
# Optimizing Efficiency and Improving Data Quality through Meaningful Custom Fix Tips and Explanations

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# Meet the Speakers

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- P21 Enterprise Subject Matter Expert
- 20+ Years Industry Experience
- User Advocate

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# Disclaimer and Disclosures

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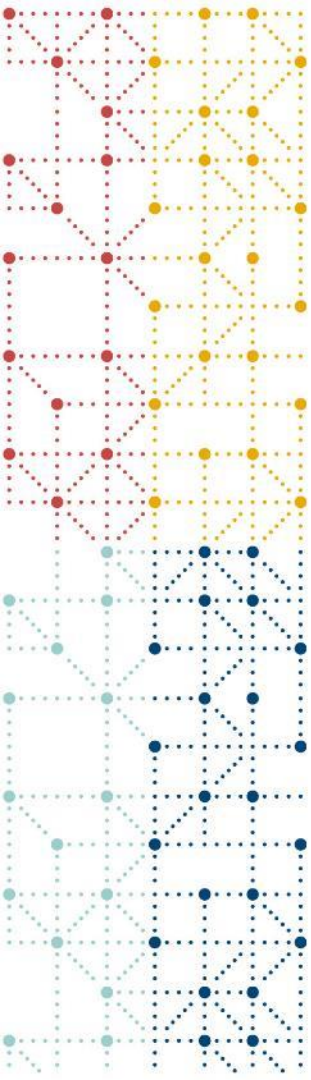
- *{Please disclose any financial relationship or conflict of interest relevant to this presentation here OR}*
- *The author(s) have no real or apparent conflicts of interest to report.*

# Agenda

1. Introduction
2. How to Eat an Elephant
3. Anatomy of a Fix Tip
4. Let's Do This! (Examples)
5. Summary



# It’s ok. Everyone has issues.

# Issues happen…

… and we want to know all about them!

cSDRG section 4.2; ADRG section 6.2; nSDRG sections 5.3 & 5.4; BDRG section 9.2

- **What** is the issue?
- **Why** is it still present?

The ***fewer issues*** there are, the ***easier*** it should be to review the submission.

# Validation nation

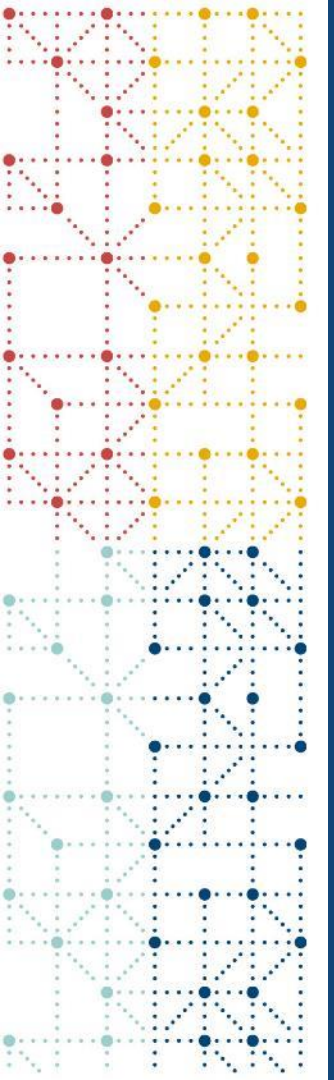
Validate *early* and *often*:

- Detect problems with clinical data standardization
- Increase:
  - **Expertise** diagnosing, triaging, resolving issues
  - Use of **defensive programming** to avoid validation issues

Comprehend validation report issues

- Different tools for validation
- Messages may not always be clear

# Error!



# How to Eat an Elephant…

# Cultivation

Thousands of rules, messages, descriptions

Where is the starting point?

- Standard
  - SDTM, ADaM, SEND, BIMO
  - Natural categories
- Importance
  - Frequency in **appearance**
    - Top Issues Report / Collate multiple validation reports
    - Sort by Severity/Impact
  - Frequency in **queries**
    - Central repository
    - Collate emails

# Time for Action

Determine best course of action

- Verify understanding of rule
  - Check:
    - Message
    - Description
    - Corresponding rule from FDA, CDISC Conformance Rules
    - IG references
    - Code for algorithm
- Thought Exercise
  - Population of value in question
- Check validation reports for issue
  - Find root cause and determine how best to address issue

# Anatomy of a Fix Tip

- Write out your thoughts
- Refine ideas by considering **length limitations** and **audience**
- Granularity
  - Example: **CT2002** can fire for all domains in all versions of SDTMIG, SENDIG, ADaMIG
    - **Overarching Fix Tip**: Remind user to ensure correct terms used as present in CDISC Submission Values in CDISC CT
    - **Standard-based Fix Tip**: Inform user issue is common for ADaM datasets using DTYPE codelist
    - **Value-level-based Fix Tip**: Inform user "MULTIPLE" and "OTHER" are used in various SDTMiG versions for variables where associated codelist does not contain those terms.

