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

Release v1.0.28.0 update

## 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:** 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:** Raise a ticket to EMA in order to amend the publication and have the assessment report published earlier.

2. **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.

3. **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.

4. **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.

5. **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.

6. **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.

7. **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.

8. **Issue:** In the CT summary screen when a temporary halt is done, the end of trial date is updated with the temporary halt date. [CTCS-21083]

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

9. **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.

10. **Issue:** The Assessor Part II Submitter doesn't receive Document Considerations Assess Part II "Task Assigned" Alert. [CTCS-23478]

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

11. **Issue:** When Member State concerned fails to submit Part II conclusion by the due date, in the timelines, the decision and its projected date are no longer displayed for that MSC. [SD-723692]

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

12. **Issue:** In some instances, a user may fail to download the structured data as part of a PDF for Part I, the actual document is generated but is empty. [SD-719049]

    **Workaround:** The sponsor users are advised, when preparing the structured data, not to include certain characters such as a square box that may have been copied and pasted in the text fields. Once the trial is submitted, in order to download the structured data, the user should make a request to the service desk.

13. **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.

14. **Issue:** In the summary page, if a medical 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

15. **Issue:** When submitting a Part I only application, in the +info pop-up is displayed as Part I & II. [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 button.

16. **Issue:** For few trials, the Part I Draft Assessment Report (DAR) templates cannot be generated [SD-731239] [PRB0040490].

    **Workaround:** RMS users need to contact Service Desk and ask for support in case they wish to generate the draft assessment report via the system.

# 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:** 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 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:** 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)" can submit the RFI.

5. **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.

6. **Issue:** The user role Assessor Part I Full rights is not receiving the notice 'RFI Response submitted' under the Part I Assessment of a Substantial Modification application when the sponsor has submitted their response to the RFI Part I [CTCS-19713]

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

7. **Issue:** At this moment there is no possibility to disable to winter clock stop within the evaluation of that clinical trial application. [CTCS-11646]

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

8. **Issue:** When a user does not authorise the trial, they complete a justification in the authorise task before submitting, this information is not displayed in the task. However, this information is saved and displayed on the assessment overview in the evaluation folder. [CTCS-23757]

   **Workaround**: The information is available on the assessment overview in the evaluation folder.

9. **Issue:** When the RMS does not authorise the Initial application, in any subsequent application (SM Part I/II and AMSC), the RMS is able to see and consolidate considerations, but currently is not able to create an RFI. [CTCS-24889]

   **Workaround**: There is no workaround until the issue is fixed. If this issue is encountered, the RMS should contact the service desk for a resolution.

10. **Issue:** The timetable is showing different due dates/status/information than the real Tasks due dates/status on the Tasks page. This does not have any impact on the Workflow as the real task due date is what the system considers. [SD-725109]

    **Workaround**: The Member States user should always confirm the dates in tasks page.

11. **Issue:** If the user tries to cancel the Revert decision, after having uploaded documents in the revert pop-up modal, an error message is displayed. The cancel revert decision action is performed even if the error is displayed, but after cancelling it, the documents added in revert modal pop-up are still displayed in Assessment table. [CTCS-24843] [CTCS-24842]

**Workaround**: The user can proceed with cancelling the revert decision. However, to prevent the error message and the display of the documents in the assessment table, the user before cancelling the revert decision, should remove the documents in the revert modal pop-up.

# 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 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.

2. **Issue:** In the ad hoc assessment, when a document is uploaded, the icons "download/edit/update/delete" are greyed out, yet fully functional. [CTCS-21638]

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

3. **Issue:** In the RFI's due date calendar, the date picket for the year is not working, and the calendar is greyed-out. [CTCS-23508]

   **Workaround:** The user can close the RFI pop-up and open it again to reset the calendar default view.

4. **Issue:** The notifications start of recruitment and restart of recruitment is not reflected in the main Notifications tab. [SD-725401]

   **Workaround**: The date is correctly displayed in the Notifications popup

5. **Issue:** The banner text related to the publication should not be visible in the ad-hoc assessment tab since nothing on the ad-hoc assessment section will be published. [CTCS-21393]

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

6. **Issue:** When the Start of Recruitment Notification is downloaded, the information of the Start of Recruitment date is missing. It is only showing the Submission date that the Start of Recruitment Notification was submitted in the system. [SD-722036]

   **Workaround**: Until the issue is fixed, there is no workaround for the download of the data. The information can be consulted in the clinical trial notification page.

