Clinical trials are becoming more and more popular in India, albeit at a much slower growth rate than expected initially. Whereas, once thought to be a domain of larger academic institutions only, gradually these have percolated down to bigger private or corporate hospitals and then into the much smaller private clinics as well. It was initially essential so as to keep pace with increasing number of clinical trials coming to India and now it is not uncommon to find a clinical study being conducted in a private clinic. It is especially common in the fields of diabetes and metabolism, psychiatry, dermatology, and ophthalmology. This article is a small endeavor toward the evaluation of pros and cons of this policy.

MY OWN JOURNEY IN CLINICAL RESEARCH

In 2006, until when I was engaged in my 7-year-old out-patient diabetic clinic, I was approached by the marketing team of a leading pharmaceutical organization. They proposed me about a phase III drug trial for the purpose of DCGI submission. I was taken aback and in a reflex I uttered, ‘do you think it is possible for me to do it?’ They tried to convince me that they have discussed about my interest in scientific activities with their research team and if I am interested, their research team will contact me further for formalities. The drug was already approved by European agencies and was awaiting US FDA clearance. This is why I could dare to use it in my clinic. I rang two senior endocrinologists to know their views about it that would it not be too risky for me to do this at a clinic level. With their emotional support, I could courage to put my first step in this unventured field for me. I would quote another incidence of 2005 when I was consultant in a big corporate hospital. A representative of a US-based research organization was introduced to me who was exploring the possibility of adding my department in the process of their drug development. I would have heard hardly 10 min of his presentation and could not prevent myself from making a very cold statement ‘do you wish to make us Indians, guinea pigs for you?’ Obviously, he didn’t take next minute in leaving my chamber.

Unfortunately, clinical research is a topic for study in business administration but not in medicine! Even during doctoral courses, Indian doctors are not exposed to drug trials. Exception would be an anecdotal student who could have some overview of it, if his guide is involved in a study. Medical text books are completely silent about it. Therefore, whatever a practitioner knows about the clinical trial is either learned in a scientific symposium or sometimes from the media. In a scientific forum, clinical studies are often presented in a very glorified manner which may appear as a very difficult task to be performed by an ordinary practitioner. Media, whereas, present them mostly for their unethical conduct or for other darker aspects. Now I realise my both reactions to be borne of these two realities only.

HOW PATIENTS REACT ABOUT CLINICAL RESEARCH AT MY CENTER?

Almost 25% of our patients outrightly reject the idea of participating in any clinical research. Even if the drug has been approved by regulatory agencies and is being observed
for some another reason, the name of clinical research is frightening to them. Some of them actually never turned back to me after they are given ICFs to study. Another 25% would deny in a more sophisticated manner that they do not have time to devote for it or would like to discuss with their family members or friends or a family doctor and skip any further conversation on it. Over a period of time, I have observed that these reactions are at least doubled whenever we try to proceed in a hasty manner. It often happens when the recruitment period for a study is about to be over. Otherwise, our usual policy is to introduce the concept of study and it’s IP over several consecutive clinical visits and to give him/her ample of time for understanding the study and decision making. We actually insist that patients should discuss about it with their co-physicians, though it has very unexpected responses as well. However coupled with all such odds, subjects who join a study are more motivated towards it and are likely to comply to the study protocol in a better manner. With these policies, the completion rate at my center is >95% except in one long-term cardiovascular outcome study in which 10% dropped out within 1 year.

