What Good Looks Like in Study Data
Standardization Plan (SDSP) and CBER
Appendix

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Objectives

• Share Merck’s experience in SDSP implementation
• Identify characteristics/considerations for authoring a high quality SDSP and CBER Appendix
Agenda

1. Background
2. Lessons Learned - SDSP
3. Lessons Learned - CBER Appendix
4. Communication Tool
5. Implementation Challenges
6. Conclusion
It’s a plan that outlines the **clinical** and **non-clinical studies** in the compound and the use data standards (CDISC, MSSO, CDRH …)

Authoring the SDSP can facilitate discussions needed for a team to identify any gaps and prepare a submission strategy

Promotes early interactions between sponsors and FDA review divisions

Living document that should be updated as trials are added to the lifecycle and shared at a stage gate or submission (eCTD Module 1.13.9)

Implementation assists in identifying potential data standardization issues early in the development program
Lessons Learned - SDSP

Retaining all Sections in SDSP Template

• Because as compound matures, some information may need to be re-visited.
• Non-pertinent sections and tables should indicate “Not Applicable”
• It makes insertion of information easier, rather than re-create sections

Identify Accurate Content

• This activity requires cross-functional orchestration
• Products with a long program requires recovery of study history
• Study details which support specific indication and study population, including trials opened under IND and supportive trials (e.g. country specific studies)
Lessons Learned – SDSP Cont.

Consider Per Population Analysis

- Because after initial approval, sponsors may decide to pursue further analysis on special populations to extend the license or product exclusivity.
- During these opportunities, author should ask whether the original data will be resubmitted or referenced to support the newly specified population and analysis.
- Reference a prior IND rather than duplicating.
- Avoid repeating study standards across multiple SDSPs to lessen the burden to manage status of the trial and standards.

Organize Trial Phases Based on Earliest Study Start Date

- Identify the study start date based on clinicaltrials.gov, especially for a single trial straddling two different phases of a lifecycle.
Lessons Learned – SDSP Cont.

Include Complimenting Exchange Standards

- The model and the implementation guide are a pair of complimenting standards
- Authors should take into consideration the pair when documenting the SDTM and ADaM standard versions in the SDSP
- Non-CDISC or sponsor proprietary data is expected to be listed as Legacy data

Document “Planned” and “Ongoing” Trials

- Identify the standard that is currently used during in-life reporting
- An alternative option: provide what is known to date and update the SDSP when collective changes are applied
Lessons Learned – SDSP Cont…

**Record Dates Using ISO Format**

- Authors are expected to use the ISO date format
- The inconsistent format makes it an unnecessary challenge for both reviewers to understand whether the date or month is reversed
Allocate time to address CBER Appendix

Domain
Refer to the valid domains in the SDTM section for the version been submitted

Custom Domain
If domain used from a later version of SDTM you can add it to the Custom domain section and identify the domain as a prototype

Required Variables
Add the variables that are helpful for reviewers except required variables in SDTM

SUPP Variables
Ensure that the SUPPQUAL section includes all SUPP variable and Prepare to give explanation of the SUPPQUAL variables

RELREC
Indicate the domains that have a relationship in the RELREC section
Communication Tool

- Time intensive task that requires careful identification of information
- SDSP and annotated case report form (acrf.pdf) can facilitate discussions; identify any gaps; and prepare a submission strategy

**Internal Use**
- Inventory of trials
- Determine which trials were developed in accordance with the FDA Data Standards Catalog
- Studies that do not conform to standards will require a waiver to seek alignment on expectations for submitting data

**External Use**
- Inventory of trials in the submission
- Documents the rationale for non-conformance that was agreed in waiver response in SDSP Section 6.

**NOTE:** SDSP is not intended to replace the waiver process
Implementation Challenges

SDSP

- Implementing SDSP after IND already started
- Orienting cross-functional authors to the data standards and acronyms
- Managing and sharing SDSP for combination therapies, multiple indications, or populations (adult v. pediatric)

CBER Appendix

- Remapping of data to meet CBER reviewing expectations and needs
- Addressing remapping of data on multiple trials using similar mappings
- Identifying the SUPPQUAL from clinical trials used for efficacy or immunogenicity analysis is not yet well-defined
- Identifying a full list of all supplemental qualifiers purpose may not be clear until product gains maturity
Conclusion

- Multi-functional engagement
- Early Interaction
- Inclusion of the aCRF and CBER Appendix
- Concurrence on Exchange Standard
- Communication Internal & External

SETS EXPECTATIONS OF AN EFFICIENT AND MEANINGFUL REVIEW
Reference

PhUSE Study Data Standardization Plan Template (v1)

PhUSE Study Data Standardization Plan Completion Guideline (v1)

FDA Guidance for Industry: Submitting Study Datasets for Vaccines to the Office of Vaccines Research and Review

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Thank You for Your Attention