

# Reporting requirements of suspected unexpected serious adverse reactions (SUSARs) applicable to Marketing Authorisation Holders

In accordance with the European Union legislation (article 17 of Directive 2001/20/EC) the sponsor of clinical trials authorised in the European Economic Area shall ensure that all relevant information about reports of SUSARs is recorded and reported to the competent authorities in all concerned member states. Cases of SUSARs associated with clinical trials authorised in the European Economic Area should be transmitted electronically as from May 2005. All sponsors are responsible for implementing standards that ensure electronic communication with regulatory authorities in full compliance with the ICH E2B (R2) standards and European Union (EU) guidelines.

## **Reporting requirements of SUSARs**

- SUSARs originating from Estonia (national):

SUSARs occurring in a study centre in Estonia should be sent directly to the European Medicines Agency via EudraVigilance database (through Gateway or Webtrader). In addition, please send the report as CIOMS form to the Estonian State Agency of Medicines to the e-mail [clinical.trials@ravimiamet.ee](mailto:clinical.trials@ravimiamet.ee)

National SUSARs that are fatal or life threatening should be reported within 7 days following the receipt of the information and followed-up within an additional period of 8 days. Other national SUSARs (not fatal and not life-threatening) should be reported within 15 days.

- SUSARs occurring outside Estonia:

SUSARs originating from other Member States or third countries should be only sent electronically to the EudraVigilance database.

## **Further information about clinical trials can be obtained from:**

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