Interview with Dominique Demolle , Co-founder & CEO, Aepodia

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Having worked in internal clinical research for Eli Lilly for 14 years, from 1993 – 2007, what has this experience taught you about what pharmaceutical companies need in an outsourcing partner, and how does Aepodia respond to those needs?

What we have seen is a transformation in the pharmaceutical industry. Large pharmaceutical companies considered it a strategic advantage to have external access to experienced staff and additional resources to support their in-house portfolio. Hence, considering that Eli Lilly is a pioneer with regard to outsourcing models, my experiences at Eli Lilly have contributed greatly towards my understanding of outsourcing in general and its strategic advantages.

As a Clinical Research Organization (CRO) being on the other side of the table, it is essential to provide support to the pharmaceutical and biotechnology industries when there are gaps in their research activities. In that respect, Aepodia’s contribution consists of extensive experience and expertise in unfulfilled domains, particularly in the biotechnology sector where we often observe a deficiency in drug development expertise.

What would you say where your proudest achievements since you founded the company in 2007?

When we entered the market in 2007, the environment in general was particularly difficult because the world was plummeting into the initial stages of the financial crisis. Needless to say, this had a traumatic effect on biotech companies, as with most, if not all industries.

From an industry perspective, I believe we are undergoing an exhaustive transformation, as I mentioned earlier. Hence I think that owing to our flexibility and adaptability to these changes have been the key to our success. We have been able to respond to shifts in demand and are extremely focused on the designs of clinical trials. Furthermore, we have provided our clients with quick access to patients in order to test their hypotheses, i.e. proof of mechanism and principal.

Aepodia aims to help its clients avoid costly late-stage clinical trial failures by improving results from early-phase clinical trials with faster and better Go/No Go decisions. Could you tell our readers about your current services portfolio and do you plan on expanding your portfolio in the future?

Our first years were primarily focused on the development of various compounds, both small and large molecules. In a rather short timeframe, we extended our portfolio to include therapeutic vaccines and the clinical development of class III medical devices, the latter being a particularly appealing market segment for companies such as ours. Having that said, given the number of universities and hospitals, I must say that we are quite fortunate to be located in Belgium.

In short, we provide our clients with strong expertise and extensive experience in the design and implementation of early clinical plans, translational medicine scientific strategies and in the execution of clinical Phase I and Phase II studies. With the critical information that we gather during our studies we enable our clients to make well-informed and rapid decisions.

In between your current activities, where do you see the most potential for growth?

In terms of activity, it is the patient trials that are going to make access to very good information for decision making possible. Today, people tend to speak about biomarkers and translational science but what is important is to detect signals that provide information for risk based decisions. There is huge amount of competition in this field and although we are not magicians, we critically analyse the data and use those results to enable our clients to make valuable and rapid decisions on future development plans.

Aepodia has developed training tools in areas such as: Clinical Research Overview, Exploratory Phase Clinical Plan and Monitoring. Could you tell our readers more about these tools? And how are they an advantage to your clients?

The most sought after educational tool is our early phase development program. In particular those that support the transition from pre-clinical to early phase developments by analysing pre-clinical data in order to be better equipped to design early phase clinical plans.

In addition to this, monitoring exercises are also popular since they are critical to guaranteeing the quality of data. After all, one may have the best protocols but if you cannot verify that it has been conducted diligently and that patient safety has been protected then the entire study can fail.

Hence, our educational tools are strictly focused on pure scientific procedures, operational activities and project management. The latter is especially important since nowadays there are so many partners around the table, so to speak. That is, although professional competencies are critical, so are people's communications skills.

Belgium's clinical trials market is undoubtedly well developed with many local and international CRO's. How does Aepodia differentiate itself in this challenging competitive landscape?

Throughout the years, we have amassed a wealth of experience within our fields of activity and therefore have a clear understanding of what is expected. For instance, when we provide support to biotech companies, we know exactly what is expected in terms of outcomes since we have been active in this field and have continued to conduct our due diligence.

Put differently, when approached by clients, we first establish their overall strategy and align ourselves with it so that we can guide them to their endpoint. Ultimately, I would not say that we are better than the competition since we have so many talented professionals here. Rather, I would say that our services are complementary to each other due to their nature.

