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The trials leader

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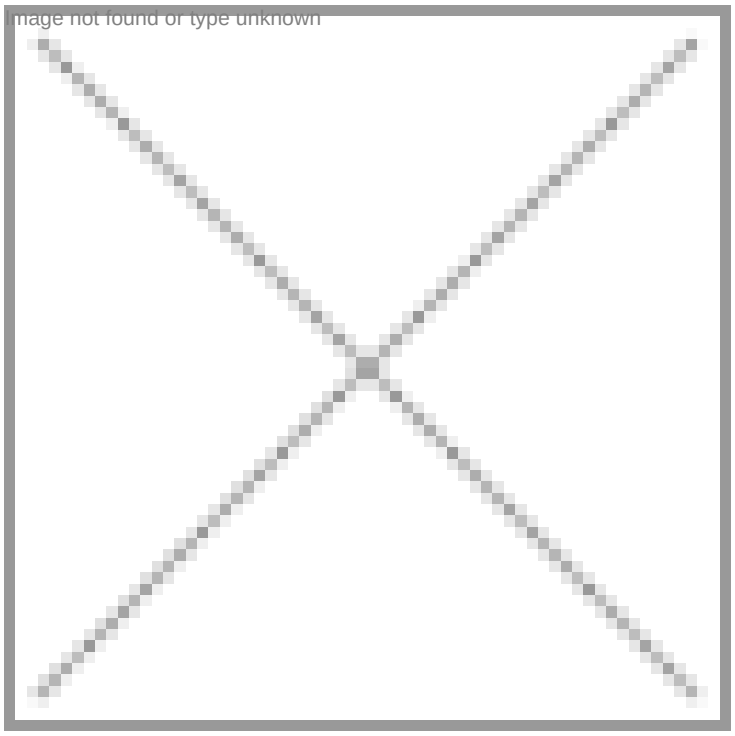
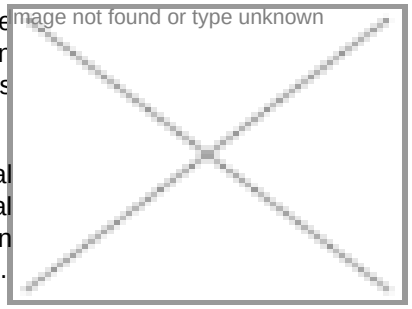


All the hard work done by the company is beginning to payoff. The company was given the first Rabo India Business Award as the "Bio start-up of 2003" for its "pioneering role in clinical development and success in conducting international clinical trials." The award was given during the Bangalore Bio 2003 event in April.



"Over the years, our confidence has grown. The confidence reposed in us by international sponsors has also grown manifold. We have conducted clinical trials for several global pharma majors and our study results have been found acceptable for regulatory filings in the advanced countries," said Dr Gautam Daftary, founder and director of SIRO Clinpharm.

SIRO is currently conducting clinical trial projects in over 30 hospitals across the country for several clients from Europe, Japan, the US and also India. SIRO has worked for at least 12 Japanese pharma companies and four each from North America and Europe. Analysts said SIRO's client base has grown significantly in the last six years. At least four Indian pharma companies too have used SIRO's services.

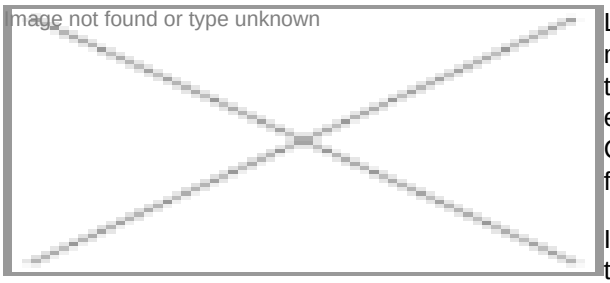
SIRO's team has 12 medical doctors and an equal number of research students besides some 12 postgraduates in pharmacy working in various divisions. Experts said SIRO is one of the few CROs in India that has the experience to conduct clinical trials to generate data that can be submitted to the US government's Food and Drug Administration (FDA). SIRO has completed some 20 projects so far.

These trials are mostly in different areas like oncology, endocrinology, truamatology, sports medicine, pulmonary diseases, pediatric diseases and infectious diseases. Elaborating SIRO's strengths Dr Daftary said, "our capabilities encompass the full range of phase I â€“IV clinical trials. We understand that each client has unique research goals and requirements. Consequently, our clinical trial services can be customized to fit the needs of each particular study. Our clinical trial and management services are conducted under standard operating procedures in accordance with Good Clinical Practice (GCP) as promulgated by the ICH (International Commission on Harmonization of medical trials data)."

The company started in a small way in May 1995 when Dr Daftary launched the SIRO Research Foundation as one of the first clinical research organization (CRO) to conduct clinical trials with global standards in the country. Though global pharma companies have been conducting clinical trials abroad for decades, India was not chosen till then for any project. The reasons were mainly lack of experience and training in conducting clinical trails, doubts over data authenticity, inability to maintain confidentiality of data and absence of global standards in the country.

