



Clinical Trials: How, When, Why, What for

Marcel C. Șarpe

Private Outpatient Care Unit, Focșani, Romania

Email address:

marcel_sarpe@yahoo.com

Abstract:

Background: The concepts behind clinical trials are ancient. “The Book of Daniel” (100 BC) chapter 1, verses 12 through 15, for instance, describes a planned experiment with both baseline and follow-up observations of two groups who either partook of, or did not partake of “the King’s meat” over a trial period of ten days. Persian physician Avicenna, in “The Canon of Medicine” (1025 AD), gave similar advice for determining the efficacy of medical drugs and substances. (Curtis L. Meinert; Susan Tonascia, 1986. *Clinical trials: design, conduct, and analysis*. Oxford University Press, USA. p. 3. ISBN 978-0-19-503568-1.)

Aims: Are clinical studies necessary?

Clinical trials are experiments or observations done in clinical research. Such prospective biomedical or behavioral research studies on human participants are designed to answer specific questions about biomedical or behavioral interventions. Clinical trials generate data on safety and efficacy. (“*Clinical Trials*”. *Bill and Melinda Gates Foundation*. Retrieved January 2014).

They are conducted only after they have received health authority/ethics committee approval in the country where approval of the therapy is sought. These authorities are responsible for vetting the risk/benefit ratio of the trial – their approval does not mean that the therapy is ‘safe’ or effective, only that the trial may be conducted.

Method: Explain the History of Clinical Trials, from the the ancient times to modern times, define and explain the process of Clinical Trials, the facts and reality of the process, the clinical phases, and most of all, the importance of those.

Results and Discussion: Fake press scandals in Romania, generalized from maybe only one case of tempering, greatly affecting the understanding of the importance of Clinical Trials in Romania (quote from media: “Guinea pigs, unapproved drugs used, astronomical sums for the corrupt doctors, etc.”). In fact, Romania is situated at the bottom of the list as for the number of clinical studies conducted here, but, instead, with very good statistical results.

Conclusion: Clinical trials are crucial, and still the perception of the Romanian population, supported by the media, and not contradicted by the authorities, are that those are only “Guinea pigs studies”. This perception should be changed, and the ones that can do that are the Medical Doctors- and this presentation is one of those steps.

Keywords:

Romanian Clinical Studies, History, Risk, Benefits