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Exploring the Clinical Trial: A Comprehensive Review

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ABSTRACT

This review article was written with the intention of providing an introduction to clinical trials, their phases, and the present state of clinical research. A clinical trial is a research study using human participants to address certain health-related problems. Clinical trials are the quickest and safest way to discover treatments that benefit patients and ways to enhance health. Investigational studies examine the safety and efficacy of novel applications of conventional therapy in a controlled setting. To assure the safety and effectiveness of any new treatment, clinical research is a crucial step in the drug discovery process. Clinical trials are essential in the worldwide scientific era of today for bringing new and improved medications to market. Human volunteers (subjects) are used in clinical trials to test prospective treatments to see whether they should be licensed for use in the general population. Any research study that prospectively subjects humans to one or more health-related interventions in order to assess the effects on health outcomes is considered a clinical trial, according to the World Health Organization. The use of clinical trial methodology to produce scientific evidence on the efficacy of treatments for all chronic conditions has become widespread. Five phases, namely phases 0, I, II, III, and IV, can be used to categorize clinical studies.

INTRODUCTION

clinical trial is a research study that examines whether a novel medical procedure or innovative application of an already-proven procedure will be a more effective means of disease prevention, detection, diagnosis, or treatment[1].

A clinical trial is a scientifically controlled study conducted to assess drug safety and efficacy in the human subject[2]. This study has many pros, developing a new treatment that has a big beneficial effect over already existing therapy, the new treatment being equal to standard treatment etc. The role of the US-FDA begins after the completion of pre-clinical evaluation and safety[3]. This practice must be stuck to good clinical practices (GCP). The criteria that must be assured during the experimental study are the well-being of the human subject, sampling, range of masking, randomization trial i.e., RCT, assessing endpoints, and evaluation of results[4].

The basic goal of drug discovery research is to create novel, safer, and more effective medications for human use. A new medicine must undergo numerous stages of rigorous testing, first on animals and then on human beings before it is released onto the market. They are the most crucial and determining factor in whether a new medicine enters the market. Without clinical trials, scientists cannot accurately ascertain if a diagnostic test is accurate in a clinical environment or whether a new medication generated in the lab or using animal models is safe or effective[2]. Clinical trial execution, however, requires a meticulous strategy based on scientific, statistical, moral, and legal considerations. Therefore, in order to preserve a relationship with patients and industry in search of the safest, most effective, and efficient remedies, it is imperative for health care professionals to comprehend the tenets on which well-conducted clinical trials hinge [5].

PHASES

Pharmaceutical companies carry out significant pre-clinical research before beginning clinical trials on a medicine[1].

Pre-clinical studies-

Pre-clinical research includes experiments on animals and in vitro (also known as test tube or laboratory) research. The study drug is administered in a variety of dosages to the animal subjects or an in-vitro substrate in order to get basic information on its efficacy, toxicity.

These tests help pharmaceutical firms determine whether a medication proposal has sufficient scientific potential to be developed further as an experimental new drug.

A medication can move to human testing after it has undergone laboratory testing[6].

Phase 0-

The U.S. Food and Drug Administration's (FDA) 2006 Guidance on experimental Investigational New Drug (IND) Studies established a new category for experimental, first-in-human trials: phase 0. By determining very early on whether the drug or agent behaves in humans as was predicted from preclinical studies, phase 0 trials are intended to hasten the development of promising medicines or imaging agents. In order to gather preliminary information on the agent's pharmacokinetics (how the body processes the drug) and pharmacodynamics (how the drug works in the body), a small number of subjects (10 to 15) are administered a single subtherapeutic dose of the study drug in Phase 0 trials[1].

Phase I-

The first time a new investigational medication is investigated in humans is in phase I trials, often known as "dose-escalation" or "human pharmacology" investigations. These trials are typically open label and involve a small number of "healthy" and/or "diseased" participants. Several statistical designs can be used to establish the MTD, or the drug dose prior to a dose-limiting toxicity. Doses are increased based on incredibly tight criteria, and participants are continuously monitored for signs of drug toxicity for an adequate amount of time. There is a chance that participants in phase I studies (or the real doctors who enroll patients) will mistakenly believe that the study's goal is therapeutic. For instance, despite substantial proof that objective response rates in phase I chemotherapeutic drug studies are alarmingly low (as low as 2.5%)[7].

