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Effective Functioning of Clinical Trials in a Site: Challenges and Recommendations

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Abstract: Clinical trials are studies conducted to determine whether a new treatment or drug is safe to use and to measure its efficacy. Some medications are brand-new, such as the COVID-19 vaccination COVISHIELD from Oxford University and AstraZeneca and COVAXIN from Bharat Biotech, which is an indigenous project. Some medicines are created based on non-patent formulations or expired patent licenses. Companies like Serum Institute of India develop the latter from existing formulations. This type of drug development may arise as an alternative in efficacy or competition in price for existing drugs on the market. For a drug to be used as a treatment, the founder of the medicine will be the sponsor that provides funding to the sites through a contract research organization. Once a site is selected, the study will commence. Volunteers will participate in the entire process, and they will be informed about their progress and any adverse events during the study. Based on the results, the efficacy of the medicine will be evaluated, and it will be brought to market as a commercial product.

Keywords: Clinical trials; GCP; Logistics; Safety; Efficacy.

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INTRODUCTION

The four stages of the clinical trial procedure each have unique qualifying standards preceding moving to the next level. After experimentation on the animals, it will be tested on a small batch of people, and gradually, the population will be increased. It will get diversified, and the vulnerable group will be provided to have the medicines to determine the efficiency and the development of the treatment. Once the phases succeed and get approval from the government bodies, then the drug can be introduced into the market.

Phase 1, known as the drug development phase, assesses the dosage and toxicity of the drug in humans. A small quantity of the drug is administered to healthy male volunteers with sound physiological health. In this phase, the dosage at which the first signs of toxicity appear is recorded. Phase 2 is regarded as a pre-clinical phase, where the trial drug's efficacy is evaluated against a particular disease. During this phase, a limited amount of the new drug is given to patient volunteers, who are monitored regularly. This phase determines the optimal dosage for patient administration. Phase 3, referred to as the clinical development phase, involves recruiting a larger number of patients to evaluate and confirm the findings from the previous two phases. To establish the efficacy of the medication, it must be compared with either a placebo or current therapy. Phase 4 includes post-marketing studies, also known as pharmacovigilance. In this phase, the long-term safety and effectiveness of the drug are evaluated in a broader population [1-3].

