



## Smart Clinical Operations in India's Compelling Clinical Trial Environment

CROS NT welcomes its first ever interview guest, Dr. Nermeen Varawalla from ECCRO. She shares her knowledge and experience on the clinical trial scenario in India's emerging market.

*By Mary Wieder, Marketing Officer CROS NT Group*

*India is a potential pharmaceutical gold mine as part of the BRICM (Brazil, Russia, India, China, Mexico) emerging markets. According to a 2009 report, India's pharma market is valued at \$8 billion and is growing at an average rate of 7,2 percent a year. The number of international clinical trials conducted in India has increased by 30% annually over the last 3 years. Multinationals are attracted to the country's market potential with a "high quality for low price" strategy, which will require an increase in CRO outsourcing.*

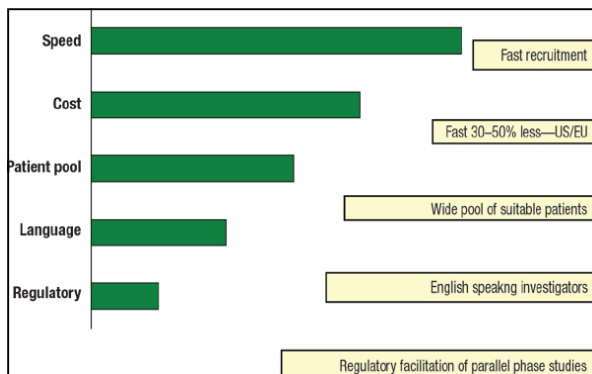
billion population, 340 million are urban and represent the population that participates in international clinical trials.

**MW: What are the recruitment statistics in India compared to elsewhere worldwide?**

**NV:** In the U.S. and Western Europe, clinical trial sites recruit an average of less than 1 evaluable subject per month. In emerging countries like India, for certain trial protocols, it is possible to enroll 4-5 evaluable clinical trial subjects per month.

**MW: Other than the population statistics you mentioned, what are other factors that influence speedier recruitment?**

**NV:** Healthcare is centralized and hospital-centric. Healthcare insurance coverage is low; hence there exists a huge unmet medical need. For example, there are approximately 3 million patients with cancer in India with about 1 million new cases detected every year.



Source: Biopharminternational.com

**Dr. Nermeen Varawalla**, Founder and CEO of ECCRO, an Indian CRO, shares her perspective on the Indian clinical trial environment in her guest interview appearance.

**MW: Dr. Varawalla, what makes India an emerging market attractive for clinical trial operation?**

**NV:** Emerging countries are essential for Phase II-IV clinical trials and India is the most attractive of them because it offers unparalleled access to clinical trial participants. India has 16% of the world's population but 20% of its disease burden. In addition to widely prevalent infectious and tropical diseases, rapid and extensive urbanization has resulted in disease prevalence similar to that found in developed countries. Of India's 1.15

**MW: If recruitment is that much more efficient, what are the costs like in comparison with established markets?**

**NV:** It is not uncommon for costs per evaluable subject to be close to 50,000 USD at sites in the U.S. and Western Europe. Clinical trial operational costs in India can be up to 60 percent lower than Western counterparts. This is a result of lower diagnostic and therapeutic costs, relatively lower investigator grants and the potential, although not always realized, of working with productive, cost effective clinical trial sites. High site productivity with elimination of the wastefulness in clinical trial conduct that has become so prevalent in the West could be the most important contributor to cost savings in India.

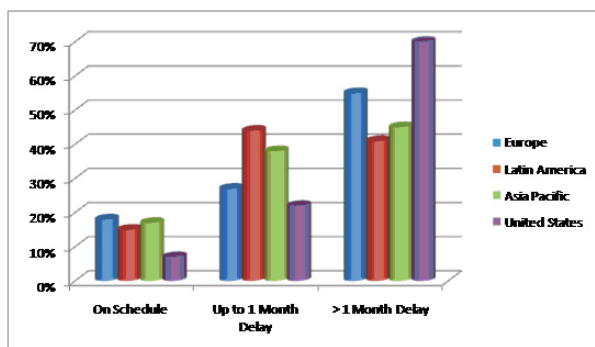
**MW: How does India's caste system and economical differences impact study results?**



**NV:** In the cities and towns of modern India, the influence of the caste system on lifestyle has become irrelevant from the clinical research perspective. Low economic standing is associated with unmet medical need, poor social and domestic support for the patient and lower standards of education. We [ECCRO], for example, take care to ensure that the patient's nutritional status is in keeping with protocol requirements. Otherwise, there is a risk of clinical data from India not being suitable for international submissions.

**MW: What can you tell me about the regulatory standards in India?**

**NV:** The present timeline for regulatory approval in India can be up to six months in duration. In order to carry out clinical trials in India for new drug substances discovered in countries other than India, submission of Phase I data generated outside India is required. Phase II-IV clinical trials can be conducted by any hospital in India.



Source: CISCRP

**MW: How does the quality of sites affect the outcome of study results? In your opinion how could India improve its quality standards?**

**NV:** India's medical institutions have varying clinical research capabilities and limited clinical trial infrastructure. Meticulous site support including training and oversight are essential to deliver data quality. India's hospitals are too busy delivering healthcare, hence must be provided with resources, processes and technology for clinical trial conduct.

