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A Review Paper on: Clinical Trials

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Abstract:
To assure the safety and effectiveness of any new treatment, clinical research is a crucial step in the drug discovery process. Clinical trials are essential in the worldwide scientific era of today for bringing new and improved medications to market. Human volunteers (subjects) are used in clinical trials to test prospective treatments to see whether they should be licensed for use in the general population. Due to a number of variables, India served as a global centre for clinical trials in the past. Clinical trials and clinical trials in India are discussed in this essay.

Keywords: Randomized trial, Key, phases, Blind trial, words: Clinical Trial

Introduction:
Clinical trials, as their name suggests, are a collection of experiments and observations performed on human participants in clinical research. To prevent, detect, treat, or manage various illnesses or medical disorders, they are conducted in the hunt for novel therapies, interventions, or diagnostics. Clinical trials are used to test new interventions to see if they are safe, effective, and superior to currently used therapies. The WHO describes a clinical trial as:
The basic goal of drug discovery research is to create novel, safer, and more effective medications for human use. A new medicine must undergo numerous stages of rigorous testing, first on animals and then on human beings, before it is released onto the market.
They are the most crucial and determining factor in whether a new medicine enters the market. Without clinical trials, researchers cannot accurately assess the efficacy or safety of novel medications created in the lab or using animal models, or the efficacy of diagnostic tests used in clinical settings.

Types of clinical trial:
Clinical trials can be classified in to various ways
One way is to classify clinical trials on basis of Mode of study

1) **Interventional Study:**
2) **Clinical Observational study:**

1) Interventional Study:
Researchers in this study track improvements in the patients' health. They provide the study subjects a specific medication, followed by the subjects who received treatment with those receiving neither care nor the minimum treatment. This kind of comparator is used study.

2) Clinical Observational study:

The researchers measure and watch the patients who receive the new medication in this study. Their results**.**

Another way is to classify trials is by their Purpose

- **Prevention Trails**
- **Screening Trials**
- **Diagnostic Trials**
- **Treatment Trails**
- **Quality of life Trails**
- **Compassionate use Trails**

1. Prevention Trails:-

To prevent disease in people who have never had it or to stop a disease from coming back. These approaches may include medications, vitamins, vaccines, minerals or lifestyle changes.

2. Screening Trials:-

Screening trials test the best way to detect Certain diseases or health conditions.

3. Diagnostic Trials:-

Diagnostic trials are conducted to find Better tests or procedures for diagnosing a Particular disease or condition.

4. Treatment Trails:-

Treatment trials_ test experimental Treatments, new combinations of drugs, or New approaches to surgery or radiation Therapy.

5. Quality of Life Trails:-

Quality of life trials(supportive care Trials) explore ways to improve comfort And the quality of life for individuals with A chronic illness.

6. Compassionate Trails:-

Expanded Access Trials provide partially tested, unauthorised therapeutics to a limited number of patients who have no realistic options. Patients with a disease for which no effective therapy has been approved, or a patient who has failed all standard treatments and is too ill to participate in randomized clinical trials

There are mainly 5 phases but only 4 are clinical and other one is pre clinical in which the drug us tested upon the various animals which have similar body functions like human beings..

Phases of clinical trails:-

- **Phase 1**
- **Phase 2**
- **Phase 3**
- **Phase 4**

1) Phase 1 studies:-

Phase 1 is the initial phase of testing for a drug or device. It typically takes several months to complete and involves a small number of healthy volunteers (20-100) to assess the safety of the drug or device. The purpose of Phase 1 is to evaluate the effect/effectiveness of the drug/device on humans, including

absorption, metabolism, and excretion (ADME). This phase also looks at dose-related side effects. About 70 percent of experimental drugs pass this phase.

2) Phase 2 studies:-

Phase II is the second phase of testing. This phase evaluates the effectiveness of the drug or device. Phase II studies typically last from a few months to two years and involve up to several hundred patients. Most Phase II studies are randomised, meaning one group of patients will receive the experimental drug while a second "control" group will receive a standard treatment or a placebo. These studies are often "blinded" meaning that neither the patients nor researchers know who has received the experimental drug, which allows researchers to provide comparative information about the safety and effectiveness of the new drug to the pharmaceutical company and the FDA. Approximately one-third of experimental drugs successfully complete both Phase I and Phase II.

