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 one year 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 (EC).
During this pilot phase, the ANSM and the EC 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 EC opinion. France was the first European country to launch a pilot phase and the first year milestone confirms the strong collective mobilization which reinforce our sustain appeal for clinical research in France.

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

- Collective adherence and constructive exchanges between sponsors, the EC and the ANSM
- Increase of sponsors' contribution (academic and industrial)
- Strong mobilisation from voluntary ethics committees (21 out of the 39 existing) and from the ANSM

1 year statement of clinical trials received during the pilot phase (28 September 2015 to 30 September 2016) versus 6-month statement (28 September 2015 to 28 March 2016)

112 clinical trial authorisation applications were received as part of the pilot phase out of the 897 total applications received by the ANSM (12,5 % applications) during one year.

This represents an increase of more than double files compared to the first 6 months (51 files submitted during the first 6 months of the pilot phase, represents about 11% of applications received by ANSM)

Comparatively for these112 applications:

	Sponsor type		Trial type				Trials involving research centres	
	academic	industrial	Phase 1	Phase 2	Phase 3	Phase 4	national	international
First 6 months (51 files)	18	33	15	13	17	6	19	32
12 months (112 files)	50	62	24	28	53	7	52	60

Clinical trials processed by 30 September 2016 (applications for which a notification was issued)

89 clinical trial authorisation applications are closed out of the 112 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
39	50	18	22	42	7	39	50

[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 89 applications, 73 were authorised by the ANSM and received a favourable opinion from the relevant EC.
The average time frame of final notification for initiation of trials is 64,3 days.

Time frames were overall met at each stage of the process (admissibility, question submission, final notification). In the majority of cases one decision was returned within deadline imposed by the current legislation.

In light of this second assessment, and in light of recent French legislative and regulatory modifications, some organizational changes as part of the extension of the pilot phase to all EC are described in an updated version of the notice to sponsor which is available on the ANSM website.

The mobilization of all the stakeholders will continue in the context of the implementation of the new regulatory and legislative changes, aiming to maintain and stabilize the French organizational process for the implementation of application of the European Regulation.

Further reading:

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) (18/01/2017) (320 ko)

Enforcement of the European Regulation on Clinical Trials on Medicinal Products : assessment six months into the pilot phase - Information bulletin (19/04/2016) (128 ko)