



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





# Content

- Technical or application-specific queries
- Using the EMA Service Desk Portal
- Pharmacovigilance-related or general queries
- Ask EMA
- Further contact details



# Introduction

The European Medicines Agency (EMA) operates a number of **service desks** to assist marketing-authorisation holders and national competent authorities in using EudraVigilance in the EEA Member States. The working hours are the same as the [EMA business hours](#).

Enquiries can be submitted through:

## EMA Service Desk portal

- Web address:  
<https://servicedesk.ema.europa.eu>
- Urgent helpline for technical enquiries:  
+44 (0)20 3660 8520/7523

Contact for:

- Business questions
- Technical questions
- Application specific questions
- QAT Testing
- Reporting Duplicates
- Medical Literature Monitoring

## Ask EMA

- Web address:  
[http://www.ema.europa.eu/ema/index.jsp?curl=pages/about\\_us/landing/ask\\_ema\\_landing\\_page.jsp&mid=WC0b01ac05806499f0](http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/ask_ema_landing_page.jsp&mid=WC0b01ac05806499f0)

Contact for:

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

## EudraVigilance Registration

- EV Service Desk  
<https://servicedesk.ema.europa.eu/jira/servicedesk/customer/portal/103>

Contact for:

- Registration questions not found in User Manual or Webpage
- QPPV/RP change – New Org first user – transmission mode change – VET-XCOMP



# Technical or application-specific queries

- To raise a technical query or request a service related to a specific application, use the **EMA Service Desk Portal**
- The portal can be accessed via this link:  
<https://servicedesk.ema.europa.eu>
- Users already registered with a system hosted by the EMA can use their existing username and password to log in (note that this does **not apply to EudraVigilance accounts**)
- Users without EMA login credentials can **create a new EMA Service Desk account** when they first use the portal.

**Login**

Username

Password

**Log in**

Keep me logged in

**Account Information**

If you have a user account for a system hosted by this organisation, you should use the username and password for this service. Otherwise please **Sign up for a new account** or Reset your credentials.

[Forgotten your password?](#)

EUROPEAN MEDICINES AGENCY  
SAFER. Smoother. Health.

**Account Management**

EMA Account Management

Password

**Create a new EMA account**  
Not sure if you have an EMA account?

[Forgot your password?](#)  
[Forgot your username?](#)

**Login**



# EudraVigilance related enquires

- Ask a question relating to EV**
- Request a service relating to EV**
- Report a technical issue**
- MLM related enquiries**
- Report the suspected duplicates in EV**
- Request QAT testing**



# Using the EMA Service Desk

- In the EMA Service Desk Portal you can choose from the below categories:
  - EudraVigilance to report on **medical literature monitoring, duplicates** or request **quality assurance test**.
  - Service Desk to report **technical issues, request a service** or **ask a technical question** relating to EudraVigilance or a specific application.

## EMA Service Desk

What do you need help with?

Which of the following best describes what you need help with?

[EudraVigilance](#)

[Service Desk](#)

[Back](#)



# Using the EMA Service Desk

- If you can't see EudraVigilance or Service Desk categories, click on 'Browse all' to make them visible.

