Overview of Clinical Data Management

Module 10 Topic 1

Objectives

- To understand the steps involved in the Clinical Data Management Process
- To understand how Clinical Data Management is structured
- To appreciate how the timing of Clinical Data Management tasks can affect the Clinical Data Management Process

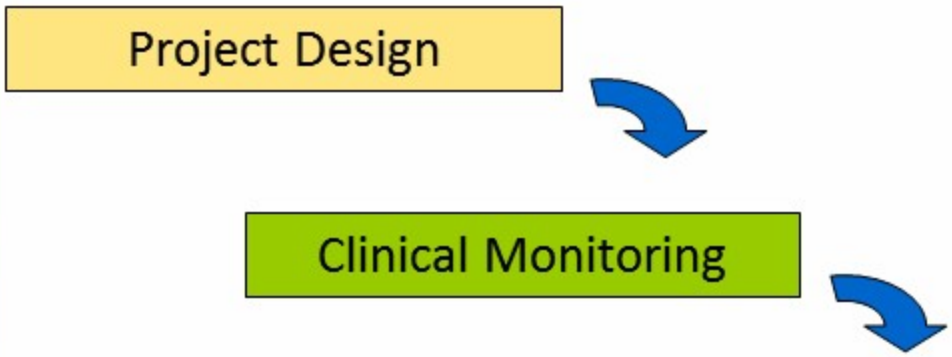
Clinical Data Management

The implementation of a system to CAPTURE clinical data to produce a high quality analysable database with complete accountability for the integrity and completeness of clinical trial data.

Clinical Project - Work Flow

Project Design

Clinical Project - Work Flow



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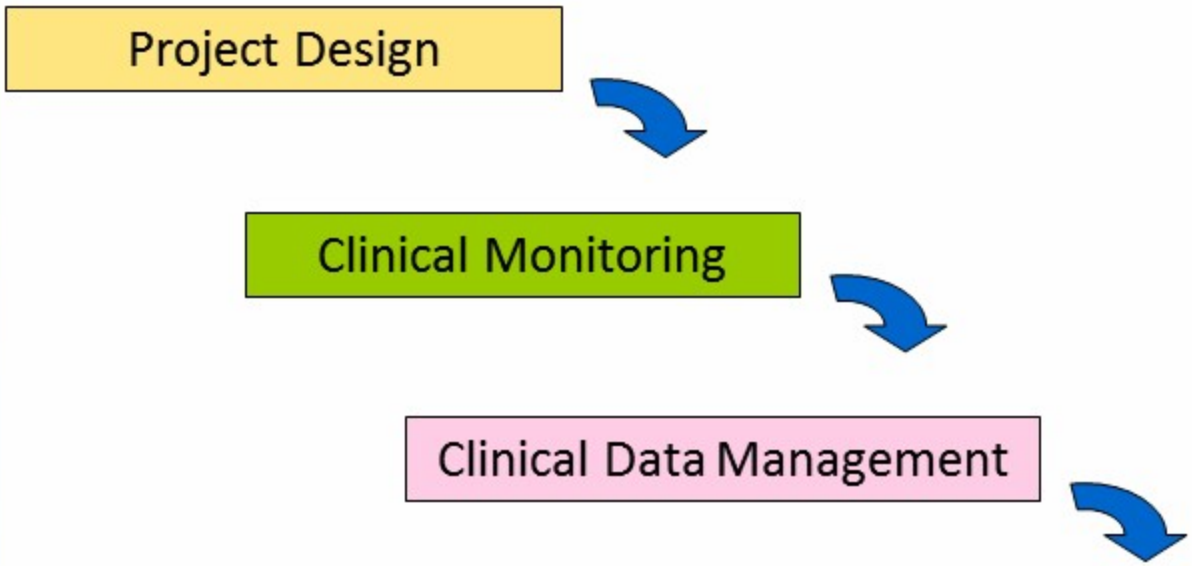

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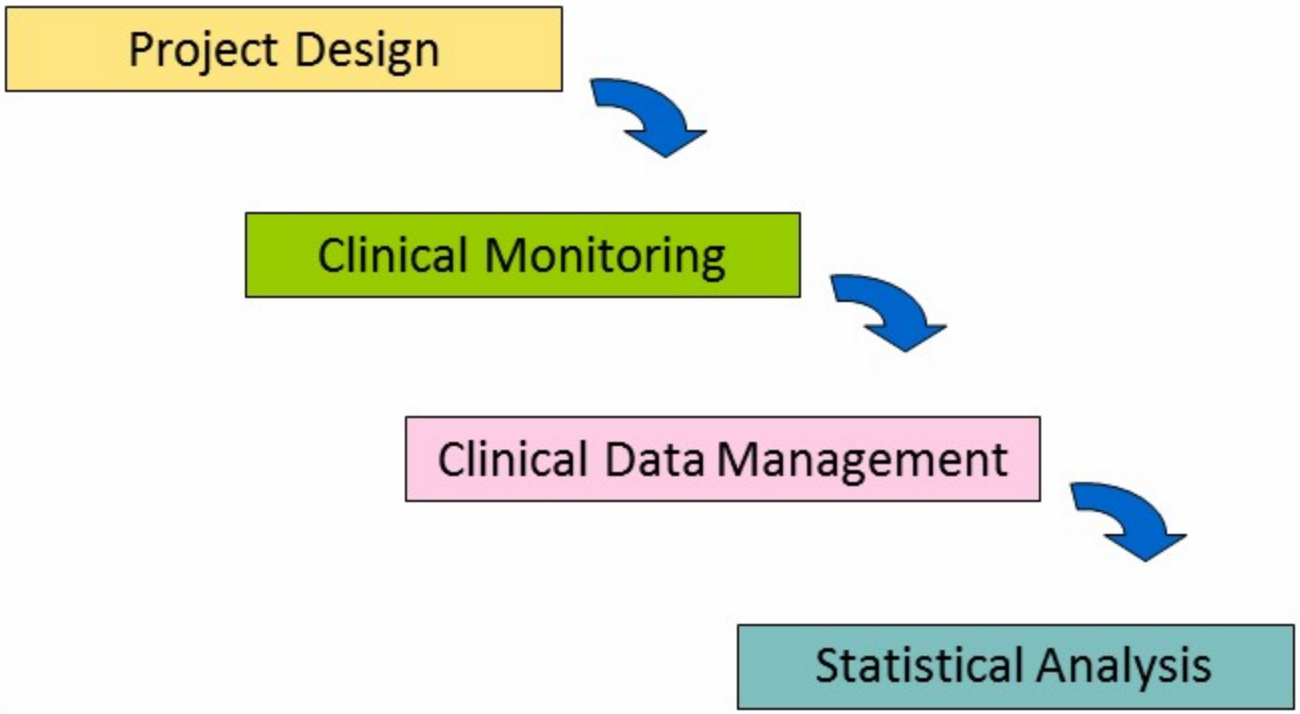

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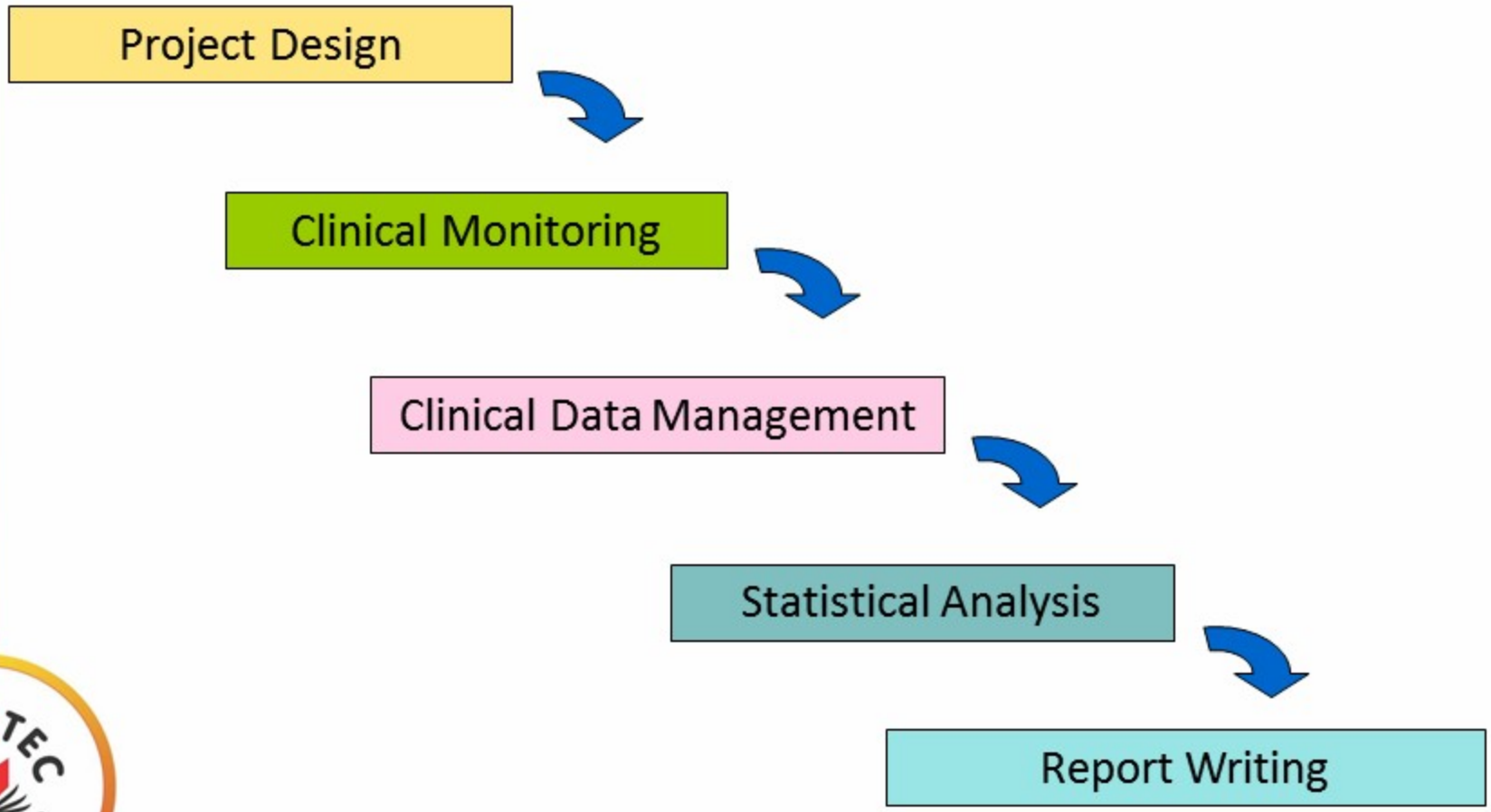
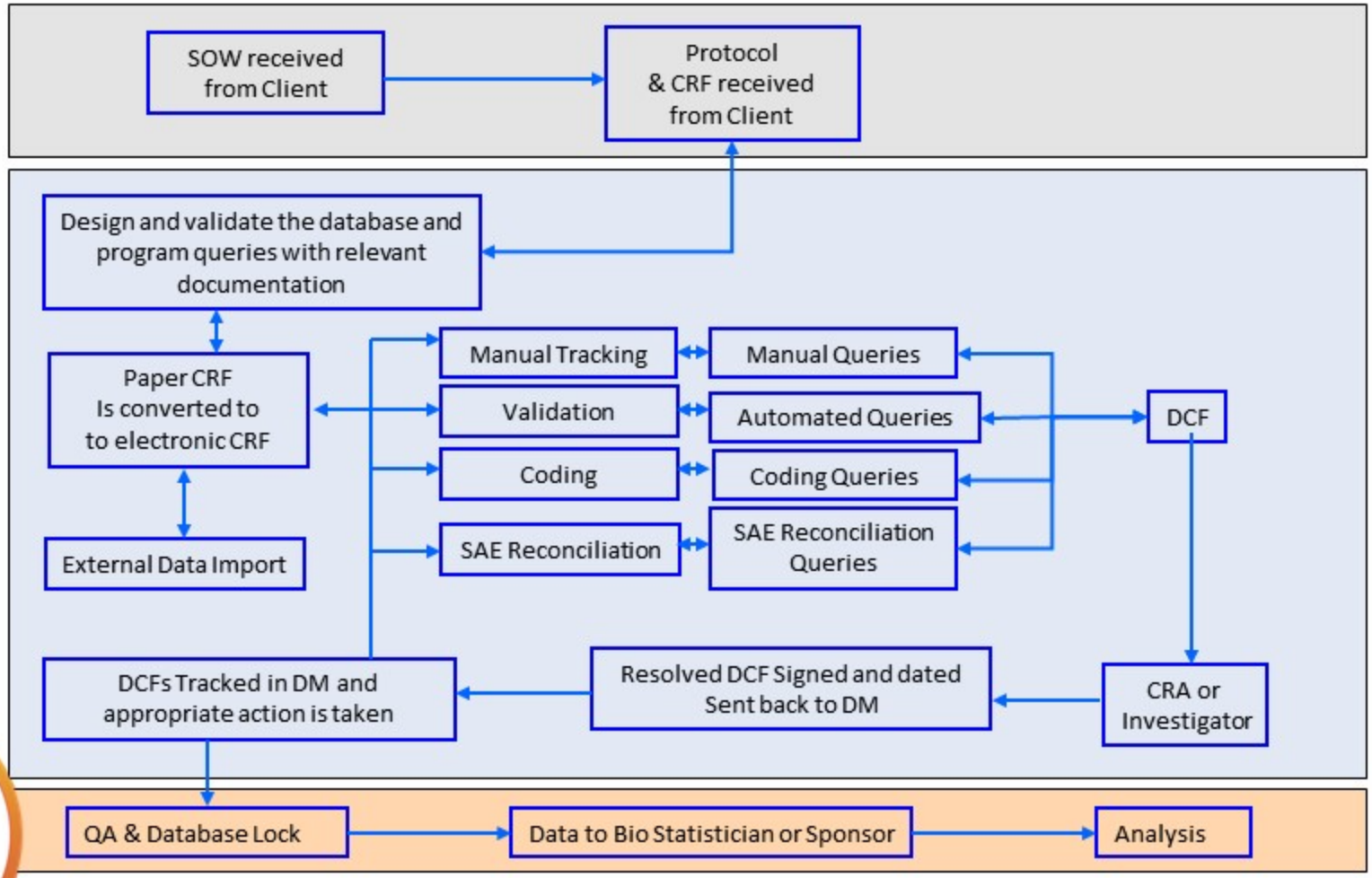


CDM : A project life cycle



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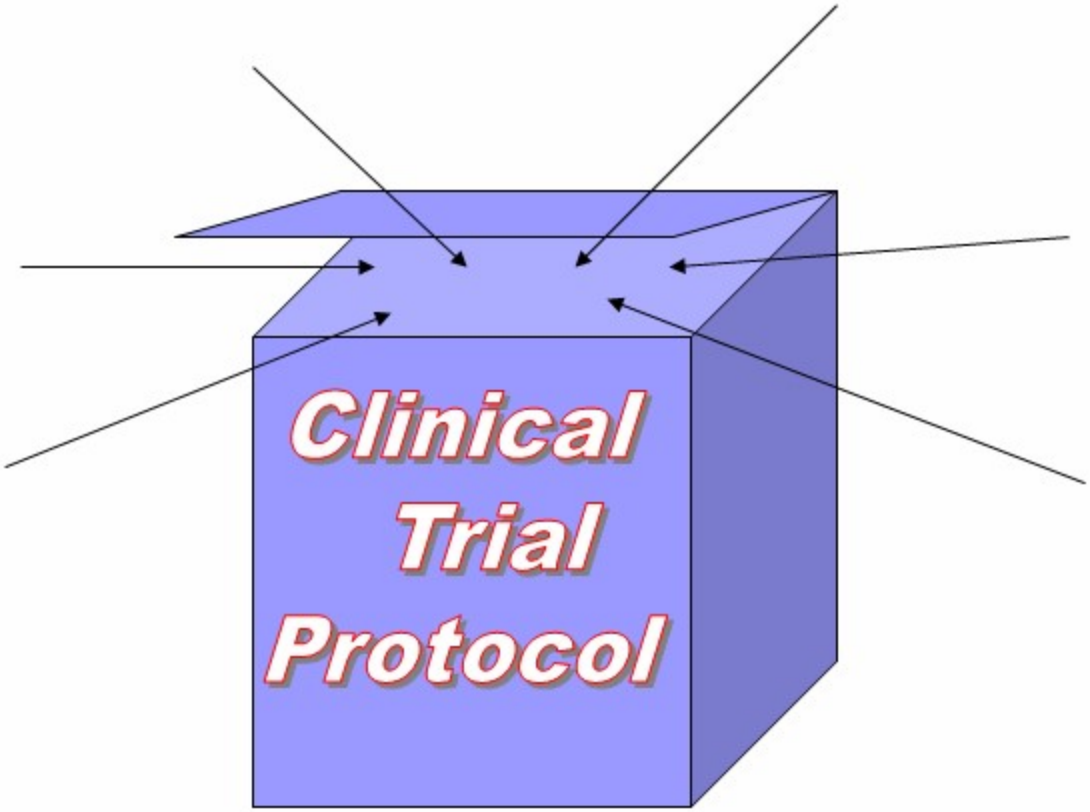

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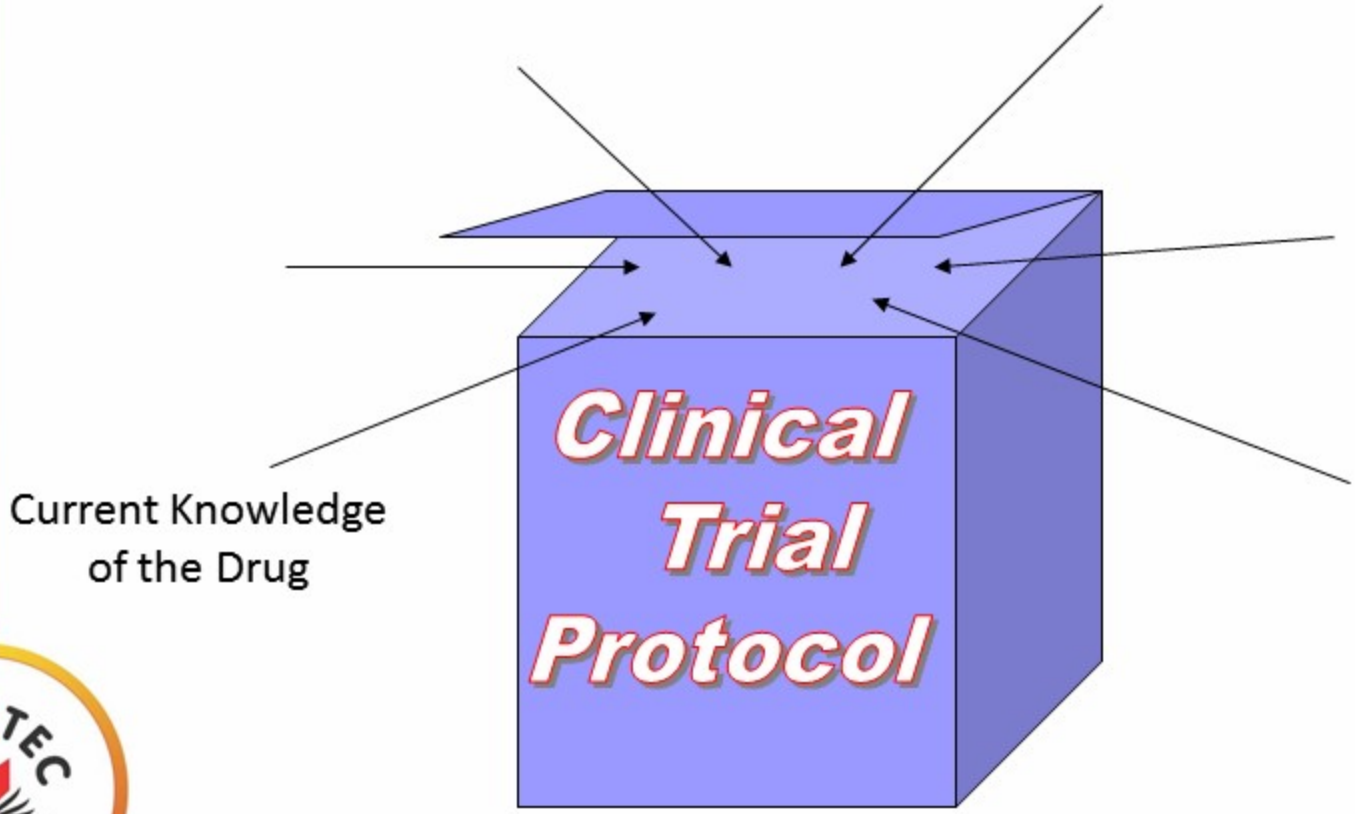

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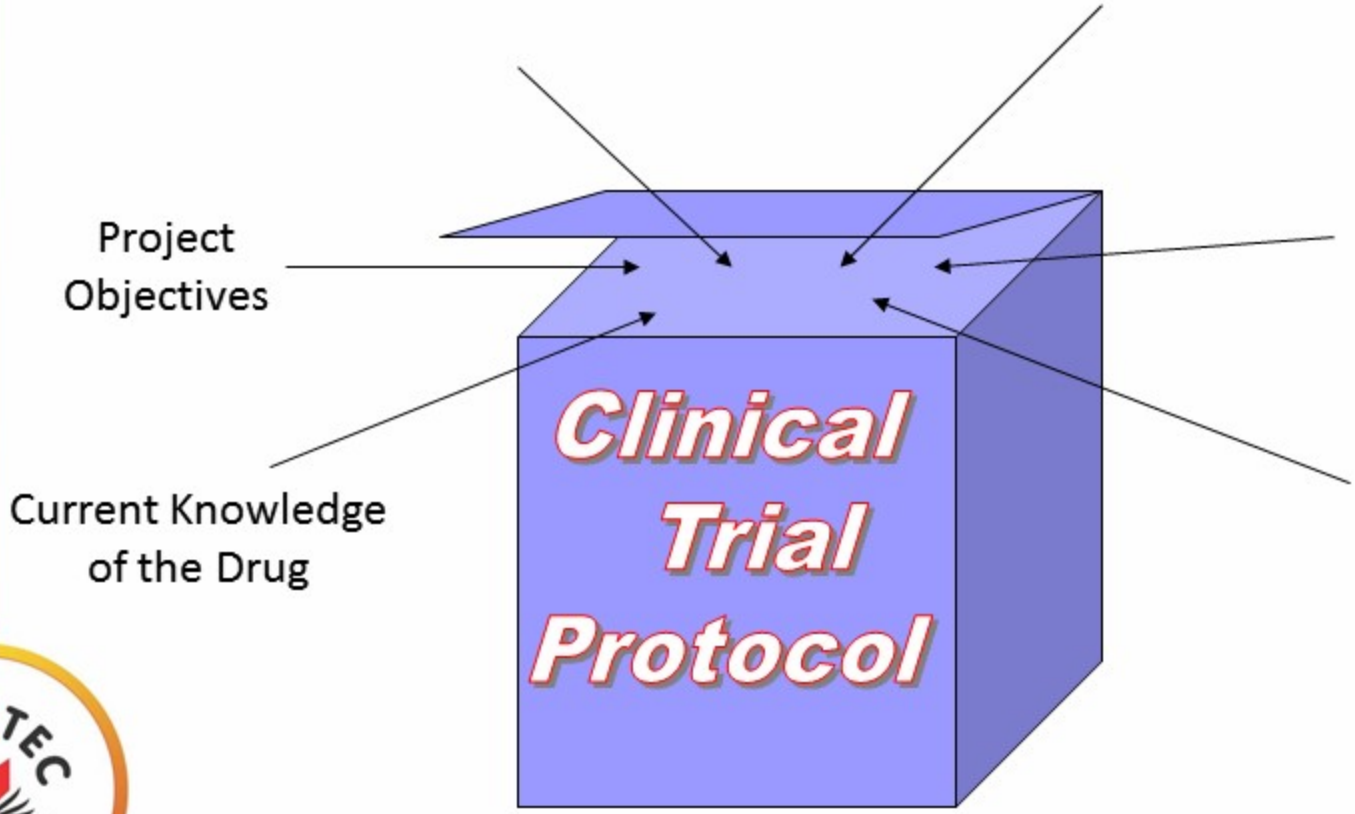

