

# Investigator Hub Sites in India: What are the Challenges?

## Alan Boyce

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**A**lan Boyce kindly stepped in for his colleague Dr Ian Smith to present an informative insight into developing investigator hub sites in India. No one can deny the buzz surrounding this country's growing clinical trials industry and an attentive audience listened to how Synexus have contributed to it by opening an investigator hub site in Bangalore early in 2006.

The presentation first looked at the growth of clinical trials within India and the reasons for this. It then went on to look at the characteristics of the hub site model, the advantages of setting this up in India and how Synexus have coped with the challenges that they have faced in doing so. The most intriguing part of this session came during the discussion, where members of the audience were allowed to express their thoughts and ideas on developing hub sites in India and pose further questions on the greatest challenges of working in this developing country.



Alan Boyce

### Why do studies in India?

Figures taken from the CIA World Factbook 2006 show that India has an area of 2,000,000km<sup>2</sup> and a population of 1.095 billion. It is this huge population that gives India an instant advantage in that there is a large pool of patients from multi-ethnic and multi-racial backgrounds available. Furthermore, there is a high population density in urban areas providing a huge concentration of patients.

The Gross Domestic Product (GDP) per capita in India stands at \$3,700 and it is estimated that 25% of the Indian population are below the poverty line. This provides the motivation for people to participate in clinical trials: the cost of medicine is high relative to earnings, meaning many people cannot afford to pay for treatment. Therefore, they are keen to take part in trials and offer high

levels of compliance. This large treatment-naïve population also gives the advantage of reducing drug/drug interactions.

Further advantages of conducting clinical trials in India include the wide range of therapeutic areas that are prevalent within the population, the number of well-trained doctors and lower labour costs. It is unknown how long labour costs will remain lower than in the West; as more pharmaceutical companies and Contract Research Organisations (CROs) enter cities such as Bangalore the demand for trained staff will drive costs upward. English is widely spoken in India, and it is felt that this is a huge benefit when comparing India with other increasingly popular areas to outsource clinical trials, such as China.

Since 2005, there have been important changes in regulations, which have allowed interest in India to grow. In 2005, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement extended patent law to offer protection for all pharmaceutical products.

Prior to this the patent was restricted to manufacturing processes rather than the product itself. Despite this change, some companies still have reservations about trading in India, particularly the US pharmaceutical industry. An amendment to Schedule Y of the Drugs and Cosmetics Act in 2005 now permits Phase II and III trials to be run concurrently, allowing India to become part of global trials. In previous years, customs had presented difficulties, but this has now been resolved with the inclusion of fees. Together with the increased availability of ethics committees, significant barriers in a number of areas have now been removed.

All of these reasons explain why there has been growth in conducting clinical trials in India. India's participation in clinical trials has quintupled between 2001 and 2005 with

clinical research outsourcing worth \$70.5 million in 2005. According to the McKinsey Report, if growth continues to this extent, then by 2010 outsourcing clinical trials in India is likely to be worth \$1.5 billion.

### What are the challenges?

While it is clear that there are numerous advantages to conducting clinical trials in India, it is not without its challenges. The biggest restriction is the relative shortage of appropriately trained staff. Several schools have been set up to provide GCP training and, thanks to the enthusiasm of the Indian people, this situation is rapidly improving.

Other challenges in India include the scattering of primary care and hospital networks and the difficulty of ensuring consistent data. Gaining informed consent is achievable with higher literacy levels in the bigger cities, but in more rural areas where literacy levels are lower, the question remains as to how much of a problem this will present.

There are also challenges for the sponsors, as the high cost of drug development results in pressure to reduce costs, provide larger numbers of patients in the quickest time possible, and deliver high-quality data. Only 20% of studies progress from Phase I trials to the market and it is believed that 70% of these studies are over-budget and over-time. Within the context of India these are important considerations.

