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REVIEW ARTICLE

Academic Clinical Trials and Data Management-A New Era in Pharmacy

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Abstract:
Although there are many definitions of clinical trial, they are generally considered to be biomedical or health related research studies in human beings that follow a pre-defined protocol. Clinical trials include both interventional and observational types of studies. Interventional studies are those in which the research subjects are assigned by the investigator to a treatment or other intervention, and their outcomes are measured by the investigators. Clinical trials are conducted in phases. In Phase I clinical trials, researchers tests a new drug or treatment in a small group of people [20-80] for the first time to evaluate its safety, determine a safe dosage range and identify side effects In Phase II clinical trial, the study drug or treatment is given to a larger group of people [100-300] to see if it is effective. And to further evaluate its safety. In Phase III studies, the study drug or treatment is given to large groups of people [1000-3000] to confirm its Effectiveness, Monitor side effects, Compare it to commonly used treatments and Collect information that will allow the drug or treatment to be used safely. In Phase IV trials, post marketing studies delineate Additional information including the drugs risks, benefits and optimal use. A protocol is a study plan on which all the clinical trials are based. The plan is carefully designed to safeguard the health of the participants as well as answer specific research questions. A protocol describes what types of people may participate in the trials; the schedule of tests, procedures, medications dosages and length of the study. A clinical data management system or CDMS is used in clinical research to manage the data of a clinical trial. The clinical trial data gathered at the investigator site in the case report form are stored in the CDMS. To reduce the possibility of errors due to human entry, the systems employ different means to verify the entry. The most popular method being double data entry.

Keywords:

Introduction

The scope of present study is very wide for development of new molecules which can be used for various novel drug delivery systems. Academic clinical trials are a valuable component of the health care system; they benefit patients and help to determine the safety and efficacy of new drugs and devices. The clinical research industry worldwide is growing at unparalleled rate. It has opened up new vistas for employment for a large number of trained professionals.

The clinical trials market worldwide is worth over USD 26 billion and the industry has employed an estimated 2,10,000 people in the US and over 70,000 in the UK, and they form one-third of the total research & development staff. There are more than 2,50,000 positions vacant globally and salaries vary in the region of approximately USD 40,000 per annum for a Clinical Research Coordinator. The career opportunity for candidates with various academic backgrounds is given below Doctors / Alternate Medicine/ Dentistry graduates: Principal Investigator, Co-investigator,

Medical Advisor, Drug Developers, Regulatory Affairs Manager and Clinical Research Physician. Para Medics / Pharmacists / Life Sciences Graduates: Medical Writers, Clinical Research Associates, Site Coordinators, Clinical Research Managers and Drug Development Associates. Management Professionals (with life sciences background): Business Development, Clinical Research Management and Regulatory Affairs Management.

A clinical trial is a research study to answer specific questions about vaccines or new therapies or new ways of using known treatments .Clinical Trials also called medical research and research studies] are used to determine whether new drugs or treatments are both safe and effective. Carefully conducted clinical trials are the fastest and safest way to find treatments that work. Leads for clinical trials usually come from researchers. New therapies are tested on people only after laboratory and animal studies show promising results. Clinical Trials make it possible to apply the latest scientific and technological advances to patients care.

1.1 PHASES OF CLINICAL TRIALS

Four phases of clinical trials and medicine development exist and are defined below. Each of these definitions is a functional one and the terms are not defined on a strict chronological basis. An investigational medicine is often evaluated in tow or more phases simultaneously in different clinical trials. Also, some clinical trials may overlap two different phases.

Phase I:

Researchers test a new drug or treatment in a small group of people (20-80) for the first time to test its safety, identify the maximum tolerated dose, find a safe dosage range and identify side effects.Initial safety trials on a new medicine. An attempt is made to establish the dose range tolerated by volunteers for single and for multiple doses. Phase I trials are sometimes conducted in severely ill patients (e.g., in the field of cancer) or in less ill patients when pharmacokinetic issues are addressed (e.g. metabolism of a new antiepileptic medicine in stable epileptic patients whose microsomal liver enzymes have been induced by other antiepileptic medicines). Pharmacokinetic trials are usually considered Phase I trials regardless of when they are conducted during a medicine's development. **(11)**

Phase II: The drug or treatment is given to a larger group of people (100-300) to see if it is effective, to further evaluate its safety and to gather additional information regarding safe dose range.

Phase IIa: Pilot clinical trials to evaluate efficacy (and safety) in selected populations of patients with the disease or condition to be treated, diagnosed, or prevented. Objectives may focus on dose-response, type of patient, frequency of dosing, or numerous other characteristics of safety and efficacy.

Phase IIb: Well controlled trials to evaluate efficacy (and safety) in patients with the disease or condition to be treated, diagnosed, or prevented. These clinical trials usually represent the most rigorous demonstration of a medicine's efficacy, sometimes referred to as pivotal trials.

Phase III

The drug or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments and collect information that will allow the drug or treatment to be used safely.

