

EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## EudraVigilance support guide

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Guidance document on the query support options offered by the EMA on EudraVigilance- and Pharmacovigilance-related queries

EMA/434681/2023

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An agency of the European Union





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# Introduction

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# Introduction

The European Medicines Agency (EMA) operates a number of **service desks** to assist Sponsors of Clinical Trials, Marketing Authorisation Holders (MAHs) and National Competent Authorities in using EudraVigilance in the EEA Member States. The working hours are the same as the [EMA's business hours](#).

Enquiries can be submitted through:

## EMA Service Desk Portal

- Web address:  
<https://support.ema.europa.eu/esc>
- Urgent helpline for technical enquiries: +31 (0)88 781 8520

Contact for:

- **Business** or **Technical** questions
- **Application-specific** questions
- Reporting **Duplicates**
- **ICSR/SUSAR compliance reports**
- **Medical Literature Monitoring (MLM)**
- **EV QAT Testing**

## EudraVigilance Registration

- Web address:  
[https://support.ema.europa.eu/esc?id=emp\\_taxonomy\\_topic&topic\\_id=5eb1d223c31415508719596ce001312b](https://support.ema.europa.eu/esc?id=emp_taxonomy_topic&topic_id=5eb1d223c31415508719596ce001312b)

Contact for:

- **Registration questions** not found in [EV Registration Manual](#) or webpage  
[EudraVigilance: how to register](#)
- **QPPV/RP change** (or **New Org first user**)
- **Transmission mode change**

## Ask EMA

- Web address:  
<https://www.ema.europa.eu/en/about-us/contacts-european-medicines-agency/send-question-european-medicines-agency>

Contact for:

- **Pharmacovigilance** or **general** questions
- **Requests for information**
- To make a formal request for **access to documents**



## EMA Service Desk portal

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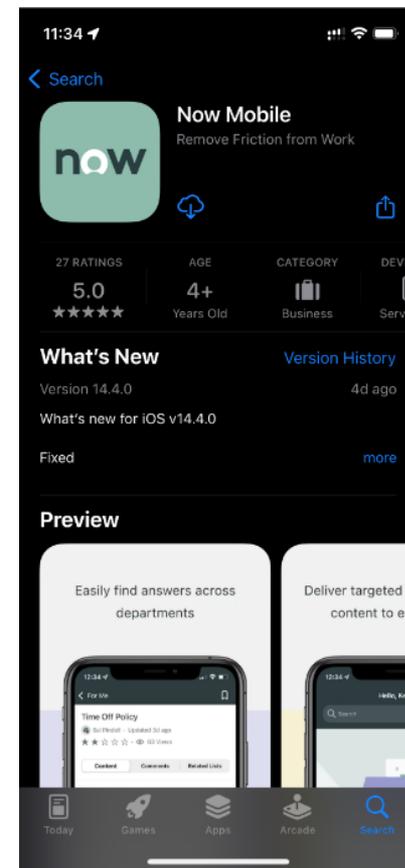
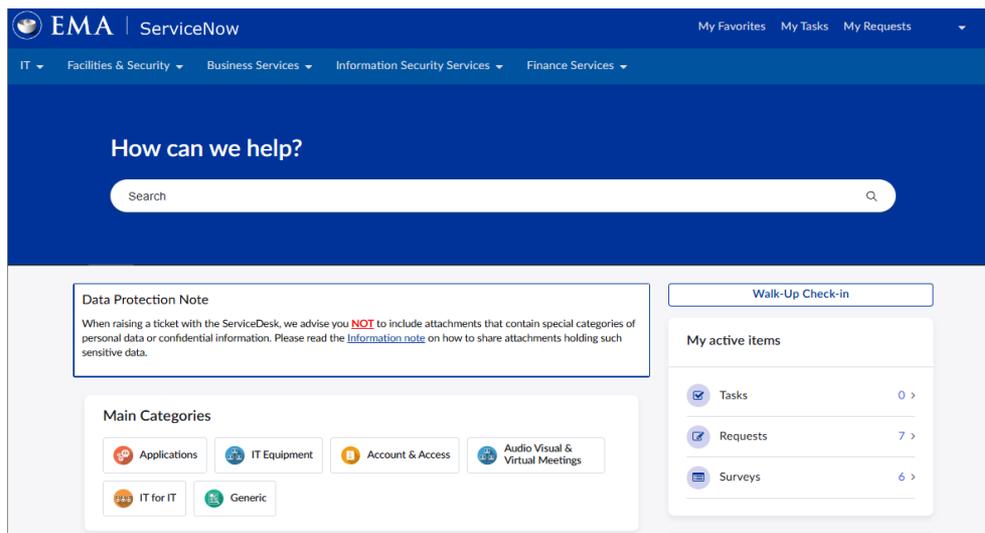
- EMA's Service Desk ticketing system
- Accessing EMA's Service Desk portal
- Two-factor authentication
- Accessing the EMA's Service Desk via mobile app



# EMA's Service Desk ticketing system

EMA introduced a new IT platform, ServiceNow, to manage the multiple Service Desks operated by the Agency.

This platform is available as a website and also has a mobile application.





## Accessing EMA's Service Desk Portal

To raise a technical query, request a service related to a specific application or ask a question, use the **EMA's Service Desk Portal**.

The portal can be accessed via this link:

<https://support.ema.europa.eu/esc>

Users can login with their email address.

Once the email is inserted, a validation code will be sent to that email address that users should enter when prompted to do so.

The image shows two screenshots of the EMA Service Desk Portal login interface. The top screenshot displays the 'Sign in' page with a 'Next' button. The bottom screenshot displays the 'Enter code' page with a 'Sign in' button.

**Sign in**

email

Next

**EMA Staff and Contractors**  
your password

**Other users:**

Follow this [guidance](#)  
password (only for le

Further guidance and  
be found [here](#)

Sign-in option

**Enter code**

We just sent a code to [redacted]

Enter code

Sign in



## Accessing EMA's Service Desk via mobile app

To access EMA's Service Desk via the mobile app, please follow these steps:

1. Search for "Now Mobile" in the App store or the Google Play Store and download the app.
2. When asked for the "Instance Address", enter the following URL: <https://support.ema.europa.eu/>
3. Enter your e-mail address.
4. Enter the validation code sent to your preferred multi-factor authentication channel (e.g. text message).

You have now accessed the Service Desk using the Service Now app.



# Before using the Service Desk Portal

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## Important notes

When raising a ticket with the ServiceDesk, please do **NOT** to include any attachments (in any file format, including screenshots) that contain:

- special categories of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership as well as genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation.
- confidential information including commercially confidential information.

This is with **exception** of confidential information that is required to support of certain business processes e.g., **SPOR/XEVMPD** and the request for addition/update of substances or standard terms etc.

In case the transmission of attachments is required for other business purposes you are requested, prior submission via the ServiceDesk, to **redact** such information where this is not required for the resolution of your request.



## Important notes

For ServiceDesk requests in relation to **ICSR/SUSAR submissions to EudraVigilance (EV)**, please be advised as follows:

- For individual case(s) already transmitted to EV, please **ONLY** reference the **complete** E2B(R3) **C.1.1 Sender's (case) safety report unique identifier**, the **C.1.8.1 Worldwide unique case identification number** or the **EV Local report number (EU-EC-xxxxxxx)**. EMA can access the cases to resolve your request.
  - For safety messages or individual cases that **failed a transmission to EV**, please only take a **screenshot of the safety Acknowledgment (ACK) Error message** and share such screenshot with the ServiceDesk. In case further information is required, you will be contacted.
- If your query does **not** refer to a case already transmitted to EV, and if EMA needs to access sensitive file(s), **the data should be shared with EMA via Eudralink to an email address that will be provided in the reply to the Service Desk ticket.**



