

PART II. Technical requirements enabling the partners to follow the new procedure for electronic reporting / info for new partners

A. How do you need to adapt your Eudravigilance system in order to be compliant with the new procedure for electronic reporting to the FAMHP?

Partners willing to comply with their obligation to report electronically to the FAMHP, must already be able to send to the EMA (both modules)

I./ Reports from interventional clinical trials that previously needed to be reported to the FAMHP with “AFIGP” as receiverID must also fully comply with the business rules (LINK : http://eudravigilance.ema.europa.eu/human/docs/guid%20Technical%20Documentation%20EMA-H-20665-04-en-Final_Revision_2.pdf) of a clinical trial in general and as these are implemented in the EMA system. Sponsors already had the obligation to send also all these reports to the EMA (EVCTMPROD). According to the new procedure, reporting directly to the FAMHP is therefore not longer required.

II./ Spontaneous reports and reports from non-interventional clinical studies and others (e.g. “registries”, “compassionate use”), for which a reporting obligation to the FAMHP using the “AFIGP” as receiverID exists, must also fully comply with the business rules of a spontaneous report in general and as these are implemented in the Eudravigilance system of the EMA.

(LINK: http://eudravigilance.ema.europa.eu/human/docs/guid%20Technical%20Documentation%20EMA-H-20665-04-en-Final_Revision_2.pdf).

Only at the level of the XML-file, the receiverID must be adapted according to the new procedure namely: from “AFIGP” to “EVHUMAN” (which corresponds to the PM-module of the EMA).

To this end, adaptations are only necessary at the level of the XML header:

See for example the chart here below:

Actual situation :	New situation :
<pre> <?xml version="1.0" encoding="UTF-8" ?> <ichicsrmessageheader lang="en"> <messageformatversion>2.1</messageformatversion> <messageformatrelease>2.0</messageformatrelease> <messagenumb>AGX000000000000XXXX</messagenumb> <messagesenderidentifier>COMPANY* </messagesenderidentifier> <messagereceiveridentifier>AFIGP</messagereceiveridentifier> <messagedateformat>204</messagedateformat> <messagedate>20110225110542</messagedate> </ichicsrmessageheader> <safetyreport lang="en"> --- <receiver> <receivertype>2</receivertype> <receiverorganization>AFIGP</receiverorganization> <receivergivenname>Margriet</receivergivenname> <receiverfamilyname>Gabriels</receiverfamilyname> <receiverstreetaddress>EUROSTATION II, 8ieme etage, Place Victor Horta 40, boite 40</receiverstreetaddress> <receivercity>Brussels</receivercity> <receiverpostcode>B-1060</receiverpostcode> <receivercountrycode>BE</receivercountrycode> <receivertel>3225248373</receivertel> <receiverfax>3225248001</receiverfax> </pre>	<pre> <?xml version="1.0" encoding="UTF-8" ?> <ichicsrmessageheader lang="en"> <messageformatversion>2.1</messageformatversion> <messageformatrelease>2.0</messageformatrelease> <messagenumb> AGX000000000000XXXX </messagenumb> <messagesenderidentifier> COMPANY* </messagesenderidentifier> <messagereceiveridentifier>EVHUMAN</messagereceiveridentifier> <messagedateformat>204</messagedateformat> <messagedate>20110225110542</messagedate> </ichicsrmessageheader> <safetyreport lang="en"> --- <receiver> <receivertype>2</receivertype> <receiverorganization>EVHUMAN</receiverorganization> <receivergivenname>Margriet</receivergivenname> <receiverfamilyname>Gabriels</receiverfamilyname> <receiverstreetaddress>EUROSTATION II, 8ieme etage, Place Victor Horta 40, boite 40</receiverstreetaddress> <receivercity>Brussels</receivercity> <receiverpostcode>B-1060</receiverpostcode> <receivercountrycode>BE</receivercountrycode> <receivertel>3225248373</receivertel> <receiverfax>3225248001</receiverfax> </pre>

* OrganizationID as known by the EMA

It is of great importance that the headquarters which are technically and practically responsible for the electronic reporting process within the organization are involved in the implementation process of this new procedure.

B. Technical problems?

As a partner (following the new procedure), reporting directly to the European central system, you should contact the EMA in case of technical problems: eudravigilance@ema.europa.eu.

In order to receive a reaction from the EMA as soon as possible, it is important to mention the following information in your mail:

- organizationID within the Eudravigilance community
- login as User
- environment in which you experience problems (Test or Production)
- clear description of the problem
- screenshots with error messages if applicable

The ICT division of the FAMHP cannot help you with technical problems/questions related to your electronic reporting process to the Eudravigilance system of the EMA.

The contact address for all other questions (technical ones excluded) related to the official communication and the new procedure for electronic reporting is icsr@fagg.be.

C. Information for new partners

1. New partners, who have previously applied for electronic reporting to the FAMHP:
 - Will be informed personally about the communication;
 - Can immediately follow the new procedure without further testing with the FAMHP (as they have already passed the testing procedure with the EMA);
 - As the FAMHP doesn't want to delay the process of electronic reporting for new partners, they can, if they are not immediately able to send to the EMA modules, still temporarily send to "AFIGP" in case of problems in complying with the new procedure*. More information can be received via icsr@fagg.be.
2. Partners who are not yet able to report electronically and currently accomplish their reporting obligations on paper or e-mail: must submit an implementation plan with timetable to the FAMHP describing how they will switch to electronic reporting*. They should have one person within their organisation trained in Eudravigilance. To meet this obligation, they can send one employee to the Eudravigilance User Training course (for more information: <http://eudravigilance.ema.europa.eu>) who needs to succeed in the exam.
3. Partners with a limited number of reports a year can register in Eudravigilance as webtrader* (more information available on <https://eudravigilance.ema.europa.eu/human/evweb01.asp>) and use the application of the EMA, after they followed the Eudravigilance training course as mentioned above.

Partners acting as webtrader in the Eudravigilance community, are immediately compliant for electronic reporting to the FAMHP and any other partner in the electronic reporting community (EMA, other Member States,...).

D. Remark for all partners

All partners that are not able to comply with the new procedure by the 1st of June 2011, need to submit an implementation plan with timetable to the FAMHP via icsr@fagg.be by the 1st of June 2011.