Mapping Training Requirements of Clinical Research Professionals in India - A Critical Imperative for Capacity Expansion

THESIS

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CERTIFICATE

This is to certify that the thesis entitled

Training Requirements of Clinical Research Professionals in India – A Critical Imperative for Capacity Expansion

which is submitted by Ms. Samyuktha Ajay, ID. No. 2004PHXF028 for award of PhD degree of the Institute embodies original work done by her under my supervision.

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Abstract

Clinical research is an imperative part of new drug development and is governed by strict regulations and guidelines that are continuously evolving. Prohibitively increasing drug development costs and decreasing efficiencies were the key drivers for off shoring clinical research to countries like India which have a large patient population, resource pool of medical and para medical graduates and a fast developing medical infrastructure.

India being a branded generic pharmaceuticals market, very little of new drug development took place here and clinical research is a very new field. The regulations and guidelines governing every aspect of clinical research mandate that appropriately qualified and trained people only take up these roles. Since competence in the role is based on knowledge and skills required for the role and these are elements best subjected to training, we chose to explore the awareness of the knowledge and skills required for these roles in India.

The first survey was done among experienced stake holders to understand from them if the importance of knowledge and skills areas was different for the different roles. The second survey was among role holders to understand their grading of importance, training received and training requirement for these items of knowledge and skills. The third objective was to check if any of the items of knowledge and skills were covered in a representative sample of our undergraduate curricula. Based on the findings of our surveys, a model for training of clinical research professionals based on a competency approach has also been developed here.

Stakeholder ratings of importance of knowledge and skills items for the different roles were largely on expected lines. The Kruskal Wallis test on rating of knowledge items clearly demonstrated that grading of importance was different for the different roles except for the sub-topics of *ICH GCP guidelines* and *Audits and inspections*, which were rated uniformly across all roles. Kruskal Wallis test was also applied on grading of skills across roles. The test showed significant differences of rating of skills between the roles. The first survey was in a small number of stakeholders and this followed by a larger one in people who worked in the different roles- role holders.

The second survey profiled our clinical research workforce- their age, educational qualifications, experience and work profiles. A role wise analysis of their rating of importance of different items of knowledge and skills, training received in the, the depth of training received and the requirement for further training was done. Our clinical research work force had representations across various roles. We had a relatively young population with majority of them having 3 years or less experience. We had 2 large groups within our respondents – the CRAs and data managers and a detailed analysis of these two groups were possible. The general trends were as could be expected from the demands of the role. Training received was however inadequate in most cases. Where training was received, it was mainly in the job and rated at awareness level. We also found in some cases deviation from the stakeholder responses for the same role. A fairly large non response for training requirement points towards an inability of the respondents to identify their own training needs probably because the field is new and they are inexperienced.

Our analysis of a sampling of educational curricula at graduation level for relevant items of knowledge and skills being covered showed that only very few topics of drug development, statistics and computing skills.

Based on the findings of the survey, we propose a structured training program that is constructed on objectively identified knowledge and skills requirements for the role. The proposed model takes into account the fact that it is a new field in India and that people who enter this profession may not themselves be aware of the demands of the role and therefore all the training requirements. The gaps we observed between stakeholder expectation of importance and role holder perception can also be addressed by objective analysis of the requirements of the job and delineating it into knowledge and skills requirements.

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GLOSSARY LIST OF ABBREVIATIONS/SYMBOLS

ADR - Adverse Drug Reaction
All noxious and unintended responses to a medicinal product related to any dose of a medicinal product.

AE- Adverse Event
Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product

Audit
A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analyzed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

CRF- Case Report Form
A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.

CT -Clinical Trial/Study
Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

Clinical Trial/Study Report
A written description of a trial/study of any therapeutic, prophylactic, or diagnostic agent conducted in human subjects, in which the clinical and statistical description, presentations, and analyses are fully integrated into a single report

CR- Clinical Research
The field of human testing or conducting trials on human beings and collecting data pertaining to and applicable to human beings.

CRA- Clinical Research Associate
A sponsor representative who oversees the conduct of a clinical trial and ensures that it meets GCP guidelines as well as national regulatory requirements. He is also called a monitor.

CRO - Contract Research Organization
A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.

DB Designer- Data base designer
The person who designs the data base into which clinical trial data is fed and stored for analysis.

DCGI- Drug Controller General of India
The apex position of the central health regulatory body of India - Central Drugs Standard Control Organization, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India.

DM- Data Management
The process of managing data – in paper form or in electronic format. In this case data generated from clinical trials. It includes processes of data entry, verification, validation, cleaning, coding, programming, analysing, tabulating and reporting.

EC- Ethics Committee
A committee of medical and non medical professionals that ensures the protection of the rights, safety and well-being of human subjects involved in a trial. This committee when operating independent of the organisation where the clinical trials are done is also called an Independent Ethics Committee (described below).

EDC- Electronic Data Capture

An Electronic Data Capture (EDC) system is a computerized system designed for the collection of clinical data in electronic format for use mainly in human trials. Typically, EDC systems provides a graphical user interface component for data entry, a validation component to check user data and a reporting tool for analysis of the collected data

GCP- Good Clinical Practice
A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

ICH – International Conference on Harmonisation
The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use is a unique project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration.

IEC- Independent Ethics Committee
An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing, approving and providing ongoing review of the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent through out the period of the trial. The legal status, composition, function, operations and regulatory requirements pertaining to Independent Ethics Committees may differ among countries, but should allow the Independent Ethics Committee to act in agreement with GCP as described in this guideline.

Informed Consent
A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

IRB - Institutional Review Board
An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

IP- Investigational Product
A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

Investigator
A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

IB- Investigator's Brochure
A compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects.

MNC- Multi-national company
A company that operated in several countries

Monitoring
The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

Multicentre Trial
A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.

NME- New Molecular entity
New molecule being developed and evaluated as a drug.

Protocol
A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guideline the term protocol refers to protocol and protocol amendments.

PK- Pharmacokinetic
Studies on the rate and extent of absorption, distribution, metabolism and elimination of drugs are called pharmacokinetic studies.

QA - Quality Assurance
All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in accordance with local regulatory and applicable guidelines.

SAE - Serious Adverse Event (SAE) or
SADR - Serious Adverse Drug Reaction (Serious ADR)
Any untoward medical occurrence that at any dose:
- results in death,
- is life-threatening,
- requires inpatient hospitalization or prolongation of existing hospitalization,
- results in persistent or significant disability/incapacity,
or
- is a congenital anomaly/birth defect

Sch Y- Schedule Y
Schedule Y is the part of the Drugs and Cosmetics Act, India that deals with regulations relating to clinical trial requirements for import, manufacture and obtaining marketing approval for a new drug in India.

SMO- Site Management Organisation
An organisation that is based at the site of the conduct of the clinical trial and manages its oversight and conduct to applicable regulations and guidelines.

SOPs- Standard Operating Procedures
Detailed, written instructions to achieve uniformity of the performance of a specific function.

Subject/Trial Subject
An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.

CHAPTER 1: Introduction

Clinical research is intended to produce knowledge, valuable for understanding human disease, preventing and treating illness, and promoting health. It embraces the continuum of human studies undertaken to produce the evidence that backs the practise of medicine today. Data generated from clinical research has become an imperative regulatory requirement for proving the safety and efficacy of any new molecular entity (NME) for which marketing permission is sought. Even after launch of the drug, clinical trials are conducted for the ongoing review of safety of the product. Today, a large component of clinical trials is driven by the pharmaceutical industry and studies on the safety and efficacy of new drugs, that follow in-vitro laboratory and animal testing are the single largest, popularly known and commercially relevant application of clinical research.

The extent of conduct of clinical research in India for NMEs has been very low or negligible. This is because India has traditionally been a branded generic pharmaceutical market where product patents were not respected. This meant that Indian pharmaceutical industry could copy and market drug molecules discovered and developed by western multinational companies (MNCs). There was therefore no incentive for indigenous drug development and hence conduct of clinical research was very poor. Lack of patent protection was also a deterrent for MNCs to conduct drug development in India. However, the increasingly stringent demands of drug development, challenges of patient recruitment, against stringent timelines and increasing cost pressures on drug development in the West were growing and off shoring to countries with a large patient and resource pool were considered options for improving drug development efficiency. India's becoming GATT compliant from 2005 and positive regulatory changes that followed have caused a sudden surge in clinical research activities in India. This has also brought to bear a paradox, where in spite of a large resource pool of qualified medical and para medical scientists, finding the right, trained resource, is a challenge.

The focus of this thesis is to profile the clinical research workforce in India - the educational and training background and to understand their training needs (components of knowledge and skills) that are important for professional competence in clinical research.

Since this is a new field, we chose to understand it from the perspective of the decision makers in the first phase and from the people in different roles in the second phase. From a capacity building perspective we analysed whether some medical and pharmacy curricula at undergraduate level covered the elements of knowledge and skills for clinical research. Lastly, a strategic model for training and education of clinical research professionals has been suggested to develop requisite competencies.

1.1 Drug Development Process:

1.1.1 Evolution of regulations in drug development: One of the earliest regulations, the original **Food and Drugs Act** was passed by US Congress in 1906 [1]. It prohibited interstate commerce in misbranded and adulterated foods, drinks and drugs. Shocking disclosures of insanitary conditions in meat-packing plants, the use of poisonous preservatives and dyes in foods, and cure-all claims for worthless and dangerous patent medicines were the major problems leading to the enactment of these laws.

In the 1930's the authorities of Great Britain set up the Therapeutic trials committee to consider applications by commercial establishment for examination of new products. The sulphanilamide elixir tragedy killed 107 persons, many of whom are children, because of the poisonous solvent diethylene glycol in the elixir. This led to the need for establishing drug safety before marketing and to enact the pending food and drug law in 1938 [1].

The Federal Food, Drug, and Cosmetic (FDC) Act of 1938 contained new provisions:

- Extending control to cosmetics and therapeutic devices.
- Requiring new drugs to be shown safe before marketing-starting a new system of drug regulation.
- Eliminating the Sherley Amendment requirement to prove intent to defraud in drug misbranding cases.
- Providing that safe tolerances be set for unavoidable poisonous substances.
- Authorizing standards of identity, quality, and fill-of-container for foods.
- Authorizing factory inspections.
- Adding the remedy of court injunctions to the previous penalties of seizures and prosecutions.

In 1961, **Thalidomide**, a new sleeping pill, caused birth defects in thousands of babies born in Western Europe. The US FDA's Food and Drugs Act which approved drugs on basis of safety alone, was amended in 1962 to include evidence of efficacy. **Kefauver-Harris Drug Amendments** were passed to ensure drug efficacy and greater drug safety. For the first time, drug manufacturers were required to prove to FDA the effectiveness of their products before marketing them. The 1962 amendments required informed consent from patients used in drug studies, and sponsoring drug companies were required to report to FDA any adverse reactions to the drug [1].

Since 1900s, the Food and Drugs Act has been amended at least one hundred times to reflect increase in complexity of drug development. Proving the efficacy and safety of the new product in systematically planned clinical trials became mandatory to support applications for approval for marketing from regulatory agencies world over. Regulations clearly defined the duration and exposure in-animal experiments that should be completed before clinical trials can begin. The risks of human exposure were controlled by systematically increasing exposure in 4 different phases of clinical trials.

1.1.2 Evolution in the conduct of clinical trials and the clinical trial process: The most known historical example of a planned controlled, comparative clinical trial was that where James Lind found [2] oranges and lemons to be the most effective of six dietary treatments for scurvy in sailors on board ships in the eighteenth century. It has come a long way since, with statistical inputs in sample size calculations and concepts of randomisation and blinding in study design to remove bias [2].

For centuries, clinical trials were ruled more by methodological considerations than personal concerns of research participants. During World War II, doctors in Nazi Germany were conducting horrifying research on prisoners in concentration camps. This research was done on involuntary participants who usually died as a result of the experiments. After the war, many of these doctors were tried at the Nuremberg trials for their crimes. The International community was shocked by the revelations of their research. As a result of the trial, the **Nuremberg Code** was created in 1948 [3]. This code for the first time addressed evaluating the risk benefit ratio of any trial in the interest of subject safety.

Voluntary consent from participants was mandatory for any clinical research. The code also stated that clinical trials should be conducted only by scientifically qualified persons and the highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment. The Code was adopted by the United Nations in 1948.

The Tuskegee experiments: Another major event that brought the issues of ethics and subject autonomy to the public was the revelation of the Tuskegee Syphilis Study. The study was conducted by the United States Public Health Service on African-American farm workers in the US from 1932 to 1972. The objective of the study was to monitor the natural course of syphilis infection without the provision of treatment. Although Penicillin, still the most effective therapy for syphilis, became available in 1943, the investigators did not provide the drug to their patients, and in fact actively dissuaded them from pursuing the treatment option for 30 years. This was done so that the treatment "would not cloud the scientific validity" of the study. The Tuskegee experiments were stopped due to public outrage after front-page reports in the *New York Times* exposed this inherently racist, demoralizing, and dehumanizing research. In 1997, President Clinton offered formal apologies to the survivors of these experiments and called the studies "blight on our record."

The many revelations of unethical medical research in the 1960s and 1970s led US Congress to pass the National Research act which created the National Commission for the Protection of Human Subjects in Biomedical and Behavioural research. The commission's final report and recommendations is known as the Belmont report [4]. The intent was to create a cohesive set of guidelines for conducting ethical research.

The principles of this report are as follows:

1. Respect for Persons: This principle acknowledges the dignity and freedom of every person. It requires obtaining informed consent from research subjects (or their legally authorised representatives)

2. Beneficence: This principle requires that researchers maximise benefits and minimise harms associated with research. Research related risks must be reasonable in light of the expected benefits.
3. Justice: This principle requires equitable selection and recruitment and fair treatment of research subjects.

The commission reaffirmed the role of the Institutional Review Boards that had been created in the 1960s. The US departments of Health and Human Services and the FDA revised their research rules based on this report.

In 1964; the World Medical Assembly issued the Declaration of Helsinki with consent being an essential requirement of ethical research [5]. It mandated, among other things that Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person.

The need to harmonise: With increased ethical awareness, improved trial methods and better understanding of clinical trial concepts, public/political concern over safety aspects and frauds and accidents during trials also increased. The realisation that it was important to have an independent evaluation of medicinal products before they are allowed on the market was reached at different times in different regions. For most countries, whether or not they had initiated product registration controls earlier, the 1960s and 1970s saw a rapid increase in laws, regulations and guidelines for reporting and evaluating the data on safety, quality and efficacy of new medicinal products. The industry, at the time, was becoming more international and seeking new global markets, but the registration of medicines remained a national responsibility. Although different regulatory systems were based on the same fundamental obligations to evaluate the quality, safety and efficacy, the detailed technical requirements had diverged over time to such an extent that industry found it necessary to duplicate many time-consuming and expensive test procedures, in order to market new products, internationally.

The urgent need to rationalise and harmonise regulation was impelled by concerns over rising costs of health care, escalation of the cost of R&D and the need to meet the public

expectation that there should be a minimum of delay in making safe and efficacious new treatments available to patients in need. It was realised that sharing clinical trial data globally could have many benefits, most importantly, the number of clinical trials required for registration in various countries, and thereby the cost for drug development could be reduced.

Harmonisation of regulatory requirements was pioneered by the European Community, in the 1980s, as the EC (now the European Union) moved towards the development of a single market for pharmaceuticals. The birth of International Conference for Harmonisation took place in 1990 with representatives of the regulatory agencies and industry associations of Europe, Japan and the USA. After a series of harmonisation meetings, the International Conference for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) issued the ICH Guidelines: Topic E6 Guideline for GCP. This guideline was approved on 17 July 1996 and implemented for clinical trials from 17 January 1997. [6].

1.1.3 Phases of clinical trials: There are 4 phases of clinical trials in new drug development (Table 1). In the phase I, studies are mostly conducted in healthy normal volunteers and are essentially safety and tolerability studies. This is followed by the phase II studies in a limited population of patients focussing on dose-concentration-efficacy relationship. The phase III focuses on confirmation of efficacy and safety in a large population. A New Drug Application (NDA) is a compilation of the results of the clinical trials on the new drug and submitted to regulatory authorities for obtaining marketing approval of a new drug. The phase IV studies, which are initiated after marketing, include monitoring of safety in thousands of patients.

Table 1. Clinical trial phases

Phase	Objective	No. of subjects	Duration
I	Safety and tolerability in normal human subjects (except in the case of oncology and AIDS)	20-100	6-9 months
II	Dose titration, Efficacy and safety in patients	300-500	6 months – 3 years
III	Efficacy, Safety, interactions in comparison with currently available treatments	800-5000	1-4 years
IV	Long term efficacy, safety, interaction in comparison with other marketed drugs and pharmacoeconomics	5000-20,000	Ongoing

The clinical trial process is subjected to strict controls and regulatory requirements at each of these stages. In order to launch a single drug, it had to be tested in about 5000 patients, involving 141 medical procedures each in more than 65 separate trials [7]. The whole process of drug development can take as long as 8-12 years and costs around $0.9 to 1.1 Billion approximately [8, 9]. Besides, the failure rate is very high and it is estimated that only one in 10,000 NMEs ever see the light of the day, all others being either discarded for safety or efficacy failures.

Any new discovery is patented as soon as it is discovered so that the benefits of exclusive marketing rights for the product for a specified period can be reaped by the discoverer. Since the life of a patent begins to tick away from the moment it is filed, the gains can be maximised by bringing the product to market earlier. This means that each day saved on testing the product can bring millions of dollars in extra revenues to the patent owners. Each day's delay in bringing the product to the market is estimated to cost the company US$1 million per day for a drug destined to make half a billion dollars in annual sales [10].

1.2 Globalisation of clinical trials with Harmonisation of regulations:

The International Conference on Harmonisation (ICH) of Technical Requirements for registration of pharmaceuticals for Human Use provided this new, tripartite Good Clinical Practise (GCP) guideline, a harmonised standard that protects the rights, safety and

welfare of human subjects, minimises human exposure to investigational products, improves quality of data, speeds up marketing of new drugs and decreases the cost to sponsors and to the public. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected and consistent with the principles of the Declaration of Helsinki, and that the clinical trial data is credible [6].

There are 13 core principles of ICH-GCP and they are as follows:

1. Clinical trials should be conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).
2. Before a trial is initiated, foreseeable risks and inconveniences should be weighed against anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.
3. The rights, safety and well-being of the trial subjects are the most important considerations and should prevail over interest of science and society.
4. The available non-clinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.
5. Clinical trials should be scientifically sound, and described in clear, detailed protocol.
6. A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/ independent ethics committee (IEC) approval/favourable opinion.
7. The medical care given to, and medical decisions made on behalf of subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.
8. Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).
9. Freely given informed consent should be obtained from every subject prior to clinical trial participation.
10. All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.

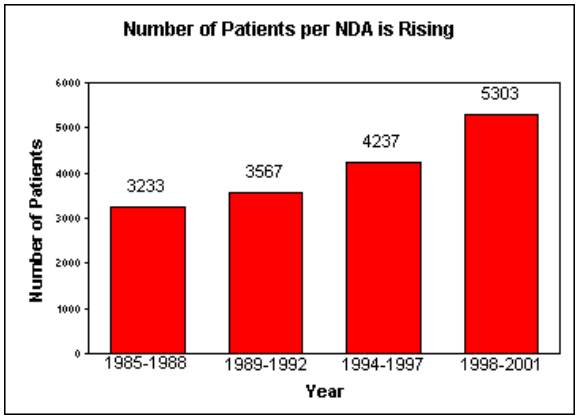
11. The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).
12. Investigational products should be manufactured, handled and stored in accordance with applicable Good Manufacturing Practice (GMP). They should be used in accordance with the approved protocol.
13. Systems with procedures that assure the quality of every aspect of the trial should be implemented.

These principles once again emphasised the ethical principles, the importance of obtaining informed consent, confidentiality and that care must be given by appropriately qualified personnel with adequate experience. It clearly delineated the roles and responsibilities of the sponsor and the investigator. The ICH GCP also specifies all the documents that need to be collated and stored before, during and after the clinical trial. The adoption of ICH GCP ushered in a new era of globalisation of clinical trials and mutual acceptance of data when done to ICH GCP standards.

1.3 Key drivers for off shoring clinical research

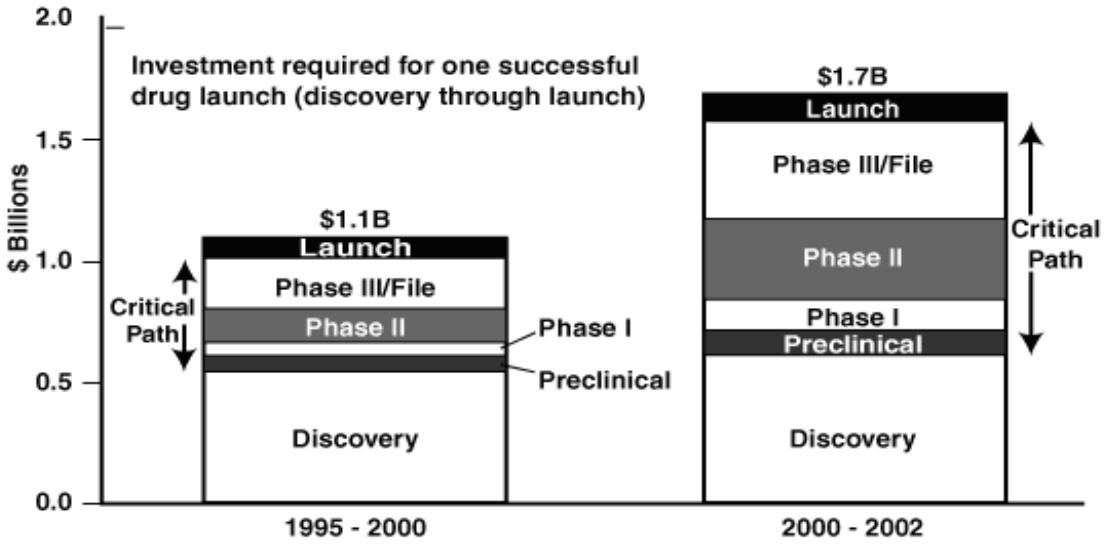
The year 2000 marked the start of a slowdown in new drug and biologic submissions to regulatory agencies worldwide [9]. Patent of 35 drugs expired between 2002 and 2007 and a declining rate of innovation forced sponsors to gather more data to differentiate products within crowded markets [11]. Regulatory requirements demanded that more patients were studies in clinical trials to shown clear superiority of products before they were granted registration. Consequently, clinical trials morphed into sophisticated multi-national operations [12-21] and the number of evaluable patients/NDA went up as shown in Figure 1 [22]. More complex clinical trial procedures are demanding more of investigative site personnel and study subjects, leading to longer clinical trials and increasing difficulty in recruiting and retaining patients 23, 24]. Pharmaceutical companies conducted fewer clinical trials because of a rapid decline in number of principal investigators in the US between 2001 and 2003 [25-26].

Figure 1. Average number of evaluable patients per NDA [22]



The investment required to launch a new drug had risen 55 percent during the five year period as shown below [9]

Figure 2. Investment Escalation per successful Compound [9]



The pharmaceutical industry made a concerted effort to restructure and reorganise its efforts and processes to speed up recruitment and hence decrease time to market. Off shoring to countries that had a larger patient pool and the required talent and infrastructure to conduct clinical research was explored. This included outsourcing to contract research organisations (CRO) that had access to expertise and patient pools in various countries. The global expectation of successful off shoring/outsourcing was to be able to produce high quality, internationally acceptable data in shorter time and lesser cost.

1.4 Clinical Research in India:

India has traditionally been a branded generic pharmaceutical market. In the interest of providing cheaper drugs to Indian patients and protecting the Indian industry, the Patent Act was amended in 1970 to withdraw product patents giving the Indian pharmaceutical industry the permission to market generic versions of drug molecules discovered and developed by western multinational companies (MNCs). Local pharmaceutical companies had no incentive for research and hence clinical research was at a negligible scale.

In 1988, the Drugs and Cosmetics Act was amended by Schedule Y, wherein the first applicant had to conduct clinical trials in 100 patients in one phase below the international phase. Subsequent applicants were required only to establish bioequivalence with the first product. This provided a boost to the generic drug industry in India.

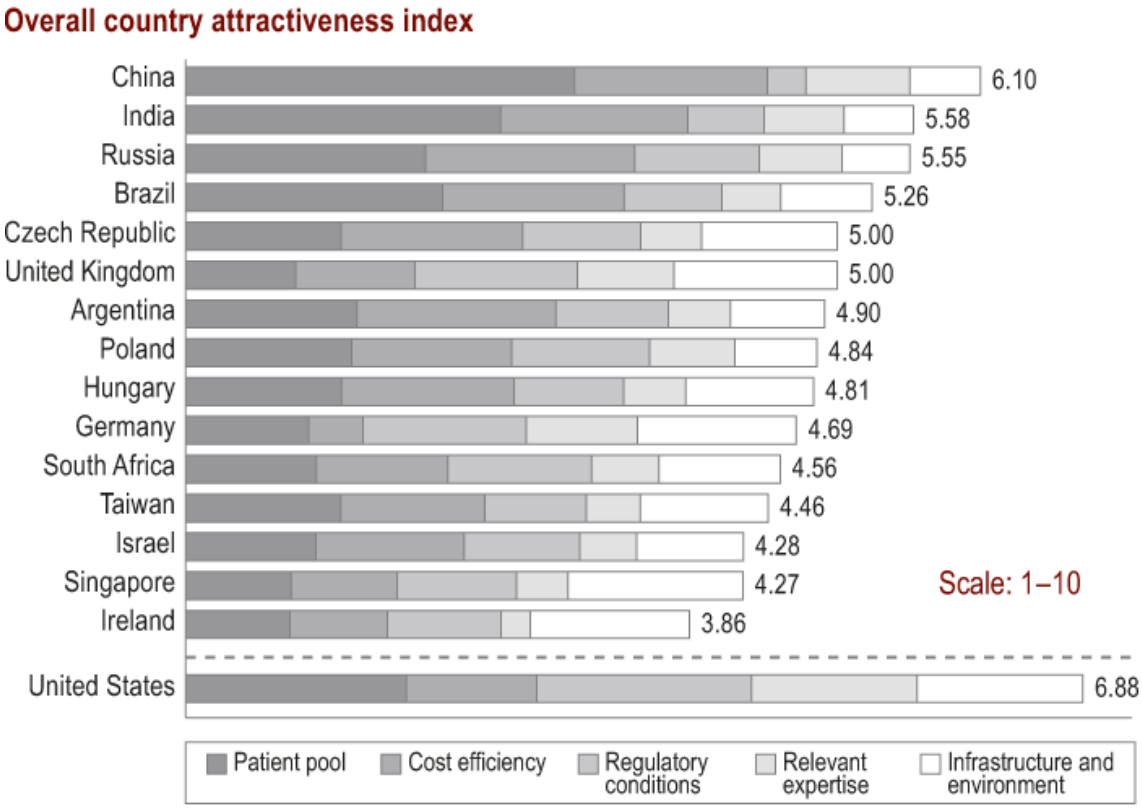
1.5 India as an off shoring/outsourcing destination: Eli Lilly was one of the first pharmaceutical companies to offshore clinical research work to India, as early as 1993, followed by Pfizer in 1995 [27]. The large CRO, Quintiles, also set up its Indian operations in 1997 [27]. The following were quoted as some of India's noted advantages besides the low cost of clinical trial conduct as compared to the west. –

- Enormous pool of treatment naive patients with diverse gene pool
- Potential for multi patient recruitment at major cities across the country
- Majority of investigators western educated
- Pool of Highly skilled and well trained doctors, investigators, and medical personnel
- Compliance with International regulatory and GCP standards

1.5.1 AT Kearney Country Attractiveness Index for Clinical Trials: The Index provides a fact-based ranking of low-cost countries, highlights the evolving clinical trials landscape by evaluating five key areas: patient availability, cost efficiency, relevant expertise, regulatory conditions and national infrastructure. It provides pharmaceutical executives with a stronger foundation from which to make more informed clinical offshore decisions.

China and India were ranked as top off shoring destinations by A.T. Kearney's country attractiveness index for clinical trials.

Figure 3. AT Kearney's Country Attractiveness Index for clinical trials [28]



Source: A.T. Kearney
Notes: Higher scores indicate higher levels of attractiveness. The 15 countries analyzed were selected based on size, diversity and geographical distribution. The Index is not meant to be comprehensive across all potential offshore locations.

1.5.2 Projections of growth Clinical research in India: Centerwatch has predicted that by 2010, the industry will spend around US$ 250-300 million on clinical trials in India [29], while McKinsey estimates a much higher figure of US$1.5-2 billion. This opportunity is expected to bring in more investment in infrastructure and employment opportunities to India.

Several pharmaceutical companies and CROs have set-up their clinical research operations in India. The direct benefits of participating in clinical trials are better and earlier access to subsidized clinical care and to newer improved medicines and treatments and foreign exchange income for the service sector. Besides, building and sustaining research capacity within developing countries is an essential and effective means of accelerating research in

local diseases and health issues [30]. It has been identified as an important millennium development goal in addressing equity in development. Participation of Indian investigators and sponsors in global clinical trials will bring about a transfer of technology by better understanding of research methodology and appreciation of the rigors of disciplined research documentation. This potential can be harnessed for formulating research proposals for local diseases like malaria and dengue.

1.6 Indian Initiatives: The Indian government has also taken various initiatives to gear up for this opportunity. The ICMR released the first ethical guidelines for biomedical research on human subjects in 2000 [31]. The Central Drugs Standard Control Organisation (CDSCO) the apex body that regulates the testing and marketing of drugs in the country reviewed its regulatory machinery. An Expert Committee set up by Central Drugs Standard Control Organisation (CDSCO) in consultation with clinical experts in the country has formulated the Indian GCP guideline in 2001, for generation of clinical data on drugs. The Drug Technical Advisory Board (DTAB), the highest technical body under Drugs & Cosmetics, Act, has endorsed adoption of this GCP guideline for streamlining the clinical studies in India. In 2005, CDSCO amended Schedule Y, for clinical trial (CT) permission and new drug development. The lag phase has been removed, enabling concurrent participation in global Phase II-Phase III studies. This schedule also stipulates the responsibilities of ethics committees, investigators and sponsors, and provides statutory support to the Indian GCP guidelines. It also specifies common formats for EC documents and informed consent and reinforcement of pharmacovigilance and SAE reporting. These regulatory initiatives taken have made India more attractive to global Pharma industry [32]. The reforms to streamline the regulatory systems which began in 2005 are continuing [33-35] in the direction of making it more robust and globally acceptable. These include-

- Removal of the lag phase for clinical trials facilitating India's participation in global clinical development programs
- Compliance to Indian GCP made mandatory, roles and responsibilities clearly defines, formats for key documents recommended
- Adverse event reporting and monitoring procedures and timelines specified
- Clinical trial application process simplified into Category A and Category B
- Separate DGFT approval not required for export of blood samples for clinical trials

- First in human studies not yet allowed for molecules discovered outside of India.
- Staff augmentation at DCGI/CDSCO office
- Reorganising and restructuring the CDSCO similar to the FDA, USA
- Collaborations with WHO, US FDA, Health Canada, ANVISA Brazil and South Africa
- Series of 'train the trainer' workshops with US FDA to train local inspectors for clinical trial inspections
- Since June 15, 2009, mandatory registration of all clinical trials to be conducted in India at ICMR's web-based clinical trial registry
- Robust review process for clinical trial proposals
- Surprise inspections of clinical trial sites in the country

Also expected in the very near future, are initiatives like-

- Registration of CROs
- Guidelines for registration of Ethics Committees
- Penal provisions for fraud and misconduct
- Registration of clinical trial sites
- Creation of an environment for Phase 0 and micro dosing studies.

1.7 The demand for trained resources: The sudden spurt of clinical research activity brings a huge demand for trained manpower in the country. Based on the McKinsey report, a projection has been made that by 2012, the manpower requirement would be approximately 50,000 professionals. Another report projects resource requirements for the various roles as shown in Table 2 below.

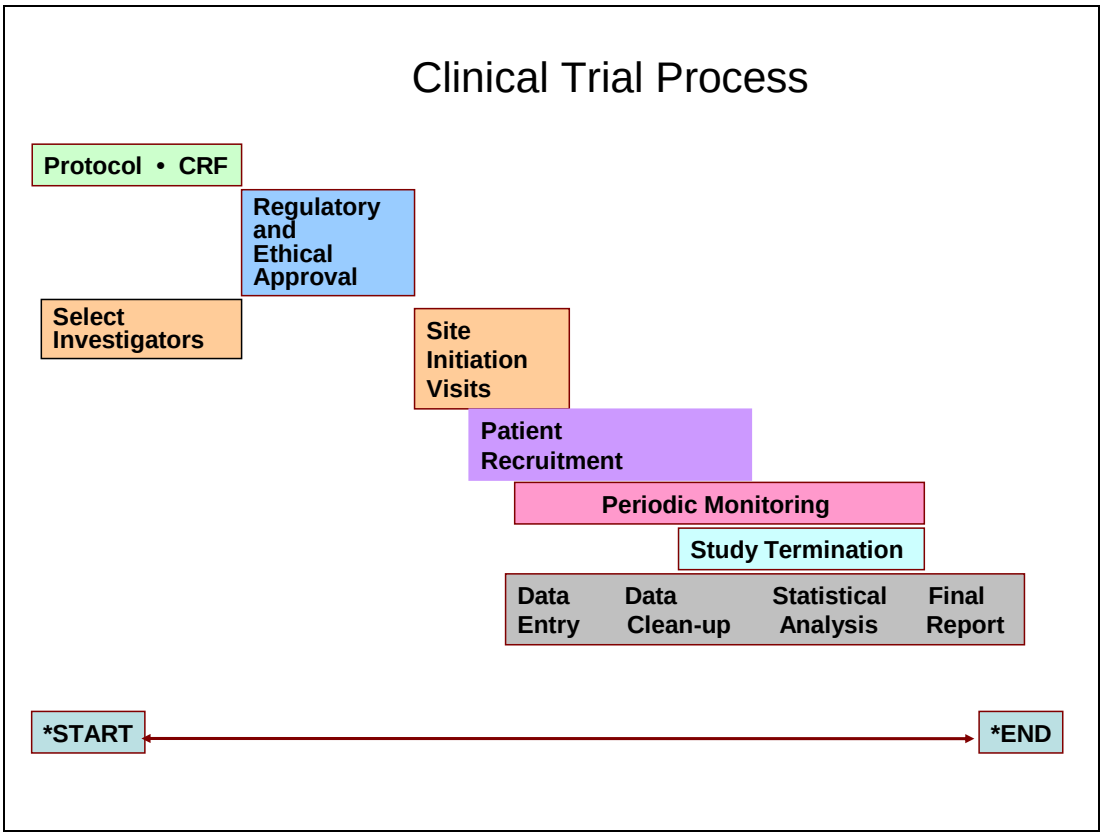
Table 2. Projections of resource requirements in the next 4 years [36]

Types of Jobs	Number of New Positions in the next 4 years
Clinical Monitors / CRAs	7000
Clinical Research Coordinators / Site Coordinators	20000
Drug Safety Personnel	2000
Project Personnel	2000
Medical Monitors	3000
Regulatory Affairs Personnel	3000
Medical Writers	1000
Quality Control / Assurance Personnel	2000
Data Management Personnel	7000
Bio Statisticians	500
Research Scientists	2000
Lab Personnel	1500
Management & Administrative Personnel	2000
(Source: Cliniminds Market Research - Interviews with HR & Clinical Research Heads)	

All GCP guidelines and regulations stipulate that clinical research activities should be undertaken only by qualified and adequately trained resources. Even though India has a large resource pool of medical and para medical graduates, availability of clinical research trained resource is a major challenge which can be better appreciated with an understanding of the complexities of clinical trial process and the specialised demands of the various roles.

1.7.1 The clinical trial process

Figure 4 below gives the clinical trial process



The protocol describes the objective(s), design, methodology, statistical considerations and organization of a trial and the case report form (CRF) is designed to record all of the protocol required information on each trial subject. Investigator selection happens on the basis of the therapy area being studied, the qualification, training and willingness of doctors in the speciality to conduct trials in their patients and having all the required facilities to do so. The protocol, informed consent forms and its certified translations and details of selected investigators form part of the essential documents that need approval from regulatory authorities and institutional (or independent) ethics committees before initiation of any trial related activities. The site initiation visit (SIV) ensures that all site staff is trained on GCP, protocol, CRF, investigational product handling and safety reporting requirements and marks the beginning of patient recruitment. Regular monitoring visits by the CRA takes place during the tenure of the clinical study till study termination and site close out to ensure that the study is being carried out in compliance with GCP, the protocol and all applicable regulations. Data management activities like data entry, clean-up and

validation take place in parallel during study conduct and culminate with preparation of the final study report based on the statistical analysis.

All these process and people in a clinical trial are governed by GCP guidelines and regulations that stipulate roles and responsibilities of the various stakeholders, the documents to be collected before, during and after the study, their place and duration of storage, the ethical and quality standards that should maintained through the process to ensure that data is credible, accurate and patients rights and safety is protected.

1.7.2 Roles and responsibilities in clinical research

Clinical research is a coordinated team effort of the people from diverse back grounds and educational qualifications, like Investigators, site coordinators, clinical research associates (CRAs or monitors), project managers, regulatory managers, project physicians, quality assurance personnel, statisticians and data management personnel; all working under the critical eye of the ethics committee, the data safety monitoring boards, regulatory agencies and corporate partners The ICH GCP guidelines clearly stipulate the qualifications roles and responsibilities of an investigator. The composition of the ethics committee and their responsibilities and the responsibilities of a sponsor have also been detailed. Many of the others roles are not clearly differentiated. They could be slightly differently understood in different organisations and in some smaller organisations; one person could be performing more than one role. The different roles demand differing competencies as they have to perform different responsibilities in the role (Table 3).

Table 3: Roles and responsibilities in clinical research.

S. No	Role in Clinical Research	Duties and Responsibilities in the role
1.	Investigator	A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.
2.	Site coordinator (Clinical Research Coordinator CRCs)	Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).
3.	Clinical Research	The sponsor representative who oversees the progress

	Associate (CRAs or Monitors)	of a clinical trial, ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).
4	Project Managers	Project managers have responsibility of oversight of the entire project and ensuring its smooth execution to agreed time lines, cost and resource allocations.
5	Regulatory Managers	Industry employed person in-charge of all regulatory documentation for clinical trial permissions and registering the product with the regulatory agencies for local marketing or exports.
6	Project Physicians	Industry employed physicians who are responsible for writing the research protocols, contributing to statistical analysis plans, medical monitoring, safety reporting and medical writing of study reports and publications.
7	Quality Assurance Personnel	Auditors are usually experienced clinical research personnel who do process or study audits either in an independent capacity or as company's internal auditors with the objective of ensuring audit trail is maintained.
8	Statistician	Qualified statisticians who are knowledgeable about clinical trial process. They write the statistical analysis plan and implement statistical analysis of the trail data depending on the type of data generated and its clinical relevance.
9	Ethics committee member	An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing, approving and providing on going review of the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent through out the period of the trial. The legal status, composition, function, operations and regulatory requirements pertaining to Independent Ethics Committees may differ among countries, but should allow the Independent Ethics Committee to act in agreement with GCP.

10	Data management personnel	Data management personnel can be data entry operators who enter physical data into electronic databases, database designers who create the structure of the database to mirror the information collected in the case recording forms, data validation officers who validate and cross check the data, medical coders who code the data according to medical dictionaries, medical writers, who write out the clinical study report and programmers who write the codes and macros for analysis of the trial data.

1.8 The talent paradox: It can be seen that the role of the investigator in a clinical trial is more than the traditional role of the doctor in the hospital who is primarily focused on treating patients in that it is much more research-oriented. Investigators should have a sound understanding of research methodology and why certain number of subjects is studied in the particular manner mentioned in the protocol. Monitors, regulatory managers, project managers, auditors and site coordinators are new roles requiring specialised knowledge and skills. All the roles require sound technical knowledge backed by training in ethics of biomedical research, statistics, regulatory aspects and clinical trial methodology. Assertive behaviour, presentation skills; conflict management and negotiation skills are necessary assets [37, 38]. These roles are also evolving with newer technologies like electronic data capture being implemented in clinical research [39].

While the country boasts of a large pool of trained and English educated medical and para-medical professionals, majority of them have little or no knowledge of clinical trials. Dr. Bhatt found less than 5% of over 1000 applicants to have adequate knowledge of GCP [40]. It is estimated that in 2002 only 5% of the specialist in cardiology, psychiatry, neurologists and oncologists and diabetologists were involved in global GCP trials [41]. Centerwatch estimates only about 250 trained investigators were present in 2003 in India [42].

1.9 Clinical research training in India: As a result of the growth in clinical research, over 25 Indian educational organisations are now offering short and long term courses and an assorted selection of different modules in clinical research. This includes a wide variety of them- some well established others new, some small and others large. A few are

affiliated with organisations in the US or Europe [43]. The Academy for Clinical Excellence (ACE) was one of the first planned training initiatives. The academy offers certificate courses on various topics and runs a post-graduate diploma in clinical research that covers in reasonable depth the entire gamut of topics in clinical research. The CDSCO office of the Central Government along with the World Health Organisation has a commitment to train regulatory personnel as well as clinical investigators of the subtleties of Good Clinical Practices (GCP) [43]. The Indian Council of Medical Research along with the Forum for Ethics Review committees in Asia and Western Pacific (FERCAP) helps setup and conduct training programs in biomedical ethics for Ethics committee members.

Courses in India have been criticised for more entrepreneurship than standardisation in the educational programs or certification of the graduates [43, 44]. Some of the apparent concerns are -

- Most formal teaching programmes abroad are spread over several years. However, in the Indian situation the clinical research professionals have to acquire the requisite training in a very short span of time to be able to ride the wave of demand in clinical research. Most courses are not differentiated by roles and are a common offering for all roles. There are very few advanced course offerings for people with experience. Also, some of these can be classroom training, while some others definitely have to be on the job training imparted by accompanied field visits and perfected by experience. Unfortunately no thought has been given to identify these gaps and build in the possible modules in the undergraduate curriculum itself.
- The focus of most clinical research trainings in India is on imparting knowledge. Business acumen and personal skills are neither discussed nor taught [40].
- Continuing medical education programs and regulatory updates: The field of biology and technology is advancing at such a rapid pace that continuing education programs are an absolute necessity to keep abreast of the latest. Guidelines and regulations are also evolving and continuously changing. However, there are no such continuing education programs or recertification mandates that motivate the professionals to seek such updates.

1.10 Objectives of the study: Since clinical research is a newly emerging field, we first undertook a survey to understand the requirements of knowledge and skills in the different

clinical research roles from experts with experience in the field, as they can be expected to have a good comprehension of the roles and responsibilities. Our second survey was on the people playing the various roles in clinical research in India, their educational qualifications, employment status, experience, training received and training required. Educational qualifications can be complemented by training and hence we attempted to identify the gaps between expected knowledge and skill areas and the undergraduate curriculum of the 2 common medical and pharmacy courses. In today's high competitive world, time is of essence and ramping up relatively quickly can be a major competitive advantage for CROs and companies in India. Hence we also chose to deliberate on a strategic model that will address the issues of breadth and depth of knowledge and balance it with the time constraints in the larger context of the industry development. We hope that the outputs of this thesis will contribute to a strategy to define the curriculum for training in the various roles in clinical research.

The proposed research objectives are:

1. Analyzing the items of knowledge and skills considered important by stakeholders and by clinical research professionals
2. Profiling the education, experience, training and requirements of clinical research workforce in various roles India.
3. Evaluating if two of the graduate curricula of medicine and pharmacy have the required elements of knowledge and skills as identified from the surveys above and identifying the gaps that exist.
4. Developing a strategic model for training and education for clinical research professionals.

1.11 Scope and Limitations of the study:

This survey was launched in 2006, and collected data from the people in stakeholder roles and people actually performing the roles (role holders) in clinical research in India. We covered all organisations- pharmaceutical compnes, CROs and academia across the country.

The data collected is already 3 years old, during which period there has been an exponential growth in clinical research in India with several more organisations and people.

Clinical research today also has seen technological advancement with new roles and specialised areas like biotechnology and vaccines.

There was no authenticated database of clinical research professionals in India. This survey was launched on database created by me, which included a large number of those whose who enquired or attended about ACE programs and also many of the new joinees being evaluated at the time of launch of the Pfizer data management engagement. Hence it is likely to have a selection bias of those interested in training and in data management roles.

Our respondents belong to organisations of various sizes and we did not segregate on the basis of size of the organisation, though it is an important determinant on the performance expectations of a role, with smaller organistion demanding more multi-tasking and flexibility and larger ones going for more differentiation.

A small number of responses in some roles do not permit adequate analysis.

In analyzing the graduate curricula for the items of knowledge and skills required for clinical research, we did so knowing that most research happens at the post graduate level in Indian educational system. We chose a 3 point rating scale for importance of knowledge and skill items, but the discriminatory value of the 3 point rating scale -'critical', 'important' and 'Not important' was probably not enough or commonly understood as witnessed by some of the item ratings.

It was difficult for us to decide a right trade off between the number of items of knowledge and skills and making the questionnaire too long.

Cost was a limiting factor in converting to electronic format for the questionnaire in the second phase and hence there were limited functionalities available. When we learnt more about competencies, we also felt that some items were wrongly classified as knowledge areas- e.g. Writing Investigator's brochure.

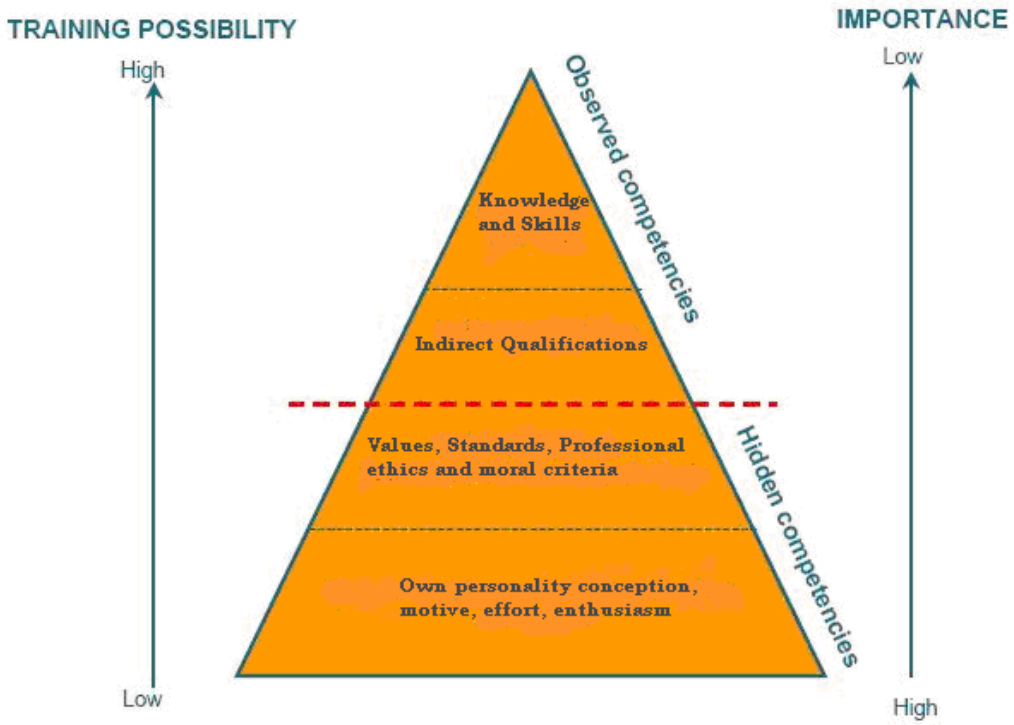
The skills items were named as they are used in common language and no behavioural indicators. It may have been prudent to start one level higher – with identifying competencies required for the roles before identifying the items of knowledge and skills required.

