EMA
EUROPEAN MEDICINES AGENCY

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
- CTIS Improvement

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.

Training on using CTIS

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

Guidance and Q&As

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

Website outages and system releases

- **CTIS Sponsor Handbook**
- **CTIS online training modules for authorities**
- **List of known issues and proposed workarounds**
- **Clinical Trials Highlights**

Submit **ServiceNow** ticket

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

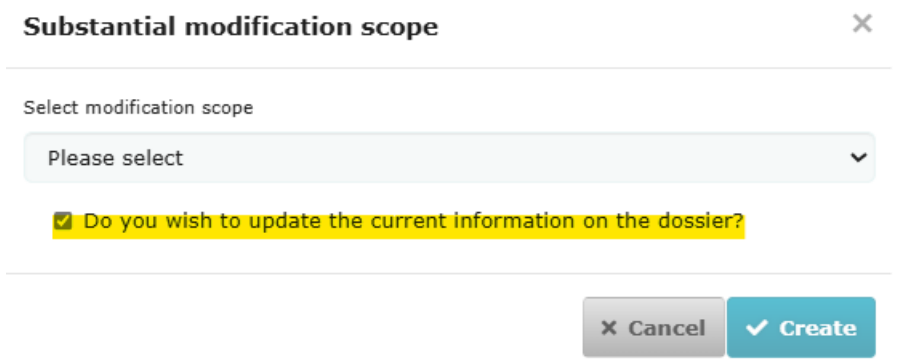
- When submitting an SM to extend the start of recruitment or to extend restart of trial make sure to select the option "***Extension to start trial recruitment beyond 2 years***" or "***Extension to restart trial beyond 2 years***" as reason for the SM and fill in the "***Recruitment start date***" 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.



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.

Legend: AMS – Additional Member State; NSM – Non-substantial Modification; SM – Substantial Modification.

