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A Comprehensive Review on Clinical Trials

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Abstract: *A clinical trial is an inquiry carried out on human participants in order to investigate specific medical-related questions. The Clinical trials are the most efficient and secure way to improve a patient's health and find a medication that works for them. In a controlled environment, investigational studies determine the safety and effectiveness of new therapeutic modalities or experimental treatments. Health issues in large populations or groups in their natural settings are the focus of observational studies. A major and highly specialised kind of biological experiment used to gauge a treatment's effectiveness is called a clinical trial. Phase I pharmacokinetics, safety, and gross effects are investigated by clinical pharmacologists on human subjects. If the medication passes the test, it advances to phase II trials, where clinical pharmacologists examine the safety, therapeutic efficacy, and pharmacokinetics of the medication on a patient subset. Hundreds of these patients are subsequently examined in phase III trials, primarily for safety and therapeutic efficacy, if the drug is approved. The medication is now authorized and on the market if this is approved. Even after the treatment has been put on the market, doctors from various clinics and hospitals still offer their assessments of it, including how effective it is in phase.* 4[1].

Keywords: NDAs, clinical studies, preclinical research, and clinical trials

I. INTRODUCTION

A clinical trial is a procedure designed to determine whether a particular drug or device is safe and effective in human subjects1-2. The World Health Organisation defines a clinical trial as any research project that aims to evaluate the effects on health outcomes by randomly assigning participants to one or more interventions linked to health. 3. Clinical trials are typically carried out when sufficient data on the nonclinical safety quality are available and have been authorised by the governing body overseeing the d rug or device4. Trial results have historically been known to depend on the quality of the product as well as the different phases of the product's development. The clinical trials4-6 are first carried out by the investigators using a small number of volunteers or patients.

The number of patients is increased as soon as positive safety and efficacy data are gathered. Additionally, multiple nations have conducted the clinical trials. New medications that fall into four phases are also included in clinical trials. For the approval of drugs, each phase is handled as a separate clinical trial. They are typically be categorised into five phases: I, II, III, IV7-8, and 0.[2]

Phase 0 trials concentrate on pharmacodynamics and pharmacokinetic studies; Phase I covers screening and safety; Phase II covers testing protocol establishment; Phase III covers final testing; and Phase IV covers post-approval studies.4- 6. Additionally, the stages of clinical trials are the processes through which scientists carry out studies with the supervision of a medical practitioner in an attempt to obtain sufficient data for methods that might be used as a therapeutic intervention. When it comes to pharmaceutical research, the phases started with drug discovery and design, went on to animal testing, and concluded with human volunteers9–10. The various phases of clinical trials are summarised in this review article.

A clinical trial is a systematic process intended to ascertain whether a medication or medical device is safe and effective in diagnosing, treating, or avoiding an illness or other health issue. A clinical trial comprises four phases: phase 0 (micro-dosing investigations), phase 1, phase 2, phase 3, and phase 4. The terms "exploratory trial phases" refer to phases 0 and 2, "non-therapeutic phase" to phase 1, "therapeutic confirmatory phase" to phase 3, and "post-approval" or "post-marketing surveillance phase" to phase 4. Phase 0, also known as the micro-dosing phase, was formerly

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conducted on animals but is currently done on human volunteers in order to determine the pharmacokinetics (dose tolerability) prior to administration as part of the phase 1 trial among healthy individuals.[3]

II. TYPES OF CLINICAL INVESTIGATION

Thereseveral classifications for clinical trials. Organising clinical trials according to the study method is one method.
Interventional Study: In this study, researchers track changes in the participants' health. The research participants are administered a specific medication, and the outcomes are compared between the treated group and the control group. This kind of study is a comparative one.
Clinical observational study: in this study, researchers track the participants' results after administering novel medication. Trials can also be categorised according to their intended use.

