



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA Account Management

Organisation User Administrator

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An agency of the European Union



Organisation Administrator Role

What is coming?

A new, streamlined way for organisations to manage their administrators for different EMA systems and business applications.

What is it?

A new role **External Organisation Administrator** in EMA Account Management.

This Administrator, once validated by EMA, can approve or reject requests to become an administrator for other EMA-run systems¹ for their organisation.

Benefit?

The new process can reduce the number of administrators that need to be validated by EMA with a proof of affiliation letter, speeding up the process of administrator approval while ensuring organisations retain control over requests for administrator roles in EMA Account Management.

The new process is optional, and organisations can continue using the existing process for administrator registration in EMA Account Management if preferred.

¹ QPPV and Responsible persons for EudraVigilance are always approved by the EMA

Example – No Organisation administrator is appointed



John works at EMA, he approves Alicia and Brian, the first organisation administrators of Pharma Co for CTIS and IRIS



Alicia, works at Pharma Co. She request access as **CTIS** High Level Administrator, her request is approved by John if she provides **supporting documentation**. She will now approve all other CTIS users for Pharma Co.



Brian, works at Pharma Co. He request access as **IRIS** User Administrator, his request is approved by John if he provides **supporting documentation**. He will now approve all other IRIS users for Pharma Co.

Example – Organisation administrator is appointed



John works at EMA, he approves Jane, the first organisation administrator of Pharma Co



Jane, work at Pharma Co. She attaches documentation to the first request as **Organisation** administrator, her request is approved by John



Alicia, works at Pharma Co. She request access as **CTIS** High Level Administrator, her request is approved by Jane. She will now approve all other CTIS users for Pharma Co.



Brian, works at Pharma Co. He request access as **IRIS** User Administrator, his request is approved by Jane. He will now approve all other IRIS users for Pharma Co.

Example – Organisation administrator is appointed



John works at EMA, he approves Jane, the first organisation administrator of Pharma Co



Jane, work at Pharma Co. She attaches documentation to the first request as **Organisation** administrator, her request is approved by John



Alicia, works at Pharma Co. She request access as **CTIS** High Level Administrator, her request is approved by Jane. She will now approve all other CTIS users for Pharma Co.



Maria, works at Pharma Co. She request access as **IRIS** Manager, her request is approved by Jane because no IRIS User Admin is appointed for Pharma Co.

Frequently Asked questions

1. Is it Mandatory to have an Organisation Administrator?

No, it is not mandatory but the new process can reduce the number of administrators that need to be validated by EMA with a proof of affiliation letter, speeding up the process of administrator approval while ensuring organisations retain control over requests for administrator roles in EMA Account Management.

2. Is there a limitation in the number of Organisation Administrators?

No, there is not limitation in the number of User Administrators, we advice to have at least 2.

3. How do we request access as Organisation Administrator?

1. Go to EMA Account Management.
2. Click on Manage My Access
3. Select **External Organisation Administrator**
4. Attach supporting documentation
5. Submit the request (more documentation on how to request access [here](#))

4. Can the Organisation Administrator approve a change of QPPV or Responsible person in EudraVigilance?

No, QPPV and Responsible persons for EudraVigilance are always approved by the EMA, for more information refer to the [EudraVigilance registration manual](#)

4. Does the Organisation Administrator have access to EMA Systems requiring approval?

No, the Organisation Administrator has access in EMA Account Management, for approvals and user administrators task. The user does not have access to other systems like IRIS, CTIS and EudraVigilance unless specific access is granted.



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Annex

Approval Model





EMA

EMA Approver



Organisation Administrator

Organisation User Admin



Organisation Application (domain) Administrator

IRIS Organisation User Admin



CTIS Organisation User Admin



Organisation Application User

IRIS Organisation Manager



IRIS Organisation Contributor



UPD Organisation Search View



SPOR Organisation User



SPOR Organisation User



- Standard Approval
- Escalation to EMA (Attachment Required)
- Escalation to Organisation Administrator
- Automated rejection

EMA approves the first user of an organisation. A proof of affiliation (attachment) is required otherwise the request is rejected.

Organisation Administrator approves other administrators and application administrators.

Organisation Application Administrator approves other administrators and access to the specific application for the organisation they manage.

If no *Organisation Application Administrator* is appointed the request is escalated to the *External Organisation Administrators*, if no *External Organisation Administrators* is appointed the request is automatically rejected