Phase IIIa: Trials conducted after efficacy of the medicine is demonstrated, but prior to regulatory submission of a New Drug Application (NDA) or other dossier. These clinical trials are conducted in patient populations for which the medicine is eventually intended.

Phase IIIa clinical trials generate additional data on both safety and efficacy in relatively large numbers of patients in both controlled and uncontrolled trials. Clinical trials are also conducted in special groups of patients (e.g., renal failure patients) , or under special conditions dictated by the nature of the medicine and disease. These trials often provide much of the information needed for the package insert and labeling of the medicine.

Phase IIIb: Clinical trials conducted after regulatory submission of an NDA or other dossier, but prior to the medicine's approval and launch. These trials may supplement earlier trials, complete earlier trials, or may be directed toward new types of trials (e.g., quality of life, marketing) or Phase IV evaluations. This is the period between submission and approval of a regulatory dossier for marketing authorization.

Phase IV

During this phase, investigators are looking for additional information, including the drug or treatment's risks, benefits, and optimal use. This trial may occur after the drug or treatment has been approved for use by the FDA.

Trials may be conducted to determine better dosing guidelines, new formulations, effects on different populations or new indications.

Studies or trials conducted after a medicine is marketed to provide additional details about the medicine's efficacy or safety profile. Different formulations, dosages, durations of treatment, medicine interactions, and other medicine comparisons may be evaluated. New

1.1 PHASES OF CLINICAL TRIALS

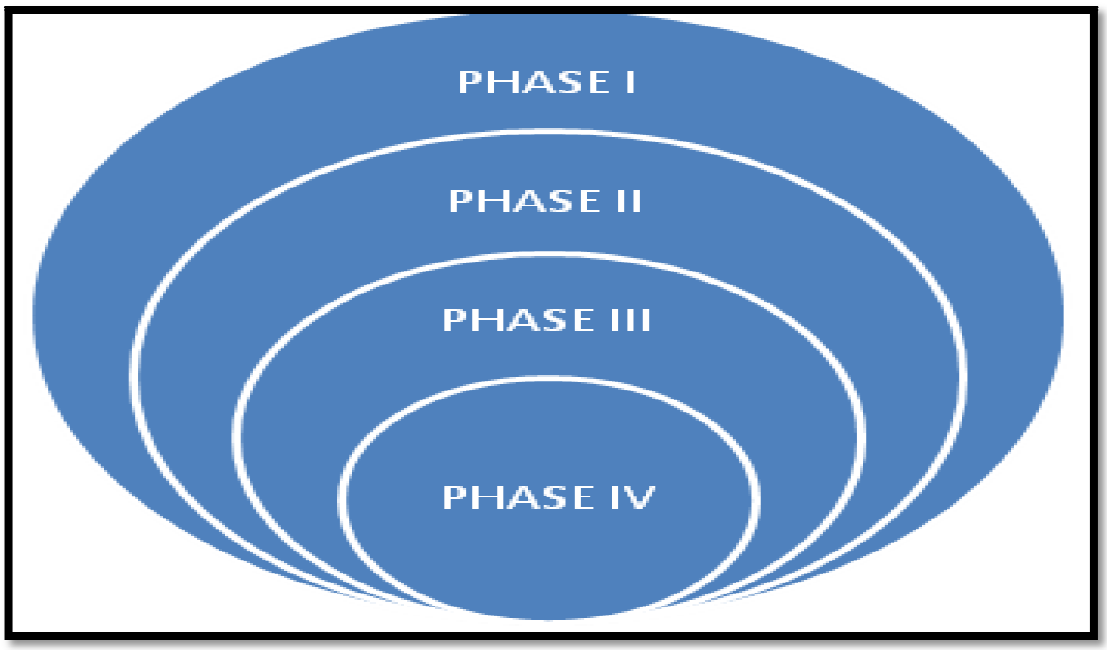


Figure No.-1 Phases of clinical trials

age groups, races, and other types of patients can be studied. Detection and definition of previously unknown or inadequately quantified adverse reactions and related risk factors are an important aspect of many Phase IV studies. If a marketed medicine is to be evaluated for another (i.e., new) indication, then those clinical trials are considered Phase II clinical trials. The term post-marketing surveillance is frequently used to describe those clinical studies in Phase IV (i.e., the period following marketing) that are primarily observational or non-experimental in nature, to distinguish them from well controlled Phase IV clinical trials or marketing studies.**(16)**

1.2. TYPES OF CLINICAL TRIALS

Some clinical trials are Blinded, Placebo controlled. The blinding can be single, double or triple blinding.**(11)**

Features of Clinical Trials

- Observational study- the investigators observe the subjects and measure their outcomes. The researchers do not actively manage the experiment.
- Interventional study- the investigators give the research subjects a particular medicine or other intervention. Usually, they compare the treated subjects to subjects who receive no treatment or standard treatment. Then the researchers measure how the subjects' health changes.

The U.S. National Institutes of Health (NIH) organizes trials into five (5) different types.

