SOFTWARES USED IN PHARMACOVIGILANCE AND CLINICAL TRIALS

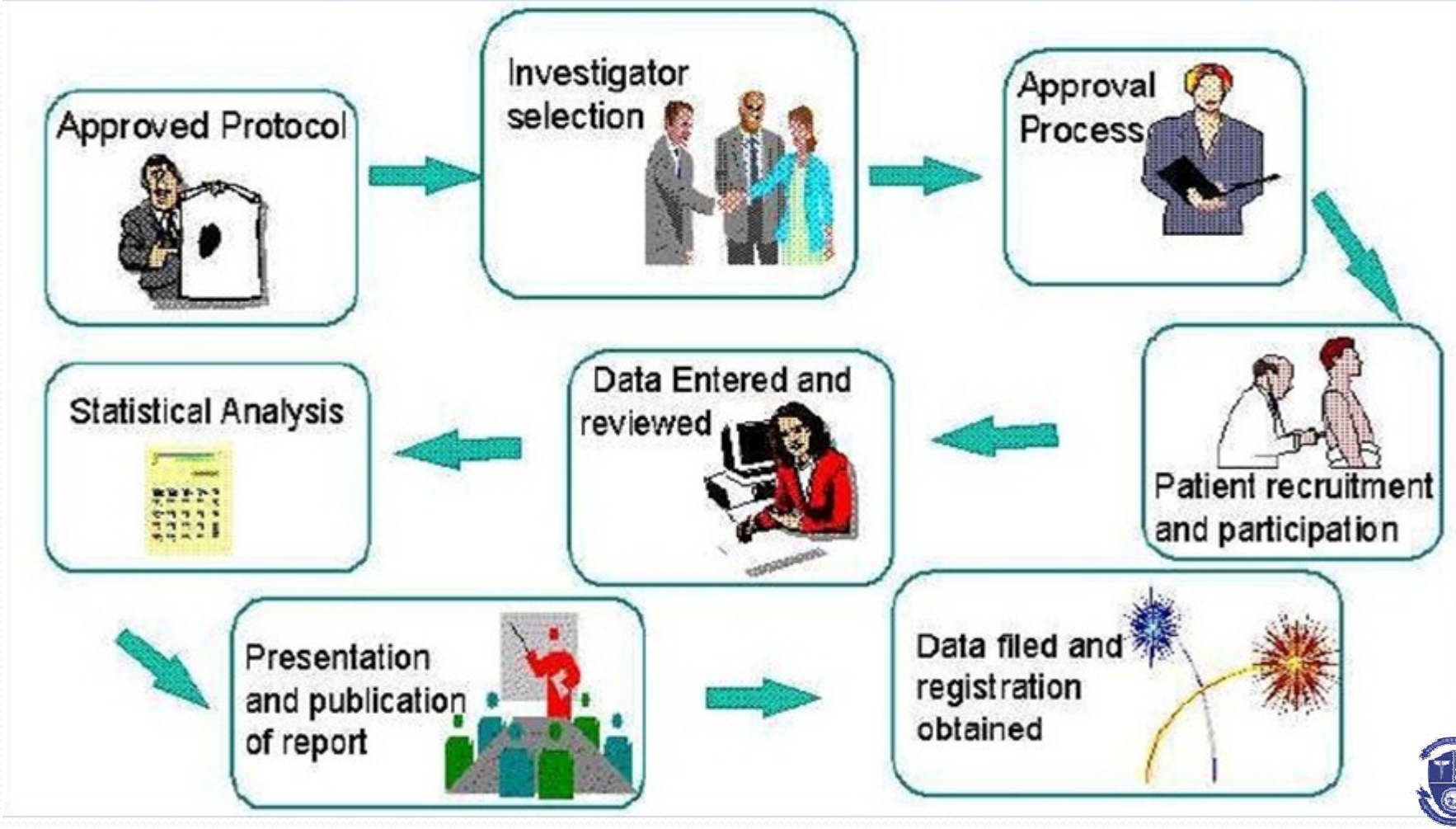
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INTRODUCTION



