

Study Data Standardization Plan Completion Guidelines

Version 1.0

Revision History

Version	Date	Summary
1.0	2018-01-25	Initial version

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Study Data Standardization Plan Completion Guidelines Overview

1. Study Data Standardization Plan Purpose

The Study Data Standardization Plan (SDSP) establishes and documents a plan for describing the data standardization approach for clinical and nonclinical studies within a development program. The SDSP also assists the FDA in identifying potential data standardization issues early in the development program. Refer to the SDSP Template for more information.

2. SDSP Overview

The SDSP has six main sections – Introduction, General Sponsor Information, Product Information, List of Studies and Standards, Non-Conformance to Supported Standards Justification, and FDA Data Standards Discussions. There is also a Center for Biologics Evaluation and Research (CBER) Appendix for relevant submissions of study data; Refer to the CBER Appendix in the SDSP Template for more information.

The SDSP template provides Sponsors with a starting framework to execute a SDSP. Excluding the CBER Appendix, which is only for programs targeting CBER submission, each Section of the SDSP template is to be included in a Sponsor's publication. Each SDSP Section includes a series of questions or sub-sections with applicable elements necessary to aid FDA Reviewers. Do not delete any primary sections or sub-sections from the final document. Provide complete answers to all required questions.

The Standardization Plan is intended to include historical, current, and planned information about the use of study data standards for clinical and nonclinical studies. There will be one SDSP per Investigational New Drug (IND) Application; multiple plans are permissible for a single compound in the event of multiple INDs or per communication with the appropriate regulatory agency. Each SDSP will be maintained throughout the development of the compound. Whether the product/compound is in-licensed, in co-development, or acquired mid-development, all in scope studies should be listed (see Section 4), regardless of which Sponsor executed the study. Refer to Sponsor Name (see Section 2.4) for more information.

The Sponsor will need to populate the document Header consistently throughout the SDSP by following the template. Be consistent with the values specified in Section 2 of the SDSP. Extending Header and/or Footer is permitted based on the Sponsor's documentation policies.

The Sponsor will maintain SDSP version history via the Revision History table immediately following the cover page. For each version exchanged with FDA, the Sponsor will provide a summary to describe key areas of change by section (e.g., Section 4.2 – inserted 2 new planned studies) and record the approved content version date on the SDSP cover page. The version of the SDSP template utilized should also be documented on the SDSP cover page. The version of the Sponsor's SDSP template is permitted on the SDSP cover page based on the sponsor's documentation policies.

3. SDSP Completion Guideline Purpose

The purpose of this document is to provide sponsors with a clear, concise set of instructions that facilitate the consistent and predictable development of the SDSP from the Study Data Standardization Plan Template. This document purposely duplicates information found in other submission documentation (e.g. clinical plan, tabulation listing of clinical studies, list of non-clinical studies, etc.) in order to provide a single point of orientation for how a Sponsor completes and an FDA Reviewer reads the SDSP. The instructions provided within this document intend to be flexible for any type of submission. A Sponsor will need to adjust or interpret as appropriate.

In addition to the SDSP Completion Guideline, Example documents are available as an additional reference on a completed SDSP. The SDSP Implementation Guide is also available to provide a sponsor the framework on when and how to generate a SDSP within the Regulatory process. The information included in this document is in accordance with the Study Data Technical Conformance Guide and the published Data Standards Catalog.

4. CBER Appendix Overview

The SDSP CBER Appendix has five main sections: Introduction, SDTM Datasets, Supplemental Qualifiers, ADaM Datasets, and Integrated Summary of Safety (ISS) and Integrated Summary of Efficacy (ISE).

5. CBER Appendix Purpose

When the SDSP supports study data intended for exchange with CBER, additional documentation is needed via the CBER Appendix. The SDSP CBER Appendix is specifically for studies and pools that plan to be submitted to CBER; do not utilize this portion of the template for other FDA centers unless instructed otherwise by the relevant review division.

6. Organization of This Document

This document has four sections: a guideline overview, SDSP Template Completion Instructions, SDSP Finalization Instructions, and CBER Appendix Completion Instructions. The SDSP Finalization Instructions describe how to create the document for official exchange with the FDA after completing the SDSP Template.