Another trend we see is that some pharmaceutical companies seem to be shifting trials to even lower-cost emerging markets, where quality is certainly improving. Will Belgium be able to retain its strong clinical research position in the coming years?

Belgium has to be extremely vigilant with regard to developments on a global level, otherwise we would risk underestimating the competition and lag behind. On the other hand, if we are successfully able to maintain or enhance our excellence, in terms of research centres and hospitals, we will certainly have a long and bright future ahead.

Similarly, I believe that investigators are generally concerned with solid science and good compounds. It is therefore imperative to retain our high academic standards and research centres in order to remain attractive as a destination for clinical research.

Some have expressed concern with regards to the new EU proposal for clinical trials which is set to erode Belgium's competitive advantage, while others are not so concerned. What is your view on this and how do you think it will affect your operations?

Since we conduct trials all over Europe, we are well acquainted with the relevant authorities that overlook the clinical trial environment. Although Belgium is well reputed for its rapid approval processes in clinical trials, another advantage it has is the widespread availability of regulatory and operational expertise that can provide guidance. As such, my primary concern is that the Belgian agency will become the member of reference due to its reputation which may lead to an overloading burden of responsibility.

On the other hand, in terms of approval duration, the aim of the new CTA is to level the playing field for all member states to around thirty days' time. As a European, I think this is a significant step forward for the EU since many people viewed it as complex due to the myriad of different authorities and procedures. As a Belgian, I simply hope that our agencies are not overloaded with advisory requests.

Could you tell us more about Aepodia's internationalization strategy and what are its plans for the future?

We do provide scientific support for clinical trials in the United-States and Singapore. However, we have not yet entered those markets operationally.

In terms of our future development, we see a clear demand for a full range of services from our clients with an increased scope of activities, going beyond scientific advice and operational support. We certainly aim to fulfil these requests and provide wide-ranging services to them by expanding the diversity of the offering we provide rather than outsourcing them for instance.

Geographically speaking, our central location in Belgium allows us to provide support activities within continental Europe. On the other hand, the US market is very competitive from an operational perspective. Since we have extensive experience with the US Food and Drug Administration, Aepodia will undoubtedly continue to support clinical trial activities in the US, but from a scientific perspective. Yet in the short term, I do not believe that we will be extending our operational capabilities there.

By contrast China poses an array of opportunities. For instance, we have already been approached to provide consulting, support and recommendation services for phase I units there. These are opportunities that we will definitely be exploring in the future.

What has been the biggest shift you have seen in the industry since you began your career?

Besides the dramatic change in the amount of outsourcing activities, I have seen two major changes in the industry. First is the externalization of competencies within the pharmaceutical

industry which were previously very much centralized. Second is the sharp increase of in-licensing activities among companies that have common intentions, goals or areas of interest.

The core asset of any service provider is its human capital. In that respect, how do you attract and retain the best talent?

In order to keep talent on board, it is essential to keep them motivated and provide them with sufficient feedback. In that context, I believe that our employees are extremely motivated to continue building what we have started here.

I also believe that people have to be passionate and proud of what they do. That is why we seek people that are able to stand before the mirror every day and believe in what they do.

How would you describe the culture of the company?

I think the most important trait is good ethics and to be respectful toward each other. In our company culture, each and every voice is significant. We have a great team here, which can bring great ideas to the organization and we show our appreciation for this by listening to them.

I strongly believe that in order to be successful, the best formula is to offer great expertise. After all we are offering a complementary service to our clients. That is, clients in general have a better understanding of the compound or device they are developing. Hence, our contribution to the process is to apply the appropriate ingredients to maximize the chances of obtaining informative data in the interest of the patient and customer.

In conclusion, where would you like to take Aepodia in to following 2 to 3 years and what goals would you like to realize?

Our aim is to continue and develop our expertise in terms of providing added value for decision making process of pharmaceutical and medical device companies.

In three years’ time, our objective is to provide our clients with a comprehensive range of services including data management, pharmacovigilance, among others, to boost our clients’ efficiency while lowering their costs. Likewise, we aim to further develop our credibility in terms of the quality of services we offer today.

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