

CTIS Service Desk and tips for the users reporting issues

CTIS Info Day, 17-Jun-2026



Contents

- What to do when experiencing issues while working with CTIS
- Some of the most common issues which could be resolved by the user
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What to do when experiencing issues while working with CTIS

Help!

1 If you cannot find an answer to your question, please consult our **training and supporting materials** on how to use CTIS.

2 Find questions and answers document on how to use CTIS.

3 See when CTIS will be unavailable due to maintenance and upgrades, overview of system releases and **list of known issues and workarounds**.

Training on using CTIS

Guidance and Q&As

Website outages and system releases



Submit
ServiceNow
ticket

- [CTIS Sponsor Handbook](#)
- [CTIS online training modules for authorities](#)
- [List of known issues and proposed workarounds](#)
- [Clinical Trials Highlights](#)

Tickets Management in ServiceNow

- **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.

CTIS: common issues which could be resolved by the user (and other tips)

Some tips and known issues:

[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.

Some tips and known issues:

[*List of known issues and workarounds*](#)



- **Of note** - For particular cases when the EoT needs to be withdrawn (e.g. protection of CCI/PD) the applicant should proceed as follows to avoid issues with generation of tasks:
 - Withdraw EoT notification for the relevant MS
 - Create the new application and submit it
 - Only after submission of the relevant application a new EoT notification can be submitted.

Some tips and known issues:

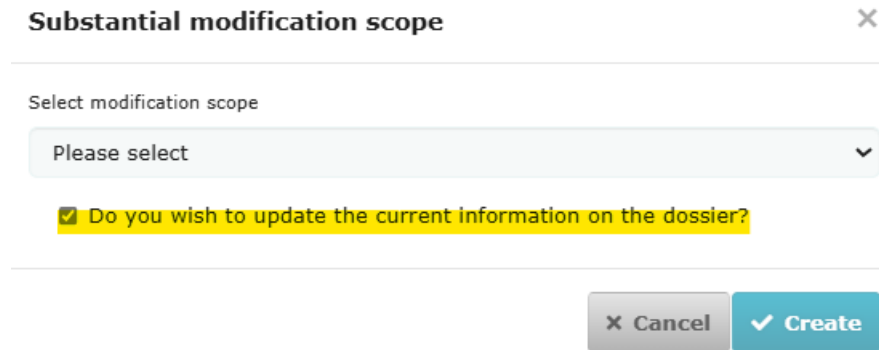
[List of known issues and workarounds](#)

- When submitting an SM to extend the start of recruitment or to extend restart of trial make sure to select the option **“Extension to start trial recruitment beyond 2 years”** or **“Extension to restart trial beyond 2 years”** as reason for the SM and fill in the **“Recruitment start date”** and **“restart date”** respectively. (Scope of the application needs to involve Part II)
- 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. (Scope of the application needs to involve Part II)

Some tips and known issues:

[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 information on the dossier?

Cancel Create

Some tips and known issues:

[List of known issues and workarounds](#)

- If a sponsor user needs to remove a document **FOR PUBLICATION** a warning message may appear to inform user to **delete first** the associated document **NOT FOR PUBLICATION**.

Users need to delete first **all** the NFP documents associated to the FOR PUBLICATION document, after the deletion they should be able to delete the FP document incorrectly uploaded.

Some tips and known issues:

[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.

Some tips and known issues:

[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

Some tips and known issues:

[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 authorized 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.

CTIS Improvement

Notices & Alerts via Email

- **Emails for notices & alerts planned to be implemented soon.**
- Recipient email address is the one specified in the user's personal profile
- Sponsor/Authority users who opt in will receive emails for N&As (according to their roles). By default, users will be opted out
- The opt-in setting applies to all Notices & Alerts

Notices & Alerts via Email

The screenshot shows the 'Personal profile' page in the 'Clinical trials (SAT-CT2 Environment)'. The page has a dark blue header with the title and navigation links: 'Clinical trials', 'User administration', 'Member states calendars', and 'Services Status'. The main content area is divided into sections: 'My info', 'My employer', and a settings section. In the 'My info' section, the 'Email' field is highlighted with a green box and an arrow pointing to a callout that says 'Recipient email address is the one specified in the user's personal profile.' In the settings section, the 'Receive notices and alerts via email' toggle is turned 'On' and is also highlighted with a green box and an arrow pointing to a callout that says 'Authority and Sponsor users are able to **opt in** to the emails via **new setting** in Personal Profile page. By default, users are opted out.' The 'My employer' section includes fields for 'Employer name' and 'Contact details /Employer address', with an 'Update employer information' button below it. The 'My info' section also includes fields for 'First name' (UAT), 'Last name' (CT), and 'Phone', with a 'Password reset' link and an 'Update personal information' link.