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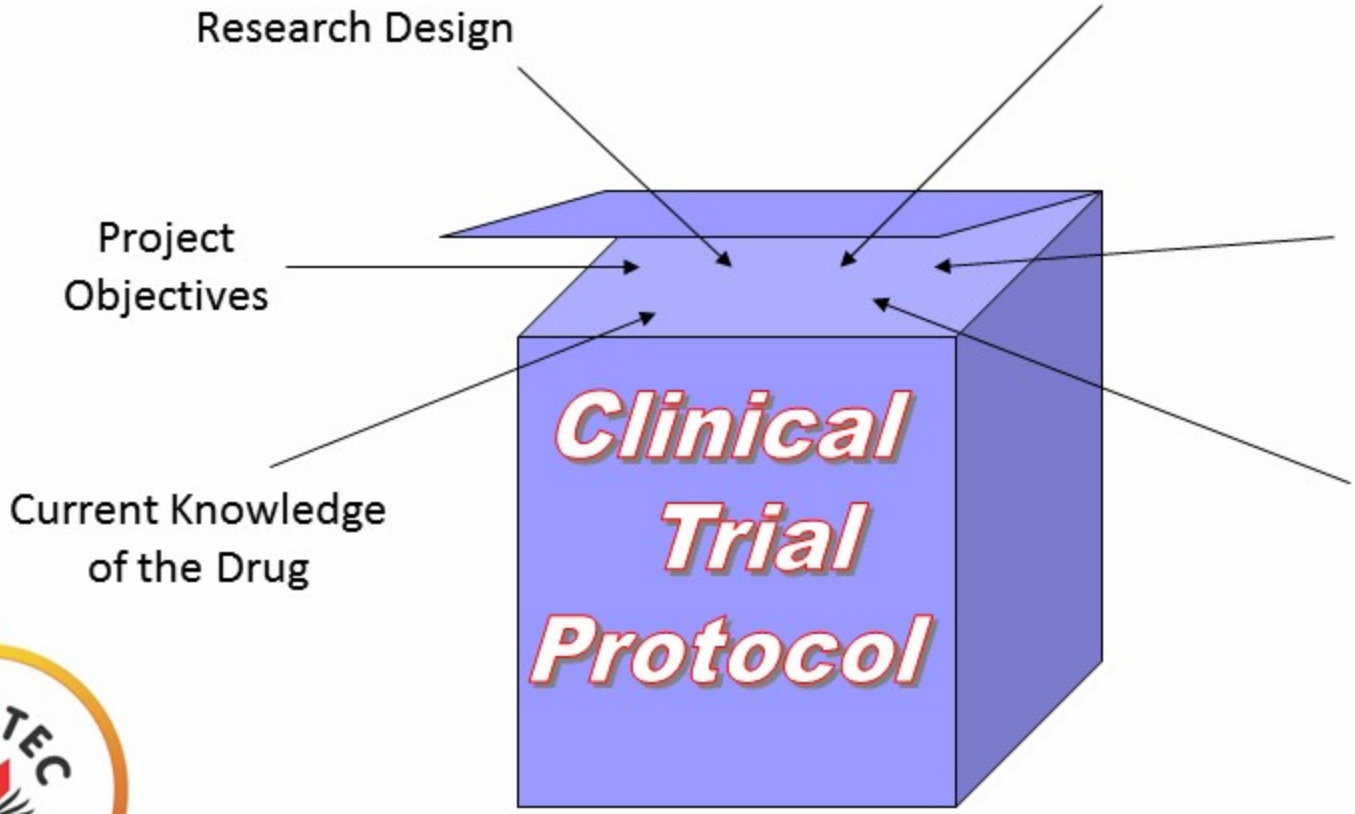

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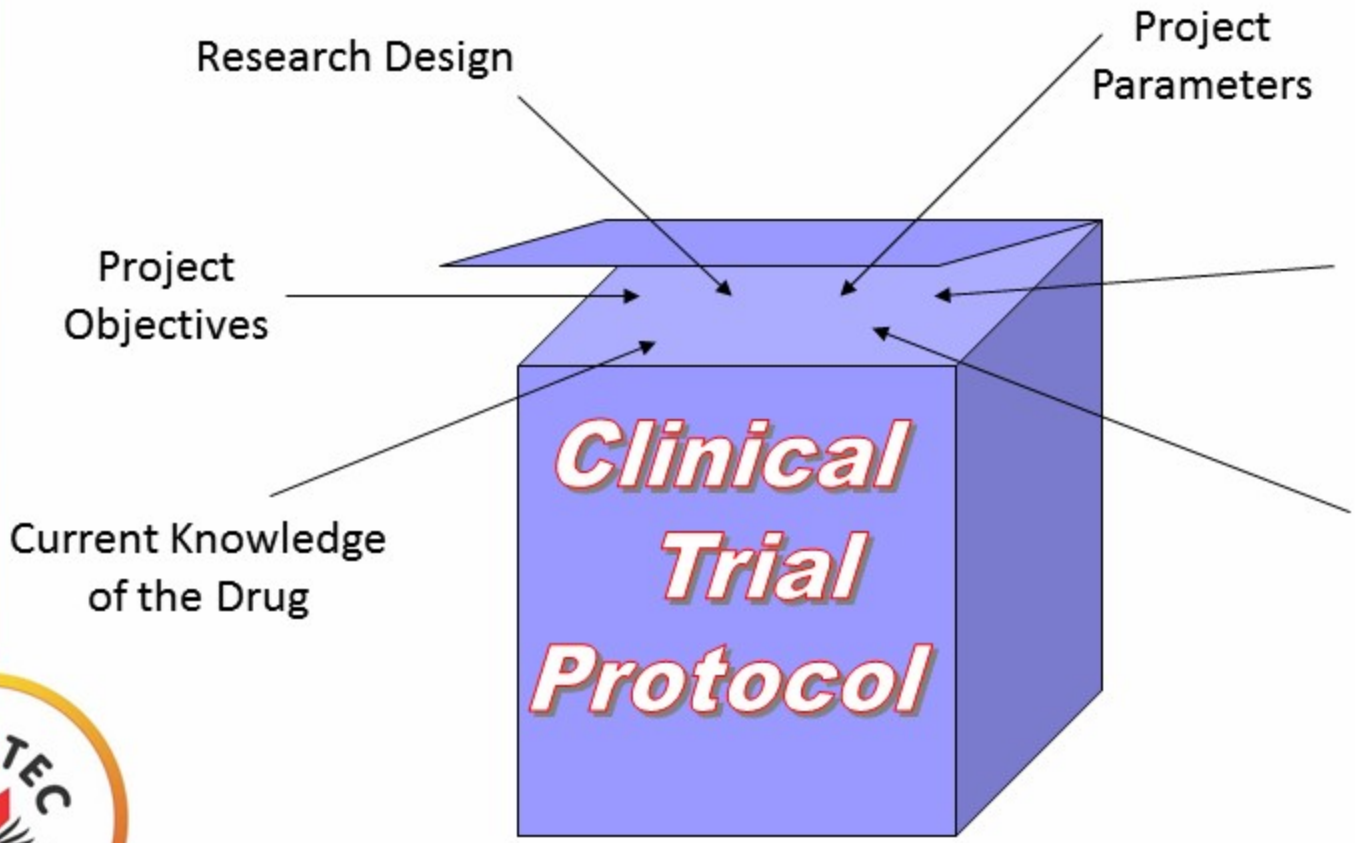

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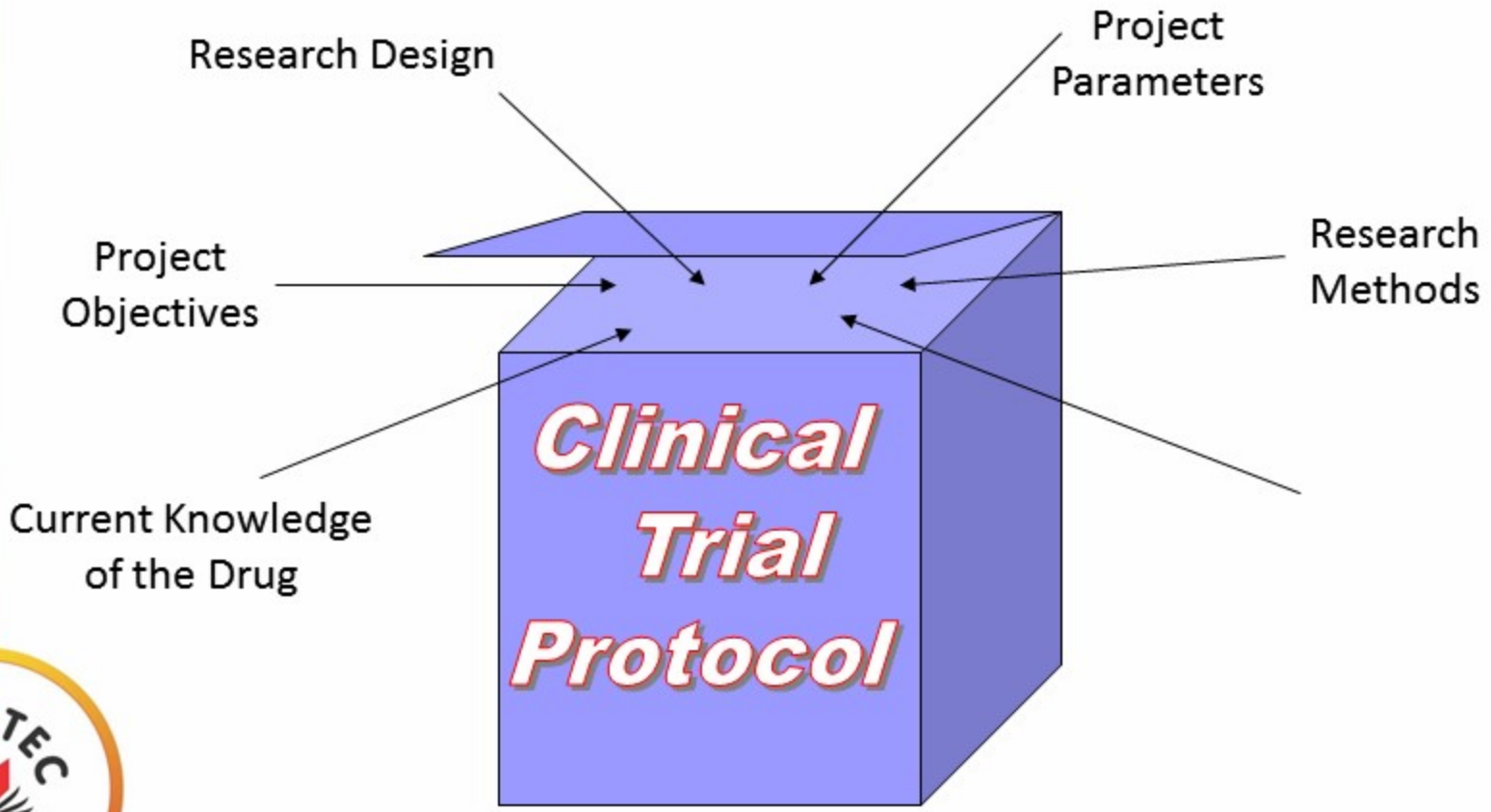

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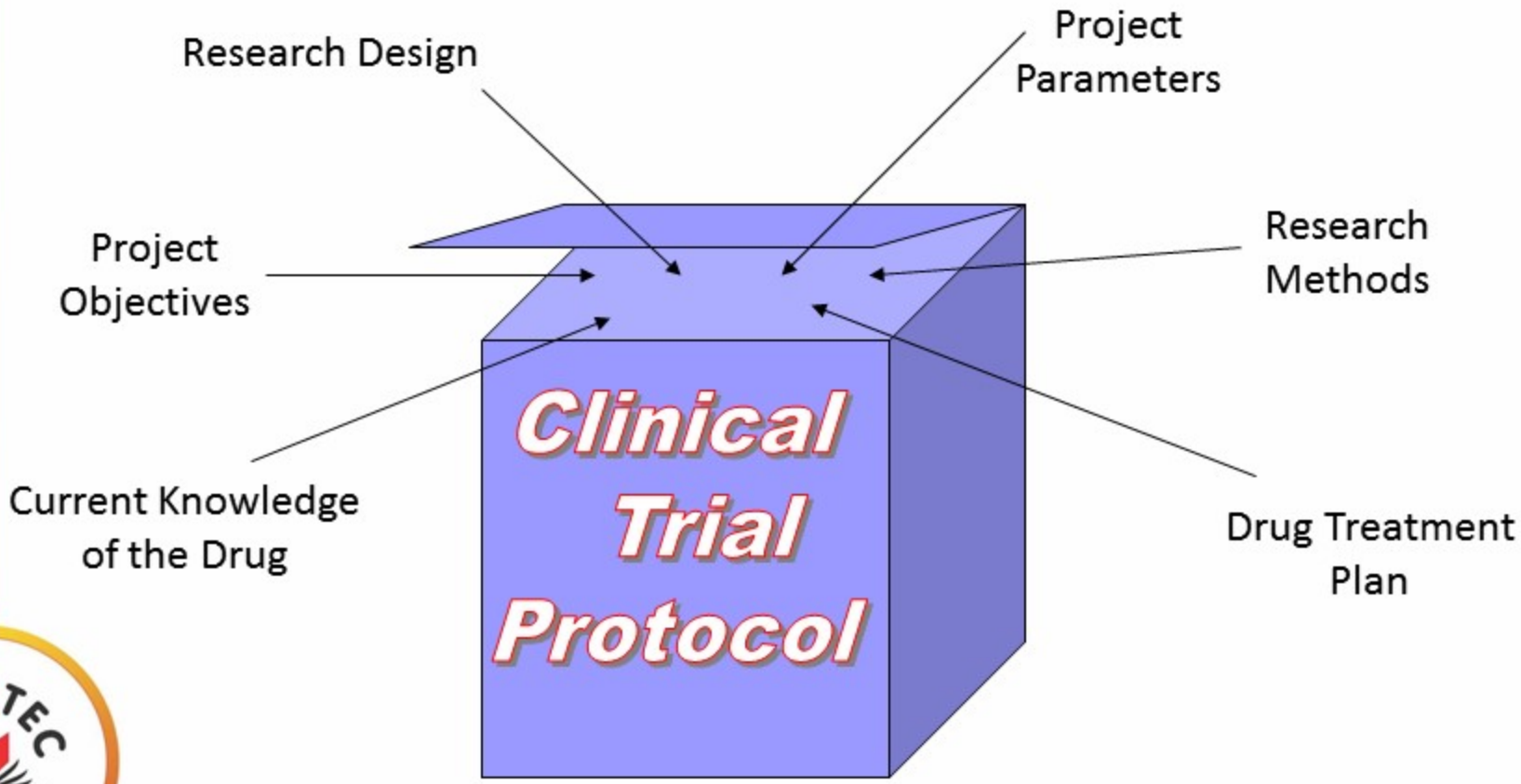

What Do I Look for in the Protocol?

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- General Information

What Do I Look for in the Protocol?

- General Information
- Phase of the Project

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- Key Safety/Efficacy Variables

What Do I Look for in the Protocol?

- General Information
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- Patient Population
- Type of Data
- Treatment Schedule
- Clinical Information
- Key Safety/Efficacy Variables
- Expected Adverse Events

The Protocol is compared to SOW for the contracted activities.

What is a CRF ???????

- CRF = Case Report Form
- A printed, optical or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.
- And can be anywhere between 50-250 pages

CRF Design should be …

- Clear, user friendly for all users.
- Inputs from Stats, Clinical, DM to be taken while designing the same.
- International Conventions
  - Date format DD-MM-YY
    MM-DD-YY
  - Number format 1,000 / 1.000
    0.5 / 0,5

The CDM Phases – Project Set Up

Clinical Database Build – creating a **screen** in the electronic database for each CRF page

How is this done ?

- Annotate CRF : identifying the way a “field on the paper/scanned CRF corresponds to an identical field in the electronic database” (e.g. CRF reads “ Patient Date of Birth” while on the electronic database you would search for this under “DOB”)
- Creation of project database
- Clinical Database acceptance testing

Database Annotated CRF

CONTEXT
CONTEXT

AstraZeneca	Protocol Number 0859IL/0078	Centre Number (CENTNUM)	Patient Number (PATNO)	Patient Initials (PATINIT)	Visit Number (VISIT) 0 1	Form ID (FORMID) 1

REFKEY

CONSENT
CONSENT1N

INFORMED CONSENT	Date of Screening Assessment : Day / month / year (CASSDT, DASSDT)

1. Was written informed consent obtained prior to randomisation ? (CPREYN *YN)
   - ☐ Yes — Date obtained : Day / month / year (CCPREDT, DCPREDT) — Obtained from : (OBPRE *REFCE) ☐ Patient ☐ Legally acceptable representative
   - ☐ No - Please answer question 2

2. Was written informed consent obtained after randomisation for the patient to continue in the study ? (CAPSTYN *YN)
   - ☐ Yes — Date obtained : Day / month / year (CCPSTDT, DCPSTDT) — Obtained from : (OBPOST *REFCE) ☐ Patient ☐ Legally acceptable representative
   - ☐ No - Please answer question 3

3. Date consent asked for : Day / month / year (CCASK, DCASK)

Reason consent not obtained : (REASNOB *REASOB)
- ☐ Patient unable to give consent and no legally acceptable representative available.
- ☐ Consent refused by the patient or legally acceptable representative
- ☐ Other, please specify : OTHSP

Investigator's Signature : INSIGYN *YN   Date : Day / month / year (CINVDT, DINVDT)

INCL
INCL1RA

INCLUSION CRITERIA

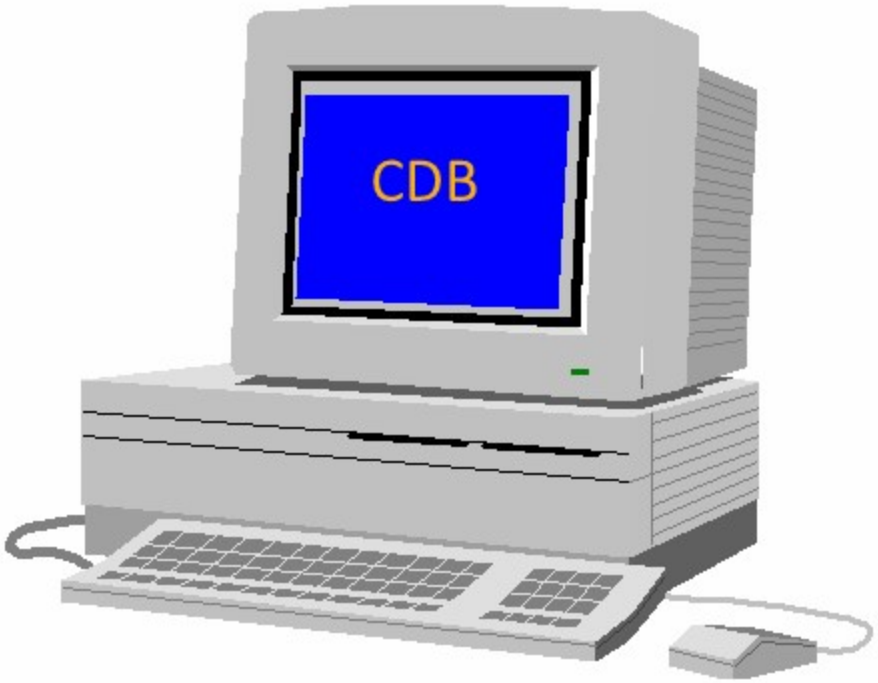
For inclusion in the study, patients must fulfil all of the following criteria : (CRTERIA *INCLCRIT) (RESPONS *YN)

		YES	NO
1.	Male or female, aged ≥ 18 years.	☐	☐
2.	Provide written informed consent prior to any study-specific procedures taking place wherever possible. Where patients are unable to provide written informed consent (for whatever reason), written informed consent from the patient's legally acceptable representative given prior to any	☐	☐

KLINTEC Academy

CDMS

Clinical database management systems (CDMS) are designed to perform many tasks



Platforms on which Databases are built

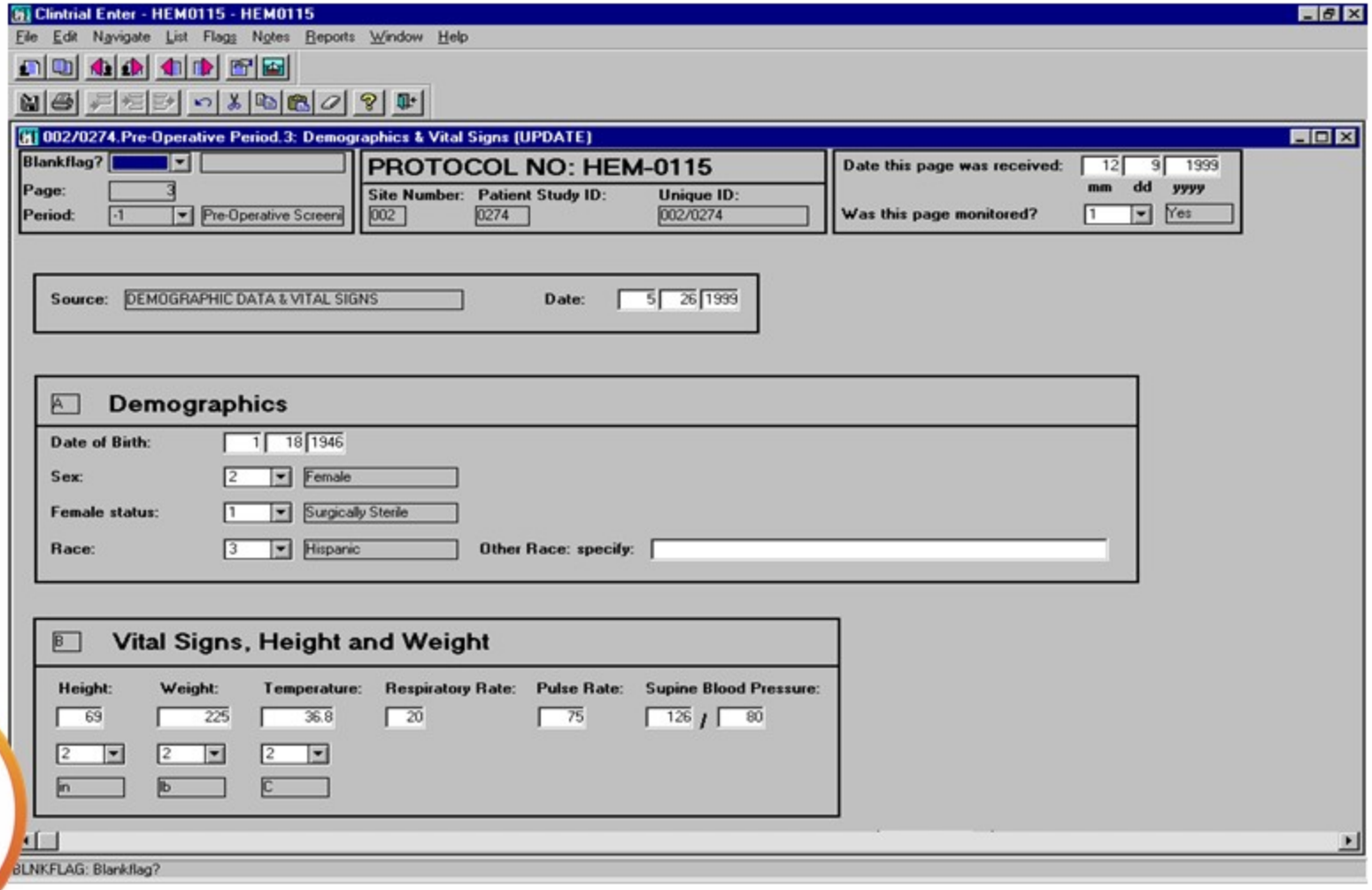
- Oracle Clinical (OC) – Version 4.0.3 (Paper / Web)
  - Is a product from Oracle itself
  - Used by more than 5 of the top 10 pharmaceutical companies
- Clintrial (CT) – Version 4.5 (Paper / RDC) &
- Inform – Version 4.0 (Web)
  - Is a product from Phaseforward itself
  - Backend is Oracle
  - Used by more than 5 of the top 10 pharmaceutical companies
  - More user friendly

Items in the Database

Clinical data management systems (CDMS) like OC / CT or Inform is designed to execute the following tasks:-

- Database build
- Design
- Enter
- Validate
- Store
- Retrieve
- Manipulate
- Trace

Example of a Clintrial Data Entry Screen



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- Each Question in a CRF = a database item.
- Items are assigned various attributes (Number, Text etc.).
- Data easier to collect and easier to analyse
  - SEX - Code-listed
  - DOB - Date
  - Weight - Numeric (specific length specified including decimal point)

Specifying Data Checks

- Specified during the project set up phase using the Clinical Database Annotated CRF
- Designed to highlight every possible inconsistency or error
- Clinical Personnel and Statisticians involvement is mandatory

CDM Phases – Data Processing Phase

How is this done ?

- Tracking (receipt of CRF's, logging in of CRF's)
- Imaging of CRFs
- Data Entry
- Data Validation
- Data Cleaning (Query resolution)
- Data Coding

Tracking

- CRF's (Paper / Fax/ Courier) are received by the CDMr / Study team and the receipts are logged into the relevant tracking system

- Manually check headers/ footer/ patient IDs and comparing with CRF transmittal log & logging discrepancies

- Updating the CRF received details into the applicable system

CRF Imaging

- Can bring in virtual resource from onsite offices when needed
- Images can be provided back to the client as PDF files at the end of the project
- Images can be provided to the client periodically as agreed
- Clinical Trial Monitors will have access to the images, therefore do not need a paper copy of the CRF

Data Entry

Various methods such as :

- Single Data Entry (SDE)

- Double Data Entry (DDE)
  - Blinded
  - Interactive

Common Problems - [Encountered while entering data]

Subject No. 05 Subject Initials [illegible]

Adverse event

Tick if NO adverse events occurred No ☐ PLEASE NOTE: In case NO adverse events leave page blank

Adverse event number 04

Diagnosis/syndrome of adverse event [illegible]

Start of adverse event: Date 02/03/2004 Time (24-hour clock) 10:45

End of adverse event: Date 30/03/2004 Time (24-hour clock) [illegible]

What is the relationship to study medication?

☐ probable ☐ possible ☑ unlikely ☐ not related ☐ insufficient data to assess

What is the intensity of the AE?

☐ mild ☑ moderate ☐ severe

Was the AE serious? No ☐ Yes ☐

What was the outcome of the AE?

☑ resolved ☐ resolved with sequelae ☐ continuing ☐ death

Were any corrective therapies administered? No ☐ Yes ☑

If yes, please complete a Concomitant Medication Form.

