Discrepancy Management

Module 10 Topic 8

Discrepancy

- What is Discrepancy?
- In simple terms it is an ERROR!
- Discrepancies are “Inconsistencies” found in clinical trial data which need to be corrected as per study protocol

Discrepancy

Why do we need this?

- Medical data is complex
- The data that is generated has regulatory implications
- In order to clean data to such a high level, questions will need to be asked
- These questions is known as Queries
- For Discrepancy we raise Query…therefore sometimes the activity that we do is known as Query management.

Types of Discrepancies

- **System generated:**
  - Univariate
  - Multivariate
- **Manually raised:**
  - Clinical Research Associate
  - Data entry
  - Data Manager raised query
  - Coders
  - Medical/ Clinical team

System Generated Discrepancy

Univariate:

- It is called as Univariate as it looks for a single field (E.g.: If data in the field is missing or incomplete)

Multivariate:

- It looks/compare with two or more different fields in single page, multiple page or multiple visits (E.g.: Conmed and Adverse event page)

Manually Generated Discrepancy

- **Clinical Research Associate:**
  After Source Data verification (SDV) or performing in-house review.

- **Data Entry Operator:**
  Operator comments

Manually Generated Discrepancy (contd)

- **Data Manger:**
  Reference to manual review, external checks, reports and listings, or some outliers detected by Statistical review

- **Coders:**
  Inconsistency in Medical terms in Medical History, Concomitant medications, Adverse event, Serious AE, etc…

- **Medical/ Clinical team**

Types of Discrepancy

- Missing pages
- Inconsistent header information
- Incomplete data
- Incorrect data
- Missing data
- Illogical data
- Illegible data
- Inconsistent data
- To check if visits are compliant with the protocol
- To check whether the subjects meet the inclusion/exclusion criteria.

Creating Queries

- In paper studies CDM staff send out “Data Clarification Forms” or DCFs in process of query management
- Other names given to this form: Query forms, Correction forms, Discrepancy forms
- In eDC, Queries are generated within the system which can be viewed by the other parties involved like Monitors and Investigator sites.
- Discrepancies covered on a single form will all belong to one site but may refer to:
  - One or more patient for that investigator
  - A single patient but multiple CRF pages
  - A single patient & a single CRF page only

Tips for Generating Query

How to write a query:

- Be accurate, specific and sufficient
- Use simple language.
- Be neutral and non threatening
- And do NOT write queries that suggest a specific answer.
- Be polite, use ‘Please clarify’, ‘Please provide’ or ‘Please amend’ and rarely use ‘Please confirm’

Tips for Generating Query (contd)

- Query the whole situation
- State the whole problem
- Request clarification, amendment, information to be provided
- If new data would require changes elsewhere, then question/ request this change as well
- Do not club together unrelated queries for the same subject

Tips for Generating Query (contd)

- Good understanding of guidelines
- Knowledge about Protocol
- State a problem in a simple way
- Be Precise or to point while wording query text
- Use proper punctuation & grammatically correct sentences
- Avoid repetition of words in query text

Tips for Generating Query (contd)

Before you query….ask yourself…

- Did I understand the nature of the problem?
- Have I ensured that issue has not already been queried or explained in comments?
- Did I consider other reasonable solutions?
- Did I state the problem and the reason for change, in a logical order?
- Will the query be easily understood by others?
- Is the language clear, polite, simple and non-leading?

Tips for Generating Query (contd)

When you start query text…remember It should

- First mention **location** of query
- Then **state** discrepancy/issue
- **Ask** for resolution

Note: A query text should never be leading to Investigator

Tips for Generating Query (contd)

- **E.g.** An Investigator has left AE form blank. It can either be the subject did not experience any AE or the investigator has forgot to mention it in the CRF

  If the subject did not experience any AE, then also it should be mentioned in the CRF.

