CLINICAL RESEARCH EDUCATION & TRAINING: OPPORTUNITIES AND ISSUES

Background

Clinical trials were initiated around 1537, but came to the limelight when James Lind in 1747 first introduced control groups in a study of scurvy. He later went on to become the father of clinical trials. Clinical trials started flourishing from 1800's, and the focus of studies used to be on study design. From 1863 onwards scientists started using placebos. Randomised studies were initiated in 1923, and from 1945 the focus moved to ethical aspects of clinical trials.

However, a lot has changed in the clinical research scenario since then. Today, clinical trials are conducted through a regulated approach following certain guidelines laid down by the International Conference on Harmonization (ICH), which is spearheaded by the USA, Europe and Japan.

Clinical research constitutes a large sector of the healthcare industry and employs a significant percentage of the healthcare workforce. The biomedical research industry spends an estimated US$38 billion worldwide annually. Out of this, the global CRO market size is US$15 billion, growing at 16% per annum.

The growing demand for clinical trial professionals has led to an increasing number of institutions offering academic programmes in clinical research. According to a 2001 CenterWatch survey, the US has slightly more than 200,000 clinical research professionals. There are 60,000 trials following the Food and Drug Administration's guidance for GCPs and more than 40,000 GCP-trained investigators, but the number of investigators is decreasing even as the number of trials increases. According to some reports there are over 1000 global competitors in the CRO segment offering various services, and it is estimated that over 40,000 subjects participate in global clinical trials every year.

Recruitment is a major stumbling block in the drug development process, and increasing staff costs mean that more and more studies will be outsourced to the emerging markets. Sponsors are looking at emerging markets to leverage the high cost of trials in the US and Europe, and to reduce time to market.

Need for Education & Training

The demand for clinical research professionals is rising globally and clinical trials are being outsourced from several countries, including rapidly growing emerging markets like India and China. As a result, human resource managers have a challenge in front of them to find out or develop the right quality of manpower. In addition to hiring experienced professionals, they need to consider clinical research professionals who have undertaken formal training or education in clinical research.

Also globally ability to fully explore the opportunities for medical advances are limited only by resources, the most important of which is the well trained clinical research and scientific workforce. In order to keep up the speed of drug and device development, we must train and develop the pool of clinical researchers with skills that match the increasing complexity and needs of the clinical research industry.

The clinical research professionals pool must be large enough to facilitate lab-to-clinic research, handle different phases of clinical trials and translate the proof of concept into the medical practice. Physicians must be well trained to work in the interdisciplinary, team-oriented, global environments that characterize today‘s emerging research efforts. Clinical researchers need to be trained in an array of disciplines important to the conduct of clinical studies, including Regulatory Affairs; Ethics; Conduct and Management of Clinical Trials; ICH GCP Principles; Roles and Responsibilities; Adverse Event Reporting; Biostatistics and large number of other subjects.

In the developed markets target audiences for clinical research education and training are often those persons who are currently active in clinical research. However, in the emerging markets the target audiences of such training programmes are graduates and postgraduates in medicine, science, pharmacy and other related subjects without experience in clinical research. This new strategy of training fresh graduates has been adopted to build capacity, and develop a new well-trained clinical research workforce in the emerging markets.

Clinical research managers / coordinators are an important part of the clinical trial process. In order to be a successful clinical trial professional the person would need to have formal training in clinical research or previous work experience in clinical trials, and a working knowledge of the clinical research industry.

Programme Content

A good clinical research training programme must provide knowledge of GCP (good clinical practices), and the Code of Federal Regulations or regulations of other countries, viz. EMEA, MHRA, Schedule Y of India, Anvisa of Brazil, TGA Australia, Health Canada and several other countries like China and Russia. It is important that the training of clinical research managers and coordinators emphasises the history of research regulation, guidelines and forms, codes of federal regulations, phases of clinical research, IEC / IRBs and submission requirements, informed consent process, protocol review and evaluation, project management, budget preparation and negotiation, regulatory submissions, adverse events, study drug accountability, and setting up one’s research site.

