PRESS RELEASE

3 March 2015

Seventh survey on the Attractiveness of France for International Clinical Research

Leem calls on all research stakeholders to consolidate the position of France and safeguard the future of innovation

The seventh survey on the Attractiveness of France for International Clinical Research commissioned by Leem and conducted on French soil between 1 January 2012 and 31 December 2013, assesses the current status of the pharmaceutical industry research. Updated every two years since 2002 using the same methodology, this survey monitors and evaluates the position of France faced to global competition, and identifies its strengths and weaknesses as the basis for proposing options for progress.

In 2014, France continued to maintain its role as one of the leading players in global clinical research, accounting for 10% of international studies (of all types). Those studies included 5.9% of all patients involved in international studies conducted by drug companies. But the position of France must now be strengthened: *"Longer trial setup lead times, a decline in certain therapeutic areas, falling performance ratios… Leem calls on all public-sector and private-sector research stakeholders to take action to consolidate, streamline and promote clinical research and its pivotal role in future innovation",* says Michel Joly, Chairman of the Leem Scientific Affairs Committee.

France continues to maintain its overall position thanks to the rise of clinical research in particular therapeutic areas.

- The percentage of phase II/III trials offered to French affiliates rose to 58% in 2014 from 43% in 2012

- Of the 563 trials conducted in France by industry players, the percentage accounted for by **oncology and onco-hematology** trials increased from 30% in 2012 to 38% in 2014

    - Oncological and onco-hematological therapeutic area also increased in importance when measured by patient numbers, which increased from 4,070 patients involved in trials in 2012 (all phases) to 5,149 patients in 2014

    - Breast and skin cancer trials (all phases) involve a large number of patients per study: 52 for breast cancer and 35.4 for skin cancer; figures significantly higher than the average number of 26 patients enrolled for so-called solid cancer trials.

- The percentages of trials conducted for **infectious diseases** (14% across all phases) and **rare diseases** (8% across all phases) remain high, effectively consolidating the position of France in these therapeutic areas.

- Nevertheless, performances in France are declining in terms of the average number of patients per trial, the average number of patients per centre, and the enrolment rate (number of patients per centre, per month). But France is maintaining its position against the wider global and European background of general decline in clinical research performance ratios

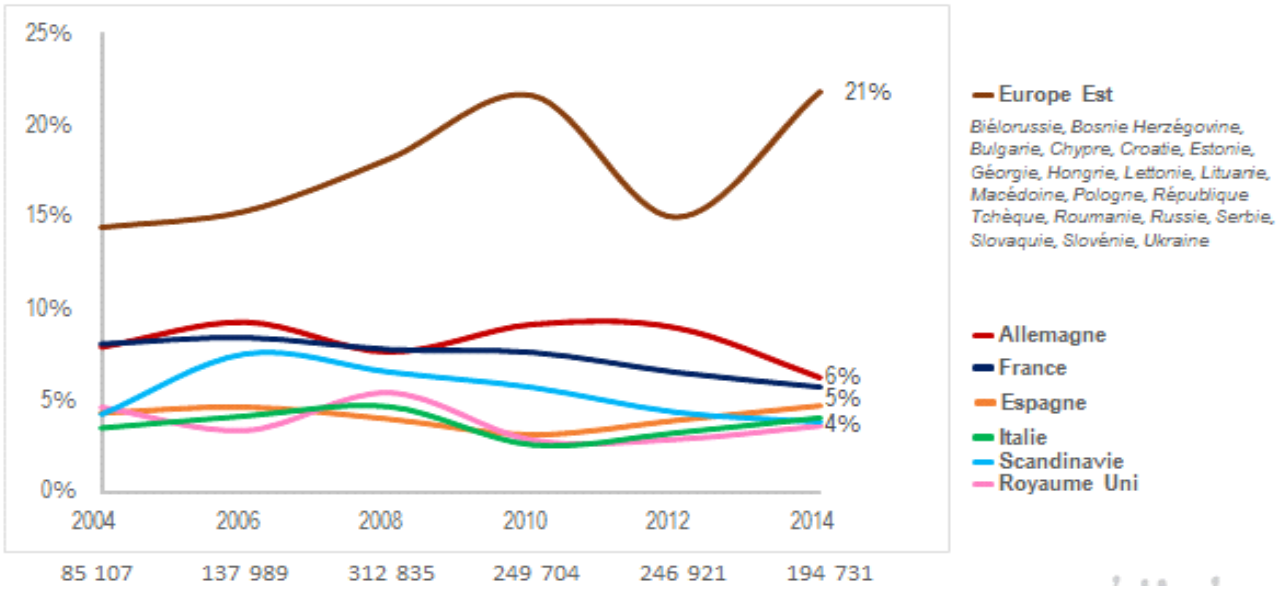
On the other hand, certain therapeutic areas appear to have been almost abandoned.

