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What the clinical research industry needs next?

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-Dr. Anand Bidarkar. The author is a well-known expert in clinical research in India and is a vice president with a leading clinical research organization. The views expressed are in his personal capacity.

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The real growth in the clinical research industry in India started with the country amending the Patent Act in the year 2005 to include product patent in pharma and agrochemicals. The industry has grown rapidly since then. According to an estimate conducted in 2009 the industry in India is between $350–400 million. It is nowhere near the projected value of over $1 billion by 2010.

Many small and mid-sized Indian Clinical Research Organizations (CROs) are now in a precarious situation because of the after effects of global recession. As a result of this, a large numbers of students who paid lakhs of rupees for fancy clinical research degrees find themselves without employment options. The CRO companies and captive units of multinational companies (MNCs) that have the business and the ability to expand find themselves constrained due to various factors.

We are in the midst of a strange paradox. The fundamental factors that made India attractive to clinical research have not changed. However, more and more people opine that conducting clinical research in India has becoming increasingly challenging. That is the bad news. The good news is that the situation can be easily remedied. The following is a five-step road map for the speedy growth of the clinical research sector in India

The first and urgent initiative is to exponentially increase the number of sites and investigators in India. An overwhelming majority of the investigators are in metro cities and are running multiple trials.

Overload of trials at the same few centers is impacting recruitment rates and quality of deliverables. Due to competing demands on their services many of the leading investigators have hiked their fees or grant expectations to unrealistic levels.

There is a huge potential business opportunity for training institutes and Site Management Organizations (SMOs). At this stage, the industry needs large SMOs with regional or even national presence with at least 200-300 centers under their belt.

The clinical research industry in India lacks the strength and the financial muscle of a unified representative body like the National Association of Software and Services Companies (NASSCOM), which was instrumental in the promotion of India's IT industry abroad. The Indian Society for Clinical Research (ISCR) is doing good work but is largely underfunded to take up high level promotional activity on behalf of the industry.

An emerging concern is the number of substandard institutes mushrooming across the country, offering fancy degrees and diplomas in clinical research. The ISCR or the government can start an accreditation program for clinical research training institutes as well as work with them to design a syllabus relevant to the industry's needs.

The next important issue is the positioning of India in terms of the quality of data generated and Good Clinical Practices (GCP) compliance. As the industry in India is fairly nascent we have to invest more resources and time in adequate training including regular refresher courses.

The regulatory authorities in India have been largely supportive of clinical trials. There are however multiple issues that are needed to be resolved to ensure growth of the industry in India. The approval process has to be more time bound, transparent and consultative.

The last but not the least is to educate the media and the masses about the need for clinical research and the process of conducting the research. The Indian media, especially the mass media is to a large extent a victim of the 'guinea pig syndrome' and tends to report everything about clinical trials through this lens. Reactions to alleged problems in clinical trials in the past have resulted in sharp reactions from the political class including threats to suspend all clinical trial activity in India. The issues were however professionally investigated and were found to be compliant with the guidelines.

The industry needs to invest significant time and effort in educating the masses and other stakeholders like the media and political class. This is essential to ensure that the perception of exploitation associated with clinical trials in India does not interfere with the rational conduct of clinical research
in India.