EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

How to register with EudraVigilance and EVDAS

Training Module EV-M1

This module explains the steps and process to be followed to register with EudraVigilance and EVDAS and how to maintain the registered user information

Content Summary

- Introduction to this training module
- Why is registration needed?
- What is the process for requesting access for EV and EVDAS?
- How can I get supporting information?

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Introduction: Target Audience

Target audience for this training module:

- National Competent Authorities (NCAs) in the European Economic Area (EEA)
- Marketing authorisation holders (MAHs)
- Commercial and non-commercial sponsors of clinical trials (Sponsors)

Introduction: Learning Objectives

At the end of module EV-M1 you should be able to:

- Understand who needs access to EV and EVDAS and why
- Understand the processes for requesting access per stakeholder group
- Understand where to obtain supporting information

Note: the main focus will be on the registration process for safety reporting

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- Why is registration needed?
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Who needs to be registered

All electronic data interchange partners are required to register in EudraVigilance:

CATEGORY 1: Regulators	**CATEGORY 2:** Pharmaceutical industry	**CATEGORY 3:** Non-commercial sponsors (NCS)
National Competent Authorities (NCAs) in the EEA including regional pharmacovigilance centres, where applicable	• Marketing authorisation holders (MAHs) including Applicants • Commercial and Non-Commercial Sponsors (CS/NCS)	Non-commercial clinical trials are conducted by researchers without the participation of the pharmaceutical industry

CROs and IT vendors should request access on behalf of the MAHs, Applicants or Sponsors for which they are operating

As of July 2017, CROs and IT Vendors for Gateway software for ICSRs may also register under a separate 'Vendor' category in EV X-COMP by sending a request to: VendorTesting@ema.europa.eu

Why do organisations need to request access to EV?

- To meet their obligations for electronic safety reporting in accordance with Article 107(3) and 107a(4) of Directive 2001/83/EC and Article 17 of Directive 2001/20/EC
- To meet the obligations for signal management as set out in Article 21 of the Commission Implementing Regulation (EU) 520/2012

	CATEGORY 1: Regulators	**CATEGORY 2:** Pharmaceutical industry	**CATEGORY 3:** non-commercial sponsors (NCS)
EV	Electronic reporting of ICSRs	Electronic reporting of ICSRs	Electronic reporting of ICSRs
EVDAS	Signal management Data analysis	Signal management for MAHs only	*Not applicable*

Prerequisites for the EV registration

Before starting the EV registration process, users need to have the following in place:

CATEGORY 1: Regulators	CATEGORY 2: Pharmaceutical industry		CATEGORY 3: Non-commercial sponsors (NCS)
	Marketing Authorisation Holder/Applicant	Commercial Sponsor	
New organisations: Provide notification of successful completion of the EudraVigilance competency assessment for at least one user			
	Obtain MedDRA license number		
	Micro and small businesses based within the EEA qualify for a EV fee waiver MedDRA subscription		Eligible for a fee waiver for MedDRA subscription
		Obtain EudraCT number from the EudraCT database	

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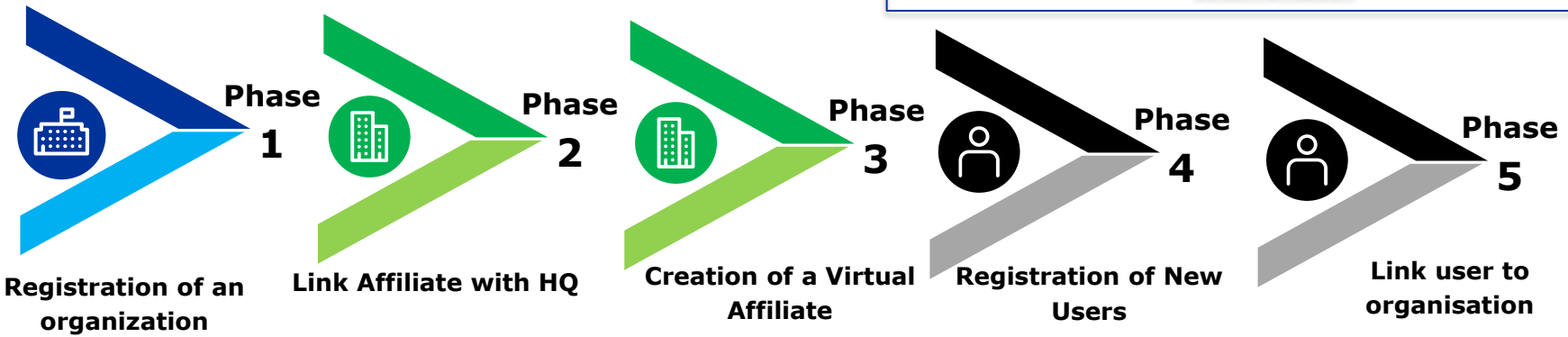
New Registrations in EV

