

ServiceNow:

An overview of FAQs, tips for opening tickets and help to avoid system errors

CTIS Info Day, 22-May-2025



Contents

- What to do when experiencing issues while working with CTIS
- Some of the most common issues which could be resolved by the user
- Submitting ServiceNow ticket and incident management



What to do when experiencing issues while working with CTIS





Help!



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If you cannot find an answer to your question, please consult our training Training on and supporting materials on how using CTIS to use CTIS. Find questions and answers Guidance and document on how to use CTIS. Q&As See when CTIS will be unavailable due to maintenance and upgrades, Website outages overview of system releases and list and system releases of known issues and workarounds.

- Sponsor quick guide: Getting started with CTIS
- <u>CTIS training material</u>
- <u>CTIS Handbook for clinical trial sponsors</u>
- List of known issues and proposed workarounds
- <u>CTIS newsflash</u>
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Submit ServiceNow ticket

CTIS: common issues (and other tips)





List of known issues and workarounds

- End of Trial and Substantial Modification: If an SM is created and submitted after an End of Trial notification has been submitted for a particular Member State, that Member State will not be included in the assessment of the SM.
- If the SM is created before the End of Trial Notification but submitted after, that Member State will still be included in the SM application. In such cases, it is advised to cancel the draft SM before submitting and create a new SM. This will ensure that the Member State where the trial has ended will not be included in the SM application.



6 CTIS Info Day - ServiceNow Legend: SM - Substantial Modification

List of known issues and workarounds

- Notices & Alerts: CTIS automatically generates an alert when a due date to submit the "Start of Recruitment" or "Summary of Results" is approaching. These alerts are meant as general reminders and are generated irrespective of the current status of the trial lifecycle. As such, an alert for "Start of Recruitment due..." may be generated even if the Start/End of Recruitment date has already been submitted. In such cases, the alert can be ignored providing the Start of Recruitment has been correctly submitted.
- Notices & Alerts: For an overview of open tasks and required actions, CTIS users are advised to regularly consult the tabs "Tasks" (Authority Workspace) and/or "Requests for Information (RFI)" (Sponsor Workspace) instead of relying solely on the notices and alerts.



7 CTIS Info Day - ServiceNow Legend: RFI - request for information

List of known issues and workarounds

- When submitting an SM to extend the start of recruitment, make sure to select the option "Extension to start trial recruitment beyond 2 years" as reason for the SM and fill in the "Recruitment start date".
- When submitting an SM to *re-start a trial* after a temporary halt due to safety/risk-benefit reasons, make sure to select the option *"restart trial"* as reason for the SM.
- After an SM is submitted, while preparing a response to validation RFI, the *Proof of Payment* documents already submitted disappeared. Please add the document back in before submitting the RFI response.



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Legend: SM - Substantial Modification; RFI - request for information.

List of known issues and workarounds

 When creating an SM, make sure not to untick the box "Do you wish to update the current information on the dossier?". If you untick this box, it will not be possible to make changes to documents or structured data, even in response to RFIs.

Substantial modification scope		×
Select modification scope		
Please select		~
Do you wish to update the current inform	ation on the dossie	r?
	× Cancel	✓ Create



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Legend: SM - Substantial Modification; RFI - request for information.

List of known issues and workarounds

- When entering text in the structured data fields, any text between two angle brackets
 (<>) will be deleted. For example, "Today is the <seventh> of June" would become "Today
 is the of June". Please use other brackets such as () {} [] or add a space between the
 angle brackets and the text.
- When entering *inclusion and exclusion criteria* the users are advised to insert a number in front of the text of the criterion, to indicate the desired order.



Legend: SM – Substantial Modification; RFI – request for information.

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List of known issues and workarounds

- Not possible to delete a document with error message informing there is a not for publication (NFP) version linked to it. This NFP document is not visible to the user – the users are advised to proceed without deleting the document and providing an explanation to the authorities.
- When two "not for publication" protocol documents are uploaded at the same time by clicking on the + button, they may not appear under the "for publication" document for which they were added. Please upload the "not for publication" protocol documents one-by-one.



List of known issues and workarounds

- To prevent applications lapsing, sponsors are advised to *submit responses to RFIs* ahead of the due date. This allows time to provide support if any issue is highlighted upon submission.
- RFI response not possible due to technical limitations of the system submit a ServiceNow ticket
- In case of technical issues in completing a *response to RFI* (e.g. uploading a certain document, or updating the IMP code in xEVMPD), sponsors are advised to *submit the RFI response despite this pending action*. Sponsors should then reach out to the MSC and request for an additional RFI to be raised. This allows more time for the sponsor to coordinate with the CTIS ServiceDesk to resolve the technical issue from the first RFI.



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Legend: MSC – Member State Concerned; RFI- request for information; xEVMPD- extended EudraVigilance medicinal product dictionary; CTIS- clinical trials information system.

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List of known issues and workarounds

- In order to prevent technical issues with the download of an application, please ensure to *remove leading and trailing spaces* when copying and pasting text from other sources into CTIS data fields. In order to check for this, after pasting text into a CTIS field, click inside the field and ensure there are no gaps between the body of the text and the cursor.
 - Place the cursor at the end of the pasted text and press
 "Backspace" button until it deletes the last character (you can type it back).
 - Place the cursor at the beginning of the pasted text and press "Delete" button until it deletes the first character (you can type it back).