CHAPTER 2: Literature review, research gaps and problem statement

2.1 Theoretical framework:

Clinical research outsourcing brought in high-end knowledge work into India. Since it is a field that deals with life and has low tolerance for ignorance or mistakes, it hinges on the availability of 'competent' workforce. Competency is any characteristic or trait that an individual uses for successful or exemplary performance of any type. Competence integrates knowledge, skills, abilities, personality traits and biological characteristics. It builds on knowledge and skills and is acquired through education, work experience and training [45, 46]. The iceberg model (figure 5) is often used to depict individual competencies. The observed competencies -Knowledge and skills and indirect qualifications have the highest possibility of training. Values, standards, professional ethics and moral criteria and conception of one's own personality, motive, effort and enthusiasm are the hidden competencies that are of high importance but do not yield to training possibility.

Figure 5. The Iceberg model of individual competencies [45, 46]



Training is most effective when it is based on identified needs of the individual. This is done by a series of structured steps- first stipulating clearly the requirements for effective performance in the job, and then evaluating the existing competencies of the individual against these to identify the gaps. These gaps form the training needs of the individual. A thorough understanding of the performance expectations of the role is therefore a prerequisite for a need analysis and designing training programs. Also, training builds on the central body of knowledge gathered in the process of formal education that the trainee will have undergone prior to commencing job oriented training.

2.2 Literature review: The focus of literature review is to charter the course of clinical research in India with respect to the challenges faced in capacity expansion and talent deployment. Particular attention was paid to initiatives on understanding the Indian workforce- their educational qualifications and experience and development through training programs in clinical research or similar new evolving fields. Internet search using keywords was the main source of references on the topic. Besides, conference proceedings, libraries, books on clinical research, online journals and news magazines related to pharmaceuticals industry were also searched. Since this is a fast evolving field, news magazine that reported on latest developments have also been used as supporting references for recent trends or developments.

2.2.1 Early reports on challenges in clinical research in India: One of the earliest reports on the strengths and weaknesses of the Indian infrastructure and identifying where new investments are needed to bring the Indian clinical drug development to internationally competitive standards was prepared by the Pharmaceutical Research and Development Committee of the Council of Scientific and Industrial research [47]. It identified reforms to allow animal importation and testing, investments in clinical trial centres conforming to good clinical practice, in vitro testing facilities, and the training of clinical pharmacologists, IP managers, and staff for the India drug approval agency as areas for improvement.

The first few reports on the challenges of developing trained resources for managing clinical research appeared in 2004 [48 - 50]. ICMR organised an interactive workshop on "Building and Managing Clinical Trial Capacity in India: Challenges in Ethics, Equity and

Efficiency" was held in Hyderabad in October 2005. The workshop covered topics of prioritisation of clinical trials, creating a faster review mechanism, regulating CROs, clinical trial registries and the role of the media [51]. A number of articles discuss availability of trained manpower as a challenge. Local educational standards in communication and comprehension were noted as not the same as developed country standards [52] and vast variations in the quality of education delivered in the medical institutions in India was also seen as an issue [53].

Besides, clinical research jobs also demand competence in various soft skills like written and verbal communication skills, interpersonal skills, negotiation skills, team work, computing skills and leadership skills. These are not specifically identified or addressed in the Indian context.

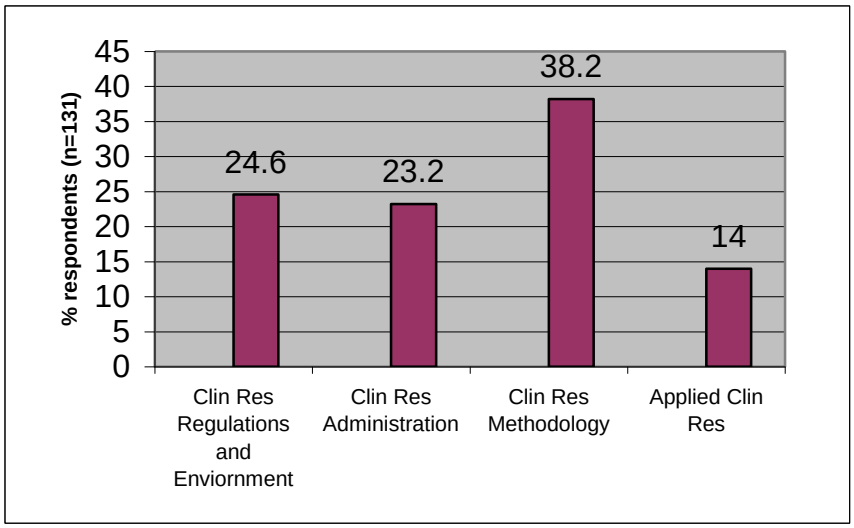
2.2.2. ACE survey on training needs: I was selected in 2003, to head the first ever clinical research training academy in India- The Academy for Clinical Excellence (ACE). To give direction to the curriculum design in ACE, we initiated a training needs survey [54] among clinical research professionals in India. The unpublished survey in two hundred and thirty five participants included investigators, academicians and professionals from the pharmaceutical industry and contract research organizations. They were asked to rate importance of importance of the following 4 modules for training-

- Clinical Research Regulations and Environment
- Clinical Research Administration
- Clinical Research Methodology
- Applied Clinical Research

A total of 131 responses were received back and the affiliations of the respondents were as below:

- Pharma company personnel – 39%
- Contract Research Organisation personnel – 24%
- Investigators – 20%
- Academia- 17%

Figure 6. Training modules considered most important [54]



Clinical Research methodology was rated by 38% of the respondents as the most important module. This formed the basis for focus group discussions within the Executive curriculum committee for designing the curriculum of the courses at ACE. The advanced monitoring course, advanced module on protocol design, and an extensive methodology module in the diploma course were offerings developed as a result of this finding.

Since very little was available in the specific context of clinical research in India, I also studied such initiatives in other evolving fields and in other countries.

2.2.3 UK study of training requirements in pharmaceutical medicine

In 1992, pharmaceutical medicine was a new and fast evolving filed. One of the earliest studies to define the boundaries of pharmaceutical medicine and to reconcile the training needs for new entrants into the field, was the survey conducted among professionals working in British Pharmaceutical industry by Faculty of Pharmaceutical medicine (FPM), in the UK in 1992 [55]. It was realised that with rapid evolution of the field, the academic base itself was not a total reflection of the professional attributes required to practise adequately within the speciality. The aims of the survey were-

- to explore areas of knowledge and skills which pharmaceutical medicine professionals considered important to their daily work,
- to ascertain which areas required training

- whether the training for an item should take place in the job experience (years 1-2) or later (years 3-4)
- to relate actual training received to perceived training needs
- to correlate the findings with demographic data relating of pharmaceutical physicians

A postal questionnaire was sent to FPM and British Association of Pharmaceutical Physicians membership posed four simple questions relating to 38 items of knowledge and skills pertinent to their daily work.

The respondents considered the following areas important -

- Basic Knowledge-Trial design, adverse events, ethics, medical therapeutics, clinical pharmacology, regulatory affairs, pharmacokinetics, pharmacology and statistics
- New Knowledge- Good Clinical Practice, study program design, and quality and audit issues.
- Personal skills- presentation, leadership, teamwork, diplomacy, training others, negotiation, writing, creative thinking and conflict management
- Business management knowledge- decision making, project planning, crisis management, personnel management, financial management, and time and stress management.

Majority thought that training should be acquired during the first 2 years after joining pharmaceutical medicine for most of the items. A comparison of training received compared with training required showed a shortfall of training in some areas of basic knowledge- marketing, industrial issues, medical information, pharmacy and notably in ethics. In new knowledge, a shortfall occurred for all items except GCP. In personal skills, only in the top three important items- presentation, leadership and teamwork, there was no great shortfall of training. Finally in business management knowledge, there was a shortfall in training received in all items except, time and stress management for which a majority of the total group had received training.

This study laid the foundation for development of the curriculum for the diploma in pharmaceutical medicine. The content has been further revised to a competency based

approach with specification of qualification at the entry level candidates. The acquisition of practical competencies is accompanied by the specialty knowledge base, and passing the Diploma in Pharmaceutical Medicine examination [56]. The syllabus for the Diploma composed of nine modules:

1. Medicines Regulation
2. Clinical Pharmacology
3. Statistics and Data Management
4. Clinical Development
5. Drug Safety
6. Healthcare Marketplace
7. Role of the Medical Department
8. Discovery of New Medicines
9. Therapeutics

2.2.4 Faculty of Pharmaceutical medicine- advanced training modules: The FPM commissioned Keele University to undertake a Delphi study to identify the range of competencies for each advanced training module and to define the knowledge and skills required to fulfil the professional roles and responsibilities of a pharmaceutical physician [57-62]. The attraction of the Delphi process is its employment of an iterative process, which is an adaptation of the Delphi forecasting technique, and has been applied in health services research [58]. It provides a survey technique for decision-making among isolated anonymous respondents. In a multi-stage process, each stage builds on the previous one aiming to guide group opinion to think through complex problems and to produce specific ideas of high quality. It had been applied to undergraduate and postgraduate medical courses [59, 60].

The purpose of the exercise was finding out from a group of experts in each particular field if the proposed competencies were those one would expect in a specialist pharmaceutical physician. More importantly, each competency was categorised on the basis of three levels of ability:

(a) being able to perform the task alone and unsupervised,

(b) performing the task as part of a team, or

(c) having an understanding of the underlying principles.

In addition, a weighting factor was applied so that a rank order of competencies was obtained. Then in a second phase the previous statements and new ones proposed by the expert panel were reassessed. A panel of correspondents for each module was drawn from Fellows, Members and Associates of the Faculty and from other experts in the field. The six panels were more or less the same size (range 27-35). There were a total of 364 statements. These were then assembled to form six curricula and the level of competency was given for each or for a group of related activities. The penultimate curricula were assessed by a taskforce in the Faculty, the Curriculum Steering Group, established for the purpose by the Specialist Training Subcommittee, and final editing and juxtapositioning of related topics was undertaken. The style and outcomes of each Delphi exercise on the six modules were analysed at the University of Keele and each was published between December 1999 and April 2000 [58-62].

2.2.6 AAMC – Medical School Objectives Project: In the US, the clinical research summit project was convened by the Association of American Medical Colleges (AAMC), the American Medical Association and the Wake Forest University School of Medicine 1995 [63]. The summit recognised nine core problems confronting the clinical research enterprise, one of them being that there was a need for more clinical investigators and for better educating all practitioners about clinical research. It provided a framework for the NIH to stimulate clinical research by increasing training and career development opportunities. A series of national clinical research roundtables ensued that provided a forum for the interested parties to identify and discuss the major barriers to the conduct of clinical research and develop strategies and approaches to overcoming them [64]. The AAMC also set up a clinical research task force to examine the current state of clinical research education in medical schools and teaching hospitals, describing the optimal infrastructure for the different categories of clinical research, addressing organisation and administration of clinical trials and exploring the interface of clinical research with evolving clinical delivery systems that are academically affiliated. In the area of education and training, the task force observed that medical students and most residents were not being exposed to the excitement of clinical research. The recommendation was that clinical research needs to be conveyed in exciting ways to students to stimulate their interest in the

career. They also observed that clinical research training programs are very heterogeneous and many have no established curricula in terms of expected competencies, skills and knowledge-based requirements for their program graduates. The group recommended that it is critical that these programs establish curriculum requirements. The AAMC developed well defined learning objectives [64], for the medical school graduate student which are described below-

Knowledge

For its part the medical school must ensure that before graduation a student will have demonstrated, to the satisfaction of the faculty, the following:

- An understanding of the ethics involved in subscribing to the principles of good clinical practice in research with human participants
- An understanding of the power of the scientific method in establishing the causation of disease and efficacy of traditional and non-traditional therapies
- Knowledge of contemporary challenges in clinical medicine
- Possession of a working knowledge of seminal clinical research findings and their patient care applications
- Understanding the interdisciplinary nature of clinical research
- Basic knowledge of information systems, biostatistics, epidemiology, and the "logic of inference"

Skills

For its part the medical school must ensure that before graduation a student will have demonstrated, to the satisfaction of the faculty, the following:

- The ability to assess and critique, at a fundamental level, research as it is reported in major medical journals, based on an understanding of how data are derived
- The ability to communicate effectively with a clinical researcher, either in a clinical or consult context
- The ability to translate current clinical research into lay language for patients
- The ability to assess on-line medical information and to assist patients and their families with these tools
- The ability to highlight important clinical research questions, stemming from a presented case or patient interaction
- The ability to reason deductively in solving clinical problems

Attitudes

For its part the medical school must ensure that before graduation a student will have demonstrated, to the satisfaction of the faculty, the following:

- Ethical sensitivity and awareness of issues related to potential conflicts of interest
- A proclivity toward scepticism, curiosity, and humility in the face of the unknown
- An appreciation of the role and importance of clinical research and investigation in the care of patients
- An understanding of the need to engage in lifelong learning to stay abreast of relevant scientific advances, especially in the disciplines of genetics and molecular biology
- An appreciation for the vast reserve of clinical information that remains unknown
- A willingness to intellectually extend a patient care interaction in order to explore the scope of questions that would improve patient care for similar cases
- An appreciation of how the body of medical knowledge is built and advanced

This report also addresses the educational strategies to be employed to understand and appreciate research methodology.

2.2.6 Capacity building in South Africa - Siyantinga Program: More recently, Silver et al [65] describe their initiative to build capacity in research sites in South Africa, while supporting professional development and career enhancement. After performing a needs assessment and evaluation of available training, a model program was designed to build and sustain capacity across the entire clinical research team at site. They also started by surveying 56 study personnel of the Universities of Cape Town and Stellenbosh about –

- the length of association in clinical research,
- specific roles and responsibilities,
- past training/experience relevant to present position,
- training received and
- interest in national recognition for clinical research.

Majority of respondents (39%) had less than one year experience. More than 50% had on the job training, while 40% had structured courses. Forty percent received ethics training, while 59% received none. Both investigators and staff requested in-depth

training/professional development, such as document handling, ethics and basic research principles. Respondents also considered training as a means to expand knowledge/skills, professional recognition and to establish a profession of clinical research.

A GCP course was then provided and a South African research firm utilized to execute and analyse a qualitative evaluation. Based on this, the following conclusions were reached:

- Instruction a person receives must be relevant to that person's present position and build upon past experiences/knowledge;
- It must be timely by keeping pace with changes and
- Assessment must be made of it regularly.

From these conclusions, a coordinated professional development program "Siyantinga Program" was created and implemented. This model includes a core curriculum of basic modules for all staff, role specific modules, and an individual development process to ensure each member of the clinical research team is prepared for his or her responsibilities. Individualization of role specific models is done by assessing and evaluating previous experience and education/training in clinical research. This helps identify the gaps in knowledge and skills necessary to perform the duties related to that position. The learning opportunities for the individual are then identified on a "Position Profile Assessment" and individual development plans which chronicle development received and new experiences and self-learning etc. The curriculum developed is composed of learning objectives, content modules- introductory, intermediate and role specific, pre- and post-tests and evaluation criteria. The contents are reviewed and revised if necessary every six months. They report that 100 staff members who participated in training program felt that their knowledge base had expanded.

2.2.7 GCP Training model in South Africa: Ms. Nomusa Joyce Raphesu of Faculty of community and Health sciences, University Western Cape worked on the development of a good Clinical Practice training model [66].

The objectives of her study were-

- To develop an instrument to be used in identifying the current GCP knowledge and training needs of clinical researchers;

- To identify the knowledge level and training needs using the designed instrument and
- Based on the findings, develop a GCP training model so as to facilitate the achievement of quality standards for the conduct of clinical trials in South Africa.

She noted that 50% of respondents achieved less than 50% of the total knowledge score in important areas that included informed consent, source data verification including writing of source notes for the patients on the clinical trials, investigator responsibilities, study agreements, patient safety, quality assurance, clinical data handling and the provisions of the local guidelines.

2.3 Research Gaps: Literature survey has brought to light the inadequate attention being paid to capacity expansion challenges in clinical research in India. While lay press reports of many of these challenges in finding trained resources, there have been no systematic studies to understand the training needs and how these can be overcome through structured training programs. The responsibilities of the role are fairly clearly delineated, but the knowledge and skills required for to perform these responsibilities have not been identified. There is also no study to profile the current workforce, the qualifications of the people taking up various roles, the training received and gaps that need to be addressed.

Differences in the standards of education from the west [52] and non-uniformity internally within India have been identified [53], bringing up the need for understanding the special training needs in the context of the Indian educational system. In this context, a bottom up approach starting with understanding of the items of knowledge and skills required for performance in each role is the mandatory to ensure that all concerns are addressed. This will also form the basis for designing entry level and advanced training courses that address the domains of learning and the different levels of competencies that different roles may demand [40].

2.4 Problem statement: The problem statement worked on in this thesis is as follows- "Is awareness and availability of training in clinical research adequate to meet the challenges of explosive growth in clinical research opportunities in India?

CHAPTER 3: Research Methodology

The proposed research objectives are:

1. Analyzing the items of knowledge and skills considered important by stakeholders and by role holders (clinical research professionals in the particular roles).
2. Profiling the education, experience, training and further training requirements of clinical research workforce in various roles India.
3. Comparing the identified items of knowledge and skills the current curricula of two highly rated undergraduate medical and pharmacy curricula in India and identifying the gaps that exist.
4. Developing a strategic model for training and education for clinical research professionals.

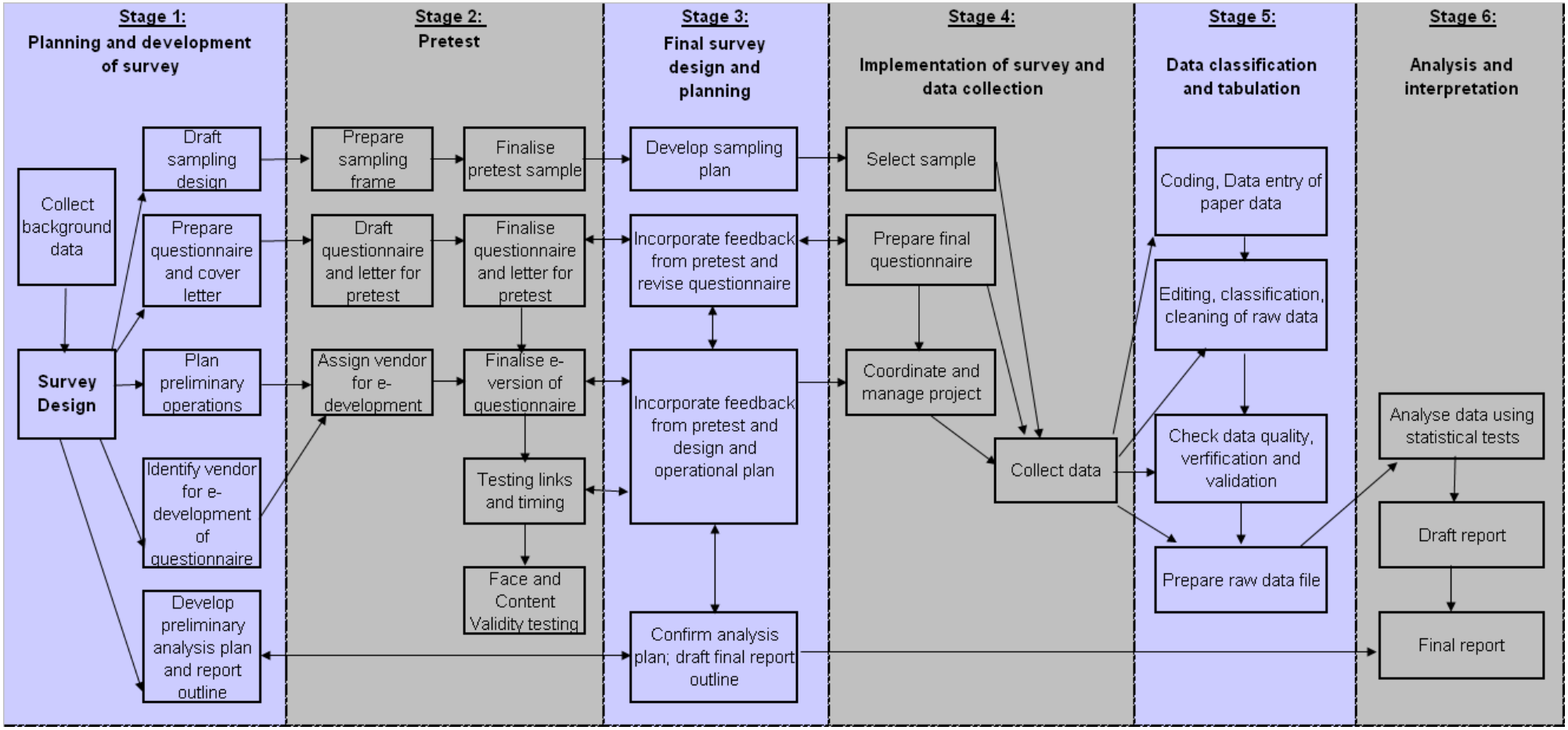
Research design:

Objective 1 and 2: To identify the items of knowledge and skills considered important by stakeholders and clinical research professionals, to profile their education, experience and training requirements; survey research method was considered most appropriate. We modelled the survey research on the lines of that done by Stonier and Gabby [55]. A specially designed questionnaire, validated and pre tested for the purpose was used to collect primary data.

The process is described in detail in Figure 7.

The results of the survey conducted for the first objective were used as inputs for the development of the second survey questionnaire.

Figure 7. Process and methodology of Survey research



3.1. Objective 1- Methodology Stages

3.1.1 Stage 1. Planning and Development of the survey:

Background data included laying out the objectives in specific, clear manner, deciding what needs to be included in the questionnaire and how to make the criteria measurable, how it can be designed for easy administration, the criteria for the sampling frame and operational feasibility. The survey respondents selected were based on the previous survey for Academy for Clinical Excellence (ACE), the criteria for the sampling was decided as people in stakeholder positions and have at least 5 years experience in clinical research. It was decided to study the knowledge and skills requirements for the following 10 roles-

1. Investigator
2. Site Coordinator
3. Clinical Research Associate (CRA)
4. Project Manager
5. Project Physician
6. Quality Assurance personnel
7. Regulatory Manager
8. Statistician
9. Ethics committee members and
10. Data management personnel

The items of knowledge for the questionnaire design were selected based on a previous experience of curriculum design of the diploma course at ACE. The executive curriculum members, all of who matched the criteria of stakeholders in our survey had, over several rounds of discussions, for developing the curriculum for a diploma program, arrived at these items of knowledge as important for various roles in clinical research (Table 4 below). The grouping of the sub-topics into six modules was also based on the focus group discussions by the Executive Curriculum Committee members. The diploma was designed on these grounds.

Skills were selected based on literature survey of the soft skills requirements of various roles (Table 5).

Table 4. Questionnaire Items: Knowledge areas

Modules	**Areas of Knowledge (Sub-topics)**
General – 3 subtopics	Scope of Clinical Research
	Orientation to Pharmaceutical Industry
	Drug development process
Ethics – 4 subtopics	Biomedical ethics- History and principles
	ICH GCP and national GCP guidelines
	EC composition and function- ICMR and ICH guidelines
	Informed consent process- principles and practice
Regulations- 3 subtopics	Regulations affecting CT for new product/generic registration in India including Schedule Y
	Regulations relating to IP labelling and import
	Regulations regarding safety and pharmacovigilance
Methodology- 7 subtopics	Framing a research proposal/protocol and experimental design
	Writing investigators brochure
	Designing case report forms and EDCs
	Writing informed consent and Patient information sheet
	Writing study reports and publication
	SOP writing
	Conducting PK studies
DM and Stats- 4 subtopics	Types of data and statistical tests for clinical trials
	Statistical considerations at the design, execution and analysis
	Data Coding and cleaning
	Software considerations in Data Management
Clinical Trial execution- 6 subtopics	Monitoring a clinical study
	Project Management in clinical research
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)
	Audits and inspection
	Clinical trial supplies management
	Pharmacovigilance and safety management

Table 5. Questionnaire items: Skills areas

Leadership skills
Team work Negotiation skills
Conflict management
Interpersonal skills
Computing skills Presentation skills
Communication skills

The introductory letter outline explaining the objectives of the survey was drafted. The questionnaire layout was drafted with items of knowledge and skills listed vertically and the various roles in clinical research horizontally were chosen. The respondents had to rate the area of knowledge/skill and the role their rating of importance of this area to performance in the role. A 3 point rating scale was chosen. .

The rating was on a 3 point scale as follows-

3- Critical- Cannot perform in current role without knowledge in this area
2- Important- Knowledge is important, but not critical to performance
1- Not Important- Knowledge is not important for performance in the current role

Statistical analysis: The type of data suggested that Kruskal Wallis test [67] needs to be applied. Hence all the data was subjected to this test.

The null hypothesis tested was that there would no differences between the grading of importance of the knowledge and skills items for the different roles.

Kruskal Wallis is a non-parametric test (distribution-free) used to compare three or more independent groups of sampled data. This, like many non-parametric tests, uses the ranks of the data rather than their raw values to calculate the statistic.

The hypotheses for the comparison of two independent groups are:

H_o: The samples come from identical populations

H_a: They samples come from different populations

The test statistic for the Kruskal-Wallis test is H. This value is compared to a table of critical values based on the sample size of each group. If H exceeds the critical value for H at some significance level (usually 0.05) it means that there is evidence to reject the null hypothesis in favour of the alternative hypothesis.

3.1.2 Stage 2. Pre-test

The specially designed questionnaire in the form of a matrix was finalised in MS word format. The pretest sample size was of 5 stakeholder members. They were emailed the draft questionnaire and a covering letter explaining the purpose of pre testing the questionnaire. They were requested to verify content validity and face validity.

Content Validity: Content Validity is based on the extent to which a measurement reflects the specific intended domain of content. Pre-test respondents were asked to reflect on whether all the items of knowledge and skills pertinent to the roles were covered. Additional items were specifically solicited.

Face Validity: Face validity is concerned with how a measure or procedure appears. Does it seem like a reasonable way to gain the information the researchers are attempting to obtain? Does it seem well designed? Does it seem as though it will work reliably? The pretest respondents were asked to confirm that the questionnaire as a MS word attachment was easy to understand and was a workable solution to gathering the information. They were also to confirm that email was an effective and reliable means of communication for the purpose of the survey.

3.1.3 Stage 3. Final Survey design and implementation planning:

The sampling plan and data base of contact details of 48 stakeholders was finalised. Feedback from the pre-test included the following-

- Clarifying the explanation of ‘critical’ to indicate that job cannot be performed without knowledge in this area
- Adding numerical 3, 2 and 1 to identify with the ratings of ‘critical’, ‘important’ and ‘not important’ respectively
- Soliciting any additional items of knowledge/skills that the respondents would like to add and

- One pre-test respondent suggested converting it to e-version for convenience of backend operations

Three of the four points of feedback of the pre-test were incorporated and the questionnaire matrix revised to form the final questionnaire. Converting to e-version worked out very expensive and was not considered worthwhile for the small sample size. Hence hard copy mail or email was chosen as the mode of communication. The cover letter assured all respondents of confidentiality and non disclosure of data by individual identity.

The participants of the pre-test confirmed content validity- i.e. the questionnaire contained all items of knowledge and skills that should be included for all the roles. There were no additions to the list. They completed the questionnaire and confirmed face validity by return email- i.e. the questionnaire was easy to understand and fill out. The final version of the covering letter and questionnaire are in Appendix 1 (a) and Appendix 1 (b).

The analysis plan included tables on the responses received for each of the roles and testing if there were differences in the responses between the roles using Kruskal Wallis test was finalised.

3.1.4 Stage 4. Implementation of survey and data collection

The final questionnaire was sent as an email attachment to all 48 stakeholders identified in the sample. A time frame of one month was given to them to complete the questionnaire and send it back by email. Follow-ups were done by emails and telephonically during this period to encourage the respondents to complete on time. Respondents had a choice of sending the completed questionnaires back electronically or by hard copy.

3.1.5 Stage 5. Data Classification and tabulation

On receipt of the competed questionnaires, the data was entered in Microsoft excel format as individual responses for grading of the areas of knowledge and skills. The data was then pooled to create a frequency distribution of the number of respondents' rating a particular item of knowledge or skills as 'critical', 'important' or 'not important'.

3.1.6 Stage 6. Analysis and interpretation

Analysis is based on-

1. **Within modules- rating of relative importance for the knowledge modules** – Since there are differing number items of knowledge in each module- e.g. 3 items in the general module, 4 in the ethics module etc., the gradewise total for all the sub-topics in the module was calculated. The distribution of the total scores for critical, important and not important ratings within each module was used to access its relative importance of the module as critical, important or not-important.
2. **Across all items** - Highest individual item scores was used to access the importance of individual items of knowledge or skills.

In discussing the results a 'significant' response was considered to be 50% or greater positive response from the total group as described by Stonier and Gabby [55].

Statistical test: Kruskal Wallis test was applied separately on the knowledge items and the skills items. All the responses (data points) across all roles for an item of knowledge (or skill) were ranked: the smallest value gets a rank of 1, the next smallest gets a rank of 2, and so on. Tied observations get average ranks. The sum of the ranks is calculated for each group, then the test statistic, H, is calculated. H is given by the below-

$$H = \frac{12}{n(n+1)} \sum_{i=1}^{k} \frac{R_i^2}{n_i} - 3(n+1)$$

Where,

n_i (i = 1, 2, ..., k) represent the sample sizes for each of the k groups (i.e., samples) in the data.

R_i = the sum of the ranks for group i.

H represents the variance of the ranks among groups, with an adjustment for the number of ties. It is approximately chi-square distributed, meaning that the probability of getting a particular value of H by chance, if the null hypothesis is true, is the P value corresponding to a chi-square equal to H; the degrees of freedom is the number of groups (k) minus 1.

In our case, n_i was 310 in most cases as there were a total of 31 respondents rating each topic for 10 roles- therefore a total of 310 ratings. In some cases, there were missing responses.

k=10 for the 10 different roles.

The null hypothesis in our case was that the ratings were from identical populations-i.e. there is no difference in the ratings for the different roles

The alternate hypothesis being that the ratings were from different populations –i.e. there is a difference between the different roles.

3.2 Objective 2- Methodology Stages

3.2.1 Stage 1. Planning and Development of the survey:

The back ground information on the items of knowledge and skills identified from the first survey was used to draft the questionnaire for the second survey. Demographic details of the respondents were planned in the first few questions. Their work profile, role, organisation, education and experience details were also included. The respondents had to mark their rating of importance of knowledge and skill areas to performance in the role. The rating for importance was on a 3 point scale was -

- ☐ Critical- Cannot perform in current role without knowledge in this area
- ☐ Important- Knowledge is important, but not critical to performance
- ☐ Not Important- Knowledge is not important for performance in the current role

Training details as to whether training was received and if so, where it was received- at graduation, on the job or at an institute was also captured.

The depth of training received was to be rated on a 3 point scale as follows-

- ☐ Awareness (understanding of underlying principles of the particular activity)
- ☐ Knowledge (able to perform task as part of a team)
- ☐ Competence (having adequate knowledge and skill to perform)

Further training requirements were also captured on a 3 point scale as follows-

- ☐ Training required (even if some training received earlier, more required)
- ☐ Training not required
- ☐ Unsure

The sample included all the people employed in different roles within clinical research departments of pharmaceutical companies or contract research organisations and/or site management organisations (SMOs) in India. I used the database I had generated on my

own from all enquiries for training at ACE and those who were seeking employment in clinical research jobs. It included all potential faculty and executive curriculum committee members to the Academy for Clinical Excellence (ACE). It was a good representation of the cross section of all the players in clinical research across the country, including academia and industry. The survey was hosted in an electronic format on a web server and the link forwarded to all potential respondents.

Considering the ease of operation, the last option was chosen, even though it worked out more expensive. No statistical tests were appropriate for data of this nature, but in discussing the results a 'significant' response was considered to be 50% or greater positive response from the total group. This criterion has also been previously adopted by Stonier and Gabby [55] in the discussion for their results. The results were analysed in terms of demographic data, knowledge and skills rated important, training received and training requirements, and the correlation of these with demographic data. The data was considered qualitative data and to be presented as descriptive analysis of the current scenario.

3.2.2 Stage 2. Pre-test

An initial testing of the hosting links and the electronic version of the draft questionnaire was done by me. When links were found to work well and there were no inconsistencies or spelling errors in the questionnaire, pre-test was embarked on.

A sample size of 12 was chosen for pre testing based on their experience in clinical research, availability and agreement to devote time and interest in this activity. The link to the specially designed electronic questionnaire was sent to these members. The respondents were requested to check if the links opened well and questionnaire was easy to understand and respond to. They were specifically asked to verify content validity and face validity.

3.2.3 Stage 3. Final Survey design and implementation planning:

The data base of the survey sampling frame was finalised.

Feedback from pre-test included the following-

1. The electronic links opened well and questionnaire was easy to understand and access.

2. Correction of the qualifications for post graduation in alternative medicine to MD (alternative medicine)
3. The units (completed yrs) in the demography data for age.
4. Suggestion on the layout of the questions so that it does not seem repetitive

The feedback was incorporated and the covering letter and the questionnaire were revised. The final version of the questionnaire was then handed over to the vendor for the development of the e-version.

The participants of the pre-test confirmed content validity- i.e. the questionnaire contained all items of knowledge and skills that should be included for all the roles.

3.2.4 Stage 4. Implementation of survey and data collection

The e-version checked against the final version and when found consistent, it was hosted on a web server. The cover letter and the questionnaire are shown in Appendix 2 (a) and Appendix 2 (b). Data entered in the link was captured at the back end as a Comma Separated Value (.CSV) file format and later analysed using excel. The survey was kept open for 18 months and reminder emails were sent at 3 months intervals.

3.2.5 Stage 5. Data Classification and tabulation

Completed questionnaires received were coded to protect the identity of the responder. The data were entered into excel format. The raw data was cleaned to exclude inconsistencies and some of the roles were regrouped into data management category. It was then edited for uniformity, verified and validated for consistency with the original data. The raw data was thus prepared for tabulation and analysis.

3.2.6 Stage 6. Analysis and interpretation

Analysis was done role wise. Demography described the age, sex, educational qualifications, years of experience and how the education and experience prepared them for the current role. Grading of importance of knowledge and skills areas, training received, depth of training received and requirement for further training were tabulated for knowledge and skills separately.

These analyses were done separately for the different roles.

Analysis is based on-

Within modules- rating relative importance for the knowledge modules – Since there is differing number items of knowledge in each module- e.g. 3 items in the general module, 4 in the ethics module etc., the grade wise total for all the sub-topics in the module was calculated. The distribution of the total scores for critical, important and not important ratings within each module was used to access its relative importance of the module as critical, important or not-important.

Across all items - Highest individual item scores was used to access the importance of individual items of knowledge or skills.

Analysis was qualitative to find the areas considered most important and the training received or required in these.

Details of the results are presented in the next chapter.

In discussing the results a 'significant' response was considered to be 50% or greater positive response from the total group as described by Stonier and Gabby [55].

3.3 Objective 3: The third objective was met by internet search for curricula of some of the most popular graduation courses as identified from the results of the survey for the second objective. Graduate curricula at 2 of the high ranking universities for medicine and pharmacy undergraduate curricula were chosen. A detailed study of the learning objectives and syllabus was done to identify items of knowledge and skills identified in the survey for objective 2 that were covered as part of the curriculum.

3.4 Objective 4: Analysis of the available inputs from the study of the previous 3 objectives was used to construct a model of training and development for the requirements of the various roles.

CHAPTER 4: RESULTS AND DISCUSSIONS

4. 1 Results of Objective 1

A total of 31 responses were received.

Table 6. Affiliations of respondents

	Indian CROs	Academia	MNC CROs	MNC Pharma	Indian Pharma
Questionnaires sent (n=48)	21	2	10	9	6
Responses received (n=31)	15	2	5	6	3

Table 7. Designations of respondents.

Head, Clinical Research	6
Head, Indian Operations	6
Study Managers	6
Senior Managers	5
Head, Business Development	4
Medical Directors	2
Head, Department of Pharmacology	1
Assistant Prof Pharmacology	1

Items of knowledge For most topics and roles, the number of responses was 31. Exceptions were-

Table 8: Exceptions to total responses

Role	**Sub-topic**	**No. of responses**
Investigator	Monitoring a clinical study	30
	Conducting PK studies	29
Site coordinator	Writing investigator Brochure	30
Project Physician	Biomedical ethics- history and principles	30
Data Management	Project Management in clinical research	29

Items of Skills Data of 26 responders were considered evaluable for the skills.

A discussion of the important findings for knowledge and skills by roles follows.

4.1.1 Investigator (Table 9, 10 and Figure 8)

Significant findings for this role were-

Knowledge Modules: Comparison of the grade wise total of all responses for each module shows that

- 50% or more respondents rated the General, Regulatory and execution modules as 'important'.
- In addition, the following sub-topics in the Ethics module were rated as 'critical' by 50% or more respondents
    - EC composition and function-ICMR and ICH guidelines
    - Informed consent process- principle and practice
- Audits and inspection was rated 'critical' by 50% or more respondents.

Figure 8 shows the ratings for the knowledge modules for the role of the investigator.

Skills: Grading of importance of skills for Investigator's role is shown in Table 10.

- All the skills, except conflict management skills were rated 'critical' by 50% or more respondents. The maximum ratings were for Negotiation skills, followed by interpersonal skills and communication skills.

The investigator is the leader of the clinical trial team at site. His role is to coordinate with the ethics committee for obtaining ethical clearance of the clinical trial protocol, recruit patients according to the inclusion and exclusion criteria of the protocol, ensure their informed consent is taken before enrolling and administer the new drug as per the protocol. He is primary responsible for the well-being of the patients in the trial and conduct of the study as per regulatory guidelines. To fulfil this role, he must be aware of the general aspects of clinical research in drug development and be thorough with the ethical aspects and regulations and guidelines that he has to comply with during the conduct of the study. The investigator is also responsible for cooperating with the monitor and the audit/inspection team and should be aware of their expectations. Managing the

clinical trial supplies at site and complying with all requirements of safety management are also important aspects of an investigator's role.

The two crucial sub-topics in ethics module- EC composition and function and Informed consent process- principles and practice and also topic of audits and inspections have been rated 'critical' by significant number of respondents, which is on expected lines.

An 'important' rating and not 'critical' rating to some of the modules and sub-topics leads us to question if respondents discriminated between 'critical' and 'important' or there was an overlap. All the sub-topics in the regulatory module and the sub-topic of ICH GCP and national GCP guidelines being rated as important (and not critical) by significant number of respondents was surprising considering that clinical research is governed by guidelines and regulations. The sub-topics relating to safety and pharmacovigilance, under regulatory modules and execution module were rated 'important' by significant number of respondents.

Within the methodology module, *Conducting PK studies* has being rated 'important' by 50% and more respondents is understandable as this is an important aspect of new drug evaluation. *Statistical considerations at the design, execution and analysis* is also rated 'important' for this role as these gives the investigator a better understanding of the structure of the protocol. Also understandable was that sub-topics like *Designing case report forms and EDCs*, or *SOP writing* were rated 'not important' by highest number of respondents. Similarly, the 2 sub-topics of *Software considerations in data management* and *Data coding and cleaning* received the highest 'not important' ratings, understandably, being areas that Investigators do not work in.

The investigator is the leader of the team at site that conducts the clinical trial. Leadership skills and conflict management skills receiving a low number of 'critical' ratings as compared to the other skills was surprising. The role may entail negotiation of finances, timelines and patient recruitment targets and it is understandable that Negotiation skills, interpersonal skills and communication skills were rated 'critical' by highest number of stakeholders.

Table 9. Knowledge areas for the investigator (n=31)

Areas of Knowledge (n=31)		Critical	Important	Not Important
General Module	Scope of Clinical Research	7	19	5
	Orientation to Pharmaceutical Industry	8	18	5
	Drug development process	13	13	5
	Gradewise total of 3 topics in general module	28	50	15
Ethics Module	Biomedical ethics- History and principles	11	15	5
	ICH GCP and national GCP guidelines	14	17	0
	EC composition and function- ICMR and ICH guidelines	17	14	0
	Informed consent process- principles and practice	18	13	0
	Gradewise total of 4 topics in regulatory module	60	59	5
Regulations Module	Regulations affecting CT for new product/generic registration in India including Schedule Y	4	23	4
	Regulations relating to IP labelling and import	3	20	8
	Regulations regarding safety and pharmacovigilance	8	20	3
	Gradewise total of 3 topics in regulatory module	15	63	15
Methodology module	Framing a research proposal/protocol and experimental design	12	12	7
	Writing investigators brochure	9	14	8
	Designing case report forms and EDCs	9	9	13
	Writing informed consent and Patient information sheet	10	12	9
	Writing study reports and publication	10	12	9
	SOP writing	8	14	9
	Conducting PK studies (n=29)	4	20	5
	Gradewise total of 7 topics in methodology module	62	93	60
DM and Stats Module	Types of data and statistical tests for clinical trials	6	16	9
	Statistical considerations at the design, execution and analysis	7	15	9
	Data Coding and cleaning	2	10	19
	Software considerations in Data Management	0	10	21
	Gradewise total of 4 topics in DM& stats module	15	51	58
Clinical Trial execution	Monitoring a clinical study (n=30)	7	19	4
	Project Management in clinical research	8	21	2
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	11	18	2
	Audits and inspection	19	12	0
	Clinical trial supplies management	13	18	0
	Pharmacovigilance and safety management	12	19	0
	Gradewise total of 6 topics in clinical Trial execution module	70	107	8

Figure 8. Knowledge areas for the Investigator (n=31)

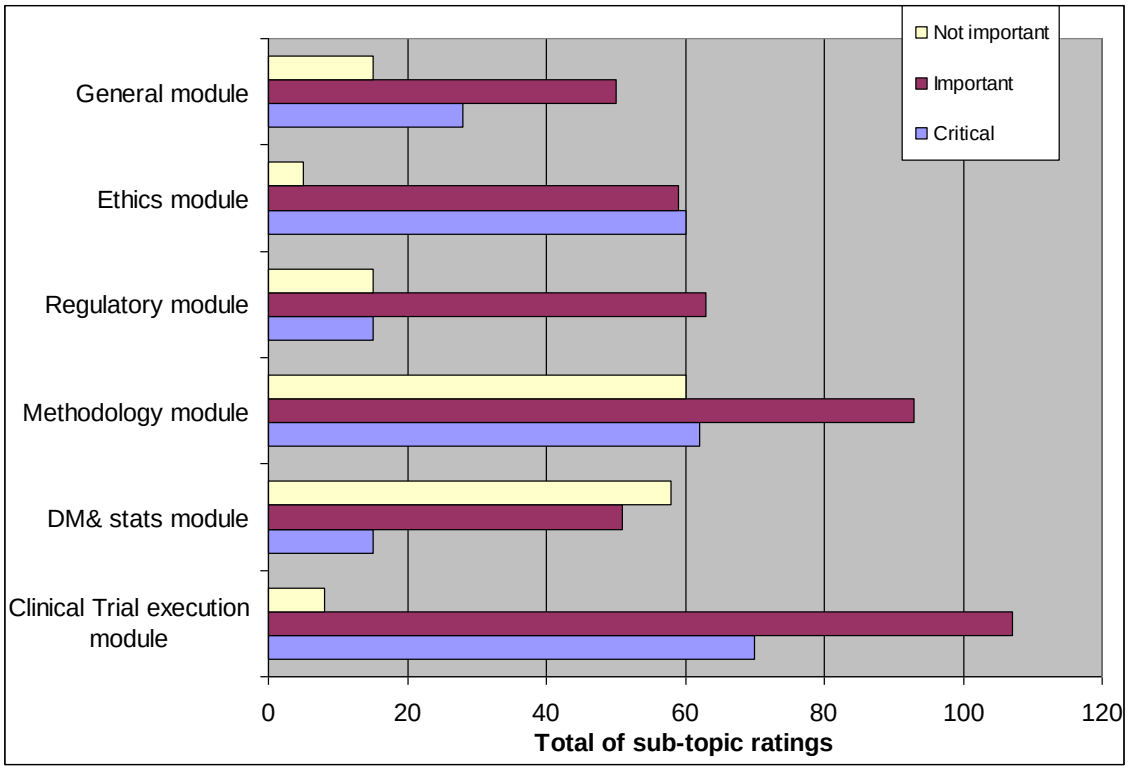


Table 10. Skills for the role of Investigator (n=26)

Skills	Rating		
	Critical	Important	Not Important
Leadership skills	16	8	2
Team work	20	6	0
Negotiation skills	24	2	0
Conflict management	13	10	3
Interpersonal skills	22	4	0
Computing skills	21	5	0
Presentation skills	19	7	0
Communication skills	22	4	0

4.1.2 Site Coordinator (Table 11, 12 and Figure 9)

Significant findings for this role were-

Knowledge Modules: Comparison of the grade wise total of all topics within modules, shows that

- 50% or more respondents rated the General, Ethics, Regulatory and execution modules as 'important'.
- In addition, the following sub-topics were rated as 'critical' by 50% or more respondents
    - EC composition and function-ICMR and ICH guidelines
    - Informed consent process- principle and practice
    - Audits and inspection
    - Clinical trial supplies management
- . The following sub-topics were rated as 'important' by 50% or more respondents in the Methodology module and the Data management and statistics module-
    - Writing investigator's brochure,
    - Types of data and statistical tests for clinical trials and
    - Statistical considerations at design, execution and analysis

Figure 9 shows the ratings for the knowledge modules for the role of the site coordinator.

Skills: Grading of importance of skills for site coordinator's role is shown in Table 12.

- All the skills, except leadership skills were rated 'critical' by 50% or more respondents. Teamwork was rated critical by highest number of respondents, followed by interpersonal skills and communication skills.

Although a PI is responsible for the study at site, he commonly depends on a site coordinator for handling many of the important day to day tasks in patient recruitment, informed consent process, documentation and management of clinical trial supplies at site. The ideal study coordinator should have prior medical experience, be familiar with clinical research methodology, medical terminology and concepts [68]. He is also usually the main point of contact for monitors.

