EudraVigilance support guide

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](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**

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

**EudraVigilance Registration**

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](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.
EudraVigilance related enquiries

- 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.
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.

![Service Desk interface](image)
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
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?

Request a Service

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**
Using the Service Desk to report a technical issue

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

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

**Create**  **Cancel**
Using the Service Desk to ask a question
Using the Service Desk to **ask a question**

![Service Desk interface](image)

**Subject**

Please ask your question

**Type of question (optional)**

Eudravigilance

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

[Create] [Cancel]
EudraVigilance specific services

EMA Service Desk

Popular
- EudraVigilance Service Desk

Browse all

Recent
- Request Quality Assurance Test · EudraVigilance
  Request QAT
- Report Duplicates · EudraVigilance
  Report the suspected duplicates
- Medical Literature Monitoring enquiries · EudraVigilance
  MLM related Enquiries
EudraVigilance Registration Queries & Requests

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.
EudraVigilance – Medical Literature Monitoring

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
- Medical Literature Monitoring enquiries
- Report Duplicates for ICSR
- Request Quality Assurance Test
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.
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.
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.
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.
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’).
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

• No registration is necessary.
Pharmacovigilance-related or general queries (2/2)

Enter your personal and organisation details in this section.

Enter details of your enquiry in this section.

Enter contact details in this section so we can get back to you.
## Contact Points Summary

<table>
<thead>
<tr>
<th>Contact point</th>
<th>Area</th>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMA Service Desk Portal</td>
<td>EudraVigilance, Technical or application-specific queries</td>
<td><strong>EMA Service Desk portal:</strong> <a href="https://servicedesk.ema.europa.eu">https://servicedesk.ema.europa.eu</a></td>
</tr>
<tr>
<td>Urgent Technical Helpline</td>
<td>Urgent technical or application-specific queries</td>
<td><strong>Urgent technical helpline:</strong> +44 (0)20 3660 8520</td>
</tr>
<tr>
<td>Ask EMA</td>
<td>Pharmacovigilance-related or General Queries</td>
<td><strong>Ask EMA:</strong> <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></td>
</tr>
<tr>
<td>EudraVigilance Registration Team</td>
<td>Registration issues</td>
<td><strong>EudraVigilance Registration Queries:</strong></td>
</tr>
</tbody>
</table>