

7 HABITS OF HIGHLY EFFECTIVE (VALIDATION ISSUE) MANAGERS

Amy Garrett, agarrett@pinnacle21.com

01 VALIDATE EARLY

Early validation saves time later. Leverage validation as a first-pass QC to find (and fix) issues before formal QC activities.

02 GATHER ALL RELEVANT INFO ABOUT ISSUES

Get full information about erred records. This can be quite time consuming but SAS[®] Macros can help¹.

03 IDENTIFY THE SOURCE(S) OF ISSUES

Categorize issues to understand where problems come from. Delegate issue categories to appropriate individuals. Most issues fall into one of the following categories:

- + **Data:** Issues with raw data. These generally require action from Data Managers (i.e. a site query).
- + **Mapping:** Issues related to mapping specs or programming. These are usually fixed by programmers.
- + **Metadata:** Issues related to the define.xml or consistency between data and define.xml. These typically require update to define.xml to correct.
- + **CRF Design:** Issues related to the way data was collected. These are not usually fixed and are instead explained in the Reviewer's Guide.

04 TRACK CHANGES BETWEEN VALIDATION REPORTS

Track changes from one validation report to the next to determine when new issues are occurring and how quickly known issues are resolved. It's also important to track **continuing issues**. Continuing issues are on both reports and possibly affect different number of records. When the same issue is present in both reports, prior comments and explanations should be copied from one report to the next.

05 COMMUNICATE ISSUES TO OTHERS

The P21 Validation Report can be distributed to communicate issues. Since all stakeholders may not be well-versed in CDISC, you should mark-up the validation report for better consumption (figure 1).

Issue Summary									
Dataset	Rule ID	Publisher ID	Message	Review Impact	Type	Found	Comments	Assigned	Tags
AE	SD0008	FDA8003, CG0379	Value for AEDECOD not found in MedDRA dictionary.	High	Error	454	Coding is ongoing - will be coded before DBL (Amy, 9/23/2019 2:08 PM)	Liz - Coder	Data
AE	SD0008C	FDA8017	Value for AEDECOD is in incorrect case	Low	Error	1923	Terms are being upcased by post-process macro. Need to update macro. (Brad, 9/23/2019 2:08 PM)	Amy	Mapping
AE	SD0012	FDA8034	AESTDY is after AEENDY	High	Error	5		Clair - DM	Data
AE	SD0013	FDA8034	AESTDTC is after AEENDTC	High	Error	1		Clair - DM	Data

Figure 1. A validation report with issue source, assignee, comments, and Reviewer's Guide explanation.

06 KNOW WHEN AND HOW TO FIX VALIDATION ISSUES

You should understand the risk of each issue and prioritize fixing issues that have the highest impact on regulatory review. To understand each issue, engage and promote issue knowledge sharing², and leverage P21 issue knowledge base with fix tips and review impact.

07 KNOW HOW TO EXPLAIN VALIDATION ISSUES

Explaining issues in the Reviewer's Guide is critical to a smooth review. You should explain issues in plain language and follow the guidance in "Best Practice for Explaining Validation Results in the Study Data"³. Implementing best practices can be a challenge, so use P21 Enterprise to manage standard explanations (figure 2).

Figure 2. Shows how your organization can have standard explanations and easily apply them to specific study issues in P21. Explanations will be automatically exported to the Reviewer's Guide in P21 Enterprise.

PINNACLE²¹

1. Amy Garrett and Chris Whalen. The Devil is in the Details — Reporting from Pinnacle 21 (OpenCDISC) Validation Report. Proceedings of the PharmaSUG 2015 Conference.

2. Ajay Gupta. Common Pinnacle 21 Report Issues: Shall we Document or Fix. Proceedings of the PharmaSUG China 2018 Conference.

3. Kristin Kelly. Best Practice for Explaining Validation Results in the Study Data. Proceedings of the PharmaSUG 2018 Conference.