- **"In AE page, question for occurrence of adverse event is left blank. Please confirm that the patient did not have any adverse event and kindly update the AE page accordingly"**

Tips for Generating Query (contd)

As per the query formula for query writing,

- "In AE page," (location of discrepancy)
- "question for occurrence of adverse event is left blank" (discrepancy stated)
- "Please confirm that the patient did not have any adverse event and kindly update the AE page accordingly"(Resolution requested)

"And this query is NOT leading"

Tips for Generating Query (contd)

- **E.g.:** On demography page date of birth given as 31Nov 2007
- Since it is very clear that November month has no 31st day, this data has to be cross verified with Investigator

Tips for Generating Query (contd)

Query text:

- "On page 3, Demography record, Date of birth is recorded as 31 Nov 2007. Please verify date of birth."

- **As per formula for query writing,**
  - "On page 3, Demography record" (location of discrepancy)
  - "the Date of birth is recorded as 31 Nov 2007" (discrepancy stated)
  - "Please provide correct date" (Resolution requested)

"And this query is NOT leading"

Sending Queries

- Query form delivered to site via fax, paper mail, CRA in person, or e-mail

- In case of remote data entry systems, queries are immediately accessible to investigator, who can view query online

Tracking Queries

- What discrepancies were sent?
  - Data management tracks flow of queries to & fro between self & investigator
- Have queries been returned & processed?
  - Data management ensures that query responses are received & integrated within specified timeliness
- Which queries went & when?
  - Tracking spreadsheets to be maintained

Resolving Queries

- Data management integrates query response into database
- Common types of resolutions:
  - Value in question maybe correct as is
  - Actual measurement may replace a missing value
  - Corrected value may replace an incorrect value
  - Value maybe wrong but no corrected value is available

Re-queries

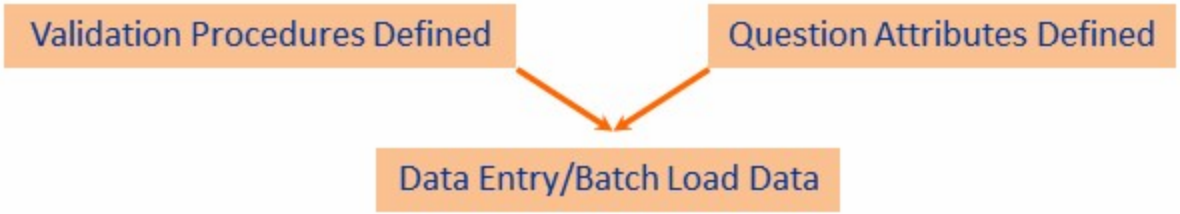
- Needed when investigator provides
  - No response
  - Incorrect response
  - Inconsistent response
  - Incomplete response (including signature)
  - Same response

- Possible approaches to handle incomplete resolutions:
  - Re-issue discrepancy on a new query form
  - Leave that one discrepancy as unresolved & await a re-send of query form
  - Leave it as unresolved & await correct CRF

Discrepancy Statuses

- Identified or registered
- Reviewed & still open
- Sent to investigator
- Passively linked
- Data updated
- Closed

Discrepancy Management Workflow



Discrepancy Management Workflow

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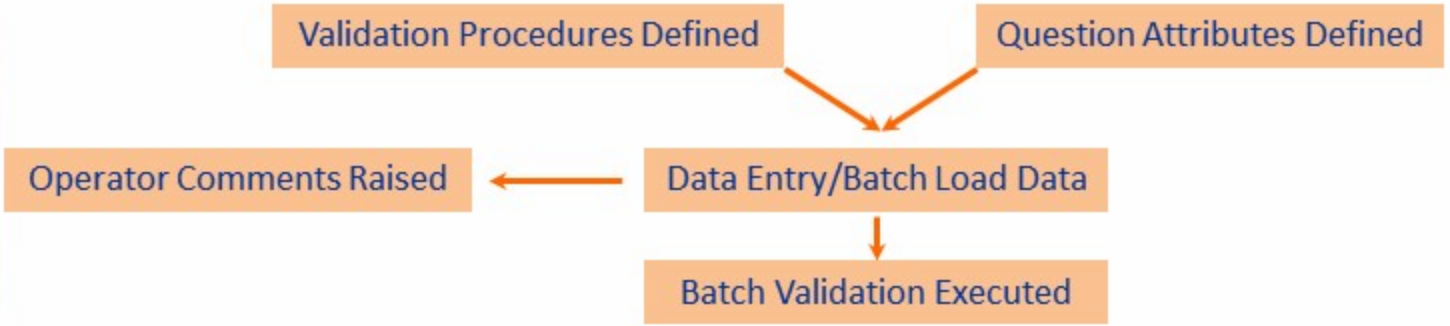

