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Clinical Trial Database Design- Requirement Understanding, Build and Implementation

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ABSTRACT: In traditional method the data was recorded in paper is where the records were maintained in hardcopy format. The data was recorded by hand as there used to be data integrity, data correctness issue. Also tracking of the data changes was even more difficult because a clinical study goes on for many years where storing of the records were also a big challenge. As a clinical study, the accuracy of the data is more important because it will be affecting human lives, so accuracy and quality of the data play a vital role which was very difficult to maintain in the traditional method. The methodology used in this framework is the Agile Software Development Technique. To create and develop eCRF and maintain the application as per client requirement and maintain the application for future update's and data lock until the study is completed. Rave is a cloud-based clinical data management system that is used to electronically capture, manage and report clinical research data. It enables the user to record patient information (i.e. visit, lab and adverse event data) using forms that are customized for each study.
Once the application clears the testing it is pushed to a live environment where the data is captured, and the programmer maintains the application.

I. INTRODUCTION

A Clinical Trial Database Design project provides overview of clinical research, which provides the capture the data in electronic format, which will be helpful in reusing the data research for many years.In a clinical trial, the participants of a particular study get a particular mediation, which will be according to a particular research plan, or protocol, which is created by the investigators. These medications can be products of the medical industry, such as devices, drugs, or procedures, which will be observed on the changes to participants' behavior, such as diet. These Clinical Trials can be a comparison of a new medical approach to a standard approach that can be already available in the market, to a placebo (inactive drug) which has non-active ingredients, or to no mediations. In some clinical trials, the examination can measure up to the interventions, which are as of now accessible to one another. Clinical trials, which are used in drug development, are conducted in different phases.

Clinical Trials are classified into 4 Phases

- Phase I preliminaries test an exploratory medication, antibody or gadget in a little gathering of individuals to assess security, conceivable results, and to decide how the medication ought to be utilized or conveyed.
- Phase II preliminaries include a bigger number of individuals than Phase I and they are intended to evaluate the wellbeing and viability of an exploratory treatment. This stage can most recent quite a while.
- Phase III thinks about the test medication or immunization to a fake treatment or standard treatment, to assess security and viability.
- Phase IV preliminaries occur after an administrative wellbeing authority, like the U.S. Food and Drug Administration, has endorsed.

Clinical Trial Database Design Management

- Clinical Database design is engaged with all parts of handling the clinical information.
- Working with a scope of Computer applications, information base frameworks to help assortment, cleaning, and the board of subject or clinical trial information.
- Clinical Database design is the assortment, blending, and validation of clinical trial information.
- During the clinical trials, the agents gather information on the patients' wellbeing for a characterized time frame period.

- This information is shipped to the trial sponsor, who then, at that point investigates the pooled information utilizing statistical examination.

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II. LITERATURE REVIEW

The drug organizations and support research need a sound and successful CDM. All around planned CRF offers the chance to limit information preparing. EDC framework is one of the best devices for clinical preliminary information assortment and information the board. [1].
Case report structure configuration is the underlying advance in making an interpretation of the convention into standard surveys and is foremost to an effective clinical preliminary. Despite the time and exertion spent directing the preliminary, theright information focuses (reaction to a CRF question/information is entered) should be gathered; something else, a significant investigation may not be conceivable.[2].
Clinical trials can be an amazing asset for showing the adequacy of a clinical intercession or treatment. The capacity of QA projects to diminish varieties in treatment conveyance and improve the nature of clinical trials has been illustrated. [3].
CDM has advanced in light of the steadily expanding request from drug organizations to quick track the medication improvement measure and from the administrative specialists to set up the quality frameworks to guarantee age of top notch information for precise medication assessment. [8].
CRF creation and Designing, Database planning and Testing, Edit checks readiness, and User Acceptance Testing (UAT) alongside record arrangement, for example, Data Management Plan, CRF Completion Guidelines, Data Entry Guidelines, and Data Validation plan. [9].
An option in contrast to clinical trials paper-based dataCapture (PDC) is web based electronic dataCapture (EDC), where the agents over the web enter information straightforwardly in the electronic data set without anyone else. [11].
One method that can diminish the quantity of information section mistakes in PC informational indexes is the utilization of a double passage information framework. At present, either accessible programming permits the production of tweaked information passage screens that intently take after or copy the information assortment structures utilized during considers. [12].
To adequately fulfill these necessities, the proposed arrangement consolidates a web stage and a Clinical Data Management System (CDMS) to abuse the qualities of Electronic Health Records (EHR) and Electronic Data Capture (EDC) frameworks. [15].
By referring to all the research papers it can be summarized that the Electronic Data Capture is very effective way handle the clinical data. Clinical data will be very safe and accurate. Which can be used future different studies in clinical Trials.

