



Research Newsletter

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Clinical Trials: Testing Medical Products on Humans



✚ Introduction

For thousands of years, people have experimented with plants as a way to cure sickness or to treat infection. Despite so much knowledge around, for many diseases we have no existing treatments. Those that exist are very minimal & are often accompanied by numerous side effects. Thus, an urgent need is felt to improve the level and quality of treatments. Vast improvements in our knowledge of working of our body in health and in sickness along with the invention of Clinical Trials have laid the foundations for medical advancements.

✚ What does a Clinical Trial mean?

‘Clinical trial’(CT) is a systematic study of new medical product(s) in human subject(s) to generate data for discovering and /or verifying the clinical, pharmacological and /or adverse effects with the objective of determining safety and /or efficacy of the new medical products e.g. drugs, diagnostics, devices, therapy protocols.



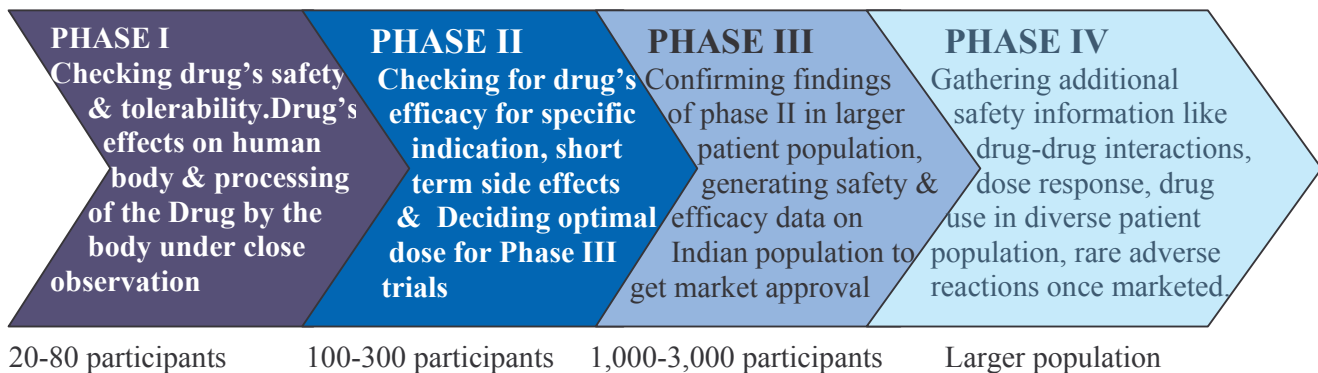
Is clinical practice different from Clinical Research?



Yes. In clinical practice, doctor uses established treatments while in clinical research evidence is collected to establish a treatment.

Before a CT, potential treatments are studied in laboratory animals to determine potential toxicity. These are called Pre-Clinical Studies. Treatments with acceptable safety profiles and good levels of promise are then passed on for CTs for trial on human beings. It is not confirmed whether the potential medical treatment offers benefit to patients until clinical research on that treatment is complete.

✚ CT Process: The four different phases of the trial



✚ Who are involved in Clinical Trials?

Pharmaceutical Company, Contract Research Organization, Investigator (Clinician), Assistant Doctors, Coordinators, Nurse and Subjects (Participants)



✚ Who can participate in clinical trials?

It is important to test medical products in a wide variety of people because drugs can work differently in people of various ages, races, ethnicity, and gender. Before the start of the trial, each potential participant is screened according to the predefined study criteria developed by researchers which usually include criteria for age, sex, type and stage of disease, previous treatment history, and other medical conditions. Some trials involve people with a particular illness or condition to be studied, while others seek healthy volunteers. Inclusion and exclusion criteria help identify appropriate participants and help exclude those who may be put at risk by participating in a CT. Volunteer is included in the research if the criteria are met.

✚ Why participate in a clinical trial?

People volunteer to participate in CTs for different reasons. Some volunteer because they want to help advance medical knowledge. Others have tried all available treatments for their condition without success.

