

## **First Survey Made Public on the Understanding and Experiences of Clinical Research Volunteers in India**

It's well known that India is a region of the world where clinical research is on the rise. research. There are many incentives for conducting research in India, including its huge population of treatment-naïve patients and lower cost of conducting trials. It's estimated that by 2010, the clinical research market in India will reach \$500-700 million<sup>1</sup>.

That growth has also brought a tremendous amount of regulatory oversight and safety measures to protect the rights of patients. But that growth 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 500 study participants. This Excel Life Sciences research brief analyzes the important findings of that study and includes comparisons to a study of U.S. patients conducted by CenterWatch.

### **Key Findings:**

- 56% of patients in India were not aware of clinical research prior to participating in a study
- 97% of patients understood the informed consent form (70% very well, 27% well)
- 97% of patients first found out about the clinical study through a physician, vs just 19-23% in the United States
- Only 8% of patients in India made the decision to participate on their own, vs 38% in the United States

### **Method:**

This research brief is comprised of proprietary data collected from the 2008 Informed Consent survey of Indian study volunteers and data from a 2005 U.S. patient survey conducted by CenterWatch. 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 Than Expected Understanding***

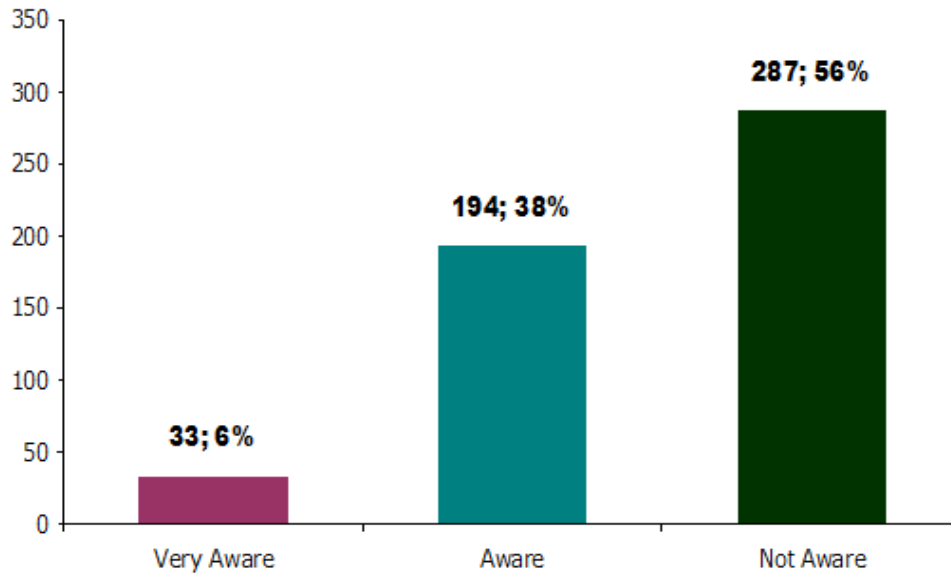
Considering that India is still an nascent market for clinical research, Excel Life Sciences was surprised to find that over 40% of patients had some understanding about clinical research trials prior to participating. Most patient though, lacked more than surface level awareness and understanding. Overall, patients seemed to have a strong understanding of what was required of them in a study and the risks of participating, however there is still room for improvement. In general, the vast majority of patients, some 97%, understood the informed consent document (70% very well, 27% somewhat well). Specifically, patients had a strong understanding of the following:

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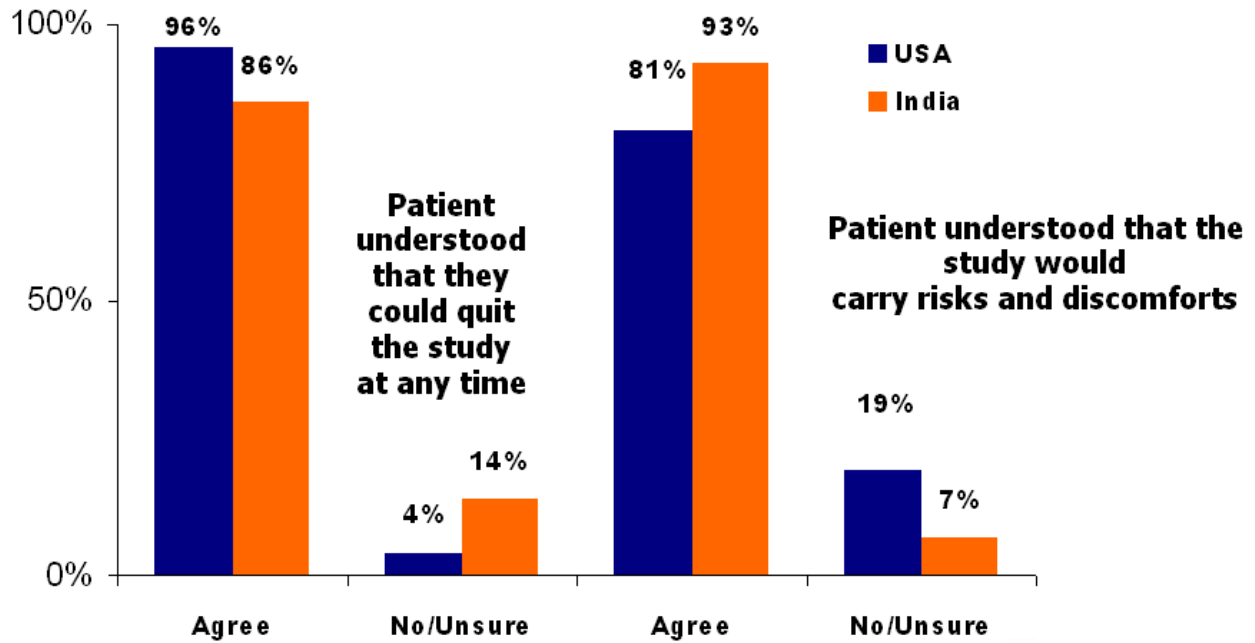
<sup>1</sup> McKinsey Quarterly Report

- ✓ 98% understood the number of times that they would have to visit the study site
- ✓ 93% understood that the study would carry risks and discomforts

### Awareness about Clinical Research



### Understanding of Study Expectations



### **Traditional Health Information Sources Used by Volunteers**

The advent and expansion of the Internet, along with the litigious healthcare environment in the United States has caused many patients to pursue a variety of information sources to make educated healthcare decisions. In fact, U.S. surveys have found that more than 60% of volunteers go outside of their managed-care setting to self-refer into clinical trials. The Excel Life Sciences survey has found that 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% of patients in the Excel Life Sciences survey, first learned about the study through a physician, including primary care (76%) or another physician (21%).

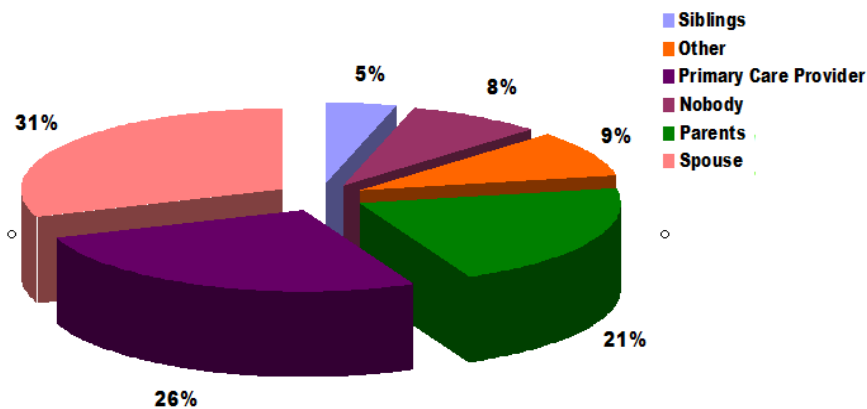
### **Patients: Decision Support System is Strong**

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

- ✓ Culturally, the role of the family and trust in their primary care physician play a very important part in a patient's decision to participate. Most patients travel with loved ones to doctor visits and the same is true for their clinical trial visits. Only 8% of volunteers made the decision to participate by themselves vs. 38% in the United States.
- ✓ 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 average study retention rates are in the low to mid 90<sup>th</sup> percentile. In comparison, the United States and Western Europe historically see an average of 25% of trial volunteers drops out of trials before completion. Higher retention rates allow studies to finish sooner and help reduce study costs and speed the development of new compounds.

### **Who Assisted with Patient's Decision?**



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The study was last updated October 2008.

**About Excel Life Sciences**

Headquartered in Chicago, IL with offices in Boston, Raleigh-Durham, Washington DC, Hyderabad, Mumbai, New Delhi and 21 other locations across India, ELS is one of the most experienced and fastest growing trial management and site support organizations in India, offering customized clinical trial solutions including: regulatory consulting, preparations, submissions and query resolution; site identification and selection; patient recruitment and retention; training of all clinical research stakeholders; technology transfer; product licensing and more.

ELS has one of the most experienced and respected clinical operations teams in India with over 125 years of collective experience in conducting more than 350 global and domestic trials at hundreds of sites and with thousands of patients. ELS has also trained over 1,500 clinical research personnel in India. For more information visit: [www.excellifesciences.com](http://www.excellifesciences.com)