Phase II-

The test drug's dose calculation for Phase I trials has already been completed, as has been previously reported. The following objective is to examine whether or whether the medicine has a biological and therapeutic level4-5. The research in Phase II trials have been carried out in large groups (100–300) and are intended to study the drug's functioning as well as Phase 1 safety assessment in the larger participants. In cases where there is sufficient evidence of metabolic rate variance, genetic testing is frequently performed. Phase II trials have been split

into two categories: Phase II b clinical trials, which have been developed to assess drug efficacy, and Phase II a clinical trials, which are typically used to assess the dose needed .Additionally, some trials have been conducted for both efficacy and toxicity in combination[3].The need for a future phase III trial is supported by the fact that a phase II trial often has limited ability to show efficacy due to its small participant pool and primary safety concerns [5].

Phase III-

the procedure of evaluating an investigational drugs safety and effectiveness in treating or preventing a certain condition or sickness on a wider group of volunteers.

Scope: A huge number of trials conducted to determine a drug's efficacy, safety, and side effects. Patients who have the ailment or illness that has to be treated, who might also have additional illnesses, and who might also be taking other drugs on top of the investigational treatment. Numerous thousands of volunteers.

Timeframe: A few months to several years.

Goal: To specify how medical professionals should administer the medication to individuals with the indicated ailment or sickness [6].

The Phase III studies have been regarded as the most expensive, time-consuming, and challenging to design and perform because to their extended duration and magnitude. Chronic conditions with a length of evaluation corresponding to the duration of the intervention may be used in phase III trials. While awaiting regulatory approval, phase III clinical trial studies frequently continue gathering outcome data, enabling patients to continue receiving potentially life-saving medications until the treatments are frequently purchased. Other justifications for continuing the trial include the possibility of post-approval "label expansion" based on evidence that the drug is effective for patients or diseases other than those for which it was initially approved for marketing, obtaining more safety data, or supporting the drug's advertising claims. Studies in this stage are occasionally labelled "phase IIIB studies." The drug may need to have greater side effect warnings, more stringent usage guidelines, or possibly be pulled off the market as a result of any recorded adverse effects[3].

Phase IV-

Post-approval research, often known as "pharmacovigilance," aims to assess a treatment's "effectiveness" or the maximum benefit in daily clinical practice. frequently underutilized in minority populations or with clients who have comorbidities when there is less than normal clinical justification for benefit extension. The importance of external validity is paramount. Technical assistance for the monitoring that is provided by regulatory agencies or sponsored businesses [8]. Post-marketing surveillance trial is another name for phase IV trial. It's possible that the trials didn't check for drug interactions, assessed the effects on certain demographics, such pregnant women, or had insufficient participants to catch uncommon adverse effects. These uncommon side effects and drug interactions may manifest after the drug is released onto the market and many thousands of people begin using it. If harmful side effects are found during Phase IV studies, a medicine may not be sold or may only be used for specific purposes [3].

Phase V –

The goal of this translational study is to "move from bench to bedside". Comparative effectiveness research and community-based research are both covered under phase V clinical studies. On acquired data, research is conducted. Every reported use is assessed. There is no patient monitoring. Its major objective is to ascertain whether a new therapy will be incorporated into widespread clinical practice[9].

TYPES-

1. Treatment trials-

Test out novel medicine combinations, innovative surgical techniques, or novel radiation therapy regimens.

2. Prevention trials-

Find more effective techniques to prevent disease in those who have never had it or to stop a disease from coming back. These strategies may consist of drugs, vitamins, vaccinations, minerals, or lifestyle modifications.

3. Diagnostic trial-

conducted to discover more accurate methods or techniques for diagnosing a specific illness or condition[1].

4. Indicative trails-

Directed to find effective diagnostic procedures or systems for a specific disease or set of circumstances.

5. Screening trials-

Examine the easiest to recognize specific illnesses or afflictions.

6. Quality life –

In Trial (or Steady Consideration preliminary stages), researchers look into ways to improve human comfort in the face of ongoing disease[3].

OBJECTIVES-

- A medical study's goals can be roughly divided into primary and secondary goals. A medical study's goal is defined by its hypothesis, which also serves as the research's main goal. It makes an effort to address the key research idea or question.

