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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]"). This number is unique and is used by EMA to identify and track the issue from reporting to resolution.

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

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1. Application Creation/Preparation on documents and data

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

1. **Issue:** In some cases, the sponsor users cannot upload the document "Proof of payment (not for publication)" in the Form tab after a Member State concerned has been added in the MSC tab. [CTCS-22809]

   Workaround: If the user encounters this issue, they can delete all uploaded document(s) in the Proof of payment section, save the section using the Save button or by pressing the padlock, then reload the page (either by navigating out of the application or pressing refresh button in the browser). Then, the user can upload all documents again.

2. **Issue:** The sponsor user may be prevented from creating a Substantial Modification after the initial application has been authorised. In this case, an error message will be displayed if the user attempts to create Substantial Modification. [CTCS-22690 & CTCS-22673]

   Workaround: The root cause of this issue relates to the functionality to link the labelling document to the Member State concerned in the product section during the drafting of the initial application. To prevent this issue from occurring, the user can avoid using this functionality. If you encounter this issue, please contact the EMA Service Desk for a resolution.

3. **Issue:** If the user has submitted a partial initial application (an initial application where part II is not submitted to one or more Member States concerned), and the application has not been decided on by all Member States concerned, the user may only submit a Substantial Modification to Part I of the application, and cannot submit a Substantial Modification to Part II, even for Member States concerned that have already authorised the initial application. [CTCS-22721]

   Workaround: The sponsor user should ensure that all Member States concerned have decided on the initial application before they submit any Substantial Modification Part I. When the Member States concerned have decided on the initial application, it will display with the status of 'Authorised', 'Authorised with conditions' or 'Not authorised'.

4. **Issue:** When a sponsor associates a co-sponsor to a clinical trial application, the users from the co-sponsor organisation with roles with the scope "all trials" have access to all details of the clinical trial where the co-sponsor is recorded. In particular, all of the co-sponsor's users that have the roles Q-IMPD Preparer, Q-IMPD Submitter, or CT Admin will have access to the quality documents such as the IMPD-Q, Scientific Advice – restricted, and Part I Assessment report – quality, RFIs and RFI responses to IMPD-Q.[CTCS-22534]

   Workaround: The lead sponsor should only associate a co-sponsor to an application if they are ensured that all users from the co-sponsor are allowed to have access to the information of this clinical trial. Otherwise, the sponsor user should not associate a co-sponsor and should instead include the co-sponsor details in the protocol and in the cover letter.

5. **Issue:** Under certain particular circumstances and when an authorised product has several packaging sizes, for example a blister pack size of 6 and 12 tablets, the search and selection of an authorised product returns duplicates that are not shown as one entry with concatenated EU MP Numbers. [CTCS-22764]

   Workaround: It is recommended that the sponsor user selects any of the EU MP numbers.

6. **Issue:** When preparing an initial application, if the user clicks on "low intervention trial" and adds a justification and then unselects the "low intervention trial" button, a warning is displayed in Part I when checking the initial application. In the warning, the "trial information section" is highlighted. However, the justification for this warning cannot be viewed by the user. [CTCS-22492]

   Workaround: The user can re-select "low intervention trial" and remove the content from the justification section, then unselect again. The user should also remove any documents added as part of the justification.

7. **Issue:** In the product section, the user can record if a particular product will not be used in a Member State concerned by recording the country name in the field "Exclude MSC". If the user attempts to remove an excluded Member State concerned, the user may not be able to unlock the section to save the changes and an error may be triggered. [CTCS-22646]

   Workaround: The user should verify if the Excluded Member State concerned is correctly entered before saving application

8. **Issue:** There are occasions when, after selection of an authorised medicinal product, the active substance details including the substance name and its EV code are not populated in CTIS [CTCS-22890]

   Workaround: The user is advised to rely on the authorised medicinal product and to ignore the fact that the active substance details are not rendered in the user interface.

9. **Issue:** When responding to an RFI, the user has the ability to 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.

10. **Issue:** When responding to an RFI Part II, the user may not be able to edit part II if some of the other Member State concerned have already decided on the application. [CTCS-22231]

    Workaround: The user should upload any documents that may need to be updated with the RFI consideration responses.

11. **Issue:** For the transition of a trial previously authorised under the Clinical Trials Directive, the user may be able to submit an initial application that does not contain a valid EudraCT number [CTCS-22853]

    Workaround: The user should verify that the EudraCT number is correct and complete (i.e. valid) before submission.

12. **Issue:** When the user submits a new multi-trial Substantial Modification, the system does not account for the winter clock stop (winter clock stop period from 22 December to 8 January inclusive) when assigning the due date for the task. [CTCS-22810]

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

13. **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.

14. **Issue:** When adding a Non Substantial Modification Part I (NSM-Part I) to trials with an Additional Member State concerned that has not decided on the application, the NSM-Part I includes this Member State concerned under the application section of the summary overview when in fact only the authorised Member States concerned should be displayed. [CTCS-22537]

    Workaround: The user should wait for the decision on the Additional Member State concerned application before creating and submitting an NSM-Part I.