## Using the Service Desk Portal

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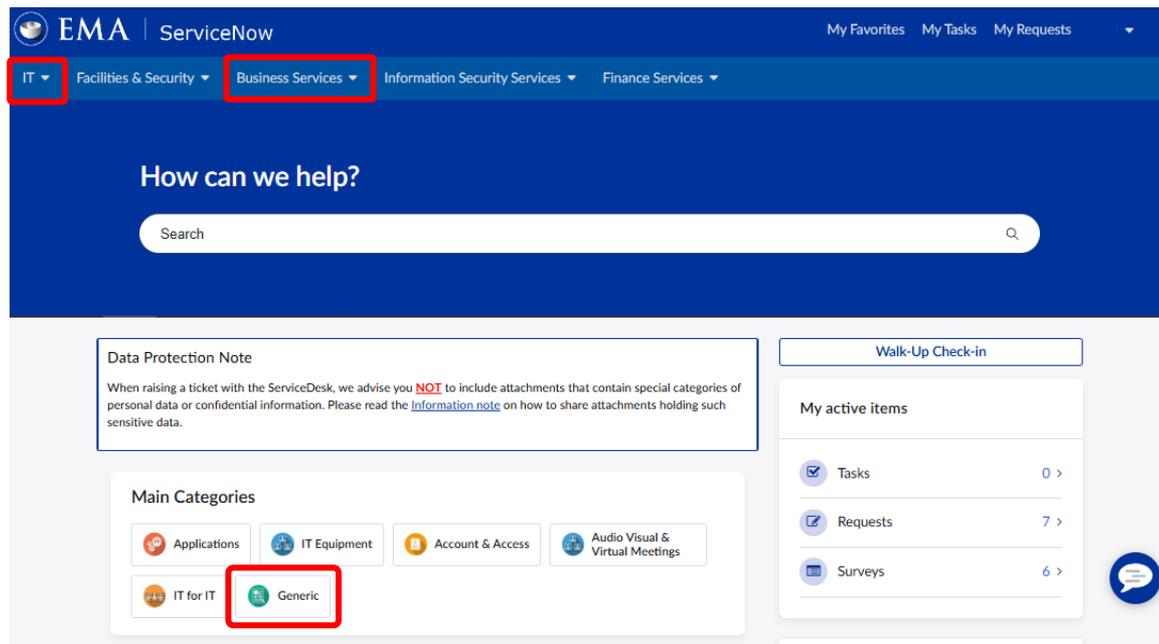
- Ask a Question, Request a Service and Report an Issue related to EV
- Raise Medical Literature Monitoring (MLM)-related queries
- Report ICSR Duplicates
- Raise ICSR/SUSAR compliance reports-related queries
- Request EV Quality Assurance Testing (QAT)
- Raise EudraVigilance Registration-related queries
- Track enquiries in EMA's Service Desk

# Using the Service Desk portal

Use the right category to log the calls related to EudraVigilance or other EMA supported IT systems such as EudraLink.

For some services (e.g. **MLM**, **ICSR duplicates**, **ICSR/SUSAR reporting compliance** or **EV QAT**) there are **specific** forms that should be used instead.

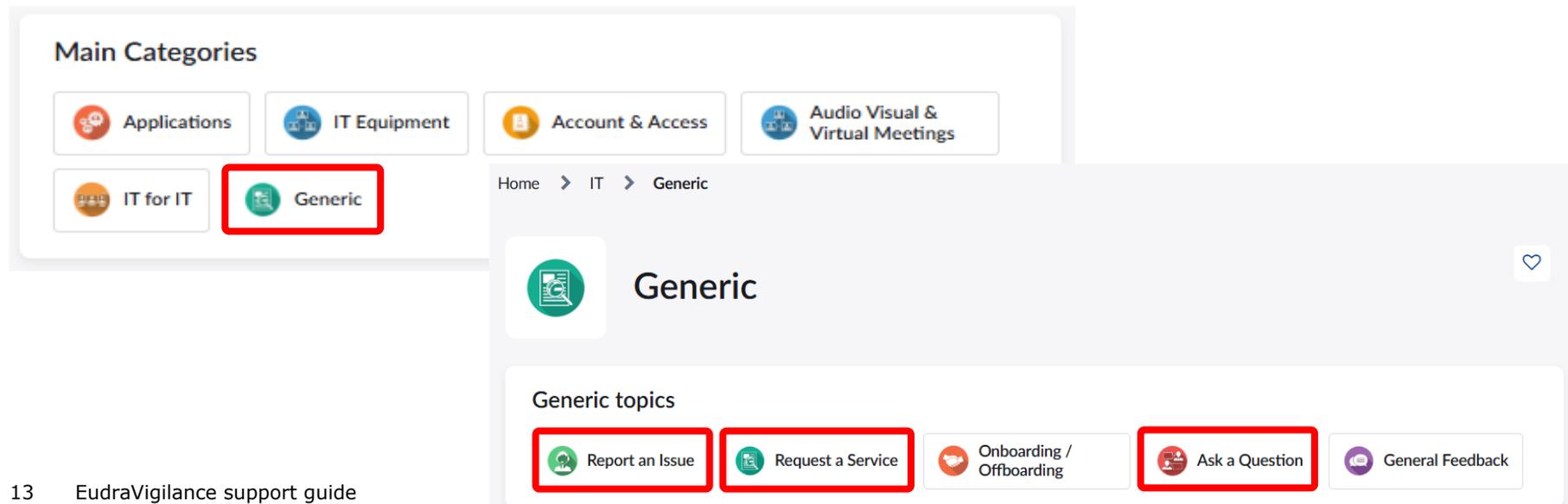
These forms can be found under "IT" or "Business Services" (or when searching for them in the Search bar).



## Using the Service Desk portal

In the Main Categories, you can access **Ask a Question**, **Request a Service** or **Report an Issue** via the “**Generic**” Main Category.

In the next slides, we’ll explain the main differences between the different options.



The screenshot displays the Service Desk portal interface. On the left, under the heading "Main Categories", there are seven buttons: "Applications", "IT Equipment", "Account & Access", "Audio Visual & Virtual Meetings", "IT for IT", and "Generic". The "Generic" button is highlighted with a red rectangular box. To the right, the breadcrumb path "Home > IT > Generic" is shown. Below this, the "Generic" category page is displayed, featuring a magnifying glass icon and the title "Generic". Underneath, the "Generic topics" section contains five buttons: "Report an Issue", "Request a Service", "Onboarding / Offboarding", "Ask a Question", and "General Feedback". The "Report an Issue", "Request a Service", and "Ask a Question" buttons are each highlighted with a red rectangular box.



## Using the Service Desk to **Ask a Question**

If you have **general** or **technical** (related to the use of EMA's IT systems) **questions**, or if you have questions or any other inquiries not falling under the "Request a Service" or "Report an Issue" sections.

Some examples:

- if you don't know how to use a system or **cannot upload a file**;
- if you've made a **mistake** when using a system (such as **EVWEB**);
- if you cannot retrieve an **ICSR** in EV or have a query related to a **case downloaded**;
- if you've received a **Negative acknowledgment (ACK)**.



Ask a Question

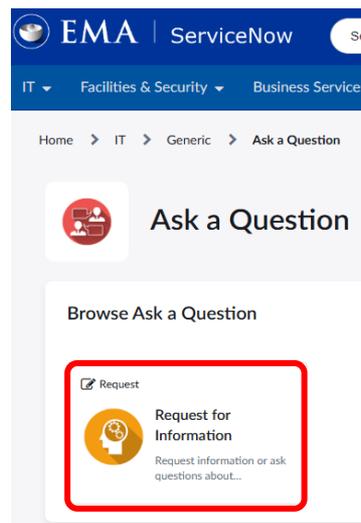
# Using the Service Desk to Ask a Question

Click on “Request for Information” and complete the form.

All the fields marked with a star \* at the beginning are mandatory.

You will have to choose a value from the drop-down menu (such as “EudraVigilance” for the Service, and then “EVWEB ICSR” or “EVDAS” for the Service Offering) and complete the free-text fields to submit your call.

An option for attaching a file is also available.



The screenshot shows the 'Request for Information' form. At the top, it says 'Request for Information' and 'Request information or ask questions about Information Management'. Below this is a yellow icon of a head with a gear and the text 'Use this service to request information.' The form contains several fields, all marked with a red asterisk (\*):

- \* Indicate required information
- \* Raise this request on behalf of: [Dropdown menu]
- \* Subject: [Text input field]
- \* Service: [Dropdown menu]
- \* Service Offering: [Dropdown menu]
- \* Description: [Text input field]

Below the form, there is a message: 'Dear ServiceDesk User, When raising a ticket with the ServiceDesk, we advise you not to include attachments that contain:' followed by a list of items:

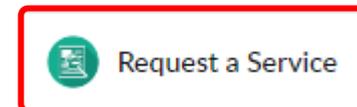
- Special categories of personal data
- Confidential information

Below this is a link: 'Please read the [Terms of use](#).' At the bottom, there is a checkbox: 'In order to add an attachment please indicate that you agree to the Terms of Use'.



## Using the Service Desk to **Request a Service**

If you need to help with **access, passwords, unlocking accounts** for the EudraVigilance systems or need to **raise specific requests**.



