Interview: Janice E. Parente – President, ethica Group, Canada

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Dr. Janice E. Parente, president and founder of ethica CRO, explains what led her company to work with pharmaceutical companies internationally and how ethica CRO's accreditations are an emblem of excellence. Furthermore, she presents ideas on how Canada could be more competitive in terms of R&D globally, by converting its weaknesses into strengths, and focusing on niche studies.

Janice, how did ethica CRO come to exist and what does it stand for today?

ethica CRO's primary focus is designing and conducting research studies for other companies, and is part of the ethica Clinical Research Inc. Group of Companies, which includes Veritas IRB, a central research ethics board (or IRB) and Merita CQA, a clinical quality assurance consulting company.

Sixteen years ago, when I founded ethica CRO, I had already been running a CRO business for ten years. With my first CRO, one of the key challenges was teaching pharmaceutical companies the concept of outsourcing clinical research activities. We had to create our market.

While phase I bioequivalence studies in Canada were being conducted at private facilities, the benefits of outsourcing of later phase studies was not a major point of discussion or interest. The management of phase II, III and IV trials remained the responsibility of in-house personnel. However, after considerable interaction with potential clients, I quickly grew my company and started conducting clinical trials in numerous therapeutic areas.

After I sold my previous company, ethica CRO was quickly established thanks to my past clients' eagerness to work with me and my new team. We were dedicated to bringing in a new dimension, the ethical dimension, focusing on integrating research participants as partners in research rather than simply subjects of research. At ethica CRO, the research participant is at the center of all our standard operating procedures, research and business activities. This means that we may suggest modifications or even decide to not submit a proposal if we believe that the research project would compromise the protection of research participants' rights and welfare.

What have been some of the main milestones of ethica CRO's path over the past decade?

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The most important milestone was the one of our accreditations, a long and challenging process that resulted in the double accreditation that we hold today. We achieved our first accreditation in 2006 from AAHRRP (Association for the Accreditation of Human Research Protection Programs), becoming the first accredited CRO in the world and the first accredited Canadian research organization. At that time, the challenge was considerable as the accreditation standards were not fully adapted to CROs. We basically had to work with AAHRPP to adjust the accreditation standards so that they could fully apply to a CRO.

Subsequently, we applied for, and received, accreditation by Alion HRPP (Human Research Protection Programs) Accreditation Services in 2013. Alion had developed accreditation standards and an approach that were more suited to the type of work we conducted. Achieving accreditation by two independent research accrediting bodies was definitely one of the greatest testimonials of ethica CRO's commitment to the quality and ethical conduct of its research.

Among our other achievements, we were the first CRO to submit a Clinical Trial Application to the NNHPD (Natural and Non-prescription Health Products Directorate) at Health Canada, which allowed us to build upon our reputation of conceptualizing and running trials with natural health products.

We have also become the CRO of choice to lead clinical projects sponsored by Canadian Department of National Defence and are working on joint program to develop a nerve agent antidote along with the Netherlands Ministry of Defence the UK Ministry of Defence.

Today, ethica CRO is renowned for being able to design and perform complex trials that fully meet the expectations of Health Canada and the FDA. Just this summer the FDA and Health Canada

audited us for two pivotal clinical studies that we conducted and submitted for regulatory approval. It was an intense process, but we passed with flying colors and with no findings noted by the auditors. If anyone is wondering what the value of accreditation is – well, this is it. Although it was not the first time that ethica CRO was audited by the FDA and Health Canada, it was the first time that the full spectrum of our services (protocol development, clinical management, site management and monitoring, data management and biostatistics) were covered within the same audit.

How do you evaluate the trend we have seen occur within the past decade where large pharmaceutical companies outsource their R&D activities to CROs and consider these as strategic partners rather than 'just' service providers?

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I think this trend has both benefits and drawbacks. On the downside, the tendency to consider their CRO partner as a preferred vendor often renders a pharmaceutical company blind to the advantages that a competing CRO could deliver. Rather than comparing the potential partners' offerings, they stick with their preferred CRO, thus preventing healthy competition.

If you are however the preferred partner, you have the opportunity to build a close relationship, one of trust and mutual understanding. As partners, each understands one's methods and styles, and relies on the history of a shared and proven track record.

In the end, whether you think this evolution positive or not, you have to adapt to it, because as a CRO your success will depend greatly on your capacity to meet the requirements of the large pharmaceutical companies.

What do you identify as the most pervasive challenges currently impacting CROs in Canada?

