

Authoring Considerations for Creating PhUSE Study Data Standardization Plan (SDSP) and CBER Appendix



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Objectives

Share Merck's experience and highlight the SDSP and CBER Appendix authoring considerations while addressing:

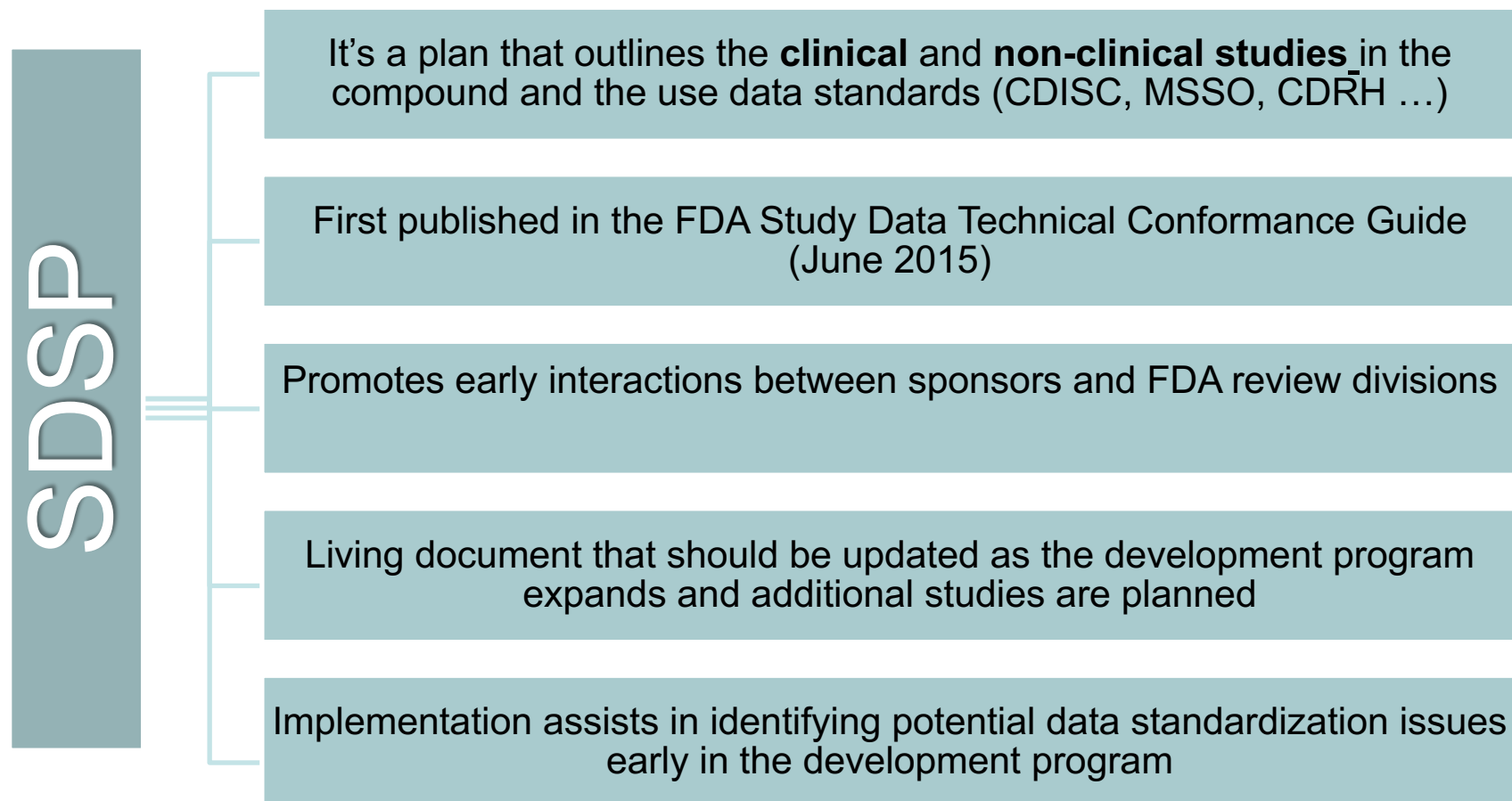
- Challenges
- Advantages
- Timing of regulatory interaction to support a CDER or CBER SDSP review

Agenda

1. Background
2. Authoring Considerations - SDSP
3. Authoring Considerations - CBER Appendix
4. Implementation Challenges
5. Advantages of SDSP and CBER Appendix Adoption
6. Timing of Regulatory Interactions
7. Conclusion

Background

Through the PhUSE and FDA collaboration, the SDSP template was streamlined to support both CDER and CBER. In March 2018, PhUSE released the SDSP (v1) template that incorporated a CBER Appendix.



Authoring Considerations - SDSP

Identify experienced team of subject matter experts

- Regulatory
- Non-Clinical and Clinical Data Management
- Non-Clinical and Clinical Scientist
- Data Standard Specialists
- Statistician
- Statistical Programming

Discuss cross-functional tasks, hand-off, and transitions

- Initial task for starting an SDSP in-life is a large undertaking requiring authors to assemble and reconcile pieces of information that collectively forms the SDSP
- 1 year raise awareness, educate users, and develop an operational process
- More time needed for products that involved partner or vendor collaborations

Review role between SDSP document owner vs. SDSP content owner

Authoring Considerations - CBER Appendix



Allocate time to address CBER Appendix

Contain additional information from clinical trials that are planned for the actual submission

Represent a smaller subset of the trials listed in the SDSP body

4 Sections of CBER Appendix

SDTM Datasets

- List all planned SDTM datasets
- Provide purpose of the data
- Identify custom domains – CBER may suggest alternative data mappings

