EUROPEAN MEDICINES AGENCY

Tips for users: reporting issues to CTIS User Support Service

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- Some of the most common issues which can be resolved by the user
- Submitting a ServiceNow ticket

Glossary

AMS	Additional Member State
CTA	Clinical Trial Application
CTIS	Clinical Trials Information System
xEVMPD	Extended EudraVigilance medicinal product dictionary
MP	Medicinal Product
NSM	Non-substantial modification
OMS	Organisation Management System
RFI	Request for information
SM	Substantial modification

Issue or question 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

Submit ServiceNow ticket

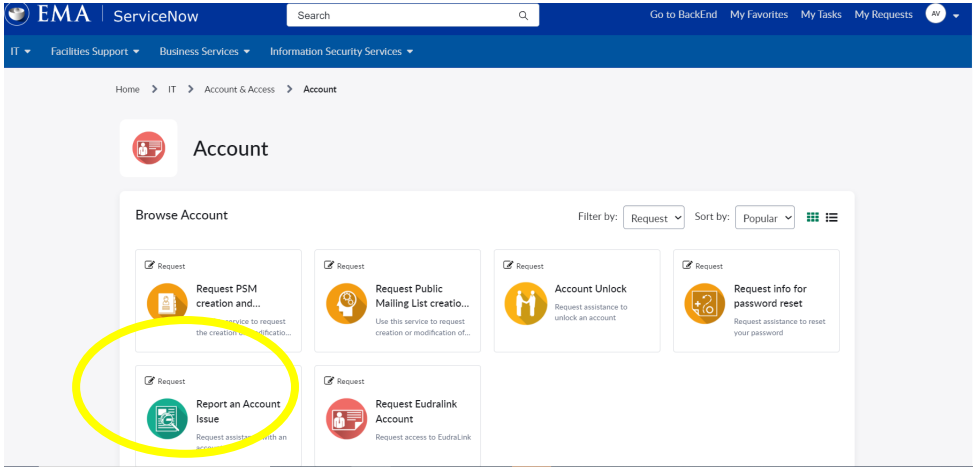
[Sponsor quick guide: Getting started with CTIS]
[CTIS training material]
[CTIS Handbook for clinical trial sponsors]
[List of known issues and proposed workarounds]
[CTIS newsflash]

CTIS: common issues which can be resolved by the user

Some tips:

- Issues with user accounts, login, passwords to be submitted via EMA account management

  (not via CTIS)



- To ask for updates or provide further information regarding an ongoing issue, add a comment on your existing ticket, to ensure faster resolution; do not open a new ticket
- ***Cancelled CTA (deleted)*** cannot be revived

Some tips:

- *When **responding to RFIs*** the users are advised to allow for at least **one extra day**, in case any interventions needed
- *RFI response not possible due to technical limitations of the system* - submit a ServiceNow ticket
- *xEVMPD updates* - **up to 48 hours** to be reflected in CTIS
- *OMS updates* – **up to 24 hours** to be reflected in CTIS

With the aim to improve speed and reliability of the search for organisations in CTIS, a new process has been activated to create an 'OMS cache', i.e. a copy of OMS data that will be available locally in the CTIS server. Under the new process, data is exported from OMS and imported to CTIS daily at 06.00 Amsterdam time. Organisations newly approved in OMS only appear in the CTIS search results one business day after users receive an email confirming the OMS registration.

Known issues and workarounds:

List of known issues and workarounds

- ***Notices and alerts not reset/refreshed*** *after login*: consult the RFI tab instead
- ***Draft application - "Check" button****, the system may not highlight fields not completed*: verify manually the telephone and the email address for the third-party organisation(s) and presence of the scientific and public contact points
- ***Download of structured data as part of a PDF for Part I, the document is empty***: when preparing the structured data, do not include certain characters such as a square box (copied and pasted) in the text fields; for submitted applications, to download structured data - make a request to service desk
- *Drafting a clinical trial application for a* ***large trial involving several member states****:* sponsors are recommended to **only provide the essential documents** required for the assessment and to fulfil the transparency requirement for publication
- *The* ***maximum limit of documents*** *that can be uploaded in one batch* in the system is **25**

Known issues and workarounds:

List of known issues and workarounds

- If **developmental/unauthorised MP is updated in xEVMPD** and referenced in CTA -> error appears when: submitting a subsequent draft application, responding to RFI, or cancelling the application. The error message reads: "The product(s) information has changed in the xEVMPD. Therefore, please update this application to include the new product information".