III. PROPOSED SYSTEM

For a Medidata client, the client will begin the work-build process in Medidata and afterward access Rave Architect to finish the process. Medidata Rave has different environment, which are Rave Architect, Rave EDC and Global Library Volumes. Rave Architect is a software-as-a-service (SaaS), web-based solution that facilities study designers to develop and maintain eCRFs and data validations for Rave EDC within a specific URL domain. Studies must be built and configured in Rave Architect in order to be viewed in Rave EDC.

The EDC module is similar to a collection of Electronic Case reports forms. All information identified with studies, sites, and subjects gathered during a clinical trial is entered and altered in the EDC module. Explicit advantages can be applied to clients dependent on their appointed jobs. Rave EDC where the actual study is pushed and maintained for the Investigator to enter the recorded data. In Rave EDC we have options to enter the data, verify the data and lock the data. All the entry or activities are also tracked in the application. Global library are reusable elements where if there is a similarity between different studies, we can use the already built study elements, which can simplify the programmer task.

Based on the client requirements the requirement is created in the excel sheet by data managers and sent it to the programmer to build the application. The programmer builds the application as per the requirements and once the application is built there will be Unit Testing and Quality testing been done on the application to ensure that the application is as per requirements and there is no deviation regarding the build.

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Block Diagram

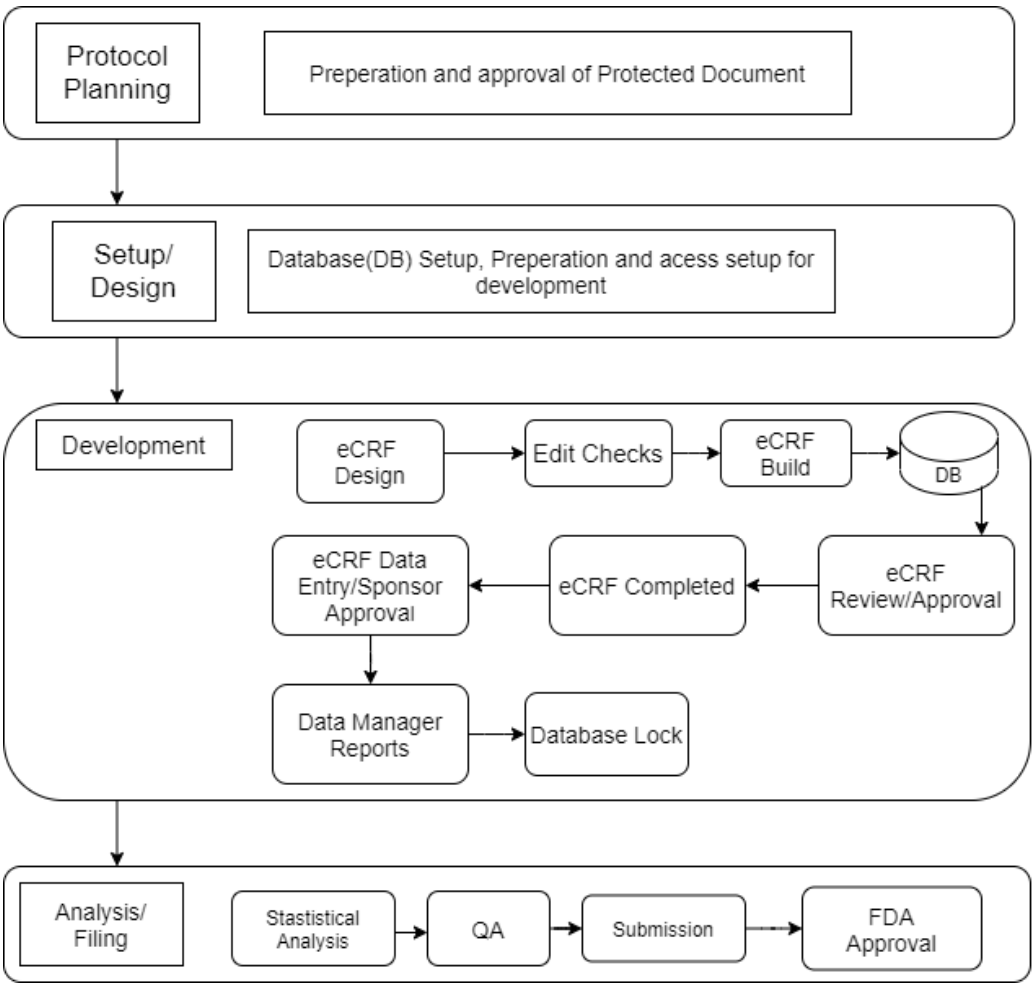

Figure 1.1. Block Diagram of Clinical Trial Database Design

The Figure 1.1 represent the Clinical Trial Database Design, whereSponsors will specifies the specification for the designing.Developers build the eCRF design and write the Edit Checks in project architecture. Custom function will be written for complex queries. Once eCRF will be approved or reviewed, then it will be ready to push into live environment to capturing data and managing data. For capturing and managing the data studies will be created in EDC System. After this Database will be locked to protect data. Captured data will be sent to FDA for Approval.

