

EUROPEAN
MEDICINES
AGENCY

CTIS Service Desk and tips for the users reporting issues



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

Issue or question while working with CTIS

Help!



Submit ServiceNow ticket

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

[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 could be resolved by the user

And other tips

Some tips and known issues:

[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...” will 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.

Legend: MSC- member state concerned; SM – Substantial Modification; SoR – start of recruitment.

Some tips and known issues:

[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.
- **Translations not copied** to the next application – the users are advised to re-upload missing documents and provide an explanation to the authorities.
- 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.

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

Some tips and known issues:

List of known issues and workarounds

- 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.
- **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.
- After clicking a button in CTIS, e.g. 'Change application' under RFI, occasionally **the page may load a bit slower** than normal. If this happens, users are advised to wait for the page to finish loading; a blue indicator will be visible at the top of the page. Please do not click again until this blue indicator has disappeared.

Legend: NFP- not for publication; RFI – request for information.

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 expiry**. This allows time for the CTIS help desk and technical team 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 an action as part of a **response to RFI** (e.g. uploading a certain document, or updating the Investigational Medicinal Product code in xEVMPD), sponsors are advised to **submit the RFI response despite this pending action**. Sponsors should then reach out to the Member State Concerned and request for an additional RFI to be raised. This allows more time for the sponsor to coordinate with the CTIS Service desk to resolve the technical issue from the first RFI.

Legend: RFI- request for information; xEVMPD- extended EudraVigilance medicinal product dictionary; CTIS- clinical trials information system.

Some tips and known issues:

[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).

Trailing Space

Trial identifiers
Full title (English) *
TEST APPLICATION

- 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).

Leading Space

Trial identifiers
Full title (English) *
TEST APPLICATION

No spaces (IDEAL)

Trial identifiers	Trial identifiers
Full title (English) *	Full title (English) *
TEST APPLICATION	TEST APPLICATION

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
- During *creation of a new organisation in OMS* via CTIS, users need to fill in the **"City" field, which is now mandatory**. If this field is left blank, users will receive an error message.
- **Cancelled initial CTA (deleted)** cannot be revived
- Users with **Sponsor admin role** only cannot create CTA

Legend: CTIS- clinical trials information system; OMS- organization management system; SM- substantial modification CTA- clinical trial application.

Some tips and known issues:

[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 and/or
 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.

Legend: RFI- request for information.

Some tips and known issues:

[List of known issues and workarounds](#)

- Sponsors are advised to **avoid creating draft applications** for Substantial Modifications, Non Substantial Modifications, or Additional Member State Concerned **while the previous application is still under evaluation**. This is because after a draft application is created, it will not include any subsequent information added to the application under evaluation, leading to discrepancies, missing data and manual work for the sponsor.
- 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.

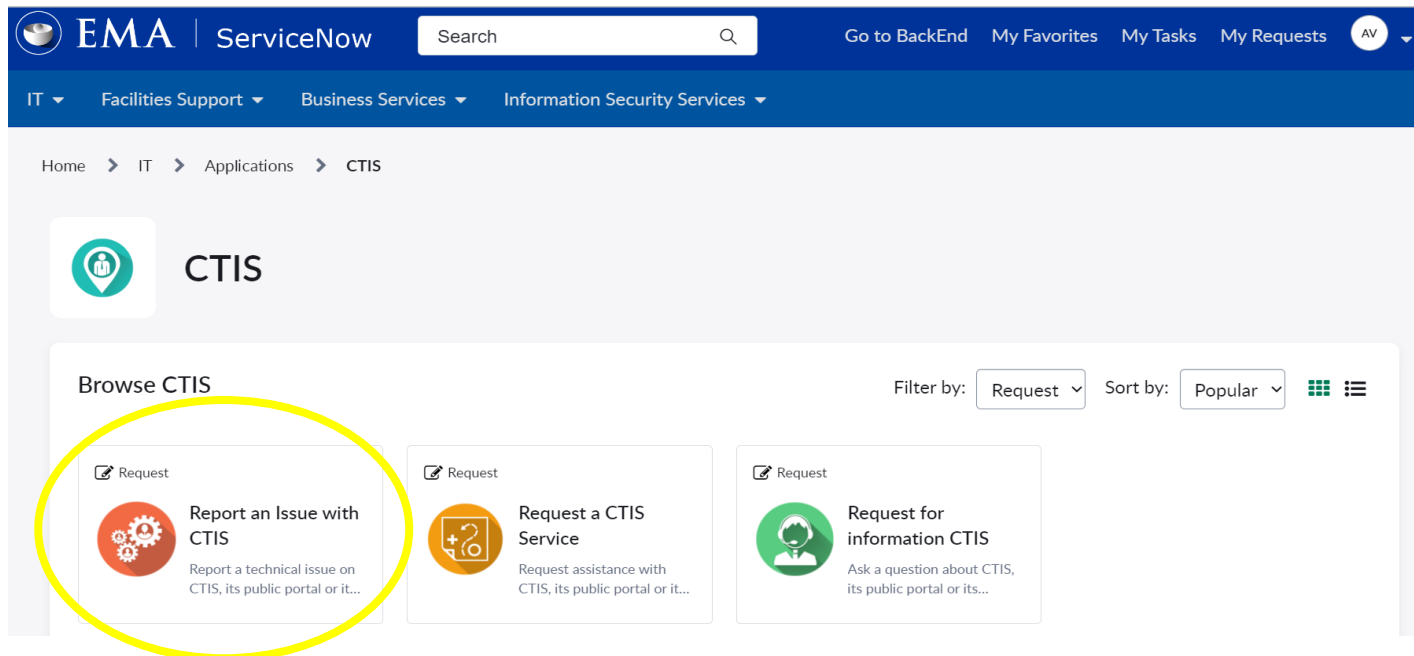
Legend: SM – Substantial Modification.

