Interview: Hristo Sabev – Director of Clinical Management, PPD, Bulgaria

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Hristo Sabev, director of clinical management for PPD in Bulgaria, shares an interesting overview of clinical research in Bulgaria and highlights PPD's commitment as one of the leading CROs in the country.

PPD has a quite unique footprint in the country due to the acquisition of AbCRO back in 2009. Can you briefly introduce to our international audience the history behind the affiliate's operations?

AbCRO was well positioned in Bulgaria at the time of the acquisition. The addition of AbCRO helped to strategically position PPD by acquiring a fully functioning CRO in Bulgaria with a high level of competency, integrity and professionalism. The transition was quite smooth because AbCRO and PPD already had worked together and both companies already knew each other before the acquisition.

As a result of AbCRO's legacy and the involvement of PPD, our operations in Bulgaria have grown steadily from 80 professionals in 2009 to more than 800 in 2017, positioning PPD as the largest CRO in Bulgaria. In fact, from a regional standpoint, we are one of PPD's largest operations in central and eastern Europe.

What has been key to successfully drive this integration?

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Firstly, it is crucial to have a clear road map and follow the planned path, but we also must maintain a certain level of flexibility since there are always unexpected situations throughout the journey. Secondly, and I believe this has been one of our chief cornerstones since the integration, the global and local management teams have done an outstanding job communicating corporate priorities from the top down, which has aligned the organization toward the same goals and has helped drive high levels of employee engagement.

In 2010, PPD opened its center for pharmacovigilance and medical communications in Bulgaria. Can you expand on the rationale behind this investment and the benefits obtained?

The pharmacovigilance function in Bulgaria was established in 2010 as part of the global PVG function and has been growing steadily ever since. Our center in Bulgaria provides global 24/7/365 support to our customers. All of our PVG teams include highly skilled people with doctorates and medical and master's degrees and a broad range of language skills. In addition to helping us better support our clients, the center also provides region-specific services to PPD's other affiliates. Pharmacovigilance and medical communication services fully comply with data privacy rules and other regulations.

The rationale behind the opening was that PPD already had relevant structure in the country and, therefore, did not have to start from scratch. Additionally, Bulgaria offers a high level of education and many people know a range of foreign languages, which is crucial to serving PPD's clients. Furthermore, the country is member of the EU, yet the total cost of labor is quite attractive in comparison to other markets.

What are PPD's key areas of focus?

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First, PPD is a people-focused company and, therefore, one of the main areas the local office has focused on is recruiting high-quality professionals and helping them develop their skills and expand their experience. Second, as a global service provider, we have the duty to ensure the quality of the services we deliver our clients by listening to them and responding to their needs. Third, we continue to pursue our purpose and mission, which are to improve health by helping our customers deliver life-changing therapies.

How are you investing in technology to enhance your operational capabilities?

We continue to invest in technology because it helps us generate better information for our clients while reducing lead times. As a service company, we rely heavily on technology to enable us to meet our clients' needs. As an example, we use Preclarus® for its reporting capabilities and the fact that it consolidates data from a variety of sources and offers visualizations, reporting, data analysis and transparency.

The growth of clinical trials in Bulgaria has been between 5 and 10 per cent on annual basis over the last years. Considering such dynamism and performance, what are the major challenges that global CROs such as PPD are facing here?

As a multinational CRO with global projects, we have to remain up to date with global changes. In all cases PPD strives to strictly comply with the latest published regulations and relevant guidance.

Expanding on local challenges, in Bulgaria, as in some other countries, we are required to submit a significant number of documents with clinical trial package to the Bulgarian competent authorities, which can impact work start timelines. At PPD, we work hard to successfully navigate regulatory guidelines and strictly adhere to all local requirements.

Considering these challenges, what techniques would you highlight to successfully navigate in the clinical research Bulgarian landscape?

In clinical research it is crucial to fully comply with local legislation and applicable EU Clinical Trials (CT) regulations. In addition, the industry through the Bulgarian Association of Clinical Research (BACR) is quite active in building relationships with the health care authorities. I believe leveraging this openness enables the industry to be at the forefront of any trend. Expanding on the latter point, I believe the industry will benefit from the government's efforts to advance digitalization. Implementing eHealth is a clear priority of the Ministry of Health since it will create a positive impact for all stakeholders, from patients to government and industry.

How is PPD playing a role in the development of the clinical research eco-system in Bulgaria?

Our operations in Bulgaria are fully aligned with the company's clear purpose (to improve health), mission (help our customers to deliver life-changing therapies) and strategy (to bend the time and cost curve of drug development). Having said that, the strong alignment among all departments within the local office and transparent communication with the competent authorities sets a standard of operation in the country.

Nevertheless, I believe that transformation needs a joint effort and, on this front, PPD has been an active member of BACR since 2007 and supports joint initiatives with the rest of the CRO industry. Through this association, training for clinical trial professionals (CRAs, study coordinators and pharmacists, among others) are organised. BACR is liaising with the competent authorities in Bulgaria and has been present at meetings with the Ministry of Health in order to propose solutions to some of the key barriers that influence the approval and execution of clinical trials.

Bulgaria, besides being a small country, is positioned as a clinical research hub for many multinational pharmaceutical companies. What are the points that support this positioning?

I am happy such process is happening in the country. The first reason Bulgaria is positioned so strongly is based on the high level of educated professionals with advanced university degrees (postgraduate, master's, medical, doctorate, etc.) and strong languages skills. Second, labor costs and the other costs of doing business here make it quite attractive, which positively impacts the cost of running clinical trials. Third, Bulgaria is within the EU and therefore the legislative framework is harmonised with that of EU. Fourth, the patient recruitment process and the operational rhythm are quite efficient, which can have a positive effect on timelines.

From the clinical trials perspective, which therapeutic areas are the most developed in Bulgaria?

Based on our experience, the most prevalent disease types are within the oncology and cardiology therapeutic areas. Consequently, these offer opportunities for patient recruitment. The country also offers good patient enrolment in a number of other therapeutic areas, such as neuroscience, gastroenterology, respiratory, endocrine, infectious diseases, etc. In addition, we are seeing a growing demand for and recruitment of patients in other medical areas such as rheumatology, autoimmune diseases, psychiatry and others.

Stratified by clinical trial phase, Phase II and III trials are the most prevalent in Bulgaria, followed by Phase IV and Phase I.

What are the main competitive advantages that position PPD as the partner of choice for the healthcare industry?

As a global company with a global footprint, we maintain high quality standards with a strong commitment to delivering on our promises. Furthermore, the fact that we are a people-oriented company ensures that we focus on attracting, retaining and developing the best people in every

country in which we have operations. In terms of service offerings, PPD is a CRO that is able to provide a wide range of services, such as global clinical development, clinical management, risk-based monitoring, and pharmacovigilance services in both the pre- and post-approval stages, as well as project management, laboratory services, consulting, etc. Additionally, and this is a consequence of all the aforementioned points, PPD has received numerous awards related to all aspects of its business. A recent example was that we were recognized as the best CRO Provider at the World ADC (antibody-drug conjugate) awards for advancing cancer research. And here in Bulgaria, we have been honored as a “True Leader” company every year since 2013.

What is your final message to our international audience?

PPD is committed to delivering a broad, high-quality range of services to our customers in Bulgaria and helping patients around the globe obtain access to the latest therapies. Bulgaria has the potential to participate in more clinical trials and PPD in particular can offer a lot to its customers. With dedicated staff and engaged managers I am confident we will continue to offer best-in-class services and support the company’s purpose and mission to improve health by helping our customers deliver life-changing therapies.

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