Trailing Space		
Trial identifiers		
Full title (English) *		
TEST APPLICATION	No spaces (IDEAL)	
	Trial identifiers	Trial identifiers
	Full title (English) *	Full title (English) *
Leading Space	TEST APPLICATION	TEST APPLICATION
Trial identifiers		
Full title (English) *		
TEST APPLICATION		



List of known issues and workarounds

- *xEVMPD updates* **up to 48 hours** to be reflected in CTIS
- OMS updates up to 24 hours to be reflected in CTIS
- **Cancelled initial CTA (deleted)** cannot be revived
- Users with **Sponsor admin role** only cannot create CTA



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Legend: CTIS- clinical trials information system; OMS- organization management system; CTA- clinical trial application. Classified as public by the European Medicines Agency

List of known issues and workarounds

- **Draft application "Check" button**, the system may not highlight fields not completed:
 - 1. Verify manually the telephone and the email address for the third party organisation(s) and presence of the scientific and public contact points
 - 2. Check if individual participants data (IPD) field has been completed.
- During the assessment of a clinical trial application, the timetable may show different due dates/status/information than the actual due dates/status on the Tasks page and RFI page. This does not impact the workflow and the actual due date of the task and RFI: users are recommended to comply with the due dates recorded with the individual tasks and RFI.



15 CTIS Info Day - ServiceNow Legend: RFI- request for information.

List of known issues and workarounds

 Sponsors are advised to avoid creating draft applications (SM, NSM, or AMS) not only while a previous application is still under evaluation, but also when a draft already exists. This is because when a draft application is created, it copies the documents and data from the last authorised application.

For example, if a draft SM Part I is created when an AMS application is already in draft, the AMS application will not include the Part I SM changes.

 When deleting a draft SM, the next one created will have number +1 from the deleted one. This is expected behaviour of the system and thus the numbers of the SM cannot be changed.



Legend: AMS – Additional Member State; NSM – Non-substantial Modification; SM – Substantial Modification. Classified as public by the European Medicines Agency

List of known issues and workarounds

- **Incident submitted in form of a request in SD**. The SD will therefore raise an incident on user's behalf and close the request. Please do not re-open the request but continue communication about the issue via newly created incident.
- Use an existing ServiceNow ticket to provide/ask for updates regarding a reported issue. Please note that even if there are no updates shared in the ticket this does not mean there is no activity on resolving the issue reported.
- Incidents that are not blocking for which there is a known Problem will be associated with the Problem. Users may be asked to agree to close the ticket, but the ticket will remain associated with the Problem even after closure.
- The users who have recently started using CTIS are advised to follow **training materials** available on EMA website and to use CTIS sandbox (training environment).

17 CTIS Info Day - ServiceNow Legend: CTIS- clinical trials information system; SD- ServiceDesk. 🕑 EMA

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CTIS: submitting a ServiceNow ticket





ServiceNow





Report an issue with CTIS

Report an Issue with CTIS

Report a technical issue on CTIS, its public portal or its training environment



Create a new ticket in case you are experiencing a disruption of a CTIS functionality (the system is not behaving as described in the Training modules). Please provide as much detail as possible, including your username and CTIS role(s), your affiliation (sponsor or authority), your location, the EU CT number of our trial (if applicable), URL of the website used, steps performed and screenshots of the issue you are facing. Please always mention deadlines, if any (e.g. RFI response due date).

Examples:

- System outages occurring out of the planned system interruptions timeframe.
- Log in issues that cannot be solved as per EMA account management
- Blocking issues that are not listed in the most recent lists of known issues & proposed workarounds and that prevent you from progressing (e.g. tabs not showing, time outs, empty warning messages).
- Inserted data or documents that are not then visible within the system, or that should not be shown in the public portal

For issues with the search function of sponsor or product, report an issue with SPOR functionalities.



Reminder where to look for information

<u>ServiceNow</u>

Name Surname	
Subject	
Subject	Subject = title of the incident Example:
Description	CTIS issue
	VS
CTIS Request Type	RFI response not possible: due 23 July 2024
User affiliation	
Please Select	

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ServiceNow

* Indicate required information

*Raise this request on behalf of

Name Surname



Detailed incident description Provide as much information as possible

- Who you are: sponsor (pharmaceutical industry, CRO, academia, etc.) or Member State (NCA, ethics committee)
- Role
- CTA number/ RFI number
- Application ID
- Location (country)
- Username
- Describe steps taken
- Indicate due date (if any)
- Attach screen shots of the issue





ServiceNow

* Indicate required information

*Raise this request on behalf of

Name Surname

*Subject

* Description

CTIS Request Type	CTIS API Gateway Manager CTIS BI CTIS for Sponsors/Authorities CTIS MS API	
	CTIS New MS-API	
	CTIS Public Portal	
User affiliation	CTIS Removal of information Request	
Please Select		-



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ServiceNow

Name Surname		×	
*Subject			
* Description			
* Description			
* Description			
* Description * CTIS Request Type			
* Description * CTIS Request Type	Please Select		
* Description * CTIS Request Type	Please Select National Competent Authority		
* Description * CTIS Request Type * User affiliation	I Please Select National Competent Authority Commercial Sponsor		
* Description * CTIS Request Type * User affiliation	Please Select National Competent Authority Commercial Sponsor Ethics Committee		

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Non-Commercial Sponsor Helpdesk

- Under "User Affiliation", Sponsors can select the option "Non-commercial Sponsor"
- Introduced to support ACT-EU deliverable launched October 2024
- Dedicated team from EMA supporting Non-commercial Sponsors
- Any Non-commercial Sponsor can access the helpdesk when submitting their queries through ServiceDesk





Thank you

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