**Clinical Data Management** is a critical process in clinical research, which leads to generation of ***high-quality, reliable, and statistically sound*** data from clinical trials.

**START-UP**

**-Database Design**(Organized Collection of CRF),

**-CRF design-**-Case Report Form (tool used to collect pt infor),

**-CCG-CRF Completion Guideline**(*Based on Protocol and CRF the CCG is designed*)

- **DMP**-Data Mgt Plan(*Documents which tells us how to manage, describe, analyze and store data, and also what mechanism to share and preserve data*.

**-DVP**-Data validation Plan(Doc which describes data quality checks, where and how to find errors.

**-DTA**-**Data transfer Agreement**, **DTS**-**Data transfer specification**.

CRF template consist: **1**.**Header information** which includes **Site no, subject id, protocol id, pt id**) **2.safety Module** which consist **Demography, AE, Vital signs, Medical history, Physical examination** and **concomitant medication. 3. Efficacy Module**(Varies Based on the diagnostic procedure and the therapeutic area e.g. Biomarkers in oncology)

**QC**- Quality Control done by the QC Team, **UAT**-User Acceptance Test done by the Data Manager, **IST**-Integrated system testing done by sponsor or DM.

**DATABASE GOES LIVE**

**Site Adds data into database**

**STUDY CONDUCT -Data Entry Source includes: 1.Direct Capture*(By Site Staff into the EDC System),* 2.Non CRF(*Direct capture of data in electronic format from internal sponsors and external vendors eg Outside Labs into the EDC)*, 3.Devices And Apps*(Mobile devices, Smart watches etc)*, 4.Electronic and Health Record System*(Data from Electronics Health records)*, 5.Safety Database*(Adverse events data)***

**- Medical Coding:*They code data entered to standard Medical terms acceptable across all platform (eg Lungs to pulmonary, eye to optical)***

**- Data Cleaning: Data Review(*Done by CDM to look for Discrepancies,mistakes or inconsistencies*)**

**-Query generation(Query raise by CMD to site)**

**-Discrepancy Mgt(*clarification and expected response from site*)**

**-Lab reconciliation(*Reconciling lab results from internal and External Lab*)**

**-SAE Reconciliation(*Reconciling Adverse Events capture for two DB systems(eg from clinical DB and Safety DB eg Argus).***

**- Resolution And Update Database:**

**- QC: *To make sure everything is in place before Data Lock***

**- Ready For FREEZE(*soft lock- can still be Changed by privileged user*) And DATA LOCK(*Final Lock- No changes are allowed*)**

**CLOSE-OUT Pre-Lock Checklist(*Data Review, Review Coding, Check SAE, Query Status, SDV by CRA, Signatures[CDM,MDR,Coder,PI,Sponsor].***

***Hard lock:***

***Sent to BIOSTATS:***

**REGULATORY GUIDELINES:**

**-Code of Federal Regulations(CFR), 21 CFR Part 11*(This demands the use of validated systems to ensure accuracy, reliability, and consistency of data with the use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records)***

***-Good Clinical Data Mgt Practices***

***-ICH-GCP E6(r2)***

**-Clinical Data Interchange Standard Consortium CDISC*(developed standards to support acquisition, exchange, submission, and archival of clinical research data and metadata.)***