**Electronic Reporting of Suspected Unexpected Serious Adverse Reactions (SUSARs)**

**related to interventional clinical trials ongoing in Romania**

In accordance with Directive 2001/20/EC, sponsors of clinical trials shall report all Suspected Unexpected Serious Adverse Reactions (SUSARs) in relation to interventional clinical trials to the competent authorities in all Member States concerned (directly or indirectly through the EudraVigilance Clinical Trial Module). SUSARs should be in accordance with the established reporting rules based on the principles outlined in 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).

The following rules apply for reporting SUSARs originating in Romania:

- Sponsors of clinical trials shall use electronic reporting of SUSARs occurring in Romania directly to the EudraVigilance Clinical Trial Module (EVCTM), with the Message/Batch receiver identifier: EVCTMPROD.
- Fatal or life-threatening SUSARs are to be reported as soon as possible and in any case no later than seven days after becoming aware of the case. If the initial report is incomplete, e.g. if the sponsor has not provided all the information/assessment within seven days, the sponsor is to submit a completed report based on the initial information within an additional eight days.
- SUSARs which are not fatal and not life-threatening are to be reported within 15 days.
- NAMMD has access to all information in the Eudravigilance database and does not require copies of these reports.
- 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).

This letter supersedes all previous documents describing NAMMD requirements for SUSARs electronic transmission and shall be in force as of 22 November 2017.