



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EudraVigilance Registration Updates

Context, Challenges, Next steps

14th industry stakeholder platform – operation of EU pharmacovigilance

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An agency of the European Union



- EMA is implementing its **new IT strategy** which will replace legacy systems and harmonise core online processes.
- One key area of effort and investment is standardising **how people and organisations register for EMA services**.
- This will bring **greater efficiencies** for both users and EMA as well **increased data security**.
- The new process for registration has **already been rolled out on several major EMA IT systems** in the past year and will be incorporated in all new systems.
- Work on integrating the new registration module into EudraVigilance began in 2017 with **go live 26 July 2018**.

EV Registration Updates: The change introduced

Unique EMA login to:

- Access data on behalf of multiple organisations **in EV**
- Request roles to EV, or any of the EMA applications in the future
- Maintain organisation information

A team of EMA data stewards has dealt with the **legacy data migration** of EudraVigilance organisations in OMS.

Transfer of EV data of Industry, NCAs, and EMA:

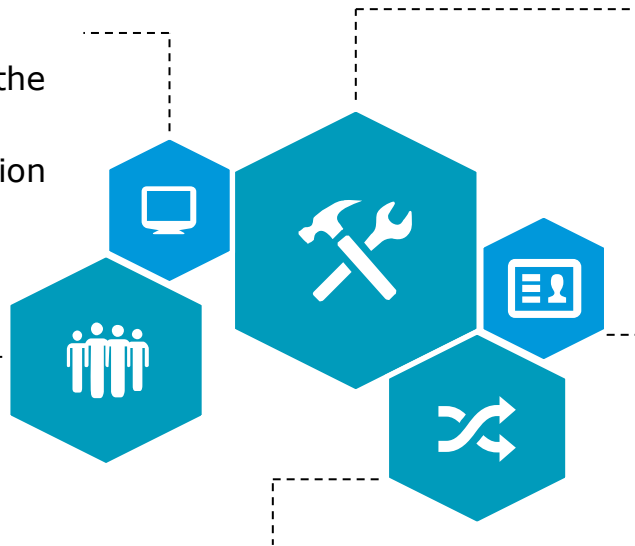
- Organisation master data to OMS
- User master data to EMA Account Management Platform
- + **synchronisation of master data back to EV**

2 allowing for central data maintenance across EMA applications.

New self-managed process for industry and NCAs to **register** users and to **grant access** to users, reducing the communication stream and registration time, including

transparent monitoring and reporting functionalities to manage and control user accounts

List of EV roles available to industry and NCAs to access EV8 and xEVMPD.



- From the **9 509** EudraVigilance organisations registered and approved before 02/07/2018:
 - **8 650** have been identified and linked with a unique record in OMS (this the main repository of the Agency for organisations registered; it is being referenced across all the main EMA business areas)
 - **859** have been identified as complex cases and needed a one-by-one analysis; this impacted **2 022 unique users**; in a first stage, **no access was granted to these users**, until the situation of the organisation was clarified so that the correct migration could take place; a dedicated communication was sent to this users in August informing them on the root cause of the delay.
- **24 748 EudraVigilance user profiles have been consolidated in 11 902 unique** EMA accounts.

Task performed	Activity volume	Reference period
Requests of access to EV processed	2 777	26 of Jul – 14 of Sep
Requests for removing of access processed	734	26 of Jul – 14 of Sep

EV Registration Updates: Challenges and Actions

Challenges	Actions
Data quality and standardisation	Analysis on a case by case basis, to ensure that the organisations were linked correctly with a unique identifier – registered in OMS (data mastering process started in April 2018) and that each user has one unique EMA account.
Corner cases - users and organisations with complex requirements (approx. 10% of the data processed) could not be automated during the migration.	Manual analysis from the EudraVigilance registration team of the users and hierarchies related to complex big organisations; <u>this activity took longer than expected.</u>
The heavy workload impacted on the systems performance and availability	Technical upgrades within days after the go-live have been put in place to ensure stability and adequate support to the increased workload.
Communication of the updates in the registration process	FAQs have been published on the EV Registration website based on the direct suggestions and the tickets opened Webinars are being held on 20, 25 and 27 of September to answer directly to queries EV registration manual has been published since July on the EV Registration website EV training has been updated in July to reflect the changes in the registration process

- Changes of QPPVs need to be notified to EMA. **Data quality** is essential for the maintenance of users and organisations.
- Clearly **define and review** your the organisation hierarchy specific to EudraVigilance – keep it simple.
- Use **unique points of contact** that can centralise the information about the EudraVigilance specific hierarchies in terms of affiliates and virtual affiliates; this hierarchy should be reviewed and cleaned periodically.
- Register for EMA access with **one email only** and inform EMA when your main email address changes; email addresses are used to uniquely identify the users and to communicate with them.
- Implement **standard and simple architectural designs; renovate ageing technology** on a periodic basis.



Thank you for your attention

Further information

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