

Study Data Standardization Plan (SDSP)

Sponsor Implementation Guide

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Disclaimer

This document offers considerations for the implementation of a SDSP. Any recommendations provided in this document should be discussed and agreed upon with your review division. Sponsors should adopt implementation practices aligned with their own SOPs and working guidelines.

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1. Introduction

1.1 Background

FDA has published a **Study Data Technical Conformance Guide**¹ (*Conformance Guide*) which provides specifications, recommendations, and general considerations around how to submit standardized data using FDA-supported CDISC data standards. The *Conformance Guide* is intended to complement and promote interactions between sponsors and FDA review divisions. Section 2 of the guide recommends that sponsors plan for the submission of standardized data through the use of a **Study Data Standardization Plan** (SDSP).

1.2 Sponsor Benefit

The development and maintenance of the Study Data Standardization Plan provides important benefits to sponsors. First, the SDSP brings internal focus and agreement to the standards throughout the project lifecycle versus an ad hoc process driven by individual studies. Second, the availability of the SDSP provides an important reference for all sponsor groups (e.g., regulatory affairs, data management). Further this document provides a means of tracking discussions and agreements with the FDA. Finally, this document will drive decisions about legacy data conversion and up-versioning of data standards to allow for pooling of data across studies at a much earlier time than pre-NDA meetings

2. Purpose

The purpose of this document is to help sponsors integrate the SDSP into the life cycle of the regulatory IND to NDA submission process. This implementation guide will provide sponsor organizations with best practices for creating Roles and Responsibilities at their organization for those who will facilitate the creation and use of the SDSP during the course of this process.

3. Scope

Provide definitions of the Roles and Responsibilities of the principal participants in the process of authoring, maintaining and managing the Study Data Standardization Plan (SDSP) at sponsor organizations. Identify the primary process steps and time points necessary to enable the SDSP.

4. SDSP Management

The SDSP is intended to be started at the IND time point. If the IND has previously occurred, the SDSP should be started immediately. All studies that are known at the time of the IND or when the SDSP starts will be recorded in the SDSP, including previously completed, ongoing and planned

¹ Available at <http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>

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studies. As more studies are planned, they will be added to the SDSP. If the compound is in-licensed, in co-development or acquired midway in development, all studies should be listed whether the sponsor or the partner led the study.

For compound indications that are in the post marketing phase, sponsors will decide when it is appropriate to create an SDSP. In these cases the SDSP would reflect only those studies that support the post marketing reporting.

The SDSP will be used as a communication tool with the FDA to ensure that the FDA reviewers understand and accept the data standards the sponsor is using for each study. Each change to the SDSP does not necessitate that an update be sent to the FDA, but the SDSP should be made available to the FDA at critical stage gate meetings. The SDSP will be provided in its final form at submission including a statement in the cover letter describing the extent to which the latest version of the SDSP was executed.

5. Roles

- SDSP Study Contact
- SDSP Owner
- SDSP FDA Liaison (may be the same as the SDSP Owner)

5.1 SDSP Study Contact

SDSP Study Contact
Expected to be familiar at a study level with CDISC data standards, can be one per study. This role could be a Data Manager, a Project Data Standards Manager, a person at the sponsor who understands CDISC data standards. This may be a different role for Non-clinical studies and for Clinical studies. The study contact may interact with other subject matter experts to provide complete and accurate information.
SDSP Study Contact Skill set
<ul style="list-style-type: none">• Full understanding of current non-clinical or clinical CDISC data standards.
<ul style="list-style-type: none">• Awareness of emerging data standards, e.g. Therapeutic Area data standards.
<ul style="list-style-type: none">• Familiarity with the FDA Data Standards Catalog and other FDA mandated standards documents.
<ul style="list-style-type: none">• Strong background with the sponsor clinical or non-clinical data systems and practices.
SDSP Study Contact Responsibilities
<ul style="list-style-type: none">• Provide the detailed study data standards information.
<ul style="list-style-type: none">• If the Study Data Reviewer Guide (SDRG) or Analysis Data Reviewer Guide (ADRG) has been created, ensure that the standards documented in the SDRG and ADRG are in sync with the SDSP.
<ul style="list-style-type: none">• As needed, communicate with the sponsor's standards department to ensure that all SDSP content is correct and up to date.

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- Communicate all FDA comments in the SDSP to the sponsor department which manages the production of study data standards deliverables.

