Interview: Patrick Winkler â?? Clinical Trial Manager & Geoffrey Bilon â?? Senior Business Development Executive, Medpace, France

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While functional outsourcing may be common for companies seeking services from CROs, Medpace believes that their robust, physician-led, full-service business model is the most efficient way to conduct clinical research. Clinical Trial Manager, Patrick Winkler, and Senior Business Development Executive, Geoffrey Bilon, share the service offerings of Medpace, as well the attributes that make Medpace unique in the CRO industry.

Although Medpace only opened their office in Lyon in March 2012, the companyâ??s history in France extends beyond this. How did the company begin, and ultimately expand to Europe?

Established in 1992 in Cincinnati, Ohio, US, Medpace is historically a US based company. Over the course of 20 years Europe has quickly became an increasingly important market region. While the full-time office in Lyon opened in 2012, we have conducted business operations in France for several years, beginning in 2005. Currently Medpace has thirteen offices in Europe We have established recognition for ourselves as an international CRO with a strong European presence.

Medpace is a global full-service CRO with a presence in over 50 countries. How does Medpace make use of France within the context of its global operations?

Europe is a critical market for all global companies, and the same has proven true for Medpaceâ??s growth and business. France is one of our largest markets, prompted by its high capacity for innovation, particularly in biotech, and the country remains key in strategies to expand our companyâ??s presence throughout Europe. As France is a leading market in the study of various disciplines, many of which overlap with the studies conducted by Medpace, notably oncology, cardio-metabolic disorders, infectious diseases and rare diseases among others. The network of researchers and professors in France has proven to be a unique asset. The network of hospitals and close proximity to various KOLs within France is invaluable when we conduct our trials.

What factors are involved when establishing clinical trials in France and how does this compare to other regions in Europe?

While it is very dependent on the indication of interest, there are certainly countries outside of France where we see higher rates of recruitment for trials, as well as other regions where recruitment numbers may be comparable. However, we always direct our efforts towards determining the best sites where we anticipate high recruitment rates. This can be the case in Eastern Europe, Asia Pacific or Latin America. Sites in various countries around the globe have developed appropriate facilities and equipment to perform complex trials, increasing the credibility and reputation of these sites, which is just as vital to successful trial procedures as recruitment. For complex trials concerning rare diseases and pediatric care, France has proven repeatedly to be an exemplary location to conduct such studies, primarily due to the countryâ??s hospitals that are well equipped for such investigations, as well as having experienced physicians in the pathologies.

Clinical trials have been under tremendous international spotlight recently following a trial conducted by the French Biotrial (and manufactured by the Portuguese Bial in the beginning of 2016). As an industry, how do you plan to demonstrate the benefits that come with conducting clinical trials?

The responsibility of a CRO, as a service provider, is to maintain a high level of ethics, good clinical practice, and patient safety at all times. We strive to uphold these values with a high standard every day. With phase I trials specifically, there is a close monitoring on safety as well as regular correspondence with investigators. It is our responsibility to safeguard patient health and safety, while also working in accordance with legal requirements. Our main objective as a CRO is to advance efficient drugs in a safe manner to provide benefit for the community as a whole.

Speaking particularly about the services and expertise provided by Medpace, how would you define your comparative advantage over other CRO players? What is your particular edge?

Medpace was founded by a physician, August J. Troendle, MD. Since its inception, it has remained a physician led CRO. This has led Medpace to function as a therapeutically focused CRO, demonstrated by the fact that the company employs thirty-five fulltime medical experts in various therapeutic areas. These physicians are involved at each step of clinical trials, and they are not simply involved in initial business negotiations. They are involved throughout the entirety of the process to ensure the best data quality for sponsors and thorough safety monitoring of patients. This is one of our key differentiators in the CRO industry, allowing Medpace to strive for the highest levels of quality.

Since its foundation, Medpace has upheld a full-service business model, meaning that all aspects of conducting clinical trials, from regulatory strategy, protocol writing to the final stage of report writing, can be done in-house. Under the same â??roof,â?• we can utilize our global central lab, bioanalytical

lab, cardiovascular, imaging core labs, and our phase I units well as a global device division. These capabilities are especially resourceful for biotech firms and mid-sized pharma companies, as they tend to lack the necessary resources to develop a full-scale trial.

Medpace is strong in oncology, cardio-metabolic disorders, gastroenterology, infectious diseases, and many other therapeutic areas; what are the most important areas for the business in France?

One very important sector that must be included is rare diseases, for which Medpace has honed its expertise. The above mentioned therapeutic areas are all very well represented in France, which makes sense as the more a company is involved in these therapeutic areas, the higher the chances are that they will be connected to the country in some capacity. For instance, there are strong cancer centers throughout France with whom we have developed strong relationships over the years. As far as rare diseases are concerned, we are involved in global programs, working on advancing promising drugs from one phase to another. Our close relations with KOLs and physicians in the cardio-metabolic field have historical importance to Medpace as well.

In the context of strong cost-containment across Western Europe and specifically in France, demonstrating indisputable drug efficiency and long-term outcomes in clinical trial results has become necessary for pharma companies to receive expected pricing and reimbursement. How can this context highlight the Medpace competitive advantage in comparison to other CROs?

As a CRO, there are different ways that we can support our clients. At Medpace, we have a global regulatory affairs group, including several former FDA employees, as well as experts from comparable backgrounds in Europe, providing a breadth of knowledge and experience. We are able to support our clients by giving advice and being involved in regulatory affairs strategy very early in the program. Medpace is known for experience in this capacity. Our expertise in late-phase trials also serves as an asset to our clients.

What would you like to see Medpace France achieve in the next five years?

Continuing growth as a company, while also maintaining the same levels of success that the company has been achieving is a priority for the coming years. For over twenty years, we have built a positive reputation worldwide, and we will strive to continue providing high quality services, as well as hiring high quality employees. Rather than a growth strategy rooted in acquisitions, we are poised at Medpace to foster organic growth and to continue expanding the potential of the areas where we perform best. It is a high priority for us to maintain our unique company culture, as well as our consistently high standards.

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