EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EudraVigilance support guide

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

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23 February 2026

An agency of the European Union

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Content

Introduction

EMA Service Desk portal

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

Before using the Service Desk Portal

Using the Service Desk Portal

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

Ask EMA

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

Additional sources of information

Contact Points Summary

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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	EudraVigilance Registration	Ask EMA
• Web address: https://support.ema.europa.eu/esc • Urgent helpline for technical enquiries: +31 (0)88 781 8520	• Web address: https://support.ema.europa.eu/esc?id=emp_taxonomy_topic&topic_id=5eb1d223c31415508719596ce001312b	• Web address: https://www.ema.europa.eu/en/about-us/contacts-european-medicines-agency/send-question-european-medicines-agency
Contact for: • **Business** or **Technical** questions • **Application-specific** questions • Reporting **Duplicates** • **ICSR/SUSAR compliance reports** • **Medical Literature Monitoring (MLM)** • **EV QAT Testing**	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**	Contact for: • **Pharmacovigilance** or **general** questions • **Requests for information** • To make a formal request for **access to documents**

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EMA Service Desk portal

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

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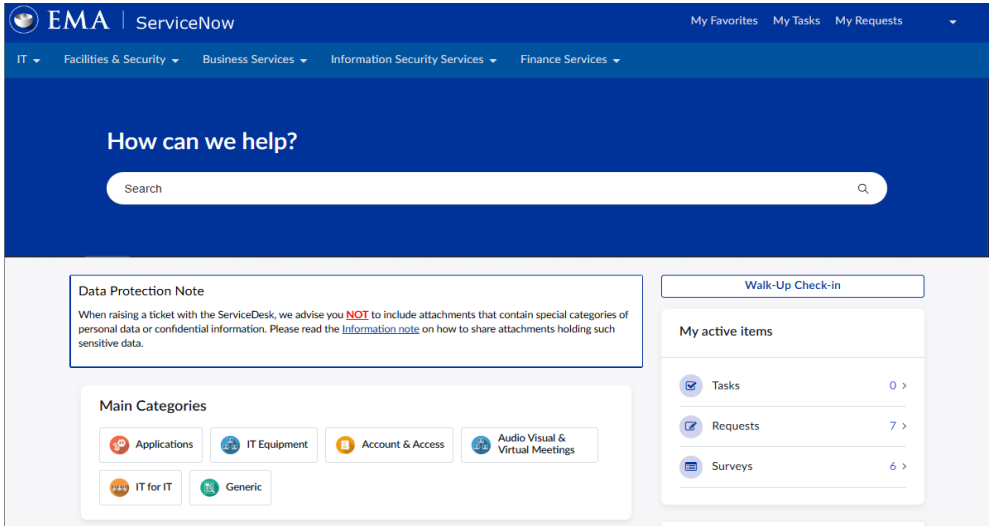
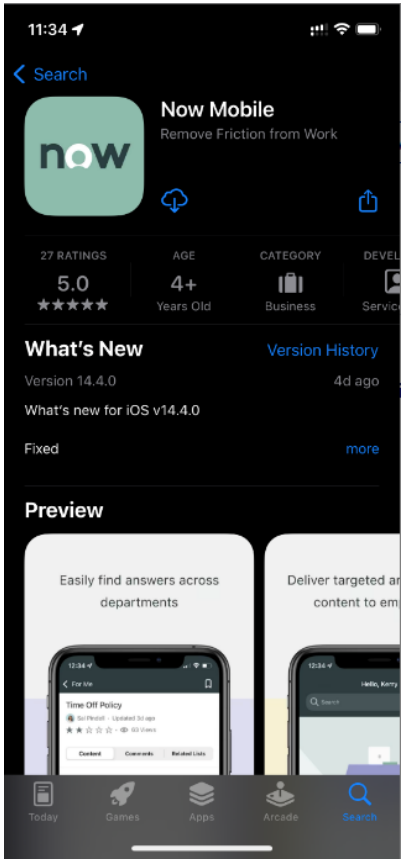
EMA's Service Desk ticketing system

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.





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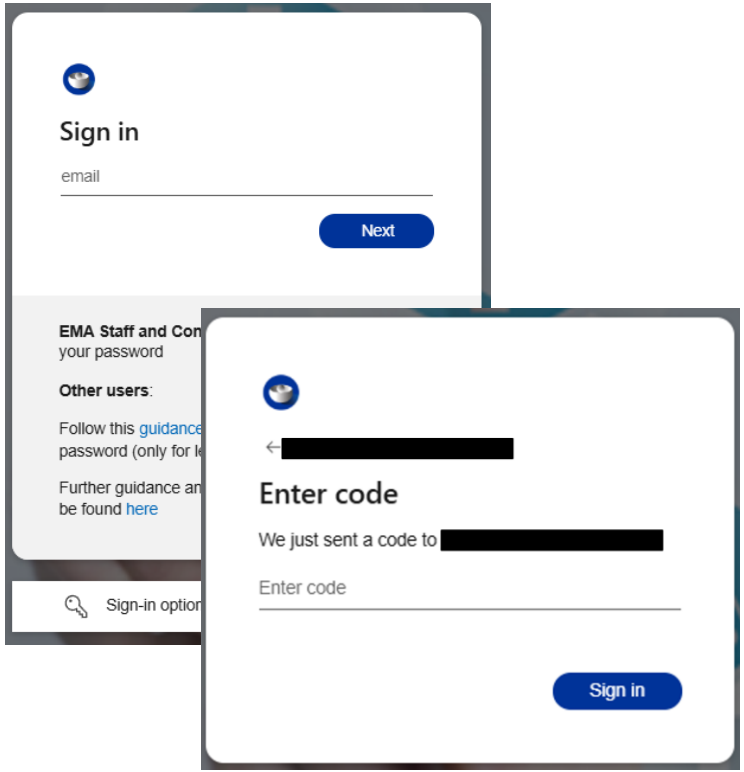
Accessing EMA's Service Desk Portal

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.



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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.

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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.

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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**.

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Using the Service Desk Portal

