



Science For A Better Life



Study Data Standardization Plan: A Cross-functional Tool to Communicate The Data Standardization Strategy

Sandra Johanssen DVM, PhD, ERT

PHUSE Computational Science Symposium EU, 19th & 20th June 2017

-
- **Background**

Study Data Standardization Plan (SDSP)



- Communication tool with FDA to ensure that data standards are accepted.

- Can be used as reference for all departments involved (regulatory, data management)

- Tracking discussions and agreements with FDA

- Just another list of studies?

- Do we really need this?

- Isn't it sufficient that clinical studies are listed?

Study Data Standardization Plan

Study Data Technical Conformance Guide



STUDY DATA TECHNICAL CONFORMANCE GUIDE

<http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM384744.pdf>

Technical Specifications Document

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)**

March 2017

- SDSP should be included in INDs
- Might be used for discussion at pre-IND stage.
- IND Location: General investigational plan.
- Recommendations on FDA's Study Data Standards Resources Web page available (Link 1)
- No specific template but reference to PHUSE Wiki example template (Link 2)

Study Data Standardization Plan

Clinical and Non-clinical Studies



STUDY DATA TECHNICAL CONFORMANCE GUIDE

<http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM384744.pdf>

Technical Specifications Document

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)**

March 2017

template is available.¹⁰ A 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

Study Data Standardization Plan

SDSP Recommendations



Link 1

<http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM447119.pdf>

CDER / CBER

Study Data Standardization Plan Recommendations

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
XYZ2	One month toxicity study in the Han Wistar rat	Repeat Dose Toxicity	SEND 3.0 Define.xml v.2.0	CDISC SEND Terminology 2014-06-27

4. List of Planned Studies and Standards

A. Nonclinical

Study ID	Brief Title	Study Type	Exchange Standards	Terminology Standards
XYZ3	Three month toxicity study in the Cynomolgus monkey	Repeat Dose Toxicity	SEND 3.0 Define.xml v.2.0	CDISC SEND Terminology (current version at study start)
XYZ4	Three month toxicity study in the Han Wistar rat	Repeat Dose Toxicity	SEND 3.0 Define.xml v.2.0	CDISC SEND Terminology (current version at study start)
XYZ5	Two-year carcinogenicity study in the Han Wistar rat	Carcinogenicity	SEND 3.0 Define.xml v.2.0	CDISC SEND Terminology (version used in XYZ4)

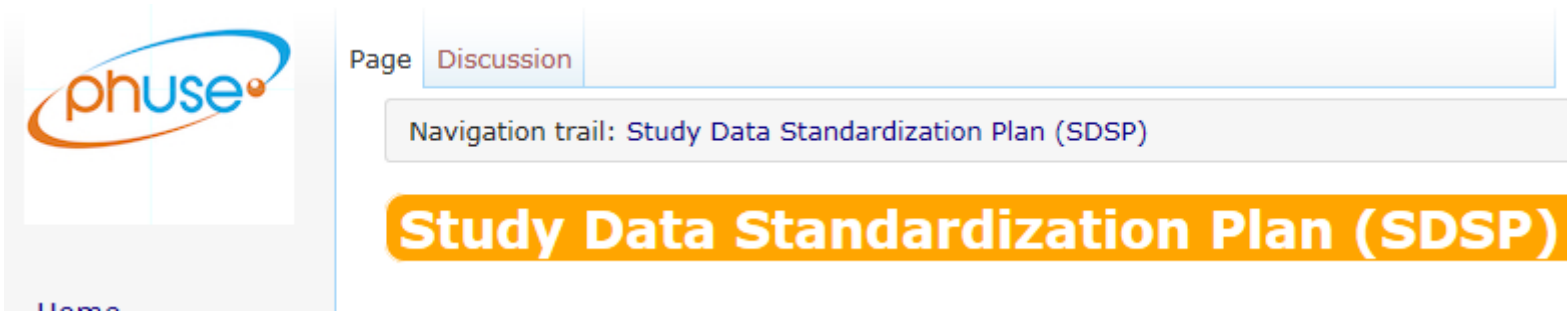
Study Data Standardization Plan

PHUSE Wiki



Link 2

http://www.phusewiki.org/wiki/index.php?title=Study_Data_Standardization_Plan_%28SDSP%29



The Study Data Standardization Plan deliverables have been sent to FDA for the next level of review. They are attached.

