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OVERVIEW OF CLINICAL TRAILS FOR NEW DRUG SAFTY AND EFFICACY

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ABSTRACT

Clinical trials is a testing research of a new drug safety and efficacy. Pre-clinical studies starts before clinical trials. In pre-clinical trial may look at whether a drug is safe or the side effects it causes; later trials aim to test whether a new treatment is better than existing treatment.

Clinical trials study on different phases that are phase 0, 1,2,3,4. Main purpose of phase 0 to help speed up and streamline the drug approved the process. In phase 1 trials to find out about closes and side effects. A phase 2 clinical trial is to evaluate the effectiveness and safety of a new drug or drug combination for a particular indication. Then in phase 3 study that tests the safety and how well a new treatment works compared with a standard treatment. The main objective of phase 4 trials is to check the drug's performance in real life scenarios. The Phase 4 studies include all studies performed after drug approved and related to the approved indication.

INTRODUCTION

Clinical research is a branch of medical science that involves studies and trials designed to evaluate new treatments, drugs, medical devices, or diagnostic tests. It aims to gather scientific evidence about the effectiveness and safety of interventions to improve patient care, guide medical practice, and inform public health decisions.

Clinical research typically involves several phases and types of studies, including:

- **Clinical Trials**: These are controlled studies that test new drugs, treatments, or interventions. Clinical trials often follow a specific structure, such as randomized controlled trials (RCTs), to ensure reliable results.
- **Observational Studies**: In these studies, researchers observe participants in their natural settings without intervening or changing their behavior. Examples include cohort studies or case-control studies.
- **Epidemiological Studies**: These studies focus on understanding the distribution and determinants of diseases in populations. They help identify risk factors and preventive measures.

Overall, clinical research is essential for developing evidence-based treatments and therapies, and it plays a critical role in advancing public health and medical practices.

Whenever we search out a new medicine then there is need of to check out that tests how well new medicines technique work in a human being. A clinical trial is a research study that test a new medical treatment or a new way of using an existing treatment 'to see if it we'll be a better way to prevent and screen for diagnose or treat disease [1]. Developers of a new drug, biological and medical devices must ensure product safety, demonstrate medical safety, and demonstrate medical benefits in human and mass produce the product [2].

For any new drug to enter in clinical trial, it must pass preclinical studies Pre-clinical studies including in vitro i.e. test tube or laboratory that is outside the body. Studies and trials on animal population .wide range of dosage of the study drug is given to animal subject or to an in vitro substrate in order to obtain preliminary efficacy, toxicity and pharmacokinetic information [1] One challenges to the validity of such trial is the tendency for assessment of outcomes to systemically deviate from truth because of predisposition in observers such as from hope or expectations [3].

Today, there are two internationally recognized human research guidelines that form the basis for the conduct of ethical clinical trial. We have chosen to use the term ethical codes rather than ethical guidelines. A code of practice defines professional rules according to which people in a particular profession are expected behave .other human research guidelines /codes of practice have emerged over the past century ,such as Nuremberg trial at the end of second world war[4]

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HISTORY OF CLINICAL TRIALS

The evolution of clinical research traverse a long and fascinating journey the the recorded history of clinical trials goes back to the biblical description in 500 B.C. [6]562 B.C. 1537: pre-James Lind era :

The world's first clinical trials is recorded in the 'book of Daniel ' in the Bible [7].Avicenna (1025 AD) in his encyclopedic 'canon of medicine ' describes some interesting rules for the testing of drug [8]. He suggested that in the clinical trial a remedy should be used in it's natural state in disease without complication .the first clinical trial of a novel therapy was conducted accidently by the famous surgeon ambrosia pare in 1537[7,9].The term clinical trial simulation may have been first used to describe a game entitled "instant experience."[10].

