **contact the ServiceDesk** for a resolution.

38. **Issue:** When trying to submit a Start of Recruitment notification the Sponsor is requested to "Please provide the reference to substantial modification that authorizes the start of recruitment." The mandatory drop-down box is empty and the Sponsor is unable to submit the notification [PRB0041979]

Workaround: If this issue is encountered, the user should **contact the ServiceDesk** for a resolution.

39. **Issue:** When submitting a notification (i.e. Start of Trial, Start of Recruitment, ...) for a transition trial, it is not possible to select a date earlier than the initial authorisation date recorded in CTIS. [PRB0040681]

Workaround: Please select the earliest date allowed by the system and attach a supporting document that specifies the correct date.

40. **Issue:** When submitting the Global End of Trial date, it is not possible to select the same date as the EEA End of Trial date. [PRB0040485]

Workaround: Please select a day later than the EEA End of Trial date as the Global End of Trial date and attach a supporting document that specifies the correct date.

41. **Issue:** For a multi-national trial, if a MSc is ended or revoked and then a Part I or Part I+II SM is created, the revoked MSc will be shown in the MSc tab. [ADO-234409]

Workaround: If the Sponsor locks the MSCs section the ended or revoked MSC disappears and after unlocking it does not appear again.

42. **Issue:** Once a document is uploaded, the selected language found in the properties cannot be edited. [PRB0040634]

Workaround: Until the issue is resolved, users may delete and upload the document again, selecting the correct language. Alternatively, users may use the 'Comments' field found in the metadata of the uploaded document placeholder, to indicate the correct language.

43. **Issue:** When an Additional Member State application is withdrawn, the system changes the overall trial status from 'Authorised' to 'Under Evaluation'. Moreover, this blocks the user from creating and submitting CT notifications.

Workaround: If this issue is encountered, the user should **contact the ServiceDesk** for a resolution.

44. **Issue:** When a new label is updated in response to an RFI, only one previous version of that label will be displayed, even if there are more previous versions for that label. [ADO-263936]

Workaround: The previous versions of the labels can be seen in the applications in which they were submitted.

45. **Issue:** When Member State concerned fails to submit Part II conclusion by the due date, in the timelines, the decision and its projected date are no longer displayed for that MSC.

[PRB0040447]

Workaround: Despite the absence of the decision and its projected timelines, the Member State concerned (MSC) will receive the decision task once the Part I conclusion has been concluded.

3. 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:** 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. [ADO-126285] [PRB0041577]

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.

2. **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. [PRB0040454]

Workaround: Users are recommended to comply with the due dates recorded within the individual tasks and RFI. The users can confirm the RFI due date in the Evaluation folder. For more information regarding the calculation of due dates and the timetable, please refer to Section 3.1 of the CTIS Sponsor Handbook.

3. **Issue:** A Sponsor user is unable to update an already submitted "Event-type" Notification (Serious Breach, Unexpected Event or Urgent Safety Measure), once the trial is halted.

Workaround: If you are unable to update an event-type notification while the trial is halted, **please contact the EMA CTIS ServiceDesk.**

4. **Issue:** When a Sponsor user creates an End of Recruitment Notification and keeps it in draft status or cancels it, the date is displayed in the Notifications tab even if it is not submitted. [PRB0041576]

Workaround: There is no workaround until the issue is resolved. If you are unable to proceed with the submission of the notification, **please contact the EMA CTIS ServiceDesk.**

5. **Issue:** When a Sponsor user creates a 3rd Country Inspectorate Inspection Notification and tries to select a "Date of Inspection" after the earliest "Start of Trial" date but before latest, the system doesn't allow it. It is only possible to select a date after the latest start of trial date. [ADO-199893]

Workaround: Please, select a date allowed by the system and attach supporting documentation to clarify the actual date.