✚ The central requirement for Clinical Research.....Participant's Written Informed Consent

- The potential participant has to sign ICF (Informed Consent Form) voluntarily.
- He/she should sign it only after being informed of all relevant aspects of the CT to his/her decision to participate verbally as well as in writing.
- He/she should read patient information sheet & sign Informed Consent Form both approved by the Ethics Committee and furnished to the Licensing Authority. Same thing applies to any subsequent changes in the Informed Consent Documents.
- Where a subject is not able to give informed consent (e.g. an unconscious person or a minor or those suffering from severe mental illness or disability), the consent may be obtained from a representative acceptable legally. If the Subject's legally acceptable representative is unable to read/write – an impartial witness should be present during the entire informed consent process who must append his/her signatures to the consent form.



Before participating, ensure: following information is provided to you & all your doubts are clarified.

- That the study involves research and explanation of the purpose of the research
- Expected duration of participation
- Description of the procedures to be followed, including all invasive procedures
- Any risks/discomforts & benefits to the Subject/others. If no benefit is expected it should be made clear.
- Alternative procedures or therapies available to the Subject
- Extent of confidentiality of subject's records & who will have access to them
- Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials)
- Compensation and/or treatment(s) available to the Subject in the event of a trial-related injury
- Whom to contact for trial related queries, rights of Subject & in the event of any injury
- The anticipated prorated payment, if any, to the Subject for participating in the trial
- Subject's responsibilities on participation in the trial
- Participation is voluntary; the subject can withdraw from the study at any time. Refusal to participate will not involve any penalty or loss of benefits to which the Subject is otherwise entitled.
- Any other pertinent information

✚ Indian Regulation of Clinical Research

Guidelines for Clinical Research

Regulatory Body:

Central Drugs Standard Control Organization (CDSCO).

DCGI (Drugs Controller General of India) heads the CDSCO.

-CDSCO-body attached to the office of the Director General of Health Services in the Ministry of Health & Family Welfare, GOI.

-looks after approval of new drugs, clinical trials in the country

-lays down the standards for drugs, controls quality of imported drugs

-provides expert advice for bringing about uniformity in the enforcement of the Drugs & Cosmetics Act.

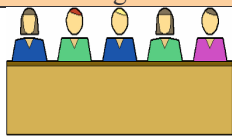
Declaration of Helsinki (1964 & Revisions) issued by World Medical Association

Indian Good Clinical Practice (GCP) (2002) issued by CDSCO

Regulation:

Schedule Y (& amendment) of the Drugs & Cosmetics Rules, 1945: the requirements & guidelines to be followed to get permission of importing &/or manufacturing New Drugs to market or to undertake CTs in India

Ethical Guidelines for Biomedical Research on Human Participants (1980 & Revisions) issued by Indian Council of Medical Research (ICMR)



✚ What is IEC?

- IEC means **Independent Ethics Committee**. When attached to an institution, it is called **Institutional Review Board (IRB)**.
- It reviews & approves the research, at appropriate intervals, makes an ongoing review. It can stop the research in case of serious flaws, unethical conduct or for safety reasons.
- This is done by a group of people from different fields - basic medical scientists, clinicians, legal expert, social scientist /representative of non-governmental voluntary agency/ philosopher / ethicist / theologian or a similar person, & lay person from the community.
- Responsible to safeguard the rights, safety & well being of all trial subjects.

Research Achievements:

1. **Publication:** Public awareness of clinical trials: A qualitative pilot study in Pune by **Joshi V, Kulkarni AA**. Perspectives in Clinical Research 2012;3:125-32.
2. **Award:** Circadian variation of HRV in healthy young adults: A novel '24-hour Minimum Activity (MA) Protocol' by Dr. Leena Phadke, Dr. K. M. Dandare, **Dr. Sanjay Phadke**, Dr. Aniruddha Joshi, Dr. Monika Gavali, Dr. Amit Inamdar **received an award at the International Conference on Basic and Applied Physiology**