Drug trials: Risk, benefit analysis

We are fortunate to live in an era where medical science is making immense progress. In today's world of technological advancement, the diagnosis and treatment mechanisms have revolutionized. This has empowered man to treat the diseases in a better way, thus shielding the survival and sustenance of mankind for centuries. This has been possible due to research, and the discovery of newer and miraculous drugs/materials. Procedural norms require the ratification and reaffirmation of biocompatibility, practical utility and applicability of these drugs/materials for human use before introduction and launch. Drugs are first tested in the laboratories and then on animals. Subsequently human trials are conducted to reassure the efficiency and effectiveness in curing diseases. This process is known as the "trial and error method," and is most significant and of paramount importance for our safety.

It has been frequently reported that most of the drug trials are unethical, illegal and are conducted on the poor and sick who become the scapegoat and victim of such trials. Though they are unwilling and disinclined for these tests, they are lured by the monetary benefits these trails offer and often are misled by projection of the idea of "miraculous cures" in their mind. They do not have enough platforms to register any protests and resentment. Instead of safeguarding the interests of the volunteers, the companies conducting the drug trials often treat them just like experimental animals. It is correctly said that creative thinkers (intellectuals) are more likely to cheat than the less creative people, mainly because it is easier for them to make up excuses explaining their misdeeds/acts. Greater creativity helps individuals to solve difficult tasks across human domain; however, can act like a double-edged sword, and cause them to mislead others and take up unethical routes for selfish motives such as monetary gain and/or fame. A number of drug trials are conducted openly in an illegal and unethical fashion without fear of law, as there are no appropriate guidelines have been laid down to safeguard the interests of people.

India has a huge population of less affording individuals who cannot afford the expensive medical treatments, and are solely dependent upon the government hospitals. They are most likely to be included in the drug trials. The investment and spending by the government on healthcare is very minimal, and spending by the family is much higher. It is very difficult in such cases to resist the temptation of incentives and monetary benefits offered to the participants of the drug trials.

Human exploitation is a simple concept. One man gains at the expense of another. A contemporary paradigm is the trend towards rapid testing of new experimental drugs. And in many countries, desperate individuals are offered such drugs which may be potentially harmful. In a developing country like India – where the health/drugs business has grown five fold in the recent years – the pharmaceutical companies find it easier to record volunteers due to the vast population and also it is economically advantageous to them over conducting trials elsewhere. The icing on the cake is the fact that it is easier for them to get away as the proper enforcement and monitoring of ethical rules and regulation is absolutely lacking. It is a matter of serious concern that in India, ethical considerations are of a very minor concern, and it is very easy for the researchers and the pharmaceutical giants who sponsor such trials to fabricate the results, for their own commercial benefits. This situation is further compounded by the additional flood of fake medicines pouring out into the markets, which does nothing to inspire any confidence in the potential probability of clinical trials.

Giving informed consent to be a part of the experiment is the golden rule of all clinical trials which goes all the way back to the Nuremberg code. Most of the patients sign on the dotted line without understanding the nature and consequences of what is being administered to them. It is the moral duty of the clinician and the researcher to forewarn the subjects regarding the efficacy of the trial drug/material and also its potential harms, as it is precious human life which is at stake, and the medical profession is known for alleviating the suffering and pain of the diseased, and not conducting scams for their monetary gains and benefits.

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