Opportunities and challenges in conducting medical research in India: Food for thought

Gitanjali B.

Section Editor, Journal of Pharmacology and Pharmacotherapeutics

There is a feeling of pride and optimism in many national forums when speakers talk about the vast potential in India for clinical trials. The rich and fertile *milieu* for clinical trials in India is sustained by the numerous contract research organizations headed by highly trained and quietly efficient scientists; the multispecialty hospitals with foreign-trained clinical investigators falling over themselves to bag the most lucrative trials in terms of remuneration; the English speaking scientists and technicians who can read, write, and understand the language better than the neighboring 'resource limited' countries; a disinterested government which cannot decide whether it should safe guard the interests of the people or turn a blind eye to the obvious violation of human rights in the name of clinical trials; poorly informed patients who feel privileged to get whatever they are offered (even if it is not in their best interests) with the quiet acceptance that this is their karma; uninformed and untrained members of ethics committees which approve questionable clinical trials … the list goes on and on.[1,2] All of them are stakeholders in the multi million dollar business of clinical trials in India. From the pharmaceutical companies which are at the top of the food chain to the patients who are at the bottom, we have got stuck in quicksand. Unless we use this window of opportunity well and astutely, we could stand to lose.

Clinical trials have opened doors for people in terms of improved job prospects. It is not only the jobs created for technical people but also the non technical staff required for maintaining Good Clinical Practice (GCP) standards -- from cleaners to security personnel. There is also a flourishing grey market in the supply of healthy volunteers, with middle men making a killing. Healthy volunteers too make a substantial amount of money by local standards. Patients stand the chance of getting new (though not necessarily better) treatment often not available or unaffordable in the country. There are professionals providing services to write up reports, protocols, manuscripts and narratives. Retirees taking up positions of clinical trial monitors, academicians organizing workshops on data monitoring, GCP and many others, pharmacologists conducting courses ranging from scientific writing to statistics … they all seem to be offshoots of the thriving clinical trial industry. The atmosphere is heady, vibrant, and pulsating with an insatiable thirst for becoming bigger and better. This is how it is meant to be. However, what should be kept in mind is that while there is a very real need for these things there are also many people both within and outside India who are ready to cash in on the myriad opportunities that are presenting themselves and use it to their advantage through unethical and dishonest practices. It is this murky miasma we should guard against.

While there is no dearth of services being offered, the real challenge comes with the quality. There is a big gap in trial know-how and ethical oversight of clinical trials.[3] The suppliers of these services depend on their track record of affiliation to other well known and renowned institutions or experts as the case may be. I will start with an example of some of the courses advertised for training in clinical trials methodology (or some particular topic on any aspect). Many of these courses/workshops have big, reputable names on their lists of faculty, but those people hardly turn up for

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Address for correspondence:
Gitanjali B, Department of Pharmacology, Jawaharlal Institute of Postgraduate Medical Education and Research, Pondicherry, India.

mentoring as promised in the advertisement for the course. If they do, they come on a flying visit to deliver a single lecture and fly out before any of the participants or students can interact with them. These fly by night operators do not do much good, usually presenting the same set of slides prepared ten years ago. There is no way to judge whether it will be worth one's time effort and money to attend/join the workshop/course.

One of the foremost challenges is that we cannot guarantee that the people undertaking clinical trials have received 'quality' training.[4] Some of them learn on the job, but others do not, and in the meantime research suffers because of substandard workers. This may not necessarily translate as poor quality or substandard research in any one project but the domino effect may be quite substantial. If this happens, we may land up in a situation where drug companies may start to look elsewhere for their trials. It is important that we take corrective action now.

The constraints when conducting medical research are not limited to clinical trials. Even someone doing basic research faces untold problems. Research committees (or institutional review boards) are usually full of clinicians who believe that all basic research must have a clinical application as a justification for research or at least the potential for a clinical application before approving a protocol. I have listened to some really absurd speculations in an attempt to provide reasons for doing basic research. Then there are issues with procurement of equipment. By the time all the requirements for procurement have been met the interest to do research wanes. There was an incident where the Head of the Department (HOD) of Pharmacology was asked by the equipment selection committee 'why do you need a high performance liquid chromatography (HPLC) system? What can it do?' The HOD thought for a second and said 'if you give a person a drug and want to know the level in the blood, all you have to do is to take one ml of blood from that patient and inject it into the HPLC machine and *voila* you will get a print out of the drug level'. Needless to say he got approval for the HPLC. This goes to prove that that committees which take important decisions are often constituted by involving very important people (may also be translated as the oldest and busiest). These people who do not know much of latest research methods, techniques or protocols (since they spend their time attending meetings) are asked to take decisions which can well decide whether an investigator can get the equipment to do research or not. This is not limited to equipment alone, but extends to consumables, reagents, and glassware as well. If you have gone through the process of buying the equipment but are not permitted to procure the chemicals and consumables you are significantly worse off than when you did not have the equipment because you will be questioned during the annual audit why the equipment is lying unused. If you say you could not get the consumables you will be told in no uncertain terms that you should have planned in advance. At the same time, if you procure the consumables and the equipment is not delivered for whatever reason, you will be again taken to task. A typical Catch 22 situation. The lack of inadequate trained staff to operate sophisticated equipment and the inadequate infrastructure to support it are important reasons for medical equipment lying unused.[5]