It takes a lot of responsibility and experience to be a clinical research professional. It is important for the clinical research professionals to understand ethical issues involved in human research, follow regulations stringently, work effectively with other stakeholders like IEC/IRB, create and conduct informed consent, manage study data, manage adverse events, understand the

community/research interface, collect high quality data, identify funding sources and prepare grant proposals, and fulfil reporting obligations.

Clinical research professionals must learn the drug development process; understand global clinical research regulations, the informed consent process and the relevant regulations; help coordinate sponsor site visits; manage clinical trial protocol; and identify ethical issues in clinical research and their impact on the development of good clinical practices.

Participating in audits is important for a clinical research coordinator because without the training, a clinical coordinator would not be able to perform or face the audit to high quality standards for an inspection. It is important to maintain a safe and quality environment in clinical settings to ensure the individuals participating in the clinical trials, and the future consumers, will be safe.

Until about the early part of 2000, a science or pharmacy graduate could easily get a job as a clinical research coordinator or find work as a CRA quite easily. However, the drug research industry has evolved significantly since then, as clinical trials outsourcing is moving to other countries. As a result of decreasing resources companies are not providing training to the entry level professionals. Most employers prefer candidates to be trained in clinical research issues.

Although there is an abundance of highly educated and skilled young scientists globally, many applicants vying for non-lab-based positions in clinical research have not been trained in the pharmaceutical industry, how to prepare for clinical trials, regulatory issues, conduct and management of clinical trials, ethical considerations, analysis and interpretation of data and other clinical trial related issues.

Programme Types & Verticals

There are several graduate, postgraduate and postdoctoral educational programmes in clinical research offered by various global universities, with a duration of between three and five years.

While universities offer comprehensive long-term programmes, there is a large number of private institutions who offer short-term specialised training programmes, certificate & diploma programmes in the conduct and management of clinical trials, regulatory affairs, ethics, drug safety, documentation, roles and responsibilities and a number of other areas. These programmes are focused, are generally of a shorter duration and are delivered by industry experts. These programmes could also be undertaken both in the classroom environment and through online / e-learning modes. This segment is gaining popularity.

While courses offered through e-learning and distance learning are a convenient alternative to traditional educational programmes, they are unable to provide hands-on experience in the conduct of clinical trials and other skills required, viz. time management, teamwork, better communication skills and several other such skillsets. However, these programmes can provide fresh graduates or entry level job seekers with a definite advantage when combined with a science background and some entry-level experience in managing clinical trials.

