Hcr65 topical paper subject recruitment essay sample

Business, Management

Introduction

Over the past few decades human beings have experienced phenomenal growth in all aspects of their lives the medical industry included. Of interest to this is the field of clinical trials given that the need for new drugs is increasing by the day. Clinical trials have been instrumental in the fight against diseases and disease-causing pathogens on globally and this so due to the discovery of new and innovative medicines. Some of the critical areas of having successful clinical trials include time constraints and patient exposure to the drugs in question specifically in relation to discovery and development. This thus implies that it is significant to not only expedite but also improve on the drug development methodologies to ensure efficiency of the process without compromising on the integrity and validity of the clinical trials. Generally the success of clinical trials is to a large extent pegged on the operational aspects of the process.

Since the operational aspect of a clinical trial is a broad area, the scope of the paper shall be limited to test subject recruitment. This of course shall be based on the adaptive design methodology; this refers to a clinical design that allows one to modify operational aspects of the process while concurrently collecting data. Test subject selection usually comes in the second phase of drug development. This comes after the most suitable treatment method of the ailment in question has been agreed upon. It is significant to point out that the duration between the second and the third phases of a clinical trial should be as minimal as possible to minimize delays in the drug development process. Below is a brief overview procedural and

operational measures that should be considered during the subject selection process.

Procedural Aspects of the Subject recruitment Process

Though the selection process lies mainly in the second phase of drug development, work on the various methodologies and approaches should begin in the planning stage of the drug development process. Specifically sequential parameters that identify rank and eliminate selection procedures should be developed and updated on a continuous basis and applied to two sample populations at a time. The following principles can be applied to ensure that the integrity, validity and efficiency aspects of clinical trials are maintained especially in relation to selection of subjects.

The researchers must outline the social value of their work. This principle mandates that more than ever the objective of drug development and to a large extent the clinical trial must be to improve people’s health and wellbeing rather for economic gains. This operational principle ensures that the clinical trial is limited to methodologies and tests that guarantee better treatment and tests for diseases. This principle also ensures that the medical community gathers more knowledge and information concerning diseases and thus it is better prepared to deal with it. If in any case a clinical trial does not have any social value then it is a waste of resources especially money and time. Such clinical trials end up being termed as unethical due to the fact that they intentionally put people at risk of harm health wise without benefit them or the society.

People should only be allowed to engage in clinical trials if and only if such experiments and processes are scientifically valid. In other words, this argument proposes that clinical trials should always produce scientific useful result and knowledge which should significantly shape the course of the medical field. This implies that the society should be in a position to accept such results and therefore clinical trials must be long enough and encompass several subjects so as not only to convince the public but also the relevant authorities. Basically operational principles of subject selection dictate that clinical should be free of bias whether intentional or accidental.

Clinical trial should also in practise have fair subject selection procedures. This implies that the involved researchers should be fair in the recruitment exercise and the final decision of the subjects to be involved in the clinical trial. The concept behind this operational principle is to ensure that the clinical trial is not only fair and just to the people who shall take part in it but also the general public that is expected to benefit from the process. Such measures are also instrumental in eliminating hints of bias in the clinical trial process. Finally, fairness in a clinical trial also means that the researchers should not only target the vulnerable members of the society such children and mentally ill people who are easy to convince but all the groupings within the society.

A lot of consideration needs to be invested in the design stage of a clinical trial; this is the case because the researchers and the subjects need to believe in the process. Based on this premise, it easier in practise for researchers to be complacent and thus flour ethical other types of

requirements for the clinical trial. For instance the researchers might decide to make the process riskier to the subjects than it is necessary or permissible. To avoid such scenario, it therefore necessary that an independent body of researchers who are not in any way affiliated reviews the research. Such a body of researchers is normally referred to as the Institutional Review Board (IRB).

In addition to the aforementioned procedural requirements for a clinical trial, people who might potential subjects of the clinical trial must be fully informed the consequences of the process to their wellbeing. This procedural measure is popularly referred to as informed consent. Below is a brief overview of the four components of the concept of informed consent. The subjects to be must be competent; this implies that they must exhibit a mental capacity that can synthesize the clinical trial information and consequently make an informed decision. Informed consent must also involve the concept of full disclosure whereby the researchers inform the subjects the goals and objectives of the clinical trial coupled with the associated health risks. This also involves the subjects being informed of what is expected of them during the clinical trial. In addition to this, informed consent can only be achieved if and only if the subjects understand what the researchers are telling them. Finally, all subjects must of their own accord volunteer for the clinical trial; this is of course free of all forms of inducement or coercion.

Impacts of the Procedural Measures to the Field of Clinical Trial

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