

Explanatory note

Clinical Trial on medicinal products - Vigilance
Data Reporting (SUSARs, expected serious
adverse reactions and other serious adverse
events)

Naming rules of the CIOMS form

- **Suspected unexpected serious adverse reaction (SUSAR)**

> 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

Particular case:

SUSARs regarding a clinical trial on medicinal products involving healthy volunteers
(whatever the clinical trial phase):

> The subject line should be written as follows:

EC-VS-SUSAR *YYYYMMDD_name of substance (or trial code no.)_Worldwide unique case identification number_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.

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- **Expected serious adverse reaction or other serious adverse event (clinical trials on a medicinal product involving healthy volunteers)**

Expected serious adverse reaction which occurred in France :

> Each notification 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:

EC-VS-EIGA *yyyymmdd_name of substance (or trial code no.)_Worldwide unique case identification number_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

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

Other serious adverse event which occurred in France :

> Each notification 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:

EC-VS-EVIG *yyyymmdd_name of substance (or trial code no.)_Worldwide unique case identification number_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

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