Dr Daftary set out to change the perceptions about India and wanted to leverage his personal experience in conducting clinical trials. He tried to build the SIRO Foundation as an independent organization that would follow world class standards in providing clinical trail solutions to large and niche companies across the world. He believed that it was only a matter of time before the global pharmaceutical industry began looking at India as a destination for clinical trials due to the various inherent advantages. It was based on the fact that the success of the software export sector had created a buzz about India as a good place for various activities of knowledge industries.

"The business model was risky since there was neither the trained pool of people nor the immediate acceptance of India as a preferred destination. However, our interaction with close business associates in Europe inspired confidence and one European company gave us the first contract even before the formation of SIRO," recalled Dr Daftary about his first experience in venturing into the clinical research area.



Later SIRO established its mark by conducting clinical trials for many more clients in a short time. The organization specialized in conducting trials for both efficacy and therapeutic segments. As the activities expanded beyond research services, the name was changed to SIRO Clinpharm in 1997. It started doing high value clinical and analytical work for various clients.

It was not just roses all the way. "There were several hurdles which had to be overcome in setting up this innovative venture," recalled Dr Daftary. SIRO had to build up capabilities down the line for conducting high quality clinical trials meeting international standards. This involved creating a core team, training, identifying investigators with the appropriate mindset, training the teams of investigators to meet ICH-GCP standards, assisting institutions in setting up independent ethics committees etc. In short, SIRO had to create the groundwork for all the processes to conduct clinical trials.

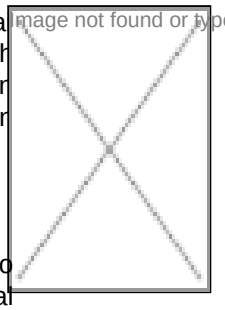
Similarly, it had to convince international sponsors about the attractiveness of India as a clinical trial destination and in particular SIRO's ability to conduct clinical trials in India which would be acceptable for registrations globally. SIRO is now ready and confident of being a part of the global clinical trial community. SIRO has plans to expand beyond the country's borders and take up similar projects in many other countries.

"While we are already a part of the network of organizations conducting global clinical studies, I believe that an association with a global CRO would be the fastest way ahead. At present we are discussing with one of the larger global CROs and are hopeful of inking the agreement in the next few weeks. I believe that SIRO is set to enter a high growth phase in the coming months, " said Dr Daftary.

Excited about the growing confidence among the clients about his company and hard work of last eight years now bearing fruit, SIRO is striving hard meet the increased expectations of the global community including investigators, sponsors and regulatory authorities to deliver consistently reliable data on new drugs and medical devices. SIRO believes that it has a significant role to play in the drug development process and it is now looking at several avenues to consolidate and enhance its knowledge and experience to grow globally.

Narayan Kulkarni

"A billion dollar clinical research opportunity lies in India"



Dr Gautam Daftary, a leading authority in new drug development in India is the founder director of Mumba based SIRO Clinpharm Pvt. Ltd. After completing his medical education in 1982 he has been working with the pharmaceutical industry and has over 20 years of experience in pharmaceutical management. In ar interview with BioSpectrum, Dr Daftary outlined the opportunities offered by the business of clinical trials ir India. Excerpts:

How do you see the growth of contract research activities in India?

India is emerging as a major center for clinical trials as big pharmaceutical companies are working hard to develop new products quickly. A large and diverse patient population, networks of academic and medical centers/hospitals, a big pool of scientists, technicians and doctors are some advantages India offers to these companies. Recognizing this potential, several clinical research organizations (CROs) and multinational companies have already set up facilities for research in India. Clinical research is projected to be a $ 1 billion opportunity for India.

Are the global regulations being followed in India?

Most teaching hospitals now have well constituted ethics committees that comply with ICH requirements for composition. All trial protocols require approvals from institutional ethics committees before they are initiated. Currently there could be some lacunae in compliance to most of the ICH â€“GCP requirements related to the functioning and standard operating procedures for ethics committees. But a conscious effort is being put in to comply with operational requirements of GCP by many institutions.

The investigator usually submits the protocols and consent documents in English and their translated versions in local languages along with other necessary information including the investigator's brochure. Approvals by ethics committees could generally take up to 60 days and occasionally the approvals come even within two weeks. There is no national level ethics committee in India. Some pharmaceutical companies have taken the initiative to form such a committee to facilitate clinical trials by doctors.

Do the regulatory mechanisms support the growth of CROs in India?

The regulators have recognized the potential benefits of encouraging clinical trials in India. The various steps taken by the government of India including the exemption of customs duty on medications used for trials, various amendments in Schedule Y and release of Indian GCP guidelines are evidence of their good intentions.