Elevate Your Game

Leveling Up SDTM Validation with the Magic of Data Managers

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Abstract

Collaborating with players armed with unique abilities is key to crafting an unbeatable strategy. Regarding standardized clinical trial data, **cross-departmental collaboration can help break down departmental siloes** while **enhancing the quality of study data**, leading to earlier availability of effective treatments.

Many organizations have enlisted SDTM programmers with unraveling SDTM validation issues. However, some issues require **tracing SDTM data back to its roots** to optimize decision-making. Integrating Data Managers into this process can help slash time to resolution and boost overall data quality.

This poster will provide important considerations on **weaving Data Managers into the SDTM validation process**. Suggested workflows will illustrate how to level up your approach to resolving validation issues. Curating appropriate FDA validation rules along with detailed examples will showcase how these are best served by Data Managers. Lastly, suggested **training and ideas to "power-up" your Data Managers** will equip you to battle issues at the source.

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Key strategies to enlist Data Managers to conquer issues

- Collate **past validation reports** and use **comments and explanations** from those reports to determine whether the issues found can be traced back to problems with raw data.
- Research **section 4.2 of the Clinical Study Data Reviewer's Guide** for past submissions and use the explanations to determine which issues were explained as data issues.
- Review the **FDA Validator rules** and evaluate which are most likely to be data issues according to the standardized data collection and mapping process in your organization.

The Data Manager

Strengths and skills:

- Familiar with form design, fields and raw data
- Ability to query sites and implement raw data checks

Benefits of involvement:

- Reduction of research and time to resolve raw data issues
- Improved study quality
- Better decision making, earlier

Tools and skills to aid in your campaign for clean, compliant data

Training for Data Managers can be as targeted or broad as required, but bear in mind Data Managers will not typically need to know how to map data or annotate an aCRF. Ensure these members of your cross-functional team can:

- Trace **SDTM variables** back to their **data collection variables**.
- Understand the **basics of CDISC** (and CDASH, if used).
- Recognize differences between (and importance of) an **eCRF**, an **eCRF annotated with EDC variables**, and **SDTM annotated CRF**.
- Become familiar with **basic mapping specification concepts**.
- Determine **which domain is mapped from which raw dataset** that corresponds to which form.
- Know what **common transformations** mean and how they impact the **raw data value**.

Conquer these Quests

SD1332

AEOUT = NOT RECOVERED/NOT RESOLVED, but an end date is provided

Identify:

2 variables involved, both collected on the CRF: AEOUT and AEENDTC.

Investigate:

Does the unresolved adverse event have an end date populated?

Resolve:

Data Managers should be able to locate this in the CRF to determine if the site needs to be queried to correct this information.

Data Management may want to determine if a raw data check should be incorporated into the CRF (if it isn't already).

SD1279

ECDOSTXT is null when ECDOSE is null and ECOCCUR does not equal 'N'

Identify:

3 main variables involved: ECDOSTXT, ECDOSE, and ECOCCUR

Investigate:

Are ECDOSE or ECDOSTXT populated with values in the raw data? Is ECOCCUR populated appropriately according to data collected on the form? Has a value been collected for the dosing information?

Resolve:

ECDOSE and ECDOSTXT may be populated using the value from a single field, e.g., ECDOSE is populated if a value is numeric and ECDOSTXT is populated if it is character. Allowable values and conditional fields are determined during eCRF build, so Data Managers can confirm if a dose was given or missed.

SD0080

AE start date is after the latest Disposition date

Identify:

2 domains are involved: AE and DS

Investigate:

Did the AE start date occur within the AE reporting period specified by the protocol?

Resolve:

Ensure AESTDTC has been reported correctly and that the participant was not off study at that time.

If dates are correct and the participant is still active in the study, this issue should resolve once the participant is off study.

If the participant completed or discontinued an ongoing study and AE start date is correct per the protocol, this should be documented in the cSDRG.

SD0036

Missing value for LBSTRESC when LBORRES is provided

Identify:

2 variables involved from the LB domain: LBORRES and LBSTRESC

Investigate:

Was LBORRES collected on the CRF?

Resolve:

LBORRES is collected on the CRF, and LBSTRESC is mapped from the LBORRES value to put collected variable into a standard format across all records, e.g., LBORRES could contain "NEG" or "NEGATIVE" or "NONE." When mapped to LBSTRESC, "NEGATIVE" could be used to keep the values standard and consistent.

If LBORRES was captured correctly and LBSTRESC is missing, this indicates a problem with mapping, which requires a programmer to resolve.

Advancing to the next level

Incorporating Data Managers into issue investigation and resolution early will help study teams **accelerate timelines** and **ensure data quality and compliance**. Scan the QR code at the top for more tips for building cross-functional teams to conquer data issues in validation reports.