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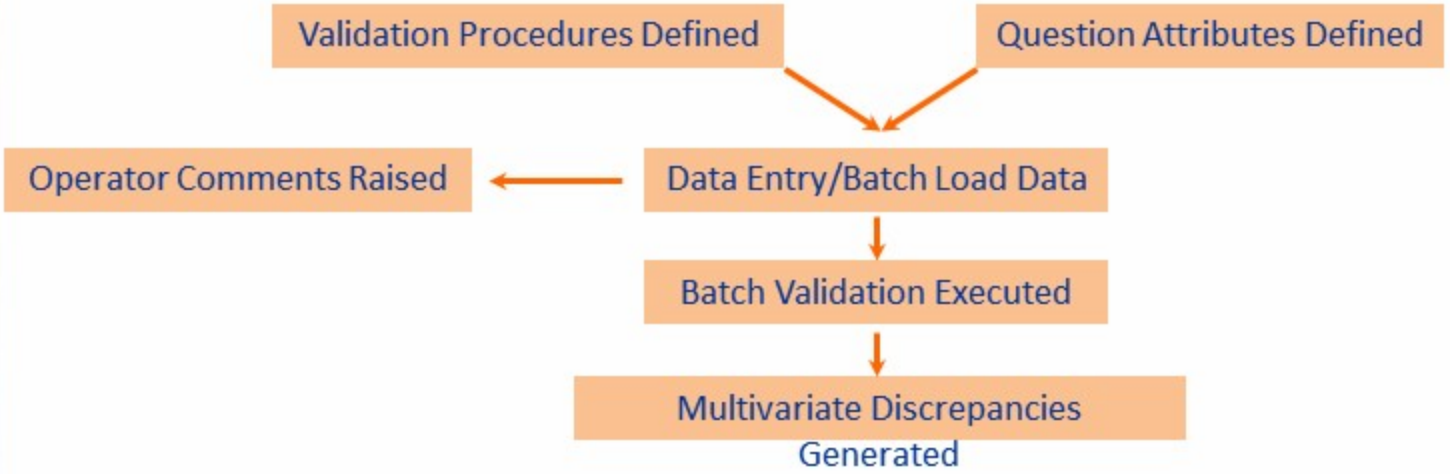

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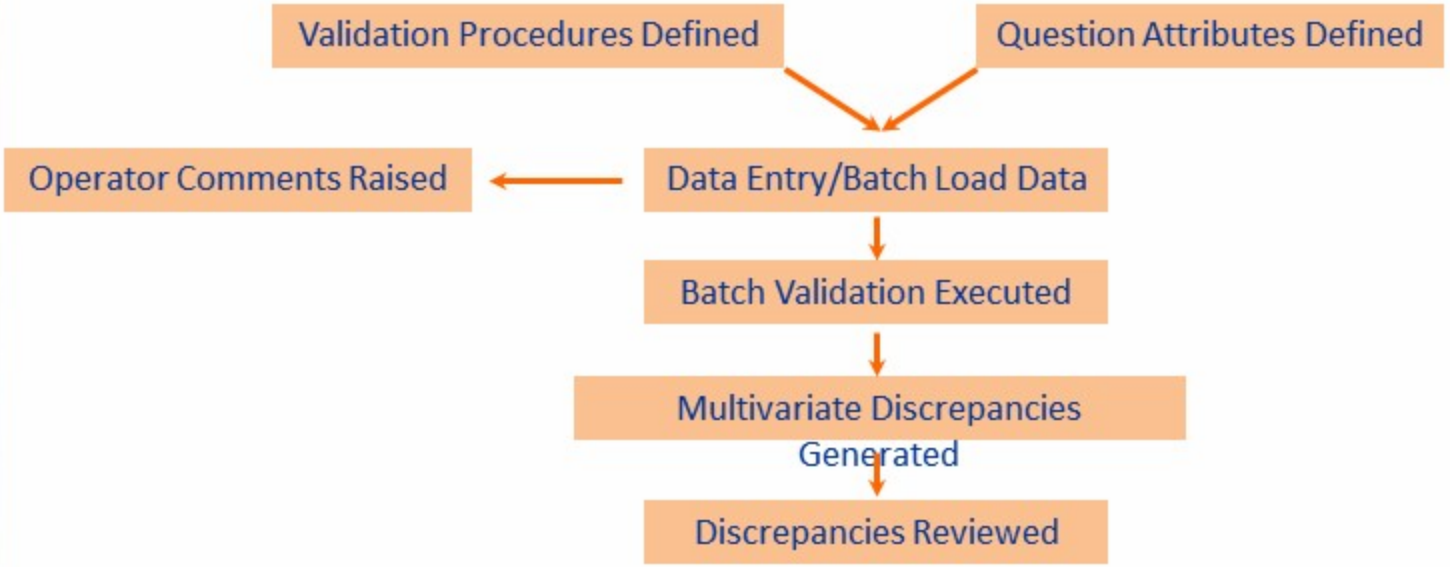

