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A Strategy for Dealing with Pinnacle 21 Errors and Warnings

Carey G. Smoak, Principle Consultant, S-Cubed, Copenhagen, Denmark

ABSTRACT

Pinnacle 21 is a widely used tool for evaluating SDTM and ADaM datasets that are to be submitted to regulatory authorities (FDA and PMDA) for approval of a drug or biologic product. Pinnacle 21 evaluates these SDTM and ADaM datatsets against published validation rules and produces a spreadsheet listing errors and warnings based on the validation rules. Have you ever wondered how to deal with all the errors and warnings that are found in a Pinnacle 21 report? In this Hands-On-Workshop you will learn a strategy for annotating Pinnacle 21 Reports to help you keep track of the types of errors and warnings that Pinnacle 21 produces. Attendees in this Hands-On-Workshop will learn practical steps for annotating a Pinnacle 21 Report to deal with the types of errors and warnings.

BACKGROUND

The background for this paper has been previously published (Smoak, Brooks 2018). Briefly, Lisa Brooks and I worked for a medium sized pharmaceutical company and oversaw a large CRO that was used for the company's large, pivotal phase III clinical trial. The company had given little oversight the CRO. Consequently, when Lisa and I ran Pinnacle 21 for the firs time, we literally found millions of errors and warnings. We had to develop a strategy for handling all these errors and warnings.

POSSIBLE WAYS TO CATEGORIZE WARNINGS AND ERRORS

Our first step was to categorize the errors and warnings for this pivotal phase III clinical trial. Based on the types of errors and warnings, we came up with the following categories.

- Controlled Terminology (CT)
- Data Issue
- Data collected this way
- Known issue – document in SDRG
- Ok or disregard
- Shrink variable length at final data transfer
- Unit conversion

Figure 1 shows a simple example of how we annotated a Pinnacle 21 report with some of the categories listed above.

Issue Summary						
Source	OpenCDISC	Publisher ID	Message	Severity	Count	Category
AE						
	CT2001	FDAC340	AESEV value not found in 'Severity/Intensity Scale for Adverse Events' non-extensible codelist	Error	414	Known (document in SDRG)
	SD0009	FDAC206	No qualifiers set to 'Y', when AE is Serious	Error	1407	Known (document in SDRG)
	SD0080	FDAC208	AE start date is after the latest Disposition date	Error	344	Data issue
	SD0090	FDAC209	AESDTH is not 'Y', when AEOUT='FATAL'	Error	402	Known (document in SDRG)
	SD0091	FDAC210	AEOUT is not 'FATAL', when AESDTH='Y'	Error	1	Data issue
	SD1082	FDAC036	Variable length is too long for actual data	Error	11	Shrink var length at final
	CT2002	FDAC341	EPOCH value not found in 'Epoch' extensible codelist	Warning	4598	Update EPOCH codelist
	SD0021	FDAC117	Missing End Time-Point value	Warning	3502	Data collected this way

Figure 1 - Example of annotated Pinnacle 21 report

Once the errors and warnings were categorized, we worked with the CRO to fix the problems. We saw a reduction of 68% in Pinnacle 21 errors and warnings in just six weeks. After an additional three months, we saw an additional 69% reduction in Pinnacle 21 errors and warnings. Using the method of categorizing Pinnacle 21 errors and warnings was key to being able to work with the CRO to reduce the errors and warnings.

CONCLUSION

Pinnacle 21 is a useful tool for checking datasets conformance to CDISC and FDA validation rules. Dealing with millions of errors and warnings from a large, pivotal clinical trial was not trivial. A system for categorizing these errors and

warnings was key to successfully working with the large CRO to fix these errors and warnings. In the end we were successful in accomplishing this goal.

REFERENCES

Smoak C, Brooks L. Practical Lessons Learned from Recent NDA and BLA Submissions to the FDA. PhUSE EU Connect Annual Conference, Frankfurt, Germany, November 4-7, 2018. https://www.lexjansen.com/phuse/2018/sa/SA06.pdf

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CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Carey G. Smoak
Principal Consultant
S-Cubed
Copenhagen, Denmark
cas@s-cubed.dk
http://www.s-cubed-global.com/