**MW: How would regulatory requirements work with outsourcing partners, let's say a CRO in Western Europe?**

**NV:** A Clinical Trial Application can be made only by a company with a legal basis in the country. A company with a legal basis in the country could be either the Indian affiliate or an international company, Indian partner of a foreign company or an Indian company itself. Applications whose protocols have already been approved by countries like U.S., UK, Germany, etc are more likely to obtain a prompt clinical trial approval in India. These regulatory authorities are deemed to be more experienced. Most major clinical institutions and hospitals in India have Ethics Committees that comply with ICH Good Clinical Practice guidelines.

In terms of recruitment, to fulfill the international regulatory requirements and meet the commercial imperatives, a proportion of the subjects in most global clinical trials should be enrolled from North America and/or Western Europe.

**MW: How would you describe the biometric side of clinical trials in India? What are the opportunities for foreign CROs to enter the Indian market in this area?**

**NV:** Some of the world's largest functional outsourcing contracts are being executed in India. India's young, hardworking, relatively cost effective work force of IT professionals, statisticians and biomedical graduates remain an attraction for foreign biometric CROs who seek to establish a more cost effective operational base.

**MW: How would ECCRO, being involved in the clinical operations, work with a biometric CRO like CROS NT in the Indian market?**

**NV:** ECCRO has elected to remain focused on Phase II-IV clinical trial conduct in India so as to be a "best in class" provider. We recognize the need for similar "best in class" partners so that we can present sponsors with a global solution with expert components. CROS NT provides these capabilities in the biometric area. By working together, much value can be delivered, irrespective of their geographic location.

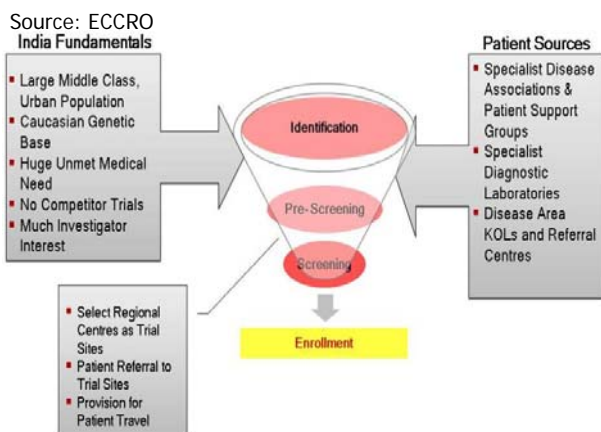
**MW: And the technology landscape concerning clinical trials in India?**

**NV:** There exists a robust IT infrastructure with an IT savvy workforce making the universal adoption of Electronic Data Capture relatively straightforward. This, of course, facilitates clinical trial conduct. EDC permits the practice of hybrid

monitoring which combines remote, office based frequent monitoring and data driven monitoring site visits.

**MW: So what would be the need for technological expertise in EDC systems and data integration?**

**NV:** Wise application of clinical data management technology is critical for ECCRO to effectively practice remote centralized monitoring combined with more interspersed data driven monitoring visits. Thus, ECCRO is keen to apply the ARITHMOS technology platform to its operational processes to manage projects in a seamless, transparent and effective manner, thereby presenting a very compelling alternative to the global CRO service offering.



The CROS NT Group would like to thank Dr. Nermeen Varawalla for participating in our first interview and contributing valuable content to our website.

**About Dr. Nermeen Varawalla**



Dr. Varawalla is the founder and CEO of ECCRO, an Indian specialist CRO for international Phase II-IV clinical trials. She is an acknowledged industry expert in the conduct of international clinical trials in India and has previously established and grown two businesses in this sector. Dr. Varawalla has participated in the design and conduct of over 50 international clinical trials. She has been trained at Seith GS Medical College and KEM Hospital, University of Bombay and is a Fellow of the College of Physicians & Surgeons in India. She was a Rhodes Fellow at the University of Oxford where she obtained a doctorate for molecular genetics research. For more information on Dr. Valawalla and ECCRO, visit the website at [www.eccro.com](http://www.eccro.com) or contact CROS NT.

**The CROS NT Group Approach**

CROS NT is always looking for new opportunities in emerging markets. For this reason, the CROS NT Group chooses its partners wisely and with a strategic angle. Even though the Indian market is unchartered for the CROS NT Group itself, some of its staff are seasoned professionals. CROS DE Vice President, Frank Freischläger, has experience setting up and managing clinical trial operations in the Indian market.

The CROS NT Group approach to partnerships is three-fold. First, the CROS NT Group requires competence in terms of technical capabilities and the ability to manage projects in line with time, budget and quality requirements.



The second consideration is communication. One of the CROS NT Group's core values is communication and the ability to form a respectful relationship with other organizations through transparent and bidirectional communication.

Finally, the CROS NT Group believes a sound partnership needs a solid contract. This means a recognition of roles and responsibilities and a recognition of contributions.

This being said, the CROS NT Group is always considering the opportunities that offer new entry into new markets. These new ventures require the right partnership.

**About the CROS NT Group**

The CROS NT Group is a global functional service CRO with expertise in biostatistics and data management, completing over 800 projects. The IT subsidiary, ARITHMOS, provides technology solutions like ePRO and data integration to increase trial success rates. Project governance between data analysis and technology is the niche for superior clinical trial results.

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