- **Prevention trials**: look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These Approaches may include medicines, vitamins, vaccines, minerals, or lifestyle changes.
- **Screening trials**: test the best way to detect certain diseases or health conditions.
- **Diagnostic trials**: conducted to find better tests or procedures for diagnosing a particular disease or condition.
- **Treatment trials**: test experimental treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.
- **Quality of life trials**: explore ways to improve comfort and the quality of life for individuals with a chronic illness (a.k.a. Supportive Care trials).

Compassionate use trials: provide experimental therapeutics prior to final FDA approval to patients whose options with other remedies have been unsuccessful. Usually, case by case approval must be granted by the FDA for such exceptions.

DESIGNING OF CLINICAL TRIAL STUDIES

Design

- Randomized: Each study subject is randomly assigned to receive either the study treatment or a placebo.
- Blind: The subjects involved in the study do not know which study treatment they receive. If the study is double-blind, the researchers also do not know which treatment is being given to any given subject. This 'blinding' is to prevent biases, since if a physician knew which patient was getting the study treatment and which patient was getting the placebo, he/she might be tempted to give the (presumably helpful) study drug to a patient who

could more easily benefit from it. In addition, a physician might give extra care to only the patients who receive the placebos to compensate for their ineffectiveness. A form of double-blind study called a "double-dummy" design allows additional insurance against bias or placebo effect. In this kind of study, all patients are given both placebo and active doses in alternating periods of time during the study.

- Placebo-controlled: The use of a placebo (fake treatment) allows the researchers to isolate the effect of the study treatment.

1.4. CLINICAL TRIALS DELIVERY MODELS

These are the models prepared to show the pattern of the clinical trials.

For every trial, the delivery models prepared is different. The delivery models are essential to understand the concept of the clinical trials study and gain the knowledge of its effect.

1.5. CLINICAL TRIALS ENVIRONMENT

For the person studying clinical trials it is very essential for them to understand about the environment of clinical trials.

The clinical trials undergoes with various phases of clinical trials such as:

1) Phase 1
2) Phase 2
3) Phase 3
4) Phase 4

He has to understand the statistics through which it undergoes. The keen knowledge about the clinical data management system, legislatures, regulatory affairs, pharmacovigilance is very essential for him.

He should be having knowledge about the protocol preparations and its drafting.

1.6. AUDIT OF CLINICAL TRIALS

"The overall aim of clinical audit is to improve patient outcomes by improving professional practice and the general quality of services delivered. This is achieved through a continuous process where healthcare professionals review patient care against agreed standards and make changes, where necessary, to meet those standards. The audit is then repeated to see if the changes have been made and the quality of patient care improved. "**Clinical Audit is directly related to improving services against a standard that has already been set by examining:**

1.Whether or not what ought to be happening is happening
2.Whether current practice meets required standards
3.Whether current practice follows published guidelines
4.Whether clinical practice is applying the knowledge that has been gained through research
5.Whether current evidence is being applied in a given Situation.

1.7. CLINICAL TRIAL PROTOCOL

The following sections should be included in the Study Protocol:

- Introduction (brief description of the problem and treatment regimen(s))
- Objectives and purposes of the study
- Study duration
- Number of subjects
- Informed Consent
- Opinion of the Ethics Committee
- Subject selection criteria:
  - Inclusion criteria
  - Exclusion criteria
- Methodology:
  - Study Plan
  - Study schedule
  - Study Visits
  - Study Assessments / Procedures
  - Definition of efficacy endpoints
  - Treatment cycles
  - Safety Reporting
  - Adverse events (AEs)
  - Serious adverse events (SAEs)
  - Abnormal laboratory test values
  - Abnormal values of other safety parameters
  - Withdrawal from the Study
- Clinical laboratory parameters
- Other safety parameters
- Concomitant medications
- Data analysis
- Appendixes

The following appendixes may be included in the Study Protocol: Patient Information Sheet/Written information and/or Informed consent form (ICF). Instruction sheet (e.g. for study subjects or study site staff).

The terms, which may be difficult for understanding by study subjects (both medical and law terms) should be avoided in translation of the abovementioned documents containing patient information. If special terms are used in the documents, they should be clarified or explained.

2. CLINICALDATA MANAGEMENT

A clinical data management system or CDMS is used in clinical research to manage the data of a clinical trial. The clinical trial data gathered at the investigator site in the case report form are stored in the CDMS. To reduce the possibility of errors due to human entry, the systems employ different means to verify the entry. The most popular method being double data entry.

Once the data has been screened for typographical errors, the data can be validated to check for logical errors. These errors are raised for review to determine if there is

an error in the data or clarification from the investigator is required. Another function that the CDMS can perform is the coding of data. Currently, the coding is generally centered around two areas; adverse event terms and medication names. With the variance on the number of references that can be made for adverse event Terms or medication names, standard dictionaries of these terms can be loaded into the CDMS. The data items containing the adverse event terms or medication names can be linked to one of these dictionaries. The system can check the data in the CDMS and compare it to the dictionaries. Items that do not match can be flagged for further checking. Some systems allow for the storage of synonyms to allow the system to match common abbreviations and map them to the correct term. As an example, ASA could be mapped to Aspirin, a common notation. Popular adverse event dictionaries are MedDRA and WHOART and popular Medication dictionaries are COSTART and WHO-DRUG.

