Clinical Research and Clinical Trials-I

Define Clinical Research:

Clinical research is a branch of healthcare science that determines the safety and effectiveness (efficacy) of medications, devices, diagnostic products and treatment regimens intended for human use. These may be used for prevention, treatment, diagnosis or for relieving symptoms of a disease. Clinical research is different from clinical practice. In clinical practice established treatments are used, while in clinical research evidence is collected to establish a treatment.

Define Clinical Trials:

Clinical trials are experiments or observations done in clinical research. Such prospective biomedical or behavioral research studies on human participants are designed to answer specific questions about biomedical or behavioral interventions, including new treatments (such as novel vaccines, drugs, dietary choices, dietary supplements, and medical devices) and known interventions that warrant further study and comparison. Clinical trials generate data on dosage, safety and efficacy.[1] They are conducted only after they have received health authority/ethics committee approval in the country where approval of the therapy is sought. These authorities are responsible for vetting the risk/benefit ratio of the trial—their approval does not mean the therapy is 'safe' or effective, only that the trial may be conducted.

Why we need the clinical trials?

Clinical trials show us what works (and what doesn't) in medicine and health care. They are the best way to learn what works in treating diseases like cancer. Clinical trials are designed to answer some important questions:

- Does the new treatment work in people? If it does, doctors will also look at how well it works. Is it better than treatment now being used? If it's not better, is it as good and cause fewer side effects? Or does it work in some people who aren't helped by current treatments?
- Is the new treatment safe? No treatment or procedure – even one already in common use – is without risk. But do the benefits of the new treatment outweigh the risks?

- Is this treatment better than the standard treatment given for this disease? Clinical trials help show if a new drug or treatment, or a new treatment combination, works better than what is now used.

Phases of Clinical Trials:

The different phases of clinical trials are:

Phase 1: The purpose of Phase 1 is to ensure that the treatment is safe in humans and to determine how and where it distributes within the body. This testing normally takes place with a small group of healthy volunteers. At the end of Phase 1, the results are collected, analyzed, and submitted to the authority for permission to proceed to Phase 2 Clinical Trials. However, if the results show that the treatment was associated with one or more serious adverse events, then the authority may not give permission to proceed to Phase 2.

Phase 2: The purpose of a Phase 2 Clinical Trial is to determine the right dosage and effectiveness in treating that particular disease. This testing normally takes place with a larger number of volunteers who have the disease. There are many different ways that a trial sponsor can conduct their trial, but the plan normally involves assigning participants to different treatment groups, where each group can receive different doses or delivery of the treatment. Normally, there is a "control group" that receives either the current standard of care, if another type of treatment is already available on the market for that disease, or a "placebo" treatment, such as a sugar pill or harmless injection that does not contain the treatment. The health of the group(s) of patients who received the different types of treatment is compared to the control groups. However, if the results show that the treatment did not work better than the current standard of care or even caused acceleration of the disease or other unexpected serious adverse events, the authority may not give permission to proceed to Phase 3.

Phase 3: A Phase 3 Clinical Trial involves a much larger group of volunteers and primarily focuses on determining whether the treatment would be safe and effective for a wide variety of people. The plan normally involves assigning participants to treatment or control groups. There can be more than one treatment group, especially if the treatment involves a combination of drugs or different components. Again, there is a control group that receives either the current standard of care regiment or a placebo treatment. After completion of Phase

3 Clinical Trials, the health of the patients who received the different types of treatment are compared to the control groups. If the results show that the treatment did not work better than the current standard of care or even caused acceleration of the disease or other unexpected serious adverse events, the authority may not give permission to proceed to apply for a New Drug Application (NDA).

Phase 4: After approval by the authority and manufacturing of the drug on a large scale by the sponsor, the process enters what is called Phase 4 Clinical Trial/Post-Market Surveillance/Report Adverse Events. For at least the entire time a treatment* is on the market, the authority monitors for public safety and potentially serious adverse events.