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*Eighth survey on the "Attractiveness of France for International Clinical Research"*

# Leem is calling on all clinical trial stakeholders to enhance France's role in future research

The eighth survey on the[1]"Attractiveness of France for International Clinical Research", conducted by Leem between January 1st and December 31st assesses the current status of research undertaken by the pharmaceutical industry. This survey has been updated every two years since 2002 using the same methodology. It serves to measure France's global competitiveness and assess its strengths and areas of excellence. It also highlights the potential for progress and emerging trends at a time when the regulatory environment in France and Europe is undergoing change.

**France has continued to be at the forefront of global clinical research, with 10% of international studies conducted in France[2]. French patients account for 8.8% of the total number of patients included in the international studies recorded in Leem 2016 survey, compared with 5.9% in 2014. This increase is due in part to the higher number of phase III and IV clinical trials conducted in France, which by definition include more patients.**

This stability should not lead stakeholders involved in clinical research in France to relax their efforts. **The importance of clinical research in the development of innovative medicines and the intensity of international competition together mean that France's position must be strengthened.**

This is particularly necessary as some signals switch to orange: ***"trial setup times still overly lengthy despite the adoption of the Sole Agreement, - decline in certain therapeutic areas in France, - reduction in the number of early-phase trials, poorer representation of France in Europe-wide clinical trials, strong competition from Eastern European countries ... Leem is urging all public-sector and private-sector research stakeholders to take action to consolidate, streamline and promote the pivotal role that clinical research plays in future innovation",*** **says Jérôme Bouyer, Chairman of Leem Scientific Affairs Committee.**

## France has the wherewithal to conduct high-quality clinical research but has registered a decline in early-phase studies in therapeutic areas other than haemato-oncology

16,622 patients were enrolled in the clinical trials conducted by the 30 companies who took part in the 2016 edition of the Leem survey (versus 14,634 in 2014), i.e. an increase of 14%.

Early-phase (Phase I) studies accounted for 17% of all studies (versus 20% in 2014) and were primarily concerned with haemato-oncology. Phase III/IV studies accounted for 56% of studies versus 50% in 2014.

The focus on early-phase trials in haemato-oncology appears to make clinical research in this area one of the France's main pull factors when it comes to international clinical research.

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[1] The eighth Leem survey was compiled in 2016 on the basis of responses received from 30 pharmaceutical companies representing 62% of the French pharmaceuticals market.

[2] Industry-sponsored interventional studies registered on the website www.clinicaltrials.gov in the period 2014-2015.

### Key figures: distribution of studies by therapeutic area

- The analysis of 507 pharma-led trials conducted in France shows that haemato-oncology increased in share from 41% in 2014 to 45% in 2016.
- Of the 87 phase I trials recorded in 2016, 90% of the trials conducted were in haemato-oncology compared with 61% in 2014 (out of 116 trials).
- The percentages of trials conducted for infectious diseases (13% across all phases) and rare diseases (5% across all phases) remain significant, thereby consolidating the position of France in these therapeutic areas.
- The therapeutic areas comprising cardiovascular disease & metabolism/diabetes and immune-inflammatory disorders stabilised in 2016, accounting respectively for 12% and 7% of trials (versus 9% and 8% in 2014).
- In contrast, neurology/psychiatry trials are finding it increasingly difficult to recruit patients and account for only 2% of phase I trials compared with 11% in 2014, suffering a significant decrease in trials across all phases from 10% in 2014 to 6% in 2016.

## France still has improvements to make, especially in terms of trial setup times.

The new legislative environment which has emerged since the 2014 survey (come into force of the Jardé Law, Solee Agreement and anticipation of the new EU regulation introducing administrative assessment and authorisation time limits of 60 days, scheduled to take effect in autumn 2018) has prompted France to take measures to reduce trial start-up times while maintaining a high level of safety for patients.
The survey shows that this time limit has not been met in almost half of the clinical trials in which France was asked to be involved.

### The numbers: clinical trial setup times

- The median time elapsed between the submission of a clinical research application to ANSM and its approval lengthened from 55 days in 2014 to 57 days in 2016.
- The median time before the Comité de Protection des Personnes (CPP - equivalent to the Institutional Review Board in the US and the Research Ethics Committee in the UK) issues an opinion remained 62 days, unchanged since 2014.