800: Arrival of placebo:

It took another century before the emergence of another important mile stone in the history of modern clinical trial; the placebo. The word first appeared in medical literature in the early 1800 [7].1943: The first double blind controlled trial patulin for common cold:

The medical analysis council (MRC) Britain dole out an attempt 1943. To analyze patulin treatment for (an extract of genus Penicillium patulinum) the respiratory disorder. This was the primary run comparative trial with synchronal management within the general population in recent time [11].

John wood wall, an English military medico of country Malay Archipelago company, had suggested the consumption of citrus, (it has AN antiscorbutic effect) from the seventeenth century, but their use didn't become widespread [12].Main text :

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Phases of Clinical Trials

Clinical trials usually progress through four phases:

Phase I: Tests safety, dosage, and side effects on a small group of healthy participants. of a clinical trial is the first stage in testing a new drug, treatment, or intervention in humans. It is primarily focused on assessing the **safety**, **dosage**, and **side effects** of the new drug or treatment. The main goal is to determine whether the intervention is safe enough to move on to further testing in larger groups of people.

- **Participant Population**:
  - Phase 1 trials typically involve a small group of healthy volunteers (20 to 100 people). In some cases, if the drug is for a specific disease (e.g., cancer), patients with the disease may be involved.
  - Healthy volunteers are usually preferred because it allows researchers to assess how the body reacts to the drug without the influence of disease-related factors.

- **Safety and Dosage**:
  - The primary goal is to evaluate the **safety** of the drug or intervention. Researchers test for any **adverse effects** and determine the highest dose that can be safely administered.
  - This phase also helps establish the **optimal dosage** (i.e., the dose that provides the best balance of efficacy and minimal side effects).
- Focus on Pharmacokinetics and Pharmacodynamics:
  - Pharmacokinetics: How the body absorbs, distributes, metabolizes, and excretes the drug (ADME).
  - Pharmacodynamics: The effects of the drug on the body, including its mechanism of action and any physiological responses.
- Monitoring and Data Collection:
  - Participants are closely monitored for any adverse events (side effects) and any changes in vital signs, lab tests, or physical assessments.
  - This data is crucial for determining whether the drug should proceed to Phase 2, where larger trials can begin to assess efficacy.

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Phase 2

- **Clinical Trial** is the second stage of clinical testing in the development of a new drug or treatment. It typically follows a successful Phase 1 trial, which focuses on assessing the safety, tolerability, and pharmacokinetics of a new drug in a small group of healthy volunteers or patients.
  - Efficacy Testing: The main goal of Phase 2 is to determine whether the drug or treatment is effective in treating the condition it is intended for. This is usually done by testing the drug in a larger group of patients who have the condition the drug is meant to treat.
  - Safety and Side Effects: Phase 2 also continues to monitor the drug's safety profile, including potential side effects and adverse reactions, but in a larger sample of people. This phase helps identify any common or severe side effects that may not have appeared in Phase 1.
  - Optimal Dosage: Researchers use Phase 2 trials to determine the optimal dose of the drug—what is most effective while being the least harmful. This often involves testing several different dosages to compare their effects.

Characteristics of Phase 2 Trials

- **Participants**: Usually between 100 and 300 patients with the disease or condition under study.
- **Duration**: Can last several months to 2 years, depending on the disease and the nature of the drug.
- **Study Design**: May be randomized, controlled, and often blind (either single or double-blind) to reduce bias. Some Phase 2 trials also include placebo groups.
- **Endpoints**: Primary endpoints often involve measures of efficacy (e.g., tumor shrinkage, symptom reduction), while secondary endpoints may include safety, quality of life, or biomarkers.