# Explanations

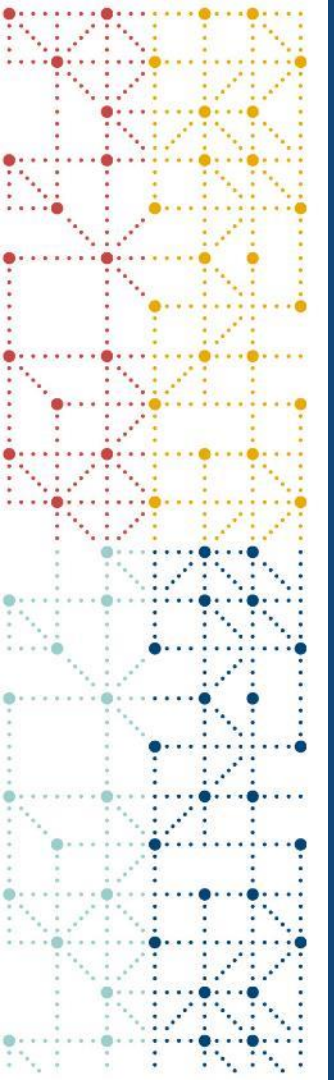
Some Fix Tips may recommend adding an Explanation to the Reviewer's Guide

- Include **detail**, but be **concise**
  - **Why** issue is still present
  - **Why** it wasn't corrected
  - **What is the effect** on the datasets/analysis

- Examples of unsuitable explanations include[1]:
  - "As per data"
  - "Data as collected"
  - "Mapped as-is"

# Storage and Maintenance

- Validation tool-based
- Searchable document
  - Excel
  - Smartsheet
  - Word
- Accessibility
  - Who can retrieve Fix Tips
  - On what basis
- Updates/Versions
- Communicating Changes



# Let’s do this!

# Slide Headline Maximum Two Lines Lorem Ipsum Dolor Sit Amet Sed Ut Labore Magnaer

## Here’s a sample slide layouts with tables:

| Column 1 | Column 2 | Column 3 |
|---|---|---|
| Item 1 | Item 1 | Item 1 |
| Item 2 | Item 2 | Item 2 |
| Item 3 | Item 3 | Item 3 |

| Column 1 | Column 2 | Column 3 |
|---|---|---|
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# SD1130: Inconsistent value for QNAM within QLABEL

*version 1.6, finalized December 2022*

| FDA Validator Rule ID | Publisher | Publisher ID | FDA Validator Rule Message | FDA Validator Rule Description |
|---|---|---|---|---|
| SD1130 | FDA | FDAB009 | Inconsistent value for QNAM within QLABEL | All values of Qualifier Variable Name (QNAM) should be the same for a given value of Qualifier Variable Label (QLABEL). |

*Version 1.5 finalized June 2019*

| FDA Business Rule ID | FDA Business Rule |
|---|---|
| **Clinical and Nonclinical** | |
| FDAB009 | All paired variables should have a one-to-one relationship. Examples include short name and name of test; parameter name and parameter code or number; variable name and variable label, etc. |

All paired variables should have a one-to-one relationship.

In the suppqual data set, verify each QNAM only has one QLABEL associated with it

# SD1144: MHSTDTC is after RFSTDTC

*version 1.6, finalized December 2022*

| FDA Validator Rule ID | Publisher | Publisher ID | FDA Validator Rule Message | FDA Validator Rule Description |
|---|---|---|---|---|
| SD1144 | CDISC | CG0079 | MHSTDTC date is after RFSTDTC | The medical history dataset includes the subject's prior history at the start of the trial. Start Date/Time of Medical History Event (MHSTDTC) should be before Subject Reference Start Date/Time (RFSTDTC). |

# SD1144: MHSTDTC is after RFSTDTC

| Rule ID | SDTMIG Version | Rule Version | Class | Domain | Variable | Condition | Rule | Document | Section | Item | Cited Guidance |
|---|---|---|---|---|---|---|---|---|---|---|---|
| CG0079 | 3.2 | 1 | EVT | MH | MHSTDTC | MHSTDTC ^= null | MHSTDTC < DM.RFSTDTC | IG v3.2 | IG v3.2[2.6]IIG v3.2[4.1.2.6]IIG v3.2[6.2] | | IG v3.2[2.6][Section 2.6: Do not create separate domains based on time, rather represent both prior and current observations in a domain (e.g., CM for all non-study medications). Note that AE and MH are an exception to this best practice because of regulatory reporting needs.]IIG v3.2[4.1.2.6][Section 4.1.2.6, Item 2.B.3.A (Discussion of --CAT/--SCAT): Adverse Events (AE), Medical History (MH) and Clinical Events (CE), for example, are conceptually the same data, the only differences being when the event started relative to the study start and whether the event is considered a regulatory reportable adverse event in the study.]IIG v3.2[6.2][Domain Code Table: The medical history dataset includes the subject's prior history at the start of the trial.][MH: The medical history dataset includes the subject's prior history at the start of the trial.][Assumption 1:The Medical History dataset generally includes the subject's prior and concomitant conditions at the start of the trial.] |
| CG0079 | 3.3 | 1 | | | | | | | | | |
| CG0079 | 3.4 | 1 | | | | | | | | | |

