

Industry Experiences in Submitting Standardized Study Data to Regulatory Authorities

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Agenda

01

Objectives and Problem Statement

02

Submission Strategy & Planning

- Study Data Submission Requirements
- Legacy Data Conversion and Up-versioning
- Incorporate and Optimize Use of SDSP

03

Communication Strategies

01 – Objectives and Problem Statement

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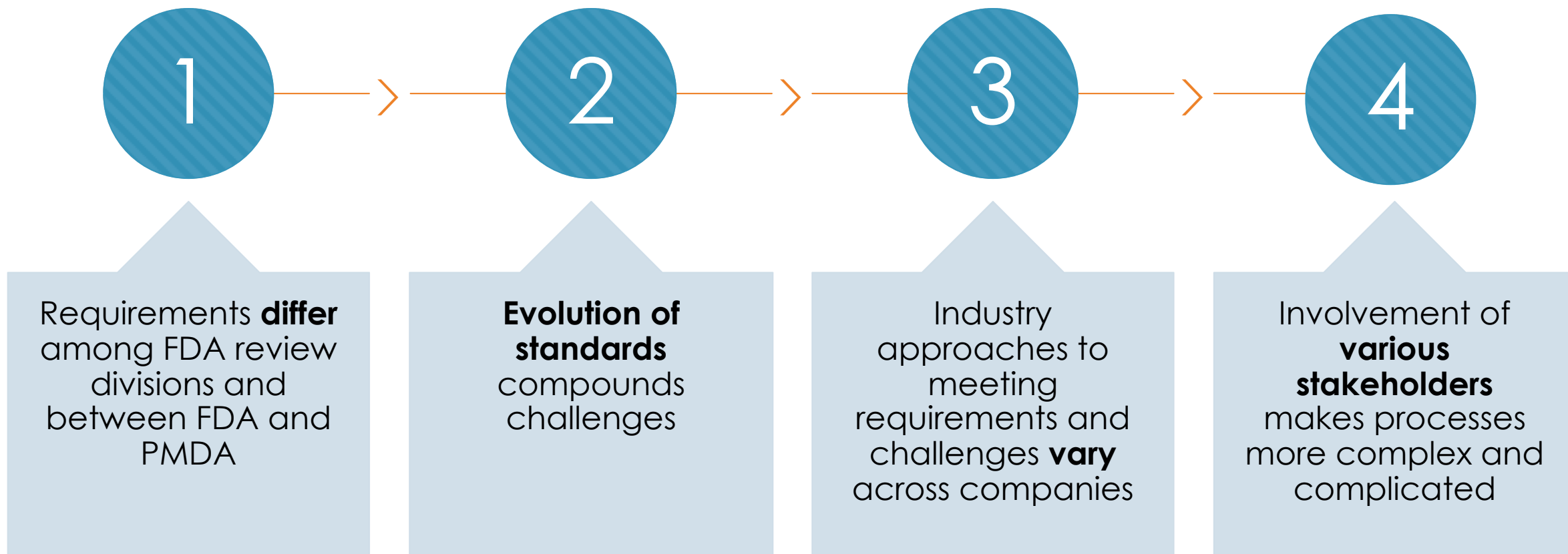
Optimizing the Use of Data Standards Working Group



Industry Experiences
Submitting Standardized Study
Data to Regulatory Authorities
Project

Objectives

- Investigate and recommend best strategy and planning practices for preparing data for a regulatory submission
- Suggest communication practices within sponsors and between sponsors and regulators that can facilitate an effective exchange of the standardized study data and the submission related information



