

Optimizing Efficiency and Improving Data Quality Through Meaningful Custom Fix Tips and Explanations

Jennifer Manzi & Julie Ann Hood, Pinnacle 21
jmanzi@pinnacle21.com ● jhood@pinnacle21.com



Issues Happen...

Not just in life, but also when it comes to standardized submission data. A clean, complete Reviewer's Guide is important when submitting clinical, nonclinical, and analysis data for regulatory review. Logic indicates that fewer issues produce to less problematic submission reviews- and shorter Reviewer's Guides! How can you and your colleagues work together to get rid of issues quickly? Enter Fix Tips!

Fix Tips are a tool that helps users determine why a validation issue is present by guiding them through the process of researching the root cause, then choosing the best option to resolve it.

Eating an elephant...

Organize by:

- by Standard
- by assigned team

Prioritize by:

- Impact on submission review
- Importance to your team
- How often an issue is queried
- How often a Rule ID fires

Strategize by:

- Understanding the rule
- Researching reasons a rule fires
- Considering multiple solutions

Anatomy of a Fix Tip

Length	Audience	Granularity	Prompt
Are there limitations? Keep content short while ensuring all necessary details are included.	Who uses the information? Ensure guidance is understandable for those who need it.	How detailed can you be? Make the information as broad or as specific as your needs dictate.	What should the user do? Provide guidance on next steps towards issue resolution.

Examples

SD1130 (FDAB0009)

Inconsistent value for QNAM within QLABEL

- In the supppqual dataset, verify each QNAM only has one QLABEL associated with it.

SD1144 (CG0079)

MHSTDTC date 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 incorrect date values cannot be fixed, explain the Issue in the Reviewer's Guide.

SD0058 (CG0013)

Variable appears in dataset, but 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.