15. **Issue:** After the user clicks on "check" in a draft application which includes incomplete details for a third party organisation in the "sponsor" section (e.g. a Contract Research Organisation), the system may highlight the Part I section "trial information" with a red icon, however the actual fields with incomplete information are not highlighted. [CTCS-21199]

    Workaround: The user should always complete the mandatory fields including phone, email, duties for each third party.

16. **Issue:** When providing a response to an RFI, the user cannot update the document "Agreement from another sponsor". [CTCS-22643]

    Workaround: The user can use the upload document functionality within each Consideration when providing a response to the RFI.

17. **Issue:** The document "agreement from another sponsor (not for publication)" submitted by the sponsor is not available to the Member State concerned in the Associated Clinical Trials section of the Part I tab in the authority workspace, nor in the downloaded zip file. [CTCS-22812]

Workaround: The sponsor user should provide the document if required, with the cover letter and ensure that they select the option "not for publication".

18. **Issue:** After the initial application is authorised, and a Substantial Modification is created, and a Member State concerned has responded with an RFI, incorrect header information may display for all draft applications (e.g. showing draft applications as under evaluation, displaying a Substantial Modification as an RFI). [CTCS-21772]

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

19. **Issue:** In the rare event that the sponsor has created a draft Substantial Modification application and they respond to an RFI with the creation of a subsequent draft version of the initial application, the sponsor may be prevented from accessing their draft Substantial Modification application. [CTCS-22634]

    Workaround: The user should submit their RFI response before attempting to work further on their draft SM.

20. **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.

21. **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.

22. **Issue:** If multiple Additional Member State concerned applications are made, the translation document in the section "all documents" in the last additional Member State concerned added may not appear. [CTCS-22213]

    Workaround: After all Member States concerned are authorised, if the user navigates inside the first additional Member State application Part I, the field and document translations for both Member State concerned applications are displayed inside their respective sections.

23. **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.

2. Authorisation and supervision of clinical trials

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

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

   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 application will lapse as well as the trial overall status once the Reporting Member State concludes on the part I assessment. Users are also advised to always check the individual Member State concerned trial status.

4. **Issue:** In the Initial Application, the decision and the decision date are not displayed in the corresponding sections when the application is tacitly authorised. [CTCS-22631]

   Workaround: The user can verify the information on the decision by accessing the summary section of the application and clicking the "+Info" button which will show that the trial has been tacitly authorised.

5. **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.

6. **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.

3. Communication between Sponsor and Member States

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

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

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

2. **Issue:** In response to an RFI during the validation phase of an initial application, if the user performs a change in the deferrals section, this is visible in the authority workspace even before the sponsor submits the RFI response. [CTCS-22725]

   Workaround: There is no workaround until the issue is fixed. It has no impact on the deferral process itself.

4. Locking mechanism

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

1. **Issue:** When two users are working at the same time and one of them locks one RFI and uploads one document, the other user is not able to see the uploaded document from the first user. [CTCS-22804]

   Workaround: The second user should wait for the first user to complete the task before refreshing the system (using F5) and being able to see the newly uploaded document.

2. **Issue:** When the sponsor is creating an application (Initial, Substantial Modification, etc.), in some cases the lock button may be blocked and some newly updated data can be lost. [CTCS-22723]

   Workaround: If the lock button appears to be blocked in the section being edited, the user should always click on the 'Save' button to ensure that no data are lost.

5. Publication

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

1. **Issue:** In the public portal, under the 'Part II conclusion' column of the decision table within the Substantial Modification Part I application, values are populated even though it is a Substantial Modification Part I only. [CTCS-22393]

   Workaround: The user can disregard the label "Part II conclusion" in the substantial modification Part I only.

2. **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.

3. 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 will display in the public website, only the identification of which Member State is the reporting Member State is not displayed.

4. Some clinical trials may not be published on the public website immediately following the decision by the Member States concerned on the initial application. [CTCS-22887] [CTCS-22898]

   Workaround
   Any backlog of outstanding public information will be processed by EMA, and the information will be made public in due course.

5. **Issue:** In some cases, authorised multi-national trials with two Member States concerned display with the status "Under evaluation" for one of the Member States concerned in the public portal. [CTCS-22806]

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

6. **Issue:** When clicking the "Last" page on Search results on the public portal, no clinical trials are displayed on-screen. [CTCS-22654]

   Workaround: Click on the actual last page instead of clicking on the "Last" button.

7. **Issue:** The Final Assessment Report document is published without considering the deferrals. [CTCS-22808]

   Workaround: The EMA can amend the publication at the request of the Member State concerned.

6. Other Issues

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

1. **Issue:** When the product name is longer than 100 characters the Annual Safety Report record cannot include the product and this prevents the validation of the Annual Safety Report and its submission. [CTCS-22893]

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

2. **Issue:** When a user that is following the trial-centric approach creates a draft initial application and creates a new sponsor organisation within CTIS, the user cannot assign roles to other users. [CTCS-22792]

   Workaround: It is recommended that the user creates the new organisations in the Organisation Management System (OMS). If the organisation is created through CTIS, the CT Admin will have to perform all the functions required within that Clinical trial.

3. **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.

4. **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).