Context Diagram

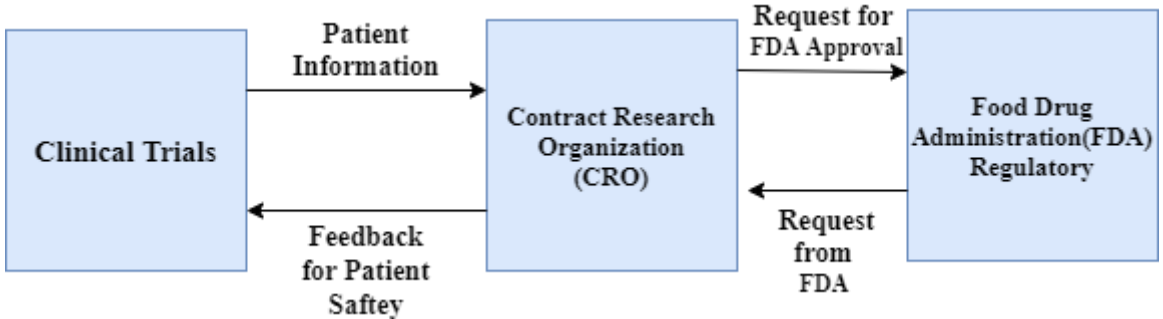

Figure 4.2. Context Diagram Clinical Trial Database Design

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In Figure 1.2 Context Diagram Clinical Trial Database Design describes, each phase of clinical trials, data will be collected and it is submitted to contract research organization (CRO). Once the CRO performs the required development and analysis, the study is submitted for FDA approval. Once the FDA approves, the response is sent to CRO, further on it is sent to sponsor. CRO sends the required feedback for patient safety back to the clinical trials.

IV. CONCLUSION

Clinical Database design is engaged with all parts of handling the clinical information. Working with a scope of Computer applications, information base frameworks to help assortment, cleaning, and the board of subject or clinical trial information.Clinical Database design is the assortment, blending, and validation of clinical trial information.During the clinical trials, the agents gather information on the patients' wellbeing for a characterized time frame period. The drug organizations and support research need a sound and successful Clinical Data Management. All around planned CRF offers the chance to limit information preparing. EDC framework is one of the best devices for clinical Trial Data Collection and information the board. It upgrades checking and information the executives, saving time span, negligible blunder and question rates, speedy appraisal, and solid outcomes.

Rave EDC is used to maintain and work on the Electronic Case Report Form where when a test data is recorded the data entry person will get to know the data entered is valid or not through edit check where a query will be fired on the specific field so that there will be less mistakes while entering data. Using derivation few field data can be automatically enteredby the system by referencing the specific field already entered such as calculating the next visit date from the previous visit date.

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