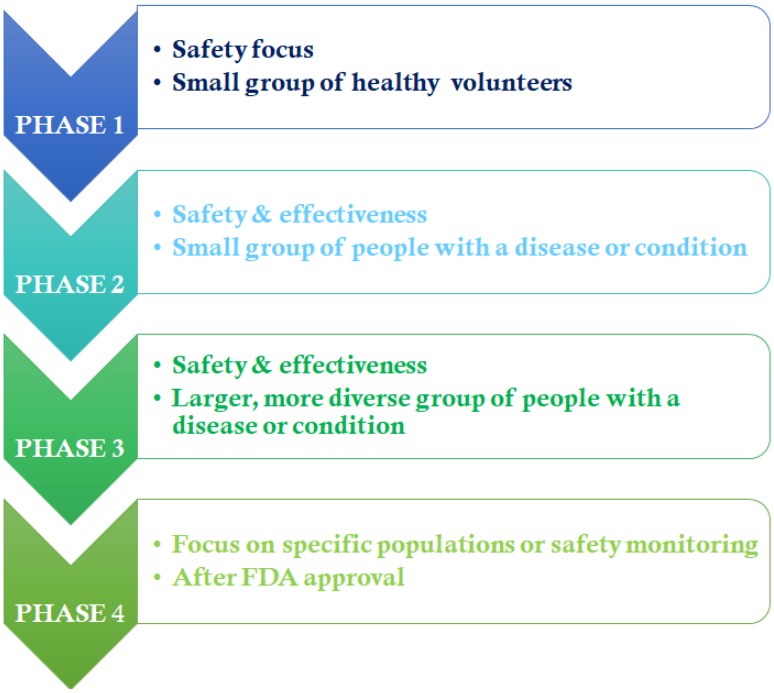

Figure1: Phases of Clinical Trials

PRINCIPLES OF CLINICAL TRIAL

Clinical trials or clinical research aim to improve knowledge of what is not fully understood, test hypotheses, and conduct research related to public health. This primarily involves gathering data and analyzing it to reach conclusions. Different types of clinical trials are generally categorized as analytical, observational, or experimental research. Clinical research is decisively categorized into non-directed data capture, directed data capture, and drug trials.A prospective or retrospective strategy might be used. It may also be a case-control study or a cohort study. Clinical trials can be used for ailments or medical condition diagnosis, prevention, investigation, or therapy discovery.Among these various categories, observational research using a cross-sectional study design is undeniably the most frequently conducted.This research aims to assess the existence or absence of a disease or condition, identify potential risk factors, and determine prevalence and incidence rates within a specified population. Based on the type of intervention, investigations can be labeled as either therapeutic or non-therapeutic [4,5].

CLINICAL TRIAL OPERATIONS AT THE INVESTIGATIONAL SITE

Choosing an investigation site is one of the most essential steps before starting clinical research. Both the researcher and the patients must agree to the protocol design and follow the deadlines established by regulatory bodies, such as Institutional Review Boards (IRBs), and the participants must fulfil the trial's inclusion requirements.

An investigator must accept the study's terms and conditions and guarantee protocol secrecy before beginning clinical research. The sponsor evaluates the feasibility of the trial's practices, considering available resources, infrastructure, qualified personnel, access to study subjects, and the potential benefits to both the institution and the investigator during the site selection visit.

The United Nations programs on Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (UNAIDS), the World Medical Association (WMA), the National Bioethics Advisory Commission (NBAC), and the Council for International Organizations of Medical Sciences (CIOMS) enforce the norms for clinical investigation trials. By adhering to these high standards, we can ensure that our trials are not only compliant but also impactful in advancing medical knowledge and patient care [6,7].

PRACTICAL ASPECTS OF A CLINICAL TRIAL OPERATION

Clinical research encompasses a variety of types, and the development of a new drug can be initiated through nationally funded projects, industry sponsorships, or individual investigators. According to the 21 Code of Federal Regulations (CFR) 312.3 and the ICH E-6 Good Clinical Practice (GCP) guidelines, an investigator is the key individual responsible for initiating and conducting clinical research. The investigator takes charge of planning, designing, conducting, monitoring, managing data, compiling reports, and overseeing all regulatory and ethical aspects of the research.

To effectively manage a clinical trial project, an investigator must submit a letter of intent, draft a comprehensive proposal, establish a clear timeline, develop a robust protocol and associated documents such as case record forms, define the budget, and identify suitable funding sources.

Quality assurance is fundamental in clinical research and must be rigorously applied according to the ICH and GCP guidelines to ensure the production of high-quality and accurate data. Every aspect of the clinical research must adhere to established standard operating procedures (SOPs), which are defined before the study commences and during the protocol preparation phase [8,9].

GOVERNING BODIES

A governing authority for the international health community is the World Health Organization (WHO). Each country has a separate authority.Each country has a separate authority. The Central Drugs Standard Control Organization (CDSCO), operating under the Ministry of Health and Family Welfare (MoHFW), establishes standards to ensure the safety, efficacy, and quality of drugs, cosmetics, diagnostics, and medical devices in India. The CDSCO is responsible for regulating the market authorization of new drugs, setting standards for clinical trials, overseeing drug imports, and granting licenses for drug manufacturing. The Central Drugs Standard Control Organization (CDSCO) and the Drug Controller General of India (DCGI) are functioning in India to govern the usage of pharmaceuticals across the country. All entities involved must adhere to the protocols set by governing bodies and follow the guidelines established by ethics committees. The federal organization known as the United States Food and Drug Administration (USFDA) is part of the United States Department of Health and Human Services (HHS).A sponsor doesn't need to be from the same country. Sponsor can be anywhere in the world and can experiment with their drugs at various sites around the globe [10,11].

SITE SELECTION PROCESS

The founder of the medicine may be considered the sponsor. He contacts the contract research organization (CRO) to look at the sites for their medicines to be experimented on. The contract Research organization looks for the site and suggests sites. The sponsor will contact the research coordinator at the site and make sure the facilities are available. Facilities such as a laboratory and a bed facility will be required. Details about the Principal Investigator, staff, and the instruments will be collected. A site selection tour and a site initiation visit will take place after the completion of the site feasibility questionnaire. Once all documentation is finalized, the study will begin for the selected volunteers [12].

