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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.

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. 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. [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.

2. **Issue:** When Sponsor user creates a Substantial Modification "Part I only – Change of Sponsor" and once the application is Authorised, all users with roles linked to the old Organization ID, for all trials or the specific clinical trial of that Substantial Modification, still have access to ASRs and AD-hoc assessments with RFI. While users with roles linked to the new Organization ID, for all trials or specific clinical trial, are not able to see the ASRs and AD-hoc assessments with RFI linked. [ADO 188270]

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

3. **Issue:** When a user creates a trial without using an organisation retrieved by OMS (indicated with valid IDs, **ORG-**), but instead, using an organisation that is registered locally in CTIS (with a temporary not validated ID, **ORQ-**), 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 ORQ-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 **ORG-ID** (providing that the request to OMS had been approved) or the CT Admin role (associated with valid **ORG-ID**), assigned to them by the Sponsor Admin of their organisation.

4. **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.

5. **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.

6. **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.

7. **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.

8. **Issue:** Sponsor user with MAH Admin role only might have issues to assign the CSR related roles to other users. [INC0094316]

Workaround: MAH Admin role can submit the CSR. Alternatively, sponsor user that holds both the MAH Admin role and other Admin roles do not face the aforementioned issue.

9. **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. [INC0087806]

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

10. **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. There is a workaround to give the user access to those ASRs they created for trials for which they don't have the ASR_SUBMITTER role, and it consists of giving the user ASR_SUBMITTER rights for the concerned trials as well.

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 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:** 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.

3. **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

4. **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.

5. **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.

6. **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.

7. **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.

8. **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.

9. **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).

10. **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.

11. **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.

12. **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.

13. **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.

14. **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.

15. **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.

16. **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.

17. **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

18. **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.

19. **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.

20. **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.

21. **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 “+”. [126512]

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

22. **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.

23. **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.

24. **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 for that MSC, for more, or even all MSCs might be removed from the timetable. [SD-723692]

Workaround: Task 'Authorise' is released in MS workspace and can be performed without any issue. Timetable is misleading, but does not have any impact on the actual workflow of the MS.

25. **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.

26. **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.

27. **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.

28. **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.

29. **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.

30. **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.

31. **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

32. **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.

33. **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.

34. **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.

35. **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.

36. **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 Second Sponsor might be mixed in the download PDF reports. [ADO 178549]

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

37. **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

38. **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.

39. **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.

40. **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.

41. **Issue:** When 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 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.

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

Workaround: Assign Viewer Part II to the affected user. OR Another user with CT Admin can download it and share with this user.

43. **Issue:** When 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.

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

Workaround: Please copy the Expired CTA. Note that when trial is copied, the origin of the copy is automatically added in the Associated Trials section.

45. **Issue:** When 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. [PRB0041826]

Workaround: 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'. Despite that, until the issue is fixed, if needed it is necessary to apply a datafix.

46. **Issue:** When Sponsor user creates a new Part I application and uploads a document in "All document" section, by selecting "Agreement from another sponsor" document type, the document is only displayed in "All document" section. The document should be added also in "Associated clinical trials" section. [PRB0041941]

Workaround: Until the issue is fixed, please add the document to the "Associated Clinical trials" section.

47. **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.

48. **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., (); {}; [].

49. **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.

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:** 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:** For some trials, the information of the Start of Recruitment (SoR) date is missing from the download report of the SoR. It is only showing the Submission date as to when the Notification was submitted in the system. [SD-722036]. In addition, the SoR date might appear wrongly in the End of Trial notification download report. [PRB0041228]

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 Sponsor user creates a Serious Breach or 3rd Party Inspectorate Inspection Notification and adds multiple sites, the sites might not be listed in order. [ADO 168539]

Workaround: Despite the trial sites are not in order, they are not missing. There is no workaround.

14. **Issue:** Sponsor user is not able to update an already submitted "Event-type" Notification (Serious Breach, Unexpected Event or Urgent Safety Measure), once the trial is halted.

Workaround: The workaround needs to be a data fix.