- 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

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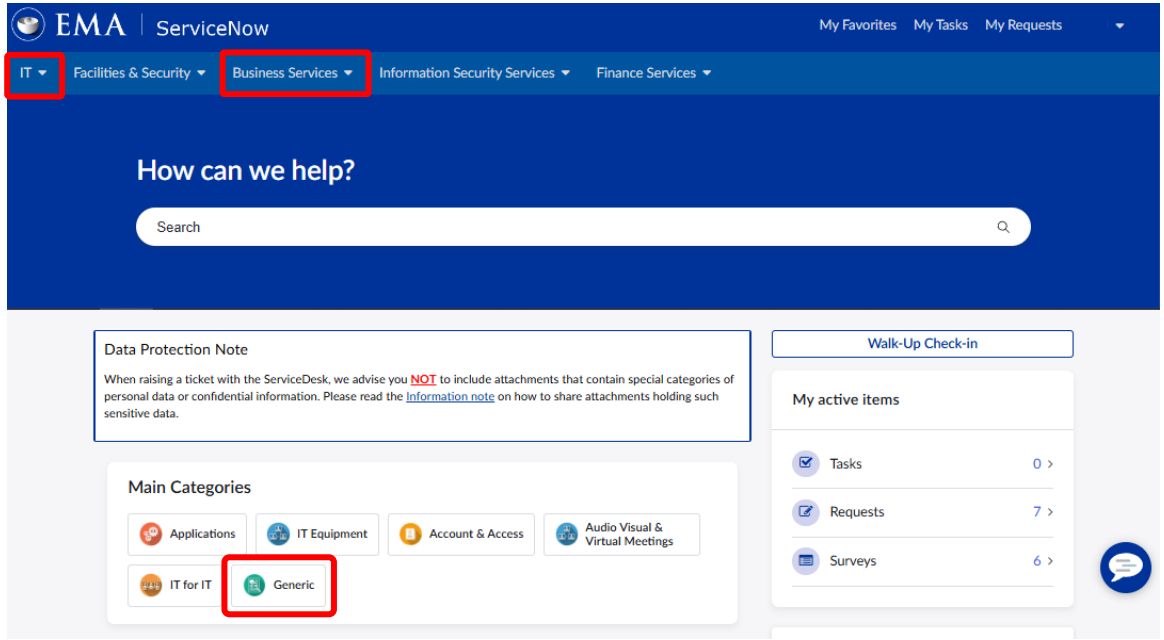
Using the Service Desk portal

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).



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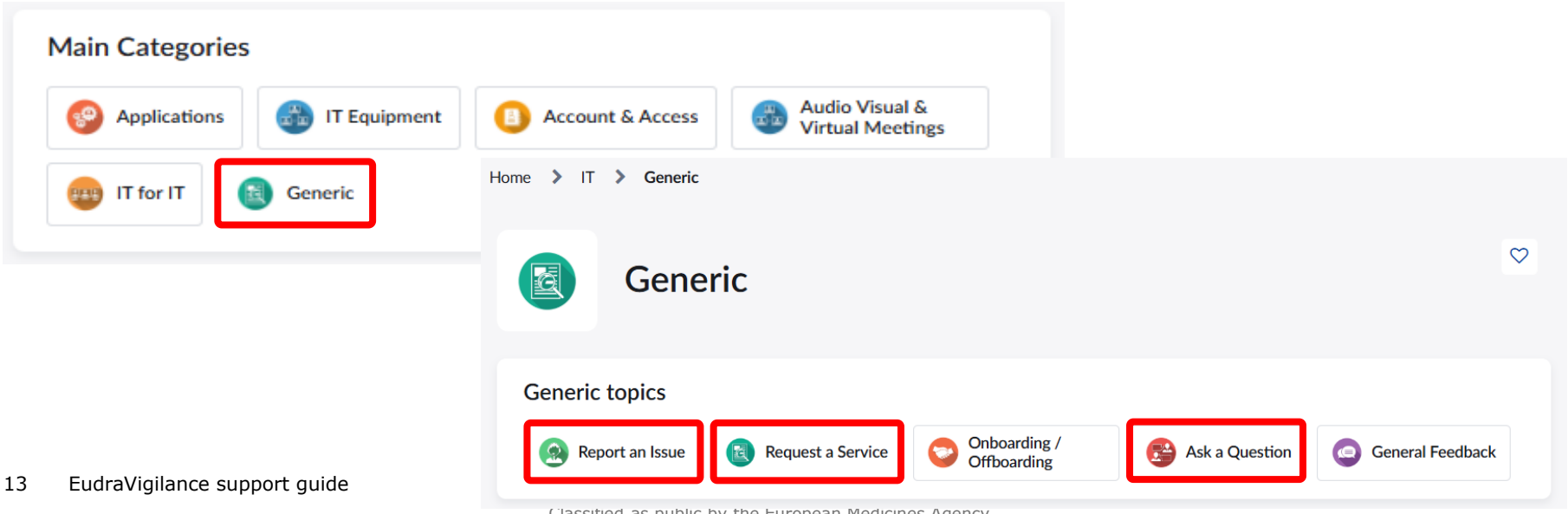
Using the Service Desk portal

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.



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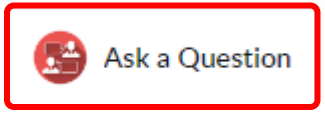
Using the Service Desk to **Ask a Question**

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)**.

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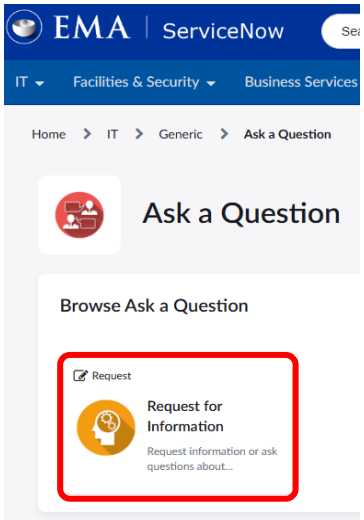
Using the Service Desk to **Ask a Question**

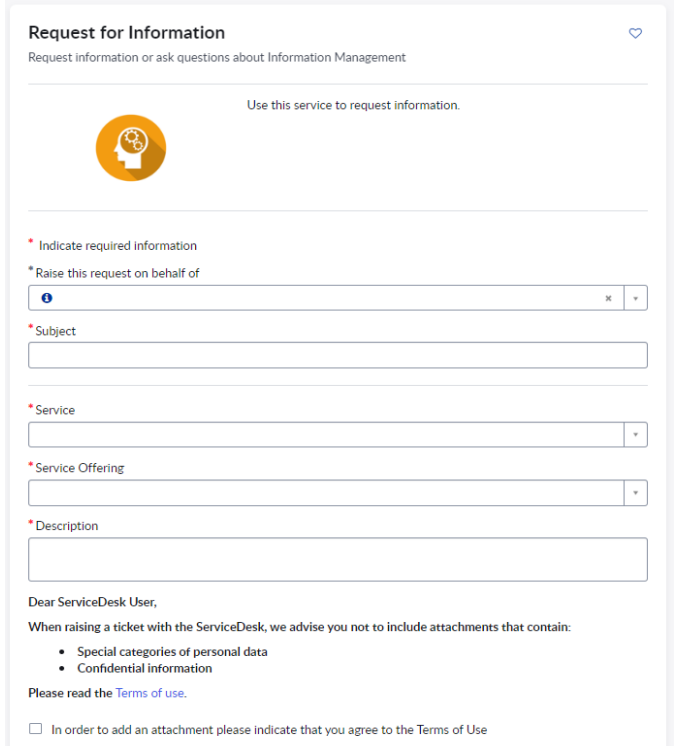
Click on "Request for Information" and complete the form.

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.





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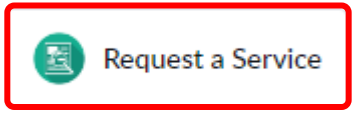
Using the Service Desk to **Request a Service**

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**.