Here I would like to share about the behavior of our subjects after completion of a study. At one time, we were perplexed with mixed thoughts about clinical research and I refused further studies to get some time so as to make a judicious decision in this matter. During this time, I observed that patients who were very meticulous during the study were now behaving very carelessly. Their clinical visits have become very infrequent, since they have to pay for their consultation now (though, to honour their valued involvement, I charge 50% of my fee from my previous study participants). They were monitoring their blood glucose values very infrequently and these were now less adequately controlled. During the course of a study, many a times I used to feel ‘should this patient has not been a study participant then I would have controlled his glucose values much rapidly’. But now, when the same doctor and the same patient have returned back to real time practice, the control was even looser. Remarks from some previous study participants on this issue were astonishing. They were monitoring their blood glucose values very infrequently and these were now less adequately controlled. During the course of a study, many a times I used to feel ‘should this patient has not been a study participant then I would have controlled his glucose values much rapidly’. But now, when the same doctor and the same patient have returned back to real time practice, the control was even looser. Remarks from some previous study participants on this issue were astonishing. They related it to (a) Financial reasons: Since there were free access to glucometer, its strips, biochemical investigations, medicines and consultancy during the study period; (b) Facilities: Since me, my co-investigators, my para-medical staff, all were accessible and available to them with smile, 24 × 7 × 30; and (c) Encouragement and emotional support: Since they were shown their weekly or fortnightly progress report and accordingly encouraged to follow better and better life style measures, on each of their clinic visits. They felt as they were not alone in their fight against their diabetes. This made me to restart clinical studies again at my center.

**INCENTIVES AND DISINCENTIVES FOR DOCTORS FOR PERFORMING CLINICAL TRIALS IN THEIR PRIVATE CLINICS**

Ever since I entered into this stream, I used to interview other investigators about their opinions on clinical trials. I asked approximately 10 endocrinologists about why did they start clinical trials in their clinic setup. Surprisingly, their responses were almost alike. After being satisfied with the clinical practice, a good physician would wish to do something which can satisfy his academic hunger or scientific quest. When viewed from outside, the clinical trial appears to be a job full of state-of-the-art scientific activity and hence, when ever given this opportunity, one will jump into it. It brings them join a different class of physicians who are considered superior to others. Experiences about how did they feel was even more interesting. Nobody found it to be of great scientific satisfaction, except for a simple contractual documentation practice. Given the option, some wished to continue it until it runs smoothly and others to stop in a year or two. Reasons, why do they wish to quit were: (1) too much of paper work, (2) monotony of job, (3) lack of scientific satisfaction and/or (4) unhappiness that clinical research agencies at times behave like police and are then actually ethical on paper only and practically lack humanitarian grounds for which Indian doctors are known. Although I have been listening to these reasons for the last 3 years, I am yet to see a person who has stopped doing it. When asked later, how do they feel about it, their responses were, (1) it’s just another ‘procedure’ available to us like angiography to cardiologists or endoscopy to gastroenterologists (2) it can be continued as a side work, and (3) it provides me money which is needed for my extensive investigator initiated clinical works.

Drug trial subjects are still recognized as guinea pigs. I have been questioned on a number of times by my colleagues whether ‘the drug you are testing has been tried on humans ever before’ or ‘do you really inform them what you are doing’. With all these apprehensions in mind, which are not often expressed in front, the ignorant section of medical fraternity tends to stay away from a person who is engaged in these activities and everybody may not feel comfortable in such conditions.

**WHY IS IT DIFFICULT TO CONDUCT A CLINICAL TRIAL IN PRIVATE CLINIC?**

Even today, most practitioners are ignorant about what a clinical trial or a clinical study is. Even when given this opportunity, they often don’t find themselves qualified enough to conduct a clinical study. If they are convinced
about this aspect as well then their next apprehension would be to justify their time investment for its extensive paper work. Most doctors who would qualify for being a researcher are too busy in their clinics and would find it difficult to devote sufficient time for table work for which they are not used to. It’s a fact that Indian doctors are very laborious in their clinical work but they are equally lousy when it comes to pen down their observations.

It took me 10 months to develop infrastructure for the first study, with all my ignorance and financial misery. Today, when I am exposed to its various dimensions, I can do four times of that in less than a month. Now I can understand it better than how difficult it may be perceived by a private practitioner, who wish to enter into clinical research for the first time, to invest money or even more precious, his time, for this new venture, whose outcomes are not yet known to him.