At the end of the clinical trial the dataset in the CDMS is analyzed and sent to the regulatory authorities for approval.

2.1DATA: Data are the information that we gain from the clinical trials

2.2CLINICAL DATABASES AND TYPES

Clinical databases may contain a large variety of data from different domains, eg, patient visits, test results, laboratory reports, diagnoses, therapy, medication, and procedures. Clinical databases may have different purposes, eg, patient management, electronic patient records, clinical research, and quality control. Clinical databases usually have a large number of users with different requirements for views of the database. The administrator does not want to view data per patient, while the nurse must be able to lookup current medication for a specific patient.

Three production databases were the basis of the 2 group's research: The Clinical Data Repository at Columbia-Presbyterian Medical Center (CPMC), the Adaptable Clinical Trials DataBase (ACT/DB), and SENSELAB.

Columbia-Presbyterian Medical Center (CPMC):-

CPMC is a large clinical repository for millions of patients dating back to the beginning of the nineteen nineties. Several front-end applications offer access to the database giving different views for health care professionals, administrators and researchers.

Adaptable Clinical Trials DataBase (ACT/DB):-

ACT/DB is a clinical-trials database built upon the same design principles as CPMC. Nadkarni et al introduce the term "entity-attribute-value (EAV) design" for generic structuring of data in a relational database [7]. The database is accessible through a generic Web-based interface (WebEAV) [4]. Web forms for displaying and editing data are generated automatically during run time from metadata stored in the database.

SENSELAB:-

SENSELAB is a database for heterogeneous neuronal data. As such it is not a clinical database. However, the SENSELAB architecture uses an object-oriented approach to the EAV model by defining classes and relations (EAV/CR). The EAV/CR architecture is useful for scientific data in general, but it is of special interest for clinical databases.

2.3COMPUTERS IN CLINICAL TRIALS AND TYPES:-

Computerized systems are used to create, modify, maintain, archive, retrieve, or transmit clinical data intended for submission to the Food and Drug Administration (FDA). These data form the basis for the Agency's decisions regarding the safety and efficacy of new human and animal drugs, biologics, medical devices, and certain food and color additives. As such, these data have broad public health significance and must be of the highest quality and integrity.

2.3.1GENERAL PRINCIPLES

A. Each study protocol should identify at which steps a computerized system will be used to create, modify, maintain, archive, retrieve, or transmit data.

B. For each study, documentation should identify what software and, if known, what hardware is to be used in computerized systems that create, modify, maintain, archive, retrieve, or transmit data. This documentation should be retained as part of study records.

C. Source documents should be retained to enable a reconstruction and evaluation of the trial.

D. When original observations are entered directly into a computerized system, the electronic record is the source document.

E. The design of a computerized system should ensure that all applicable regulatory requirements for recordkeeping and record retention in clinical trials are met with the same degree of confidence as is provided with paper systems.

F. Clinical investigators should retain either the original or a certified copy of all source documents sent to a sponsor or contract research organization, including query resolution correspondence.

G. Any change to a record required to be maintained should not obscure the original information. The record should clearly indicate that a change was made and clearly provide a means to locate and read the prior information.

H. Changes to data that are stored on electronic media will always require an audit trail, in accordance with

appendix. Documentation should include who made the changes, when, and why they were made.

I. The FDA may inspect all records that are intended to support submissions to the Agency, regardless of how they were created or maintained.

J. Data should be retrievable in such a fashion that all information regarding each individual subject in a study is attributable to that subject.

K. Computerized systems should be designed: (1) So that all requirements assigned to these systems in a study protocol are satisfied (e.g., data are recorded in metric units, requirements that the study be blinded); and, (2) to preclude errors in data creation, modification, maintenance, archiving, retrieval, or transmission.

2.3.2DATA ENTRY

A. Electronic Signatures

To ensure that individuals have the authority to proceed with data entry, the data entry system should be designed so that individuals need to enter electronic signatures, such as combined identification codes/passwords or biometric-based electronic signatures, at the start of a data entry session.

B. Audit Trails

Requires persons who use electronic record systems to maintain an audit trail as one of the procedures to protect the authenticity, integrity, and, when appropriate, the confidentiality of electronic records.

C. Date/Time Stamps

Controls should be in place to ensure that the system's date and time are correct.The ability to change the date or time should be limited to authorized personnel and such personnel should be notified if a system date or time discrepancy is detected. Changes to date or time should be documented.

2.3.3 SYSTEM FEATURES

A. Systems used for direct entry of data should include features that will facilitate the collection of quality data.

B. Systems used for direct entry of data should be designed to include features that will facilitate the inspection and review of data. Data tags (e.g., different color, different font, flags) should be used to indicate which data have been changed or deleted, as documented in the audit trail.

C. Retrieval of Data

Recognizing that computer products may be discontinued or supplanted by newer (possibly incompatible) systems, it is nonetheless vital that sponsors retain the ability to retrieve and review the data recorded by the older systems. This may be achieved by maintaining support for the older systems or transcribing data to the newer systems.