The trends of knowledge and skills rating are very similar for the roles of investigator and site coordinator. The sub-topics in ethics module- *EC composition and function- ICMR and ICH guidelines* and *Informed consent process- principles and practice* and also that of *Audits and inspections and Clinical trial supplies management* have been rated 'critical' by significant number of respondents, which is on expected lines. Processes not impacted by them like *Data coding and cleaning* and *Software considerations in data management* were rated 'not important' by significant number of respondents.

It was surprising to note that all the modules including some of the foundational sub-topics like that of *ICH GCP and national guidelines* and those under the regulations module were rated 'important' and not 'critical'. *Pharmacovigilance and safety management,* a crucial part of the site coordinator's role to ensure patient safety, has received almost equal number of critical and important ratings. This again brings to fore the question whether respondent perception of 'critical' rating was being sufficiently different from the 'important' rating of in fact there were overlaps.

This role of the site coordinator involves being the point of contact for subjects enrolling in the clinical trial and for monitors from the sponsor/CRO. Communication skills are obviously critical as also opined by the stakeholders. Coordination also involves a lot of team work and interdependencies and it is very much expected that team work skills followed by interpersonal skills are rated 'critical' by the highest number of respondents for this role.

Table 11. Knowledge areas for the role of Site Coordinator (n=31)

Areas of Knowledge (n=31)		Critical	Important	Not Important
General Module	Scope of Clinical Research	8	19	4
	Orientation to Pharmaceutical Industry	8	18	5
	Drug development process	14	12	5
	Gradewise total of 3 topics in general module	30	49	14
Ethics Module	Biomedical ethics- History and principles	10	18	3
	ICH GCP and national GCP guidelines	13	18	0
	EC composition and function- ICMR and ICH guidelines	17	14	0
	Informed consent process- principles and practice	17	14	0
	Gradewise total of 4 topics in regulatory module	57	64	3
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	4	24	3
	Regulations relating to IP labelling and import	3	19	9
	Regulations regarding safety and pharmacovigilance	8	21	2
	Gradewise total of 3 topics in regulatory module	15	64	14
Methodology module	Framing a research proposal/protocol and experimental design	12	12	7
	Writing investigators brochure	6	16	8
	Designing case report forms and EDCs	8	9	14
	Writing informed consent and Patient information sheet	15	13	3
	Writing study reports and publication	9	13	9
	SOP writing	8	14	9
	Conducting PK studies	2	13	16
	Gradewise total of 7 topics in methodology module	60	90	66
DM and Stats	Types of data and statistical tests for clinical trials	7	17	7
	Statistical considerations at the design, execution and analysis	6	16	9
	Data Coding and cleaning	2	11	18
	Software considerations in Data Management	1	11	19
	Gradewise total of 4 topics in DM& stats module	16	55	53
Clinical Trial execution	Monitoring a clinical study	8	19	4
	Project Management in clinical research	11	19	1
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	8	18	5
	Audits and inspection	18	13	0
	Clinical trial supplies management	18	13	0
	Pharmacovigilance and safety management	15	16	0
	Gradewise total of 6 topics in clinical Trial execution module	78	98	10

Figure 9. Knowledge areas for the role of Site Coordinator (n=31)

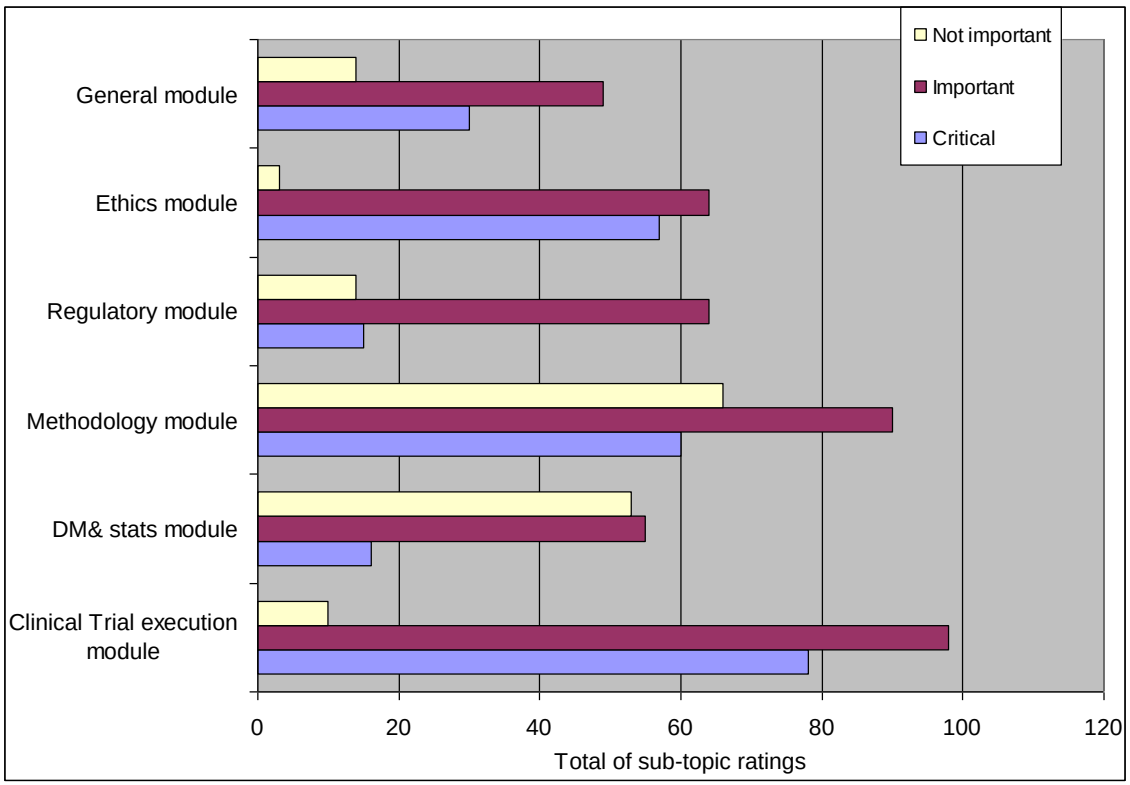


Table 12. Skills for the role of Site Coordinator (n=26)

Skills	Rating		
	Critical	Important	Not Important
Leadership skills	8	8	10
Team work	24	2	0
Negotiation skills	17	5	4
Conflict management	14	10	2
Interpersonal skills	22	4	0
Computing skills	15	10	1
Presentation skills	19	5	2
Communication skills	21	5	0

4.1.3 Clinical Research Associate (Tables 13, 14 and Figure 10)

Significant findings for this role were-

Knowledge Modules: Comparison of the grade wise total of all topics within modules, shows that

- 50% or more respondents rated the General, Ethics and execution modules as 'Critical'.
- Regulations module was rated 'important' by 50% or more respondents.
- In addition, the following sub topics were rated 'important' by 50% or more respondents:
    - *Framing a research proposal/protocol and experimental design* and *Designing case report forms and EDCs* were rated 'important' by significant number of respondents.

Figure 10 shows the ratings for the knowledge modules for the role of the CRA.

Skills: Grading of importance of skills for CRA's role is shown in Table 14.

- All the skills except leadership skills were rated 'critical' by more than 50% of respondents.

The CRA is key to ensuring that the clinical trial is being conducted in compliance with the protocol, the regulatory requirements and GCP guidelines. As a sponsor representative, he liaises with the site to ensure that all essential documents are in place and site staff is trained on all aspects of the study before initiation and that recruitment takes place as planned. On an ongoing basis he monitors that all activities are in compliance with the protocol and regulations, informed consent documents are in order and investigational product accountability is maintained. To perform these activities, the monitor should know what is expected from him and be well versed with the guidelines and regulations applicable. The ICH guidelines gives direction to the competencies expected from a CRAs by mentioning- "Monitors should be appropriately trained, and should have the scientific and/or clinical knowledge needed to monitor the trial adequately". The type of scientific qualification may be very important to the CRA role,

but personality traits are increasingly being emphasised upon as he is the key to getting work done at site and maintaining site relationships [38].

As expected, we found the General, ethics and execution module, especially the sub topics of *Monitoring a clinical study* and *Clinical trial supplies management* to receive the highest number of 'critical' ratings for this role. A rating of 'important' for all the sub topics in the regulatory module and an almost equal distribution of 'critical' and 'important' ratings for the Ethics module sub-topics was surprising and even leads us to question if respondents viewed the rating of 'important' as very close to 'critical' or even overlapping. It was also interesting to note that while significant number of stakeholders rated the execution aspects of pharmacovigilance and safety management as 'critical', the regulations pertaining to the same were rated 'important'.

The CRA role demands ensuring that clinical trials are done to expected standards, which entails team work, conflict management, negotiation, interpersonal and communication skills. The CRA is also expected to do site training and presentation skills' being rated 'critical' is on expected lines. It was interesting to note that for such a critical role, that demands excellent site relationship building and proactive decision making, leadership skills were rated almost equally in all three ratings of 'critical', 'important' and 'not important' by respondents. Given that this industry is still very new in India, the stakeholders' perspective may be to have CRAs who can be directed and guided till experience and expertise builds in.

Table 13. Knowledge areas for the role of CRA (n=31)

Areas of Knowledge (n=31)		Critical	Important	Not Important
General Module	Scope of Clinical Research	11	16	4
	Orientation to Pharmaceutical Industry	18	13	0
	Drug development process	18	13	0
	Gradewise total of 3 topics in general module	47	42	4
Ethics Module	Biomedical ethics- History and principles	15	16	0
	ICH GCP and national GCP guidelines	17	14	0
	EC composition and function- ICMR and ICH guidelines	16	15	0
	Informed consent process- principles and practice	17	14	0
	Gradewise total of 4 topics in regulatory module	65	59	0
Regulations module	Regulations affecting CT for new product/generic registration in India including Schedule Y	9	21	1
	Regulations relating to IP labelling and import	10	19	2
	Regulations regarding safety and pharmacovigilance	9	20	2
	Gradewise total of 3 topics in regulatory module	28	60	5
Methodology module	Framing a research proposal/protocol and experimental design	4	19	8
	Writing investigators brochure	4	15	12
	Designing case report forms and EDCs	6	16	9
	Writing informed consent and Patient information sheet	10	14	7
	Writing study reports and publication	6	14	11
	SOP writing	7	13	11
	Conducting PK studies	2	17	12
	Gradewise total of 7 topics in methodology module	39	108	70
DM and Stats module	Types of data and statistical tests for clinical trials	6	14	11
	Statistical considerations at the design, execution and analysis	5	15	11
	Data Coding and cleaning	2	11	18
	Software considerations in Data Management	9	12	10
	Gradewise total of 4 topics in DM& stats module	22	52	50
Clinical Trial execution	Monitoring a clinical study	23	8	0
	Project Management in clinical research	18	13	0
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	16	15	0
	Audits and inspection	18	13	0
	Clinical trial supplies management	22	9	0
	Pharmacovigilance and safety management	20	11	0
	Gradewise total of 6 topics in clinical Trial execution module	117	69	0

Figure No.10 Knowledge areas for role of CRA (n=31)

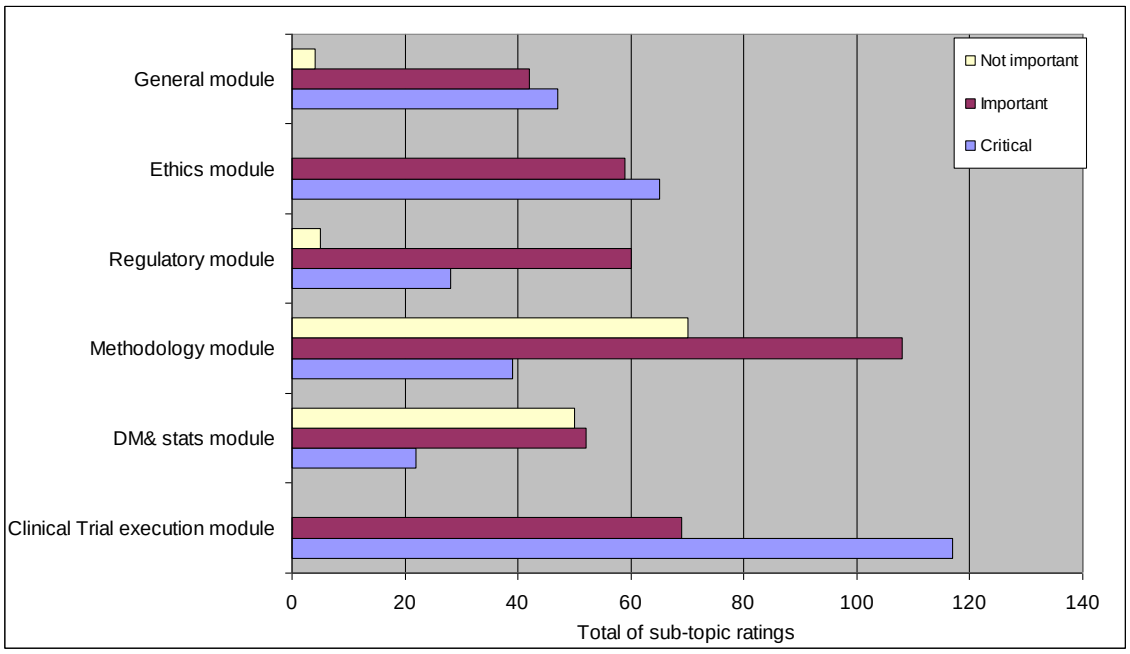


Table 14. Skills for the role of CRA (n=26)

Skills	Rating		
	Critical	Important	Not Important
Leadership skills	8	9	9
Team work	23	3	0
Negotiation skills	22	4	0
Conflict management	23	3	0
Interpersonal skills	22	4	0
Computing skills	18	8	0
Presentation skills	22	4	0
Communication skills	22	4	0

4.1.4 Project Manager (Table 15, 16 and Figure 11)

Significant findings for this role were-

Knowledge Modules: Comparison of the grade wise total of all topics within modules, shows that –

- 50% or more respondents rated the General, Regulations, Methodology and execution modules as 'Important'.
- In addition, the following sub-topics were rated 'critical' by 50% or more respondents-Drug development process
    - EC composition and function- ICMR and ICH guidelines
    - Audits and inspection
    - Clinical trial supplies management
- All the sub-topics in the regulations module were rated 'important' by 50% or more respondents

Figure 11 shows the ratings for the knowledge modules for the role of the project physician.

Skills: Grading of importance of skills for project manager's role is shown in Table 16.

- All the skills except interpersonal skills and computing skills were rated 'critical' by 50% or more respondents.

It is the Project Manager's responsibility to see the project through its different stages to completion. He is responsible for monitoring and improving the metrics related to cost, quality and timelines for the project [69]. A person playing this role should have an overall understanding of all aspects of clinical research. With globalisation of clinical trials, project managers are expected to manage projects across continents and therefore be adept at communication skills and cultural competence.

Stakeholders endorsed the view that project managers have to be adept at all aspects of clinical research by rating the general, regulations, methodology and execution modules as 'important'. 50% or more respondents also rated the pertinent sub topics in the other two

modules as ‘critical’ or ‘important’.

‘Project Management in clinical research was rated as ‘important’ by more than 50% respondents, while we expected to see higher number of ‘critical’ ratings here. We are led to ponder if project management is recognised as a competence of its own accord and implemented as an important application. Contract and agreements are important documents for the project manager’s reference of achievable metrics and milestone payment terms. Significant number of stakeholders rated the subtopic of *legal issues in clinical research* as ‘important’.

As the single point of contact for all project related matters, it was not surprising to see that communication skills were rated ‘critical’ by highest number of respondents. Negotiation for better resourcing, prioritisation with multiple project teams is a challenge project managers face and highest number of stakeholders rated negotiation and conflict management skills as ‘critical’. Interpersonal skills, computing skills and team work being rated almost equally between ‘critical’ and ‘important’ was interesting considering that these skills are almost crucial for the role of project manager.

Table 15. Knowledge areas for role of Project Manager (n=31)

Areas of Knowledge (n=31)		Critical	Important	Not Important
General	Scope of Clinical Research	9	19	3
	Orientation to Pharmaceutical Industry	9	20	2
	Drug development process	16	12	3
	Gradewise total of 3 topics in general module	34	51	8
Ethics Module	Biomedical ethics- History and principles	11	12	8
	ICH GCP and national GCP guidelines	14	17	0
	EC composition and function- ICMR and ICH guidelines	16	15	0
	Informed consent process- principles and practice	12	16	3
	Gradewise total of 4 topics in regulatory module	53	60	11
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	9	17	5
	Regulations relating to IP labelling and import	11	16	4
	Regulations regarding safety and pharmacovigilance	11	16	4
	Gradewise total of 3 topics in regulatory module	31	49	13
Methodology module	Framing a research proposal/protocol and experimental design	7	18	6
	Writing investigators brochure	8	19	4
	Designing case report forms and EDCs	7	15	9
	Writing informed consent and Patient information sheet	10	15	6
	Writing study reports and publication	7	17	7
	SOP writing	12	16	3
	Conducting PK studies	12	16	3
	Gradewise total of 7 topics in methodology module	63	116	38
DM and Stats	Types of data and statistical tests for clinical trials	5	16	10
	Statistical considerations at the design, execution and analysis	3	18	10
	Data Coding and cleaning	2	7	22
	Software considerations in Data Management	4	9	18
	Gradewise total of 4 topics in DM& stats module	14	50	60
Clinical Trial execution	Monitoring a clinical study	11	19	1
	Project Management in clinical research	11	20	0
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	9	22	0
	Audits and inspection	17	14	0
	Clinical trial supplies management	16	15	0
	Pharmacovigilance and safety management	15	16	0
	Gradewise total of 6 topics in clinical Trial execution module	79	106	1

Figure 11. Knowledge areas for the role of Project Manager (n=31)

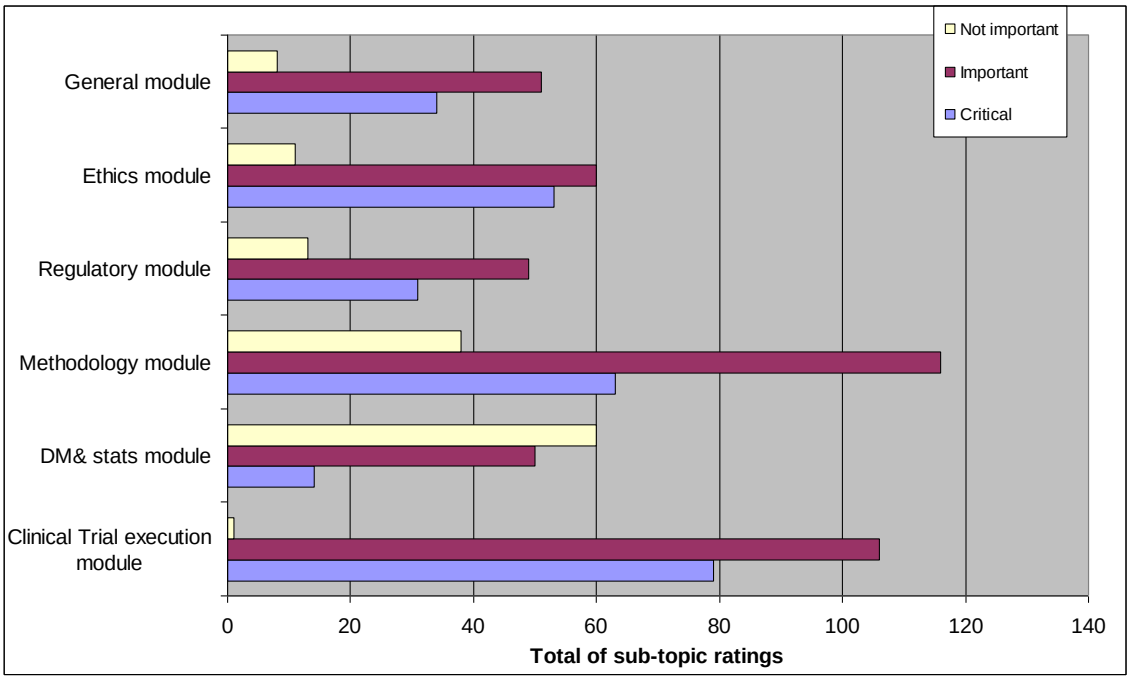


Table 16. Skills for the role of Project Manager (n=26)

Skills	Rating		
	Critical	Important	Not Important
Leadership skills	18	7	1
Team work	14	12	0
Negotiation skills	21	5	0
Conflict management	20	6	0
Interpersonal skills	12	13	1
Computing skills	12	12	2
Presentation skills	18	8	0
Communication skills	22	4	0

4.1.5 Regulatory Manager (Table 17, 18 and Figure 12)

Significant findings for this role were-

Knowledge Modules: Comparison of the grade wise total of all topics within modules, shows that

- Regulatory module was rated 'critical' by 50% or more respondents
- 50% or more respondents rated the General, Ethics, Methodology and Execution modules as 'Important'
- Data management and statistics module was rated 'not important' by significant number of respondents.
- In addition, the following sub-topics were rated 'critical' by 50% or more respondents-
    - Legal issues in clinical research
    - Audits and inspection
    - Pharmacovigilance and safety management

Figure 12 shows the ratings for the knowledge modules for the role of the regulatory manager.

Skills: Grading of importance of skills for regulatory manager's role is shown in Table 18.

- Computing skills and presentation skills were rated 'critical' by 50% or more respondents.
- Team work was rated 'important' by more than 50% respondents.

The regulatory manger's main role is to compile all the regulatory documentation for obtaining permissions for from regulatory bodies for the import of clinical trial supplies, export of clinical trial samples and conduct of clinical trials. This includes awareness of the subtleties of what documentation is required and which regulatory agencies approval is needed for the different classes of NMEs studied- drugs, medical devices, biologicals etc. Since most of clinical trials are done for international registration, being updated on international regulatory requirements is mandatory. The regulatory manager is also the point of contact for inspections from regulatory agencies and he will have to abreast of inspection procedures and requirements.

Stakeholders endorse the importance of the regulations module for this role by significant number of them giving 'critical' ratings for all the 3 sub topics in this module and the sub topic *Audits and Inspection 'critical' ratings by 50% or more respondents.* Pharmacovigilance and safety management- both execution and regulations are rated 'critical' because management of adverse event reporting and periodic safety update reports are an important aspect of the regulatory manager's role.

All the data management and statistics module sub topics were rated 'not important' by highest number of respondents, understandably because regulatory managers are not in this work process. Similarly, in the methodology module, 4 of the sub topics relating to work process that regulatory managers are not involved with were rated 'not important' by highest number of respondents. Regulatory managers are not involved in clinical trial execution and we were surprised to find three sub topics in the execution module- being rated 'critical' by highest number of respondents.

With regulatory submissions being compiled electronically and moving towards electronic submissions, it was understandable that highest number of stakeholders rated computing skills as 'critical'. Regulatory managers are also expected to present data to regulatory authorities and presentation skills being rated 'critical' by highest number of stakeholders is also understandable. Given the amount of communications a regulatory manager has to do, most of it at a global level, it was surprising to find communication skills not receiving significant 'critical' ratings.

Table 17. Knowledge areas for role of Regulatory Manager (n=31)

Areas of Knowledge (n=31)		Critical	Important	Not Important
General	Scope of Clinical Research	8	21	2
	Orientation to Pharmaceutical Industry	10	21	0
	Drug development process	10	21	0
	Gradewise total of 3 topics in general module	28	63	2
Ethics Module	Biomedical ethics- History and principles	9	19	3
	ICH GCP and national GCP guidelines	11	20	0
	EC composition and function- ICMR and ICH guidelines	11	20	0
	Informed consent process- principles and practice	8	21	2
	Gradewise total of 4 topics in regulatory module	39	80	5
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	21	10	0
	Regulations relating to IP labelling and import	19	12	0
	Regulations regarding safety and pharmacovigilance	20	9	2
	Gradewise total of 3 topics in regulatory module	60	31	2
Methodology module	Framing a research proposal/protocol and experimental design	3	7	21
	Writing investigators brochure	0	4	27
	Designing case report forms and EDCs	0	3	28
	Writing informed consent and Patient information sheet	8	21	2
	Writing study reports and publication	8	21	2
	SOP writing	9	21	1
	Conducting PK studies	2	6	23
	Gradewise total of 7 topics in methodology module	30	83	104
DM and Stats	Types of data and statistical tests for clinical trials	2	4	25
	Statistical considerations at the design, execution and analysis	1	3	27
	Data Coding and cleaning	0	3	28
	Software considerations in Data Management	0	3	28
	Gradewise total of 4 topics in DM& stats module	3	13	108
Clinical Trial execution	Monitoring a clinical study	9	22	0
	Project Management in clinical research	12	18	1
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	21	10	0
	Audits and inspection	21	10	0
	Clinical trial supplies management	9	22	0
	Pharmacovigilance and safety management	17	14	0
	Gradewise total of 6 topics in clinical Trial execution module	89	96	1

Figure 12. Knowledge areas for the role of Regulatory Manager (n=31)

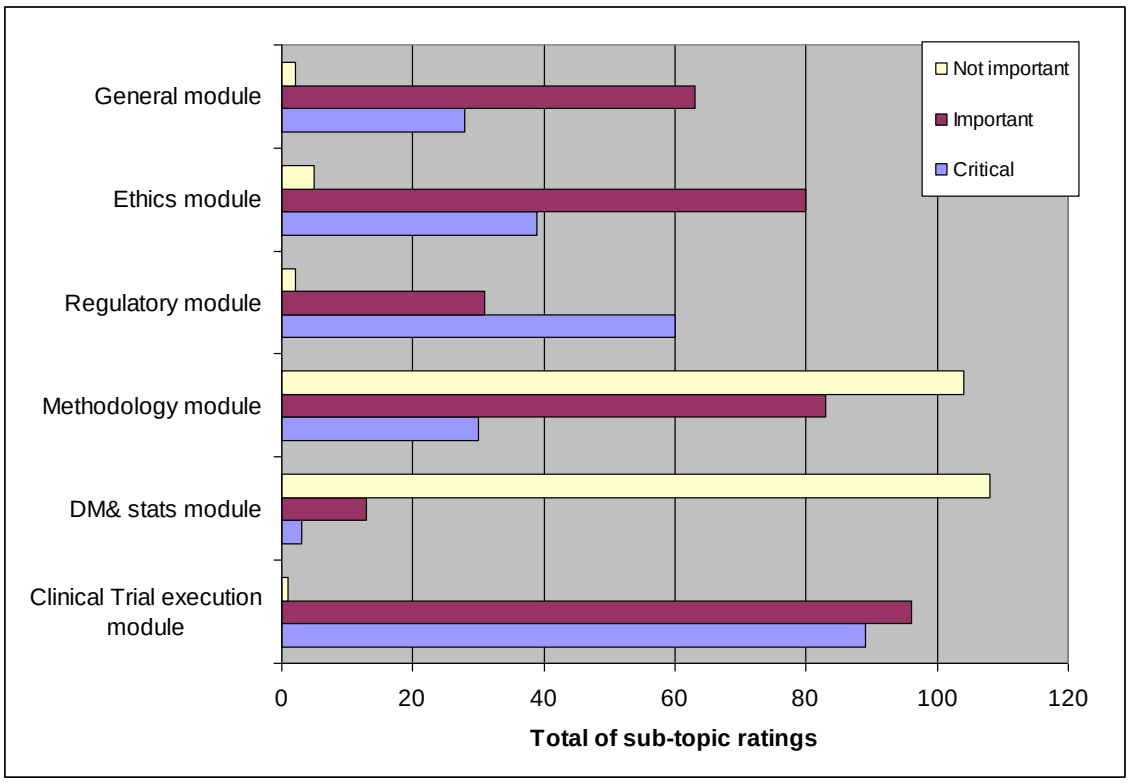


Table 18. Skills for the role of Regulatory Manager (n=26)

Skills	Rating		
	Critical	Important	Not Important
Leadership skills	11	15	0
Team work	9	17	0
Negotiation skills	9	14	3
Conflict management	12	14	0
Interpersonal skills	15	11	0
Computing skills	23	3	0
Presentation skills	22	4	0
Communication skills	15	11	0

4.1.6 Project Physician (Table 19, 20 and Figure 13)

Significant findings for this role were-

Knowledge Modules: Comparison of the grade wise total of all topics within modules, shows that-

- General and Execution module were rated 'critical' by 50% or more respondents
- Ethics and regulatory modules were rated 'important' by 50% or more respondents
- In addition, The following sub-topics were rated 'critical' by 50% or more respondents-
    - ICH GCP and national GCP guidelines
    - EC composition and function-ICMR and ICH guidelines
    - Regulations affecting CT for new products/generic registration in India including schedule Y
    - Framing a research proposal/protocol and experimental design
    - Writing informed consent and patient information sheet
    - Writing study reports and publication
    - Statistical considerations at the design, execution and analysis

Figure 13 shows the ratings for the knowledge modules for the role of the project physician.

Skills: Grading of importance of skills for project physician's role is shown in Table 20.

- All the skills except interpersonal and computing skills were rated 'critical' by 50% or more respondents.
- Negotiation skills and presentations kills were rated 'critical' by maximum number of respondents.

The project physician's role is to act as the scientific expert to support clinical development of a new product. He prepares the clinical development plan and contributes to development of the protocol and other important study related documents like the investigator's brochure, patient information sheet and informed consent documents. In all these activities, compliance to regulations is primary. Scientific orientation and team work are the two most important characteristics sought in a project

physician [38]. Knowledge of therapy area, research methodology, regulatory and ethics and good communication skills are important attributes for a clinical research role [70].

Clinical research and its scope is still a new and relatively unknown field to medical graduates who can take up roles of project physicians and this probably the reason why the general module was rated 'critical' by the highest number of respondents. The project physician has an important role in study design and methodology and it was expected to see the areas directly impacted by the role- the sub topics of *Pharmacovigilance and safety management*, *Writing study reports and publications*, *Framing a research proposal/protocol and experimental design*, *Writing patient information sheet* were rated 'critical' by respondents. In the data management and statistics module, it was heartening to see that the sub topic *Statistical considerations at the design, execution and analysis* was rated 'critical' as this is an important consideration for project physician's when they design study protocols.

Negotiation, presentation, team work and conflict management skills were rated 'critical' by highest number of respondents. Project physicians have to work with people from diverse backgrounds and team work and conflict management skills rated 'critical' by highest number of respondents will be certainly assets for this role. This is also one of the few roles that stakeholders marked 'critical' for leadership skills.

Table19. Knowledge areas for role of Project Physician (n=31)

Areas of Knowledge (n=31)		Critical	Important	Not Important
General Module	Scope of Clinical Research	16	15	0
	Orientation to Pharmaceutical Industry	17	14	0
	Drug development process	20	11	0
	Gradewise total of 3 topics in general module	53	40	0
Ethics Module	Biomedical ethics- History and principles	13	16	1
	ICH GCP and national GCP guidelines	18	13	0
	EC composition and function- ICMR and ICH guidelines	17	14	0
	Informed consent process- principles and practice	12	19	0
	Gradewise total of 4 topics in regulatory module	60	62	1
Regulations module	Regulations affecting CT for new product/generic registration in India including Schedule Y	16	15	0
	Regulations relating to IP labelling and import	9	18	4
	Regulations regarding safety and pharmacovigilance	15	16	0
	Gradewise total of 3 topics in regulatory module	40	49	4
Methodology module	Framing a research proposal/protocol and experimental design	18	13	0
	Writing investigators brochure	14	17	0
	Designing case report forms and EDCs	9	19	3
	Writing informed consent and Patient information sheet	19	8	4
	Writing study reports and publication	22	7	2
	SOP writing	11	19	1
	Conducting PK studies	12	15	4
	Gradewise total of 7 topics in methodology module	105	98	14
DM and Stats module	Types of data and statistical tests for clinical trials	9	13	9
	Statistical considerations at the design, execution and analysis	17	12	2
	Data Coding and cleaning	2	9	20
	Software considerations in Data Management	3	9	19
	Gradewise total of 4 topics in DM& stats module	31	43	50
Clinical Trial execution	Monitoring a clinical study	14	15	2
	Project Management in clinical research	15	14	2
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	18	12	1
	Audits and inspection	19	11	1
	Clinical trial supplies management	11	20	0
	Pharmacovigilance and safety management	21	10	0
	Gradewise total of 6 topics in clinical Trial execution module	98	82	6

Figure 13. Knowledge areas for the role of Project Physician (n=31)

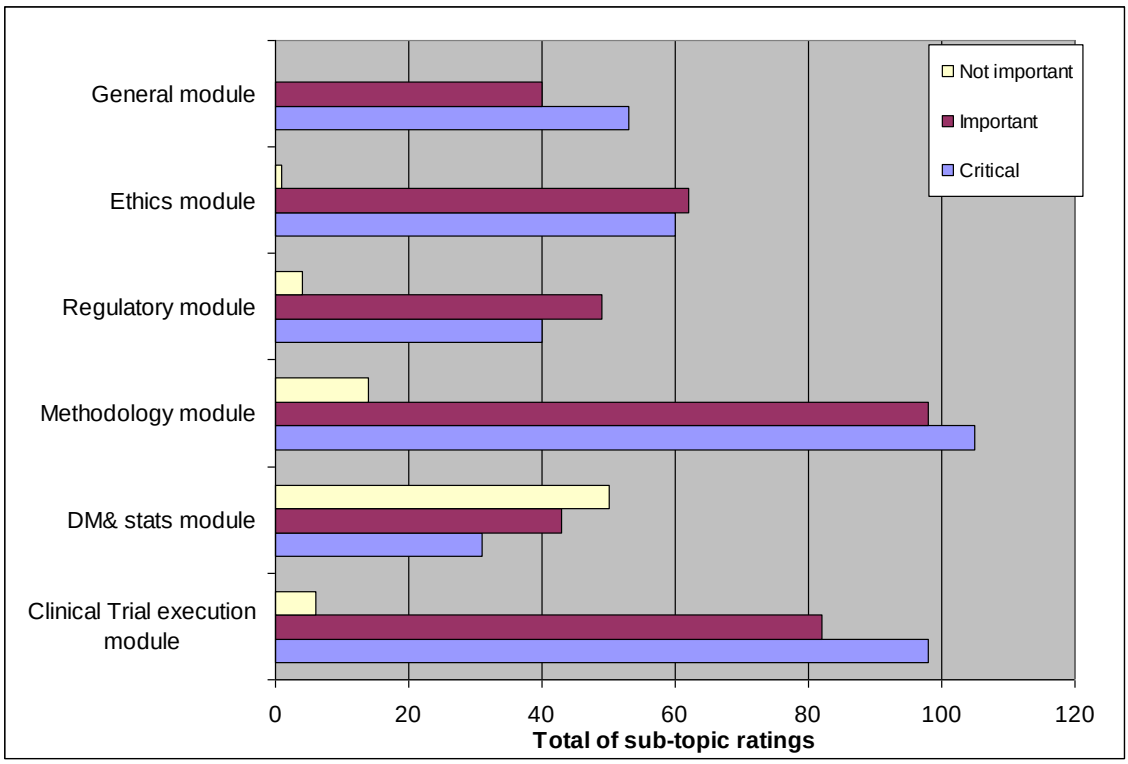


Table 20. Skills for the role of Project Physician (n=26)

Skills	Rating		
	Critical	Important	Not Important
Leadership skills	22	4	0
Team work	23	3	0
Negotiation skills	24	2	0
Conflict management	23	3	0
Interpersonal skills	15	11	0
Computing skills	12	14	0
Presentation skills	24	2	0
Communication skills	18	8	0

4.1.7 Quality Assurance (QA) personnel (Table 21, 22 and Figure 14)

Significant findings for this role were-

Knowledge Modules: Comparison of the grade wise total of all topics within modules, shows that-

- General, Regulations and Execution modules were rated 'critical' by 50% or more respondents
- Ethics, Methodology and Data Management & statistics modules were rated 'important' by 50% or more respondents
- In addition, the following sub-topics were rated 'critical' by 50% or more respondents-
    - ICH GCP and national GCP guidelines
    - SOP writing

Figure 14 shows the ratings for the knowledge modules for the role of the QA personnel.

Skills: Grading of importance of skills for QA personnel's role is shown in Table 22.

- Team work, conflict management, interpersonal skills, communication skills and leadership skills were rated 'critical' by 50% or more respondents

The role of the QA person or auditor as he is often referred to as critical to ensuring quality data is generated while complying with all applicable ethical and regulatory guidelines and protocol specific requirements. He provides an independent assessment of trial activities with the purpose of prevention, detection and correction of errors, deviations or violations in a clinical trial. He is the vital link between monitoring activities and regulatory inspections. The QA personnel are also custodians of the company policies, Standard Operating Procedures (SOPs) and working practices that ensure adherence to all applicable guidelines and regulations and provide standard templates and checklists where applicable to simplify procedures and add clarity.

The knowledge required of an auditor [71] are those of a good clinical research professional and include medical or para medical background, clinical research methodology and management, GCP and regulatory guidelines, SOPs and protocol knowledge, therapy area and quality policies.. Skill sets include excellent communication and interpersonal skills, eye for detail, positive attitude, diplomacy and confidence. Given the diversity of functions in clinical research, it is not always possible for an auditor to have experience in all the functions or know them in details. Here training plays an even greater role in bringing the auditor up to speed.

On expected lines, we found that all the subtopic of *Audits and Inspection* was rated 'critical' by the 27 of 31 of respondents. The sub-topic of *ICH GCP and national GCP guidelines*, all the sub topics in the regulations module, and *SOP writing* were also rated 'critical' by highest number of respondents endorsing the role requirement to be up to date with regulations and guidelines. Most of the other sub topics, in the methodology module were rated 'important' by highest number of respondents. The sub topic of *Designing case report forms and EDCs* is one that is not related to the job profile of an auditor and highest number of stakeholders rated this as 'not important'. It was surprising to find that the sub topic of *Monitoring a clinical study* was rated 'critical' by highest number of respondents.

Team work, interpersonal skills and conflict management skills were rated by highest number of respondents as 'critical' because the auditors have to elicit cooperation from other team members and have their complete cooperation in many audit related decisions.

Table 21. Knowledge areas for the role of QA Personnel (n=31)

Areas of Knowledge (n=31)		Critical	Important	Not Important
General	Scope of Clinical Research	15	15	1
	Orientation to Pharmaceutical Industry	16	15	0
	Drug development process	18	13	0
	Gradewise total of 3 topics in general module	49	43	1
Ethics Module	Biomedical ethics- History and principles	14	17	0
	ICH GCP and national GCP guidelines	18	13	0
	EC composition and function- ICMR and ICH guidelines	12	19	0
	Informed consent process- principles and practice	12	19	0
	Gradewise total of 4 topics in regulatory module	56	68	0
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	19	12	0
	Regulations relating to IP labelling and import	18	13	0
	Regulations regarding safety and pharmacovigilance	18	13	0
	Gradewise total of 3 topics in regulatory module	55	38	0
Methodology module	Framing a research proposal/protocol and experimental design	8	18	5
	Writing investigators brochure	6	19	6
	Designing case report forms and EDCs	4	9	18
	Writing informed consent and Patient information sheet	10	19	2
	Writing study reports and publication	13	18	0
	SOP writing	19	12	0
	Conducting PK studies	3	19	9
	Gradewise total of 7 topics in methodology module	63	114	40
DM and Stats	Types of data and statistical tests for clinical trials	8	19	4
	Statistical considerations at the design, execution and analysis	12	15	4
	Data Coding and cleaning	8	14	9
	Software considerations in Data Management	8	14	9
	Gradewise total of 4 topics in DM& stats module	36	62	26
Clinical Trial execution	Monitoring a clinical study	18	13	0
	Project Management in clinical research	8	19	4
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	14	17	0
	Audits and inspection	27	4	0
	Clinical trial supplies management	15	16	0
	Pharmacovigilance and safety management	16	15	0
	Gradewise total of 6 topics in clinical Trial execution module	98	84	4

Figure 14. Knowledge areas for the role of QA Personnel (n=31)

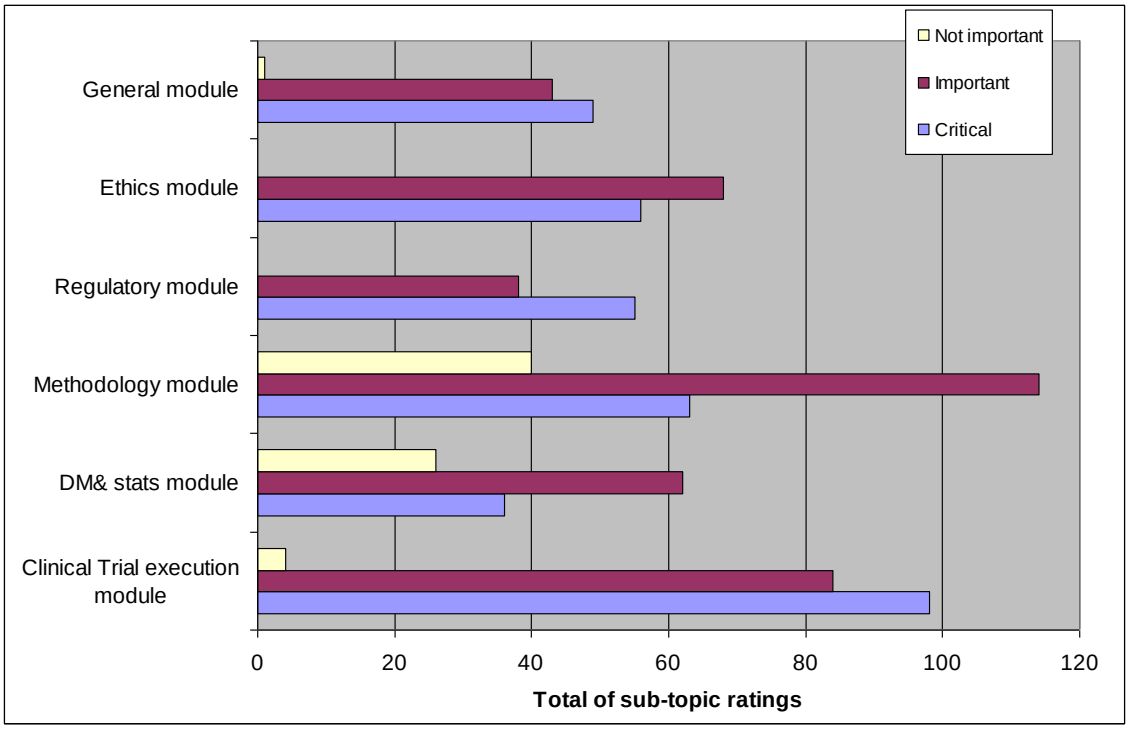


Table 22. Skills for the role of QA personnel (n=26)

Skills	Rating		
	Critical	Important	Not Important
Leadership skills	17	9	0
Team work	23	3	0
Negotiation skills	8	15	3
Conflict management	21	5	0
Interpersonal skills	23	3	0
Computing skills	11	15	0
Presentation skills	12	14	0
Communication skills	18	8	0

4.1.8 Statistician (Table 23, 24 and Figure 15)

Significant findings for this role were-

Knowledge Modules: Comparison of the grade wise total of all topics within modules, shows that-

- Data management module rated 'critical' by 50% or more respondents.
- General, Regulations, and Clinical Trial Execution modules were rated 'important' by 50% or more number of respondents.
- In addition, the following sub-topics were rated 'critical' by 50% or more respondents
    - ICH GCP and national GCP guidelines
    - Regulations affecting CT for new product /generic registration in India including Schedule Y
    - Framing a research proposal/protocol and experimental design

Figure 15 shows the grade wise total of ratings for the sub-topics in the 6 knowledge modules for the role of the Statistician.

Skills: Grading of importance of skills for Statistician's role is shown in Table 24.

- Interpersonal, presentation, communication and computing skills was rated 'critical' by 50% or more respondents.

A statistician's input is required at the design, execution and analysis stage of the clinical trial. He is part of the team that decides on the number of patients to be studied, the design of the study, the statistical test to be applied based on the power of the study and the statistical analysis plan implementation. He is also involved in the interpretation of the data and its clinical relevance. For this role, besides a sound understanding of statistics and its application to clinical trials, the statistician has to have a good understanding of the clinical trial process, the guidelines and regulations governing it.

The data management and statistics module was the only module rated 'critical' by highest number of respondents. On expected lines, all the stakeholders rated the sub

topic of Statistical considerations at design, execution and analysis as ‘critical’ for this role. Types of data and statistical tests for clinical trials were rated ‘critical’ by highest number of respondents. *Software considerations in data management* was rated by almost equal numbers as ‘critical’ and ‘important’. *Data coding and cleaning* was the only sub-topic in the data management and statistics module that was rated ‘not important’ by highest number of respondents as this activity is not related to the role of a statistician. A statistician’s inputs are taken in *Framing a research proposal/protocol and experimental design* and this is the only sub topic in the methodology module that most stakeholders rated as ‘critical’.

It is common experience that statisticians are generally unaware of jobs in clinical research and in this context it was surprising that the general module was not rated ‘critical’, but ‘important’ by highest number of respondents.

Statisticians have to adept at writing the draft study reports and making presentations on the data to the rest of the study team. Hence it is not surprising to find communication and presentation skills being rated critical for this role.