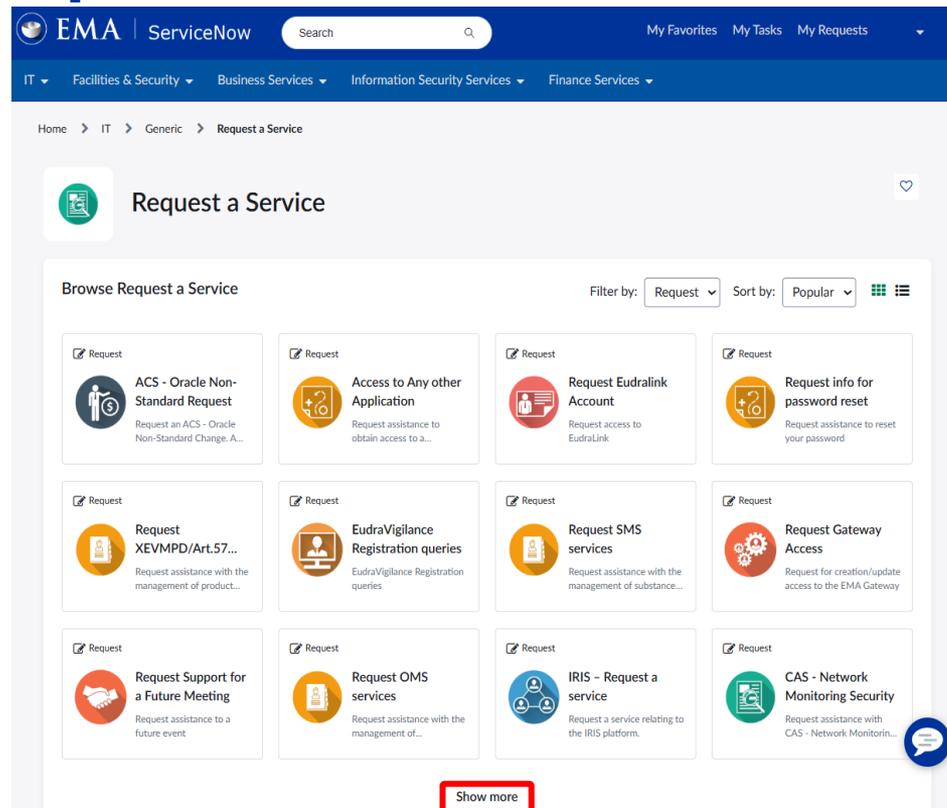
Some examples:

- If you need to request **Gateway** or **Eudralink** access;
- If you need a service related to **EV Registration, Art.57/XEVMPD** or **SPOR**.

# Using the Service Desk to Request a Service

Select the service that corresponds to the one you wish to raise a call for (for example: "Request Eudralink Account").

You can expand the options currently displayed by clicking on "Show more".



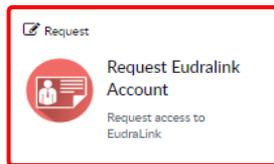
# Using the Service Desk to Request a Service

Once you've selected the Service, you should complete the corresponding form.

All the fields marked with a star \* at the beginning are mandatory.

You will have to choose a value from the drop-down menu (if applicable) and complete the free-text field(s) to submit your call.

An option for attaching a file is also available.



**Request Eudralink Account** Request access to EudraLink

Use this service to request changes in permission settings for EudraLink.



\* Indicate required information

\* Raise this request on behalf of

\* Motivation  Please indicate what you intend to use your Eudralink account for. This should relate to pharmaceutical regulatory purposes or communications that are relevant to EMA.

\* Summary

\* Confirmation

I confirm my understanding of the Eudralink policy

- I am aware that the Eudralink user account is strictly personal, and I certify that I will not permit any other person to use my account.
- I will not disclose my account password to any third party.
- I am aware that the Eudralink service could be suspended for maintenance purposes or could be suspended for unpredictable causes due to system or network failures.
- I certify that I will use Eudralink services for Pharmaceutical Regulatory purposes only or communications that are relevant to EMA.

## Using the Service Desk portal to **Report an Issue**

If an EudraVigilance-related **system is unavailable OR is malfunctioning** (i.e., needs **fixing**).

For example: EVWEB, EVDAS or EudraLink is unavailable.

### Notes:

**Errors/mistakes** made by users, for example when submitting a case in EVWEB, are **NOT** Issues and should be reported **only** via “**Ask a Question**”.

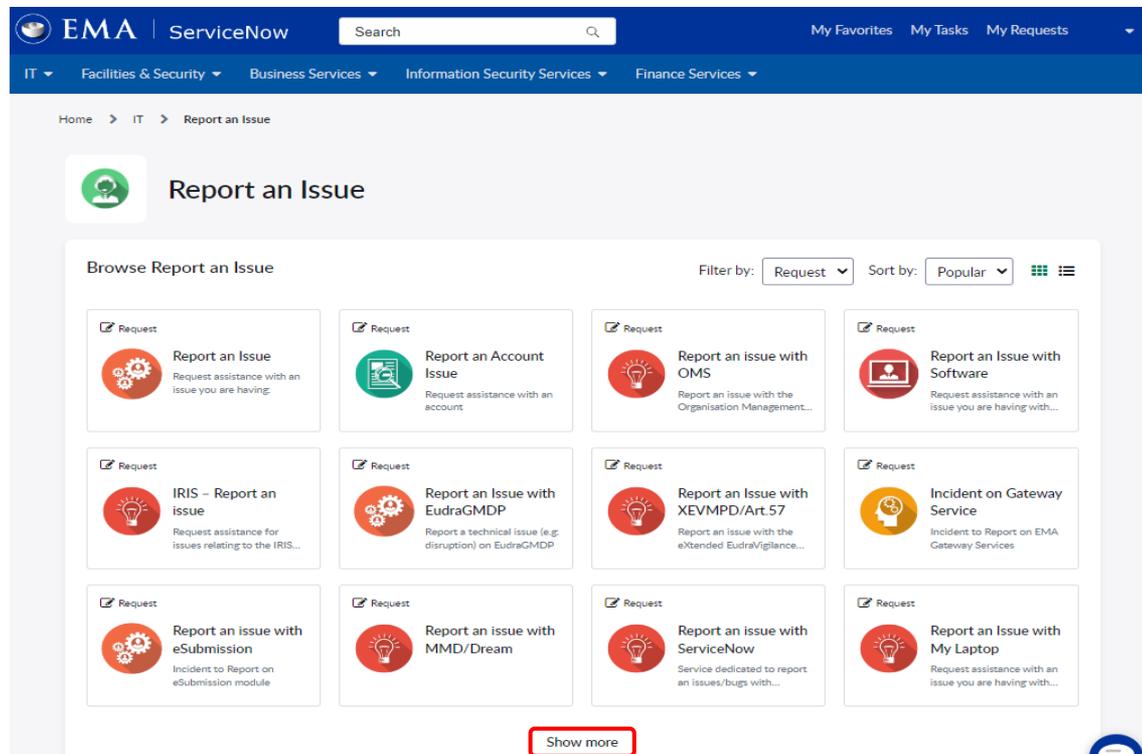
Also, for queries related to **missing** or **delayed ACKs**, please use this [Service Desk](#) instead.



# Using the Service Desk to Report an Issue

Select the service that corresponds to the one you wish to report a problem (for example: "Report an Issue with XEVMPD/Art.57").

Please note you can expand the options currently displayed by clicking on "Show more".



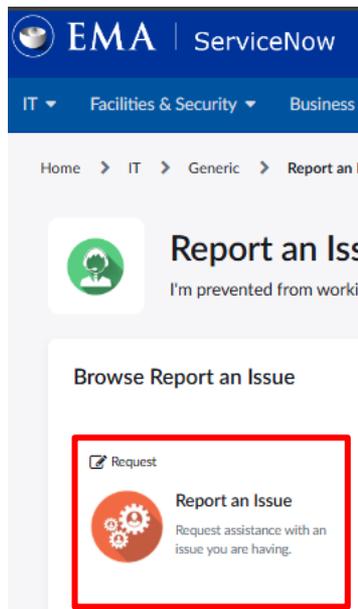
# Using the Service Desk to Report an Issue

Once you've selected the Service, you should complete the corresponding form.

All the fields marked with a star \* at the beginning are mandatory.

You will have to choose a value from the drop-down menu (if applicable) and complete the free-text field(s) to submit your call.

An option for attaching a file is also available.



The screenshot shows the 'Report an Issue' form in ServiceNow. The title is 'Report an Issue' and the subtitle is 'Request assistance with an issue you are having.' The form includes a gear icon and a text area for the issue description. Below this is a section for 'Examples' with a list of items: 'Report an issue with business applications / software / network connectivity' and 'Issues with audio visual meeting room equipment (e.g. projectors, voting system or audio quality)'. The form has several mandatory fields marked with a red asterisk: 'Indicate required information', 'Raise this request on behalf of' (with a dropdown menu), 'Service' (with a dropdown menu), 'Service Offering' (with a dropdown menu), 'Subject', and 'Description'. There is also a 'Dear ServiceDesk User,' section with a list of items: 'Special categories of personal data' and 'Confidential information'. At the bottom, there is a checkbox for 'In order to add an attachment please indicate that you agree to the Terms of Use'.



