System In Clinical Trial

TOOLS & VALIDATION PROCESS



Module 10 Topic 12

Types of Systems

- Clinical Trial Management System (CTMS)
- Data Capture / Electronic Data Capture (eDC)
- Data Management Work Bench or Life Sciences Hub (DMW or LSH)
- Medical Coding (MC)
- Visualization & Reporting
- Electronic Trial Master File (eTMF)



CTMS

 A Clinical Trial Management System (CTMS) is a system which maintains and manages planning, performing and reporting functions, along with participant contact information, tracking deadlines and milestones.

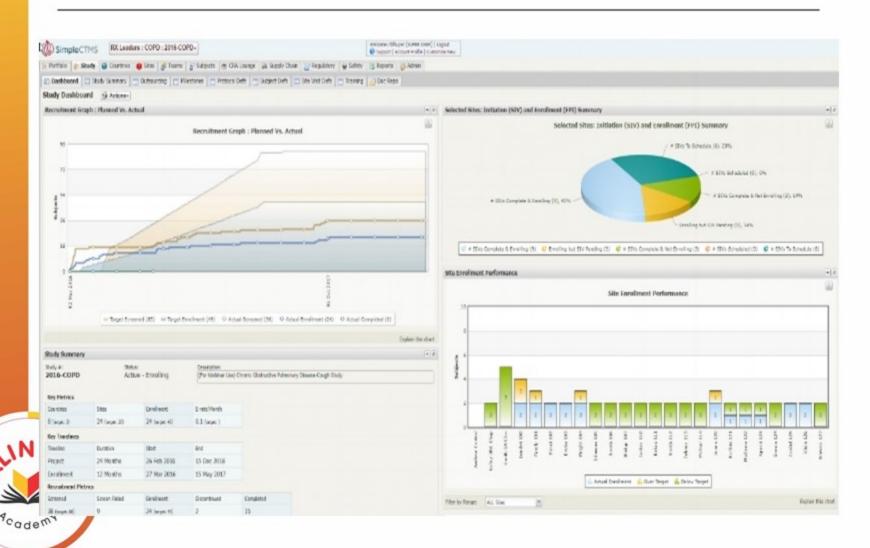


Features of CTMS

- Easy to use, flexible, customizable
- Runs in standard web browsers
- Supports large, interdisciplinary global teams or small studies and teams
- Portable for next study
- Information available 24/7
- Well defined user groups includes internal and external users, multiple departments and external vendors
- One system for both blinded and unblinded user types
- Multi-study and portfolio management within one system



Features of CTMS (contd)



Features of CTMS (contd)

- Portfolio and Study Management
- Countries Planning and Management
- Site and Investigator Management
- Subject Management
- Study Team Management
- CRA Workspace
- Regulatory Affairs and Safety

