Challenges in clinical research

For conducting good clinical research, certain principles need to be followed. In this article, the principles of Ethics, Transparency and Scientific Unbiasedness are laid out and argued for becoming the basics of planning, conducting and reporting clinical research.

India is an important hub for conducting clinical research. Large customer base, a big treatment naive patient population and talent pool of clinical researchers make India an attractive destination for clinical research.[1,2] One aspect that will contribute to success in this endeavor would be how clinical researchers plan, conduct and report research. Good research needs to be driven by three basic principles.

The first principle of Ethics should be the bedrock of all clinical research. Every clinical research endeavor (single case studies, randomized clinical trials, observational studies, etc.) needs to adhere to ethical tenets of Respect, Beneficence and Justice. Respecting individuals participating in clinical trials by treating them as autonomous agents, conducting clinical research that intends well-being and thereby ensuring Beneficence, and planning clinical research in such a way that the associated benefits and burdens are clearly accounted for need to be adhered to.[3-5] The second principle of Transparency tasks researchers to be factual about the planning, conduct and reporting of research. Reporting guidelines like CONSORT[6] and STROBE[7] are propagating this through use of checklists. Reporting is the end point of an endeavor which starts with proper planning and continues with proper conduct of the experiment. The principle of Transparency will ensure that each step that is taken during the planning, conduct and reporting is taken only after due thought process has gone into justifying the step that was taken. Transparency will create confidence in the consumers of the clinical research endeavor. The third principle of Scientific Unbiasedness is based on scientific and communication excellence. This is achieved by evaluating the clinical research endeavor holistically. By holistically, we mean that the final interpretation is not only based on internal validity of the clinical research but also on generalizability. The end result should ensure that clinical researcher and consumers of this research are closer to the truth. Note that a particular clinical research endeavor might be biased but with proper communication (e.g. by acknowledging this bias) it could result in coming closer to the truth and as such becoming scientifically unbiased.

These principles are universal and all existing and future guidelines can be framed under them. Statistical principles can play a role in ensuring that clinical research is aligned along these principles. Ideas like hypotheses testing, confidence intervals, sample size, randomization and blinding, bias and bias reduction, design of experiments, statistical interpretation of data and meta-analyses can be applied to make the clinical research ethical, transparent and scientifically unbiased.[8]

The challenge this year and going forward is to embed these principles within the clinical research fraternity. This can be achieved by having these principles as a central theme of workshops and trainings associated with clinical research. Personally, I will take up this challenge by training clinical researchers working in colleges, universities, research institutes, corporations and government agencies. I will hold workshops on Research Methodology and Statistical Concepts for Clinical Research, and both these workshops would have Ethics, Transparency and Scientific Unbiasedness as central themes. The workshops would be held at academic institutes and at meetings organized by professional societies and associations.

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