# EudraVigilance – MLM queries

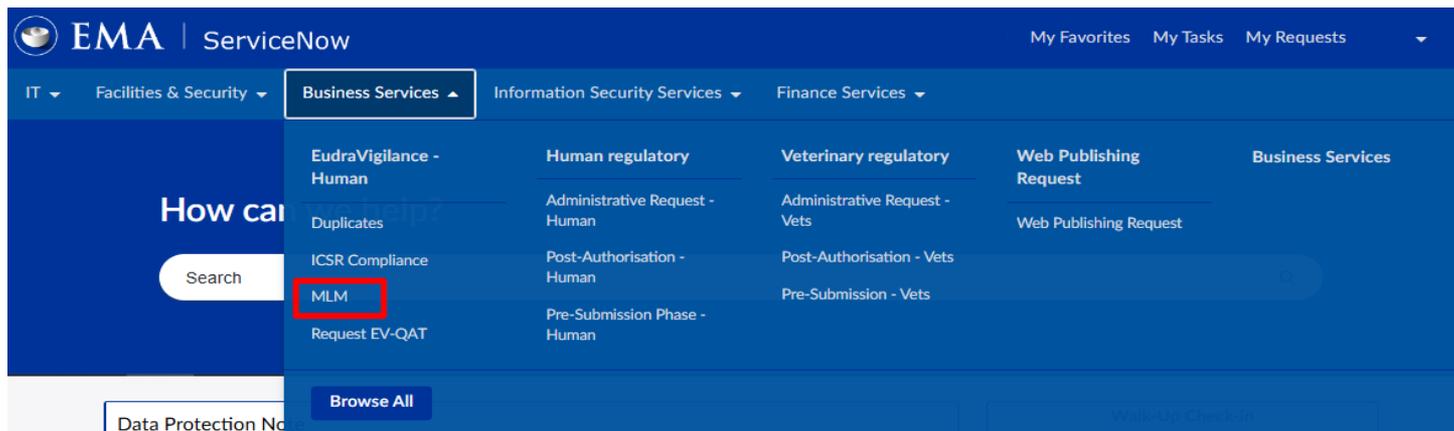
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## Raise Medical Literature Monitoring (MLM)-related queries

General guidance on the EMA's MLM Service is detailed in the webpage [Medical literature monitoring](#) and in the document [Monitoring of medical literature and the entry of relevant information into the EudraVigilance database by the European Medicines Agency – Questions and Answers](#).

To raise a query related to the MLM Service, go to “Business Services” and click on “MLM”.



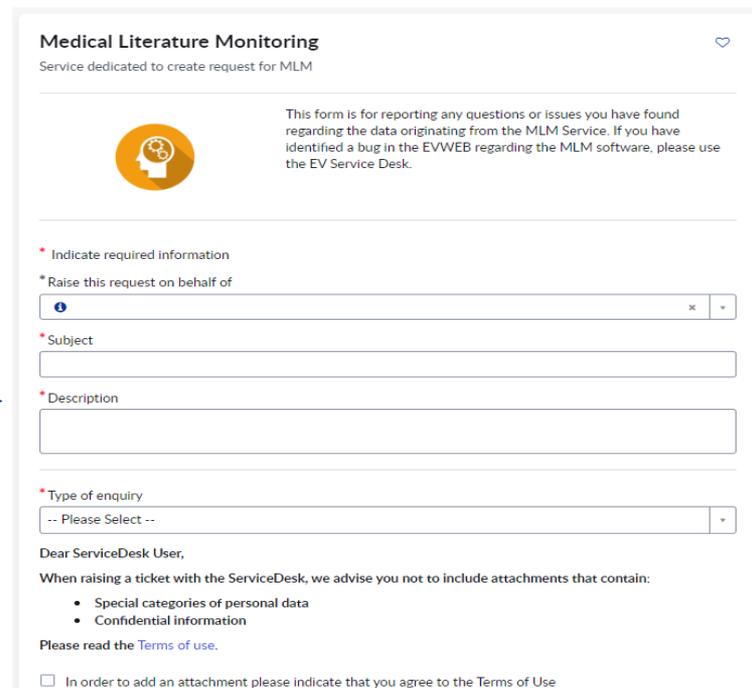
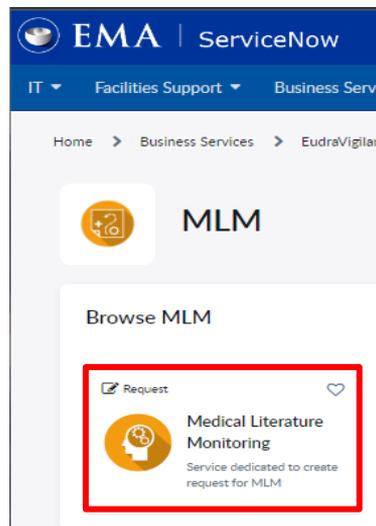
# Raise Medical Literature Monitoring (MLM)-related queries

Click on “Medical Literature Monitoring” and complete the form.

All the fields marked with a star \* at the beginning are mandatory.

You will have to choose a value from the drop-down menu and complete the field(s) with free text in order to submit your call.

An option for attaching a file is also available.



The screenshot shows the 'Medical Literature Monitoring' form. At the top, it says 'Service dedicated to create request for MLM'. Below this is a description: 'This form is for reporting any questions or issues you have found regarding the data originating from the MLM Service. If you have identified a bug in the EVWEB regarding the MLM software, please use the EV Service Desk.' The form contains several fields, each marked with a red asterisk to indicate they are mandatory: 'Raise this request on behalf of' (a dropdown menu), 'Subject' (a text input field), 'Description' (a larger text input field), and 'Type of enquiry' (a dropdown menu with the text '-- Please Select --'). Below the form, there is a message: 'Dear ServiceDesk User, When raising a ticket with the ServiceDesk, we advise you not to include attachments that contain: Special categories of personal data, Confidential information'. A link for 'Please read the Terms of use.' is provided. At the bottom, there is a checkbox labeled 'In order to add an attachment please indicate that you agree to the Terms of Use'.

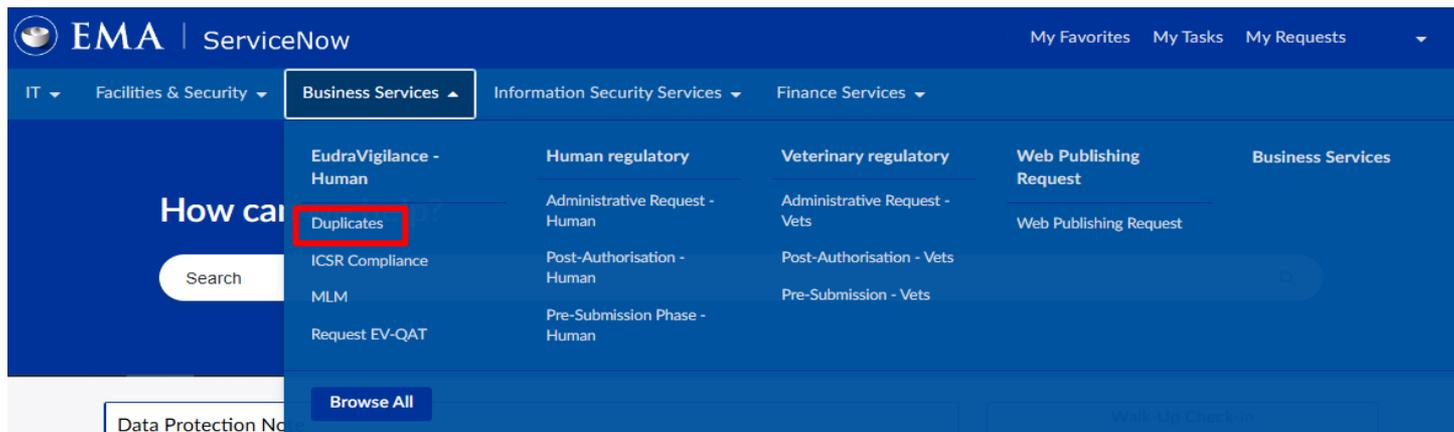


# EudraVigilance – Report ICSR Duplicates

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# EudraVigilance – Report ICSR Duplicates

To report ICSR duplicates in EV, go to “Business Services” and click on “Duplicates”.



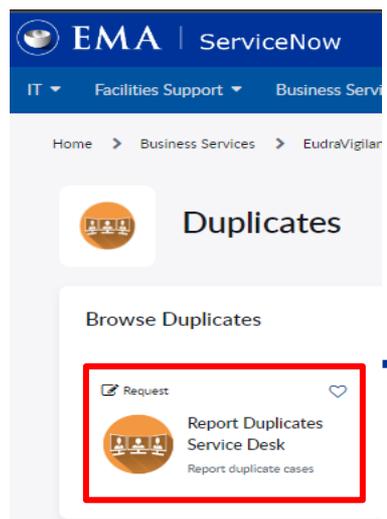
# EudraVigilance – Report ICSR Duplicates

Click on “Report Duplicates Service desk” and complete the form.

