# What is Clinical Research

**Shah Navas P**

Research Cell, IMA KSB, TC 7/171, Kumaranasan Nagar, Ulloor, Trivandrum*

ABSTRACT

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It is a systematic study for new drugs / devices/ interventions in human subjects to generate data for discovering or verifying the Clinical, Pharmacological (including pharmacodynamic and pharmacokinetic) or adverse effects with the objective of determining safety and efficacy of these interventions.

Our country is also now fast emerging as a favoured destination for clinical trials by global pharmaceutical and biotech companies that are looking for partnerships or setting up new operations. Two major reasons for its popularity are: easy access and availability of a large, diverse and therapy-naïve population with vast gene pool and lower cost of technical services resulting into lower per patient trial cost. India also has the advantage of having a large pool of highly trained physicians, nurses, and technical personnel; numerous world-class medical facilities; broadly developed information technology infrastructure; a favourable IPR environment and use of English as the primary business and medical language.

**Keywords:** Clinical trials, Research question, Study design, Validation, Data collection.

*See End Note for complete author details

It is a systematic study for new drugs / devices/ interventions in human subjects to generate data for discovering or verifying the Clinical, Pharmacological (including pharmacodynamic and pharmacokinetic) or adverse effects with the objective of determining safety and efficacy of these interventions. Intervention refers either to a drug, a procedure or a technological device, thus implying that biomedical engineering scientists and professionals might be involved in it.

India is a developing country with a population of now over 1 billion and the majority of us live in poverty with little access to advancing frontiers of modern medicine. But on the flip side it is also among the most industrialized countries in the world, with the largest pool of English-speaking scientific and technical professionals outside the so called developed world. It has a down-to earth but strong pharmaceutical industry. It also continues to be the world leader in the information technology sector, which has spawned a ever growing bioinformatics industry. In fact, India's success in information technology–its computer software and services industry grew from about $500 million to more than $6 billion in exports over the last decade. But it has also negative factors as well for an unbridled growth like, unfriendly governmental regulatory issues, lack of a intellectual property rights environment, and almost nonexistent integration between academic and private sector science. Despite these hurdles, India has made impressive growth in the healthcare sector, both through public sector efforts as well as through private domains.

Our country is also now fast emerging as a favoured destination for clinical trials by global pharmaceutical and biotech companies that are looking for partnerships or setting up new operations. Two major reasons for its popularity are: easy access and availability of a large, diverse and therapy-naïve population with vast gene pool and lower cost of technical services resulting into lower per patient trial cost. India also has the advantage of having a large pool of highly trained physicians, nurses, and technical personnel; numerous world-class medical facilities; broadly developed information technology infrastructure; a favourable IPR environment and use of English as the primary business and medical language. The total value of clinical research performed in India in 2004-05 was about US$100 million. The major companies involved in clinical research in India have a wide range of services to offer. Thus, the healthcare domain needs to know the companies operating in this field.

Health Research aims at bringing modern health technology to people by encouraging innovations related to diagnostics, treatment methods as well as prevention of diseases and translating these innovations into products/ procedures by facilitating evaluation/

**Corresponding Author:**
Dr. Shah Navas P, Vice-Chairman, Research Cell, IMA KSB, TC 7/171, Kumaranasan Nagar, Ulloor, Trivandrum-11.
Phone: 0471-2552565, Mobile: 94471 69693. Email: drshahnavas@gmail.com

testing in synergy with other departments well as other science departments and introducing these innovations into public health service through health systems research.

Clinical Research faces perhaps a certain grain of confusion. Often, it is mistakenly reduced to case report. Caveats of even greater risks may be hidden in the secrets of patents and interests of manufacturers covertly promoting their products. Thus, clear state clinical interventions, well located within the scientific frame, are essential for enhancing the importance and complexity of human health in this new 21st century.

Clinical Research, a branch of Applied Research, finds in clinical trials the most definitive tool for evaluation of its actual applicability. A properly planned and executed clinical trial is a powerful experimental technique for assessing the effectiveness of an intervention. A clinical trial compares the effect and value of intervention(s) against a control in human beings. Clinical Research always presents early stages where the laboratory work is mandatory. There is laboratory work during drug, device and/or procedure development, animal studies and early tests in small number of human beings. Case reports, typical of the hospital, find their place as a warning of adverse effects or as a flag of an unexpected beneficial effect.

A clinical trial must have a primary question. It should be carefully selected, as any subsidiary question must be, too. Otherwise, the investigators may lose the track. The study population has to defined, underlying the importance of clear eligibility criteria, the latter having a direct influence on the recruitment of participants and, thus, on the final number involved in the project. The basic study design; the demand of a control group and the need of randomization for assigning participants to control and intervention groups are also to be framed right from project design stage.

