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Review Article

OVERVIEW ON CLINICAL TRIAL AND PHASES OF CLINICAL TRIAL

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ABSTRACT

A clinical trial is a human volunteer research study designed to answer health challenges. Clinical trials are the quickest and safest way to discover treatments that work in people and to improve health. Clinical research is an important aspect of the drug discovery process since it ensures safety and efficacy of a new medicine. Clinical studies can potentially expose participants to unexpected hazards, and misleading information obtained from defective trials might result in patients being harmed unnecessarily. Clinical trials are required in today's worldwide scientific era for bringing newer and better medications to market. Human volunteers (subjects) are used in clinical studies to discover, if possible, therapies are effective, safer and should be approved for widespread use among the general public. In the year 2000. India was a global hotspot for clinical trials, due to a variety of factors in previous years. Clinical trials in India are discussed in this study.

KEY WORDS: Clinical Phases, Trial Designing, Drug Development.

INTRODUCTION:

Clinical trials, as the name implies, are a series of experiments and observations carried out for the purpose of determining the effectiveness of a treatment. Human beings are used in research. They are completed new therapies, interventions, or testing are being sought as a method of preventing, detecting, treating, or managing

wide range of disorders or medical conditions. Clinical Trials aid in establishing whether a new remedy is effective, how safe and effective it is, and better than treatments are already available. WHO recommends a clinical trial is defined as:

'Any research project that assigns 'human participants (individuals or groups of humans) to assess the effects of one or more health-related interventions on health outcomes'

The most important part of drug discovery research leads to the development of better, safer, and more effective medications. It's being made available to the rest of the world. Prior to the start of a new year, when a new drug is presented to the market, it must be accepted ,through a series of rigorous methods of analysis .Animals were used as test subjects first, followed by people. They are the most crucial and decisive component of any new venture. The drug is about to hit the market. Clinical studies aren't possible without animal being used .Researchers are unable to ascertain whether or not new drugs created in a lab or by using animal models effective or safe to use? whether a diagnostic test in a clinical environment is accurate?[1-3]

CLINICAL TRIALS CAN BE CATEGORIZED IN A NUMBER OF WAYS.

One method is to categorize clinical trials according to the research mode.

1) **Interval Study**: In this study, researchers track how patients health changes over time. They administer a specific drug to the research patients, then compare them to those who received no treatment or the normal treatment. This is a comparative study of some sort.

2) **Clinical observational study**: In this study, researchers watch and measure the results of participants who have been given a new drug.

Another method to categorize trials is based on their objective.

Prevention Trails, trials to prevent disease in persons who have never had it before or to keep a disease from reoccurring. These Medicines, for example, could be used ,vitamin supplements, vaccinations, minerals, or a healthy lifestyle, changes.

Screening trials examine the most effective means of detecting cancer ,certain illnesses or medical conditions.

Diagnostic trials are used to develop new tests or processes for diagnosing a disease or condition.

Experimental treatments are put to the test in **treatment trials**. Treatments, new drug combinations, or innovative surgical or radiation techniques therapy.

Trials of quality of life (supporting care trials) look seek ways to make things more comfortable. Improving the quality of life for people with disabilities a long-term illness .

Expansion of compassionate use trials or Trials of access provide a partially tested, a tiny proportion of people with unapproved therapies of those who don't have any other options. This is an illness for which there is no cure. There is no viable treatment that has been approved, or a patient who has previously failed all of his or her tests traditional treatments, as well as whose health is at risk too damaged to be eligible for involvement in randomized clinical trials.

CLINICAL TRIAL PHASES

- **Phase I studies** are used to determine a drug's or device's safety. This is the first stage of testing. This could take a few months to finish. A small number of people are normally involved in this phase. Volunteers who are in good health (20 to 100).

The purpose of the phase one trial is to determine the effect/effects of the drug or gadget on humans, as well as how it is used absorption, metabolism and excretion (ADME).This phase also looks at the effects of the dose. Approximately 70% of experimental medications make it through this stage of testing.

- **Phase II studies** are used to evaluate a drug's or device's efficacy. This is the second stage of the testing process. It can take anywhere from a few months to two years. Hundreds of people are involved in the project's completion. Randomization is used in the majority of phase II research. Studies in which one group of patients is given the same treatment as the other.

A second "control" group was given the experimental medicine, is given either the normal treatment or a placebo. Often these studies are "blinded," which means that no one knows who is participating in them. Neither the patients nor the researchers are aware of who is involved and has been given the experimental medication. This enables to provide the medication, researchers business and the Food and Drug Administration (FDA) with comparison data information about the relative safety of the environment the new drug's effectiveness . Approximately one-third of Both are effectively completed with Phase I and Phase II studies.