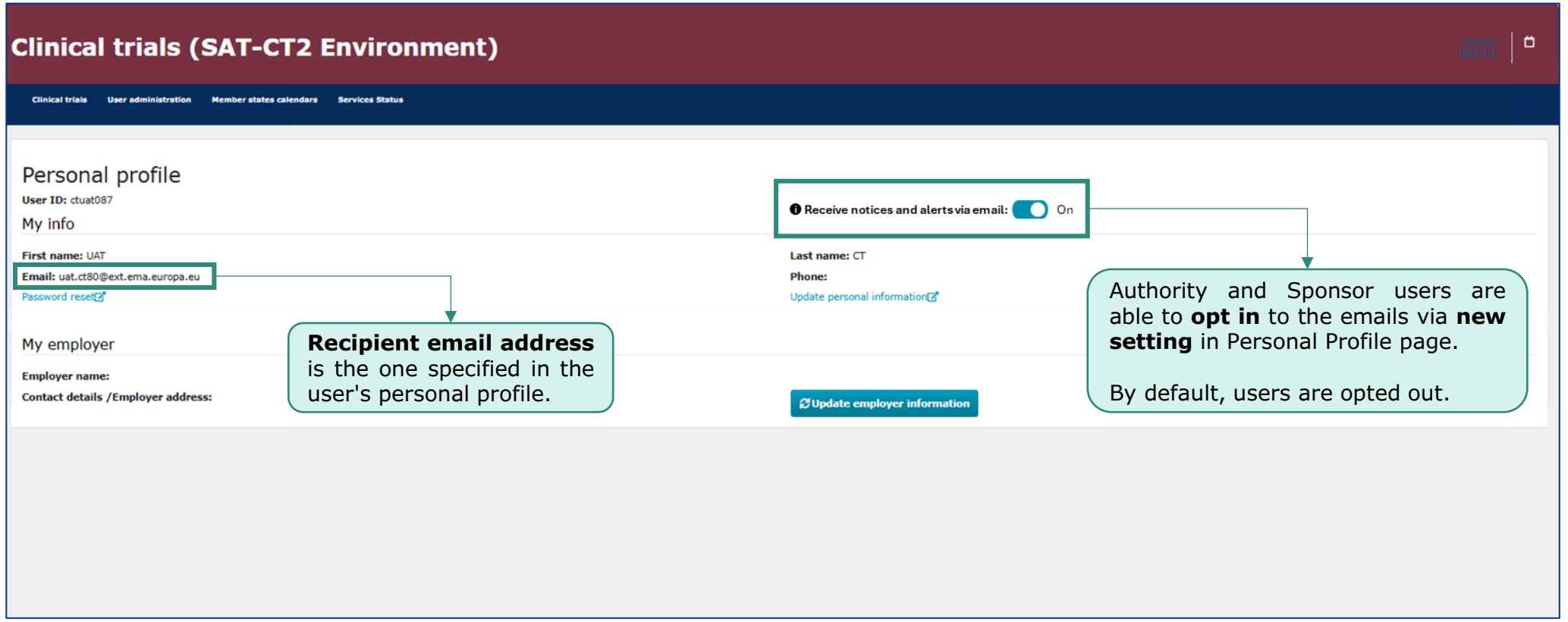
CTIS Improvement

Notices & Alerts via Email

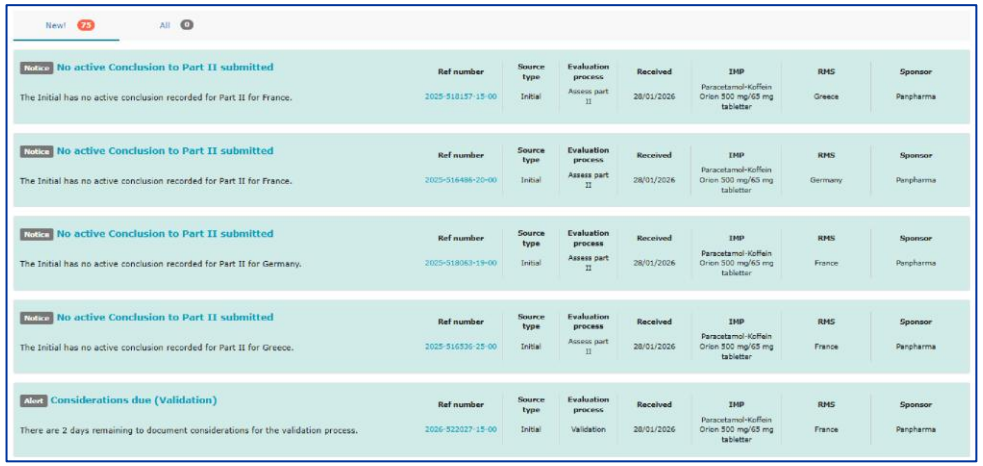
- **Emails for notices & alerts planned to be implemented soon.**

