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SOFTWARES IN PHARMACOVIGILANCE AND CLINICAL TRIALS

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ABSTRACT

Software plays a crucial role in clinical research Starting from study start up to study close out. Software is accessible at any time from any computer with internet access. It helps investigators, co-ordinators and administrators to reduce burden and facilitate the trial with better communication between research team members. Integration of these software greatly enhance the speed and efficiency in maintaining, managing, planning, performing and reporting of the study data. For clinical trial management certain software like OpenClinica, RealTime-CTMS were used for patient management and recruitment, investigator management, regulatory compliance at the study site and CRO (Contract Research Organization) offices. ClinTrial, Macro, eClinical Suite were used in the Clinical Data Management for CRF(Case Report Form) designing, CRF annotation, database designing, data-entry, data validation, discrepancy management and data extraction by the sponsor or CRO's, where as Pharmacovigilance software like Argus, ArisGlobal, Pvnet were the drug safety databases used during the study and VigiFlow, VigiBase were used in post marketing surveillance by the sponsor site, CRO's, hospitals, AMC's(Adverse Drug Reaction Monitoring Centres) to store the safety profile and adverse event reports of the drug. Thus, these softwares are the great tools in clinical research domain to collect trial specific data to track study performance, schedule, monitor and many more.

KEYWORDS: Softwares, Clinical trial, Pharmacovigilance, adverse events, CRO.

INTRODUCTION

Software reduces administrative burdens and workloads by consolidating information in a single location that facilitates collaboration between all the research personnel supporting the

clinical trial. For investigators it helps in easily creating the protocol, throughout the trial it tracks the participants in enrolling and their progress, also tracks the financial activity associated with it, facilitate the better communication between team members. For administrators it helps to maintain trials and financial activity related to multiple departments, investigators and participants, facilitate compliance and support institution-specific processes.[1]

Softwares used in Clinical research are broadly divided into different domains.

1. Clinical Trial management.
2. CDM (Clinical Data management)
3. Pharmacovigilance.

1. Clinical Trial Management System (CTMS)

This is a software system which maintains and manages planning, performing and reporting functions. It is used at the sites where clinical research is conducted such as research hospitals, physician practices, academic medical centres and cancer centres and pharmaceutical and biotechnology industries. It is involved in Patient management and recruitment, investigator management at the study site and CRO site.

Softwares for CTMS

(a) **Open clinica**: it is a free, open source web based software for electronic data capture built by Akaza research, helps in management of diverse clinical studies through a single interface also in clinical data entry and validation, data extraction. (b) **Realtime CTMS:** Developed by realtime CTMS. It is a CTMS designed to streamline operations within a clinical research site. It manages critical functions of research such as patient recruitment, study tracking, financial accounting, scheduling, reporting.(c) **Allergo CTMS :** Developed by Forte research systems. This software is built exclusively for investigator sites and research groups. It gives immediate access to information about the entire clinical trial in one place and immediate visibility into activities and statuses for each trial and maintains control over the financial health. (d) **Clinical conductor CTMS**: Developed by Bio optronics, leading CTMS for research sites, site networks, hospitals, AMC's(ADR Monitoring Centres), CRO(contract Research Organisations) and health system.(e) **Bioclinica CTMS** : Developed by Bioclinica, this software is flexible and supports studies of all types, sizes and complexity. (f) **Ag clinical**: Developed by Aris global. It is a cloud based solution with clinical trial activities like planning, tracking and control for life science organisations. **(g) Clinical Trials**

Management: Developed by Clin plus. It is designed to help expedite clinical trials specially sponsors and CRO's, improves user accessibility and communications. (h) **Open Text Clinica**: developed by open Text. Improves case report forms (CRF) tracking process. It scans the reports and stores each image making them easy to search and retrieve.(i) **Ques Gen platform**: Web-based solution designed specifically for configuring and managing clinical databases. [2] (j) **Clinplus CTMS :** this software has quick study setup with fully integrated monitoring tools and good system integration.[3]

2. CLINICAL DATA MANAGEMENT (CDM)

CDM is the process of collection, cleaning and management of subject data in compliance with regulatory standards. The main objective of this is to generate high-quality, reliable, and statistically sound data from clinical trials for accurate drug evaluation and reduce the number of errors and missing data. To meet this objective best practices are employed to make sure that the data is complete, reliable and process completely and this has been facilitated by the use of software application. Some of the processes involved in CDM include : Case report form (CRF) designing, CRF annotation, Data base designing, Data entry, Data validation, Discrepancy management, Medical coding, Data extraction and Data base locking.[4]

