

Interview with Jerry Welkenhuysen-Gybels, Managing Director, Business & Decision Life Sciences

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Business & Decision Life Science was founded back in 2007, although that department existed within the group's structure long before that. Could you highlight the reasons why a special business unit dedicated to the life sciences industry needed to be created back in 2007?

Founded in 1992, Business & Decisions Group performed its first international acquisitions at the turn of the millennium in 2000. The first acquisition of Flux consultancy by Business & Decision was an addition to our traditional portfolio oriented towards business intelligence and CRM related services. Within the same year Business & Decision Group acquired SPS Infoquest with branches in the UK and Belgium. SPS Infoquest offices in Belgium included a department providing biometric services in consultancy and staffing towards the pharmaceutical industry. This department served as the seed that originated and flourished into Business & Decision Groups life science activities.

I joined Business & Decision in 2004 as a bio-statistic's consultant and became responsible for the life sciences department in 2006. Business & Decision Life Sciences (B&DLS) was founded in 2007 to consolidate the group's life sciences activities. Since the establishment of this business unit, we have broadened our services portfolio from resources and staffing activities with a strong focus on biometrics to a comprehensive CRO portfolio, including: pharmacovigilance, quality assurance and regulatory affairs. Our second step forward has been providing actual CRO services including providing resources for the customer and assuming project management responsibilities and delivering results.

In parallel, these have been the two changes we implemented. We have grown significantly to about 280 employees within Business & Decision Life Sciences, of which 170 are based in Belgium, 30 in France and the others divided among the Netherlands, Switzerland, Tunisia and the US.

What have been the main challenges of starting up the life sciences business unit and what were the key elements to its success according to you?

The key to our success has certainly been dedicating our focus to the industry and leveraging our existing customer relationships more thoroughly to maximize our product penetration. Naturally, it is easier to cross-sell within an existing client rather than by acquiring new customers as a whole.

One of our major challenges was recruiting the right people in a time where we did not enjoy a well-known reputation such as some of the larger international companies established in Belgium. However, now that we have established ourselves in the regional market, we receive an array of spontaneous applications due to the fact that we have grown one of the largest local CRO's. Of course, this makes our lives in terms of customer and resource acquisition a lot easier.

Similarly, another one of our challenges was to convince potential and existing customers of our capabilities. Generally, our clients were satisfied with the quality of our resources and services we provided but setting up a CRO activity is an additional step due to quality assurance and internal stability that is required for such activity.

In that respect, the success of our CRO activities derives from our recognized expertise in the Clinical Data Interchange Standards Consortium (CDISC) field. CDISC's mission is 'to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.' Globally, there are only two companies involved in the CDISC field. In fact, the Director of B&DLS CRO services is the chair of the European CDISC Coordinating Committee, which organizes CDISC activities and conferences in Europe. Furthermore, he is the official CDISC instructor in Europe. Clearly, this is a great advantage for B&DLS as it places us at the forefront of this field.

Submissions of New Drug Applications to the Food & Drug Administration (FDA) require the submission of clinical study data in line with CDISC standards. This creates a string demand for coaching people in the particularities of CDISC procedures which B&DLS has a particularly strong team of employees in. Our reputation and expertise in the CDISC niche has generated significant amount of new business.

The Business & Decision Group, has announced a consolidated revenue of €115.2m for the first half 2012. Out of this €115.2m, what is the contribution of the Business & Decision Life Sciences segment? And more specifically, what is the contribution of the Belgium affiliate in the B&DLS to this?

B&DLS contributes approximately 10% to the Groups consolidated revenues, a large proportion of which is derived from our Belgium operations.

The core focuses of our activities in Belgium are staffing and CRO activities. Actually, we distinguish between three modes of delivery: staffing, CRO activities and an intermediate mode which is a service platform where people work from our offices and remotely connect and work on our clients system.

You mentioned earlier that the initial focus was mainly on staffing and CRO activities were integrated into that. How do you expect the evolution of this to continue? Are the CRO activities growing faster than your staffing activities?

Looking at the Belgium market for staffing, we have grown substantially; 20 % growth in revenues this year alone. In addition to this, our CRO activities have doubled in terms of turnover compared to last year. This spectacular growth of CRO activities has certainly attracted our attention and we are certainly dedicating more efforts there.

Furthermore, we find the combination of our staffing and CRO activities quite beneficial because our staffing services generally generate lower margins. However, due to the long term nature of the contracts we conclude with customers, it provides a more stable platform of revenue generation. This creates a financial certainty that we used to invest in our other CRO activities that require a higher level of investment and infrastructure in terms of quality management. Inherently, CRO activities are more volatile with regard to resource requirements.

What would you say makes BDLS the partner of choice for pharma and biotech companies? What is so unique about BDLS?

Staffing is a very competitive business which ultimately boils down to providing excellent resources, with the right competences, at a fair price. To be able to be the partner of choice, it is essential to have a solid recruitment infrastructure, which we have been able to achieve in order to respond adequately to customer needs.

What sets us apart from other staffing companies is our effort to counsel people once they are placed at a customer. If a complication exists, such as lack of performance or interpersonal

problems, we do our utmost to accommodate our customers. This is something we do better than our competitors, especially international competitors who tend to have a hit and run policy.

