Review Article

Building research capacity in India: The Masters in Clinical Research program at the Tata Memorial Centre

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Abstract

Clinical research is an essential part of evidence-based medicine. The conduct of high-quality clinical research requires the backing of strong infrastructure, especially well-trained clinical research professionals. Tata Memorial Centre is the largest public cancer center in India and has been offering a Masters degree in Clinical Research since 2014. In this article, we look at the need for clinical research training, the evolution of this course and the impact it has had on clinical research capacity in India

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INTRODUCTION

Clinical research is the backbone on which medical progress occurs. It helps find new and better ways to prevent, detect, diagnose, and treat disease.[1] The advancement of health care depends on high quality clinical research with strict adherence to international and local regulations and guidelines, with the patient at the center of all research efforts. Clinical research has been globalized over the last two decades, not just because of the regulatory challenges and costs of conducting trials in countries such as the United States of America but also growing realization that the results of research need to be applicable across diverse geographic and socioeconomic regions. This is exemplified by the fact that studies registered at clinicaltrials.gov as of July 18, 2017, showed that 36% of clinical trials were conducted only in the USA, whereas 47% were carried out solely in other countries, many of which were developing nations.[2,3]

Developing countries such as India offer several advantages for the conduct of clinical trials. The large population offers a pool of participants with diverse genetic make-up who can participate in clinical trials. India has established capacity in medical and scientific skills and information technology. The medical education curriculum is in English and most medical specialists are fluent in English. The costs involved in the conduct of a trial are less than those in developed countries. It has been estimated that the cost of conducting research in India is among the least in the world after Russia, Argentina, and China and roughly half that in the US or UK.[2]

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The clinical trials industry in India faced some challenges between 2011 and 2014 due to changes in the regulatory framework. This resulted in a significant decline in clinical trial activity and a diminished presence in the global clinical trial market. However, since 2014, the guidelines and regulations were rationalized, giving an impetus once again to the clinical trial industry. The pharmaceutical industry in India is currently estimated to be the third largest in the world in terms of volume and the thirteenth largest in terms of value, (approximately Rs 1,00,000 crore) with an annual growth rate of 13%–15%.[4]

The participant, investigator, sponsor, and the Institutional Review Board/Independent Ethics Committee (Institutional Ethics Committee [IEC]) are the key stakeholders in clinical research, supported by other players including the regulators, contract research organizations, and support staff such as clinical research coordinators (CRCs), and clinical operations teams consisting of clinical research associates and project managers. In addition, aspects of research such as regulatory affairs, data management, medical writing, and pharmacovigilance are gaining increasing importance.

Indian doctors have longer working hours and deal with much higher patient loads than their counterparts in developed countries.[5] Very few institutes in India offer protected time for research and clinicians have to multi-task between their clinical, administrative, and research responsibilities. Therefore, there is a need for adequate infrastructure and trained clinical research professionals to facilitate the conduct of good-quality clinical research in India.

Several institutes across the country offer training in clinical research in various formats—full-time versus part-time, in-person versus online—with durations ranging from weeks to years. Most of these courses have wide eligibility criteria, allowing entry to individuals with diverse backgrounds.[6] Almost all of them have self-structured, unregulated curricula with largely didactic sessions and offer little or no hands-on training.[7,8] Only a handful of these courses have a University affiliation and recognition.[6] The fee for these courses is also quite steep, putting them out of the reach of many aspiring applicants.[6]

The Masters of Science in Clinical Research program at the Tata Memorial Centre

The Tata Memorial Centre (TMC), affiliated to the Homi Bhabha National Institute is the largest cancer hospital and research institute in India, with the mandate of service, research, and education in cancer.[9] It is a grant-in-aid institution under the Department of Atomic Energy (DAE). The TMC has a strong background of clinical research and has been the base for the conduct of several practice-changing trials.[10-13] Many of the researchers at TMC have been investigators on both academic and industry-initiated research projects. The Clinical Research Secretariat (CRS) at TMC, established in 1996, was one of the first of its kind in the country, offering research support to investigators for the planning and conduct of trials. The DAE Clinical Trials Centre has complemented the activities of the CRS by funding and facilitating the conduct of these research studies. The Homi Bhabha National Institute is an Indian deemed university established by the DAE in 2006, which offers a variety of academic programs and degrees at the doctoral and masters level, and pursues research in accordance with its mandate.[14]

Recognizing the need for trained human resource in clinical research, the TMC launched a postgraduate Masters in Science (M.Sc.) degree in Clinical Research in September 2014, under the HBNI.[15] The goal of this course was to build capacity for trained personnel for supporting clinical research in India, using a combination of class room training and actual hands-on experience in the conduct of research studies. The M.Sc. programme is structured as a 2-year course followed by a mandatory 1-year internship at the TMC.

Selection process

Entry into the course is open to graduates with a science background. The selection of candidates is through a competitive process which includes an online examination followed by an interview. At present, the course capacity is 10 candidates each year; however, considering the expanding need for trained research professionals, the capacity is being expanded to 20 per batch from the next academic year. So far, six batches of students have been admitted into this course.