Study Data Standardization Plan Template Completion Instructions

This section provides companion instructions for the SDSP Template. Unless indicated the section numbering corresponds directly to the SDSP Template. Section headings in *italics* (e.g., *1. Introduction*) does not contain any content and are included for completeness.

The first page should be completed with the Sponsor Name, Name of Product, Indication, and IND number. If the IND number is not available, remove the 'IND' on the page.

The "Approved SDSP Content Version" should reflect that date the SDSP content was approved if applicable. The "SDSP Template" date applies to the date associated with the version of the SDSP template that was used to create the SDSP.

1. Introduction

1.1. Purpose

This required sub-section states the purpose of the SDSP. The SDSP Template includes standard text that should not be changed by a Sponsor.

1.2. Scope

This required sub-section documents the scope of the SDSP. The SDSP Template includes standard text that should not be changed by a Sponsor.

1.3. Acronyms

This required sub-section documents any industry, sponsor-specific or non-industry standard acronyms used in the SDSP. A Sponsor is responsible for providing any additional values mentioned throughout their executed SDSP in the Acronym sub-section. A Sponsor should avoid altering values provided in the SDSP template. Any acronyms not used should be removed from the table.

1.4. Definitions

This required sub-section documents key definitions associated with terminology used throughout the Sponsor's SDSP. A Sponsor is responsible for providing any additional term descriptions utilized in the Definitions sub-section. Document terminology that is unique to the Sponsor organization (i.e., nomenclature that is not common within the industry) or terminology for which the Sponsor organization maintains an alternative understanding to a commonly used term (i.e., nomenclature that is common within the industry but used within the Sponsor with a different definition). A Sponsor may expand definitions provided in the SDSP template, but should avoid contradicting the foundational meaning of those terms provided in the SDSP template. The Sponsor should highlight any alterations to the SDSP Template definitions and discuss as appropriate with FDA.

2. General Sponsor Information

Note: the section numbering utilized below does not correspond directly to the SDSP Template, as this format is tabular.

2.1. Name of Product

This required item provides the compound or drug product generic name or sponsor-defined identifier (e.g. number). Be consistent with IND and other regulatory documentation. Trade Names should not be included in this overview table; if a Sponsor desires, trade names may be documented in the Product Information (see Section 3).

2.2. Indication

This required item describes the disease or therapeutic indication as directed by the associated IND. There will be one SDSP per indication, however the studies provided within the SDSP may include unique sub-sets of the indication or other indications treated by the

same compound. This detailed population is described in Section 3 (Product Information). Populating this field with controlled terminology (i.e., SNOMED) is encouraged, however is not required.

2.3. IND

This item relates the SDSP to the associated Investigational New Drug (IND) application. Populate with a valid IND number unless the SDSP is part of the General Investigational Plan or the IND number has not been assigned. If the plan is for a pre-IND then IND number will be blank.

2.4. Sponsor Name

This required item provides the Regulator with the primary Sponsor responsible for information contained within the SDSP. If multiple Sponsors support the SDSP and associated IND, each Sponsor may elect to be listed. Be consistent with other regulatory documents.

2.5. Sponsor Contact

This required item provides the Regulator with at least one SDSP Owner or primary point of contact for information contained within the SDSP. Provide first name followed by last name. The functional area of this contact is at the discretion of the Sponsor (e.g., for one Sponsor the SDSP Owner may be from Regulatory while at another Sponsor the SDSP Owner may be from Data Standards). If multiple Sponsors support the SDSP and associated IND, each Sponsor may elect to name a contact. If multiple names are provided for the same Sponsor or across multiple Sponsors, a primary representative should be distinguished. Be consistent with other regulatory documents.

2.6. Sponsor Contact Email

This required item provides the Regulator with the email address(es) for the name(s) provided in Sponsor Contact. At least one valid email address for the primary point of contact, the SDSP Owner, must be listed.

