study data standardization plan – a first insight

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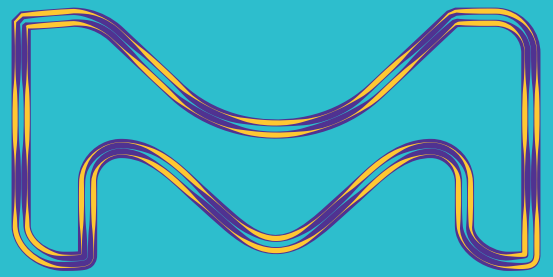

MERCK

Study Data Standardization Plan
Agenda

1. FDA Requirements for Submission of Data
2. Details on the FDA-Guidance
3. SDSP Templates
4. Standards/Versions to be Addressed in the SDSP
5. Example
6. Lessons Learned
7. Conclusions

01

FDA Requirements for submission

FDA Requirements for Submission of Data

FDA documents and sources to be considered for submission

http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm

✓ Providing Regulatory Submissions in Electronic Format — Standardized Study Data Guidance for Industry	Binding FDA Guidelines Last version: December 2014
✓ FDA Data Standards Catalog	To ensure that all standard versions acceptable by FDA. Last version: 29 September 2016 *Consider: not only CDISC standards, but also medical dictionaries and electronic formats*
✓ Study Data Technical Conformance Guide	Details FDA requirements for submission packages Current Version March 2017

FDA Requirements for Submission of Data
FDA documents and sources to be considered for submission

http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm

✔ Providing Regulatory Submissions in Electronic Format — eCTD Specifications - Guidance for Industry	Binding FDA Guidelines Last Version May 2015
✔ FDA Important Notices for e-submission Related to e-submission (use link on this slide on the top)	Ad hoc updates related e.g. to changes in ICH guidelines may have impact on dossier preparation
✔ FDA Important Notices and statements to data standards	Useful information about FDA position to some data questions: e.g. use of SI units and FDA validation rules

02 Details on the FDA- guidance

FDA's Standardized Study Data Guidance for Industry
Details regarding SDSP

- Binding guidance for all trials starting (first subject in) on/after December 17, 2016
- Sponsors to submit a Study Data Standardization Plan (SDSP) as part of the IND application
- Latest Time Point for Discussion of SDSP at EOPII
- Access Data Standards Catalog provided by the FDA to identify the most current version of standards (at study start-up)

FDA’s Standardized Study Data Guidance for Industry
Complexity of SDSP

- Many different standards and versions are available, choose the correct ones
- Versioning of the standards, and related standard documents are independent (e.g. SDTM Model and SDTM IG). This makes it more complicated
- Applicable standards and versions need to be collected from several stakeholders, in particular from Data Management, Biostatistics and Regulatory, and also Pre-Clinical

FDA’s Standardized Study Data Guidance for Industry - SDSP
Challenges of the SDSP

- Frequently revised version updates provided by authorities and CDISC
- SDSP is a living document, regular updates needed
- Evaluate data standards versions during the lifecycle of the SDSP and discuss whether updates of the submission package according to current standards are needed
- Start early creating the SDSP, but keep an eye on new released FDA requirements

03 SDSP templates

SDSP Templates

- Template developed by the Pharmaceutical Users Software Exchange (PhUSE), working closely together with the FDA.
- http://www.phusewiki.org/wiki/index.php?title=Study_Data_Standardization_Plan_(SDSP)

- Template provided by the FDA
- http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM447119.pdf

04 standards/ versions to be addressed

Relevant Standards to be Addressed
CDISC (Clinical Data Interchange Standards Consortium)

- SDTM (Study Data Tabulation Model) Model
- SDTM Implementation Guide
- ADaM (Analysis Data Model) Model
- ADaM Implementation Guide
- Define.xml (as documentation standard)
- Additional Therapeutic Area User Guides (TAUG) including SDTM and ADaM updates, currently there are about 50 TAUGs published or under development
- Accompanying companion standards, e.g. for SDTM Guidance on Associated Persons and Pharmacogenomics

Relevant Standards to be Addressed
In addition

- Controlled Terminology by NCI (National Cancer Institute)
- Additional Controlled Terminology used, e.g., MedDRA, WHO, SNOMED, UNII, RTF

05 example

Example

06 Lessons learned

Our Lessons Learned (1)

- People:
  - Involve all stakeholders in your company to create the SDSP. Collaboration is essential
  - Assign one department which takes the ownership of the SDSP
  - Train your stakeholders on SDSP

- Timeframe:
  - For two submissions SDSP was created retrospectively
  - Discuss upfront with the submission team within your company which template shall be used for submission
  - For future submissions at Merck the SDSP should be available latest for the EOP2 meeting

Our Lessons Learned (2)

- Authorities:
  - FDA: did not provide feedback on our SDSPs
  - PMDA: does not use the SDSP, they have a document named “form 8”
  - Use the SDSP as communication tool for meetings with the FDA

07 conclusions

Conclusions

- SDSP recommended by the FDA
- Discuss upfront within the submission team within your company which SDSP-template shall be used
- Collaboration between different stakeholders in your company (Regulatory, Pharmacologic Department, Data Management, Biostatistics, Project Management, Pre-Clinical Department) essential to create the SDSP
- Responsibility/Ownership and timelines for creating the document need to be clear

any questions?