5.2 SDSP Owner

SDSP Owner
For each IND to NDA FDA submission process, sponsors should identify a person who has the primary responsibility for managing all aspects of the creation and maintenance of the SDSP. Also, the SDSP Owner is responsible for ensuring that the SDSP is included in a timely manner in communications with FDA review divisions. The role should be agreed to and endorsed by senior management.
SDSP Owner Skill set
<ul style="list-style-type: none">• Have a broad understanding of current non-clinical and clinical CDISC data standards.• Awareness of the emerging data standards, e.g. Therapeutic Area data standards.• Aware of the FDA Data Standards Catalog and other mandated standards documents.• Good communications skills. If needed, be able to explain the SDSP details to the FDA.• Aware of key contacts in all areas of sponsor departments, Data Management, Statistics, Clinical Research Science, Regulatory Affairs etc.• Able to act as a Project/Program Manager across several months/years of the submission.
SDSP Owner Responsibilities
<ul style="list-style-type: none">• Establish by authoring or pulling together the information needed to create the SDSP and maintain the content of the SDSP throughout the SDSP lifecycle in consultation with other relevant sponsor groups in the organization.• Ensure that study data standards are defined as early as possible.• Serve as an overseer, coordinator and guide as sponsor groups develop their study data plans, interacting with SDSP Study Contacts as needed.• More than one active plan per product/indication or drug project can be managed at one time by one or more SDSP Owners.• Ensure that sponsor Regulatory submission representatives understand the need for the SDSP and its use in FDA discussions.• If needed, participate in discussions with FDA regulatory reviewers to resolve any gaps in the data standards that are concerns for the reviewers.• Ensure that all FDA comments are documented in the “FDA Discussions” Section within the SDSP to capture all decisions that were made between the sponsor and the FDA concerning the study data standards.• Return all FDA comments and decisions in the SDSP to the SDSP Study Contacts.

5.3 SDSP FDA Liaison

SDSP FDA Liaison (can be the SDSP Owner)
<ul style="list-style-type: none">• As needed, attend FDA meetings and present the SDSP at to the FDA review division to ensure that they have a clear understanding and approval of the content of the SDSP.

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| <ul style="list-style-type: none">• Record any regulatory interaction regarding the use of data standards in the SDSP |
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6. Sponsor Management Responsibilities

- Ensure there is support by upper management to implement the SDSP.
- Create and appoint the appropriate roles at the sponsor organization.
- Offer sponsor education on the use of the SDSP.

7. SDSP Timelines and Triggers

7.1 Timelines

- Start the SDSP as early as possible, preferably at the pre-IND meeting.
- Add as much data standards information that is known at this time point.
- Update the SDSP prior to meetings or communications with FDA where the SDSP will be discussed, making sure to keep a clear change history of the SDSP for transparency.

7.2 Possible Triggers for SDSP updates

- In preparation for IND (e.g. preIND meetings)
- The initial IND filing
- New study added or planned
- Changes to planned studies
- Integrated analysis plan defined
- Upcoming regulatory interaction with FDA (e.g. EOP2, Type B/C, pNDA)
- Agreements between regulatory authority and sponsor
- The NDA filing

It is not necessary to share updates with FDA for each update to the SDSP.

8. SDSP Communications/Meetings with FDA

- Communicate the SDSP at key stage gate time points of the filing and/or as determined by the associated FDA review division.

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- Critical changes or updates to the use of data standards should be agreed upon with FDA prior to submission. An FDA Type C meeting can be requested, if outside the window of other regulatory meetings.
- For pre-IND meetings, the SDSP can be part of the General Investigational Plan.
- For pre-NDA and end of phase 2 meetings, the SDSP can be included in the briefing document as an appendix.
- At submission the SDSP can reside in eCTD Module 1 with links to Module 4 and 5.
- After submission, the SDSP should be updated and maintained as needed (i.e. adding new studies/pooled analysis) per FDA request.

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.

9. Definitions

eCTD	The electronic common technical document (eCTD) is an interface and international specification for the pharmaceutical industry to agency transfer of regulatory information.
FDA	The United States Food and Drug Administration.
IND	The FDA's Investigational New Drug (IND) program is the means by which a pharmaceutical company obtains permission to ship an experimental drug across state lines (usually to clinical investigators) before a marketing application for the drug has been approved.

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NDA	The FDA's New Drug Application (NDA) is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S.
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