There is not an abundance of quality Canadian CRO players, and the competition with American and European CROs is fierce. Our foreign competition has offices in Canada, and they can always lean on their global headquarters should unexpected challenges present themselves. But this comes at a cost, both financially and in terms of responsiveness. We put considerable effort in educating pharmaceutical companies that ethica CRO is much better suited to run small and medium sized studies on Canadian soil than any of the global CROs.

As a majority of the Phase II and III studies conducted in Canada are actually conceived and financed by foreign head offices, we typically end up working with study team leaders located

outside of Canada. This has led to us acquiring the majority of our work from clients located in the US or Europe. Very often, even the investigative sites under our management will be located outside of Canada. By default, the majority of our CRO services are international.

What is the scope of ethica CRO's international presence?

There were two aspects to our internationalization. Firstly, since the Canadian market was quite limited, we reached out to pharmaceutical companies all around the world, selling our proven record of delivering services of the quality expected by both Health Canada and the FDA. Then, convinced by the quality of our work and our accreditations, we attracted the interest of more and more foreign companies. Many European and Asian now use ethica CRO as the conduit for their North American research operations. This lead us to where, today, we conduct studies all around the world, including Brazil, Argentina, India, Australia, New Zealand, Europe, and especially, the USA.

How do you assess the attractiveness of the Canadian clinical trials and R&D environment, and what could be done to render it more attractive?

Canada is in itself a perfect place to conduct research. Canadians have again and again proven their ability to produce top-quality research and our centers of excellence are of the highest repute.

Study Sponsors want a quick and simple path for site identification that leads to reduced study start-up times. Recent initiatives such as the Canadian Clinical Trials Coordinating Centre (CCTCC), a unique collaboration between government, industry, and healthcare institutions, enables Sponsors and CROs to quickly identify clinical research sites and investigators.

Canada could find advantage by positioning itself as a country of excellence for smaller studies or more complex studies requiring innovative designs, the type ethica CRO has excelled with in the past. For example, drug device combinations or studies incorporating omic technologies.

Health Canada's Medical Device Bureau and NNHPD does not have a fixed review timeline for trial applications, unlike the Therapeutic Products Directorate with its 30-day review target. Simply by adopting a similar 30-day review timeline, Canada would increase its opportunities to attract more R&D for medical devices and natural health products.

Lastly, and perhaps most importantly, Investigators and investigative sites, CROs, institutions and biobanks should all be accredited to conduct research on humans. This would allow Canada to provide, as a country, consistency and excellence with all of the clinical research conducted here.

How does your service portfolio respond to those challenges?

At ethica CRO, we have watched the market evolve and have seen which companies survive and which do not. We thus moved into the niche of complex studies, for which out-of-the-box thinking is required, while maintaining all of the regulatory rigor expected by regulatory bodies.

We operate in almost all therapeutic areas, leaving out only oncology. We have covered infectious diseases, neurology, psychiatry, dermatology, pulmonology, metabolism, gastrointestinal, HIV and cosmeceuticals, amongst others. Some of the big trends we are observing are cosmeceuticals and medical devices and in the future, we will begin to see the development of personalized devices for many diseases.

There is a growing importance of technology platforms within the CRO landscape in addition to more traditional project management and clinical research expertise, artificial intelligence (AI) being but one of them. Where do you see this trend move?

We are always on cutting edge at ethica CRO and have quickly adapted to new trends. I believe that we will see the importance of AI exponentially expand and play into everything, including drug discovery, health monitoring, as well as data capture for clinical studies. As with everything, the real question is how does this impact the research participant.

The biggest question here is that of the whereabouts of the collected data. It needs to be clear for the participant, where his or her data is going, how it is being processed and how it is being secured. Before jumping into new technologies, we should ensure that we know the answers to those questions and that the environment we provide is perfectly safe. It really is a matter of ethics.

What are ethica CROs main differentiation points when compared with global CRO giants?

We are leaders in research ethics. And we present to our clients something no one else does, a participant-centric risk management platform. Our accreditations speak for themselves. As for our history of regulatory audits, we know our business – as confirmed by the FDA and Health Canada.

We have a history of running very complex studies and we are not hard pressed to adapt to any type of study design.

Finally, compared to a large CRO, we provide equitable services with considerable cost savings. We do not “over-engineer” study management logistics in order to employ excess capacity. Rather, we

provide streamlined and personalized Sponsor/CRO communications to minimize costs and increase responsiveness.

What will be ethica CRO’s key priorities in the years to come?

We will replicate our successful internationally model to Canada. Furthermore, we will maintain our strong focus on medical devices, as well as on drug device combinations. Additionally, with genotypes and phenotypes playing bigger roles in the design of personalized treatments, integrating omic technologies to our research designs will be a competitive key advantage.

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