

7 Habits of Highly Effective (Validation Issue) Managers

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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

Dashboard

Analysis Support

Datasets

Issues

History

More Reports

Comparison ✕

Q Search

Change Type

☒ New

☐ Resolved

☐ Updated

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Dataset	Rule	Description	Severity	Rate	Change	Risk	Status
New (5 Issues)							
GLOBAL	SD0061	Domain referenced in define.xml but dataset is missing	Warning	100% ⓘ	-		Open
GLOBAL	SD1107	Missing LB dataset	Warning	100% ⓘ	-		Open
GLOBAL	SD1108	Missing VS dataset	Warning	100% ⓘ	-		Open
GLOBAL	TS0001	Missing LB dataset	Error	100% ⓘ	-		Open
GLOBAL	TS0022	Missing VS dataset	Error	100% ⓘ	-		Open

Habit Five Communicates Issues to Others

Issue Summary									
Dataset	Rule ID	Publisher ID	Message	Severity	Found	Comments	Assigned	Tags	Explanation
AE	CT2001		AEACN value not found in 'Action Taken with Study Treatment' non-extensible codelist	Error	2362		Amy	mapping	
AE	CT2001		AEOUT value not found in 'Outcome of Event' non-extensible codelist	Error	2244		Amy	mapping	
AE	CT2001		AESEV value not found in 'Severity/Intensity Scale for Adverse Events' non-extensible codelist	Error	5		Amy	mapping	
AE	SD0008	FDAB003	Value for AEDECOD not found in MedDRA dictionary	Error	453	terms haven't been coded yet. (Amy, 1/9/2019 4:02 PM)	Cody	study design	
AE	SD0008C	FDAB017	Value for AEDECOD is in incorrect case	Error	1924	terms haven't been coded yet. (Amy, 1/9/2019 4:02 PM)	Cody	data collection	
AE	SD0012	FDAB034	AESTDY is after AEENDY	Error	5	One issue is related to SD0013 below, which cannot be fixed, but the other 4 are data issues (Amy, 1/9/2019 4:10 PM)	Brad	data collection	
AE	SD0013	FDAB034	AESTDTC is after AEENDTC	Error	1		Brad	data collection	This check fired for 1 records in AE where AESTDTC is after AEENDTC: USUBJID = XYZ-415, AESTDTC = 2011-09-05, AEENDTC = 2011-10 Though AEENDTC of '2011-10' is after AESTDTC of '2011-09-05', the dates cannot be compared because AEENDTC is a partial date. A complete date was not obtained prior to patient being lost-to-follow.
AE	SD0091		AEOUT is not 'FATAL', when AESDTH='Y'	Error	3	FATAL has be populated from the CRF - needs DM to query site (Amy, 1/9/2019 4:10 PM)	Amy	data collection	
AE	SD1015		Invalid EPOCH	Error	147	EPOCH is null for these record - need to check programming logic (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

Sample Study

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AE - Adverse Events (8 Issues)

SD0009: No qualifiers set to 'Y', when AE is Serious	Data Programming	157	+15	High	Open
SD0059: Define.xml/dataset variable type mismatch	Programming Define	2	0	High	Open
SD0080: AE start date is after the latest Disposition date	Data	13		High	Open
SD0091: AEOUT is not 'FATAL', when AESDTH='Y'	Data Spec Programming	60	+7	High	Open
SD1082: Variable length is too long for actual data	Programming	9	+3	High	Open
SD1076: Model permissible variable added into standard domain		1	0	Low	Open
SD1096: High risk of truncated value for AETERM variable	Programming	1		Low	Open
SD1201: Duplicate records in AE domain	Data Programming	7	-12	Low	Open

CM - Concomitant Medications (7 Issues)

SD0035: Missing value for CMDOSU, when CMDOSE, CMDOSTXT or CMDOSTOT is provided	Data Programming	28	0	High	Open
CT2002: CMDOSU value not found in 'Unit' extensible codelist	Programming Define	1336	+34	Low	Open
SD0021: Missing End Time-Point value	Data Programming	6901	-78	Low	Open
SD0022: Missing Start Time-Point value	Data Programming	8	0	Low	Open
SD0031: Missing values for CMSTDTC, CMSTRF and CMSTRTP, when CMENDTC, CMENRF or CMENRTPT is provided	Data Spec Programming	5		Low	Open
SD0042: CMSTAT does not equal 'NOT DONE', when CMPRESP='Y' and CMOCCUR is NULL	Data Programming	341	0	Low	Open
SD1076: Model permissible variable added into standard domain		1	0	Low	Open

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'.

Common Source: Programming, Define

Review Impact: High

Dataset: AE

Affected: 2

Assignee: Michael Beers

Status: Open

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

Issue Details - SD0021 (AE) ← → ×

Details Records Explanation ☒

Explanation

B *I*

Subject XYZ-0001 did not have end dates or references collected and so could not populated in SDTM

Save Undo

Suggested Explanations

Copy	Suggested Explanation	Suggested Because...
«	Either: "<Some subjects (list subjects if three or less)\Subject <list subject> did not have end dates or references collected and so could not populated in SDTM." or: Neither end points or references were collected for any subject.	Recommended by your organization

Found 1 suggestions

Check ID	Diagnostic Message	FDA Severity	Dataset	Count (Issue Rate)	Explanation
SD0011	ARM is not 'Screen Failure', when ARMCD equals 'SCRNFAIL', or vice versa	Error	DM	25 (100.00%)	<Explanation>
SD0012	AESTDY is after AEENDY	Error	AE	5 (0.28%)	<Explanation>
SD0013	AESTDTC is after AEENDTC	Error	AE	1 (< 0.1%)	<Explanation>
SD0015	Negative value for SUDUR	Error	SU	3997 (96.76%)	<Explanation>
SD0017	Invalid value for RPTEST variable	Error	RP	53 (25.24%)	<Explanation>
SD0019	Invalid value for TSPARM variable	Error	TS	1 (3.70%)	<Explanation>
SD0021	Missing End Time-Point value	Warning	AE	576 (24.23%)	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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