3) Phase 3 studies:-

This stage evaluates randomised, blind trials involving hundreds to thousands of patients. This is a significant test, Which can persist for many years. It gives researchers and regulatory authorities a more full grasp of the efficacy of the medication or gadget, the advantages, and the variety of potential side effects. About 70% to 90% of medications that are tested in Phase III trials succeed in getting beyond this stage. A pharmaceutical business may submit an FDA marketing request once Phase III is finished.

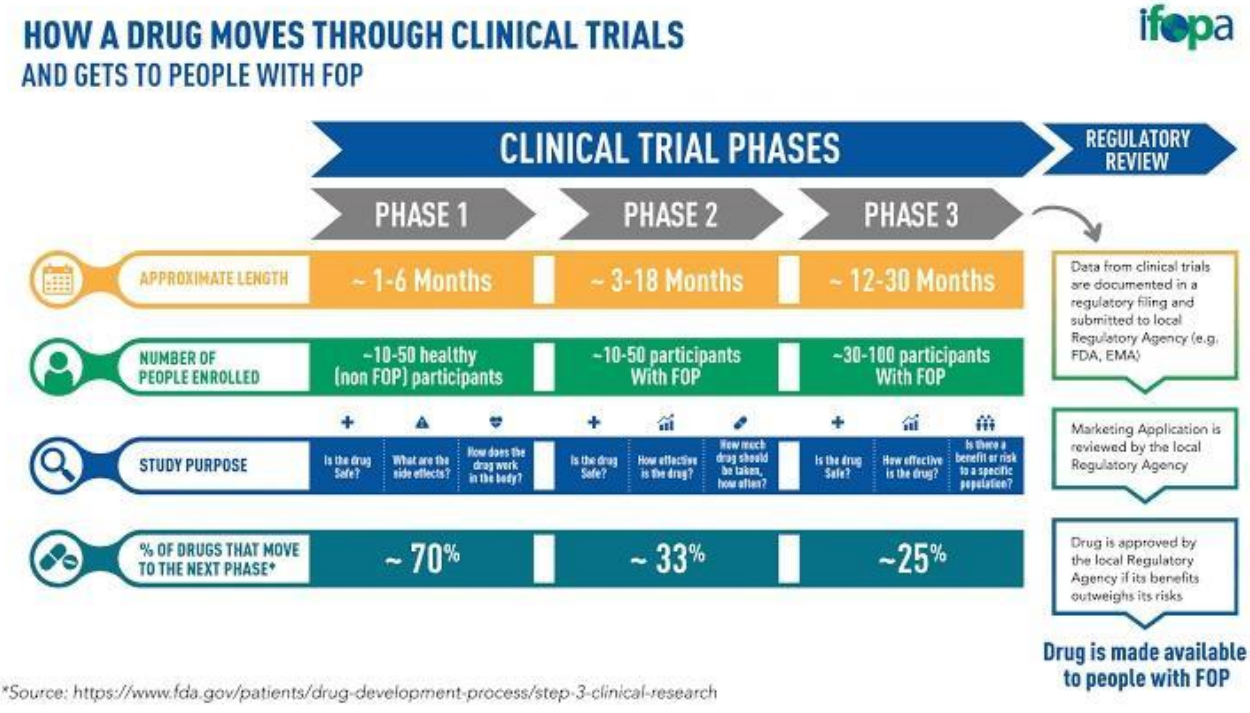
4) Phase 4 studies:-

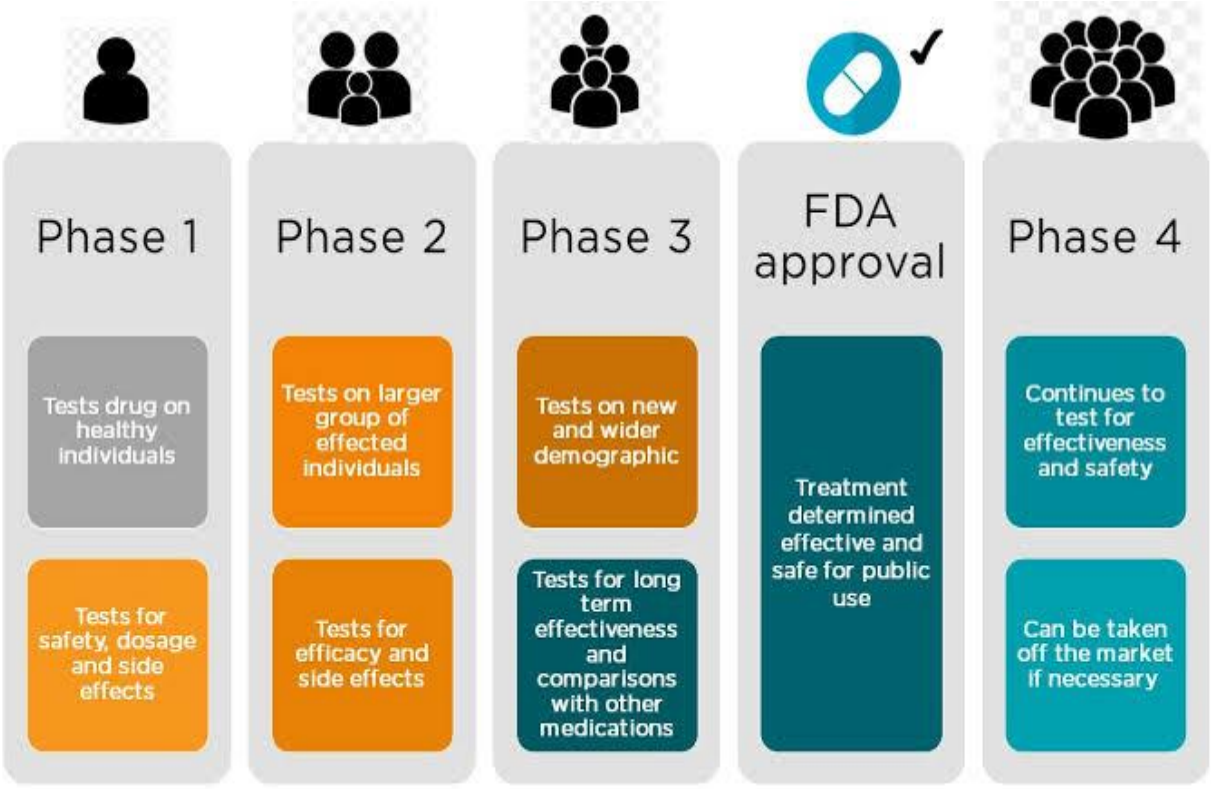
Post-marketing surveillance trials are another name for this period. They take place after a medication or device has received regulatory authority's approval for sale to consumers. At this stage, pharmaceutical companies have several goals:

(1) to compare a drug with other drugs already on the market;

(2) to track a drug's long-term effectiveness and impact on a patient's quality of life; and

(3) to assess the cost-effectiveness of a drug therapy in comparison to other existing and new therapies. A medication or device may be pulled off the market as a consequence of a phase IV study, or usage limits may be imposed on the product depending on the research's findings.





Trail Design:

- **Adaptive Trail:**

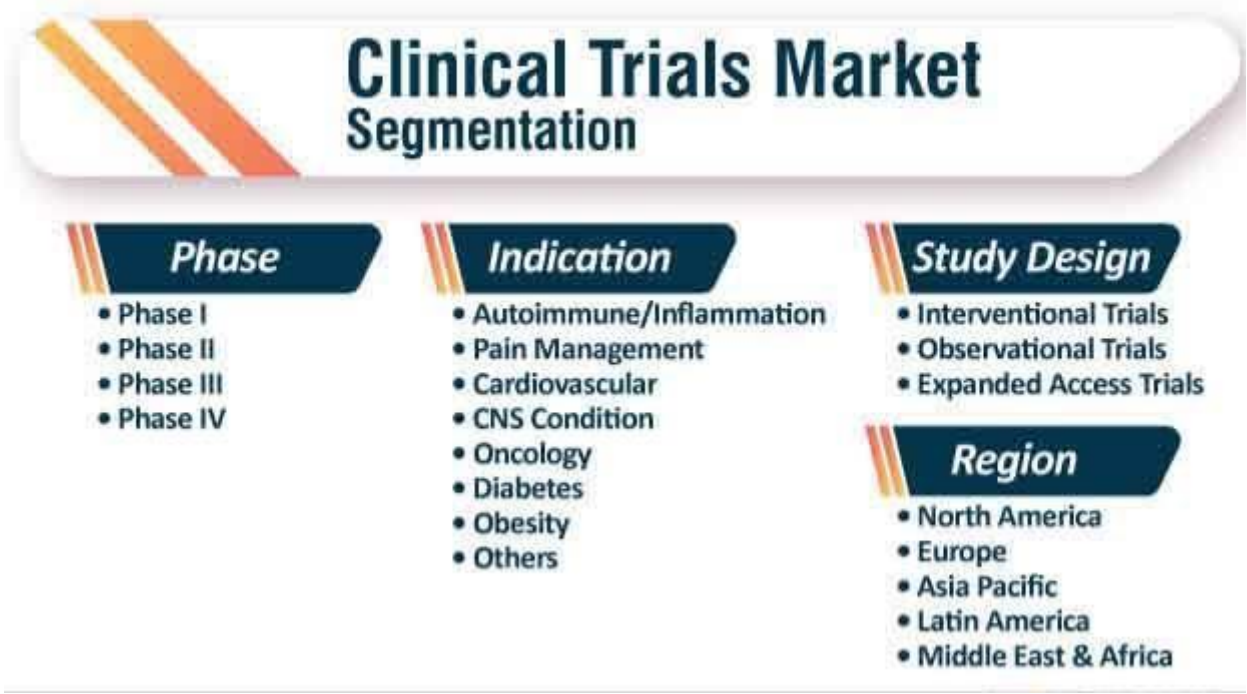
The goal of an adaptive clinical trial is to quickly determine which drugs have a therapeutic effect by adjusting dose levels. This type of trial evaluates a device or treatment by observing participant results on a prescribed schedule, and then adjusting trial protocol parameters to match those observations. Parameters that can be changed include: dosage, drug under study, patient selection parameters, sample size and mix.

- **Randomized Trail:-**

The aim of randomised trials is to lessen bias while evaluating novel medicinal therapies. Each participant in this trial is randomly assigned To either get a placebo or the experimental therapy.The control group is the one that receives a placebo.

- **Blind Trail:-**

In a blind trial, the participants in the study are unaware of which study treatment they are receiving and for what reason. In a double blind trial, neither the subjects nor the investigator / doctor are aware of which medication is being administered. Neither the patients nor researchers monitoring the outcome of the study are aware of which patients are receiving which treatment until the end of the study. It is highly effective in reducing BIA.



Clinical Trials In India:

India is known as an ideal location for carrying out international clinical trials. An estimated 20% of clinical trials conducted worldwide are carried out in India. India, the second most populous nation in the world, can make a considerable contribution to international drug development programmes.

India can make a big contribution to international drug development initiatives. India offers an opportunity in terms of the availability of sizable patient populations, highly educated talent, a wide range of diseases, lower operating costs, lower drug costs compared to other developed countries, and a favourable 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 General (India) (DCGI) is the counterpart of the US Food and Drug Administration (FDA) and the European Medicines Agency (EMEA) in India. In India, the DCGI is the government agency in charge of all matters pertaining to pharmaceuticals.

As the FDA commissioner's counterpart, the DCGI. Schedule Y is followed by India for drug studies. Similar to 21CFR:312 of the IND rules. For the purpose of individually regulating various product types, DCGI is not divided into numerous centres and offices across India. On every application submitted to the DCGI, however, he personally signs.

These comprise all applications for marketing authorisation of medicines and medical equipment, as well as those for import and export, in addition to clinical trial applications.

Of regulated goods as well as for production. India adheres to the ICH E6 recommendations for clinical studies. A localised version of GCPs was made available by the Indian Council of Medical Research (ICMR) to address concerns unique to India's clinical operations.