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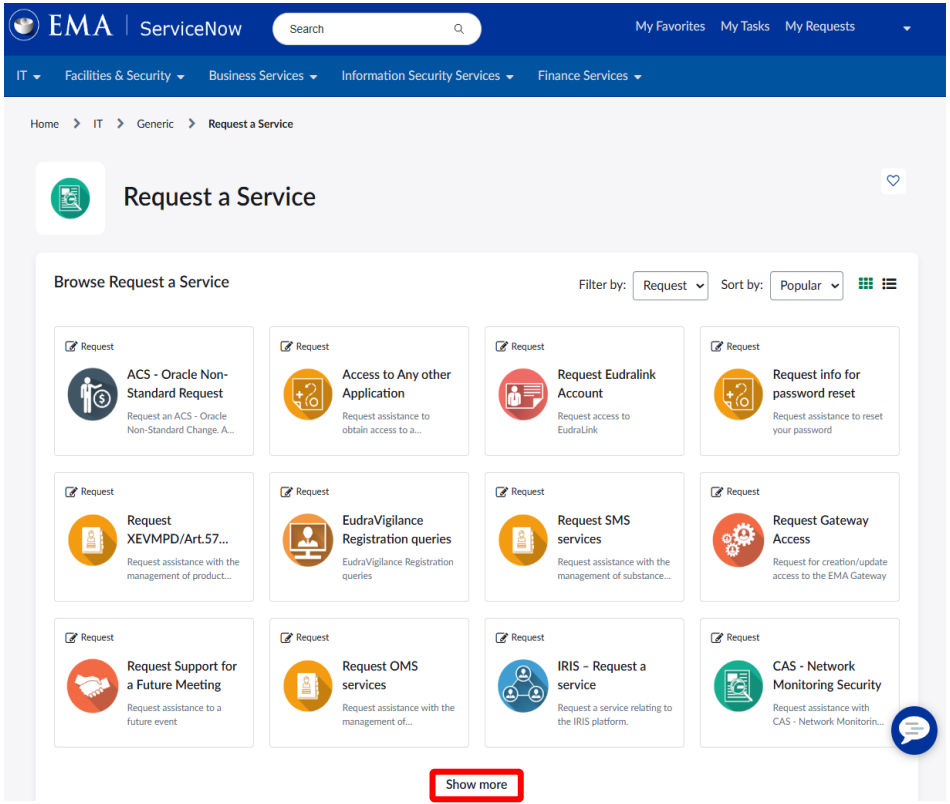
Using the Service Desk to **Request a Service**

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”.



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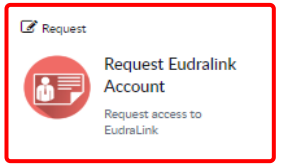
Using the Service Desk to **Request a Service**

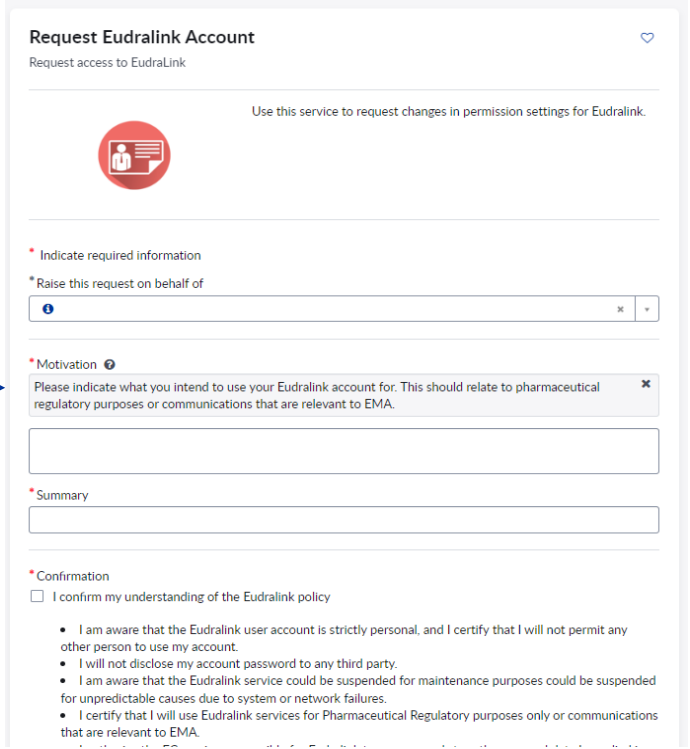
Once you've selected the Service, you should complete the corresponding form.

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.





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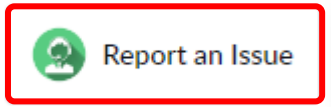
Using the Service Desk portal to **Report an Issue**



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 reported **only** via "**Ask a Question**".

Also, for queries related to **missing** or **delayed ACKs**, please use this Service Desk instead.

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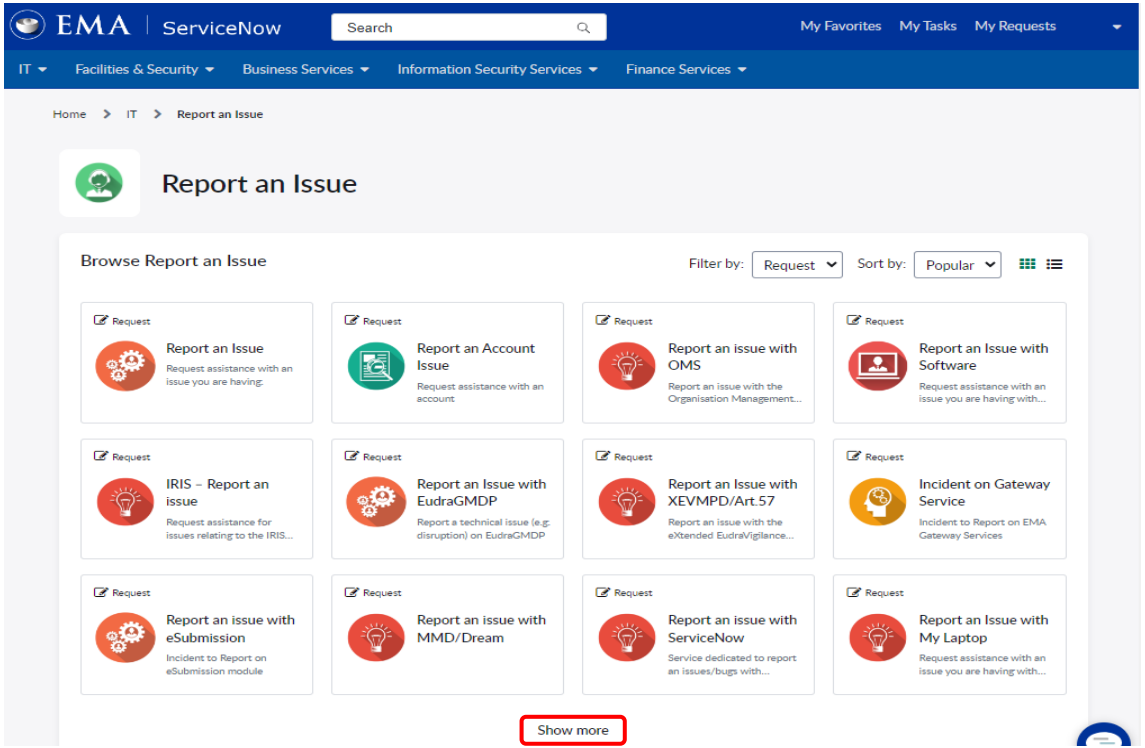
Using the Service Desk to **Report an Issue**

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”.



