Who can't participate in clinical trial ?

Groups thought not to have autonomy to give informed consent:

- Children
- mentally impaired
- Prisoners.
- Historically women were excluded if she's of reproductive age (ages 18-45).
- Pregnant women (actually, the fetuses).

To safe guard these groups, special requirements such as:

- Only parent can consent for minor
- Consents must be in subject's native language.
- Prisoners: only some types of research allowed.

Types of clinical trial

- ***Intervention or treatment trials*-** Tests experimental treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.

- ***Prevention trials*-** look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. This approach may include medicine, vitamins, vaccines, mineral or life style changes.

- ***Diagnostic trials*-** are conducted to find better tests or procedures for diagnosing a particular disease or condition.

- ***Screening trials*-** test the best way to detect certain diseases or health conditions.

- ***Quality of life trials*-** also known as supportive care trials. Explore way to improve comfort and quality of life for individuals with chronic illness.

Protocol

- The protocol describes the scientific rational objective(s), design. Methodology, statistical considerations & organization of planned trial.
- The protocol contains a precise study plan for executing the clinical trial, not only to assure safety & health of the trial subjects, but also to provide an exact template for trial conduct by investigators at multiple locations to perform study in exactly same way .
- The protocol also gives the study administrators (often a contract research organization), as well as of physicians, nurses & clinical administrators, a common reference document for site responsibilities during the trial.

Phases for clinical trial

- Clinical trials involving new drugs are commonly classified into various phases. Each phase of drug approval process is treated as a separate clinical trial.
- The drug development process will proceed through various phases over many years.
- If the drug passes through the phases, it will usually be approved by the national regulatory authority for use in the general population.
- Various phases are :

1. Pre-clinical
2. Phase 0
3. Phase I
4. Phase II
5. Phase III
6. Phase IV