1. Prevention trials to stop an illness from spreading to people don't have it or to quit an illness from returning. Medications, vitamins, immunisations, minerals, and lifestyle modifications are a few examples of these methods.
2. Clinical trials evaluate the most effective means of identifying specific illnesses or medical conditions.
3. The purpose of diagnostic trials is to develop more precise procedures or diagnostics for determining a certain disease or condition.
4. Novel drug combinations, surgical methods, radiation therapy schedules, and experimental treatments are being tested in treatment studies.
5. Trials focusing on improving the comfort and quality of life for those with chronic illnesses are known as quality of life trials, or supportive care trials.
6. Trials for expanded access or compassionate use offer partially tested options. Unapproved treatments to a small subset of patients for whom there are no practical alternatives. This pertains to an illness for which there is currently no approved treatment, or it involves a patient whose health is too poor to be eligible for randomised clinical trials, or who has already exhausted all conventional therapies.[4]

III. VARIOUS STAGES OF CLINICAL RESEARCH

Preclinical Research on Rats, Mice, Rabbits, and Monkeys
Phase I: Safety and tolerability assessment in human pharmacology trial
Phase II: Exploratory trial - assessment of short-term adverse effects and efficaciousness
Phase III: Verification of treatment benefits through a confirmatory trial
Phase IV: Post-Marketing Trials: Research conducted following a drug's approval
Phase V – Translation research – Research on data collected

IV. PRE-CLINICAL STUDY

Pre-clinical research includes trials conducted on animal populations as well as in vitro (i.e., in a laboratory or test tube). The investigational medication is given at varying dosages to the animal subjects or an in-vitro substrate to gather preliminary data on efficacy, toxicity, and pharmacokinetics. This information helps pharmaceutical companies determine whether to proceed with additional testing or not. Pharmaceutical companies use these experiments to determine whether a drug has scientific merit or not.
Furthermore, the determination of whether it has been necessary for additional development as a novel experimental medication.

Phase 0

It has been said that Phase 0 is merely an introduction to the trials. The US the 2006 recommendations on exploratory investigational new drug (IND) trials published by the Food and Drug Administration (FDA) were followed initially when conducting the human trials. Phase 0 trials are also known as micro dose studies, and their goal is to develop a promising medication with the precise qualities that preclinical research predicted11,13. In addition, one of the unique characteristics of Phase 0 is that a single sub therapeutic small number of patients or volunteers (10–150) are administered a dose of the study medicine in order to collect preliminary data on the pharmacokinetic and

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pharmacodynamics features of the drug. Suddenly, Phase 0 trials don't offer any precise information regarding the test drug's effectiveness and safety. Moreover, Phase 0 studies are carried out by drug development companies to rank drug candidates and determine the pharmacokinetic parameters on humans for future development.

Phase I

The initial phase of testing with human subjects is known as a phase I trial. Usually, a limited (20–80) healthy volunteer group will be selected. Trials aimed at evaluating a drug's tolerability, pharmacokinetics, pharmacodynamics, and safety (pharmacovigilance) are included in this phase. These studies are frequently carried out at an inpatient clinic staffed by full-time personnel who are able to keep an eye on the patient. The patient is typically monitored for a number of the drug's half-lives after administration. Additionally, phase I trials typically involve dose-ranging, or studies to determine the appropriate dosage for medical use.

Typically, the testdose average is a small portion of the dose that harms animals when tested on them. Healthy volunteers are typically included in phase I trials. Real patients are utilized in specific situations, though, such as when they are terminally ill and have no other options for treatment. The most common instances of this exception to the rule are in HIV medication trials and oncology (cancer). Regarding their stay at the volunteer centre, volunteers receive an inconvenience fee. Pay varies based on length of participation, from a small sum for a brief stay to a larger amount up to approximately £4,000

Phase I trials come in various forms.

