SARASWATI INSTITUTE OF PHARMACEUTICAL SCIENCES
(Managed by Shree Saraswati Education Sansthan –Gujarat)
Recognized by the Government of Gujarat & Affiliated to Gujarat Technological University, Ahmedabad
Approved by the All-India Council of Technical Education (AICTE) & Pharmacy Council of India (PCI), New Delhi
Accredited by: National Board of Accreditation – NBA (B.Pharm, 2021-2024)

CLINICAL RESEARCH 858801

# CLINICAL TRIALS

## INTRODUCTION TO CLINICAL TRIALS

PREPARED BY:
Dr. Monvi Sachdev
Assistant Professor
PharmD

# What is a Clinical Trial

Definition of a clinical trial:-

A systematic study of new drugs in human subject to generate data for discovering or verifying the clinical pharmacological and adverse effect with the objective of determining the safety and the efficacy of the new drug.

# Types Of Clinical Trials

| Treatment Trials | Prevention Trials | Diagnostic Trial | Screening Trial | QOL Trial |
|---|---|---|---|---|
| They test new treatment, new combination of drugs or new approaches to surgery or radiation therapy | They look for ways to prevent diseases in people and also to prevent recurring. These approaches may include medicine, vitamin, vaccines. Mineral and lifestyle changes | They are conducted to find better test procedures for diagnosing a particular disease condition | They test the best way to detect certain health or disease condition | Explore the ways to increase the comfort and improve the QOL for individual with chronic illness |

# PARTICIPATION

- Participants play a major role in their own healthcare , gain accesses to new research treatment before they are widely available in the market
- All trails have guidelines to whether who can participate (i.e. inclusion & exclusion criteria)
- These criteria are based on factors like age, gender type, comorbid condition, type of treatment preferred
- Some trials need participants with illness while other seek healthy participants.

# PROCESS

- Depends upon the type of trial being conducted.
- Team includes doctors and nurses social workers and other HCP.
- Check the health and monitor the trial.

# INFORMED CONSENT

- Informed consent is the process of learning key fact about CT before deciding whether to participate or not.
- Informed consent is not a contract and the pt may withdraw from the study at any time.

# BENEFIT OF CLINICAL TRIAL

- Play and active role in their own health care
- Gain access to new treatments before they are widely available in market
- Obtain expert medical care during the trial
- Help others by contributing to the research
- Tailored Treatment Approaches
- Potential Financial Assistance

# INFO FOR SUBJECT BEFORE TRIAL

- What is the purpose of the study
- Who is going to be in the study
- Why do researcher believe that the new treatment is effective
- What kind of test and treatment are involved
- How might the trial affect my daily life
- How long will the trial last
- Will hospitalization be required
- Who will pay for the treatment
- Who will be incharge of my care