Interview: Janet McDougall â?? President; John Amrhein â?? Vice President, McDougall Scientific, Canada

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Janet McDougall, president and founder of McDougall Scientific and John Amrhein, vice president in charge of business development, discuss the challenges that SME CROs are facing in Canada today, competing with the CRO giants, but also highlight the unique differentiation points McDougall Scientific is able to put forward, such as their core activity as statisticians, a service much in demand today.

Janet, you founded McDougall Scientific over 30 years ago, when regulations for human research were still in their infancy. What drove you to found the company in 1984?

I worked as a clinical trials statistician in a pharmaceutical company and enjoyed the work very much. An opportunity arose to work in manufacturing during a transition phase for the pharma company and I chose not to return to my clinical position when the transition was completed. I was attracted to the idea of having a broader range of challenges than was possible in one company. When an opportunity arose to work for a couple of pharmaceutical companies, I pursued this and somehow ended up taking this concept from my attic into a company. There was no grand business plan, as the idea of contract research organizations (CROs) was an unknown. The interest was always to produce good science, which is still the foundation of the company today.

What is the range of services that you are able to offer to your customers?

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The core of the company is statistics and statistics consulting. We support the statistical planning with needed technologies such as electronic data capture (EDC), interactive voice response systems (IVRS) managing randomization and trial supplies, creating submission ready data sets e.g. SDTM and AdAM and we recently launched an electronic trial master file (eTMF). The technology support is especially important for the mid-sized and smaller emerging biotech companies that do not have the infrastructure to conduct trials on their own; , the eTMF which is deployed per project, and as such is flexible and cost-effective, is an excellent example of the partnering.

As adaptive designs and Bayesian approaches gain importance in the design of effective clinical trials, more of our work is dedicated to client education. It is extremely important that our partners understand what is being done and how they derive benefits for their dug development program. The governance of clinical trial documents and data in a highly regulated world is another example of the importance of partnering and providing rationale. Many of our clients from the academic space believe research funded by government grants and research required by a regulatory body (e.g. FDA, Health Canada) follows the same process, when in fact it is very different.

Where do most of your clients come from today?

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Ten years ago, our clients were almost exclusively biotech companies. The 2008 recession taught us the hard lesson to diversify our portfolio in order to rely on the financial stability of larger pharmaceutical companies. They today represent about 30 to 40 percent of our business.

Another 30 or 40 percent of our business comes from mid-sized players, while emerging biotech companies make up for about 30 percent as well. Big loves big, and many international corporations have preferred supplier contracts with larger CROs. However, when they realized that a lack of competition drove the prices of big CROs to astronomic heights, many turned to work with smaller CROs like us.

Another trend with large MNCs is the tendency to centralize and bring all outsourced functions home, in the hopes of saving money. However, the result is always the same and no money is saved, but by the time those companies realize that it does not save them anything, they have to rebuild their infrastructure, which is where we can help. Over the years, McDougall Scientific has seen several of these cycles, and we patiently waited and picked up work when it was our turn to step in.

How do you position yourself as a smaller player to attract both larger and smaller clients?

In 2008, the big CROs started to enter our market and increasingly went after the smaller biotechs. Suddenly, we were confronted with the names of big CROs when competing for business, instead of the names of our fellow mid-sized and smaller CRO peers. What happened however, is that, although the economy has picked up again, the large CROs have not left our initial market. They established themselves and created special teams for the biotech sector. When we are going up against a big CRO, I put forward our adaptability and flexibility, which big CROs cannot match.

Our flexibility and capacity to adapt on a project basis really is our strength. as, we do not have the bureaucracy of a large CRO. If the needs on a project change, we are able to incorporate those quickly.

Moreover, our clients know that the team they interact with during the hiring phase will also be the one conducting the project. We do not sell the A team and then put the C team on the project. Everyone in the management team is involved on an operational level. We supervise but remain attentive to each project. Many of our larger clients are very happy to work with a smaller CRO. They appreciate the continuity and have found in us a partner to trust.

What do you consider to be your key performance indicators today?

One KPI we look at internally is our capacity of performing tasks in an efficient manner. Decreasing the amount of effort we allocate to a task that has a fixed cost allows us to be very cost competitive. Nonetheless, sales are not our main interest when it comes to measuring our performance. We much more turn towards client satisfaction and scientific quality. Those are also the elements that secure the business for the future. Often, we are brought in on a rescue mission for a project. Being able to turn it around, we gain a new customer. Loyalty is our best salesforce, and loyalty does not originate in sales, but in the quality we produce.

