IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.67
Volume 5, Issue 2, March 2025

A Review on Clinical Trial

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Abstract: *Clinical trials are essential research studies conducted on human volunteers to evaluate the safety and effectiveness of new treatments. These trials are the fastest and most reliable method for discovering effective medical solutions and improving human health. The process involves multiple phases, beginning with Phase I, where the pharmacokinetics, safety, and general effects of a drug are studied in healthy volunteers. If successful, Phase II testing follows, focusing on the drug's safety and efficacy in selected patients. In Phase III, the drug undergoes testing on a larger group of patients to further assess its effects. Upon successful completion of Phase III, the drug is approved for market release. Phase IV studies continue to monitor the drug's long-term safety and effectiveness, with input from healthcare providers regarding adverse drug reactions (ADR). Clinical trials, alongside observational studies, are crucial for advancing medical knowledge and ensuring that treatments are both safe and effective for broader populations.*

Keywords: Clinical trail, Phases, Safety, Efficiency, Clinical studies, ICH Guideline

I. INTRODUCTION

A clinical trial is a research study conducted on human volunteers to answer specific health questions. Well-conducted clinical trials are the fastest and safest way to find effective treatments and improve human health. A clinical trial determines whether a clinical trial or new treatment is safe and effective in a controlled setting. Observational studies investigate the health of various groups of people or populations in natural settings. Clinical trials are an important and specific form of biological experimentation designed to evaluate the effectiveness of a treatment. In the first phase, hospital doctors studied the pharmacokinetics, safety and general effects of the drug on human volunteers. If the drug passes the test, it will move on to Phase II testing, where clinical researchers will study the pharmacokinetics, safety and efficacy of the drug in selected patients, and now it will be tested primarily on hundreds of selected patients for safety and efficacy. Phase III clinical trials, where researchers will study its effects. If the bill passes, the drug will now be approved and will be released to the market. Doctors in many hospitals and clinics will give their opinions on the use of ADR and Phase IV drugs, even after they are released to the market.[1]

II. HISTORY

Perhaps the first ever clinical trial was **James Lind's** demonstration in 1753 that citrus fruits cured scurvy. He compared the effects of various different acidic substances ranging from vinegar to cider, on groups of sailors, and found that the group who were given oranges and lemons had largely recovered from scurvy after 6 days.

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The Principal of ICH Guideline

1 Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and theapplicable regulatory requirement(s).

2 Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should beinitiated and continued only if the anticipated benefits justify the risks.

3 The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.

4 The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.5 Clinical trials should be scientifically sound, and described in a clear, detailed protocol.

6 A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favourable opinion.

7 The medical care given to, and medical decisions made on behalf of, subjects shouldalways be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.

8 Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).

9 Freely given informed consent should be obtained from every subject prior to clinical trial participation.

10 All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.[3]

PRECLINICAL TRAIL

The goal of preclinical studies is to provide information about the safety and efficacy of a drug candidate before it is tested in humans. They can also provide evidence of the biological effects of a substance and often include both in vitro and in vivo studies. Clinical trials must follow established guidelines established by established researchers to ensure positive results and must comply with regulations from agencies such as the FDA before being submitted for approval under an IND. A good understanding of drug interactions and toxicity levels is essential to determining whether clinical trials are appropriate and safe, and will be determined if pharmacokinetic, pharmacodynamic, and toxicology studies are available.[4]

CLINICAL TRAIL

Phase 0

Phase 0 is an option for first-in-human clinical trials conducted under the U.S. Food and Drug Administration's (FDA) 2006 IND phase guidance. Phase 0 is designed to determine whether the drug or drug candidate is effective in human studies. Performance in the trial is based on the preclinical expectation that the drug or drug candidate will be effective. Special features of a Phase 0 trial include administering a single therapeutic dose of the investigational drug to a small number of subjects (10 to 15) to collect preliminary data on pharmacokinetics (how the body processes drugs) and pharmacodynamics (how the body processes drugs).