All the fields marked with a star \* at the beginning are mandatory.

You will have to choose a value from the drop-down menu and complete the free-text field(s) to submit your call.

An option for attaching a file is also available.



### Report Duplicates Service Desk

Report duplicate cases



Use this form to report suspected duplicate cases you have found in EudraVigilance.

Please enter case numbers or safety report IDs in full E2B format or local report numbers.

Please only enter the identification numbers of cases you have found in, or submitted to, EudraVigilance. If you have found an identification number in the 'Other case identifiers' section of a case, you do not need to report this.

Please do not attach any individual cases. We will be able to access them in EV with the identifiers.

If you are attaching a line listing of cases, please indicate which cases you suspect of being duplicates.

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\* Indicate required information

\* Raise this request on behalf of

i

\* Description

\* Choose one of the below types of Reference Numbers

Please click in the text box and choose a reference number you are providing for the reported duplicate. \*

-- Please Select --

\* Number of cases to be reported

-- Please Select --

Note

If you have more than 15 suspected duplicates, please attach the spreadsheet in the requested format.

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Dear ServiceDesk User,

When raising a ticket with the ServiceDesk, we advise you not to include attachments that contain:

- Special categories of personal data
- Confidential information

Please read the [Terms of use](#).

In order to add an attachment please indicate that you agree to the Terms of Use



# EudraVigilance – ICSR/SUSAR compliance reports queries

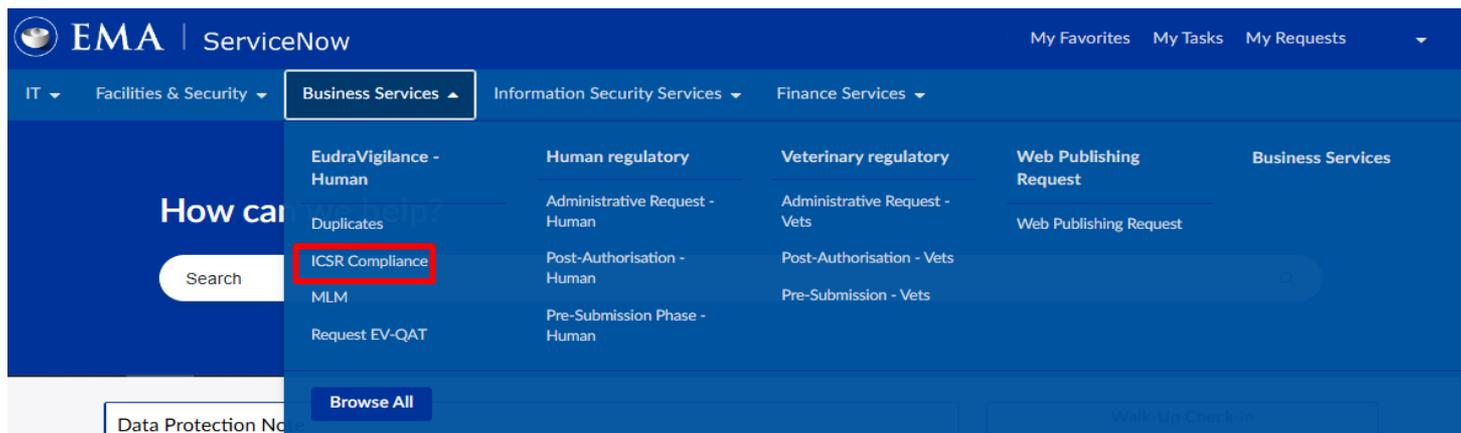
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## EudraVigilance – ICSR/SUSAR compliance reports-related queries

General guidance on the EMA's Compliance Notification is detailed in the [EMA's Compliance notifications explanation and Q&A](#).

If your question is not answered in the Q&A section, then go to “Business Services” and click on “ICSR Compliance”.



# EudraVigilance – ICSR/SUSAR compliance reports-related queries

Click on “ICSR Compliance” and complete the form.

All the fields marked with a star \* at the beginning are mandatory.

You will have to choose a value from the drop-down menu (if applicable) and complete the free-text field(s) to submit your call.

An option for attaching a file is also available.



### ICSR compliance notification question ♥

Questions regarding the ICSR compliance notification report sent by EMA

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Before raising a ticket, please ensure that you check first the [Compliance Q&A document](#)

Please use this form for any questions that you have regarding the automated monthly ICSR reporting compliance notifications sent by EMA and that are NOT answered in the [Compliance Q&A document](#). Please include a copy of the report in question & the local report numbers (those beginning EU-EC-) of any ICSRs which you have specific questions about. Please do NOT attach any sensitive document (such as XML files, ICSR or CIOMS Forms, RTF documents or print screens of the cases) to your ticket. All the Agency needs is the copy of the compliance report and the local report numbers that you have questions about.

If you have other technical or specific questions regarding 7/15/90-day reporting compliance of individual cases, please use the [Ask a Question](#).

If you have general (PV) questions regarding 7/15/90-day reporting compliance, then please use [Ask-EMA](#).

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\* Indicate required information

\* Raise this request on behalf of

i x ▾

\* Description

Dear ServiceDesk User,

When raising a ticket with the ServiceDesk, we advise you **NOT** to include attachments that contain:

- Special categories of personal data
- Confidential information

Please read the [Terms of use](#).

In order to add an attachment please indicate that you agree to the Terms of Use

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 \* Add attachments



# EudraVigilance – Request EV QAT

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## EudraVigilance – Request EV QAT

EudraVigilance Quality Assurance Testing (QAT) needs to be completed with EMA whenever an organisation wishes, for example, to:

- Have the **EV transmission mode changed from WebTrader to Gateway Trader**;
- Start using **EVPOST** (for organisations using EVWEB);
- Upgrade their **PV database** (for organisations operating as Gateway traders or using EVPOST).
- Also, software/IT developers who offer software solutions related to electronic reporting can test their new software (and subsequent versions) with EMA – please refer to: [IT vendors and third-party service providers](#).

This is further detailed on EMA's webpage [EudraVigilance: electronic reporting](#). Please also refer to [EV Registration Manual](#) (namely to section 6.1).



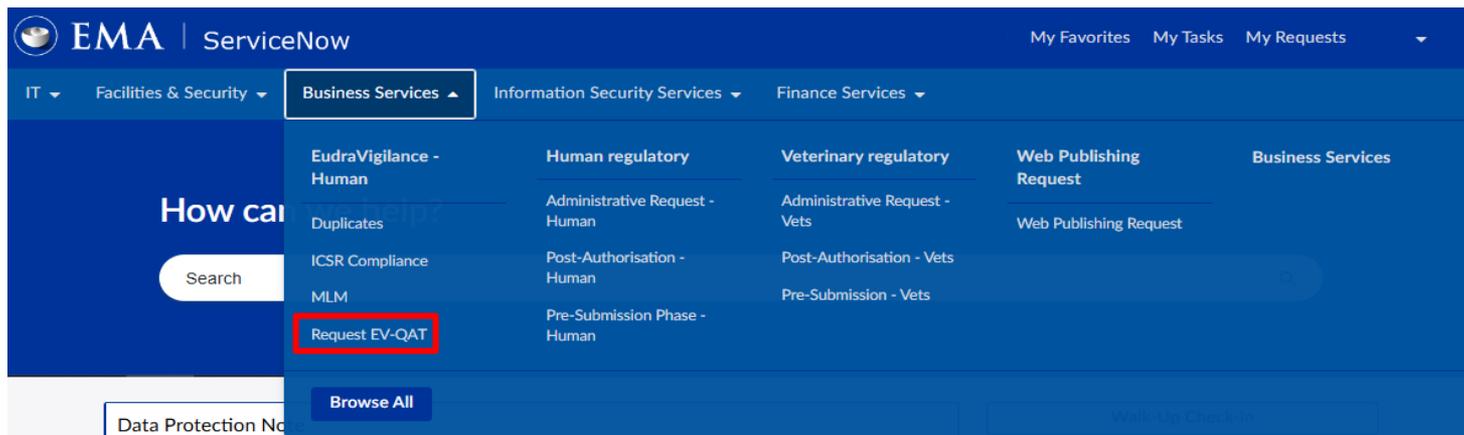
## EudraVigilance – Request EV QAT

Before initiating QAT (also known as Step 5 testing) with EMA, **all organisations are required to complete the EV Testing Step 4 themselves in advance.**

Guidance on how to complete these 2 testing steps is available on the EMA's webpage [EudraVigilance: electronic reporting](#).

# EudraVigilance – Request EV QAT

To request EV QAT, go to “Business Services” and click on “Request EV-QAT”.



