

Explanatory note

Clinical Trial Vigilance Data Reporting (SUSARs) Excluding Health Products

From 13th April 2015, the clinical trial vigilance data reporting (SUSARs) will be modified as follows: only the CIOMS form should be addressed to ANSM. The accompanying form is not anymore mandatory (Withdrawn). The other procedures are not modified.

Naming rules of the CIOMS form



> Each SUSAR must be reported in an individual email message.

It should be sent to : declarationsusars@ansm.sante.fr

> The subject line should be written as follows:

SUSAR_YYYYMMDD_name of substance (or trial code no.)_Worldwide unique case identification number_CT

Ex : SUSAR_20140115_SUBSTANCE_123456789_CT

> The following document should be attached to the message:

- CIOMS form (PDF format) / File name labelled as follows: *YYYYMMDD_name of substance (or trial code no.)_Worldwide unique case identification number_CT_C*

Ex : 20140115_SUBSTANCE_123456789_CT_C

> An acknowledgement of receipt will be automatically sent by return email.