- The domains of cardiovascular and diabetes/metabolic research have continued the decline that began in 2008, delivering performances significantly below the global and European averages:
    - average number of patients per trial: 28, whereas the European average is 59, and the global average 78
    - average number of patients per centre: 4.2, whereas the European and global averages are 7 and 6.9 respectively
    - enrolment rate: 0.6, whereas the global average is 1.2, and the European average 1.3

France is therefore particularly well positioned in three therapeutic areas: cancer treatment, rare diseases and infectious diseases. On the other hand, the domains of cardiovascular and diabetes research remain the poor relations.

France is defending its positions against international competition: like its European neighbours, France must compete with the power of North America. For all practical purposes, North America remains one of Europe's main competitors, whilst on the European stage, the 'old' Europe of Germany, UK, France, Spain, Italy, etc. must also compete with the significant threat posed by Eastern Europe rise in 2014.

Trend in the percentage breakdown of patients enrolled over the six surveys in European countries



The position of France must be consolidated by building on synergy between stakeholders and process streamlining.

In terms of infrastructure and healthcare system quality, the perception of France remains satisfactory overall, despite a significant increase in the time taken to set up clinical trials:

- The 2014 survey shows that CPP approval lead times increased by 14.8%, from 54 days in 2012 to 62 days in 2014
- Similarly, the median time elapsed between the submission of a clinical research application to the ANSM and its approval has lengthened from 49 days to 55 days, reflecting an increase of 12.2%
- More concerning is the fact that the lead time for signature of the first hospital contract lengthened by 9.4% between 2012 and 2014, bringing the median lead time to 122.5 days. This trends marks a real U-turn on hospital contract signature lead times, returning France to figures last seen in the 2008 survey
- The enrolment rate (the number of patients enrolled per centre, per month), which is 1 in France, remains ahead of the world and European averages of 0.9, evidencing that when France does decide to embark on a clinical trial, it is efficient in enrolling patients for that trial. **However, pre-trial lead times are still penalising France.**

"Improving French lead times and performances is not something that can be legislated for. What is needed is to streamline the system and simplify it through more effective synergy between clinical research stakeholders: drug companies, of course, but also investigators, hospitals, patients, researchers, public authorities, CPP, etc. That is what we are trying to achieve with the introduction of the single contract measure we proposed via the Sectoral Strategic Committee, which was subsequently taken up in a DGOS (Directorate of Healthcare Delivery) ministerial directive, and has applied since June last year". The single contract expressly targets the issue of pre-trial lead times by proposing a simplified administrative process", explains Patrick Errard, Chairman of Leem.

The seventh Leem survey was compiled in 2014 on the basis of responses received from 36 pharmaceutical companies representing 66.3% of the French drugs market. The 2014 survey covered 493 international phase II and phase III trials with French input (420 trials in 2012) involving 31,200 centres and 193,058 patients (245,895 in 2012).

The full survey results are available to download from:
http://fr.calameo.com/read/00204928466387fe2f059

Press contacts: Stéphanie Bou – Tel.: +33 (0)1 45 03 88 38 - Mobile: +33 (0)6 60 46 23 08 - e-mail: sbou@leem.org
Virginie PAUTRE – Tel.: +33 (0)1 45 03 88 87 - e-mail: vpautre@leem.org
Jean-Clément Vergeau – Tel.: +33 (0)1 45 03 86 82 – email: jcvergeau@leem.org