Hubert Mechin â?? President, AFCROs

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Hubert Mechin, president of AFCROs, the association that groups clinical research organisations in France, details the organisationâ??s efforts to help its members stay abreast of changes in the European regulatory environment and its creation of a clinical research code of conduct. He discusses Franceâ??s competitive edge in clinical trials based on expertise in real-world data springing from the countryâ??s large clinical database, and the potential impact of Artificial Intelligence (AI) on the industry.

Could you provide a brief overview of AFCROs, the companies it represents, and its current mission?

Today, AFCROs celebrates two decades as the Association of Clinical Research Organisations in France, boasting a membership count of 101, making it the largest association in Europe within this domain. We pride ourselves on inclusivity, representing a diverse array of entities, from multinational giants to local French CROs, and even nimble start-ups focusing on niche services like IT and digital solutions. Our association serves as a dynamic platform, hosting regular events, forums, and publications to foster collaboration and knowledge exchange. With events like the Innovation in Clinical Research Forum and Clinical Research Day, we delve into specific topics and real-world data reviews, catering to a global audience by offering publications in both French and English.

At AFCROs, we foster innovation and adaptation to navigate the intricate web of regulations that govern our field. With the ever-evolving landscape of regulations, our 10 working groups diligently monitor changes, organising publications and events to keep our members abreast of the latest developments. Notably, we are preparing for the EU Data Actâ??s impending impact, recognising the significance of compliance with European regulations such as GDPR. Four years ago, recognising the need for a specific code of conduct in clinical research, we spearheaded its development, earning accolades as France emerged as a leader in managing and finalising this vital document, which is set to be published in the coming months, offering guidance and standards for the entire clinical research community.

What factors contribute to Franceâ??s competitiveness in attracting clinical trials, and how does its performance compare on a European scale?

Franceâ??s competitive edge in attracting clinical trials stems from several key factors. Firstly, our extensive experience and expertise in real-world data analytics stand out. The Systeme National des Donnees de Sante (SNDS) is one of the largest clinical databases globally, accessible since 2016. Leveraging this resource, we conduct numerous real-world studies, positioning France among the leaders in real-world evidence generation within Europe.

Secondly, our nation boasts robust proficiency in oncology and rare diseases. These areas are focal points for clinical trials in France, with a multitude of renowned reference centres specialising in rare diseases. The strong governmental support for rare disease initiatives, such as the Rare Disease Plan, underscores our commitment to advancing research in this domain. Additionally, Franceâ??s oncology sector ranks highly, with numerous cutting-edge research initiatives and renowned centers of excellence.

Thirdly, Franceâ??s academic centres play a pivotal role in driving clinical research forward. These institutions are highly dynamic, engaging in a wide array of clinical trials in collaboration with both CROs and industry stakeholders. The collaborative environment fostered between academia, private companies, and government entities ensures a vibrant and diverse clinical research landscape in France. This strong partnership between the public and private sectors contributes significantly to our competitiveness in clinical trials. Overall, our strengths in real-world evidence, oncology, rare diseases, and academic research collectively position France as a leading destination for clinical trials within Europe.

Compared to the rest of Europe and considering Spainâ??s notable ascent in clinical trial numbers, what areas can France strengthen to sustain its competitiveness?

One issue is the complexity of administrative tasks, especially in negotiating contracts with hospitals. This can lead to delays in getting clinical research projects off the ground. Another challenge is recruiting patients for trials, particularly when many are already receiving treatment. Finding eligible patients who have not undergone treatment yet can be difficult. Interestingly, some less economically developed countries excel in this area due to having more eligible patients.

Furthermore, French investigators sometimes face delays, impacting the speed of clinical research. This slower pace is especially notable in areas like CNS studies, cardiovascular research, and diabetes trials. Consequently, France may lag behind countries like Spain, Italy, or Germany, especially in phase three trials.

Despite these challenges, France maintains strengths in post-approval studies, leveraging expertise in databases and excelling in oncology and rare diseases. While Spain may lead in certain aspects of clinical research, France still holds its own, capitalising on its strengths to remain competitive globally.

In the wake of the pandemic, there has been a significant increase in hybrid clinical trials in France, with 40 percent now incorporating digitalised steps for patients, compared to just ten percent previously. Where does France today stand in terms of continuing the momentum of trial digitalisation and decentralisation?

COVID-19 certainly presented a prime opportunity for us to embrace these trends with hybrid trials. France certainly has a hold on technology, especially with the wealth of start-ups developing such tools. However, post-COVID, regulatory hurdles have emerged as a significant challenge. Convincing regulatory bodies of the viability of these tools remains an ongoing struggle. Despite having the necessary technology at our disposal, we are still in the process of testing and conducting proof of concepts for projects involving IT tools. This cautious approach may result in us losing ground to countries that are more agile in adopting these innovations. The pace of regulatory approval for digital tools isnâ??t as swift as it was for vaccines during the pandemic, posing a hindrance to our progress in this area.

Earlier, you mentioned the perpetual regulatory changes in clinical research. With the implementation of the EU Clinical Trials Regulation two years ago and the impending establishment of the EU Health Data Space, how do your members perceive these new regulationsâ??as burdensome challenges or exciting opportunities?

The EU Clinical Trials Regulation (CTR) is not exactly new, and while it has required some adjustments to data entry processes, it has not posed significant challenges. There have not t been many complaints about its complexity, so I would not say it isoverly complicated.

Regarding the EU Health Data Space, I would not view it as a threat either. France has a strong track record in managing databases, notably with our SNDS. We are actively engaged in discussions with other European countries, so I do not perceive it as a threat. Instead, I see it as an opportunity for us to collaborate and leverage our expertise in data management.

As someone with personal experience in launching, building, then selling CROs, how would you assess the landscape for budding entrepreneurs in your industry in France today?

In France, we are seeing a steady influx of new members joining our association, with new companies emerging each month. Interestingly, many of these newcomers are IT professionals or engineers developing tools and services tailored for decentralised trials. Additionally, there is significant funding available from capital funds to support these ventures. Personally, as someone with experience in entrepreneurship, I find France to be an attractive environment for budding entrepreneurs in the clinical research industry. While I cannot say for certain whether we have more initiatives than other countries, I can attest to the vibrancy of the market here and the many opportunities available for those looking to innovate in clinical research.

Looking ahead, what emerging trends do you anticipate will wield the most significant impact on the CRO industry in France?

Artificial intelligence is poised to revolutionise our industry, and we are already seeing its impact. We are actively working within AFCROs to help our members adapt to this significant change. The digital transformation is also reshaping the way we work, offering new opportunities for innovation. Leveraging existing databases, particularly in clinical trials, will be crucial moving forward. In the next three to five years, we anticipate a dramatic shift in how we engage with our clients. Our recent publication on innovation in clinical trials delves into this topic, highlighting the evolving landscape. However, not all CROs may be equipped to navigate these changes, especially older, more traditional companies. Many French CROs were established in the 1980s, and their leadership may struggle to adapt. Nonetheless, it is an exciting time to witness the evolution of our market.

Is there any final message you would like to convey on behalf of the French clinical research sector?

While we may have encountered challenges in certain phases of clinical research, particularly phases two and three, France remains a highly competitive player in phase four and post-approval studies. With access to one of the worldâ??s largest clinical databases and a strong focus on technology, including digital solutions and artificial intelligence, we are well-positioned for continued success. Our expertise in oncology and rare diseases further strengthens our position. While we may not be at the very top, we are certainly among the top three active countries in the field.

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