# 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:** For substantial modification applications, during the validation period the task "Assess RFI response" is created with the evaluation process "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.

2. **Issue:** When the RFI is sent in the Validation phase, in the Conclusion sub-section, it is stated that the application is valid although the Reporting Member State/Member State concerned 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.

3. **Issue:** In the summary tab, under application details, the statement "considerations are pending to be consolidated" appears despite the fact that all consolidated considerations are already concluded. [CTCS-20694]

   **Workaround:** The message disappears when manually refreshing the page. Nothing in the workflow is blocked and it is possible to proceed with CT tasks. It is only the auto-refresh that is not present.

4. **Issue:** After sharing an Ad-hoc assessment, if any changes are applied and a new RFI is created, the RFI number should be incremented. [CTCS-23085]

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

5. **Issue:** In Additional Member State concerned application, after the first RFI in Part I, the data picker allows a due date that exceeds the extended authorise task due date. [CTCS-24215]

   **Workaround:** The RMS should not pick a date that exceeds the authorise task due date.

6. **Issue:** In an additional MSC application, when the RMS is creating the first RFI, the RFI Date picker does not allow the choice of a due date later than Authorize task's due date. [CTCS-24214]

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

7. **Issue:** When the MS user uploads a quality supporting document while creating an RFI, there is no label. However, once the document is uploaded, the label "for publication" is displayed, which is not correct, as this document type is never published. [CTCS-24763]

   **Workaround:** There is no workaround until the issue is fixed. The user is advised that this document type is never published.

8. **Issue:** In a specific scenario with an Additional MSC application, the "Authorise" task is not extended when an RFI has been issued on the same date of the due date of the authorise task, for the Part I phase after the Part II phase has been completed. [CTCS-24786]

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

9. **Issue:** In a specific scenario when a CT is draft or submitted near winter clock stop, when the first RFI Part II is created near the due date of Submit Part II conclusion task, the calendar/date picker gives only 10 days duration. This is applicable to all application types. [CTCS-24760]

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

10. **Issue:** The Member State concerned that did not authorise the Initial application still gets the 'Assess RFI Response' task when Sponsor responds to Part I RFI raised in Additional MSC application. [SD-725701]

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

11. **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.

# 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 are displayed on the public website, only the identification of which Member State is the Reporting Member State is not displayed.

# 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 role 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. **Issue:** 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. [SD-720325]

   **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:** 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.

7. **Issue:** When searching by “created date”, in the task tab advance search filter, if the user selects only the current date, information is not displayed [SD-678421]

   **Workaround:** The user needs to select in the first box of the created filter a date before the desired date, and in the second box the actual desired date.

8. **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.

9. **Issue:** Any Administrator user, when assigning roles, has the ability to populate the fields “Organisation name” and “NOA Organisation name”, by typing directly any text without any system validation. When the user performs this action and confirms it, an internal error is displayed. [CTCS-23511]

   **Workaround:** The user should always search for the correct organisation by clicking in the magnifying glass icon provided.

10. **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

11. **Issue:** In the tasks screen, when the user combines the basic search field with ASR ID and the advanced search, with ASR under the “Application and Non-SM type” field, no results are displayed. [CTCS-22978]

    **Workaround:** Search by ASR ID and remove the filter in advance search.

12. **Issue:** The Decision Maker Submitter role has the impression that they can create an RFI in part II as the RFI button is enabled when it should not. However, when clicking on it an error message "Permission denied! Cannot create RFI" appears [CTCS-23765]

    **Workaround:** If the user needs to create an RFI, it is possible to give additional role to the user to perform the required task.

13. **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. [CTCS-23442]

    **Workaround:** Even if the name of the organisation is not rendered correctly, the Sponsor user can still request a role.

14. **Issue:** In the task screen, the filter "My tasks" is not working properly. [SD-726689] [SD-726668] [SD-731533]

    **Workaround:** In the advanced search, the user can search for their tasks by searching by username and tasks assigned.

15. **Issue:** Issue in the MS API when calling the ´applicationId´ endpoint, in the response, two clinical trial sponsor IDs appear with the same organization ID while in CTIS only one sponsor is listed. [SD-723812]

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