SAD

Studies with single ascending doses give the medication to small groups of participants just once while they are observed and tested for a long time. If there are no adverse side effects and the pharmacokinetic data closely match projected safe values, the dose is increased and a new batch of participants is given a greater dose. This is done until the drug's Maximum Tolerated Dosage (MTD), predetermined pharmacokinetic safety levels are met, or unbearable side effects start to show up.

MAD

Several Ascending to learn more about the pharmacokinetics and pharmacodynamics of the drug at different doses, dose studies are carried out. Phase II Additionally, some trials have been conducted in a combined manner for both toxicity and efficacy. Phase II trials are conducted in specialised clinical settings, such as hospitals and universities)16–17. Phase II, which has the widest range of failures, exhibits a wide range of toxicity. The claim is reinforced by the observation that only 25% of novel drugs advance to phase II trials.

Phase III

It has been proposed that phase III clinical trials be created to examine a new drug's effectiveness and therapeutic impact in clinical settings18. Phase III trials, a large number of patients (300–3000 or more), in an attempt to arrive at a definite evaluation of the new therapy by comparison with standard drug treatment, have been carried out randomly. Because of their greater scope and length, Phase III studies have also been considered the most expensive, time-consuming, and difficult to organise and carry out. Phase III studies may make use of chronic disorders whose evolutionary stage aligns with the duration of the intervention18–19. Certain Phase III trials must be conducted as per regular protocol until the regulatory submission is finished and sent to the appropriate regulatory agency. After Phase III trials have produced data on drug satisfaction, the report is combined with a thorough description of the manufacturing process, a detailed description of the formulation, and information on the drug's half-life. Additionally, the gathered data is sent to the sponsor in an attempt to obtain approval for the drug's marketing through a "regulatory submission." Additionally, a drug is promptly recalled from the market if any side effects are documented anywhere.

Phase IV

The technical support of the pharmaceutical after obtaining sales authorization4-5 is covered by Phase IV, commonly referred to as "Post marketing surveillance" or pharmacovigilance. Sponsoring organisations or government agencies

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can help with Phase IV trials to discover a new market for the drug. Using a considerably bigger patient group and longer duration of follow-up, the goal of these trials is to see if any long-term adverse effects that were unable to detect during Phase II and Phase III trials have been reported. But the medication takes about 12–18 years to go from the lab to this point.

Phase V

Effectiveness and community-based research studies are also referred to by the term "phase V," which was recently introduced in the literature. As "translational research."The employed determine how a novel clinical treatment fits into a wide range of public health procedures. The Phase V trials are specifically intended to test the mechanism's ability to be generalised to a large sample size. They are generally referred to as "field research."

Adaptive clinical trial: - By varying dosage levels, adaptive trials aim to rapidly identify medications with therapeutic effects. This trial assesses a medical treatment or device by tracking participant outcomes according to a predetermined schedule and making adjustments to the trial protocol based on those observations. Dosage, medication under trial, patient selection standards, sample size, and mix are some of the parameters for modifications.

Randomized trial: - Randomized trials are used to test new drug treatments with less bias. Every research each trial participant is randomly allocated to receive either the study treatment or a placebo. They give the control group a placebo. A randomized trial is used to evaluate the effectiveness and potency of a medication.

Blind trial: - - In blind trials, the research subjects are unaware of the kind of care they are getting or its intended use. Both the subjects and the researcher/physician are blind to the medication being administered in double blind trials. Until the study is over, neither the patients No one at the research team monitoring the outcomes knows which patient receiving which treatment. Reducing bias is a very effective method.

V. CLINICAL TRIALS IN INDIA

India is thought to be a good location for international clinical trials. India is thought to be the site of almost 20% of all clinical trials carried out worldwide. India, the second most populous nation in the world, offers a number of advantages for international drug development programmes, including access to large patient populations, highly educated talent, a wide range of diseases, lower operating costs, lower drug costs than in other developed nations, and a supportive environment for business and intellectual property. Moreover, the Indian Drugs Controller General's office, which is comparable to the European Medicines Agency (EMEA) in India and the US Food and Drug Administration (FDA),finds it easier to establish clinical sites when English is the primary language (DCGI). The federal representative in charge of all matters pertaining to pharmaceuticals in India is the DCGI. The FDA commissioner is akin to the DCGI. For drug trials, India adheres to Schedule Y, which is the same as the IND regulations found at 21 CFR:312.