D. Reconstruction of Study

2.3.4 SECURITY

A. Physical Security

In addition to internal safeguards built into the system, external safeguards should be in place to ensure that access to the computerized system and to the data is restricted to authorized personnel.

B. Logical Security

Access to the data at the clinical site should be restricted and monitored through the system's software with its required log-on, security procedures, and audit trail. The data should not be altered, browsed, queried, or reported via external software applications that do not enter through the protective system software. There should be a cumulative record that indicates, for any point in time, the names of authorized personnel, their titles, and a description of their access privileges. The record should be in the study documentation accessible at the site.

SYSTEM DEPENDABILITY

The sponsor should ensure and document that computerized systems conform to the sponsor's established requirements for completeness, accuracy, reliability, and consistent intended performance.

SYSTEM CONTROLS

A. Software Version Control

Measures should be in place to ensure that versions of software used to generate, collect, maintain, and transmit data are the versions that are stated in the systems documentation.

B. Contingency Plans

Written procedures should describe contingency plans for continuing the study by alternate means in the event of failure of the computerized system.

C. Backup and Recovery of Electronic Records

Backup and recovery procedures should be clearly outlined in the SOPs and be sufficient to protect against data loss. Records should be backed up regularly in a way that would prevent a catastrophic loss and ensure the quality and integrity of the data. Backup records should be stored at a secure location specified in the SOPs. Storage is typically offsite or in a building separate from the original records. Backup and recovery logs should be maintained to facilitate an assessment of the nature and scope of data loss resulting from a system failure.

3. TRAINING OF PERSONNEL

A. Qualifications

Each person who enters or processes data should have the education, training, and experience or any combination thereof necessary to perform the assigned functions. Individuals responsible for monitoring the trial should have education, training, and experience in

the use of the computerized system necessary to adequately monitor the trial.

B. Training

Training should be provided to individuals in the specific operations that they are to perform.

Training should be conducted by qualified individuals on a continuing basis, as needed, to ensure familiarity with the computerized system and with any changes to the system during the course of the study.

C. Documentation

Employee education, training, and experience should be documented.

4.RECORDS INSPECTION

A. FDA may inspect all records that are intended to support submissions to the Agency, regardless of how they were created or maintained. Therefore, systems should be able to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the Agency. Persons should contact the Agency if there is any doubt about what file formats and media the Agency can read and copy.

B. The sponsor should be able to provide hardware and software as necessary for FDA personnel to inspect the electronic documents and audit trail at the site where an FDA inspection is taking place.

5. CERTIFICATION OF ELECTRONIC SIGNATURES

As required by CFR, persons using electronic signatures to meet an FDA signature requirement shall, prior to or at the time of such use, certify to the agency that the electronic signatures in their system, used on or after August 20, 1997, are intended to be the legally binding equivalent of traditional handwritten signatures. (14)

6.ELECTRONIC DATA CAPTURE

An Electronic Data Capture (EDC) system is a computerized system designed for the collection of clinical data in electronic format for use mainly in human clinical trials.

Typically, EDC systems provide:

- a graphical user interface component for data entry
- a validation component to check user data
- a reporting tool for analysis of the collected data

EDC systems are used by life sciences organizations, broadly defined as the pharmaceutical, medical device and biotechnology industries in all aspects of clinical research,[1] but are particularly beneficial for late-phase (phase III-IV) studies and pharmacovigilance and post-market safety surveillance. EDC can increase the data accuracy and decrease the time to collect data for studies of drugs and medical devices.

7. DEVELOPMENT OF DATA ENTRY PLATFORMS

It is a software specialized in production and implementation of data entry, management and analysis solutions for biomedical and statistical studies Data Management Platform provides simple means to design and manage multiple projects. Powerful software for data collection and management

Application areas

Biomedical research data management (a successful application for biobanks exists)
Clinical study tracking and documentation
Questionnaire based studies and surveys (CAPI)
Custom databases for different needs
Internet-independent data collection
Graphical UI to universal query engine and customized data reporting.

Its advantages

Proven development methodologies
Cost effective solutions
Easy-to-use end product matured by feedback gained from industry professionals
In-depth data analysis provided on demand
Full support for implementations (13)

8.DATA SAFETY AND MONITORING:

Data and Safety Monitoring Boards (DSMB) will be used primarily for randomized controlled trials but may be appropriate in other settings (e.g., multi-agent Phase II trials across multiple institutions), depending on risks involved, study sponsors, and potential conflicts of interests. Outside of a randomized controlled trial, interpretation of the need for a DSMB will be primarily left to the discretion of the Principal Investigator, but the IRB or other oversight individuals may query the Principal Investigator regarding the need for a DSMB if deemed appropriate.

Responsibilities of a DSMB:

1. The primary responsibility of the DSMB is to review interim analyses of outcome data and to recommend whether the study needs to be changed or terminated based on these analyses.
2. The DSMB also determines whether, when, and to whom outcome data should be released prior to the scheduled reporting of study results at the time specified in the protocol.
3. The DSMB reviews interim toxicity data.
4. The DSMB reviews major modifications to the study prior to their implementation (e.g. termination, dropping an arm based on toxicity results, increasing target sample size).

