Agence nationale de sécurité du médicament et des produits de santé

Information to clinical trials sponsors

Set up of Unit in charge of "Early phase Clinical Trials" and consequences for sponsors

In accordance with the action plan announced by the Ministry of Health, the ANSM is about to implement a dedicated Unit in charge of early phase clinical trials. The whole instruction process of all early phase clinical trials will be organized in the Division of Authorization and Innovation Policies specialized in the management of such clinical trials.

From the 18th of December 2017, this Unit will handle all early phase clinical trials which are defined as First in human / early clinical trials including those which generate initial knowledge in humans on tolerability, safety, pharmacokinetics and pharmacodynamics for medicines[1]. **These trials** are undertaken in healthy volunteers or patients. **These are phase 1 or phase1-2 trials (as soon as phase 1 takes place in the French territory).**

All procedures will be handled by this Unit: National procedures ("classic" or "Pilot Phase-EU regulation") and European (VHP = Voluntary Harmonized Procedure).

This Unit will not be in charge of clinical trials involving gene and cell therapy products, cells, tissues, organs, vaccines and medical devices.

1. concerning electronic exchanges (e-mails) related to the implementation and conduct of clinical trials

All e-mails related to clinical trials on medicinal products will have to be sent to usual e-mail addresses:

- aec-essaiscliniques@ansm.sante.fr
- ams-essaiscliniques@ansm.sante.fr
- phasepilote.reglement@ansm.sante.fr (in case of Pilot Phase-EU regulation procedure)

➢ formatting

A defined formatting of the subject of e-mails and naming of files proposed in the "*Practical Information Guide for Applicants: Clinical Drug Trials submitted within the Pilot Phase to ANSM (French National Agency for Medicines and Health Products Safety) and the CPP (French Ethics Committee*)" is highly recommended.

➢ identification

In order to allow an optimal dispatching to this Unit, the word "PREC"must be added to the mail object of all electronic exchanges.

All these information will be detailed in the next updated version of the "*Notice to Applicants of clinical trials on medicinal products including clinical trials on advanced therapy medicinal products (ATMP) – Medicinal product trial implementation and procedures in France / volume 1*". This version is expected to be online within February 2018.

[1] Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products (EMEA/CHMP/SWP/28367/07 Rev. 1)

2. concerning e-mails related to vigilance of clinical trials

These vigilance signals must be sent electronically to the usual dedicated boxes.

- identification

In order to allow an optimal dispatching to the dedicated Unit, it is necessary

- for declarations of new developments, urgent safety measures, annual safety reports: **add in the subject of the e-mail the words "PREC".**

- for SUSARs statements: to follow the instructions of the ANSM available on the site at http://ansm.sante.fr/Activites/Medicaments-et-produits-biologique/Avis-aux-promoteurs-Formulaires

All these information will be detailed in the next updated version of the "*Notice to Applicant on Vigilance of Clinical Trials / Volume 2*".