Investigator's name (block letters or stamp): Dr. Elger CE

Signature: [signature] Date: 07/04/2004

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Data Validation

- Validation is a process which is run after data entry is complete

- This enables us to check for all inconsistencies in the form of a query which is then worded accordingly and sent out in a QF

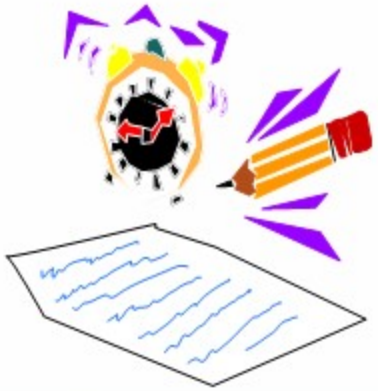
Data Cleaning

- Data is cleaned and in the process Queries are generated.

- Queries can be either:
  - **Electronic queries:** these are generated by the system automatically for missing data, out of range values, etc. These are also manually reviewed

  - **Manual:** these are queries that are generated on manual review of CRFs (e.g. incorrect header information, text fields/comments section)

Queries will address



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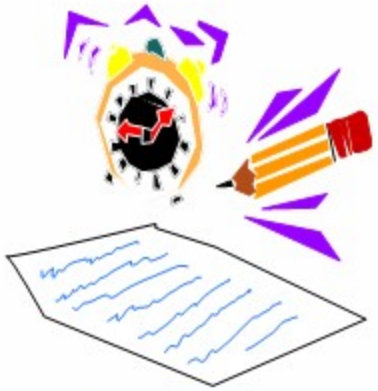

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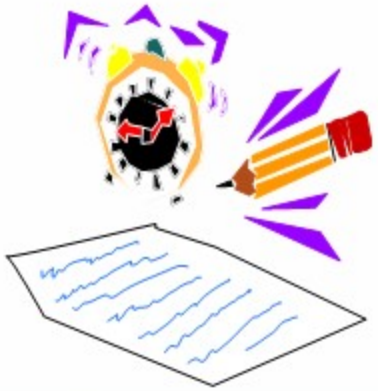

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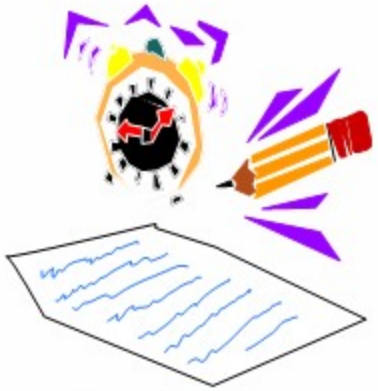

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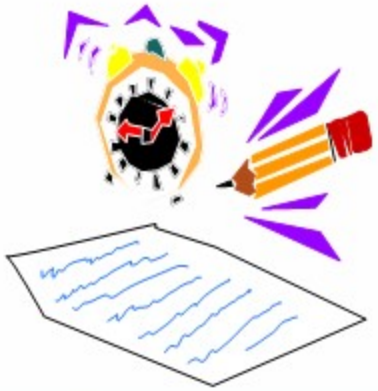
- Quality (are dates in logical sequence or not ?)



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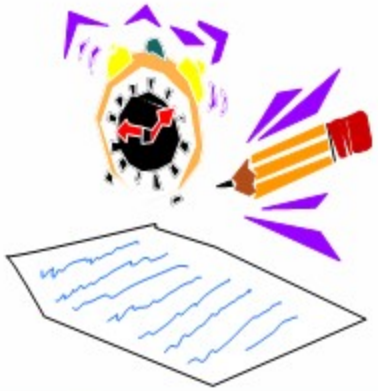

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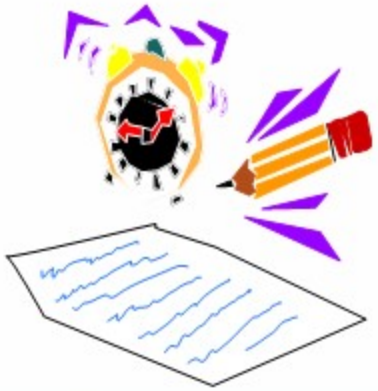

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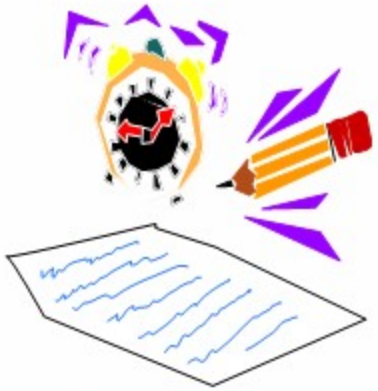
- GCP



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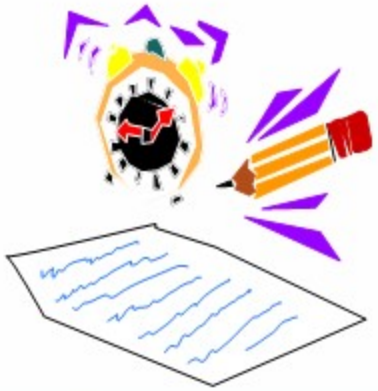


Clinical Coding

- What is Clinical Coding ?
- Why do we need it ?
- How do we do this ?

Quality Control (QC)

- What is QC ?
- **Why is it required ?**
- How is this done ?

Quality Control (QC)

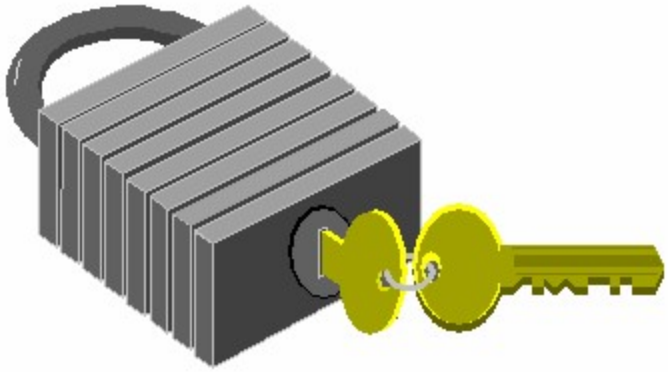
- This is done at 2 points :
  - Start – up QC (one from each site)
  - QC a maximum of 20 critical data fields in ALL CRFs

- End of study QC (sqrt(n)+1) or 20 CRF's; which ever is less

CDM – Database lock & data transfer

- Data base Lock : can be different types of locks
  - Soft lock
  - Hard lock

- After final inspection
  - All access to database removed
  - Data forwarded to Bio-statistics
  - Paper CRF's archived



CDM – Summary

CDM – Summary

Set-up Phase

CDM – Summary

CDM – Summary

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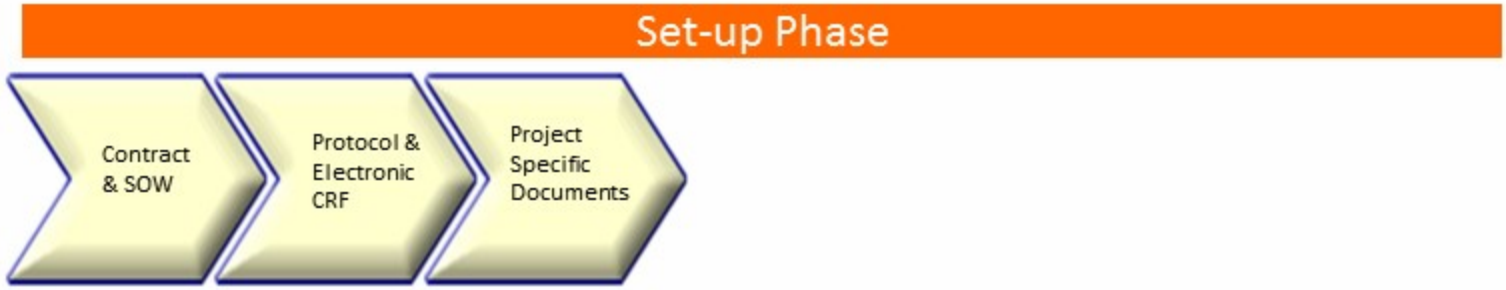
Set-up Phase
Contract & SOW
Protocol & Electronic CRF
Project Specific Documents

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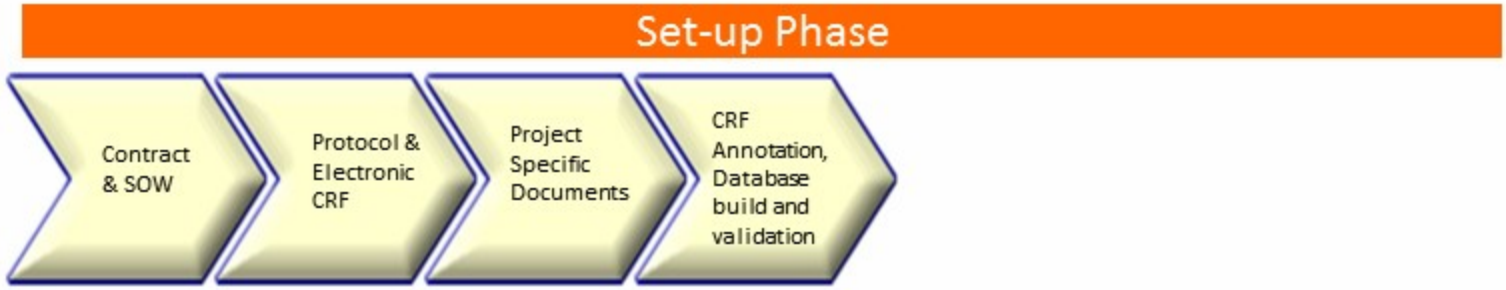
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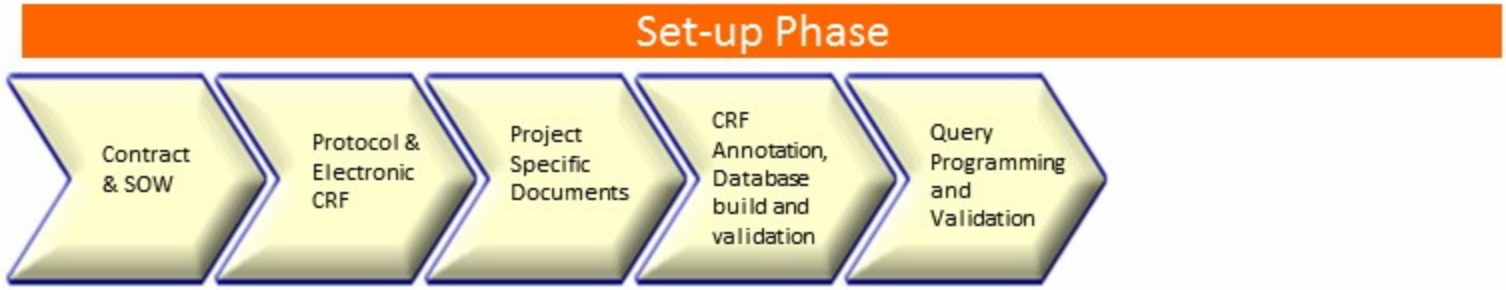
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Project Specific Documents
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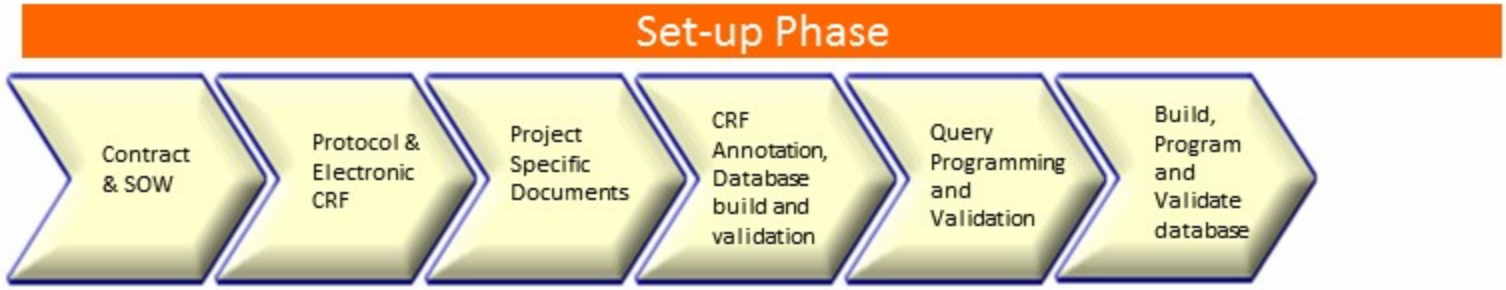
Query Programming and Validation

CDM – Summary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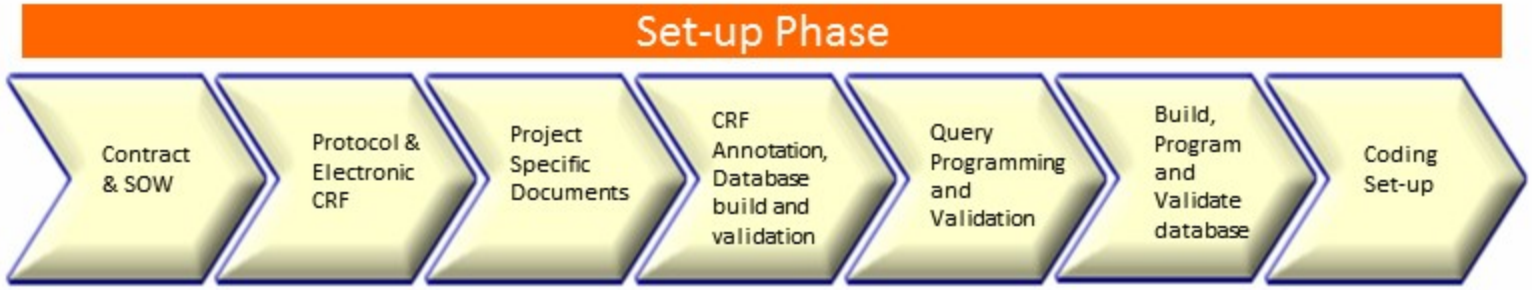
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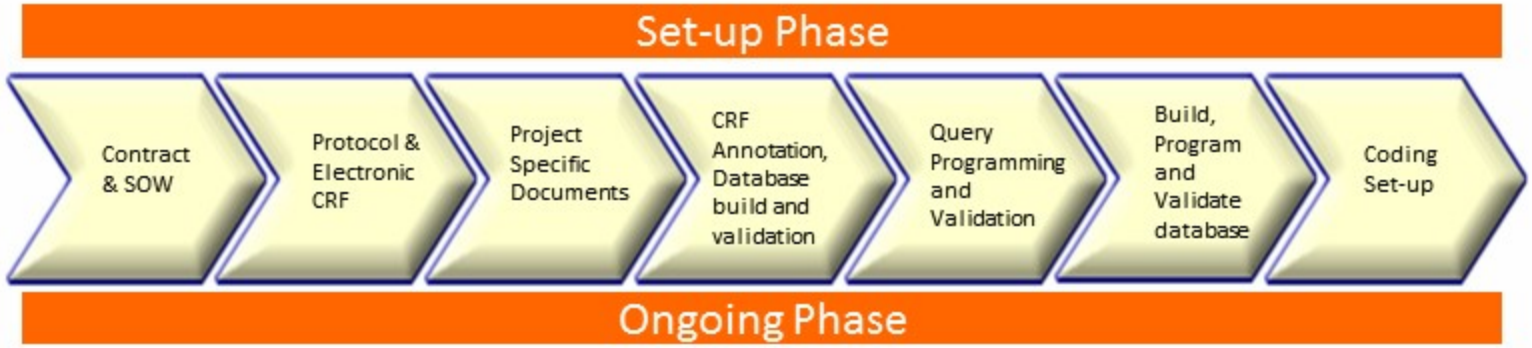

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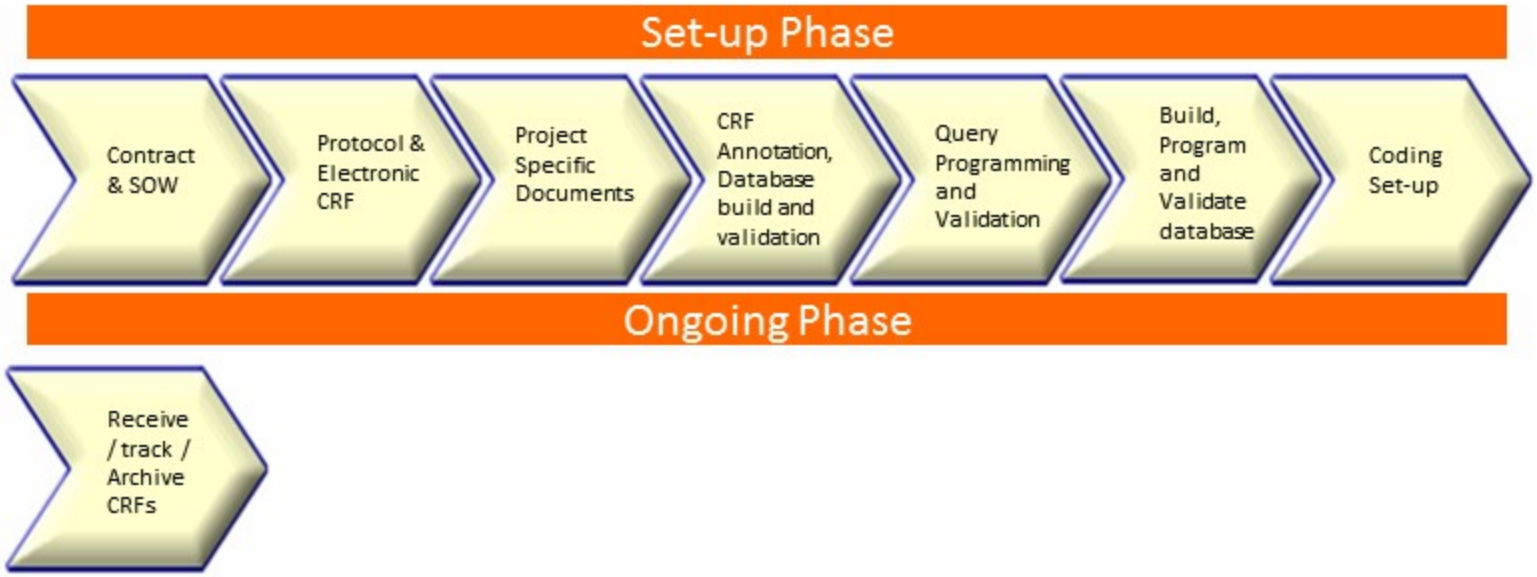
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Ongoing Phase
Receive / track / Archive CRFs

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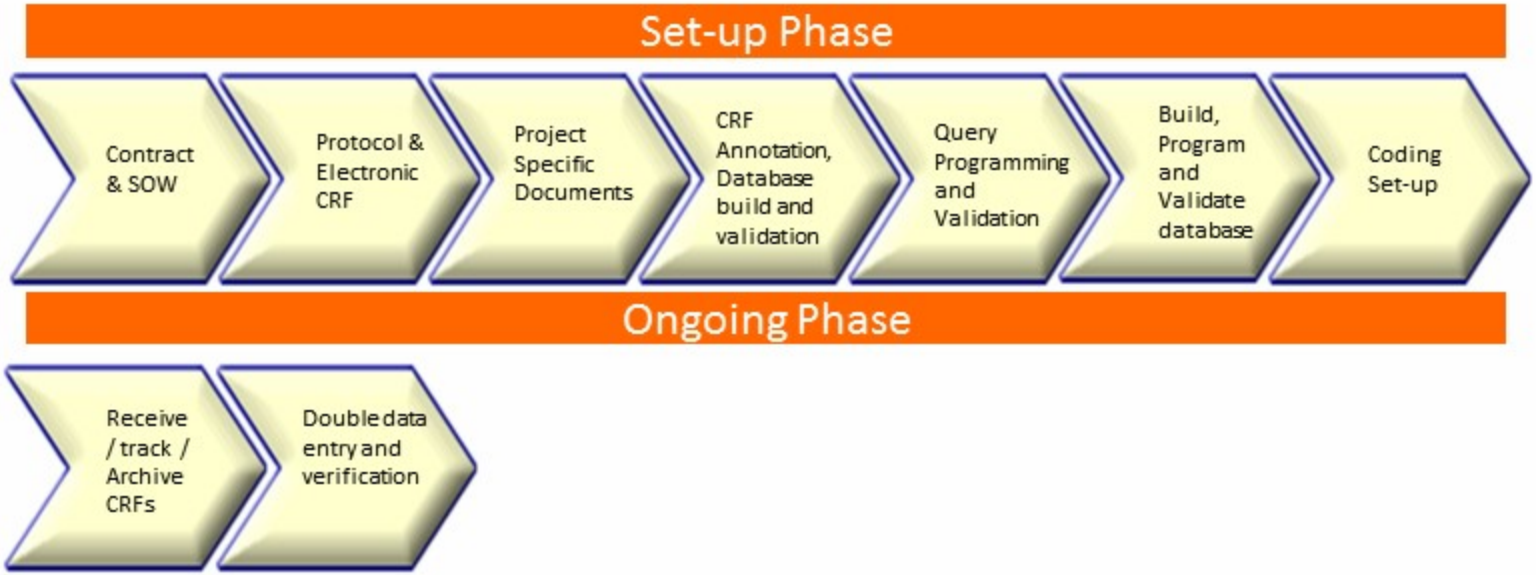
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Double data entry and verification

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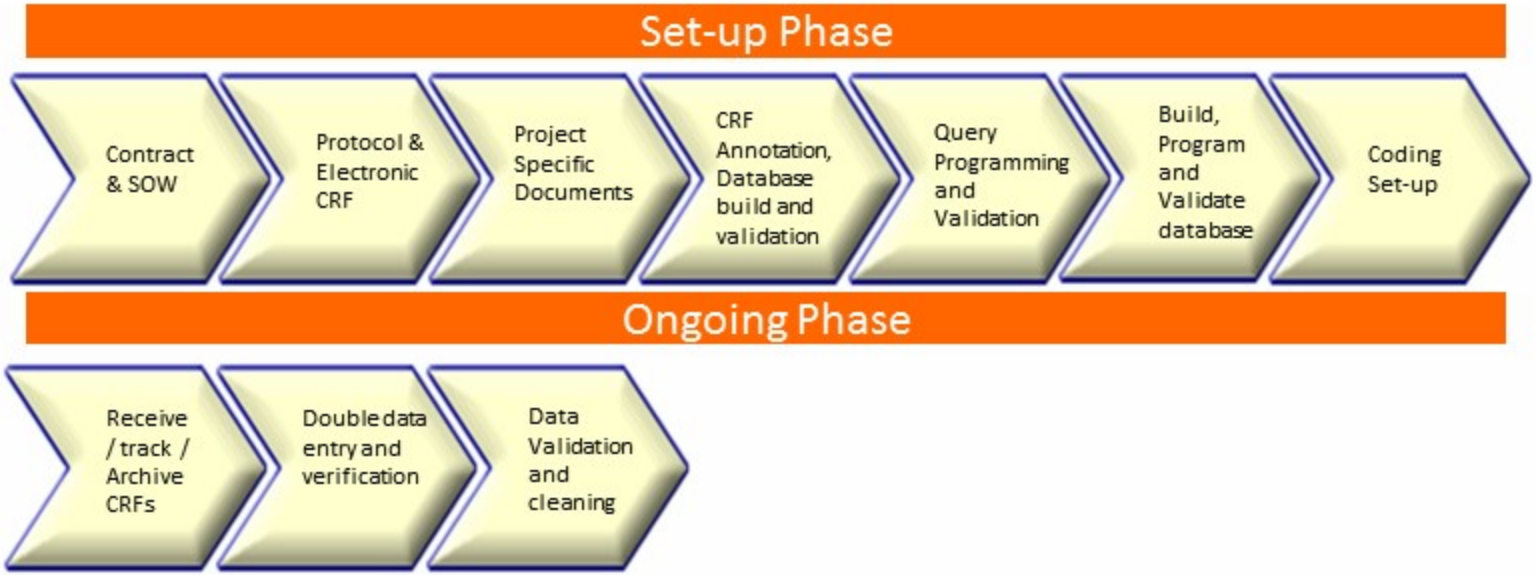
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Data Validation and cleaning