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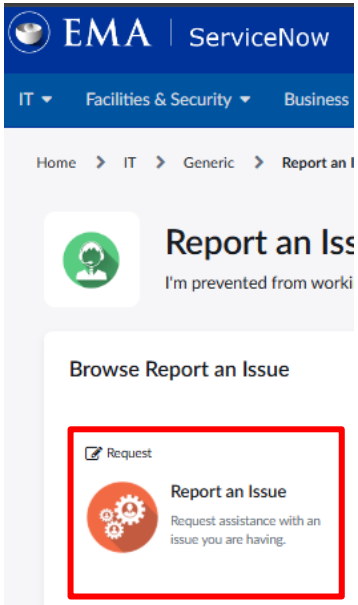
Using the Service Desk to **Report an Issue**

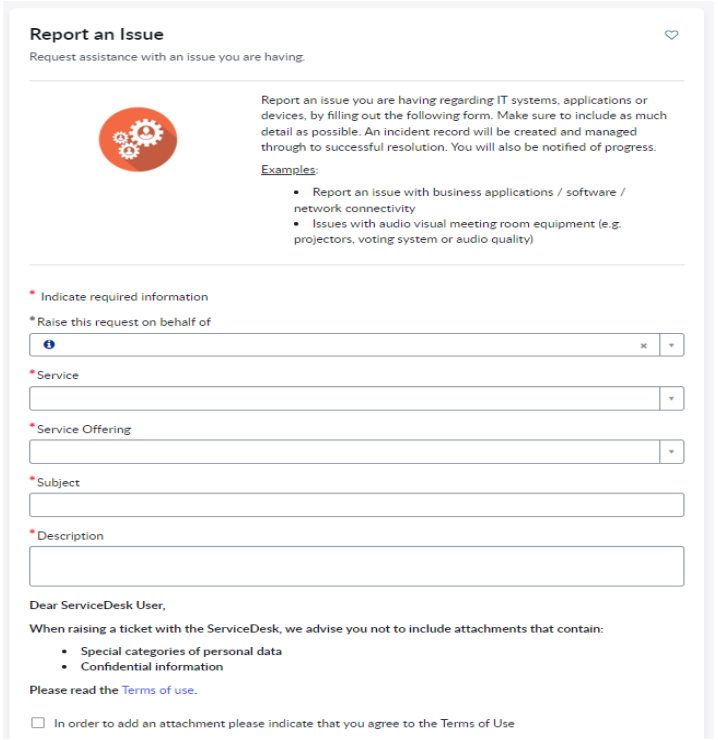
Once you've selected the Service, you should complete the corresponding form.

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.





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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".

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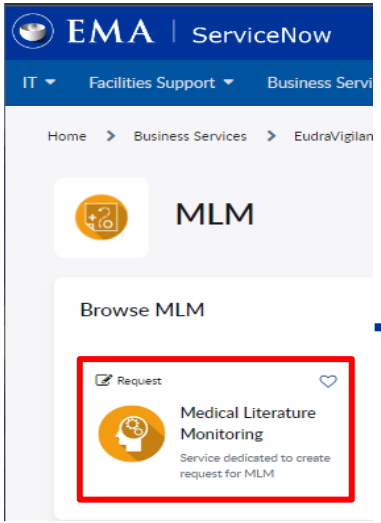
Raise Medical Literature Monitoring (MLM)-related queries

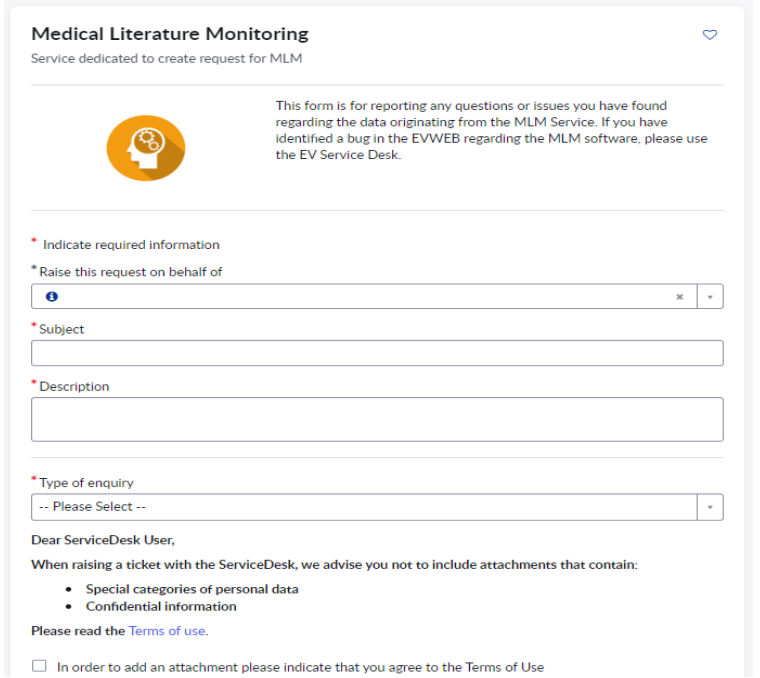
Click on “Medical Literature Monitoring” and complete the form.

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.





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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”.

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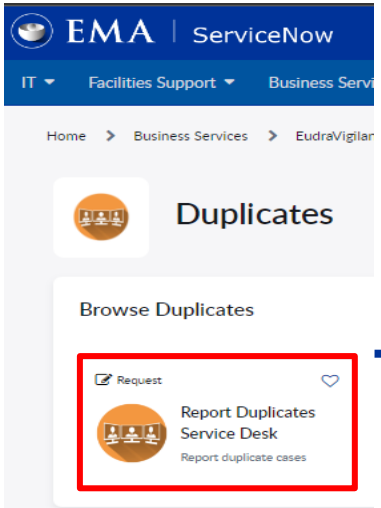
EudraVigilance – Report ICSR Duplicates

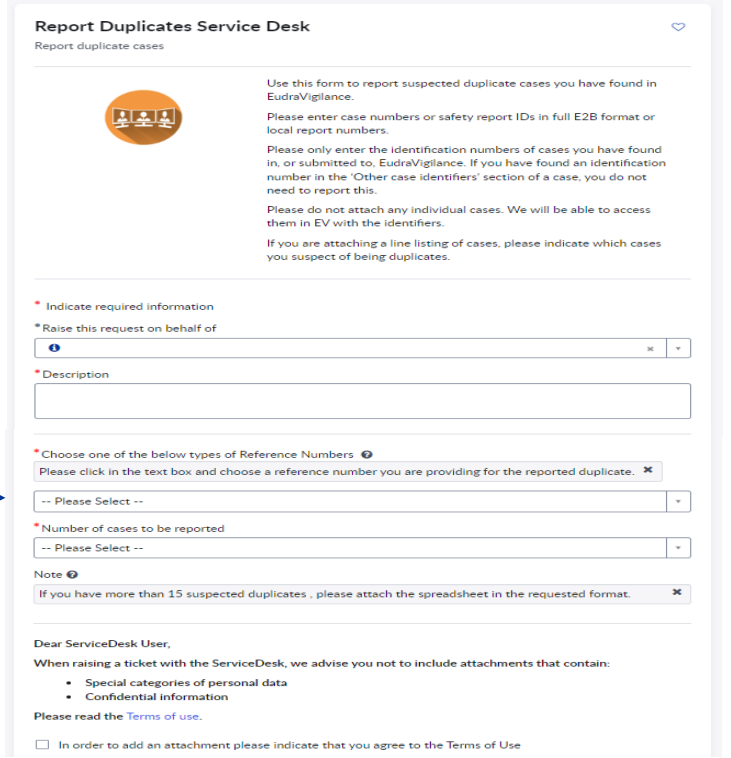
Click on "Report Duplicates Service desk" and complete the form.