Phase 3

- A **Phase 3 clinical trial** is a critical stage in the clinical development of a new drug or treatment, following successful Phase 1 and Phase 2 trials. Phase 3 trials are typically the last step before a drug or treatment is submitted for regulatory approval by agencies like the U.S. Food and Drug Administration (FDA) or the European Medicines Agency (EMA)
  - **Confirm Efficacy**: Phase 3 trials are designed to provide definitive evidence that the new treatment is effective in treating the targeted condition, and that its benefits outweigh any risks. The trial often compares the new drug to a placebo or an existing standard-of-care treatment.
  - **Monitor Long-term Safety**: In addition to assessing efficacy, Phase 3 trials are also focused on gathering more comprehensive data on the drug's safety profile, including rare or long-term side effects that might not have appeared in earlier phases.
  - **Establish Dosing and Administration Protocols**: While Phase 2 trials may have identified the optimal dose, Phase 3 trials aim to confirm the most effective and safest dosing regimen over an extended period, sometimes looking at different populations or patient subgroups (e.g., elderly, children, or those with co-morbidities).

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 Support Regulatory Submission: The data gathered during Phase 3 trials are the primary evidence submitted to regulatory authorities to seek approval for the new treatment. A successful Phase 3 trial is often a prerequisite for marketing approval.

➢ **Characteristics of Phase 3 Trials**

Participants: Phase 3 trials usually involve a much larger sample size than earlier phases, often ranging from several hundred to several thousand patients. These patients typically have the disease or condition the drug is intended to treat, and the trial is conducted across multiple sites, sometimes internationally.

Study Design: Phase 3 trials are often randomized, double-blind, and controlled, meaning neither the participants nor the researchers know who is receiving the experimental treatment and who is receiving the control (e.g., placebo or standard treatment). This helps reduce bias and ensures more reliable results.

Duration: Phase 3 trials can last from several months to a few years, depending on the nature of the disease, the treatment, and the specific endpoints being studied.

Endpoints: The primary endpoints focus on clinical outcomes that directly relate to patient health, such as survival rates, disease progression, symptom relief, or quality of life. Secondary endpoints might include biomarkers, patient-reported outcomes, or other factors relevant to treatment impact



Phase 4

Clinical Trial, also known as a **post-marketing study**, is conducted **after a drug or medical device has been approved** by regulatory agencies (like the FDA or EMA) and is available on the market. The primary goal of Phase 4 trials is to gather more data on the drug's long-term effectiveness, safety, and overall risk-benefit profile in a broader population, once it is being used outside of the controlled conditions of the earlier trial phases.

Here's a breakdown of the key objectives and characteristics of Phase 4 trials

1. Safety Monitoring

- **Long-term safety:** Phase 4 trials can detect rare side effects or long-term risks that were not apparent in earlier phases due to the limited sample size and duration of Phase 1-3 studies.
- **Real-world data:** Since the drug is being used in the general population, Phase 4 studies help to identify potential interactions with other medications, contraindications, or adverse reactions that might not have been previously observed.

2. Efficacy in a Broader Population

- **Diverse patient groups:** Drugs may be tested in different age groups, ethnic populations, or in patients with comorbidities who were excluded from earlier trials. This helps determine how effective the drug is across diverse groups.
- **Expanded indications:** Phase 4 trials may explore new uses for the drug or confirm its effectiveness for conditions other than the original approved indication (off-label uses).

3. Comparative Effectiveness

- **Head-to-head studies:** Some Phase 4 trials compare the new drug with other available treatments to see which is more effective or safer in the real world.

4. Cost-effectiveness Analysis

- Assess whether the drug or treatment is cost-effective compared to alternatives, considering the broader economic impact of widespread use



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Objective and scope of ICH good clinical trials

- Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible. The objective of this ICH GCP Guideline is to provide a unified standard for the European Union (EU), Japan and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.
- The guideline was developed with consideration of the current good clinical practices of the European Union, Japan, and the United States, as well as those of Australia, Canada, the Nordic countries and the World Health Organization (WHO).
- This guideline should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities. The principles established in this guideline may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects.

