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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. Where a datafix is required, this is indicated in the workaround specifying that the user should contact the EMA CTIS ServiceDesk.

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 (“[ADO-xxxxxx]” or “PRB-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. [ADO-126298]

**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 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.

3. **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. [ADO-270712]

**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.

4. **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. [ADO-126243]

**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:** In the section "Full trial information", the system does not display the number of subjects per Member State concerned. [ADO-126223]

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

2. **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". [ADO-126300]

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

3. **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. [ADO-126284]

**Workaround:** It is possible to consult these documents in the application.

4. **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" [ADO-126402]

**Workaround:** The user should navigate to the initial application to review the decision on the application.

5. **Issue:** The Assessor Part II Submitter doesn't receive Document Considerations Assess Part II "Task Assigned" Alert. [ADO-126434]

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

6. **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. [PRB0040447]

**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.

7. **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. [ADO-127070]

**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

8. **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] [PRB0042497]

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

9. **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]
- the End of Recruitment section of the downloaded PDF report, a Start of Recruitment date is populated that is incorrect (same as the End of Recruitment date). The Start of Recruitment date is correctly reflected in the Start of Recruitment section. [PRB0041594]

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

10. **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., (); {}; [].

11. **Issue:** For submitted trials, when sponsor users create new application drafts to respond to RFIs or to submit new applications, or non-SMs, the cloned documents from previous versions might be listed in the section 'ALL DOCUMENTS'. The problem might appear in both workspaces (Sponsor and Authority). [PRB0041274]

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

12. **Issue:** Once a document is uploaded, the selected language found in the properties cannot be edited. [PRB0040634].

**Workaround:** Until the issue is resolved, users may delete and upload the document again, selecting the correct language. Alternatively, users may use the 'Comments' field found in the metadata of the uploaded document placeholder, to indicate the correct language.

### 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:** 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. [ADO-126239]

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

2. **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. [ADO-126260]

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

3. **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. [PRB0040454]

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

4. **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 [ADO-126859 and ADO-126860].

**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.

5. **Issue:** In Substantial modification part I, decision supporting documentation is not visible after Authorise task's completion. [ADO-126614]

**Workaround:** By current system design, the supporting documentation uploaded when authorising an application are linked to the Part II of an application and are therefore not available for a Part I only application.

6. **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.

- 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.

- Issue:** In a trial that has ended in the RMS, or has not been authorised in RMS, the RMS maintains its role and coordinates the Validation and the Part I Assessment of the subsequent SMs. The RMS can perform the respective hard tasks without any issues, but the buttons used to assign soft tasks to users miss from the "Tasks" tab. [ADO-267625] [PRB0041660]

**Workaround:** Until the issue is fixed, MS users could use alternative ways to perform the soft tasks (via "Evaluation" page), coordinate and signal the assignment and completion of the soft tasks.

- FAR Part I is not visible in Additional MSC applications for which a Part I RFI was submitted.

**Workaround:** Until the issue is fixed, MS users could find the FAR in the previous application with authorised Part I.

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

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

- Issue:** In the ad hoc assessment, when a document is uploaded, the icons "download/edit/update/delete" are greyed out, yet fully functional. [ADO-126154]

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

- 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

3. **Issue:** When the MS submits an ASR RFI, sponsors can see up to 10 (consolidated) considerations in their workspace. [PRB0042358]

**Workaround:** Until the issue is resolved, MS users are advised to add up to 10 considerations in an ASR RFI. If more considerations are needed, those can be included in the initial 10 considerations, or in a supporting document.

## 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:** 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. [PRB0040436]

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

2. **Issue:** When submitting a new RFI, in some cases a wrong submission date of the RFI is recorded on the UI. The concerned business rules are not affected. [PRB0042595]

**Workaround:** There is no workaround until the issue is fixed. The bug does not have any impact on the workflow.

## 6. Publication

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

## 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. [ADO-126354]

**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:** 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.

3. **Issue:** When the user performs a search by email in the user administration advance search, no results are returned. [ADO-126528]

**Workaround:** The user can use other fields to perform the search e.g., username

4. **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.

5. **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".

6. **Issue:** In the search field 'Therapeutic area' of the Trial Advanced Search, many values are missing from the drop-down list [PRB0042235].

**Workaround:** Please, use other search fields until the problem is fixed.

## 8. Additional Notes

In this new section, cases that might be confusing for some users, but are according to the design are listed.

1. When user adds a medicinal product (MP) (authorised/unauthorised) in a CT, CTIS retrieves various characteristics from xEVMPD. CTIS will retrieve the Active Substance Name that was originally associated with the PRD when it was registered in xEVMPD. If there are multiple versions of the PRD in the xEVMPD and multiple entries for the Active Substance Name have been added in xEVMPD, CTIS will keep retrieving the original entry and not the most updated one. If user removes and adds the MP to

the trial, CTIS will keep reading the original active substance name. Until a new CTIS version improves the integration between CTIS and xEVMPD, if sponsor users cannot retrieve the most updated Active substance name version, they should use the field "Active substance other descriptive name" found in the 'Active substance' tile of Part I / PRODUCTS section.