Phase 2

A Phase I trial is the first phase of testing on human subjects. A group of volunteers (20-80) is usually selected. This phase includes studies designed to evaluate drug safety (pharmacovigilance), tolerability, pharmacokinetics, and pharmacodynamics. These tests are usually performed in clinical laboratories where full-time staff can monitor the subjects. People who receive the drug are usually monitored for several lifetimes of the drug. Phase I trials usually also include a dose-escalation study (also called a dose-escalation study) to find the appropriate dose for therapeutic use. The doses tested are usually a small fraction of those that cause harm in animal studies. Phase I trials usually involve healthy volunteers. However, in some cases, real patients are used, such as those with a disease for which no other treatment options are available. This exception is most common in oncology (cancer) and HIV drug trials. Volunteers will be paid a non-refundable fee for their time at the Volunteer Centre. Earnings range from a small amount for a short period to a large amount such as £4,000, depending on the length of the partnership. There are different types of Phase

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I trials: Time 1. If no adverse events were observed and the pharmacokinetic data were estimated to be within the safe range, the dose was increased and then more food was given to a new group of people. This process continues until a pharmacokinetically safe level is reached or until unacceptable side effects occur, at which point the drug is considered to be at its maximum dose (MTD). > 2. MAD A large number of dose-ranging studies are conducted to better understand the pharmacokinetics and pharmacodynamics of various doses

Phase III

Phase **III** trials are randomized, controlled, multi-center studies conducted in large numbers of patients (300–3,000 or more, depending on the disease/treatment being studied) to evaluate how well drugs compare to existing drugs and how well they compare to the "gold standard" treatment. Because of their size and length, Phase III trials are the most expensive, time-consuming, and most difficult to design and conduct, especially in chronic care settings. It is common for some Phase III trials to continue while awaiting submissions to the relevant regulatory authorities. Two Phase III studies have been completed to establish the safety and efficacy of the drug and to gain approval from regulatory authorities (FDA (US), TGA (Australia), EMEA (EU), br>, etc.). Full descriptions of human and animal studies, manufacturing processes, formulation details, and shelf life. This data collection also includes "management reports" that are submitted to the relevant regulators in various countries for review. The sale should be accompanied by appropriate instructions and guidance, but if adverse reactions occur at any point, these drugs should be immediately withdrawn from the market. While most companies do not take this approach, it is not uncommon to see many drugs on the market undergo Phase III clinical trials.

Phase IV

Studies are also known as postmarketing surveillance. Phase IV studies involve safety monitoring (pharmacovigilance) and ongoing support after a drug has been introduced to the market. Phase IV studies may be required by regulatory agencies or conducted by a company for promotional purposes (finding new markets for the drug) or for other reasons (for example, the drug has not been tested for interactions with other drugs or in certain populations (for example, pregnant women are rarely included in the study). or long-term side effects seen in phase 4 trials may lead to discontinuation of the drug or some recent withdrawals, including cerivastatin (brand names Baycol and Lipobay), troglitazone (Rezulin), and rofecoxib (Vioxx). 2[5]

Time required

S.no	Phases	Time period {yrs}
1	Drug discovery	2-5
2	Preclinical	1.5-2
3	Clinical	5-7
4	Regulatory	1.5
5	Phase IV	4
	Total	Approx 20 yrs

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[6]

III. TYPES

Types of clinical trials
1) prevention trial
2) Treatment trial.
3) Diagnosist trial.
4) Screening
5) Quality of life trial.