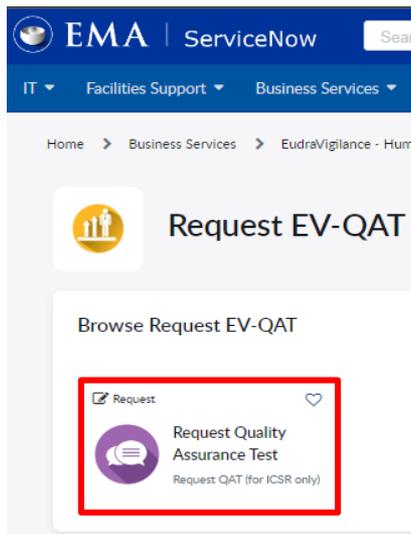
# EudraVigilance – Request EV QAT

Click on “Request Quality Assurance Test” and complete the form.

All the fields marked with a star \* at the beginning are mandatory.

You will have to choose a value from the drop-down menu and complete the free-text fields to submit your call.

An option for attaching a file is also available.



**Request Quality Assurance Test**  
Request QAT (for ICSR only)

- \* Indicate required information
- \* Raise this request on behalf of
- \* Subject
- \* Description
- \* XCOMP Organisation Sender Identifier (this EV Sender identifier has the format "ORXnnnnnnnn" or "VXnnnnnnnn")
- \* Organisation Name
- \* Are you using a Gateway or the EVPOST function?
- \* Please confirm that you've completed Step-4 testing prior to submitting this QAT request, as explained at the top of this form (if you need support to complete Step 4 testing, then please mention it in the "Description" field of this form).
- \* Are you a Software Vendor, a CRO/Service Provider or MAH/Sponsor/NCA?
- \* Name of the PV software
- \* Version of the PV software
- \* Configurations of the PV software



# EudraVigilance Registration

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## EudraVigilance Registration Queries & Requests

Please note that the EMA EV registration team only deals with queries for the following EV Human production topics:

- **New Organisation;**
- **QPPV/RP change** or **first user activation;**
- **Change in transmission mode.**

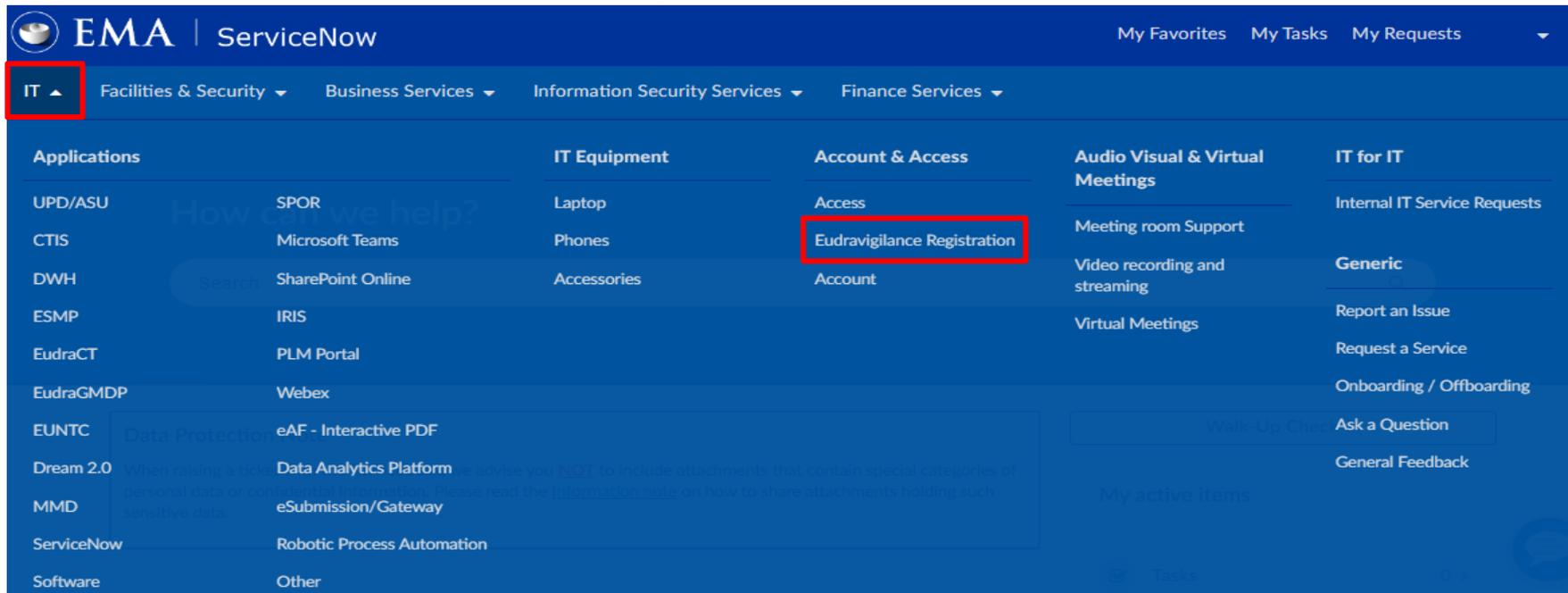
For more information, please refer to the webpage [EudraVigilance: how to register](#) and to the documents [EV Registration manual](#), [EudraVigilance registration documents](#) and [New Organization First User QPPV/RP or Change of EU QPPV/RP](#).

Other EudraVigilance-related queries should be sent as EMA Service Desk requests:

- **Ask a Question;**
- **Request a Service;**
- **Report an Issue.**

# EudraVigilance Registration Queries & Requests

In the "IT" section, click on "EudraVigilance Registration", under "Account & Access".



The screenshot shows the EMA ServiceNow user interface. At the top, the EMA logo and 'ServiceNow' are displayed. On the right, there are links for 'My Favorites', 'My Tasks', and 'My Requests'. Below this is a navigation bar with 'IT' highlighted in a red box, followed by 'Facilities & Security', 'Business Services', 'Information Security Services', and 'Finance Services'. The main content area is a grid of service categories. The 'Account & Access' column has 'EudraVigilance Registration' highlighted in a red box. Other categories include Applications, IT Equipment, Audio Visual & Virtual Meetings, and IT for IT.

Applications	IT Equipment	Account & Access	Audio Visual & Virtual Meetings	IT for IT
UPD/ASU	Laptop	Access	Meeting room Support	Internal IT Service Requests
CTIS	Phones	<b>EudraVigilance Registration</b>	Video recording and streaming	Generic
DWH	Accessories	Account	Virtual Meetings	Report an Issue
ESMP				Request a Service
EudraCT				Onboarding / Offboarding
EudraGMDP				Ask a Question
EUNTC				General Feedback
Dream 2.0				
MMD				
ServiceNow				
Software				

# EudraVigilance Registration Queries & Requests

Click on “EudraVigilance Registration queries” and complete the form.

All the fields marked with a star \* at the beginning are mandatory.

You will have to choose a value from the drop-down menu and complete the free-text fields to submit your call.

An option for attaching a file is also available.



### EudraVigilance Registration queries

EudraVigilance Registration queries



- For new access or password reset please go to [EMA Account Management](#).
- For user password reset or unlocking your account, please go to the [Account Unlock - Employee Center \(europa.eu\)](#).
- To create new organizations or manage an existing one, please log into [SPOR Organization Management System](#).
- For QPPV/RP changes please check our [Registration Manual](#).

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\* Indicate required information

\* Raise this request on behalf of

\* Subject

\* Description

\* EV-Environment type

\* EV-Request type

- Registering/Changing MAH QPPV/RP
- EU QPPV
- Responsible Person
- Amending my organization profile
- Registering/Disabling an org/user
- Other

Dear ServiceDesk User,

When raising a ticket with the ServiceDesk, we advise you not to include attachments that contain:

- Special categories of personal data
- Confidential information

Please read the [Terms of use](#).

In order to add an attachment please indicate that you agree to the Terms of Use



## EMA Service Desk – Tracking enquiries

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- Tracking enquiries
- Adding colleagues to the Watch List
- Resolving enquiries

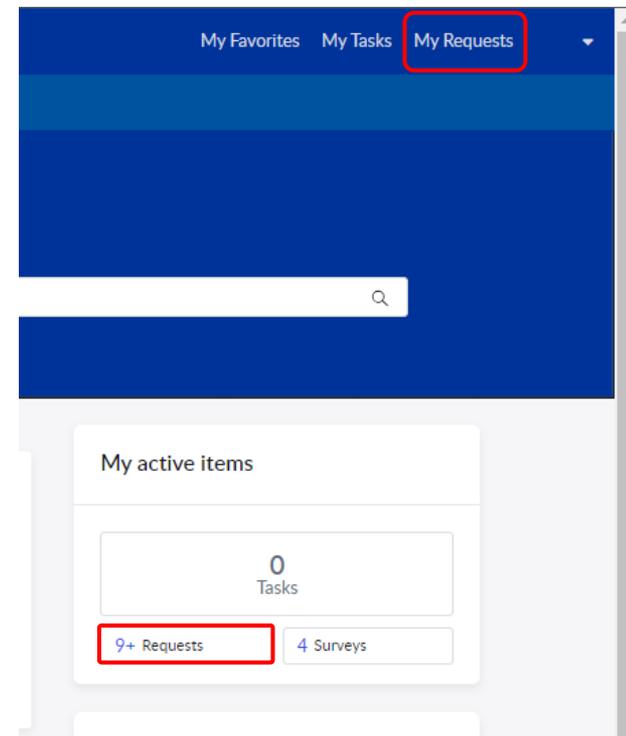


## EMA Service Desk – tracking enquiries

Once you have submitted an enquiry, you will receive an email notification with a **reference number** of your enquiry.

