



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) e-learning

Session 1.2: Registration with EudraVigilance

Version 5.5





EudraVigilance registration

Before the electronic submission of Extended EudraVigilance product report message (XEVPRM) in the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD), also referred to as 'Article 57 database' can be initiated, marketing authorisation holders (MAHs) need to [register with EudraVigilance](#).

- Organisations are required to register electronically via the [Organisations Management System \(OMS\)](#).
- User management takes place via the [EMA Account Management Platform](#).



Who can register with EudraVigilance

Registered organisations can be:

- Pharmaceutical companies (marketing-authorisation holders, applicants), their affiliates and users;
- Commercial and non-commercial sponsors, their research departments and their users;
- National competent authorities (NCAs) and their users.

Clinical research organisations (CROs), IT vendors and third-party service providers that do not qualify as sponsors, MAHs or applicants cannot register with the EudraVigilance production environment. These entities may be registered by the MAH, applicant, commercial or non-commercial sponsor as a third-party service provider acting **on behalf of these organisations** by providing services related to EudraVigilance.



EudraVigilance registration: new organisations

- New organisation must register in OMS;
- The first user must self-register in the EMA Account Management Platform and submit an [EMA Service Desk portal](#) request for their role [e.g., qualified person for pharmacovigilance (QPPV) or responsible person (RP)] to be approved by the EMA;
- The QPPV/RP will then be able to approve access to new users and remove existing users;
- *'Notification of successful completion of the XEVMPD knowledge evaluation'* must be provided for at least one user during the organisation's registration;
- Detailed information is available in the ['EMA EudraVigilance Registration Manual'](#).



EudraVigilance registration: already registered organisations

MAH organisations already registered with EudraVigilance without access to the XEVMPD should request an update of their EudraVigilance profile in order to successfully submit XEVPRMs by submitting a request via the [EMA Service Desk portal](#):

- The QPPV or their deputy/RP shall request for their XEVMPD community for the external compliance (XCOMP) testing environment to be enabled in EV; XCOMP profile is automatically created once one organisation is created in OMS/Production;
- The Organisation ID shall be specified in this request.



Registration of third party service providers

- Third party service providers (e.g. CROs) cannot register by themselves, they need to be registered on behalf of the MAH/applicant/commercial or non-commercial sponsor organisation as a virtual affiliate.
- CRO users will need to request a 'contributor' role via the EMA Account Management Platform for the specific organisation.
 - If users work for multiple organisations, they will need to request a 'contributor' role for each of those organisations separately.



Contact details and further information

- Detailed steps and definitions are described on the “Registration with EudraVigilance” webpages, section ['EudraVigilance: How to register' webpage](#).
- Questions related to the EudraVigilance registration process should be submitted via the [EMA Service Desk Portal](#).