- [Study Data Standardization Plan Template](#)
- [Study Data Standardization Plan Template Updated 28March2017](#)
- [Study Data Standardization Plan Sponsor Implementation Guide](#)
- [Study Data Standardization Plan Completion Guidelines](#)
- [Study Data Standardization Plan Asthma Example Document](#)
- [Study Data Standardization Plan Oncology Example Document](#)
- [SDSP Deliverables Zipped](#)

-
- **Implementation at Bayer**

Study Data Standardization Plan Implementation



Study Data Standardization Plan (SDSP) **Sponsor Implementation Guide**

http://www.phusewiki.org/wiki/images/2/2d/SDSP_Sponsor_Implementation_Guide.pdf

- Provides guidance about different roles like
 - SDSP owner – creation and maintenance of SDSP
 - SDSP study contact – familiar with CDISC standards on study level
 - SDSP FDA liason – attend FDA meetings, present SDSP (can be SDSP owner)
- At Bayer, the owner of the SDSP is Clinical Data Management

Study Data Standardization Plan Template

A screenshot of a web-based form titled "Study Data Standardization Plan". The form is enclosed in a blue dashed border and has a small Bayer logo in the top right corner. It contains several input fields and a "Version" field. The fields are: a large empty text area at the top; a text field labeled "Study Data Standardization Plan"; a text field labeled "<Sponsor Name>"; a text field labeled "<Name of Product>"; a text field labeled "<Indication>"; a text field labeled "<IND>"; and a text field labeled "Version: ccyy-mm-dd". The form is set against a light gray background.

- Bayer Template generated from the PHUSE template

Study Data Standardization Plan Template



Study Data Standardization Plan Completion Guideline

V0.9
2017-02-16

<p><Sponsor>: <Name of Product>: <Indication>: <IND></p>		
--	--	--

¶

• 1. → **Introduction**¶

• 1.1 → **Purpose**¶

The purpose of the Study Data Standardization Plan (SDSP) is to establish and document a plan for describing the data standardization approach for studies within a development program. The Study Data Standardization Plan (Standardization Plan) assists FDA in identifying potential data standardization issues early in the development program 1.¶

• 1.2 → **Scope**¶

The scope of this document is for use with FDA submissions only. After it has been approved for use, the scope could expand to be used with other regulatory agencies after the proper discussions.¶

The SDSP is intended to include historical, current, and planned information about the development of the compound and indication. Multiple plans are permissible within a

Kommentar [SJ 1]: The comments are taken from the SDSP completion guideline, the entire completion guideline can be found here: http://www.phusewiki.org/wiki/images/1/1/SDSP_Completion_Guidelines_updated1.pdf

- Relevant parts of the completion guideline were included in the template as comments.

Study Data Standardization Plan Template



1 <Sponsor>: <Name of Product>: <Indication>: <IND>	
--	--

4. → List of Studies and Standards

4.1 → Nonclinical

Study-Identifier ^α	Brief-Title ^α	Study-Type ^α	Study-Status ^α	Study-Start-Date ^α	Exchange-Standards ^α	Terminology-Standards ^α
α	α	SINGLE-DOSE-TOXICITY¶ ¶ REPEAT-DOSE-TOXICITY¶ ¶ CARCINOGENICITY ^α	COMPLETED¶ ONGOING¶ PLANNED ^α	ccyy-mm-dd¶ <(forecasted-Protocol-sign)> ^α	LEGACY¶ ¶ SDTM-v<version>¶ SEND-IG<version>¶ ¶ tumor.xpt¶ ¶ ts.xpt¶ ¶ define.xml<version>¶ ¶ No-Electronic-Data ^α	Sponsor-Defined¶ Terminology¶ ¶ CDISC-SEND¶ Terminology¶ <date>¶ ¶ NONE ^α