Membership:
A DSMB is composed of individuals not otherwise connected with the particular clinical investigation. For specific trials conducted under sponsorship of the University of Chicago and without appropriate resources to do so otherwise, the Associate Dean for Clinical Research will appoint DSMB members for a designated term that will extend until all protocol-specified primary events have occurred or as determined by the DSMB itself based on the study outcomes. The size of the committee should be limited and will be determined by the Associate Dean for Clinical Research.

SAS PROGRAMMING:
SAS (pronounced "sass", originally *Statistical Analysis System*) is an integrated system of software products provided by SAS Institute that enables the programmer to perform:

- data entry, retrieval, management, and mining
- report writing and graphics
- statistical analysis
- business planning, forecasting, and decision support
- operations research and project management
- quality improvement
- applications development
- data warehousing (extract, transform, load)
- platform independent and remote computing

In addition, SAS has many business solutions that enable large scale software solutions for areas such as IT management, human resource management, financial management, business intelligence and customer relationship management.

9.PROGRAM DOCUMENTATION
A documentation generator is a programming tool that generates documentation intended for programmers (API documentation) or end users (End-user Guide), or both, from a set of specially commented source code files, and in some cases, binary files.
Document generation can be divided in several type of documents:

- Batch documents (all automated documents)
- Interactive documents (documents that can not be produced automatically)
- Text block correspondence (documents created based on pre defined text blocks)
- Forms (forms for websites)

You can place every type of document you come across in one of these categories. A lot of software solutions are offered on the internet that can automate these processes.

10.PROGRAM VALIDATION
Program Validation helps clients ensure that key business systems are functional and in compliance with applicable regulations - including planning, protocol development, execution and systems certification - to minimize business risk. An important part of business risk management is directly related to a company's computer systems. Our regulatory software validation services offer the distinct benefits of:

- Evaluating regulatory compliance
- Identifying associated risk factors
- Improving schedule visibility, assuring milestone achievement and project success
- Providing a qualified, third-party analysis of software systems
- Program validation and testing

In order to facilitate the validation and testing of software systems in the most time and cost-efficient manner possible, we follow a proven process of:

- Conducting an assessment of critical needs
- Drafting project specifications for client approval
- Setting finite objectives for each phase of the testing process
- Developing a matrix of testing scripts tailored to meet those objectives
- Reporting the results of our comprehensive testing, including completeness metrics
- Re-validation to accommodate changes resulting from ongoing upgrades and system maintenance **(7)**

CONCLUSION:

From the above study we can conclude that the clinical trial study is essential to understand the pharmacology and the use of drug. This study is also very essential for the approval of drugs for marketing. The clinical research, trials and data management studies are at booming stage. The new molecules excellent safety profile obtained after clinical trials is a key factor in allowing long term treatment of a illness. Preparation and Drafting of protocol is very essential and it can be studied by studying clinical trials and data management. New molecules can be tested for their effectiveness by their pharmacokinetic study and their safety can be studied in clinical trials. Life expectancy of a patient suffering from dangerous diseases increases in clinical trials by process of patient recruitment. Thus clinical trials is told as “Medical science of new era.”