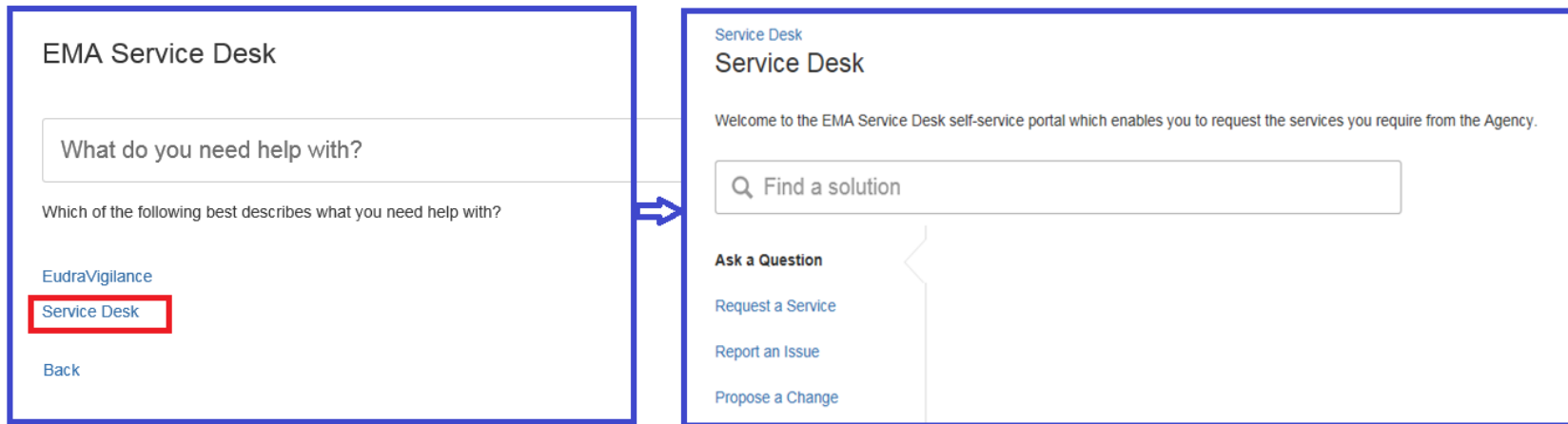
The screenshot displays the EMA Service Desk interface. On the left, under the 'Popular' section, there are three links: 'CSO', 'EudraVigilance', and 'Service Desk'. Below these, there is a 'Browse all' link. On the right, the 'Service Desk' header is followed by 'EudraVigilance' and a welcome message. A search bar is present with the placeholder text 'What do you need help with?'. Below the search bar, there is a list of service categories, each with an icon and a brief description:

- EudraVigilance Registration queries**: Queries related to EudraVigilance Registration
- Medical Literature Monitoring enquiries**: MLM related Enquiries
- Report Duplicates for ICSR**: Report suspected duplicates for ICSR only
- Request Quality Assurance Test**: Request QAT



# Service Desk specific queries

From the Service Desk you can **report technical issues**, **request a service** or **ask a technical question** relating to EudraVigilance or a specific application.







# Using the Service Desk

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

- **Request a Service:** If you need to help with access, passwords, unlocking accounts for the EudraVigilance systems.
- **Report an Issue:** If you need to report anything related to EudraVigilance that needs fixing - for ex. bugs, error messages, error with uploads etc.
- **Ask a Question:** For questions or any other inquiries not falling under the Request a Service and Report an Issue.



# Using the Service Desk to **request a service**

Service Desk

## Service Desk

Welcome to the EMA Service Desk self-service portal which enables you to request the services you require from the Agency.

### Change Status Report

To see the report [click here](#)

What do you need help with?



Ask a Question

**Request a Service**

Report an Issue



### Access, permission, content updates and password requests

Request access to an application or system (e.g. EudraLink), permission changes (e.g. public folders in Outlook, ACL for Documentum), content update (e.g. update profiles in ECD) and password resets



# Using the Service Desk to **request a service**



Service Desk / Service Desk

## Access, permission, content updates and password requests

Search for an object

- BI Eudravigilance Veterinary (EVDAS VET)
- BI Eudravigilance Human (EVDAS HUM)
- Eudravigilance Art 57
- Eudravigilance Core
- Eudravigilance DD Client
- Eudravigilance DD Client Algorithm
- Eudravigilance Human

Subject

Please add a title for the request

Software

Please describe the type of request (access, permission or password reset). If a request for access or permission change

Description

Justification for the request is mandatory. Please provide the name of the manager that is authorised to approve this request, if needed. Please indicate how it is affecting your ability to work, other people, and how urgent it is

Attachment *(optional)*

Drag and drop files, paste screenshots, or [browse](#)

Please upload any attachments you consider useful

[Create](#) [Cancel](#)



# Using the Service Desk to **report a technical issue**

Service Desk

## Service Desk

Welcome to the EMA Service Desk self-service portal which enables you to request the services you require from the Agency.

### Change Status Report

To see the report [click here](#)



Ask a Question

Request a Service

**Report an Issue**



Report an issue with business applications / software

Issues (known as incidents) with business applications (e.g. DREAM, SAP, MMS) or software (e.g. MS Office, Windows)




Audio visual, conferencing, virtual meeting, multimedia services or AV equipment


Issues (known as incidents) with audio visual meeting room equipment (e.g. projectors, voting system or audio quality)



# Using the Service Desk to **report a technical issue**

 [Service Desk](#) / [Service Desk](#)  
Report an issue with business applications / software

Summary  
  
Please add a title for the issue

Software  
   
Please select the required application/software from the catalogue

Description  
  
Please describe the issue being experienced. Please indicate how it is affecting your ability to work, other people, and how urgent it is.