1) Prevention Trial

The prevention trial is a 12 month two-arm randomiz red clinical trial (RCT) in adults 50-80 years old experiencing cognitive decline. our study clinicians will refer patients for enrollment based on three categories
1) A diagnosis of mild AD according to criteria established by the National Institute of Neurological and communicative Disorders and stroke (AD and Related DisorderAssociation [NINCDS-ADRDa).
2) Those with mild cognitive impairement will be diagnosed according to the patersen method.
3) Subjective memory impairment as assessed by Neuropsychological assessements and self-report .The objective is to evaluate the efficacy of a coached, data -driven, multi-modal lifestyle intervention to treat cognitive decline subject will be randomized into one of two.Group 1 (Active control) or Group 2 (Intervention).Group 1 [Data-driven clinical recommendations R] will serve as the active control Groupsand will receive data-driven clinical. group recommendations by a study physician based on study assessments and clinical lab values.Group 2 (Data-driven multi-modal intervention with coaching (MMIC)) will receive the same clinical recommendations & also an intensive multi" -modal intervention with healthcouching support of ressouries . to carry out these recommendations. These include health coaching sessions (with an RDN). dietary counselling sessions (with an RDN) and group cognitive and physical exercise classes with a certified personal trainer & a computer basedNeurocognitive program at home. Both groups will be measured for treatment related.changes in Cognitive & functional abilities. quality of life, biological and with biochemical measures.

2) Treatment Trial

Clinical trials are research studies that test a medical, surgical or behavioral intervention inpeople. These trials are the primary way that research. determine if a new form of treatment or prevention, such as a new drug diet or medical device is safe and effective in people. For example a pacemaker.Researchers in treatment trials in stages. Thesestages are called phases. The early phases aim to find out more about the safety & side effects of a new treatments. Later phases aim to seeif a new treatment works better than the current treatment. OR IF new treatment works better than dummy drug.For trials that compare two or more treatments, you are put into a treatment group at Random. This is randomized trial .They are the best way to get reliable information about how well a new treatment works.

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3) Screening

Screening test people for the early signs of Cancerbefore they have any symptoms. As with prevention trials, screening thinks can be for the general population or they can be for a group of people who have a higher than normal risk of developing a certain Cancer . Researchers may plan screening tricks to see if new tests are reliable enough to detest particular types of cancer. OR they may try to find out if there is an overall benefit & in picking up the cancer early.4)

4) Diagnostic Trial

The diagnostic trial is generally used in two distinct ways in the literature The first it is used for studies covering earlier development phases that merely evaluate the accuracy of diagnostic tests in detecting disease or severity of disease. A research study that evaluates methods of detecting disease Pr known or diagnostic trial A diagnostic test is any approach used to gather. clinical Information for the purpose of making clinical decision . Some examples of diagnostic tests include X-rays, biopsy, pregnancy tests, medical histories and route from physical examinations

5) Quality of life trial

Health related quality of life is increasingly used us an end point in clinical trials. Particularylyin disease with poor prognosis such Las metastatic cancer, quduity of life may be major Concern. However, clinicians or still relictant to accept. quality of life as an end point equivalent to more objective end points. such as size of the tumor as assessed by Imaging ordisease free Survial in patients with Cancer.The past 4 decades have seen the development of a new technology in medicine that is based entirely on data obtained from patients' self-report of their symptoms & Functional status. The assessment in clinical trial have been -particularly useful for elucidating the effects of Various research & their treatments on patient lives and have provided additionalinformation that enhances the that usual clinical end points used for determining the benefits and toxicity of treatment.The development of multidimensional self-report QOL instruments has allowed investigators to measure the adverse impact of disease and the treatment on well-being and functioning and evaluate the efficacy of interventions designed to prevent or treat these adverse effects. Findings from QOL research suggest that routine use of QOL instruments as port of clinical practice has the potential to improve the quality ofcare that patients receive as well as their health status.[7,8]

IV. ROLE OF PHARMACIST IN CLINICAL TRAIL:

Pharmacists play a vital role in clinical trials, ensuring the safe and effective use of investigational products.

Pre-Clinical Trial Phase

1. Protocol development: Pharmacists contribute to the development of clinical trial protocols, ensuring that the investigational product is used safely and effectively.
2. Investigational product management: Pharmacists oversee the procurement, storage, and handling of investigational products.

Clinical Trial Phase

1. Dispensing and administration: Pharmacists dispense and administer investigational products to participants, ensuring compliance with the protocol.
2. Medication management: Pharmacists monitor and manage medication use, identifying potential interactions and adverse effects.
3. Adverse event reporting: Pharmacists report and manage adverse events related to the investigational product.4. Compliance monitoring: Pharmacists ensure compliance with Good Clinical Practice (GCP) guidelines, regulatory requirements, and institutional policies.