The randomization process is essential to avoid any possible bias and errors of observations. Randomization can be simple, blocked or stratified. More elaborate procedures make use of adaptive methods. Bias, as a systematic error is one of the main concerns and blinding of data collection is necessary to avoid such errors. Blinding can be single, double or triple. Sample size, addresses the question of how many subjects are needed for the study to be relevant statistically. The trial must have sufficient statistical power to detect differences between groups. Therefore, calculation of sample size with provision for adequate levels of significance is essential.

No study can be better than the quality of its data. Monitoring and even auditing are thus necessary. The history of new medical interventions abounds in sad experiences. Hence, adverse effects, if any at all, must be searched and assessed.

Compliance, participant adherence, lost to follow up are also serous snags even in well conducted studies. Survival analysis, monitoring response variables, issues in data analysis, closing out i.e. how to terminate the study properly, reporting and interpreting of results are also issues of major importance.

## CLINICAL RESEARCH IN INDIA

Before a drug is introduced in the market, it has to pass a lengthy approval process involving a series of clinical trials. This process is called clinical research.

What are the career prospects and scope of clinical research in India? A fledgling industry till a while back, clinical research is now ready to take off in India. In fact, we are the second most preferred destination for outsourcing clinical trials for the global pharma industry today, which is 90 per cent cheaper than the West.

Global consultancy McKinsey & Co estimates that by 2010, global pharma majors would spend around $1-1.5 billion just for drug trials in the country. According to a Confederation of Indian Industry study, clinical trials in India in 2002 generated $70 million in revenues. It predicts that it would grow to $200 million by 2007 and anywhere between $500 million and $1 billion by 2010. Almost all top names, including Novo Nordisk, Aventis, Novartis and GlaxoSmithKline, have started running clinical drug trials in India lately, while some, such as Eli Lilly and Pfizer, which started much earlier, conduct tests on a number of their new drugs. Besides, a variety of both India-based and global contract/clinical research organizations that specialize in outsourced clinical trials management are working to expand India's clinical-trials business. These include Quintiles, Omnicare, Pharma Net and Pharm-Olam (all US-based).

There are more than 50,000 jobs in clinical research in India. Reason? India offers a large native patient base with a truly diverse gene pool on which broad-based clinical trials can be validated. Our climatic conditions also offer a perfect breeding ground for a range of different diseases. The only impediment preventing the industry from expanding is a severe shortage of clinical research associates and chemists familiar with

complex chemical synthesis. Globally, more than 2.5 lakh positions are lying vacant.

There is an increasing demand for CRP's (Clinical Research Professionals) by pharmaceutical companies like Pfizer, Merck, GlaxoSmithKline, Ranbaxy, Cipla etc who can design, code, conduct and report clinical trials with a clear understanding of Good Lab Practices including an understanding of Indian and international regulatory and research standards. Poaching within the industry is rampant. Clinical Research Associates (CRAs) with even one- year of training are prime targets for poaching while anyone with 4-5 years of experience is considered as a 'rare diamond'. You could be working in-house with pharma or research or onsite interacting with the study coordinator and investigators conducting the clinical trial. Although many CR institutes enroll science graduates, they essentially end up doing data- management work. Medical professionals are best suited for going into actual CR work. So, it's good times ahead for those opting for CR as a career.

## ANATOMY OF A RESEARCH PROJECT

The foundation of scientific advancement is building up research projects. A research question is formulated, methods are derived to answer the question, data are collected and analyzed, and conclusions are drawn. Within this framework are several key concepts that are discussed in the following text, including formulation of the research question, use of efficient study design, avoidance of error and bias, and appropriate data analysis

## METHODS

Performing methodologically rigorous scientific research is not a trivial task. The optimal research study will be directed at an important, precisely defined clinical question, with a specified target population matched by the subject selection. The most efficient study design will be used and the sample size will be sufficient to limit errors to acceptable levels. Further, biases are to be avoided, and the results made more reliable, internally valid, and generalizable to the population at study and possibly beyond. Success at such demanding research endeavors is certainly possible only thru targeted training and learning

## AGENCIES INVOLVED IN CLINICAL RESEARCH IN INDIA

### Indian Council of Medical Research (ICMR)

The Indian Council of Medical Research (ICMR) is one of the oldest medical/health research organisations in the world, having been established in 1911. The council has a network of 21 permanent research institutes and six Regional Medical Research Centres in addition to a number of Centres for Advanced Research distributed throughout the country. Grants-in-aid is being given to ICMR on year to year basis for undertaking research. ICMR's main research programs are conducted largely through extra-mural research programme by involving 33 Human Reproduction Research Centre located in most states in the medical colleges and other scientific institutions in different parts of India. ICMR is an autonomous organisation attached to the Ministry of Health and Family Welfare whose e- mail address is mohfw@mohfw.delhi.nic.in / http:// www.nic.in/ mohfw.