In a medical study, secondary objectives are frequently used to investigate other research issues or to provide more details about the intervention or exposure being studied. Assessments of the intervention's safety and tolerability, its impacts on secondary outcomes (such as quality of life or adverse events), and subgroup studies to determine which patient populations will benefit from the intervention the most are examples of secondary aims[10].

- Finding out whether the attempted intervention was successful in treating the disease or medical condition is the clinical research's main goal. It is crucial to recognize that research planning significantly affects the research findings, and that only a well-designed and carried out clinical study can improve the findings.

- Improvement in patient management is one of clinical research studies' main goals. The majority of clinical research studies focus on finding a novel medicine to treat a medical problem for which there is currently no effective treatment[11].

- To evaluate the effectiveness and safety of a drug that has already been commercialized.
- To determine whether the new treatment is more successful for the patient's condition than the already prescribed, accepted treatment or gadget[6].
- To assess the effectiveness and safety of drugs or medical treatments in people in order to find novel remedies for medical use[12].

MATERIALS & METHODS-

I. Selection criteria: -

Which subjects are included and which are excluded are determined by selection criteria. The goal is to select the right volunteers from a narrowly specified community based on characteristics like age, gender, disease kind and stage, prior treatment experience, and other health issues. Women who are capable of having children, pregnant women, nursing moms, and subjects who cannot follow protocol (such as alcoholics or drug users) are a few examples of exclusion criteria. Another is concurrent therapy that may impact the course of the disease or cause drug interactions [13].

Inclusion or exclusion criteria-

There are rules about who can take part in clinical studies. The inclusion/exclusion criteria include information on these. "Inclusion criteria" are requirements that someone must meet in order to take part in a clinical trial. "Exclusion criteria" are those that restrict participation or exclude individuals. These standards are based on things like age, gender, the kind and stage of an illness, prior medical conditions, and treatment histories. A participant must meet the study's eligibility requirements before enrolling in a clinical trial. Others require healthy volunteers, while certain research projects require persons with specific disorders or illnesses to be researched in clinical trials. Both are required for some studies. Inclusion and exclusion criteria aren't intended to reject specific individuals; rather, they're meant to find the right participants, keep them secure, and make sure researchers can get the data they need[6].

II. Data collection: -

Even among a homogeneous sample of trials chosen to satisfy the requirements of a single organization (NHS), economic data gathering varies. A checklist is suggested for best practices in relation to economic data gathering inside clinical trials based on our findings, as well as related evaluations and guidelines, as well as the areas that still need to be improved.

Methods for data collection-

The techniques used to gather patient-level data have been divided into the following categories for the review's needs:

1. Medical records obtained from standard main and secondary care sources (such as patient notes and databases);

2. Prospective forms filled out by trial researchers or healthcare professionals (not abstracted from common sources or based on patient recall);

3. Prospective forms filled out by trial researchers or healthcare professionals (based on patient recall);

4. Patient or carer-written diaries (caregiver here refers to a person who is not a healthcare professional);

5. Forms that patients or caregivers completed[14].

Mobile data collecting differs from traditional data collection in a number of significant ways. In the new method, clinic employees enter patient information at the point of care using a mobile device. After that, QC staff accesses an internet platform and checks the data for accuracy and completeness. The data is extracted, then it is transferred into the EDC system. All other data fields are safely maintained in the mobile platform but are not exported; only those data fields that are a part of the study's CRF are included in the data export. The study investigator logs into the EDC system to verify and approve the uploaded data as a last step[15].

III. Clinical trial design:-

To ensure that the study's validity is preserved or retained, the clinical trial designs may need to be modified[16].

Adaptive trial design: -

Clinical trial designs that are adaptable enable changes to be made to research in response to accumulated data, increasing trial flexibility, ethics, and effectiveness. IN a conventional clinical trial, the design is predetermined, the study is conducted, and the findings are analysed afterward. As part of the trial procedure, adaptive designs, by contrast, pre-plan potential alterations based on the data gathering throughout the trial[17].In adaptive trial

designs, the research design is modified and improved based on interim trial data in a planned manner without compromising the study's validity or integrity. An adaptive trial can investigate a wider range of doses in the exploratory setting, assign a larger percentage of the enrolled subjects to the treatment arms that are performing well, drop arms that are performing poorly, and select doses that are more likely to be successful in the confirmatory Phase. Adaptive design can help with the early detection of effective treatments, decisions about dropping underperforming trial arms, deciding whether to end the trial for futility, and adjusting sample sizes at interim time points to make sure the trial is powerful enough[18].The notion of adaptive designs is relevant to drug trials, including those for biologics and medical devices at various stages of development and in many therapeutic areas. Its use is very broad[19].