An Institutional Review Board (IRB) in the US is comparable to an IEC in India. Before enrolling any subjects, all sites must receive both the DCGI's and IEC's clearance. While processing a clinical trial application in the US, other European nations, and Australia typically takes two to four weeks, it often takes four to eight weeks in India.

Conclusion:

Before being used, a medicine or gadget must undergo a clinical trial to verify its efficacy and safety in humans. Clinical trials may offer solutions. Relating to whether or not to utilise a medication that could help millions of patients all throughout the world. Although the clinical trial application filing process is a drawn-out process in India; Although it involves numerous bodies, including the NDAC, Technical Review Committee, Apex Committee, and Ethics Committee, clinical trials in India have experienced significant modifications since 2008 and are continuously changing. India has become a hotspot for clinical trials worldwide as a result of these reforms. India can make a big contribution to international drug development programmes because it is the second most populous nation in the world.

References:

1. http://www.temple.edu/pascope/about_trials.htm
2. Clinical trial Wikipedia, the free encyclopedia. Available from: URL http://en.wikipedia.org/ Wiki/clinical_trial.
3. ICH Harmonized Tripartite Guideline for Good Clinical Practice 'Academy For Clinical Excellence'.
4. The Lancet (2009). "Phase 0 trials: A platform For drug development?". The Lancet. 374 (9685): 176–118
5. Yang, Z. J., et al. (2010). "Motivation for Health Information Seeking and Processing About Clinical Trial Enrollment." Health Communication 25(5): 423-436.
6. Life Sciences Strategy Group, (May 2009) "Clinical Trial Technology Utilization, Purchasing Preferences & Growth Outlook" Syndicated Publication,
7. "India: Prime Destination for Unethical Clinical Trials". Common Dreams.
8. Paul J, Seib R, Prescott T (Mar 2005). "The Internet and Clinical Trials: Background, Online Resources, Examples and Issues" (Free full Text). Journal of medical Internet research. 7 (1): E5.
9. ICH Guideline for Good Clinical Practice: Consolidated Guidance.
10. Pharmabiz.com, Mumbai (May 2014),ISCR Releases Guide for clinical trial participants on International Clinical Trials Day.
11. Hannan, E. L. (2008). "Randomized clinical Trials and observational studies: Guidelines for Assessing respective strengths and Limitations". JACC: Cardiovascular Interventions.1 (3): 211–7
12. Rang, HP; Dale, MM; Ritter, JM; Moore, PK (2003). Pharmacology 5 ed. Edinburgh: Churchill Livingstone.
13. Image reference - https://images.app.goo.gl/w9GYyspathRyjfeA6
14. CDSCO Central Drugs Standard Control Organization. 2010a. Available from: http://www.cdsco.nic.in/writereaddata/Notificatiohn%20 on%20 Compensation%20on%20clincial%20trial%20 (1).Pdf.
15. Major hurdles cleared for clinical trials in India: Experts. Available from: http://articles.economictimes.indiatimes.com/2015-07-23/news/64773370_1_clinical-trials-suneela-thatte-iscr
16. Indian GCP Guidelines. 2004. [Last accessed on 2014 Jan 24]. Available from: http://www.cdsco.nic.in/html/GCP1.html.
17. World Medical Association Declaration of helsinkiethical Principles for medical research involving Humansubjects. 2008. [Last accessed on 2013 Dec 23]. Available from: http://www.wma.net/en/30publications/10policies/b3/

18. ICH Guideline for good clinical practice E6 (R1) current Step 4 version dated 10 June 1996. [Last accessed on 2013 Dec 20]. Available from:http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf.
19. International ethical guidelines for biomedical research Involving human subjects prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the world health Organization (WHO) 2002. [Last accessed on 2013 Dec Available from: http://www.cioms.ch/publications/layout_guide2002.pdf.
20. ICMR Ethical guidelines for biomedical research on Human participants. 2006. [Last accessed on 2014 Jan
21. Available from: http://www.icmr.nic.in/ethical_guidelines.pdf. US-FDA 21 CFR Part 50. 2012. [Last accessed on 2013 Dec 20]. Available from:http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=5.
22. Guidance for institutional review boards and clinical Investigators 1998 update. [Last accessed on 2014 Jan
23. Availablefrom:http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113793.htm.