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.





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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 in not answered in the Q&A section, then go to "Business Services" and click on "ICSR Compliance".

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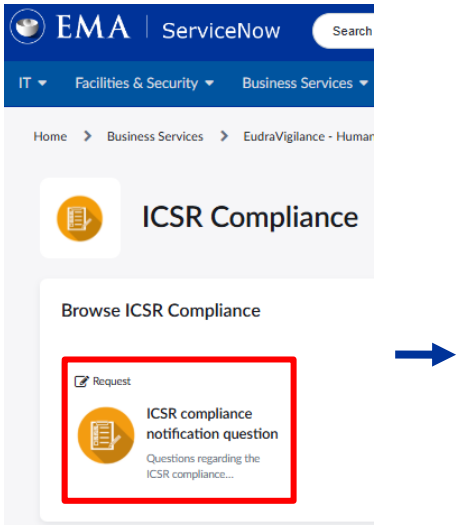
EudraVigilance – ICSR/SUSAR compliance reports-related queries

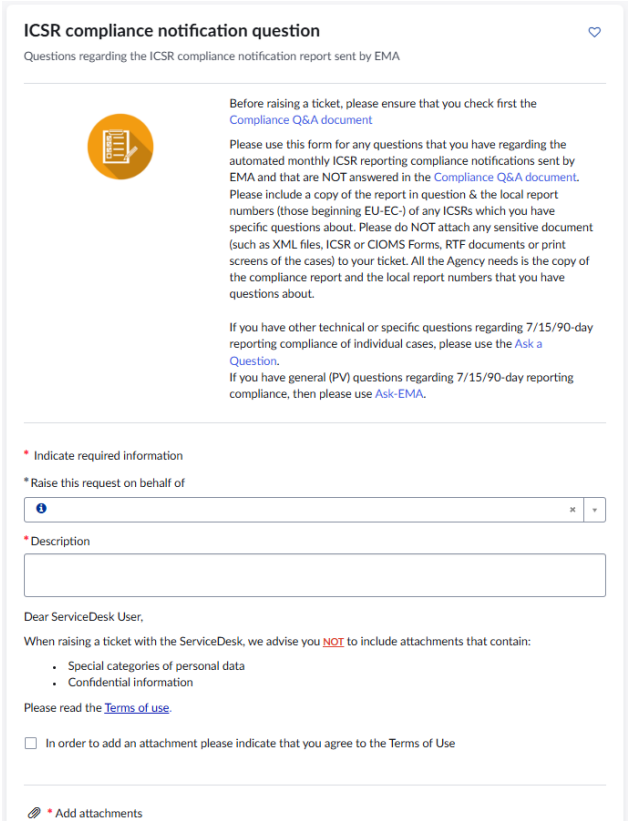
Click on "ICSR Compliance" and complete the form.

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.





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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).

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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.

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EudraVigilance – Request EV QAT

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

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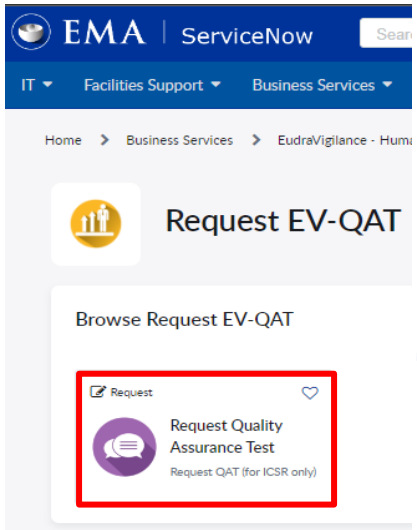
EudraVigilance – Request EV QAT

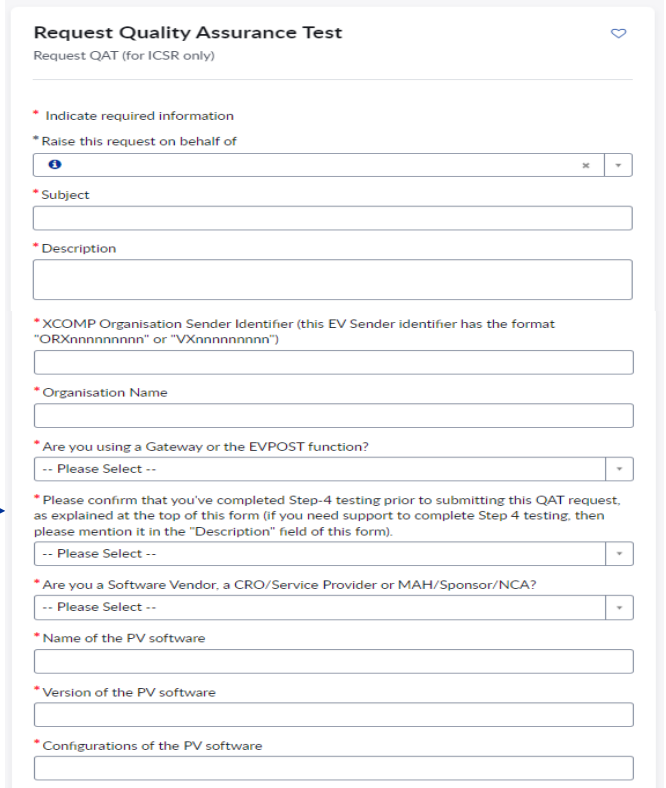
Click on "Request Quality Assurance Test" and complete the form.

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.





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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**.

