Accreditation - A solution for problems or a fresh problem?

Clinical research has been going on in India for the last few decades, but it was only in recent times that roles and responsibilities of stakeholders were defined, and detailed regulations and guidelines formed. New drug trials had been few and far between, and it was only in this century that the clinical trial industry began to be recognized as a specialty on its own. Around 2004, there was hope that India could become a hub for clinical research, and trial numbers and active sites began to grow. This phase of growth was rudely interrupted due to allegations of misdemeanor in some trials. Few unscrupulous investigators,[1] working at poor quality sites with inadequate supervision by both the regulators[2] and Ethics Committees (ECs) gave the industry a bad name.[3] With the media latching on to the issue, the debate reached the Parliament and the Supreme Court. Clinical trials began to be perceived as nontransparent,[4] and the industry took a severe beating.

To stem this trend, the regulator made many changes in procedures and rules, but these were mostly knee jerk reactions to either outcry of the people, or admonishment of courts. This led to a slowdown of the clinical trial industry in 2010, and it has not yet recovered to its past level. The Indian government appointed a committee headed by Prof. Ranjit Roy Choudhary to develop guidelines for the conduct of trials, approval of new drugs, and ban of unwanted drugs, activities that are as different from each other as chalk and cheese. The committee did a thorough study and made over 25 recommendations, among which was the one to accredit sites, principal investigators (PIs), and ECs, a job that has been outsourced to National Accreditation Board for Hospitals (NABH). The process of training and empanelling assessors for evaluating the ECs, sites, and investigators has begun, and two training programs have already been completed.

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Some sites did not wait for the regulator to come up with an accreditation process and opted for overseas accreditation. International registration and accreditation has been available since long. So far, 527 Indian ECs had been registered with the office of human research protections (OHRP in US) but only about 300 have maintained their registration. In any case, active registration with OHRP only means that the ECs are compliant with the basic OHRP rules of the constitution of the committee. International accreditation agencies like Association for the Accreditation of Human Research Protection Programs (AAHRPP) and Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) have been active in the country for quite some time now. The difference between the two agencies is that SIDCER accredits the ECs only, while AAHRPP additionally accredits sites and investigators too.

Six Indian ECs have been accredited by AAHRPP and eight have been accredited by SIDCER. The accreditation process by either of these organizations takes a long time and is thorough covering most of the essential aspects of their function. NABH has accepted the recommendations made by experts and set up accreditation criteria on the lines of those of AAHRPP.[5] To be accredited, the site, PI and EC must comply with national and international regulations and AAHRPP criteria. Accreditation is a mark of excellence that goes beyond regulatory compliance and may provide accredited organizations a competitive advantage over non-accredited organizations. ECs that have sought AAHRPP and SIDCER accreditation have done so voluntarily and at a significant cost and effort, but they will have to seek NABH accreditation, which is only fair.

Coming to the accreditation process itself, it is clear that NABH has been very thorough. In 2013, the government had made registration of ECs with the Central Drugs Standard Control Organization (CDSCO) compulsory and stopped the approval of new trials by ECs till registration was done. This process lasted over 6 months, and the country lost over 40 trials from National Institutes of Health alone in this period. It is feared that trial approval may be stopped till accreditation. How long this process will take and what it is going to cost in terms of lost

opportunities, is anybody's guess, this is the first worry of the stakeholders in clinical research.

The accreditation process looks great on paper, but when it is implemented, one is not sure how closely the implementation will follow the plans. Only when the accreditation of a few sites, PIs and ECs takes place can those who are familiar with AAHRPP or SIDCER's procedures be able to comment on the relative merits of the process. Be that as it may, presently indications are that all will have to undergo accreditation, whether they are already accredited by AAHRPP or SIDCER. The importance of having national accreditation, even if international accreditation exists cannot be underrated, and will only affect a handful of ECs.

If one expects accreditation to be a panacea for all ills, disappointment is guaranteed. The original rules and regulations concerning the functioning of ECs and PIs have a few inadequacies, which will not be corrected. For example, though the chairperson of the EC cannot be from within the organization, there is no bar on owners/directors of the organization serving the EC as members. The presence of such members damages the independence of the ECs. Another problem is the one concerning independent ECs. These ECs are authorized to only review proposals for bioavailability and bioequivalence studies, but it is not clear if they are allowed to review and approve nonregulated biomedical research. Many institutes have independent ECs that review projects of postgraduate students and a variety of biomedical studies. Their argument is that CDSCO controls "clinical trials" (as defined in rule 122 DAA), and biomedical studies are not regulated by CDSCO, hence can be reviewed by independent ECs. The government needs to address these issues urgently and unless rules are amended total safety is not assured.

The government has capped the number of trials that an investigator can undertake to three, for which there is widespread opposition. It is also understood that 50% of all trials will be "reserved" for public sector hospitals. Both these steps are not in favor of the industry or the country, and should be reversed early, at least before accreditation begins. Accreditation, which ensures adherence to rules, will not solve problems created by rules. "Accreditation is not a quick fix, but a long-term strategy" is how senior industry expert Potkar puts it.[6]

Of the 1,87,040 trials conducted world over, India's share is a measly 2,600 (1.3%), and the number of trials actually recruiting is 595. Our contribution to new drug development is almost nonexistent; there is an urgent need for the government to look beyond its own experts, and hospitals to do research. Since the beginning of the new patent regime in 2005, Indian pharmaceutical industry has done its bit by developing new molecules, biosimilars etc., if the clinical trial industry cannot keep up with it, then the advantages that India offers to the world of clinical research will not fructify. Our country has been on the fringe of clinical research, and it will continue to remain there.

Ravindra B. Ghooi

Director, Scientia Clinical Services, Pune, Maharashtra, India.

Address for correspondence:
Dr. Ravindra Ghooi,
Scientia Clinical Services, G-801, Rohan Nilay, Aundh, Pune - 411 007, Maharashtra, India.
E-mail: ravindra.ghooi@gmail.com

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