18 March 2020
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Information Management

Subject: EudraVigilance XCOMP test system Upgrade to use the EMA Account Management Portal on Thursday 26/03/2020 and Friday 27/03/2020

To: all XCOMP registered users (EV7 art.57 and EV8 ICSR) + all Production QPPVs

Dear EudraVigilance XCOMP users,

Following the implementation of the EMA's Identity Account Management (IAM) platform, the EMA has worked towards integrating this system with EudraVigilance. The first step was carried out in July 2018 when the EudraVigilance production registration system was replaced by the new IAM platform. The next step has been to implement the IAM platform for the XCOMP environment. This means that the same **self-service process** MAHs, NCAs and sponsors currently use to **manage user access and maintain accurate data on their organisation will now be available for the XCOMP test environment.**

This essential upgrade to the EudraVigilance XCOMP user and organisation management system will be carried out from Thursday 26th March 2020 from 09:00 CET to Friday 27th March 2020 17:30 CET.

Important information to users:

It will now be possible to request user access to the EV XCOMP test environment in the same system used for the production environment.

- Legacy XCOMP Gateway Organisations/User accounts:

    - Organisations with a legacy XCOMP Gateway account can continue to use these legacy accounts to send test files and receive back acknowledgements via their XCOMP gateway connection

    - All legacy XCOMP personal user accounts associated with a legacy XCOMP gateway organisation will no longer function in the new XCOMP environment. Users wishing to access EVWEB (ICSRs & XEVMPD) and the restricted area will need to re-register under a new XCOMP organisation registration

- EVWEB/EV POST function Organisations/users:

    - All legacy XCOMP personal user accounts will no longer function in the new XCOMP environment. Users wishing to access XCOMP EVWEB (ICSRs & XEVMPD) and the XCOMP restricted area will need to re-register under a new XCOMP organisation registration

- New Registration process for organisations and users:

    - The EudraVigilance organisation ID for new registrations will follow a similar format to the production system. The system will use the same numerical part as the OMS Org ID, however it will have the prefix **ORX** rather than **ORG**

- All registered Responsible Persons (including main QPPV) and their trusted deputies in the production EudraVigilance system will automatically be assigned the same roles to their organisation in the XCOMP environment. If you wish to use XCOMP these new organisation registrations need to be activated by the RP user through completing the organisation profile in XCOMP (EVTEST) EudraVigilance restricted area. In order to access XCOMP environment with production credentials, you will need to reset your password by using this link: https://register.ema.europa.eu/identityiq/external/emaForgotPassword.html

- The log in credentials (username and password) will be the same as those used in production

- If other users with the organisation wish to have or need access to XCOMP they will need to request the role "**EV Human XCOMP User**" in the IAM registration system for that organisation. This will then need to be approved by a registered responsible person or trusted deputy in their own organisation

- For a new organisation the nominated responsible person needs to register for a production account and an XCOMP account will be automatically created at the same time. The XCOMP organisation will still need to be activated through completing the organisation profile in the EV restricted area

- Software vendors:

  - Existing software vendors already registered in XCOMP will maintain their current gateway connection

  - New software vendors will follow the new IAM registration process for XCOMP access

The updated EudraVigilance registration web page and registration user manual will be published on the 26th March 2020, please refer to these for further information.

Downtime period information:

As a result of the downtime period required, key components of the EV system will not be available on that day in the EudraVigilance XCOMP test environment:

- the EVWEB functionality for electronic reporting of ICSRs by National Competent Authorities (NCAs), marketing authorisation holders (MAHs) and sponsors of clinical trials (sponsors) will not be available

- the EVWEB functionality for electronic reporting of medicinal products / active substances MAHs and sponsors will not be available

- The EV restricted area for the user and organisation management will not be available

Please note that the electronic submission of ICSRs, XEVPRMs and Acknowledgments via the EudraVigilance production gateway by NCAs, MAHs and sponsors will not be affected by this downtime i.e. messages can be sent to the system as usual and Acknowledgements from the EudraVigilance system will be sent only after the completion of the upgrade work.

We thank you for your cooperation and understanding.

European Medicines Agency