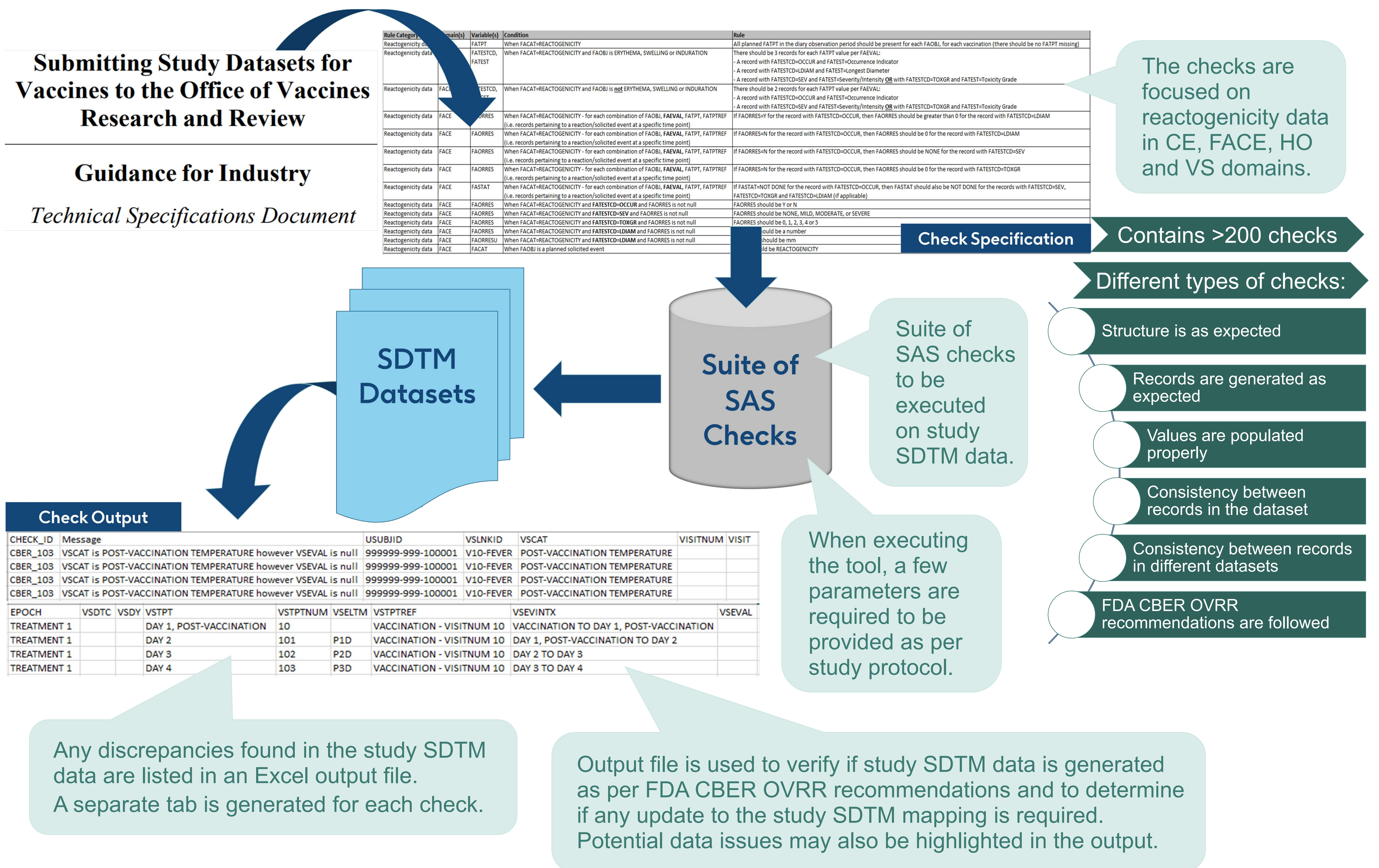


Introduction

A primary objective in many Vaccine trials is to evaluate the reactogenicity of the study vaccine. Occurrence of reactogenicity events is used as a safety endpoint. How the reactogenicity data is to be represented in SDTM is described in the CDISC Vaccines Therapeutic Area User Guide v1.1. In addition, the FDA guidance “Submitting Study Datasets for Vaccines to CBERR OVR Technical Specifications Document V2.1” contains several recommendations on how reactogenicity data should be stored in SDTM. GSK also received additional recommendations from FDA CBERR OVR at project level.

Suite of Vaccine Standards Conformance Checks

At GSK, a suite of SAS conformance checks has been developed to assess if study SDTM data is aligned with FDA CBERR OVR recommendations. These checks are designed to detect any misalignment with the referenced guidance.



Conclusion

- The conformance checks are designed to support the review of reactogenicity data in the study SDTM datasets.
- The suite of SAS checks can be executed at different time points during the trial, which is very beneficial for the study.
- Inconsistencies in the SDTM mapping can already be detected at study set-up and a final run may be performed before database lock to ensure the study SDTM data is adequate to be submitted to FDA CBERR OVR.
- At this moment, the conformance checks are focused on reactogenicity data. Checks for other type of data described in the FDA guidance may be included in future enhancement.

Abbreviations	References
FDA CBERR OVR: FDA's Center for Biologics Evaluation and Research – Office of Vaccine Research and Review	FDA guidance “Submitting Study Datasets for Vaccines to CBERR OVR Technical Specifications Document V2.1”: https://www.fda.gov/media/112581/download
	CDISC Vaccines Therapeutic Area User Guide v1.1: https://www.cdisc.org/standards/therapeutic-areas/vaccines/vaccines-therapeutic-area-user-guide-v11/html

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