7 Habits of Highly Effective (Validation Issue) Managers

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PhUSE US Connect 2019
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Validation Issues

• Validation report identifies areas of non-compliance
  • 100s of issues
• Review of validation report is manual
  • Time to review a report is varied
• Why are some people faster than others?
• Room for process?
The 7 Habits

1. Validates early
2. Gathers all relevant info about issues
3. Identifies the source(s) of issues
4. Tracks changes between validation reports
5. Communicates issues to others
6. Knows when to fix validation issues
7. Knows when to explain validation issues
Habit One Validate Early

• Leverage validation tools to find mistakes before a programmer does
  • Programming errors
  • Mapping spec errors
• Saving Time = Saving $$$
• It’s trendy
Habit Two: Gather All (relevant) Info About Issues

• Efficiently look into the data for more details about an issue – sometimes even all the way back to EDC
  • Validator Tools – Pinnacle 21 Enterprise provides more details than Community
  • SAS Macros - *The Devil is in the Details – Reporting from Pinnacle 21 Validation Report* (Garrett and Whalen, 2015).
  • Challenging trace all the way back EDC
Habit Three Identify the Source(s) of Issues

• Knowing the sources of issues can help discover patterns and data quality gaps.
  • Assign a source to an issue directly in Excel
  • P21E supports issue tags (source) to help group issues
  • Too often, a source is not captured and only comments are entered which limits the ability to improve your process.

• Most issues fall into one or more of the categories:
  • Data collection error
  • Programming/spec error
  • Metadata (define.xml)
  • Sponsor-defined addition
  • Study is ongoing
  • False positive
Habit Four Track Changes Between Validation Reports

• Three types of issue changes to track
  • New issues
  • Resolved issues
  • Updated issues
Habit Five  Communicates Issues to Others

<table>
<thead>
<tr>
<th>Dataset</th>
<th>Rule ID</th>
<th>Message</th>
</tr>
</thead>
<tbody>
<tr>
<td>AE</td>
<td>C20001</td>
<td>AFACN value not found in 'Action Taken with Study Treatment' non-extensible codelist</td>
</tr>
<tr>
<td>AE</td>
<td>C20001</td>
<td>AIDENT value not found in 'Outcome of Event' non-extensible codelist</td>
</tr>
<tr>
<td>AE</td>
<td>C20001</td>
<td>ASEV value not found in 'Severity/Intensity Scale for Adverse Events' non-extensible codelist</td>
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<tr>
<td>AE</td>
<td>S00038</td>
<td>FDA8003 Value for ADECOD not found in MedDRA dictionary</td>
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<tr>
<td>AE</td>
<td>S00038C</td>
<td>FDA8017 Value for ADECOD is in incorrect case</td>
</tr>
<tr>
<td>AE</td>
<td>S00012</td>
<td>FDA8034 AESTDY is after AENDTY</td>
</tr>
</tbody>
</table>

Issue Summary

<table>
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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>AE</td>
<td>S00013</td>
<td>FDA8034 AESTDTTC is after AEENDTTC</td>
</tr>
<tr>
<td>AE</td>
<td>S00015</td>
<td>FDA8034 AREDIT value not 'FATAL', when AEDOTH=&quot;Y&quot;</td>
</tr>
<tr>
<td>AE</td>
<td>S00012</td>
<td>FDA8034 AESTDY is after AENDTY</td>
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This check fired for 1 records in AE where AESTDTTC is after AEENDTTC: USPID = 924-415, AEIDTTC = 2011-09-05, AEENDTTC = 2011-10.

Though AEENDTTC of '2011-10' is after AEIDTTC of '2011-09-05', the dates cannot be compared because AEENDTTC is a partial date. A complete date was not obtained prior to patient being lost-to-follow.

This issue is related to S00013 below, which cannot be fixed, but the other 4 are data issues 5 (Amy, 1/9/2019 4:10 PM) Brad data collection

This issue is related to S00012 below, which cannot be fixed, but the other 4 are data issues 5 (Amy, 1/9/2019 4:10 PM) Brad data collection

FATAL has been populated from the CRF - needs DM to query site (Amy, 1/9/2019 4:10 PM) Amy data collection

EPDCH is null for these record - need to check (Amy, 1/9/2019 4:15 PM) Amy mapping
Habit Six Knows When & How to Fix Validation Issues

• Some issues **resolve** over time
  • Variable length is longer than max length of data
  • Start date is after last disposition date

• Some issue **should** be fixed
  • Issues related to data collection
  • Issues related to define.xml (DD and OD prefix)

• Some issues **MUST** be fixed
  • PMDA: Reject issues
  • FDA: Reject and High Impact issues
Habit Six: Knows When & How to Fix Validation Issues
Habit Six Knows When & How to Fix Validation Issues

- How can any one person know how to fix all the possible issues?
  - Experience
  - Common Pinnacle 21 Report Issues: Shall we Document or Fix (Gupta, 2018)
  - Pinnacle 21 Fix Tips

SD0059: Define.xml/dataset variable type mismatch

Variable DataType in define.xml must match variable Type in dataset. Define-XML data types of 'integer' and 'float' match dataset type of 'Num', all other match 'Char'.

<table>
<thead>
<tr>
<th>Common Source:</th>
<th>Programming, Define</th>
</tr>
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<tbody>
<tr>
<td>Review Impact:</td>
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<tr>
<td>Dataset:</td>
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<tr>
<td>Affected:</td>
<td>2</td>
</tr>
<tr>
<td>Assignee:</td>
<td>Michael Beers</td>
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<tr>
<td>Status:</td>
<td>Open</td>
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</tbody>
</table>

P21 Fix Tips:
- Check the program and specs to verify type is set correctly. If so, then update the define.xml to match.
- Check the define.xml and verify type is correct. If so, update program/specification to match.
Habit Seven Knows How to Explain Validation Issues

• Any issue that remains must be explained
  • Consistent explanations across studies for the same issues – only data specific details should change
  • *Best Practice for Explaining Validation Results in the Study Data (Kelly, 2018)*

• How to implement best practices?
  • Internal master document of Issue Explanations
  • Manage them in a different system
Habit Seven Knows How to Explain Validation Issues

- Subject XYZ-0001 did not have end dates or references collected and so could not populated in SDTM.
Thank You! Questions?

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