- Only SEND relevant study types will be listed

Study Data Standardization Plan

Template - Examples



4.1 → Nonclinical

Study-Identifier ^α	Brief-Title ^α	Study-Type ^α	Study-Status ^α	Study-Start-Date ^α	Exchange-Standards ^α	Terminology-Standards ^α
T102xxx-y PHxxx ^α	BAY-xxxxxxx-14-day oral toxicity study in rats with daily administration ^α	REPEAT DOSE TOXICITY ^α	COMPLETED ^α	2016-03-24 ^α	No electronic data ^α	NONE ^α

- Non-mandatory study, no electronic data, no TS.xpt submitted

Study Data Standardization Plan

Template - Examples



4.1 → Nonclinical

Study-Identifier	Brief-Title	Study-Type	Study-Status	Study-Start-Date	Exchange-Standards	Terminology-Standards
T102xxx-y PHxxx	BAY-xxxxxxx-14-day oral toxicity study in rats with daily administration	REPEAT DOSE TOXICITY	COMPLETED	2016-03-24	ts.xpt	NONE

- Completed, non-mandatory study, no electronic data, TS.xpt submitted

Study Data Standardization Plan

Template - Examples



4.1 → Nonclinical

Study-Identifier	Brief-Title	Study-Type	Study-Status	Study-Start-Date	Exchange-Standards	Terminology-Standards
TBD	BAY-xxxxxx-13-week oral toxicity study in dogs with daily administration	REPEAT-DOSE-TOXICITY	PLANNED	TBD	SEND-IG Version TBD	CDISC-SEND-Terminology (current version at study start)

- Planned study

Study Data Standardization Plan

Template - Examples



4.1 → Nonclinical

Study-Identifier ^α	Brief-Title ^α	Study-Type ^α	Study-Status ^α	Study-Start-Date ^α	Exchange-Standards ^α	Terminology-Standards ^α
T102xxx-y [¶] PHxxx ^α	BAY-xxxxxxx-14-day oral toxicity study in rats with daily administration [¶]	REPEAT-DOSE TOXICITY [¶]	COMPLETED [¶]	2017-02-22 ^α	SEND-IG-3.0 ^α	CDISC-SEND [¶] Terminology [¶] 2017-03-31 [¶]

- SEND compliant study

-
- **Lifecycle**

Study Data Standardization Plan Lifecycle



STUDY DATA TECHNICAL CONFORMANCE GUIDE

Technical Specifications Document

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)**

March 2017

The SDSP should be updated in subsequent communications with FDA as the development program expands and additional studies are planned. Updates to the SDSP 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 SDSP was executed.

Study Data Standardization Plan

Alignment



Study Data Standardization Plan (SDSP)

Sponsor Implementation Guide

http://www.phusewiki.org/wiki/images/2/2d/SDSP_Sponsor_Implementation_Guide.pdf

8.1 Stage Gates

<i>Stage Gate</i>	<i>Expectation</i>
Pre-IND	Provide all known studies and their data standards information.
IND	Ensure initiation of the SDSP at this time point if not earlier.
End of Phase II	Add more about the studies expected in the submission and the plan for possible integration of standards.
Type C meeting to discuss data standards	If not given time at other FDA meetings, communicate the SDSP to FDA to ensure their agreement to the SDSP.
Pre- NDA meeting	Provide SDSP as a confirmation of all prior agreements around data standards.
Submission	Include in eCTD.

Study Data Standardization Plan (SDSP)

Summary



- SDSP fosters alignment of the study data standardization strategy with FDA.

- Maintenance of the document over the project development program and alignment at stage gates

- Good guidances available to set-up and implement the SDSP.

- As cross-functional tool it has to be implemented in different functions



Science For A Better Life



Thank you!

Study Data Standardization Plan (SDSP)

Questions for Discussion



- When to submit an SDSP in a rolling submission?

- How to indicate that a study was converted?

eCTD Overview

Location of Study Data Standardization Plan



- Study Data Standardization Plan is part of General Investigational Plan