Problem Statement

02 - Submission Strategy & Planning

Study Data Submission Requirements

- For NDAs, BLAs, ANDAs, and supplemental applications, FDA mandates studies starting **AFTER December 17, 2016** to submit study data according to the FDA Data Standards Catalog unless a waiver is granted.
- For INDs, the FDA requirement applies for studies that start (first informed consent date) after December 17, 2017.
- Retired standard that is no longer supported in the FDA Data Standard Catalog is expected to be up-versioned unless a waiver is granted.
- Study with Start Date BEFORE Dec 17, 2016 for NDAs, BLAs, ANDAs (Dec 17, 2017 for INDs) can be submitted in legacy format. (FDA consultation recommended)
- PMDA standardized study data requirements are dictated by the **submission date AFTER March 31, 2020.**

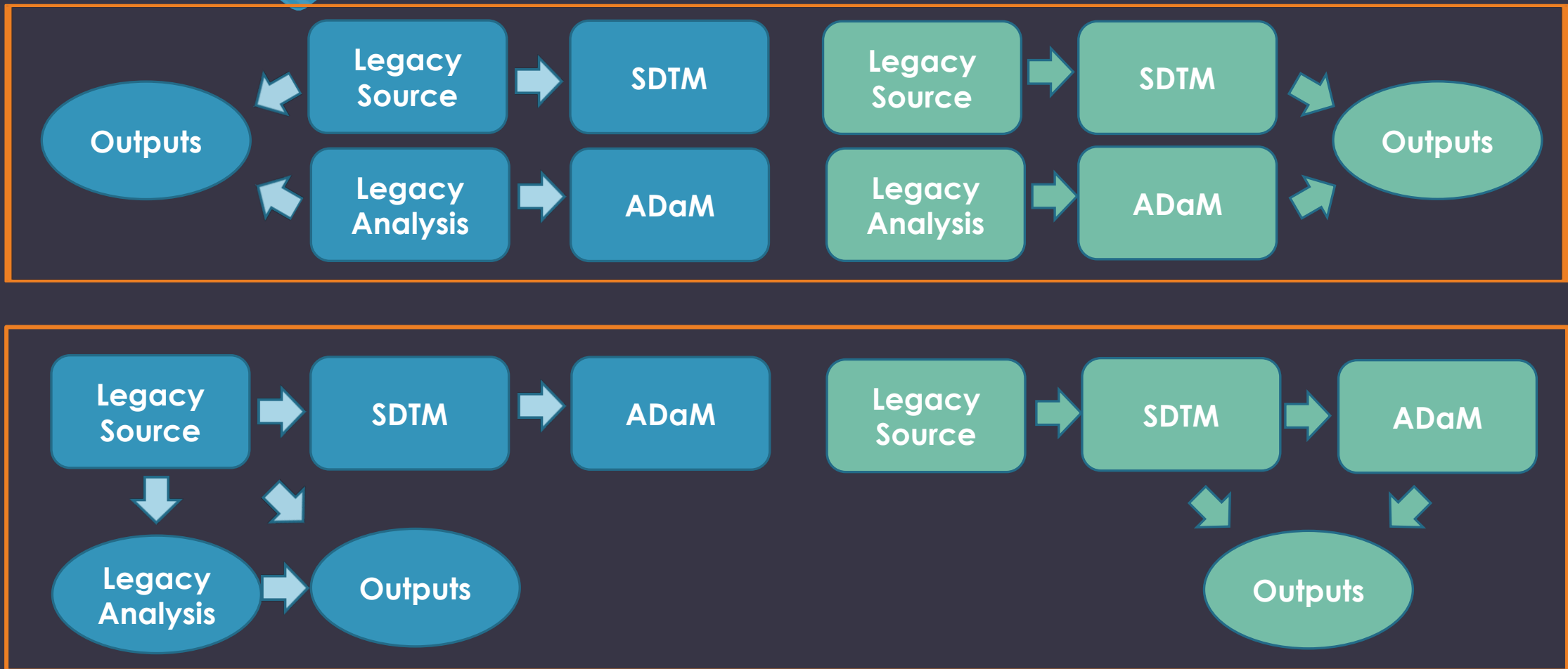
Industry Experiences in Submitting to FDA and PMDA

- Can we create a single study data package and submit it to both FDA and PMDA?
- What would you recommend if a study is submitted to both FDA and PMDA?
- What if I do not know if we submit to PMDA?