Example:

Sponsor Name	Drug Company 123
	ABC Pharmaceuticals
Sponsor Contact	John Dough (Primary)
	Jane Doe
Sponsor Contact Email	JD@drugcompany.com (John Dough - Primary)
	JDoe@ABCpharma.com (Jane Doe)

End of Example

3. Product Information

This required section is free-text to give the Sponsor an opportunity to describe the product under development and provide further details about the intended indication(s) (i.e., treatment, prevention, curative, etc. or specific sub-types of the broader indication) and patient populations (i.e., adult, pediatric, geriatric, etc).

Summarize all intended indications and patient populations involved in each planned, ongoing, or completed study. Consider including information similar to what is expected in a Trial Summary domain. If a study is for an indication not stated in sub-section 2.2, include it here.

Redundancy is acceptable to provide context within the scope of the SDSP. When redundant, be consistent with regulatory documents. Or alternatively, avoid redundancy by referencing documents where additional product information can be obtained (e.g. FDA Briefing Document).

4. List of Studies and Standards

This required section documents a Sponsor's list of studies and associated standards. A study could be in more than one SDSP.

Within the Nonclinical study table listing:

- All studies within the relevant IND(s) which are in scope of the applicable standard(s) in the Data Standards Catalog should be listed.
- Sort by Study Identifier.

Within the Clinical study table listing:

- All studies within the relevant IND(s) should be listed, regardless if study data would be submitted (i.e. as opposed to submitting clinical study data as part of a pooled analysis).
- Each study should be grouped by phase/type of study/indication. Name each phase consistently with Trial Phase (TPHASE) CDISC Controlled Terminology. A sponsor may insert additional table breaks/sections per phase subgroups (i.e., IIA and IIB may be grouped separately). Studies that combine phases (e.g. Phase 1/2) are listed once; do not repeat combination studies in each phase. If more uniqueness is needed for the groupings, the titles can be expanded using Study Type (STYPE) CDISC Controlled Terminology and/or therapeutic indication.
- Within each group of studies, sort by Study Identifier.

Within the Pooled table listings, sort by Pool Identifier.

It is acceptable for a supplemental New Drug Application (sNDA) or New Line Extension (NILEX) to list the IND# of a previous NDA submission. The studies that were part of the previous submission do not need to be listed unless there is pertinent information that should be shared with FDA. Prior to each section (4.1 and 4.2) reference the IND or NDA that was submitted previously. *It is important to leave the tables in the SDSP for future use. Do not remove the tables.*

4.1. Nonclinical

Note: the section numbering utilized below does not correspond directly to the SDSP Template,

as this format is tabular.

This sub-section summarizes studies related to non-human subjects. However, if a Sponsor has no nonclinical studies to list, this must be noted as such on the line before the table, i.e., “To be populated at a later date.” *Do not remove the table. Leave it in the SDSP for future use.* The SDSP will be updated and maintained throughout the development of the product/compound as new nonclinical studies are planned, started, and completed. It is acceptable to delete the contents of the table (template language) as long as the table itself is not deleted.

If a SDSP has been previously submitted, a new SDSP is created for the same compound (different indication), and no nonclinical studies are going to be added, reference the previous IND before the table. Leave the table in case there is a need to add a nonclinical study for the new indication. The contents can be removed as it is from the template.

4.1.1 Study Identifier

This item provides the unique study number or study identifier for ongoing or completed studies. For planned studies, this item should be marked as “TBD” (To Be Determined) if the study identifier has not yet been determined. When applicable, be consistent with regulatory documents (e.g., as referenced in the eCTD).

4.1.2 Brief Title

This item provides an abbreviated summary of the study title to highlight its overall purpose. For planned studies, this title is understood to be draft and subject to change.

4.1.3 Study Type

This item provides brief textual description of the study type. Where controlled terminology exists for the study type, such as ICH or Study Type SEND Controlled Terminology, use this for the value. This can be taken directly from the study protocol or developed specifically for the SDSP.

4.1.4 Study Status

This item communicates the relative progress/development of the study. Indicate each listed study as: COMPLETED, ONGOING, or PLANNED. Refer to Definitions provided in Section 1.4.