Table 23. Knowledge areas for the role of Statistician (n=31)

Areas of Knowledge (n=31)		Critical	Important	Not Important
General	Scope of Clinical Research	16	15	0
	Orientation to Pharmaceutical Industry	7	22	2
	Drug development process	21	10	0
	Gradewise total of 3 topics in general module	44	47	2
Ethics Module	Biomedical ethics- History and principles	7	13	11
	ICH GCP and national GCP guidelines	16	15	0
	EC composition and function- ICMR and ICH guidelines	7	13	11
	Informed consent process- principles and practice	6	12	13
	Gradewise total of 4 topics in regulatory module	36	53	35
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	16	15	0
	Regulations relating to IP labelling and import	7	15	9
	Regulations regarding safety and pharmacovigilance	9	17	5
	Gradewise total of 3 topics in regulatory module	32	47	14
Methodology module	Framing a research proposal/protocol and experimental design	18	11	2
	Writing investigators brochure	12	15	4
	Designing case report forms and EDCs	12	15	4
	Writing informed consent and Patient information sheet	9	19	3
	Writing study reports and publication	11	19	1
	SOP writing	7	10	14
	Conducting PK studies	9	12	10
	Gradewise total of 7 topics in methodology module	78	101	38
DM and Stats	Types of data and statistical tests for clinical trials	27	4	0
	Statistical considerations at the design, execution and analysis	31	0	0
	Data Coding and cleaning	0	6	25
	Software considerations in Data Management	16	15	0
	Gradewise total of 4 topics in DM& stats module	74	25	25
Clinical Trial execution	Monitoring a clinical study	1	20	10
	Project Management in clinical research	2	20	9
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	3	20	8
	Audits and inspection	13	18	0
	Clinical trial supplies management	0	9	22
	Pharmacovigilance and safety management	7	12	12
	Gradewise total of 6 topics in clinical Trial execution module	26	99	61

Figure 15. Knowledge areas for the role of Statistician (n=31)

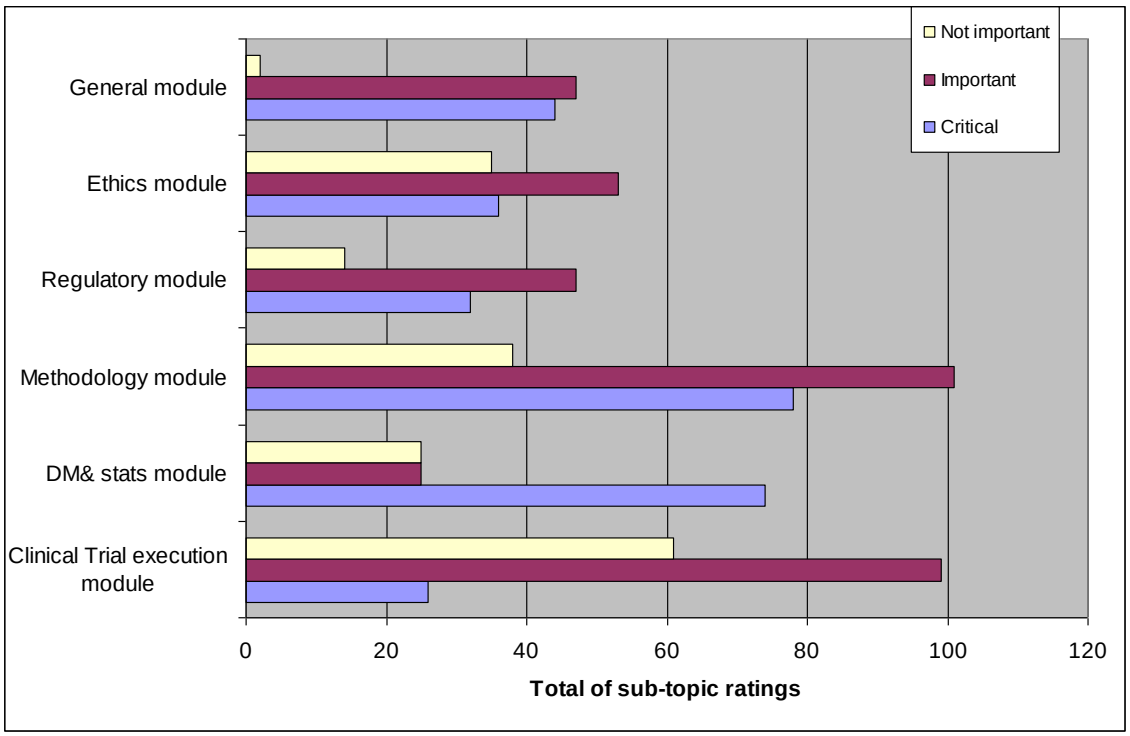


Table 24. Skills for the role of Statisticians (n=26)

Skills	Rating		
	Critical	Important	Not Important
Leadership skills	7	7	12
Team work	12	14	0
Negotiation skills	15	11	0
Conflict management	8	7	11
Interpersonal skills	18	8	0
Computing skills	25	1	0
Presentation skills	17	9	0
Communication skills	16	10	0

4.1.9 Ethics Committee (EC) member (Table 25, 26 and Figure 16)

Significant findings for this role were-

Knowledge Modules: Comparison of the grade wise total of all topics within modules, shows that-

- Ethics modules received 'critical' ratings from 50% or more respondents
- Execution module was rated 'important' by 50% or more respondents
- In addition, the following sub topics were rated 'critical' by 50% or more respondents-
  - Scope of clinical research
  - Drug development process
  - Regulations affecting CT for new product/generic registration in Indian including Schedule Y
  - Writing study reports and publications
  - SOP writing
  - Legal issues in clinical research
  - Audits and inspections

Figure 16 shows the grade wise total of ratings for the sub-topics in the 6 knowledge modules for the role of the EC member.

Skills: Grading of importance of skills for EC member's role is shown in Table 26.

- Team work was rated 'critical' by 50% or more respondents.

The ethics committee is a diverse group of people with the common objective of ensuring that the rights and safety of the patients is protected while data of the highest quality is generated. They have a critical role in safeguarding the rights, safety, and well-being of all trial subjects, especially in trials that may include vulnerable subjects. The composition and function of ethics committees and their responsibilities, procedures and records to be maintained are very clearly delineated in the ICG GCP guidelines.

A sound understanding of ethical aspects and regulatory requirements, besides a reasonable grasp of scientific content is mandatory for the role. As custodians of patient

rights and safety, they will also have to ensure provisions for indemnity, compensation and insurance. Considering the special situation of clinical research being a new field in India, the revised Schedule Y of Drugs and Cosmetic Rules devotes significant attention to the roles and responsibilities of ECs, prescribes the composition of ECs as per the ICMR guidelines and even provides formats for the EC approval letters. The diverse nature of the group is the biggest challenge for training.

It was on expected lines that all the sub topics in the Ethics module was rated 'critical' by highest number of respondents for this role. Also understandable was that 2 sub topics in the clinical trial execution module- Legal issues in clinical research and Audits and inspections were rated 'critical' by highest number of respondents. The sub-topic of *Regulations affecting clinical trials for new product/generic registration in India including Schedule Y* are areas that EC members should be aware of and these were rated 'critical' by highest number of respondents. The Data Management and statistics module and methodology module being rated 'not important' by highest number of respondents was also not surprising as ethics committee members are not involved in the designing or methodology of the clinical trials or the data management aspects. It was surprising that highest number of respondents rated *SOP writing* and *Writing study reports* and publications as 'critical' because ethics committee members are not expected to write SOPs or study reports. Also surprising was that the critical areas of *Regulations regarding safety and pharmacovigilance* was not rated 'critical' by 50% and more respondents.

The Ethics committee functions only as a team and it was expected to see team work being rated 'critical' by highest number of respondents. Given the kind of issues they will need to debate and arrive at a decision, we would have expected 'conflict management and interpersonal skills as critical skills. However, stakeholders have rated both these skills and communication skills as critical and important, almost equally.

Table 25. Knowledge areas for the role of Ethics Committee members (n=31)

Areas of Knowledge		Critical	Important	Not Important
General Module	Scope of Clinical Research	17	14	0
	Orientation to Pharmaceutical Industry	10	16	5
	Drug development process	18	13	0
	Gradewise total of 3 topics in general module	45	43	5
Ethics Module	Biomedical ethics- History and principles	26	5	0
	ICH GCP and national GCP guidelines	22	9	0
	EC composition and function- ICMR and ICH guidelines	29	2	0
	Informed consent process- principles and practice	28	3	0
	Gradewise total of 4 topics in regulatory module	105	19	0
Regulations module	Regulations affecting CT for new product/generic registration in India including Schedule Y	17	14	0
	Regulations relating to IP labelling and import	4	19	8
	Regulations regarding safety and pharmacovigilance	13	11	7
	Gradewise total of 3 topics in regulatory module	34	44	15
Methodology module	Framing a research proposal/protocol and experimental design	3	8	20
	Writing investigators brochure	0	12	19
	Designing case report forms and EDCs	0	7	24
	Writing informed consent and Patient information sheet	0	2	29
	Writing study reports and publication	29	2	0
	SOP writing	27	4	0
	Conducting PK studies	3	16	12
	Gradewise total of 7 topics in methodology module	62	51	104
DM and Stats module	Types of data and statistical tests for clinical trials	2	9	20
	Statistical considerations at the design, execution and analysis	0	2	29
	Data Coding and cleaning	0	2	29
	Software considerations in Data Management	1	2	28
	Gradewise total of 4 topics in DM& stats module	3	15	106
Clinical Trial execution	Monitoring a clinical study	11	20	0
	Project Management in clinical research	1	19	11
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	19	10	2
	Audits and inspection	18	13	0
	Clinical trial supplies management	12	18	1
	Pharmacovigilance and safety management	13	17	1
	Gradewise total of 6 topics in clinical Trial execution module	74	97	15

Figure 16. Knowledge areas for the role of Ethics Committee member (n=31)

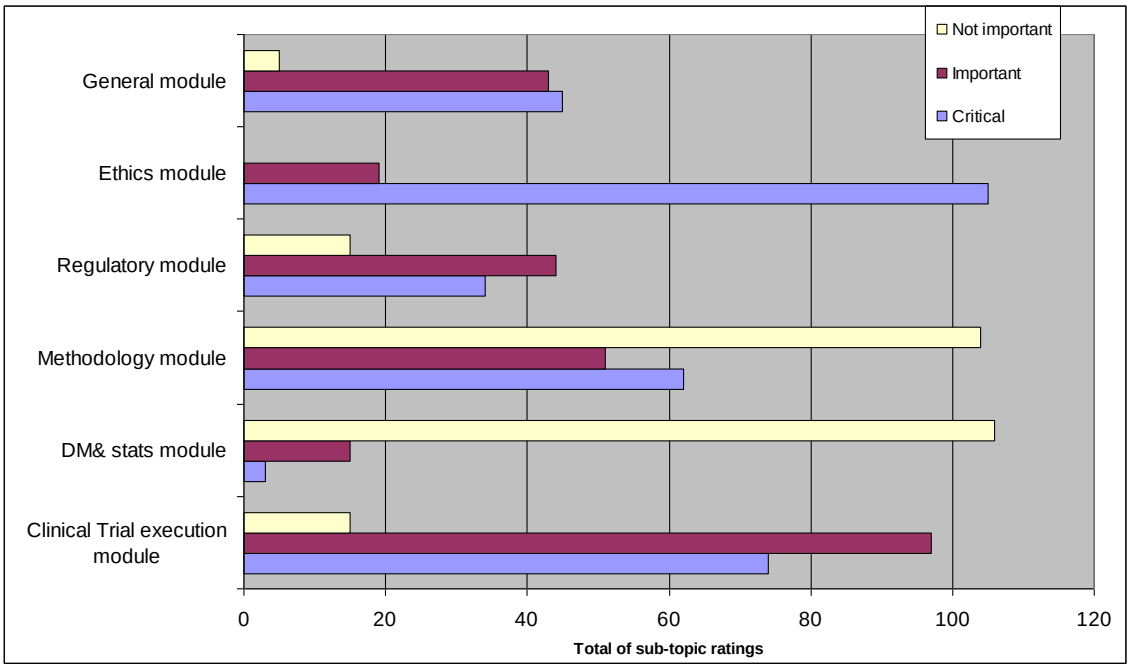


Table 26. Skills for the role of Ethics Committee members (n=26)

Skills (n=26)	Rating		
	Critical	Important	Not Important
Leadership skills	7	9	10
Team work	20	6	0
Negotiation skills	8	10	8
Conflict management	12	14	0
Interpersonal skills	13	13	0
Computing skills	6	16	4
Presentation skills	8	14	4
Communication skills	12	12	2

4.1.10. Data Management (DM) personnel (Table 27, 28 and Figure 17)

Significant findings for this role were-

Knowledge Modules: Comparison of the grade wise total of all topics within modules, shows that-

- DM and statistics module and clinical trial execution modules were rated 'critical' by 50% or more respondents
- The ethics, regulations and methodology modules were rated 'important' by 50% or more respondents.

Figure 17 shows the ratings for the knowledge modules for the role of the DM personnel.

Skills: Grading of importance of skills for DM personnel's role is shown in Table 28.

- Team work, Computing skills, presentation and communication skills were rated 'critical' by 50% or more respondents.

Data management is a vast discipline that embraces a variety of roles including data entry, data validation, database designers, medical coders, SAS- programmers, statisticians and medical writers. Each of these is a specialised activity requiring many specialised skills and knowledge [72]. Data entry person enters patient data from the case report forms and lab reports into the specially created database.

- Data base designers are adept at programming and creating databases into which patient data generated in clinical studies in fed into.
- Data validation person verifies the completeness and accuracy of the data.
- Medical coders apply medical dictionaries to report a common term for drugs and medical conditions.
- SAS-programmers write the program codes for classifying and analysing data.
- The medical writer along with a multifunctional team interprets the data and statistical tables and writes out the clinical study report as per the guidelines. This report is part of the compilation for regulatory submission.

On expected lines, three of the four sub-topics in the Data management and statistics module were rated ‘critical’ by highest number of respondents. *Statistical considerations at design, execution and analysis* was rated ‘important’ by highest number of respondents. *Audits and Inspections* was also rated ‘critical’ by highest number of respondents.

Considering that data management as a clinical trial process is newer than study conduct in India, it was not surprising to find highest number of stakeholders rating *SOP writing* as ‘critical’. However, with the same consideration, it was surprising to find that the general and regulations module was rated ‘important’ and not ‘critical’ by the highest number of respondents. It was surprising to note that both the sub topics relating to safety and pharmacovigilance in the regulations module and execution module were rated ‘critical’ by highest number of respondents. This could indicate a stakeholder focus on adverse event and safety data management.

Also surprising was that Types of data and statistical test for clinical trials was rated ‘critical’ by as many as 27 of the 31 respondents. Data management personnel are generally not involved with statistical considerations and this finding was unexpected.

Data management is done using advanced technical software and computing skills, followed by team work, presentation and communication skills were rated ‘critical’ by highest number of respondents.

Table 27. Knowledge areas for the role of Data Management personnel (n=31)

Areas of Knowledge (n=31)		Critical	Important	Not Important
General Module	Scope of Clinical Research	7	12	12
	Orientation to Pharmaceutical Industry	10	12	9
	Drug development process	13	12	6
	Gradewise total of 3 topics in general module	30	36	27
Ethics Module	Biomedical ethics- History and principles	12	11	8
	ICH GCP and national GCP guidelines	15	16	0
	EC composition and function- ICMR and ICH guidelines	9	19	3
	Informed consent process- principles and practice	9	21	1
	Gradewise total of 4 topics in regulatory module	45	67	12
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	8	23	0
	Regulations relating to IP labelling and import	1	29	1
	Regulations regarding safety and pharmacovigilance	23	8	0
	Gradewise total of 3 topics in regulatory module	32	60	1
Methodology module	Framing a research proposal/protocol and experimental design	2	27	2
	Writing investigators brochure	3	27	1
	Designing case report forms and EDCs	9	22	0
	Writing informed consent and Patient information sheet	4	15	12
	Writing study reports and publication	11	18	2
	SOP writing	22	9	0
	Conducting PK studies	2	19	10
	Gradewise total of 7 topics in methodology module	53	137	27
DM and Stats	Types of data and statistical tests for clinical trials	27	4	0
	Statistical considerations at the design, execution and analysis	12	19	0
	Data Coding and cleaning	22	9	0
	Software considerations in Data Management	29	2	0
	Gradewise total of 4 topics in DM& stats module	90	34	0
Clinical Trial execution	Monitoring a clinical study	15	16	0
	Project Management in clinical research	12	17	0
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	11	20	0
	Audits and inspection	23	8	0
	Clinical trial supplies management	19	12	0
	Pharmacovigilance and safety management	22	9	0
	Gradewise total of 6 topics in clinical Trial execution module	102	82	0

Figure 17. Knowledge areas for the role of Data Manager (n=31)

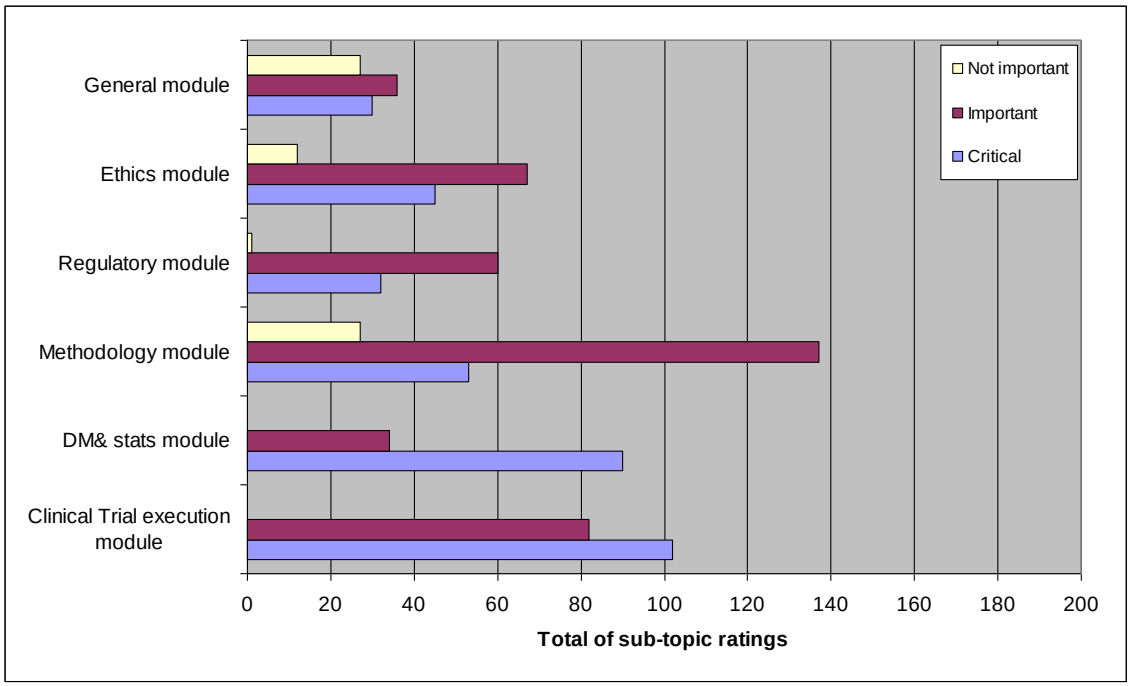


Table 28. Skills for the role of Data Management personnel (n=26)

Skills	Rating		
	Critical	Important	Not Important
Leadership skills	9	8	9
Team work	21	5	0
Negotiation skills	15	9	2
Conflict management	13	13	0
Interpersonal skills	12	14	0
Computing skills	25	1	0
Presentation skills	20	6	0
Communication skills	19	7	0

4.1.11 Statistical Analysis of results of Objective 1:

The grading given by the respondents for each of the areas of knowledge and skills was tabulated into a frequency distribution for all the roles. Kruskal Wallis test was applied to evaluate if the responders demonstrate different expectations of knowledge and skills for the different roles and if this difference was statistically significant.

Kruskal Wallis test

Kruskal Wallis test was applied separately on the knowledge items and the skills items. All the responses (data points) across all roles for an item of knowledge (or skill) were ranked: the smallest value got a rank of 1, the next smallest got a rank of 2, and so on. Tied observations got average ranks. The sum of the ranks was calculated for each group, then the test statistic, H, was calculated (Tables 29, 30).

The formula for H is as below

$$H = \frac{12}{n(n+1)} \sum_{i=1}^{k} \frac{R_i^2}{n_i} - 3(n+1)$$

Where,

n_i (i = 1, 2, ..., k) represent the sample sizes for each of the k groups (i.e., samples) in the data.
R_i = the sum of the ranks for group i.
H represents the variance of the ranks among groups, with an adjustment for the number of ties. It is approximately chi-square distributed, meaning that the probability of getting a particular value of H by chance, if the null hypothesis is true, is the P value corresponding to a chi-square equal to H; the degrees of freedom is the number of groups (k) minus 1.

Table 29: Kruskal Wallis test: Knowledge

Topic	n	k	H corrected for ties	Df	p value
Scope of CR	310	10	34.65	9	p <0.05
Orientation to Pharma Industry	310	10	28.52	9	p <0.05
Drug development process	310	10	18.64	9	p <0.05
Biomedical ethics- History and principles	309	10	40.86	9	p <0.05
ICH GCP and national GCP guidelines	310	10	11.27	9	NS
EC composition and function- ICMR and ICH guidelines	310	10	54.22	9	p <0.05
Informed consent process- principles and practice	310	10	60.62	9	p<0.05
Regulations affecting CT for new product/generic registration in India including Schedule Y	310	10	53.51	9	p<0.05
Regulations relating to IP labelling and import	310	10	60.36	9	p<0.05
Regulations regarding safety and Pharmacovigilance	310	10	35.66	9	p<0.05
Framing a research proposal/protocol and experimental design	310	10	75.89	9	p<0.05
Writing investigators brochure	309	10	93.61	9	p<0.05
Designing case report forms and EDCs	310	10	89.1	9	p<0.05
Writing informed consent and Patient information sheet	310	10	79.84	9	p<0.05
Writing study reports and publication	310	10	66.41	9	p<0.05
SOP writing	310	10	75.04	9	p<0.05
Conducting PK studies	308	10	53.16	9	p<0.05
Types of data and statistical tests for clinical trials	310	10	122.72	9	p<0.05
Statistical considerations at the design, execution and analysis	310	10	153.91	9	p<0.05
Data Coding and cleaning	310	10	117.27	9	p<0.05
Software considerations in Data Management	310	10	151.45	9	p<0.05
Monitoring a clinical study	309	10	60.78	9	p< 0.05
Project Management in clinical research	308	10	59.85	9	p<0.05
Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	310	10	46.14	9	p<0.05
Audits and inspection	310	10	21.41	9	NS
Clinical trial supplies management	310	10	89.72	9	p<0.05
Pharmacovigilance and safety management	310	10	37.6	9	p<0.05

A significant H value shows that responders clearly demonstrated differences in the importance of the various areas of knowledge for different roles. The two sub-topics for which responders rated the training needs for all the 10 roles equally were *ICH GCP and GCP guidelines* and *Audits and Inspection*.

Table 30. Kruskal Wallis test: Skills

Topic	n	k	H corrected for ties	Df	p value
Leadership skills	260	10	55.87	9	p <0.001
Team work	260	10	125.02	9	p <0.001
Negotiation skills	260	10	119.95	9	p <0.001
Conflict management	260	10	88.82	9	p <0.001
Interpersonal skills	260	10	32.24	9	p <0.001
Computing skills	260	10	67.85	9	p <0.001
Presentation skills	260	10	40.51	9	p <0.001
Communication skills	260	10	20.59	9	p <0.01

A significant H value shows that responders clearly demonstrated differences in the importance of the various skills for different roles. Stakeholders' responses show that for the various roles in clinical research, skills required were different.

4.1.12 Discussion of results of Objective 1

The results of our survey, as discussed were largely on expected lines and based on the performance expectations of the role in consideration. The following matrix of relative importance of modules to the various roles can be collated from the grading of importance by 50% or more respondents.

Table 31. Knowledge modules by significance to the role

Legend: **C**: Critical, **I**- Important, **N**- Not important

A blank indicates no clear trend

Roles/Modules	General	Ethics	Regulatory	Methodology	DM & Stats	CT execution
Investigator	I	-	I	-	-	I
Site Coordinator	I	I	I	-	-	I
CRA	C	C	I	-	-	C
Project Manager	I	-	I	I	-	I
Regulatory Manager	I	I	C	-	N	I
Project Physician	C	I	I	-	-	C
Q A personnel	C	I	C	I	I	C
Statistician	I	-	I	-	C	I
E C members	C	C	-	-	N	I
D M personnel	-	I	I	I	C	C

Clear trends as shown by a rating of 50% or more respondents emerge as above. Difference between roles was also endorsed by a significant H value in the Kruskal Wallis test.

In some instance we found constituent sub topics being rated differently than when the entire module was taken as a whole. The classification of knowledge sub topics according to grading of importance by 50% or more respondents is as shown in Table 32 below-

Table 32. Knowledge sub topics critical to the role

S. No	Role	Sub-topics rated 'Critical'
1.	Investigator	• EC composition and function – ICMR and ICH guidelines • Informed consent process- principles and practice • Audits and Inspection
2.	Site coordinator	• EC composition and function – ICMR and ICH guidelines • Informed consent process- principles and practice • Writing informed consent and patent information sheet • Audits and Inspection • Clinical Trial supplies management
3.	CRA	• Orientation to pharmaceutical industry • Drug development process • ICH GCP and national GCP guidelines • EC composition and function – ICMR and ICH guidelines • Informed consent process- principles and practice • Monitoring a clinical study • Project management in clinical research • Legal issues in clinical research • Audits and inspections • Clinical Trial supplies management • Pharmacovigilance and safety management
4.	Project manager	• Drug development process • EC composition and function – ICMR and ICH guidelines • Audits and inspection • Clinical trial supplies management
5.	Regulatory Manager	• Regulations affecting clinical trials for new product/generic registration in India including Schedule Y • Regulations relating to IP labelling and import • Regulations regarding safety and pharmacovigilance • Legal issues in clinical research • Audits and inspection • Pharmacovigilance and safety management
6.	Project Physician	• Scope of clinical research • Orientation to pharmaceutical industry • Drug development process • ICH GCP and national guidelines • EC composition and function – ICMR and ICH guidelines • Regulations affecting clinical trials for new product/generic registration in India including Schedule Y • Framing a research proposal/protocol and experimental design • Writing informed consent and patient information sheet • Writing study reports and publications • Statistical considerations at the design, execution and analysis

		• Legal issues in clinical research • Audits and inspection • Pharmacovigilance and safety management
7.	Quality assurance personnel	• Orientation to pharmaceutical industry • Drug development process • ICH GCP and national guidelines • Regulations affecting clinical trials for new product/generic registration in India including Schedule Y • Regulations relating to IP labelling and import • Regulations regarding safety and pharmacovigilance • SOP writing • Monitoring a clinical study • Audits and inspection • Pharmacovigilance and safety management
8.	Statistician	• Scope of clinical research • Drug development process • ICH GCP and national guidelines • Regulations affecting clinical trials for new product/generic registration in India including Schedule Y • Framing a research proposal/protocol and experimental design • Types of data and statistical test for clinical trials • Statistical considerations at the design, execution and analysis • Software considerations in data management
9.	EC member	• Scope of clinical research • Drug development process • Biomedical ethics-history and principles • ICH GCP and national GCP guidelines • EC composition and function – ICMR and ICH guidelines • Informed consent process- principles and practice • Regulations affecting clinical trials for new product/generic registration in India including Schedule Y • Writing study reports and publications • SOP writing • Legal issues in clinical research • Audits and inspection
10.	Data Management personnel	• Regulations regarding safety and pharmacovigilance • SOP writing • Types of data and statistical test for clinical trials • Data coding and cleaning • Software considerations in data management • Audits and inspection • Clinical trial supplies management • Pharmacovigilance and safety management

This is an important finding to understand that respondents have differentiated the needs of the roles at the level of individual knowledge items because at the module level which may not have enough granularity for rating of importance of the sub-topics within. Such differentiation is essential to consider when tailoring advanced level courses to specific needs or designing just in time training that have all the minimum essentials to meet immediate requirements.

Similarly, a matrix of relative importance of skills for the various roles can also be collated from the highest grading response as follows-

Table 33. Skills by significance to the role

Roles/Skills	Leadership	Teamwork	Negotiation	Conflict Mgt	Interpersonal skills	Computing	Presentation	Communications
Investigator	C	C	C	C	C	C	C	C
Site Coordinator	-	C	C	c	C	C	C	C
CRA	-	C	C	C	C	C	C	C
Project Manager	C	C	C	C	-	-	C	C
Regulatory Manger	I	I	I	I	C	C	C	C
Project Physician	C	C	C	C	C	I	C	C
Q A personnel	C	C	I	C	C	I	I	C
Statistician	-	I	C	-	C	C	C	C
E C members	-	C	-	I	C=I	I	I	-
D M personnel	-	C	C	C=I	I	C	C	C

Communication skills have been rated critical across all roles, except EC member role, followed by interpersonal skills and team work. This is not difficult to guess considering the diverse teams that work together to produce results. No clear trends emerge for leadership skills for site coordinator, CRA, Statistician, EC member and DM personnel role, leaving us wondering if leadership skills were understood as important from a leading perspective or only from a management hierarchy perspective.

The results of our survey revealed trends that were generally expected. Taking a cut for significance as a response by 50% or more respondents helped us to objectively identify trends. However, the number of respondents was small and in instances, differences between critical and important were really small. Besides, there were a few instances of surprising trends that we could not explain with our understanding of the roles. We therefore thought it would be advantageous to do a larger survey on role holders that would also include aspects of training received and needed in the areas of knowledge and skills.

CHAPTER 4: RESULTS AND DISCUSSIONS

4.2 Results of Objective 2

The total of 306 responses was received. However, 52 responses were incomplete in the demography data and another 73 responses were incomplete in most of the training needs data and hence 125 responses were considered in evaluable. The analysis included 181 responses.

4.2.1 All respondents:

4.2.1.1 Demography

Table 34 shows the demographic details of the total group. It included 98 males (54%) and 83 females (46%) with an average age of 28.3 years.

Their educational qualifications were- Graduates -66%, post-graduate-25% and Doctorates -9%.

Of the respondents who were employed (96%), 28% worked in a CRO of Indian origin, 22% in an MNC Pharma company and 16% in a MNC CRO. Majority (85%) worked in clinical research functions

43% of them had one year or less clinical research experience. Only 11% had more than 5 years experience in clinical research.

30% felt that the education prepared them very well for their current job, 41% rated this as adequately.

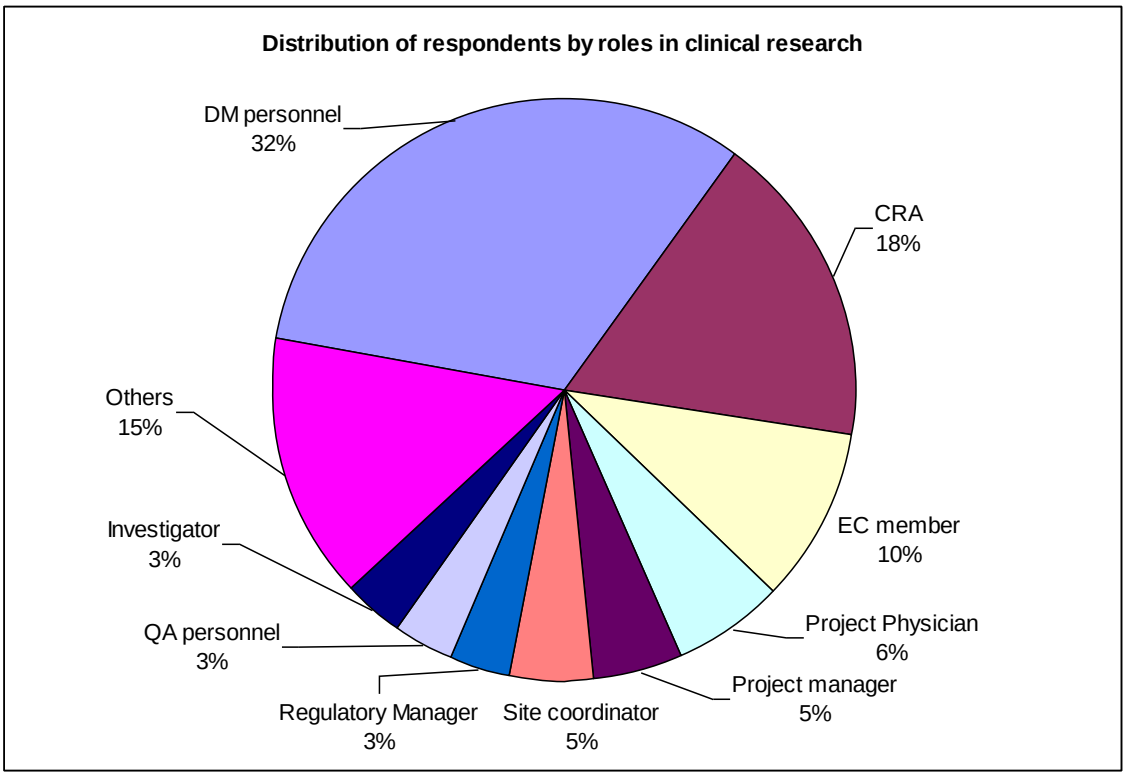
51% of the respondents felt that their employment experience as preparing them very well for the current role.

Table 33. Demography- Total Group (n=181)

1	**Sex**	**n**	**%**
	• Males	98	54
	• Females	83	46
	Average Age	28.3 yrs	
2	**Qualification**	**n**	**%**
	• Graduation	119	66
	• Post graduation	45	25
	• Doctorate	17	9
3	**Employment status**	**n**	**%**
	• Employed	173	96
	○ In CR	154	85
	○ Other	19	11
	• Unemployed	8	4
4	**Type of organisation**	**n**	%
	• CRO- Indian	50	28
	• MNC Pharma	40	22
	• MNC CRO	29	16
	• Hospital	22	12
	• Indian Pharma	18	10
	• Others	11	6
	• SMO	6	3
	• NA	5	3
5	**Clinical Research Experience**	**n**	**%**
	• One year or less	78	43
	• 1-3 years	68	38
	• 3-5 years	13	7
	• More than 5 years	20	11
	• NA	2	1
6	**Education preparing for current job**	**n**	%
	• Very well	54	30
	• Adequately	74	41
	• Poorly	30	17
	• Education unrelated	23	13
7.	**Employment experience preparing for current job**	**n**	%
	• Very well	93	51
	• Adequately	64	35
	• Poorly	13	7
	• Employment unrelated	11	6
8.	**Role in CR**	**n**	**%**
	• DM personnel	57	32
	• CRA	31	17
	• EC member	17	10
	• Project Physician	11	6
	• Project manager	9	5
	• Site coordinator	8	4
	• Regulatory Manager	6	3
	• QA personnel	6	3
	• Investigator	6	3
	• Others	26	14
	• NA	4	2

Distribution of respondents by role is as shown below.

Figure 18. Distribution of respondents by roles in clinical research



The largest group was of 57 data management personnel (32%), which included statisticians, database designers, coding analysts and data acquisition.

Table 35. Job titles of respondents classified as Others

Research Specialist	6
Consultant	3
Business Development	3
Document specialist	3
Research Fellow	2
Phlebotomist	2
Medical monitor	2
Pharmacovigilance	2
Team Lead,- bio analytical	1
Head, bio analytical	1
Student	1

The response of the ‘Others' group have been included in the analysis of the whole sample. However, as this group is diverse, their responses as a sub-group have not been analysed.

4.2.1.2 Knowledge Areas: (Tables 36, 37, 38 and 39)

A. Grading of importance (Table 36).

Knowledge Modules: Comparison of the grade wise total of all responses for each module shows that

- 50% or more respondents rated the General, Ethics, Regulatory and execution modules as 'critical'.
- In addition, the following sub-topics of SOP writing was rated as 'critical' by 50% or more respondents

.**No response** ranged between 5% and 9.9%.

B. Training received (Table 37).

- Majority of respondents were not trained. A significant number (A 50% or greater response) were trained in the all the sub –topics of the Ethics module. Most of these were trained on the job.
- Significant numbers of respondents were not trained in the sub-topics of *Conducting PK studies, Data coding and cleaning* and *Software considerations in data management.*

No response ranged between 24.9% and 37%

Table 36. Importance of knowledge areas (n=181)

Areas of Knowledge		Rating						No Response	
		Critical		Important		Not Important			
		n	%	n	%	n	%	n	%
General	Scope of Clinical Research	116	64.1	52	28.7	4	2.2	9	5.0
	Orientation to Pharmaceutical Industry	97	53.6	67	37.0	4	2.2	13	7.2
	Drug development process	118	65.2	42	23.2	9	5.0	12	6.6
	Total of topics in General Module	**331**	**61.0**	**161**	**29.7**	**17**	**3.1**	**34**	**6.3**
Ethics	Biomedical ethics- History and principles	119	65.7	50	27.6	2	1.1	10	5.5
	ICH GCP and national GCP guidelines	118	65.2	51	28.2	0	0.0	12	6.6
	EC composition and function- ICMR and ICH guidelines	127	70.2	41	22.7	0	0.0	13	7.2
	Informed consent process- principles and practice	119	65.7	49	27.1	0	0.0	13	7.2
	Total of topics in Ethics Module	**483**	**66.7**	**191**	**26.4**	**2**	**0.3**	**48**	**6.6**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	110	60.8	58	32.0	1	0.6	12	6.6
	Regulations relating to IP labelling and import	114	63.0	49	27.1	8	4.4	10	5.5
	Regulations regarding safety and pharmacovigilance	107	59.1	56	30.9	4	2.2	14	7.7
	Total of topics in Regulations Module	**331**	**61.0**	**163**	**30.0**	**13**	**2.4**	**36**	**6.6**
Methodology	Framing a research proposal/protocol and experimental design	87	48.1	63	34.8	19	10.5	12	6.6
	Writing investigators brochure	84	46.4	63	34.8	19	10.5	15	8.3
	Designing case report forms and EDCs	81	44.8	64	35.4	22	12.2	14	7.7
	Writing informed consent and Patient information sheet	89	49.2	57	31.5	18	9.9	17	9.4
	Writing study reports and publication	90	49.7	62	34.3	18	9.9	11	6.1
	SOP writing	94	51.9	59	32.6	19	10.5	9	5.0
	Conducting PK studies	59	32.6	57	31.5	47	26.0	18	9.9
	Total of topics in Methodology Module	**584**	**46.1**	**425**	**33.5**	**162**	**12.8**	**96**	**7.6**
DM and Stats	Types of data and statistical tests for clinical trials	84	46.4	60	33.1	25	13.8	12	6.6
	Statistical considerations at the design, execution and analysis	84	46.4	55	30.4	30	16.6	12	6.6
	Data Coding and cleaning	75	41.4	60	33.1	29	16.0	17	9.4
	Software considerations in Data Management	77	42.5	61	33.7	28	15.5	15	8.3
	Total of topics in DM & Stats Module	**320**	**44.2**	**236**	**32.6**	**112**	**15.5**	**56**	**7.7**
Clinical Trial execution	Monitoring a clinical study	103	56.9	58	32.0	9	5.0	11	6.1
	Project Management in clinical research	100	55.2	59	32.6	9	5.0	13	7.2
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	102	56.4	60	33.1	10	5.5	9	5.0
	Audits and inspection	113	62.4	53	29.3	4	2.2	11	6.1
	Clinical trial supplies management	108	59.7	56	30.9	6	3.3	11	6.1
	Pharmacovigilance and safety management	111	61.3	51	28.2	7	3.9	12	6.6
	Total of topics in Clinical Trial execution Module	**637**	**58.7**	**337**	**31.0**	**45**	**4.1**	**67**	**6.2**

Table 37. Training in knowledge areas (n=181)

Areas of Knowledge		Training						No Response	
		Not received		At Graduation		On the Job			
		n	%	n	%	n	%	n	%
General	Scope of Clinical Research	65	35.9	2	1.1	62	34.3	52	28.7
	Orientation to Pharmaceutical Industry	69	38.1	4	2.2	66	36.5	42	23.2
	Drug development process	42	23.2	5	2.8	82	45.3	52	28.7
	Total of topics in General Module	**176**	**32.4**	**11**	**2.0**	**210**	**38.7**	**146**	**26.9**
Ethics	Biomedical ethics- History and principles	28	15.5	15	8.3	82	45.3	56	30.9
	ICH GCP and national GCP guidelines	27	14.9	1	0.6	100	55.2	53	29.3
	EC composition and function- ICMR and ICH guidelines	24	13.3	0	0.0	108	59.7	49	27.1
	Informed consent process- principles and practice	28	15.5	1	0.6	101	55.8	51	28.2
	Total of topics in Ethics Module	**107**	**14.8**	**17**	**2.3**	**391**	**54.0**	**209**	**28.9**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	49	27.1	1	0.6	77	42.5	54	29.8
	Regulations relating to IP labelling and import	44	24.3	1	0.6	80	44.2	56	30.9
	Regulations regarding safety and pharmacovigilance	36	19.9	0	0.0	88	48.6	57	31.5
	Total of topics in Regulations Module	**129**	**23.8**	**2**	**0.4**	**245**	**45.1**	**167**	**30.8**
Methodology	Framing a research proposal/protocol and experimental design	72	39.8	2	1.1	59	32.6	48	26.5
	Writing investigators brochure	80	44.2	0	0.0	52	28.7	49	27.1
	Designing case report forms and EDCs	79	43.6	0	0.0	54	29.8	48	26.5
	Writing informed consent and Patient information sheet	64	35.4	0	0.0	67	37.0	50	27.6
	Writing study reports and publication	71	39.2	2	1.1	51	28.2	57	31.5
	SOP writing	72	39.8	0	0.0	57	31.5	52	28.7
	Conducting PK studies	95	52.5	0	0.0	19	10.5	67	37.0
	Total of topics in Methodology Module	**533**	**42.1**	**4**	**0.3**	**359**	**28.3**	**371**	**29.3**
DM and Stats	Types of data and statistical tests for clinical trials	85	47.0	3	1.7	41	22.7	52	28.7
	Statistical considerations at the design, execution and analysis	82	45.3	4	2.2	43	23.8	52	28.7
	Data Coding and cleaning	101	55.8	0	0.0	31	17.1	49	27.1
	Software considerations in Data Management	94	51.9	0	0.0	32	17.7	55	30.4
	Total of topics in DM & Stats Module	**362**	**50.0**	**7**	**1.0**	**147**	**20.3**	**208**	**28.7**
Clinical Trial execution	Monitoring a clinical study	69	38.1	0	0.0	56	30.9	56	30.9
	Project Management in clinical research	75	41.4	0	0.0	45	24.9	61	33.7
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	89	49.2	0	0.0	35	19.3	57	31.5
	Audits and inspection	49	27.1	0	0.0	87	48.1	45	24.9
	Clinical trial supplies management	62	34.3	0	0.0	63	34.8	56	30.9
	Pharmacovigilance and safety management	58	32.0	1	0.6	68	37.6	54	29.8
	Total of topics in Clinical Trial execution Module	**402**	**37.0**	**1**	**0.1**	**354**	**32.6**	**329**	**30.3**

C. Depth of training received (Table 38).

- Those who were trained, reported Awareness level of training by 37% for Ethics module to 53.7% for Methodology module.
- The depth of training responses did not reach significant levels.

D. Requirement for training (Table 39)

- Most of the modules were rated as 'training required' by respondents, with Ethics module receiving the highest percentage (30.4%), closely followed by Regulations (30.2%) and DM & stats module (30.1%).
- Responses did not reach significance level in any module or sub topic.

No response ranged from 67.4%% to 80.1%.

Table 38. Depth of training in knowledge areas

Areas of Knowledge		Training received n (100%)	Rating							
			Awareness		Knowledge		Competence		No Response	
			n	%	n	%	n	%	n	%
General	Scope of Clinical Research	64	33	51.6	11	17.2	0	0.0	20	31.3
	Orientation to Pharmaceutical Industry	70	28	40.0	14	20.0	0	0.0	28	40.0
	Drug development process	87	39	44.8	19	21.8	3	3.4	26	29.9
	Total of topics in General Module	**221**	**100**	45.2	**44**	19.9	**3**	1.4	**74**	33.5
Ethics	Biomedical ethics- History and principles	97	44	45.4	23	23.7	1	1.0	29	29.9
	ICH GCP and national GCP guidelines	101	38	37.6	31	30.7	6	5.9	26	25.7
	EC composition and function- ICMR and ICH guidelines	108	36	33.3	26	24.1	18	16.7	28	25.9
	Informed consent process- principles and practice	102	33	32.4	32	31.4	15	14.7	22	21.6
	Total of topics in Ethics Module	**408**	**151**	37.0	**112**	27.5	**40**	9.8	**105**	25.7
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	78	44	56.4	14	17.9	0	0.0	20	25.6
	Regulations relating to IP labelling and import	81	39	48.1	17	21.0	3	3.7	22	27.2
	Regulations regarding safety and pharmacovigilance	88	43	48.9	20	22.7	3	3.4	22	25.0
	Total of topics in Regulations Module	**247**	**126**	51.0	**51**	20.6	**6**	2.4	**64**	25.9
Methodology	Framing a research proposal/protocol and experimental design	61	36	59.0	7	11.5	0	0.0	18	29.5
	Writing investigators brochure	52	28	53.8	2	3.8	0	0.0	22	42.3
	Designing case report forms and EDCs	54	25	46.3	4	7.4	0	0.0	25	46.3
	Writing informed consent and Patient information sheet	67	37	55.2	4	6.0	0	0.0	26	38.8
	Writing study reports and publication	53	30	56.6	3	5.7	0	0.0	20	37.7
	SOP writing	57	32	56.1	2	3.5	0	0.0	23	40.4
	Conducting PK studies	19	7	36.8	0	0.0	0	0.0	12	63.2
	Total of topics in Methodology Module	**363**	**195**	53.7	**22**	6.1	**0**	0.0	**146**	40.2
DM and Stats	Types of data and statistical tests for clinical trials	44	18	40.9	0	0.0	1	2.3	25	56.8
	Statistical considerations at the design, execution and analysis	47	22	46.8	2	4.3	0	0.0	23	48.9
	Data Coding and cleaning	31	15	48.4	0	0.0	0	0.0	16	51.6
	Software considerations in Data Management	32	13	40.6	0	0.0	0	0.0	19	59.4
	Total of topics in DM & Stats Module	**154**	**68**	44.2	**2**	1.3	**1**	0.6	**83**	53.9
Clinical Trial execution	Monitoring a clinical study	56	17	30.4	23	41.1	2	3.6	14	25.0
	Project Management in clinical research	45	15	33.3	11	24.4	0	0.0	19	42.2
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	35	13	37.1	4	11.4	0	0.0	18	51.4
	Audits and inspection	87	41	47.1	9	10.3	0	0.0	37	42.5
	Clinical trial supplies management	63	21	33.3	12	19.0	3	4.8	27	42.9
	Pharmacovigilance and safety management	69	34	49.3	7	10.1	3	4.3	25	36.2
	Total of topics in Clinical Trial execution Module	**355**	**141**	39.7	**66**	18.6	**8**	2.3	**140**	39.4

Table 39. Requirement for training in knowledge areas (n=181)

Areas of Knowledge		Training Requirement						No Response	
		Required		Not required		Unsure			
		n	%	n	%	n	%	n	%
General	Scope of Clinical Research	33	18.2	2	1.1	1	0.6	145	80.1
	Orientation to Pharmaceutical Industry	29	16.0	2	1.1	2	1.1	148	81.8
	Drug development process	37	20.4	2	1.1	0	0.0	142	78.5
	Total of topics in General Module	**99**	**18.2**	**6**	**1.1**	**3**	**0.6**	**435**	**80.1**
Ethics	Biomedical ethics- History and principles	42	23.2	0	0.0	0	0.0	139	76.8
	ICH GCP and national GCP guidelines	58	32.0	0	0.0	0	0.0	123	68.0
	EC composition and function- ICMR and ICH guidelines	58	32.0	0	0.0	0	0.0	123	68.0
	Informed consent process- principles and practice	62	34.3	0	0.0	0	0.0	119	65.7
	Total of topics in Ethics Module	**220**	**30.4**	**0**	**0.0**	**0**	**0.0**	**504**	**69.6**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	51	28.2	2	1.1	1	0.6	127	70.2
	Regulations relating to IP labelling and import	51	28.2	2	1.1	2	1.1	126	69.6
	Regulations regarding safety and pharmacovigilance	62	34.3	0	0.0	0	0.0	119	65.7
	Total of topics in Regulations Module	**164**	**30.2**	**4**	**0.7**	**3**	**0.6**	**372**	**68.5**
Methodology	Framing a research proposal/protocol and experimental design	47	26.0	0	0.0	0	0.0	134	74.0
	Writing investigators brochure	44	24.3	0	0.0	0	0.0	137	75.7
	Designing case report forms and EDCs	51	28.2	2	1.1	2	1.1	126	69.6
	Writing informed consent and Patient information sheet	47	26.0	0	0.0	0	0.0	134	74.0
	Writing study reports and publication	48	26.5	0	0.0	0	0.0	133	73.5
	SOP writing	54	29.8	0	0.0	0	0.0	127	70.2
	Conducting PK studies	33	18.2	3	1.7	0	0.0	145	80.1
	Total of topics in Methodology Module	**324**	**25.6**	**5**	**0.4**	**2**	**0.2**	**936**	**73.9**
DM and Stats	Types of data and statistical tests for clinical trials	54	29.8	2	1.1	0	0.0	125	69.1
	Statistical considerations at the design, execution and analysis	59	32.6	4	2.2	0	0.0	118	65.2
	Data Coding and cleaning	52	28.7	7	3.9	0	0.0	122	67.4
	Software considerations in Data Management	53	29.3	3	1.7	2	1.1	123	68.0
	Total of topics in DM & Stats Module	**218**	**30.1**	**16**	**2.2**	**2**	**0.3**	**488**	**67.4**
Clinical Trial execution	Monitoring a clinical study	44	24.3	0	0.0	0	0.0	137	75.7
	Project Management in clinical research	60	33.1	0	0.0	0	0.0	121	66.9
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	51	28.2	0	0.0	0	0.0	130	71.8
	Audits and inspection	44	24.3	0	0.0	0	0.0	137	75.7
	Clinical trial supplies management	38	21.0	0	0.0	0	0.0	143	79.0
	Pharmacovigilance and safety management	52	28.7	0	0.0	0	0.0	129	71.3
	Total of topics in Clinical Trial execution Module	**289**	**26.6**	**0**	**0.0**	**0**	**0.0**	**797**	**73.4**

4.2.1.3 Skills: (Tables 40, 41, 42 and 43)

A. Importance of Skills (Table 39)

- All the skills were rated 'critical' by 50% or more respondents, the range being from 71.3% for computing skills to 58.6% for leadership skills.