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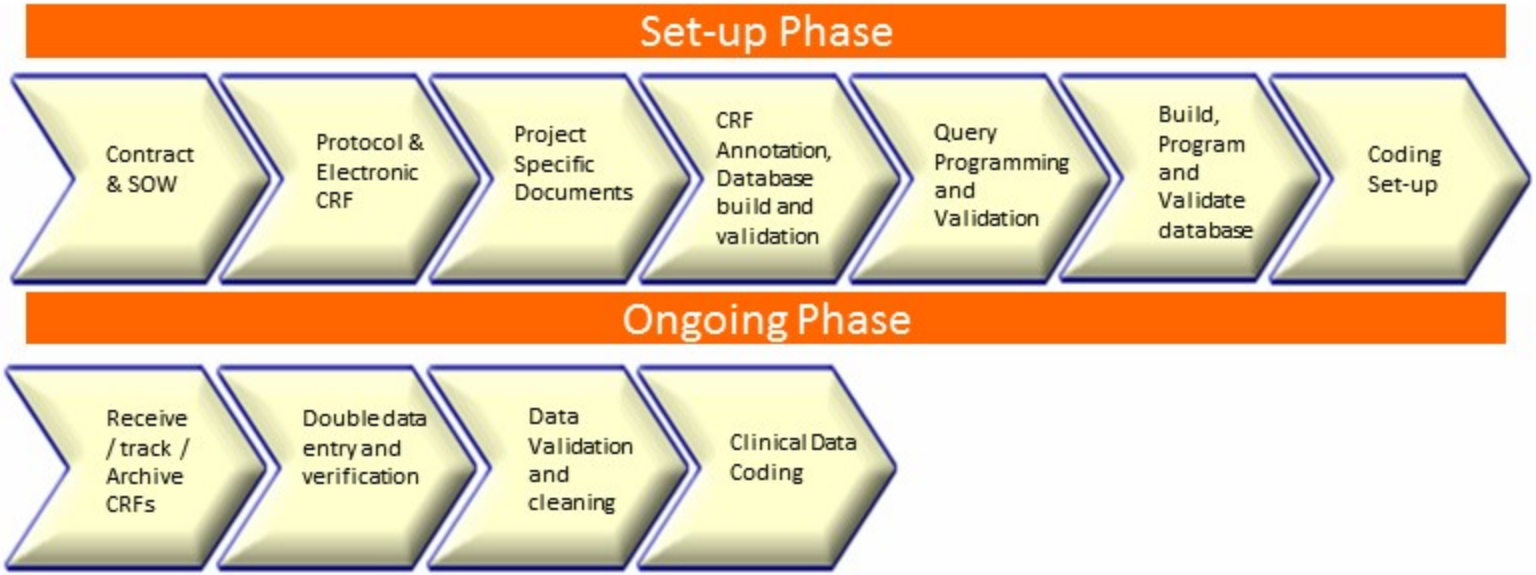
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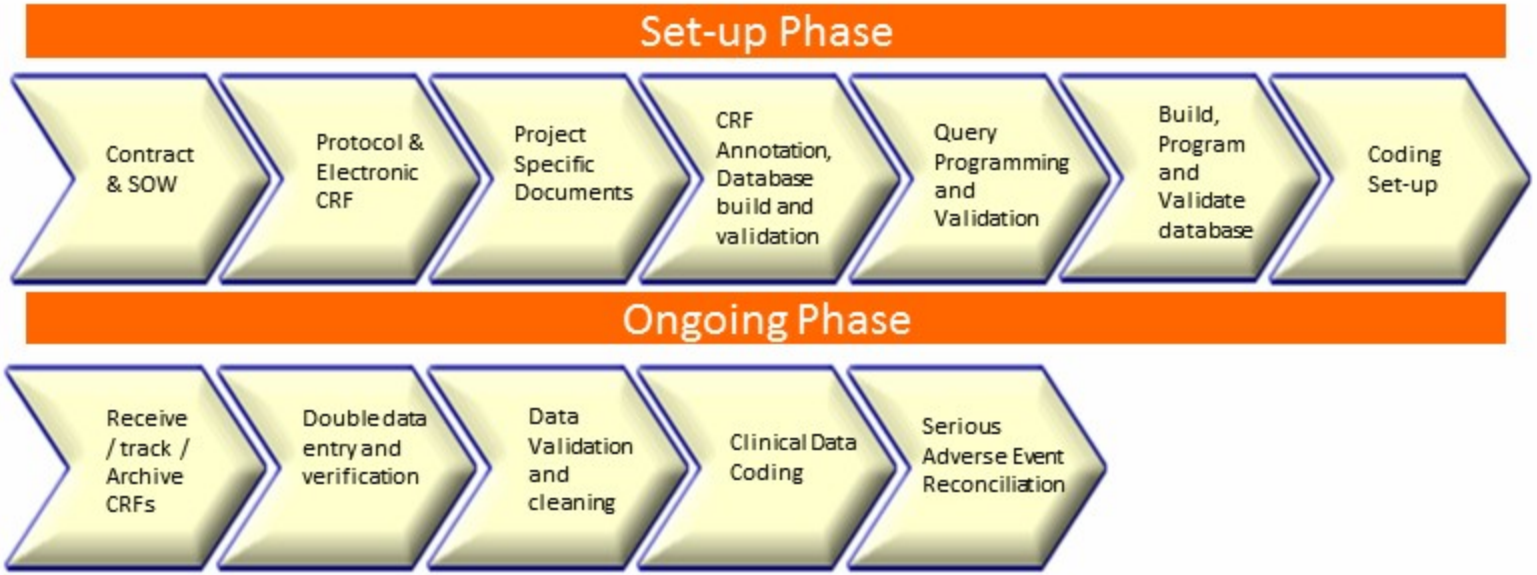
Clinical Data Coding

CDM – Summary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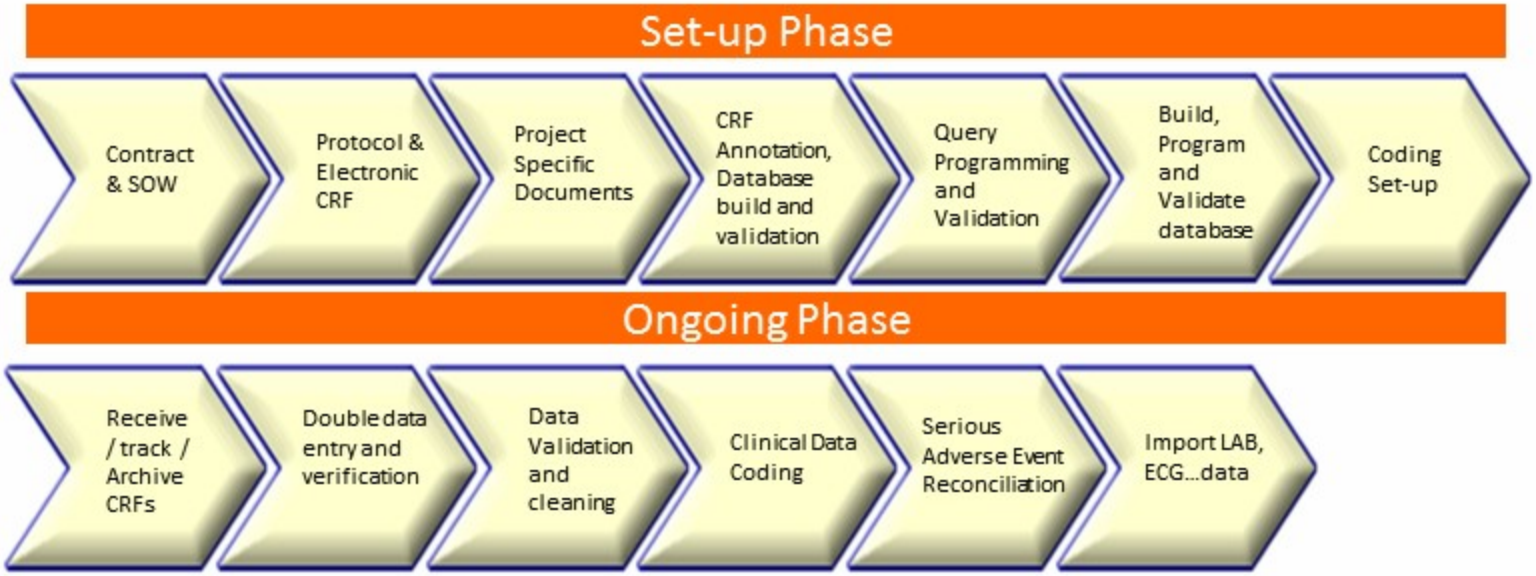
Serious Adverse Event Reconciliation

CDM – Summary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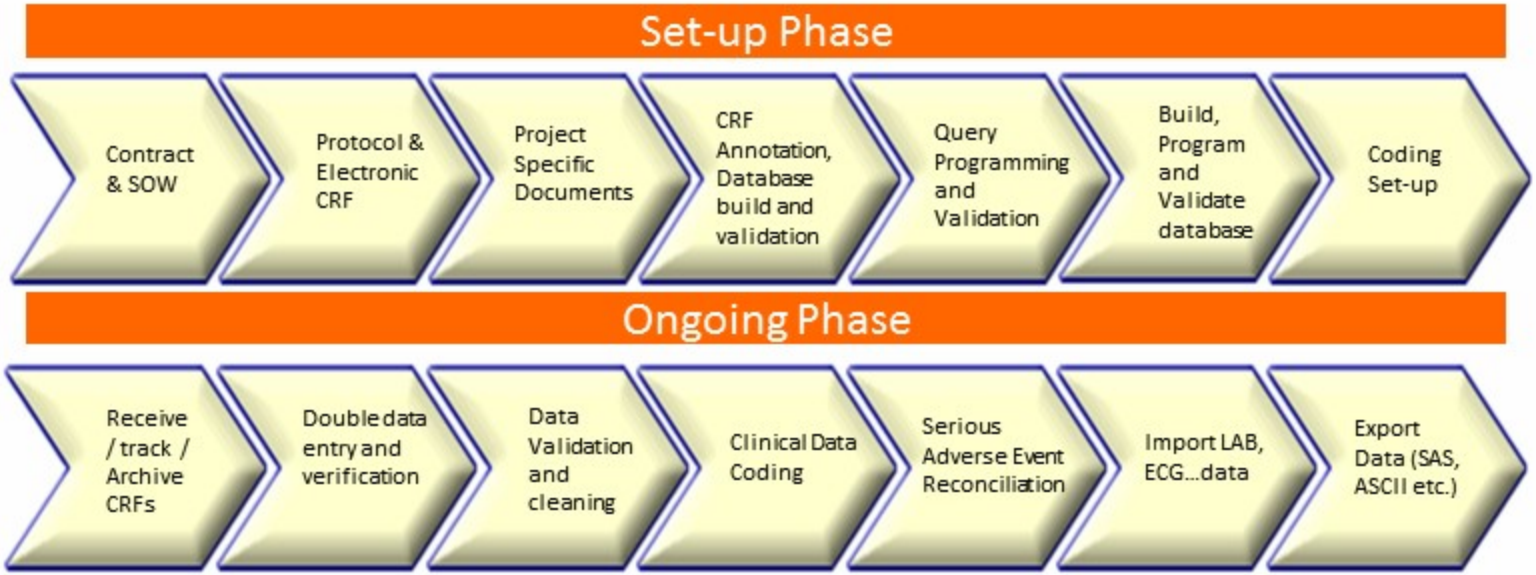
Serious Adverse Event Reconciliation
Import LAB, ECG…data

CDM – Summary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Import LAB, ECG…data
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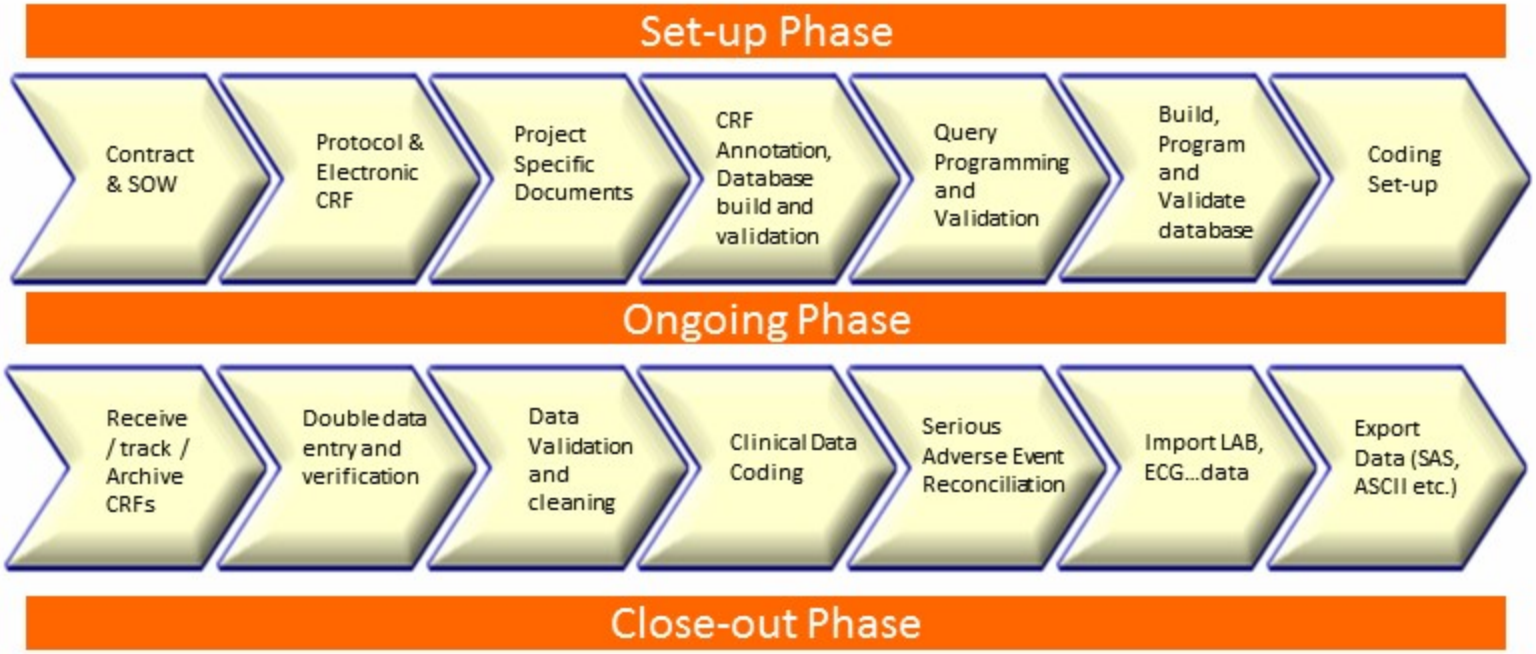
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Close-out Phase

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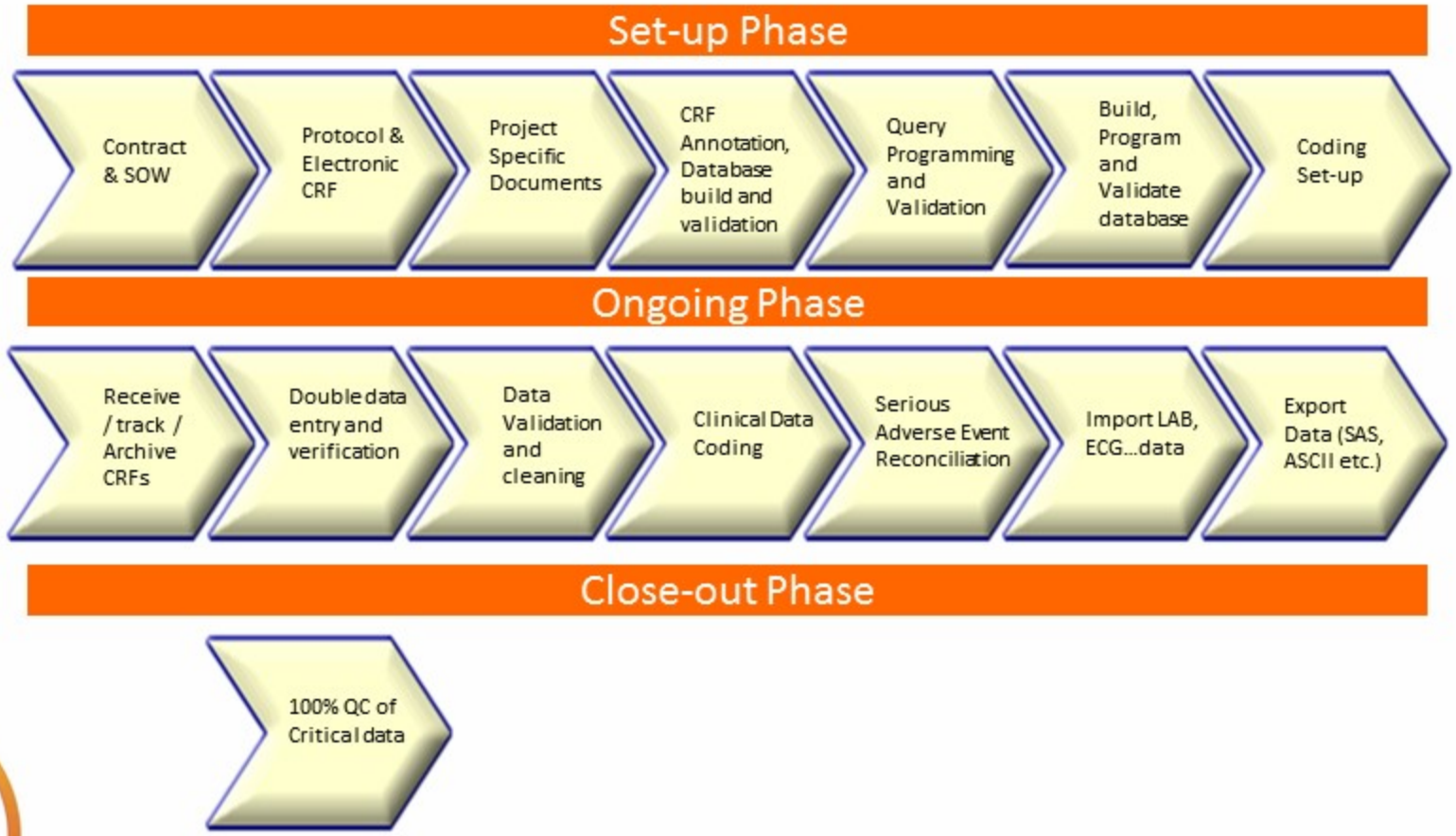
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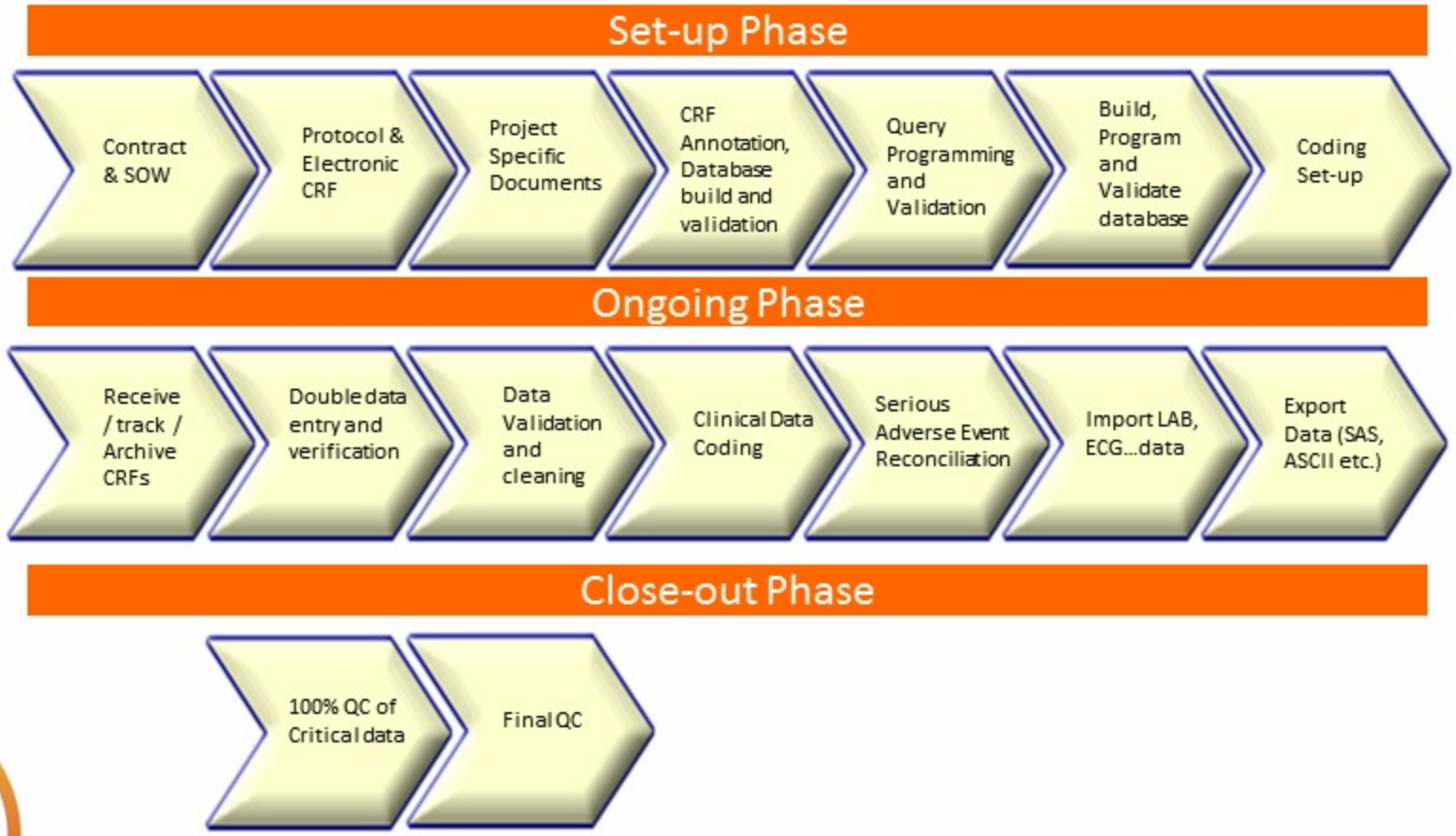
Close-out Phase
100% QC of Critical data

CDM – Summary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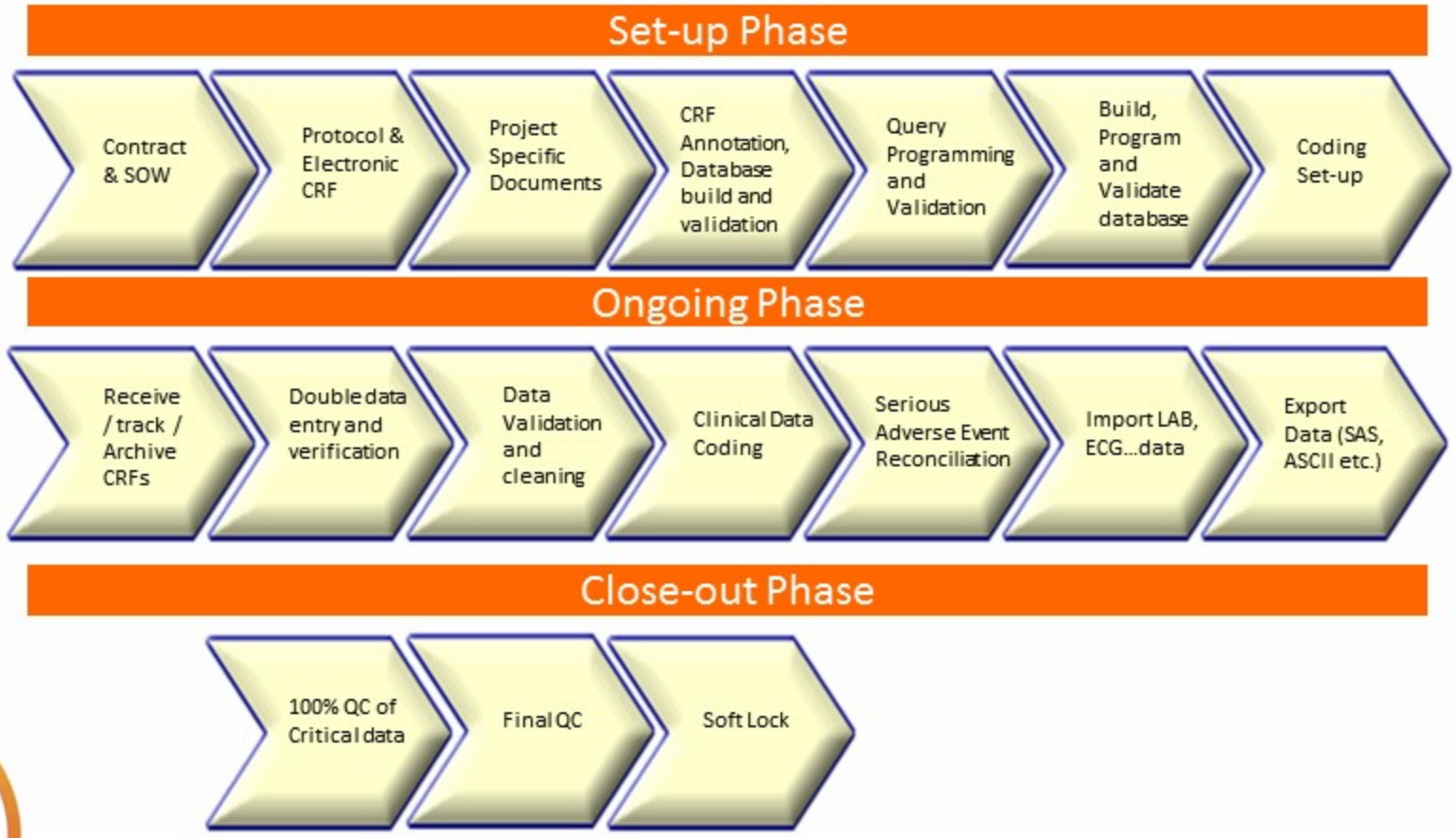
100% QC of Critical data
Final QC

