Ninth survey on the Attractiveness of France for International Clinical Research"

Pharmaceutical companies are calling on stakeholders to continue mobilising for clinical research in France

The ninth survey commissioned by Leem on the "Attractiveness of France for International Clinical Research" takes stock of the research undertaken by the pharmaceutical industry between 1 January 2016 and 31 December 2017. Updated every two years since 2002 using the same methodology, this survey monitors and assesses France's standing in the face of global competition, identifying its strengths and weaknesses as the basis for proposing ways to move forward.

This year, the Leem survey has been expanded by adding an international comparison based on an analysis of the *clinicaltrials.gov* database, which supplements the survey conducted among pharmaceutical companies in France.

THE MAIN LESSONS LEARNT

Clinical research is evolving in a fiercely competitive international setting.

- In 2017, the pharmaceutical industry initiated more than 2,600 clinical drug trials.
- The United States/Canada region was involved in 57% of these new industry-sponsored clinical trials while Europe accounted for 38% of them.
- France for its part was involved in 11.9% of the new clinical trials launched worldwide, i.e. a total of 313 trials, behind the United Kingdom (17.9%), Germany (17.3%) and Spain (14.5%).

Tough years for French clinical research.

The period that this survey set out to assess was a complicated one for French clinical research. In late 2016, several changes simultaneously made to the regulatory framework (Jardé law, random CPP[1] selection, single agreement) were imposed on clinical research stakeholders, all of which required change management interventions and impacted on their activities.

- Between 2015 and 2017, the number of new industry trials initiated in France fell on average by 13% per year. This decline is greater than that of our European neighbours (-8% per year on average in Germany, -2% per year on average in Spain and stable in the United Kingdom).

[1] CPP: Institutional Review Board (USA) or Ethics Committee (UK)

- France's participation in new phase 1 industry trials was 6% over this period, far behind its European competitors (United Kingdom 12%, Germany 10%) and even further behind the United States, which is involved in 48% of these early trials.
- Approval times have lengthened and still exceed the regulatory timescales; as a result, it takes nearly 7 months between approval of an initial application and inclusion of the first patient.

France's main strengths.

- Cancer therapy is a field in which France still ranks high, participating as it does in 19% of oncology trials initiated worldwide and in 45% of industry trials opened for this disease in France.
- Rare diseases account for 14% of all trials conducted and as such are also a recognised area of excellence.

It should be noted that these two areas of French expertise are also given support through dedicated public health plans designed to build links between research, innovation and excellence in care.
More generally, French clinical research relies for its effectiveness on the ability of clinical trial centres to recruit patients into clinical trials.

- French investigators across more than 3,300 centres that have opened are meeting 85% of their recruitment targets for the 200 trials that completed the patient inclusion phase during the survey period (up to 100% in oncology).

The Strategic Council for the Healthcare Industries (CSIS): measures recently taken and statement of intent.

In 2018, a number of measures are expected to enhance France's appeal as a clinical research destination: the introduction by ANSM of an "early phase" unit and of fast-track schemes, the new law on random CPP selection, further implementation of the single agreement.

Making France more attractive for clinical research was one of the key issues raised at the latest meeting of the Strategic Council for the Healthcare Industries in July 2018. The government's stated objective is for France to be at the forefront of European clinical research within 5 years.

"*The CSIS was the springboard for positive action.*", Leem Director General Philippe Lamoureux says. "*Among its attendees were Health authorities, hospitals, CPPs and industry ... All these stakeholders are mobilised to build on France's appeal as a clinical research destination. We hope their effects will soon be seen, especially an increase in the number of phase 1 and 2 industry trials initiated in France, because attracting support for the early-stage clinical development of new drugs is the first step to providing French patients with access to the innovations currently being tested".*

LEEM WANTS TO FOCUS ON FOUR PRIORITIES AND CONCRETE WAYS FORWARD

PRIORITY 1
Shorten times for regulatory approval and inclusion in clinical trials.

WAYS FORWARD

- A "clinical trials" plan is already under way at ANSM with a fast track scheme and a dedicated early trials unit.
- A new information system has been installed within the CPPs.
- A new random selection method has been voted in by Parliament for the assignment of dossiers to the CPPs.

PRIORITY 2
Increase patient inclusion in the clinical trial centres

WAYS FORWARD
Better identify which patients to include (reliance on molecular tests, closer links between retail pharmacies and hospitals, etc.) and better inform patients about clinical research

PRIORITY 3
Promote a network of multi-skilled clinical research professionals

WAYS FORWARD

- Improve initial and in-service clinical research training for doctors.
- Attract mathematicians, artificial intelligence specialists.
- Develop public-private partnerships through staff exchanges
- Promote interactions with patient associations.

PRIORITY 4
Incorporate data use into the research process

WAYS FORWARD

- Develop expertise and the inclusion of study-based data generated under real-life conditions of use
- Make better use of the personal data produced by patients throughout their care pathway

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