

Now Is the Time to Decide the Future of Clinical Research in India

By Norman M. Goldfarb

The clinical research industry is rapidly globalizing. The number of FDA-registered studies in India has grown five-fold in the past three years. Numerous factors are driving this growth, including the availability of qualified study subjects, low costs, capable people, use of English language, and supportive government policies.

India's clinical research industry is at a critical point. Decisions made over the next few years will determine the future of the industry. In particular, the industry will decide whether it will compete on cost or on quality, reliability and customer service. Customers always prefer low prices to high prices, but they hate the risk associated with poor-quality, unreliable sites, especially sites located half-way around the world. And, let's not forget that poor-quality and unreliability dramatically increase costs for both the customer and the supplier. Given India's natural advantages, intelligent policies will make the nation's clinical research industry unstoppable.

Like the United States, India is a large, diverse country. Entrepreneurial creativity and energy drive both countries forward. In the United States, the result is a large clinical research industry of very mixed quality. For example, 30% of research sites in a typical study enroll zero – yes zero – subjects. Data quality in the United States is about average for the world – 14 data queries per 100 case report form pages – but only after a costly and time-consuming inspection process by site monitors. At least one large research site in India generates data with one-third that data query rate, and most of those data queries are clarifications, not errors.

Like any new industry, clinical research in India faces numerous challenges. In this context, advantages become disadvantages because they lead to complacency. Why worry about the long term when short-term growth is easy? The reason is simple: While the industry is still relatively small, it can see the advantages of working together for common goals. As it grows, this sense of identity dissipates and the opportunity is lost. For example, the U.S. industry, given its size and diversity, is almost powerless to take common action.

Some shared goals for India's clinical research industry might include: (1) joint marketing programs, (2) accreditation of research sites, and (3) standardization of contracts and forms.

The U.S. clinical research industry assumes that it will always be the world leader and the role of developing countries is to learn from the U.S. This assumption is true today, but, if India's clinical research industry sets its mind to it, the relationship will soon be equalized or even reversed. I would not be surprised if the day comes when the U.S. clinical research industry realizes that its complacency is no longer justified, and it looks to India for the way forward.

Norman M. Goldfarb is Managing Partner of First Clinical Research, a provider of a clinical research best practices consulting and training services. Contact him at (650) 465-0119 or ngoldfarb@firstclinical.com.