15. **Issue:** When 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. However, from user's view, this can only be confirmed by clicking on the MSC and checking the notifications status.

16. **Issue:** When Sponsor user indicates an End of Trial date and then an Anticipated Date of Summary Results no later than 12 months from the End of Trial Date or even less (6 months if Paediatric trial), the system highlights in red the dates and the field "Justification that results will be later than 12 months" (6 months if Paediatric trial) as mandatory and user is not able to proceed until provide the justification. [PRB0041577]

Workaround: Please add in the justification field the following content: "Justification added due to CTIS system limitation."

17. **Issue:** When Sponsor user creates an SM to change of sponsor, while there was already an ASR or an Ad-hoc created for that trial where Sponsor user is changing the sponsor, the first sponsor of the clinical trial can still have access to this ASR or AD-hoc, even though is not the sponsor of that trial anymore. [ADO - 188270]

Workaround: There is no workaround to solve the issue.

18. **Issue:** When Sponsor user creates a 3rd Country Inspectorate Inspection Notification and tries to select a "Date of Inspection" after the earliest "Start of Trail" 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. [PRB0041775]

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

19. **Issue:** When 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.

20. **Issue:** When Sponsor user withdraws an application, the justification for withdrawal is not displayed in the application, in the UI of the sponsor workspace. [PRB]

Workaround: The user can see the withdrawal justification in the download file of the application.

21. **Issue:** When 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.

22. **Issue:** When Sponsor user submits a SM for an extension of Start recruitment date of trial, 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.

23. **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 shall contact Service Desk

24. **Issue:** When the user creates a Safety Urgent Measure in response to a SUSAR, the mandatory field 'World wide unique identifier' can host values up to 20 characters, while the value can be much longer. An error will appear if user exceeds the 20 characters.

Workaround: An improvement is planned [126811] 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

25. **Issue:** When sponsor users try to submit a Start of Trial notification for non-transition trials, they can select a date from the authorisation date and onwards. But if a non-SM has been submitted after the authorisation date, the system mistakenly considers the non-SM submission date to be the authorisation date and does not allow users to select a date before the non-SM submission date as the Start of Trial. [PRB0040515]

Workaround: Until the issue is fixed, sponsor users are advised to submit the notification with a dummy date that CTIS will allow them to use (after the submission date of the last non-SM). They can add the real start of date in the notification report.

26. **Issue:** Sponsor users cannot create, submit or update notifications (Unexpected Event, Serious Breach, Urgent Safety Measure, ...) when the trial is on halt.

Workaround: Until the issue is fixed, sponsor users could withdraw temporarily the Halt notification, submit/update the SB/UE/USM/3CII, then resubmit the Halt notification.

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 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.

2. **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.

3. **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.

4. **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.

5. **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.

6. **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.

7. **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

8. **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.

9. **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.

10. **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.

11. **Issue:** When creating an Ad-hoc assessment and link it to a Clinical Trial in "Withdrawn", "Under Evaluation" or "Not Authorised", after saving and share the assessment, the Member States Concerned are not displayed in the assessment and in the Search page of the Ad-hoc assessment. [ADO 159601]

Workaround: Despite the Member States Concerned are not displayed in the system User Interface, the search is working properly.

5. 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

6. 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.

7. 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.** [CTCS-22798]

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. [CTCS-22595]

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

3. **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.

4. **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.

5. **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.

6. **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.

7. **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.

8. **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.

9. **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.

10. **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.

11. **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.

12. **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".

13. **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.

8. ADDITIONAL NOTES

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

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. If a trial has been halted (temporary halt), other notifications cannot be submitted until the trial restarts. Otherwise, as a workaround to submit other notifications, the temporary halt could be withdrawn and resubmitted after the submission of the new notification.

3. If a sponsor user needs to remove a document FOR PUBLICATION, while preparing an RFI response, or an SM application, a warning message will appear to inform user to delete first the associated document NOT FOR PUBLICATION. After removing the NOT FOR PUBLICATION document, the user will need to save the draft, before attempting to remove the document FOR PUBLICATION.

4. 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. User should not use it.

5. If 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.

6. 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.