Abstract

Methods: A review of academic clinical trials and documents dealing with the proper conduct of clinical trials was combined with both personal and published regulatory experience concerning the quality of data produced by academic clinical trials.

Results: Academic clinical trials often produce data that are not accepted by regulatory authorities for the approval or labeling of the treatments studied in the trials. Participants in such trials are therefore exposed to risks without producing any personal or societal benefits; by definition, such trials are unethical.

Conclusions: It is proposed that only clinical studies, including those done by academics, that are designed, conducted and monitored in such a way as to produce data suitable for regulatory approval should be funded, approved by institutional review boards/ethics committees, or conducted in the developed or developing world. Increased training of academic investigators, institutional review boards/ethics committees, as well as the public and private groups that fund clinical trials, are needed to decrease the number of unethical academic clinical trials performed.

Key words: academic clinical trials, developing world, ethics, regulatory approval.

Disclosure of Interest: None declared.

RESEARCH PROPOSAL WRITING

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Background: Proposal writing is a skill of fundamental importance to the researchers, and the proposal is an important step in developing a research project that gives an overview of it. It enables other people to understand the scope of the research and the significance of the research, as well as the proposed methodology and chosen research method. The purpose of this paper is to define the research proposal and review its importance and its different types. It also provides a generic outline that focuses on the components and sections of the research proposal and the basic format of each section.

Objectives: The main objectives are to highlight the importance of writing a research proposal. It also aims to define the research and its different types as well as to identify the components and sections of a research proposal and to explain the content of each section.

Methods: A comprehensive literature review on research proposal writing has been conducted by using academic databases and some search engines. The focus was on the general format, guidelines, and presentation that suit students and scholars in different disciplines of life sciences. Various sections of a research proposal are discussed in detail. The focus is to motivate young researchers to take up challenging problems.

Results: The basic definitions of research and proposal in general and in health in particular were given and explained. Useful guidelines for the identification and selection of a research topic were also discussed in detail. The questions relating to whether a research problem is adequately analyzed and whether it is clearly stated were also addressed. Development of research objectives and literature reviews were also discussed. A special emphasis was given to elements of the “Methods” section of a research proposal, as well as the development of a work plan, and the preparation of a budget was highlighted.

Key words: proposal, research, research health system, research methodology.

Disclosure of Interest: None declared.

CLINICAL RESEARCH AND STANDARD OF CARE: AN UNRESOLVED QUESTION?

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Background: Ever since the 1996 revision of the Declaration of Helsinki, the World Medical Association has attempted to address ethical and scientific concerns of its diverse stakeholders for Articles 33 (use of placebo) and 34 (posttrial provisions), most recently in 2013. Both are inextricably linked to standard of care, an essential element of any comparative, interventional clinical trial. But has this now 20-year-long ethical debate truly been put to rest? The choice of standard of care in clinical trials remains a complex issue, particularly for comparative trials conducted in emerging countries. Interpretations of the Declaration of Helsinki as the cornerstone document for medical ethics range from best intervention available worldwide to any locally available standard of care for the comparator group, which in the worst case could mean no interventional care at all.

Objectives: Our aim was to examine the current status of clinical research practice and ethical guidance on standard of care, with a focus on international health research, and to review corresponding guidance issued by pharmaceutical sponsors in their publicly accessible policies on clinical research.

Methods: We reviewed ethical recommendations before and after 2013 and scientific literature, as well as major clinical trial registries (European Union, United States, and World Health Organization), to assess current clinical research practice related to standard of care. Furthermore, the websites of the top-ranked 25 pharmaceutical companies on sales figures in 2014 were reviewed for publicly accessible policies with reference to standard of care in clinical trials in emerging regions.

Results: After a period of active scientific-ethical debate before the 2013 revision of the Declaration of Helsinki, few ethical discussions or recommendations have since been published that could provide additional guidance to clinical researchers. The recent scientific literature reflects the continued challenge for researchers to design an ethically and scientifically sound study, especially in vulnerable populations. However, ~20% of registered open clinical trials across major trial registries are designed with a placebo control, suggesting that the question of standard of care remains highly pertinent. The review of pharmaceutical sponsor websites revealed a highly variable picture with regard to publicly available policies or statements on this issue, particularly for research conducted in low- to middle-income countries. The review outcome spans results from any policy published to very clearly worded statements on clinical research in developing countries, the standard of care aspect during the trial conduct, and regulatory strategies after completion of product development.

Conclusions: Investigators, ethics committees, and sponsors continue to be confronted with the challenge of ensuring ethically and scientifically sound clinical studies with appropriate standard of care. We have attempted to examine available ethical guidance and summarize recommendations for clinical trial designs that could assist in addressing these challenges. Care should be taken to maintain a high level of awareness for the importance of a sound ethical framework for a scientifically valid clinical trial design. Pharmaceutical companies, as major sponsors of clinical research, should demonstrate awareness and an appropriate management of these aspects, particularly in regions with limited resources. As part of the ongoing debate on transparency, one option could be to formulate positions and make them available to the public, regardless of whether such a statement is legally required. A few examples already exist where such clarifying statements have been provided. This approach would prepare the ground for an open and transparent communication to agencies, ethics committee, and, last but not least, patients.

Key words: bioethics, clinical research, Declaration of Helsinki, international health research, placebo, standard of care.

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