INVESTIGATIONAL PRODUCT

The sponsor will send investigational goods to the location. The Investigational product will be made available to the site by courier, and the Investigational product has to be maintained at a stable temperature, for which gel packs are commonly used. The Investigational product kit has to be surrounded by gel packs until it gets into the reefer of the site. Once it is moved for injection, then the Investigational product has to be transferred within gel packs until it is given to the volunteer in an aseptic room. In some cases, a temperature logger will be attached to the box containing the Investigational product kit. The temperature will be tracked with the help of this logger. The temperature of the Investigational product has to be noted in the mornings and evenings with the maximum, minimum, and current temperature. The site must be ready to afford the expenses of storing drugs with an uninterrupted power supply and usage of generators in emergencies. Each Investigational product will have an expiry date, and if the expiry date is crossed, then that product has to be returned to the sponsor. Every kit has to be made accountable. The usage, storage, and disposal of drugs have to be informed to the sponsor as well as the Clinical Research Associate, and documents containing the usage of drugs. An accountability log has to be maintained, stating the time, date, subject, with the consent of the Principal Investigator and coordinators [3,13].

BLOOD SAMPLES

Some studies require blood samples to be transported to the labs recommended by the sponsors for results. Enough Blood samples will be collected from the volunteers. It will be centrifuged. Samples will be categorized into two types: whole blood and plasma. Some of them have to be frozen, and some kits containing samples have to be maintained at ambient temperature. These samples have to be labeled and stored, and shipped to the laboratory without losing the stability of the blood sample [14].

LOGISTICS

Logistics is involved in both the Investigational product and blood samples. The Investigational product and blood samples are used to send via courier, which may include roadways as well as airways, depending upon the study and sponsor. Blood samples will be transported in a box containing dry ice. The box should be well packed with dry ice pieces or dry ice pellets, and the samples have to be placed between that, and again, the samples have to be covered with dry ice. Every consignment has to be signed by the Research coordinator at the site [15].

VOLUNTEERS

The volunteers are the primary source of this entire process. The coordinators, physicians, and staff are responsible for ensuring that the volunteers remain throughout the process and have to record every

improvement as well as adverse events. Then, the information must be reported to the CRA and the medicine's sponsor. The cooperation of the volunteers is much more important to get efficient results. Based on the duration of the study, the volunteers have to be followed by the coordinators regarding queries and issues. Counseling and support of the clinical research coordinator before and after injection have to be more effective [5].

CHALLENGES

Operational challenges faced by the site during a study include the following:

- Management of the arrival, storage, and maintenance of the investigational product during a power outage.
- Stability of blood Sample
- Satisfaction and cooperation of the Volunteer
- Lack of Facilities, including calibrated instruments, standard facilities
- Not acknowledging or failing to add necessary information in paperwork, including date and time errors in Data entry [3,7].

SITE RECOMMENDATIONS

- A proper SOP has to be designed for the redundant issues.
- Usage of online sites for data entry will be more effective
- Patient details can be entered in Excel may be with the help of spreadsheets by Google, to immediately have an idea about the ongoing process of every patient inthe study at the site, which will be easier to notice everything at a glance instead of piling up papers.
- Effective personnel have to be in a position to remind about the visits, premedication to the volunteers, and about shipping orders, along with acknowledgement [2,15].

CONCLUSION

Clinical process is a challenging area that includes desirable results that lead to glory as well as undesirable consequences. There are a lot of people out there who cannot afford to get highly priced drugs. Whatever the negativity may arise, it has to be admitted that clinical trials have improved the lives of many who are not capable enough to bear the drug available on the market. Adhering to the GCP guidelines on ethics for protecting human/participants' rights and acquiring informed consent from all the participants as prescribed by the regulatory agencies isa prerequisite for conducting a successful clinical research/trial.Yet this has to be done ethically. Apart from the drug in the vial, Proper SOP, trained personnel, and proper functioning are also necessary for the effective functioning of a site.

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