A step-by-step training document with screenshots is available on the EV registration page to guide users in the system through the steps listed below, EudraVigilance Registration training documentation



Actions performed by the NCA/MAH/Sponsor

- **Pre-requisites**
- **Online registration details**
- **Prepares registration documents in-house**

New registrations: Phase 1 - Registration of an organization in EudraVigilance Human Production

Ensure you have the pre-requirements in place

Complete the online registration details

Send the required registration forms to the EV Registration team via Service Desk

- Access EMA Account Management portal and request SPOR Unaffiliated Role
- Log into SPOR Portal and click "Create New Organization". Search your organization in OMS. If not found, click on Register organization and follow the SPOR Manual guideline
- Once OMS registration is successful, access EMA Account portal and request the EU QPPV/ Responsible Role
- Raise a Service Desk request with required documents for EMA to validate and approve your role
- Access the EV Restricted Area and confirm the Organization Category, Transmission mode and Regulatory contact point email. Save changes

A prerequisite for being able to register an organisation in the SPOR Portal is to have an EMA Account user with access to SPOR.

New registrations: Phase 1 - Registration of an organization in EV Human XCOMP

Ensure you have the pre-requirements in place ✓

Complete the online registration details

Send the required registration forms to the EV Registration team

- Access Online registration link for XCOMP
- Complete Steps 1 to 5 of the form with Organization, QPPV/RP details, MedRA License and transmission mode information and Regulatory contact point.
- **Review**, **print** and **submit** the form. Send this form together with required documents via a JIRA ticket to the EV Registration team

Following successful completion of all steps the QPPV/RP will receive a unique username and password to access EudraVigilance XCOMP.

New registrations: Phase 2 – Link Affiliate* to HQ in EudraVigilance Human Production

Successful completion of Phase 1

Link Affiliate to HQ

- QPPV/RP/Trusted Deputy accesses the Restricted Area of EudraVigilance via the link EudraVigilance Production
- Select **'Manage your profile'**
- Select **'Manage Hierarchy'**
- Ensure the QPPV/RP of the potential Affiliate is the same as HQ to guarantee visibility of all available organizations to affiliate
- Select organization from left column and move it to the right. The organization is now affiliate of the HQ
- **To remove** an affiliate, contact Service Desk Ticket.

*An Affiliate is an organisation that has a different legal entity from the HQ organisation; it has to be registered in the OMS Portal independently from the HQ organisation.

New registrations: Phase 2 – Link Affiliate* to HQ in EudraVigilance Human XCOMP

Successful completion of Phase 1 ✓

Provide Affiliate/Virtual Affiliate Information

Send the Required Information to the Registration team via Service Desk

- QPPV/RP/Trusted Deputy accesses the Restricted Area of EudraVigilance via the link 

- Select **'Manage your profile'**
- Select **Add Affiliate/Virtual Affiliate manage Hierarchy**
- Provide **Organisation** Information
- Provide **Responsible User** information**, Transmission mode** selection, **Third Party** Information and **Access rights** selection
- **Review, print** and **submit** the affiliate/virtual affiliate form

*An Affiliate in XCOMP must not be registered in the OMS Portal.

