

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

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## 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

**Are there limitations?**  
Keep content short while ensuring all necessary details are included.

### Audience

**Who uses the information?**  
Ensure guidance is understandable for those who need it.

### Granularity

**How detailed can you be?**  
Make the information as broad or as specific as your needs dictate.

### Prompt

**What should the user do?**  
Provide guidance on next steps towards issue resolution.

## Examples

|                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>SD1130 (FDAB0009)</b><br>Inconsistent value for QNAM within QLABEL        | <ul style="list-style-type: none"><li>In the suppqul dataset, verify each QNAM only has one QLABEL associated with it.</li></ul>                                                                                                                                                                                                                                                                                                                                                                              |
| <b>SD1144 (CG0079)</b><br>MHSTDTC date is after RFSTDTC                      | <ul style="list-style-type: none"><li>Verify the derivation for RFSTDTC is correct and programmed correctly.</li><li>If RFSTDTC is derived correctly, verify the medical history start date for this record and the date used to populate RFSTDTC are correct.</li><li>If the dates are correct, determine if this has been correctly reported as a medical history event instead of an adverse event.</li><li>If incorrect date values cannot be fixed, explain the Issue in the Reviewer’s Guide.</li></ul> |
| <b>SD0058 (CG0013)</b><br>Variable appears in dataset, but not in SDTM model | <ul style="list-style-type: none"><li>When this issue appears related to SUBJID, check mapping to determine if SUBJID is being populated for multiple enrollments.<ul style="list-style-type: none"><li>If yes, explain this in the Reviewer’s Guide.</li><li>If no, remove SUBJID from the domain.</li></ul></li></ul>                                                                                                                                                                                       |