In India, the DCGI signs all applications filed with his office, including those for clinical trials, marketing approval of medications and medical equipment, manufacture, and the import and export of goods under regulation. The DCGI is not divided into multiple centres and offices to separately regulate different kinds of products. India conducts clinical trials in accordance with ICH E6 guidance. An Indian version of GCPs for conducting clinical operations has been released by the Indian Council of Medical Research (JCMR) to address issues unique to India. An Institutional Review Board (IERB) in the US is comparable to an IEC in India. Before any subjects can be enrolled, all sites must receive approval from the IEC in addition to the DCGI. The application process for a clinical trial takes approximately 4–8 weeks in India, whereas it takes about 2–4 weeks in the US, other European nations, and Australia to process an application.

VI. REGULATIONS AND THE PROCESS OF DRUG APPROVAL

A new drug's approval is currently subject to many regulatory requirements across different countries. It is nearly impossible to apply a single regulatory framework for marketing authorization applications (MAA) across multiple nations. As a result, it is essential to understand the legal requirements for MAA in each nation. A new drug application (NDA), which is submitted to the relevant regulatory agency, requests authorization to commercialise a novel drug. If they submit preclinical and clinical test results, a description of the manufacturing process, and drug information in order to be granted permission.

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Once the agency receives the NDA, it goes through a technical screening process. This assessment makes sure that enough information has been provided in each field to support "filing" the application. Three options are available for sending an NDA to the sponsor after it has been reviewed.

Not approvable- list of shortcomings in this letter and provide an explanation for each

Approvable- It indicates that the medication may be approved notwithstanding a few minor issues that may be fixed, such as labelling modifications and the potential need to commit to conducting post-approval research.

Approval- It says the medication is authorized. The regulatory body offers the applicant the chance to meet with the agency and go over the shortcomings whether the action performed is either one that can be approved or not.[5]

VII. INDIAN LAW AND REGULATION STANDARDS

The Central Drugs Standard Control Organisation (CDSCO) and the State Licencing Authority (SLA) oversee the following: new drug approval procedures, regulatory requirements, certificate of pharmaceutical product (COPP), and organisational structure. The functions of CDCs are outlined in the organization Central Drugs Standard Control Organisation chart (CDSCO).

Organization locations.

Legal specifications and

The primary regulatory body overseeing clinical trials, medications, and pharmaceuticals is the CDSCO.

The central drug authority, CDSCO, is designated by the Drug and Cosmetics Act to carry out tasks allocated to the federal government. The operations of the CDSCO are managed from its main office in New Delhi by the Ministry of Health and Family Welfare, Government of India's Directorate General of Health Services.

An organization's licenced, manufactured, and managed pharmaceutical products must meet acceptable standards for quality, safety, and efficacy. This is the aim of a drug regulatory authority.

VIII. INDIA'S DRUG CONTROLLER

The Indian Drug Controller General is in charge of the Central Drug Standard Control Organisation, which regulates pharmaceuticals and devices in the country. He or she is responsible for authorising new drugs, medical supplies, and clinical trials to be conducted in India. The state drug control agency will function under the DCGI, and he is appointed by the federal government. The drug technical advisory board ({dtab}) and the drug consultative committee ({dcc}) offer guidance to the dcgi.

