Interview: Victor Strugo â?? Managing Director, Triclinium Clinical Development, South Africa

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The MD of Triclinium Clinical Development discusses how South Africaâ??s established First and Third World research opportunities and long-established GCP culture have made it a uniquely attractive country for clinical trials; how Triclinium has grown during a challenging decade, emerging as the largest independent home-bred CRO, winning significant preferred provider agreements and competing successfully against resource-rich international companies; and how the Triclinium brand is poised to take root in new territories.

You founded Triclinium in the year 2000 after a career spanning multinational pharma, CROs and academic trial sites. What particular niche did you see in the South African CRO industry when founding the company?

The first home-bred CRO was established in South Africa in 1990 and soon acquired by one of the multinationals that came into the country during that decade. Come 2000, I could see that there were still opportunities for a local company that thoroughly understood the local research paradigm

to thrive in the growing CRO space. In February 2000, I therefore opted to leave RhÃ´ne-Poulenc Rorer as it was absorbed into the emerging Aventis, believing that my network of investigators and international client contacts formed a solid foundation for a new independent CRO. At first we were essentially a regulatory and monitoring specialist that in-sourced related services such as biometrics. Within two years, we were winning large late-phase contracts that passed FDA inspection. The resulting increased awareness of our regional success (not only in South Africa but the whole sub-Saharan region) enabled our gradual growth to a one-stop full-service CRO. Realising that the next big African research wave after the ARVs would be the challenging development of AIDS and TB vaccines, the best strategic decision we made was to actively express an interest in donor-funded Product Development Partnerships (PDP) working towards eliminating the diseases of poverty. Key investigators endorsing our work quality and ethic led to us winning a substantial amount of this work, which in turn helped us attract and retain excellent staff to whom working on projects of high regional relevance really matters.

How would you characterise the environment for clinical trials in South Africa and how does it compare to the environment in other emerging markets?

South Africaâ??s combined characteristics of first and third world medicine have long been recognised as attractive to clinical research. Two decades of social upliftment have additionally established a third tier of affordable semi-private medicine that brings treatment-naÃ¯ve populations closer to state-of-art diagnostic methods and research-equipped facilities.

Other significant advantages are being in western Europeâ??s time zone, the use of English as the language of clinical trial conduct and data recording (although we have 11 official languages) and year-round recruitment in global trials due to the inverse seasonality of the southern hemisphere. We also have a long-established GCP culture: the first global registration trials were done here in the 1970s, since when the South African investigative community has grown, both in the high-tech private sector and the larger academic-affiliated public sector, accelerated by the Medicine Control Councilâ??s (MCC) conscious push for trial sponsors to build research capacity. The stringent national and ethical review systems for clinical trials provide further assurance of global standards. In our experience, the MCC has an unfairly persistent reputation for slowness: it is not unusual for robust applications to be approved in three months, and initiated within four.

Over the last 10 years, most top global CROs have set up fully-fledged operations in South Africa to serve the continent. To what extent does South Africa act as a regional hub for clinical trials?

From the first democratic elections in 1994, it was predictable that South Africa would be an appropriate hub for extending clinical research northwards. Triclinium started working in Kenya in our first year. We have since managed trials in 16 African countries. The enduring role played by grant-funded organisations in creating this growing pool of competent research sites must be acknowledged. Initially most trials were monitored from South Africa but skills transfer and growing resident experience now allows us to employ Kenyan and other nationals in situ. Currently about 70 percent of Tricliniumâ??s work is still performed in South Africa, but that is changing. Saturation of target populations is driving our growth not only up the continent but also beyond African shores in the foreseeable future.

What has been your main focus of attention over the last few years?

Our most significant strategic decision, when we were still very small, was to seek actively to engage in supporting donor-funded research on the diseases of poverty at a time when large CROs were pursuing preferential agreements with big pharma companies. Targeting such organisations with the

strong endorsement of influential investigators who recognised the quality of our services led to us being selected in 2011 as one of six Preferred Provider CROs by the Global Health Clinical Consortium, a group of 14 PDPs working on new medicines for neglected diseases. Five of these organisations are still on board; although still the smallest, Tricliniumâ??s project award rate is disproportionately high considering that three are big multinationals. The credibility and organisational growth resulting from this engagement have increased our visibility to Pharma as a one-stop option to manage increasingly large multinational projects. We are also sub-contracted via the U.S. Division of AIDS (DAIDS) of the National Institute of Allergy and Infectious Diseases (NIAID) to provide regional regulatory support for the P5 Partnership that is developing preventive HIV vaccine regimens in Africa. Going forward, we are in the process of developing novel solutions to increase efficiency and data quality by radically overhauling the traditional way clinical and data monitoring operations collaborate and moving swiftly toward a far more integrated approach.

There are a lot of strong, global CROs in South Africa. What sets Triclinium apart from other actors in the industry?

You should ask this question to our clients and investigators, but I believe that our size is a key advantage, having reached the critical mass to deliver the service levels expected of a large CRO, yet retained short internal communication lines. Our senior managers are experienced, accessible and respected for their ethical values and â??can doâ?• culture. This simple approach is the Triclinium brand. It has fostered a strong sense of staff loyalty and the kind of enduring client relationships that maintain an 80 percent repeat business rate. Having almost doubled in size to over 80 staff in the last two years and as we now spread to new territories, we have to add new ideas, skills and cultural modalities to the strong foundation. People must want to belong; clients must know why the want to work with us. Those who trust one another succeed together.

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