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Letter to the Editor

Participation in clinical trials is the best way for the management of cancer

Sir,

The drugs which we are using to treat any type of disease or condition - from a simple viral fever to the life-threatening cancer or epidemic diabetes - are the results of challenging clinical trials. These trials are the only way to plausibly determine the safety and efficacy of the drugs for a particular therapeutic interest.[1] Drugs have to pass through several stages of development before they become eligible for trials on human.[2] The trials are undertaken only after animal experiments have proven their safety, and approved and regulated by regulatory bodies. After this step, the safety and effectiveness of a drug on humans needs to be proven beyond doubts before it can be commercially available in the market. This is also followed by post marketing surveillance.

The growing burden of cancer as a global health problem is underscored by its rapidly increasing incidence. Today the trend in the management of cancer has changed and it's now based on molecular profiling of tumors as against the last decades where the diagnosis was primarily based on morphology and histology and only cytotoxic drugs were used which cause damage to both the tumor cells and the normal cells of the body.

The basic foundation of any clinical trial is the **"**principle of essentiality**"** as elucidated by the Indian Council of Medical Research. A clinical trial is undertaken, simply because, it needs to be done to advance science. The prestigious United States agency, National Comprehensive Cancer Network believes that the best management of a cancer patient is in a clinical trial and this is embarked in every page of the guidelines for the management.[4] Clinical trials translate the results of basic scientific research into latest ways to diagnose and treat cancer besides new methods of screening for cancer. However, a patient may ask a question that whether it is direct benefit via treatment outcomes through the trials or it is indirect benefit.

Due to heavy work load on an oncologist (at least in government set up), it's very difficult give sufficient time to each and every patient in routine clinical practice. During a clinical trial, there is a dedicated research team that helps doctors/oncologist to take best possible care of the patients and follow the treatment guidelines as closely as possible.

Nowadays, promising monoclonal antibodies are being used in various clinical trials, so many pharmaceutical companies are conducting various clinical trials on these targeted therapies such as rituximab, trastuzumab, imatinib, erlotinib, lapatinib, bevacizumab, and cetuximab. These agents have revolutionized the treatment of a variety of cancers and give better outcomes.[1]

In India, various phase III global trials are ongoing with a stringent common protocol for already well-tested drugs which have already passed through animal experiments as well as Phase I, II in different geographical regions of the world. Hence, the risks to the patients are minimal. In any case, without a trial it is impossible to determine if and how a drug works. The factors such as racial characteristics, genetic make-up, and individual biochemistry also have a bearing on the outcome of a trial. Using an example of breast cancer monoclonal antibody, i.e. Trastuzumab as a case in point, without a clinical trial it would have been impossible to learn that the drug is only useful for patients who have tumours that are HER2 positive.[3] Second good example of monoclonal antibodies is for lymphoma patients in which rituxiamb drastically impacts on CD20 positive disease.

Advantage of participation in clinical trials

1. Give standard treatment
2. New drug regimen for better treatment
3. Regular follow up under dedicated doctor's team
4. Enhance the quality of life
5. Develop the anti-tumor agents
6. To know about the AE/SAEs and co morbid disease through routine investigations

If we compare the cancer treatment through clinical trials versus simple site specific protocol then it becomes evident that each and every site or institution has its own protocol, in which some of the patients could not afford the treatment regimen in a particular protocol, some of them could not timely follow due to social reasons.

Most of them are not aware about the disease condition due to lack of awareness and time pressure on the part of the doctors. Meanwhile if they participate in clinical trials then patient is explained at each and every point of the disease with the treatment regimen.

In clinical research, every step is similar to the stairs which denote step by step procedure, so firstly explaining what's the disease and stage of the disease in proper way to patient and his/her relatives simultaneously detailing the previous results along with the merits and demerits of the drug and best supportive treatment which give better outcomes and increase the quality of life. The patient and relatives are also ensured about the compensation in case of any injury or death. All the safety assessment and routine checkups are under the trial procedure and expenses are taken care of by the sponsor. As we know the treatment of cancer is very costly and lengthy, so through a clinical trial, the patient is relieved from the financial burden as well.

Although the advances made in the cancer management are based on the results of the hundreds of clinical trials that assess the benefit of the new therapeutics on the patient survival and quality of life, there is an ever increasing paradigm shift in the treatment by improved anti-tumor activity of newly developed agents.

Well-conducted clinical trials are essential for successful oncology drug development, and consequent improvement in outcomes of the anti-neoplastic treatment. Without trials there is no other way by which the pharmaceutical industry can advance to improve disease management and the quality of life of a cancer patient. Enrollment of cancer patients into well designed clinical trials should be encouraged not only to advance science further but also for the improved care of the patient.

Indra Bhadu[1], Shekhar Goel[1], Akhil Kapoor[2]*, Surender Beniwal[2], Nivin Raj R[1]

[1]Department of Clinical Operations, SIARAM Clinical Research Pvt. Ltd., Bikaner, Rajasthan
[2]Department of Oncology, Acharya Tulsi Regional Cancer Treatment & Research Institute, S. P. Medical College, Bikaner, Rajasthan

***Correspondence to:**
Dr. Akhil Kapoor,
E-mail: kapoorakhil1987@gmail.com

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