- **Studies in the third phase** This stage evaluates randomized and blind trials involving hundreds to thousands of patients. This is a large-scale experiment, which can endure for several years It gives you everything you need. Researchers and regulatory agencies with a better understanding a detailed grasp of the program's success advantages and potential uses of a medication or gadget undesirable effects that could occur . About 70% to 90% of drugs that enter Phase III trial successfully complete this phase of testing ,a pharmaceutical company now make a request for FDA approval .So that the drug can be marketed.
- **Studies in the fourth phase -** Post marketing Surveillance Trials are another name for this period. They take place after a medicine or gadget has been tested. After receiving approval from the FDA, the product was approved for consumer sale. A supervisory authority Pharmaceutical businesses at this point, you should have a few goals in mind: (1) to begin with compare a medicine against other drugs on the market; (2) to track a drug's long-term effectiveness the success of the treatment and its impact on the patient's quality of life determining the cost-effectiveness of life; and (3) determining the cost-effectiveness of a pharmacological therapy in comparison to other available and novel therapies.

Phase IV investigations can lead to the development of a medication or device. Devices can be removed from the market or limits imposed on it with the help of the study[4-6]

DESIGNING A TRIAL

An adaptive clinical trial's goal is to swiftly identify medications that have a promising future. Adjusting dosage amounts has a therapeutic impact. This study looks at how well a medical equipment or treatment works, by keeping track of participant results on a set of criteria. In accordance with those observations, a protocol was developed. Dosage, medication, and other parameters are among the parameters that can be changed. Trial in progress, patient selection criteria, and sample size and variety.

Randomized trial: - Randomized trial's purpose aims to eliminate bias in the testing of new medication treatments. In Each study subject is assigned at random in this trial to be randomly assigned to either the trial therapy or a placebo. The control group receives a placebo.

A randomized trial is performed to evaluate a drug's effectiveness and efficacy.

Blind trial: In a blind trial, the participants are unaware of the study treatment they will get and for what purpose. In Subjects and investigators in double-blind experiments .The doctor is unaware of the drug that has been administered. Neither the patients nor the researchers who are keeping an eye on them are aware of this. As a result, you'll be able to tell which patient is receiving treatment. Until the trial is finished, you won't know which treatment you'll get. It's a fantastic idea. It is a good way to reduce bias.

CLINICAL TRIALS ARE BEING CONDUCTED IN INDIA.

India is regarded as a desirable location for conducting international clinical trials. Nearly 20% of all global clinical trials are anticipated to be undertaken in India. India, as the world's second most populous country, can make a considerable contribution to global drug development projects. In comparison to other developed countries, India offers an opportunity in terms of large patient populations, highly educated talent, a wide range of diseases, lower operating costs, lower medication costs, and a favorable economic, intellectual property environment. Most importantly, the use of English as the primary language makes it simple to set up clinical sites in India. The office of the Drugs Controller is India's counterpart of the US Food and Drug Administration (FDA) and the European Medicines Agency (EMEA). India's Controller General (DCGI). The DCGI is a non-profit organization. In India, the federal authority in charge of all pharmaceutical concerns. The DCGI is the FDA commissioner's equivalent. For drug trials, India follows Schedule Y, which is identical to the IND regulations 21CFR:312. In India, the DCGI is not divided into multiple locations and offices to control different types of items separately. However, the DCGI personally signs all applications submitted to his office. These applications comprise not just clinical trial applications, but also all applications for medication and medical device marketing approval, import and export of regulated products, and manufacturing[7-9]. An Indian version of GCPs was released by the Indian Council of Medical Research (ICMR) for use in India. particular concerns pertaining to the performance of clinical procedures In India, an IEC is analogous to an Institutional Evaluation Committee. In the United States, there is an Institutional Review Board (IRB). All websites must comply with this requirement. In addition to the DCGI's, have IEC approval Before enrolling any subject, you must get permission. India is one of the world's most populous.

CONCLUSION

A clinical trial is required for a medicine or device to ensure its safety and efficacy in humans before it is approved for use in humans use. Clinical trials may be able to help. about the use or non-use of a medicinal agent can help millions of sufferers all around the world. Despite this, the clinical trial filing process In India, applying for a visa takes a long time; NDAC, Technical Review Committee, Apex Committee, and Ethics Committee are only a few of the bodies involved in clinical trials in India. From 2008 to the present, there have been numerous changes. Still evolving. As a result of these changes, India has become a Clinical trials have a worldwide hub. As the second, India, the world's most populous country, can contribute considerably to the global pharmaceutical industry programmers for development.

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