The Technical Conformance Guide outlines that the SDSP should include a list of planned studies. Planned studies are included at the Sponsor’s discretion. A Sponsor may opt to list a limited subset of planned Nonclinical studies (e.g., reproductive or carcinogenicity studies, or others most relevant to the clinical development plan). The Sponsor should consider including studies relevant for the clinical development plan where FDA supported standards will be utilized.

Each time the SDSP is updated, a Sponsor will review these *Study Status* values per the product or compound’s development plan and revise any study as appropriate. A Sponsor’s SDSP Version Control strategy should consider how to handle noting or removing PLANNED studies that are not executed.

4.1.5 Study Start Date

This item provides study start date; Refer to Definitions. Enter date in ISO format. An impartial date is allowed (e.g., 2016-01). If *Study Status* is PLANNED, the Sponsor may enter a forecasted protocol signature date (with notation for transparency) or record value as “TBD” (To be Determined). Each time the SDSP is updated, a Sponsor will review these forecasted dates and revise the target as appropriate.

4.1.6 Exchange Standards

This item provides the Sponsor’s current or intended file format(s) of the data exchange. From the values provided in the SDSP template, select those that will be included in the data transmission and specify their appropriate version. More than one exchange format may be listed for a study. Remove any terms from the SDSP Template that do not apply to that study. Any variation from FDA supported standards per the FDA Data Standards Catalog should be further described in Section 5.

Legacy data is non-CDISC, sponsor proprietary, electronic data; noting that PDFs are not electronic study data. Electronic study data submitted in a format never supported in the FDA data standards catalog or in FDA guidance, is considered LEGACY data. If a Sponsor has determined that no electronic datasets will be exchanged (e.g., simply a report will be sent via .pdf), then record “No Electronic Data”. Do not add further details in Section 5 for the following situations: LEGACY, tumor.xpt, or No Electronic Data.

4.1.7 Terminology Standards

This item refers to the various standard terminology code sets or controlled sources utilized in the exchange standards, e.g., CDISC SEND. The SDSP Template provides common examples and may not include all values accepted by FDA. Refer to the FDA Standards Catalog for the complete set. Only list those terminology standards that will be included in the data transmission and provide the applicable publication date or version(s) of each terminology standard.

If the dictionary source is still unknown (i.e., study is planned but terminology details have not been established), simply note as such (e.g. “TBD”).

4.2. Clinical

Note: the section numbering does not correspond directly to the SDSP Template, as this format is tabular.

This sub-section summarizes studies related to human subjects/patients. However, if a Sponsor has no clinical studies to list, this must be noted as such, i.e., “To be populated at a later date.” *Do not remove the table. Leave it in the SDSP for future use.* The SDSP will be updated and maintained throughout the development of the product/compound as new clinical studies are planned, started, and completed. At this time, post-marketing studies are not expected to be included in the SDSP.

Otherwise complete this sub-section as follows:

4.2.1 Study Identifier

This item provides the unique study number or study identifier for ongoing or completed studies. For planned studies, this item should be marked as “TBD” (To Be Determined) if the study identifier has not yet been determined. When applicable, be consistent with regulatory documents (e.g., as referenced in the eCTD).

4.2.2 Brief Title

This item provides an abbreviated summary of the protocol title to highlight its overall purpose. For planned studies, this title is understood to be draft and subject to change.

4.2.3 Study Design

This item provides a brief textual description of the protocol design and, if applicable, a visual representation for clarity. For PLANNED studies or if a study is not found on clinicaltrials.gov, deduce (if possible) from the Protocol or other supporting documents the parameters specified below based on the type of study (Interventional, Observational, Expanded Access). It is acceptable to also document “TBD” (To Be Determined) if information is not currently available.

For particularly complex study design (e.g., adaptive designs), an electronic image file may be embedded or inserted via screenshot or a visual representation from the protocol or developed specifically for the SDSP description of the protocol design; add as an appendix for ease of navigation.

Interventional Studies:

List the relevant descriptions using the order in Table 1. Utilize CDISC Controlled Terminology or values from clinicaltrials.gov whenever possible. A study can be found on the clinicaltrials.gov site by using any part of the study identifier in the Search box. If there is overlap in the valid values between these two sources, CDISC terminology is preferred. When multiple values are applicable to a parameter, separate each term with “/”. Ensure uniqueness between each parameter listed. For example, Trial Type could be Pharmacogenetic/Pharmacogenomic and the Primary Purpose could be Treatment. If the only valid value for Trial Type Response is the same as a Primary Purpose, only list it once.

