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Commentary

# Basic Clinical Trials and their Different Phases

**Yoko Urasaki***

*Department of Pharmacology, College of Pharma Science, Hiroshima University, Tokyo, Japan*

## DESCRIPTION

A clinical trial refers to a type of research study conducted to determine the effectiveness, safety, and potential side effects of a particular medical treatment, drug, or device. Clinical trials involve volunteers and are designed to evaluate the efficacy of new drugs, treatments, and procedures before they are approved for general use. The purpose of clinical trials is to gather scientific evidence that supports or refutes the hypothesis that a particular intervention is safe, effective and beneficial for patients.

### Types of clinical trials

Clinical trials can be categorized into different types based on various criteria such as study objectives, number of participants, and study design. Below are some of the most common types of clinical trials.

**Treatment attempts:** A therapeutic trial aims to evaluate the effectiveness of a new drug, treatment, or cure for a particular condition or disease. These studies usually involve two or more groups of participants, one group receiving an experimental treatment and the other group receiving a placebo or standard treatment.

**Prevention attempts:** Prevention studies are designed to assess the effectiveness of specific interventions in preventing the development of a disease or condition. These studies are often done in people who are at high risk of developing the disease.

**Diagnostic attempt:** A diagnostic study aims to evaluate the accuracy and reliability of a new diagnostic test or procedure for a particular disease or condition.

**Screening studies:** Screening studies are conducted to determine the effectiveness of a particular screening test or procedure in identifying individuals at risk of developing a disease or condition.

**Quality of life studies:** Quality of life studies are used to assess the impact of specific interventions on a patient's quality of life.

**Observation attempt:** Observational studies look at people over a period of time to collect data about a particular disease or condition. These studies did not include interventions or treatments.

### Clinical trial phases

Clinical trials are typically conducted in stages, each designed to collect specific information about the experimental intervention. Below are the four phases of the clinical trial.

**Stage 1:** Phase 1 trials are conducted to evaluate the safety and tolerability of new drugs, treatments, or therapies. These studies usually involve a small number of healthy volunteers who are closely monitored for side effects.

**Stage 2:** Phase 2 trials are designed to evaluate the efficacy and safety of new interventions in large groups of patients with a disease or condition. These studies involve hundreds of participants and aim to determine optimal doses and dosing regimens for experimental treatments.

**Stage 3:** Phase 3 trials are being conducted to confirm the efficacy and safety of experimental interventions in larger populations. These studies typically involve thousands of participants and are often randomized, double-blind, and placebo-controlled.

**Stage 4:** A Phase 4 trial is a post-marketing study conducted after an experimental intervention has been approved for use by regulatory authorities. These studies aim to collect additional information on the safety, efficacy and long-term effects of interventions. Ethical Considerations: Clinical trials involve human subjects and must be conducted in a manner that ensures the safety, welfare and rights of participants. Several ethical principles guide the conduct of clinical trials.

**Correspondence to:** Yoko Urasaki, Department of Pharmacology, College of Pharma Science, Hiroshima University, Tokyo, Japan, E-mail: yoko@ui.jp

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