Randomization: -

The aim of randomized trials is to lessen bias while evaluating novel medicinal therapies. Each participant in this experiment is allocated at random to receive either the study treatment or a placebo[2]. A crucial component of the clinical trial is randomization. Clinical research involves following governmental regulations. Valid statistical inference methodology is provided by randomization testing. Randomization plays a crucial role in the planning, execution, analysis, and interpretation of RCTs. Fit-for-purpose randomization techniques and randomization-based inferences are two related randomization topics that have attracted a lot of attention recently[20]. The efficacy of a new pharmacological medicine or medical technology is commonly assessed using this research methodology, which is perhaps the most reliable one. This research has a very low bias, and the conclusions they reach are regarded as reliable. The trial drug is given to the treatment group in randomized controlled research, whereas the placebo group receives a blank substance that is strikingly similar to the trial drug but lacks the pharmacological component[16].

Blinding:-

The study participants are unaware of the study treatment they are receiving. The researchers are not aware of which treatment a person receives if the study is double-blind. To stop researchers from treating the two groups differently, this is the intention. a "double-dummy" design, a type of double-blind study[21]. The information that is most typically withheld from these groups in a blinded clinical study is the treatment assignment. However, it is often possible to blind some of the aforementioned groups to new information. For instance, it is

possible to blind laboratory technicians, outcome assessors, and result adjudicators to the fundamental clinical and demographic characteristics of the research population as well as the trial's overarching goal[22].

Placebo -

In clinical trials, placebos are used to reduce physician and patient bias. This is especially important when evaluating new medications for illnesses including bronchial asthma, angina pectoris, pain, and psychiatric disorders. In these situations, the actual medication and the placebo should be identical in terms of physical attributes including colour, smell, taste, and form[1].

The extraordinary complexity of the mind-body connection is demonstrated by research on the placebo response, particularly the psychological and neurobiological mechanisms underlying placebo analgesia. Conditioning and anticipation are the psychological processes of placebo analgesia that have sparked the most research. The classical conditioning theory serves as the foundation for the conditioning mechanism.

Levine et al.'s (1978) demonstration that placebo analgesia was reversed by the opioid antagonist naloxone, suggesting a potential mediation function for endogenous opioids, rendered the neurobiological processes of the placebo response noteworthy[23].

IV. Data Management: -

A system for managing clinical trial data is referred to as a clinical data management system. In this system, the efficient support of clinical data management dimensions results in increased results accuracy and the prevention of clinical trial divergence[24]. The process of managing the data during clinical trials is known as clinical data management (CDM). One of the most valuable resources for sponsor research and pharmaceutical product manufacturers are clinical data. The CDM stage of clinical research is crucial because it results in the production of high-quality, trustworthy, and statistically sound data from the clinical trials. The clinical study may be carried out in a single or multiple research centres, and the researcher gathers patient data during the clinical trial.

CLINICAL DATA MANAGEMENT: ROLES AND RESPONSIBILITIES: -

Different duties and responsibilities are given to the team members in a CDM team. A life science degree and familiarity with computer programs should be the very minimum educational requirements for team members in CDM. Medical graduates are ideal for the position of medical coder. However, paramedical graduates are also hired in the sector as medical coders. All CDM teams need to fill a few crucial jobs. The following roles can be regarded as the bare minimum for a CDM team: Data entry assistant, designer, medical coder, clinical data coordinator, database programmer, data manager, and quality control associate[25].

V. Ethical Considerations: -

Before submitting our plans to the relevant Central Ethic Committee or deciding whether to participate in a particular clinical trial as investigators, we always conduct our own confidential evaluation of the clinical trial's ethical basis[26].

The investigators and sponsors of the clinical research must make sure that the study is carried out in accordance with participant safety and ethical (Declaration of Helsinki/ICMR Ethical Guidelines for Biomedical Research on Human Subjects) standards. A written agreement or contract between the sponsor and the institution and the investigator is required. Before the trial begins, the sponsor should make the protocol, standard operating procedures (SOP), and the investigational brochure available for review and analysis. The sponsor must make sure that the study is carried out in accordance with good clinical practice (GCP) criteria[27]. Informed Consent: - Clinical studies ask participants to sign a "informed consent" form before beginning the study. The paper contains information on its goal, duration, necessary steps, hazards, potential advantages, and essential contacts. The decision to sign the document is then up to the participant. The participant may withdraw at any moment without incurring any penalties, hence the document is not a contract. A recruit is given important information as part of the legal procedure of informed consent before deciding whether or not to participate[21].