New registrations: Phase 3 – Creation of a Virtual Affiliate

Provide virtual affiliate information

- QPPV/RP/Trusted Deputy accesses the Restricted Area of EudraVigilance via the link EudraVigilance Production
- Select **'Manage your profile'**
- Select "**Create Virtual affiliate"**
- Provide **virtual affiliate name, transmission mode** selection, MedDRA license information
- Select **Contributor user** information and **access rights**

*A Virtual Affiliate is a profile that exists mainly for allowing the submission of data in EV through different profiles/organisation IDs; this Virtual Affiliate must not be registered as organisation in OMS.

New registrations: Phase 3 - Registration of a new user in EV Human XCOMP

Successful completion of Phase 1 ✓

Provide user information

Raise a Service Desk Request for the activation of the registration of the user to the EV Registration team

QPPV/RP/Trusted Deputy accesses the restricted area of EudraVigilance via the 'Registered users' login using their credentials

Select **'Manage your profile'**

Select `**Add HQ user**`.

Set as **QPPV** (if applicable)

Select **individual user rights**

Browse	Browse and send ICSRs	Send extended medicinal product reports	Browse and send extended medicinal product reports	L2B Access
Send ICSRs	No access rights			

New registrations: Phase 4 - Registration of a new user in EV Human Production

Provide user information

- If you do not have an EMA account, register at EMA Account Management Platform
- Select 'Create a new EMA account'
- Complete `**Self-service Registration Form'** and press `**Register**`
- Follow the instructions on the next page to complete the registration

Following successful completion of this phase 4, the user will receive an EMA unique username & password

New registrations: Phase 5 – Link user to organisation in EV Human Production Registration (1)

