



Explanatory Note

Clinical Trial on medicinal products – Vigilance Notifications by sponsor of SUSARs, expected serious adverse reactions and others serious adverse events

Naming rules



1. Notification of 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 of the email should be written as follow:

SUSAR_aaaammjj_name of substance (or trial code)_**EUDRACT Number_Country initials**_Worldwide unique case identification number_(0 if initial notification or 1/2/3 etc. for follows-up) _CT

Ex : SUSAR_20190406_substance_2019-004525-56_FR_528963458_(0)_CT

- The CIOMS form or ICSR (R3) in PDF format should be annexed with the file name as follow:

aaaammjj_name of substance (or trial code)_**EUDRACT Number_Country initials**_Worldwide unique case identification number_(0 if initial notification or 1/2/3 etc. for follows-up) _CT_C

Ex : 20181123_substance_2015-004523-12_FR-2018-000152_(1)_CT_C

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

2. Notification of SUSAR occurred in a healthy volunteer

- The subject line of the email should be written as follow:

EC-VS-SUSAR_aaaammjj_name of substance (or trial code)_**EUDRACT Number_Country initials**_Worldwide unique case identification number_(0 if initial notification or 1/2/3 etc. for follows-up) _CT

Ex : EC-VS-SUSAR_20190406_SUBSTANCE_2019-004525-56_FR_528963458_(0)_CT

- The CIOMS form or ICSR (R3) in PDF format should be annexed with the file name as follow:

aaaammjj_name of substance (or trial code)_**EUDRACT Number_Country initials**_Worldwide unique case identification number_(0 if initial notification or 1/2/3 etc. for follows-up) _CT_C

Ex : 20190406_SUBSTANCE_2019-004525-56_FR_528963458_(0)_CT_C

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



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

3.1. Notification of expected serious adverse reactions involved healthy volunteer and 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 of the email should be written as follows:

EC-VS-EIGA_ aaaammjj_name of substance (or trial code)_**EUDRACT Number_Country initials_**Worldwide unique case identification number_(0 if initial notification or 1/2/3 etc. for follows-up)_**CT**

Ex: EC-VS-EIGA_20180115_SUBSTANCE_2015-004525-22_UK_123456789_(0)_CT

- The CIOMS form or ICSR (R3) in PDF format should be annexed with the file name as follows:

aaaammjj_name of substance (or trial code)_**EUDRACT Number_Country initials_**Worldwide unique case identification number_(0 if initial notification or 1/2/3 etc. for follows-up)_**CT_C**

Ex: 20180115_SUBSTANCE_2015-0045-22_UK_123456789-(0)_CT_C

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

3.2. Notification of serious adverse events involved healthy volunteer and 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 of the email should be written as follows:

EC-VS-EVIG_ aaaammjj_name of substance (or trial code)_**EUDRACT Number_Country initials_**Worldwide unique case identification number_(0 if initial notification or 1/2/3 etc. for follows-up)_**CT**

Ex: EC-VS-EVIG_20180115_SUBSTANCE_2016-004585-43-UK_123456789_(2)_CT_C

- The CIOMS form or ICSR (R3) in PDF format should be annexed with the file name as follows:

aaaammjj_name of substance (or trial code)_**EUDRACT Number_Country initials_**Worldwide unique case identification number_(0 if initial notification or 1/2/3 etc. for follows-up)_**CT_C**

Ex: 20180115_SUBSTANCE_2016-004585-43-UK_123456789-(2)_CT_C

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