Informed consent, a guiding concept for behaviour in medical research, has its origins in the Nuremberg Code of 1947 and the Helsinki Declaration of 1964.In clinical research, informed consent has two distinct objectives within its ethical and legal foundations3: (i) to respect and enhance a participant's autonomy; and (ii) to safeguard individuals from harm. An internationally recognized norm requires that participants give their written informed permission before being enrolled in a study[28].

VI. Endpoints / Outcomes:-

The clinical trial's success in determining whether a treatment's ability to prolong a patient's life and improve their quality of life is determined by the study's endpoints. The clinical study results' validity is established by the endpoints. Endpoints come in a variety of forms, including primary, secondary, tertiary, and surrogate endpoints (lab measures, bodily indicators, etc.)[11]. Late-stage clinical trials are designed to produce data with sufficient generalizability and validity to be applied to practice and policy to enhance health outcomes. Therefore, it is essential that the selected endpoints have relevance for the doctors, patients, and decision-makers who will ultimately use the evidence derived from these trials. Understanding the traits and attributes of endpoints can help in the selection process[29].

When planning clinical trials, it is essential to choose the right outcomes or domains in order to directly compare the effects of various interventions while minimizing bias. The targeted outcomes must be pertinent and significant to key stakeholders, such as patients and the general public, health care professionals, and anyone making decisions about health care, if the findings are to have an impact on policy and practice. It is becoming increasingly apparent that the outcomes assessed in clinical trials have not received enough consideration. These problems could be resolved by creating and applying a core outcome set, a set of outcomes that are agreed upon to be standardized and should, at the very least, be evaluated and reported in all studies for a certain clinical area[29].

VII. Protocol:-

An agreement in writing between researchers, participants, and the scientific community is known as a protocol. The protocol must explain to the study staff how the research treatments will be chosen, how the volunteers will be handled, and what evaluations will be carried out. The reference comprehensive operational manual explains who is running the trial, who is funding it, where it will be conducted, and on whom it will be conducted. It also explains what is being tested, why this research is necessary, what risks are involved, what procedures are involved, how data will be collected, how many patients are required, and what should be done in case of an emergency. The standard operating procedure (SOP) is described[13].

All randomized clinical trials, in general, need a protocol to explain the rationale, chosen approach, security precautions for study participants, proposed statistical analysis, and information about organizational/administrative and research funder details from the beginning of the trial until reporting of the results. As a result, transparent, thorough, and

clearly defined procedures continue to be crucial to the success of clinical trials because they allow for a thorough and rapid evaluation of the experiment [6].A list of elements is not all that the protocol is. It should be a well-organized record that offers the necessary background and narrative to comprehend all of the trial's components. For instance, to enable replication by people with the necessary experience, the description of a complex intervention may need to include training materials and figures. A research ethics committee (REC) or institutional review board (IRB) must examine and approve the entire protocol[30].

ROLE OF PHARMACISTS IN CLINICAL TRIALS: -

Pharmacists have historically played a variety of roles in clinical trial research, from delivering drugs and maintaining records for medication accountability to acting as study coordinators and principal investigators.

There are several ways that a pharmacist may be asked to deliver information on clinical trials, just as there are numerous career paths for pharmacists. talking to a patient or caretaker about clinical trial participation, looking for a particular clinical trial when a patient wishes to take part, adhering to evidence-based guidelines that urge involvement in clinical trials when there are no available treatments for the existence of the specific medical problem or conversing with other members of the healthcare team a patient are a few instances of how pharmacists may be knowledgeable requested to give details about clinical trials[31].

The Clinical Trials Pharmacist performs the following duties as a vital element of the pharmacy staff:

• Offering knowledge on the design and formulation of medications.

• Monitoring of investigational drug (ID) indications, dose, administration, contraindications, harmful effects, and interactions.

• Adherence to IRBs in the protection of human subject of medicine dispenses and receipts.

• Charged with collecting unneeded medication from patients and destroying any leftovers.

• Identification card packaging, labelling, and substance analysis.