Successful completion of Phase 4 ✓

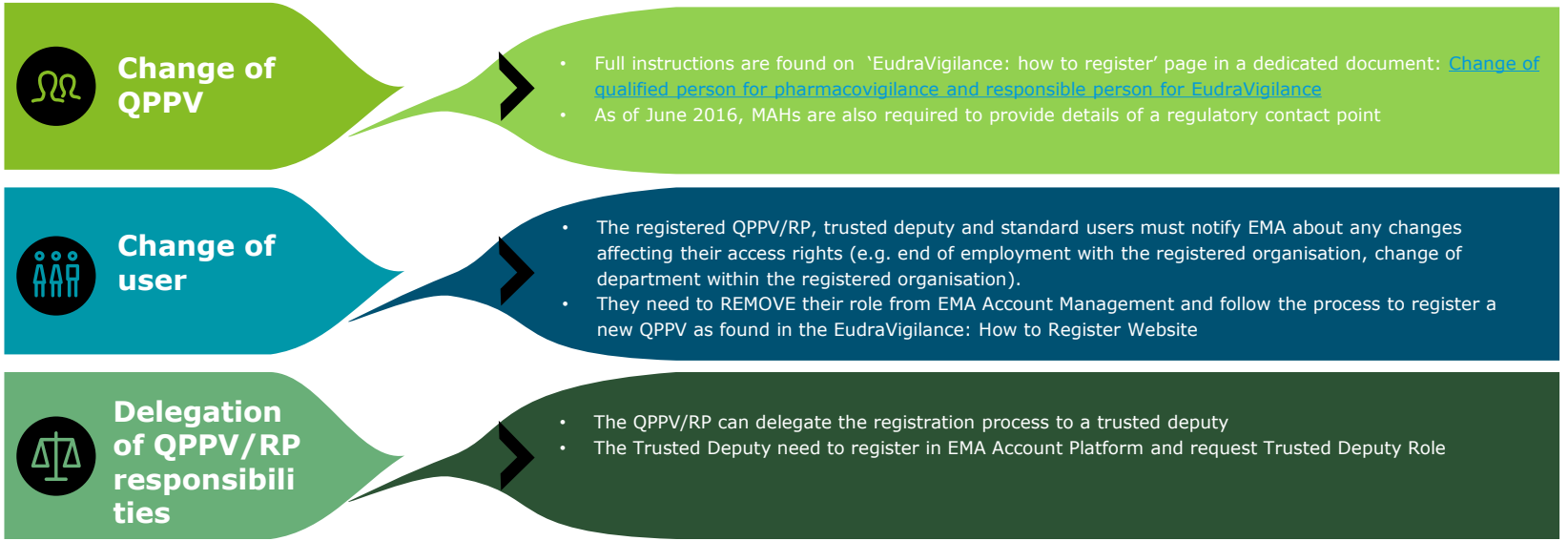
Select role and organisation

EV QPPV/Trust deputy of the organisation approves the request

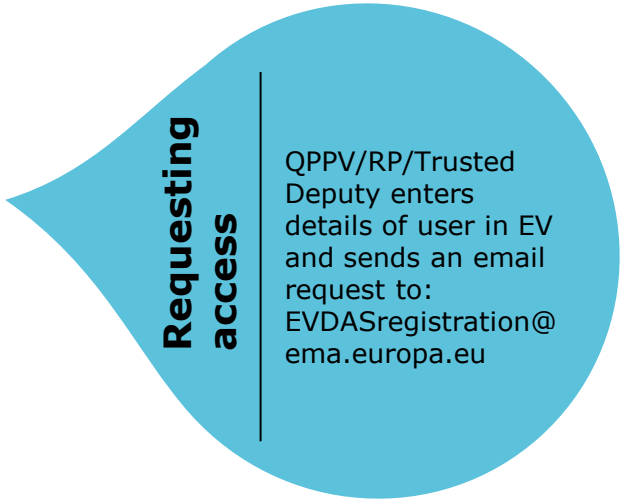
- User logs in EMA Account Management Platform
- Select **'Manage my access'**
- Search the **EV role** suitable for your needs; when submitting the role request, indicate the organisation on behalf of which you will access data in EV (you will be prompted with a dedicated form for this step).
- Responsible/Trusted Deputy gets an e-mail communication of your new role request.
- QPPV/Responsible/Trusted Deputy logs in EMA Account Management and approve/reject the request for the EV role.

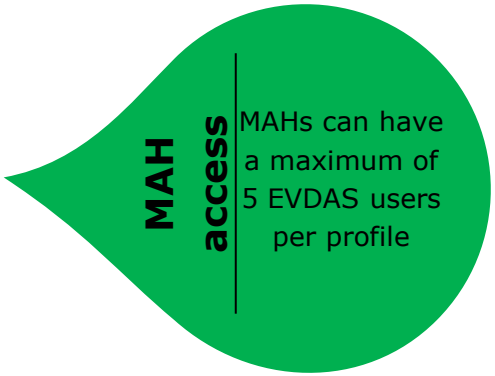
Roles for a specific organisation can only be submitted one at a time. Please request first a base role.

