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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. 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 **Issue:** In some cases, the sponsor users cannot upload the document "Proof of payment (not for publication)" in the Form tab after a Member State concerned has been added in the MSC tab.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:** Member State and Sponsor users may be prevented to download the document 'Content labelling of IMP's' and assess its content when this document is linked to a product. [SD-658262]

   Workaround: There is no workaround. Member State or Sponsors users need to notify the CTIS service desk to apply a technical workaround on their behalf. The Member State should not raise a consideration for the sponsor to attach a new document as this will not fix the problem.

3. **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.

4. **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.

5. **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.

6. **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.

7. **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.

8. **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.

9. **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.

10. **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-22810]

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

11. **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.

12. **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.

13. **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".

14. **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.

15. **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.

16. **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.

17. **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.

18. **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.

19. **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).

20. **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 in main screen, and actions can be complete, save and confirmed in the main screen.

21. **Issue:** In the medical condition when searching by MedDRA is it not possible to search by classification code. [CTCS-21992]

    Workaround: To search by classification code, the user needs to type a term name, then clear and then type again the classification code.

22. **Issue:** In the deferrals section when 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.

23. **Issue:** In a specific scenario where an additional MSC application is created and and the user attempts to submit it without a cover letter, when the user 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.

24. **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.

31**. Issue:** When the Part I document 'Content labelling of IMP's' is linked to a product, the document cannot be deleted. [SD-622201]

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

32. **Issue:** In a draft application, when the user clicks on the button 'Cancel' to cancel the application, a pop-up window is displayed which has an 'x' in the upper corner that allows the user to close the pop-up window. If the user clicks on that 'x' in the upper corner, the pop-up closes but also the draft application is automatically cancelled. In the same manner, the Amend role assignment action is confirmed when the user clicks to close the "Amend" confirmation pop-up window using the 'x'. [SD-637630]. [CTCS-23076].

Workaround: Users should not use the 'X' functionality but only click on 'cancel' or 'confirm' in the pop-up windows throughout the system.

33. **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-635525 or 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.

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

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

2. Authorisation and supervision of clinical trials

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

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

   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:** 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.

3. Communication between Sponsor and Member States

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

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

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

2. **Issue:** In the response to an RFI, when the user changes the application and they lock the Member States concerned section of the MSC tab, if the user navigates out of the application and navigates back to the MSC 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 MSC tab without receiving the error message.

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.

5. Publication

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

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

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

2. 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.

3. 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.

4. **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.

5. **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.

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, 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 sponsor cannot create Organisation via CTIS when creating a new CT application, adding a clinical trial site or adding a legal entity. [SD-631869]

   Workaround: It is recommended that the user creates the new organisations in the Organisation Management System (OMS).

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).

5. **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.