Attachment (optional)  
  
Please upload any attachments you consider useful, including screenshots as needed

Search for an object

Eudravigilance

- BI Eudravigilance\_Veterinary (EVDAS VET)
- BI Eudravigilance\_Human (EVDAS HUM)
- EudraVigilance\_Art 57
- EudraVigilance\_Core
- EudraVigilance\_DD Client
- EudraVigilance\_DD Client Algorithm
- EudraVigilance\_Human




## Using the Service Desk to **ask a question**

Service Desk  
**Service Desk**

Welcome to the EMA Service Desk self-service portal which enables you to request the services you require from the Agency.


- Ask a Question**
- Request a Service
- Report an Issue
- Propose a Change

 **Question**  
Ask a general question



# Using the Service Desk to **ask a question**

Service Desk / Service Desk

 **Question**

Subject

Please ask your question


Type of question *(optional)*

Please choose from the menu the question type

Description *(optional)*

Please provide any further detail as needed


Attachment *(optional)*

 Drag and drop files, paste screenshots, or [browse](#)



# EudraVigilance specific services

EMA Service Desk



## Popular

[EudraVigilance](#)

Service Desk

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[Browse all](#)

## Recent



[Request Quality Assurance Test - EudraVigilance](#)

Request QAT



[Report Duplicates - EudraVigilance](#)

Report the suspected duplicates



[Medical Literature Monitoring enqui... - EudraVigilance](#)

MLM related Enquiries





# EudraVigilance Registration Queries & Requests

Service Desk

## EudraVigilance

Welcome! You can raise an EudraVigilance related request from the options provided on this portal. **For any other queries not related to the below options, please use the EMA Service desk**

What do you need help with?



**EudraVigilance Registration queries**  
Queries related to EudraVigilance Registration



**Medical Literature Monitoring enquiries**  
MLM related Enquiries



**Report Duplicates for ICSR**  
Report suspected duplicates for ICSR only



**Request Quality Assurance Test**  
Request QAT



# EudraVigilance Registration

- Please note that the EV registration team only deals with the following for EV Human production:
  - QPPV/RP change or first user activation
  - New Organization
  - Change in transmission mode
- Other EudraVigilance issues should be sent as EMA Service Desk requests:
  - Request a Service
  - Report an Issue
  - Ask a Question

**Please refer to the red links as shown in the screenshot, and refer to the [EV webpage](#) for information and manuals**

## Service Desk / EudraVigilance 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 EMA Service Desk.
- 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.

Raise this request on behalf of

Lobato Pardo Marta

Summary

Please enter a summary for your request.

EV-Environment type

None

Please select the environment you would like to check from the drop down menu.

EV-Request type

- Registering/Changing MAH QPPV/RP
- EU QPPV
- Trusted Deputy
- Responsible Person
- Amending my organization profile
- Amending my user profile
- Registering/Disabling an org/user
- Transmission mode
- Access rights and roles
- Managing affiliates and/or Virtual affiliates
- Other

Please select the components you wish to be tested. Multiple selections are possible.

Description (optional)

Attachment (optional)

Drag and drop files, paste screenshots, or browse



# EudraVigilance – Medical Literature Monitoring

Service Desk

## EudraVigilance

Welcome! You can raise an EudraVigilance related request from the options provided on this portal. **For any other queries not related to the below options, please use the EMA Service desk**

What do you need help with?



**EudraVigilance Registration queries**  
Queries related to EudraVigilance Registration



**Medical Literature Monitoring enquiries**  
MLM related Enquiries



**Report Duplicates for ICSR**  
Report suspected duplicates for ICSR only



**Request Quality Assurance Test**  
Request QAT



# EudraVigilance - MLM enquiries

- Chose the Medical Literature Enquiries and complete the form.
- You have the option to add a description and an attachment may that be necessary.



Service Desk / EudraVigilance

## Medical Literature Monitoring enquiries

Summary

Description *(optional)*

Attachment *(optional)*

 Drag and drop files, paste screenshots, or  
[browse](#)

Create

Cancel



# EudraVigilance – Report Duplicates

Service Desk

## EudraVigilance

Welcome! You can raise an EudraVigilance related request from the options provided on this portal. **For any other queries not related to the below options, please use the EMA Service desk**

What do you need help with?