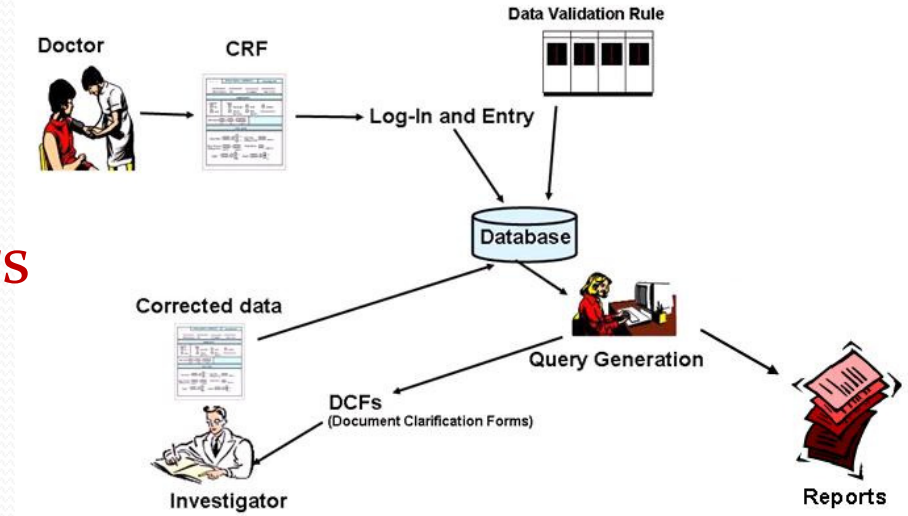
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- Clinical Trials software reduces administrative burdens and workloads by consolidating information in a single location that facilitates collaboration between all the research personnel.



- Benefits:
  - Accurate, legible, original and authentic
  - Complete, consistent and enduring
  - Available when needed

How it helps?



- Investigators and Co-ordinators
  - Easily create protocols
  - Track enrolment and progress
  - Communication with research personnel's
  - Track financial activity
- Administrators
  - Report on clinical trials for multiple departments
  - Verify compliance with institutional requirements
  - Customise the trial environment

Softwares used in Clinical research are broadly divided into different domains

- Trial management
- CDM
- Pharmacovigilance

Clinical Trial Management System

- Software system used to manage clinical trials in clinical research.
- Maintains and manages planning, performing and reporting functions.
- Patient management and recruitment, investigator management at the study site and CRO site.

Softwares for CTMS

SOFTWARES	FEATURES
Open Clinica	Unified interface, Electronic data capture
RealTime-CTMS	Patient recruitment, study tracking, financial accounting, scheduling
Allergo CTMS	Activity and status of trial
Clinical Conductor CTMS	Research sites, AMC's, CRO's
Bio Clinica CTMS	Supports studies of all types
BSI CTMS	BSI Business systems Integration

Contd..

SOFTWARES	FEATURES
Ag Clinical	Planning and tracking clinical trial activities.
Clinical Trials Management	For sponsors and CRO's to expedite clinical trials
Ques Gen Platform	Web-based solution designed specifically for configuring and managing clinical databases
Open Text Clinicals	Case report tracking process

Clinical Data Management

- CDM is the process of collection, cleaning, and management of subject data in compliance with regulatory standards.

- Generation of high- quality, reliable, and statistically sound data from clinical trials.

Objective:

- To provide high quality data for accurate drug evaluation.

Contd..

Processes involved in CDM :

1. Case Report Form (CRF) designing
2. CRF annotation
3. Database designing
4. Data entry
5. Data validation
6. Discrepancy management
7. Medical Coding
8. Data extraction
9. Database locking

Softwares for CDM

Most of the CDMS used in pharmaceutical companies are commercial.

Softwares	Features
ORACLE CLINICAL	Integrated CDM and remote data capture
CLINTRIAL	Provide real time data access and enhanced data quality
MACRO	EDC for all trials from phase 1-4
RAVE	Flexible, scalable, configurable
E Clinical Suite	Simple, fast and affordable for collection of data

Softwares	Features
Open Clinica	EDC
Open CDMS	enable researches to manage full cycle of their clinical research
Trial DB	EDC
Phosco	EDC

Medical Coding

- Medical coding helps in identification and proper coding of medical terminologies related to the trial.
- MedDRA - coding of adverse events
- WHO-DDE - coding the medications
- WHO-ART -adverse reactions terminology
- WHO HD – herbal concomitant medications
- WHO DDC – translates into WHO DDE

PHARMACOVIGILANCE

Pharmacovigilance 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

ARIS g

- Leading Pharmacovigilance and clinical safety system
- Manage adverse event reporting and adverse reaction
- Applicable for vaccines, biologics, devices
- Flexible and scalable
- Can be used by small companies and large organisations

PvNET

- Supports to segregate data entry, scientific assessment
- Extensive data validation and cross validation checks
- MedRA version management
- Covers full spectrum of developing good safety report

ARGUS

- Manage data from multiple sources
- Access flexible drug safety databases

Softwares Contd..

Softwares	Features
Oracle AERS	Reporting and analysis of serious adverse events of all medicinal products
PV Works	Collect and report safety data to meet all common international regulations
Clintrace	Clinical reearch, post approval marketing, drug surviellance
Pcv manager	Based on E2b and medDRA industry data standards

Post Marketing Surveillance

TOOLS:

- VigiFlow –Collection and analysis of individual case safety reports
- VigiLyze -Facilitates analysis of vigibase data
  -Global, National view of an ADR
  -Monitor international patient safety data
- VigiBase-Information about safety profile of drugs and competitive products & optimise queries
- PaniFlow- Monitor ADR during influenza pandemic

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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thank you!