Note: It is not necessary to list the Parameter name – only the value(s) for the parameter are required. Please refer to the Example documents¹ as an additional reference.

Table 1:

Parameter	Applicable CDISC Controlled Terminology
Allocation	
Control Group	Control Type Response (TCNTRL)
Intervention	Intervention Model Response

Model	(INTMODEL)
Masking	Trial Blinding Schema Response (TBLIND)
Trial Type Response	Trial Type Response (TTYPE)
Primary Purpose	

Observational Studies:

List the relevant descriptions using the order in Table 2; note that some parameters are not required. Utilize CDISC Controlled Terminology or values from clinicaltrials.gov whenever possible. A study can be found on the clinicaltrials.gov site by using any part of the study identifier in the Search box. If there is overlap in the valid values between these two sources, CDISC terminology is preferred. When multiple values are applicable to a parameter, separate each term with “/”. Ensure uniqueness between each parameter listed.

Table 2:

Parameter	Required
Observational Study Model	Yes
Time Perspective	Yes
Biospecimen Retention	No
Biospecimen Description	No
Enrollment	Yes
Target Follow-Up Duration	Yes
Number of Groups/Cohorts	Yes

Expanded Access Studies:

For expanded access trials, leave this column blank.

4.2.4 Study Status

This item communicates the relative progress/development of the study. Indicate each listed study as: COMPLETED, ONGOING, or PLANNED. Refer to Definitions provided in Section 1.4.

Each time the SDSP is updated, a Sponsor will review these *Study Status* values per the product or compound’s development plan and revise any study as appropriate. A Sponsor’s

SDSP Version Control strategy should consider how to handle noting or removing PLANNED studies that are not executed.

4.2.5 Study Start Date

This item provides study start date; Refer to Definitions. Enter date in ISO format. An impartial date is allowed (e.g., 2016-01). If *Study Status* is PLANNED, the Sponsor will enter a forecasted first subject consent date (with notation for transparency) or record value as “TBD” (To Be Determined). Each time the SDSP is updated, a Sponsor will review these forecasted dates and revise the target as appropriate.

4.2.6 Exchange Standards

This item provides the Sponsor’s current or intended file format(s) of the data exchange. From the values provided in the SDSP template, select those that will be included in the data transmission and specify their appropriate version. More than one exchange format may be listed for a study. Remove any terms from the SDSP Template that do not apply to that study. Any variation from FDA supported standards per the FDA Data Standards Catalog should be further described in Section 5.

When specifying the appropriate version of the FDA supported standard, document the primary source upon which the files are based. For example, if the majority of exchanged SDTM datasets for a study uses SDTM Implementation Guide 3.1.2 with the incorporation of updates from Amendment 1, list “SDTM v1.2/SDTM IG 3.1.2 Amendment 1” even if this study also added a handful of provisional domains made available by CDISC, published formally in later SDTM version. A study’s additions of provisional domains, Therapeutic Area User Guide content, more current CDISC publications, etc. are noted in Section 5 of the SDSP.

Studies that include datasets using legacy data standards should be recorded as “ANALYSIS LEGACY or TABULATION LEGACY”. If both TABULATION and ANALYSIS datasets use LEGACY formats, both values should be listed. Do not add further details in Section 5 for LEGACY studies.

When study data is up-versioned from legacy data standards to standardized data (i.e. SDTM, ADaM) it is encouraged to list the legacy format and then add the additional information below the ‘Up-version<ed>’ text in the template. Refer to the example documents in which this is included.

There is one known exception to documenting the majority source with ADaM. If a study’s exchange of analysis datasets includes CDISC’s Subject-Level Analysis Dataset (ADSL) but all remaining datasets for the Sponsor’s LEGACY conventions, list “ANALYSIS: LEGACY and ADaM ADSL”

It is acceptable to document TBD (To Be Determined) for SDTM, ADaM, and define.xml for PLANNED studies if the versions could change by the time the study starts. Otherwise, list

all versions in which standardized data was created for a study. For example, if the first database lock utilized SDTM v1.1/IG 3.1.1 and was then up-versioned to SDTM v1.2/IG 3.1.2 Amendment 1, list the original version and then add the additional information below the 'Up-version<ed>' text in the template. Refer to the example documents in which this is included.