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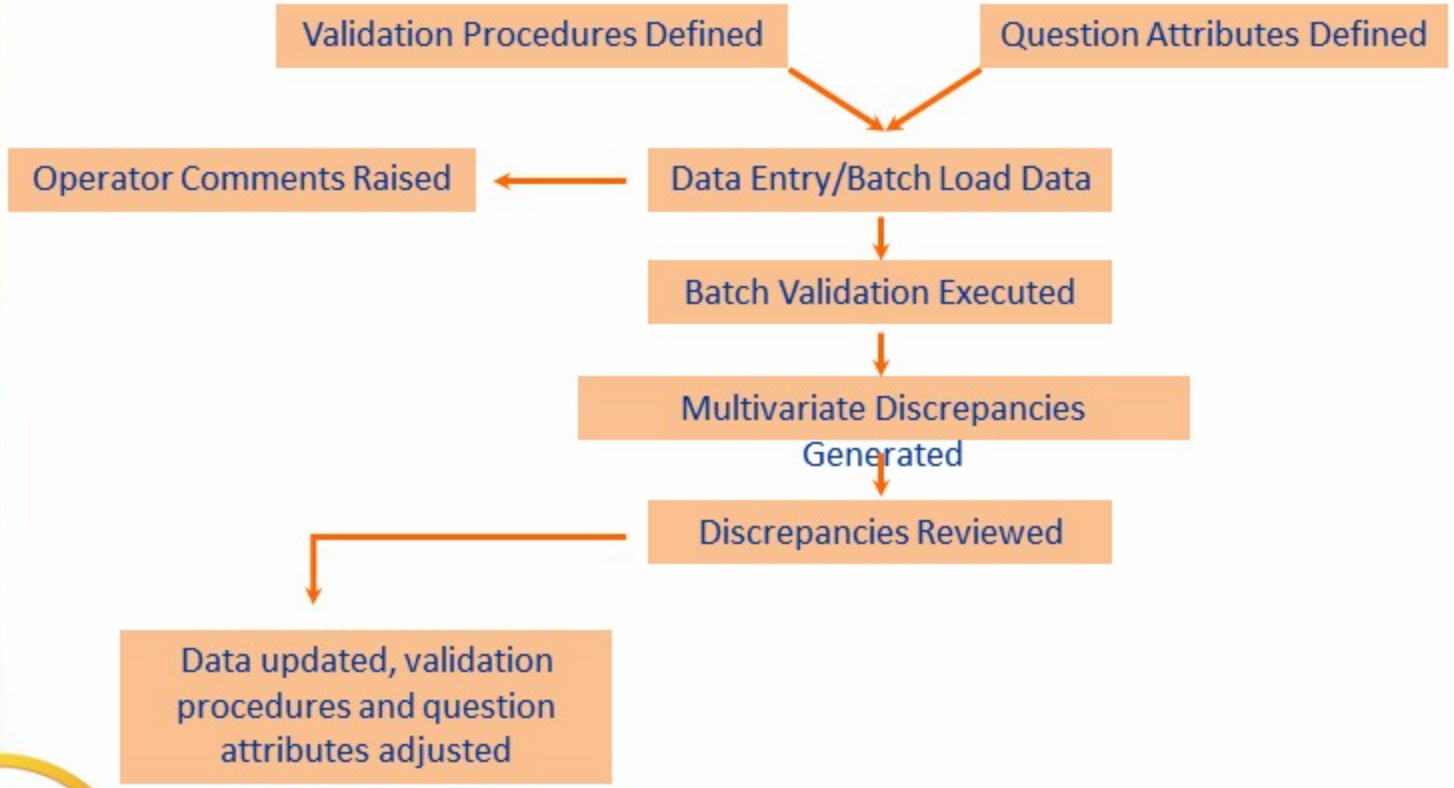