Disruptive technologies such as artificial intelligence (AI) and big data are sure to touch all fields in healthcare. They carry much promise but will also require major investments from those willing to embrace them. How are you integrating these in your strategy?

As a smaller player, we cannot take the same risks as larger companies. We are concentrating on more mature technologies, the mobile market for instance. McDougall still works with a 100 percent closed system today. Out of conviction, we stayed clear of any cloud-based technology, and have a very cautious and security focused attitude towards data management. Not only do we wish to protect ourselves, but we are also wary of undertaking risks for our clients. It is important we can ensure their safety, because they do not have the time to do so.

AI and Big Data manifest themselves in bipharma in a number of ways. For example, predictive analytics are applied to thousands of compounds under development in the drug discovery phase to help decide which ones proceed to pre-clinical. Large data methods are also needed to sift through biomarkers to determine which ones predict treatment response. McDougall is helping several clients learn how and where they can augment clinical trial data with real-world evidence to more efficiently answer research questions facing them. In pharmacovigilance, causality is of utmost interest and Bayesian network models are gaining prominence to provide probable cause to adverse events.

What other challenges do you see arising for CROs in the future?

Costing is a big subject and a challenge to us. We need to support our electronic infrastructure in a safe and compliant manner which brings with it costs we cannot pass on to our clients as they are highly price sensitive. Hence, our only way to gain margins is through gains in productivity, but we have become so good, there is not much space left to increase cost efficiency here.

Consolidation is another issue. There are fewer CROs and we have seen some mega mergers in the industry. As a result, certain competitors have very deep pockets, and the capacity to allocate resources to projects in numbers we cannot match. Moreover, they are the ones controlling the messages to our clientele because they quickly put out the blogs and whitepapers, and it is tough for us to get ahead of that.

Our big pharma clients turn to us for real-life evidence. They all want to reduce the costs of clinical trials by enrolling less patients and relying more on electronic medical records, hospital records, registries, social mediaâ?¦ They lack the methodology to obtain this data however, and to some extent, we can procure it by quacking of conversations between the right players. However, I also

ask: who owns this data? Some might say the patient, others the hospitals, and some even say â??we do!â?• I believe this web has to be untangled before we can move forward with more real-life evidence.

In fact, we see this domain as the next big one governments have to deal with. While in the US patients do not own their data, in Canada the system is even more complex, as every province has its own regulations on data.

What is the plan for the future at McDougall Scientific?

I matured as the company has matured, and my responsibilities have evolved with our business. There was always a balancing of doing the work as well as getting the work. John was brought onboard as a senior statistician, but quickly migrated to overseeing business development. While most of our clients are still coming from repeat business, we have extended our tendrils towards a more strategic approach to market.

We have made the choice to pursue a slower more organic growth at McDougall Scientific; we call it Smart Growth â?? testing out ideas, usually technology, and de-risking them before committing to them. Our other pathway is through strategic partnerships â?? working with people and companies that share the same passion for innovation and quality; trust is a core element of these relationships

Having been around the industry for so long, what keeps you fascinated about it?

The science and statistics. I have always been driven more by the science rather than the business aspect and, today, statistics is evolving so quickly as a discipline that it is tremendously exciting and challenging to keep up. The young people we hire are incredibly agile and knowledgeable; there is never a boring day. As statisticians we are in interesting times, with so much data being acquired yet the need for reliable data for decision making is paramount; it is a balancing act. It is a good time to be a statistician.

We can always remind ourselves that our work does make a difference, it can eventually save lives because of the evidence we bring. A mediocre job may muddy the water to a degree that the new treatment being tested cannot be recognized for either its potential or worse, its harmful effects. This results in a waste of money and opportunity and patients might die because a beneficial treatment is not approved or a harmful effect is not detected.

The recent trends have allowed us to work on unique designs more and more. Bayesian has become a game changer; we are able to uncover so many more answers than previously. Platform trials in which patients and protocol are shared by sometimes ten different pharmaceutical companies are very much in vogue. Particularly in oncology, basket and umbrella trials are a trend. Cancers are no longer classified; everything is being verified through biomarkers. The analysis of this information requires unique and sophisticated statistical approaches; this is where our work comes in. It has blown open the doors to new possibilities for all pharmaceutical companies.

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