CDM – Summary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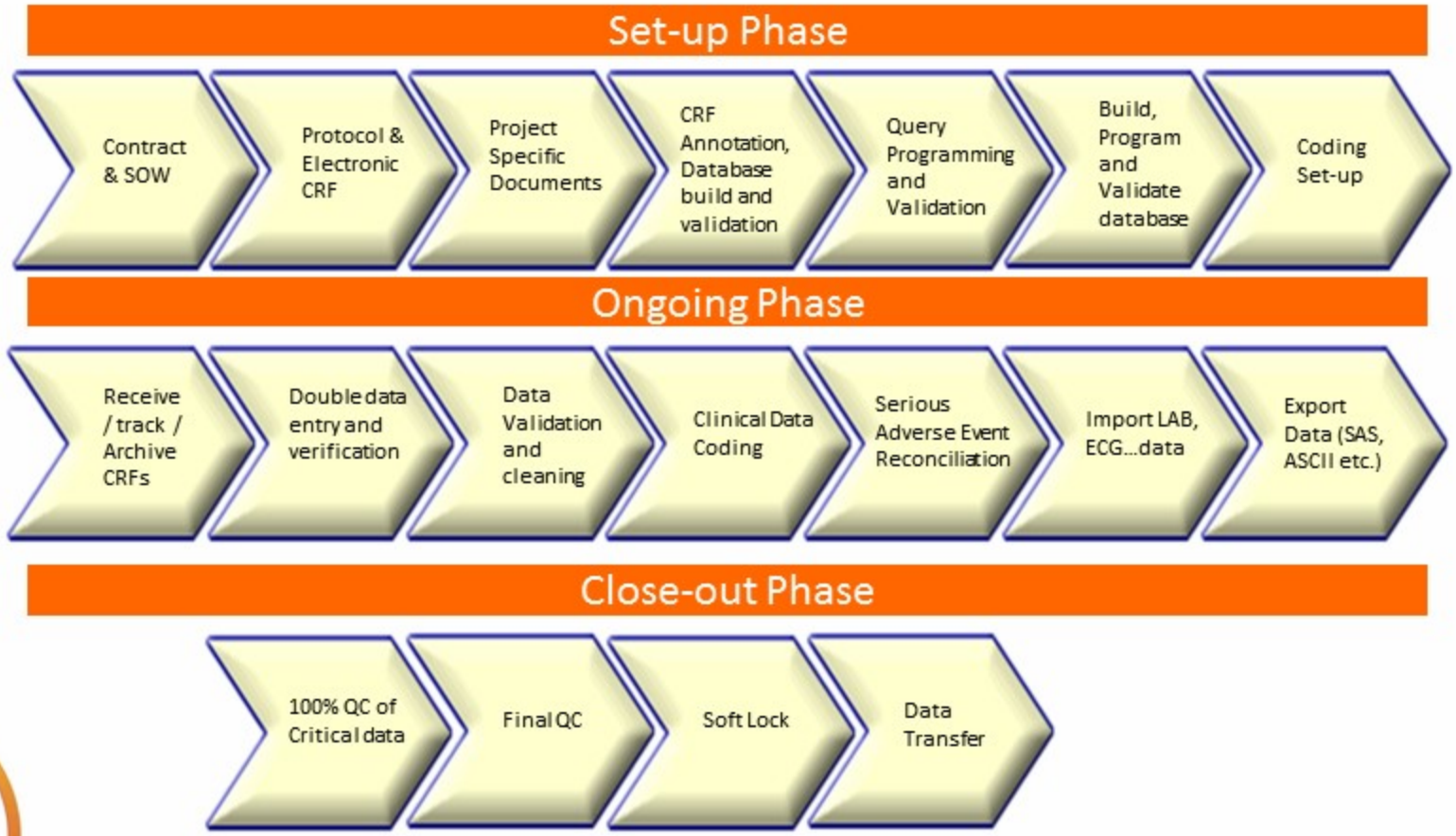
100% QC of Critical data
Final QC
Soft Lock

CDM – Summary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Final QC
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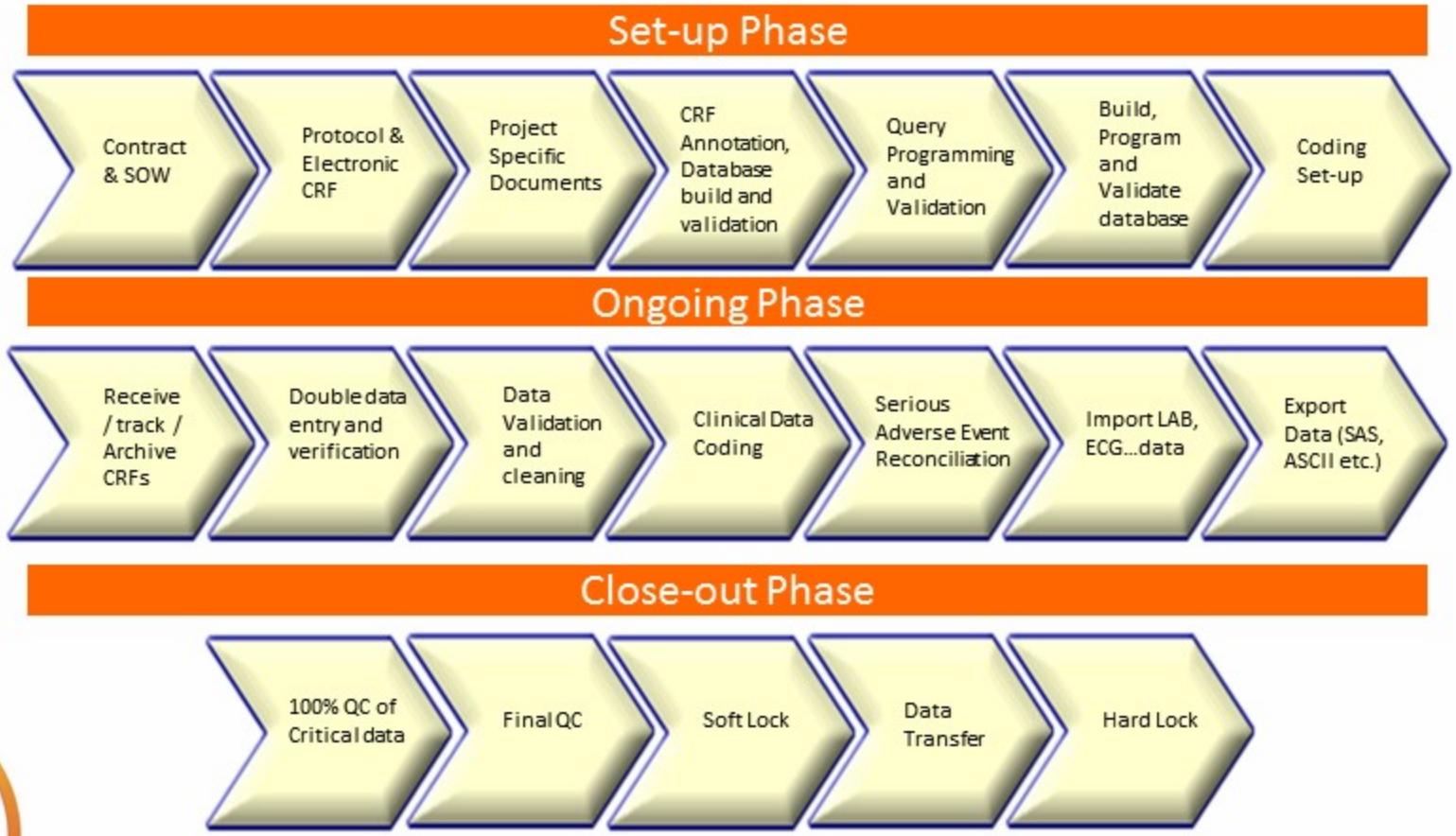
Data Transfer

CDM – Summary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Final QC
Soft Lock
Data Transfer
Hard Lock

CDM – Workflow Summary (I / II)

DM Documentation

CDM – Workflow Summary (I / II)

DM Documentation

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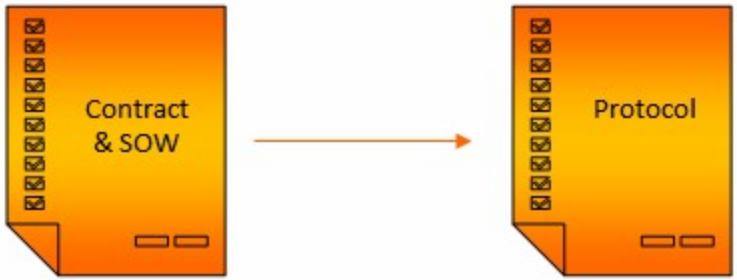
DM Documentation



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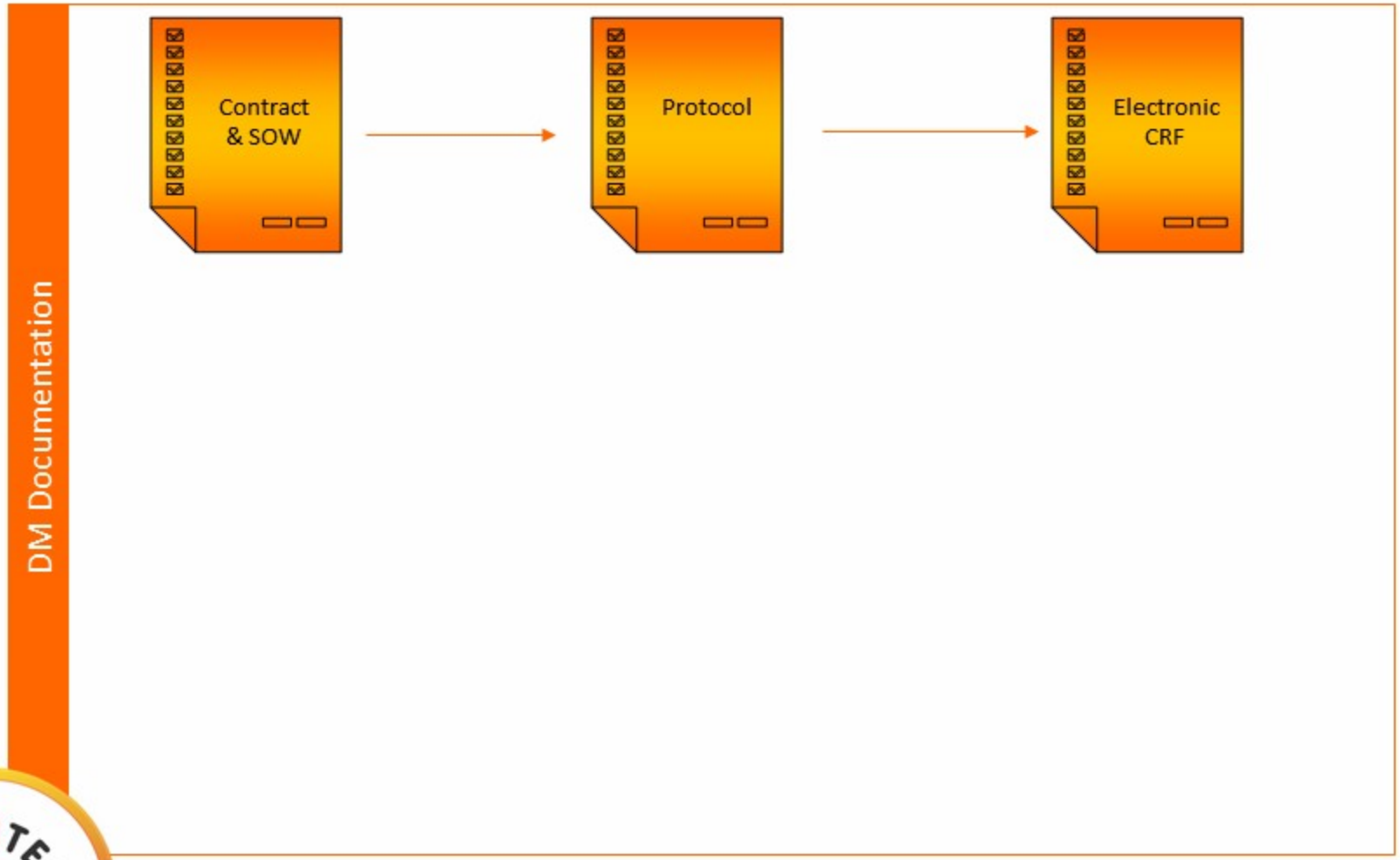

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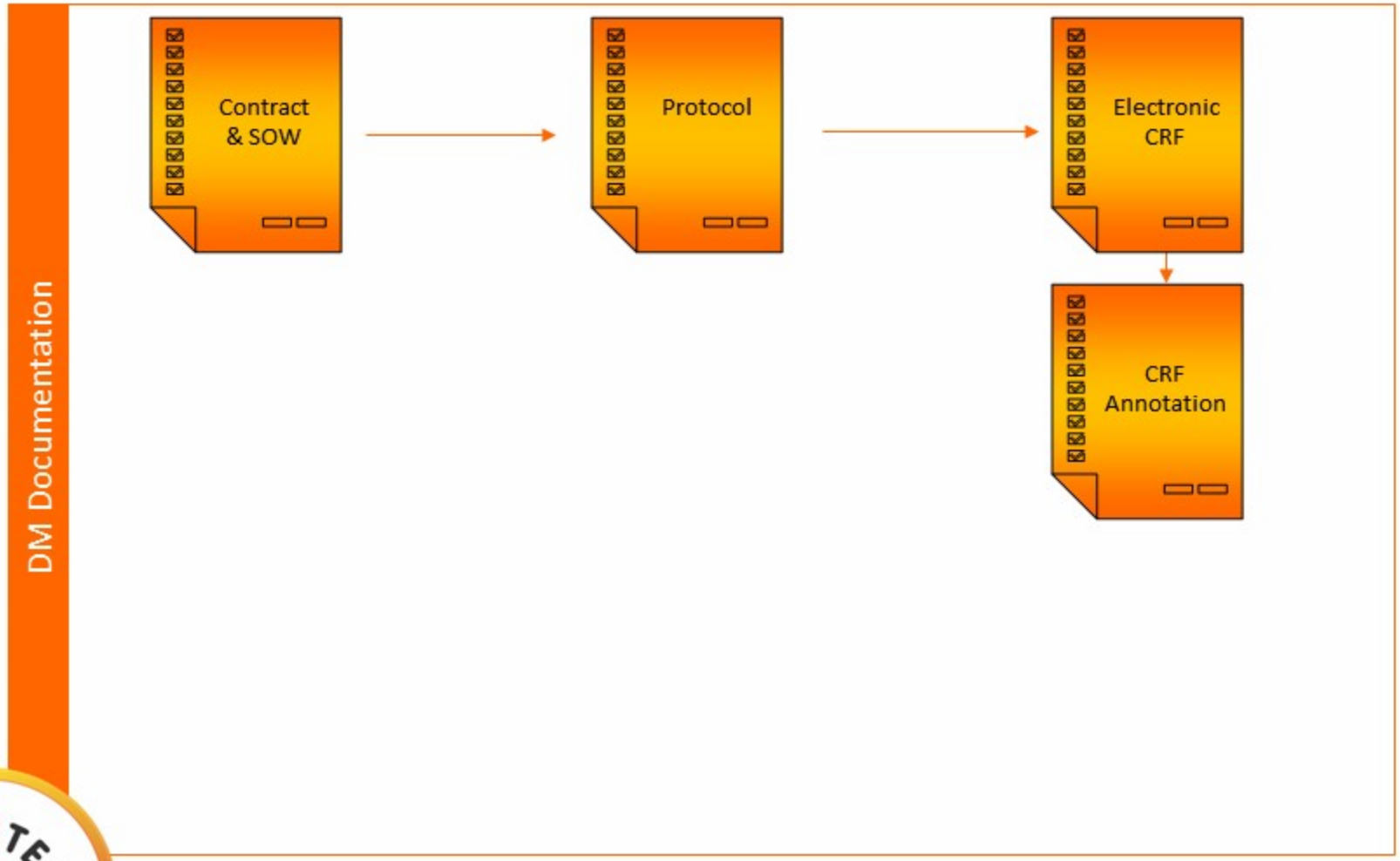

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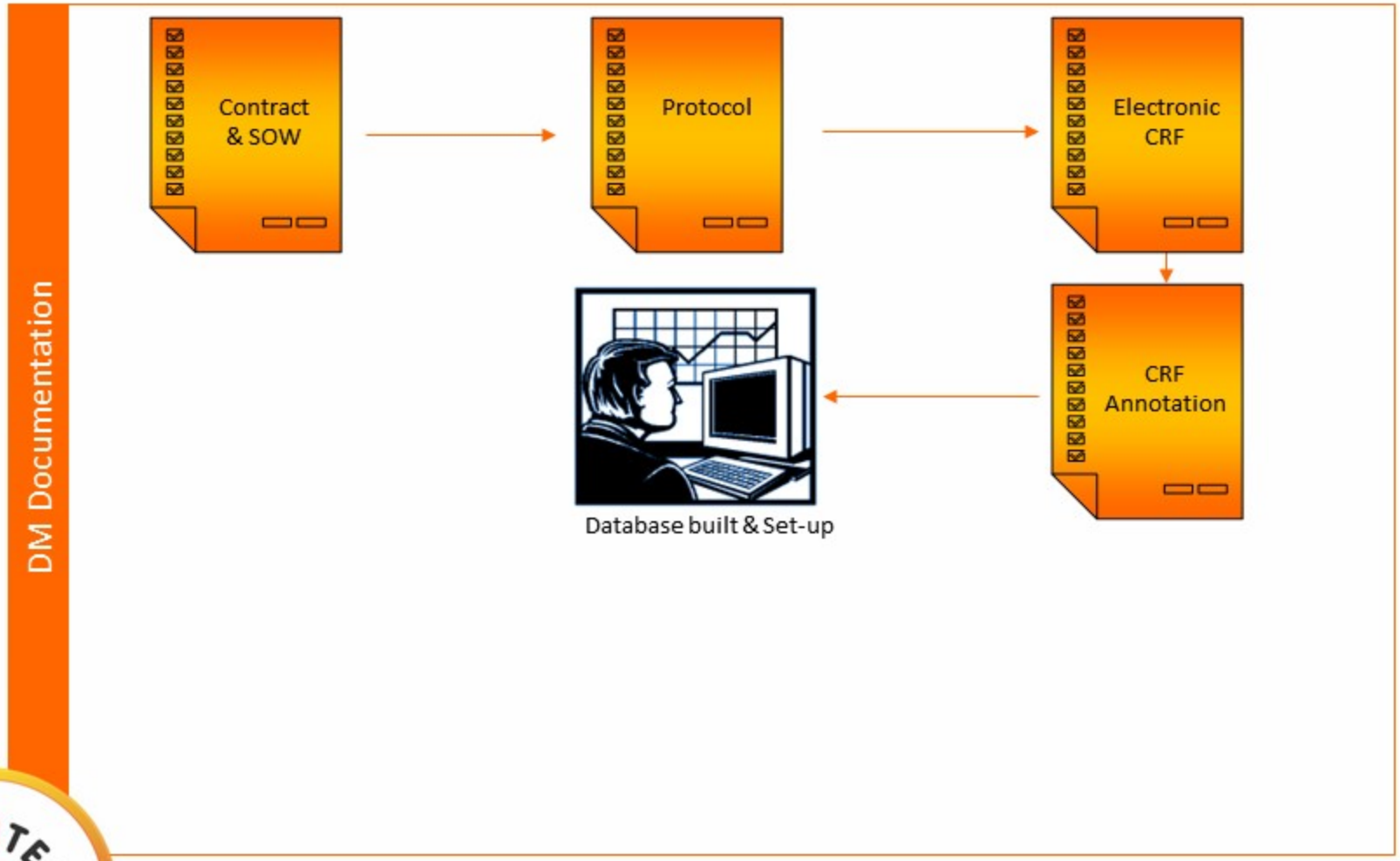

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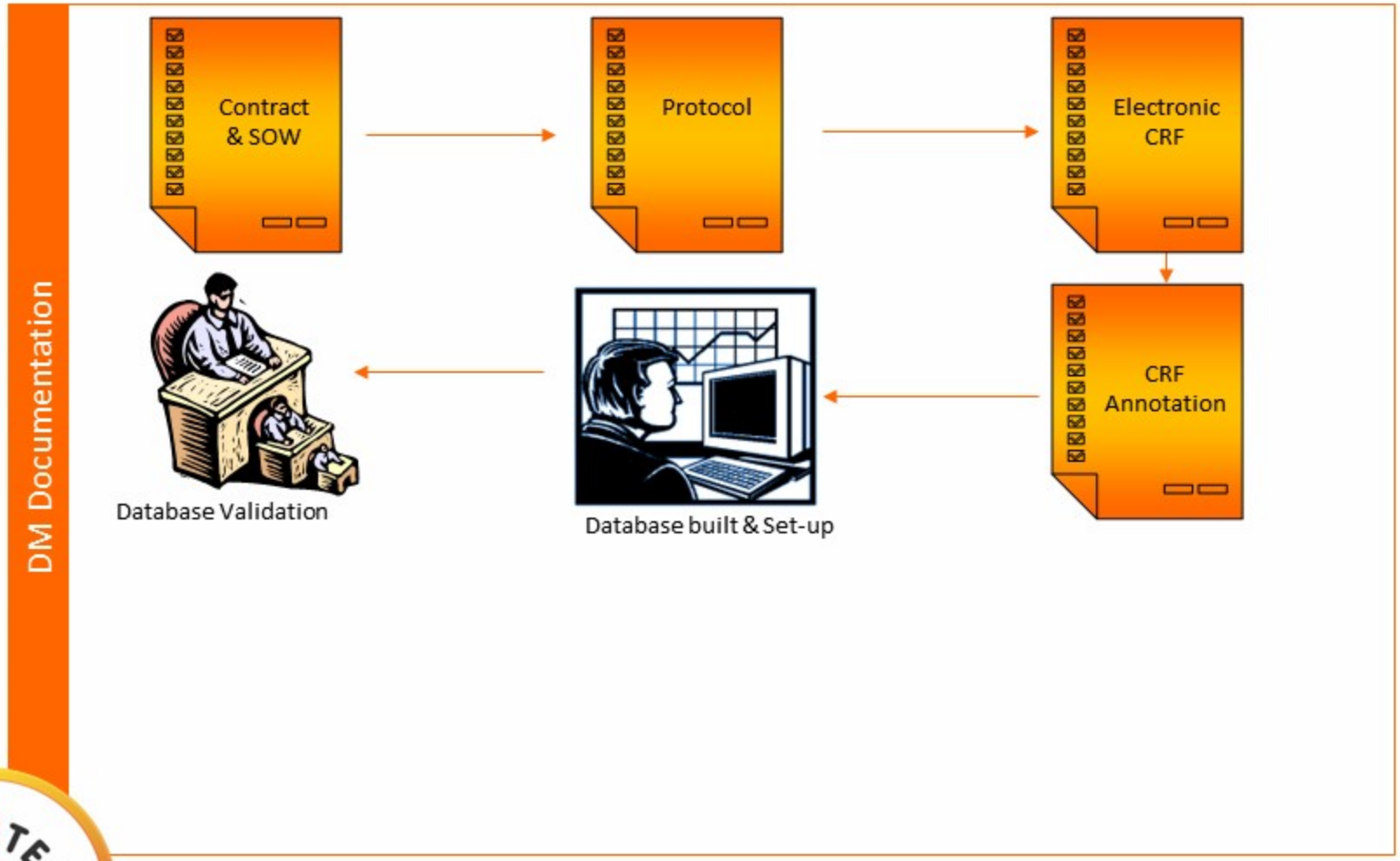

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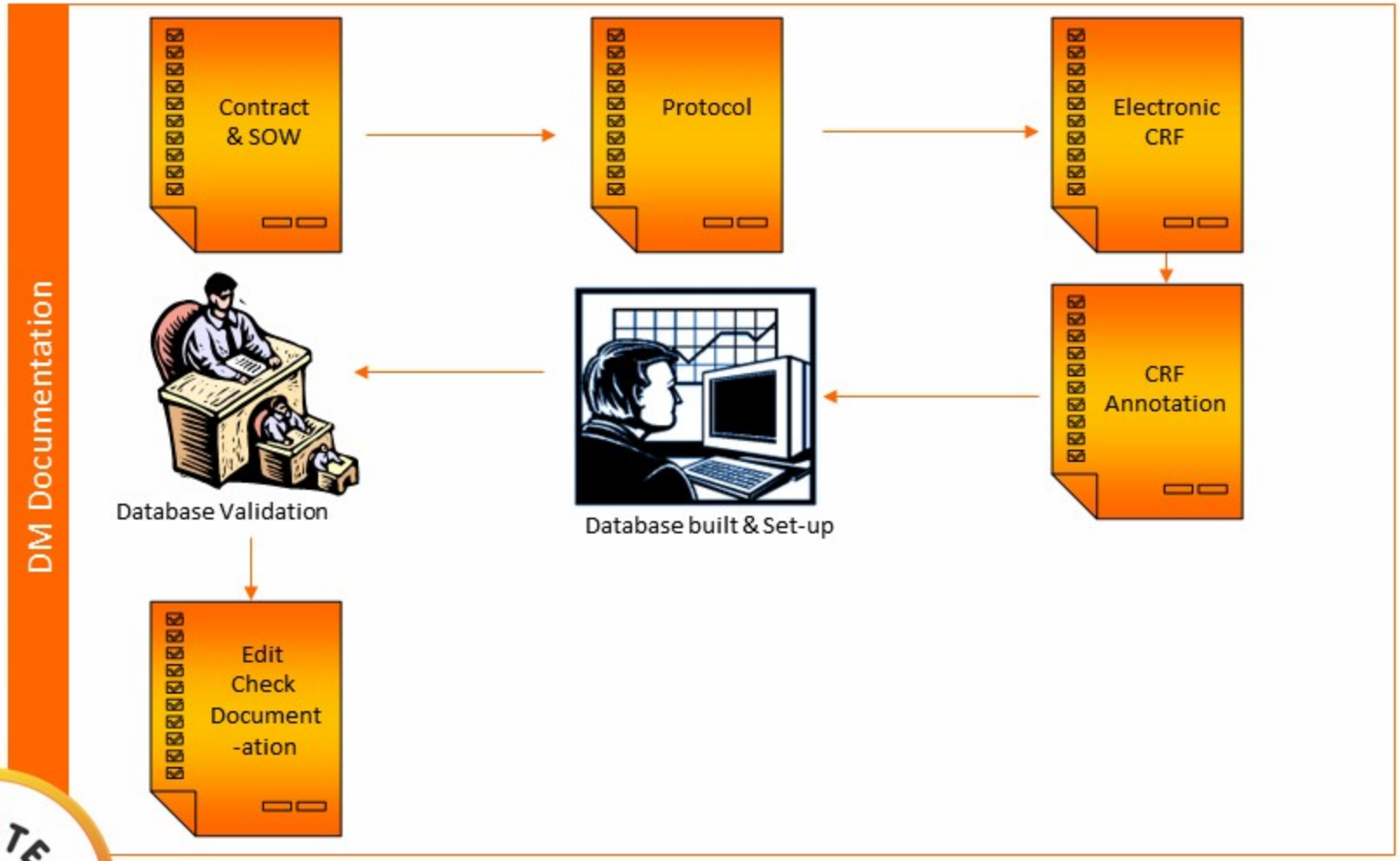

