PP19 – The Truth About False Positives

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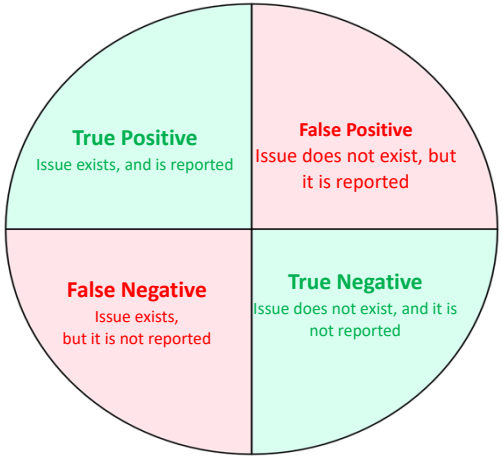
Abstract: It is a common misconception that many of the automated validation rules produce 'false positive' messages. A 'false positive' is a validation result that appears when it shouldn't. Though this sometimes occurs in validation, the notion that a rule is firing erroneously is sometimes due to the user not fully understanding what the rule is meant to check in the data. In earlier versions of validation tools, this occurrence was much more common. But over time, the number of false positive messages has significantly been reduced through efforts to improve the rules in order to 'reduce the noise'. Examples of rules commonly believed to be false positives will be discussed as well as explanations for what the rule is actually checking. Rules that may have produced false positives in the past that are now updated to fire in the correct scenario will also be noted.

Introduction

The idea of false positives seems to be a misunderstood concept. The chart below shows the four different outcomes of a validation rule.



A common approach for sponsors/CROs across the industry is to dismiss validation issues with explanations of 'False Positive' in the reviewers guide.

MY Data is Fine! It MUST be a False Positive!

The following are some examples seen in industry where the explanation in the cSDRG cites 'False positives' as the reason the issue remains in the validation report. And in the specific situation, it was not…..

Example 1

Check ID	Diagnostic Message	Severity	Explanation
CT2004	TSVALCD value not found in 'No Yes Response Code' non-extensible codelist when TSPARMCD == 'RANDOM'	Error	This is a bug in the Pinnacle 21 software. Reference: https://www.pinnacle21.com/forum/issue-ct2004. This issue will be fixed in the next release

The value in TSVALCD for a TSVAL of 'Y' in the TS dataset was the following: 'C66739F'. The TSVALCD for 'Y' should be 'C49488'. The sponsor was so sure that their data was correct that they:

A) Didn't even look at it
B) Took the time to search the P21 Forum instead

Example 2

Check ID	Diagnostic Message	Severity	Explanation
SD1079	Variable is in wrong order within CO domain	Warning	Order is matching with SDTMIG. Pinnacle 21 check misfires.

COSEQ and COREF were flagged by this rule. The reason the rule fired was because COLNKID had been added but in the wrong order according to Table 2.2.4 in SDTM v1.4. Also, since CO is a Special-Purpose domain, only certain Identifier and Timing variables can be added. COLNKID is not one of them.

Initiative to 'Reduce the Noise'

Pinnacle 21 has undertaken an effort to reduce false positives resulting from validation rules. This effort is somewhat of a balancing act, in that, it must be done carefully, weighing the risk of increasing false negatives.

The following are a few examples where adjustments have been made to a rule in an effort to reduce the noise:

- **SD1117** (Duplicate Records)
  - Key variables have been added, such as additional Qualifier and Timing variables
- **SD1078** (Permissible variable with missing value for all records)
  - Downgraded from a 'Warning' to a 'Notice' for SDTM
  - Removed for SEND
- **SE0063A** (SEND/dataset variable label mismatch)
  - Removed for SEND
- **SD1076** (Model permissible variable added into standard domain)
  - EPOCH variable excluded so that rule will not fire

In addition to trying to 'reduce the noise', occasionally we improve rules to minimize false negatives. The following is an example of a validation rule that has been adjusted to reduce false negatives:

- **SD0047** (Missing value for --ORRES, when --STAT or --DRVFL is not populated)
  - Updated to fire when –STAT is missing (and not just included but null)

Conclusion

Though 'false positives' may sometimes exist in a validation report, it has become a less common occurrence as validation rules are improved in order to 'reduce the noise'. Thus, it is important that users investigate issues that may seem at first glance to be firing erroneously. This ensures that real problems in the data are not being overlooked. The more thorough a sponsor can be when reviewing and explaining validation messages, the faster the study can be reviewed when submitted.

PINNACLE 21