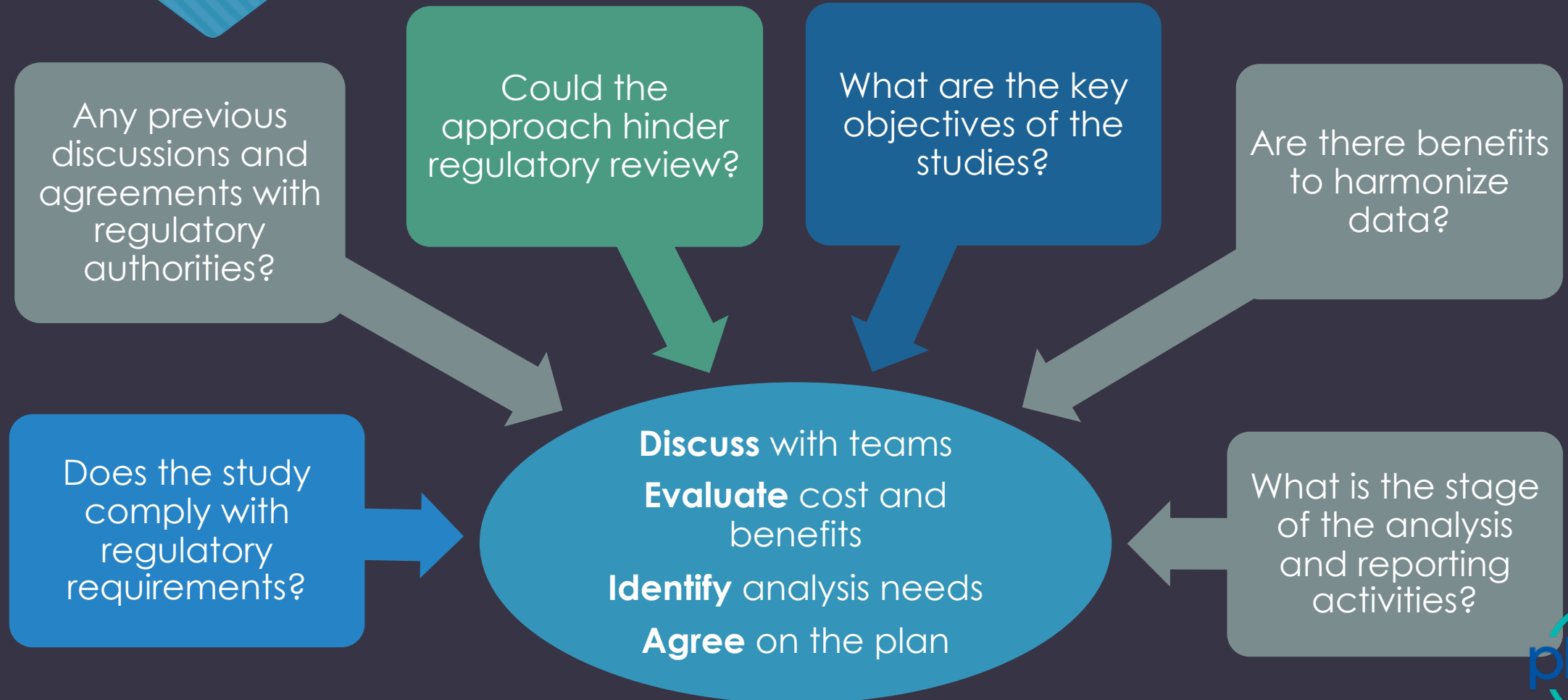
Legacy Data Conversion & Up-Versioning

- A critical part of submission strategy
- Requires a plan at the early stage of submission cycle
- Two types of studies needing conversion or up-versioning:
 - Legacy studies whose data is not of CDISC standard
 - Studies that followed earlier version of standard that is not supported by regulatory authorities anymore according to Data Standard Catalog