• The range of lots, expiration date, precise use, posology, management, garage, and ROA must all be verified (in accordance with the sponsor).

• Providing high-quality medications that adhere to the sponsor's guidelines for trials.

• A pharmacist serving as the CRC assists the researcher in adhering to the requirements of the study in order to obtain reliable trial results.

• A pharmacist serving as CRA ensures clinical data accuracy and legal compliance.

• Fulfilling the duties of the staff pharmacist, oncology/IV admixture pharmacist, and patient care in addition to move-related duties.

• Fulfilling obligations related to communication.

• Fulfilling obligations related to schooling.

• As needed, performs additional tasks in line with the job classification[32].

DISCUSSION: -

Study's advantages and limitations: -

In comparison to earlier research in this field, this work's key advantages include a bigger volume of clinical trial data and analysis that is more in-depth and detailed. Numerous variables were examined for the first time in the context of trial design quality and research transparency. The study also offered a novel way to visualize trial features, allowing for quick assimilation of similarities and variations across many aspects. The underlying dataset and the techniques utilized to annotate and integrate the data were both subject to significant constraints in the study [16]. We discovered from these registered clinical studies that the majority of registered clinical research still adhered to the classic, conservative study design paradigm and did not take "timely-ness" into account[33].

We also need to talk about how much the country has benefited from clinical trial operations over the past few years, both from an industrial and public health standpoint. The current situation demonstrates that Indians are vulnerable to both communicable and non-communicable diseases, indicating the significant incidence of these illnesses. This indicates that a significant portion of the populace is afflicted by one of the ailments listed above; as a result, India should permit clinical trials for these illnesses. The proportion of CTs to all cancer, diabetes, CVD, asthma, and COPD studies in 2012 was 12.71, 10.62, 3.23, 2.30, and 2.41 percent, respectively. The CTs for contagious diseases like HIV (.77%), TB (.66%), malaria, and other diseases spread by vectors (.77%) are incredibly low. The primary cause is

that, for commercial, political, or financial gain, the majority of CROs focus on non-communicable disease trials (cancer, diabetes, CVD). Both in industrialized and developing nations, there is a strong demand for medications to treat diabetes, cancer, and CVD. However, communicable disease is recognized as a phenomenon of developing countries. Therefore, compared to medications for communicable diseases, non-communicable disease drugs have a larger market and higher demand in western countries. Pharmaceutical businesses so primarily focus on creating high-demand (and high-value) medicines in low-cost location[34].

Over time, as trial designs have become more complicated, so have the variety and complexity of endpoint types that might be used. Growing acceptance of the necessity of involving various end-user groups in endpoint determination is a crucial first step in enhancing the worth of research projects and the probability of translating research findings. Despite the fact that this subject has seen substantial advancements, it is obvious that the science of choosing and optimizing endpoints for clinical trials is still in its infancy[29].Although the CONSORT statement offers instructions on how to report results for randomized controlled trials, there is no guidance available to inform the best endpoint selection, nor is there a methodology available to quantify endpoints as best as possible, so choosing the best endpoints will likely continue to be up to the trial designers and sponsors[35].

CONCLUSION: -

Overall, the present work concluded that it is critical to explain clinical research, how it was carried out, and the phases of clinical trials. to comprehend the need for a medicinal therapy to go through several stages before being marketed, as well as the significance of a population's safety and health. Due to the direct connection between drug safety and efficacy evaluation parameters and public health, it is crucial to uphold the highest level of quality and standards. A clinical trial is undertaken in human volunteers for any new drug in accordance with ICH and GCP principles to determine whether it has any beneficial properties. Investigational novel drugs go through clinical phases I, II, III, and IV after preclinical development. These stages include a thorough discussion of the pharmacokinetic, pharmacodynamic, and side effect profiles. Clinical trials that are properly planned and carried out can make a significant contribution to the national drive to increase the effectiveness and efficiency of healthcare in the United States. Physicians and patients can continue to have faith in the prescribed therapy by using strict procedures for novel drug

research and approval. We think that rigorous adherence to the standards for clinical trials is vital to increase the calibre of research and registered clinical research programs. Additionally, the clinical studies being undertaken right now by many hospitals are not effectively integrated or organized. Clinical trials are also used to examine some treatments whose safety is highly questionable or for which there has been no in vitro testing, which raises the risk to participants.

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