SUPPQUAL

- Include a list of supplemental domains and variables – CBER may suggest alternative data mappings
- Identify the origin back to a corresponding CRF question or derivation information
- Identify the supplemental qualifiers contributing to the key analysis

ADaM Datasets

- Include for each clinical trial with a planned analysis
- Include legacy analysis dataset name and label

ISS & ISE

- List trials included in the pooled analysis
- Identify the pooled datasets and purpose (efficacy, safety, other)
- Identify the clinical trial phase and contributing datasets used to support the analysis

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 QNAM and QLABELs 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



Advantages of SDSP and CBER Appendix Adoption

Details the evolution/adoption of data standards throughout the project lifecycle

Gains concurrence on the data structure to avoid rework

Provides an inventory of all trials operating under the IND, for internal and external teams

Serves as a communication tool for sharing data standards implemented during product development

Value to Sponsor and Agency

Tracks discussions and agreements with the FDA on the use of data standards

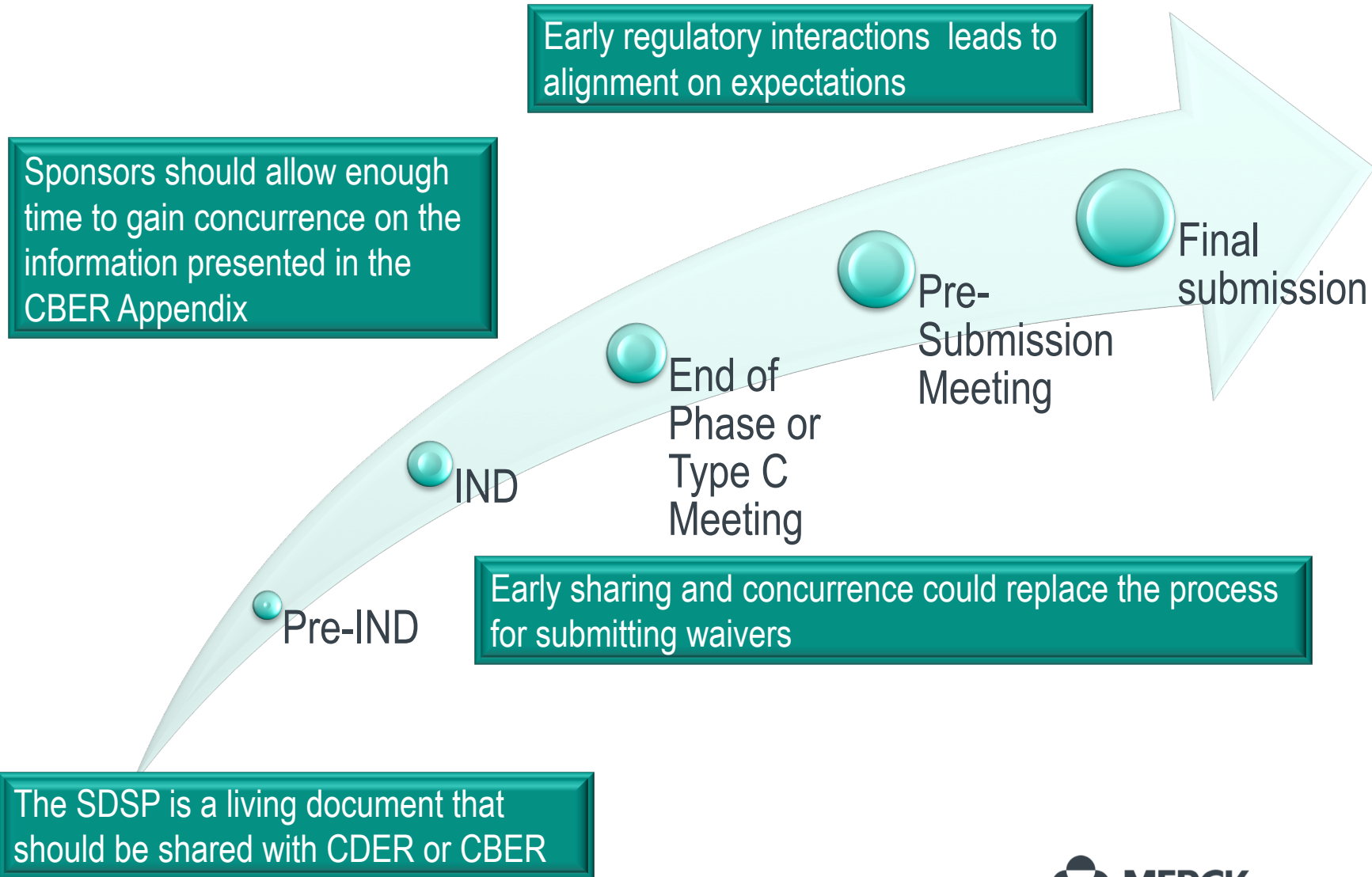
Drives discussions about legacy data conversion and up-versioning

CBER Appendix

Identifies the standard and custom domains and variables used to support the analysis

Drives study and pooled analysis discussions

Timing of Regulatory Interactions



Conclusion

SDSP AUTHORIZING CONSIDERATIONS

CROSS- FUNCTIONAL ENGAGEMENT

REGULATORY INTERACTIONS

Ample of time to compile and confirm content

Author and share the SDSP throughout product development

Align on data standard expectations early

Special Thanks



Ellen Asam, Director, Statistical Programming

Brooke Hinkson, Director, Global Clinical Data Standards

Merck SDSP SME Team

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>

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thank you

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謝謝 dakujem vám
ngiyabonga
dziękuję
merc
baie dankie
धन्यवाद molte grazie
gracias
obrigada
obrigado
teşekkür ederim
شكرا
tack så mycket
gràcies
tānan
dank u
teşekkür edire
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