

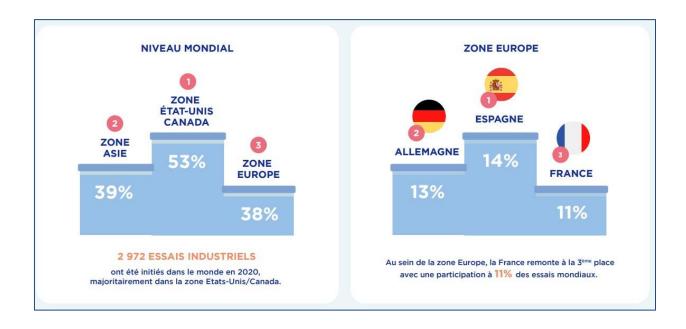
Press release 13 December 2021

France is ranked again in European Top 3 for clinical research

Clinical trials are essential for early patient access to innovative treatments, but they also help to maintain the expertise of healthcare professionals and our country's excellence in research. Each year, Leem publishes a report on France's position in the internationally competitive world of clinical research. Results of this 11th annual attractiveness survey are encouraging.

France is ranked again in European Top 3...

Having contributed to 319 clinical trials during the year (equivalent to 11% of trials conducted globally by pharmaceutical companies), France has regained its No. 3 ranking in Europe, having lost this status in 2015. Germany and the UK both lost ground to Spain and France respectively. France is still ranked No. 2 for oncology (15% contribution to trials worldwide) and No. 4 for early-stage trials (5% contribution). France ranks No. 4 in Europe for clinical trials to develop COVID-related preventive and therapeutic treatments.



The sample taken from the Leem OSCAR database of 194 trials has enabled us to identify the key therapeutic areas in mainland France: 45% of trials target oncology, 20% rare diseases, 9% immune system diseases and 8% Advanced Therapy Medicinal Products (ATMPs).



Clearly, the pandemic has impacted the startup lead times of other so-called 'non-Covid' trials: in France, it took an average of 236 days from authorisation, contracting and centre organisation before the first patient was enrolled (compared with 204 days in 2018/2019). Conversely, the lead times for COVID-19 trials have been dramatically reduced to the point where the first patients were inducted after only 3-5 weeks.

... But Europe has been overtaken by Asia

Despite the unprecedented context of 2020, the pharmaceutical industry launched 2,972 new clinical trials worldwide during the year. Of these, 246 focused on COVID-19; 75% were phase 2 and 3 trials, and 94% were treatment focused.

Although clinical research levels remained stable overall, the regional dynamic has changed: North America remains the world Number 1, but Europe has dropped from second to third place having been overtaken by Asia. In 2020, North America (down to 53% from 57%), Europe (down to 38% from 44%), South America and Africa all saw a decline in clinical activity, while the reverse was true in Asia (up to 39% from 35%) and Australia (up to 13% from 12%).

The effective introduction of the European Clinical Trials Regulation should make Europe more competitive, but competition from other regions of the world, and particularly Asia, will remain a very significant factor. Within Europe, France has set itself the ambition of being increasingly competitive, and the Healthcare Innovation 2030 plan announced by the French President in June 2021 will undoubtedly contribute to that outcome. "The measures adopted by the CSIS in this respect are very encouraging. They should make it possible to seize this change of direction in 2022, and return France to a leading position in Europe", says Leem Chairman Frédéric Collet.

The French Social Security Finance Bill (PLFSS) was one of the first tangible examples of this change, since it puts these guidelines into practice by introducing additional company-sourced funding to update the functional operation of France's Comités de Protection des Personnes (CPP - equivalent to Institutional Review Boards in the US and Ethics Committees in the UK). Added to which, the collaboration between university hospitals and industrial sponsors introduced by the CSIS should also have the result of shortening lead times for the enrolment of patients into clinical studies. Lastly, France must rapidly expand its methodological expertise to ensure that these new approaches to clinical research are fully exploited.

About the survey

The 11th survey commissioned by Leem on the 'Attractiveness of France for Clinical Research' takes stock of the clinical trials initiated in France by pharmaceutical companies between 1 January 2020 and 31 December 2020. Now conducted annually, this survey monitors and assesses the status of France compared with its global competitors, and identifies its strengths and weaknesses as the basis for proposing routes for progress.

The international comparison is based on analysis of the clinicaltrials.gov database, whereas the data used to investigate how clinical trials are conducted in France were entered into the OSCAR database by pharmaceutical companies and their CROs.

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