Review Article

CLINICAL TRIAL AND DATA MANAGEMENT

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ABSTRACT

Clinical trials are the process by which a new drug's safety and effectiveness are tested as part of the FDA approval process. When a company discovers and develops a new drug, they must first run extensive pre-clinical trials prior to testing the drug candidate on people. Clinical trials that are well-designed and well-executed are the best approach for eligible participants to play an active role in their own health care and Gain access to new research treatments before they are widely available. Management of data in clinical trials is a valuable work for anyone involved in any type of clinical trial, from large multicenter trials to small single-investigator studies.

Keywords: Clinical trials, Data management, Clinical studies.

INTRODUCTION

Clinical trials are also called clinical studies, research protocols or medical research and often compare one drug against another to see which is more effective, or the medicine or procedure in a specific demographic group or for a specific disease. Clinical trials are designed to help find out how to give a new treatment safely and effectively to people. New therapies are designed to take advantage of what has worked in the past and to improve on this base. There are certain steps and protocols, which needed to be followed while carrying out the actual clinical trials. Treatments now being used (standard treatments) are the base for building new, hopefully better, treatments[1,2]. The pharmaceutical industry is the main sponsor of medicines research in the UK. Sponsors have to demonstrate the safety, quality and efficacy of a potential new medicine – called an investigational medicinal product (IMP) – through a series of rigorous trials in humans in order to obtain a license, so that doctors can give the medicine to patients. But before an IMP can be given to humans, sponsors must first test it thoroughly in animals. The main aims of these pre-clinical studies are:

• to find out the effects of the IMP on body systems (pharmacodynamics);

• to study the blood levels of the IMP, and how it is absorbed, distributed, metabolised and eliminated after dosing (pharmacokinetics);

• to find out if a range of doses of the IMP, up to many times higher than those intended for use in humans, are toxic to animals10 and if so, to identify the target organs and the margin of safety in terms of (a) the no observed-adverse-effect dose level (NOAEL) relative to body weight and (b) IMP exposure - the concentration of the IMP in the bloodstream over 24 hours (toxicokinetics)[3]. and

• to make a formulation of the IMP, such as a capsule or injection, suitable for early studies in humans.

After the pre-clinical studies, there are four phases of trials in humans, which in practice often overlap. Phases 1 to 3 are done before a license is granted and phase 4 is done after authorisation[4].

DEFINITION

The broad definition of clinical trial includes definitions allowing for use of the term in references to studies involving a single treatment (e.g. as in most Phase I trials and some Phase II drug trials) and for studies involving use of an external control (e.g. studies involving historical controls) The treatment can be anything considered to hold promise in caring for the sick, in the prevention of disease, or in the maintenance of health[5]. The National Library of Medicine defined a clinical trial in 1980 as: a pre-planned, usually controlled trial of the safety, efficacy, or optimum dosage schedule of one or more diagnostic, therapeutic, or prophylactic drugs or techniques in humans selected according to predetermined criteria of eligibility and observed for predefined evidence of favourable and unfavourable effects.

REGULATIONS FOR CLINICAL TRIALS

Clinical trials are closely supervised by appropriate regulatory authorities. All studies that involve a medical or therapeutic intervention on patients must be approved by a supervising ethics committee before permission is granted to run the trial. The local ethics committee has discretion on how it will supervise non interventional studies (observational studies or those using already collected data). In recent years, there have been many changes to the regulatory aspects of clinical trials. Most changes stem from the introduction of Good Clinical Practice (GCP), Good Manufacturing Practice (GMP) and