Types of databases

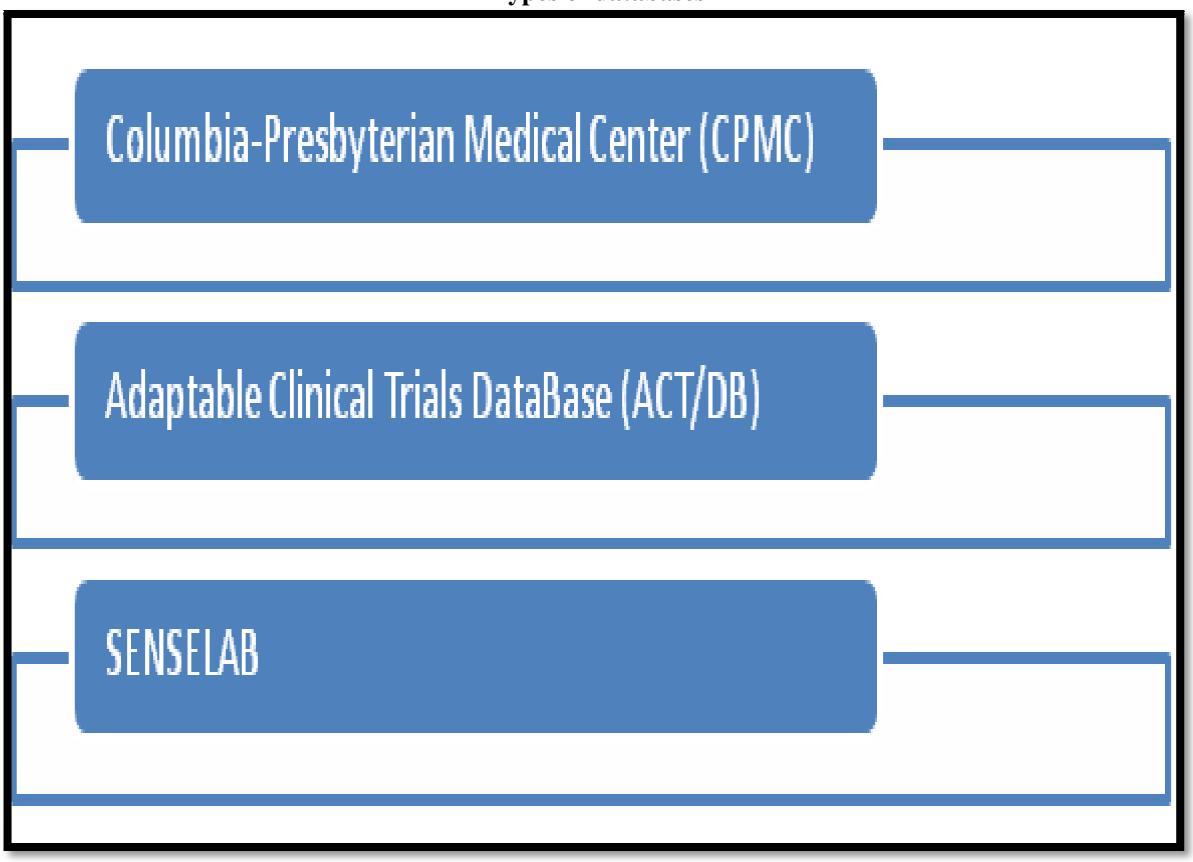


Figure No.-2 Types of databases

DATA ENTRY

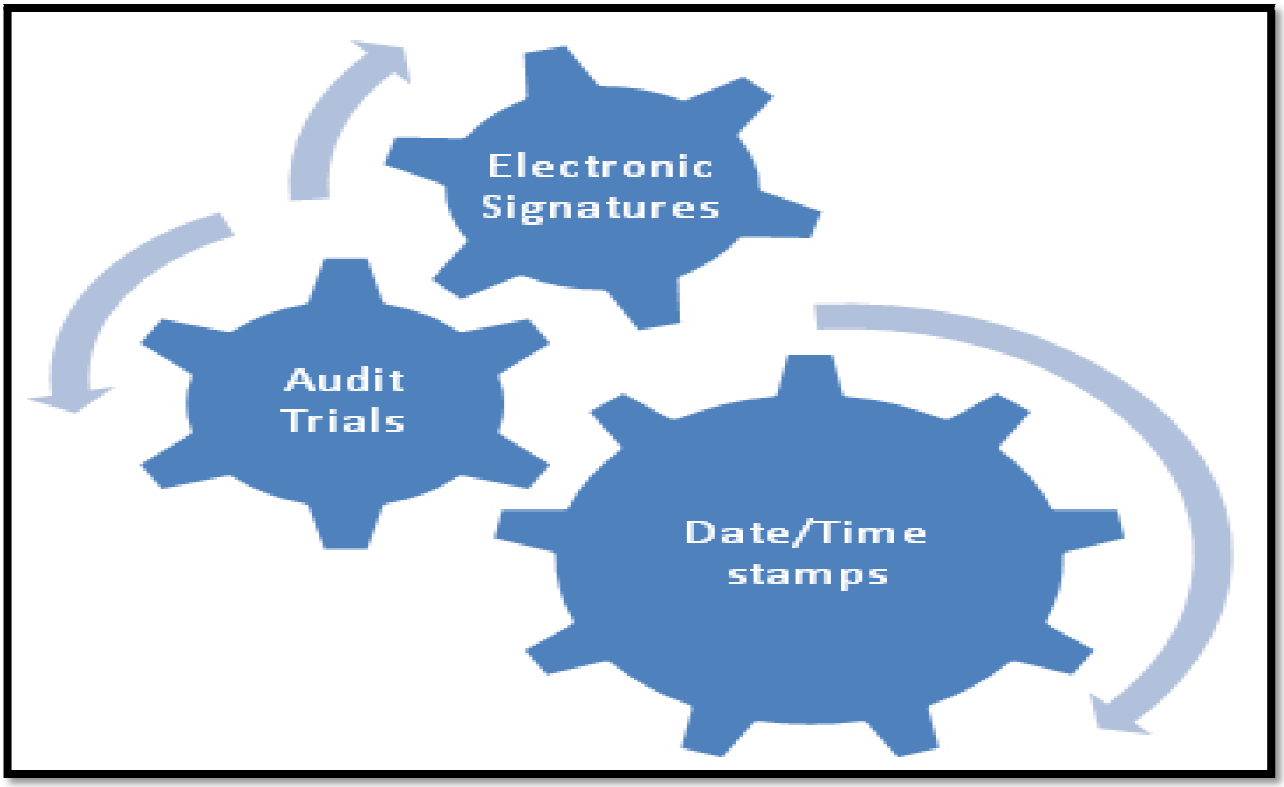


Figure No.-3 Types of dataentry

SYSTEM CONTROLS:

