Protocol Development in Clinical Trials for Healthcare Management

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INTRODUCTION

Clinical research is a branch of medical science which deals with any research or study in living humans. Clinical research is a process consisting of pre-clinical testing of newly developed drugs and filing of Investigational New Drug Application (IND). Phases in clinical trial involves three phases. Phase I is for assessment of safety of drug. Phase II involves effectiveness testing. Phase III is for large-scale testing, approval to use new drug i.e. licensing, approval of drug and post-marketing surveillance for reporting of any other adverse events. (Manavalan and Sinfield, 2017;Thorat, et. al., 2010;Gandhi, 2011)

Clinical research involves systematic investigation for treating the diseased conditions, overall health improvement and longevity of human. This involves volunteer participants for biomedical research with scientific guidelines. The research is conducted with pre-defined procedures, investigations are carried out carefully and outcome is recorded. The ethical principles are strongly utilized for protection of identity of participants. The clinical research allows identifying new curative and preventive ways to understand the prognosis of disease, diagnose and treat the diseases in human. (Thorat, et. al., 2010 ;Gandhi, 2011;Bajpai, 2013).

CLINICAL RESEARCH

Clinical trial is a research study, also called as clinical study. This study includes testing of new treatments or modification of existing therapy on human volunteers. The study determines the safety and efficacy of drug therapy for commercial use in various populations. They provide better way to screen, diagnose, prevent and cure a disease. Clinical trials are carried out for the new treatments under research whose outcome is unknown and previously not studied. Clinical trials follow a pre-designed plan for health-related research studies in human. Clinical trial is defined as the systematic study of new drugs in human to generate data for discovering and verifying the clinical, pharmacological and adverse effects with objective of determination of safety and efficacy of the new treatment. (Bajpai, 2013;Manavalan and Sinfield, 2017)

Research team in clinical trial includes doctors, nurses and health care professionals. They monitor participants and do their health checkups regularly. The research team works with participants in all

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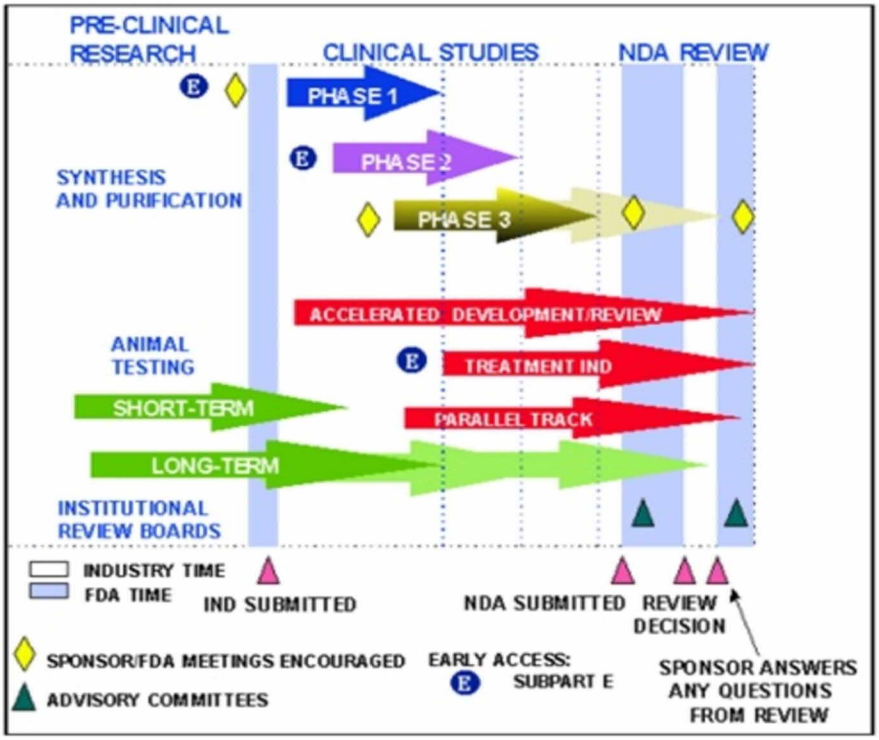
types of trials. Role of participants or volunteers is more active in clinical research. They are important as they get new therapies to treat a disease before these are available for commercial use. For the safety of volunteers or participants involved in clinical research, there are guidelines for appropriate selection. After qualifying the eligibility criteria they can take part in clinical trial. (Crisp and Burke, 2005;Gandhi, 2011).

The plan with all details of the clinical trial is called as research protocol. Every study has different protocol depending upon type of trial. If the protocol is carefully followed during the clinical trial process then trial becomes more successful. Design of trial plan takes care of safety of participants. So, the research protocol should be designed carefully. The protocol describes all the details of the study. (Thorat, et. al., 2010). Figure 1 represents general flow for study of the drug throughout clinical research.

Figure 1. Representation of clinical research and phases of clinical trial(Source: Thorat, et. al, 2010)



CLINICAL TRIAL PHASES

Preclinical trial study is done on laboratory animals before testing the drug on human. This testing determines safety of drug for human consumption in disease treatment. After completion of preclinical study, filing of an investigational new drug application (IND) must be done. (Thorat, et. al., 2010; Gandhi, 2011).

Phase I study is carried out on 20-80 healthy human volunteers. It determines the safety, pharmacological actions including adverse effects, drug dose and tolerability. The drugs used in the treatment of life-threatening diseases are not studied in this phase. Phase II is carried out on 100-300 patients meeting selection criteria called as volunteers or participants. It is aimed for safety, efficacy and effectiveness of the drug and determines the therapeutic potential of the drug. It also reports the adverse effects of