Softwares for CDM

Many software tools are available for data management and these are called CDMS (clinical data management softwares). Most of the CDMS used in pharmaceutical companies are commercial, these software tools are expensive and need sophisticated information technology infrastructure to function. Commonly used CDM tools are: (a) **Oracle clinical :** Developed by Oracle, it has the provision of integrated clinical data management and remote data capture. (b) **Clintrial :** Developed by Phase Forward. This software streamlines the paper based clinical data entry and provides real time data access and enhanced data quality.(c) **Macro :** Developed by Infer Med, electronic data capture for all trials from phase1 to phase 4, scaling from a single site to large international sites. (d) **RAVE :** Rave flexibility accommodate your workflow requirements, scales from one study to hundreds and from phase 1-4 and easily configure CRF's workflows.[5] (e) **e-Clinical suite :** its simple, fast affordable tool for collection of data in clinical trials.

Open source tools: these are the CDM softwares which are available free of cost. These open source softwares can be downloaded from their respective websites. Among them the

prominent ones are : **Open Clinica :** A web based system for electronic data capture and forms the platform for clinical research. **Open CDMS:** it enables clinical researchers to manage full life cycle of their clinical research project from design to archiving without any specialist knowledge. **Trial DB** and **Phosco-EDC** for Electronic data capture.

2.1 Medical Coding

Medical coding classifies the medical terms on the CRF to standard dictionary terms so as to avoid unnecessary duplication and to maintain the uniformity in the process. It helps in proper coding of medical terminologies related to the trial. various medical dictionaries are used which are available online, Commonly, Medical Dictionary for Regulatory Activities (MedDRA) is used for the coding of adverse events as well as other illnesses. WHO-DDE(World health organisation Drug Dictionary Enhanced) - coding the medications. WHO-ART -adverse reactions terminology. WHO HD – herbal concomitant medications.[6]

3. Pharmacovigilance

It is a safety database**,** Used for Adverse Event Reporting**,** Adverse Drug Reaction Data Management**,** Regulatory reporting of ICSR (Individual Case Safety Reporting)**,** Signal detection in Adverse Drug Reactions.

Softwares for pharmacovigilance

(a) **Aris G :** It's the world's leading pharmacovigilance and clinical safety system, about more than 300 companies are maintaining their clinical drug safety data in Aris G.[7] it manages adverse event reporting and adverse reaction requirements not just for drugs but also for vaccines, biologics and devices, it is flexible and fully scalable that is it can be used by both small companies in the early stages of clinical Trials for reporting severe adverse events and large organisations with worldwide pharmacovigilance operations.(b) **PvNet :** This software supports to segregate data entry, scientific assessment, helps in Extensive data validation and cross validation checks, it has MedRA version management and Covers full spectrum of developing good safety report.[8] (c) **ARGUS :** provides comprehensive foundation for case management and reporting, also helps to manage the data from multiple sources, meet strict global compliance guidelines and have access to flexible drug safety databases. (d) **Oracle AERS :** Provides single global solution in managing worldwide safety information, it involves reporting and analysis of serious adverse events for all medicinal products including drugs, medical devices, vaccines, biologics, gene therapies.(e) **PV Works:** provides comprehensive data entry and reporting, it collect and report safety data to

meet all common international Pcv manager regulations including ICH, FDA. (f) **Clintrace:** It is a drug safety software solution that helps customers comply with complex global safety regulations and reporting associated with clinical research, post approval marketing, drug surveillance by expediting the clinical evaluation and tracking of adverse events. (g) **Pcv Manager**: A drug safety management software based on E2B and MeDRA industry data standards that enables to classify, create, review, submit and maintain pharmacovigilance data and adverse event reports.[9]

3.1 Post marketing surveillance

Tools: **VigiFlow** – helps in the Collection and analysis of individual case safety reports. **VigiLyze** -this facilitates the analysis of vigibase data. It is a powerful search and analysis tool that provides access to Global, regional or National view of an ADR and Monitor international patient safety data. **VigiBase**- Gives the information about safety profile of drugs and competitive products & optimise the queries**. PaniFlow**- Helps to Monitor ADR following administration of drugs and vaccines against influenza virus during the pandemic.[10]

CONCLUSION

Softwares provide high quality data by reducing and minimising errors according to regulatory standards. The data generated is of persistent quality and plays a significant role in the outcome of the study. Hence the softwares play important role not only in reducing time, but also helps to improve the data quality and cost factor in Clinical Research domain.

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