  → The sponsor is not able to submit the application, respond to RFI, cancel the application

✓ Solution: the sponsor needs to **update the unauthorised product record in CTIS**. Only the structured data should be updated (associated documents will remain in the draft application unless deleted by the user). To update the unauthorised product, the sponsor needs to:

1. identify the product requiring update;
2. remove the unauthorised product (only the structured data);
3. search for it using the updated substance EV code; and
4. add the product in the application.

Known issues and workarounds:

List of known issues and workarounds

- *CTA with **unauthorised (development) product** - sponsor tries to submit CTA or respond Validation RFI or respond PI Ass. RFI, error message triggered and wrong product highlighted:* navigate to Part I when clicking on the button "Check" or "Submit" to see the correct product record needing an update.
- *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. The users can confirm the RFI due date in the Evaluation folder and raise a ticket to confirm any other due dates with the service desk.

Known issues and workarounds:

List of known issues and workarounds

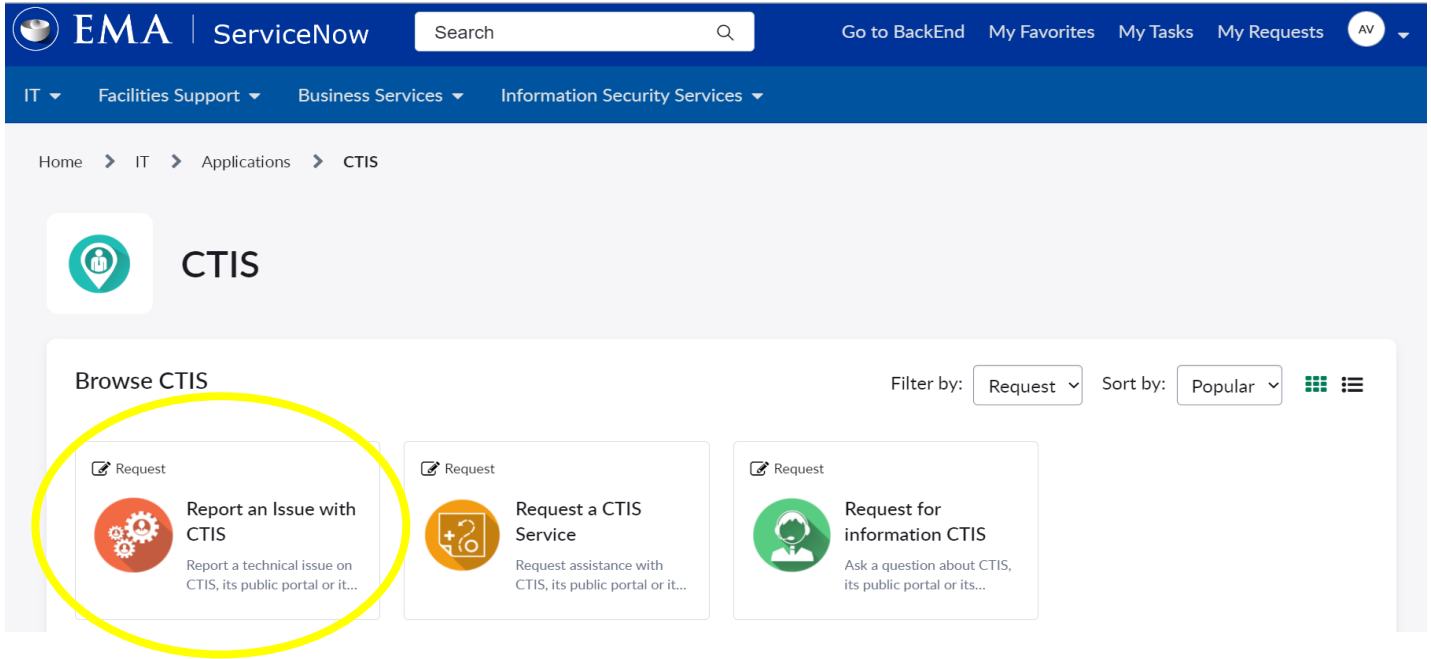
- ***Transitioning trials to CTIS***: sponsors are advised to raise a ticket with the CTIS User Support Service if they cannot find the trial that they wish to transition in CTIS when searching by EudraCT number
- Users with ***Sponsor admin role*** only cannot create CTA