Clinical trials (SAT-CT2 Environment)

Clinical trials | User administration | Member states calendars | Services Status

Personal profile
User ID: ctuat087

My info
First name: UAT
Email: uat.ct80@ext.ema.europa.eu
Password reset

My employer
Employer name:
Contact details /Employer address:
Update employer information

Settings
Receive notices and alerts via email: ☒ On
Last name: CT
Phone:
Update personal information

Recipient email address is the one specified in the user's personal profile.

Authority and Sponsor users are able to **opt in** to the emails via **new setting** in Personal Profile page.
By default, users are opted out.

Notices & Alerts via Email

New! 75 All 6							
Notice No active Conclusion to Part II submitted	Ref number	Source type	Evaluation process	Received	IMP	RMS	Sponsor
The Initial has no active conclusion recorded for Part II for France.	2025-518157-15-00	Initial	Assess part II	28/01/2026	Paracetamol-Koffein Orion 500 mg/65 mg tabletter	Greece	Panpharma
Notice No active Conclusion to Part II submitted	Ref number	Source type	Evaluation process	Received	IMP	RMS	Sponsor
The Initial has no active conclusion recorded for Part II for France.	2025-518488-20-00	Initial	Assess part II	28/01/2026	Paracetamol-Koffein Orion 500 mg/65 mg tabletter	Germany	Panpharma
Notice No active Conclusion to Part II submitted	Ref number	Source type	Evaluation process	Received	IMP	RMS	Sponsor
The Initial has no active conclusion recorded for Part II for Germany.	2025-518063-19-00	Initial	Assess part II	28/01/2026	Paracetamol-Koffein Orion 500 mg/65 mg tabletter	France	Panpharma
Notice No active Conclusion to Part II submitted	Ref number	Source type	Evaluation process	Received	IMP	RMS	Sponsor
The Initial has no active conclusion recorded for Part II for Greece.	2025-516530-25-00	Initial	Assess part II	28/01/2026	Paracetamol-Koffein Orion 500 mg/65 mg tabletter	France	Panpharma
Alert Considerations due (Validation)	Ref number	Source type	Evaluation process	Received	IMP	RMS	Sponsor
There are 2 days remaining to document considerations for the validation process.	2026-522027-15-00	Initial	Validation	28/01/2026	Paracetamol-Koffein Orion 500 mg/65 mg tabletter	France	Panpharma



All notices & alerts generated in CTIS on a particular day are **sent via email overnight using a batch job.**



[2024-500004-38-00] Alert - RMS Selected

Sender: <no-reply-ctis@ema.europa.eu>
To: uat.ct654@ext.ema.europa.eu

Thu 26/01/2023 05:26


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Dear user,
This is an automated message from the CTIS notices and alerts to inform you that: **France has been selected as the RMS for the trial**

For more information on actions and timelines, refer to the [sponsor handbook](#)

In case this message refers to a Request for Information (RFI), ensure you respond within the due date specified in CTIS, otherwise your application will lapse.

[RMS Selected](#) Mon 14/11 15:45

Ref number: [2024-500004-38-00](#)

Source type: **Initial**

Evaluation process: **Validation**

Received: **14/11/2024**

IMP: **Paracetamol Accord 1000 mg comprimate efervescente**

RMS: **France**

Sponsor: **Panpharma**

This is an automated message from CTIS notices and alerts. Please do not reply to this email, as responses are not monitored. The information contained in this message is intended solely for the designated recipient and may include confidential or system-related content.

If you have received this message in error, please report the issue to the [Service Desk](#)


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Notices & Alerts via Email

Clinical trials (DEV-SA Environment) UAT CT

Clinical trials Notices & alerts 1 Clinical study reports Annual safety reporting RFI User administration

Notices and alerts are deleted and no longer visible 90 days after they are received.

You can opt in to receive notices and alerts via email on your Personal Profile page.

Notices & alerts 1

Enter EU CT ID or ASR ID (Business Keys) or use advanced search. **SEARCH** Advanced Search ▾

Showing 1 - 1 of 1 items 1 of 1 pages < 1 >

Sort by: **Received** ▾

New! 1 All 955

A **concise message** regarding this setting is placed on the **N&A page** in CTIS for **discoverability**



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

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