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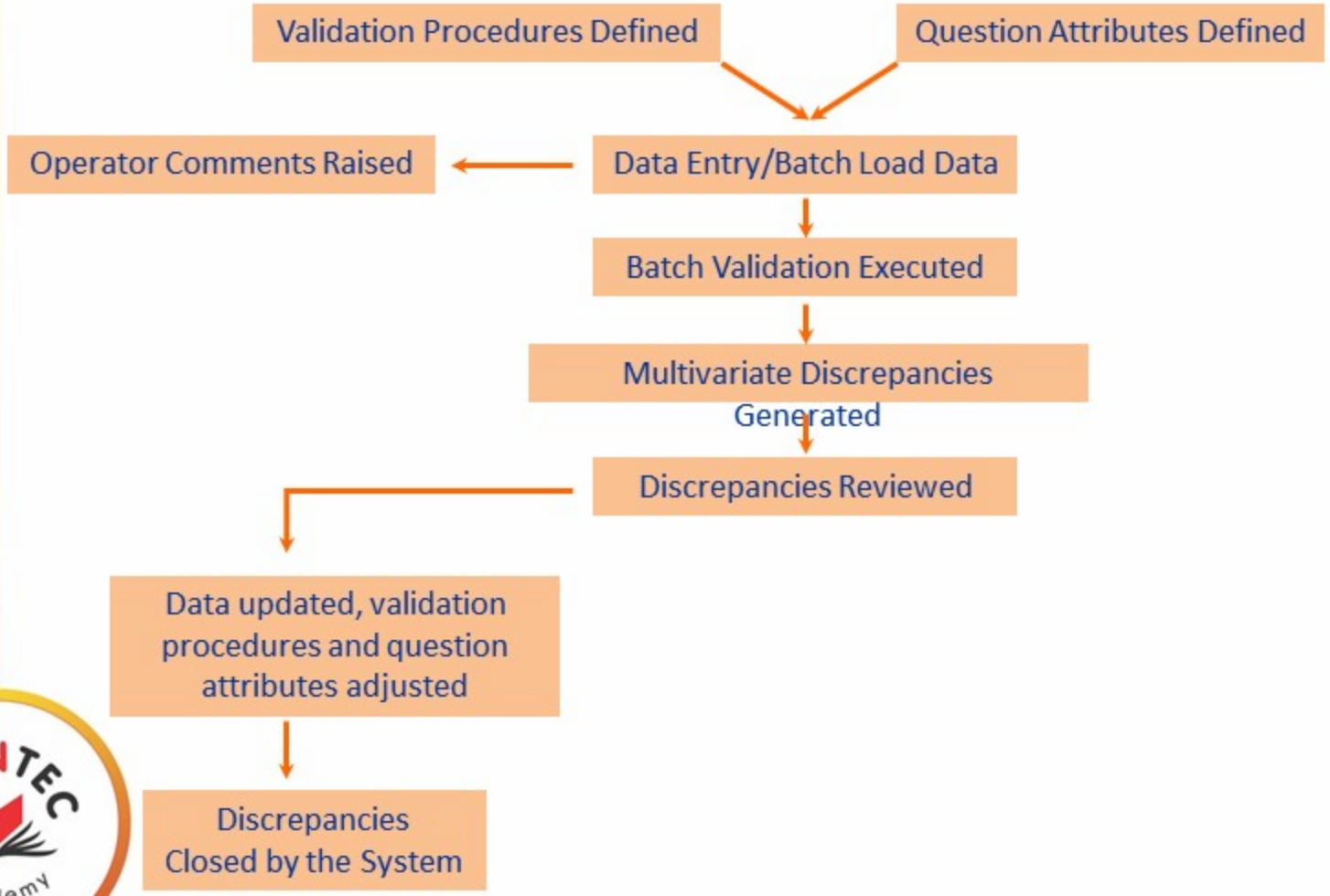