4.2.7 Terminology Standards

This item refers to the various standard terminology code sets or controlled sources utilized in the exchange standards, e.g., CDISC SDTM, MedDRA, WHO-DD, LOINC, SNOMED, etc. The SDSP Template provides common examples and may not include all values accepted by FDA. Refer to FDA Standards Catalog for the complete set. Only list those terminology standards that will be included in the data transmission and provide the applicable publication date or version(s) of each terminology standard. Documenting a publication date or documentation version will vary by the originating source.

If the dictionary source is still unknown (i.e., study is planned but terminology details have not been established), simply note as such (e.g. "TBD"). It is acceptable to list more than one CDISC foundational publication (e.g., ADaM 2014-Sep-26 and 2015-Dec-18). Even if a Sponsor extended the controlled terminology, reference the FDA-accepted source.

For Coding dictionaries, provide the initial version and the final version.

It is acceptable to document "TBD" (To Be Determined) for PLANNED studies if the versions could change by the time the study starts. Otherwise, list all versions of terminology standards that were utilized in the study. For example, if the first database lock utilized MedDRA 18.0, but the final database lock utilized MedDRA 19.1, list the original version as 18.0 and the final version as 19.1. Refer to the example documents in which this is included.

4.3. Pool

This sub-section documents data pools. If a Sponsor has no pools to list (i.e., no pools are PLANNED, ONGOING, or COMPLETED), this fact must be noted as such on the line before the table, i.e., "The compound has no planned, ongoing or completed pools." *Do not remove the table. Leave it in the SDSP for future use.* The SDSP will be updated and maintained throughout the development of the product/compound as new data pools are planned, started, and completed. A sponsor may insert additional table breaks/sub-sections if multiple indications must be pooled. It is acceptable to delete the contents of the table (template language) as long as the table itself is not deleted.

Otherwise complete this sub-section as follows:

4.3.1 Pool Identifier

This item provides the pool number or identifier (e.g., ISE-Solid Tumors or ISS-001).

4.3.2 Data Pool

This item provides a list of studies to be included in the data pool. Provide the Study Identifier(s) for all studies in each data pool. All listed studies should be included in Section

4 of the SDSP. If the list of studies is unknown (i.e., the pool is PLANNED), provide a brief description to provide context for the pool.

4.3.3 Pool Status

This item communicates the relative progress/development of the study. Indicate each listed study as: COMPLETED or PLANNED. Refer to Definitions provided in Section 1.4.

4.3.4 Pool Description

This item describes the pool as either ISS or ISE. The Sponsor may also elaborate in free text any additional information critical to the pool or describe the domains pooled (e.g. safety subset including AE and VS).

4.3.5 Exchange Standards

This item provides the Sponsor's current or intended file format(s) of the data exchange for the pooled data. From the values provided in the SDSP template, select those that will be included in the data transmission and specify their appropriate version. Remove any terms from the SDSP Template that do not apply to the pool. Any variation from FDA supported standards per the FDA Data Standards Catalog should be further described in Section 5.

4.3.6 Terminology Standards

This item refers to the various standard terminology code sets or controlled sources utilized in the exchange standards, e.g., CDISC SDTM, MedDRA, WHO-DD, LOINC, SNOMED, etc. The SDSP Template provides common examples and may not include all values accepted by FDA. Refer to FDA Standards Catalog for the complete set. Only list those terminology standards that will be included in the data pooling and provide the applicable publication date or version(s) of each terminology standard. Documenting a publication date or documentation version will vary by the originating source.

If the dictionary source is still unknown (i.e., pooling is planned but terminology details have not been established), simply note as such (e.g. "TBD"). Even if a Sponsor extended the controlled terminology, reference the FDA-accepted source.

For Coding dictionaries, provide the provide the initial version and the final version.

