

FDA SEND Submissions: Does the Pinnacle 21 Open Source Community Validator Predict Findings from FDA’s SEND Validators?



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Introduction

The Pinnacle 21 Community SEND validator is an open source tool used by many sponsors to evaluate SEND datasets for compliance to CDISC’s SEND standard. An appreciation of how well it predicts results from the different SEND validators used by FDA SEND at this point in time is important. Our poster presentation summarizes and compares FDA SEND validator findings to Pinnacle 21 SEND validator findings (current version, 2.1.0) for several recent FDA SEND repeat-dose toxicology submissions.

Methods

Before submission to FDA in early January 2016, the SEND datasets were validated using the Pinnacle 21 Community Validator (formerly OpenCDISC)., Version 2.1.0. All Errors, Warnings, and Notices in the Pinnacle 21 validation report were addressed before FDA submission until only false positive Warnings and Notices remained.

Comparison of SEND Validator Rules For FDA and Pinnacle 21

The Pinnacle 21 Community SEND Validator, Version 2.1.0, includes all of the published FDA Specific SEND Validation Rules, Version 2.1 (most recent version). Out of more than 200 SEND validation rules, we found 4 differences:

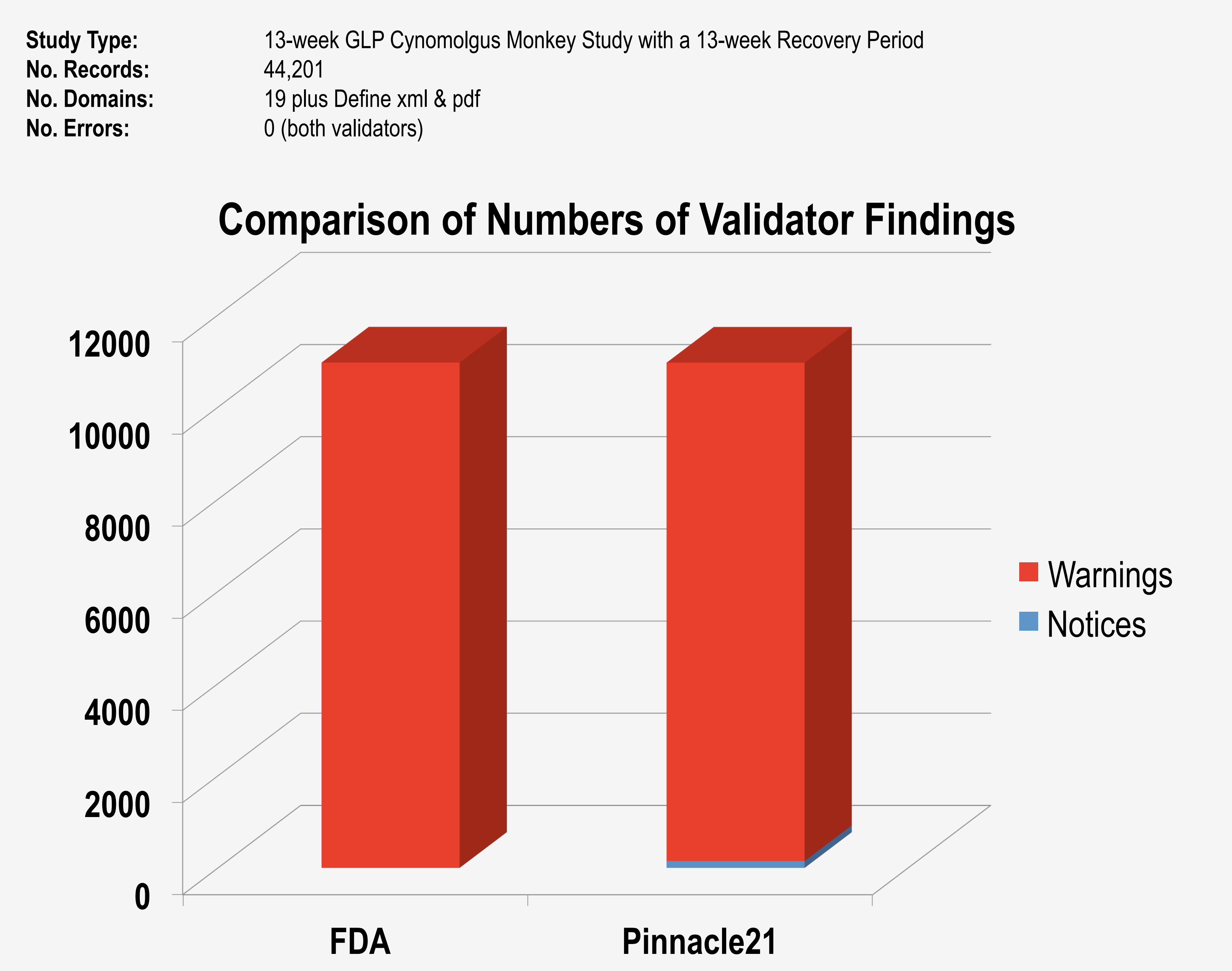
FDA SEND Validation Rule	Message	Difference
FDAN014	Domain table should have at least one record	An Error for FDA; a Warning for Pinnacle 21. FDA rule pertains to TX, TS, and DM.
FDAN019	Null value in variable marked as Required.	An error for FDA; a Warning for Pinnacle 21. FDA rule pertains to TS.
FDAN031	Model permissible variable added into standard domain.	A Warning for FDA; a Notice for Pinnacle 21.
FDAN055	Permissible variable with missing value for all records.	A Warning for FDA; a Notice for Pinnacle 21.

