29 February 2024

EMA/385007/2017

Information Management Division

Connecting to the Agency ESTRI Gateway

using an AS2 compatible product

For Safety Reports – ICSRs/ SUSARs

You are required to provide the below information of your gateway and your profile will be created on the EMA system.

Please use this form to enter your organisation details following the example in the [EMA connection gateway template form](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/connection-template-ema-estri-gateway-using-as2-compatible-product_en.pdf).

***Note:***

The organisation identifiers (IDs) assigned as part of the EudraVigilance registration process must be identical to the routing IDs on this form. The Routing IDs must be composed of capital A to Z and/or the numbers 0 to 9 without any special characters. Also note that only standard ASCII characters can be used in the profile information.

|  |  |  |
| --- | --- | --- |
| Community Type | TESTING | PRODUCTION |
| Organisation Name |  |  |
| Routing ID |  |  |
| Address |  |
|  |  |
|  |  |
|  |  |
| Gateway Support Name |  |
| Gateway Support Phone |  |
| Gateway Support Email |  |

|  |
| --- |
| Gateway Transports |
|  | **TESTING** | **PRODUCTION** |
| AS2 IP Address |  |  |
| AS2 Hostname |  |  |
| Receive Port |  |  |
| Transmit Port |  |  |
| Exchange Point |  |  |
| AS2 ID |  |  |
| ***Please note the following items for AS2:****Your AS2 ID must match your routing ID.**We transmit and receive only on the above ports.**MDNs must be sent ASYNCHRONOUSLY.****AS2 partners 🡪 EMA****:**Need to add 18.156.142.227 (PROD and XCOMP), TEST (3.121.50.54) in* *your firewall only if you restrict outgoing traffic at your firewall when sending files to EMA.**Please note that we do not block any incoming traffic, the pgateway is open to entire Internet* |