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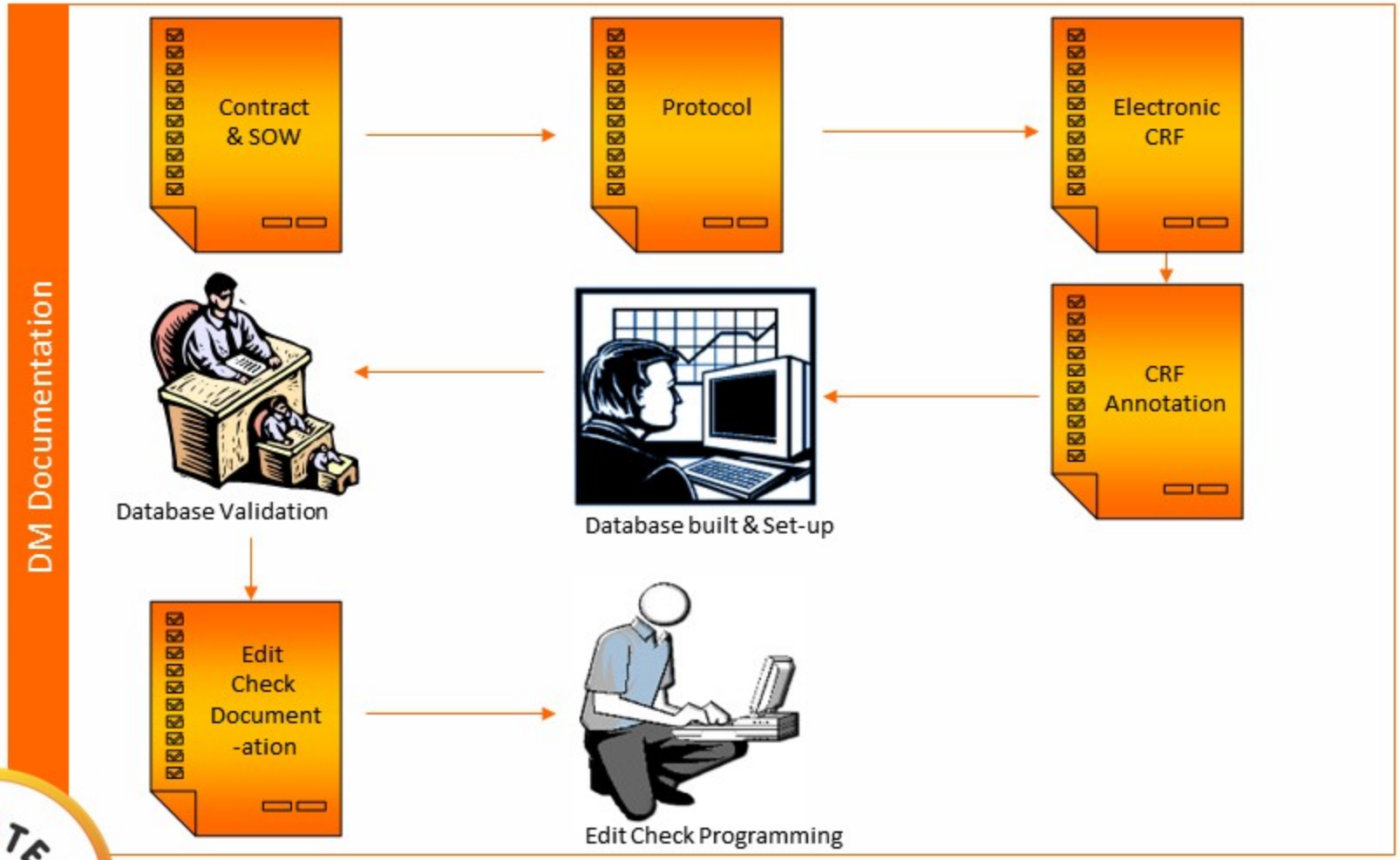

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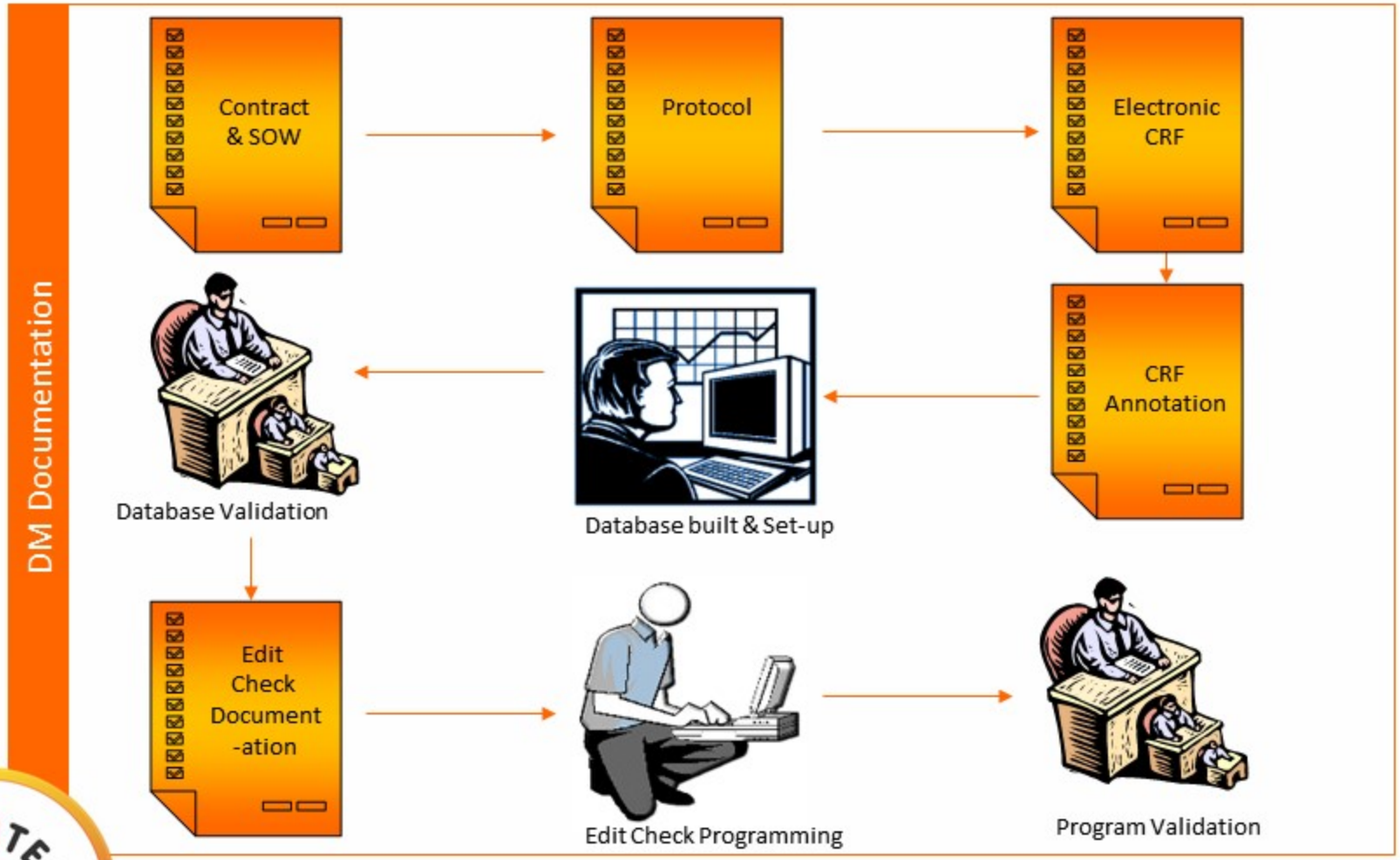

KLINTEC Academy

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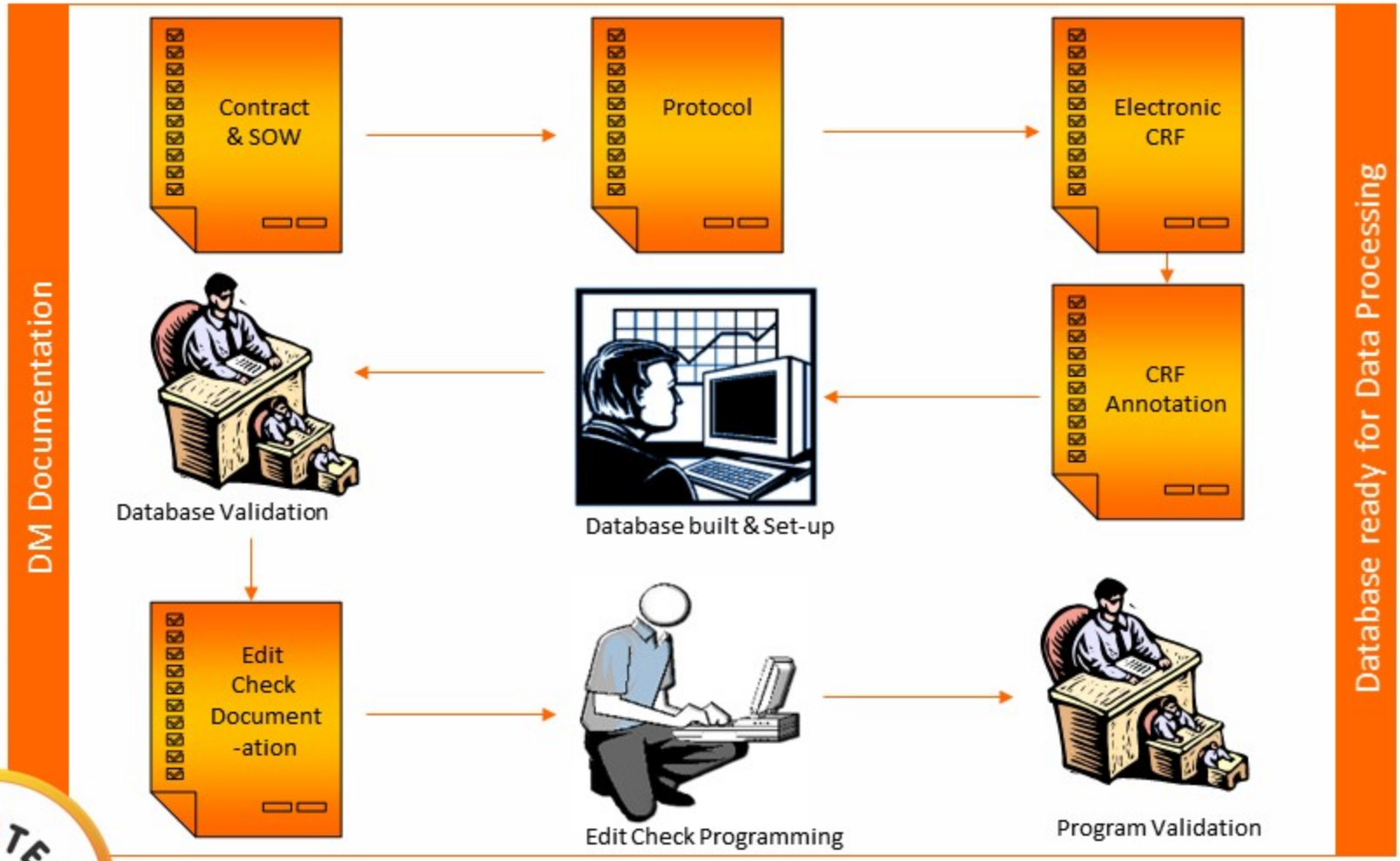
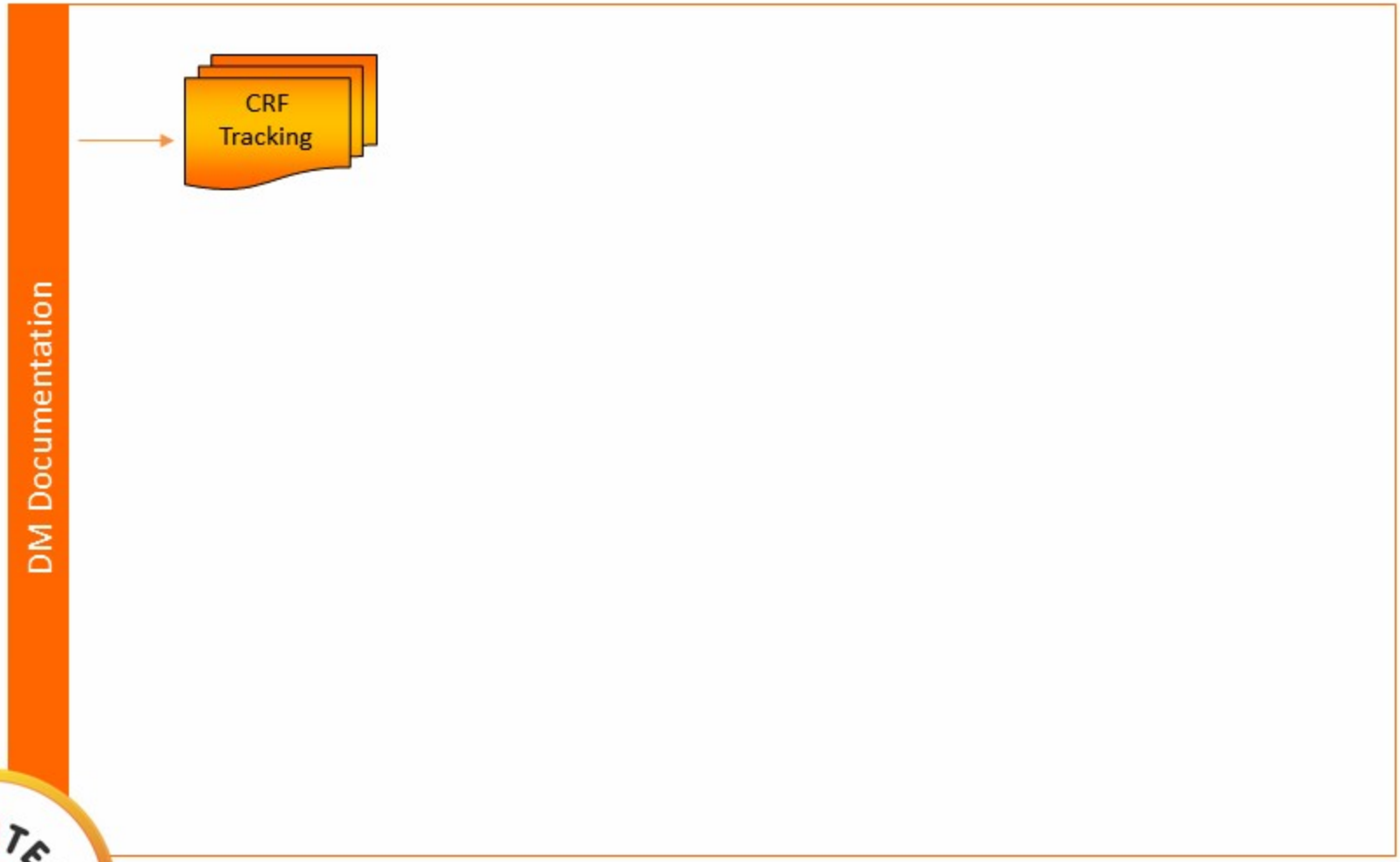


KLINTEC Academy

CDM – Workflow Summary (II / II)

DM Documentation

CDM – Workflow Summary (II / II)



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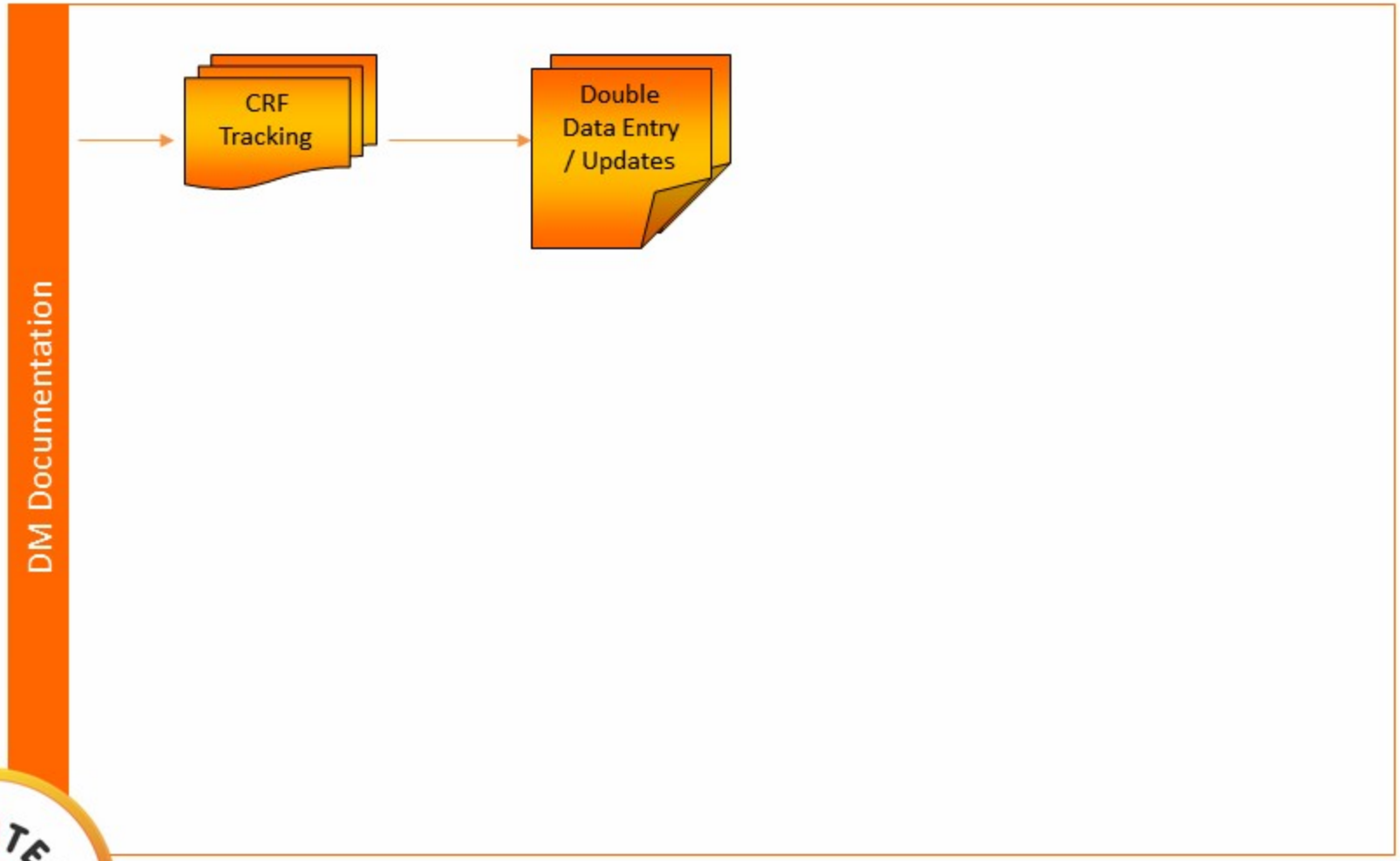

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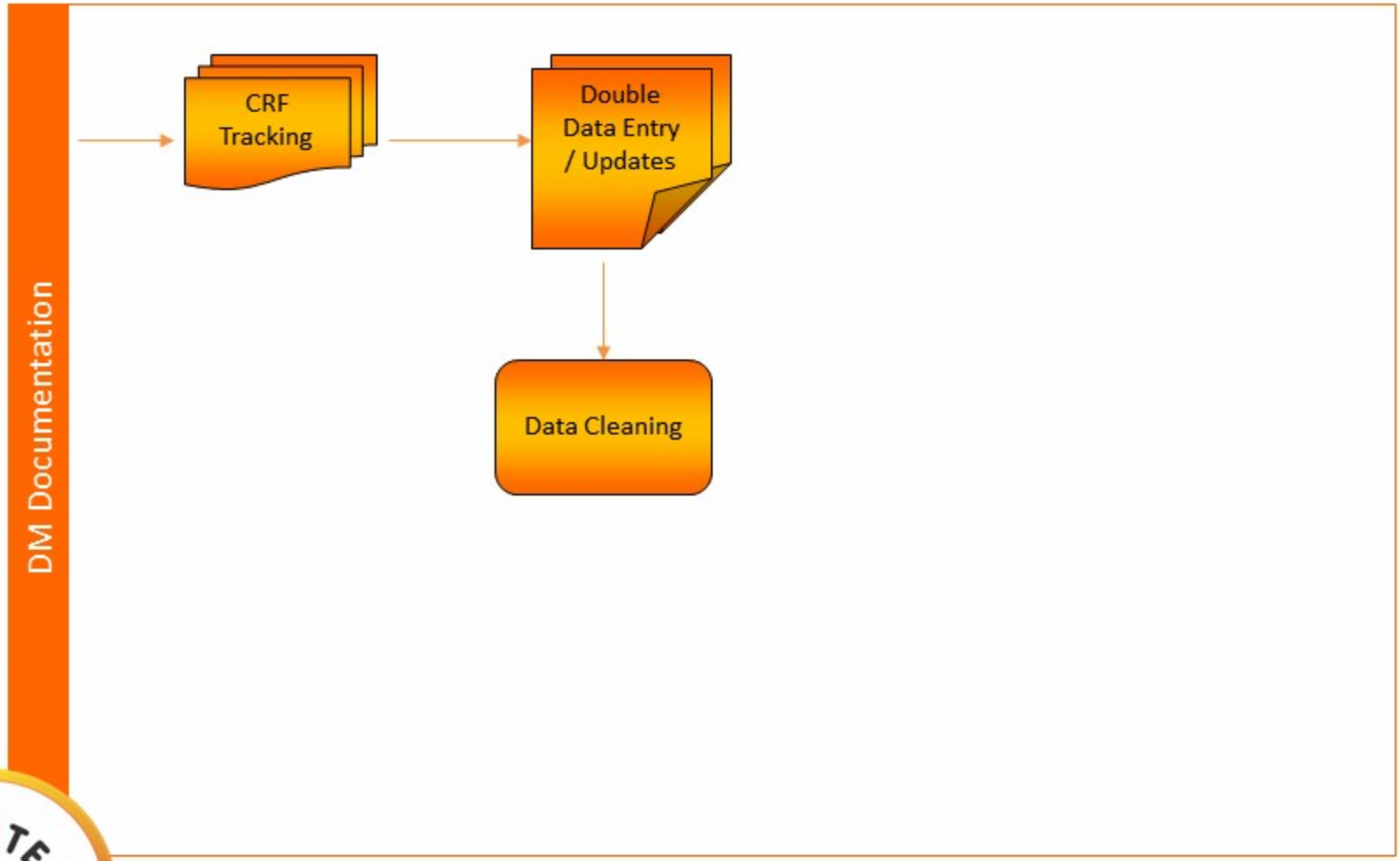