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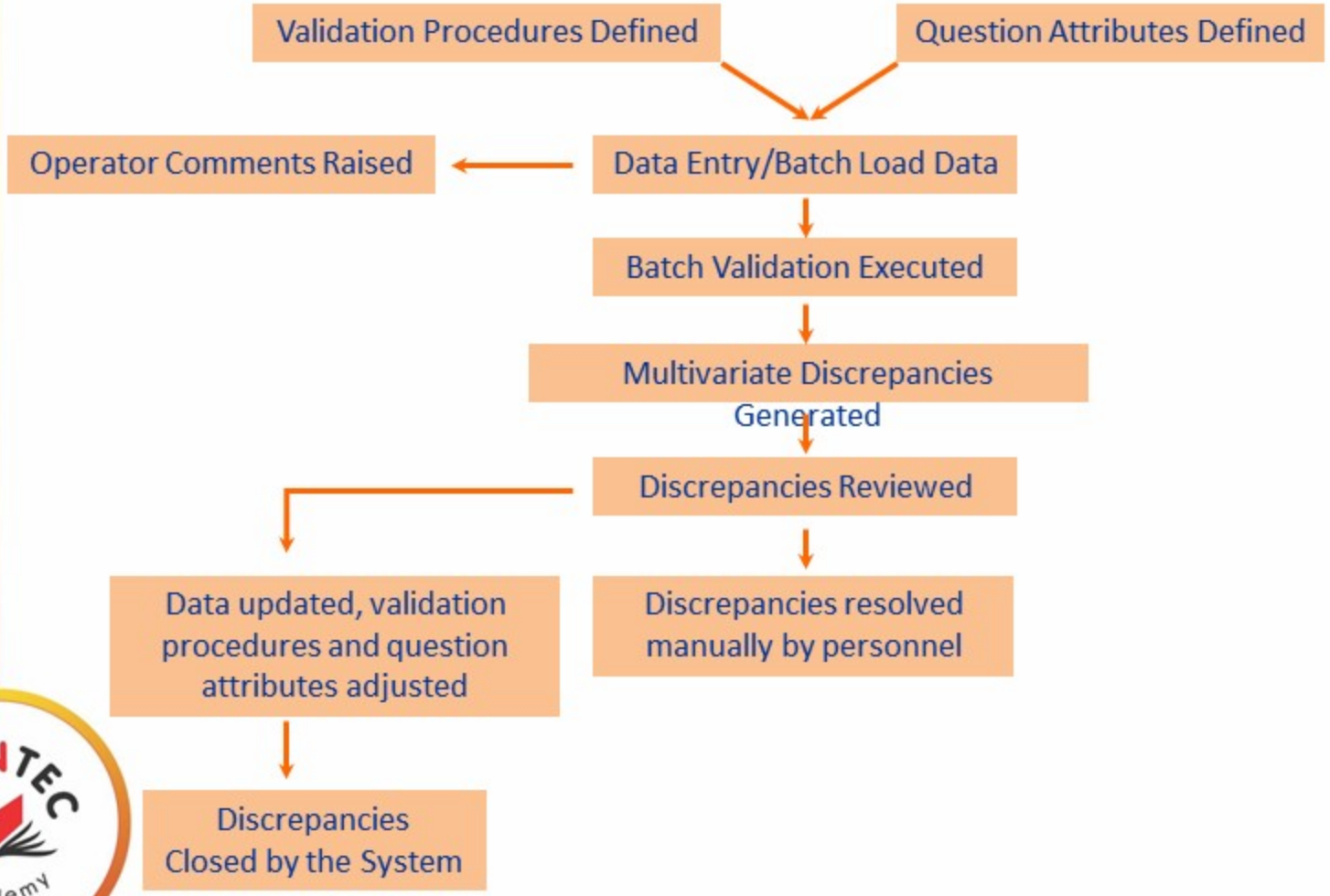

