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Clinical Trials Information System (CTIS) List of known issues for Member State, European Commission or EMA users

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Introduction

The purpose of this document is to describe issues known to occur in the authority 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 of documents and data

This section contains the known issues that authority users may encounter when assessing new applications, or substantial or non-substantial modifications, or completing related actions.

1. **Issue:** A Member State (MS) user can satisfactorily assess an Additional Member State concerned application. However, there is a rare scenario which may prevent this and for which there is no specified workaround. This issue can occur in a multinational clinical trial where one Member State concerned authorises the trial and the other one does not authorise it. In this case, if the sponsor user submits an Additional Member State concerned to re-add a Member State concerned that did not authorise the trial in the first place, this Member State concerned may be prevented from completing the Submit Part II Conclusion task. [CTCS-22720]

2. **Issue:** The MS user can complete the "validation" task in all instances. However, after having completed the validation task, the system still conveys the task as pending. [CTCS-22879]

   Workaround: The MS user should refresh their screen (either by pressing the 'Search' button again, or by using the browser's refresh button) to see the updated task status.

3. **Issue:** In some cases, during Part I assessment, when the Member State concerned shares considerations within the required timelines, the system may trigger an incorrect warning that states that the considerations are being shared late and may not be addressed by the reporting Member State. [CTCS-22880]

   Workaround: The Member State concerned and reporting Member State should disregard the warning message.

4. **Issue:** The Member State user may not have the ability to change the deferral of the assessment report to have it published at the time of decision. The assessment report is then published alongside the protocol as per the sponsor deferral request. [CTCS-22851]

   Workaround: EMA can amend the publication and have the assessment report published earlier.

5. **Issue:** The "agreement from another sponsor (not for publication)" document 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".

6. **Issue:** When the sponsor user submits a new multi-trial Substantial Modification, the system creates two 'Submit validation decision' tasks, instead of only one. [CTCS-22810]

   Workaround: The Member State user should only use the first task and ignore the other one.

7. **Issue:** When the sponsor user adds the same substance more than once and adds different details for the medical device per each substance, the system always saves the medical device information under the first Investigational Medicinal Product (IMP). [CTCS-22802]

   Workaround: The medical devices can be defined only for the first IMP from the Role until this issue is fixed.

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

   Workaround: This issue is limited to this particular scenario, there is no workaround until this issue is fixed.

9. **Issue:** When two additional Member State concerned applications are submitted simultaneously, the second Additional Member State concerned cannot create Part I Considerations if a first Additional Member State concerned has already authorised the application. [CTCS-22660]

   Workaround: The additional Member States concerned are advised to communicate on their considerations prior to finalising the authorisation of their application There is no workaround until this issue is fixed.

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

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

11. **Issue:** In the section Online references, the link does not redirect the user to the correct web page. [CTCS-23026]

    Workaround: The user needs to directly access to the corresponding webpages and search the content.

12. **Issue:** When Substantial Modification Part II only is submitted, in the hard tasks (e.g. validation decision), the evaluation process is displayed as "Validate SM Part I and II", when it should read " SM Part II". [CTCS-22931]

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

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.

2. Authorisation and supervision of clinical trials

This section contains the known issues related to the activities of the application authorisation and supervision by the Member States, such as disagreement or viewing tasks.

1. **Issue:** Intended disagreement can be submitted by MS users without the justification. [CTCS-22768]

   Workaround: When submitting an intended disagreement, the MS user should fill in all the fields in the form, including the justification.

2. **Issue:** The assessment documents in the Submit Part II Conclusion task cannot be downloaded via the download button present in the top right of the task display. [CTCS-22709]

   Workaround: The MS user can download the documents via the download icon next to each of the documents uploaded.

3. **Issue:** During the assessment of Part II, the Submit RFI soft task for Part II is not triggered by the system, but the MS user is able to create and raise an RFI for part II. [CTCS-22739]

   Workaround: The MS user should, following the consolidation of the considerations in relation to part II, create and submit the RFI as required.

4. **Issue:** In an initial application where a 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.

5. **Issue:** The validator part II submitter role may be prevented from creating RFI in the validation assessment for a Substantial Modification Part II only application. [CTCS-22814]

   Workaround: MS users with the role validator submitter full rights (Part I and Part II) user can submit the RFI.

6. **Issue:** During the reporting Member State selection process, if a consideration is raised before the reporting Member State is selected and users from the Member States concerned do not actively complete the reporting Member State selection hard tasks, the reporting Member State won't be selected automatically. As a result of this, the validation hard task will not be triggered and it will not be possible to consolidate any validation considerations. [CTCS-22838]

Workaround: It is recommended that the reporting Member State selection tasks are completed actively, and the Member State concerned users should not raise a consideration until the reporting Member State selection process is completed.

7. **Issue:** In the rare event that a Member State did not authorise the initial application but was later added through an additional Member State concerned application, and a Non-Substantial Modification is added before the Additional Member State application is decided on, the Member State may be prevented from applying a Corrective Measure. [CTCS-22827]

   Workaround: In this scenario, the sponsor is advised to submit the Non-Substantial Modification after the Additional Member State application is authorised. If you encounter this scenario, please contact the EMA Service Desk for a resolution.