It is acceptable to document "TBD" (To Be Determined) for PLANNED pools if the versions could change by the time the pooling starts. Otherwise, list all versions of terminology standards that were utilized in the pool. For example, if the first database lock utilized MedDRA 18.0, but the final database lock utilized MedDRA 19.1, list the original version as 18.0 and the final version as 19.1. Refer to the example documents in which this is included.

5. *Non-Conformance to Supported Standards Justification*

Note: the section numbering does not correspond directly to the SDSP Template, as this format is tabular.

This section summarizes a Sponsor's justification for standards non-conformance. The SDSP non-conformance documentation is intended to be a general overview so that Reviewers can anticipate and plan for variation in exchange standards (i.e., particular datasets not used or non-extensible codelists enhanced). The Study Data Reviewer's Guide (SDRG) will provide the detailed documentation of non-conformance within a submission (i.e., specifics on variable-level and submission codes). However, if all studies and pools listed by the Sponsor conform to exchange standard requirements per the Data Standards Catalog, this must be noted as such on the line before the table, i.e., "All studies are conformant." *Do not delete the table as it may be needed in a future update to the SDSP.* Do not use this section for describing Exchange Standards of "Legacy" for studies that started prior to the FDA requirement. It is acceptable to delete the contents of the table (template language) as long as the table itself is not deleted.

Otherwise, complete this section as follows:

5.1. Study Identifier

This item provides the protocol number or identifier that requires further justification for non-conformant standardization strategies. This value links this record to the study listed in the relevant Non-Clinical, Clinical or Pool sub-section of the SDSP Section 4. Sort this table by Study Identifier.

5.2. Expected Standard

This item provides the FDA's intended file format of the data. If a study is non-conformant to multiple expected standards, it may be listed once or in multiple rows. If the same justification applies to all expected standards, a study may be documented once (e.g. listing SDTM, ADaM, and define.xml within the same table cell). However if there are different justifications that must be described in some length, a study may be listed more than once, with each expected standard and corresponding provided standard listed separately.

5.3. Provided Standard

This item provides the Sponsor's intended file format of the data that corresponds with the value entered in "Expected Standard."

Refer to the Expected Standard on addressing a study with multiple non-conformant standards.

5.4. Justification for Non-Conformance to Supported Standards

This required item provides the Sponsor's rationalization for the discrepancy between the Expected Standard vs. Provided Standard.

If Exceptions to submit standardized study data using a standard that is unsupported or retired per the Data Standards Catalogue have been confirmed by the FDA, these agreements should be noted in Section 6.

If appropriate, list the FDA Discussion Date to link this row with another record in the FDA

Data Standards Discussions Section. At a minimum the Sponsor must populate with the date when agreement was reached by the FDA and Sponsor. Enter date in ISO format.

6. *FDA Data Standards Discussions*

This required section is intended to serve as a log of interactions related to the SDSP. If a Sponsor gets direction from the FDA related to another compound or through other standards related discussion (i.e. audits), it is up to the Sponsor whether to include that exchange within this document. If the Sponsor feels that this related exchange is important to document (i.e. if it justifies non-conformant data standards strategies), then this can be included.

In the initial creation of the SDSP, leave the table as is in the template with the exception of the last column (Result/Agreement). Delete what is in that column only and in the line above the table insert text to indicate that this section will be updated after FDA has reviewed the document, (i.e. "This section will be updated after the comments from the FDA are received.").

If the Sponsor has no FDA Standards Discussions to document, this must be noted as described above. Otherwise complete as follows:

6.1. *Date of Discussion*

This item links this row with the Non-Conformance to Supported Standards Justification item. At a minimum the Sponsor must populate with the date when agreement was reached by the FDA and Sponsor. Enter date in ISO format. Include any other significant dates associated with the item as detail in the FDA Discussion section.

6.2. *Meeting Identifier*

This item indicates the meeting identifier as tracked by the Sponsor. The value may be a number or a meeting name/topic. Populate the reference id, if known.

6.3. *Form of Discussion*

This item indicates the mode of discussion (i.e., face-to-face meeting, e-mail, letter).

6.4. *Result/Agreement*

This item provides a brief, concise information related to data standards – do not attempt to include other information gathered of the FDA dialogue.

