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Clinical trials 2030: working with the tech (r)evolutions now underway to boost the competitiveness of France

Artificial intelligence, big data, digitalisation... new technologies are revolutionising clinical trials and the way patients participate in them. But we need to understand more about this crucial transformation. The care pathway begins not when a pharmaceutical product enters the market, but when it enters the clinical trial stage. To assess the current status of these (r)evolutions and France's readiness to embrace them, Leem commissioned IQVIA to conduct its **Clinical Trials 2030** survey.

Five evolutions that benefit patients

Five key evolutions will shape clinical research in 2030:

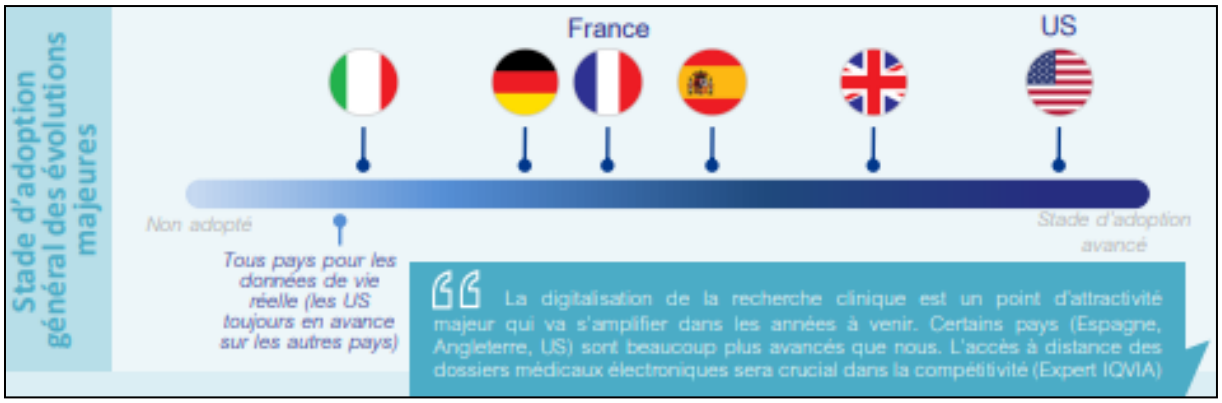
- The patient-centric decentralisation of clinical trials, primarily as a result of digitalising trials (telemedicine, e-consent, home monitoring, etc.). 70% of patients involved in a clinical trial live more than 2 hours' journey time from the clinical trials centre
- Real-time integration of data. 80% of pharmaceutical companies have put in place strategic partnerships for the collection and use of real-life data
- The development of biomarkers, which improve clinical trial quality and safety for patients, at the same time as optimising access for sponsors
- The introduction of pharmaceutical-related solutions. Some of these innovations can now extend to the prevention, management and treatment of medical conditions
- And lastly, the growing number of advanced therapy medicinal products. As a result, 33% of all clinical trials launched in 2020 included an advanced therapy medicinal product

Of these five developments, the strategic priority is undoubtedly the digitalisation of clinical trials, which is quick to implement, especially in France, where conditions already in place favour its rollout.

As a result of the health crisis, 40% of clinical trials are now hybrid (i.e. involve patients in at least one digitalised step), compared with just 10% before the crisis emerged.

France has the expertise, and now finds itself at a crossroads

The US and UK are currently leading the way in all these key developments. They should therefore be seen as a source of inspiration.



France has key assets, including its expertise in health data and the willingness and commitment of all stakeholders. It also has a formally structured data protection framework. And France is equally attractive in terms of the excellence of its opinion leaders, the fact that clinical trials authorisation is centralised in the hands of a single ethics committee, and its Research Tax Credit scheme.

Nevertheless, in today's highly competitive international environment with so many innovations under development - many of them stimulated by Covid-19 - France must now strengthen its position. A number of additional initiatives are therefore needed to boost its attractiveness as a base for clinical trials.

Harmonisation and trajectory

Leem has brought forward a series of proposals for boosting the competitiveness of France in the market for innovative clinical research:

- Prioritise **operational targets** at national level
- **Remove regulatory barriers** to innovation in clinical research
- Enable **the interoperability** of **digital systems** and **tools**
- Set up and run **experimental pilot projects** around clinical trial decentralisation this year

- Develop **a tool for patients** that provides a **comprehensive and up-to-date** list of trials open for inclusion.
- Encourage hospitals to **expand the collection of real-life data**, at the same time as taking quality standards to a new level

At a time when the government has expressed its intention of establishing France as the European leader for clinical trials, the IQVIA survey results published today provide the roadmap for achieving this goal. Firstly, by increasing our methodological and operational expertise in new types of clinical trial: the Haute Autorité de Santé has been consulted about this goal, and Leem looks forward to learning its conclusions. Secondly, by facilitating the transfer of data outside the European Union, particularly where international clinical trials are concerned. This is a non-negotiable condition for conducting effective research and succeeding in the challenges around providing access to innovation.

In the meantime, pharmaceutical companies continue to strive to conduct the highest quality of clinical research, because this is key to enabling patient access to innovative therapies.

Read the full text and a summary of the survey report at www.leem.org

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Press contacts:
Stéphanie Bou - +33 (0)6 60 46 23 08 - sbou@leem.org
Virginie Pautre - +33 (0)6 31 86 82 70 - vpautre@leem.org
Alice Roznowiez - +33 (0)6 08 97 50 49 - aroznowiez@leem.org