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

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

9. **Issue:** When a sponsor 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 Authority issues a disagreement with the Assignor selection, the proposed Reporting Member State is set as the Reporting Member State as per the Clinical Trials Regulation. However, the system does not generate a Reporting Member State Selected notice. [CTCS-17242]

    Workaround: The Member State user can see the selected Reporting Member State from the Evaluation tab of the clinical trial application.

11. Issue: When the user attempts to amend a user role assignment and clicks to the 'X' to close the confirmation pop-up window rather than to proceed to amend the role, the role is amended despite the closer of the pop-up. The same happens with the confirmation pop-up windows in 'Express willingness', 'Submit Part II Conclusion', 'Authorise', 'Share Considerations', 'Part I Conclusion' and 'Submit CM' tasks [SD-637630], [CTCS-23076]

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

3. Collaboration between Member States and Ad-hoc/safety information

This section contains the known issues related to the Ad-hoc assessment functionality.

1. **Issue:** The ad-hoc search functionality does not work when using the ad-hoc assessment number or the "Ended" status. [CTCS-22807]

   Workaround: The user is advised to use other filters for the search, such as Assessing Member State or Creation Date.

2. **Issue:** The pop-up alert "Leave site?" appears when trying to log out of the clinical trial application when the MS user is currently in an Ad-hoc assessment page after RFI submission. [CTCS-22583]

   Workaround: Before logging out of the application, the user is advised to ensure changes are saved in the ad-hoc assessment by clicking on the 'Save' button or the lock mechanism, to avoid losing any changes made.

3. **Issue:** The MS user cannot save an Ad-hoc assessment after navigating from the Notices & Alerts tab based on the notice "Discussion initiated". When the MS user tries to save in this scenario, the system returns an error. [CTCS-22659]

   Workaround: The MS user is advised to navigate into the Ad-hoc assessment finding through the Ad-hoc assessment tab and not using the Notices & Alerts tab.

4. **Issue:** The MS Admin user cannot assign the same user role to a user under different, affiliated, NOA Organisations. The message "A user cannot have duplicate roles. Please delete one of the duplicate roles" is displayed. [CTCS-21505]

   Workaround: It's possible to perform this action if the user creates another email account.

4. Communication between Sponsor and Member States

This section contains the known issues related to the RFI functionality that the users might face when performing the change application process.

1. **Issue:** When raising considerations, sharing consolidated considerations or preparing the considerations to be included in an RFI, if the user selects 'All considerations' using the tick-box to 'select all', not all considerations may be selected. This happens when many considerations are created and the screen splits those into different pages. The issue is present under 'All considerations', 'Consolidate considerations' and in the RFI pop-up. [SD-658027]

   Workaround: User should select 'all considerations' on the first page and navigate to the next pages, selecting all the remaining ones to share considerations or prepare the RFI.

   If the user already sent an RFI and there are remaining considerations, the user can send a second RFI including all remaining considerations.

2. **Issue:** The "Assess RFI response" task during validation of SM Part II is only created for the assessment phase 'Assess part II' instead of 'validation'. Hence, Validator roles are unable to assign themselves to such tasks. [CTCS-22930]

   Workaround: There is no workaround for these user roles until the issue is fixed. The process is not blocked for other user roles and it is recommended that the Assessor part II roles assess the responses provided to the validation RFI.

3. **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.

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: The impact is limited to those cases where supporting documentation is provided, considering it is not a mandatory. 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 will display in the public website, only the identification of which Member State is the Reporting Member State is not displayed.

3. **Issue:** 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:** The CT Coordinator role can perform and coordinate tasks that they do not have the permissions to perform or coordinate. This issue prevents visibility of the tasks that the user with the CT Coordinator should execute from the "My group" filter or the "coordinator" filter, as users with this role have access to all tasks. [CTCS-22733]

   Workaround: The CT Coordinator role should only be given to a limited number of users within a MS group who already have the rights to perform all the other tasks.

2. The European Commission Administrator (Admin) role can view Member State users from the User Management tab when they should only be able to view European Commission users. [CTCS-22799]

   Workaround: There is no workaround until the issue is fixed, however there is no possibility for the European Commission Admin to manage these users, they only view them.

3. **Issue:** The Annual Safety Reporting Task "Finalise assessment" remains in 'Assigned' status even after the MS user completes it. Despite this issue, the workflow completes and the Annual Safety Reporting is finalised as expected. [CTCS-22811]

   Workaround: The user can disregard the "Assigned" status once the task is completed.

4. **Issue:** After an Annual Safety Report is finalised, the sections "Safety Assessing Member State selection" and "Finalise assessment" become empty in the Authority workspace. [CTCS-22633]

   Workaround: The Safety Assessing Member State can manually input the relevant information in their Annual Safety Report supporting document.

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.

6. **Issue:** The role "MS admin" does not appear in the list of roles under the profile of users that have only have that user role. [CTCS-23355].

Workaround: As soon as the users are assigned additional roles, then the role is displayed under their profile.