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Trial volunteers are aware of process

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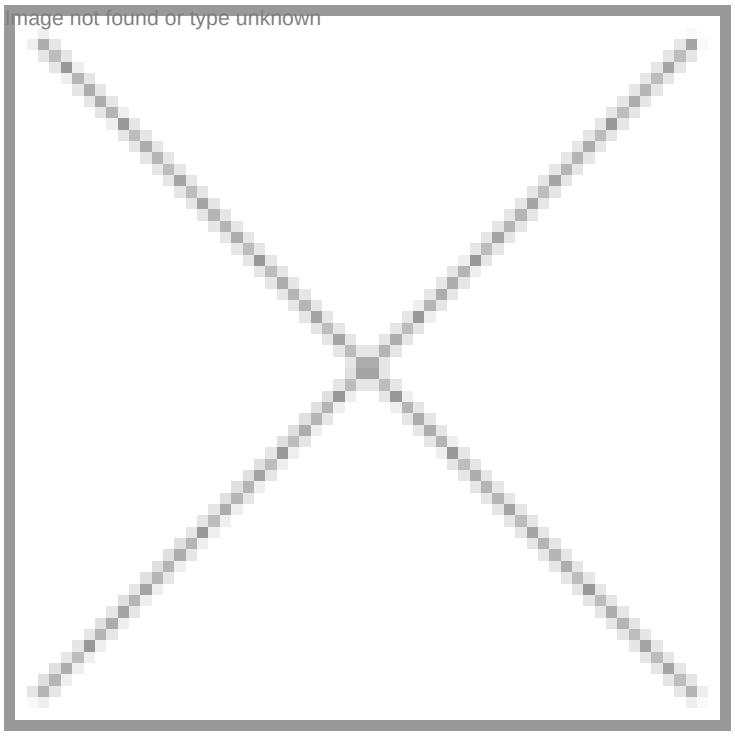

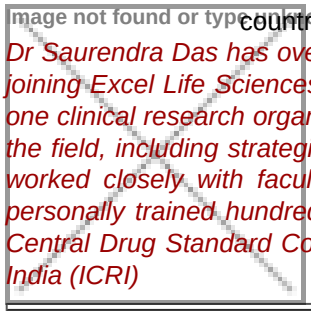

country head and executive director of operations, Excel Life Sciences, Uttar Pradesh

Dr Saurendra Das has over 12 years of experience in coordination of all phases of global and domestic clinical trials. Prior to joining Excel Life Sciences, Dr Das was responsible for establishing two major site management organizations (SMOs), and one clinical research organization (CRO) in India. He has led large clinical operations teams and brought many innovations to the field, including strategies, systems and processes, for faster enrollment and increased retention. As an active trainer, he worked closely with faculties from the Harvard Medical International for developing a global training program, and has personally trained hundreds of pharma, CRO, SMO, central lab and site employees. Dr Das has worked as faculty for the Central Drug Standard Control Organization (CDSCO), World Health Organization (WHO) and Institute of Clinical Research India (ICRI)

It is well-known that India is a region where clinical research is on the rise. India has several advantages to its credit that include huge population of treatment-näive patients and cost-efficient clinical trials. It is rightly estimated that by 2010, the clinical research market in India will reach 2,344-2,812 crore ($500-600 mn).

That growth brought a tremendous amount of regulatory restriction and safety measures to protect the rights of patients. It has also attracted a tremendous amount of scrutiny and negative media coverage. However, not much information has been publicized regarding Indian patient's knowledge and understanding of clinical research and their experiences, especially with the informed consent process.

Excel Life Sciences has recently conducted a survey of over 900 study participants. This research brief analyzes the findings of the study, and includes comparisons of the findings with the study conducted on US patients by CenterWatch. This is also

the first such survey to be made public.

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Findings of the study

About 97.7 percent patients who participated in the survey understood the informed consent form (70 percent very well, 27 percent well).

About 99 percent of patients came to know about the clinical study through a physician, as against just 23 percent in the US.

Only nine percent of patients in India made the decision to participate on their own, as compared to 38 percent in the US.

About 63 percent of patients were not aware of clinical research prior to participating in a study.

Research methodology

The research brief comprises of proprietary data collected from the 2009 informed consent survey of Indian study volunteers, and data from a 2005 US patient survey, conducted by CenterWatch and publicized at the 2006 DIA Annual Meeting. Excel Life Sciences collected the survey data through clinical research coordinators supporting studies at active clinical research sites. Data was collected from July 2008, and the survey is ongoing.

Observations and conclusions

Better understanding: Considering that India is still a nascent market for clinical research, it is surprising to find that over 40 percent of the patients in the survey, had some understanding about clinical research trials prior to participating. Overall, patients seemed to have a strong understanding of what was required of them in a study and the risks involved in it.

In general, the vast majority of patients, some 97 percent, understood the informed consent document (70 percent very well, 27 percent somewhat well). Specifically, patients had a strong understanding of the following:

About 98 percent understood the number of times they would have to visit the site.

About 95 percent understood that the study would carry risks and discomforts.

Traditional health information sources: The advent and expansion of the internet, along with the litigious healthcare environment in the US, has caused many patients to pursue a variety of information sources to make educated healthcare decisions. In fact, US surveys have found that more than 60 percent of volunteers go outside of their managed-care setting to self-refer into clinical trials. The Excel Life Sciences survey has found there is a much more traditional information system in place in India, where patients still turn to their physicians for information about their health. In total, 97 percent of patients in the Excel Life Sciences survey, first learned about the study through a physician, including primary care (76 percent) or another physician (21 percent).

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According to survey findings, there is both a cultural and operational support system in place in India, to assist patients with informed decision making:

Culturally, the role of the family and trust in their primary care physician, play a very important role in a patient's decision to participate. Most patients travel with loved ones to visit doctor, and the same is true for their clinical trial visits. Only nine percent of volunteers made the decision to participate in the trial, by themselves.

Operationally, the sites involved in the survey had a dedicated, highly-trained clinical research coordinator working at the study site, assisting busy physicians with running the trial, and helping to answer questions patients or their loved ones have, about the study and informed consent form.

When considering this support system in India, it is interesting to note that Excel Life Sciences has found that the average study retention rates are in the low-to-mid-90th percentile. Higher retention rates allow studies to finish sooner, and help reduce study costs and speed the development of new compounds.