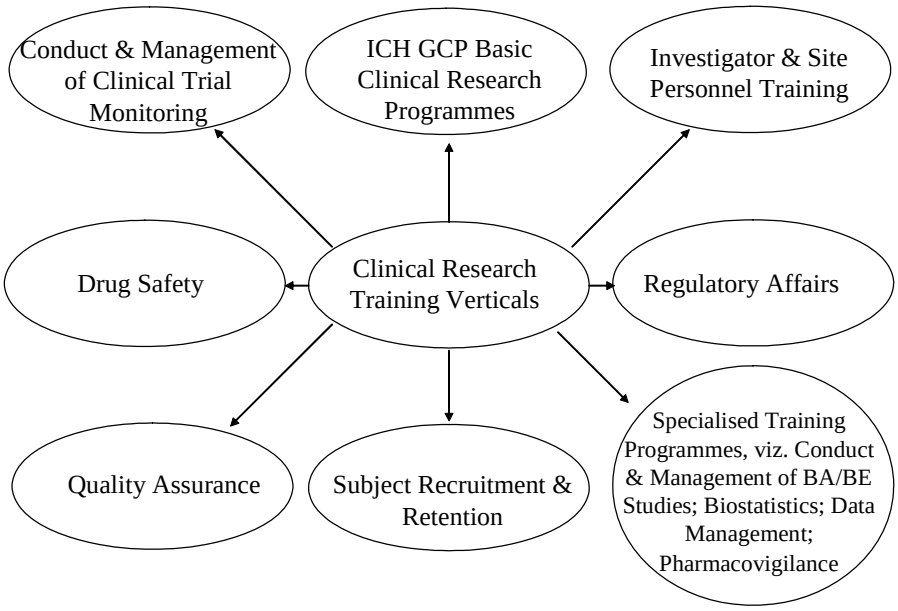
Types of Training Programs

Clinical research professional organisations like SoCRA, ACRP, etc. need to play a wider role in the emerging clinical research markets and not restrict their programmes only to the US market or only to experienced professionals. Most of these professional bodies offer certifications for their members only after a documented two years' experience in clinical research. As the business of clinical trials is moving towards emerging markets, these professional groups should offer accreditation / certification support to local institutions in these markets.

A number of pharmaceutical companies and contract research organisations conduct internal training programmes for their employees. However, these programmes vary from organisation to organisation depending upon the funding, training resources, workload and several other factors. Sometimes these programmes may not be very effective as they may be delivered by the in-house training teams with limited perspective, and the programmes may not be fully structured.

Education and training in clinical research continues to vary considerably: online programmes, certificate and diploma programmes and graduate & postgraduate degrees. Most of these programmes vary from country to country, and there is no standardisation of the course curriculum.

There is a need for short-term specialised programmes. Although university programmes offer long-term programmes on clinical research, there is a great need for short duration specialised programmes on subjects like pharmacovigilance, drug safety, biostatistics, quality assurance in clinical research, bioequivalence & bioavailability, subject recruitment & retention, regulatory issues and several other such topics. These programmes provide more practical training to the students in the workshop environment.



Challenges in Clinical Research Education & Training

In the absence of a standardised curriculum there are gaps in the training programmes.

There are several factors which limit the implementation of quality clinical research education and training programmes. One of the critical issues is the quality of training facilities. There is a lack of commitment in the industry and investigators to train budding clinical research professionals.

Some other issues are the allocation of training budgets by companies. Most companies consider training and education to staff as an incentive rather than an investment to improve the quality of clinical trials conducted by them.

Another issue which impacts training is the high cost of the large number of programmes. Most of the programmes offered have prohibitive costs, hence most students and even working professionals cannot afford these programmes.

There are several other challenges which need to be addressed to implement the quality programmes, viz. who should be trained, who should provide training, course design, programme delivery mechanisms, cost, role of the industry, accreditation, what role professional associations could play in setting the benchmarks, whether there is a need for formal university programmes or whether certification / diploma programmes are able to address the needs of the industry. Several such questions are unanswered today.

Like other professional education programmes, e.g. management education, there is a great need for the educational and training institutions to arrive at a common forum together and device a strategy to address the above challenges.

References:

1. Interviews conducted with several clinical research professionals

2. www.cliniminds.com

3. Clinical Research Coordinator Training:

www.mcrfmd.com/links/Research_**Coordinator**_Brochure.pdf

4. Aureus Research Consultants

www.aureusresearch.com/facts.htm

5. Clinical Research Coordinator training

www.datapharmaustralia.com/Datapharm_**training**_2005.pdf

6. Clinical Coordinator Program Training

www.e**clinical**researchconsulting.com/**coordinator_training**.php

7. Clinical Coordinator Training

www.barnettinternational.com/RSC_PDFUploads/BrochureS04.pd

8. International Biopharmaceutical Association Publication - Clinical Coordinator Training: Why is it So Important? Christopher Coles

9. Issues in clinical research manager education and training - Publication: Research Practitioner; Publication Date: 01-Mar-07; Author: Carter, Sheree C., Jester, Penelope M., Jones, Carolynn Thomas