Conversion/Up-Versioning Methodologies



Decide on Strategy for Legacy Data Conversion/Up-Versioning



Incorporate and Optimize Use of SDSP

- In 2014, FDA recognized the need for SDSP in FDA Industry Guidance and Study Data Technical Conformance Guide
- Benefits:
 - outlines the studies
 - summarizes exchange standards
 - provides documentation on non-conformance and regulatory concurrence on data plans prior to a submission
- CBER Appendix – supplemental information needed to support meaningful CBER review

Organizational Approaches to Developing SDSP



Document Owner: Regulatory Affairs

Content Owners: Statisticians & Programmers

- Programmers have knowledge of SDTM and ADaM
- Statisticians have study level and integrated analysis knowledge
- Cross-functional areas are supportive content providers

Document Owner: Regulatory Affairs

Content Owner: Data Management

- Data Management already has Controlled Terminology, dictionary versions and exchange standards from team
- Leverage project management skills
- Cross-functional areas are supportive content providers

Document Owner: Regulatory Affairs

Content Owners: Standards working with the study team

- Centralize the SDSP authoring from a group who oversees data standards and up-versioning
- Consistent across all company submissions
- Eliminates duplicated efforts
- Promotes study data standards awareness
- The Standards representative heavily relies on other functional areas to provide their respective information

Evaluate Submission Strategy Using SDSP

Conform to Expected Standards

- Decide on Legacy Data Conversion Strategy and Planning considering various factors
- Revisit the SDSP to reflect the data standard implemented at submission

Non-conform to Expected Standards

Apply for waiver to seek alignment on submitting data

03 - Communication Strategies

Communication Strategies

- Organize and communicate decisions and strategies internally before presenting the situation for regulatory agreement.
- Share the submission plan utilizing the SDSP at each stage gate interactions with FDA to align on the strategy.

FDA Communications

- **Type A Meetings** – needed to help an otherwise stalled product development program proceed
- **Type B Meetings**
 - Pre-IND meetings
 - Certain End-of-Phase 1 meetings
 - End-of-Phase 2 and pre-Phase 3 meetings
 - Pre-NDA/BLA meetings
- **Type C Meetings** – any other meetings that fall outside A & B and can be technical in nature
- **SDSP**
- **Waiver** of electronic submission requirements for standardized study data
- **General Correspondences**
 - e-mail or phone FDA project managers
 - CDER and CBER edata mailbox

PMDA Communications



Attachment 8 and Attachment 8-2 should be prepared prior to the consultation. Sponsors can request the following meetings with PMDA:

- **Clinical Trial Consultation** (normally, End of Phase 2) – Identify the study data and/or analysis data planned for electronic submission necessary for a new drug application.
- **e-Data Consultation Meetings** include discussions on:
 - **Consultation on Exemption** - Discuss and reach agreement on the exemption to submit electronic study data submission or conduct legacy data conversion
 - **Consultation on Preparation**- Discuss and review methods for storing data; handling variables; legacy data conversion; submission method to send study data
 - **Consultation on Data Format** – Discuss validation results
- **Pre-NDA Meeting** – Occurs approximately two months prior to the planned filing date for final Confirmation on the submission package

Conclusion

Submitting standardized study data to regulatory authorities is a critical and complex process and it requires strategy, planning and communication. Sponsors need to proactively identify and prepare for challenges throughout the submission life cycle.

- Understand which regulatory authority the submission goes to and its regulations
- Convert legacy study data according to Data Standards Catalog and/or based on the agreement between the sponsor and regulatory authority
- Utilize the SDSP/Attachment 8 (8-2) to aide in internal planning, development, and submission of standardized study data
- Communicate strategy and implementation plans for submitting standardized study data at regulatory meetings

It is essential to start the process early and revisit it by taking steps above in order to deliver a high quality and compliant submission package in a lean, resourceful, and cost-effective way.

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