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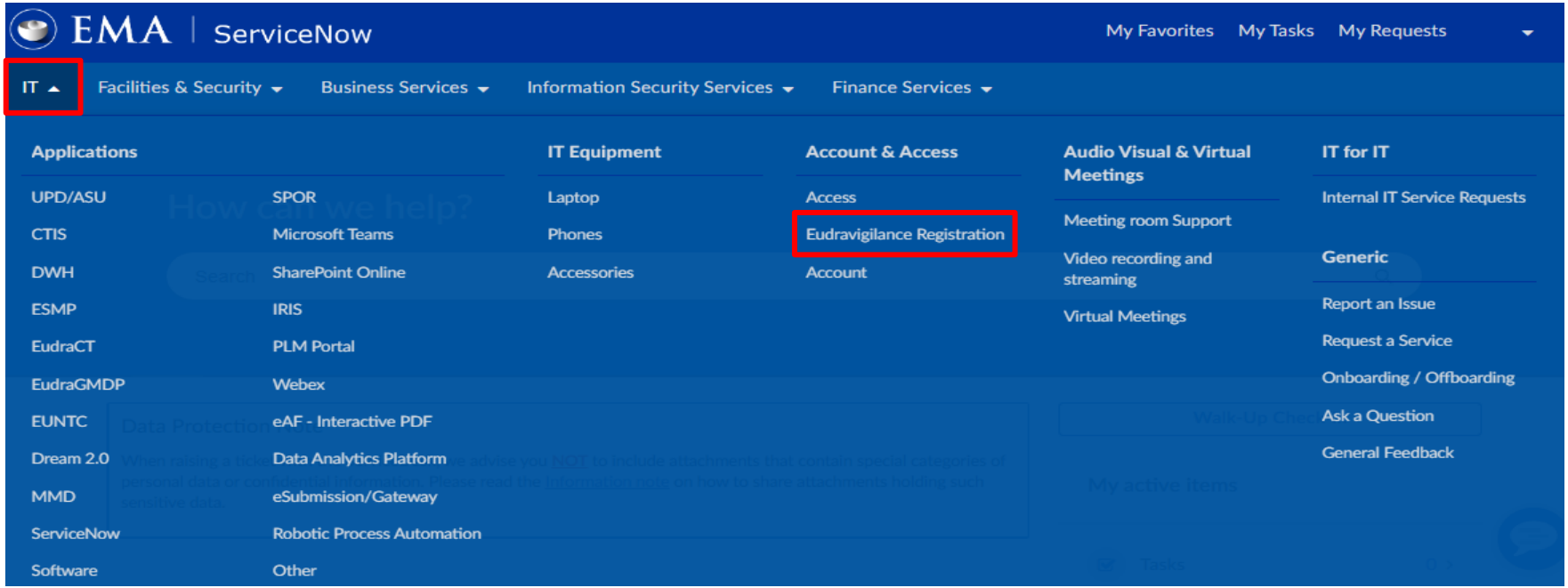
EudraVigilance Registration Queries & Requests

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



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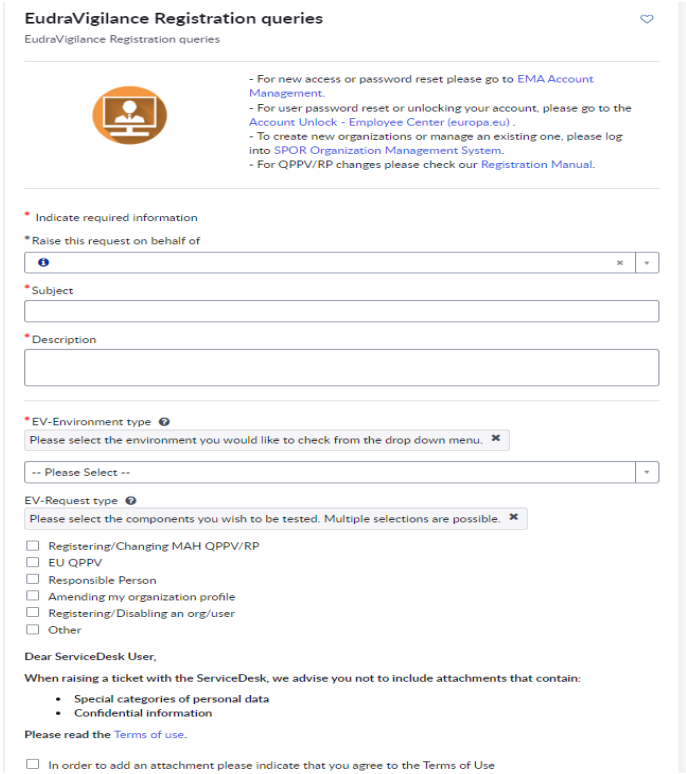
EudraVigilance Registration Queries & Requests

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.



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EMA Service Desk – Tracking enquiries

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

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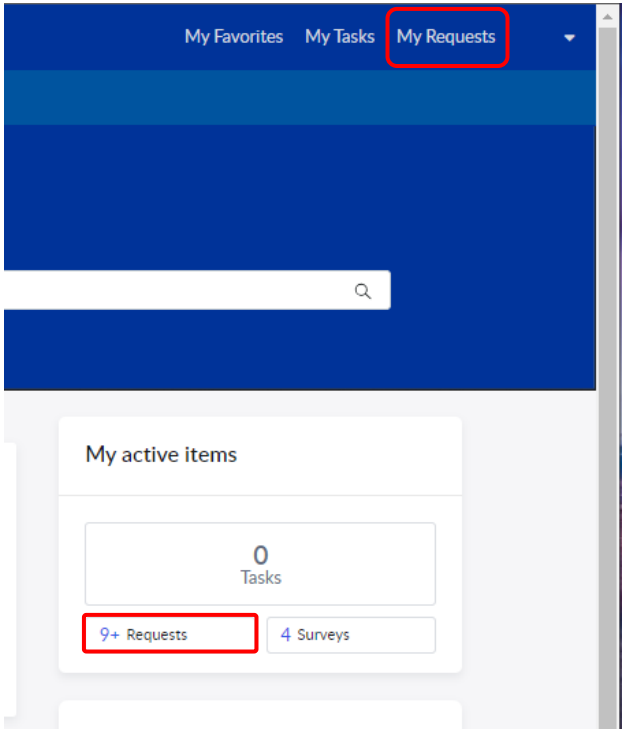
EMA Service Desk – tracking enquiries

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**.



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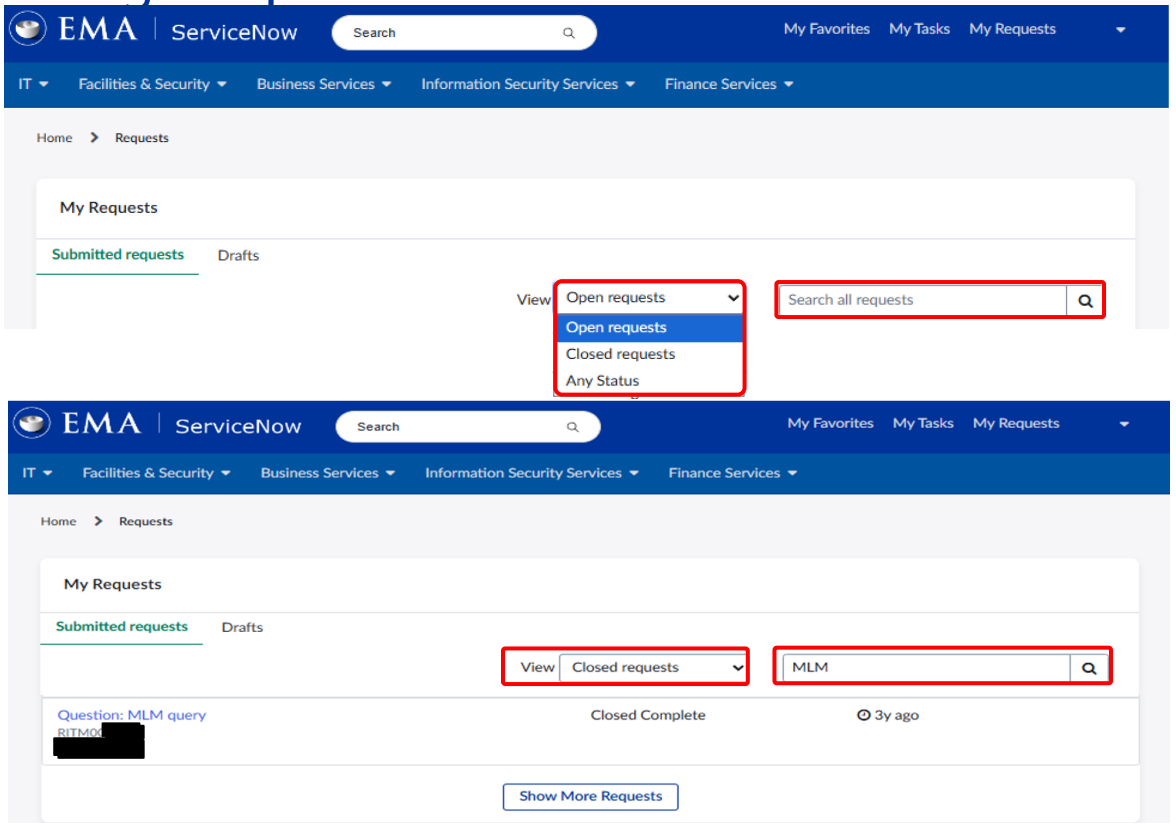
EMA Service Desk – tracking enquiries