**EudraVigilance Registration queries**  
Queries related to EudraVigilance Registration



**Medical Literature Monitoring enquiries**  
MLM related Enquiries



**Report Duplicates for ICSR**  
Report suspected duplicates for ICSR only



**Request Quality Assurance Test**  
Request QAT



# EudraVigilance – Report Duplicates

- All the fields marked with a star\* at the end are mandatory.
- You will have to choose a value from the drop down menu or complete the field with free text in order to submit your call.

Service Desk / EudraVigilance  
Report Duplicates

Choose one of the below types of Reference Numbers \*

Local Report Number  
Case Number  
Safety Report ID

None

Case 1 \*

Case 2 \*

Any other additional suspected duplicate(s)? (optional)  
None

Attachment (optional)  
Drag and drop files, paste screenshots, or  
browse

Create Cancel

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

Please enter the reference number for the Case 1 which you suspect having duplicates.

Please enter the reference number for the suspected duplicate - Case 2.

If you suspect additional duplicates for the Case 1, please chose 'Yes' and add them in the text boxes below. I no other duplicates, please leave the field with the default value 'None'.

If you have more than 10 suspected duplicates, please attach the spreadsheet in the requested format.



# EudraVigilance – Request QAT

Service Desk

## EudraVigilance

Welcome! You can raise an EudraVigilance related request from the options provided on this portal. For any other queries not related to the below options, please use the EMA Service desk

What do you need help with?



**EudraVigilance Registration queries**  
Queries related to EudraVigilance Registration



**Medical Literature Monitoring enquiries**  
MLM related Enquiries



**Report Duplicates for ICSR**  
Report suspected duplicates for ICSR only



**Request Quality Assurance Test**  
Request QAT



# EudraVigilance – Request QAT

- All the fields marked with a star\* at the end are mandatory. You will have to choose a value from the drop down menu of each field or complete them with free text.
- The default value 'None' in this form is not considered a choice and you won't be able to log the call if not choosing a value from the drop down menu.
- An option for attaching a file is available.



Service Desk / EudraVigilance

## Request Quality Assurance Test

If you need to request an EudraVigilance Quality Assurance Test please complete the form below. One of our Service Desk agents will process the information and will come back to you in order to plan the test. You will receive confirmation emails when your request is being progressed or when more information is needed from your side.

XCOMP Organisation Sender Identifier \*

Please enter your XCOMP Organisation Identifier.

Organisation Name \*

Please enter your Organisation name.

Are you using a Gateway or the EVPOST function? \*

Please enter the EV Channel you are using.

Have you completed Step-4 testing? \*

For information about step 4 testing please go the following [web page](#)

Are you testing E2B(R2) or E2B(R3) submission? \*

Please choose from the drop down.

Are you a software vendor or service provider? \*

Software / Version / Configurations \*

Please indicate software, version and any specific configuration settings you are using.

Comments (optional)

Attachment (optional)

📎 Drag and drop files, paste screenshots, or browse

Create

Cancel





# EMA Service Desk – tracking enquiries

- Once you have submitted an enquiry, you will receive an email notification with a **reference number** for your enquiry (to the email address you provided on registration).
- When your enquiry has been updated, you will receive an **email notification** containing a **link to the enquiry update**.
- An overview of all of your raised queries can be viewed by clicking on the **“Requests”** link at the top of any EMA Service Desk page.
- If you are searching for a particular logged query, type the reference number in the ‘Search for requests’ to view it.

Service desk  
Requests

Requests 9

Export

Open requests Created by me Any request type

|

Type	Reference	Summary	Service desk	Status	Requester
	EV-53	QAT	EudraVigilance	OPEN	Inga Test1
	EV-48	Duplicate Detection	EudraVigilance	IN QUEUE	Inga Test1
	EV-46	Rakesh mim	EudraVigilance	IN QUEUE	Inga Test1

All Requests

Service Desk  
Requests

Export

Open requests Created by me Any request type

EV-53

Type	Reference	Summary	Service desk	Status	Requester
	EV-53	QAT	EudraVigilance	OPEN	Inga Test1

1-1 of 1



# EMA Service Desk – tracking enquiries

- You have the option to filter request you want to view, for ex. 'Closed request' for the 'MLM'.
- When viewing your requests you have the option to export the logged request in a CSV file.
- You can export in CSV format either 'All request' or the 'Current requests' (the last one is handy when you filter for particular requests, for ex. 'Closed request').