France is still penalised by lengthy trial start-up times. The lack of resources allocated to both ANSM and the CPPs are set to further exacerbate administrative delays, especially since ANSM has now been entrusted, under the Jardé Law, with new methodological assessment tasks. In addition, the random selection of the CPPs under the Jardé Law has led to grave concerns: this random selection process implies that all CPPs are able to assess all research protocols concerning all diseases. However, the 2016 survey shows that 50% of clinical trials are assessed by 9 out of 40 CPPs.

## France has shown improvements across all performance indicators in trials conducted between 2014 and 2016 but must step up its efforts in the face of increasing international competition

In a worldwide context of improved clinical research performance, France performance is relatively stronger than its than its immediate neighbours in terms of average number of patients per study and per centre as well as enrolment rate.

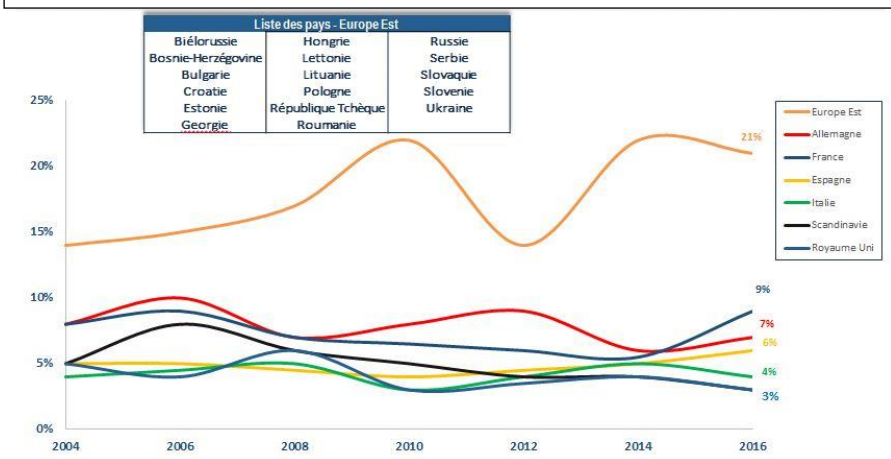
Western Europe is nevertheless meeting fierce competition from Eastern Europe, which already featured large in the 2012 and 2014 surveys.

## The numbers: performance indicators in clinical studies

The average number of patients per study in France rose from 23 to 34, at virtually the same rate as Spain (from 29 to 43), while the United Kingdom fell from 29 to 27 and Italy rose from 27 to 29. Germany and Eastern Europe remain in the lead in Europe (49 patients per study versus 38 and 42 respectively in 2014).

- The average number of patients in France per study and per centre is 5.8. France has overtaken the United Kingdom (3.9), Germany (4.1), Italy (4.6), Spain (5.2) and the United States (4.7), but not Eastern Europe (6.2).
- The average enrolment rate in France per study was 2.6 patients per centre per month in 2016, far ahead of the United Kingdom (0.9), Spain (1.5), Eastern Europe (1.5), Germany (1.4), Italy (1.6), and the United States (0.8).
- The proportion of patients enrolled in Eastern Europe in relation to the total number of patients enrolled in trials involving France, was 21% in 2016 compared with 22% in 2014, a stable trend that reflects the importance of Eastern Europe in competition for clinical trials.

Trend in the distribution of patients enrolled in European countries (%) for studies conducted in France




## The 5 proposals put forward by Leem to enhance France's role in global clinical research

- Reduce clinical trial setup times: provide ANSM and the CPPs with the human, technical and financial resources to enable them to respond to regulatory changes
- Facilitate clinical research diversification: structure research in non-hospital settings and in inpatient-outpatient networks, foster post-marketing research by introducing incentives to medical and allied healthcare professionals, structurally develop clinical research sectors beyond haemato-oncology
- Improve clinical research training: adapt the initial and continuing training given to healthcare professionals
- Involve and mobilise more patients: design an information platform so that clinical research can be explained to patients along with opportunities for them to take part
- Increase the visibility of France's clinical research organisation internationally: map out offers from clinical trial sites, steering bodies, ongoing trials

*"Ensuring that France remains an attractive destination for clinical research must become a priority issue for the country*", according to Patrick Errard, Chairman of Leem. "***For patients, because rapid access to innovation is crucial, including at the early stages of development. But also for the vitality of our economy, because countries with strong clinical research potential will have a valuable asset on which to build the major industrial hubs of tomorrow.*** *To achieve this, public health priorities need to be clearly identified along the same lines as the plans for cancer and rare diseases. We want to engage in constructive dialogue with the new Government on the subject of clinical research with a view to enhancing the attractiveness of France and improving the continuum between research, innovation and care.*"

***The survey is available to download from www.leem.org***

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