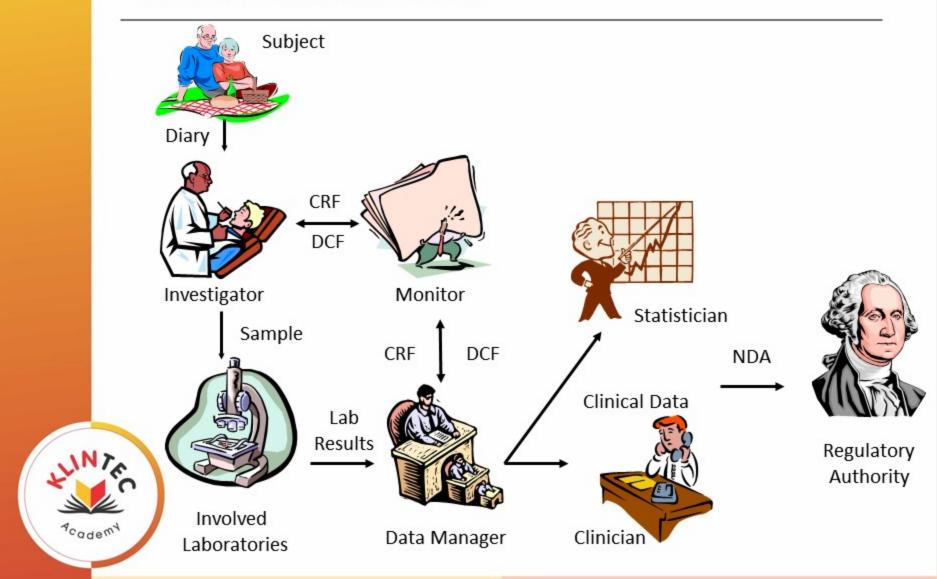


Data Capture or eDC

- Compatibility
- Ease of Use
- Common Sense Organization
- Internal Communication
- Versioning
- Backup and Security
- Mobile Compatibility
- Workflow and Project Management
- Collaboration
- Scalability



It's all about Data



Preferred Software Characteristics

- Standards based
- Well known → many skilled practitioners available
- Readily mastered and modified
- Should run on any platform
- Should be affordable for small groups in resource constrained countries



Technology Best Practices

- Audit trail must be independently generated
- Ensure that system maintains a "irrefutable link" between documents, metadata and the electronic signature.
- Establish clear electronic signature manifestations for all electronic records.
- Validate the system.
- Establish role-based access and control.
- Establish password and identification controls.
- Series of signings.
- Avoid hybrid systems, where practical.
- Do not over customize technology solutions.



DMW (Data Management Workbench) or LSH (Life Science Hub)

- Comprehensive data management for EDC, labs, and clinical data providers
- Cross data source discrepancy management, and data cleansing
- Rich mapping and transformation capabilities
- Automated data loading for seamless collaboration with data providers
- Integration with Oracle InForm
- Benefits
- Accelerates study setup and conduct, delivering cleaner data faster



DMW (Data Management Workbench) or LSH (Life Science Hub) (contd)

- Increases data quality
- Provides better regulatory compliance
- Enables more informed decision-making
- Saves time and cost by reducing time-consuming manual processes



MC (Medical Coder)

- Significantly reduces manual coding efforts for leading dictionaries with customized algorithms, synonym lists and rule-based propagation functions
- Integrates with EDC systems permitting sitequerying functionality for coding resolution
- Users provided with role-based authorization matrix including manifested hierarchies for approval workflow and overrides
- Provides users ready-to-run reports for coding classification, consistency, coded items and user reports interactive reporting screens for coding classification, coded items, approved items and multiple workflow steps



MC (Medical Coder) (contd)

- Allows coding, term and dictionary upgrades within an active study-code to multiple dictionaries concurrently allowing more productivity for users
- Clinical studies Models used for Coding -Concomitant medication, Medical History, Adverse Events, Physical Examination



Visualization & Reporting

- Graphic Patient Profile
- Patient Review Tracking
- Tabular Patient Profile
- Formated Patient Profile
- Patient view
- SAS as Data Source
- Date wise Patient report
- Graphical view



Visualization & Reporting (contd)

- Risk Assesment
- Benefit Risk Analysis
- Baseline and Endpoints
- SAS programs
- Patient Narratives
- Multi-study analysis
- Output & Setup



eTMF

- Electronic Trial Master File
- eTMFs have rapidly replacing paper trial master files in CROs, Pharmas, Biotechs, and the Device industry.
- An industry coalition, the TMF Reference Model (TMF RM), meeting under the auspices of the Drug Information Association (DIA), has been instrumental in developing a reference model to standardize TMF document collection and management.



eTMF (cond)

- Robust Access Control
- Unlimited Roles
- Customizable archiving
- Missing Essential Documents Report
- Electronic Notifications
- Electronic signatures
- Managing Communications
- Robust, Flexible Reporting and Search Capabilities
- Account Management
- Metadata Management
- TMF Processes