In the spirit of collaborative Open-source software development, we discussed these differences with Pinnacle 21 and were informed that these four differences will be addressed in the next release of the Community SEND validator, resulting in 100% concurrence with published FDA validation rules.

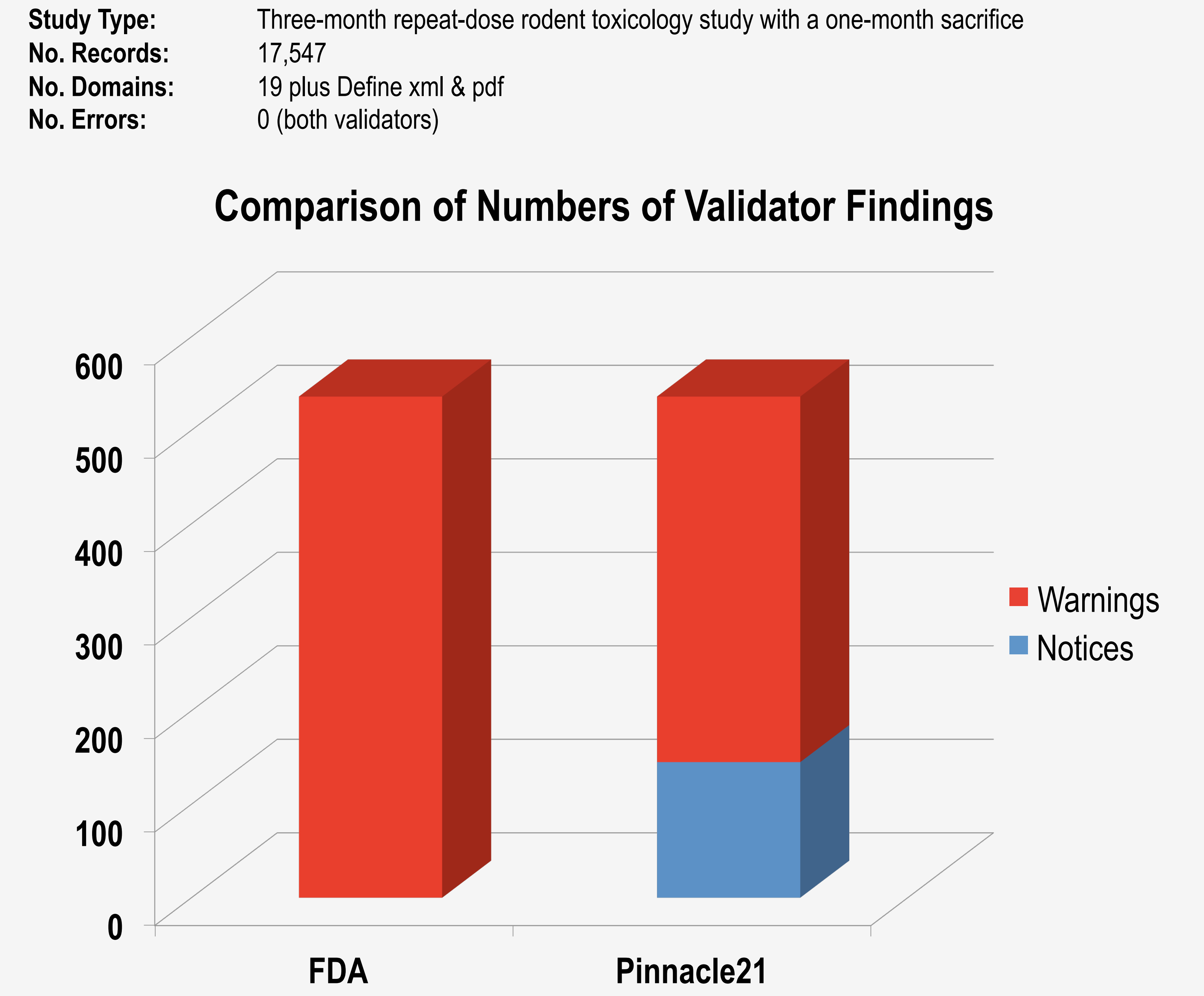
FDA Validation Rules Cited by Both Validators in 2 FDA Submissions - All were False Positives

FDAN031	Model permissible variable added into standard domain
FDAN035	Variable is in wrong order in domain
FDAN055	Permissible variable with missing value for all records
FDAN148	Missing values for both MADTC and MADY variables
FDAN154	Missing value for LBORRESU, when LBORRES is provided
FDAN169	Missing value for LBORRES, when LBORRESU is provided
FDAN212	Duplicate records
FDAN232	No result modifier (--RESMOD) qualifier for -- domain
FDAN341	Value not found in SEND Trial Summary Parameter Test Code Extensible code list

Comparison 1



Comparison 2



For both comparisons., the only difference in validation findings from FDA and Pinnacle 21 validation reports is that FDAN055 is considered a Warning by FDA and a Notice by Pinnacle 21.

Conclusion

Comparison of validation findings for two SEND FDA submissions supports the conclusion that the Pinnacle 21 Community Validator predicts FDA validator findings for both the number of findings and validation rules cited. We also conclude that both validators produced the same findings on a domain-by-domain basis (data not presented in this poster.) The only difference for these submissions is that FDAN055 was reported as a Warning by FDA and a Notice by Pinnacle 21. We recommend addressing all Errors, Warnings, and Notices from the Pinnacle 21 validation report until only false positive Warnings and Notices remain in advance of submitting SEND datasets to FDA. While use of a good SEND validator is critical, it does not obviate the need to visually examine each domain for SEND compliance by knowledgeable individuals.