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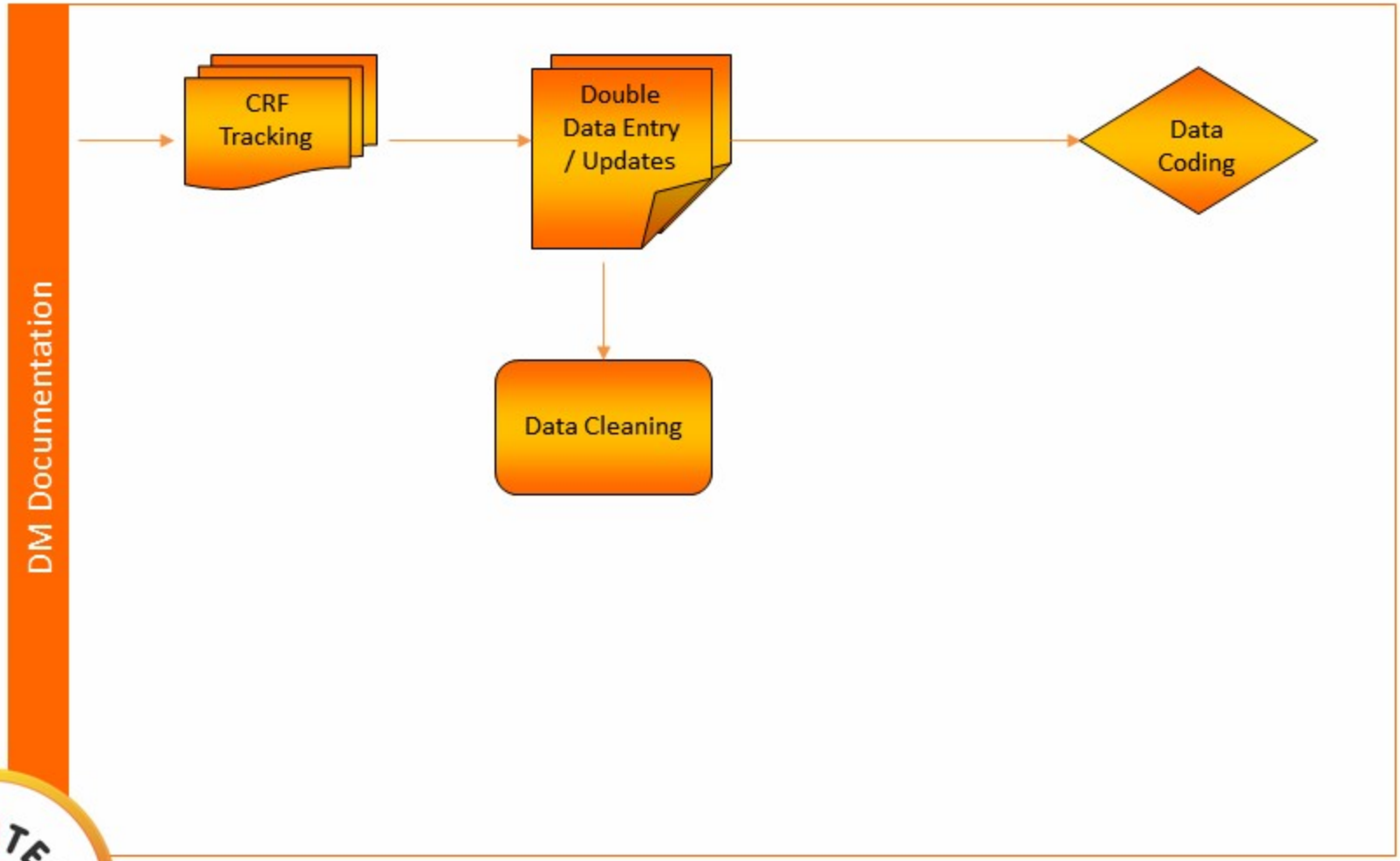

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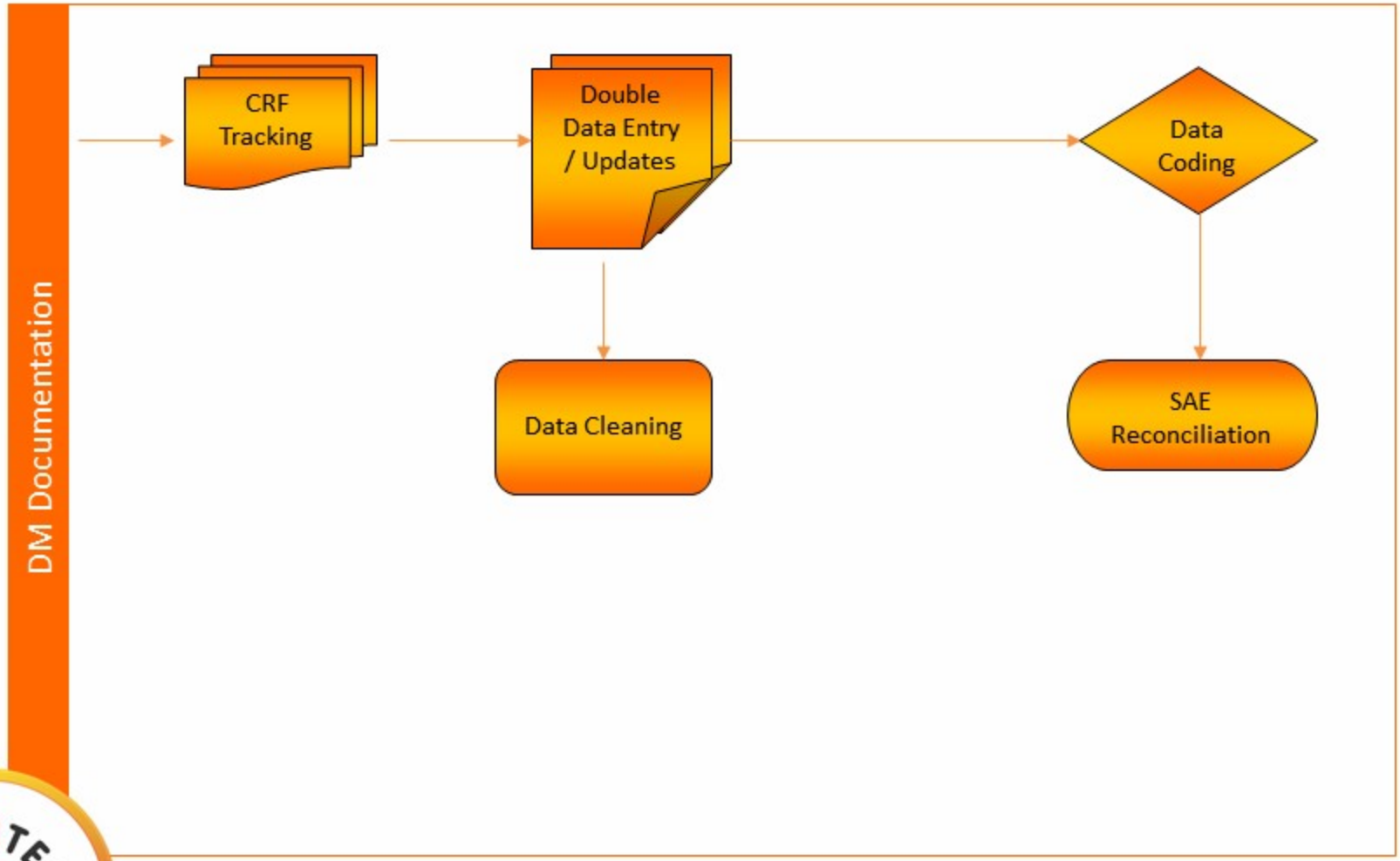

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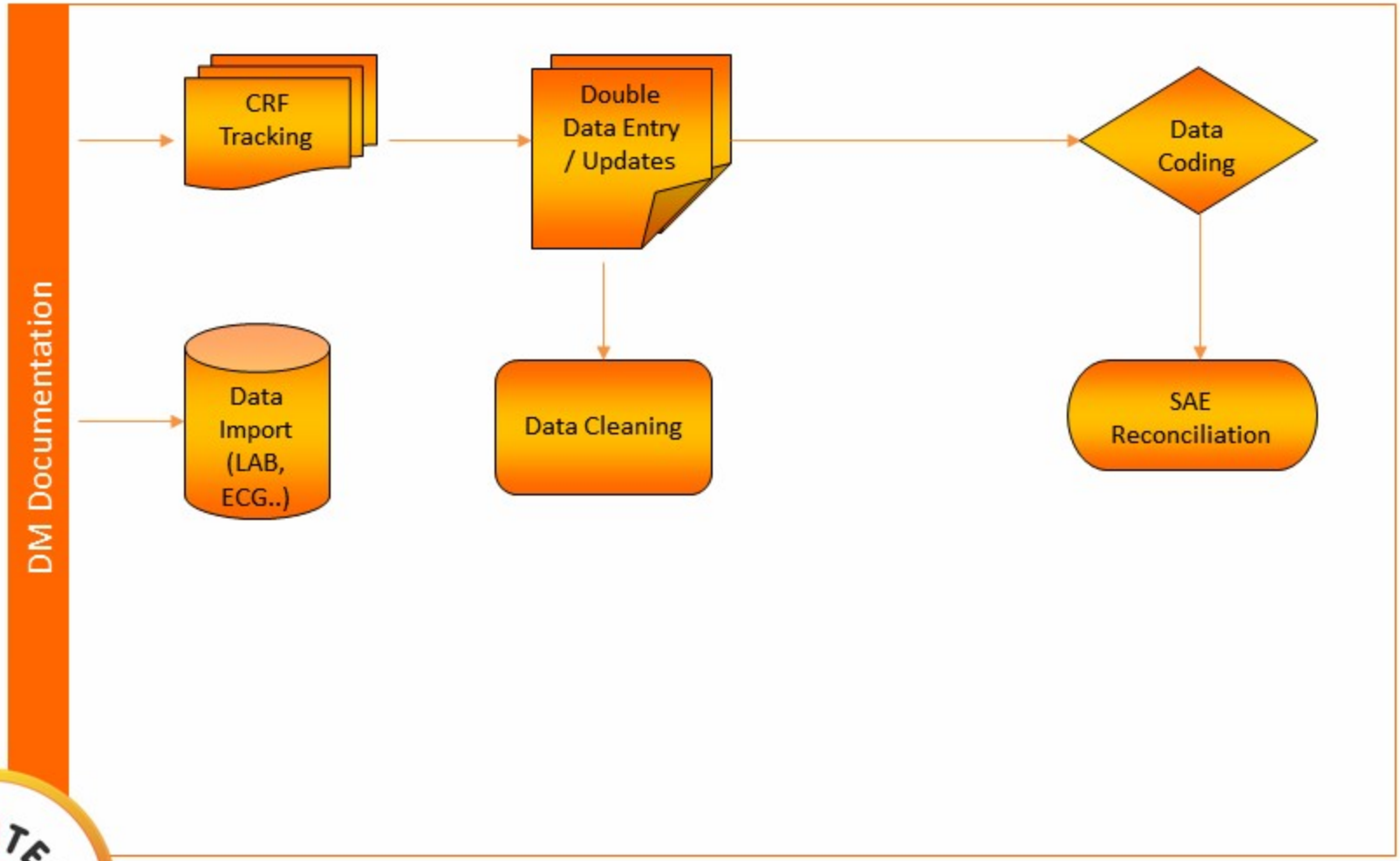

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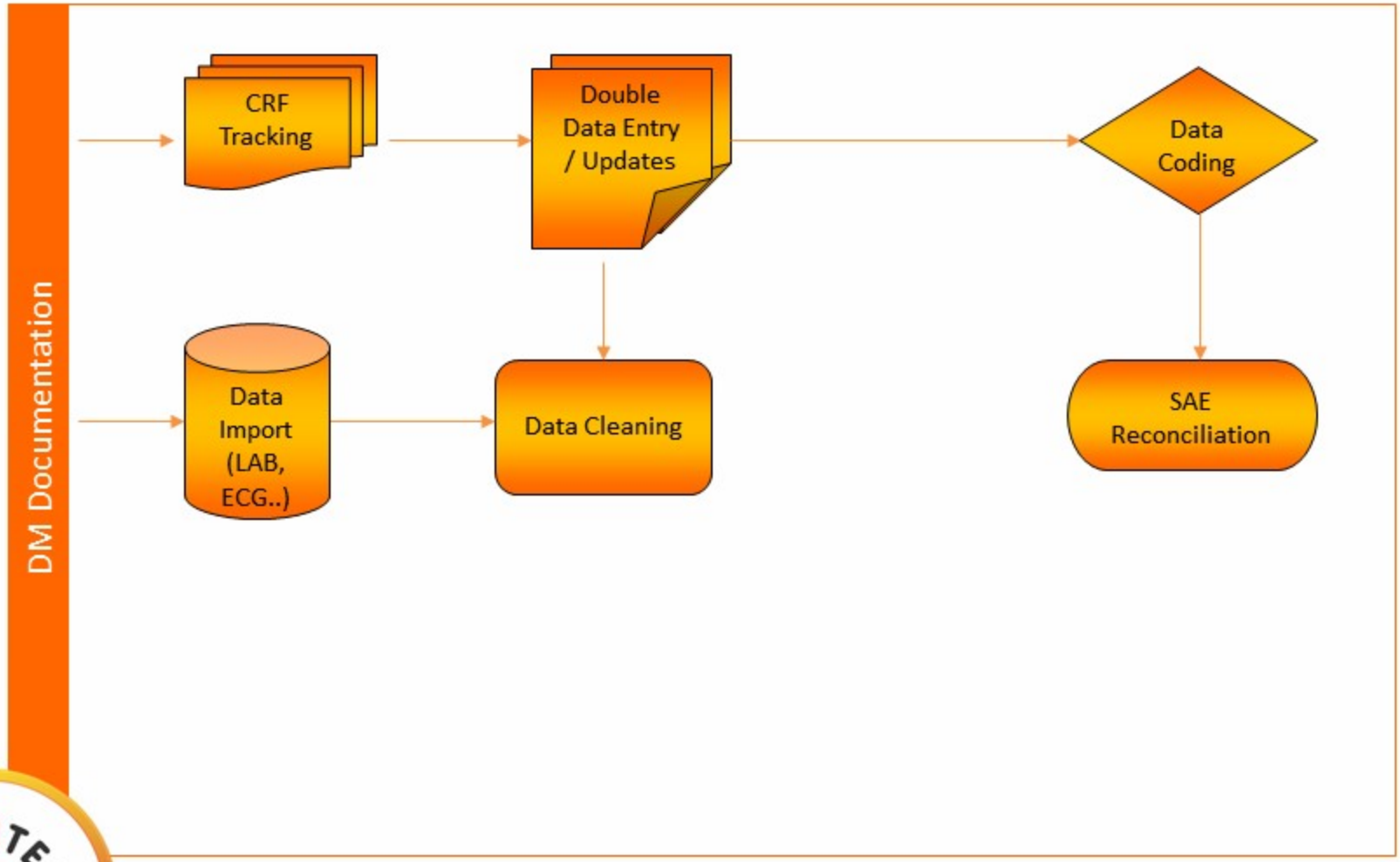

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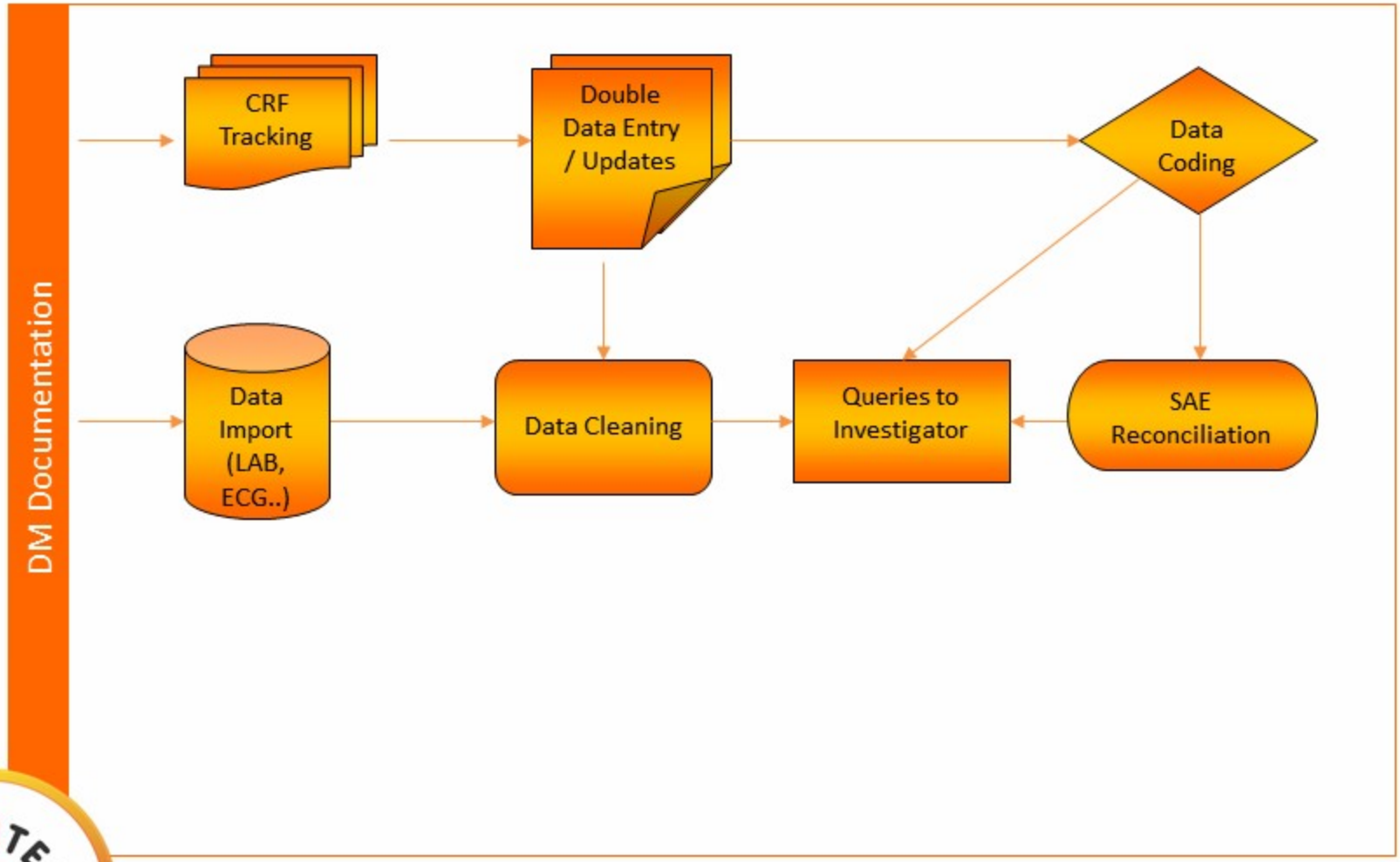

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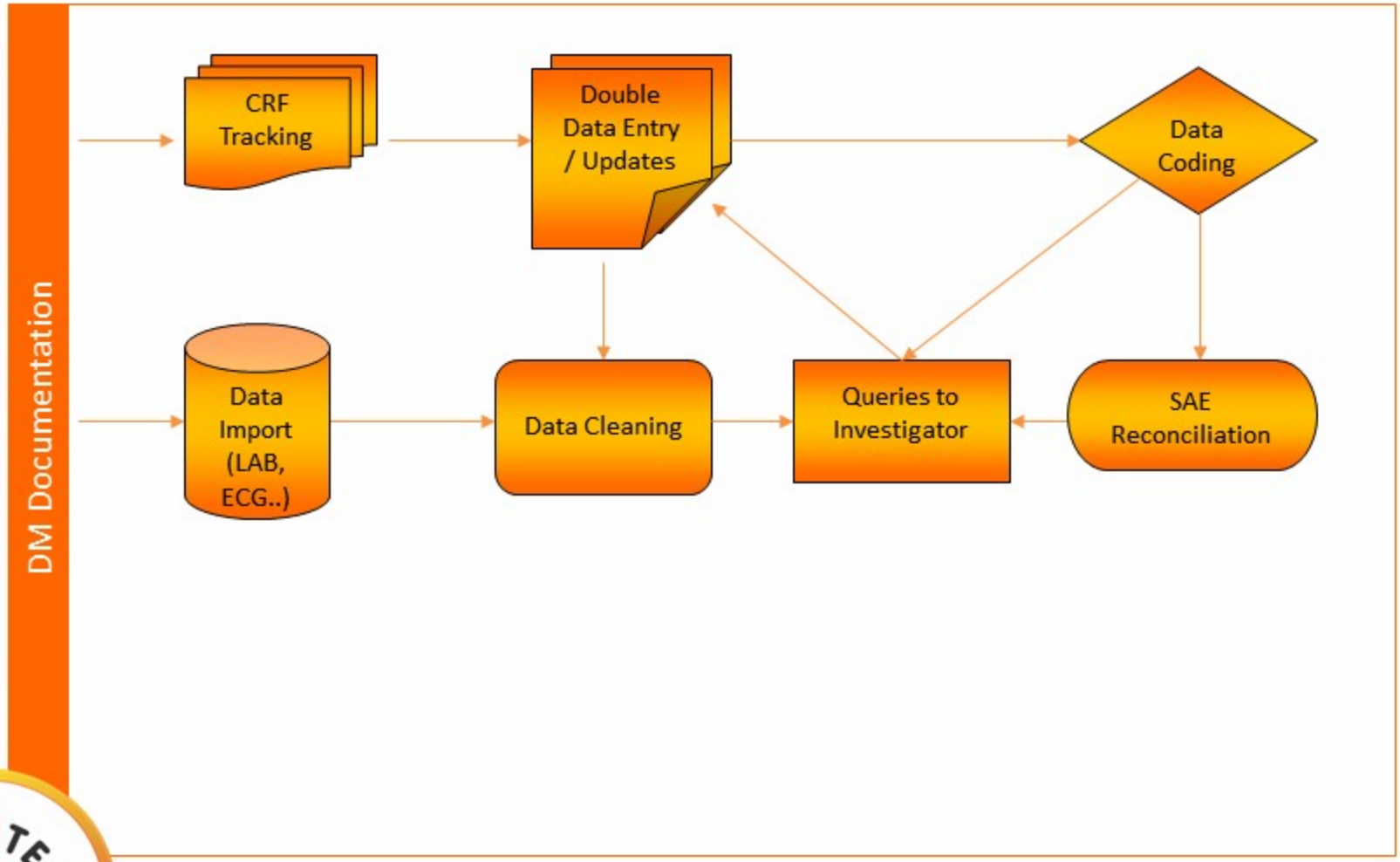

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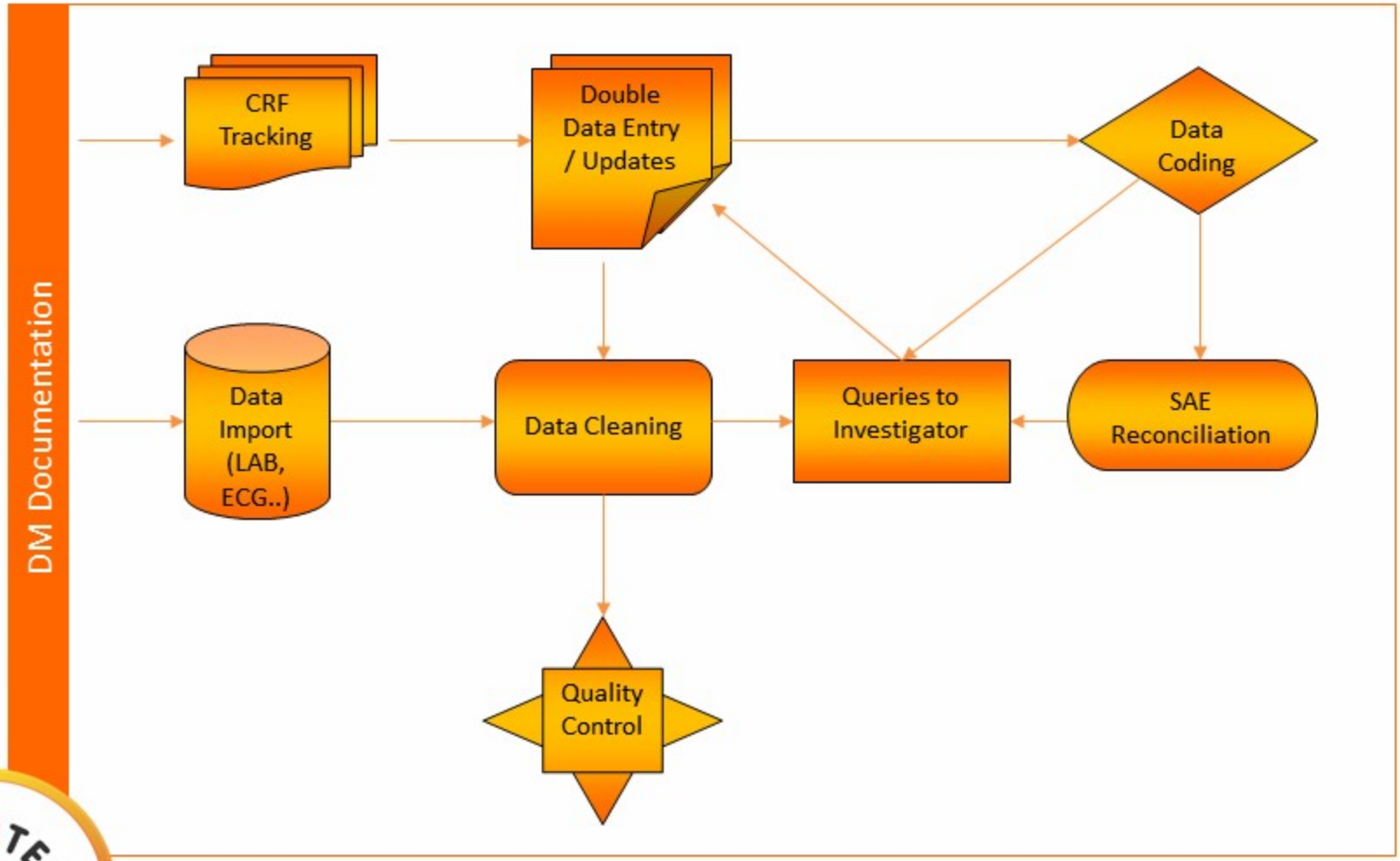