6. **Issue:** When a Sponsor user resubmits an Additional Member State Concerned (AMSC) application where a previously Initial application has been authorised with conditions, the conditions are not displayed inside the Authorised task. [ADO-159805]

Workaround: The user can see the conditions correctly displayed in "Assessment overview" section and in the download.

7. **Issue:** When a Sponsor user tries to submit an ASR, by selecting a clinical trial which test product has more than 256 characters in its active substance name, the system doesn't allow it and the following errors messages are displayed: "Please ensure that all mandatory fields have been populated, RSI documents provided (where applicable) and disclaimer selected." and "An internal error occurred. Please contact your administrator." [PRB0041957]

Workaround: Until the issue is fixed, a data-fix must be applied. **Please contact the EMA CTIS ServiceDesk.**

8. **Issue:** When a Sponsor user submits an SM for an extension to the Start of Recruitment date, the Recruitment Start Date that has been populated in the FORM page of the SM is reflected mistakenly in the Notifications tab, without the user having submitted any Start of Recruitment notification. [PRB0041834]

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

9. **Issue:** When the user submits an *SM Part I – Change of Sponsor* type- for a trial that at least for one MSC the status was Ended or Revoked before the creation of the SM, it is possible after its authorization that the change of sponsor is not completed with access to users of new sponsors not being granted. [PRB0042050]

Workaround: Until the issue is fixed, users that deal with this issue should **contact the EMA CTIS Service Desk.**

10. **Issue:** When the user creates an Urgent Safety Measure in response to a SUSAR, the mandatory field 'Worldwide Unique Identifier' can host values up to 20 characters. If the user tries to enter a

Worldwide Unique Identifier that is longer than 20 characters, an error message will appear. [ADO-126811].

Workaround: An improvement is planned to address this issue. Until the improvement is released, the users are advised to add the full identifier in one of the other available free text fields and fill in the field (mandatory) 'World wide unique identifier' with a smaller value.

11. **Issue:** When a Part I RFI is raised during the assessment of an Additional Member State Application, the Final Assessment Report is not visible in the evaluation section. [PRB0042185]

Workaround: The Final Assessment Report is available in the evaluation section of the initial application.

4. 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:** 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 "HTTP 404 Not Found" displayed. [PRB0040538]

Workaround: User will need to navigate to the "Evaluation" page of the trial and expand the section for the concerned RFI. If the button "Change application" is seen, user shall click on it and try to lock the MSC section again. If the button "Discard changes" is viewed, user shall click on it and start the RFI response preparation from scratch. MSC section could be locked/edited.

2. **Issue:** The alert RFI sent to the sponsor is not received. [PRB0040619]

Workaround: There is no workaround until the issue is fixed. However, the RFI information can be consulted in the RFI tab. Sponsor users are advised to consult the Notices & Alerts as well as the RFI tab.

3. **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. [PRB0040638]

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

4. **Issue:** During the change of application in the context of an RFI part II, if the sponsor adds new documents in the form section but decides later to discard the changes, the documents in this section are still visible as they were already submitted. [ADO-127036]

Workaround: There is no workaround until the issue is fixed. **Please contact the EMA CTIS ServiceDesk.**

5. **Issue:** When submitting a new RFI, in some cases a wrong submission date of the RFI is recorded on the UI. The concerned business rules are not affected [PRB0042595]

Workaround: There is no workaround until the issue is fixed. The issue does not impact the workflow.

5. Publication

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

1. **Issue:** CTIS does not allow deletion of a "for publication" version if one or more associated "not for publication" versions are still present.

Workaround: You need to first delete all the "not for publication" documents (even the ones of the previous versions) before deleting the associated "for publication" document. After removal of the "for publication" and "not for publication" versions, the corrected documents can be uploaded in the appropriate order. Please proceed as follows:

- I) Download locally the existing "not for publication" documents
- II) Delete all "not for publication" versions (including the previous versions belonging to previous applications)
- III) Delete the "for publication" version uploaded in error
- IV) Re-upload the required "not for publication" version(s).

