

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



Background

SDSP

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

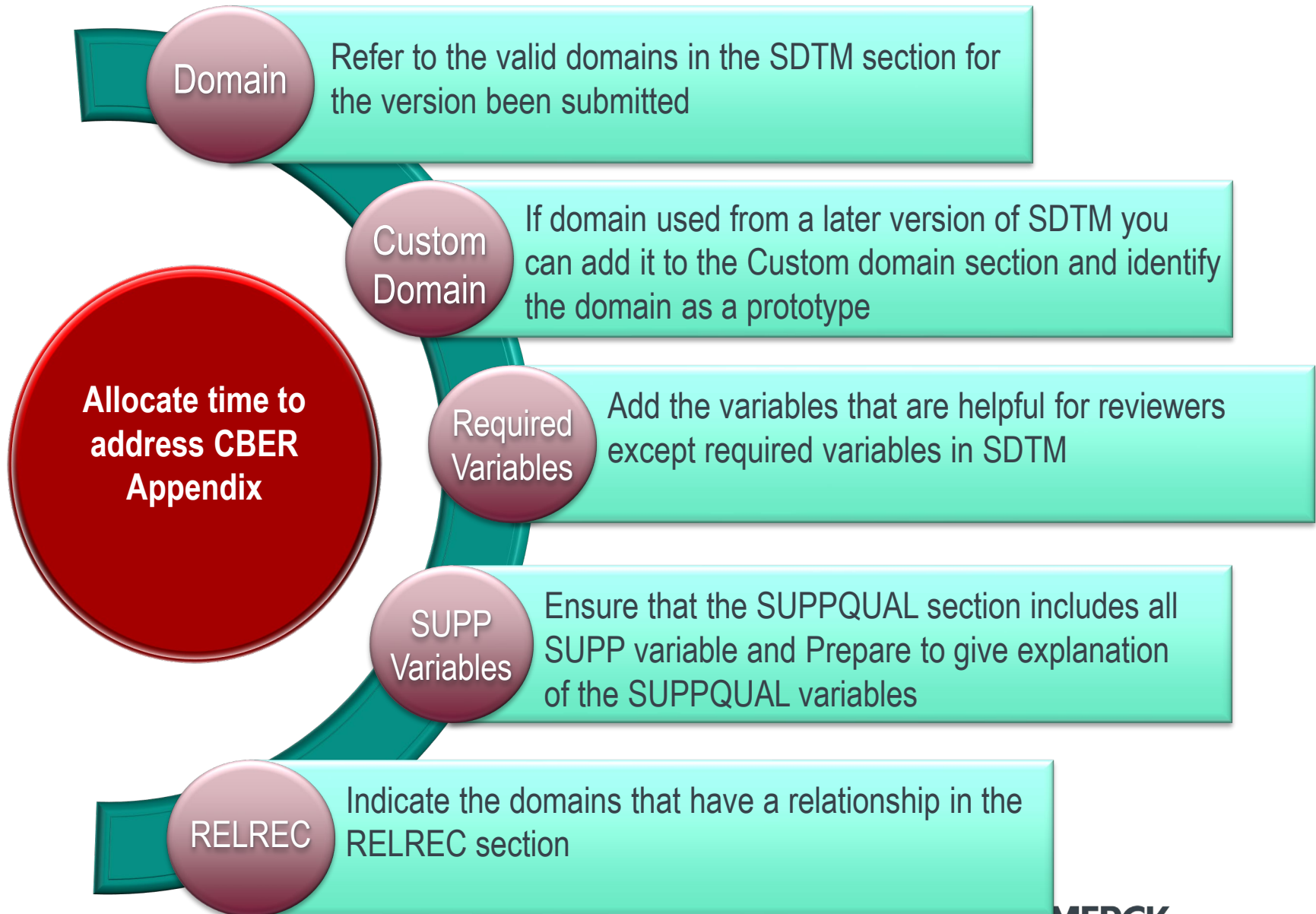
- Identify the standard that is currently used during in-life reporting
- An alternative option: provide what is known to date and update the SDSP when collective changes are applied

