Explanatory Note

Clinical Trial on medicinal products conducted in healthy volunteers in France under the Jardé law – Vigilance Notifications by sponsor to the ANSM of SUSARs, expected serious adverse reactions and others serious adverse events involved a healthy volunteer

1. SUSAR notification involved a healthy volunteer in France and abroad

- **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_**CT**

Ex : EC-VS-SUSAR_20190406_SUBSTANCE_2019-004525-56_FR_528963458_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.

NB: Also report to the Eudravigilance database (EVCTM clinical trials module).

2. 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 follow**:

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

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

3. 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 follow**:

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

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

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