Quick interactive guide to EudraVigilance (EV) registration process

This presentation is interactive.

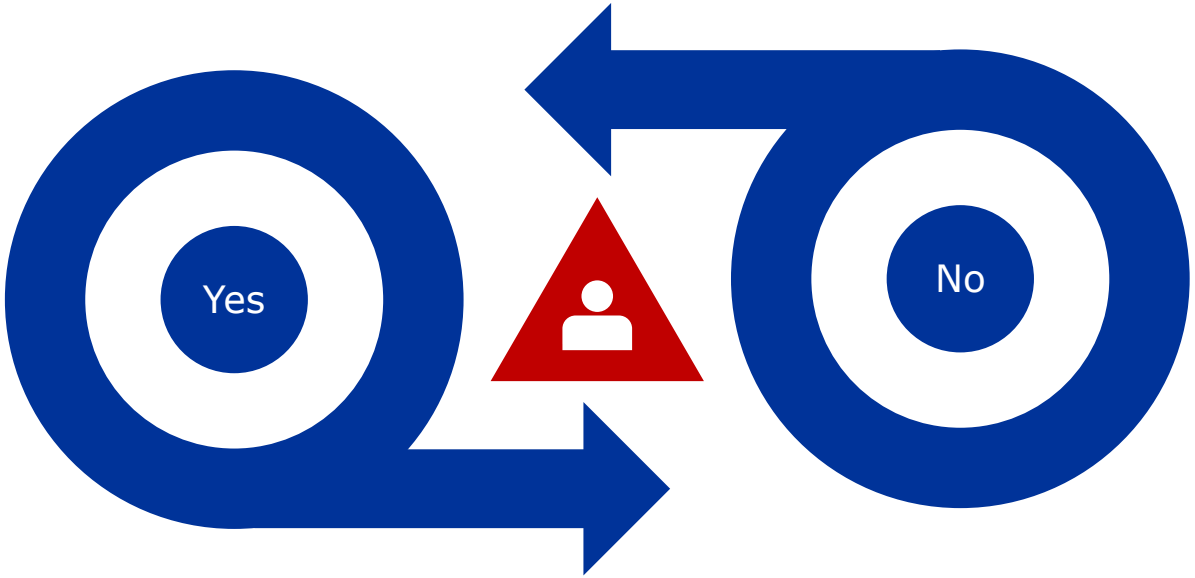
Please follow the instructions and click on the appropriate icon to be directed to the relevant section.

Click the button to start

START

Do I have an EMA account?

Please, click on the **Yes** or **No** buttons.



User registration with EMA

01 **Go to EMA Account Management Portal**

Link: http://register.ema.europa.eu

02 **Create an account**

03 **Request substance, product, organisation and referential (SPOR) unaffiliated role**

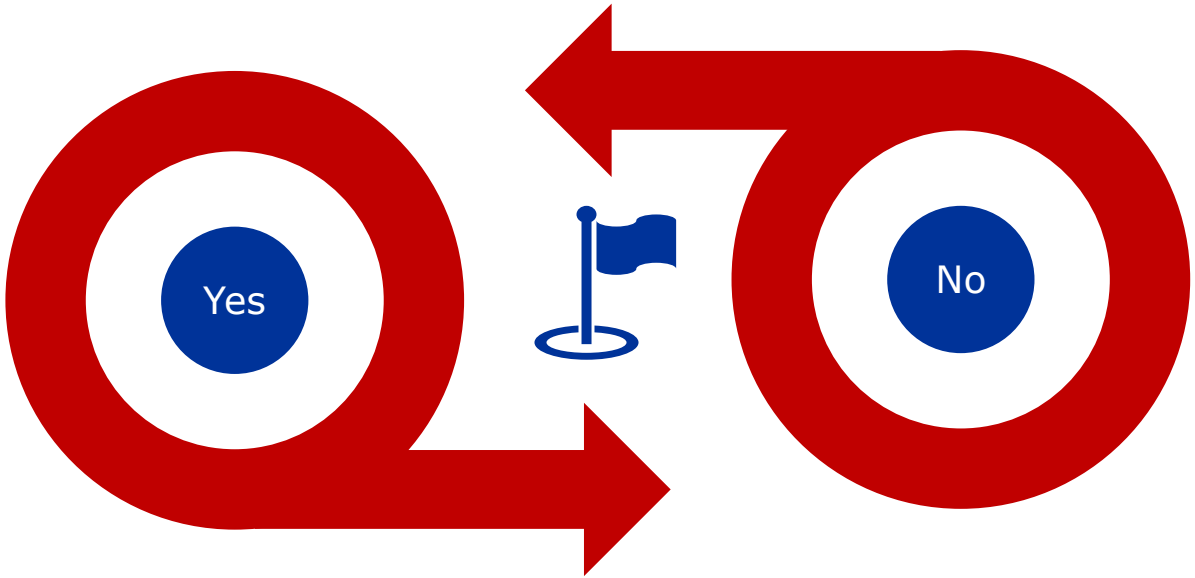
It will be approved automatically

Click to Go Back

Click here for the next step

Is my organisation registered with EMA?

Please, click on the **Yes** or **No** buttons.