➢ **The objective** of **ICH Good Clinical Practice**:

The objective of **ICH Good Clinical Practice (GCP)** is to ensure the safety, well-being, and rights of trial participants, as well as the integrity and reliability of clinical trial data. GCP provides a set of internationally recognized ethical and scientific quality standards for designing, conducting, recording, and reporting clinical trials. Its primary goals include:

- **Protection of Participants**: Ensuring that the rights, safety, and confidentiality of clinical trial participants are upheld at all times.
- **Scientific Integrity**: Ensuring that clinical trials are scientifically sound, well-designed, and carried out to produce valid and reliable results.
- **Compliance with Ethical Principles**: Ensuring that clinical trials are conducted in accordance with ethical principles, particularly the Declaration of Helsinki, and regulatory requirements.
- **Data Accuracy and Reliability**: Ensuring that the data generated from clinical trials is accurate, complete, and verifiable, contributing to credible conclusions about the efficacy and safety of a treatment or intervention.

the **scope** of ICH International Council for Harmonisation:

➢ **The** scope of ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) covers a broad range of areas related to the development, registration, and post-market surveillance of pharmaceuticals. ICH's aim is to harmonize the technical requirements for drug development and approval across major pharmaceutical markets, including the United States, Europe, and Japan, while promoting global public health and safety.

The Specific Scope of ICH includes

1. Clinical Trials and Good Clinical Practice (GCP):

- **ICH E6**: Guidelines on Good Clinical Practice (GCP) provide a unified standard for designing, conducting, and reporting clinical trials across international borders. This ensures that clinical trials are scientifically sound and that the safety, well-being, and rights of participants are prioritized.
- Covers ethical considerations, safety monitoring, data integrity, and regulatory compliance in clinical research.

2. Pharmaceutical Development and Quality:

- **ICH Q series** (e.g., ICH Q8, Q9, Q10): These guidelines relate to the development and manufacturing of pharmaceutical products, focusing on aspects like quality by design (QbD), quality risk management, and lifecycle management of medicines.
- Covers topics like stability testing, quality assurance, and the overall lifecycle of a pharmaceutical product from development to post-marketing.

3. Regulatory Harmonization:

- ICH aims to harmonize technical and regulatory standards across the key pharmaceutical regions (U.S., Europe, Japan, and more recently, other regions such as Canada, Switzerland, and the WHO) to streamline the drug approval process and reduce duplication.
- The goal is to create a more efficient process for drug development and approval, while maintaining high standards for safety and efficacy.

4. Pharmacovigilance and Safety Monitoring:

- **ICH E2E**: Guidelines on pharmacovigilance and the monitoring of post-market drug safety.
- These standards help in monitoring adverse drug reactions and other safety concerns during clinical trials and after a product has reached the market, ensuring patient safety and regulatory compliance.

5. Biotechnology and Biopharmaceuticals:

- **ICH S6**: Guidelines for the preclinical safety evaluation of biotechnology-derived pharmaceuticals.
- This scope includes specific guidelines for the development of biologics (e.g., monoclonal antibodies, gene therapies, vaccines) and their approval processes.

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6. Statistical Principles and Data Analysis:

- ICH guidelines also cover the statistical methods required in clinical trials, such as proper randomization, blinding, sample size calculations, and handling of missing data, to ensure the accuracy and validity of trial outcomes.

7. Pharmaceutical Registration

Q	S	E	M
"Quality" Topics, i.e., those relating to chemical and pharmaceutical Quality Assurance (Stability Testing, Impurity Testing, etc.)	"Safety" Topics, i.e., those relating to in vitro and in vivo pre-clinical studies (Carcinogenicity Testing, Genotoxicity Testing, etc.)	"Efficacy" Topics, i.e., those relating to clinical studies in human subject (Dose Response Studies, Good Clinical Practices, etc.)	"Multidisciplinary" Topics, i.e., cross-cutting Topics which do not fit uniquely into one of the above categories (MedDRA, ESTRI, M3, CTD, M5)

- ICH supports the development of technical documentation and standardized formats for regulatory submissions, such as the **Common Technical Document (CTD)**, which is used for drug registration worldwide.
- The CTD structure is designed to be used for the submission of marketing authorization applications to regulatory authorities across various jurisdictions.

