

Registration with Eudravigilance for the reporting SUSARs in Eudravigilance

The study sponsor should register with Eudravigilance (EV) centrally. Depending on the expected number of SUSARs and number of sites, multiple persons can be trained to enter SUSARs. For studies with a low number of SUSARs and sites without experience in EV, it is recommended from an efficiency and quality perspective, to train centrally 2 persons on the entry of SUSARs (to have a back-up available).

The document [Eudravigilance registration documents \(europa.eu\)](#) describes in detail what is needed for registration with EV, including the links to the different EMA systems.

Registration

For registration with EV, the following steps need to be taken:

1. Create an EMA account. Users who already have access to other EMA systems, like CTIS, can use those login details and do not need to create a new account.
2. Registration of the organisation in the EMA Organisation Management System (OMS).
3. Request the appropriate role via the EMA Account Management Portal. In this case 'EV CS/NCS responsible'.
4. Thereafter create a ticket with the EMA Service Desk in which the requested documents should be attached. An overview of the documents that are needed, can be found on page 2 of the document [Eudravigilance registration documents \(europa.eu\)](#).

Training

One of the documents that should be attached to the ticket is a copy of the 'notification of successful completion of the Eudravigilance ICSR and XEVMPD knowledge evaluation' for at least one of the users.

Non-commercial sponsors can complete an online training: [Eudravigilance training and support | European Medicines Agency \(europa.eu\)](#).

A more extensive (online) training (subject to fee) is being delivered by DIA. Information can be found on: [Eudravigilance training and support | European Medicines Agency \(europa.eu\)](#).