B. Training received (Table 40)

- Majority of respondents were not trained in the skills
- Respondents reported receiving on the job training in Team work (15.5%), presentation skills (15.5%) and communication skills 13.3%, however, these were not considered significant.

No response ranged between 45.9% and 53%.

C. Depth of skills training received (Table 40).

- Depth of training received did not reach significance level in any skill.
- Majority of respondents, who were trained, reported 'awareness' level of training for all skills.
- Knowledge level was reported for Team work, computing skills, presentation skills and communication skills.
- 'Competence' level of computing skills training was rated by 36.2% respondents.

D. Requirement for skills training (Table 41)

- No significant responses were seen in requirement for training.
- The responses ranged from 8.8% for computing skills to 19.3% for interpersonal skills. .

No response was in the range of 80.7 % to 91.2%.

Table 40. Rating of Importance of skills – Total group (n=181)

Skills	Number of responses						No Response	
	Critical		Important		Not Important			
	n	%	n	%	n	%	n	%
Leadership skills	106	58.6	42	23.2	14	7.7	19	10.5
Team work	113	62.4	45	24.9	4	2.2	19	10.5
Negotiation skills	108	59.7	44	24.3	9	5.0	20	11.0
Conflict management	119	65.7	40	22.1	6	3.3	16	8.8
Interpersonal skills	117	64.6	42	23.2	4	2.2	18	9.9
Computing skills	129	71.3	36	19.9	2	1.1	14	7.7
Presentation skills	124	68.5	40	22.1	1	0.6	16	8.8
Communication skills	120	66.3	39	21.5	1	0.6	21	11.6

Table 41. Training received in skills – Total group (n=181)

Skills	Number of responses						No Response	
	Not received		Received at					
	n	%	Graduation		On the job		n	%
			n	%	n	%		
Leadership skills	89	49.2	0	0.0	2	1.1	90	49.7
Team work	66	36.5	4	2.2	28	15.5	83	45.9
Negotiation skills	81	44.8	0	0.0	4	2.2	96	53.0
Conflict management	82	45.3	0	0.0	5	2.8	94	51.9
Interpersonal skills	79	43.6	0	0.0	17	9.4	85	47.0
Computing skills	49	27.1	27	14.9	20	11.0	85	47.0
Presentation skills	49	27.1	8	4.4	28	15.5	96	53.0
Communication skills	63	34.8	4	2.2	24	13.3	90	49.7

Table 42. Depth of Skills Training received – Total group

Skills	Number of responses							No Response	
	Training received (n=100%)	Awareness		Knowledge		Competence			
		n	%	n	%	n	%	n	%
Leadership skills	2.0	2		0	0.0	0	0.0	0	0.0
Team work	32	27	84.4	3	-	0	0.0	2	6.3
Negotiation skills	4.0	4		0	0.0	0	0.0	0	0.0
Conflict management	5.0	4		0	0.0	0	0.0	1	20.0
Interpersonal skills	17	15	88.2	0	0.0	1	-	1	5.9
Computing skills	47	16	34.0	6	-	17	36.2	8	17.0
Presentation skills	36	10	-	5	-	7	-	14	38.9
Communicatio n skills	28	16	57.1	3	-	3	-	6	21.4

Table 43. Requirement of Skills training – Total group (n=181)

Skills	Number of responses						No Response	
	Required		Not required		Unsure			
	n	%	n	%	n	%	n	%
Leadership skills	28	15.5	2	1.1	5	2.8	146	80.7
Team work	29	16.0	2	1.1	0	0.0	150	82.9
Negotiation skills	23	12.7	2	1.1	1	0.6	155	85.6
Conflict management	32	17.7	0	0.0	0	0.0	149	82.3
Interpersonal skills	35	19.3	0	0.0	0	0.0	146	80.7
Computing skills	16	8.8	0	0.0	0	0.0	165	91.2
Presentation skills	27	14.9	0	0.0	0	0.0	154	85.1
Communication skills	19	10.5	2	1.1	0	0.0	160	88.4

4.2.1.4. Discussion- Total Group:

Response rates in surveys of clinical research professionals regarding training needs have not been exceptionally good. Stonier and Gabby could achieve 58% response [55]. Acharjya reports [] of less than 10% response rate in her survey of training needs of all research nurses of the ICR database. Another study in study coordinators selected from the ACRP list serv reported 25% response rate [74]. We got a response rate in was 65% in our first survey among stakeholders and around 20% in the second survey among role holders. Our response rate is still encouraging enough to provide a foundation to our understanding of training needs this new enterprise in our country.

Our clinical research workforce is young, with majority of them having 3 years or less experience. We saw representations across all roles showing the diversity of operations being done in India. The two predominant roles being that of CRA and Data managers as reflected in the role distribution. International clinical research workforce and has average experience of over 10 years in the industry [75].

A significant, though expected finding is that the General, Ethics, Regulations and Execution modules are rated of critical importance. 61% of our respondents rated the regulations module as 'critical' and 46.1% rated the methodology module as 'critical'. In the ACE survey [54], methodology module was rated important by more respondents (38.2%) than the regulations module (24.6%).

Training received is significant only in the Ethics module. This is in one way reassuring considering that ethical concerns have been and will always be primordial when conducting clinical trials in a new, developing country like India and awareness of regulations and guidelines is the first mandatory step towards compliance. However, it remains an area of concern that the number of respondents reporting being trained in the other modules rated critical is less than 50%. Also concerning is that the even though the modules were rated, critical, they not marked as training requirements by significant number of respondents.

Training received was predominantly on-the-job ranging between 20.3% and 54%

across modules. This is also supported by the 86% reporting that their employment experience (even though low as can be seen from the average experience) prepared them very well or adequately. Only a small percentage (0.1% to 2.3%) report to have received any training at graduation and yet 71% respondents report that their education prepared them very well or adequately for the job. This is probably because a large part of recruitment in the clinical research industry is freshers who lack understanding of job requirements.

All the skills were rated 'critical', with computing skills received the highest rating for importance. However, majority of respondents were not trained in these skills. Considering the amount of work that is done using computing skills, this finding is on expected lines. Also on expected lines is the observation that most of on the job training is done in team work, communication skills and presentation skills.

A significant finding was large percentage of non response to the training requirement question. We did not get a chance to systematically seek answers to the reasons for the poor response rate, but have attempted to seek clarification if the poor response was because respondents did not know the answer or did not want to answer.

- The respondents probably did not know the answer because they are inexperienced and new to the industry or to the role. An analysis of experience level and no response categories did not yield any clear trends.
- Respondents not wanting to answer could be due to also probably because questions were iterative and did not require a response, If some item was graded as 'critical' or 'important' , it obviously meant a training was required or vice-versa. In the General module, the sub-topic of Scope of clinical research had 172 respondents to grading of importance and 145 non responders to the training requirement for the same sub-topic.

Our respondent population had 2 fairly large groups- the Data management group (n=57) and CRAs (n=31) and an analysis of the data for these two roles separately to identify and emerging trends was carried out.

4.2.2 Data Management Group:

4.2.2.1 Demography

Table 44 shows the demographic details of the Data Management group. It included 20 males and 37 females with an average age of 29.2 years. All were employed, 55 in clinical research and 2 in other employment. 63.2% of respondents were graduates, 37% had post-graduates qualifications and 19 % had doctorates.

Maximum numbers, 27 (47.4%) worked for a CRO of Indian origin and 20 (35.1%) for an MNC Pharma company. Most of them (54.4%) had less than one year's clinical research experience and only 3 of them had more than 5 years experience. 23 (40.4%) of them thought their education prepared them well for the current job, while 22 (38.6%) rated it as adequate preparation. 29 (50.9%) felt that their employment experience had prepared them very well for the current job.

Table 44. Demography- Data Management Group (n=57)

1	**Sex**	**n**	**%**
	• Males	20	35
	• Females	37	65
	Average Age	29.2 yrs	
2	**Qualification**	**n**	**%**
	• Graduation	36	63.2
	B. Pharm	10	
	B. Sc	11	
	Alternate Medicine	8	
	BAMS	5	
	BHMS	3	
	Others (BE-3, BCA-1, BTech-2)	6	
	MBBS	1	
	• Post graduation	10	17.5
	M. Pharm	0	
	M. Sc	1	
	Others (MBA-1, PGDCR-4, MCA-4)	9	
	• Doctorate	11	19.3
3	**Employment status**	**n**	%
	• Employed		
	○ In CR	55	96.5
	○ ·Other	2	3.5
4	**Type of organisation**	**n**	**%**
	• CRO- Indian	27	47.4
	• MNC Pharma	20	35.1
	• MNC CRO	9	15.8
	• Indian Pharma	1	1.8
5	**Clinical Research Experience**	**n**	**%**
	• One year or less	31	54.4
	• 1-3 years	19	33.3
	• 3-5 years	4	7
	• More than 5 years	3	5.3
6	**Education preparing for current job**	**n**	**%**
	• Very well	23	40.4
	• Adequately	22	38.6
	• Poorly	9	15.8
	• Education unrelated	3	5.3
7	**Employment experience preparing for current job**	**n**	**%**
	• Very well	29	50.9
	• Adequately	22	38.6
	• Poorly	5	8.8
	• Employment unrelated	1	1.8

4.2.2.2 Knowledge Areas:

A. Grading of importance (Table 45).

Knowledge Modules: Comparison of the grade wise total of all responses for each module shows that

- 50% or more respondents rated the General, Ethics and Data management and statistics modules as 'critical'.
- In addition, the following subtopics were rated 'critical' by 50% or more respondents-
    - Regulations relating to IP labelling and import
    - Audits and inspection
    - Clinical trial supplies management
    - Pharmacovigilance and safety management

No response ranged between 1.8% and 7%.

B. Training received (Table 46).

- Majority of respondents were not trained. Of 57 respondents, only 15 to 25 reported receiving training, which was less than 50% response and not considered significant.
- 21.9% respondents reported not to have received training in Data management and statistics module. 29.8% were not trained in Data coding and cleaning and Software considerations in data management.
- Training received was mostly on the job training and this ranged between 15.5% in the CT execution module to 39.9% in the Ethics module.

No response ranged between 31.6% and 61.4%

Table 45. Importance of knowledge areas- Data Management (n=57)

Areas of Knowledge		Rating						No Response	
		Critical		Important		Not Important			
		n	%	n	%	n	%	n	%
General	Scope of Clinical Research	36	63.2	19	33.3	0	0.0	2	3.5
	Orientation to Pharmaceutical Industry	26	45.6	29	50.9	0	0.0	2	3.5
	Drug development process	33	57.9	13	22.8	7	12.3	4	7.0
	Total of topics in General Module	**95**	**55.6**	**61**	**35.7**	**7**	**4.1**	**8**	**4.7**
Ethics	Biomedical ethics- History and principles	30	52.6	24	42.1	0	0.0	3	5.3
	ICH GCP and national GCP guidelines	32	56.1	21	36.8	0	0.0	4	7.0
	EC composition and function- ICMR and ICH guidelines	33	57.9	20	35.1	0	0.0	4	7.0
	Informed consent process- principles and practice	26	45.6	27	47.4	0	0.0	4	7.0
	Total of topics in Ethics Module	**121**	**53.1**	**92**	**40.4**	**0**	**0.0**	**15**	**6.6**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	25	43.9	29	50.9	0	0.0	3	5.3
	Regulations relating to IP labelling and import	31	54.4	25	43.9	0	0.0	1	1.8
	Regulations regarding safety and pharmacovigilance	25	43.9	28	49.1	0	0.0	4	7.0
	Total of topics in Regulations Module	**81**	**47.4**	**82**	**48.0**	**0**	**0.0**	**8**	**4.7**
Methodology	Framing a research proposal/protocol and experimental design	20	35.1	31	54.4	2	3.5	4	7.0
	Writing investigators brochure	20	35.1	31	54.4	2	3.5	4	7.0
	Designing case report forms and EDCs	24	42.1	30	52.6	0	0.0	3	5.3
	Writing informed consent and Patient information sheet	22	38.6	30	52.6	2	3.5	3	5.3
	Writing study reports and publication	26	45.6	28	49.1	2	3.5	1	1.8
	SOP writing	25	43.9	28	49.1	3	5.3	1	1.8
	Conducting PK studies	17	29.8	21	36.8	15	26.3	4	7.0
	Total of topics in Methodology Module	**154**	**38.6**	**199**	**49.9**	**26**	**6.5**	**20**	**5.0**
DM and Stats	Types of data and statistical tests for clinical trials	32	56.1	23	40.4	0	0.0	2	3.5
	Statistical considerations at the design, execution and analysis	30	52.6	20	35.1	5	8.8	2	3.5
	Data Coding and cleaning	33	57.9	20	35.1	0	0.0	4	7.0
	Software considerations in Data Management	32	56.1	23	40.4	0	0.0	2	3.5
	Total of topics in DM & Stats Module	**127**	**55.7**	**86**	**37.7**	**5**	**2.2**	**10**	**4.4**
Clinical Trial execution	Monitoring a clinical study	24	42.1	25	43.9	5	8.8	3	5.3
	Project Management in clinical research	24	42.1	26	45.6	4	7.0	3	5.3
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	25	43.9	25	43.9	6	10.5	1	1.8
	Audits and inspection	30	52.6	22	38.6	2	3.5	3	5.3
	Clinical trial supplies management	30	52.6	23	40.4	2	3.5	2	3.5
	Pharmacovigilance and safety management	30	52.6	24	42.1	1	1.8	2	3.5
	Total of topics in Clinical Trial execution Module	**163**	**47.7**	**145**	**42.4**	**20**	**5.8**	**14**	**4.1**

Table 46. Training in knowledge areas- Data Management roles (n=57)

Areas of Knowledge		Training						No Response	
		Not received		At Graduation		On the Job			
		N	%	n	%	n	%	n	%
General	Scope of Clinical Research	14	24.6	0	0.0	15	26.3	28	49.1
	Orientation to Pharmaceutical Industry	20	35.1	0	0.0	16	28.1	21	36.8
	Drug development process	9	15.8	0	0.0	22	38.6	26	45.6
	Total of topics in General Module	**43**	**25.1**	**0**	**0.0**	**53**	**31.0**	**75**	**43.9**
Ethics	Biomedical ethics- History and principles	4	7.0	0	0.0	18	31.6	35	61.4
	ICH GCP and national GCP guidelines	2	3.5	0	0.0	25	43.9	30	52.6
	EC composition and function- ICMR and ICH guidelines	4	7.0	0	0.0	27	47.4	26	45.6
	Informed consent process- principles and practice	9	15.8	0	0.0	21	36.8	27	47.4
	Total of topics in Ethics Module	**19**	**8.3**	**0**	**0.0**	**91**	**39.9**	**118**	**51.8**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	12	21.1	0	0.0	16	28.1	29	50.9
	Regulations relating to IP labelling and import	12	21.1	0	0.0	17	29.8	28	49.1
	Regulations regarding safety and pharmacovigilance	12	21.1	0	0.0	16	28.1	29	50.9
	Total of topics in Regulations Module	**36**	**21.1**	**0**	**0.0**	**49**	**28.7**	**86**	**50.3**
Methodology	Framing a research proposal/protocol and experimental design	18	31.6	0	0.0	19	33.3	20	35.1
	Writing investigators brochure	18	31.6	0	0.0	16	28.1	23	40.4
	Designing case report forms and EDCs	11	19.3	0	0.0	25	43.9	21	36.8
	Writing informed consent and Patient information sheet	12	21.1	0	0.0	22	38.6	23	40.4
	Writing study reports and publication	13	22.8	0	0.0	20	35.1	24	42.1
	SOP writing	18	31.6	0	0.0	21	36.8	18	31.6
	Conducting PK studies	22	38.6	0	0.0	3	5.3	32	56.1
	Total of topics in Methodology Module	**112**	**28.1**	**0**	**0.0**	**126**	**31.6**	**161**	**40.4**
DM and Stats	Types of data and statistical tests for clinical trials	7	12.3	3	5.3	22	38.6	25	43.9
	Statistical considerations at the design, execution and analysis	9	15.8	3	5.3	20	35.1	25	43.9
	Data Coding and cleaning	17	29.8	0	0.0	19	33.3	21	36.8
	Software considerations in Data Management	17	29.8	0	0.0	17	29.8	23	40.4
	Total of topics in DM & Stats Module	**50**	**21.9**	**6**	**2.6**	**78**	**34.2**	**94**	**41.2**
Clinical Trial execution	Monitoring a clinical study	25	43.9	0	0.0	3	5.3	29	50.9
	Project Management in clinical research	20	35.1	0	0.0	6	10.5	31	54.4
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	23	40.4	0	0.0	4	7.0	30	52.6
	Audits and inspection	9	15.8	0	0.0	25	43.9	23	40.4
	Clinical trial supplies management	24	42.1	0	0.0	3	5.3	30	52.6
	Pharmacovigilance and safety management	19	33.3	0	0.0	12	21.1	26	45.6
	Total of topics in Clinical Trial execution Module	**120**	**35.1**	**0**	**0.0**	**53**	**15.5**	**169**	**49.4**

C. Depth of training (Table 47)

Modules- Grade wise total of all the topics within each module shows-

- Of the respondents who received training, highest number rated an 'awareness' level of depth of knowledge for all modules (25% to 81.3%).
- Of the respondents reported to have been trained (17 to 25) in the various sub-topics of the data management module, 11-25 reported awareness level and two reported 'knowledge level of training (sub-topic- *Statistical considerations at the design, execution and analysis*) and only one reported competence level of training (sub-topic-*Types of data and statistical test for clinical trials*)

.

No response ranged between 16% and 66.7%.

D. Requirement for training (Table 48)

Modules-

- Most of the modules were rated 'training required', but none reached a significant level of 50% or more respondents.
- DM & stats module receiving the highest number of responses (32%).
- *Software considerations in Data management* was the item rated by the highest number of respondents (38.6%), followed by *Data coding and cleaning* (33.3%) as 'training required'.

No response ranged from 61.4% to 93%.

Table 47. Depth of training in knowledge areas- Data Management roles

Areas of Knowledge		Training received n (100%)	Rating							
			Awareness		Knowledge		Competence		No Response	
			n	%	n	%	n	%	n	%
General	Scope of Clinical Research	15	7	46.7	2	13.3	0	0.0	6	40.0
	Orientation to Pharmaceutical Industry	16	7	43.8	2	12.5	0	0.0	7	43.8
	Drug development process	22	13	59.1	5	22.7	0	0.0	4	18.2
	Total of topics in General Module	**53**	**27**	50.9	**9**	17.0	**0**	0.0	**17**	32.1
Ethics	Biomedical ethics- History and principles	18	12	66.7	3	16.7	0	0.0	3	16.7
	ICH GCP and national GCP guidelines	25	11	44.0	10	40.0	0	0.0	4	16.0
	EC composition and function- ICMR and ICH guidelines	27	12	44.4	9	33.3	0	0.0	6	22.2
	Informed consent process- principles and practice	21	13	61.9	4	19.0	0	0.0	4	19.0
	Total of topics in Ethics Module	**91**	**48**	52.7	**26**	28.6	**0**	0.0	**17**	18.7
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	16	9	56.3	0	0.0	0	0.0	7	43.8
	Regulations relating to IP labelling and import	17	9	52.9	0	0.0	0	0.0	8	47.1
	Regulations regarding safety and pharmacovigilance	16	11	68.8	0	0.0	0	0.0	5	31.3
	Total of topics in Regulations Module	**49**	**29**	59.2	**0**	0.0	**0**	0.0	**20**	40.8
Methodology	Framing a research proposal/protocol and experimental design	19	15	78.9	0	0.0	0	0.0	4	21.1
	Writing investigators brochure	16	13	81.3	0	0.0	0	0.0	3	18.8
	Designing case report forms and EDCs	25	14	56.0	4	16.0	0	0.0	7	28.0
	Writing informed consent and Patient information sheet	22	13	59.1	4	18.2	0	0.0	5	22.7
	Writing study reports and publication	20	12	60.0	3	15.0	0	0.0	5	25.0
	SOP writing	21	14	66.7	1	4.8	0	0.0	6	28.6
	Conducting PK studies	3	1	33.3	0	0.0	0	0.0	2	66.7
	Total of topics in Methodology Module	**126**	**82**	65.1	**12**	9.5	**0**	0.0	**32**	25.4
DM and Stats	Types of data and statistical tests for clinical trials	25	12	48.0	0	0.0	1	4.0	12	48.0
	Statistical considerations at the design, execution and analysis	23	15	65.2	2	8.7	0	0.0	6	26.1
	Data Coding and cleaning	19	13	68.4	0	0.0	0	0.0	6	31.6
	Software considerations in Data Management	17	11	64.7	0	0.0	0	0.0	6	35.3
	Total of topics in DM & Stats Module	**84**	**51**	60.7	**2**	2.4	**1**	1.2	**30**	35.7
Clinical Trial execution	Monitoring a clinical study	3	1	33.3	0	0.0	0	0.0	2	66.7
	Project Management in clinical research	6	2	33.3	0	0.0	0	0.0	4	66.7
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	4	1	25.0	0	0.0	0	0.0	3	75.0
	Audits and inspection	25	14	56.0	0	0.0	0	0.0	11	44.0
	Clinical trial supplies management	3	1	33.3	0	0.0	0	0.0	2	66.7
	Pharmacovigilance and safety management	12	9	75.0	0	0.0	0	0.0	3	25.0
	Total of topics in Clinical Trial execution Module	**53**	**28**	52.8	**0**	0.0	**0**	0.0	**25**	47.2

Table 48. Requirement for training in knowledge areas-Data Management roles (n=57)

Areas of Knowledge		Training Requirement						No Response	
		Required		Not required		Unsure			
		n	%	n	%	n	%	n	%
General	Scope of Clinical Research	5	8.8	0	0.0	0	0.0	52	91.2
	Orientation to Pharmaceutical Industry	6	10.5	0	0.0	0	0.0	51	89.5
	Drug development process	7	12.3	0	0.0	0	0.0	50	87.7
	Total of topics in General Module	**18**	**10.5**	**0**	**0.0**	**0**	**0.0**	**153**	**89.5**
Ethics	Biomedical ethics- History and principles	6	10.5	0	0.0	0	0.0	51	89.5
	ICH GCP and national GCP guidelines	7	12.3	0	0.0	0	0.0	50	87.7
	EC composition and function- ICMR and ICH guidelines	8	14.0	0	0.0	0	0.0	49	86.0
	Informed consent process- principles and practice	9	15.8	0	0.0	0	0.0	48	84.2
	Total of topics in Ethics Module	**30**	**13.2**	**0**	**0.0**	**0**	**0.0**	**198**	**86.8**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	4	7.0	0	0.0	0	0.0	53	93.0
	Regulations relating to IP labelling and import	5	8.8	0	0.0	0	0.0	52	91.2
	Regulations regarding safety and pharmacovigilance	9	15.8	0	0.0	0	0.0	48	84.2
	Total of topics in Regulations Module	**18**	**10.5**	**0**	**0.0**	**0**	**0.0**	**153**	**89.5**
Methodology	Framing a research proposal/protocol and experimental design	8	14.0	0	0.0	0	0.0	49	86.0
	Writing investigators brochure	7	12.3	0	0.0	0	0.0	50	87.7
	Designing case report forms and EDCs	12	21.1	0	0.0	0	0.0	45	78.9
	Writing informed consent and Patient information sheet	9	15.8	0	0.0	0	0.0	48	84.2
	Writing study reports and publication	12	21.1	0	0.0	0	0.0	45	78.9
	SOP writing	9	15.8	0	0.0	0	0.0	48	84.2
	Conducting PK studies	2	3.5	0	0.0	0	0.0	55	96.5
	Total of topics in Methodology Module	**59**	**14.8**	**0**	**0.0**	**0**	**0.0**	**340**	**85.2**
DM and Stats	Types of data and statistical tests for clinical trials	15	26.3	0	0.0	0	0.0	42	73.7
	Statistical considerations at the design, execution and analysis	17	29.8	0	0.0	0	0.0	40	70.2
	Data Coding and cleaning	19	33.3	0	0.0	0	0.0	38	66.7
	Software considerations in Data Management	22	38.6	0	0.0	0	0.0	35	61.4
	Total of topics in DM & Stats Module	**73**	**32.0**	**0**	**0.0**	**0**	**0.0**	**155**	**68.0**
Clinical Trial execution	Monitoring a clinical study	13	22.8	0	0.0	0	0.0	44	77.2
	Project Management in clinical research	13	22.8	0	0.0	0	0.0	44	77.2
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	11	19.3	0	0.0	0	0.0	46	80.7
	Audits and inspection	10	17.5	0	0.0	0	0.0	47	82.5
	Clinical trial supplies management	8	14.0	0	0.0	0	0.0	49	86.0
	Pharmacovigilance and safety management	12	21.1	0	0.0	0	0.0	45	78.9
	Total of topics in Clinical Trial execution Module	**67**	**19.6**	**0**	**0.0**	**0**	**0.0**	**275**	**80.4**

4.2.2.3 Skills:

A. Importance of Skills (Table 49).

- Majority of respondents (70.2% to 82.5%) considered all the skills critical.
- Computing skills have been marked ‘critical’ by the highest number of respondents (82.5%).

B. Training received in skills (Table 50).

- Majority of respondents had not received training in skills,
- 5.3% to 14.4% respondents had received on the job training

No response ranged from 61.4% to 68.4%.

C. Depth of training received (Table 51)

- Most of the respondents who received training, rated it at ‘awareness’ level.
- 4 respondents rated ‘competence’ for computing skills.

D. Requirement for training (Table 52)

- 3.5 % respondents (negotiation skills) to 12.3% respondents (team work, interpersonal, computing and presentation skills) marked training as required for the various skills.

No response rates were in the range of 87.7% to 99.5%.

Table 49. Rating of Importance of skills – Data Management (n=57)

Skills	Number of responses						No Response	
	Critical		Important		Not Important			
	n	%	n	%	n	%	n	%
Leadership skills	44	77.2	9	15.8	3	5.3	1	1.8
Team work	43	75.4	13	22.8	0	0.0	1	1.8
Negotiation skills	40	70.2	14	24.6	1	1.8	2	3.5
Conflict management	43	75.4	12	21.1	1	1.8	1	1.8
Interpersonal skills	41	71.9	15	26.3	0	0.0	1	1.8
Computing skills	47	82.5	9	15.8	0	0.0	1	1.8
Presentation skills	41	71.9	15	26.3	0	0.0	1	1.8
Communication skills	40	70.2	14	24.6	0	0.0	3	5.3

Table 50. Training received in skills – Data Management group (n=57)

Skills	Number of responses						No Response	
	Not received		Received at					
	n	%	Graduation		On the job		n	%
			n	%	n	%		
Leadership skills	18	31.6	0	0.0	2	3.5	37	64.9
Team work	16	28.1	0	0.0	8	14.0	33	57.9
Negotiation skills	18	31.6	0	0.0	0	0.0	39	68.4
Conflict management	17	29.8	0	0.0	3	5.3	37	64.9
Interpersonal skills	18	31.6	0	0.0	4	7.0	35	61.4
Computing skills	17	29.8	2	3.5	3	5.3	35	61.4
Presentation skills	13	22.8	0	0.0	5	8.8	39	68.4
Communication skills	13	22.8	0	0.0	5	8.8	39	68.4

Table 51. Depth of Skills Training received – Data Management

Skills	Number of responses				No Response
	Training received	Awareness	Knowledge	Competence	
Leadership skills	2	2	0	0	0
Team work	8	8	0	0	0
Negotiation skills	0	0	0	0	0
Conflict management	3	3	0	0	0
Interpersonal skills	4	3	0	0	1
Computing skills	5	1	0	4	0
Presentation skills	5	0	0	0	5
Communication skills	5	0	0	0	5

Table 52. Requirement of Skills training – Data Management (n=57)

Skills	Number of responses						No Response	
	Required		Not required		Unsure			
	n	%	n	%	n	%	n	%
Leadership skills	6	10.5	0	0.0	0	0.0	51	89.5
Team work	7	12.3	0	0.0	0	0.0	50	87.7
Negotiation skills	2	3.5	0	0.0	0	0.0	55	96.5
Conflict management	6	10.5	0	0.0	0	0.0	51	89.5
Interpersonal skills	7	12.3	0	0.0	0	0.0	50	87.7
Computing skills	7	12.3	0	0.0	0	0.0	50	87.7
Presentation skills	7	12.3	0	0.0	0	0.0	50	87.7
Communication skills	6	10.5	0	0.0	0	0.0	51	89.5

4.2.2.4 Discussion – Data Management group

We combined all the various roles in Data management (like data entry, validation, programming, medical coding, statisticians and medical writers) under one heading as the individual numbers were too small for separate analysis.

Data management as a clinical research process has been outsourced to India, much later than the study management process. The role of the clinical data manager was and the competencies required was poorly understood till a few years back [76]. 87.7% of our data management group had less than 3 years clinical research experience, again showing a relatively young industry. In India, most of data management outsourcing has been to large IT companies, with international project management. This means that data management teams are interacting across the globe with their international counterparts and need to be excellent in communication skills and cultural understanding.

Scope of clinical research was rated critical by the highest number of respondents, probably because it is a new field and understanding its scope is important for career decisions of new entrants, especially SAS programmers who were otherwise only aware of careers in finance sector or IT industry. Highest number of respondents reported receiving on the job training for *EC composition and function- ICMR and ICH guidelines*, which again is an area that data management personnel do not directly impact in day to day working. From a holistic understanding perspective, awareness of the processes that feed into the data management is certainly a value-add in better performance. Hence it may not be unfair to assume that those who have not been trained in these aspects have received basic training.

Highest number of respondents (30-33 of the 57 role holders) has rated the various sub-topics in the Data management and statistics module as 'critical'; while stakeholders rated all the sub-topics except the *Statistical considerations at the design, execution and analysis* as critical. This is probably because the role holders group also had statisticians who rated this module as critical, while the stakeholders might have considered Data management personnel and statisticians roles separately while rating.

Most of respondents were trained on the job and but only one respondent reported 'competence' level of training in the sub topic of types of data and statistical considerations for clinical trials. *Software considerations in data management* was rated as training requirement by highest number of respondents (38.6%). 12 respondents each also marked sub topics of *Designing case report forms and EDCs* and *Writing study reports and publications* as training requirements

It was interesting to note that significant number of role holders and stakeholders rated the 2 sub topics pertaining to Pharmacovigilance and safety management in the regulations module and the execution module as 'critical', probably indicating the emergence of safety data management and pharmacovigilance as an important field in data management.

Role holders had marked sub-topics in the execution module like *Monitoring a clinical study* and *clinical trial supplies management* as training requirements. These are areas the data management personnel are never involved in and indicate either a lack of complete understanding of role specific needs or an interest in switching jobs for career growth.

Table 53. Stakeholder and role holder responses for knowledge- Data management

Roles/Modules	General	Ethics	Regulatory	Methodology	DM & Stats	CT execution
D M personnel (Stakeholders)	-	I	I	I	C	C
DM personnel (Role holders)	C	C	I	I	C	C

A comparison of the grading of knowledge areas (Table 53) shows that both stakeholders and role holders had similar perceptions about grading of Methodology, Data management and statistics and Clinical trial execution modules.

For the other modules, the perceptions of both the respondents were different. The role holders considered general and ethics modules critical. However, stakeholders considered ethics as important and for the general module these ratings were more or less equal.

A comparison of role holders and stake holders rating (Table 54) for the various skills shows that role holders rated all the skills as critical, while stakeholders considered communication, presentation, computing, negotiation and team work as critical.

Table 54. Stakeholder and role holder responses for skills- Data Management.

Roles/Skills	Leader ship	Team work	Negotia tion	Conflict Mgt	Interpers onal	Compu ting	Presen tation	Communic ations
DM personnel (stake holders)	-	C	C	C=I	I	C	C	C
DM personnel (role holders)	C	C	C	C	C	C	C	C

The difference is in leadership skills, conflict management, and interpersonal skills. Stakeholders have several years of experience and are probably better equipped to rate the items of knowledge and skills important to the role. The relative inexperience of the role holders shows in their not being able to discriminate clearly, because they may not also be completely aware of the job demands.

4.2.3 CRAs

4.2.3.1 Demography (Table 55)

CRA group included 22 males and 9 females with an average age of 26.7 years.

Of the respondents, 64.5% were graduates, 35% had post-graduates qualifications. All of them were employed in clinical research.

Majority worked in a CRO of Indian origin, followed by Indian pharma company and MNC CRO. 27 (87%) of them had 3 or less experience in clinical research; only one CRA had more than 5 years experience.

Of the 31 CRAs, 15 (48.4%) felt their education prepared them very well or adequately for the job, while 10 (32.3%) felt poorly prepared.

Majority (74.2%) of them rated their employment experience as preparing them very well or adequately for the job.

Table 55. Demography- Clinical Research Associates (n=31)

1	**Sex**	**n**	**%**
	Males	22	71
	Females	9	29
	Average Age	26.7 yrs	
2	**Qualification**	**n**	**%**
	• Graduation	**20**	**64.5**
	B. Pharm	9	
	B. Sc	8	
	Alternate Medicine (BAMS)	2	
	MBBS	1	
	• Post graduation	**11**	**35.5**
	Others (PGDCR-5, MTech-1, DBM-1)	7	
	M. Pharm	4	
3	**Employment status**	**n**	**%**
	• Employed		
	○ In CR	31	100
4	**Type of organisation**	**n**	**%**
	• CRO- Indian origin	10	32.3
	• MNC CRO	7	22.6
	• Indian Pharma	7	22.6
	• Hospital	1	3.23
	• MNC Pharma	1	3.23
	• NA	4	12.9
	• Others (MNC-IT)	1	3.23
5.	**Clinical Research Experience**	**n**	**%**
	• One year or less	17	54.8
	• 1-3 years	10	32.3
	• 3-5 years	2	6.45
	• More than 5 years	1	3.23
	• NA	1	3.23
6	**Education preparing for current job**	**n**	**%**
	• Very well	7	22.6
	• Adequately	8	25.8
	• Poorly	10	32.3
	• Education unrelated	6	19.4
7	**Employment experience preparing for current job**	**n**	**%**
	• Very well	13	41.9
	• Adequately	10	32.3
	• Poorly	4	12.9
	• Employment unrelated	4	12.9

4.2.3.2 Knowledge Areas:

A. Grading of importance (Table 56)

Knowledge Modules: Comparison of the gradewise total of all responses for a module shows that-

- Four of the six modules- General, Ethics, Regulations and CT execution module were rated 'critical' by 50% or more respondents.
- The Ethics module received the highest number of 'critical' ratings (72.6% of respondents).
- In addition, the following sub topics were rated 'important by 50% or more respondents-
    - Designing case report forms and EDCs
    - Conducting PK studies
    - Types of data and statistical test for clinical trials
- All the sub-topics in the clinical trial execution module were rated 'critical' by more than 50% of respondents. Monitoring a clinical study received the highest number (74.2%) of critical ratings.

No response ranged between 0% and 19.4%.

B. Training received in knowledge areas is shown in Table 57.

Modules: Gradewise total of all topics within modules, shows that-

- 50% or more respondents had received training in the modules marked critical- General, Ethics, regulatory and execution modules.
- Training received was mostly on the job and highest in the Ethics module (75.8%).

No response ranged between 16.1% and 32.3%.

Table 56. Importance of knowledge areas- CRAs (n=31)

Areas of Knowledge		Rating						No Response	
		Critical		Important		Not Important			
		n	%	n	%	n	%	n	%
General	Scope of Clinical Research	19	61.3	11	35.5	0	0.0	1	3.2
	Orientation to Pharmaceutical Industry	15	48.4	13	41.9	0	0.0	3	9.7
	Drug development process	18	58.1	11	35.5	0	0.0	2	6.5
	Total of topics in General Module	**52**	**55.9**	**35**	**37.6**	**0**	**0.0**	**6**	**6.5**
Ethics	Biomedical ethics- History and principles	22	71.0	8	25.8	0	0.0	1	3.2
	ICH GCP and national GCP guidelines	22	71.0	9	29.0	0	0.0	0	0.0
	EC composition and function- ICMR and ICH guidelines	23	74.2	5	16.1	0	0.0	3	9.7
	Informed consent process- principles and practice	23	74.2	5	16.1	0	0.0	3	9.7
	Total of topics in Ethics Module	**90**	**72.6**	**27**	**21.8**	**0**	**0.0**	**7**	**5.6**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	19	61.3	9	29.0	0	0.0	3	9.7
	Regulations relating to IP labelling and import	16	51.6	9	29.0	3	9.7	3	9.7
	Regulations regarding safety and pharmacovigilance	17	54.8	12	38.7	0	0.0	2	6.5
	Total of topics in Regulations Module	**52**	**55.9**	**30**	**32.3**	**3**	**3.2**	**8**	**8.6**
Methodology	Framing a research proposal/protocol and experimental design	8	25.8	6	19.4	15	48.4	2	6.5
	Writing investigators brochure	8	25.8	7	22.6	14	45.2	2	6.5
	Designing case report forms and EDCs	7	22.6	3	9.7	19	61.3	2	6.5
	Writing informed consent and Patient information sheet	8	25.8	5	16.1	15	48.4	3	9.7
	Writing study reports and publication	7	22.6	6	19.4	15	48.4	3	9.7
	SOP writing	9	29.0	6	19.4	14	45.2	2	6.5
	Conducting PK studies	2	6.5	3	9.7	23	74.2	3	9.7
	Total of topics in Methodology Module	**49**	**22.6**	**36**	**16.6**	**115**	**53.0**	**17**	**7.8**
DM and Stats	Types of data and statistical tests for clinical trials	7	22.6	6	19.4	16	51.6	2	6.5
	Statistical considerations at the design, execution and analysis	11	35.5	7	22.6	12	38.7	1	3.2
	Data Coding and cleaning	4	12.9	9	29.0	15	48.4	3	9.7
	Software considerations in Data Management	5	16.1	9	29.0	15	48.4	2	6.5
	Total of topics in DM & Stats Module	**27**	**21.8**	**31**	**25.0**	**58**	**46.8**	**8**	**6.5**
Clinical Trial execution	Monitoring a clinical study	23	74.2	5	16.1	0	0.0	3	9.7
	Project Management in clinical research	19	61.3	6	19.4	0	0.0	6	19.4
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	18	58.1	9	29.0	2	6.5	2	6.5
	Audits and inspection	18	58.1	11	35.5	0	0.0	2	6.5
	Clinical trial supplies management	19	61.3	10	32.3	0	0.0	2	6.5
	Pharmacovigilance and safety management	21	67.7	8	25.8	0	0.0	2	6.5
	Total of topics in Clinical Trial execution Module	**118**	**63.4**	**49**	**26.3**	**2**	**1.1**	**17**	**9.1**

Table 57. Training in knowledge areas- CRAs (n=31)

Areas of Knowledge		Training						No Response	
		Not received		At Graduation		On the Job			
		n	%	n	%	n	%	n	%
General	Scope of Clinical Research	9	29.0	0	0.0	12	38.7	10	32.3
	Orientation to Pharmaceutical Industry	7	22.6	0	0.0	16	51.6	8	25.8
	Drug development process	2	6.5	0	0.0	19	61.3	10	32.3
	Total of topics in General Module	**18**	**19.4**	**0**	**0.0**	**47**	**50.5**	**28**	**30.1**
Ethics	Biomedical ethics- History and principles	2	6.5	2	6.5	20	64.5	7	22.6
	ICH GCP and national GCP guidelines	1	3.2	0	0.0	23	74.2	7	22.6
	EC composition and function- ICMR and ICH guidelines	0	0.0	0	0.0	26	83.9	5	16.1
	Informed consent process- principles and practice	0	0.0	0	0.0	25	80.6	6	19.4
	Total of topics in Ethics Module	**3**	**2.4**	**2**	**1.6**	**94**	**75.8**	**25**	**20.2**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	6	19.4	0	0.0	19	61.3	6	19.4
	Regulations relating to IP labelling and import	5	16.1	0	0.0	19	61.3	7	22.6
	Regulations regarding safety and pharmacovigilance	3	9.7	0	0.0	22	71.0	6	19.4
	Total of topics in Regulations Module	**14**	**15.1**	**0**	**0.0**	**60**	**64.5**	**19**	**20.4**
Methodology	Framing a research proposal/protocol and experimental design	11	35.5	0	0.0	13	41.9	7	22.6
	Writing investigators brochure	15	48.4	0	0.0	9	29.0	7	22.6
	Designing case report forms and EDCs	16	51.6	0	0.0	9	29.0	6	19.4
	Writing informed consent and Patient information sheet	11	35.5	0	0.0	13	41.9	7	22.6
	Writing study reports and publication	12	38.7	0	0.0	12	38.7	7	22.6
	SOP writing	13	41.9	0	0.0	11	35.5	7	22.6
	Conducting PK studies	22	71.0	0	0.0	2	6.5	7	22.6
	Total of topics in Methodology Module	**100**	**46.1**	**0**	**0.0**	**69**	**31.8**	**48**	**22.1**
DM and Stats	Types of data and statistical tests for clinical trials	22	71.0	0	0.0	2	6.5	7	22.6
	Statistical considerations at the design, execution and analysis	19	61.3	0	0.0	6	19.4	6	19.4
	Data Coding and cleaning	25	80.6	0	0.0	0	0.0	6	19.4
	Software considerations in Data Management	22	71.0	0	0.0	0	0.0	9	29.0
	Total of topics in DM & Stats Module	**88**	**71.0**	**0**	**0.0**	**8**	**6.5**	**28**	**22.6**
Clinical Trial execution	Monitoring a clinical study	0	0.0	0	0.0	23	74.2	8	25.8
	Project Management in clinical research	9	29.0	0	0.0	14	45.2	8	25.8
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	11	35.5	0	0.0	12	38.7	8	25.8
	Audits and inspection	0	0.0	0	0.0	22	71.0	9	29.0
	Clinical trial supplies management	0	0.0	0	0.0	22	71.0	9	29.0
	Pharmacovigilance and safety management	0	0.0	0	0.0	21	67.7	10	32.3
	Total of topics in Clinical Trial execution Module	**20**	**10.8**	**0**	**0.0**	**114**	**61.3**	**52**	**28.0**

C. Depth of training received (Table 58)

Modules- Grade wise total of all the topics within each module shows-

- 22-23 respondents reported to be trained in 4 of the 6 sub-topics in the CT execution module at 'awareness' or 'knowledge' level. None reported 'competence' level.
- Of the 31 CRAs, 22-26 (71%-84%) reported to be trained in the Ethics module. Majority (7-11) of them reporting 'awareness' level of training. 11 CRAs, reported 'competence' level of training in *EC composition and function-ICMR and ICH guidelines* sub-topic.
- 19-22 of the 31 CRAs reported to be trained in the Regulations module, where they reported awareness level (40%) and knowledge level (46.7%).
- Maximum number of respondents rated an 'awareness' level of depth of knowledge for all modules.

D. Requirement for training in these knowledge areas is shown in Table 59.

Modules-

- 50% or more respondents reported training requirement in 3 of the sub topics of the Ethics module and all the sub topics in the regulations (65.6%) modules.

Knowledge items-

- Project management in clinical research was a sub topic rated by 50% and more respondents as training required. The rest of the sub topics in the execution module were marked required by 16.1% to 29% respondents.

No response ranged from 34.4% for the regulations module to 100% for the general module.