8. Ethical and Social Considerations:

- **ICH E7**: Guidelines on the conduct of clinical trials in special populations (e.g., pediatrics, geriatrics, and patients with chronic diseases).
- Ensures that clinical trials address diverse patient needs and uphold ethical standards in all patient groups.
-

Overview of ICH topic selection of drug in clinical trial

- ❖ The **selection of a drug** for a clinical trial is a crucial step in the development of a new therapeutic agent, as it directly impacts the design, conduct, and outcomes of the trial. This process involves a comprehensive evaluation of several factors to ensure that the drug is suitable for testing in humans and that it has the potential to provide meaningful benefits to patients. Below are key considerations and steps involved in the **selection of a drug for a clinical trial**:

1. Preclinical Data and Evidence

Before a drug is tested in humans, a significant amount of preclinical data must be gathered. This data helps establish a foundation for clinical testing.

Pharmacology: The drug's mechanism of action, target(s), and biological effects should be well understood.

Toxicology: Safety profiles, including any potential toxicity, side effects, and doses that are likely to be safe for human testing, must be established through animal models and laboratory studies.

Pharmacokinetics (PK): Studies to determine how the drug is absorbed, distributed, metabolized, and excreted (ADME), as well as its half-life and other relevant factors.

Pharmacodynamics (PD): Understanding the drug's effect on the body, including the dose-response relationship, is essential.

2. Regulatory Approval (IND/CTA Submission)

Before initiating clinical trials, the sponsor (usually the drug developer) must submit an application to regulatory authorities:

- Investigational New Drug (IND) Application: In the U.S., the sponsor submits an IND to the FDA to gain approval to begin clinical testing in humans. In other regions, this process is referred to as a Clinical Trial Application (CTA) submitted to local regulatory agencies (e.g., EMA in Europe, PMDA in Japan).
- The application includes the results of preclinical studies, proposed clinical trial protocols, and other key data such as the drug's manufacturing information and proposed dose.

3. Efficacy Potential

The drug must show promise in terms of **efficacy** or therapeutic benefit based on preclinical data, including:

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Target Disease**: The drug should address an unmet medical need or show significant potential to improve the management of an existing disease.**
Mechanism of Action (MoA)**: The drug should have a well-understood MoA that is expected to have a clinically meaningful effect on the disease process. This could include targeting specific receptors, enzymes, proteins, or pathways involved in the disease.**
Preclinical Efficacy**: Positive results from preclinical models (such as animal models) or in vitro (cell culture) testing, showing that the drug has the potential to exert a beneficial effect in the target disease.**

4. Safety Profile

The safety of the drug is paramount when selecting a candidate for clinical trials. A thorough **risk assessment** must be performed, including:

- **Toxicity**: Preclinical studies should identify any potential for acute or chronic toxicity, organ damage, or other harmful effects at various dose levels.
- **Side Effects**: Preclinical models should also look for signs of side effects, such as cardiovascular, neurotoxic, or reproductive toxicity, that could impact clinical trial safety.
- **Dose Range**: The highest dose that is well tolerated in animals (without causing toxicity) can help define the starting dose in human clinical trials.

5. Formulation and Route of Administration

The drug must be formulated in a manner suitable for clinical testing, and the route of administration must be determined.