A lot can be shared by clinical research coordinators in this regard. Thankfully this is now a growing facility in India, but, demand still outnumbers our resources manyfolds. More so, it is difficult to retain a qualified CRC in a private clinic as they would prefer a corporate hospital or MNC for obvious reasons of salary and professional growth. A private clinic, therefore, is usually left with self-trained paramedical workers or B grade qualified CRCs. The investigator, therefore, is not relieved much from his clerical burden in given circumstances.

Private clinics have limited resources in terms of space and equipments. Equipments can be easily procured with study start up cost, but this is progressively being eroded from clinical trial agreements in the name of global recession. Metros are obvious choices of MNCs which have better connectivity but space is a real problem in these cities. On the contrary, B class cities may have lesser constraints in terms of space, but at the cost of poorer connectivity and hence are not chosen easily for logistic reasons.

Furthermore, if a study warrants any procedure or hospitalization then a private clinic lies at a distinct disadvantage. Moreover, if any SAE occurs during the study then also it is difficult to manage without external support.

**IS THERE ANY ADVANTAGE IN CONDUCTING A CLINICAL TRIAL IN A PRIVATE CLINIC?**

Private practitioners may be at disadvantage in terms of exposure and infrastructure but not in their independence and enthusiasm. They can do what so ever they want. If enthusiastic, they can easily surpass all shortcomings and do even better than who work in government or corporate hospitals. Since they are usually present over their site, most of the time, they may have better supervision over entire activities. They are easily available for other study-related activities such as during investigator meeting, site initiation, or monitoring. These are often ignored by hospital-based investigators in favor of subinvestigators. Studies in many such institutional sites are actually conducted entirely by regular or some times by temporary subinvestigators which can at no cost equate wisdom of the principal investigator.

Private clinics are exceptionally prompt in responding to study-related deficiencies at the site as these do not require approvals from higher authorities. Be it manpower or infrastructure, it can be easily customised in a private clinic as per the need of the study. Initiating the clinical study in private clinics is definitely less time consuming than in institutions. Clinics can thus prove out to be especially helpful as rescue sites.

Private clinics usually cater to a population from short distances in comparison to institutions. Visits, especially unscheduled ones, can easily be followed in these clinics. Doctor–patient relationship is mostly more intimate in these set ups which may help in confidence building of the patient when it comes to take final decision to join a study or not. Drop outs are particularly lesser in clinics.

**MY APPREHENSIONS ABOUT CONDUCTING A CLINICAL TRIAL AT MY CLINIC**

Among sponsors, data management team, central lab, CRO, and the clinic, the clinic is the smallest unit and actually the least unsupported one. Whereas everybody is working at an organizational manner and working only on paper and hence are strongest in having complete legal cover. On the contrary, a trial site at a private clinic level is working all alone and is almost everywhere being managed by 1–2 or at the most three doctors. Obviously they are more insecure. Since they are in direct contact with the patient, they are the most vulnerable population to be affected by any mishappening, if it occurs with any patient. Remember, just one incidence which brings them in news and their professional carrier is over!

The clinical trial site is probably considered to be the weakest link of the clinical trial chain and hence can be easily be victimised for any body’s fault. Once I complained for wild fluctuations in HbA1c of a trial subject. HbA1c rose by 2.1% and then fell by 1.8%, within a month. The central lab responded by quoted that the sample must have changed at the site. When informed that there was only on trial subject who visited on that
day whereas the lab might have many, CRA forwarded me the suggestion of central lab that site needs training about processing blood samples!

If any deviation from the written protocol is observed at the site, it has to be notified to the IEC and if serious enough, to DCGI. If similar deviation in the conduct of study happens from the other side, does it carry the same implications? The clinic is all alone in this situation.

Are CR agencies apprehensive too, about conduct of clinical trials in a private clinic?

During an interview with a CRA, he shared his concern towards genuineness of medical records in a private clinic. PI undoubtedly has got an overall control of all activities at the site including patient’s history and other related records. Moreover, local labs and even institutional ethics committees can also be at least influenced by the PI. It is therefore extremely important that the site should have definite credentials before being selected.

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