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Nathalie Giraud, director of integrated monitoring investigator services & head of France at PPD, breaks down the strengths and weaknesses of the French clinical trials environment and stresses the importance of France in PPD's overall operations. She also explains how the contract research organization is catering to the needs of biopharma companies and adapting to the ever-changing clinical trials landscape.

What do you see as the main trends driving the French CRO market?

According to a report published by LEEM, the association of French pharmaceutical companies, France is losing its competitive position in clinical research. While this might be the case in general, this is not what I observe from my perspective. France remains very competitive in certain therapeutic areas, such as oncology, where the expertise of French KOLs is respected worldwide. In the case of PPD in France, we attract many early-phase oncology trials. Other areas of expertise in France are infectious diseases and rare diseases. Clinical trials are becoming increasingly complex in terms of study design and data collection, as well as being more closely targeted to small patient populations.

As with any country, France has a list of proscribed steps we need to follow to start a clinical trial. For instance, before initiating a trial, we first need to receive authorization from the French

National Agency for Medicines and Health Products Safety (Agence Nationale de Sécurité du Médicament et des Produits de Santé, ANSM) and the Committees of Protection of Persons (Comités de Protection des Personnes, CPP), as well as performing required administrative processes to execute contracts with sites. It is understandable that ANSM places tighter requirements on safety than other countries in light of the Biotrial Phase I accident involving a healthy volunteer in France in 2016.

To enhance the contract execution process and reduce setup delays, in 2016 the government introduced a simplified process based on a “sole agreement” contracting model, which was a key step to speeding up the process. We need to continue to work closely with public hospitals and private sites to reduce the time spent on budget negotiations.

The clinical trial approval process and timelines in France are longer than some of the Western EMEA countries, but timeline delays at the CPP are being addressed. It is important we continue efforts to streamline our local processes to maximize all the potential France has and to bring more clinical trials to patients.

Recently, a number of reforms have been implemented to reduce timelines. Have you seen any concrete changes?

The previously mentioned LEEM study has resulted in an improvement since mid-2018 and we applaud the government’s efforts to simplify processes. One of its goals is to reduce the time it takes the CPP to make a decision, which it is working hard to achieve. At the same time, ANSM now has a committee with a timeline, which was not the case two years ago. So, progress is being made.

Despite the challenges, France remains an attractive destination for clinical trials. How strategic is France in your European and global operations?

France is definitely a key country for PPD. First, in terms of workforce, as France is one of our largest operations in the EMEA region, and our clinical team makes up a significant portion of that group, which also includes a dedicated trial startup team.

Second, while the startup phase can be challenging, the site activation phase functions extremely well because French sites are known for their efficiency at recruiting patients. One of our ongoing

goals is to continue to build strong partnerships with sites to accelerate patient recruitment by assessing the population, establishing the target and working together closely to ensure we meet our clients' targets. In fact, our France operation is one of PPD's best worldwide in terms of patient recruitment and quality delivery.

Looking at major trends in the CRO market, we see an increasing number of local players as well as consolidation among global players. How does PPD differentiate itself?

PPD differentiates itself from other players in two ways. First of all, PPD focuses on being more flexible in its delivery models and operational structure. This means we are able to adapt to the needs of both small biotech ventures and large pharmaceutical companies. Second, PPD – through its Accelerated Enrollment Solutions business unit – has the largest global network of exclusive research sites, which gives us a competitive advantage in terms of patient recruitment.

How are you adapting to the demands of biopharmaceutical companies?

While the demands of biotech companies differ from large pharma, in the end, they both expect fast trial startup and recruitment. The main difference lies in how they are structured. Biotech companies have small teams and flat organizational structures. They expect to collaborate with a partner who works as they do. To better respond to their unique needs, we have established PPD® Biotech, a specialized unit within the PPD organization that caters to these small biotech companies.

How do you expect digitalization to shape the landscape of clinical research?

PPD has developed a cloud-based data and analytics platform called Preclarus® that gives teams and clients transparent, real-time access to all clinical trial operations, including patient and lab data. Data stewardship is an essential part of the culture at PPD and employees in all functions are required to update the data in a timely manner. We train our personnel on how to use dashboards and reporting tools to inform their day-to-day decisions for the benefit of our clients. Another opportunity presented by digitalization is the use of centralized monitoring to analyze study data in real time to detect any emerging risks far earlier than currently possible, which helps improve both

patient safety and data quality.

What are your top priorities for the coming years?

Our priority is to further enhance the contribution of PPD within the French clinical research environment by being a leader in terms of quality, compliance, and efficient and effective recruitment, which we hope will continue to foster the importance of France in clinical research. And, we remain focused on preparing our operational teams to adapt to the ever-changing clinical research environment and its ongoing transition toward digitalization and risk-based monitoring.

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