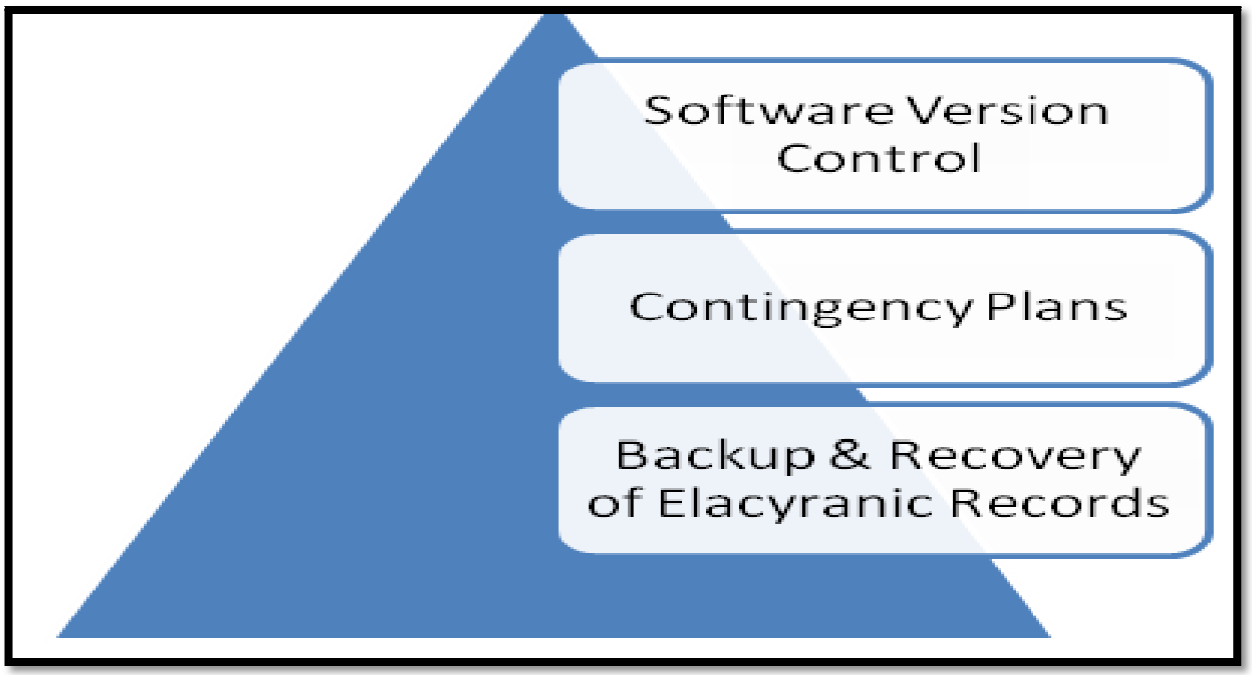
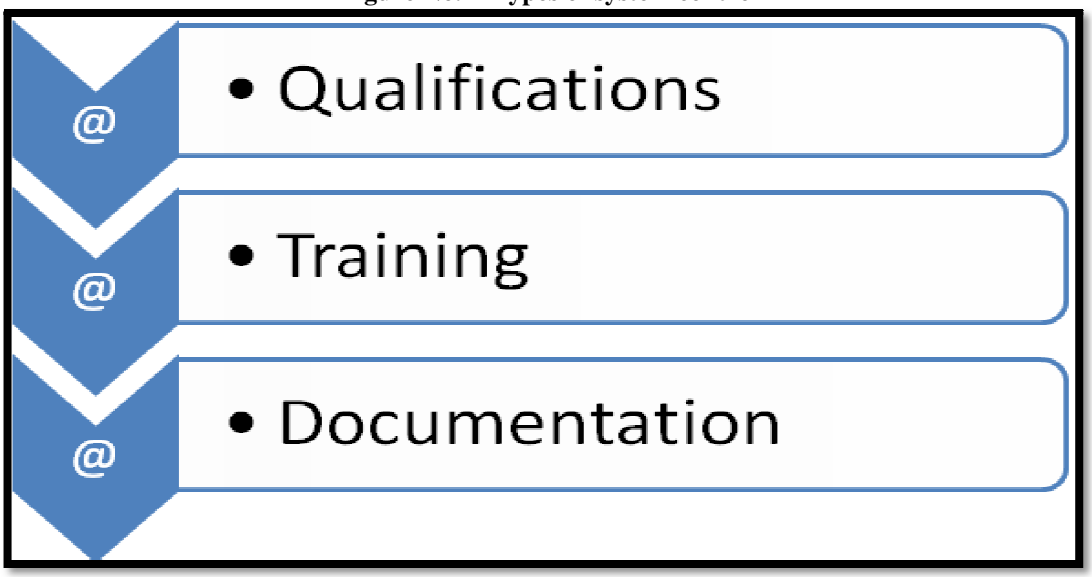


Figure No.-4 Types of system control



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