The Sponsor Administrator role has only permissions to manage users' access (e.g. assign/amend/revoke roles or approve role requests). This role needs to be combined with the CT Admin role for the creation of initial CTAs or, for the creation of subsequent CTAs (e.g., SM, AMS and NSM), with the CT Admin or Application submitter role. Module 7 Sponsor business process roles CTIS Role matrix

CTIS: submitting a ServiceNow ticket

Submitting a ServiceNow ticket

ServiceNow



Report an issue with CTIS

Reminder of where to look for information

Report an Issue with CTIS

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

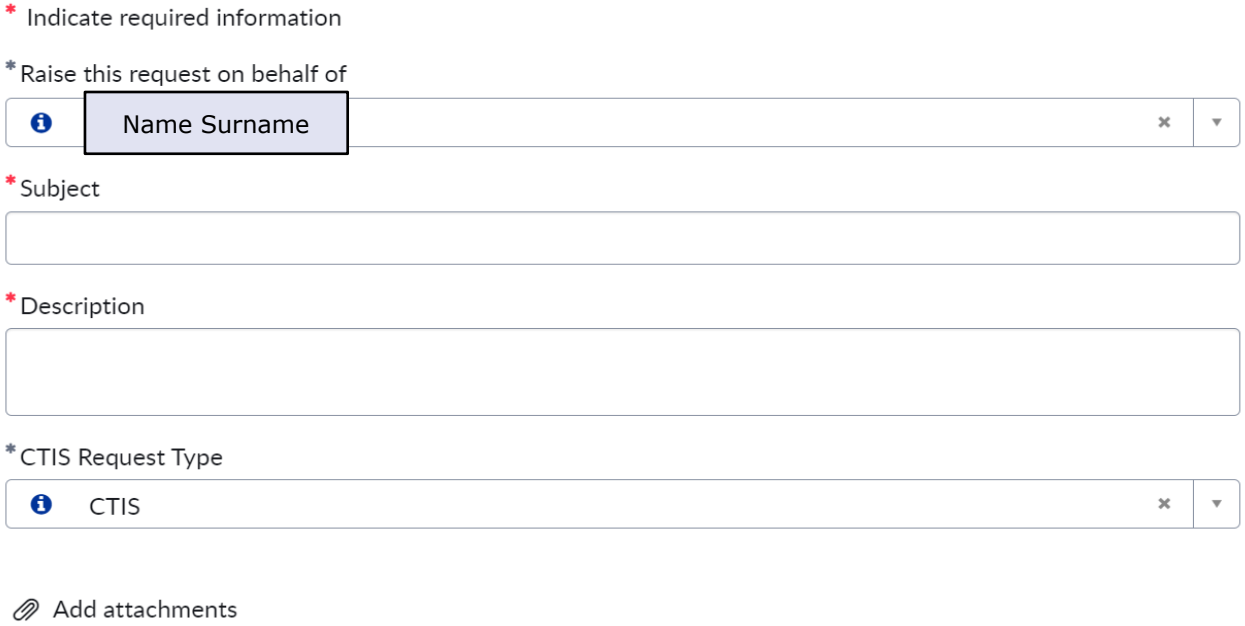
Create a new ticket in case you are experiencing a disruption of a CTIS functionality (the system is not behaving as described in the Training modules). Please provide as much detail as possible, including your username and CTIS role(s), your affiliation (sponsor or authority), your location, the EU 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:

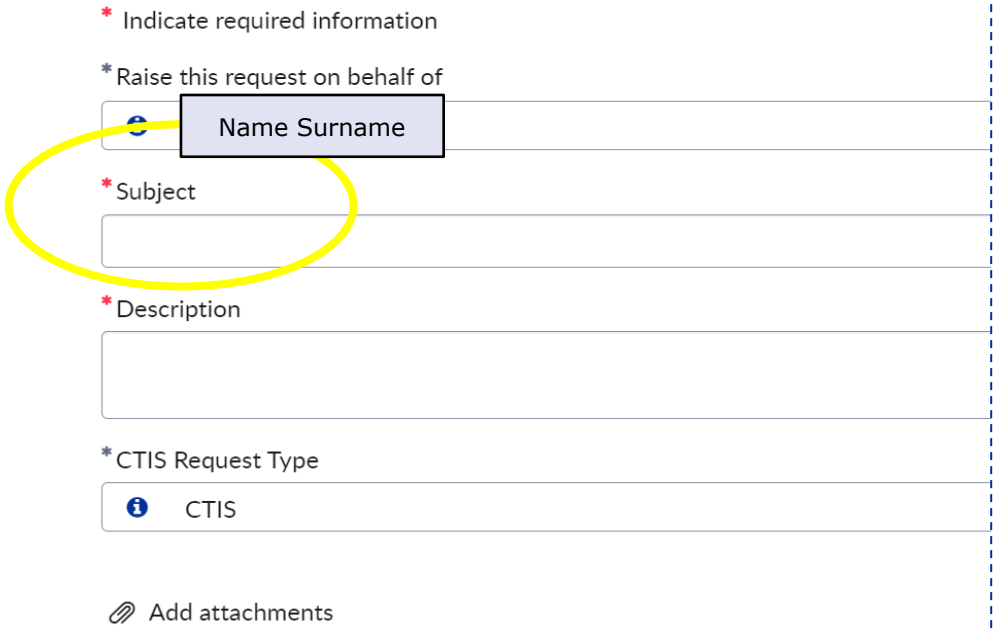
- System outages occurring out of the planned system interruptions timeframe.
- Log in issues that cannot be solved as per EMA account management
- Blocking issues that are not listed in the most recent lists of known issues & proposed workarounds and that prevent you from progressing (e.g. tabs not 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.

Submitting a ServiceNow ticket



Submitting a ServiceNow ticket



Subject = title of the incident

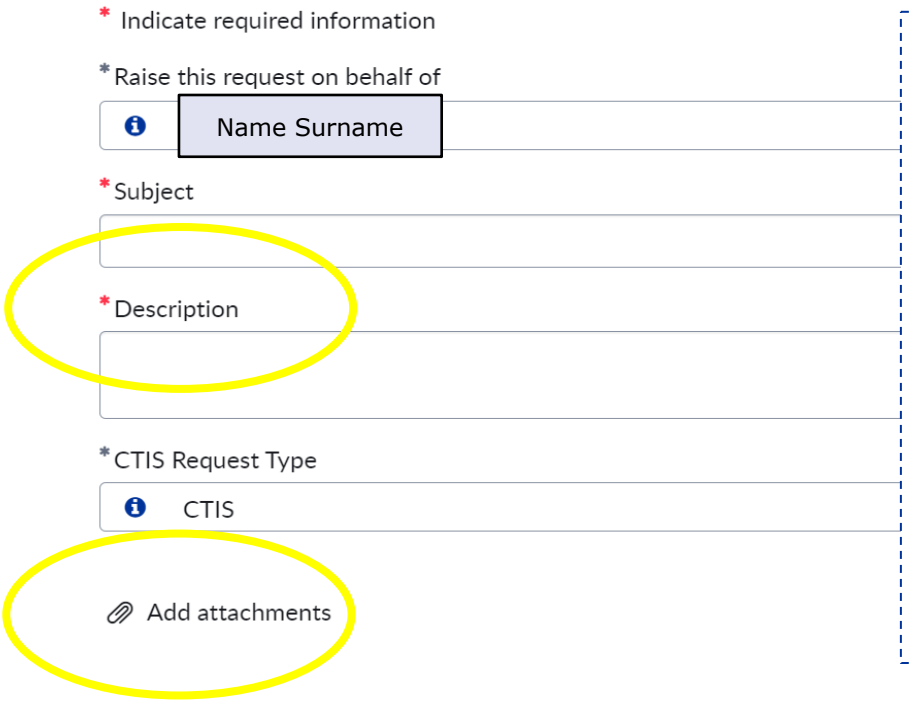
Example:

CTIS issue

vs

RFI response not possible: due 23 September 2023

Submitting a ServiceNow ticket

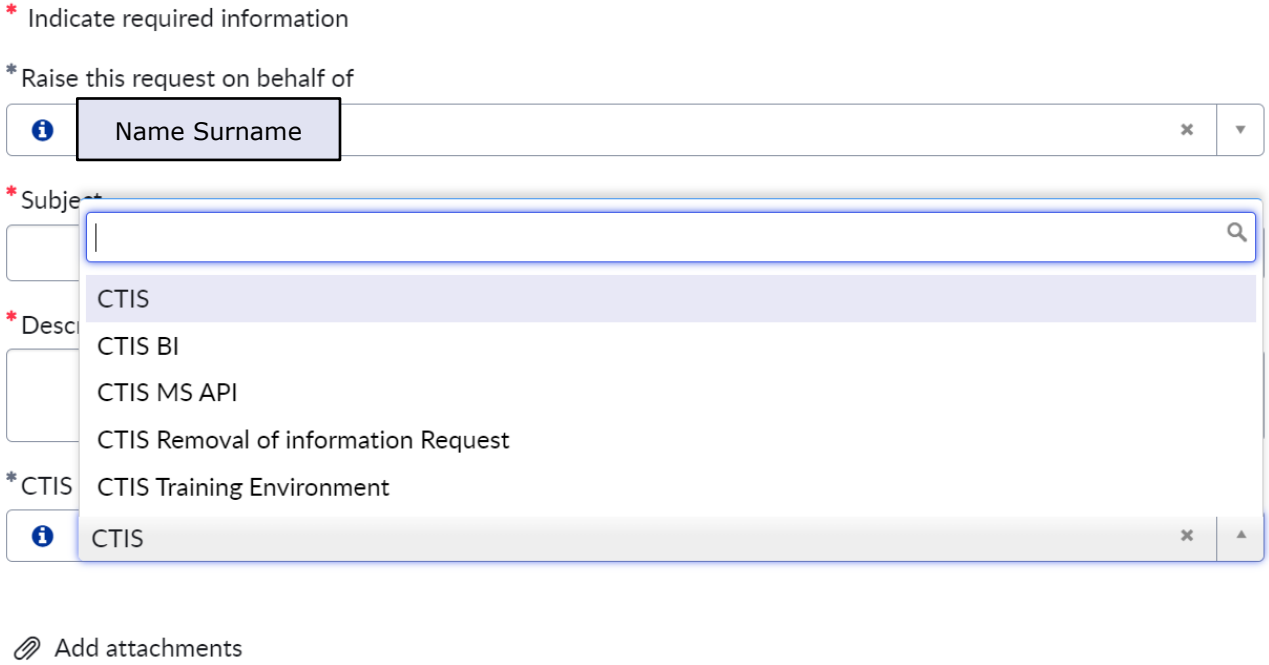


Detailed incident description

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
- Due date (if any)
- Attach screen shots of the issue

Submitting a ServiceNow ticket



Further information

Clinical Trials Information System: training and support

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