Interview with Paula G. Strassmann, President and Founder, PGS Medical Statistics

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PGS is a member of ABRACRO, but is in a unique position as both a CRO and a service provider to CROs and pharmaceutical companies. Can you elaborate on the niche PGS plays in the Brazilian market and the pharmaceutical sector?

PGS is a company focused on statistics , data management and data base as well providing in both version electronic and paper CRF. The goal that PGS plays is to follow and accompanying service from the beginning till the end of the project. PGS counts nearly 40 very highly-trained employees across different fields, with backgrounds ranging from pharmaceuticals, to IT, psychology, and statistics.
As mentioned before, PGS also serves other CROs, and that’s because in Latin America very few companies develop the services that we can provide here.

The history of the company dates back nearly 40 years. I’m a statistician and I start and the built PGS from the ground up. The company was developed to such point that in 1998 it was able to be sold to Quintiles, however, after some years I realized that my entrepreneurial spirit made my eager to work by myself again! Therefore, I decided to start a new company from scratch. Today, PGS provides services to some of the biggest CROs in the market in Latin America, in addition to some operations in Latin America, Asia and some sites in Europe. Last year an Indian company contracted us to take care of a project here in Latin America. Besides that , we also provide support in clinical trials for Cleveland Clinic , Florida, USA.

You mention a long growth trajectory. What have been some of the most important growth points?

When I started PGS, clinical research in Brazil was only just begging. Some call us like an “Icon” of clinical trials, because we have been in the business for a very long time. I was the first consultant for statistical programs in the pharmaceutical industry.

Until 1998, PGS was a small business with 10-12 employees, but we had very good clients in Brazil. During my experience at Quintiles, I travelled extensively to do onsite benchmarking, and learned about SOPs, rules, and how large international companies really worked. It was an excellent school, and personally very interesting, and gave me the necessary tools to start the second company as a multi-professional group, with all the rules, all the SOPs, and all the validation.

Though the new company created in 2002 was a professional group with a more organized focus, the quality of the service was the same; nowadays I have the best statistician group in Latin America. What is different is that PGS have a lot of software and licences that the FDA requires such as Medical Dictionary and the SAS statistics program. Furthermore, we created a software called PGS Trials for develop eCRF (Intellectual property) based in our expertise of more than 25 years in data management and data base for clinical trials.

You mentioned the internationalisation of clinical trials. Data processing and data transfer can be done as easily in Brazil as it can in Asia. How can PGS remain competitive against countries like India and China, whose far lower costs would seem to make them ideal hubs for outsourcing?

What makes PGS the partner of choice? The fact that we work very close with our clients, better , really like partners. PGS is really well-known in the market, and the relationships we have built with the clients are the reason we have been approached so much with purchase offers.

Regarding the competitive advantage against a country like India is that, even though they may have more people working, there is a greater zone time barrier and quality. China, while there is still a language problem, tends to be more competitive. Brazilians overall perform at a much higher service quality, and are much better at performing under deadlines and dealing with authorities like ANVISA and CONEP, which can take a long time.

In fact, the quality of the services that PGS can provide is globally competitive .

What is the importance of PGS Trials in your services and day-to-day operations?

75% of the current trials are done using eCRF. Why PGS ? In my vision is because PGS provides the full package and therefore full support during the entire trial process. Everything here is integrated,

and everyone works together. The Statistician , the Project Manager, the DM Manager, the Validation Manager and the IT Manager discuss together how the project is progressing and how each department can support the project. Everybody here gets trained, understands the protocol, what is going on, and what clinical trials are.

At the moment, PGS is working on almost 70 projects in different stages: some in feasibility, some in programming, and some in medical writing.

When we met with Mister Harada at ABRACRO last week, he mentioned that Brazil offers great advantages for companies in clinical trials, and believes the country will become a hub for clinical trials. Do you share this optimism?

Yes, I do. Brazil is developing a lot, and the economy is more stable now a day, with a large base of highly-skilled professionals, and the government seems committed to constant improvement in this regard. In fact, the government is actually paying for post-graduation programmes outside the country, and President Dilma has opened a lot of possibilities for people to go and work and learn abroad to bring more technology and knowledge to Brazil. The front-runner to be a Latin American hub used to be in Argentina, but now the most of the companies are moving their operations and offices to Brazil. With all the modifications in the government ANVISA and CONEP, the possibilities are changing and growing every day.

The most important fact remains that Brazil, now with a better economy , have better capability to manage the Latin America market.
What is your vision for the future? How would we find PGS in 2016?

First of all, you will find PGS bigger! I’m investing in the company . I believe in the market and in the ability of PGS to serve it. Furthermore, in five years you will see some technological breakthroughs .

The fact is that the market is changing. Companies realize that third parties are much cheaper and more efficient than having the same capabilities in-house. PGS, with a sector-leading flexibility and history of top-tier service to a broad range of clients, will continue to benefit from this trend.

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