IG v3.3[2.6][Do not create separate domains based on time; rather, represent both prior and current observations in a domain (e.g., CM for all non-study medications). Note that AE and MH are an exception to this best practice because of regulatory reporting needs]IIG v3.3[4.2.6][Item 2.B.3.A (Discussion of –CAT/–SCAT): Adverse Events (AE), Medical History (MH), and Clinical Events (CE), for example, are conceptually the same data, the only differences being when the event started relative to the study start and whether the event is considered a regulatory reportable adverse event in the study.]IIG v3.3[6.2][Domain Code Table: The medical history dataset includes the subject's prior history at the start of the trial.][MH: The medical history dataset includes the subject's prior history at the start of the trial.]

# SD1144: MHSTDTC is after RFSTDTC

Verify the derivation for RFSTDTC is correct and programmed correctly.

If RFSTDTC is derived correctly, verify the medical history start date for this record and the date used to populate RFSTDTC are correct.

If the dates are correct, determine if this has been correctly reported as a medical history event instead of an adverse event.

If the date values are incorrect and cannot be fixed, explain the issue in the Reviewer's Guide.

# Challenges

- Custom Standards
- Regulatory Authorities
- CDISC vs Agency
- Standard Versions
- Interpretation of Implementation Guide

# SD0058: Variable appears in dataset, but is not in SDTM model

Multiple Enrollments

SUBJID added to domains

*version 1.6, finalized December 2022*

| FDA Validator Rule ID | Publisher | Publisher ID | FDA Validator Rule Message | FDA Validator Rule Description |
|---|---|---|---|---|
| SD0058 | CDISC | CG0013, CG0542, CG0564, CG0565, CG0566, CG0567, 2, 10, 30, 31, 32, 268, 269, 270 | Variable appears in dataset, but is not in SDTM model | Only variables listed in SDTM model should appear in a dataset. New sponsor defined variables must not be added, and existing variables must not be renamed or modified. |

# SD0058: Variable appears in dataset, but is not in SDTM model

| Rule ID | Rule | Document | Section | Item | Cited Guidance |
|---|---|---|---|---|---|
| CG0013 | Variable = Model List of Allowed Variables for Observation Class | IG v3.2\|Model v1.4 | IG v3.2[2.5]\|Model v1.4[3.2.22] | | IG v3.2[2.5][Sponsors may not add any other variables. . . . Standard variables must not be renamed or modified for novel usage. Using SDTM-specified standard variable names.]\|Model v1.4[3.2.22][Each observation can be described by a series of named variables.] |
| CG0013 | Variable = Model List of Allowed Variables for Observation Class | IG v3.3\|Model v1.7 | IG v3.3[2.5]\|Model v1.7[3.2.2 2.1] | | IG v3.3[2.5][Sponsors may not add any other variables. . . . Standard variables must not be renamed or modified for novel usage]\|IG v3.3[2.5][[Using SDTM-specified standard variable names]\|Model v1.7[3.2.2 2.1][Each observation can be described by a series of named variables. Domain-specific variables, a concept introduced in SDTM v1.5, are for use in a limited number of designated domains and will be identified in the appropriate implementation guide.] |
| CG0013 | Variable = Model List of Allowed Variables for Observation Class | IG v3.4\|Model v2.0 | 2.5\|Model Concepts and Terms --Variables\|The General Observation Classes | | IG v3.4[2.5][Sponsors may not add any variables other than those described in the preceding three bullets. . . . Standard variables must not be renamed or modified for novel usage.]\|Model 2.0[Model Concepts and Terms --Variables][Each observation consists of a series of named variables.]\|Model 2.0[The General Observation Classes]Domain-specific variables, a concept introduced in SDTM v1.5, are for use in a limited number of designated domains and will be identified in the appropriate implementation guide.] |

# SD0058: Variable appears in dataset, but is not in SDTM model

When this issue appears related to SUBJID, check mapping to determine if SUBJID is being populated for multiple enrollments. If yes, explain this in the reviewer's guide. If no, remove SUBJID from the domain.

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All paired variables should have a one-to-one relationship.

In the suppqual data set, verify each QNAM only has one QLABEL associated with it

# ★★★ Summary

Steps (**Eating the Elephant**)

- Gather and prioritize issue list
- For each issue:
  - Determine best course of action
  - Write the Fix Tip
    - If needed, write an Explanation
- Store and Maintain

Benefits

- Consistency
- Quality
- Time Saving

# We all got issues!

Fix tips to the rescue!

# Keep in touch:

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# Thank You!