CTIS Pre-requisites:
Checklist

16 November 2023

Prior to starting using CTIS, users must make sure they have covered the below actions/systems

- ✓ **EMA account** - any CTIS user needs to have an EMA account. Go to EMA Account Management and click on "Create a new EMA account". Follow the EMA procedure for authentication method here.

- ✓ **Sponsor organisation is registered in OMS** - Log in to OMS with your EMA account.

- ✓ **Sponsor Administrator is registered in IAM** – request the first Sponsor Administrator role for your organisation in EMA Account Management

- ✓ **Sponsor organisation to register with EudraVigilance** either via Gateway or the EudraVigilance web application (EVWEB). More information on how to register with Eudravigilance is available here.

Organisations should refer to the section 'Who needs to report what' on EudraVigilance: electronic reporting to find out whether to register for safety reporting, product reporting or both.

Requisites for registration for commercial and non-commercial sponsors can be found at: EudraVigilance registration documents (europa.eu)

EVWEB enables the submission of a case (i.e., SUSAR) to EudraVigilance. In addition, it allows the registered user(s) to register a new medicinal product in xEVMPD (medicinal product dictionary).

- Commercial organisations can be registered if one of their users attends the DIA trainings.
- Non-commercial organisations can be registered if one of their users pass the assessment related to the e-learnings or attends the DIA training.
- For EudraVigilance access, users should log into the EMA Account Management portal and request a 'EudraVigilance role'. For more details, see the Registration manual.

EMA organises 1 day (two half days) courses specifically for clinical trial sponsors including non-commercial sponsors. These focus on how to add investigational medicinal product information to the XEVMPD. Learn more about product registration **here**.

As soon as an organisation is registered, all its users may practically access EV. No further checking to other users' (not to the first user's) training is done by EMA.

✓ **For more support, read the CTIS online modular training, the sponsor handbook and Commission Q&A EudraLex Volume 10.**