An overview of all your raised queries can be seen by clicking on the “**Requests**” button, under “My active items”, or on the “**My Requests**” button at the top of any EMA Service Desk page.

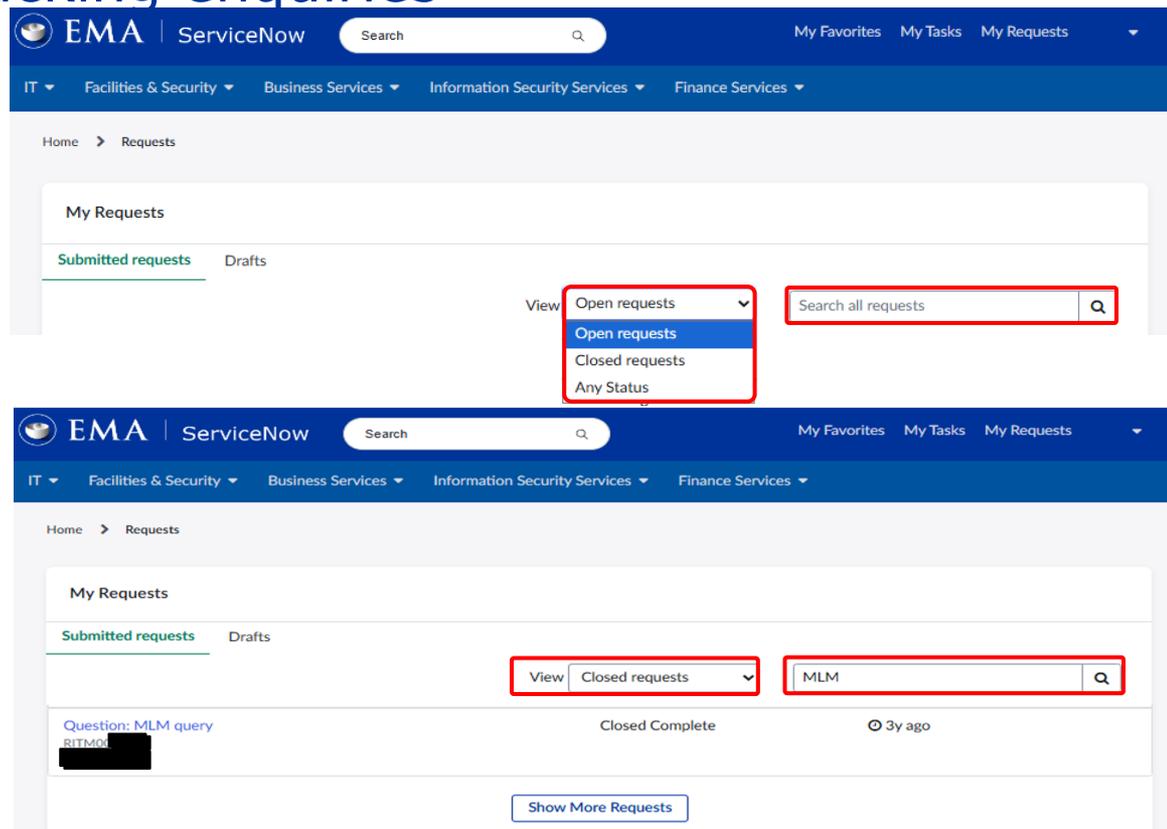
You will receive an email notification when your enquiry has been **updated, resolved, closed** or **put on hold**.



## EMA Service Desk – tracking enquiries

If you are searching for a particular logged query, type the **reference number** or the **topic/subject** of your query in the “**Search all requests**” search bar to view the results retrieved.

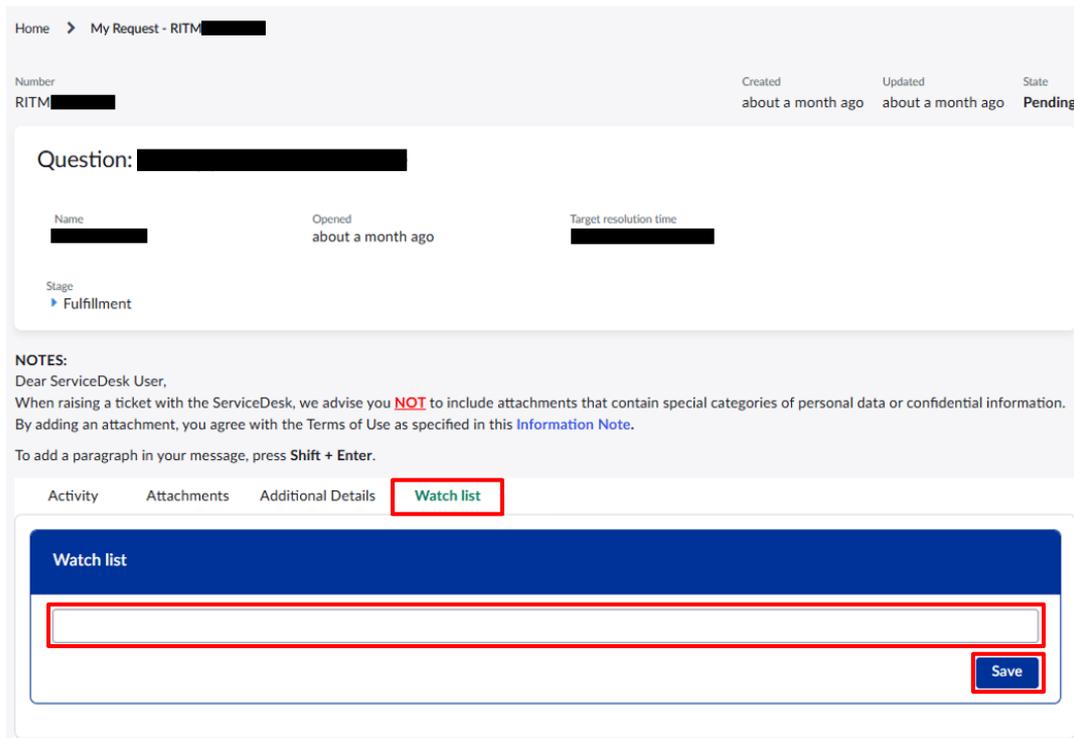
You have the option to filter the request you want to view in the “**View**” section. For example, “Closed Request” for “MLM”.



# EMA Service Desk – adding colleagues to the ticket’s Watch List

Once a ticket is created with EMA, you can **add colleagues to the ticket’s Watch List** (enter their email address in the search bar and then click on “Save”).

Once added to the Watch List, they will receive email notifications whenever your ticket is updated (for example, when its status changes to “Pending” or “Verification”) and will also have access to the ticket details, view comments, and contribute with further updates as needed.