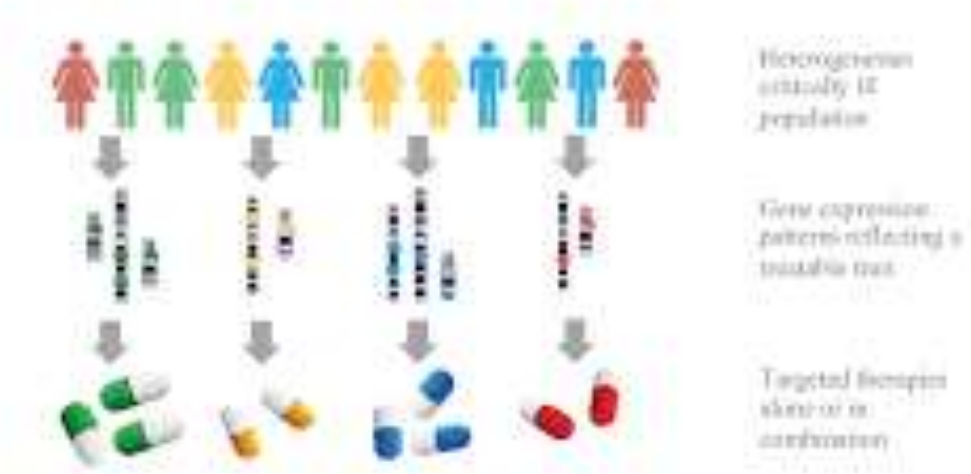
- **Formulation**: This could be in the form of oral tablets, injectable solutions, topical creams, or other forms. The formulation must be stable, effective, and suitable for the intended patient population.
- **Route of Administration**: The route (oral, intravenous, subcutaneous, etc.) needs to be feasible for both the clinical trial and for potential future clinical use. This choice can affect the drug's bioavailability and ease of use.

6. Regulatory and Ethical Considerations

- **Ethical Justification**: The drug must have a strong ethical rationale for clinical testing. For instance, the potential benefits to patients should outweigh the risks.
- **Ethics Committee/Institutional Review Board (IRB) Approval**: In addition to regulatory approval, the drug and the trial protocol must undergo ethical review to ensure that the trial will be conducted with respect for participants' rights and safety.

7. Patient Population

The selection of the appropriate patient population for the clinical trial is critical for the trial's success:



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Target Population: The drug must be tested in the population for which it is intended (e.g., cancer patients, patients with chronic diseases). Inclusion and exclusion criteria are defined to select individuals who are most likely to benefit from the drug and who meet safety requirements.
Pre-existing Conditions: Consideration should be given to any comorbidities, which might affect the drug's safety or efficacy.
8. Clinical Trial Design and Feasibility
Study Design: The choice of trial design (e.g., randomized controlled trial, open-label study) should be based on the drug's characteristics, including its expected effect, safety profile, and the target population.
Endpoints: Primary and secondary endpoints must be defined clearly to measure the drug's effectiveness (e.g., symptom reduction, survival rates, biomarkers).
Feasibility: The ability to recruit patients, the trial's geographic locations, timelines, and costs should all be considered.
9. Market Considerations
While not directly related to clinical trial selection, practical considerations for the commercial potential of the drug may influence its selection for trial:
Competitive Landscape: Whether the drug offers a new or improved approach to treating a disease that has existing therapies.
Market Need: The potential demand for the drug and the market gap it aims to fill.
Regulatory Pathway: The possibility of obtaining fast-track approval, orphan drug status, or breakthrough therapy designation, which could expedite the clinical trial process.

Selection of Drug
A small group of healthy volunteers (often 20–100) participate in the initial round of human testing. This stage is mostly concerned with assessing pharmacokinetics, safety, and tolerance. The maximum tolerated dose (MTD) of the medication is determined by administering it at ever greater doses. Phase 2: A bigger group of people with the ailment the medication is intended to treat—typically several hundred—participate in this phase. Its objective is to evaluate the medication's safety profile and efficacy. This stage is primarily concerned with early signs of treatment efficacy.

Phase 2: This phase involves a larger group of participants (usually several hundred) who have the condition the drug is designed to treat. It aims to assess the drug's efficacy and further evaluate its safety profile. This phase is more focused on preliminary indications of therapeutic effectiveness.

Phase 3: A much larger group of participants (hundreds to thousands) are involved in this phase, which aims to confirm the drug's effectiveness, monitor side effects, and compare it to commonly used treatments. Phase 3 trials are usually multicenter, randomized, and controlled studies. Data from this phase is often submitted for regulatory approval.