Post-Clinical Trial Phase

1. Data analysis and interpretation: Pharmacists1. contribute to the analysis and interpretation of clinical trial data, providing insights on the investigational product's safety and efficacy.
2. Study close-out: Pharmacists ensure that all study-related activities are completed, and the investigational product is properly disposed of.

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Additional Roles

1. Principal investigator: Pharmacists may serve as principal investigators, overseeing the entire clinical trial process.2. Study coordinator: Pharmacists may work as study coordinators, managing the day-to-day activities of the clinical trial.
3. Research pharmacist: Pharmacists may work as research pharmacists, focusing on the development and implementation of clinical trials.

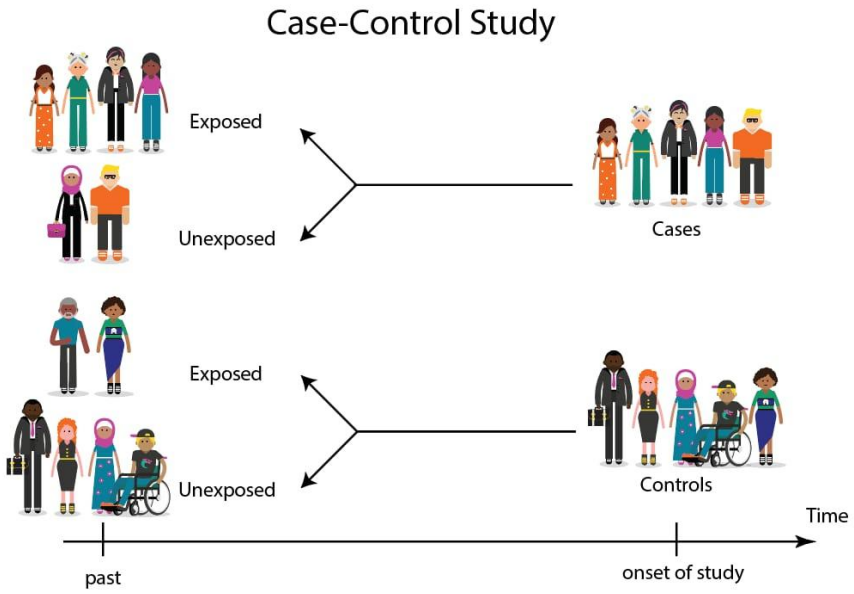
Skills and Qualifications

1. Clinical pharmacy expertise: Pharmacists should have a strong foundation in clinical pharmacy practice.
2. GCP training: Pharmacists should have completed GCP training to ensure compliance with regulatory requirements.
3. Research experience: Pharmacists with research experience are well-suited for clinical trial roles.
4. Communication and collaboration skills: Pharmacists should have strong communication and collaboration skills to work effectively with multidisciplinary team.[9]

V. OBSERVATIONAL STUDY DESIGN

Case-control study

Case-control studies compare groups, such as subjects with a disease or condition under study (cases) to subjects without the disease or condition (controls). Investigators study the medical or lifestyle histories of those in each group to determine factors that may be associated with the disease or condition.If a factor is found more commonly in the cases than in the controls, the investigator may hypothesize that the exposure is linked to the disease. For example, in the investigation of riskfactors for depression in intensive care unit (ICU) patients, the patients with depression were defined as cases; and sex, age, length of ICU stay, and individual medications were considered as risk factors associated with depression.[10]



Cohort study

Cohort studies are a type of longitudinal study, an approach that follows study participants over time. Specifically, cohort studies recruit and follow study participants who share common characteristics. Baseline information on the individual cohort members are gathered first to get detailed picture of the cohort. Then, investigators collect data from different time points in the study. Investigators compare the development of disease between two groups, the exposed and the nonexposed groups, generated from the baseline information. Also, by comparing data from the follow-up points, investigators can evaluate the effects of factors on health. #Cohort studies can be prospective or retrospective.[11]