### The Hub site model

Alan then went on to introduce the hub site model. According to GSK, "a hub site is an institution or group that offers professional clinical services to pharma in the form of recruitment of significant numbers of patients and the conduct of the clinical trial." Hub sites recruit large volumes of high quality patients for the global pharmaceutical industry for the lowest total cost by:

- Proactively recruiting patients into clinical trials
- Managing those patients throughout the total study life
- Conducting all trial activities at their own sites through their own medics, nurses and support staff

The efficiencies of the hub sites are clear, offering huge savings in time and cost. While some standard sites will enrol a small number of patients, using a smaller number of sites that cost less and recruit higher numbers is

clearly beneficial. Alan presented some study data to highlight this: 8,000 patients were required for a diabetes trial, using 780 sites worldwide, 10 of which were hub sites. Despite hub sites only accounting for 1.3% of the total sites, they actually recruited 1,023 patients, 11.6% of the total requirement. Alan was eager point out that he does not suggest only using hub sites on clinical trials, but merely to use them as a base to quickly recruit the bedrock of patients.

The advantages of using hub sites are:

- Simplified contract arrangements
- Improved access to patient populations
- Excellent patient retention

Hub sites also provide centralised locations for monitoring, consistently abide by high standards of Good Clinical Practice and produce reliable data on time.

### Meeting the challenges with the hub site model

Alan then went back to the difficulties of working in India and explained how hub sites can address these. In answer to the problem of diffuse primary care, hub sites provide their own networks and placed in the right location, they can attract patients. Hub sites also have their own medical facilities, and their own GCP-trained staff who can also be trained to company Standard Operating Procedures (SOPs), enabling them to produce consistent data. In answer to the problem of informed consent, fully trained investigators are trusted by sponsors and the public to gain this.

With regards to the challenges that the sponsors face, hub sites reduce enrolment delays by recruiting large numbers rapidly, and consistently deliver large numbers of patients by identifying and retaining the right patients. Hub sites reduce costs for the sponsors as they require fewer contracts, submissions and monitoring visits and can deliver consistent, standardised data, thus answering the need to deliver high quality data. The presentation concluded with the statement that the challenges for sponsors and those inherent in the location can be met by the hub site model more effectively than any other.

### Discussion

As expected, the questions and reactions from the audience formed a very interesting part of the presentation. Several of the questions focussed on how the hub sites recruit patients. Alan informed us that patients are

usually passers-by that will just volunteer themselves for trials. The audience were then keen to learn how the hub site manages to obtain a correct and reliable medical history of the Indian patients. The answer was that they rely on the Principal Investigators to collect a patient history and while they can never be sure that this is 100% correct, so far they have been happy that the data collected is sufficient. Furthermore, when conducting audits on these sites it has been reported that the source documents are excellent. While Bangalore is one of the most advanced cities in India, they agree that when they expand into the more rural parts of India this is going to prove more of a challenge. It is also important that they continue to carry out trials on less complex diseases. Should they ever carry out any complicated studies from their hub site in India, then they must ensure that the patient history they collect is sufficient to carry out the programme and does not put the patient at risk.

Another query was on the 'self-selecting patients' and whether Synexus actually did anything to coerce people in. Alan pointed out that they are unable to advertise patient recruitment using 'Western methods' (ie, radio,

newspaper, TV adverts etc.) and confirmed they were currently working in conjunction with Indian organisations to come up with other ideas for recruitment advertising.

Other questions in this discussion highlighted some of the other challenges of working in India. One question concerned the location of the hub sites. Synexus currently have their hub site located in the South of India, but agreed that if rapid development continues in cities like Bangalore, they would expand into the North of India. Not only does this again raise the question of literacy levels in different locations of India, but also the possibility of finding genetic differences between the Northern and Southern regions of India.

## Conclusion

This was an enjoyable and informative presentation and the number of questions and comments during the discussion showed just how topical India currently is in this industry. Hub sites do appear to answer many of the challenges of working in India and although there are still several that are unanswered, the passion and drive of the Indian people will ensure that they work long and hard to solve these.

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