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"Review On Clinical Research And It's Phases"

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ABSTRACT :-

This article contains all the information regarding the conduction of community trials of a new drug that is yet to be launched in the market for the public use.It also include the clinical trials design. Further, it also provides vital information about the various phases of the clinical trials. The role of important regulatory authorities such as FDA and it's monitoring post approval of the drug is also included here. This article also involves the information about the changes that are required in conducting clinical trials if any incompatibility occurs.

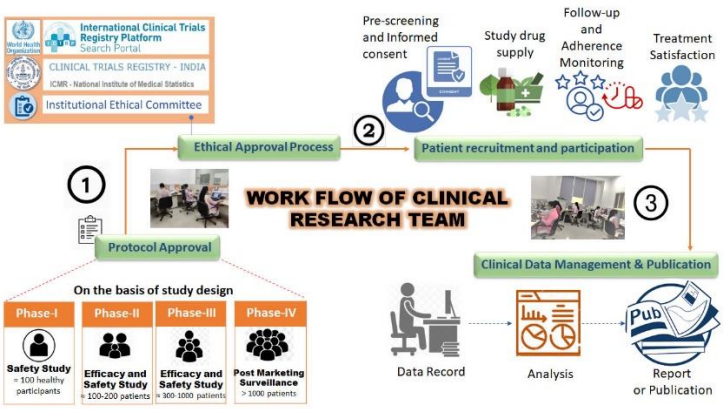
KEYWORDS :-

Adverse drug effect, Clinical Trials, Therapeutic effect, FDA.

INTRODUCTION :-

A Clinical Trial is a research study that tests a new medical treatment or a new way of using an existing treatment to see if it will be a better way to prevent disease. Clinical research refers to systemic investigation in a human being for evaluating the safety and efficacy of a new drug. The need for novel medication development has increased as a result of the threat that various diseases suffering humans on a daily basis and the limited number of accessible therapies. Before doing clinical trials, clinical trials designing is must to do. According to clinical trials designing, clinical trials must be done. For any new drug to enter in clinical trial, it must pass preclinical studies. Pre-clinical studies involve in vitro (test-tube or Laboratory) studies and trials on animals. After Pre-clinical trials, clinical trials gets started to do study of identical drug on human beings. Clinical research constitutes approximately three important stages for bringing new drug to market such as;

1. Drug discovery
2. Pre-Clinical testing
3. Clinical trials.
4. FDA Drug Review.
5. FDA Post-Market Drug Safety Monitoring.



Clinical Trial Design :-

The sequence or structure of activities which are carried out during the clinical trials is called as Clinical Trial Design. This Clinical Trial Design is divided into two groups Observational studies and Experimental studies.

- Observational Studies :- It consist of two ways in studies they are descriptive studies and analytical studies.
- Experimental Studies :- It include practical studies of drugs on living beings.

I. Observation Studies :-

It is divided into two main groups :-

1. Prospective :- This study determines what will happen in future. Observational study in future outcomes.
   a) Concurrent :- This is also called as Cohort study. It determines a characteristics study of drug which are risky or which are protective for human health. Subject who have characteristics are exposed and those who don't have characteristics they are non exposed.
   b) Non-Concurrent :- Researcher or scientist select exposed and non exposed subjects and try to find information on these subjects upto present time. It also requires less execution time and having less cost.
   c) Cross-sectional :- It is also called as Prevalence study. They are comparison of presence of event between person with or without the characteristics at one point of time.
2. Retrospective :- This study determines what had happened by looking at previous conditions. Shorty this study is depends on the past conditions.
   a) True retrospective :- The researcher or scientist randomly select two groups of subjects irrespectively of their nature that is exposed or non exposed at the time of selection. Then researcher retrospectically gives exposure to a characteristics for longer time. Those who are affected by disease called as 'Case' and those who are not they are called as 'Control'. So this is all together is called as Case Control Study.
   b) Cross-sectional :- It is also called as Transversal retrospective study. In this study the exposure is done in present time only.

II. Experimental Studies :-

It is also divided into two main groups:-

1. Community Trials :-

Community trials are designed to test the effectiveness of new treatments or interventions in real-world settings, where people live, work, and play. These trials often involve collaboration between researchers, health care providers, and community members, and they aim to address health disparities and improve health outcomes for diverse populations. Community trials may involve testing new drugs, medical devices, behavioral interventions, or other treatments, and they may take place in schools, workplaces, clinics, or other community settings. The results of community trials can inform public health policy and practice, and help to improve the health and well-being of communities.

The community trials are conducted by the researchers and investigators for a new drug that is to be

marketed. The primary aim of conducting community trials is to test the safety and efficacy of the drug by testing it on a particular selected group of individuals. In community trials, a group of people is selected randomly based on their ability to showcase the symptoms of the disease on being exposed to the diseased conditions. In community trials, the researchers communicates with the subjects and asks various individuals about various side effects that they are experiencing. Based on that, the researchers evaluate their results of the experiments that are being carried out. This information also helps researchers about the continuity of the experiments. If the adverse effects are seen to be worst, the trials must be stopped immediately after the occurrence of the incidence.

2. Clinical Trials :-

It is defines as "A type of research study that test the drug on human or new medicine before it comes to the Market." It is a life cycle of any product how it comes to the market after doing the various testing. Clinical Trials plays an integral role in the development of new medical approaches. There are four clinical trials are given below.