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".



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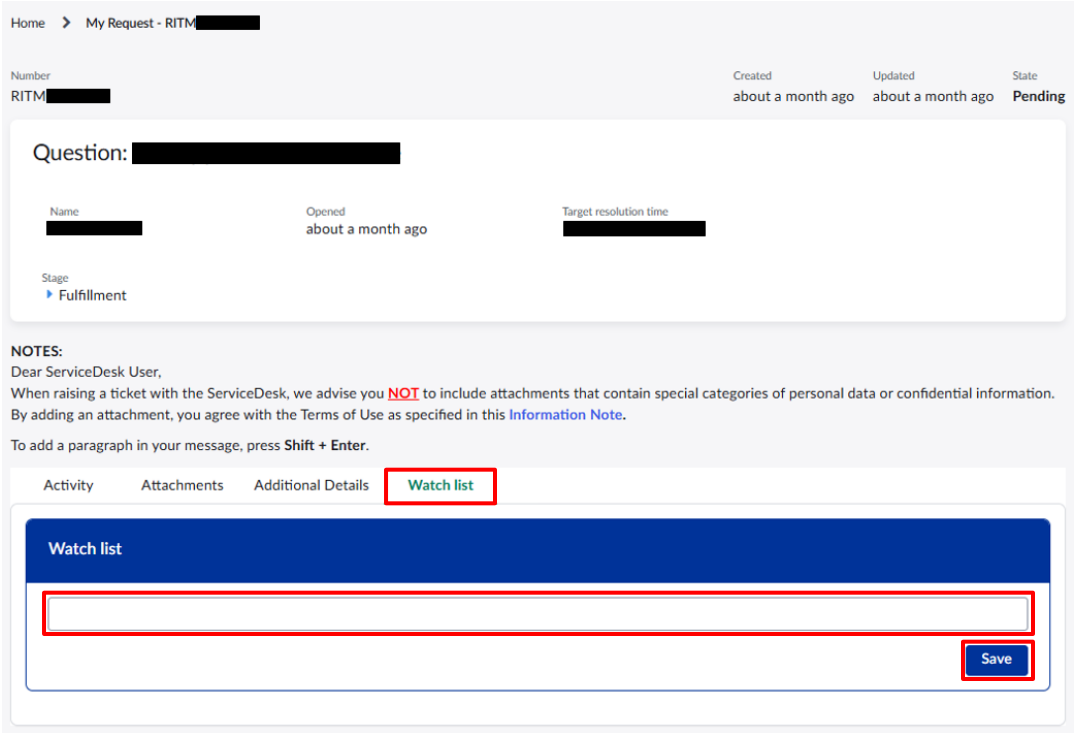
EMA Service Desk – adding colleagues to the ticket's Watch List

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.



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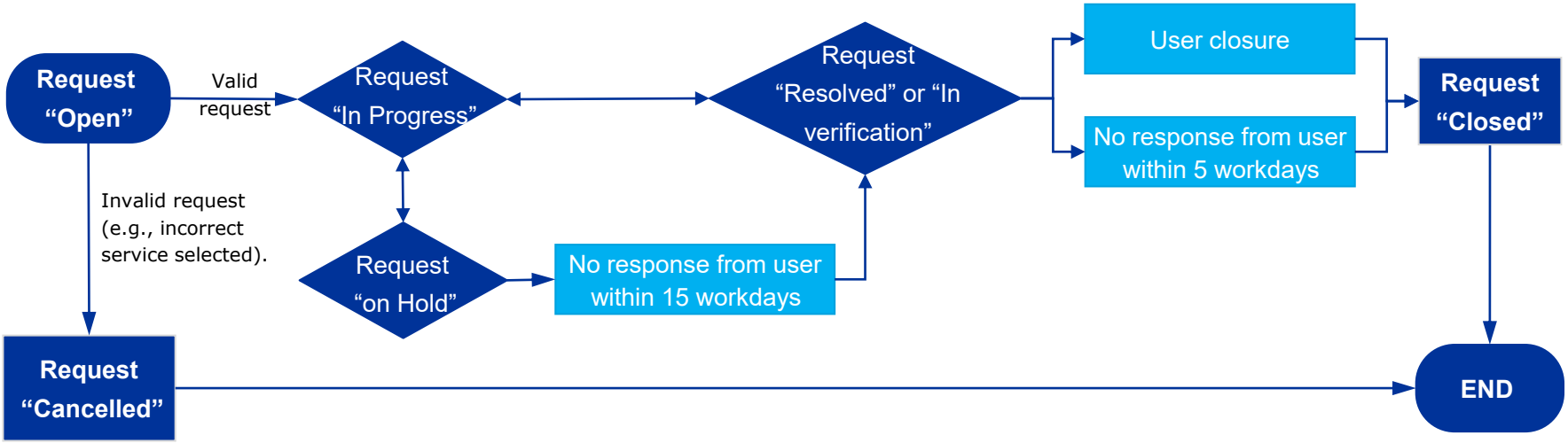
EMA Service Desk – Resolving enquiries

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.



