Mahesh Fulwani, Raviraj Pardeshi

Department of Cardiology, Shrikrishna Hrudayalaya and Critical Care Centre, Opposite New English School, Congress Nagar Square, Dhantoli, Nagpur, Maharashtra, India

Address for correspondence:
Dr. Mahesh Fulwani, Shrikrishna Hrudayalaya and Critical Care Centre, Opposite New English School, Congress Nagar Square, Dhantoli, Nagpur, Maharashtra, India.
E-mail: drmaheshfulwani@gmail.com

Journey from clinical practice to clinical research

Abstract

We have experienced a significant change into 'the way we practice' since we stepped into the area of clinical research. The training in good clinical practice (GCP) made us capable of imparting the excellence. We describe the experience of our journey from clinical practice to clinical research.

Key words: Clinical research associate, clinical research organization, good clinical practice, informed consent process, investigational product

We have been practicing cardiology since more than a decade and are involved actively in clinical trial since past 5 years. We have experienced a significant change into 'the way we practice' since we stepped into the area of clinical research. The infrastructure, patients, disease, and treatment (drugs) are same (or similar) but our approach of treating the patients is changed. Initially, this change was limited to the 'patient population', which became 'clinical trial participant' and received a new identity called as 'subject'. Gradually, we started following the same for other patients also, thinking that they may also become 'subject(s)' on some day. The transition was not deliberate to change the 'patients' to 'subjects' but to have the excellence in terms of recording and reporting the process. The process, effective enough to manage the disease was there in place from the beginning but we realized that it should be decorated to be 'explicitly good'.

The training from sponsors, good clinical practice (GCP) and continuous watch of clinical research associates (CRAs) (monitors) to see that the protocol is followed made us capable of imparting the excellence. Initially, we were quite reluctant to adhere to the guidelines and had often an argument with the monitors visiting the site. We have been doing the things the way they should have been done with the utmost honesty but were not stressing on 'writing or documenting it'. The dictum of 'not documented – not done' was not having practical importance for us as we were doing everything but mentioning that 'it is done' was not always there, especially for the topics, which, in our view, were of least importance, as far as overall outcome of a trial in concerned.

Usually, the vital areas of any clinical trial consist of the trial participant (subject) who has participated voluntarily, the drug (investigational product (IP)), and the subject consuming or using the IP and its documentation by the site. This is the most prominent area where the emphasis should be given to the fullest possible extent. We ensure that we report this with utmost seriousness and according to us; this is key area pertaining to the outcome of a trial. The process is not much different in clinical practice. The events are recorded (though they are not reported) and managed accordingly.

We have transitioned ourselves in capturing this in 'clinical trial manner' even in routine practice also. But the journey is not yet smooth completely. The ideas are not clear and differ from person to person, from agency to agency and

Access this article online	
Quick Response Code:	Website: www.picronline.org
	DOI: 10.4103/2229-3485.111799

from protocol to protocol. There are different set of requirements from sponsor(s), medical monitors, data managers, prarmacovigilance and CRA. The scenario become more troublesome if there is change of clinical research organization (CRO) or CRA, and most of the times, the site is held responsible and answerable for the lacunae, which, in fact, may not be on part of site, per say. There is utmost importance to 'writing' in clinical research. But it is not always possible to record and report everything practically during clinical practice.

During informed consent process (ICF) process, many technical difficulties are faced. Like, asking the subjects to read the informed consent form in local languages, sometimes explaining the words, which are probably translated electronically (not by someone who is literary expert), and are beyond understanding, to get the form signed by them, is easier said than done. Later, if a monitor or somebody from the quality control unit of CRO or sponsor questions the authenticity of the process (because of some shortfall in documenting the process-which are often based on subjective perception of the person reviewing the process) or doubting on a signature (particularly if the subject signs two subsequent/ different ICFs and there is little variation in the style of signature), the situation is tricky both for P.I. and site-personnel. To give an explanation for this, make the P.I. and the site personnel to feel that they have committed a crime and are now pleading for a bail. The 'subject' is most important factor in any clinical trial who is, unfortunately, ignored by everyone, except the investigator. It is undoubtedly true that he or she is enrolled only after providing thorough information and requirement of protocol; but still, in real life, it may not be possible for everyone to abide with the protocol.

At the time of scheduled closure of the trial or during premature closure of the study, there is immense pressure from the monitors to complete the assessment on the scheduled date. Often, the subjects are not aware in advance that there medication will be discontinued and are not prepared for end of the study visit. The subjects, who were happy with their participation in a trial, usually cannot cope with the situation. The P.I. has to handle this carefully as some kind of 'emotional bond' develops between the site and the subject. This cannot be felt by the CRO or sponsor who were not in direct communication with the subject. Transition of this subject from clinical research practice to clinical practice is more difficult.

We often wonder why only high recruiting sites are subjected to audit and inspection. Also, to what extent the results of clinical trials influence the practice of individual doctors is a matter of concern. More often, the information generated from the trial is presented in the way, which cannot often be closely related to the horizon of activities of day to day patient care. If I have been prescribing Metoprolol (B-Blocker) and have experienced (though I have not conducted or involved in any trial on Metoprolol) that it is more efficacious over other agent in that category, and some trial has shown that it is inferior in some aspect to another agent in the category, I doubt that I will stop prescribing Metoprolol to my patients in routine clinical practice. Had I been served as an investigator in a trial, scenario would have been different. I do not think that the percentage of clinician involved actively is more than 5%. There has to be some system to keep others (those who are not directly involved) 'informed' about the development of drug and its journey through different phases of clinical studies or trial. In some of the scientific sessions; when we present the new information, which is contrary to the facts known earlier, I found it difficult to convince the same to our senior colleagues. Often, there is absolute denial of the new findings and they claim that this not what they have been seeing with the particular drug (s) for over years and decades. Finally, clinical research practice definitely helps the site to start GCP actively. Though the site may be treating patients well, it is documenting the things which are more emphasizing though correctly from medico legal purpose also. An adverse event, SAE or death, if is informed and captured in the way it is done in clinical research practice, our half of 'medical negligence' cases would not be recorded and if recorded the negligence would not be proved.

To conclude, we have a long journey of cardiology practice from 'clinical' to 'research' and we are going further for best possible care of subjects.

How to cite this article: Fulwani M, Pardeshi R. Journey from clinical practice to clinical research. Perspect Clin Res 2013;4:142-3.

Source of Support: Nil. **Conflict of Interest:** None declared.