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GLOSSARY

- **TRIAL -** A large number of participants, a small difference between treatment and control groups may be statistically significant.
- **CLINICAL STUDY -** Study specialized or therapeutic care that requires on going assessment, planning, intervention and evaluation by health care professionals.
- **CLINIC-** A facility devoted to diagnosis and treatment or rehabilitation of outpatients.
- **CLINICAL TRIAL-** video A controlled research study of the safety and effectiveness of drugs, devices or techniques that occurs in four phases, starting with the enrolment of a small number of people, to the later stages in which thousands of people are involved prior to approval by the licensing authority.

DIFFERENT TYPES OF CLINICAL TRIALS

- **Screening (Early detection) trials-**test the best way to detect certain diseases or health conditions.
- **Diagnostic trials -** are conducted to find better tests or procedures for diagnosing a particular disease or condition. Diagnostic trials usually include people who have signs or symptoms of the disease or condition being studied.
- **Prevention trials -** Look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These

approaches may include medicines, vaccines, vitamins, minerals, or lifestyle changes.

- **Treatment trials -** Test experimental treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.

DIFFERENT PHASES OF CLINICAL TRIALS

- **PRE-CLINICAL -** It involves in vitro (test tube) and in vivo (animal) experiments using wide ranging doses of the study drug to obtain preliminary efficacy, toxicity and pharmacokinetic information.
- **PHASE I TRIALS -** Initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses.
- **PHASE II TRIALS -** Controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition.
- **PHASE III TRIALS-** Expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained.
- **PHASE IV TRIALS -** Post-marketing studies.

CLINICAL TRIAL STUDY TEAM

A clinical trial is a research study that tests a new medical treatment or a new way of using an existing treatment to see if it will be a better way to prevent and screen for diagnose or treat a disease.

- **REQUIREMENTS OF CLINICAL TRIAL STUDY TEAM-**

• Sufficient study staff to perform clinical research

• Appropriate skill set and training

• Follow GCP (Good clinical practices) standard

• Follow protocol requirements

- **RESEARCH TEAM ROLE -**

Research Team Ensures that-

• The correct version of the protocol is followed.

• Potential participants are provided with information

• The consent of informed consent form is properly stated Reporting of

• Any failures in these respects or suspected misconduct Report..:

• Adverse incidents, events or during reactions.

- **RESEARCH TEAM RESPONSIBILITY-**

• Appropriate skill set and training

• GCP (Good clinical Practice) Standards

• Follow protocol requirements

- **MEMBERS OF CLINICAL RESEARCH TEAM -**

- Principal investigator
- Co- and Associate Investigator
- Clinical Research Coordinator
- Data manager and Clinical Pharmacist
- Statistician
- Patients
- Institutional Review Board
- Regulatory Bodies.

INVESTIGATOR

- A investigator is the person who holds the responsibility for execution of clinical research.
- The investigator leads the research at the research site . It is the prime responsibility of investigator to ensure that the study is conducted in accordance with protocol, GCP and relevant regulations, and rights, safety and well being of research subjects as well protected during the research.
- Investigator should be well versed with: ICH-GCP guidelines Applicable regulatory requirement} As a leader investigator delegates' research related tasks to other research staff. But he or she must oversight each and every delegated task even after delegating the task to others.
- **CO-INVESTIGATOR –**

  A member of the research team designated and supervised by the Protocol Investigation to perform critical study-related procedures and to make important study-related decisions sub-investigators as those individuals

authorized to make medical judgments and decisions regarding study subject.

- **INVESTIGATORS' RESPONSIBILITIES**

1. Conducting the trial ,statement, protocol, and applicable regulations.
2. Protecting the rights, safety, and welfare of trial participants.
3. Obtaining informed consent from all trial participants.
4. Maintaining proper records.
5. Managing all progress reports, safety reports, financial disclosure reports.
6. Discussed in the Roles and Responsibilities module Based on GCP guidelines.
7. Ensuring that the Investigational Product. 8. Used in accordance with the approved protocol.

- **INVESTIGATOR'S ROLE-**

1. Interactions for applicable federal, state, and local regulatory authority.
2. Follow ethical principles and standards.
3. Discipline in designing and conducting clinical trials for policies, procedures.
4. Education programs are provided.
6. Refer to Section Good Clinical Practice (GCP) Course for training requirements.
7. The ultimate responsibility for the scientific, technical, and administrative aspects of the research project.

STUDY-COORDINATOR Coordinator Research Committee (CRC)

He has a critical role in facilitating, supporting and coordinating daily clinical research study activities. The CRC works under the direction of the PI who will delegate specific clinical research study related tasks.

- **ROLE-**

1. Conduct of a research study.

2. The CRC carries forward the research goals.

3. CRCs are often involved inessential duties that ensure compliance with the protocol and protection of human subjects.

4. Preparing the Institutional Review Board (IRB) submission.

5. writing the informed consent document, recruiting and consenting participants.

6. coordinating and conducting study visits, adverse event reporting, completing case report forms (CRF's)

7. managing data and collecting biological specimens.

- **RESPONSIBILITIES-**

1. Complete the required of Course before initiation of any clinical research related activity. Human Research Protection Program(HRPP) Collaborative Institutional Training Initiative (CITI)

2. Provide regulatory, institutional, sponsor and protocol requirements for the study.

3. Complete with all IRB decisions, conditions and requirements.

4. Ensure all studies have current IRB approval.

5. Coordinate with the PI and other key research personnel.

6. Ensure that Protected Health Information (PHI) will not be disclosed to any parties.

SPONSOR

sponsor is an "individual ,organisation or partnership that takes on overall responsibility for effective arrangements being in place to set up, run and report on a research project".

- **ROLE OF SPONSOR-**

1. Financial
2. Reputation
3. Legal

- **SPONSOR'S RESPONSIBLE-**

• Selecting and providing qualified investigators.

• Ensuring proper monitoring of the investigation.

• Ensuring conducted in accordance with the plan and protocols.

• Maintaining an effective respect to the investigation.

CLINICAL MONITOR

The person with direct access to patient's medical records to verify data and procedure acting with in the constraints of the applicable regulatory requirement to maintain the confidentiality of subjects' identities and sponsor's proprietary information.

- **ROLE-**

1. Director monitoring.
2. Medical monitoring .
3. Management monitoring.
4. Scientific monitoring.

- **RESPONSIBILITY-**

• Assign to appropriate protocols.

• Review from activities as applicable.

• Review protocol rules.

•Advise protocol team on safety oversight.

• Evaluate and reviews safety reports.

• Assist with pharmacovigilance activities.

CONTRACT RESEARCH ORGANIZATION

A Contract Research Organization (CRO) is a service organization which provides various‖ pharmaceutical research that is essential for conducting clinical trials in the present various complications are involved in the drug process.

- **ROLE-**

1. Project management.
2. Database design & build.
3. Data entry & validation.
4. Clinical trial data management.
5. Medicine and disease coding.
6. Quality and metric reporting.
7. Statistical analysis plans and reports.
8. Validation programming.
9. Safety and efficacy summaries.
10. Final study report.

- **RESPONSIBILITY-**

1. Evaluate feasibility.
2. Provide adequate, well manage staff.
3. Conduct study actives.
4. Manage processes.
5. Ensure that the solution are cost-effective.