### Department of Health Research (DHR)

It aims at bringing modern health technology to people by encouraging innovations related to diagnostics, treatment methods as well as prevention- vaccines; translating the innovations into products/ processes by facilitating evaluation/ testing in synergy with other departments of MOH&FW as well as other science departments and introducing these innovations into public health service through health systems research.

### Clinical Trials Registry-India (CTRI)

The CTRI is an online register of clinical trials being conducted in India. The mission of the Clinical Trials Registry-India (CTRI) is to encourage all clinical trials conducted in India to be prospectively registered before the enrollment of the first participant and to disclose details of the 20 mandatory items of the WHO International Clinical Trials Registry Platform (ICTRP) dataset. Any researcher who plans to conduct a trial involving human participants, of any intervention (drug, surgical procedure, preventive measures, lifestyle modifications, devices, educational or behavioral treatment, rehabilitation strategies and complementary therapies) are expected to register the trial in CTRI before enrollment of the first participant. Registration is voluntary but some fields marked* are mandatory for registration to proceed. Some fields marked WHO also need to be filled if the trial is to receive a registration number and fulfill WHO/ICMJE requirements. Incomplete entries will be given a provisional registration number that will not suffice for purposes of publication in journals that endorse the ICMJE recommendations for trial registration. Registration of trials in the CTRI is free. All registered trials will be made publicly available. The

CTRI will be searchable by anyone free of charge. The Clinical Trials Registry- India (CTRI) has been set up by the ICMR's National Institute of Medical Statistics (NIMS) and is funded by the Department of Science and Technology (DST) through the Indian Council of Medical Research (ICMR). It also receives financial and technical support through the WHO, WHO-SEARO, and the WHO India Country office.

**Institute of Clinical Research (ICRI)**

ICRI in partnership with Cranfield University offers various clinical research educational programmes. It has campuses in Delhi, Ahmedabad, Mumbai, Bangalore, Hyderabad, UK, Cochin and conducts various study courses, full time/ part time in clinical research for all kinds of healthcare personnel. These courses offered are recognised by Cranfield University and not by AICTE, India.

**Academy for Clinical Excellence (ACE)**

The Academy for Clinical Excellence (ACE) is a clinical research training institute run by Pfizer India Ltd in partnership with Suven Life Sciences Ltd. and Bombay College of Pharmacy. The Academy is situated on the campus of Bombay College of Pharmacy at Kalina in Mumbai. ACE is conceptualized to be a not-for-profit pioneering clinical research training academy. ACE and Edutech have jointly developed an e-Learning program on Clinical Research as part of the distance learning programs. It is a web based certificate program consisting of CDs containing the audio visual lecture sessions, assignments, self evaluation quiz and other teaching accessories.

Learners can be based anywhere and take the course. They can pace study according to their individual schedules. Lectures by top industry professionals ensure high quality of learning content, offering the quality of classroom training program Online assessments leading to a 'Diploma in Clinical Research' at the end of the course.

**Scope of Clinical Research and Clinical Trials In India**

According to a recent global survey India is the second most preferred destination for outsourcing clinical trials and clinical research services second to China with Russia being at third place. India has the advantage because of large patient pool, faster enrollment, and low cost.

Already big pharma MNC's like Eli Lilly, Aventis, Novartis, Astra Zeneca and Pfizer, Johnson & Johnson, GSK, Merck, Amgen, Eisai and Bristol- Myers Squibb are conducting clinical trials in India.

There are about 300 domestic companies and 100 multinationals doing clinical trials in India. Students of pharmacy, life-sciences and even doctors are looking at clinical research as a career option, as companies are recruiting even trainees at salaries of about Rs 2.5 lakh per annum. Novartis has recently opened their Clinical research Unit at Hyderabad which in future may employ 5000 professionals. Paraxel International and Genzyne have also opened new centers at Hyderabad and Bangalore respectively. Domestic Indian companies are also expanding their clinical research and data management domains with acquisitions and new centers.

## END NOTE

**Author Information**

Dr. Shah Navas P,
Vice-Chairman, Research Cell, IMA KSB,
TC 7/171, Kumaranasan Nagar,
Ulloor, Trivandrum-11.
Email: drshahnavas@gmail.com
Phone: 0471-2552565 Mobile: 94471 69693

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