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

Lessons Learned - *CBER Appendix*



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

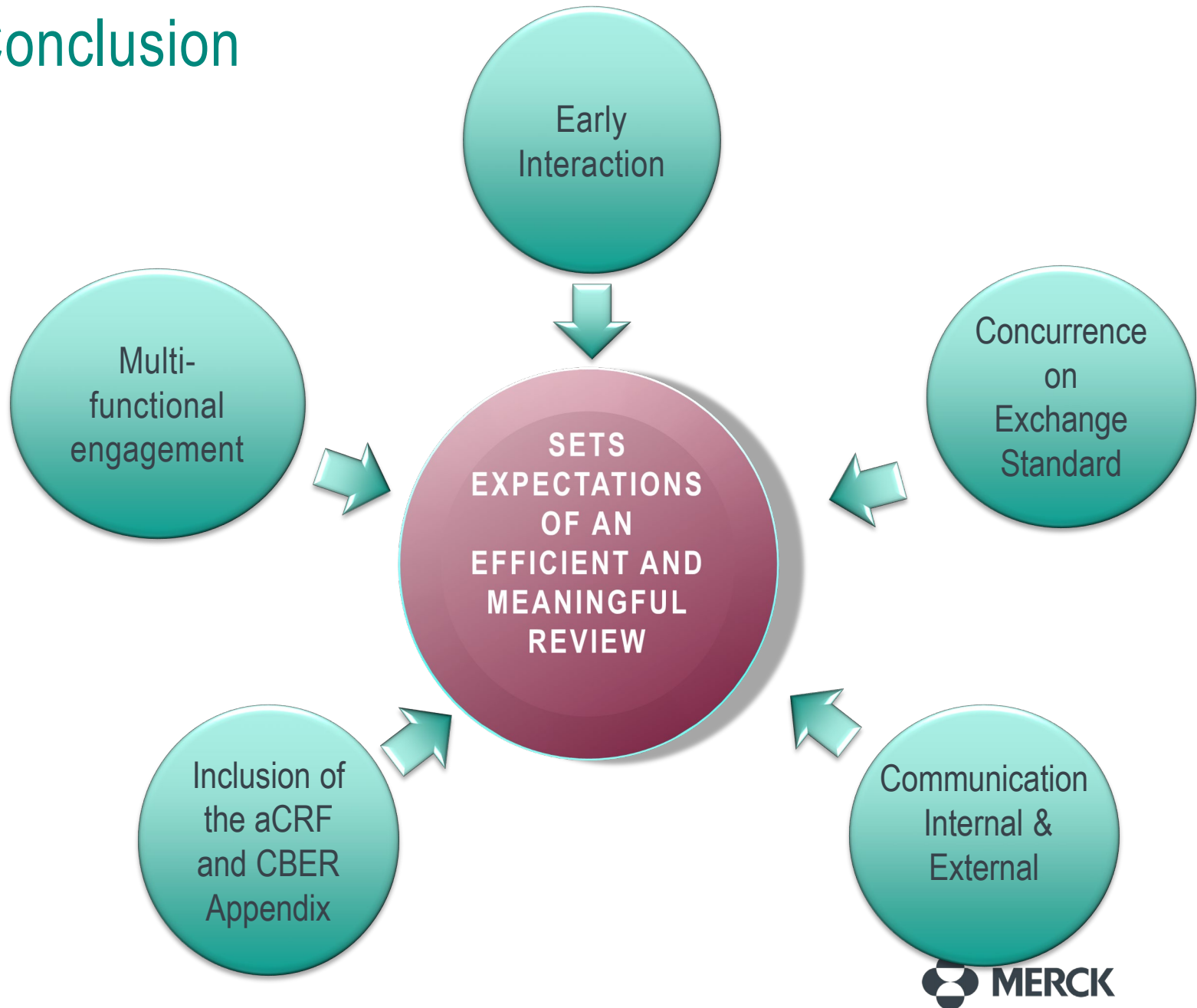
- Implementing SDSP after IND already started
- Orienting cross-functional authors to the data standards and acronyms
- Managing and sharing SDSP for combination therapies, multiple indications, or populations (adult v. pediatric)

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



Reference

PhUSE Study Data Standardization Plan Template (v1)

<https://www.phuse.eu/documents//sop/wp/phuse-tp001-study-data-standardization-plan-v1-8409.docx>

PhUSE Study Data Standardization Plan Completion Guideline (v1)

<https://www.phuse.eu/documents//sop/wp/phuse-wp001-sdsp-completion-guideline-v1-8407.pdf>

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

<https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/General/UCM605147.pdf>

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Thank You for
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