Agence nationale de sécurité du médicament et des produits de santé

# Information Update

## Application of the Regulation (EU) on clinical trials on medicinal products: ANSM to implement a pilot phase

**A European regulation on clinical trials on medicinal products for human use was published in the Official Journal of the European Union on 27 May 2014. It should enter into effect as of 28 May 2016 provided that a single European portal is implemented for all clinical trial stakeholders.**
**In the interim, the French National Agency for Medicines and Health Products Safety (ANSM) is implementing a pilot phase with a view to applying this regulation, and is doing so in cooperation with clinical trial stakeholder representatives (academic and industrial sponsors, Research Ethics Committees). Thirteen Research Ethics Committees (known as CPPs in French for *Comités de Protection des Personnes*) out of the 39 existing French CPPs have volunteered to take part in this pilot phase.**

### The European regulation: context and objectives

A European regulation on clinical trials on medicinal products for human use was published in the Official Journal of the European Union on 27 May 2014[1].
This new regulation aims to:

- reinforce European innovativeness and attractiveness in the biomedical research sector
- facilitate patient access to innovative treatments with guaranteed safety on the European territory
- reinforce the transparency of and access to clinical trial data from the moment the trials are authorised to the moment their results are published.

This regulation provides for:

- the implementation of a rapid, centralised and coordinated process for assessing requests for authorisation of a clinical trial and modifications whenever a trial is being conducted in at least one European Union Member State. This regulation establishes the submission by the clinical trial sponsor of one application dossier through a single submission portal that will group all the information pertaining to this clinical trial and will be partially accessible to the public.
- a two-part scientific and ethical review to be conducted within a specified deadline:
    - Part I: an *assessment coordinated between relevant Member States* and leading to a single decision
    - Part II: an *assessment performed by each relevant Member State* and leading to a national decision
- the concept of tacit authorisation.

### Implementation of a pilot phase with a view to applying this regulation

Applying this regulation requires the competent authorities and the Research Ethics Committees of the Member States to adopt new work methods. To prepare for this, particularly with respect to dossier assessment deadlines and organising the coordination of the 39 existing CPPs, the ANSM is implementing a pilot phase.
This will enable the new organisation required by this regulation to be simulated while complying with current regulations.

Since April 2014, this project, which is being overseen by the ANSM's Evaluation Division, has been promoted by representatives of all stakeholders: representatives of academic and industrial sponsors, of CPPs, of the *Direction Générale de la Santé* (French General Health Directorate) and of the ANSM to define the various organisational phases of the assessment process on the one hand and to identify solutions for ensuring cooperation between the ANSM and the CPPs at each dossier review phase on the other hand.

[1] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014, repealing Directive 2001/20/EC

It is important to specify that:

- to date, 13 CPPs have volunteered for this pilot phase
- sponsor participation is also voluntary
- France is the first European country to launch a pilot phase in preparation for the application of the European regulation.

**What does this pilot phase mean for each partner, in concrete terms?**

For the sponsors:

- preparing for the new procedures related to the application of the European regulation
- implementing a single submission review calendar
- receiving a single ANSM authorisation notification and a single CPP opinion notification
- eventually, facilitating the procedure for submitting clinical trial authorisation requests.

For the CPPs:

- standardising clinical trial management and assessment practices
- preparing for the future assessment calendar restrictions defined by the European regulations
- strengthening relationships with the ANSM.

For the ANSM:

- preparing for the centralisation of clinical trial authorisation requests
- reinforcing the ANSM's positioning on a European level
- strengthening relationships with the CPPs.

## Preliminary pilot phase calendar

- 29 June 2015: informational meeting on the project entitled, "Pilot phase for the European regulation on clinical trials on medicinal products"
- September 2015: launch of the pilot phase.