Clinical Drug Trials

A CLINICAL TRIAL IS A MEDICAL EXPERIMENT ON HUMAN BEINGS

Types of Clinical Trials

- **Prophylactic Trials**
- Assess the effectiveness of a Preventive treatment
- Sample is divided into two groups.
- Of the two only one group receive preventive treatment

- **Therapeutic Trials**
- Compares a new treatment with best of current treatment
- Sample is divided into two groups.
- One group receive new treatment and other is given best of current treatment

Termonology of Clinical Trials

- Treatment
  - Test new approaches to treat a disease
- Prevention
  - What approaches can prevent disease
- Early-detection/screening
  - What are new ways to find hidden disease
- Diagnostic
  - How can new tests or procedures ID disease

Procedure to conduct clinical trial

- Objective of Clinical trial
- Preparation of Clinical trial known as Protocol
- Outlining of design and method of conducting a clinical trial
- Determination of sample size
- Allocation of treatment

Phases of Clinical Trials

	Phase 1	Phase 2	Phase 3	Phase 4
No. of Participants	30 -60	100-150	300 to thousands	Several hundreds to several thousands
Purpose	*Human volunteer *Major side effects *Maximum tolerating dose	*Determine efficacy *Short term side effects *Identify dose schedule for different age groups	*Known as RCT Phase *Compare new agent with standard treatment	*Post – market Long-term safety and efficacy

Institutional Review Board (IRB)

- All clinical trials must be approved and monitored by an IRB.
- IRB is an independent committee of physicians, nurses, statisticians, community advocates and others.
- The function of the IRB is to ensure that a clinical trial is ethical and the rights welfare of study participants are protected.