Table 58. Depth of training in knowledge areas- CRAs

Areas of Knowledge		Training received n (100%)	Rating							
			Awareness		Knowledge		Competence		No Response	
			n	%	n	%	n	%	n	%
General	Scope of Clinical Research	12	7	58.3	5	41.7	0	0.0	0	0.0
	Orientation to Pharmaceutical Industry	16	5	31.3	10	62.5	0	0.0	1	6.3
	Drug development process	19	5	26.3	11	57.9	0	0.0	3	15.8
	Total of topics in General Module	**47**	**17**	36.2	**26**	55.3	**0**	0.0	**4**	8.5
Ethics	Biomedical ethics- History and principles	22	11	50.0	9	40.9	0	0.0	2	9.1
	ICH GCP and national GCP guidelines	23	9	39.1	9	39.1	3	13.0	2	8.7
	EC composition and function- ICMR and ICH guidelines	26	9	34.6	3	11.5	11	42.3	3	11.5
	Informed consent process- principles and practice	25	7	28.0	12	48.0	5	20.0	1	4.0
	Total of topics in Ethics Module	**96**	**36**	37.5	**33**	34.4	**19**	19.8	**8**	8.3
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	19	11	57.9	6	31.6	0	0.0	2	10.5
	Regulations relating to IP labelling and import	19	6	31.6	8	42.1	0	0.0	5	26.3
	Regulations regarding safety and pharmacovigilance	22	7	31.8	14	63.6	0	0.0	1	4.5
	Total of topics in Regulations Module	**60**	**24**	40.0	**28**	46.7	**0**	0.0	**8**	13.3
Methodology	Framing a research proposal/protocol and experimental design	13	9	69.2	2	15.4	0	0.0	2	15.4
	Writing investigators brochure	9	7	77.8	2	22.2	0	0.0	0	0.0
	Designing case report forms and EDCs	9	5	55.6	0	0.0	0	0.0	4	44.4
	Writing informed consent and Patient information sheet	13	9	69.2	0	0.0	0	0.0	4	30.8
	Writing study reports and publication	12	9	75.0	0	0.0	0	0.0	3	25.0
	SOP writing	11	9	81.8	0	0.0	0	0.0	2	18.2
	Conducting PK studies	2	2	100.0	0	0.0	0	0.0	0	0.0
	Total of topics in Methodology Module	**69**	**50**	72.5	**4**	5.8	**0**	0.0	**15**	21.7
DM and Stats	Types of data and statistical tests for clinical trials	2	1	50.0	0	0.0	0	0.0	1	50.0
	Statistical considerations at the design, execution and analysis	6	3	50.0	0	0.0	0	0.0	3	50.0
	Data Coding and cleaning	0	0		0		0		0	
	Software considerations in Data Management	0	0		0		0		0	
	Total of topics in DM & Stats Module	**8**	**4**	50.0	**0**	0.0	**0**	0.0	**4**	50.0
Clinical Trial execution	Monitoring a clinical study	23	8	34.8	15	65.2	0	0.0	0	0.0
	Project Management in clinical research	14	6	42.9	7	50.0	0	0.0	1	7.1
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	12	8	66.7	2	16.7	0	0.0	2	16.7
	Audits and inspection	22	15	68.2	4	18.2	0	0.0	3	13.6
	Clinical trial supplies management	22	12	54.5	7	31.8	0	0.0	3	13.6
	Pharmacovigilance and safety management	21	17	81.0	2	9.5	0	0.0	2	9.5
	Total of topics in Clinical Trial execution Module	**114**	**66**	57.9	**37**	32.5	**0**	0.0	**11**	9.6

Table 59. Requirement for training in knowledge areas-CRAs (n=31)

Areas of Knowledge		Training Requirement						No Response	
		Required		Not required		Unsure			
		n	%	n	%	n	%	n	%
General	Scope of Clinical Research	0	0.0	0	0.0	0	0.0	31	100.0
	Orientation to Pharmaceutical Industry	0	0.0	0	0.0	0	0.0	31	100.0
	Drug development process	0	0.0	0	0.0	0	0.0	31	100.0
	Total of topics in General Module	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**	**93**	**100.0**
Ethics	Biomedical ethics- History and principles	0	0.0	0	0.0	0	0.0	31	100.0
	ICH GCP and national GCP guidelines	19	61.3	0	0.0	0	0.0	12	38.7
	EC composition and function- ICMR and ICH guidelines	19	61.3	0	0.0	0	0.0	12	38.7
	Informed consent process- principles and practice	22	71.0	0	0.0	0	0.0	9	29.0
	Total of topics in Ethics Module	**60**	**48.4**	**0**	**0.0**	**0**	**0.0**	**64**	**51.6**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	20	64.5	0	0.0	0	0.0	11	35.5
	Regulations relating to IP labelling and import	19	61.3	0	0.0	0	0.0	12	38.7
	Regulations regarding safety and pharmacovigilance	22	71.0	0	0.0	0	0.0	9	29.0
	Total of topics in Regulations Module	**61**	**65.6**	**0**	**0.0**	**0**	**0.0**	**32**	**34.4**
Methodology	Framing a research proposal/protocol and experimental design	12	38.7	0	0.0	0	0.0	19	61.3
	Writing investigators brochure	11	35.5	0	0.0	0	0.0	20	64.5
	Designing case report forms and EDCs	13	41.9	2	6.5	0	0.0	16	51.6
	Writing informed consent and Patient information sheet	12	38.7	0	0.0	0	0.0	19	61.3
	Writing study reports and publication	11	35.5	0	0.0	0	0.0	20	64.5
	SOP writing	14	45.2	0	0.0	0	0.0	17	54.8
	Conducting PK studies	6	19.4	3	9.7	0	0.0	22	71.0
	Total of topics in Methodology Module	**79**	**36.4**	**5**	**2.3**	**0**	**0.0**	**133**	**61.3**
DM and Stats	Types of data and statistical tests for clinical trials	14	45.2	2	6.5	0	0.0	15	48.4
	Statistical considerations at the design, execution and analysis	11	35.5	2	6.5	0	0.0	18	58.1
	Data Coding and cleaning	8	25.8	3	9.7	0	0.0	20	64.5
	Software considerations in Data Management	11	35.5	0	0.0	0	0.0	20	64.5
	Total of topics in DM & Stats Module	**44**	**35.5**	**7**	**5.6**	**0**	**0.0**	**73**	**58.9**
Clinical Trial execution	Monitoring a clinical study	5	16.1	0	0.0	0	0.0	26	83.9
	Project Management in clinical research	16	51.6	0	0.0	0	0.0	15	48.4
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	9	29.0	0	0.0	0	0.0	22	71.0
	Audits and inspection	7	22.6	0	0.0	0	0.0	24	77.4
	Clinical trial supplies management	7	22.6	0	0.0	0	0.0	24	77.4
	Pharmacovigilance and safety management	9	29.0	0	0.0	0	0.0	22	71.0
	Total of topics in Clinical Trial execution Module	**53**	**28.5**	**0**	**0.0**	**0**	**0.0**	**133**	**71.5**

4.2.3.3 Skills:

A. Grading of Importance of Skills (Table 60)

- All the skills were rated 'critical' by 50% or more respondents.
- Presentation (74.2%), communication skills (74.2%) and interpersonal skills received the maximum 'critical' ratings (67.7%).

B. Training received in these skills (Table 61)

- Of the 31 CRAs, 17-20 (54.8% to 64.5%) had not received training in most of the skills, highest (20), being for leadership and negotiation skills.
- Training received was highest in communication skills (48.4%), computing (29%), and presentation skills (22.6%).

No response ranged from 19.4% to 38.7%.

C. Depth of training received (Table 62)

- 6 of 7 respondents who were trained in team work, reported 'awareness' level.
- 'Competence' was reported by maximum respondents (10/12) in computing skills training, 7 of 13 trained in presentation skills and 3 of 11 trained in communication skills

D. Requirement for training (Table 63)

- The highest number required conflict management training (16.1%), interpersonal skills (9.7%) and leadership skills (9.7%).

No response ranged from 77.4% in leadership skills to 100% in computing and presentation skills.

Table 60. Rating of Importance of skills – CRAs (n=31)

Skills	Number of responses						No Response	
	Critical		Important		Not Important			
	n	%	n	%	n	%	n	%
Leadership skills	17	54.8	11	35.5	3	9.7	0	0.0
Team work	19	61.3	10	32.3	2	6.5	0	0.0
Negotiation skills	18	58.1	8	25.8	5	16.1	0	0.0
Conflict management	19	61.3	8	25.8	4	12.9	0	0.0
Interpersonal skills	21	67.7	7	22.6	3	9.7	0	0.0
Computing skills	20	64.5	11	35.5	0	0.0	0	0.0
Presentation skills	23	74.2	7	22.6	0	0.0	1	3.2
Communication skills	23	74.2	7	22.6	0	0.0	1	3.2

Table 61. Training received in skills – CRAs (n=31)

Skills	Number of responses						No Response	
	Not received		Received at					
	n	%	Graduation		On the job		n	%
			n	%	n	%		
Leadership skills	20	64.5	0	0.0	0	0.0	11	35.5
Team work	18	58.1	3	9.7	4	12.9	6	19.4
Negotiation skills	20	64.5	0	0.0	0	0.0	11	35.5
Conflict management	19	61.3	0	0.0	0	0.0	12	38.7
Interpersonal skills	17	54.8	0	0.0	4	12.9	10	32.3
Computing skills	9	29.0	12	38.7	0	0.0	10	32.3
Presentation skills	7	22.6	6	19.4	7	22.6	11	35.5
Communication skills	15	48.4	2	6.5	9	29.0	5	16.1

Table 62. Depth of Skills training received – CRAs

Skills	Number of responses				No Response
	Training received	Awareness	Knowledge	Competence	
Leadership skills	0	0	0	0	0
Team work	7	6	0	0	1
Negotiation skills	0	0	0	0	0
Conflict management	0	0	0	0	0
Interpersonal skills	4	4	0	0	0
Computing skills	12	1	1	10	0
Presentation skills	13	4	2	7	0
Communication skills	11	5	3	3	0

Table 63. Requirement of Skills training – CRAs (n=31)

Skills	Number of responses						No Response	
	Required		Not required		Unsure			
	n	%	n	%	n	%	n	%
Leadership skills	3	9.7	0	0.0	4	12.9	24	77.4
Team work	2	6.5	0	0.0	0	0.0	29	93.5
Negotiation skills	2	6.5	0	0.0	1	3.2	28	90.3
Conflict management	5	16.1	0	0.0	0	0.0	26	83.9
Interpersonal skills	3	9.7	0	0.0	0	0.0	28	90.3
Computing skills	0	0.0	0	0.0	0	0.0	31	100.0
Presentation skills	0	0.0	0	0.0	0	0.0	31	100.0
Communication skills	1	3.2	0	0.0	0	0.0	30	96.8

4.2.3.4 Discussions- CRA role

In our survey, we found the rating of importance for the different modules is in line with their job expectations. The Ethics module was rated as 'critical' by the highest number of respondents. Highest number of respondents (74.2%) rated the sub-topics of *EC composition and function- ICMR and ICH guidelines, Informed consent process- principles and practise* and *Monitoring a clinical study* as 'critical', which is very reassuring considering these are the most stressed upon areas in monitoring.

Most of the respondents who were trained, reported to have received on the job training and this ranged from 75.8% in the Ethics module, 64.5% Regulatory module and 61.3% in Execution module. However, it was disheartening to note that most of the CRAs reported only 'awareness' level of training, excepting 11 CRAs who reported 'competence' level in *EC composition and function-ICMR and ICH guidelines* sub-topic. Training received was lowest in the Data management and Statistics module (6.5%), obviously because CRAs are not involved in data management activities.

As expected, highest number of respondents (65.6%) reported training required for the Regulations module. Also more than 50% respondents rating project management in clinical research is very much on expected lines as CRAs, look to project manager's role as a career growth option. There were no takers for the general module and the basic ethics sub topic of history and evolution, once again indicating the requirement of training being progressive to the next level. It was reassuring to note that Regulations regarding *Safety and Pharmacovigilance* was rated by the highest number of respondents (71%) as training required reinforcing their commitment to safety reporting which is an area of concern often in countries like India.

A comparison of the trends we observed in stakeholders and role holders rating of knowledge modules for the CRA is as follows-

Table 64. Stakeholder and role holder responses for knowledge areas- CRA

Roles/Modules	General	Ethics	Regulatory	Methodology	DM & Stats	CT execution
CRA (Stakeholders)	C	C	I	-	-	C
CRA (Role holders)	C	C	C	N	N	C

The methodology and DM & stat module being rated 'not important' by CRA role holders, while no clear trend emerged as in 50% or more stakeholders rating for these 2 modules. Most of the sub-topics in the methodology module (except *Writing study reports and publications* and *Conducting PK studies*) are about the structuring, planning and set-up phase of clinical trials and 'not important' rating to these by roles holders leads us to suspect a larger emphasises on operations or implementation.

Majority of respondents in our survey rated skills as 'critical' to performance with presentation and communication skills receiving the maximum 'critical' ratings. All respondents reported to have been trained in team work and interpersonal skills.

Table 65. Stakeholder and role holder responses for skills- CRAs.

Roles/Skills	Leadership	Team work	Negotiation	Conflict Mgt	Interpersonal	Computing	Presentation	Communications
CRA (stakeholders)	-	C	C	C	C	C	C	C
CRA (Role holders)	C	C	C	C	C	C	C	C

Both stakeholders and role holders seem to uniformly agree on the importance of the various skills for the role of CRA except leadership skills, where no clear trends emerge from stakeholders and role holders rate this as 'critical'.

Increasingly, the role is being looked as from the perspective of what needs to be accomplished for success of the trial and hence CRA has been portrayed as trainer, negotiator, facilitator and communicator. [77]. With increasing focus on site relationships

as fundamental to trial success and the CRA being key to this, the evolution of his traditional role of compliance monitor to a new one of site relationship builder is being discussed [78]. The traditional role had requirements for knowledge of protocol, GCPs, data collection, therapeutic area and medical terminology. The new transformed role demands customer service principles, proactive patient recruitment/retention planning and site performance management as knowledge base. Zimmerman [79] includes skills in using and troubleshooting hardware- computers, peripherals and other office apparatus and knowledge of multiple software programs- standard word processing database, project management, productivity programs and custom designed intranet software program as important competencies in preparing CRAs for the 21st century.

The challenge to define the training requirements of this role can be understood from the predicament that even the Association of Clinical Research Professionals (ACRP), the leading certifier of CRAs for the last several years, is still trying to define what the minimum education and training requirements for CRAs ought to be [80].

Other roles:

4.2.4 Ethics Committee members

Table 66 shows the demographic details of the EC members group. Majority of them (76.4%) were graduates. Their average age was 36.4 years. 58.8% reported that their education adequately prepared them for their job and 41.1% reported that their employment experience prepared them adequately for the job.

Table 67 to Table 70 shows the Grading of Importance of Knowledge, Training received, Depth of training received and Requirement for training in knowledge areas for EC members.

- Gradewise total of the items in each module shows that 50% or more respondents rated the general, ethics and regulatory modules as 'critical'.
- In addition, the following subtopics were rated 'critical' by 50% and more respondents-
    - writing investigator's brochure,
    - writing informed consent form and patient information sheet,
    - writing study reports and publication
    - SOP writing
    - Legal issues in clinical research
    - Audits and inspection
- 50% or more respondents received training in all the sub topics of the general, and ethics module and the sub topic of *Regulations regarding safety and pharmacovigilance*.
- Most of training received was on the job.
- Most of the respondents who received training reported 'awareness' level for the depth. 'Knowledge' level of depth was reported by 4-8 of the 14-15 trained respondents in all the items of the Ethics module.
- 1-7 respondents rated all the items across modules as requirement for training.

Table 71 to Table 74 shows the Grading of Importance of Skills, Training received, Depth of training received and Requirement for training in these areas for EC members.

- All the skills, except leadership skills and negotiation skills were rated critical by 50% or more respondents.
- Majority of respondents were not trained in the skills. Only 2 respondents reported to have received training in computing skills at graduation.
- Training requirement was reported by 5 respondents for team work, 4 each for conflict management and 3 for negotiation skills.

Table 66. Demography of Ethics Committee members (n=17)

1	**Sex**	**n**
	Males	8
	Females	9
	Average Age	36.4 yrs
2	**Qualification**	**n**
	Graduation	**13**
	B. Pharm	2
	B. Sc	2
	Alternate Medicine (BAMS)	2
	MBBS	1
	Others (BA-3, LLB-2, Diploma-1)	6
	Post graduation	**4**
	M. Pharm	1
	Alternate Medicine (BAMS)	1
	Others (MCom-1, MBA-1)	2
3	**Employment status**	**n**
	Employed	
	• In CR	9
	• Other	8
4	**Type of organisation**	**n**
	• Hospital	8
	• MNC Pharma	1
	• SMO	1
	• Others	7
5	**Clinical Research Experience**	**n**
	• One year or less	8
	• 1-3 years	7
	• 3-5 years	2
6	**Education preparing for current job**	**n**
	• Very well	1
	• Adequately	10
	• Poorly	1
	• Education unrelated	5
7	**Employment experience preparing for current job**	**n**
	• Very well	4
	• Adequately	7
	• Poorly	1
	• Employment unrelated	5

Table 67. Importance of knowledge areas-EC members (n=17)

Areas of Knowledge		Rating			No Response
		Critical	Important	Not Important	
General	Scope of Clinical Research	12	2	2	1
	Orientation to Pharmaceutical Industry	12	5	0	0
	Drug development process	14	2	1	0
	Total of topics in General Module	**38**	**9**	**3**	**1**
Ethics	Biomedical ethics- History and principles	14	3	0	0
	ICH GCP and national GCP guidelines	13	4	0	0
	EC composition and function- ICMR and ICH guidelines	14	3	0	0
	Informed consent process- principles and practice	15	2	0	0
	Total of topics in Ethics Module	**56**	**12**	**0**	**0**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	13	4	0	0
	Regulations relating to IP labelling and import	13	2	2	0
	Regulations regarding safety and pharmacovigilance	12	2	2	1
	Total of topics in Regulations Module	**38**	**8**	**4**	**1**
Methodology	Framing a research proposal/protocol and experimental design	8	7	1	1
	Writing investigators brochure	9	6	1	1
	Designing case report forms and EDCs	5	9	2	1
	Writing informed consent and Patient information sheet	9	7	0	1
	Writing study reports and publication	9	8	0	0
	SOP writing	10	7	0	0
	Conducting PK studies	5	12	0	0
	Total of topics in Methodology Module	**55**	**56**	**4**	**4**
DM and Stats	Types of data and statistical tests for clinical trials	7	5	4	1
	Statistical considerations at the design, execution and analysis	6	8	3	0
	Data Coding and cleaning	6	6	3	2
	Software considerations in Data Management	5	7	3	2
	Total of topics in DM & Stats Module	**24**	**26**	**13**	**5**
Clinical Trial execution	Monitoring a clinical study	8	7	2	0
	Project Management in clinical research	7	8	2	0
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	9	8	0	0
	Audits and inspection	11	5	0	1
	Clinical trial supplies management	6	9	2	0
	Pharmacovigilance and safety management	8	4	4	1
	Total of topics in Clinical Trial execution Module	**49**	**41**	**10**	**2**

Table 68. Training received in knowledge areas- EC members (n=17)

Areas of Knowledge		Training			No Response
		Not received	Received		
			At Graduation	On the Job	
General	Scope of Clinical Research	7	0	9	1
	Orientation to Pharmaceutical Industry	4	0	9	4
	Drug development process	2	0	11	4
	Total of topics in General Module	**13**	**0**	**29**	**9**
Ethics	Biomedical ethics- History and principles	0	2	13	2
	ICH GCP and national GCP guidelines	0	0	14	3
	EC composition and function- ICMR and ICH guidelines	0	0	15	2
	Informed consent process- principles and practice	0	1	13	3
	Total of topics in Ethics Module	**0**	**3**	**55**	**10**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	7	0	5	5
	Regulations relating to IP labelling and import	6	0	8	3
	Regulations regarding safety and pharmacovigilance	0	0	9	8
	Total of topics in Regulations Module	**13**	**0**	**22**	**16**
Methodology	Framing a research proposal/protocol and experimental design	3	0	5	9
	Writing investigators brochure	6	0	6	5
	Designing case report forms and EDCs	7	0	2	8
	Writing informed consent and Patient information sheet	5	0	8	4
	Writing study reports and publication	7	0	3	7
	SOP writing	4	0	2	11
	Conducting PK studies	7	0	0	10
	Total of topics in Methodology Module	**39**	**0**	**26**	**54**
DM and Stats	Types of data and statistical tests for clinical trials	10	0	1	6
	Statistical considerations at the design, execution and analysis	8	0	1	8
	Data Coding and cleaning	9	0	0	8
	Software considerations in Data Management	9	0	1	7
	Total of topics in DM & Stats Module	**36**	**0**	**3**	**29**
Clinical Trial execution	Monitoring a clinical study	9	0	1	7
	Project Management in clinical research	8	0	1	8
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	9	0	3	5
	Audits and inspection	8	0	7	2
	Clinical trial supplies management	8	0	5	4
	Pharmacovigilance and safety management	8	0	6	3
	Total of topics in Clinical Trial execution Module	**50**	**0**	**23**	**29**

Table 69. Depth of training in knowledge areas- EC members

Areas of Knowledge		Total trained	Rating			No Response
			Awareness	Knowledge	Competence	
General	Scope of Clinical Research	9	5	2	0	2
	Orientation to Pharmaceutical Industry	9	2	2	0	5
	Drug development process	11	5	0	0	6
	Total of topics in General Module	**29**	**12**	**4**	**0**	**13**
Ethics	Biomedical ethics- History and principles	15	7	4	0	4
	ICH GCP and national GCP guidelines	14	6	4	0	4
	EC composition and function- ICMR and ICH guidelines	15	5	7	0	3
	Informed consent process- principles and practice	14	3	8		3
	Total of topics in Ethics Module	**58**	**21**	**23**	**0**	**14**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	5	3	0	0	2
	Regulations relating to IP labelling and import	8	5	2	0	1
	Regulations regarding safety and pharmacovigilance	9	7	0	0	2
	Total of topics in Regulations Module	**22**	**15**	**2**	**0**	**5**
Methodology	Framing a research proposal/protocol and experimental design	5	3	0	0	2
	Writing investigators brochure	6	2	0	0	4
	Designing case report forms and EDCs	2	1	0	0	1
	Writing informed consent and Patient information sheet	8	5	0	0	3
	Writing study reports and publication	3	2	0	0	1
	SOP writing	2	2	0	0	0
	Conducting PK studies	0	0	0	0	0
	Total of topics in Methodology Module	**26**	**15**	**0**	**0**	**11**
DM and Stats	Types of data and statistical tests for clinical trials	1	0	0	0	1
	Statistical considerations at the design, execution and analysis	1	0	0	0	1
	Data Coding and cleaning	0	0	0	0	0
	Software considerations in Data Management	1	0	0	0	1
	Total of topics in DM & Stats Module	**3**	**0**	**0**	**0**	**3**
Clinical Trial execution	Monitoring a clinical study	1	0	0	0	1
	Project Management in clinical research	1	0	0		1
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	3	1	0	0	2
	Audits and inspection	7	2	1	0	4
	Clinical trial supplies management	5	2	0	0	3
	Pharmacovigilance and safety management	6	2	0	0	4
	Total of topics in Clinical Trial execution Module	**23**	**7**	**1**	**0**	**15**

Table 70. Requirement for training in knowledge areas- EC members (n=17)

Areas of Knowledge		Training Requirement			No Response
		Required	Not required	Unsure	
General	Scope of Clinical Research	5	0	0	12
	Orientation to Pharmaceutical Industry	6	0	0	11
	Drug development process	7	0	0	10
	Total of topics in General Module	**18**	**0**	**0**	**33**
Ethics	Biomedical ethics- History and principles	5	0	0	12
	ICH GCP and national GCP guidelines	6	0	0	11
	EC composition and function- ICMR and ICH guidelines	7	0	0	10
	Informed consent process- principles and practice	4	0	0	13
	Total of topics in Ethics Module	**22**	**0**	**0**	**46**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	5	0	0	12
	Regulations relating to IP labelling and import	5	0	0	12
	Regulations regarding safety and pharmacovigilance	6	0	0	11
	Total of topics in Regulations Module	**16**	**0**	**0**	**35**
Methodology	Framing a research proposal/protocol and experimental design	3	0	0	14
	Writing investigators brochure	4	0	0	13
	Designing case report forms and EDCs	2	0	0	15
	Writing informed consent and Patient information sheet	4	0	0	13
	Writing study reports and publication	1	0	0	16
	SOP writing	4	0	0	13
	Conducting PK studies	5	0	0	12
	Total of topics in Methodology Module	**23**	**0**	**0**	**96**
DM and Stats	Types of data and statistical tests for clinical trials	4	0	0	13
	Statistical considerations at the design, execution and analysis	6	0	0	11
	Data Coding and cleaning	7	0	0	10
	Software considerations in Data Management	4	0	0	13
	Total of topics in DM & Stats Module	**21**	**0**	**0**	**47**
Clinical Trial execution	Monitoring a clinical study	5	0	0	12
	Project Management in clinical research	6	0	0	11
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	7	0	0	10
	Audits and inspection	6	0	0	11
	Clinical trial supplies management	5	0	0	12
	Pharmacovigilance and safety management	7	0	0	10
	Total of topics in Clinical Trial execution Module	**36**	**0**	**0**	**66**

Table 71. Grading of importance of skills – Ethics Committee Members (n=17)

Skills	Number of responses			No Response
	Critical	Important	Not Important	
Leadership skills	8	5	2	2
Team work	9	3	0	5
Negotiation skills	8	4	1	4
Conflict management	9	4	0	4
Interpersonal skills	10	3	0	4
Computing skills	10	3	0	4
Presentation skills	9	4	0	4
Communication skills	9	4	0	4

Table 72. Training received in skills – Ethics Committee Members (n=17)

Skills	Number of responses			No Response
	Not received	Received at		
		Graduation	On the job	
Leadership skills	5	0	0	12
Team work	4	0	0	13
Negotiation skills	5	0	0	12
Conflict management	4	0	0	13
Interpersonal skills	5	0	0	12
Computing skills	4	2	0	11
Presentation skills	4	0	0	13
Communication skills	3	0	0	14

Table 73. Depth of Skills Training received – EC members

Skills	Number of responses				No Response
	Training received	Awareness	Knowledge	Competence	
Leadership skills	0	0	0	0	0
Team work	0	0	0	0	0
Negotiation skills	0	0	0	0	0
Conflict management	0	0	0	0	0
Interpersonal skills	0	0	0	0	0
Computing skills	2	2	0	0	0
Presentation skills	0	0	0	0	0
Communication skills	0	0	0	0	0

Table 74. Requirement of Skills training – EC members (n=17)

Skills	Number of responses			No Response
	Required	Not Required	Unsure	
Leadership skills	0	0	1	16
Team work	5	0	0	12
Negotiation skills	3	0	0	14
Conflict management	4	0	0	13
Interpersonal skills	4	0	0	13
Computing skills	0	0	0	17
Presentation skills	0	0	0	17
Communication skills	0	0	0	17

Discussion- Ethics Committee (EC) members' role.

The Schedule Y stipulates the composition of the Ethics committee to be as at least 7 members and a mix of medical and non medical, scientific and non scientific persons, including lay public to reflect different viewpoints. Our survey respondents had varied qualifications, including 6 non science graduates. However, no lay person was there. All our survey respondents reported to have received training in the Ethics module and they rated the training at awareness or knowledge level. Only 5-9 respondents reported to be trained in the Regulations module and this too mostly at awareness level. Being in an important decision making capacity, the EC members should be expected to have sound understanding of ethics and regulatory module. Increasingly, drug development is moving towards more complex molecules and even more complex protocols. Which ethics committee members should be able to review and evaluate. This may require them to have sufficient understanding of methodological aspects as well. It was heartening to see that 12 respondents had rated the regulations relating to pharmacovigilance and safety management as 'critical' and as many as 9 had received training on this topic. Protecting the rights and well being of the patient and being aware of the regulatory provision and timelines for safety reporting is critical to this.

9 respondents rated Legal issues in clinical research as 'critical' and 8 as 'important'. However, only 3 had received training in this aspect and it has been rated as one of training requirements by highest number of respondents.

8-10 respondents rated the various skills as 'critical' to the role, but only 2 of them reported to have received training in any skill, in this case computing skills. Considering that it is collective wisdom that prevails in decision making of ethics committee, it was easy to understand that Team work was rated by highest number of respondents as training requirement.

The international scenario in EC training is fast moving to structured training in various levels. Nell [81] has identified the following knowledge and skills –

General aspects of clinical research and scientific practise, ethics and GCP and other regulations, evidence based medicine, biostatistics and

specific aspects of special patient populations, therapy areas and trial types.

This is proposed to be covered in a two-tier training system starting with basic training and then specific training. Chadwick [82] also refers to 3 levels of training-

- The Institutional official level of understanding ethical basis
- The EC members training for good grasp of ethical basis and approval
- A third level for the EC chair with working knowledge of ethical basis and the regulations for EC operation
- The expert level of training for EC staff

Collis sums up the Latin American experience [83] by saying that EC training should be developed in each country and adapted to the particular idiosyncrasy of each country.

A survey by ICMR, on the ethics committee review in India [84] showed that decision making by EC members was by consensus / majority approach and the competence of the ethics committee was questionable. Nigel [85] describes the training efforts that organisations like ICMR are taking in training ethics committees. However, training initiatives for non-academic institutions is still largely non-standardised and industry led.

Stakeholders rating of importance of modules were very similar to the role holders rating. Ethics module received critical ratings and the sub topics SOP writing, Legal issues in clinical research and Audits and inspection were rated critical by both. Stakeholders also rated the CT execution module as 'important' for this role, probably because they felt that EC members should know how in reality the clinical trial takes place and an understanding of these execution aspects will help in review of the trials. Stakeholders rated team work as critical, while role holders rated all the skills except leadership and negotiation skills, probably because they were unable to differentiate what is important to the role.

4.2.5 Project Physicians

Table 75 shows the demographic details of the Project Physicians group. The group had 7 males and 4 females with an average age of 32.4 years. There were 8 graduates and three post-graduates. 7 of them worked in the pharmaceutical industry. Majority (8 of 11) had less than 3 years of clinical research experience. 10 reported that their education prepared them very well or adequately for the job and all 11 felt their employment experience prepared them well for the job.

Table 76 to Table 79 shows the Grading of Importance of Knowledge, Training received, Depth of training received and Requirement for training in knowledge areas.

- Gradewise total of the items in each module shows that all the modules except the Data management and statistics module were rated 'critical'
- In addition, two sub –topics in the data management and statistics module-*Types of data and statistical test for clinical trials* and *Statistical considerations at the design, execution and analysis stage* were rated 'critical'.
- Majority of respondents were not trained. The highest reported training was 4-5 respondents in the Regulations module, followed by the Ethics module (3-5 respondents).
- Most of the training was reported to be done on the job and at 'awareness' level.
- One respondent each rated training in *EC composition and function-ICMR and ICH guidelines* and *Informed consent process – principles and practise* at 'knowledge' level.
- Training required was marked by only 2-4 respondents across all topics.

Table 80 to Table 83 shows the Grading of Importance of Skills, Training received, Depth of training received and Requirement for training in these areas for Project Physicians.

- Using 50% response as a cut off, team work, conflict management, computing skills, presentation skills and communication skills were 'critical' for the role
- Leadership skills and conflict management were rated by 5 respondents as training not received.
- Depth of training was rated as awareness level by 2 respondents. One respondent each for 'knowledge' and 'competence' level for computing skills training.
- Five respondents rated leadership skills and four each rated team work, negotiation skills, interpersonal skills and presentation skills as training requirements.

Table 75. Demography- Project Physicians (n=11)

1	**Sex**	**11**
	• Males	7
	• Females	4
	Average Age	32.4 yrs
2	**Qualification**	
	• Graduation	**8**
	MBBS	7
	B. Pharm	1
	• Post graduation	**3**
	M. Sc	1
	Others (PGDCR, Bioinformatics)	2
3	**Employment status**	**11**
	• Employed	
	○ In CR	11
4.	**Type of organisation**	**11**
	• MNC Pharma	4
	• Indian Pharma	3
	• CRO- Indian origin	2
	• SMO	1
	• MNC CRO	1
5	**Experience**	**11**
	• One year or less	4
	• 1-3 years	4
	• 3-5 years	1
	• More than 5 years	2
6	**Education preparing for current job**	**11**
	• Very well	5
	• Adequately	5
	• Poorly	1
7	**Employment experience preparing for current job**	**11**
	• Very well	6
	• Adequately	5

Table 76. Importance of knowledge areas-Project Physicians (n=11)

Areas of Knowledge		Rating			No Response
		Critical	Important	Not Important	
General	Scope of Clinical Research	7	3	0	1
	Orientation to Pharmaceutical Industry	5	3	1	2
	Drug development process	7	3	0	1
	Total of topics in General Module	**19**	**9**	**1**	**4**
Ethics	Biomedical ethics- History and principles	6	2	0	3
	ICH GCP and national GCP guidelines	7	3	0	1
	EC composition and function- ICMR and ICH guidelines	7	2	0	2
	Informed consent process- principles and practice	5	3	0	3
	Total of topics in Ethics Module	**25**	**10**	**0**	**9**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	7	4	0	0
	Regulations relating to IP labelling and import	7	2	0	2
	Regulations regarding safety and pharmacovigilance	6	2	0	3
	Total of topics in Regulations Module	**20**	**8**	**0**	**5**
Methodology	Framing a research proposal/protocol and experimental design	7	3	0	1
	Writing investigators brochure	5	3	0	3
	Designing case report forms and EDCs	7	3	0	1
	Writing informed consent and Patient information sheet	5	3	0	3
	Writing study reports and publication	5	4	0	2
	SOP writing	7	3	0	1
	Conducting PK studies	3	6	0	2
	Total of topics in Methodology Module	**39**	**25**	**0**	**13**
DM and Stats	Types of data and statistical tests for clinical trials	7	3	0	1
	Statistical considerations at the design, execution and analysis	6	3	0	2
	Data Coding and cleaning	4	7	0	0
	Software considerations in Data Management	4	5	0	2
	Total of topics in DM & Stats Module	**21**	**18**	**0**	**5**
Clinical Trial execution	Monitoring a clinical study	7	3	0	1
	Project Management in clinical research	6	4	0	1
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	7	3	0	1
	Audits and inspection	7	4	0	0
	Clinical trial supplies management	7	2	0	2
	Pharmacovigilance and safety management	7	2	0	2
	Total of topics in Clinical Trial execution Module	**41**	**18**	**0**	**7**

Table 77. Training received in knowledge areas- Project Physicians (n=11)

Areas of Knowledge		Training			No Response
		Not received	Received		
			At Graduation	On the Job	
General	Scope of Clinical Research	4	0	3	4
	Orientation to Pharmaceutical Industry	4	0	3	4
	Drug development process	4	1	2	4
	Total of topics in General Module	**12**	**1**	**8**	**12**
Ethics	Biomedical ethics- History and principles	3	1	2	5
	ICH GCP and national GCP guidelines	3	1	3	4
	EC composition and function- ICMR and ICH guidelines	2	0	4	5
	Informed consent process- principles and practice	2	0	5	4
	Total of topics in Ethics Module	**10**	**2**	**14**	**18**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	2	0	5	4
	Regulations relating to IP labelling and import	3	0	4	4
	Regulations regarding safety and pharmacovigilance	2	0	5	4
	Total of topics in Regulations Module	**7**	**0**	**14**	**12**
Methodology	Framing a research proposal/protocol and experimental design	4	0	3	4
	Writing investigators brochure	4	0	3	4
	Designing case report forms and EDCs	5	0	2	4
	Writing informed consent and Patient information sheet	3	0	4	4
	Writing study reports and publication	3	2	2	4
	SOP writing	2	0	4	5
	Conducting PK studies	3	0	3	5
	Total of topics in Methodology Module	**24**	**2**	**21**	**30**
DM and Stats	Types of data and statistical tests for clinical trials	3	0	4	4
	Statistical considerations at the design, execution and analysis	4	0	3	4
	Data Coding and cleaning	4	0	2	5
	Software considerations in Data Management	4	0	2	5
	Total of topics in DM & Stats Module	**15**	**0**	**11**	**18**
Clinical Trial execution	Monitoring a clinical study	4	0	1	6
	Project Management in clinical research	4	0	3	4
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	3	0	2	6
	Audits and inspection	3	0	4	4
	Clinical trial supplies management	3	0	3	5
	Pharmacovigilance and safety management	4	0	2	5
	Total of topics in Clinical Trial execution Module	**21**	**0**	**15**	**30**

Table 78. Depth of training in knowledge areas- Project Physician

Areas of Knowledge		Total trained	Rating			No Response
			Awareness	Knowlge	Competence	
General	Scope of Clinical Research	3	2	0	0	1
	Orientation to Pharmaceutical Industry	3	3	0	0	0
	Drug development process	3	2	0	0	1
	Total of topics in General Module	**9**	**7**	**0**	**0**	**2**
Ethics	Biomedical ethics- History and principles	3	2	0	0	1
	ICH GCP and national GCP guidelines	4	2	0	0	2
	EC composition and function- ICMR and ICH guidelines	4	2	1	0	1
	Informed consent process- principles and practice	5	3	1	0	1
	Total of topics in Ethics Module	**16**	**9**	**2**	**0**	**5**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	5	3	0	0	2
	Regulations relating to IP labelling and import	4	2	1	0	1
	Regulations regarding safety and pharmacovigilance	5	3	0	0	2
	Total of topics in Regulations Module	**14**	**8**	**1**	**0**	**5**
Methodology	Framing a research proposal/protocol and experimental design	3	3	0	0	0
	Writing investigators brochure	3	2	0	0	1
	Designing case report forms and EDCs	2	1	0	0	1
	Writing informed consent and Patient information sheet	4	2	0	0	2
	Writing study reports and publication	4	2	0	0	2
	SOP writing	4	2	0	0	2
	Conducting PK studies	3	2	0	0	1
	Total of topics in Methodology Module	**23**	**14**	**0**	**0**	**9**
DM and Stats	Types of data and statistical tests for clinical trials	4	2	0	0	2
	Statistical considerations at the design, execution and analysis	3	2	0	0	1
	Data Coding and cleaning	2	1	0	0	1
	Software considerations in Data Management	2	1	0	0	1
	Total of topics in DM & Stats Module	**11**	**6**	**0**	**0**	**5**
Clinical Trial execution	Monitoring a clinical study	1	1	0	0	0
	Project Management in clinical research	3	2	0	0	1
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	2	1	0	0	1
	Audits and inspection	4	2	0	0	2
	Clinical trial supplies management	3	2	0	0	1
	Pharmacovigilance and safety management	2	1	0	0	1
	Total of topics in Clinical Trial execution Module	**15**	**9**	**0**	**0**	**6**

Table 79. Requirement for training in knowledge areas- Project Physicians (n=11)

Areas of Knowledge		Training Requirement			No Response
		Required	Not required	Unsure	
General	Scope of Clinical Research	2	0	0	9
	Orientation to Pharmaceutical Industry	3	0	0	8
	Drug development process	2	0	0	9
	Total of topics in General Module	**7**	**0**	**0**	**26**
Ethics	Biomedical ethics- History and principles	3	0	0	8
	ICH GCP and national GCP guidelines	2	0	0	9
	EC composition and function- ICMR and ICH guidelines	3	0	0	8
	Informed consent process- principles and practice	2	0	0	9
	Total of topics in Ethics Module	**10**	**0**	**0**	**34**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	3	0	0	8
	Regulations relating to IP labelling and import	3	0	0	8
	Regulations regarding safety and pharmacovigilance	3	0	0	8
	Total of topics in Regulations Module	**9**	**0**	**0**	**24**
Methodology	Framing a research proposal/protocol and experimental design	2	0	0	9
	Writing investigators brochure	2	0	0	9
	Designing case report forms and EDCs	2	0	0	9
	Writing informed consent and Patient information sheet	3	0	0	8
	Writing study reports and publication	3	0	0	8
	SOP writing	3	0	0	8
	Conducting PK studies	2	0	0	9
	Total of topics in Methodology Module	**17**	**0**	**0**	**60**
DM and Stats	Types of data and statistical tests for clinical trials	3	0	0	8
	Statistical considerations at the design, execution and analysis	4	0	0	7
	Data Coding and cleaning	2	0	0	9
	Software considerations in Data Management	2	0	0	9
	Total of topics in DM & Stats Module	**11**	**0**	**0**	**33**
Clinical Trial execution	Monitoring a clinical study	2	0	0	9
	Project Management in clinical research	3	0	0	8
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	3	0	0	8
	Audits and inspection	3	0	0	8
	Clinical trial supplies management	2	0	0	9
	Pharmacovigilance and safety management	2	0	0	9
	Total of topics in Clinical Trial execution Module	**15**	**0**	**0**	**51**

Table 80. Rating of Importance of skills – Project Physicians (n=11)

Skills	Number of responses			No Response
	Critical	Important	Not Important	
Leadership skills	5	1	0	5
Team work	6	2	0	3
Negotiation skills	5	2	0	4
Conflict management	6	2	0	3
Interpersonal skills	5	2	0	4
Computing skills	6	1	0	4
Presentation skills	6	1	0	4
Communication skills	6	1	0	4

Table 81. Training received in skills –Project Physicians (n=11)

Skills	Number of responses			No Response
	Not received	Received at		
		Graduation	On the job	
Leadership skills	5	0	0	6
Team work	2	0	2	7
Negotiation skills	4	0	0	7
Conflict management	5	0	0	6
Interpersonal skills	3	0	2	6
Computing skills	1	2	2	6
Presentation skills	2	0	2	7
Communication skills	2	0	2	7

Table 82. Depth of Skills Training received – Project Physicians

Skills	Number of responses				No Response
	Training received	Awareness	Knowledge	Competence	
Leadership skills	0	0	0	0	0
Team work	2	2	0	0	0
Negotiation skills	0	0	0	0	0
Conflict management	0	0	0	0	0
Interpersonal skills	2	2	0	0	0
Computing skills	4	2	1	1	0
Presentation skills	2	2	0	0	0
Communication skills	2	2	0	0	0

Table 83. Requirement of Skills training – Project Physicians (n=11)

Skills	Number of responses			No Response
	Required	Not Required	Unsure	
Leadership skills	5	0	0	6
Team work	4	0	0	7
Negotiation skills	4	0	0	7
Conflict management	2	0	0	9
Interpersonal skills	4	0	0	7
Computing skills	1	0	0	10
Presentation skills	4	0	0	7
Communication skills	2	0	0	9

Discussions- Project Physicians' role: The project physician's is expected to have medical training so as to be able to support the drug development program with the required focus on therapeutics. Contrary to general expectations, our project physician's group had three non- physicians. This is not very unexpected in the Indian context, considering how little medical graduates know about the clinical research career. The objective of the medicine course in India is heavily oriented towards therapeutics and very little training is done on training in research. Yet, 10 respondents felt their education prepared them very well or adequately for the job.

All the modules except DM and statistics module were rated 'critical' for this role, endorsing the importance of an overall exposure in the role. However, respondents were not trained in critical knowledge areas – 4 had not received training in *The drug development process, Framing a research proposal/protocol and experimental design, Writing an investigator's brochure* or *Pharmacovigilance and safety management.* 3 each were not trained in *Writing informed consent and patient information sheet; Writing study reports and publication and Types of data and statistical tests for clinical trials.* These are critical knowledge areas to the role

Most of those who were trained were done so on the job and they reported largely an awareness level of training. Only 2 respondents reported to be trained in the legal aspects of clinical research which is a very critical aspect of a Project physician's role.

Statistical considerations at the design, execution and conduct stage was marked as training requirement by 4 respondents.

It was interesting to analyse the responses for the data management and statistics module. Highest number of stakeholder respondents had marked this module as 'not important' for the role. However, 4-7 role holders rated this module as 'critical', 2-4 had received training, of which 2 were in the very niche activity of data coding and cleaning. This is probably because medical coding activity using MedDRA is better supported by a person with medical background.

Team work, conflict management, computing skills, presentation skills and

communication skills were ‘critical’ for the role, however, training was received only by 2 respondents each for team work, interpersonal skills, presentation skills and communication skills and by 4 for computing skills. The project physician’s role is different from the traditional role of a physician in that it demands more team work and project leadership to drive the drug development plan through its various phases Leadership skills has been identified as training requirement by 5 respondents.

The Faculty of pharmaceutical medicine, UK has over several years defined and refined the Diploma in Pharmaceutical Medicine and the Higher Medical Training Program in the speciality of pharmaceutical medicine for those physicians interested in a career in the pharmaceutical industry [56]. There are as yet no formal structured programs for pharmaceutical physicians’ in India.

Stakeholder ratings and role holder ratings of importance of modules appear to be largely similar, except that stakeholders were able to differentiate the critical (general and execution modules) and important modules (ethics and regulatory), while role holders rated all the modules, except data management and statistics as ‘critical’. The skills rating differed in that stakeholders rated all skills except interpersonal and computing skills as critical, while role holders rated computing skills also as critical.

4.2.6 Project Managers

Table 84 shows the demographic details of the Project Managers group. There are 6 males and 3 females of an average age of 28.4 years. There were 3 graduates, 5 post graduates and one doctorate. Three each worked for an MNC Pharma and MNC CRO. Six of them had 3 years or less of experience. Seven felt their education prepared them well for the current job and 5 felt their employment experience prepared them well for the current job.

Table 85 to Table 88 shows the Grading of Importance of Knowledge, Training received, Depth of training received and Requirement for training in knowledge areas for Project Managers.

- All the modules were rated 'critical' for the role by 50% or more respondents. Except the sub topic of *Orientation to the pharmaceutical industry*, all the sub topics in all the modules were rated 'critical' by 50% or more respondents.
- Majority of training received (6-7 respondents) was in Ethics and Regulations modules and on the job.
- Six of the 9 project managers reported to have received project management training on the job.
- 1-5 respondents rated all the items across modules as training requirements.

Table 89 to Table 92 shows the Grading of Importance of Skills, Training received, Depth of training received and Requirement for training in these areas for Project Managers.

- All the skills were rated 'critical' for the role by 50% or more respondents.
- Majority had not received training in the skills.
- Training was received on the job, by 3 respondents for Interpersonal skills and Presentation skills, 2 each for team work, negotiation skills and communication skills.
- Depth of training was reported at awareness level in most cases, except 2 respondents who reported knowledge level training for presentation skills
- Only 3 respondents marked negotiation skill as a training requirement.

