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

Release v1.0.47.1 update

Minor changes have been added since the v1.0.47.0 version

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. 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:** 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:** 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.

3. **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.

4. **Issue:** When an Authority user, with multi-role assignment, tries to assign NOA Admin role for two different organisations to the same user, the system displays the following error message "A user cannot have duplicate roles. Please delete one of the duplicate roles". [ADO 158736]

Workaround: The Authority user should add the roles one by one in this case, instead of using the multi-role assignment.

5. **Issue:** MS Admin users might be able to still see other users as MS Admins in user Administration tab, even after the roles of the latter ones have been removed in IAM. The user whose MS 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.

6. **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. 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 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.

13. **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

14. **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.

15. **Issue:** When Sponsor user withdraws one of the Member State Concerned, the Authorisation task of the withdrawn MSC is cancelled, but once the Authority user clicks on the task, in the decision area, it is possible to see Authorised status. [ADO 127115]

    Workaround: This issue does not have direct impact in the Clinical Trial status, nor in the workflow.

16. **Issue:** Different issues when Authority user downloads the Clinical Trial in PDF format:

    - When selecting the Additional Member State Concerned application to be downloaded, it is not correct to see a Validation folder. [ADO 129949]
    - In Application section inside the Validation task, the information displayed is not correct and it is not according to the one completed by the RMS. [ADO 164768]
    - When Sponsor user downloads the trial in PDF format, when it has as a Legal Representative and a different Sponsor, the information displayed is mixed, this is, Sponsor details are mixed with Legal Representative details. [ADO 178549]

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

17. **Issue:** In a multinational Clinical Trial, when a Substantial Modification Part I&II is submitted, with Part II not for all MSCs, the Proof of Payment document does not appear for the MSCs that their Part II was not modified. [PRB0040819]

    Workaround: Proof of Payment is not mandatory and as a last resort it can be added with Cover Letter/Supporting documents.

18. **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., (); {}; [].

3. 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 Authority users without the justification. [CTCS-22768]

   Workaround: When submitting an intended disagreement, the Authority 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 Authority 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: Authority 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.

12. **Issue:** In Substantial modification part I, decision supporting documentation is not visible after Authorise task's completion. [CTCS-24237]

    Workaround: The Member State users need to contact the EMA Service Desk.

13. **Issue:** When Sponsor user creates an SM to change 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.

14. **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.

15. **Issue**: When Sponsor user withdraws an application, the justification for withdrawal is not displayed in the application, in the UI of the sponsor/authority workspace.

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

16. **Issue**: In an Additional Member State Concerned application, Part I subtasks "Consolidate Considerations" and "Submit RFI" expires in the day before the due date, this is, the due date for both tasks are correctly calculated, but the timer is executed one day before the due date. [PRB0041943]

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

4. 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 Authority 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:** 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: 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.

7. **Issue:** When creating an Ad-hoc assessment and link it to a Clinical Trial that is in status "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. 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 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.

2. **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.

3. **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.

4. **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.

5. **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.

6. **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.

7. **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.

8. **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.

9. **Issue:** In some cases, when the RMS creates an RFI, the column Application section parts in the "All considerations" tab, erroneous letters are shown. [CTCS-25254] [127114]

   Workaround: The user should refresh the browser more than once.

10. **Issue:** When a Member State Concerned does not authorise a trial via Initial application, but then authorises it via an Additional Member State Concerned application, it is not possible for Member States Concerned and RMS to submit Part II RFIs in Substantial Modification Part I and II or Part II only. [ADO 179876] [PRB0041272]

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

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: 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.

7. Other Issues

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

1. **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.

2. **Issue:** The Annual Safety Reporting Task "Finalise assessment" remains in 'Assigned' status even after the Authority 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.

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:** 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.

6. **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.

7. **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

8. **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.

9. **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.

10. **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.

11. **Issue:** In the task screen, when filtering by Evaluation Process "Assess ASR", in advanced search, the search is not returning results. [ADO 125877] [CTCS-18285]

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

12. **Issue:** Authority user cannot submit a Corrective Measure (CM) due to existence of draft Sponsor Opinion Request. [ADO 126240]

    Workaround: Please delete the draft Sponsor Opinion Request before submitting the CM.

13. **Issue:** When the Authority user creates a Consideration for Part I and shares the consideration, the "Consolidate considerations" task is generated with the status "Pending". If the "Consolidate considerations" task expires, the "Remaining" days field is not empty and mistakenly shows the number of remaining days to conclude the task. [ADO 126970]

    Workaround: Please ignore the "Remaining days field".