

## India's Informed Consent

It's well known that India is a region of the world where clinical research is on the rise. It's estimated that by 2010, the clinical research market in India will reach between \$500 and \$600 million, according to Pricewaterhouse Cooper's September 2008 Forecasting Report.

That growth has brought a tremendous amount of regulatory oversight and safety measures, while also attracting a great amount of scrutiny and negative media coverage.

However, not much information has been publicized regarding Indian patients' knowledge, their understanding of clinical research, or their experiences, especially in regard to the Informed Consent process.

This data is comprised from Excel Life Science's survey of over 500 study participants in India and a U.S. patient survey conducted by CenterWatch.

Considering that India is still a 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 patients, though, lacked more than surface level awareness and understanding. Overall, they seemed to have a strong understanding of what was required of them in a study and the risks of participating.—*Excel Life Sciences (www.excellifesciences.com)*

## A Bittersweet Harmony

The renowned Dutch "consensus" or "polder" model is at the basis of the described and achieved goals in Dr. Gunning-Scheper's article, "A New Phase of Medicine," which appeared in the February 2009 issue.

Although this consensual approach ensures commitment of all stakeholders resulting in improvement of the quality of research, it also poses challenges in terms of meeting regulatory requirements for clinical research in human subjects.

Both clinical research involving trial subjects and the classic academic research need to reconcile with the complex regulatory

environment, which has differentiated rules for different types of interventions.

In this tightening regulatory environment, the cooperation between the various UMCs has resulted in a common educational program for the postacademic training for researchers conducting "investigator driven studies."

With this clinical research education initiative, an educational program has been developed that strengthens our position as a country to provide good quality and regulatory compliant clinical research whereby the data generated is mutually recognized worldwide.

The advantage of the Dutch approach or "polder model" is that the stakeholders come to a consensus based on a common objective.

However, the downside of the model is that the road to consensus can be long, expensive, frustrating, with changing views and positions, and where conviction and commitment can waiver. Nonetheless, we Dutchmen will get there.

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