Explanatory Note

Clinical Trial on medicinal products – Notifications by sponsor of new events, Urgent Safety Measures (USM) and Annual Safety Report (ASR) / Development Safety Update Report (DSUR)

Notifications

Each notification must be reported in an individual email message

It should be sent to: vig-essaiscliniques@ansm.sante.fr

1.1. For new event/USM, with the attached ANSM document entitled « Notification form of a new event and/or Urgent Safety Measure (USM) concerning clinical trials on medicinal product» available on its website (Accueil > Activités > Médicaments et... > Avis aux promoteurs - Formulaires and with any other relevant documents (PDF or word format).

1.2. For ASR/DSUR, with the attached Annual Safety Report (PDF or word format)

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

Naming Rules

1. New event with or without Urgent Safety Measure (USM) notification

The subject line of the email should be written as follows:

- **In case of new event without Urgent Safety Measure(s):**

FN_EUDRACT Number*_DCI or substance name (or trial code)_(0 if initial notification or 1/2/3… for follow-up)

- **In case of new event with Urgent Safety Measure(s):**

MUS_EUDRACT Number*_DCI or substance name (or trial code)_(0 if initial notification or 1/2/3… for follow-up)

- **In case of new event without or with Urgent Safety Measure(s) occurred in a First in Human clinical trial involving healthy volunteers in France:**

EC_VS_FIM_FN_ EUDRACT Number*_DCI or substance name_(or trial code)_(0 if initial notification or 1/2/3… for follow-up)

EC_VS_FIM_MUS_ EUDRACT Number*_DCI or substance name (or trial code)_(0 if initial notification or 1/2/3… for follow-up)

**if many clinical trials are concerned, please specify the EUDRACT number of the last clinical trial authorised in France*

Naming Rules

2. Annual Safety Report Transmission (ASR/DSUR)

The subject line of the email and attached document should be written as follows:

ASR_EUDRACT Number*_DCI or substance name (or trial code)_version

**if many clinical trials are concerned, please specify the EUDRACT number of the last clinical trial autorised in France*