The CDSCO's functions

1) Clinical trial and New drug approval.
2) Licenses and registration for imports.
3) Blood banks, live vaccines, LVPs and certain medical devices and diagnostic agents are licensed.
4) The D and C Act and Rules are being amended.
5) Prohibition of medications and makeup.
6) Personal license, authorization for testing, as well as nods for export.
7) Central laboratories medications.
8) The Indian Pharmacopoeia was published.
9) Keeping an eye on negative drug reactions.
10) Technical assistance with Cdscoal matters.[6]

Pharmaceutical Product Certificate (COPP)

The pharmaceutical product certificates are granted by the World Health Organisation (WHO), which also determined the applicant's status in the exporting country and the status of the pharmaceutical product. Because approved information, manufacturing processes, and arrangements can vary for various pharmaceutical forms and strengths, it is granted for a single product.

1. When a product is contaminated, For the purpose of registration (Licencing and Authorization) or registration renewal, the importing country requires it.

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2. Regarding the extent of distribution or commercialization in that nation.
3. The World Health Organization advises certification to support inadequate drug regulatory without adequate facilities for quality assurance in the countries of import, authorities or drug regulatory bodies cannot evaluate the quality of pharmaceutical products before registering or importing them.

WHO

In compliance with the regulations, the relevant zonal or sub-zonal officers should receive the application for a WHO GMP Certificate for a pharmaceutical product. WHO-GMP standards provide that after an inspection and satisfactory clearance by CDSCO officers, zonal/sub-zonal officers on behalf of the Drugs Controller General (India) should issue the COPP.

IX. INVESTIGATION NEW DRUG APPLICATION

Introduction

A request for authorization to begin a clinical investigation on a novel medication is made to the Food and Medicine Administration via an Investigational New Drug Application (IND). A company can start and carry out clinical studies of their new drug product by submitting an application for IND. The necessary information is sent to the FDA. by the IND application to determine if the recent medication and planned present a reasonable risk to the study participants who are human. Sponsor submits a new drug application (IND) to the FDA or DCGI conduct person clinical trials. A sponsor is required to wait 30 days following the submission of the IND Application before starting any clinical trials. Human clinical trials cannot start until the FDA thaub Local Institutional Revitalization Board (IRB)have reviewed the IND.

IND types

1. Marketing IND

These applications are made solely by companies to obtain marketing approval for new products.

2. Non-Commercial (Research) INDs

These INDS are research submitted for non-commercial purposes. These are:

1) Investigative IND: Sent by the physician who is responsible for the administration and grants additional IP initiation and conduct of the trial. To publish a study of an unapproved drug or a drug approved for a new indication or new patie nt population, a physician may submit an IND for the study.

2) Emergency Use IND: 21 CFR Sec. 312.23 or one. 312.34, the IND allows the FDA to approve the use of an experim ental drug in an emergency situation, which prohibits the submission of an IND. It may also be used for patients who do not meet the requirements of the approved study protocol or who do not meet the requirements of the approved study p rotocol.

3) Therapeutic IND -

Also known as an Expanded Access IND, this IND may refer to experimental drugs that show promise in serious and lif e-threatening conditions, immediately following definitive clinical action and subject to FDA review.

Three main categories of information must be included in the IND application:

1.Animal medicine and toxicology studies: Preclinical data to determine whether products are safe enough for human tr ials at this early stage. Any prior drug use in humans is also included.

2. Manufacturing information: Details about the Product components, production facilities, safety and controls used in production to guarantee that the business can sufficiently make and deliver reliable batches of the medication.

3. Details about the investigator and the clinical protocol Comprehensive protocols are needed for proposed clinical studies to ensure that participants are not put yourself on the wrong side. Also detailed information on the qualifications that researchers (not just doctors) must have when conducting medical studies.

Lastly, pledges to follow the investigational new drug regulations, secure the study was reviewed by the IRB and informed consent was obtained from all subjects.

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Applications of IND

1.The FDA is involved in the development of a new molecule while it is being evaluated for pharmacological and toxic ological potential in animals, and the drug's sponsor wants to test its diagnostic and therapeutic potential in humans.