CTIS: submitting a ServiceNow ticket

And incident management

Submitting ServiceNow ticket

ServiceNow



The screenshot displays the EMA ServiceNow interface. At the top, there is a navigation bar with the EMA logo, a search bar, and links for 'Go to BackEnd', 'My Favorites', 'My Tasks', and 'My Requests'. Below this is a secondary navigation bar with categories: 'IT', 'Facilities Support', 'Business Services', and 'Information Security Services'. The main content area shows a breadcrumb trail: 'Home > IT > Applications > CTIS'. A large icon for 'CTIS' is visible. Below the icon, there is a 'Browse CTIS' section with filters for 'Request' and 'Sort by: Popular'. Three request cards are displayed:

- Report an Issue with CTIS**: Report a technical issue on CTIS, its public portal or it... (This card is circled in yellow)
- Request a CTIS Service**: Request assistance with CTIS, its public portal or it...
- Request for information CTIS**: Ask a question about CTIS, its public portal or its...

Report an issue with CTIS

Report an Issue with CTIS



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

Reminder where to
look for information



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 ServiceNow ticket

* Indicate required information

* Raise this request on behalf of

* Subject

* Description

* CTIS Request Type

* User affiliation

Submitting ServiceNow ticket

* Indicate required information

* Raise this request on behalf of



Name surname

* Subject

* Description

* CTIS Request Type

* User affiliation

-- Please Select --

Subject = title of the incident

Example:

CTIS issue

VS

**RFI response not possible:
due 23 July 2024**

Submitting ServiceNow ticket

* Indicate required information

* Raise this request on behalf of

* Subject

* Description

* CTIS Request Type

* User affiliation

-- Please Select --

Detailed incident description

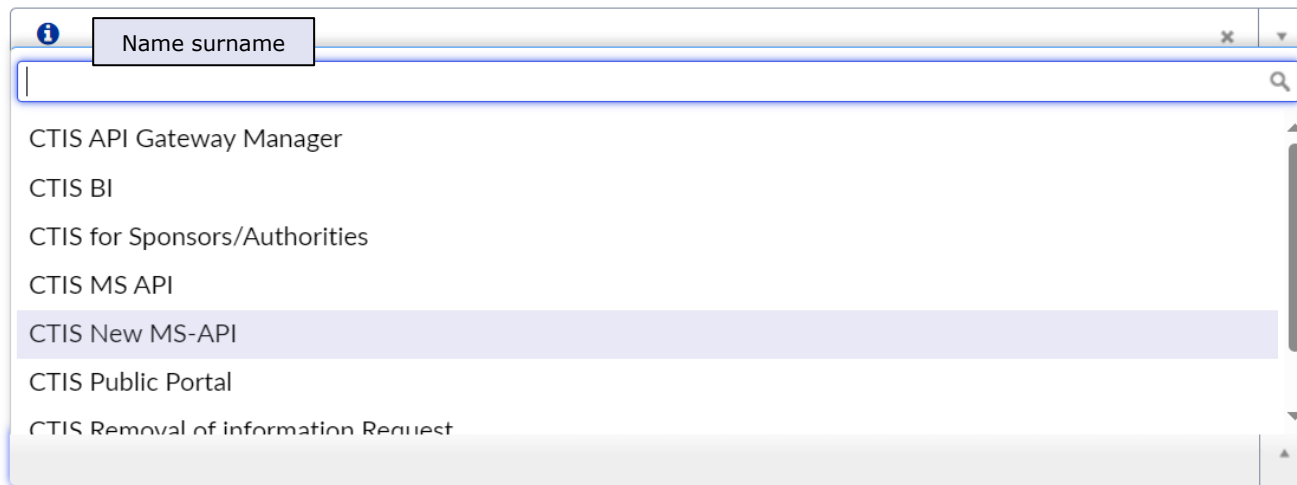
Provide as much information as possible

- 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**

Submitting ServiceNow ticket

* Indicate required information

* Raise this request on behalf of



The screenshot shows a dropdown menu for the 'Name surname' field. The menu is open, displaying a list of options. The option 'CTIS New MS-API' is highlighted in blue. The other options are: CTIS API Gateway Manager, CTIS BI, CTIS for Sponsors/Authorities, CTIS MS API, CTIS Public Portal, and CTIS Removal of information Request. The dropdown has a search icon in the top right corner and a scroll bar on the right side.

* User affiliation



The screenshot shows a dropdown menu for the 'User affiliation' field. The menu is closed, and the text '-- Please Select --' is visible in the input field. The dropdown has a small downward arrow icon in the top right corner.



Submitting ServiceNow ticket

* Indicate required information

* Raise this request on behalf of

* Subject


-- Please Select --
National Competent Authority
Commercial Sponsor
Ethics Committee
Non-commercial Sponsor
Other
-- Please Select -- 

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