One of the tricks used by faculty for procuring very expensive equipment is to say you will share this facility with whosoever wants to use it for research purposes. The administrators love such altruistic humans and make a big song and dance about having a national facility which will promote research. The hitch comes when you actually try to get some experiments done using the system or samples analyzed using the equipment. Excuses for shaking off persistent researchers will range from ''only my technician will touch the system, otherwise I will be answerable if something goes wrong'' to ''we are urgently processing some samples for one of our doctoral students, meet me in a month's time and I will tell you when we can set aside some time for you.'' The month will stretch to another one and so on. By this time you would have got the message. The idea of centralized research and laboratory facilities in India is a myth. Most scientists will guard their equipment like Crown jewels, even if it is not used and rotting away in a corner.

So how do you beat the system and buy the equipment you need for research? The only way to beat this system is to play along and massage the egos of the people who make up these committees. About two decades ago I wanted to procure a computerized polysomnography system for doing sleep studies. The equipment was very expensive, sleep research was in its infancy and there was very little awareness regarding sleep disorders. In order to buy the equipment I needed to get the members of the equipment purchase committee to agree that the price was justified, and that the equipment was indeed a useful addition to the department. I canvassed for the procurement as if I were a politician asking for votes, meeting each member separately and explaining to them that the polysomnography equipment will be useful in his/her own specialty; e.g., I told the pulmonologist that it is needed for diagnosis of apneas, the neurologist that we can do studies in narcoleptics, the internal medicine specialist that we could do studies in nocturnal epilepsy, the urologist that we could study erectile dysfunction, the otorhinolaryngologist that we could do assessments after surgery was done in obstructive sleep apnea patients and so on. Perhaps I sounded pretty convincing but in the end, I got the machine. Each member of the committee was convinced that the equipment will open research opportunities in his/her own field. Though one could consider this a devious manner of tricking members of the committee, at times you are left with no other choice.

Even if you have the equipment, the consumables, the patients/volunteers/animals now comes along a bigger hurdle – the ethics committee (whether human or animal) meeting. At times it seems to me that the only aim of ethics committees is to prevent research. The flimsiest reasons (I do not mean ethical reasons) are cited for not permitting a project. However, on the other side of the spectrum, trials of questionable ethical practices are permitted, perhaps as a favor to those wanting to conduct the trials but also due to plain ignorance. If you want to try out an old drug for a new indication you have to get the permission from the Drugs Controller General of India (DCGI). Anyone who has written to the DCGI's office will tell you that letters do not get acknowledged, leave alone getting answered. This means there will be no way you can get permission to do a study even if you want to use vitamin B complex in insomnia. Ethics committees in India, do not try to promote or supervise research.[6] One of the recognized roles of ethics committees is to facilitate research. Most of the ethics committees in India do not undertake that role and believe that their role stops with approval or rejection of a research proposal.

If you finally succeed in getting all approvals and reaching the point of actually doing research, your woes do not stop. Electricity will conspire to work against you. At times even water will have to be collected and stored the previous day. If you plan to collect your samples and store them in a freezer with plans to analyze them later, you may be in for a rude shock because there would have been a prolonged period during which there would have been no electricity and even the generator back-up would not have been working. One of my close friends did a project and collected tissue samples for histological examination. After nearly one year, he was ready to process the tissues. He asked one of the cleaners to clean the shelves as there was a lot of dust. The next day he found that all his samples had been thrown away and the bottles washed and cleaned. After this incident, till this day, my friend cleans his own work place.

Having funds to procure equipment, chemicals, kits etc., no way guarantees you will get quality equipment. Companies try to sell older models of their equipment at high cost. The quality of chemicals is suspect due to poor storage practices. I once procured a radioimmunoassay kit for estimation of serum melatonin. When the kit arrived I noticed it was an expired kit. Therefore, I returned it after making a mark with a marker pen on the underside of the vials of the standards. The kit was replaced after a month, the packing and labeling was perfect. When I took out the standards, the marks I had made on the vials of the previous kit were found intact. Though I tried my best to complain to the foreign company (which manufactured the kit) and made a hue and cry nothing substantial came out of it.

The Medical Council of India is trying to encourage medical teachers to do research. Given these issues, I would not be surprised if there is a strong objection to this move. A huge teaching burden by itself is a disincentive. Add to that the fact that the MCI has extended the age of retirement and reduced the number of faculty needed in each specialty. Nothing will irritate an ageing head of the department or senior professor more than the sight of young enthusiastic faculty trying to do research. The objections from the seniors will come down fast and with constant regularity forcing the youngsters to stop just for the sake of maintaining peace. But the thrill when you get that significant *P* value; or the graph that you predicted; or the gel picture you imagined; or the growth in your culture plate will be the true catalyst and inspiration that will keep you doing your little bit for research, no matter what the odds are against you.

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