

<https://www.youtube.com/watch?v=bctaWQTYHJc>

1.3. Types of Clinical Trials - Video

- Prevention trials: These trials test new ways to prevent diseases or conditions.
- Treatment trials: These trials test new treatments for diseases or conditions that already exist.
- Diagnostic trials: These trials test new ways to diagnose diseases or conditions.
- Supportive care trials: These trials test new ways to improve the quality of life for people with chronic illnesses.

1.4. The different phases of clinical trials

- 1.4.1. **Discovery and Development:** This initial phase involves identifying potential drug candidates, often through high-throughput screening of large libraries of compounds. Scientists test these potential drugs in vitro (in test tubes or cell cultures) and in vivo (in animal models) to evaluate their ability to interact with the target molecule and produce the desired therapeutic effect.
- 1.4.2. **Preclinical Research:** Once promising drug candidates are identified, they undergo extensive preclinical testing to assess their safety, efficacy, and pharmacokinetics (how the drug is absorbed, distributed, metabolized, and eliminated from the body) in animal models. This phase aims to rule out major safety concerns and provide preliminary evidence of efficacy before proceeding to human testing.

Types of Preclinical Research:

1. In Vitro Studies: Cell cultures and isolated tissues are used to study the effects of potential drugs on specific molecular and cellular processes. These studies

provide initial insights into the drug's mechanism of action, its potential therapeutic effects, and its toxicity at the cellular level.

2. **In Vivo Studies:** Animal models, such as mice, rats, rabbits, and monkeys, are used to assess the drug's safety, efficacy, and pharmacokinetic properties in a living organism. These studies provide more comprehensive information about the drug's effects on the body, including its absorption, distribution, metabolism, and excretion.

Key Objectives of Preclinical Research:

1. **Safety Assessment:** Preclinical research aims to identify potential safety concerns, such as toxicity, adverse reactions, and interactions with other medications. This information is crucial for determining the appropriate dosage and route of administration for the drug in human trials.
2. **Efficacy Assessment:** Preclinical studies evaluate whether the drug candidate has the desired therapeutic effect in animal models of the target disease or condition. This information provides preliminary evidence of the drug's potential effectiveness in humans.
3. **Pharmacokinetic Assessment:** Preclinical studies assess how the drug is absorbed, distributed, metabolized, and excreted by the body. This information is crucial for optimizing the drug's formulation, dosage, and administration schedule to ensure optimal efficacy and safety.
4. **Target Validation:** Preclinical studies can help validate potential drug targets by demonstrating that interfering with the target's activity leads to the desired therapeutic effect. This validation process helps refine the drug development process and increase the likelihood of success in clinical trials.

Significance of Preclinical Research:

1. **Reduces Risk of Human Trials:** Preclinical research helps identify potential safety concerns and lack of efficacy early in the drug development process, reducing the risk of exposing human participants to harmful or ineffective drugs.
2. **Informs Clinical Trial Design:** Preclinical data provides valuable information for designing clinical trials, including selecting appropriate dosage ranges, identifying potential side effects, and determining the most relevant patient populations to study.
3. **Optimizes Drug Development:** Preclinical research helps optimize the drug development process by identifying promising drug candidates early on, reducing the time and resources required to bring effective treatments to patients.

1.4.3. Clinical Development

- Phase 1: Tests the safety of the new treatment in a small group of participants.
- Phase 2: Expands the study to a larger group with the target condition, evaluating both safety and effectiveness.
- Phase 3: Dives deeper, involving a vast number of participants for comprehensive assessment of safety and efficacy.
- Phase 4: Monitors long-term safety and effectiveness for treatments already approved.

1.4.4. The Clinical Trial Process

1. **Planning:** Defining the research question and designing the trial.
2. **Recruitment:** Identifying and enrolling eligible participants.
3. **Treatment:** Administering interventions and monitoring participants.
4. **Data Collection:** Gathering and analyzing data on safety and efficacy.
5. **Results:** Reporting findings and drawing conclusions.