Responsible Person for **Eudravigilance**

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Reading time: 6 minutes

Introduction

EudraVigilance is a centralised European database of suspected adverse reactions to medicines that are authorised or being studied in clinical trials in the European Economic Area (EEA).

EudraVigilance is the system for managing and analysing information on suspected adverse reactions to medicines which have been authorised or being studied in clinical trials in the European Economic Area (EEA). The European Medicines Agency (EMA) operates the system on behalf of the European Union (EU) medicines regulatory network.

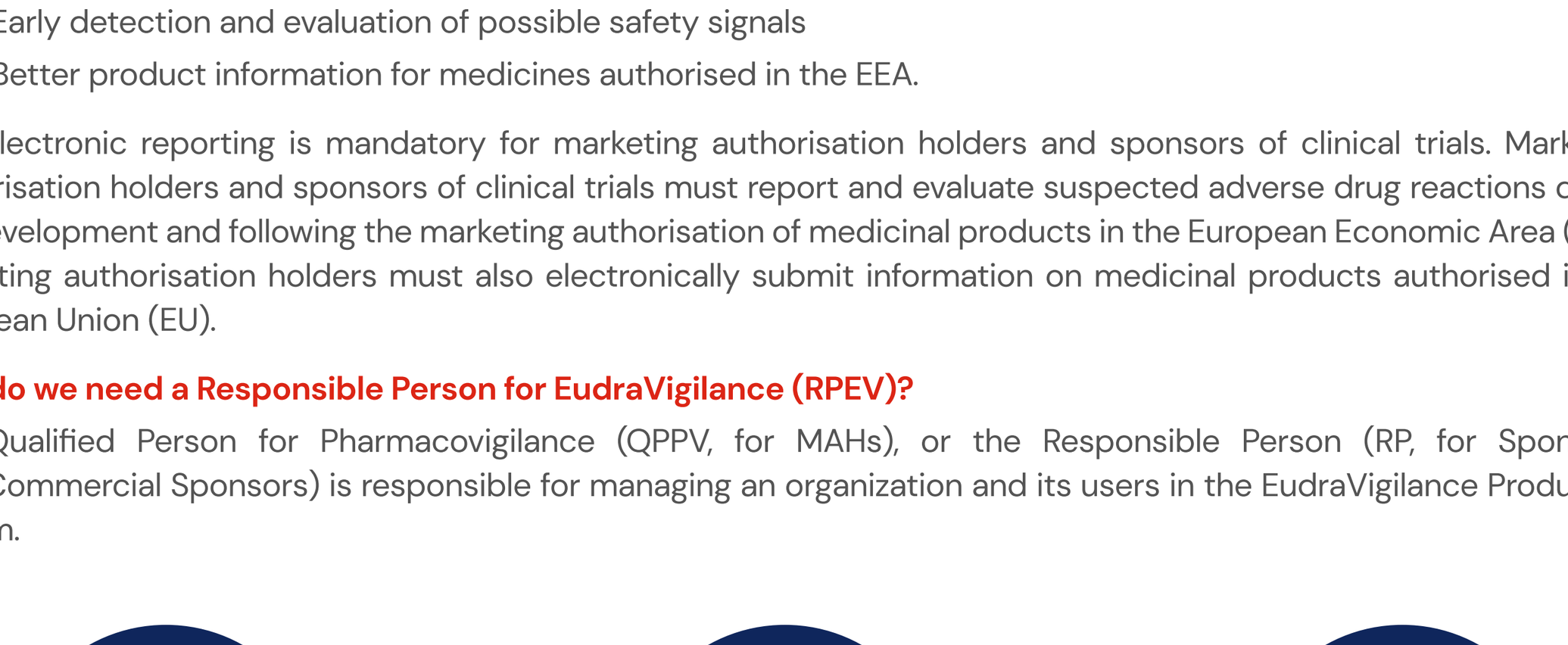
EudraVigilance supports safe and effective use of medicines by facilitating::

- Electronic exchange of ICSRs (Individual Case Safety Reports) between EMA, NCAs, MAHs and CT Sponsors in the EEA
- Early detection and evaluation of possible safety signals
- Better product information for medicines authorised in the EEA.

This electronic reporting is mandatory for marketing authorisation holders and sponsors of clinical trials. Marketing authorisation holders and sponsors of clinical trials must report and evaluate suspected adverse drug reactions during the development and following the marketing authorisation of medicinal products in the European Economic Area (EEA). Marketing authorisation holders must also electronically submit information on medicinal products authorised in the European Union (EU).

Why do we need a Responsible Person for EudraVigilance (RPEV)?

The Qualified Person for Pharmacovigilance (QPPV, for MAHs), or the Responsible Person (RP, for Sponsors/ Non-Commercial Sponsors) is responsible for managing an organization and its users in the EudraVigilance Production system.



For an individual to provide RP services to a sponsor/non-commercial sponsor, any one user in the individual's organization should successfully complete the EudraVigilance ICSR knowledge evaluation and XEVMPD knowledge evaluation. To ensure the quality of data submitted to the EMA, the EMA offers training courses on ICSR and Product submissions using EVWeb, after which users may undergo knowledge evaluations.