Table 84. Demography- Project Managers (n=9)

1	**Sex**	**9**
	Males	6
	Females	3
	Average Age	28.4 yrs
2	**Qualification**	
	• Graduation	**3**
	B. Pharm	2
	B. Sc	1
	• Post graduation	**5**
	MD/MS	2
	M. Pharm	1
	Alternate Medicine	1
	Others (MBA)	1
	• Doctorate	1
3	**Employment status**	**9**
	• Employed	
	• In CR	9
4	**Type of organisation**	**9**
	• MNC Pharma	3
	• MNC CRO	3
	• CRO- Indian origin	2
	• Indian Pharma	1
5	**Experience**	**9**
	• One year or less	2
	• 1-3 years	4
	• 3-5 years	2
	• More than 5 years	1
6	**Education preparing for current job**	**9**
	• Very well	3
	• Adequately	4
	• Poorly	2
7	**Employment experience preparing for current job**	**9**
	• Very well	2
	• Adequately	3
	• Poorly	3
	• Employment unrelated	1

Table 85. Importance of knowledge areas-Project Managers (n=9)

Areas of Knowledge		Rating			No Response
		Critical	Important	Not Important	
General	Scope of Clinical Research	5	3	0	1
	Orientation to Pharmaceutical Industry	4	5	0	0
	Drug development process	7	2	0	0
	Total of topics in General Module	**16**	**10**	**0**	**1**
Ethics	Biomedical ethics- History and principles	7	1	1	0
	ICH GCP and national GCP guidelines	6	2	0	1
	EC composition and function- ICMR and ICH guidelines	7	1	0	1
	Informed consent process- principles and practice	8	0	0	1
	Total of topics in Ethics Module	**28**	**4**	**1**	**3**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	7	1	0	1
	Regulations relating to IP labelling and import	7	1	0	1
	Regulations regarding safety and pharmacovigilance	7	1	0	1
	Total of topics in Regulations Module	**21**	**3**	**0**	**3**
Methodology	Framing a research proposal/protocol and experimental design	6	1	0	2
	Writing investigators brochure	6	1	0	2
	Designing case report forms and EDCs	5	2	0	2
	Writing informed consent and Patient information sheet	6	1	0	2
	Writing study reports and publication	5	2	0	2
	SOP writing	6	1	0	2
	Conducting PK studies	6	1	0	2
	Total of topics in Methodology Module	**40**	**9**	**0**	**14**
DM and Stats	Types of data and statistical tests for clinical trials	7	1	0	1
	Statistical considerations at the design, execution and analysis	7	0	0	2
	Data Coding and cleaning	5	2	0	2
	Software considerations in Data Management	5	2	0	2
	Total of topics in DM & Stats Module	**24**	**5**	**0**	**7**
Clinical Trial execution	Monitoring a clinical study	6	2	0	1
	Project Management in clinical research	7	1	0	1
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	5	2	0	2
	Audits and inspection	6	1	0	2
	Clinical trial supplies management	7	1	0	1
	Pharmacovigilance and safety management	7	1	0	1
	Total of topics in Clinical Trial execution Module	**38**	**8**	**0**	**8**

Table 86. Training received in knowledge areas- Project Managers (n=9)

Areas of Knowledge		Training			No Response
			Received		
		Not received	At Graduation	On the Job	
General	Scope of Clinical Research	3	1	4	1
	Orientation to Pharmaceutical Industry	3	1	4	1
	Drug development process	0	2	6	1
	Total of topics in General Module	**6**	**4**	**14**	**3**
Ethics	Biomedical ethics- History and principles	1	1	6	1
	ICH GCP and national GCP guidelines	0	0	7	2
	EC composition and function- ICMR and ICH guidelines	0	0	7	2
	Informed consent process- principles and practice	0	0	7	2
	Total of topics in Ethics Module	**1**	**1**	**27**	**7**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	1	0	7	1
	Regulations relating to IP labelling and import	0	0	6	3
	Regulations regarding safety and pharmacovigilance	0	0	7	2
	Total of topics in Regulations Module	**1**	**0**	**20**	**6**
Methodology	Framing a research proposal/protocol and experimental design	2	0	6	1
	Writing investigators brochure	2	0	5	2
	Designing case report forms and EDCs	3	0	5	1
	Writing informed consent and Patient information sheet	4	0	4	1
	Writing study reports and publication	4	0	2	3
	SOP writing	4	0	1	4
	Conducting PK studies	5	0	1	3
	Total of topics in Methodology Module	**24**	**0**	**24**	**15**
DM and Stats	Types of data and statistical tests for clinical trials	5	0	1	3
	Statistical considerations at the design, execution and analysis	5	0	1	3
	Data Coding and cleaning	6	0	0	3
	Software considerations in Data Management	5	0	0	4
	Total of topics in DM & Stats Module	**21**	**0**	**2**	**13**
Clinical Trial execution	Monitoring a clinical study	1	0	7	1
	Project Management in clinical research	2	0	6	1
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	5	0	3	1
	Audits and inspection	1	0	7	1
	Clinical trial supplies management	2	0	5	2
	Pharmacovigilance and safety management	2	0	5	2
	Total of topics in Clinical Trial execution Module	**13**	**0**	**33**	**8**

Table 87. Depth of training in knowledge areas- Project Managers

Areas of Knowledge		Total trained	Rating			No Response
			Awareness	Knowle	Competence	
General	Scope of Clinical Research	5	2	0	0	3
	Orientation to Pharmaceutical Industry	5	2	0	0	3
	Drug development process	8	2	0	3	3
	Total of topics in General Module	**18**	**6**	**0**	**3**	**9**
Ethics	Biomedical ethics- History and principles	7	0	2	0	5
	ICH GCP and national GCP guidelines	7	0	2	2	3
	EC composition and function- ICMR and ICH guidelines	7	0	1	3	3
	Informed consent process- principles and practice	7	0	2	4	1
	Total of topics in Ethics Module	**28**	**0**	**7**	**9**	**12**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	7	2	2	0	3
	Regulations relating to IP labelling and import	6	0	2	3	1
	Regulations regarding safety and pharmacovigilance	7	0	3	0	4
	Total of topics in Regulations Module	**20**	**2**	**7**	**3**	**8**
Methodology	Framing a research proposal/protocol and experimental design	6	2	3	0	1
	Writing investigators brochure	5	2	0	0	3
	Designing case report forms and EDCs	5	2	0	0	3
	Writing informed consent and Patient information sheet	4	3	0	0	1
	Writing study reports and publication	2	2	0	0	0
	SOP writing	1	1	0	0	0
	Conducting PK studies	1	1	0	0	0
	Total of topics in Methodology Module	**24**	**13**	**3**	**0**	**8**
DM and Stats	Types of data and statistical tests for clinical trials	1	1	0	0	0
	Statistical considerations at the design, execution and analysis	1	0	0	0	1
	Data Coding and cleaning	0	0	0	0	0
	Software considerations in Data Management	0	0	0	0	0
	Total of topics in DM & Stats Module	**2**	**1**	**0**	**0**	**1**
Clinical Trial execution	Monitoring a clinical study	7	0	3	2	2
	Project Management in clinical research	6	1	4	0	1
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	3	0	2	0	1
	Audits and inspection	7	3	1	0	3
	Clinical trial supplies management	5	0	2	1	2
	Pharmacovigilance and safety management	5	0	1	3	1
	Total of topics in Clinical Trial execution Module	**33**	**4**	**13**	**6**	**10**

Table 88. Requirement for training in knowledge areas- Project Managers (n=9)

Areas of Knowledge		Training Requirement			No Response
		Required	Not required	Unsure	
General	Scope of Clinical Research	3	0	0	6
	Orientation to Pharmaceutical Industry	2	0	0	7
	Drug development process	3	0	0	6
	Total of topics in General Module	**8**	**0**	**0**	**19**
Ethics	Biomedical ethics- History and principles	5	0	0	4
	ICH GCP and national GCP guidelines	3	0	0	6
	EC composition and function- ICMR and ICH guidelines	4	0	0	5
	Informed consent process- principles and practice	4	0	0	5
	Total of topics in Ethics Module	**16**	**0**	**0**	**20**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	2	0	0	7
	Regulations relating to IP labelling and import	3	0	0	6
	Regulations regarding safety and pharmacovigilance	4	0	0	5
	Total of topics in Regulations Module	**9**	**0**	**0**	**18**
Methodology	Framing a research proposal/protocol and experimental design	3	0	0	6
	Writing investigators brochure	4	0	0	5
	Designing case report forms and EDCs	3	0	0	6
	Writing informed consent and Patient information sheet	3	0	0	6
	Writing study reports and publication	2	0	0	7
	SOP writing	4	0	0	5
	Conducting PK studies	5	0	0	4
	Total of topics in Methodology Module	**24**	**0**	**0**	**39**
DM and Stats	Types of data and statistical tests for clinical trials	1	0	0	8
	Statistical considerations at the design, execution and analysis	2	0	0	7
	Data Coding and cleaning	2	0	0	7
	Software considerations in Data Management	2	0	0	7
	Total of topics in DM & Stats Module	**7**	**0**	**0**	**29**
Clinical Trial execution	Monitoring a clinical study	4	0	0	5
	Project Management in clinical research	2	0	0	7
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	2	0	0	7
	Audits and inspection	3	0	0	6
	Clinical trial supplies management	2	0	0	7
	Pharmacovigilance and safety management	2	0	0	7
	Total of topics in Clinical Trial execution Module	**15**	**0**	**0**	**39**

Table 89. Rating of Importance of skills – Project Managers (n=9)

Skills	Number of responses			No Response
	Critical	Important	Not Important	
Leadership skills	5	1	0	3
Team work	7	1	0	1
Negotiation skills	7	1	0	1
Conflict management	7	0	0	2
Interpersonal skills	7	0	0	2
Computing skills	7	1	0	1
Presentation skills	7	0	0	2

Table 90. Training received in skills – Project Managers (n=9)

Skills	Number of responses			No Response
	Not received	Received at		
		Graduation	On the job	
Leadership skills	4	0	0	5
Team work	2	0	2	5
Negotiation skills	2	0	2	5
Conflict management	3	0	1	5
Interpersonal skills	1	0	3	5
Computing skills	4	0	0	5
Presentation skills	2	0	3	4
Communication skills	2	0	2	5

Table 91. Depth of Skills Training received – Project Managers

Skills	Number of responses				No Response
	Training received	Awareness	Knowledge	Competence	
Leadership skills	0	0	0	0	0
Team work	2	2	0	0	0
Negotiation skills	2	2	0	0	0
Conflict management	1	1	0	0	0
Interpersonal skills	3	3	0	0	0
Computing skills	0	0	0	0	0
Presentation skills	3	1	2	0	0
Communication skills	2	2	0	0	0

Table 92. Requirement of Skills training – Project Managers (n=9)

Skills	Number of responses			No Response
	Required	Not Required	Unsure	
Leadership skills	0	0	0	9
Team work	0	0	0	9
Negotiation skills	3	0	0	6
Conflict management	0	0	0	9
Interpersonal skills	0	0	0	9
Computing skills	0	0	0	9
Presentation skills	0	0	0	9
Communication skills	0	0	0	9

Discussion - Project Managers' role

Our survey respondents had 3 graduates and 5 postgraduates of which only one MBA qualified project manager. Majority of them had 1-3 years of experience and even the average age was less than 2 years greater than that of the CRAs. This probably reflects the rapid growth of the industry that has afforded young and relatively inexperienced people getting the early promotions to the role of project managers, even without additional qualifications like MBA.

Respondents marked all the modules as critical, but only 6-7 received training in the ethics and regulations modules, in the sub topic of project management in clinical research and in *Audits and inspections*. Handling contracts and indemnity/insurance issues is a critical part of the project manager's role and 5 had not received training in this sub-topic.

With clinical trials going global, a new project management model in which project managers have greater leadership roles and contribute strategically in developing trial plans, risk management and sharing best practices across global teams is evolving [86]. New skill sets like data analysis proficiency, knowledge of global regulations, sensitivity to cultural differences, risk management skills and sharing of best practices are being suggested in the new model [86]. Communication, cost, scope, drug development and time are rated as the most important project management knowledge areas and CROs were found to do better in cost and scope and large pharmaceutical companies in communication, drug development and time [87].

4.2.7 Site Coordinators

Table 93 shows the demographic details of the Site Coordinators group. There were 3 males and 5 females with an average age of 27.3 years. Majority (6) were graduates, with one each who were post graduate and doctorate. Six of them (6) were employed in clinical research. Five of the 8 site coordinators were having one year or less experience. All of them felt that their education and employment experience prepared them very well or adequately for the job.

Table 94 to Table 97 shows the Grading of Importance of Knowledge, Training received, Depth of training received and Requirement for training in knowledge areas for Site Coordinators.

- Gradewise total of the items in each module shows that General, Ethics, regulatory and execution modules are rated 'critical' by 50% or more respondents.
- 50% or more respondents reported being trained in the ethics module subtopics. However, one respondent reported not to have received in the sub-topic of *ICH GCP and national GCP guidelines.*
- Greater depth of training than awareness level was reported in all the modules except the methodology and DM & stats modules. All the sub-topics in the Ethics module, *Regulations regarding safety and pharmacovigilance* and *clinical trial supplies management* were areas where 'competence' was reported by 1-3 respondents.
- Highest number of respondents reported *Legal issues in clinical research* and *Pharmacovigilance and safety management* as a training requirement.

Table 98 to Table 101 shows the Grading of Importance of Skills, Training received, Depth of training received and Requirement for training for Site Coordinators.

- Computing, Presentation and communication skills were rated critical by 50% or more respondents and team work was rated 'important' by 50% respondents.
- Majority of the respondents had not received training in the skills. .
- Most skills were rated as requirement for training by 2 respondents each except for communication skills.

Table 93. Demography- Site Coordinators (n=8)

1	**Sex**	**8**
	Males	3
	Females	5
	Average Age	27.3 yrs
2	**Qualification**	
	• Graduation	**6**
	MBBS	2
	B. Sc	1
	Alternate Medicine (BAMS-2, BHMS-1)	3
	• Post graduation	**1**
	Others (Dip in Hosp Med)	1
	• Doctorate	1
3	**Employment status**	**8**
	• Employed	
	• In CR	6
	• Other	2
4	**Type of organisation**	**8**
	• Hospital	5
	• SMO	2
	• MNC CRO	1
5	**Experience**	**8**
	• One year or less	5
	• 1-3 years	3
6	**Education preparing for current job**	**8**
	• Very well	5
	• Adequately	3
7	**Employment experience preparing for current job**	**8**
	• Very well	5
	• Adequately	3

Table 94. Importance of knowledge areas- Site Coordinators (n=8)

		Rating			No Response
Areas of Knowledge		Critical	Important	Not Important	
General	Scope of Clinical Research	4	3	0	1
	Orientation to Pharmaceutical Industry	4	2	0	2
	Drug development process	5	2	0	1
	Total of topics in General Module	**13**	**7**	**0**	**4**
Ethics	Biomedical ethics- History and principles	5	2	0	1
	ICH GCP and national GCP guidelines	4	2	0	2
	EC composition and function- ICMR and ICH guidelines	6	1	0	1
	Informed consent process- principles and practice	6	1	0	1
	Total of topics in Ethics Module	**21**	**6**	**0**	**5**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	4	2	0	2
	Regulations relating to IP labelling and import	4	1	1	2
	Regulations regarding safety and pharmacovigilance	4	2	0	2
	Total of topics in Regulations Module	**12**	**5**	**1**	**6**
Methodology	Framing a research proposal/protocol and experimental design	5	3	0	0
	Writing investigators brochure	4	2	1	1
	Designing case report forms and EDCs	4	3	0	1
	Writing informed consent and Patient information sheet	4	2	0	2
	Writing study reports and publication	5	3	0	0
	SOP writing	3	4	0	1
	Conducting PK studies	1	4	2	1
	Total of topics in Methodology Module	**26**	**21**	**3**	**6**
DM and Stats	Types of data and statistical tests for clinical trials	2	4	0	2
	Statistical considerations at the design, execution and analysis	2	2	3	1
	Data Coding and cleaning	1	2	3	2
	Software considerations in Data Management	1	2	3	2
	Total of topics in DM & Stats Module	**6**	**10**	**9**	**7**
Clinical Trial execution	Monitoring a clinical study	4	2	0	2
	Project Management in clinical research	3	4	1	0
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	4	3	0	1
	Audits and inspection	6	2	0	0
	Clinical trial supplies management	5	1	0	2
	Pharmacovigilance and safety management	5	1	0	2
	Total of topics in Clinical Trial execution Module	**27**	**13**	**1**	**7**

Table 95. Training received in knowledge areas-Site Coordinators (n=8)

Areas of Knowledge		Training			No Response
		Not received	Received		
			At Graduation	On the Job	
General	Scope of Clinical Research	2	0	3	3
	Orientation to Pharmaceutical Industry	4	0	3	1
	Drug development process	2	0	4	2
	Total of topics in General Module	**8**	**0**	**10**	**6**
Ethics	Biomedical ethics- History and principles	2	2	3	1
	ICH GCP and national GCP guidelines	1	0	6	1
	EC composition and function- ICMR and ICH guidelines	0	0	6	2
	Informed consent process- principles and practice	0	0	6	2
	Total of topics in Ethics Module	**3**	**2**	**21**	**6**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	5	0	2	1
	Regulations relating to IP labelling and import	3	0	3	2
	Regulations regarding safety and pharmacovigilance	2	0	5	1
	Total of topics in Regulations Module	**10**	**0**	**10**	**4**
Methodology	Framing a research proposal/protocol and experimental design	4	0	0	4
	Writing investigators brochure	5	0	0	3
	Designing case report forms and EDCs	5	0	0	3
	Writing informed consent and Patient information sheet	1	0	3	4
	Writing study reports and publication	4	0	0	4
	SOP writing	5	0	0	3
	Conducting PK studies	4	0	0	4
	Total of topics in Methodology Module	**28**	**0**	**3**	**25**
DM and Stats	Types of data and statistical tests for clinical trials	4	0	1	3
	Statistical considerations at the design, execution and analysis	4	0	1	3
	Data Coding and cleaning	5	0	0	3
	Software considerations in Data Management	5	0	0	3
	Total of topics in DM & Stats Module	**18**	**0**	**2**	**12**
Clinical Trial execution	Monitoring a clinical study	2	0	3	3
	Project Management in clinical research	2	0	1	5
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	5	0	0	3
	Audits and inspection	0	0	5	3
	Clinical trial supplies management	0	0	5	3
	Pharmacovigilance and safety management	0	0	5	3
	Total of topics in Clinical Trial execution Module	**9**	**0**	**19**	**20**

Table 96. Depth of training in knowledge areas- Site Coordinator (n=8)

Areas of Knowledge		Total trained	Rating			No Response
			Awareness	Knowlge	Competence	
General	Scope of Clinical Research	3	3	0	0	0
	Orientation to Pharmaceutical Industry	3	2	0	0	1
	Drug development process	4	2	2	0	0
	Total of topics in General Module	**10**	**7**	**2**	**0**	**1**
Ethics	Biomedical ethics- History and principles	5	2	1	1	1
	ICH GCP and national GCP guidelines	6	1	2	1	2
	EC composition and function- ICMR and ICH guidelines	6	1	0	3	2
	Informed consent process- principles and practice	6	0	2	4	0
	Total of topics in Ethics Module	**23**	**4**	**5**	**9**	**5**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	2	1	0	0	1
	Regulations relating to IP labelling and import	3	1	0	0	2
	Regulations regarding safety and pharmacovigilance	5	0	2	3	0
	Total of topics in Regulations Module	**10**	**2**	**2**	**3**	**3**
Methodology	Framing a research proposal/protocol and experimental design	0	0	0	0	0
	Writing investigators brochure	0	0	0	0	0
	Designing case report forms and EDCs	0	0	0	0	0
	Writing informed consent and Patient information sheet	3	2	0	0	1
	Writing study reports and publication	0	0	0	0	0
	SOP writing	0	0	0	0	0
	Conducting PK studies	0	0	0	0	0
	Total of topics in Methodology Module	**3**	**2**	**0**	**0**	**1**
DM and Stats	Types of data and statistical tests for clinical trials	1	1	0	0	0
	Statistical considerations at the design, execution and analysis	1	0	0	0	1
	Data Coding and cleaning	0	0	0	0	0
	Software considerations in Data Management	0	0	0	0	0
	Total of topics in DM & Stats Module	**2**	**1**	**0**	**0**	**1**
Clinical Trial execution	Monitoring a clinical study	3	1	2	0	0
	Project Management in clinical research	1	1	0	0	0
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	0	0	0	0	0
	Audits and inspection	5	1	2	0	2
	Clinical trial supplies management	5	0	1	2	2
	Pharmacovigilance and safety management	5	1	2	0	2
	Total of topics in Clinical Trial execution Module	**19**	**4**	**7**	**2**	**6**

Table 97. Requirement for training in knowledge areas- Site Coordinators (n=8)

Areas of Knowledge		Training Requirement			No Response
		Required	Not required	Unsure	
General	Scope of Clinical Research	1	0	1	6
	Orientation to Pharmaceutical Industry	0	0	2	6
	Drug development process	2	0	0	6
	Total of topics in General Module	**3**	**0**	**3**	**18**
Ethics	Biomedical ethics- History and principles	2	0	0	6
	ICH GCP and national GCP guidelines	2	0	0	6
	EC composition and function- ICMR and ICH guidelines	2	0	0	6
	Informed consent process- principles and practice	2	0	0	6
	Total of topics in Ethics Module	**8**	**0**	**0**	**24**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	1	0	1	6
	Regulations relating to IP labelling and import	1	0	2	5
	Regulations regarding safety and pharmacovigilance	0	0	0	8
	Total of topics in Regulations Module	**2**	**0**	**3**	**19**
Methodology	Framing a research proposal/protocol and experimental design	1	0	0	7
	Writing investigators brochure	0	0	0	8
	Designing case report forms and EDCs	1	0	2	5
	Writing informed consent and Patient information sheet	1	0	0	7
	Writing study reports and publication	0	0	0	8
	SOP writing	1	0	0	7
	Conducting PK studies	0	0	0	8
	Total of topics in Methodology Module	**4**	**0**	**2**	**50**
DM and Stats	Types of data and statistical tests for clinical trials	0	0	0	8
	Statistical considerations at the design, execution and analysis	2	0	0	6
	Data Coding and cleaning	1	0	0	7
	Software considerations in Data Management	0	0	2	6
	Total of topics in DM & Stats Module	**3**	**0**	**2**	**27**
Clinical Trial execution	Monitoring a clinical study	0	0	0	8
	Project Management in clinical research	2	0	0	6
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	3	0	0	5
	Audits and inspection	0	0	0	8
	Clinical trial supplies management	0	0	0	8
	Pharmacovigilance and safety management	3	0	0	5
	Total of topics in Clinical Trial execution Module	**8**	**0**	**0**	**40**

Table 98. Rating of Importance of skills – Site Coordinators (n=8)

Skills	Number of responses			No Response
	Critical	**Important**	**Not Important**	
Leadership skills	2	2	2	2
Team work	1	4	1	2
Negotiation skills	3	2	1	2
Conflict management	3	2	1	2
Interpersonal skills	2	3	1	2
Computing skills	5	2	1	0
Presentation skills	4	3	1	0
Communication skills	3	3	0	2

Table 99. Training received in skills – Site Coordinators (n=8)

Skills	**Number of responses**			**No Response**
	Not received	**Received at**		
		Graduation	**On the job**	
Leadership skills	6	0	0	2
Team work	6	0	0	2
Negotiation skills	6	0	0	2
Conflict management	6	0	0	2
Interpersonal skills	6	0	0	2
Computing skills	5	1	0	2
Presentation skills	6	0	0	2
Communication skills	6	0	0	2

Table 100. Depth of Skills Training received – Site Coordinators

Skills	Number of responses				No Response
	Training received	Awareness	Knowledge	Competence	
Leadership skills	0	0	0	0	0
Team work	0	0	0	0	0
Negotiation skills	0	0	0	0	0
Conflict management	0	0	0	0	0
Interpersonal skills	0	0	0	0	0
Computing skills	1	1	0	0	0
Presentation skills	0	0	0	0	0
Communication skills	0	0	0	0	0

Table 101. Requirement of Skills training – Site Coordinators (n=8)

Skills	Number of responses			No Response
	Required	Not Required	Unsure	
Leadership skills	2	0	0	6
Team work	2	0	0	6
Negotiation skills	2	0	0	6
Conflict management	2	0	0	6
Interpersonal skills	2	0	0	6
Computing skills	2	0	0	6
Presentation skills	2	0	0	6
Communication skills	1	0	0	7

Discussion -Site Coordinator's role:

Majority of our study coordinators were graduates from varied disciplines (Medical, science and alternative medicine) with majority having less than one year's experience and yet all of them felt their education and employment experience prepared them very well or adequately for the job.

As the main point of contact for patient enrolment, drug dispensing and documentation maintenance at site, the site coordinator's role is crucial to project success. It was encouraging to see that most of our survey respondents were trained in topics crucial to their role -the Ethics module, in *regulations regarding safety and pharmacovigilance , audits and inspection, clinical trial supplies management* and *pharmacovigilance and safety management*.

However, considering that most of the time the site coordinator is in charge of the investigational product handling at site, it was surprising to find one of them rating *Regulations relating to IP labelling and import* as 'not important'. One of them reported not to have received training in *ICH GCP and national GCP guidelines* which are the fundamental guidance for all clinical research.

It was reassuring to see that 'competence' level of training was reported by 1-4 respondents in the Ethics module, by 3 in the *Regulations regarding safety and pharmacovigilance* and by 2 respondents in the *Clinical trial supplies management* module as these directly impact areas of work of a site coordinator.

Respondents marking 'unsure' for training requirements – 2 for *Regulations relating to IP labelling and import*, 1 for *Regulations affecting clinical trials for new product/generic registration in India including Schedule Y* and 2 more for *Orientation to pharmaceutical industry* left us wondering if indeed the understanding of the role is complete for our respondents.

Stakeholders rated the general, ethics, regulatory and execution modules as ‘important’, while role holders rated the same modules as ‘critical’, once again raising the issue of the difference perceived between ‘critical’ and ‘important’ ratings. There were differences in the rating of skills as well. Stakeholders rated all the skills except leadership skills as ‘critical’, with team work being rated ‘critical’ by highest number of respondents. Role holders rated team work as ‘important’ and computing, presentation and communication skills as ‘critical’.

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Site coordinators’ training requirements seem not to have received enough attention, even internationally. 45% of 132 research coordinators reported no formal training [88]. Raybuck [89] in a review of the literature concluded that their role is vague and ill defined, with little emphasis on the need for advanced educational preparation.

4.2.8 Regulatory Managers

Table 102 shows the demographic details of the Regulatory Managers group. The 6 regulatory managers included 4 males and 2 females with an average age of 27 years. There were 4 graduates and 2 post graduates and all were employed in clinical research. All had experience of 3 years or less. 5 of 6 respondents felt their education prepared them adequately and all of them felt their employment experience prepared them very well to adequately for the job.

Table 103 to Table 106 shows the Grading of Importance of Knowledge, Training received, Depth of training received and Requirement for training in knowledge areas for Regulatory Managers.

- Gradewise total of the items in each module shows that the ethics, regulatory and execution modules were rated critical by 50% or more respondents.
- Training not received in the Regulations module was reported by 3 respondents in the sub-topic of *Regulations relating to safety and pharmacovigilance* and one respondent in the sub-topic *Regulations relating to IP labelling and import*. 3 respondents also reported not receiving training in *Legal issues in clinical research* and 2 respondents in *Audits and Inspections*.
- Most training was on the job and at 'awareness' level. 2 respondents each reported 'knowledge' level of training in the Regulations module.

Table 107 to Table 110 shows the Grading of Importance of Skills, Training received, Depth of training received and Requirement for training in these areas for Regulatory Managers.

- All the skills were rated 'critical' by 50% or more respondents.
- Conflict management, computing skills and presentation skills and interpersonal skills were rated critical by highest number of respondents
- Majority of them had not received training in leadership skills, negotiation skills, conflict management and interpersonal skills.
- Leadership skills, conflict management and communication skills were rated as requirements for training.

Table 102. Demography- Regulatory Managers (n=6)

1	**Sex**	**6**
	Males	4
	Females	2
	Average Age	27 yrs
2	**Qualification**	
	• Graduation	**4**
	B. Sc	2
	B. Pharm	1
	Others…..	1
	B. Com	1
	• Post graduation	**2**
	M. Pharm	1
	M. Sc	1
3	**Employment status**	**6**
	• Employed	
	o In CR	6
4	**Type of organisation**	**6**
	• Indian Pharma	2
	• MNC Pharma	2
	• CRO- Indian origin	2
5	**Experience**	**6**
	• One year or less	3
	• 1-3 years	3
6	**Education preparing for current job**	**6**
	• Very well	1
	• Adequately	5
7	**Employment experience preparing for current job**	**6**
	• Very well	3
	• Adequately	3

Table 103. Importance of knowledge areas- Regulatory Managers (n=6)

Areas of Knowledge		Rating			No Response
		Critical	Important	Not Important	
General	Scope of Clinical Research	1	2	2	1
	Orientation to Pharmaceutical Industry	1	3	1	1
	Drug development process	3	2	1	0
	Total of topics in General Module	**5**	**7**	**4**	**2**
Ethics	Biomedical ethics- History and principles	3	2	1	0
	ICH GCP and national GCP guidelines	3	2	0	1
	EC composition and function- ICMR and ICH guidelines	4	1	0	1
	Informed consent process- principles and practice	3	2	0	1
	Total of topics in Ethics Module	**13**	**7**	**1**	**3**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	4	1	0	1
	Regulations relating to IP labelling and import	4	2	0	0
	Regulations regarding safety and pharmacovigilance	4	2	0	0
	Total of topics in Regulations Module	**12**	**5**	**0**	**1**
Methodology	Framing a research proposal/protocol and experimental design	3	3	0	0
	Writing investigators brochure	2	3	0	1
	Designing case report forms and EDCs	2	3	0	1
	Writing informed consent and Patient information sheet	3	2	0	1
	Writing study reports and publication	3	2	0	1
	SOP writing	3	2	0	1
	Conducting PK studies	1	4	0	1
	Total of topics in Methodology Module	**17**	**19**	**0**	**6**
DM and Stats	Types of data and statistical tests for clinical trials	1	4	0	1
	Statistical considerations at the design, execution and analysis	1	3	2	0
	Data Coding and cleaning	0	3	2	1
	Software considerations in Data Management	2	2	1	1
	Total of topics in DM & Stats Module	**4**	**12**	**5**	**3**
Clinical Trial execution	Monitoring a clinical study	4	2	0	0
	Project Management in clinical research	5	1	0	0
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	5	1	0	0
	Audits and inspection	5	0	0	1
	Clinical trial supplies management	4	2	0	0
	Pharmacovigilance and safety management	4	2	0	0
	Total of topics in Clinical Trial execution Module	**27**	**8**	**0**	**1**

Table 104. Training received in knowledge areas- Regulatory Managers (n=6)

Areas of Knowledge		Training			No Response
		Not received	Received		
			At Graduation	On the Job	
General	Scope of Clinical Research	4	1	1	0
	Orientation to Pharmaceutical Industry	5	0	1	0
	Drug development process	4	0	0	2
	Total of topics in General Module	**13**	**1**	**2**	**2**
Ethics	Biomedical ethics- History and principles	3	1	2	0
	ICH GCP and national GCP guidelines	3	0	2	1
	EC composition and function- ICMR and ICH guidelines	2	0	3	1
	Informed consent process- principles and practice	1	0	3	2
	Total of topics in Ethics Module	**9**	**1**	**10**	**4**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	0	1	4	1
	Regulations relating to IP labelling and import	1	1	3	1
	Regulations regarding safety and pharmacovigilance	3	0	2	1
	Total of topics in Regulations Module	**4**	**2**	**9**	**3**
Methodology	Framing a research proposal/protocol and experimental design	3	0	2	1
	Writing investigators brochure	2	0	2	2
	Designing case report forms and EDCs	4	0	0	2
	Writing informed consent and Patient information sheet	2	0	2	2
	Writing study reports and publication	3	0	0	3
	SOP writing	2	0	3	1
	Conducting PK studies	4	0	0	2
	Total of topics in Methodology Module	**20**	**0**	**9**	**13**
DM and Stats	Types of data and statistical tests for clinical trials	4	0	1	1
	Statistical considerations at the design, execution and analysis	3	1	1	1
	Data Coding and cleaning	4	0	0	2
	Software considerations in Data Management	3	0	1	2
	Total of topics in DM & Stats Module	**14**	**1**	**3**	**6**
Clinical Trial execution	Monitoring a clinical study	3	0	2	1
	Project Management in clinical research	3	0	2	1
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	3	0	1	2
	Audits and inspection	2	0	3	1
	Clinical trial supplies management	2	0	3	1
	Pharmacovigilance and safety management	1	0	3	2
	Total of topics in Clinical Trial execution Module	**14**	**0**	**14**	**8**

Table 105. Depth of training in knowledge areas- Regulatory Managers (n=6)

Areas of Knowledge		Total trained	Rating			No Response
			Awareness	Knowlge	Competence	
General	Scope of Clinical Research	2	2	0	0	0
	Orientation to Pharmaceutical Industry	1	1	0	0	0
	Drug development process	0	0	0	0	0
	Total of topics in General Module	**3**	**3**	**0**	**0**	**0**
Ethics	Biomedical ethics- History and principles	3	2	0	0	1
	ICH GCP and national GCP guidelines	2	2	0	0	0
	EC composition and function- ICMR and ICH guidelines	3	2	0	1	0
	Informed consent process- principles and practice	3	2	0	0	1
	Total of topics in Ethics Module	**11**	**8**	**0**	**1**	**2**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	5	2	2	0	1
	Regulations relating to IP labelling and import	4	2	2	0	0
	Regulations regarding safety and pharmacovigilance	2	1	0	0	1
	Total of topics in Regulations Module	**11**	**5**	**4**	**0**	**2**
Methodology	Framing a research proposal/protocol and experimental design	2	1	0	0	1
	Writing investigators brochure	2	0	0	0	2
	Designing case report forms and EDCs	0	0	0	0	0
	Writing informed consent and Patient information sheet	2	1	0	0	1
	Writing study reports and publication	0	0	0	0	0
	SOP writing	3	1	0	0	2
	Conducting PK studies	0	0	0	0	0
	Total of topics in Methodology Module	**9**	**3**	**0**	**0**	**6**
DM and Stats	Types of data and statistical tests for clinical trials	1	1	0	0	0
	Statistical considerations at the design, execution and analysis	2	1	0	0	1
	Data Coding and cleaning	0	0	0	0	0
	Software considerations in Data Management	1	0	0	0	1
	Total of topics in DM & Stats Module	**4**	**2**	**0**	**0**	**2**
Clinical Trial execution	Monitoring a clinical study	2	2	0	0	0
	Project Management in clinical research	2	1	0	0	1
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	1	1	0	0	0
	Audits and inspection	3	1	0	0	2
	Clinical trial supplies management	3	1	0	0	2
	Pharmacovigilance and safety management	3	1	0	0	2
	Total of topics in Clinical Trial execution Module	**14**	**7**	**0**	**0**	**7**

Table 106. Requirement for training in knowledge areas- Regulatory Managers (n=6)

Areas of Knowledge		Training Requirement			No Response
		Required	Not required	Unsure	
General	Scope of Clinical Research	4	0	0	2
	Orientation to Pharmaceutical Industry	2	0	0	4
	Drug development process	2	0	0	4
	Total of topics in General Module	**8**	**0**	**0**	**10**
Ethics	Biomedical ethics- History and principles	3	0	0	3
	ICH GCP and national GCP guidelines	4	0	0	2
	EC composition and function- ICMR and ICH guidelines	2	0	0	4
	Informed consent process- principles and practice	3	0	0	3
	Total of topics in Ethics Module	**12**	**0**	**0**	**12**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	0	0	0	6
	Regulations relating to IP labelling and import	1	0	0	5
	Regulations regarding safety and pharmacovigilance	0	0	0	6
	Total of topics in Regulations Module	**1**	**0**	**0**	**17**
Methodology	Framing a research proposal/protocol and experimental design	3	0	0	3
	Writing investigators brochure	2	0	0	4
	Designing case report forms and EDCs	4	0	0	2
	Writing informed consent and Patient information sheet	0	0	0	6
	Writing study reports and publication	2	0	0	4
	SOP writing	4	0	0	2
	Conducting PK studies	0	0	0	6
	Total of topics in Methodology Module	**15**	**0**	**0**	**27**
DM and Stats	Types of data and statistical tests for clinical trials	4	0	0	2
	Statistical considerations at the design, execution and analysis	2	0	0	4
	Data Coding and cleaning	2	0	0	4
	Software considerations in Data Management	1	0	0	5
	Total of topics in DM & Stats Module	**9**	**0**	**0**	**15**
Clinical Trial execution	Monitoring a clinical study	2	0	0	4
	Project Management in clinical research	3	0	0	3
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	4	0	0	2
	Audits and inspection	2	0	0	4
	Clinical trial supplies management	1	0	0	5
	Pharmacovigilance and safety management	3	0	0	3
	Total of topics in Clinical Trial execution Module	**15**	**0**	**0**	**21**

Table 107. Rating of Importance of skills – Regulatory Managers (n=6)

Skills	Number of responses			No Response
	Critical	**Important**	**Not Important**	
Leadership skills	3	0	2	1
Team work	4	1	0	1
Negotiation skills	3	2	1	0
Conflict management	6	0	0	0
Interpersonal skills	5	0	0	1
Computing skills	6	0	0	0
Presentation skills	6	0	0	0
Communication skills	5	1	0	0

Table 108. Training received in skills – Regulatory Managers (n=6)

Skills	**Number of responses**			**No Response**
	Not received	**Received at**		
		Graduation	**On the job**	
Leadership skills	3	0	0	3
Team work	0	0	2	4
Negotiation skills	3	0	0	3
Conflict management	3	0	0	3
Interpersonal skills	3	0	0	3
Computing skills	0	3	0	3
Presentation skills	1	2	0	3
Communication skills	1	2	0	3

Table 109. Depth of Skills Training received – Regulatory Managers

Skills	Number of responses				No Response
	Training received	Awareness	Knowledge	Competence	
Leadership skills	0	0	0	0	0
Team work	2	2	0	0	0
Negotiation skills	0	0	0	0	0
Conflict management	0	0	0	0	0
Interpersonal skills	0	0	0	0	0
Computing skills	3	3	0	0	0
Presentation skills	2	2	0	0	0
Communication skills	2	2	0	0	0

Table 110. Requirement of Skills training – Regulatory Managers (n=6)

Skills	Number of responses			No Response
	Required	Not Required	Unsure	
Leadership skills	3	0	0	3
Team work	0	0	0	6
Negotiation skills	0	0	0	6
Conflict management	3	0	0	3
Interpersonal skills	0	0	0	6
Computing skills	0	0	0	6
Presentation skills	0	0	0	6
Communication skills	2	0	0	4

Discussion- Regulatory Manager's role:

Changes in the Regulatory systems to bring it to international standards were one of the main impetuses that gave assurance to the global MNCs to want to conduct clinical trials here. Regulations have been fast evolving in the last few years [32, 33], making it imperative for the regulatory professional to be up to date with regulations that impact clinical research and how they can be implemented.

Our regulatory managers were mostly science graduates (3), one commerce graduate and 2 post graduates. They had less than 3 years experience in clinical research. Regulations are not part of educational curriculum and yet all our respondents felt their education prepared them adequately to very well for the job.

3 respondents were not trained in the sub-topic of *Regulations relating to safety and pharmacovigilance* and one respondent in the sub-topic *Regulations relating to IP labelling and import*, areas that are crucial to a regulatory manager's role.

Most of the training received was on the job, but it was interesting to note that one respondent each reported to be trained in 2 regulatory sub topics at graduation. As far as we know, graduation courses do not cover regulations pertaining to clinical research and this must be either because he did in parallel a course pertaining to regulations when he was doing graduation. Most of training received was a 'awareness' or 'knowledge' level except for a solitary case where 'competence' was reported in EC composition and function – ICMR and ICH guidelines sub topic.

Stakeholders rated the regulations module as 'critical' and the other modules except data management and statistics as 'important'. Role holders rated the General, Ethics, regulatory and execution modules are rated 'critical'. This probably reflects the inability of the role holders to differentiate the critical from the important. There was more agreement in the rating of skills. Both Stakeholders and role holders rated computing skills and presentation skills as critical for the role. In addition, role holders also rated communication skill as 'critical'.

4.2.9 QA personnel

Table 111 shows the demographic details of the QA personnel group, which included 3 males and 3 females with an average age of 28.3 years. Most had between one and 3 years of clinical research experience.

Table 112 to Table 115 shows the Grading of Importance of Knowledge, Training received, Depth of training received and Requirement for training in knowledge areas for QA personnel.

- Gradewise total of the sub topics within modules, show that all the modules except the DM& stats module were rated 'critical' by 50% or more respondents. The DM & stats module received more 'important' ratings.
- *SOP writing* and *Writing informed consent and Patient information sheet* were the 2 knowledge items that got critical ratings by highest number of respondents.
- 4 respondents reported not receiving training in *Audits and inspections*.
- Only 1-3 respondents reported receiving training, all on the job and mostly at awareness level.
- 3-4 respondents marked all the sub-topics, including *Audits and Inspection* as training requirements

Table 116 to Table 119 shows the Grading of Importance of Skills, Training received, Depth of training received and Requirement for training in these areas for QA personnel.

- All the skills were rated 'critical' by 50% or more respondents. Conflict management skills were rated critical by highest, four respondents.
- All those who responded reported not to have received training in leadership skills and negotiation skills.
- 3 respondents received training in Team work, on the job and rated at awareness level by 2 respondents.
- Knowledge level was reported in computing skills training by 2 respondents
- 4 Respondents each marked leadership skills and interpersonal skills as training requirements.

Table 111. Demography- QA Personnel (n=6)

1	**Sex**	**6**
	Males	3
	Females	3
	Average Age	28.2 yrs
2	**Qualification**	
	• Graduation	3
	B. Pharm	2
	Alternate Medicine	1
	• Post graduation	2
	M. Pharm	1
	Others (PDCR)	1
	• Doctorate	1
3	**Employment status**	**6**
	• Employed	
	○ In CR	6
4	**Type of organisation**	**6**
	• MNC Pharma	3
	• CRO- Indian origin	2
	• Others	1
5	**Experience**	**6**
	• One year or less	1
	• 1-3 years	3
	• 3-5 years	2
6	**Education preparing for current job**	**6**
	• Very well	1
	• Adequately	5
7	**Employment experience preparing for current job**	**6**
	• Very well	4
	• Adequately	2

Table 112. Importance of knowledge areas- QA personnel (n=6)

Areas of Knowledge		Rating			No Response
		Critical	Important	Not Important	
General	Scope of Clinical Research	3	3	0	0
	Orientation to Pharmaceutical Industry	4	2	0	0
	Drug development process	4	2	0	0
	Total of topics in General Module	**11**	**7**	**0**	**0**
Ethics	Biomedical ethics- History and principles	3	2	0	1
	ICH GCP and national GCP guidelines	3	2	0	1
	EC composition and function- ICMR and ICH guidelines	3	2	0	1
	Informed consent process- principles and practice	4	2	0	0
	Total of topics in Ethics Module	**13**	**8**	**0**	**3**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	4	2	0	0
	Regulations relating to IP labelling and import	4	1	0	1
	Regulations regarding safety and pharmacovigilance	4	2	0	0
	Total of topics in Regulations Module	**12**	**5**	**0**	**1**
Methodology	Framing a research proposal/protocol and experimental design	3	3	0	0
	Writing investigators brochure	3	3	0	0
	Designing case report forms and EDCs	4	2	0	0
	Writing informed consent and Patient information sheet	5	1	0	0
	Writing study reports and publication	4	2	0	0
	SOP writing	5	1	0	0
	Conducting PK studies	3	2	0	1
	Total of topics in Methodology Module	**27**	**14**	**0**	**1**
DM and Stats	Types of data and statistical tests for clinical trials	3	3	0	0
	Statistical considerations at the design, execution and analysis	2	3	0	1
	Data Coding and cleaning	2	4	0	0
	Software considerations in Data Management	3	3	0	0
	Total of topics in DM & Stats Module	**10**	**13**	**0**	**1**
Clinical Trial execution	Monitoring a clinical study	3	3	0	0
	Project Management in clinical research	4	2	0	0
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	3	2	0	1
	Audits and inspection	4	2	0	0
	Clinical trial supplies management	4	2	0	0
	Pharmacovigilance and safety management	2	4	0	0
	Total of topics in Clinical Trial execution Module	**20**	**15**	**0**	**1**

Table 113. Training received in knowledge areas- QA personnel (n=6)

Areas of Knowledge		Training			No Response
		Not received	Received		
			At Graduation	On the Job	
General	Scope of Clinical Research	3	0	2	1
	Orientation to Pharmaceutical Industry	4	0	2	0
	Drug development process	5	0	1	0
	Total of topics in General Module	**12**	**0**	**5**	**1**
Ethics	Biomedical ethics- History and principles	2	0	3	1
	ICH GCP and national GCP guidelines	4	0	2	0
	EC composition and function- ICMR and ICH guidelines	4	0	2	0
	Informed consent process- principles and practice	3	0	2	1
	Total of topics in Ethics Module	**13**	**0**	**9**	**2**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	3	0	2	1
	Regulations relating to IP labelling and import	2	0	2	2
	Regulations regarding safety and pharmacovigilance	4	0	2	0
	Total of topics in Regulations Module	**9**	**0**	**6**	**3**
Methodology	Framing a research proposal/protocol and experimental design	5	0	1	0
	Writing investigators brochure	4	0	2	0
	Designing case report forms and EDCs	5	0	1	0
	Writing informed consent and Patient information sheet	3	0	1	2
	Writing study reports and publication	2	0	2	2
	SOP writing	3	0	2	1
	Conducting PK studies	2	0	2	2
	Total of topics in Methodology Module	**24**	**0**	**11**	**7**
DM and Stats	Types of data and statistical tests for clinical trials	4	0	1	1
	Statistical considerations at the design, execution and analysis	3	0	2	1
	Data Coding and cleaning	4	0	2	0
	Software considerations in Data Management	3	0	2	1
	Total of topics in DM & Stats Module	**14**	**0**	**7**	**3**
Clinical Trial execution	Monitoring a clinical study	4	0	2	0
	Project Management in clinical research	3	0	2	1
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	4	0	2	0
	Audits and inspection	4	0	2	0
	Clinical trial supplies management	3	0	2	1
	Pharmacovigilance and safety management	4	0	2	0
	Total of topics in Clinical Trial execution Module	**22**	**0**	**12**	**2**

Table 114. Depth of training in knowledge areas- QA personnel (n=6)

Areas of Knowledge		Total trained	Rating			No Response
			Awareness	Knowlge	Competence	
General	Scope of Clinical Research	2	0	2	0	0
	Orientation to Pharmaceutical Industry	2	1	0	0	1
	Drug development process	1	1	0	0	0
	Total of topics in General Module	**5**	**2**	**2**	**0**	**1**
Ethics	Biomedical ethics- History and principles	3	2	0	0	1
	ICH GCP and national GCP guidelines	2	1	0	0	1
	EC composition and function- ICMR and ICH guidelines	2	1	0	0	1
	Informed consent process- principles and practice	2	1	0	0	1
	Total of topics in Ethics Module	**9**	**5**	**0**	**0**	**4**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	2	1	1	0	0
	Regulations relating to IP labelling and import	2	1	0	0	1
	Regulations regarding safety and pharmacovigilance	2	1	0	0	1
	Total of topics in Regulations Module	**6**	**3**	**1**	**0**	**2**
Methodology	Framing a research proposal/protocol and experimental design	1	1	0	0	0
	Writing investigators brochure	2	1	0	0	1
	Designing case report forms and EDCs	1	0	0	0	1
	Writing informed consent and Patient information sheet	1	0	0	0	1
	Writing study reports and publication	2	1	0	0	1
	SOP writing	2	0	0	0	2
	Conducting PK studies	2	1	0	0	1
	Total of topics in Methodology Module	**11**	**4**	**0**	**0**	**7**
DM and Stats	Types of data and statistical tests for clinical trials	1	0	0	0	1
	Statistical considerations at the design, execution and analysis	2	1	0	0	1
	Data Coding and cleaning	2	1	0	0	1
	Software considerations in Data Management	2	0	0	0	2
	Total of topics in DM & Stats Module	**7**	**2**	**0**	**0**	**5**
Clinical Trial execution	Monitoring a clinical study	2	1	0	0	1
	Project Management in clinical research	2	0	0	0	2
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	2	1	0	0	1
	Audits and inspection	2	0	0	0	2
	Clinical trial supplies management	2	1	0	0	1
	Pharmacovigilance and safety management	2	0	0	0	2
	Total of topics in Clinical Trial execution Module	**12**	**3**	**0**	**0**	**9**

Table 115. Requirement for training in knowledge areas- QA personnel (n=6)

Areas of Knowledge		Training Requirement			No Response
		Required	Not required	Unsure	
General	Scope of Clinical Research	2	0	2	0
	Orientation to Pharmaceutical Industry	2	1	0	0
	Drug development process	1	1	0	0
	Total of topics in General Module	**5**	**2**	**2**	**0**
Ethics	Biomedical ethics- History and principles	3	2	0	0
	ICH GCP and national GCP guidelines	2	1	0	0
	EC composition and function- ICMR and ICH guidelines	2	1	0	0
	Informed consent process- principles and practice	2	1	0	0
	Total of topics in Ethics Module	**9**	**5**	**0**	**0**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	2	1	1	0
	Regulations relating to IP labelling and import	2	1	0	0
	Regulations regarding safety and pharmacovigilance	2	1	0	0
	Total of topics in Regulations Module	**6**	**3**	**1**	**0**
Methodology	Framing a research proposal/protocol and experimental design	1	1	0	0
	Writing investigators brochure	2	1	0	0
	Designing case report forms and EDCs	1	0	0	0
	Writing informed consent and Patient information sheet	1	0	0	0
	Writing study reports and publication	2	1	0	0
	SOP writing	2	0	0	0
	Conducting PK studies	2	1	0	0
	Total of topics in Methodology Module	**11**	**4**	**0**	**0**
DM and Stats	Types of data and statistical tests for clinical trials	1	0	0	0
	Statistical considerations at the design, execution and analysis	2	1	0	0
	Data Coding and cleaning	2	1	0	0
	Software considerations in Data Management	2	0	0	0
	Total of topics in DM & Stats Module	**7**	**2**	**0**	**0**
Clinical Trial execution	Monitoring a clinical study	2	1	0	0
	Project Management in clinical research	2	0	0	0
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	2	1	0	0
	Audits and inspection	2	0	0	0
	Clinical trial supplies management	2	1	0	0
	Pharmacovigilance and safety management	2	0	0	0
	Total of topics in Clinical Trial execution Module	**12**	**3**	**0**	**0**

Table 116. Rating of Importance of skills – QA personnel (n=6)

Skills	Number of responses			No Response
	Critical	Important	Not Important	
Leadership skills	3	2	1	0
Team work	3	2	1	0
Negotiation skills	3	2	0	1
Conflict management	4	2	0	0
Interpersonal skills	3	3	0	0
Computing skills	3	2	1	0
Presentation skills	3	3	0	0
Communication skills	3	2	1	0

Table 117. Training received in skills – QA personnel (n=6)

Skills	Number of responses			No Response
	Not received	Received at		
		Graduation	On the job	
Leadership skills	3	0	0	3
Team work	0	0	3	3
Negotiation skills	2	0	0	4
Conflict management	2	0	1	3
Interpersonal skills	1	0	2	3
Computing skills	0	1	2	3
Presentation skills	1	0	1	4
Communication skills	2	0	1	3

Table 118. Depth of Skills Training received – QA personnel

Skills	Number of responses				No Response
	Training received	Awareness	Knowledge	Competence	
Leadership skills	0	0	0	0	0
Team work	3	2	0	0	1
Negotiation skills	0	0	0	0	0
Conflict management	1	0	0	0	1
Interpersonal skills	2	2	0	0	0
Computing skills	3	1	2	0	0
Presentation skills	1	1	0	0	0
Communication skills	1	0	0	0	1

Table 119. Requirement of Skills training – QA personnel (n=6)

Skills	Number of responses			No Response
	Required	Not Required	Unsure	
Leadership skills	4	0	0	2
Team work	2	0	0	4
Negotiation skills	3	0	0	3
Conflict management	0	0	0	6
Interpersonal skills	4	0	0	2
Computing skills	0	0	0	6
Presentation skills	0	0	0	6
Communication skills	0	0	0	6

Discussion- QA Personnel's role

Majority of our respondents (5/6) had 3 years or more experience in clinical research which is considered essential for an auditor's role. All the modules, except the DM and stats module and their sub-topics were rated 'critical' by the respondents. We found gaps in the training in our QA personnel respondents. Of 6 total respondents, 5 respondents were not trained in *Drug development process,* 4 each not having received training in *ICH GCP and national guidelines, EC composition and function-ICMR and ICH guidelines, Regulations affecting safety and pharmacovigilance, execution aspects of Pharmacovigilance and safety management, Audits and Inspection* and 3 in *SOP writing.* Training, when received was mainly on the job and at 'awareness' level.