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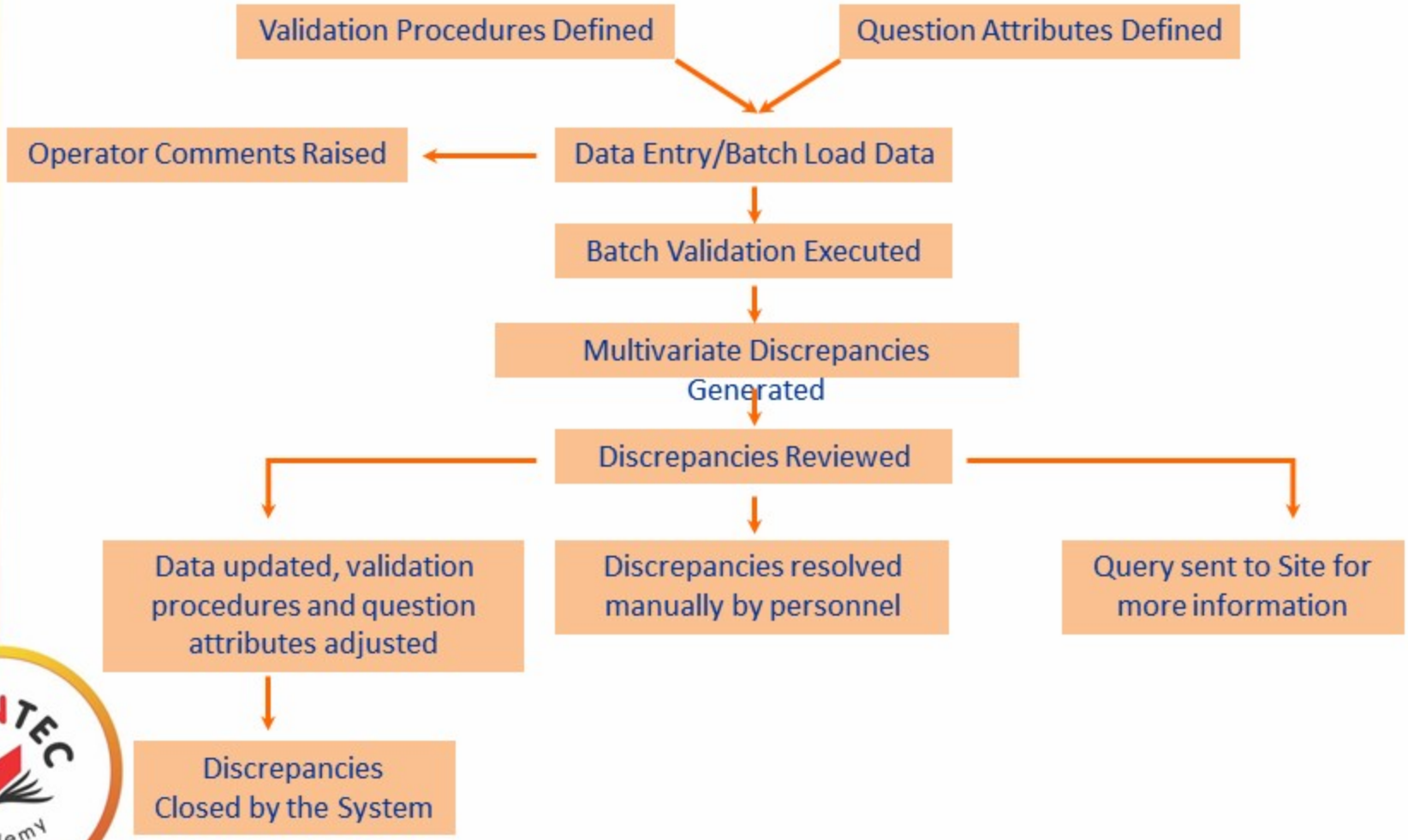