Requests 9

Service Desk  
Requests

Open requests  
Any status  
Open requests  
Closed requests

Created by anyone



Summary

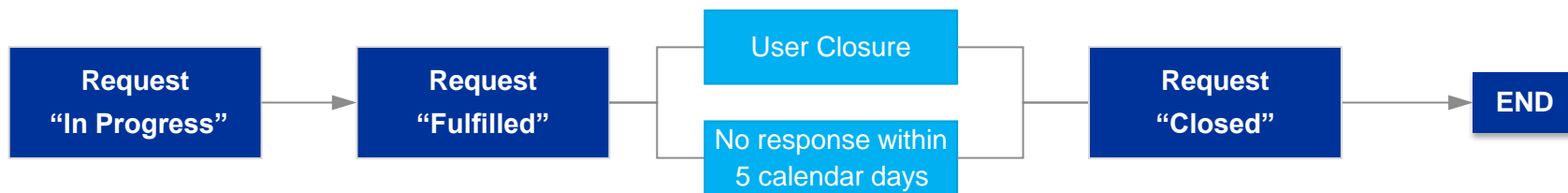
Any request type  
Any request type  
**EUDRAVIGILANCE**  
Report Duplicates  
Medical Literature Monitoring enquiries  
Request Quality Assurance Test

Export  
CSV(All requests)  
CSV(Current requests)

				Requester
	EV-53	QAT		Inga Test1
	EV-48	Duplicate Detection	EudraVigilance	Inga Test1
	EV-46	Rakesh mlm	EudraVigilance	Inga Test1



# EMA Service Desk – Resolving enquiries



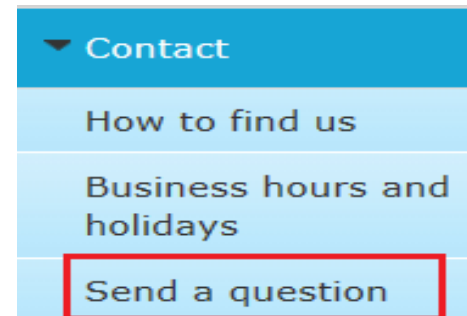
- Resolved enquiries will be attributed with a status of **“Request Fulfilled”**
  - If further clarification is requested or an action related to the enquiry is needed, queries can be **re-opened within five calendar days of being resolved**.
- Users can manually close the query via the detailed query page in the “My Requests” section. Queries will be **automatically closed within five calendar days**.



## Pharmacovigilance-related or general queries (1/2)

- To raise a general query, ask EMA a specific question about a pharmacovigilance-related issue, request 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:  
[http://www.ema.europa.eu/ema/index.jsp?curl=pages/about\\_us/landing/ask\\_ema\\_landing\\_page.jsp&mid=WC0b01ac05806499f0](http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/ask_ema_landing_page.jsp&mid=WC0b01ac05806499f0)
- **No registration is necessary**

**About Us > Contact > Send a question**





# Pharmacovigilance-related or general queries (2/2)

**Your name\***

Title  First name  Surname

**Organisation/employer**

**Who you are\***

Please select

**Location\***

Please select a country

**What is the subject of your enquiry?\***

**Your question(s)\***

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.

**Your email address\***

**Please repeat your email address\***

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

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

Enter **contact details** in this section so we can get back to you.



# Contact Points Summary



Contact point	Area	Contact
EMA Service Desk Portal	EudraVigilance, Technical or application-specific queries	<b>EMA Service Desk portal:</b> <a href="https://servicedesk.ema.europa.eu">https://servicedesk.ema.europa.eu</a>
Urgent Technical Helpline	Urgent technical or application-specific queries	<b>Urgent technical helpline:</b> +44 (0)20 3660 8520
Ask EMA	Pharmacovigilance-related or General Queries	<b>Ask EMA:</b> <a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/ask_ema_landing_page.jsp&amp;mid=WC0b01ac05806499f0">http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/ask_ema_landing_page.jsp&amp;mid=WC0b01ac05806499f0</a>
EudraVigilance Registration Team	Registration issues	<b>EudraVigilance Registration Queries:</b> <a href="https://servicedesk.ema.europa.eu/jira/servicedesk/customer/porta/103/create/602">https://servicedesk.ema.europa.eu/jira/servicedesk/customer/porta/103/create/602</a>