An auditor's role is often perceived as policing and finding discrepancies in others work. It calls for excellent skills for him to gain cooperation from the project team and making them understand the implications and wanting to implement the corrective and preventive actions. Stakeholders rated team work, conflict management, interpersonal skills and communication skills as 'critical' to the role. Role holders rated all the skills as 'critical'.

Stakeholders rated the general, regulations and execution modules as 'critical' to the role and the other 3 modules as 'important'. Role holders rated all the modules except DM and statistics as 'critical'. The difference in stakeholder expectations and role holder perception can be understood as lack of clarity on part of role holders. This may be because of inadequate experience in auditing role, even though they may have had other clinical research experience.

4.2.10 Investigators Role

Table 120 shows the demographic details of the Investigators group of 5 males and one female. All of them had 3 or less years of experience in clinical research and most of them thought their education and employment experience prepared them very well for their role as investigator.

Table 121 to Table 124 shows the Grading of Importance of Knowledge, Training received, Depth of training received and Requirement for training in knowledge areas for Investigators.

- Gradewise total of items within each module showed that all the modules were rated critical by 50% or more respondents. The Ethics module received the highest critical ratings with all the investigators rating all the sub-topics as critical.
- Training not received was reported highest in 2 sub-topics of DM & stats module and *legal* issues in clinical research. 1-2 Respondents were not trained in the ethics module, 2-4 in the methodology module and 1-6 in the execution module.
- Most training received was on the job. Training at graduation has been reported on *Orientation to the pharmaceutical industry*, *Drug development process*, *Biomedical ethics- history and principles*, *Framing a research proposal* and *Pharmacovigilance and safety management*
- Respondents marked training in the Ethics module at 'knowledge' and 'competence' level

Table 125 to Table 128 shows the Grading of Importance of Skills, Training received, Depth of training received and Requirement for training in these areas for Investigators.

- All the skills were rated 'critical' by 50% or more respondents.
- Teamwork, negotiation, conflict management, interpersonal skills, computing skills and presentation skills were rated 'critical' by all 6 respondents.
- Training not received in leadership skills was reported by 5 respondents and 4 each for negotiation, conflict management, interpersonal skills and communication skills.
- On the job training was reported in presentation skills, interpersonal skills, computing and communication skills

Table 120. Demography- Investigators (n=6)

1	**Sex**	**6**
	• Males	5
	• Females	1
	Average Age	31.7 yrs
2	**Qualification**	
	• Graduation	**4**
	MBBS	4
	• Post graduation	**2**
	MD/MS	2
3	**Employment status**	**6**
	• Employed	
	○ Other	6
4	**Type of organisation**	**6**
	• Hospital	5
	• SMO	1
5	**Experience**	**6**
	• One year or less	3
	• 1-3 years	3
6	**Education preparing for current job**	**6**
	• Very well	1
	• Adequately	5
7	**Employment experience preparing for current job**	**6**
	• Very well	5
	• Adequately	1

Table 121. Importance of knowledge areas- Investigator (n=6)

Areas of Knowledge		Rating			No Response
		Critical	Important	Not Important	
General	Scope of Clinical Research	5	1	0	0
	Orientation to Pharmaceutical Industry	6	0	0	0
	Drug development process	6	0	0	0
	Total of topics in General Module	**17**	**1**	**0**	**0**
Ethics	Biomedical ethics- History and principles	6	0	0	0
	ICH GCP and national GCP guidelines	6	0	0	0
	EC composition and function- ICMR and ICH guidelines	6	0	0	0
	Informed consent process- principles and practice	6	0	0	0
	Total of topics in Ethics Module	**24**	**0**	**0**	**0**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	5	1	0	0
	Regulations relating to IP labelling and import	5	1	0	0
	Regulations regarding safety and pharmacovigilance	6	0	0	0
	Total of topics in Regulations Module	**16**	**2**	**0**	**0**
Methodology	Framing a research proposal/protocol and experimental design	5	1	0	0
	Writing investigators brochure	4	2	0	0
	Designing case report forms and EDCs	2	4	0	0
	Writing informed consent and Patient information sheet	5	1	0	0
	Writing study reports and publication	4	2	0	0
	SOP writing	4	2	0	0
	Conducting PK studies	4	0	2	0
	Total of topics in Methodology Module	**28**	**12**	**2**	**0**
DM and Stats	Types of data and statistical tests for clinical trials	4	2	0	0
	Statistical considerations at the design, execution and analysis	4	2	0	0
	Data Coding and cleaning	3	1	2	0
	Software considerations in Data Management	3	1	2	0
	Total of topics in DM & Stats Module	**14**	**6**	**4**	**0**
Clinical Trial execution	Monitoring a clinical study	4	2	0	0
	Project Management in clinical research	4	2	0	0
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	4	2	0	0
	Audits and inspection	5	1	0	0
	Clinical trial supplies management	6	0	0	0
	Pharmacovigilance and safety management	6	0	0	0
	Total of topics in Clinical Trial execution Module	**29**	**7**	**0**	**0**

Table 122. Training received in knowledge areas- Investigators (n=6)

Areas of Knowledge		Training			No Response
		Not received	Received		
			At Graduation	On the Job	
General	Scope of Clinical Research	3	0	1	2
	Orientation to Pharmaceutical Industry	4	1	0	1
	Drug development process	3	2	0	1
	Total of topics in General Module	**10**	**3**	**1**	**4**
Ethics	Biomedical ethics- History and principles	2	2	0	2
	ICH GCP and national GCP guidelines	2	0	2	2
	EC composition and function- ICMR and ICH guidelines	1	0	3	2
	Informed consent process- principles and practice	1	0	3	2
	Total of topics in Ethics Module	**6**	**2**	**8**	**8**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	2	0	1	3
	Regulations relating to IP labelling and import	2	0	2	2
	Regulations regarding safety and pharmacovigilance	1	0	1	4
	Total of topics in Regulations Module	**5**	**0**	**4**	**9**
Methodology	Framing a research proposal/protocol and experimental design	2	2	1	1
	Writing investigators brochure	4	0	1	1
	Designing case report forms and EDCs	4	0	2	0
	Writing informed consent and Patient information sheet	4	0	2	0
	Writing study reports and publication	4	0	2	0
	SOP writing	3	0	2	1
	Conducting PK studies	5	0	0	1
	Total of topics in Methodology Module	**26**	**2**	**10**	**4**
DM and Stats	Types of data and statistical tests for clinical trials	5	0	0	1
	Statistical considerations at the design, execution and analysis	6	0	0	0
	Data Coding and cleaning	6	0	0	0
	Software considerations in Data Management	5	0	1	0
	Total of topics in DM & Stats Module	**22**	**0**	**1**	**1**
Clinical Trial execution	Monitoring a clinical study	4	0	2	0
	Project Management in clinical research	5	0	1	0
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	6	0	0	0
	Audits and inspection	3	0	2	1
	Clinical trial supplies management	1	0	5	0
	Pharmacovigilance and safety management	1	1	3	1
	Total of topics in Clinical Trial execution Module	**20**	**1**	**13**	**2**

Table 123. Depth of training in knowledge areas- Investigators (n=6)

Areas of Knowledge		Total trained	Rating			No Response
			Awareness	Knowlge	Competence	
General	Scope of Clinical Research	1	1	0	0	0
	Orientation to Pharmaceutical Industry	1	1	0	0	0
	Drug development process	2	1	1	0	0
	Total of topics in General Module	**4**	**3**	**1**	**0**	**0**
Ethics	Biomedical ethics- History and principles	2	0	2	0	0
	ICH GCP and national GCP guidelines	2	0	2	0	0
	EC composition and function- ICMR and ICH guidelines	3	0	2	0	1
	Informed consent process- principles and practice	3	0	1	2	0
	Total of topics in Ethics Module	**10**	**0**	**7**	**2**	**1**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	1	0	1	0	0
	Regulations relating to IP labelling and import	2	1	1	0	0
	Regulations regarding safety and pharmacovigilance	1	1	0	0	0
	Total of topics in Regulations Module	**4**	**2**	**2**	**0**	**0**
Methodology	Framing a research proposal/protocol and experimental design	3	1	2	0	0
	Writing investigators brochure	1	1	0	0	0
	Designing case report forms and EDCs	2	2	0	0	0
	Writing informed consent and Patient information sheet	2	2	0	0	0
	Writing study reports and publication	2	2	0	0	0
	SOP writing	2	1	1	0	0
	Conducting PK studies	0	0	0	0	0
	Total of topics in Methodology Module	**12**	**9**	**3**	**0**	**0**
DM and Stats	Types of data and statistical tests for clinical trials	0	0	0	0	0
	Statistical considerations at the design, execution and analysis	0	0	0	0	0
	Data Coding and cleaning	0	0	0	0	0
	Software considerations in Data Management	1	1	0	0	0
	Total of topics in DM & Stats Module	**1**	**1**	**0**	**0**	**0**
Clinical Trial execution	Monitoring a clinical study	2	1	1	0	0
	Project Management in clinical research	1	1	0	0	0
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	0	0	0	0	0
	Audits and inspection	2	1	1	0	0
	Clinical trial supplies management	5	0	2	0	3
	Pharmacovigilance and safety management	4	2	2	0	0
	Total of topics in Clinical Trial execution Module	**14**	**5**	**6**	**0**	**3**

Table 124. Requirement for training in knowledge areas- Investigators (n=6)

Areas of Knowledge		Training Requirement			No Response
		Required	Not required	Unsure	
General	Scope of Clinical Research	1	2	0	3
	Orientation to Pharmaceutical Industry	0	2	0	4
	Drug development process	2	2	0	2
	Total of topics in General Module	**3**	**6**	**0**	**9**
Ethics	Biomedical ethics- History and principles	3	0	0	3
	ICH GCP and national GCP guidelines	3	0	0	3
	EC composition and function- ICMR and ICH guidelines	2	0	0	4
	Informed consent process- principles and practice	2	0	0	4
	Total of topics in Ethics Module	**10**	**0**	**0**	**14**
Regulations	Regulations affecting CT for new product/generic registration in India including Schedule Y	2	2	0	2
	Regulations relating to IP labelling and import	3	2	0	1
	Regulations regarding safety and pharmacovigilance	4	0	0	2
	Total of topics in Regulations Module	**9**	**4**	**0**	**5**
Methodology	Framing a research proposal/protocol and experimental design	3	0	0	3
	Writing investigators brochure	2	0	0	4
	Designing case report forms and EDCs	3	0	0	3
	Writing informed consent and Patient information sheet	3	0	0	3
	Writing study reports and publication	3	0	0	3
	SOP writing	2	0	0	4
	Conducting PK studies	2	0	0	4
	Total of topics in Methodology Module	**18**	**0**	**0**	**24**
DM and Stats	Types of data and statistical tests for clinical trials	2	0	0	4
	Statistical considerations at the design, execution and analysis	3	2	0	1
	Data Coding and cleaning	0	4	0	2
	Software considerations in Data Management	0	3	0	3
	Total of topics in DM & Stats Module	**5**	**9**	**0**	**10**
Clinical Trial execution	Monitoring a clinical study	2	0	0	4
	Project Management in clinical research	4	0	0	2
	Legal issues in clinical research (legal, contractual, insurance, indemnity etc)	4	0	0	2
	Audits and inspection	3	0	0	3
	Clinical trial supplies management	4	0	0	2
	Pharmacovigilance and safety management	4	0	0	2
	Total of topics in Clinical Trial execution Module	**21**	**0**	**0**	**15**

Table 125. Rating of Importance of skills – Investigators (n=6)

Skills	Number of responses			No Response
	Critical	**Important**	**Not Important**	
Leadership skills	4	1	0	1
Team work	6	0	0	0
Negotiation skills	6	0	0	0
Conflict management	6	0	0	0
Interpersonal skills	6	0	0	0
Computing skills	6	0	0	0
Presentation skills	6	0	0	0
Communication skills	5	1	0	0

Table 126. Training received in skills – Investigators (n=6)

Skills	**Number of responses**			**No Response**
	Not received	**Received at**		
		Graduation	**On the job**	
Leadership skills	5	0	0	1
Team work	2	1	0	3
Negotiation skills	4	0	0	2
Conflict management	4	0	0	2
Interpersonal skills	4	0	2	0
Computing skills	2	2	2	0
Presentation skills	1	0	3	2
Communication skills	4	0	1	1

Table 127. Depth of Skills Training received – Investigators

Skills	Number of responses				No Response
	Training received	Awareness	Knowledge	Competence	
Leadership skills	0	0	0	0	0
Team work	1	1	0	0	0
Negotiation skills	0	0	0	0	0
Conflict management	0	0	0	0	0
Interpersonal skills	2	1	0	1	0
Computing skills	4	0	0	2	2
Presentation skills	3	0	1	0	2
Communication skills	1	1	0	0	0

Table 128. Requirement of Skills training – Investigators (n=6)

Skills	Number of responses			No Response
	Required	Not Required	Unsure	
Leadership skills	1	2	0	3
Team work	1	2	0	3
Negotiation skills	4	2	0	0
Conflict management	3	0	0	3
Interpersonal skills	2	0	0	4
Computing skills	2	0	0	4
Presentation skills	5	0	0	1
Communication skills	2	2	0	2

Discussion- Investigators' role

The responsibilities of an investigator are delineated very well in the ICH GCP and guidelines. It sums up the knowledge and skills expectations of an Investigator by stating that the investigator(s) should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirement(s), and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB/IEC, and/or the regulatory authority. A qualified physician (or dentist, when appropriate), who is an investigator or a sub-investigator for the trial, should be responsible for all trial-related medical (or dental) decisions.

It was surprising for us to find 4 medical graduates in our respondent group because investigating a new product is usually assigned to an expert in the therapy area which is usually a post graduate qualified specialist in the field of study. All of our respondents had 3 years or less of clinical research experience and though their education and employment experience prepared them very well or adequately for the job.

It was reassuring to find that Ethics, regulations and the pertinent sub-topics in the execution module were rated critical by all 6 respondents. However, all 6 reported not receiving training in Legal issues in clinical research and one each in EC composition and function-ICMR and ICH guidelines, Informed consent process- principles and practice, regulations regarding safety and pharmacovigilance, clinical trial supplies management and execution aspects of pharmacovigilance and safety management. Most training took place on the job and was at 'awareness' level, except for 2 respondents rating informed consent process-principles and practice at 'competence' level. Most respondents marked sub-topics in Ethics, regulations, methodology and execution modules as training requirements.

Stakeholders rated the general, regulatory and execution modules as 'important' and 2/3 sub-topics in ethics module as 'critical' for the role. Role holders rated all the modules except DM and statistics module as 'critical'. We tend to agree more with the ratings of

the role holders in this case. In skills ratings also, there was disagreement between stakeholder and role holder ratings. Stakeholders rated all the skills except conflict management as ‘critical’ while role holders rated all skills, with conflict management as the highest rating for ‘critical’ for the role.

Investigator training is one of the most stressed on points in clinical research today. The NIH has specified that all NIH intramural clinical principal investigators are required to take a course and successfully complete a final exam. The FDA has issued a new guidance document [90] for industry that clarifies what it means by adequate training for investigators. The clinical investigator should ensure that there is adequate training for all staff participating in the conduct of the study. The investigator should specifically anticipate the possibility of staff turnover during the conduct of the study (particularly if the study is of long duration) and plan to ensure that there is adequate training of any replacement staff. These are leading to a new model for training clinical investigators and formal clinical research training programs are replacing on-the job training.

Objective 3

Analysis of the educational qualifications of our survey respondents as per figure below was undertaken to understand the most common course in clinical research professionals.

Table 129. Distribution of respondents by qualifications (n=181)

Graduation	**119**
B. Pharm	38
B. Sc	36
Alternate Medicine	16
MBBS	16
Others…..	13
Post graduation	**45**
M. Pharm	8
M. Sc	5
MD/MS	4
Alternate Medicine	2
Others…	26
Doctorates	**17**

Pharmacy was the most popular undergraduate course with as many as 35% of respondents being pharmacy graduates, followed by BSc and then by MBBS.

Bachelor of Science (BSc) has a variety of specialisations and we did not have a classification of the candidates by specialisation. Besides, the curricula for BSc, except for BSc (Information technology) were not available on internet search. Therefore an analysis of the BSc curricula was not considered.

Methodology: The graduation curricula at two of the top most universities for pharmacy and medicine, as given below, were chosen as a representative sample. An internet search of the learning objectives and syllabus was done to determine if the items of knowledge and skills identified in the survey (objective 2) were covered as part of the curriculum.

MBBS: AIIMS and MUHS

Pharmacy: BITS, Pilani, Mumbai University

Results: The curricula of MBBS and Pharmacy courses are as shown here.

We found that none of the items of knowledge or skills were named as learning objectives in the medicine curricula at the graduation level, though demonstrated proficiency in communication skills and medical research is an objective.

The only relevant items covered in the pharmacy curricula were Drug Development, (as part of pharmaceutics), Quality Assurance & regulatory affairs, pharmacokinetics and clinical pharmacy, elements of statistics and computing skills.

Table 130. **BITS, Pilani – Pharmacy Curriculum**

Pharmaceutical Analysis
Microbiology
Natural Drugs
Forensic Pharmacy
Anatomy, Physiology and Hygiene
Dispensing Pharmacy
Industrial Pharmacy
Pharmacology and Toxicology
Medicinal Chemistry
Instrumental Methods of Analysis
Physical Pharmacy
Veterinary Pharmacy
Pharmaceutical Management & Quality Control
Biopharmaceutics
Pathophysiology
Pharmaceutical Formulations and Biopharmaceutics
Cosmetic Science
Pharmacognosy
Hospital Pharmacy
Biochemical Engineering
Applied Pharmaceutical Chemistry
Phytochemistry
Special Projects
Application of Statistics and Computer in Pharmacy
Fermentation & Biotechnology
Chemistry of Natural Drugs
Molecular Biology & Immunology
Chemistry of Macromolecules
Disinfection and Sterilisation
Quality Assurance & Regulatory Affairs
Advanced Pharmacology
Pharmacokinetics & Clinical Pharmacy
Pharmaceutical Biotechnology
Clinical Pharmacy and Therapeutics
Pharmacy Practice
Pharmaceutical Administration and Management
Advanced Medicinal Chemistry
Chemistry of Natural Drugs & Macromolecules
Dosage Form Design
Laboratory Project

Table 131. Pharmacy Curriculum – Mumbai University

Year 1	General Chemistry
	Organic Chemistry
	Anatomy, Physiology and Pathophysiology
	Physical Pharmacy
	Pharmaceutics
	Pharmaceutical Engineering
	Pharmaceutical Analysis
	Microbiology
Year 2	Anatomy, Physiology and Pathophysiology
	Organic Chemistry
	Pharmaceutical Analysis
	Biochemistry
	Pharmaceutics
	Pharmaceutical Engineering
	Mathematics
	Computer Laboratory
	Pharmacology
	Dispensing Pharmacy
	Statistics
	Psychology and Sociology
Year 3	Pharmaceutical and Medicinal chemistry
	Pharmaceutics
	Hospital Pharmacy and Drug Store Management
	Pharmacology
	Biochemistry
	Biotechnology and Fermentation process
	Pharmaceutical Management
	Pharmaceutical Chemistry
	Pharmaceutical analysis
	Cosmeticology
	Pharmacology
	Pharmacognosy
	Pharmaceutical Management
Year 4	Pharmaceutical and medicinal chemistry
	Pharmaceutical analysis
	Pharmaceutics
	Biopharmaceutics and pharmacokinetics
	Pharmacology and Toxicology
	Pharmacognosy
	Pharmaceutical Chemistry
	Pharmaceutical technology
	Forensic Pharmacy
	Clinical Pharmacy and Drug interactions
	Pharmacognosy
	Pharmaceutical analysis

Table 132. **AIIMS MBBS Course**

The MBBS course comprises four and a half years, followed by compulsory rotatory internship of one year. The MBBS course is divided in to three phases, viz., Pre-clinical, Para-clinical and Clinical Phase, during which following subjects are introduced:

Pre-clinical: Anatomy, Bio-chemistry, and Physiology

Para-clinical: Community Medicine; Forensic Medicine, Pathology, Pharmacology, Microbiology, Clinical postings in wards, OPDs to begin here;

Clinical: Community Medicine, Medicine and allied subjects (Psychiatry, Dermatology); Obstetrics. Gynaecology; Pediatrics; Surgery and allied subjects (Anesthesiology, E.N.T., Ophthalmology, Orthopedics); Clinical postings;

Goals and objectives of undergraduate course (MBBS)
At the end of the MBBS course, the learner shall be able to:

1. Diagnose and manage common health problems of the individual and the community appropriate to his/her position as a member of the health team at primary, secondary and tertiary levels;
2. Be competent to practice preventive, promotive, curative and rehabilitative medicine in respect to the commonly encountered health problems;
3. Practice Evidence Based Medicine, appreciating the rationale for different therapeutic modalities and be familiar with the administration of "essential drugs" and their common side effects;
4. Appreciate the psycho-social, cultural, economic, and environmental factors affecting health, and develop humane attitude towards the patients/relatives, in discharging one's professional responsibilities;
5. Be familiar with the various National Health Programs, and the ways in which they are being implemented;
6. Acquire basic management skills in the area of materials, financial and human resources;
7. Demonstrate communication skills, both verbal and written to establish effective communication with the clients (patients, relatives, and general public), health team partners, and scientific community;
8. Practice medical ethics in patient care, service delivery, and research.

9. Develop attitude for self learning and acquire necessary skills including the use of appropriate technologies, for pursuing self directed learning for a life time.

Table 133. MBBS- Maharashtra University of Health Sciences

PHASE-I
1 – Human Anatomy
2 – Physiology including bio-physics
3 – Biochemistry
4 – Introduction to community medicine including Humanity.

PHASE II
General and Systemic Pathology
Hematology, Microbiology, Immunology and systemic bacteriology
Pharmacology and Pharmacotherapeutics
Forensic Medicine and medical jurisprudence including toxicology

PHASE III
Introduction to Medicine
Infectious Diseases/Tropical diseases
Cardiovascular System
GIT, Liver, Pan.
Chest
TB
Psychiatry
Neurology
Haematology/Haemato-oncology
Skin / STD
Endocrinology
Nephrology
Clinical Nutrition
Radiology
Ophthalmology
Preventive Oncology

As the industry matures and enters the next phase of research compliance, there will be no excuse for ignorance and zero tolerance for mistakes [91, 92]. New entrants will find it increasingly more difficult to come in [92, 93], and training and certification will become even more important [93]. Given this, a detailed competency mapping of the roles is a good solution to finding all training needs, the timing of training and depth to which it is required in the immediate role and developmentally.

Our study brings to light some of the challenges in identifying training needs of a diverse group like clinical research professionals. Objectively identifying the key items of knowledge and skills competencies required and then layering the training into -basic training that is applicable to any new entrant, advanced training for specialised functions and project specific training is a probable alternative explored in our model.

CHAPTER 5: PROPOSED MODEL FOR TRAINING AND EDUCATION FOR CLINICAL RESEARCH PROFESSIONALS

Introduction: The proposed model presented here is based on the following important assumptions that are also supported by the findings of our surveys-

1. Different items of knowledge and skills are important for successful performance of the various roles in clinical research.

2. Because the field is new, there are very few experienced people in the field and new role holders may or may not often know what they need to know to perform well in the role.

3. Since this is a global industry, the roles and the performance standards should be globally recognised and accepted.

It is therefore imperative the differences are objectively delineated and addressed in structured training programs. Therefore, our model begins with the defining the competencies expected of an individual for a particular role and then designing required training to achieve the competencies identified. This is an application of competency mapping and competency based training that usually discussed in human resource management.

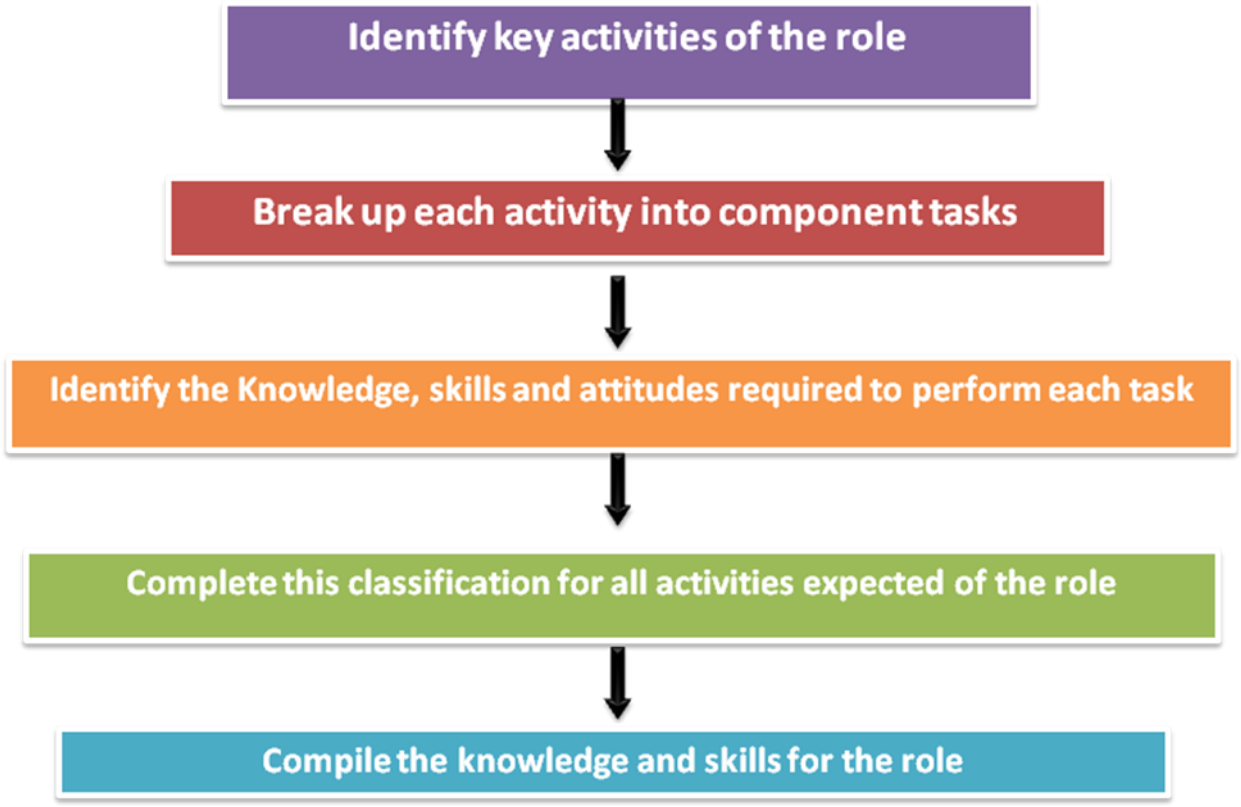
Competency can be defined as any underlying characteristic required for performing a given task, activity, or role successfully can be considered as competency. Competency may take the form of Knowledge, Skills or Attitude, or other characteristics of an individual including: Motives, Values, Traits, and Self Concept etc.

Competency levels: Different job functions and tasks are performed at different levels. Competencies should ideally be layered in simple steps

- to allow building on growing underpinning knowledge and experience
- to allow assessment of learning at each stage

Competency mapping is the process of identification of the competencies required to perform successfully a given job or role or a set of tasks at a given point of time. It consists of breaking a given role or job into its constituent tasks or activities and identifying the competencies (technical, managerial, behavioural, conceptual knowledge, attitudes, skills, etc.) needed to perform the same successfully.

Figure 19. Process of task analysis**:**



Competency based training in clinical research: Bhatt in his article [ ] on training gaps refers to different competency levels, both in knowledge and skills that a medical adviser or project physician needs to acquire and compares with that a CRA needs to acquire. The difference in competencies of the various roles has led to discussions on competency based education for clinical research staff [94, 95]. However, the process of identifying the knowledge and skill components required for the competency by task analysis has not been elucidated.

An example of how this is done for the role of CRA is shown below-

Competency: The CRA is expected to be competent at monitoring at site.

- This competency can be broken down into 6 important **tasks**- planning monitoring visits, Informed consent document (ICD) verification, IP accountability, SAE reporting , Source data verification and monitoring documentation.
- Each task is then broken down into **activities**. In this example the task of monitoring documentation is taken and broken down into –generating Trial master file (TMF) and site master file (SMF), collating essential documents etc.
- Each of these activities is then broken down further into constituent **knowledge** and **skills** that are required to perform these. Some of these will be basic knowledge, some advanced, as in role specific and some others specific to the project.

Table 134. Task analysis for the competency - monitoring at site

1	**Competency: Monitoring at site**				
	Tasks				
	1	Planning monitoring visits			
	2	ICD verification			
	3	IP accountability			
	4	SAE reporting verification			
	5	Source Data verification			
	6	Monitoring documentation			
		Activities			
		1	Generate TMF and SMF		
		2	Collate essential documents		
			Knowledge		
			1	ICH GCP and Schedule Y guidelines	Basic
			2	Local regulatory procedures	
			3	Completeness and accuracy of documents	Advanced
			4	Review completeness of documents	
			5	Protocol	Specific
			6	Sponsor SOPs and specific templates	
			Skills		
			1	Written and oral communication	Basic
			2	Presentation skills	
			3	Interpersonal skills	
			4	Computing skills	
			5	Conflict management	Advanced
			6	leadership skills	

This process when completed for all the tasks that comprise the competency of monitoring at site, gives a compilation of all the items of knowledge and skills required for a training course on “effective monitoring at site”.

Advantages of this model -

1. Competencies to be achieved on successful completion of the training program are stated upfront and participants know the end result they are aiming to achieve. This is especially useful when the role is new and the role holder is himself unaware of what is expected of him.
2. Supporting theory is integrated with skills practise and essential knowledge is learned to support the performance of the skills.
3. Intermittent assessments serve as a guide for course corrections in the training program.
4. Since the objective is clear upfront, there is more ownership and motivation of the participant.
5. The competence is layered as basic, advanced and project specific and allows for interruptions to training, different rates of learning.
6. The understanding of competence is detailed and it reduces risk of gaps in perceptions.
7. It applies to all staff - the ‘trainee’ may be someone of long experience, but new to the role or task. In this case s/he can be expected to have some basic knowledge/skills and only advanced and project specific need to be imparted.
8. It serves as an ideal base for a structured ahead-of the curve training in preparation for a higher role.
9. This format leaves room for a variety of techniques to assess the learning
10. For roles that have globally accepted standards of performance, a generic competency mapping can be done for the roles in the industry.

Challenges in this model -

1. The key activities of the roles and their performance standard will have to clearly identify so that competencies can be mapped. This will be challenging in an environment where roles are constantly evolving and changing.

2. Competency mapping and individual assessment of competencies are rigorous time consuming processes.
3. Since competencies are contextual, competency mapping will have to fine-tuned in every organisation if one generic template for a globally standard role is used.
4. Training curriculum has to be so designed that knowledge is delivered through didactic classroom lectures, and participants are allocated a simulated environment to acquire the skill and then practice until competent. During this time the trainer functions as a coach providing continuous feedback and reinforcement to participants. Only when participants are assessed and determined to be competent on a model, do they work with clients. Administration of a midcourse questionnaire to determine if the participants have mastered the new knowledge associated with the skills and are conscious of its applicability was done. Satisfactory completion of training is based on achievement of all specified competencies.
5. Most often trainers need initial training and assistance to avoid the tendency to 'teach as we were taught'.
6. The model is only as effective as the process used to identify the competencies.

Conclusions:

Competency mapping and competency based training is likely to be an effective solution in a situation where there is a lot of variability of the curricula at the graduation level and performance standards expected from the roles are globally accepted standards of performance.

Chapter 6: Special Contribution

This is probably the first study of its kind that lays out the landscape of the clinical research workforce in India- their educational backgrounds, training and experience in the industry.

The relatively low base of experienced people in our industry underscores the importance of structured training programs for capacity building.

The findings of our study show that requirements of knowledge and skills are different for the different roles and therefore 'one size fits all' kind of trainings that are currently being offered at many training institutions are at best a basal exposure and not adequate.

The study also exposes gaps – in areas of knowledge and skills that have been identified as critical or important to performance in which role holders have not received training, also in stakeholder expectations and role holder perceptions.

Training that role holders have received is still largely on the job, which may have lacunae and subjectivity. The competency based model proposed sets the path for more structured training programs where training is complete and composite and designed to meet definite objectives.

Chapter 7: Future Scope of work

Further work needs to be done on a more composite data base of clinical research professionals in India. Our work has shown that identifying training needs from the role holders in a new field like clinical research has the limitation of respondents not knowing what they should know. It may be therefore be better to understand these needs from the by stratification by qualifications, work place and experience. To meet the challenge of covering all areas of knowledge and skills, it may be better to draw an outline of the competencies required for each role and have them endorsed or refuted by stakeholders by a Delphi method or focus group discussions. This will ensure common minimum performance criteria for the roles across organisations and can be matched to global standards. Further, the knowledge, skills and attitudes required for each of these competencies can be delineated, and again endorsed by stakeholders across organisations. Such a competency map, validated by both stake holders can then become the basis for designing training courses, entry criteria to them, bridging courses and assessments.

We have seen people with various qualifications taking up roles in clinical research. Also, our existing clinical research workforce has people of differing competency levels, by virtue of their exposure (or lack of it) to training and on the job mentoring. Defining the competencies required for each of the roles will help design entry criteria either based on the candidate having some of those competencies or being able to gather them through bridging courses. This will ensure that all the candidates taking up a course will have the same basal level of competencies that the course seeks to build on.

Satisfactory completion of training is based on achievement of all specified competencies as found on assessments- either in a simulated or real environment. Assessments form an important part of competency based training. They serve to warn of areas where greater attention is required or course corrections may be warranted. Stating of the objectives upfront will set a clear direction both from the trainer and the trainee on what needs to be achieved and what will be assessed at the end of the course.

Chapter 8: Conclusions

With a group as diverse and unique as that in our clinical research industry, it is hard to draw, broad, sweeping conclusions. Nevertheless, our findings provide insight into the clinical trials landscape in India. A generally discernable trend is that there are definite role related differences in requirements of knowledge and skills for performance in the job. This difference is perceived at module level and at the level of sub-topics within the module. The 2 modules that are basic to clinical research – the General and Ethics seem to have larger applicability across all roles in clinical research. Specific modules like Data Management and statistics and within it niche topics like data coding and cleaning found acceptance only with Data management personnel. Also, the execution module was found more acceptable to the CRA or project manager roles, the methodology module to the project physician role etc. This translates into the fact that different training modules will be applicable for different roles, especially at advanced training level.

Majority of our CR workforce had less than 3 year experience in CR and seemed to have some lack of clarity of their training requirements. The immediate training needs seem to overlap with developmental needs of the future because there seem to be lack of clarity on the career path. Knowledge items are more understandable and evaluable and hence received more discriminatory responses compared to the softer aspects of skills, most of which were rated critical for all the roles. New entrants are probably not adequately aware of the career and training needs to be driven by the experienced stakeholders. However, stakeholders internationally admit that they 'fell into clinical research unexpectedly' [96-98]. They themselves may not have undergone a structured training program which was even not available till very recently. On-the-job mentoring by supporting colleagues and learning by mistakes were the order of the day. This could probably be one of the reasons why despite proven research that education and training directly benefits performance, there is not as much enthusiasm from stakeholders to drive such programs [99]. If new role holders are probably unaware of their own training requirements, the onus of defining training needs and driving training would fall on the stakeholders.

However, our survey showed that there were some gaps and areas of differences between stakeholder expectations for the role and role holder's perceptions for the same. If

stakeholders have the onus of driving training, it is important to create awareness and buy-in at stakeholder level on the knowledge and skills required for competence in a role.

Additional education and advanced leadership training have been consistently identified as important for career advancement in surveys [75, 100]. To decide the right training program to pursue one must also devote some time to serious career planning, to understand the demands of various roles, how they fit in with work life balance priorities and what qualification and competencies are to be acquired to perform well in these roles. There are some websites of societies like ACRP or ICR, besides the book by Dr. Stonier [43] that provides such guidance. However, these have an international perspective and some differences with its applicability in India.

Our survey data also shows that most training that happens today is still at awareness level. It is important to understand this and the process of how different training methods can be used to bring this to higher competence level. This will probably mean having more structured training methods and hands on learning to compliment.

Our clinical research workforce, like any other in the world, had people with different levels of learning- some novices, who had not received training, some who had received training in 'awareness' level, and a few in knowledge and even fewer in competence levels. Training needs of such a population will also demand training modules cater to different competency levels. An eminent educator has opined that it would be a terrible mistake to have a single syllabus for such a population [101]. Courses will have to be designed to specific learning objectives that define the end result in competency levels and assessments will have to be built in to assess entry level competency before assigning a program to a person. Bert Spilker [101] assumes that somewhere between 100- 200 modules would be required for all levels of need in pertinent topics.

Skills' training is an important aspect that is neglected. The basic skills like communication, interpersonal, presentation, team work and computing skills are a requirement for all roles. More complex skills like leadership skills and conflict management are probably still ill understood and need more consideration. Also important is the timing of training and order in which training needs to be done.

We began an enquiry into the problem statement - “Is awareness and availability of training in clinical research adequate to meet the challenges of explosive growth in clinical research opportunities in India? We conclude that both awareness and availability are probably inadequate. Structured training programs need to be designed considering the specific needs of the role and the level of competence of the participants.

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APPENDICES

LIST OF PUBLICATIONS AND PRESENTATIONS

Publications

1. Samyuktha Ajay. A Career In Clinical Research for Pharmacists- Pharmatimes, Vol 35, Dec 2003, pgs 22-23.

2. Samyuktha Ajay Clinical Data Management and its scope in India Vol 37, No.7, July 2005, pgs 19-20

3. Ajay S and Bhatt A. Knowledge and Skills at the study site: Requirements for clinical research professionals in India: A survey CR Focus Vol 19, Number 7, July 2008 pp 36-39.

4. Bidarkar A and Ajay S. India's Talent Crunch. Applied Clinical Trials; Vol 17, Number 11 Nov 2008 pp 72-74.

Submitted

5. Chandra S and Ajay S. Competency-based Training for Efficient Capacity Expansion in a Resource Constrained Environment of Clinical Research Outsourcing in India. Submitted to IJBIT, Dec 2008.

Presentations

1. Presented paper on Clinical Research-New avenues in teachers' refresher course on conducted from 3rd Jan to 9th Jan 2004 at Allana College of Pharmacy, Pune.

2. Presentation in UDCT auditorium for pharmacy students on Careers in Clinical Research on Nov 20th 2003 under the aegis of the National Pharmacy week celebrations.

3. Delivered an invited lecture on Clinical Trials: Training Issues at Microcon Mumbai 2003- XXVII National Conference of Indian Association of Medical Microbiologists, Mumbai, November 8th 2003.

4. Made a presentation on Clinical Research In India during ACE's advanced module certificate course on Clinical Research: From Theory to Practice, October 22, 2003.

5. Presented a paper on Training Clinical Research Professionals-an unmet need at the CII conference on Clinical Research-Road Map for India, September 24-25, 2003, New Delhi.
6. Presentation on ICH GCP and Indian Guidelines during ACE's certificate course on Foundations of Clinical Research and GCP at Hyderabad, February 22, 2003.

7. Presentation on Supply and Handling of Investigational product during ACE's certificate course on Foundations of Clinical Research and GCP at Ahmedabad, February 1, 2003.

8. The talent paradox – Addressing the challenges of talent availability and retention in clinical research in India DCC India 2007 July 11-12, Taj Lands End, Mumbai.

9. From Talent constrained to talent enriched- The Siro perspective presented at the 1st Annual Conference of the Indian Society for Clinical Research – "Clinical Research in India, Mumbai, 10-13 Jan 2008.

10. 'Competency-Based Training Initiatives: Bridging the Talent Gap in Clinical Research Outsourcing in India' presented in the "The 5th Annual HR Conference" organised by Institute of Technology & Management (ITM), on 19th December, 2008

11. "Knowledge and Skills for Clinical Research Industry Professionals- CRAs and Project Managers" presented at 2nd Annual Conference of the Indian Society for Clinical Research – "Clinical Research in India – Translating Rhetoric to Reality, Mumbai, 10-13 Jan 2009

BRIEF BIOGRAPHY OF THE CANDIDATE

Ms. Samyuktha Ajay, is a Pharmacy post graduate from Mumbai university. She has over 20 years work experience in the pharmaceutical and clinical research space – with the likes of Glaxo India Ltd., Pfizer Pharmaceutical India Pvt. Ltd., and CROs like ICON Clinical Research and Siro Clinpharm India Pvt Ltd.

India's premier clinical research training academy- Academy for Clinical Excellence (ACE) was set-up under her directorship. An active member of Indian Pharmaceutical Association and the Institute of Human Potential and Development, she has a keen interest in training and development.

BRIEF BIOGRAPHY OF THE SUPERVISOR

Dr. Arun D. Bhatt President, ClinInvent Research Pvt Ltd.
He is an MD (Medicine) from KEM Hospital and a member Faculty of Pharmaceutical Medicine of Royal College of Physicians UK. He is an elected Fellow Indian College of Physicians. He has a gold medal in pharmacology from Mumbai University and is trained in clinical pharmacology in Switzerland and Germany.

Dr. Arun Bhatt has extensive experience of clinical research in pharmaceutical industry.
He has worked as a consultant in Pharmaceutical Medicine & Clinical Pharmacology and was the Chief Executive Officer of CMI (India) Pvt Ltd, a German Herbal R & D company. Prior to this, Dr. Bhatt was the Medical Director of Novartis India Limited. He was the President, Indian Society for Clinical Pharmacology and Therapeutics. He is Convenor Training Council of Indian Society for Clinical research. He is on the advisory committee of several clinical research education institutes.

Dr Bhatt is a recipient of Bilcare Research Academy's **"Scientific Achievement Award".**

Dr Bhatt is a regular faculty for workshops / training programmes in clinical research and GCP. He is President of Indian Society for Clinical research. He is a visiting faculty at SNDT University Mumbai and Ph. D. Examiner University of Mumbai.

Dr. Bhatt runs a regular column on Good Clinical Practice – Question Answers.

Dr Bhatt has more than 100 publications in national and international journals.
Dr Bhatt has published a book "Clinical Trials and Good Clinical Practice in India – Your Questions Answered".