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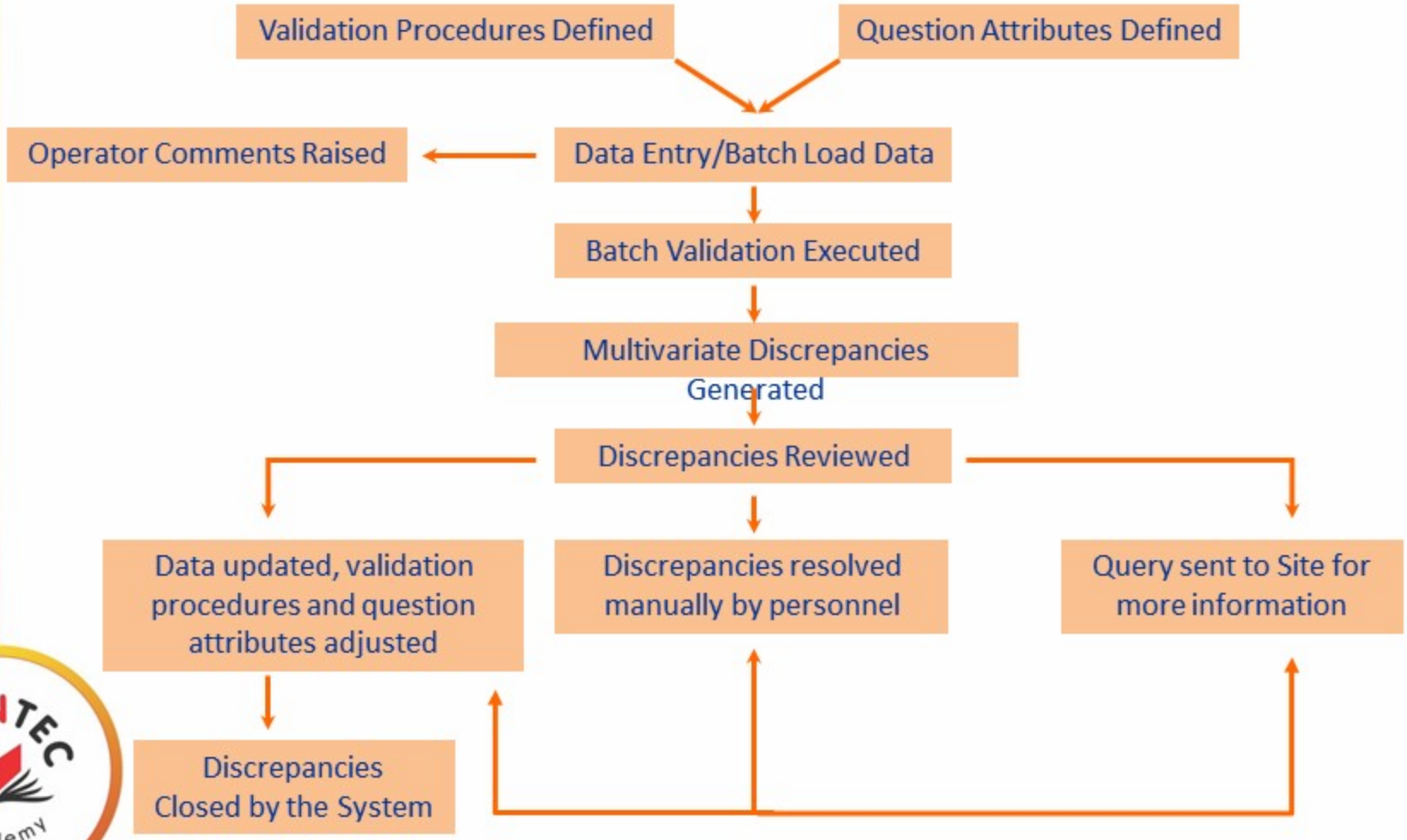

Discrepancy Management system

- Discrepancy management systems are designed to:
  - Supplement Data Management system.
  - Provide summary information on causes of discrepancies and their resolution.
  - Provide metrics on time to resolve issues.
  - Help eliminate over-reporting & reporting of duplicates.

Discrepancy Management system

Helps us identify

- Source of discrepancy
- Date & time it was identified
- Linked or duplicate discrepancies
- Status of discrepancy in system
- Data & time query sent to investigator
- Query form identifier
- Final resolution
- Date & time of resolution
- Source of resolution

Questions???