Agence nationale de sécurité du médicament et des produits de santé

Information bulletin

Enforcement of the European regulation on clinical trials on medicinal products: assessment six months into the pilot phase

In order to prepare for the enforcement[1] of the European regulation on clinical trials on medicinal products for human use (EU Regulation no. 536/2014), the *Agence nationale de sécurité du medicament* (French National Agency of Medicine and Health Product Safety) (ANSM) set up a pilot phase in September 2015, in conjunction with the stakeholders concerned: academic and industrial sponsors, and ethics committees (CPP).
During this pilot phase, the ANSM and the CPP undertake to evaluate trials within 60 days at the latest, and to forward a single notification to the sponsor which will include the ANSM decision and the CPP opinion. France was the first European country to launch a pilot phase and the first six-month milestone demonstrates strong collective mobilization which reinforce appeal for clinical research in France.

The first thing to come out of the pilot phase is positive progress for all concerned:

- Cooperative support, strengthening of relations and improved communication between sponsors, the CPP and the ANSM
- Significant contribution from sponsors (academic and industrial)
  - Better visibility of application processing progress with a single application processing schedule
  - Streamlined procedures with same-day complete dossier submission and receipt of a single notification
- Strong mobilisation from voluntary ethics committees (21 out of the 39 existing) and from the ANSM
  - Careful preparation ahead of future assessment deadline constraints
  - Harmonisation of clinical trial management and authorisation practices

6-month assessment of trials received during the pilot phase (28 September 2015 to 28 March 2016)

51 clinical trial authorisation applications were received during the pilot phase out of the 465 total applications received by the ANSM (11% of applications).

For the 51 applications:

Sponsor type		Trial type				Trials involving research centres	
academic	industrial	Phase 1	Phase 2	Phase 3	Phase 4	national	international
18	33	15	13	17	6	19	32

Clinical trials processed by 28 March 2016 (applications for which a notification was issued)

26 clinical trial authorisation applications are closed out of the 51 received during the pilot phase

Sponsor type		Trial type				Trials involving research centres	
academic	industrial	Phase 1	Phase 2	Phase 3	Phase 4	national	international
11	15	8	7	7	4	12	14

[1] Initially set to take effect in May 2016, enforcement shall only become effective with the setting up of the single European portal.

Out of the 26 applications, 21 were authorised by the ANSM and received a favourable opinion from the relevant CPP.
The average time frame of final notification for initiation of trials is 57.4 days.

Time frames were also met at each stage of the process (admissibility, question submission, final notification). One decision was returned within the 60-day deadline imposed by the current legislation.

In light of this initial assessment, improvements were made and the practical guideline was clarified, especially for understanding the D45 milestone, which is the deadline for sponsors to respond to questions submitted by the ANSM and/or the relevant CPP. An updated version of the notice to sponsors will shortly be available on the ANSM website.

Stakeholders continue to work together. The new processing procedures will be gradually consolidated through to enforcement of the European regulation.

Further reading:
Enforcement of the European regulation on clinical trials on medicinal products: the ANSM starts a pilot phase – Information update (14/04/2015)

See section Pilot phase: enforcement of Regulation (EU) no. 536/2014 of the European Parliament and of the Council of 16 April 2014 repealing Directive 2001/20/EC