CDISC GS User Group Meeting

Study Data Standardization Plan

15 Sep 2015

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2. Planning and Providing Standardized Study Data

2.1 Study Data Standardization Plan

For clinical and nonclinical studies, sponsors should include a plan (e.g., in the IND) describing the submission of standardized study data to FDA. The Study Data Standardization Plan (*Standardization Plan*) assists FDA in identifying potential data standardization issues early in the development program. Sponsors may also initiate discussions at the pre-IND stage. For INDs, the *Standardization Plan* should be located in the general investigational plan. The *Standardization Plan* should include, but is not limited to the following:

1. List of the planned studies
2. Type of studies (e.g., phase I, II or III)
3. Study designs (e.g., parallel, cross-over, open-label extension)
4. Planned data standards, formats, and terminologies and their versions or a justification of studies that may not conform to the currently supported standards

The *Standardization Plan* should be updated in subsequent communications with FDA as the development program expands and additional studies are planned. Updates to the *Standardization Plan* should not be communicated each time a study is started. The cover letter accompanying a study data submission should describe the extent to which the latest version of the *Standardization Plan* was executed.

SDSP - Study Data Standardization Plan
FDA Technical Conformance Guide - Essentials

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Requested in FDA Study Data Technical Conformance Guide:

- assists FDA in **identifying** potential data standardization **issues**
- **early** in the development program
  (Sponsors may also initiate discussions at the pre-IND stage
- **clinical** and **nonclinical** studies, completed and planned
- **describing** planned submission of **standardized study data** to FDA

SDSP **should include**, but is not limited to the following:

1. List of the planned studies
2. Type of studies (e.g., phase I, II or III)
3. Study designs (e.g., parallel, cross-over, open-label extension)
4. Planned data standards, formats, and terminologies and their versions or a justification of studies that may not conform to the currently supported standards

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FDA Homepage: Study Data Standards Resources

3. **Study Data Technical Conformance Guide v2.2.** Click here to access the Guide. This Guide provides technical specifications, recommendations, and general considerations on how to submit standardized electronic study data.

3a. Recommendations for Preparing a Study Data Standardization Plan (click here)

Template from FDA Homepage

SDSP - Study Data Standardization Plan
FDA Recommended SDSP Template Content

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CDER / CBER

Study Data Standardization Plan Recommendations

ABC Pharma Company

Study Data Standardization Plan

1. General Sponsor Information

2. Product Information

3. List of Completed Studies and Standards

A. Nonclinical

Study ID	Brief Title	Study Type	Exchange Standards	Terminology Standards
XYZ1	One month toxicity study in the Cynomolgus monkey	Repeat Dose Toxicity	SEND 3.0 Define.xml v.2.0	CDISC SEND Terminology 2014-06-27

SDSP - Study Data Standardization Plan
FDA Recommended SDSP Template Content (cont)

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B. Clinical

Study ID	Brief Title	Study Design	Exchange Standards	Terminology Standards
Phase 1 Studies				
ABC#1	A randomized, open-label, single-dose, two-arm crossover, pharmacokinetic (PK), bioequivalence/bioavailability study in healthy adult volunteers, 18 to 45 years of age.	Comparative, randomized, open-label, 2-way crossover, single-dose, PK study	SDTM 1.2/SDTM I.G. v. 3.1.2 Define.xml v.2.0	CDISC Terminology MedDRA v.15 (Adverse Events) WHO-DD (Medications)

4. List of Planned Studies and Standards

- A. Nonclinical
- B. Clinical

5. References

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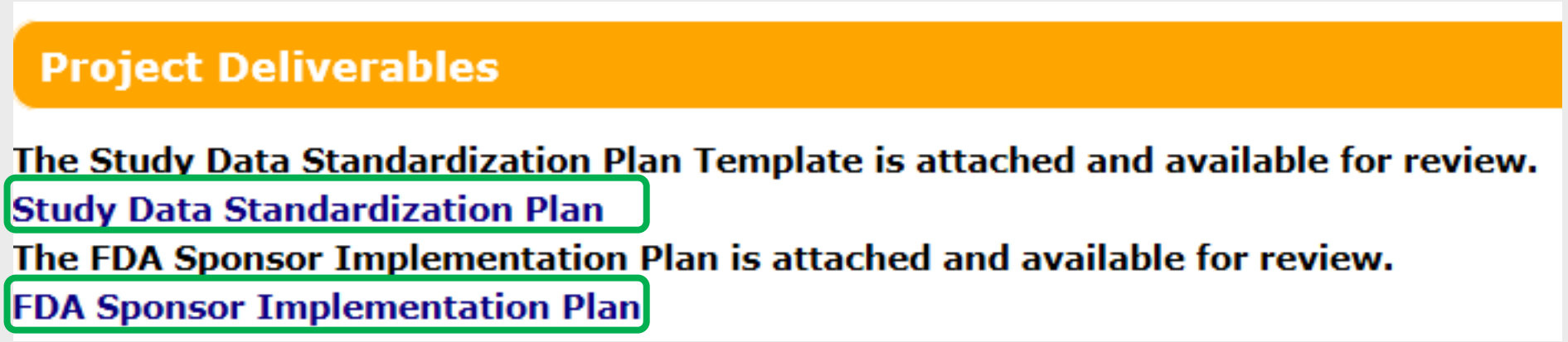
Phuse Study Data Standardization Plan (SDSP) Homepage



Project Deliverables

The Study Data Standardization Plan Template is attached and available for review.

Study Data Standardization Plan

The FDA Sponsor Implementation Plan is attached and available for review.

FDA Sponsor Implementation Plan

SDSP - Study Data Standardization Plan Phuse Template TOC

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Table of Contents

SDSP - Study Data Standardization Plan
Phuse Template List of Studies

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List of Studies and Standards

Nonclinical

Study Identifier	Brief Title	Study Type	Study Status	Study Start Date	Exchange Standards	Terminology Standards
		REPEAT DOSE TOXICITY	COMPLETED ON-GOING PLANNED	DDMONYYYY <forecast>	SEND <version> Define.xml	CDISC SEND Terminology <date>

Clinical

Study Identifier	Brief Title	Study Design	Study Status	Study Start Date	Exchange Standards	Terminology Standards
Phase 1 Studies						
		COMPARATIVE, RANDOMIZED, OPEN-LABEL	COMPLETED ON-GOING	DDMONYYYY <forecast>	LEGACY SDTM	CDISC Terminology <date>

SDSP - Study Data Standardization Plan
Phuse Template List of Studies (cont)

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Non-Conformance to Standards Justification

Study Identifier	Expected Standard	Provided Standard	Waiver	Justification for Non-Conformance to Standards
	SDTM IG <version> ADaM IG <version> SEND <version>		Date submitted <DDMONYYYY> Date approved <DDMONYYYY>	