

A Report
Workshop on Best Practices in Clinical Drug Trials on Human Beings
held on 2nd July 2011 at Chalissery Hall, D Block
Jubilee Mission Medical College, Thrissur

Creation of awareness among various stakeholders involved in clinical drug trial system is a condition precedent for ensuring the conduction of drug trials ethically sound and corruption free. Many of the doctors, hospital management, and ethics committee members in particular are ignorant about the best clinical practices in clinical drug trials. In order to overcome this situation we proposed to organize quarterly workshop for the doctors, hospital management, ethics committee members and other interested groups who are directly and indirectly involved in the drug trial system. Participants of the workshop being of such stature, it was essential to



have the best resource person in this field for the presentation. Dr. Anoop Thekkuveetil, a senior scientist and member secretary of Ethics committee of Sree Chithira Tirunal Institute for Science and Technology, Thiruvananthapuram was the right choice in this regard. But his date was not available until July; hence we could organize the quarterly workshop only on 2nd July. Dr. V.K. Ramankutty, Principal Jubilee Mission Medical College with whom we are in good terms from the first phase of the project agreed to associate with the workshop and the venue for the workshop was fixed at Jubilee Mission Medical College.

Workshop was started with a welcome speech by Prof. N.N. Gokuldas, Chairman, Jananeethi and a well known activist in the health sector, followed by a short presidential address by Dr. V.K. Ramankutty, Principal, JMMC, Thrissur.

Dr. Anoop, started his power point presentation by explaining the very term ethics and its importance in clinical drug trials with interesting examples. He analyzed the history and important principles of best practices of clinical trials as enshrined in the ICMR and other international guidelines like Helsinki Declaration. During the presentation he pointed out the present flaws in the drug trial system with the help of examples like controversial Tuskegee



trial that took place in United States. He said that the patient has every right to know the details of the study including the risks and benefits. But unfortunately ignorance among the general public about legal and ethical issues and the lack of accountability leads to gross violation of patient's rights. He shared his own experience as

member secretary of the ethics committee and underlined its importance in monitoring drug

trials. He interacted with the participants of workshop and clarified their doubts. A short film on Miligrams theory on Obedience to Authority was screened whereby he tried to establish how even the harmless people do harm to people in the name of obedience to authority.

He concluded the presentation with a note of appreciation, that such initiatives will produce healthy debates and debates are necessary to create a critical mass who will demand for best practices in clinical drug trials. Adv.Sunilkumar.P. project coordinator proposed vote of thanks.



Adv. George Pulikuthiyil
Project Director



Advocate Sunilkumar P.
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