**Study Data Standardization Plan Case Studies and Considerations**

**ABSTRACT**

This paper is intended to cover Study Data Standardization Plan (SDSP) case studies focusing on different stages over a drug development lifecycle. Drug development lifecycle and stage gates contained include the following:

- New product phase (pre IND, IND)
- Retrospective/ongoing programs phase (of phase I/pre-NDAs/BLA)
- New protocol phase (phase I or multiple INDs can be combined)
- Submission of draft SDSP (pre IND, IND, and phase I) vs. final SDSP (after IND filing)
- Versioning the SDSP covering updates and changes
- Consistency checks between SDSP with data standards and CBER appendix
- Practices in CBER and CBER requirements
- CBER appendices key for completion — SDSP Authoring & Reviewing Responsibility Chart

**NATURAL TEXT**

**SDSP SCENARIO FOR NEW PROGRAM PHASE**

The new program phase is always initiated from the start with a final SDSP. If it is a pre IND meeting, then onward with the original IND or as an amendment if the original IND has already been submitted. For CBER submission, submit the CBER appendix within the SDSP for the IND. CBER appendices could be easy to add on to this stage.

**Table 1A. Section 4.1 Nonclinical Section from SDSP Template**

**SDSP FOR ALREADY APPROVED/ SUPPLEMENTAL PROGRAM (nda/BLA)**

The applicable program phase is when the FDA has approved a fully approved product for sharing an rnds/nda/BLA meeting and at the nda/BLA approval.

**Table 2B. Section 5 Noncompliance to Supported Standards Justification Section from SDSP Template**

**VERSING ONE SDSP COVERING UPDATES AND CHECKS**

When the SDSP needs to be updated, the current version should be changed back to the previous version for consistency.

**Table 4. SDSP Authoring and Reviewing Responsibility Chart**

**CONSISTENCY CHECKS BETWEEN SDSP AND OTHER SUBMISSION DOCUMENTS**

It is important to ensure the information in SDSP is accurate and consistent among submission documents.

**Table 3. SDSP and Other Submission Requirements**

**REFERENCES**


**ACKNOWLEDGMENTS**

Ogie Akinwande, Merck, Inc. Andrey Batskov, Merck, Inc.

Author Disclaimer

This paper is specific to Merck’s SDSP implementation process, including experiences and scenarios Merck has encountered within its development programs for submission. The experience and scenario found has been experienced with the SDSP being shared with the team to benefit others within industry, but based on the context and environment of the process. The experience and scenario found should not be equated to any specific company or industry, but instead to a shared experience in the drug development industry to benefit from.