



A Complete Over Review on Drug Discovery Process in Aspects of Clinical Research

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Abstract: Clinical Research plays a major role in health care. Nowadays Clinical Research is a health care profession that gives you all information about new tests and treatments and the effectiveness of that medication on human health. Clinical research is origin Form the year 1747. This paper presentation aims to give an overview about all the key concepts of research and all this information is very important for the viewers to study or to identify how the science is working and how to perform the new experiments and various research are to be done and how the drug is going to market. In clinical research, we aim to design a study that would be able to drive a valid and meaningful scientific conclusion using appropriate statistical methods. A conclusion derived from the research study is to improve the health care and safety of individuals resulting from inadvertent harm to patients. Hence, this requires well designed clinical research study that rests on a strong foundation of methodology, and all are governed by ethical principles. The purpose of this review is to provide an overview to the reader of the basic study design and all the aspects and applicability in clinical research. It was the Belmont Report that finally explicated the principle of informed consent proposed 30 years prior in the Nuremberg Code. Informed consent, now a mandatory component of clinical trials that must be signed by all study participants (with few exceptions), must clearly state. This is a research study (including an explanation of the purpose and duration; and the risks, benefits, and alternatives of the intervention), Participation is voluntary, the extent to which confidentiality will be maintained exact information for questions or concerns.

Keywords: Clinical Research, Phases, Clinical Trial, Safety, CDSCO, Efficacy.

INTRODUCTION

Clinical research is the branch of a health care professional that determines the safety of those participants who freely participate in the clinical trial process. It plays a major role in human safety and this process aims to establish new tests and treatments and therapies for the betterment of humans. To understand the key concepts to conduct the research activity that conforms to the highest standard for the protection of human research subjects. All in-depth working knowledge of regulatory authorities, statistical principles, epidemiological methodology, health services, disease prevention & health promotion. According to the regulatory requirements, there should be an independent ethics committee, stakeholders, sponsor company and all needed committee members are to be needed to regulate the appropriate process of trial. The main motto of this process is when the study is ongoing all the data generated from the study it should be confidential and only there will be the only access to the regulatory bodies of clinical research. There are various types of study in the clinical research which are Experimental studies, Observational studies, Randomised studies, Single-arm, Double arm study, Single-blind, Double-blind, Triple blind

study, Placebo control parallel group of study are the various types which we are going to discuss in the review.

CLINICAL RESEARCH

Clinical research is a health care profession that is used to discover and identify the safety and effectiveness of the medication, medical device, biological products, diagnosis product, treatment intended for human use. Clinical research is important because those approaches can be medical behavioural and help to manage and save the life also trial tests how well new approaches & interventions work in people. Each study answers scientific questions & used to prevent and treat disease. The research activities take place all over the world like Health Care Provider Officers, mainly in hospitals, medical centres, community & university Hospital & clinics, Veterans and military hospitals.

CLINICAL TRIAL

The clinical trial is the part of a clinical research study that tests how well intervention work in a group of people, test for a new method of screening, prevention, diagnosis, & therapy which is conducted in phases of the clinical trial to increase the safety & efficacy.

1. DRUG DEVELOPMENT PROCESS

The Drug Discovery, there will be nonclinical, clinical, post-approval is done, during the process, we are going to study in-vitro & in-vivo testing under the good laboratory practices. Basic research that gives an early discovery and further it goes to preclinical. The main objective of that study is cost reduction, failure reduction. Clinical testing is done under good clinical practices in which knowledge gained from one phase is assessed before processing in the next phase. The first three phases are studied under the guideline of good clinical practices. Therapeutic use of a drug in a general heterogeneous population is done in post-marketing surveillance.

1.1 IND Application: Before a clinical trial

1.2 NDA\BLA Application: After phase 3

1.3 FDA File: After phase 3

1.4 Non-Clinical Research: Good Laboratory Practices

1.5 Clinical Research: Good Clinical Practices

2. PHASES OF CLINICAL RESEARCH:

2.1 Phase 0

This phase is called Human Micro-dosing. In this, we are going to study less than 1% of a therapeutic dose of an investigational product, which gathers preliminary data on pharmacokinetic and pharmacodynamic by giving the single sub-therapeutic dose. The duration of that phase is 7-10 days on 10-15 healthy volunteers that show a selection of lead candidates with no therapeutic and diagnostic intent.

2.2 Phase 1

This phase is known as Human Pharmacology that is also called “The first inpatient”. In this phase homogeneous population is used to study safety and tolerability. The pharmacokinetic and pharmacodynamic data their dose and dose range and how many of maximum tolerated dose of that experimental drug possess in phase 1 trial.

2.3 Phase 2

It is the therapeutic exploratory phase which contains 100-300 volunteers for 2 years. Dose exploration and effectiveness is preliminary evidence which gives dose-response and exploration of a dose is studied inhomogeneous population, 35% of the experimental drug possess of the phase 1 trial. Drug-drug interaction and adverse events are also studied in this phase.

2.4 Phase 3

Therapeutic confirmatory phase in this phase we study long-term safety that gives a labelling claim for that drug by studying all the aspects like collecting the information and allowing the drug or treatment to be used for safety. NDA files after phase 3 depend on risk-benefit assessment and adverse events required for safety.

