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Electronic Reporting of Suspected Unexpected Serious Adverse Reactions (SUSARs) related to interventional clinical trials to the Romanian National Agency for Medicines and Medical Devices (NAMMD)

In accordance with Directive 2001/20/EC, sponsors of clinical trials are requested to submit to the National Agency for Medicines and Medical Devices (NAMMD) all Suspected Unexpected Serious Adverse reactions (SUSARs) in relation to interventional clinical trials ongoing in Romania.
The NAMMD has implemented an electronic data exchange system regarding suspected adverse reactions using the webtrader component of EudraVigilance Web Application (EVWEB). The NAMMD requests all Sponsors of clinical trials, initiated or ongoing as of 01 January 2007, to electronically submit SUSARs as Individual Case Safety Reports (ICSRs), in full compliance with ICH E2B(R2)/(M2) and Community guidelines and all MedDRA coded medical information.

The following rules apply:

- Sponsors of clinical trials should report electronically SUSARs occurring in Romania to both EudraVigilance Clinical Trial Module (EVCTM) with the message receiver identifier **EVCTMPROD** and to NAMMD with the message receiver identifier **NMA**.

- Sponsors of clinical trials approved in Romania shall report SUSARs occurring outside Romania, including all SUSARs occurring outside the EEA, directly to the EVCTM, using the message receiver identifier EVCTMPROD. The NAMMD does not wish to receive SUSARs of foreign origin even if the same study is conducted in Romania and/or if a study with the same investigational medicinal product is conducted in Romania. The European Medicines Agency (EMA) has provided the NAMMD with access to EudraVigilance, therefore enabling the NAMMD to retrieve such reports directly. Reporting obligations are met by submission to the EVCTM of reports on SUSARs occurring outside Romania.

- Reporting of other serious events related to clinical trials are not requested.

- For detailed reporting procedures, sponsors shall follow the Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use ('CT-3') (2011/C 172/01).

- For electronic transmission, the NAMMD uses the Eudravigilance Webtrader, therefore Sponsors of Clinical Trials need no compatibility test with the NAMMD. The NAMMD does not require sponsors already in production with the EVCTM to perform additional tests for SUSAR electronic transmission.

Sponsors of clinical trials not yet reporting electronically should start preparations for SUSAR electronic transmission following the rules and procedures for reporting to EudraVigilance, including testing with the EMA. For details, please refer to http://eudravigilance.ema.europa.eu

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RETROSPECTIVE REPORTING OF SUSARs TO THE EVCTM (BACKLOG MANAGEMENT)

For clinical trials started or ongoing after 01 January 2007, the NAMMD requests sponsors to retrospectively report to the EVCTM, using the message receiver identifier EVCTMPROD, SUSARs originating in Romania and not already submitted electronically to the EudraVigilance. SUSARs to be transmitted retrospectively shall comply with ICH and EU guidelines and standards, including MedDRA coded medical information.

To exclude them from expedited reporting compliance checks, retrospectively transmitted SUSARs need to be clearly flagged in the EudraVigilance Clinical Trial Module. This requires use in the ICH M2 message header identifier M1.1 "Message type" of the term "backlog" instead of "ichicsr". The field value is case sensitive and shall be reported in lower case. Backlog messages shall not contain more than 100 retrospective SUSARs. Prior to transmitting retrospective SUSARs to the EVCTM production environment, senders of retrospectively transmitted SUSARs shall perform some form of initial testing with the EMA. Alternatively, retrospective SUSARs may be transmitted via physical media in line with applicable ESTRI recommendations (floppy disks, CD-R, DVD).

Sponsors shall submit to the NAMMD a list of all the SUSARs that have occurred in Romania since 01 January 2007, explicitly stating for each SUSAR whether a report has been sent to the EVCTM.

This letter supersedes all previous documents describing NAMMD requirements for electronic transmission of SUSARs and shall be in force as of 01 August 2014.

Marius SAVU, M.D.,
President of the National Agency for Medicines and Medical Devices, Romania