Process for modifying existing registrations in EV

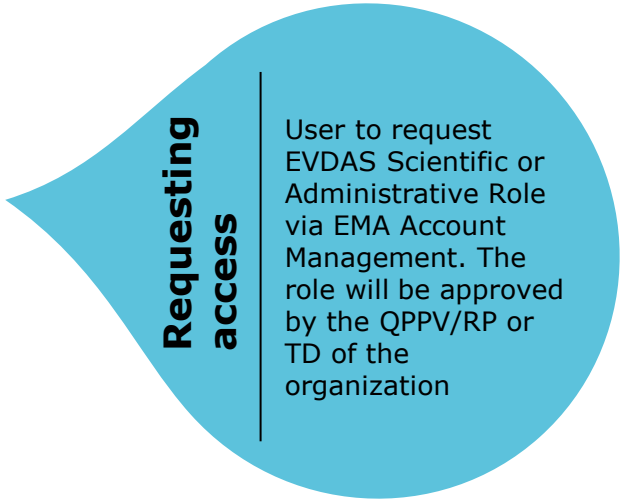


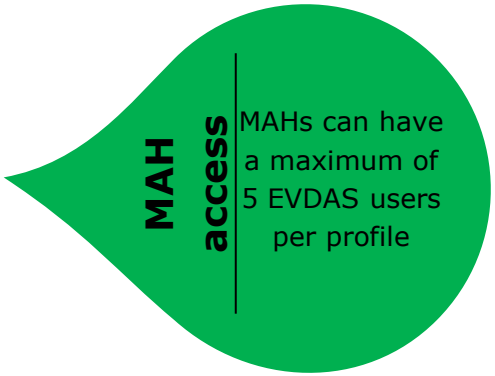
Registration process in EVDAS for XCOMP Environment



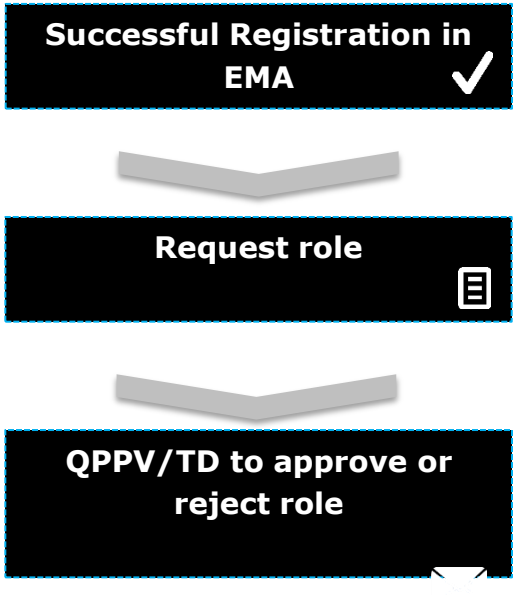


Registration process in EVDAS for EV Human Production





New registrations: Phase 5 - Registration of EVDAS users in EudraVigilance Production Environment



- User registers in EMA Account Platform
- User requests EVDAS scientific or administrator role
- QPPV/Responsible/Trusted Deputy approves or rejects the request for the EVDAS role.
- If approved, user can access EVDAS at https://bi.ema.europa.eu With the EMA Account credentials and view active substance groupings, e-RMRs and line listings

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Further guidance

EudraVigilance: how to register page
on the EMA corporate website

Human Regulatory > Pharmacovigilance > EudraVigilance > EudraVigilance: how to register

EudraVigilance: how to register

Pharmaceutical companies holding or applying for a marketing authorisation in the European Economic Area (EEA), sponsors of clinical trials and national competent authorities in the EEA need to register with EudraVigilance (EV) for the electronic data interchange of pharmacovigilance information. The registration process is a pre-requisite for safety reporting and product reporting.

On this page

- Classification of electronic data interchange partners
- Required action before starting registration
- Registering for safety and product reporting
- Training and testing requirements
- Starting the electronic registration process
- Submitting registration documents
- Delegating the registration process
- Change of QPPV/RP
- Legal framework

EudraVigilance Registration team

Via Service Desk

Related registration documentation and a link to the registration form are included on the page

Login for registered users

EudraVigilance **XCOMP (Test)**

EudraVigilance **Production**

Related EU legislation

- Directive 2001/83/EC
- CT-3
- Regulation (EC) 726/2004

Related documents

- EudraVigilance online test environment registration form
- EudraVigilance online production environment registration form

Please refer to this page for the most up to date information on the registration processes

Summary

We have now reached the end of the EV-M1 module and you will now be able to:

- Understand who needs to register in EV and EVDAS and why
- Understand the processes for registration by type of registration and by stakeholder group
- Understand where to obtain supporting information

Acronyms (1)

Acronym	Description
CROs	Clinical research organisations
EV	EudraVigilance
EVDAS	EudraVigilance Data Analysis System
ICSR	Individual Case Safety Report
NCA	National competent authority
MAH	Marketing authorisation holder
QPPV	Qualified person responsible for pharmacovigilance
RP	Responsible person

Thank you for your attention

Further information:
https://servicedesk.ema.europa.eu

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