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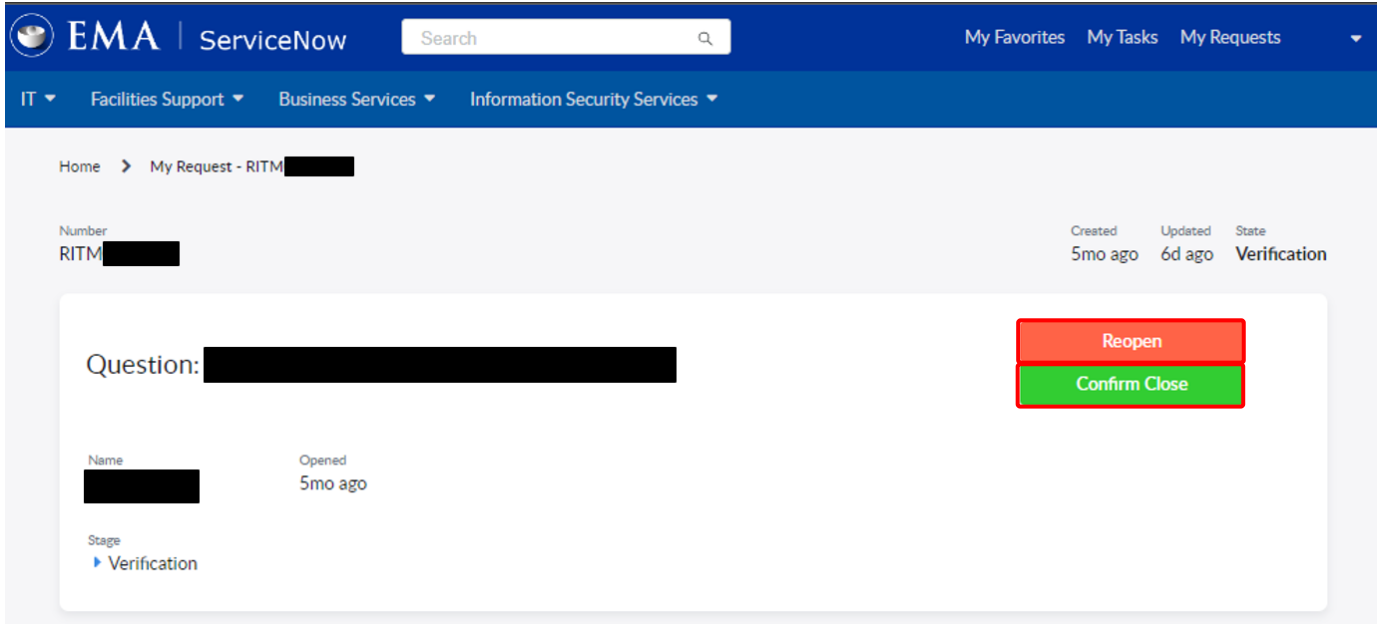
EMA Service Desk – Resolving enquiries

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



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Ask EMA

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

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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.

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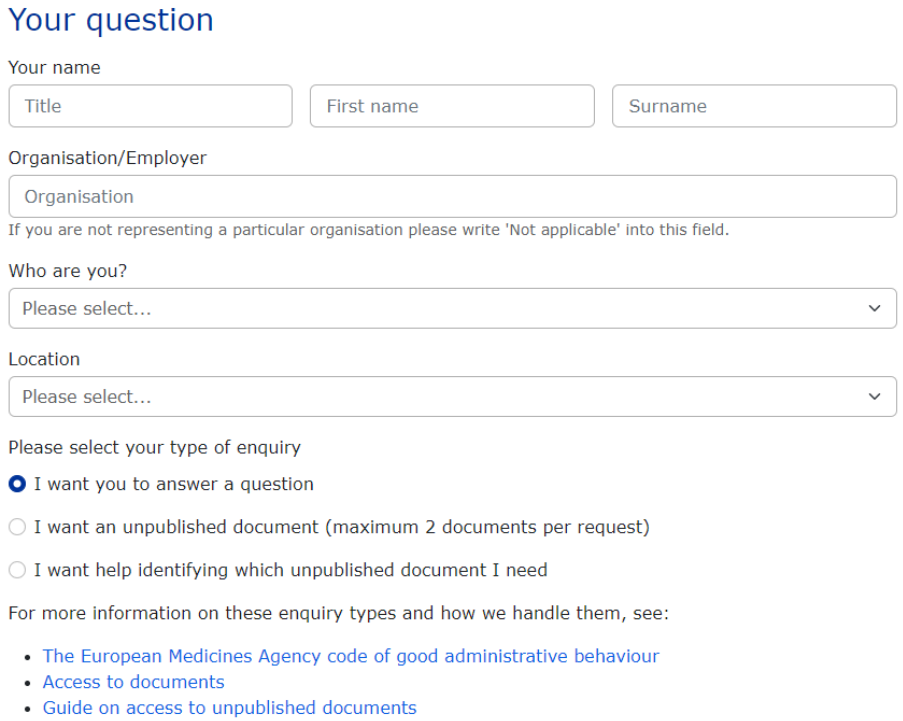
Ask EMA



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

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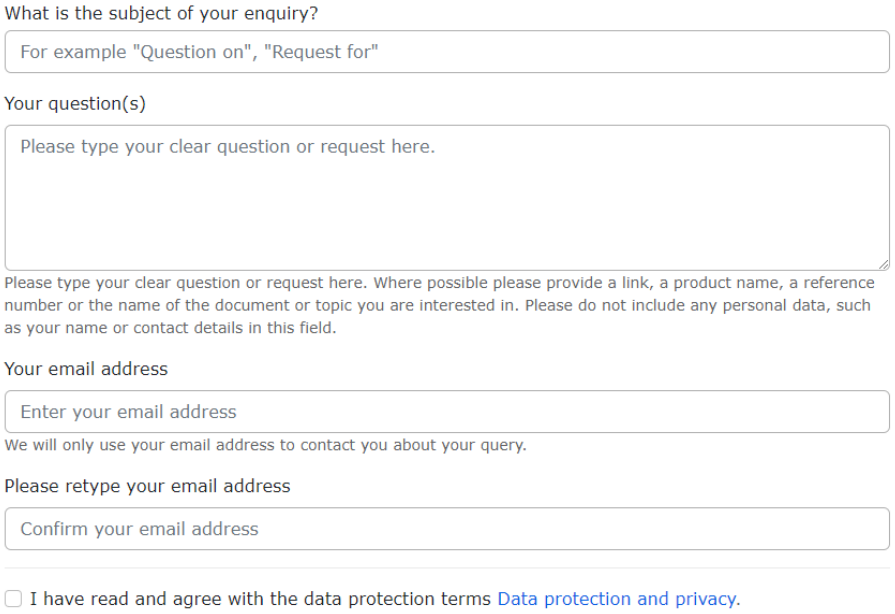
Ask EMA



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.

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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

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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

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Contact Points Summary

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Contact Points Summary

Contact point	Areas	Contact
EMA Service Desk Portal	• EudraVigilance • Technical- or application-specific queries • MLM • Duplicates • ICSR compliance reports • EV QAT	**EMA Service Desk portal:** https://support.ema.europa.eu/esc
EudraVigilance Registration Team	• EV Registration-related issues	**EudraVigilance Registration Queries:** https://support.ema.europa.eu/esc?id=emp_taxonomy_topic&topic_id=5eb1d223c31415508719596ce001312b
Ask EMA	• Pharmacovigilance-related enquiries • General Queries • Access to documents	**Ask EMA:** https://www.ema.europa.eu/en/about-us/contacts-european-medicines-agency/send-question-european-medicines-agency
Urgent Technical Helpline	• Urgent technical or application-specific queries	**Urgent technical helpline:** +31 (0)88 781 8520

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Further information

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

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