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Information Management Division

Vendor registration in the EudraVigilance external compliance testing environment (XCOMP)

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In order to facilitate and simplify gateway testing for submission of safety reports to EudraVigilance, the Agency allows access for software Vendors and third party service providers to the EudraVigilance external compliance testing environment (XCOMP) via a gateway connection as stand-alone organisations. Access to EVWEB will not be provided.

Disclaimer – Use of EudraVigilance test system (XCOMP)

The European Medicines Agency provides the possibility for regulators, pharmaceutical industry, non-commercial sponsors, and third party service providers (further referred to as 'electronic data interchange partners') to register and connect to the EudraVigilance test system (XCOMP) in order to analyse whether their software is compatible with the new EudraVigilance system.

However, the Agency accepts no responsibility or liability whatsoever (including, but not limited to, any direct or consequential loss or damage that might occur to you and/or any other third party) arising out of, or in connection, with the EudraVigilance test system (XCOMP).

It is the Agency's goal to minimise disruption caused by technical errors. However, the Agency cannot guarantee that the EudraVigilance test system (XCOMP) will not be interrupted or otherwise affected by such problems. The Agency accepts no responsibility whatsoever with regard to such problems incurred as a result of using the system.

This disclaimer is not intended to limit the liability of the Agency in contravention of any requirements laid down in applicable legislation nor to exclude its liability for matters which may not be excluded under that law.

Liability

Please note that any misuse of the EudraVigilance test system (XCOMP) (e.g. by sending large volume of data, preventing others from testing), would result in the withdrawal of access to the system.

Vendor organisations - registration steps

The process for registering IT system Vendors in XCOMP follows the same process as for other organisations for the Production EudraVigilance system. The main difference is that the Responsible person for EudraVigilance nominated by the system Vendor will choose the Vendor specific base role, instead of one of the Production QPPV/RP base roles.

The nominated person from the Vendor will need to perform the following steps in order to successfully complete their registration in XCOMP:

1. Register in the [EMA Account Management portal](#);
2. Request "SPOR unaffiliated role" via the portal;
3. Register the Vendor organisation in the [Organisation Management System](#) (OMS) – for more information see Section 4. of the [EudraVigilance registration manual](#);
4. Request the base role "**EV Human XCOMP Vendor Responsible person**" via the [EMA Account Management portal](#);

5. Raise a [Service Desk](#) call via the EV Registration section including the role request ID generated by the EMA Account Management portal. The ticket should be addressed to the EV Registration team who will approve the “EV XCOMP Vendor Responsible person” role.
6. When the Vendor role has been approved, a separate [Service Desk](#) ticket should be raised, addressed to the Gateway support team, attaching a completed [Gateway connection form](#) and the Vendor’s encryption certificate. The relevant EV XCOMP vendor organisation ID should be included in the form. In their request Vendors are required to clearly indicate that they wish to set up a Gateway testing profile for a Vendor organisation. The Gateway support team will then send the Vendor the EMA connectivity details.

When the gateway set-up is complete, the Vendor is notified and can commence testing.

Note: Vendors do not receive access to EVWEB in EV XCOMP.

Vendors can perform testing for a specific version and build of their database and have the completion of this testing confirmed by the EMA by contacting the Quality Assurance Testing team via the [Service Desk](#) platform.

The EMA will confirm if this precise version and configuration of the database has completed testing. Significant changes to the database will require re-testing with the EMA.

Disclaimer – Completion of testing process

The confirmation provided upon completion of the testing process through the EudraVigilance test system (XCOMP) is for information purpose only, and does not entail any implicit or explicit

recommendation or endorsement by EMA. The electronic data interchange partner is restricted from using this confirmation as an endorsement by EMA.

By confirming the completion of the testing process EMA makes no warranty of any kind, implicit or explicit, including, without limitation, the implied warranty of merchantability, fitness for a particular purpose, non-infringement and data accuracy of the software. EMA neither represents nor warrants that the operation of the software will be uninterrupted or error-free, or that any defects will be corrected. EMA does not warrant or make any representations regarding the use of the software or results thereof including but not limited to the correctness accuracy, reliability, or usefulness of the software.

Removal of a Vendor’s access from EudraVigilance

To disable a Vendor organisation profile in XCOMP, the registered Responsible person for the Vendor should request the deactivation of their role via the EMA Account Management portal. A [Service Desk](#) request should then be raised, providing the removal request ID which will be generated by the EMA Account Management system. The request should be addressed to the EV Registration team.

Changing connection details

If a Vendor needs to change their gateway connection details, they should log a request via the [Service Desk](#) portal addressed to the Gateway support team. The request should include the Vendor name and EV organization ID (Routing ID), as well as the Vendor’s new connection details.