Course curriculum

The course curriculum is divided into seven modules, starting with classes on human physiology, basic understanding of various diseases and their management, the need for clinical research, research study designs, the drug development process, ethics in clinical research, national and international regulations and guidelines, and stakeholder responsibilities. The students are also trained in protocol writing, preparation of informed consent documents, basic biostatistics, safety reporting, data monitoring, investigational product management, scientific communication, and research in alternative systems of medicine. Besides these main topics, the students receive

training in clinical data management, pharmacovigilance, epidemiology research, project management and quality management, and receive overall career guidance. At the end of each module, internal written evaluation examinations are conducted; in addition, there is a university examination at the end of each year.

Along with didactic teaching (for 5 to 6 hours per week), the students are simultaneously posted in various Disease Management Groups (DMGs) in TMC for approximately 40 hours per week, for a total of 2 years. Each DMG treats and has research activities related to a particular set of health conditions, for example, breast cancer DMG, gastrointestinal cancer DMG and so on. During these postings, the students are involved in the ongoing research activities, from protocol development to submission and conduct of trials, initially under supervision of the trained CRCs and later independently. In this manner, they are able to experience the application of what they have learnt in the classroom. Students also have some specific rotations in areas outside the DMGs such as the IEC to understand the processes involved in the approval of research projects, the Data Safety Monitoring Unit (DSMU) for study monitoring, Phase 1 clinical trials unit for the experience of early phase trials, Central Laboratory posting, epidemiology and community medicine to understand aspects of prevention and screening, and as observers with an industry sponsor.

During their final 1-year internship period, the students are posted in two DMGs of their choice for 6 months each where they manage projects under direct supervision of the primary researcher, including all aspects of research such as protocol writing, regulatory submissions, screening and consenting patients, randomization, administering study interventions, study assessments, data management, reporting of adverse events, and compiling study reports. In addition, the interns get practical training in study monitoring when they monitor academic studies for the DSMU. The extensive hands-on experience they receive is a unique feature of the training and develops them into well-rounded professionals capable of directly taking up major clinical research responsibilities. Some of the students receive opportunities to be part of ongoing workshops and conferences, where in addition to honing their research skills, they cultivate planning, administrative and communications skills, which will form an important part of their future careers.

Course fee and logistics

The course fee has been deliberately kept at a minimum to encourage students from all socioeconomic strata to apply and benefit from this training. Students receive a monthly stipend through all 3 years of the course. In addition, whenever possible, subsidized accommodation and food arrangements are made to help them.

Career options

Students who completed this course in the last 5 years have received job placements almost immediately after their internship. The career options have included both academic and industry positions such as clinical trial coordinators, clinical research associates and opportunities in data management, regulatory affairs, and medical writing.

DISCUSSION

The globalization of clinical research raises ethical concerns about the applicability, value and affordability of the research to participants in resource-constrained settings and whether vulnerable populations are being exploited for the benefit of patients in more developed countries. However, it is important to note that clinical research offers several benefits to the host country. With the increasing prevalence of noncommunicable diseases such as cardiovascular conditions and cancer, it is important to test interventions on a global scale so that results of studies can be generalizable across populations. More importantly, it is important to undertake research in areas affecting low- and middle-income countries, such as head and neck and gall bladder cancers, for which local trained resources are required. Clinical research also helps to strengthen health-care infrastructure, build local research capacity, and benefit the economy.

The clinical trials industry in India has seen rapid growth in the last few years and is likely to accelerate further in the near future. This is likely to have benefits in terms of faster development of biosimilar drugs and novel cost-effective therapies. However, to maintain standards in clinical research and ensure that the principles of good clinical research practice are complied with, this growth needs to be matched by increased research capacity in the form of well-trained clinical research professionals.

In contrast to the many other clinical research training courses offered in the country, the M.Sc. Clinical Research course at TMC is unique due to the intense level of applied training that the students receive during the 3 years of the course. This ensures that the knowledge gained is not just theoretical but also practical. The structured curriculum, periodic evaluations, practical assignments, and supervised work experience ensure that the progress of the students is well-monitored. In addition, the course

syllabus is frequently updated to include current topics that are relevant. For example, recent modules have included sessions on training on New Drugs and Clinical Trials Rules, 2019, managing studies during the COVID-19 pandemic, and Indian Council of Medical Research guidelines for Ethics Committee functioning during the COVID-19 pandemic.

The M.Sc. Clinical Research course is an excellent example of successful collaboration between academia and industry to create local human resource for conducting research of local as well as global importance. Recognizing the value of this course and the need for well-trained clinical research professionals, industry colleagues have been hugely supportive of this initiative. Many of the key leaders in pharmaceutical research have offered their services (pro bono) as faculty for this course. The insights provided by the faculty from the industry have helped to shape the course structure and curriculum over the years. In addition, industry sponsors have accommodated the students as observers during their training.

SUMMARY

The M.Sc. Clinical Research degree at TMC offers a holistic curriculum with a balance of theoretical and applied teaching and is a unique opportunity for students interested in pursuing a career in clinical research to receive a well-rounded training to develop the skill sets that are needed. Similar courses should be conducted in other academic universities to increase the pool of well-trained clinical research professionals in the country.

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Conflicts of interest
There are no conflicts of interest.

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