Explanatory Note

Clinical Trial on medicinal products – Notifications by sponsor of new events and Urgent Safety Measures (USM)

Notifications

Each notification must be reported in an individual email message to the following email address: vig-essaiscliniques@ansm.sante.fr

with the attached ANSM document entitled « Notification form of a new event and/or Urgent Safety Measure (USM) concerning clinical trials on medicinal product**»** (***https://ansm.sante.fr/vos-demarches/industriel/declaration-devenements-et-deffets-indesirables-graves-de-faits-nouveaux-avec-ou-sans-mesures-urgentes-de-securite-rapport-annuel-de-securite***) and any other relevant documents (PDF or word format).

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

Naming Rules

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)
- **In case of new event with Urgent Safety Measure(s):**
  MUS_EUDRACT Number*_DCI or substance name (or trial code)
- **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
  EC_VS_FIM_MUS_ EUDRACT Number*_DCI or substance name

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