2.5 Phase 4

Post Marketing Surveillance is required to check long-term toxicity and effectiveness in a large heterogeneous population. It is an ongoing process to check the safety and efficacy of that drug is going to market. The focus of that PMS study is to prevent the disease by diagnosis and checking the drug efficacy, treatment, and safety of that individual.

Clinical trial conducts by Pharmaceutical Companies, Biotechnology Companies, Contract Research Organisation, Academic/Research Institution, Co-operative Groups.

3. STAKEHOLDERS IN CLINICAL RESEARCH:

Stakeholders are the person or group of an organization who has a huge interest in a particular clinical decision & evidence to support that decision, they also play a major role in direction of health care industries they provide funding, support, strategies, direction & gives a solution in process of research. Principle investigator, Study Sponsors, Regulatory Authorities, Ethics Committee, Study Participants, CRO. who plays a major role and gives the answer to the perception of public towards clinical research, Ethics Committee & Regulatory Authorities has responsibility ensure the right safety and well-being to the human subject, reporting of adverse event and serious adverse event, quality assurance to coarse complains to GCP guidelines of CDSCO & International Council for Harmonisation of Technical Requirement for Pharmaceutical for Human Use

3.1 CRO: IQVIA, Paraxel, Health Covance, Torrent, Sanofi, PPD, ICON, Lotus Lab, Syneos Health,

3.2 Regulatory Authority: DCGI, CDSCO.

3.3 Ethics Committee: Chairperson, Medical scientists, Clinicians, Social Worker, Legal Person, Ley Person, EC Member Secretary.

4. INFORM CONSENT IN CLINICAL TRIAL:

A person who is thinking about being part of the clinical trial is said to be a potential research subject in which the process of communication between you and your health care provider often leads to giving an appropriate information, treatment, care, service about the whole study and they make you give you an appropriate decision about whether to start or stay in that trial. The concept of informed consent is derived from "Nuremberg Code" in 1947. According to International Council for Harmonisation-Good Clinical Practices, the process by which the subject is voluntarily confirmed his/her willingness to participate in trial after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. It is not a contract it is a voluntary decision of participants if the study participant wants to withdraw the study or they want to terminate the study without giving any reason or facing any penalty participants have full right to terminate at any stage of a trial.

5. PROCEDURE OF CLINICAL TRIAL:

When the subject comes to participation, the principal investigator has a responsibility to take an informed consent before the start of the clinical trial. If the formalities are to be done that subject goes for the screening visit in which laboratory tests are to be done. After that randomization and enrolment of a subject according to the study protocol then study visit is started, after that AE & SAE reporting to the Regulatory Authorities. Then drug goes to the market for the study of that compound in a large population and sees the effect of a drug on a large population. During the whole process of the clinical trial, pharmacovigilance plays a major role throughout the study and also after the completion of the study.

6. ETHICAL CONSIDERATION:

An Institutional Review Board (IRB) is an independent body established to protect the rights and welfare of human research participants. Under Title 45 Part 46 of the Code of Federal Regulations (45 CFR 46), any research that is federally funded must be reviewed and approved by an IRB. An IRB has specific authority over the conduct of research under its jurisdiction. No clinical study may begin enrolling participants until it has received IRB approval. The IRB has the authority to Approve disapprove, or terminate all research activities that fall within its local jurisdiction according to relevant federal regulations and institutional policy. Require modifications in protocols, including protocols of previously

approved research. The purpose of an IRB is to safeguard the rights, safety, and well-being of all human research participants. The IRB fulfils this purpose by Reviewing the full study plan (see section IRB responsibilities for the documents which comprise a full protocol) for a research study to ensure that the research meets the criteria and reviewing proposed changes to previously approved studies.

7. Role of clinical pharmacist in hospital:

The goal of a clinical Pharmacist is to support to provide the best quality drug therapy for the patients. These may also include:

- Prescription monitoring
- Maximize drug efficiency
- Minimize drug toxicity and promote cost-effectiveness
- Therapeutic drug monitoring of drugs with a narrow therapeutic index
- Drug information services
- Patient services
- Patient counselling
- Improving patient compliance collecting past medical history

8. Role of pharmacist in clinical research:

Pharmacists have a major carrier in the research sector because pharmacists belong to a paramedical pattern. They work with the hospital clinical research team and also with the community of ethics committee. In industry, there is the major section related with the research department and various other departments like Marketing, Research, Publications, Hospital, Community, Industrial, Quality, Academia, Regulatory. The career of pharmacist in the research field in the role of Clinical research coordinator, Clinical trial assistant, Clinical site monitor, Clinical research associate, Project manager, Data management.

CONCLUSION: As per all processes of review we studied all aspects of the clinical trial which I being worked in the training of CRC what is role and responsibility of towards the right, safety, and well-being of the individual that gives us another view towards life and save the life in aspects of safety and efficacy. This review gives you a piece of information about how that science is being worded on the health of an individual, research can give as the knowledge about the medication in which is gives benefit to the betterment of subject.

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