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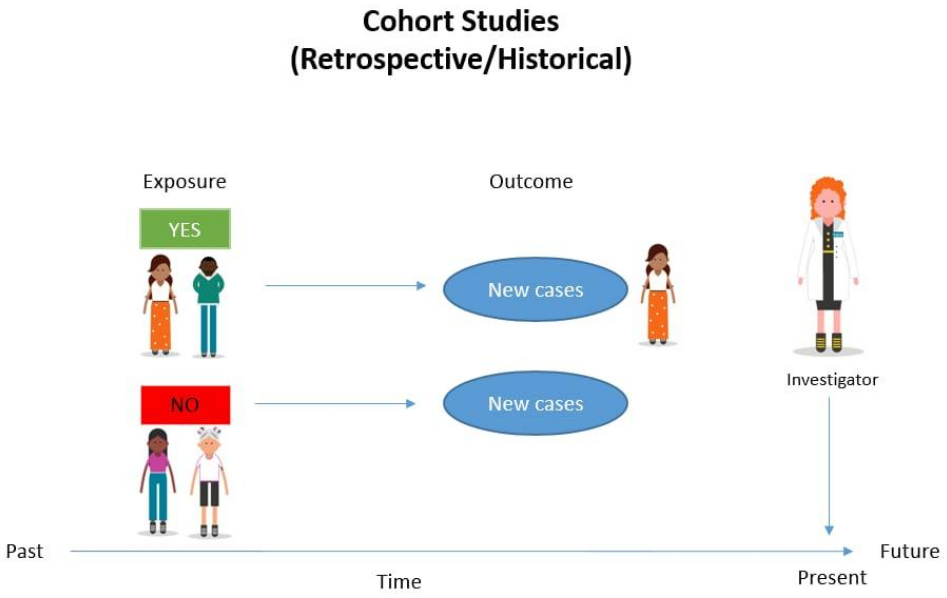
Prospective Cohort Study:
Researchers recruit participants and follow them over time to study how an exposure leads to disease. Example: Tracking syncope patients from an emergency department visit to assess outcomes over 30 days.

Retrospective Cohort Study:
Researchers analyse past records to study exposure-disease relationships. Example: Using administrative data to examine how primary care factors affect emergency department visits over three years.[12][13][14]



A nested case-control study is a study:
design where cases (subjects who develop the disease) and controls are selected from a defined cohort with suspected risk factors. Controls are chosen randomly from those still at risk at the time each case develops the disease, ensuring they are time-matched. Each case can have multiple controls (typically up to five), and individuals can serve as controls multiple times before potentially becoming cases.This design allows for matching on confounders and is efficient for studying rare outcomes. For example, one study used this method to examine the link between opioid prescriptions and opioid-related adverse events (ORAEs) in individuals aged 65 and older, matching controls using incidence density sampling.[15]

Case-Cohort study :
Case cohart study is an alternative to the nested case-control study, differing mainly in how controls are selected. In a case-cohort design, a random subcohort is chosen from the entire cohort at baseline, and all cases (participants who develop the disease of interest) are included. This allows for early baseline data collection and enables studying multiple disease outcomes using the same subcohort, unlike nested case-control studies.[16]

Cross-sectional study
A cross-sectional study is a type of observational study that involves data collected at a defined time; a cross-sectional study analyzes data from a population, or a representative subset, at a specific point in time. These studies are often used to assess the prevalence of acute or chronic conditions but cannot be used to answer questions about the causes of disease or the results of interventions. That is, cross-sectional data cannot be used to infer causality because temporality is not known. Cross-sectional studies may involve special data collection, including questions about the past, but often rely on data originally collected for other purposes.[17][18]

