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Editorial

Editorial on Ethics of Global Clinical Trials

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INTRODUCTION

Clinical research by academic institutions and pharmaceutical companies has followed the general trend of globalization and has moved inexorably towards Low and Middle Income Countries (LMIC). This trend has raised various concerns, including whether the research being conducted is of value to public health in these countries or whether economically disadvantaged populations are being exploited for the benefit of patients in rich countries. Nevertheless, clinical trials and the research and health care that accompany them can directly benefit patients, in particular those who would otherwise have no or only little access to health care services. It is therefore a matter of striking a fine-tuned balance between the economic and research interests of pharmaceutical companies and academia and the needs of patients in LMIC to make sure that all sides benefit

Clinical trials constitute a prerequisite for the development of new and improved therapeutically tools in medicine. It is therefore of utmost importance that such trials are designed to fulfill high scientific and ethical standards and also are meticulously conducted, recorded, terminated, and reported according to pre-established criteria detailed in the study protocol. Several incidents of scientific misconduct have caused widespread concern within the medical community and among involved authorities and have spurred the development of rules for conduct of clinical trials. Scientific misconduct broadly falls into one of three categories: piracy, plagiarism, and fraud. The reason for scientific misconduct can be factors such as pressure to publish in order to get funding, personal ambition, vanity, or direct financial gain. There are three broad approaches to prevent scientific fraud and misconduct: education, training, and the establishment of ethical standards.

The process of planning and conducting a clinical trial is complicated and it is associated with various risks and issues. Clinical trials require significant investments of human, financial, time and other resources. Poor study planning and management are often contributing factors to the failure of clinical trials, which are very common occurrences. It is estimated that about 34.6% of all clinical trials fail during Phase 1, while 51.7% and 51% fail during the Phase 2 and Phase 3 respectively. It is possible to increase Probability of Success (POS) rates of clinical trials by implementing effective technological solutions in order to more appropriately utilize limited research funds.

In many cases, therefore, studying local health needs will not necessarily generate immediate benefits for poorer communities. Nonetheless, studies that are responsive to local health needs will generate information that is necessary to improve public health in the long run. “When you ensure that the information is relevant to the local population, you build the foundation of knowledge necessary to generate beneficial interventions and policies, and this is a kind of benefit itself”, London commented. Making important new treatments available in LMIC should be considered a health priority, but this might take years or even decades at the current rate of progress. For participants in clinical trials, it will therefore be important to help them to bridge the gap between the end of the trial and the time the drug becomes available in their country.

Conducting clinical trials in LMIC is not intrinsically immoral. Indeed, trials sometimes represent the only medical treatment that patients in deprived settings can hope to receive, and can also provide other advantages at the personal, community and national levels. Nonetheless, taking advantage of people's deprivation to impose on them the risk of health research can be exploitive if it is not carefully planned and regulated. At the moment, there is such a variety of legislation that the conduct of trials differs widely, often depending on why a company decided to use a developing country in the first place. Trials that address locally relevant diseases and that will deliver affordable drugs and care for the local population are certainly to be lauded. Ones that do not provide immediate or obvious benefits locally are less laudable and must be assessed on a case-by-case basis.

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