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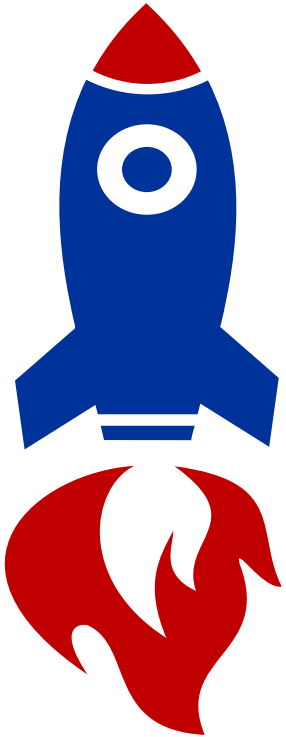
Organisation Registration in OMS



01 **Log into Organisations Management System (OMS) with single sign on**

Link: https://spor.ema.europa.eu/omswi/#/

02 **Search for your organisation**

03 **If organisation is found, return to EMA Account Management Portal and request role for that organisation**

04 **If the organisation is not found, register the new organisation**

Click to Go Back

Click here for the next step

Pharmacovigilance main contact request access to EV

Log into EMA Account Management Portal
Link: http://register.ema.europa.eu

Request role of EU qualified person for pharmacovigilance (QPPV) or registered person (RP)

Raise a Service Desk request
Attach the required registration documents (including the gateway transmission mode)

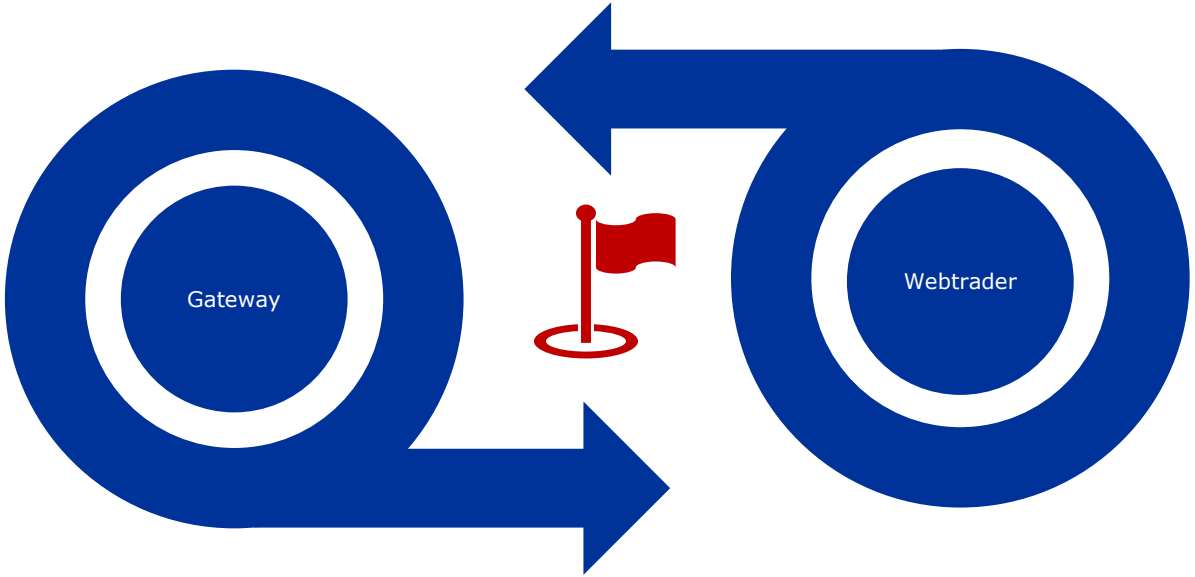
Submit a validation of role request
Add organisation 'ID' and 'Name' in the text box

Click to Go Back

Click here for the next step

Do I need Webtrader or Gateway Transmission mode?

Please, click on the **Gateway** or **Webtrader** buttons.



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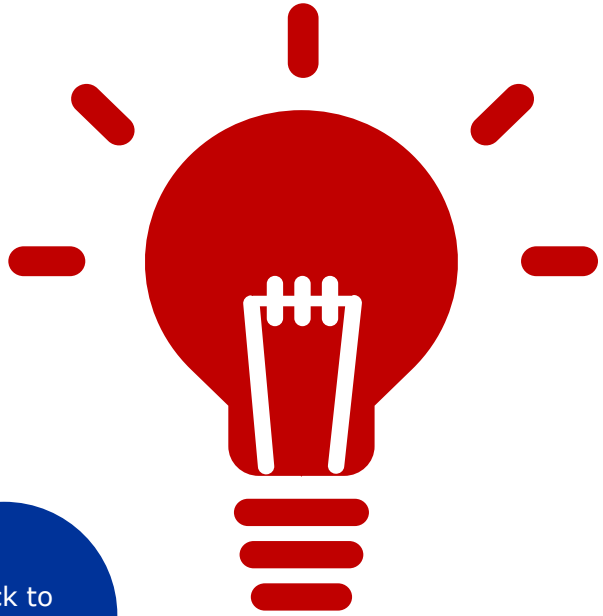
Set a Gateway



Attach the connectivity and encryption forms to the JIRA Service ticket for the ‘QPPV’ / ‘RP’ role validation request.

Click to Go Back

Click here for the next step

Start using EV

Once EMA has your approved role, access your EudraVigilance restricted area. Once there, confirm category, transmission mode and add a regulatory contact point email address.

Click to Go Back

Click to start over