The above applies for any kind of application. Previous "not for publication" versions will also remain available in the prior CTA.

6. Other Issues

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

1. **Issue:** The "search for organisation" feature, which is an integration with the Organisation Management System (OMS), **does not support non-Latin characters.** [ADO-126255]

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

2. **Issue:** The user is not able to remove a location associated with an organisation by accessing the relevant functionality in CTIS. [ADO-126224]

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

3. **Issue:** When the user performs a search by email in the user administration advance search, no results are returned. [ADO-126528]

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

4. **Issue:** When a role is requested, the sponsor admin user cannot change the dates in the "authorise date" field when approving the role. [ADO-126144]

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

5. **Issue:** When a role has expired, and the sponsor admin user re-assigns it again, upon confirmation of 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. [ADO-126548]

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

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

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

7. **Issue:** In Sponsor workspace, when searching for RFIs by using only "Submit Date" filter in the Advanced Search, some RFIs cannot be found on any page of the results list. [PRB0041713]

Workaround: Please use other advanced criteria., (e.g., filter by "Pending").

8. **Issue:** In the search field 'Therapeutic area' of the Trial Advanced Search, many values are missing from the drop-down list. [PRB0042235]

Workaround: Please use other search fields until the problem is fixed.

9. **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. [ADO-126614]

Workaround: By current system design, the supporting documentation uploaded when authorising an application are linked to the Part II of an application and are therefore not available for a Part I only application.

10. **Issue:** If an application has more than 10 inclusion or exclusion criteria, the order of the inclusion and/or exclusion may change in the downloaded pdf of the structured. The same may also occur in the Part I section within the application itself [PRB0040425].

Workaround: Until this issue is resolved, Sponsor users are advised to include a number in front of the inclusion/exclusion criteria when entering the information in CTIS.

7. ADDITIONAL NOTES

In this new section, cases that might be confusing for some users, but are according to the design are listed.

1. For Question 3.5 of Q&A on CTR document, and for paragraph 147, A Part II SM application cannot be submitted while there is an ongoing assessment of Part I (SM Part I, or SM Part I & II). A Part I assessment needs to be performed by all MSCs of a trial. No application should be created, as the draft could not be submitted (according to the system design) before the completion of the evaluation (by all MSCs) of an application in which Part I has been modified.
2. When sponsor user creates a new trial, the 'Transition trial' tick-in box can be seen in the initial pop-up form 'Create new Trial', although the transition period is over. Users should not use it.
3. If a Sponsor user uploads the interim summary of results, the document type appears to be that of 'Summary of results (for publication)', while a message appears in the end of the placeholder mentioning '*The above document(s) will be published*', interim results are not to be published, and user shall ignore the abovementioned messages.
4. CTIS automatically generates an alert when a due date to submit the "Start of Recruitment" or "Summary of Results" is approaching. These alerts are meant as general reminders and are generated irrespective of the current status of the trial lifecycle. As such, an alert for "Start of Recruitment due..." will be generated even if the Start/End of Recruitment date has already been submitted. In such cases, the alert can be ignored providing the Start of Recruitment has been correctly submitted.
5. When user adds a medicinal product (MP) (authorised/unauthorised) in a CT, CTIS retrieves various characteristics from xEVMPD. CTIS will retrieve the Active Substance Name that was originally associated with the PRD when it was registered in xEVMPD. If there are multiple versions of the PRD in the xEVMPD and multiple entries for the Active Substance Name have been added in xEVMPD, CTIS will keep retrieving the original entry and not the most updated one. If user removes and adds the MP to the trial, CTIS will keep reading the original active substance name. Until a new CTIS version improves the integration between CTIS and xEVMPD, if sponsor users cannot retrieve the most updated Active substance name version, they should use the field "Active substance other descriptive name" found in the 'Active substance' tile of Part I / PRODUCTS section.