On the other hand, pharmaceutical companies used to submit their own internal database standards to the FDA. Once an application was submitted, the FDA had to figure out where to find relevant data; a time consuming process of course. Therefore the CDISC standards have been defined with the result that as of 2006 a significant proportion of clinical trials data is submitted to the FDA in accordance with those standards. Consequently, this had the effect of requiring clinical trial data conducted five to ten years ago to be converted into the appropriate format. Converting that clinical data to CDISC standards is a significant generator of business for B&DLS. Furthermore, we see that companies are increasingly implementing CDISC standards in their systems, presenting us with a wealth of opportunities. In fact, we have signed a number of agreements with large pharmaceutical companies to implement these standards.

In general, it has become apparent to us that we often establish our relationships with our clients on a management consulting basis, however, as this relationship evolves, they often request that we assist them to implement systems and often in that sense manage their relationships with their other CRO's in order to adapt their software.

When do you expect the CDISC standards to become mandatory?

This is still unclear. The FDA is currently working on the guidelines and in their material they have communicated that the CDISC standards will soon become a requirement. However, de facto it is the standard since the majority of submissions are according CDISC standards.

Belgium is an attractive clinical trial market, but some pharmaceutical companies seem to be shifting trials to even lower-cost emerging markets, where quality is increasingly strong. Given this scenario, will Belgium be able to retain its strong clinical research position in the coming years according to you?

I believe Belgium's clinical industry's main attraction is the high quality of work done here as well as the availability of a range of outstanding research centres to work with. Furthermore this nation has developed a strong research position because of an attractive regulatory landscape and its fiscal incentives for R&D in particular. For these reasons, I am convinced that Belgium will maintain its strong clinical research position over the medium term.

Where I do foresee some challenges in the future relates to our experienced population when it comes to healthcare. Recruiting patients for trials is challenging in general, however this is even

more difficult in countries with a well-developed healthcare system since they already have access to a good level of innovative drugs across a wide spectrum of therapeutic areas.

What effect will the EU proposal for clinical trials that is set to erode the country's rapid approval timeframes have on your operations over the medium to long term in Belgium?

The EU harmonization on clinical trials will certainly erode Belgium's competitive advantage in terms of timelines for setting up a study. On the other hand however, this country has a dense medical network with strong hospitals. Having said that, pharmaceutical companies tend to see great potential in collaborating with key opinion leaders for conducting clinical trials and this will continue to attract such sponsors.

Fortunately, the impact on B&DLS clinical activities will be limited since we are not highly dependent on clinical trials in Belgium. The majority of our work is conducted for companies that have research facilities in Belgium but their trials are conducted worldwide. Furthermore, we are not heavily involved in the operational aspect of the trials in this nation per say.

What would you identify as the main opportunities for the future?

A study by PriceWaterhouseCoopers demonstrated that data is becoming increasingly available either through clinical trials, social media or electronic patient records. For that reason, one of our efforts is to standardize the wealth of data that is available in our domain of activities. Combining our CDISC expertise with our standardization capabilities places us ideally to conduct these activities. Needless to say, we therefore expect a good level of future growth stemming directly from this particular niche. Indeed, we have seen that companies are recognizing the need to use data from different sources rather than just clinical trials.

Another aspect where we will be focusing on in the future is our CRO activities that have started with CDISC. This serves as a differentiator to reopen previously closed doors. Based on this activity we have been able to attract a lot of new customers. Moreover, once we have established a relationship with a customer we aim to introduce them to the advantages of our other services as well.

In terms of expansion we will focus more aggressively on expanding our capabilities in standardized CRO services, not only in Belgium but across the whole of Europe.

B&DLS has a global presence in nine countries across Europe, North America, Asia and North Africa. What are the latest developments of its international strategy? How is Belgium looking at expanding its operations, more organically or externally through partnerships or acquisitions?

In general, the company's growth so far has been organic, through green field investments, although our French affiliate was established through an earlier acquisition. This has worked out well so far but we are beginning to see some limitations to this, mainly in our managerial resources. This is of particular importance since the role of the Belgian office is to serve as the headquarters of B&DLS. Hence, we require the right people with the right skills in Belgium that can drive the company's expansion forward with the objective of becoming one of the largest European CRO's.

Our strategy is twofold. First, we aim to expand our R&D presence in key regions in Europe. More specifically, we intend to strengthen our presence in France, UK and Switzerland. Second, we aim to increase our geographic scope in order to offer a full range of CRO services across the European market.

Moreover, considering the fact that B&DLS is an independent business unit within the Business & Decisions Group, consolidated on a group level, financial analysts and investment professionals are not highly exposed to B&DLS. Hence, another one of my objectives is to increase our brand awareness to these players as well.

As a company to whom clients outsource clinical research, you need to demonstrate added value. For this, high quality staff is key. How do you attract and retain the best talent?

With regard to finding a management team for a CRO, there is no better place than Belgium. That is, a management team comes down to a few key people who have experience with the clinical research environment.

I believe that B&DLS's successful business performance and open culture serves as a strong motivator for our workforce. For instance, we tend to define a perimeter of action for our employees and within that perimeter we provide them with enough freedom to make their own decisions and to develop their skills. Our growth in the last five to six years has helped us to retain talent. Undoubtedly, B&DLS's growth presents our employees with equally attractive opportunities to grow along with the company.

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