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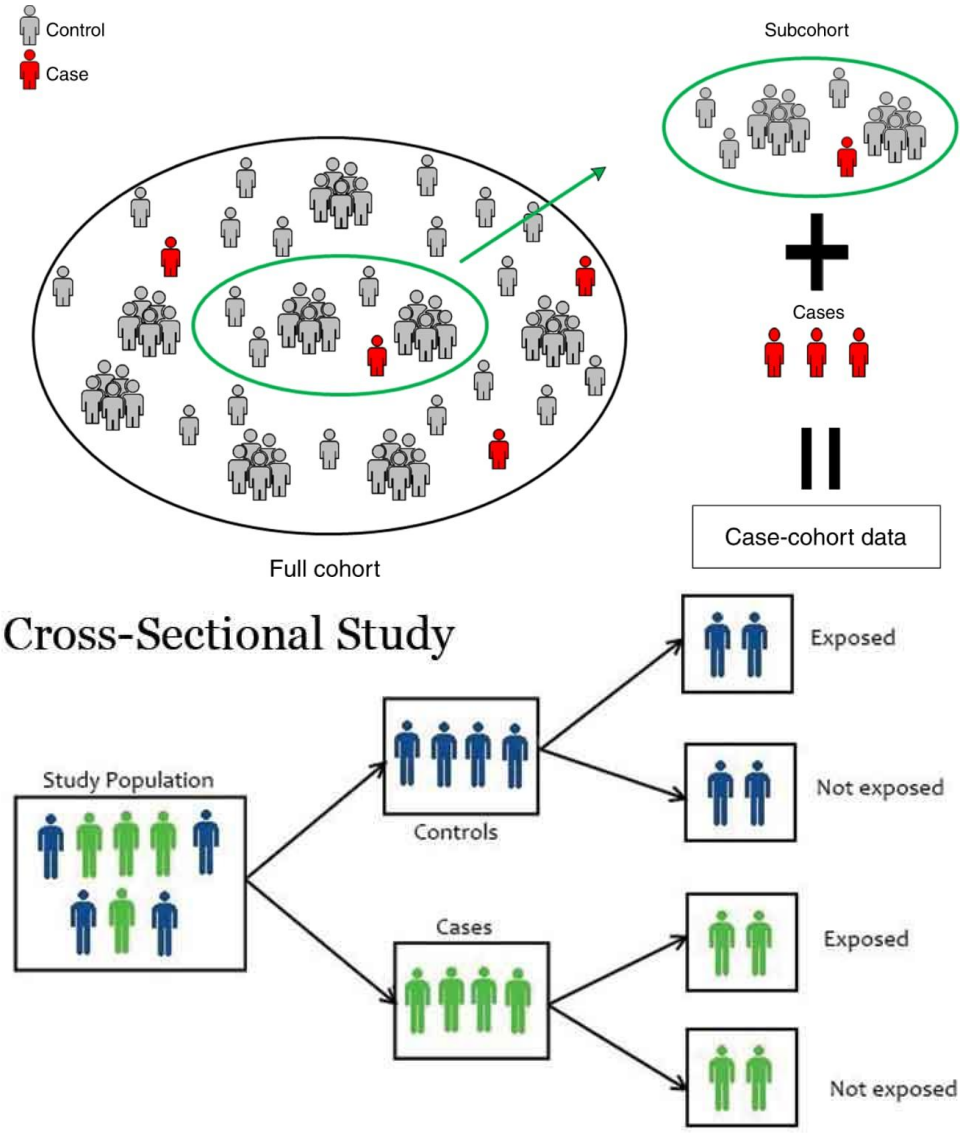

VI. CONCLUSION

Clinical trials are a cornerstone of medical research, providing the necessary evidence to evaluate the safety and effectiveness of new treatments. Through its distinct phases—Phase I, II, III, and IV—clinical trials offer a systematic approach to understanding how a drug works, its potential side effects, and its overall benefit to patients. By first testing on healthy volunteers, then moving on to carefully selected patient populations, and finally undergoing large-scale testing, clinical trials ensure that only the most effective and safe treatments reach the market. Even after a drug's approval, Phase IV trials continue to monitor its long-term safety and efficacy, incorporating real-world data from healthcare providers. Together with observational studies, clinical trials play an essential role in advancing medical knowledge, improving patient care, and ensuring that treatments are both safe and effective for the wider population.

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IJARSCT
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International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
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