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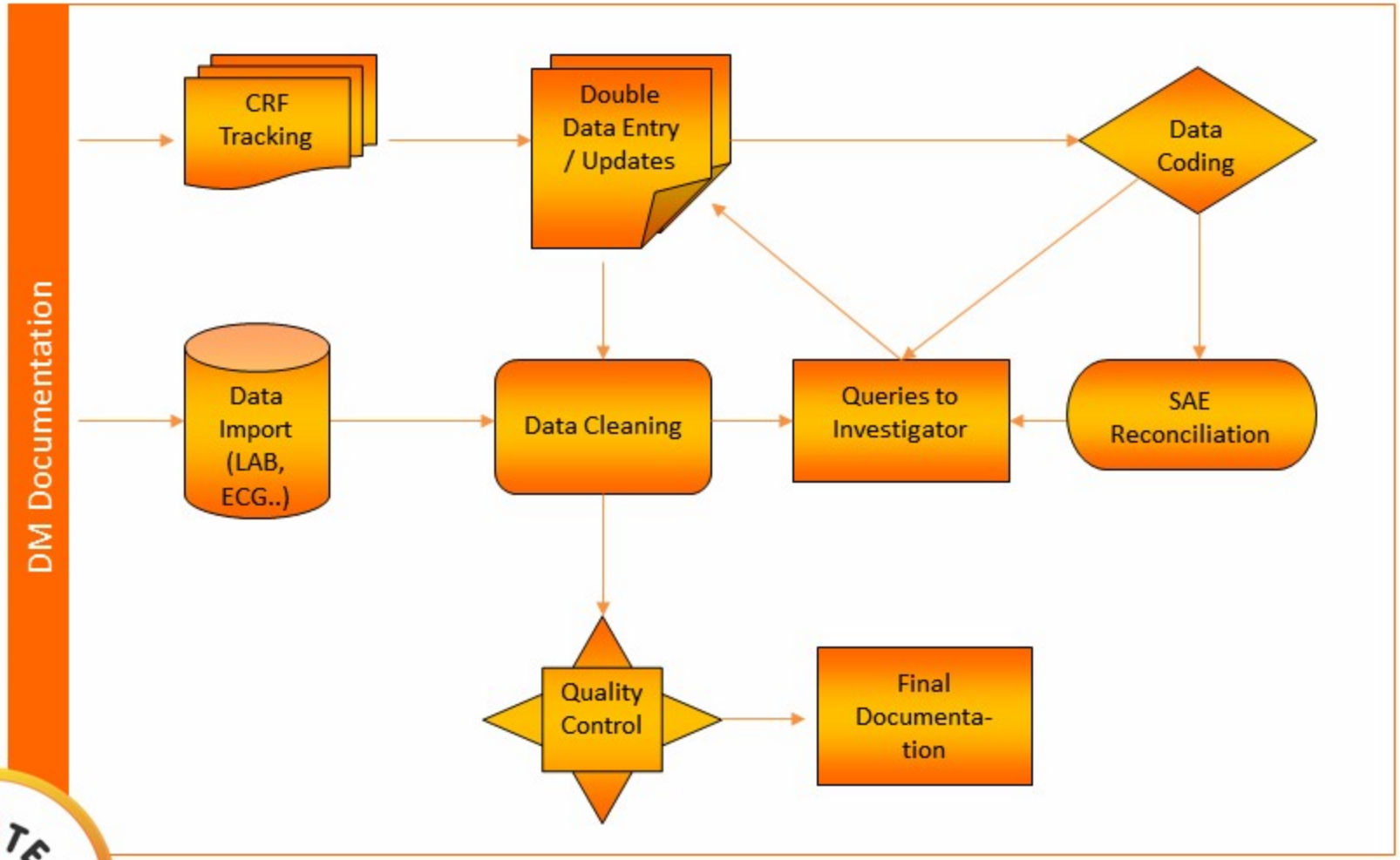

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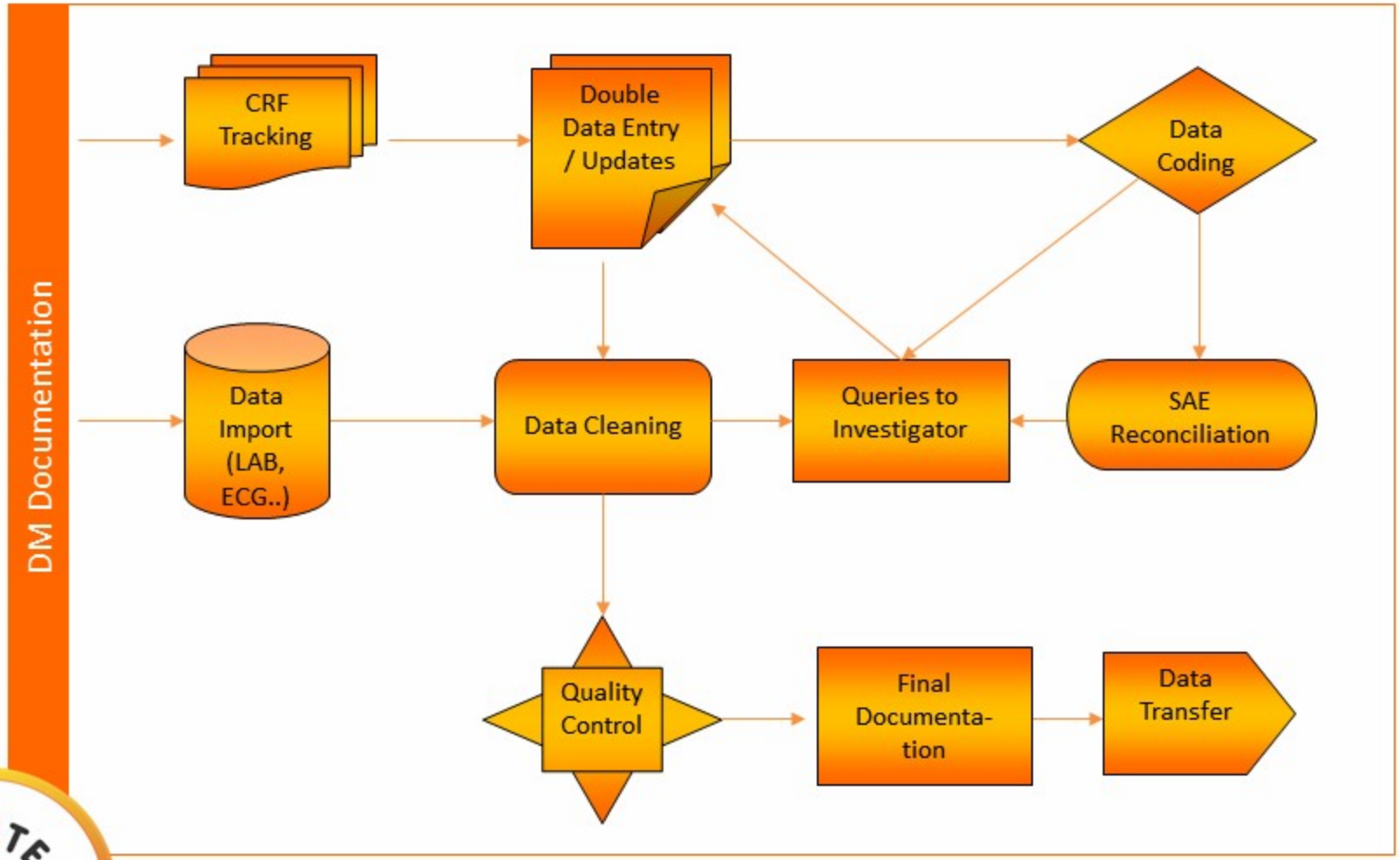

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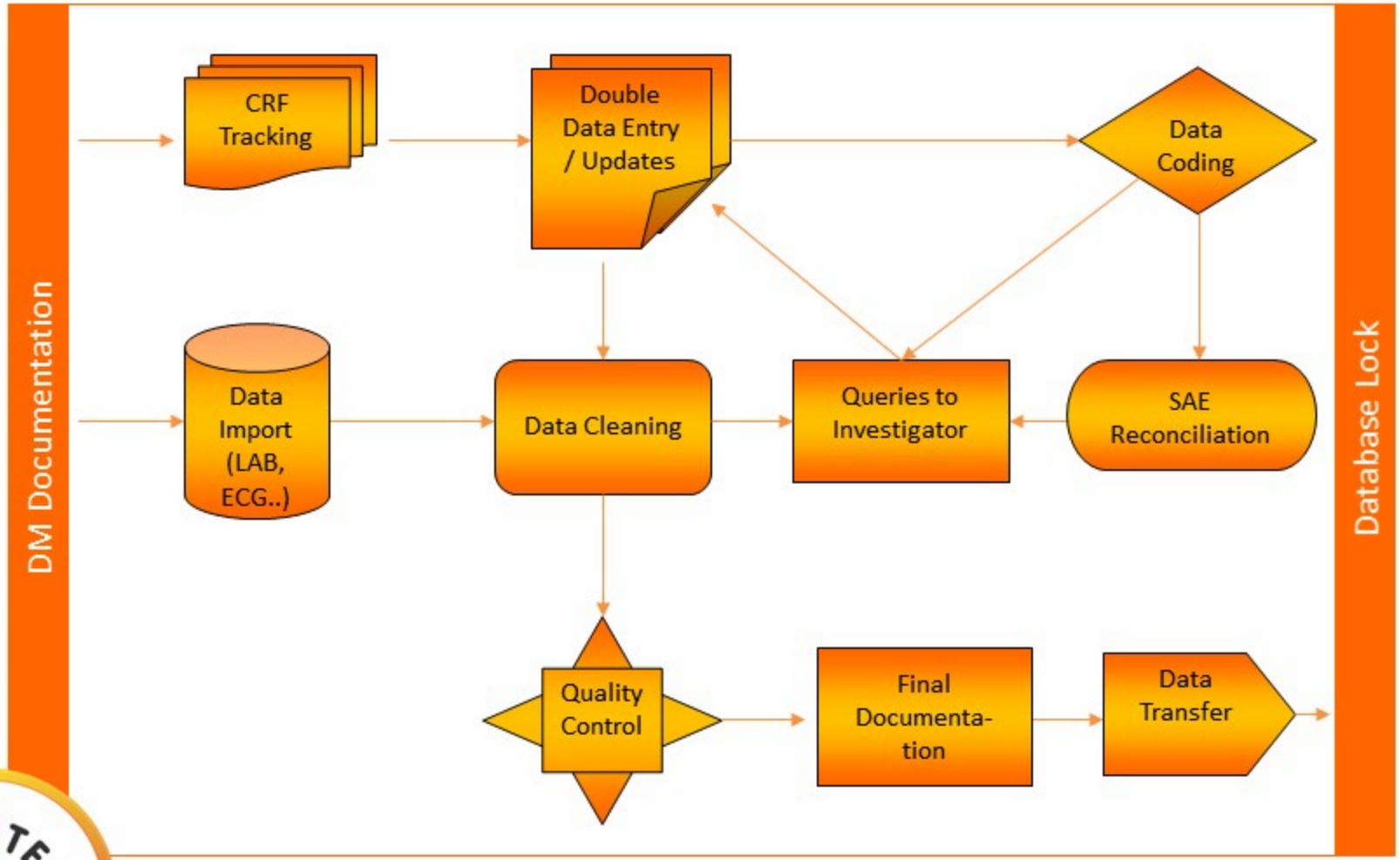
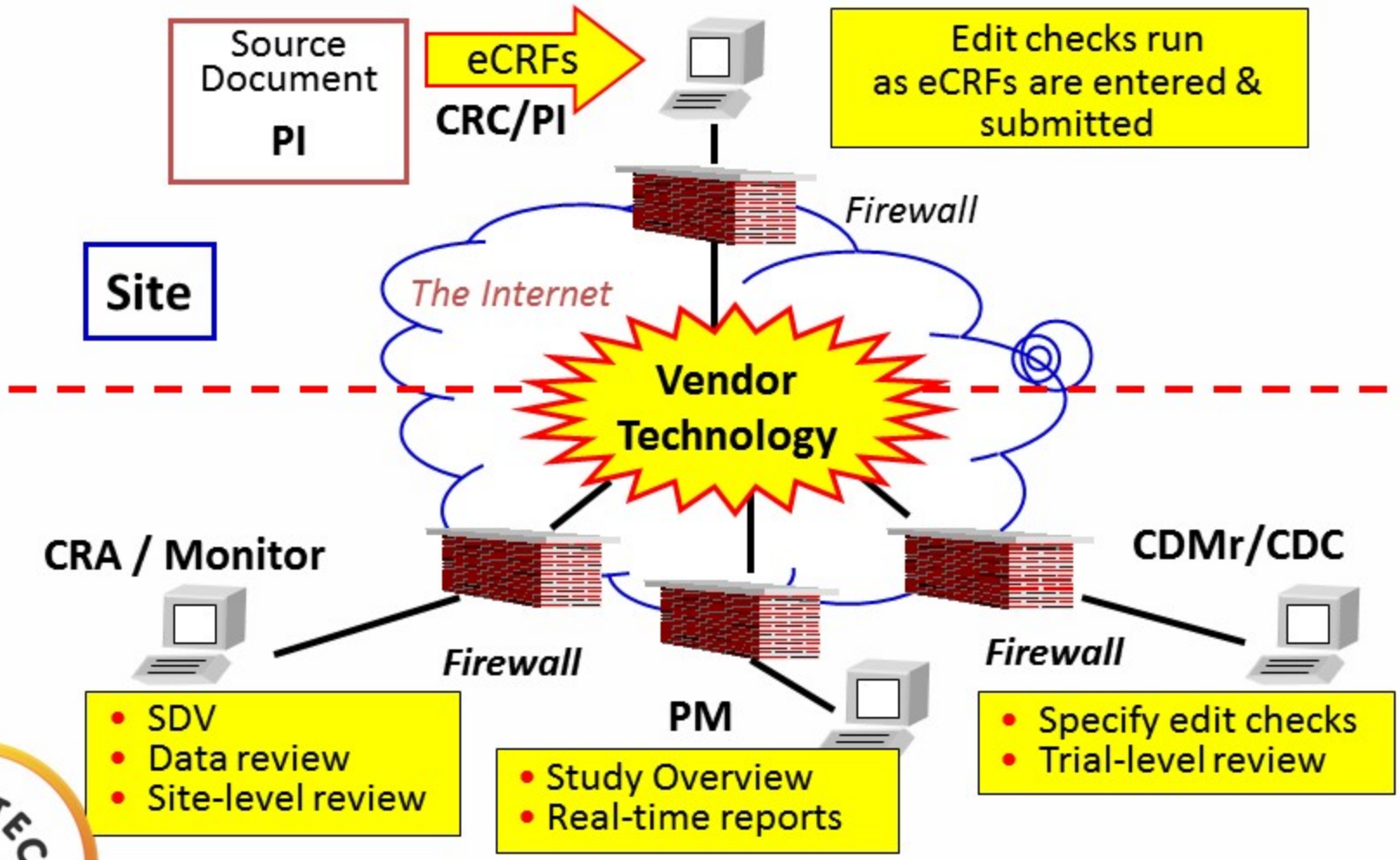
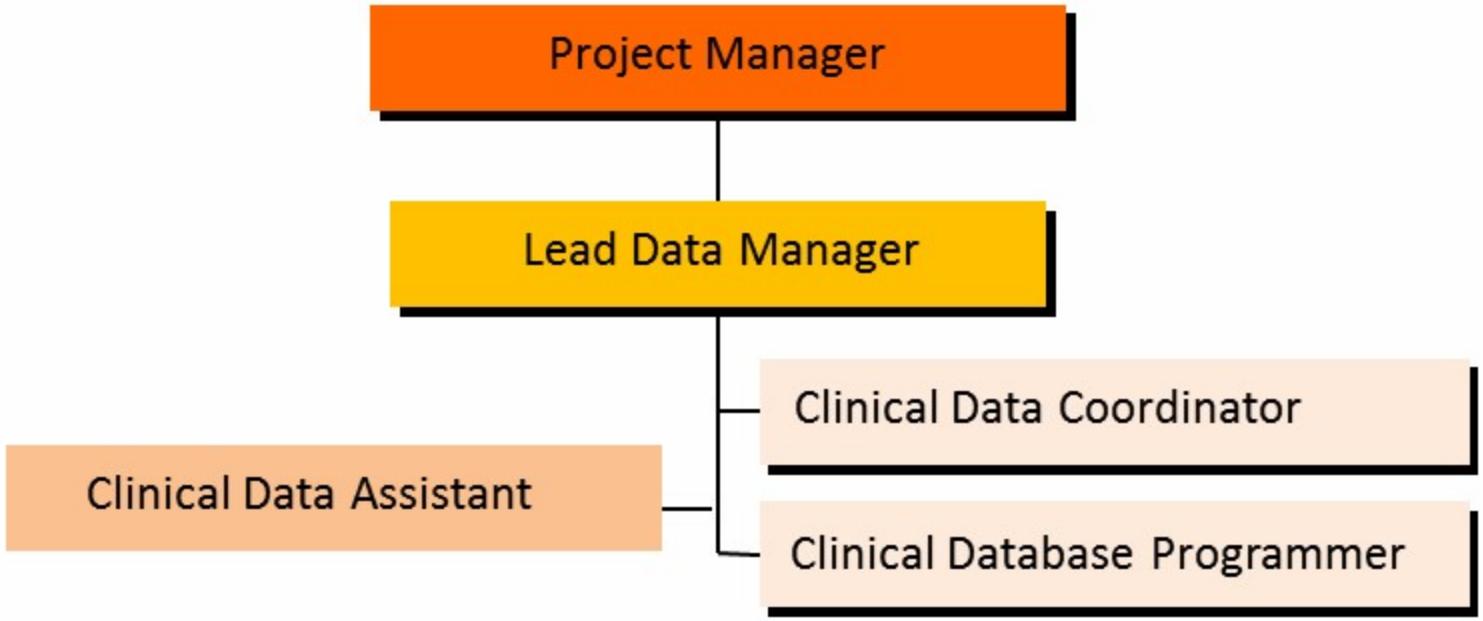


eDC


Source Document
PI
eCRFs
CRC/PI
Edit checks run as eCRFs are entered & submitted
Firewall
Site
The Internet
Vendor Technology
CRA / Monitor
CDMr/CDC
Firewall
Firewall
PM
• SDV
• Data review
• Site-level review
• Study Overview
• Real-time reports
• Specify edit checks
• Trial-level review

A project is therefore handled by various team players

Example of a CDM project Team



Data Management Plan

Planning of CDM activities

- What is the work to be performed
- Task ownership matrix
- Risk involved and Business Continuity Plan (BCP)
- SOPs or guidelines that will apply
- What document or output to collect or produce
- How it will be collected
- Archival

Project Manager: CDM

- Oversee all processes in Clinical Data Management for specific trials.
- Manage and co-ordinate projects.
- Understand and comply with CRO and customer-specific Standard Operating Procedures (SOPs).
- Provide training in:
  - The operational techniques and activities undertaken within the Data Management department.
  - CRO Clinical Data Management SOPs.
- May serve as Clinical Data Manager.

Project Manager: CDM (contd)

- Ensure that projects are completed within budget constraints.
- Provide regular reports on budget recognition.
- Resource management.
- Recruitment selection.
- Identification of training needs.

Lead Data Manager

- Primary point of contact for data management issues.
- Gather information relevant to CDM.
- Develop project documentation.
- Deliver CDM products, e.g., database, QFs, reports, etc.
- Project Set-up, Maintenance, and Documentation.

Clinical Data Coordinator (CDC)

- Perform manual reviews on data.
- Code clinical data.
- Assist data capturing staff on illegible text.
- May serve as Lead Data Manager.
- Perform and/or initiate comprehensive data management tasks.
- Perform and/or initiate comprehensive quality control.
- Provide data management expertise and data co-ordination process improvement to the Data Management department.
- Independently bring project solutions to the Data Management department.

Clinical Data Coordinator (CDC) (contd)

- Provide Data Management with clinical expertise.
- Understand and comply with CRO and customer-specific Standard Operating Procedures.
- Develop and maintain good communication and working relationships with Data Management team.
- May interact with corporate team and Data Management team members to negotiate time lines and responsibilities.
- May assist with instruction and/or training of Clinical Data Co-ordinators

Clinical Database Programmer

- Design and test a database according to CRO or client requirements.
- Responsible for documentation that complies with database design and validation e.g. Data Entry Guidelines and Data Validation Guidelines.
- Perform Validation Programming.
- Validate all Validation Programming according to standards agreed to for that specific project.
- Merge data if required by client.
- Perform Batch Loading of data into applicable Database Management System.

Clinical Database Programmer (contd)

- Download data to the format required by client.
- Understand and comply with CRO and customer-specific Standard Operating Procedures.
- Assist with development and implementation of new technology.
- May assist with instruction and/or training of Database Programmers.
- Develop and maintain good communication and working relationships with Data Management team.
- Perform other duties as directed by the Project Manager or Head of Data Management.

Data Entry Assistants

- Enter data as supplied by the Lead Data Manager.
- Enter and/or verify data accurately into study database in accordance with Data Entry Guidelines.
- Perform comparisons during verification in accordance with Data Entry Guidelines.
- Process, log and track clinical study documents in accordance with the Tracking Guidelines.
- Document data problems as appropriate according to data instructions.
- May assist with resolution of data problems.
- Assist in the Quality Control of a project.

Data Entry Assistants (contd)

- May perform quality control checks as directed by the Lead Data Manager or Head of Data Capturing.
- Understand and comply with CRO and customer-specific Standard Operating Procedures.
- Ability to work according to deadlines.
- Perform general secretarial tasks as authorised by the Lead Data Manager.
- Perform other duties as directed by the Project Manager or Head of Data Capturing.
- Develop and maintain good communication and working relationships in the Data Management team.

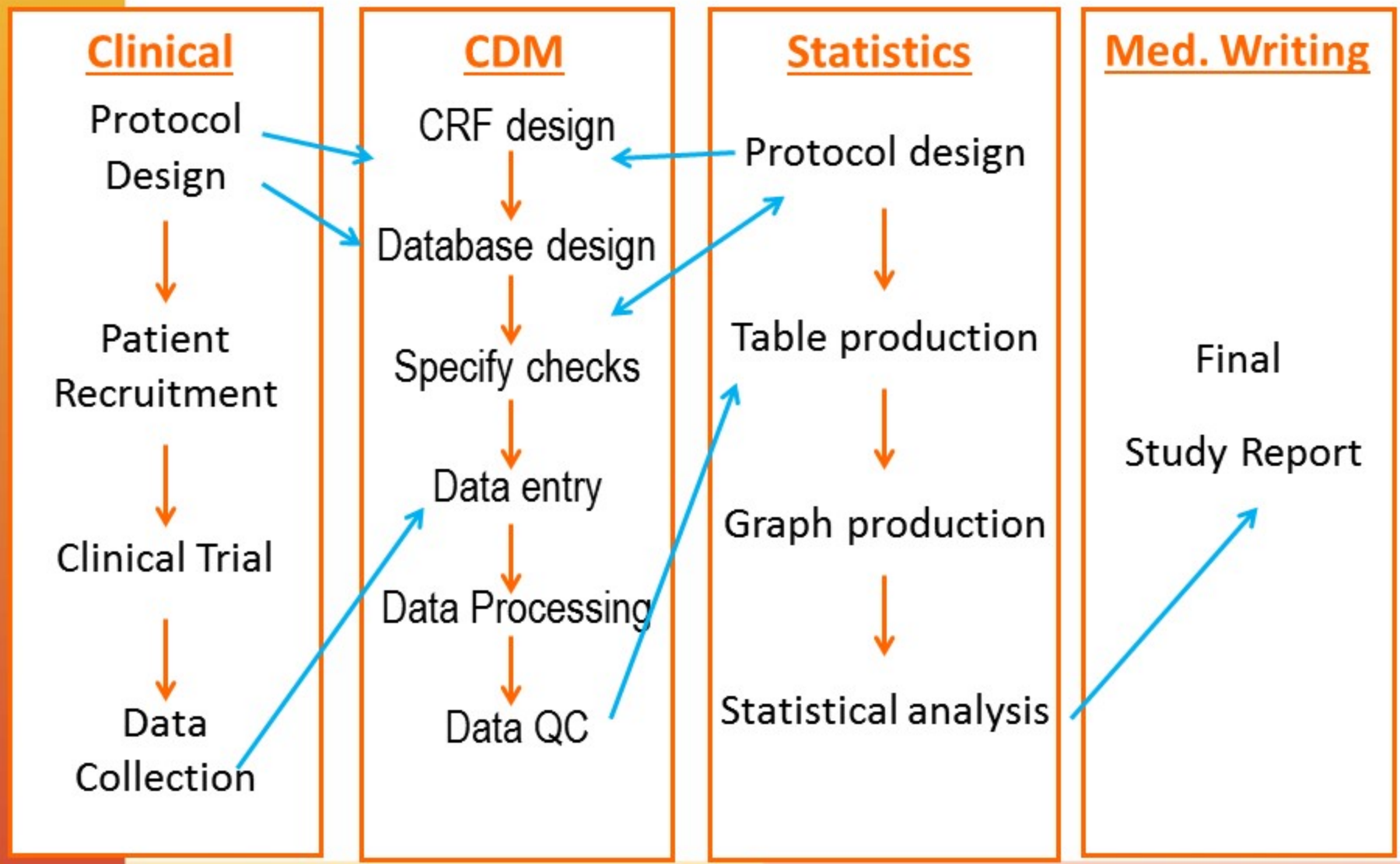
Biostatistician

- Writes the Programming Specs which define what fields will be used for analysis, how the computer generated tables and appendix listings should look, and what variables will need to be created.

Medical Writer

- Writes the Project Report that is in a format compliance to FDA submissions

In summary….Where does CDM fit in?



Questions