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Regulatory structure must evolve

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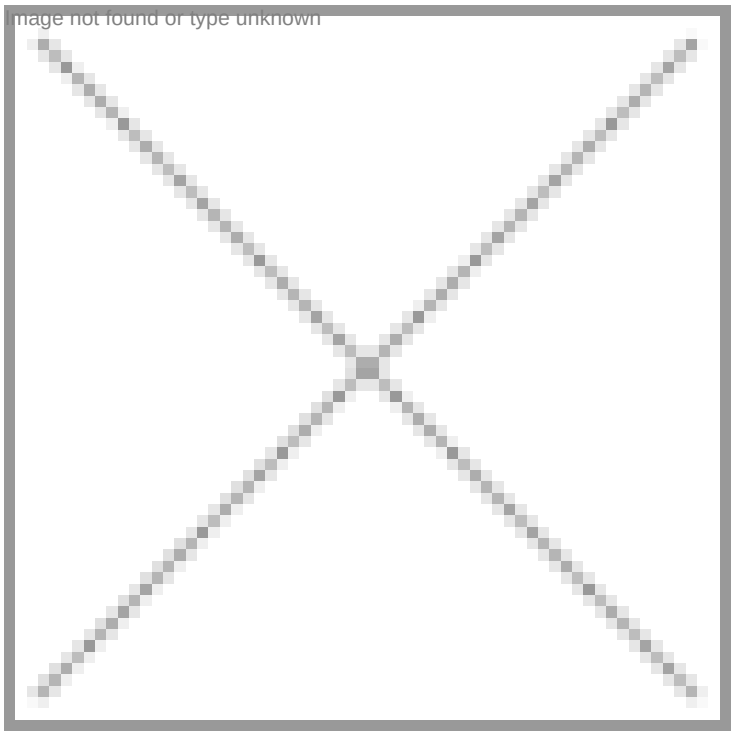

Image not found or type unknown 21drgautamdaftarysiro **Dr Gautam Daftary** Founder and director, SIRO Clinpharm	A bachelor of medicine by qualification and an industrialist by profession, Dr Gautam Daftary is the founder and director of SIRO Clinpharm. He is associated with many other businesses, the most prominent being Bharat Serums & Vaccines Ltd, which was established in 1971

SIRO Clinpharm began its operations in 1996 in India. After the Government of India adopted product patent in 2005 as part of signatory to TRIPS, the floodgates opened for the clinical research organizations. In the next three years, we felt a need to expand our operations and that is when we acquired a German CRO in 2008 having operations in Germany, Greece, Romania, Estonia, the Baltic states and Israel.

In early 2009, SIRO opened offices in Czech Republic and Spain in Europe. In 2010, it continued with its expansion program and entered into alliances with CROs in South Korea, Taiwan and an SMO in Sri Lanka. In early 2011, SIRO further expanded to bring Malaysia on its clinical monitoring map.

The objective was clear - to become a global CRO by 2011 providing clinical and data related services from phase I through IV - and all the countries where we expanded have been contributing to the growth of the organization. Traditionally, SIRO Clinpharm has been in the business of patient recruitment and has strong site relationships in its countries of operations. Realizing the importance of other services in clinical development during its growth journey over a period of last few years, SIRO started offering data management, biostatistics and statistical programming and medical writing in 2001.

Subsequently, SIRO came into other services like feasibility and clinical trial supplies management. We are in the process of launching the Strategic Center of Excellence in Data, Analytics and Medical Writing (SCEDAM), a strategic business unit of

SIRO especially to cater to the needs of clients who want to enter into a long-term relationship with a CRO for data related services and medical writing.

Considering a very low level of awareness in India about medical writing while simultaneously anticipating huge demand and supply gap in near future, SIRO has also set up a medical writing training institute Center of Excellence for Medical Writing (CEMW).

SIRO offers various services in stand alone or bouquet form in different countries in Asia and Europe, where it hasoperations as of now.

SIRO is strong in various therapeutic areas including oncology, diabetes, cardiovascular, respiratory system, and CNS to name a few. We have successfully managed projects in these therapeutic areas in various countries of Europe and Asia.

In the last five years, SIRO has managed more than 300 projects in clinical monitoring, more than 320 in clinical data management, more than 780 in biostatistics and statistical programming. In medical writing, SIRO has worked on 160 CSRs, more than 13 manuscripts and about 3,000 narratives.

The ICH GCP guidelines, which form the basis for Indian GCP, came into existence in the mid 20th century in developed countries with the US, Europe and Japan as founder members, whereas till the beginning of the 21st century, clinical research itself was in a nascent stage in India.

Despite all the media attention that India received in the last five years or so for clinical research, India is still responsible for not more than two percent of clinical trials being conducted globally. It thus goes without saying that the regulatory structure in European countries where SIRO has its presence is far more evolved and robust than that in India.

All the countries in Europe that are part of European Union are harmonized with the European Clinical Trials Directive 2001/20/EC (EUCTD), introduced in 2001 with an aim to standardize clinical trials throughout the European community. The process of approval and time-lines still differ from country to country within the European Union, for example regulatory time-lines in Germany are about eight weeks whereas the same in France are about 10 weeks.

From a clinical development perspective, the market in India has seen rapid growth over the last five years, except this year when the number of trials being conducted declined. Globally, the CRO market size was estimated to be about $20 billion in 2008 and is expected to grow to about $35 billion by 2015. European Union and in particular EU countries with SIRO's presence have shown growth in the number of clinical trials. As per data extracted from EMEA website, top EU countries have shown a compound annual growth rate (CAGR) of about 11 percent from 2005 to 2010.

However, the trend is downward since 2008, especially in Western European countries like France and the UK. According to me, the consolidation wave in CRO markets is likely to continue.

At the same time, recent strategic deals between big pharma and few CROs clearly show that the outlook towards CROs in the world over has changed from â€œfee for service partnersâ€? to â€œimportant change makersâ€?.