2. The molecule becomes a new drug according to the special rules of drug control and changes its policy according to t he Federal Food, Drug and Cosmetic.

3. Before a drug is shipped or distributed across state lines, it must first be approved for marketing.

4. A new drug's IND, or notice of claimed investigational exemption, needs to be submitted to the appropriate regulatory body.[7]

X. NEW DRUG APPLICATION (NDA)

In the United States, an application for marketing authorization for a new drug product is called a New Drug Applicatio n (NDA) and is submitted to the FDA. The purpose of the NDA is to provide FDA officials with sufficient information to determine whether the drug is safe and effective for its intended use and whether the drug is more effective than lous y. Is a prescription required? What information should be included? Are there necessary procedures (good manufacturin g) and quality control followed during the production of the product to protect the identity, integrity, quality and purity of the medicinal product? The safety and effectiveness of all drugs whose contents have been confirmed by research res ults have been proven, but they were not used in these studies for many reasons. [8]

ROLE OF PHARMACISTS IN CLINICAL TRIALS

First and foremost, chemists play a vital role in research and clinical trials by providing the facilities needed for the appropriate storage of investigational medicinal products (IMPs), which can be done in a refrigerator or at a controlled room temperature. Temperature monitoring is done on a regular basis and is documented. Additionally, it is the chemist's responsibility to make sure that IMPs are always in stock and that patients are dispensed them appropriately. Add to written recordgiven, the Patient Information Leaflet or the Informed Consent Form, patients are counselled on how to properly use the IMPs.

Patients' IMP returns are tallied and recorded in order to assess treatment compliance. Pharmacists shall additionally guarantee that injectable IMPs are prepared in compliance with the trial's specifications and are administered correctly. In addition to overseeing clinical trials, oncology chemists frequently conduct research projects with the goal of enhancing patient outcomes for patients receiving

Use of other supportive medications such as chemotherapy or blood transfusion, anti-emetics, etc. Pharmacists frequently carry out research projects called Drug Utilisation Evaluations (DUEs). The goal of these initiatives is to help our patients use medications sensibly.[9]

Basically, giving patients' drug usage patterns and our doctors' prescribing habits some insight. Because chemists make sure medications are used appropriately, DUEs are sometimes referred to as drug audits. Furthermore, chemists carry out observational surveys with the goal of examining the viewpoints and attitudes of doctors or patients regarding medications. Survey results are utilised to enhance the care we give to our patients.

The oncology pharmacy at NCC is currently carrying out two surveys. The purpose of these studies is to look into how patients use complementary and alternative therapies as well as how they feel about using oral anti-cancer medications safely. Patients are frequently surveyed by pharmacy students who have received the necessary training to conduct research. We would like to use this chance to express our gratitude to each and every one of our patients who has agreed to take part in the survey[10]

XI. CONCLUSION

From a public health perspective, clinical trials and research are important. Scientists, healthcare professionals, and the public can benefit from clinical research by better understanding and better preparing for global diseases. Additionally, clinical trials may help address ubiquitous health challenges such as

Full sim no Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2)outbreak and the emergence or emergence of other microbe's diseases. Clinical research is needed to develop drugs, products and vaccines.The researchers must stay current on clinical research and testing methods and techniques, as detailed in this review.

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Drug tests are performed by volunteers to verify the properties of new drugs and follow ICH and GCP guidelines. After preclinical development, new drug Trials were conducted in phases I, II, III and IV of treatment. They has go through the stage.

This phase provides a comprehensive description of pharmacokinetics, pharmacodynamics, potential positive or negative effects and post-marketing analysis.

New drug testing is generally divided into four stages; Each phase has a drug approval review process for each phase. Drug development often goes through several stages over many years.

Although many studies have been conducted on the characteristics and methods of various clinical trials, more research is needed to investigate all the conditions and instructions that must be followed to complete subsequent clinical trials.[11]

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