Registration of Responsible Person in EudraVigilance

Registration of a Responsible Person could entail one of the following two scenarios:

Scenario 1: Change of RP (when there is still an RP in the organization), or

Scenario 2: New RP registration (when the first user of a new organization is registering as RP)

A set of documents must be submitted to the EMA to register the Responsible Person in either of the above scenarios.

Documents Required	Scenario 1 (Change of RP)	Scenario 2 (New RP)
Cover letter from the headquarters lever of the organization on a headed paper. The Cover letter should be signed by the new RP of by a person ina position above that at the headquarters leverl= (i.e., director of the organization or similar), or by the legal representative or Commercial and Non-Commercial Sponsors.	The cover letter should state the name and position of the previous RP and the name, position and contact details of the new RP.	The cover letter should state the name, position and contact details of the new RP.
Email Confirmation from the OMS Data Stewards acknowledging the successful creation of the new organization.	Not required, as the organization is already registered with OMS by the older RP.	Required
Copy of the ID card or driver's license or passport, with the full name and signature visible. Any other information contained on the ID document may be blacked out.	Required	Required

Documents Required	Scenario 1 (Change of RP)	Scenario 2 (New RP)
User declaration form for RP, including the type and same of the organization, user's details, and dated and signed by the user.	Required	Required
EudraVigilance ICSR and XEVMPD submission training.	A declaration from the QPPV/RP that the organization has a suitably trained person or submission of ICSRs and XEVPRMs. This declaration can be included in the cover letter or in the body of the email submitted via the EV Registration Service Desk. Submitting copies of ICSR and XEVMPD Certificates is not necessary when changing the QPPV/RP.	A copy of the notification of successful completion of the EudraVigilance ICSR and XEVMPD knowledge evaluation for at least one user to access the production environment, as applicable.
Form A- for Sponser based in the EEA. Signed by the Sponsor's legal representative person appointing the new responsible person for clinical trails, including the name and the contact details of this person. The legal representative person and responsible person address should be for the respective organizations the work for.	Required	Required
Form B- for Sponsor's based outside the EEA only. Signed by someone from the Sponsor appointing the Sponsor's legal respresentative person in the EEA, including the name and the contact details of this person.	Required	Required The legal representative person address should be for the organization the legal representative works for.
A EudraCT number for a study the sponsor is conducting.	Required	Required

Conclusion

We hope that this blog was helpful in understanding the role of a Responsible Person and the process of registration of a RP with the EMA.

Please reach out to us if you require RP services in the EEA, or wish to understand more about the registration process for the RP.

References

1. EMA EudraVigilance Registration Manual. 17 March 2022. EMA/13454/2020, Rev. 11. European Medicines Agency.
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3. New Organization First User QPPV/RP or Change of EU QPPV/RP. 29 April 2021. EMA/503895/2018. European Medicines Agency.
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5. EudraVigilance | European Medicines Agency (europa.eu)
6. Some images from Pixabay (www.pixabay.com)

Authors

Dr. Sumit Verma – President, Clinical Safety and PV

Dr. Sumit Verma is a medical graduate with specialization in anesthesiology and has more than 15 years of experience in the pharmaceutical industry, clinical medicine, clinical research, and pharmacovigilance. He has built teams that have consistently delivered and exceeded customer expectations across pharmacovigilance domains such as case processing, signal management, risk management, aggregate reports, and clinical safety. He has co-authored two books – one on pharmacovigilance and another on pharmacology.

Tanvi Chaturvedi– Senior Manager, Clinical Safety and Pharmacovigilance

Tanvi is a pharma professional with more than 10 years of experience in pharmacovigilance. She has expertise in pharmacovigilance and clinical safety processes, including pre-approval, postmarketing and late phase safety requirements and has managed end-to-end project setup for EU and US based projects that include process development, safety database and medical information database setup with data migration and validation, transition of overall PV services, team selection and mentoring, and troubleshooting across PV verticals. Has experience across various domains like ICSR processing in safety databases, literature management, aggregate reporting, signal management, regulatory intelligence, EudraVigilance systems, system automation, process development and transition, and pharmacovigilance quality assurance. She is eligible to provide Responsible Person for EudraVigilance (RPEV) services to Sponsors of Clinical Trials in the EU.

About Soterius

Soterius is a strong team of pharma professionals who design customized, innovative, and cost-efficient processes for clinical safety, pharmacovigilance, and medical affairs. Our deep industry knowledge and up to date insights let us combine agile, people powered intelligence in pioneering customer centric solutions. Our innovative technology solutions include engagement tools and communications platforms to create a unified and compliant medical access facility. With a strong global presence, we provide comprehensive clinical and post marketed safety services, that include aggregate report writing, signal detection and management, global literature surveillance, risk management, case processing and regulatory reporting. We use state-of-the-art technologies to solve complex safety operations problems, be it case processing, intake, site reporting for clinical trials, or literature search and management. We have one of the most accurate solutions for case intake and case processing using AI.

We support companies from the initial development stage of a drug/vaccine to the approval and ultimate marketing of the therapy, supporting ongoing operations and regulatory commitments globally.