- 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

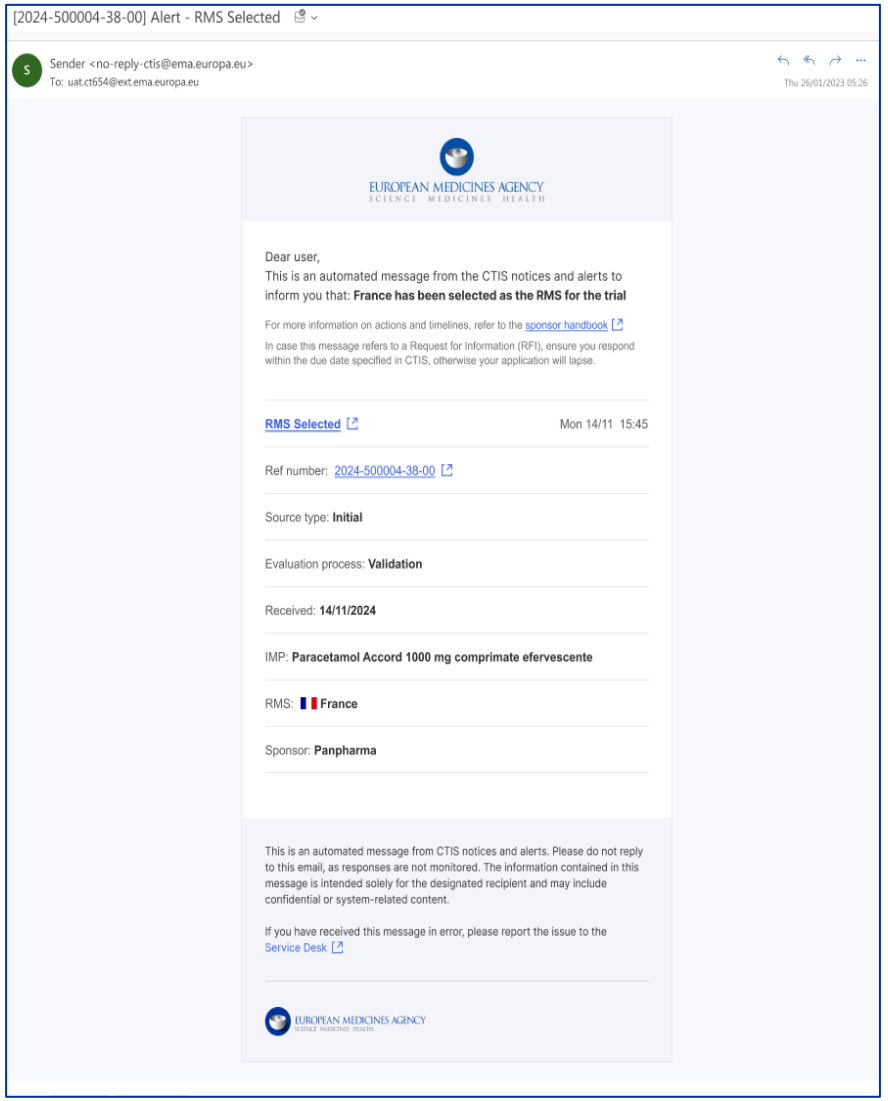
Notices & Alerts via Email



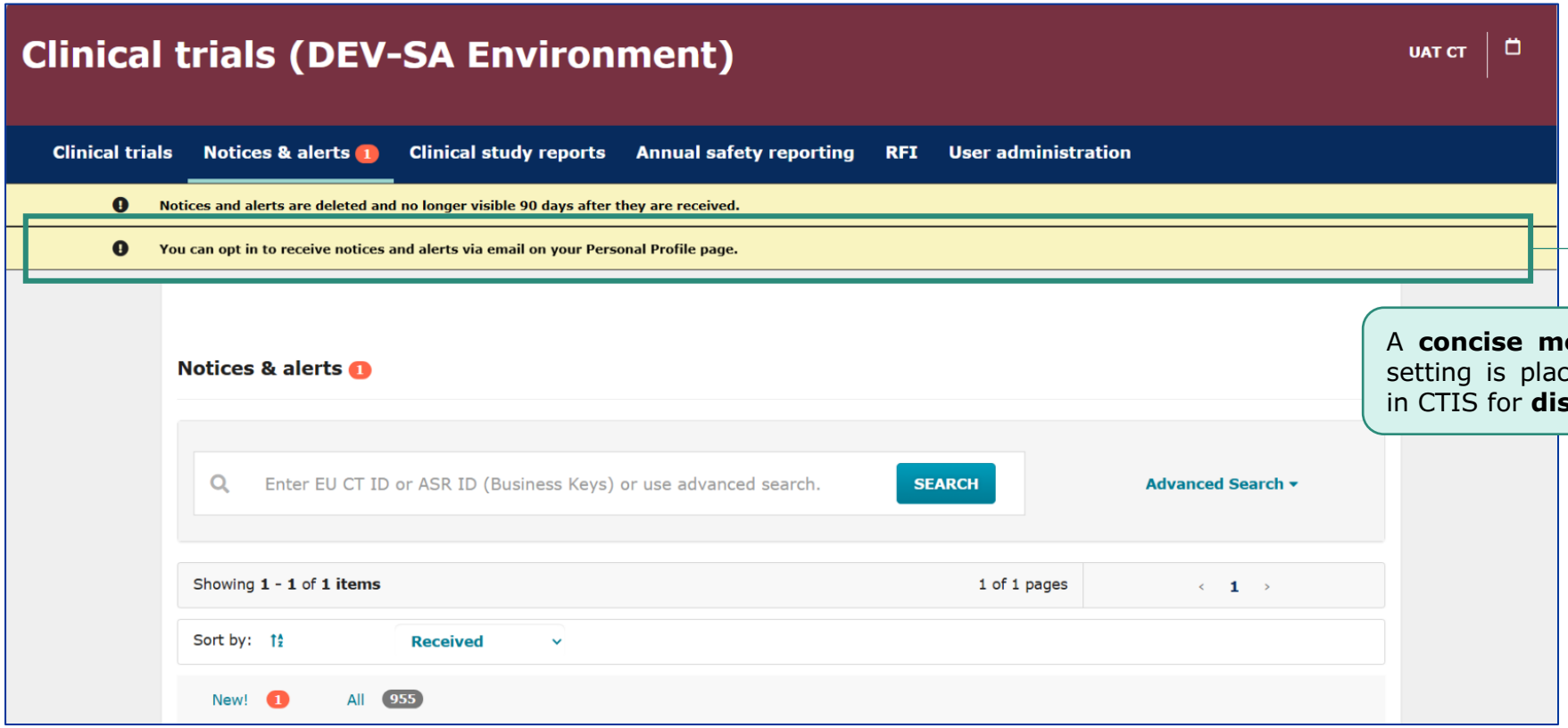
Notices & Alerts via Email



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



Notices & Alerts via Email



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

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Thank you

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