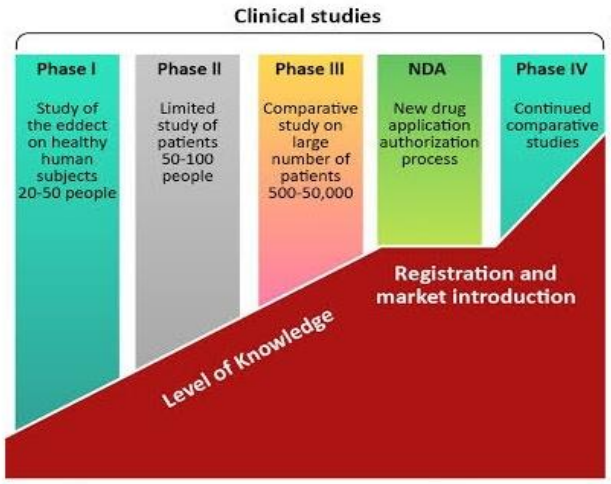
Clinical Trials Process :-

➢ **Preclinical Trials :-**

1) Preclinical studies or Nonclinical studies is a stage of research that begins before clinical trials (Testing in humans).
2) Laboratory research are done and then it is decided that the treatment is useful and safe or not.
3) In Pharmacology study the animal testing are done to see its effect.
4) After all this studies, if drugs get approved then the product goes for testing on Human.
5) Duration – 1 to 3 years

Clinical Studies :-

- Phase 0 (Human Micro Dosing Study)
- Phase 1 (Clinical Pharmacology Study)
- Phase 2 (Exploratory Study)
- Phase 3 (Confirmatory Study)
- Phase 4 (Post marketing Study)



❑ Phase 0 :-

1) Phase 0 is also called as Human Micro Dosing Study.
2) In Phase 0, small amount doses of New Drug are tested on few peoples (10-15 patients).
3) They test that how drug acts on the Human Body and how it responds.
4) If the medication acts differently than expected, the investigators will likely to do some additional preclinical research before deciding whether to continue the trial.
5) After this, if drug get passed then futher drug goes to the Phase 1 studies

❑ Phase I :-

1) Phase 1 is also called as Clinical Pharmacology Study.
2) New treatment or therapies are tested in a small group of people (20-80 peoples) to determine safety and identify side effect.
3) Phase 1 studies sometimes include people with vitiligo (skin infection) but some are also healthy patient without any medical conditions are also included.
4) The investigator have usually completed animal trials with the drug and now want to know if there are any harmful effect of the drug on the human beings.
5) Phase 1 studies last for several months.
6) Approximately 70% of drug goes to next phase.

❑ Phase II :-

1) Test are performed on larger group of people with a medical condition
2) (100-300 peoples) for further safety and treatment effectiveness studies.
3) These trial are done for different doses of a medication or concentration of a product to determine which works the best.
4) After that they also notice that any side effect may occur or not.
5) Phase 2 studies can last from several months to 2 years.
6) Phase 2 is also called as Exploratory Study.
7) Approximately 33% of drug goes to next phase.

❑ Phase III :-

1) Phase 3 is divided into two phases that are Phase 3A and Phase 3B, Phase 3A studies are done before the NDA (New Drug Application) and Phase 3B studies are done after the NDA approval but sometime only Phase 3 is carried out to gather the information about efficacy and safety of the product.
2) In this trial may compare which group of patients has better survival rates.
3) Test the safety and how well a new treatment works compared with a standards treatment.

4) The studies are done on large number of peoples (1000-3000 peoples).
5) Phase 3 is also called as Confirmatory Study.
6) Approximately 25-30% of drug goes to next phase.

FDA Approval :-

1) After all 3 phases passed then the product goes to the NDA.
2) The NDA is submitted the product detail to the Licencing Authority like FDA (Food and Drug Administration.)
3) That body gives approval and then it gets marketing permission.

❑ **Phase IV :-**

1) It also called "Post Marketing Studies", these trials are conducted to obtain more information about risk, benefits and best use of drug or therapy after the U.S Food and Drug Administration (FDA) has approved it.
2) During the phase 4 period, researcher review what happens when people in real world situations use the treatment.
3) In this phase large number of participants (around more than 10,000) are present.
4) These studies provide information about side effects and efficacy that wasn't detected during earlier phase studies.
5) Approximately 70-90% of drug goes to next Phase.

CONCLUSION:-

From this article we came to a conclusion that for achieving the therapeutic and commercial success of a new drug that is yet to be discovered, one should conduct all the phases of a clinical trials so that no further consequences can be seen on human beings.

By conducting each phase carefully, the researcher would know the therapeutic effects and side effects of the drug. If it is not meeting the standard satisfactory requirements that needs to be fulfilled, the drug should be withdrawn from the ongoing phase of the clinical trial.

By conducting the community trials, we came to know that, how a particular group of subjects would react to a new drug, if they are exposed to the certain conditions.The results obtained for both community and clinical trials and are evaluated. Based on results, the future of that particular new drug is decided ie. whether to continue it's sell in the market or to stop it's sell and recall it for conducting more research, and then sell it again for treating the needy patients.

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