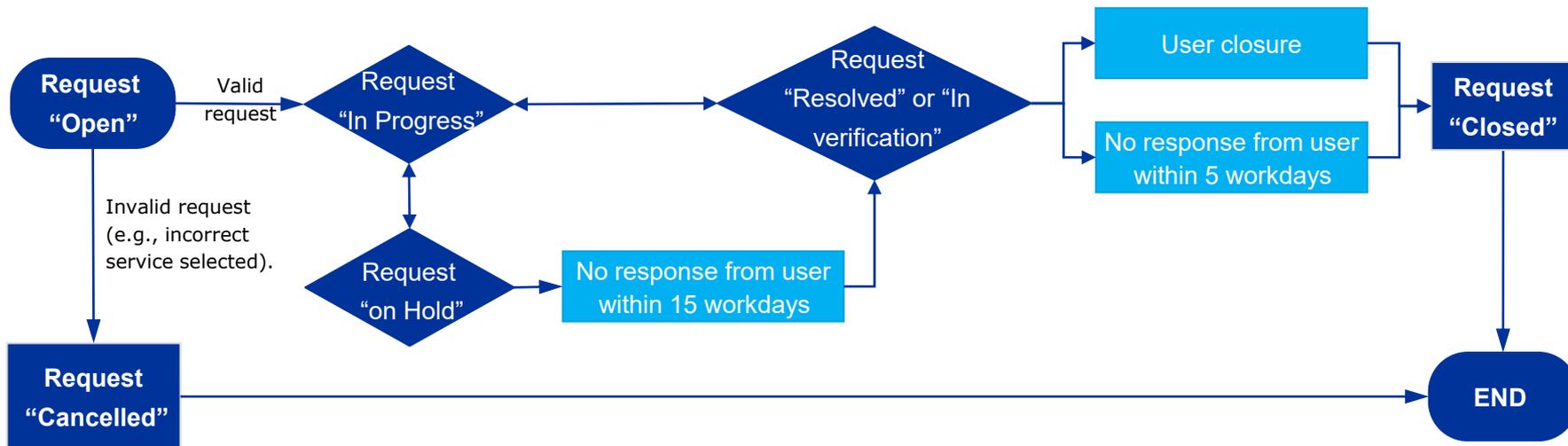


The screenshot shows the 'My Request - RITM' page. At the top, it displays the ticket number 'RITM [redacted]', creation and update dates 'about a month ago', and the state 'Pending'. Below this, the 'Question:' field contains a redacted question. Further down, the 'Name:' field is redacted, and the 'Opened' date is 'about a month ago'. The 'Target resolution time' is also redacted. The 'Stage' is 'Fulfillment'. A 'NOTES' section follows, containing a message to the user about attaching personal data. At the bottom, the 'Watch list' tab is selected, showing a search bar and a 'Save' button.

# EMA Service Desk – Resolving enquiries

Resolved enquiries will be have the status “**Resolved**” or “**In verification**”.

If further clarification is needed, your enquiry can be re-opened within five workdays of the ticket being resolved.





## EMA Service Desk – Resolving enquiries

Users can manually close the query via the detailed query page in the “My Requests” section. Queries will be automatically closed within five workdays.

The screenshot displays the EMA ServiceNow interface. At the top, there is a navigation bar with the EMA logo, 'ServiceNow', a search bar, and links for 'My Favorites', 'My Tasks', and 'My Requests'. Below this is a secondary navigation bar with categories like 'IT', 'Facilities Support', 'Business Services', and 'Information Security Services'. The main content area shows a breadcrumb trail 'Home > My Request - RITM [redacted]'. A table lists the request details:

Number	Created	Updated	State
RITM [redacted]	5mo ago	6d ago	Verification

Below the table, the 'Question:' field is redacted. To the right of the question, two buttons are highlighted with red boxes: a red 'Reopen' button and a green 'Confirm Close' button. Further down, the 'Name' field is redacted, and the 'Opened' date is '5mo ago'. The 'Stage' is 'Verification'.



## Ask EMA

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- General- or Pharmacovigilance-related questions
- Requests for information
- Formal request for access to documents



## Ask EMA

To raise a **general query**, ask EMA a specific question about a **pharmacovigilance-related issue**, **requests for information** or to make a **formal request for access to documents** that are not already published on Agency's website, use the web form available under the link:

<https://www.ema.europa.eu/en/about-us/contacts-european-medicines-agency/send-question-european-medicines-agency>

**Home > About us > Contacts at the European Medicines Agency > Send a question to the European Medicines Agency**

No registration is necessary.



# Ask EMA

## Your question

Your name

Organisation/Employer

If you are not representing a particular organisation please write 'Not applicable' into this field.

Who are you?

Location

Please select your type of enquiry

- I want you to answer a question
- I want an unpublished document (maximum 2 documents per request)
- I want help identifying which unpublished document I need

For more information on these enquiry types and how we handle them, see:

- [The European Medicines Agency code of good administrative behaviour](#)
- [Access to documents](#)
- [Guide on access to unpublished documents](#)



Enter your **personal** and **organisation's details** in this section.



# Ask EMA

What is the subject of your enquiry?

For example "Question on", "Request for"

Your question(s)

Please type your clear question or request here.

Please type your clear question or request here. Where possible please provide a link, a product name, a reference number or the name of the document or topic you are interested in. Please do not include any personal data, such as your name or contact details in this field.

Your email address

Enter your email address

We will only use your email address to contact you about your query.

Please retype your email address

Confirm your email address

I have read and agree with the data protection terms [Data protection and privacy](#).



Enter the **details of your enquiry** in this section



Enter your **contact details** in this section so that the Agency can get back to you.



## Additional sources of information

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# Additional sources of information

## EV:

- [EudraVigilance system overview](#)
- [EudraVigilance: electronic reporting](#)
  - [Preparing for the electronic exchange of safety reports](#)
  - [Masking of personal data in ICSRs/SUSARs submitted to EudraVigilance](#)
  - [What to do in case of system failure](#)
- [Announcement of the EMA Management Board – Confirmation of the mandatory use of the ISO Individual Case Report standard based on ICH E2B\(R3\) modalities and related ISO standard terminology](#)
- [The launch of the new EudraVigilance System – Questions and answers \(Q&A\) from stakeholders](#)
- [EU Individual Case Safety Report \(ICSR\) Implementation Guide](#)

- [ICH E2B \(R3\) Guideline](#)
- [User Guide: Use of EDQM terminologies for Dose Forms and Routes of Administration for Individual Case Safety Reports in E2B\(R3\) message](#)
- [Mandatory use of ISO ICSR/ICH E2B\(R3\) and EDQM terminology for Dosage Forms \(DF\) and Routes of Administration \(RoA\) Change management plan](#)
- [EudraVigilance: Obtaining EDQM terms from SPOR](#)
- [EU R2 Dosages to EDQM mapping](#)
- [UCUM units for E2B\(R3\)](#)
- [EU E2B\(R3\) code lists](#)
- [EudraVigilance - EVWEB User Manual](#)
- [Change management for the EudraVigilance system](#)
- [EudraVigilance training and support](#)



# Additional sources of information

## EV Registration:

- [EudraVigilance: how to register](#)
- [EMA EudraVigilance Registration Manual](#)
- [EudraVigilance registration documents](#)
- [New Organization First User QPPV/RP or Change of EU QPPV/RP](#)

## SUSARs:

- [EU Clinical Trials Regulation](#)
- [EU Clinical Trials Regulation – Q&A](#)
- [Reporting safety information on clinical trials](#)
- [Recommendations on the use of Auxiliary Medicinal Products in Clinical Trials written and endorsed by the Clinical Trials Coordination and Advisory Group \(CTAG\)](#)

## ICSRs:

- [GVP Module VI](#)
- [GVP Module VI – Addendum I](#)
- [GVP Module VI – Addendum II](#)
- [CHMP Guideline on detection and management of duplicate individual cases and Individual Case Safety Reports \(ICSRs\)](#)
- [Compliance notifications explanation and Q&A – Background to the compliance calculations & anticipated questions from stakeholders](#)

## MLM:

- [Medical literature monitoring](#)
- [Monitoring of medical literature and the entry of relevant information into the EudraVigilance database by the European Medicines Agency - Questions and Answers](#)



# Contact Points Summary

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# Contact Points Summary

Contact point	Areas	Contact
<b>EMA Service Desk Portal</b>	<ul style="list-style-type: none"> <li>• EudraVigilance</li> <li>• Technical- or application-specific queries</li> <li>• MLM</li> <li>• Duplicates</li> <li>• ICSR compliance reports</li> <li>• EV QAT</li> </ul>	<p><b>EMA Service Desk portal:</b>  <a href="https://support.ema.europa.eu/esc">https://support.ema.europa.eu/esc</a></p>
<b>EudraVigilance Registration Team</b>	<ul style="list-style-type: none"> <li>• EV Registration-related issues</li> </ul>	<p><b>EudraVigilance Registration Queries:</b>  <a href="https://support.ema.europa.eu/esc?id=emp_taxonomy_topic&amp;topic_id=5eb1d223c31415508719596ce001312b">https://support.ema.europa.eu/esc?id=emp_taxonomy_topic&amp;topic_id=5eb1d223c31415508719596ce001312b</a></p>
<b>Ask EMA</b>	<ul style="list-style-type: none"> <li>• Pharmacovigilance-related enquiries</li> <li>• General Queries</li> <li>• Access to documents</li> </ul>	<p><b>Ask EMA:</b>  <a href="https://www.ema.europa.eu/en/about-us/contacts-european-medicines-agency/send-question-european-medicines-agency">https://www.ema.europa.eu/en/about-us/contacts-european-medicines-agency/send-question-european-medicines-agency</a></p>
<b>Urgent Technical Helpline</b>	<ul style="list-style-type: none"> <li>• Urgent technical or application-specific queries</li> </ul>	<p><b>Urgent technical helpline:</b>  +31 (0)88 781 8520</p>



## Further information

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If urgent assistance is needed with EMA's IT systems, please phone **+31 (0)88 781 8520**

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Telephone** +31 (0)88 781 6000

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)

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