Phase 4: These are post-marketing studies conducted after a drug has been approved and is on the market. They help monitor long-term safety, effectiveness, and rare adverse effects that might not have been detected in earlier trials.
2. Regulatory Oversight and Ethical Considerations
Drug use in clinical trials is tightly regulated by government agencies such as:
U.S. FDA (Food and Drug Administration)
EMA (European Medicines Agency)
Other national regulatory bodies
Ethical principles include:
Informed consent: Participants must understand the potential risks and benefits of participating and voluntarily agree to it.
Safety monitoring: Ongoing safety assessments are conducted, including monitoring adverse events (side effects) through mechanisms like Data Safety Monitoring Boards (DSMBs).
Randomization and blinding: Randomized controlled trials (RCTs) are considered the gold standard, and blinding (where the participants or researchers do not know which treatment is being given) helps reduce bias.
3. Drug Administration in Trials
The actual use of the drug in clinical trials can take different forms, including:
Oral administration (e.g., pills, tablets)
Injectables (e.g., intravenous or subcutaneous)
Topical (e.g., creams or ointments)
Inhalation (e.g., nebulizers, inhalers)
Implants (e.g., slow-release capsules or devices placed under the skin)
The method of administration depends on the drug's formulation and the intended use.

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4. Placebo and Control Groups
Many clinical trials use a placebo (an inactive substance) or an active control (another treatment) to compare the effects of the new drug against a baseline. This helps to determine whether any observed effects are truly due to the drug itself and not other factors (e.g., psychological effects or natural disease progression).
5. Pharmacovigilance and Adverse Events
Adverse events (AEs) and serious adverse events (SAEs) are closely monitored during clinical trials. These could range from mild side effects (e.g., headache, nausea) to more severe reactions (e.g., organ toxicity, life-threatening conditions). If serious side effects occur, the trial may be paused or terminated.
Pharmacovigilance systems are put in place to track and analyze adverse events, even after a drug is approved for use, to ensure ongoing safety.
6. Participant Eligibility and Drug Use Criteria
Inclusion criteria: Specifies the characteristics required for participants to be eligible, such as age, gender, and diagnosis of the condition.
Exclusion criteria: Details factors that would disqualify individuals from participating, like pre-existing conditions or concurrent medication use that could interfere with the study results.
The drug is often tested in different population subgroups to understand its effects across varying age groups, genders, and ethnicities.
7. Risks and Benefits of Drug Use in Trials
Participants face certain risks in clinical trials, especially in earlier phases:
Unforeseen side effects or adverse reactions.
Ineffective treatment or treatment that is no better than existing options.
Possibly receiving a placebo (in randomized controlled trials), meaning they might not receive any active treatment.
However, the potential benefits of participating in clinical trials include:
Access to new treatments that may not yet be available to the general public.
Close monitoring by medical professionals during the trial.
Contributing to medical research that could benefit others with the same condition.
8. Monitoring and Data Collection
Data is systematically collected on how participants respond to the drug. This includes:
Efficacy outcomes (e.g., improvement in symptoms, disease markers)
Safety outcomes (e.g., adverse events)
Pharmacokinetic and pharmacodynamic data (e.g., drug absorption, metabolism)
Data are analyzed to determine if the drug works as intended and whether it is safe for broader use.

CONCLUSION

Drug use in clinical trials is a critical part of the medical research process, enabling new treatments to be tested in human populations under controlled conditions. Rigorous oversight ensures participant safety, and the results help shape future therapeutic strategies. The process is designed to balance risk with potential benefits, contributing to the overall advancement of medical knowledge and treatment options.

In the context of clinical trials, drug use during clinical phases refers to the administration and monitoring of an investigational drug (or therapeutic intervention) in human participants across different phases of the clinical trial process. Each phase of clinical trials serves a specific purpose in evaluating the safety, efficacy, pharmacokinetics, and overall suitability of a drug for public use. Let's break down how drug use is managed and evaluated at each clinical phase.

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