7. *References*

This required section provides key sources for the SDSP. A sponsor may elect to expand the list of references.

Study Data Standardization Plan Finalization Instructions

This section describes how to create the document for submission after completing the SDSP Template.

1. Create hyperlinks between Section 4 and Section 5

Create links between Sections 4 and 5 via Study Identifier.

Select the text in the first column of Table 4.1, 4.2, and/or 4.3 that needs a hyperlink.

Right click the selected text and choose “**Hyperlink**” from the menu. In the left panel of the Hyperlink window, make sure that “**Place in this document**” is selected. Then, in the list of document places select the Non-Conformance to Supported Standards Justification header and click **OK**. Ctrl+click the hyperlink to test it.

2. Create hyperlinks between Section 5 and Section 6

Create links between Sections 5 and 6 via Date of discussion.

Select the text in the last column of Table 5 that needs a hyperlink. **Right click the selected text** and choose “**Hyperlink**” from the menu. In the left panel of the Hyperlink window, make sure that “**Place in this document**” is selected. Then, in the list of document places select the FDA Data Standards Discussion header and click **OK**. Ctrl+click the hyperlink to test it.

3. Update the Table of Contents, document header, and content version date

After all edits have been completed, update the table of contents at the top of the document.

Right click on any line in the table and select “**Update Field**.” In the dialog window, select “**update entire table**,” then click **OK**.

Confirm that the required portions of the header (Name of the Product and Indication) are populated consistently. Be consistent with the values specified in Section 2 of the SDSP. Extending Header and/or Footer is permitted based on the Sponsor’s documentation policies.

Confirm the content version date is correct before converting the document to PDF format. This step may be done at the time of PDF creation, depending on the process documented by a Sponsor.

4. Convert the document to PDF format

These instructions are for Microsoft Word 2003 or newer, using either the Adobe Acrobat plug-in or the MS Office PDF creation feature.

4.1. Using the Adobe Acrobat plug-in for Microsoft Office:

Click the **Acrobat tab** in the Word menu at the top of the screen. Select “**Create PDF**.” If a dialog window pops up asking you to save and continue, click **Yes**. In the second dialog window, **navigate to the directory** in which you want to save the PDF, **name the file “study-data-standardization-plan.pdf”**, and click **Save**.

4.2 Conversion without Adobe Acrobat plug-in:

Click the **Office button** at the top left of your screen. Select “**Save As,**” then “**PDF or XPS**”. **Navigate to the directory** in which you want to save the PDF, name the file “**study-data-standardization-plan.pdf**”, and click **Save**.

4.3 Formatting and verifying the PDF

Open the PDF. Go to the **File menu** and select “**Properties.**” Navigate to the **Initial View tab**. In the drop-down menu for **Navigation tab**, select “**Bookmarks Panel and Page.**” In the drop-down menus for both **Page Layout** and **Magnification**, select “**Default.**” Click **OK**.

Go to the **Document menu** and select “**Reduce File Size.**” In the drop-down menu, select “**Acrobat 5.0 and later.**” Click **OK**, then **navigate to the directory** in which you want to save the PDF, name the file “**study-data-standardization-plan.pdf**”, and click **Save**.

Go to **File**, and select “**Properties.**” Verify at the bottom of the dialog window that the **PDF version is 1.4**.

CBER Appendix Completion Instructions

This section provides companion instructions for the CBER Appendix. Unless indicated the section numbering corresponds directly to the SDSP Template. Section headings in *italics* (e.g., *1. Introduction*) does not contain any content and are included for completeness.

1. Introduction

1.1. Purpose

This required sub-section states the purpose of the CBER Appendix. The SDSP Template includes standard text that should not be changed by a Sponsor.

1.2. Scope

This required sub-section documents the scope of the CBER Appendix. The SDSP Template includes standard text that should not be changed by a Sponsor.

2. SDTM Datasets

Complete one CBER Appendix SDTM table per clinical study, even if the same domains, variables, and associated comments are utilized across multiple studies. Please note that supplemental qualifiers are documented in a separate section, refer to Section 3 *Supplemental Qualifiers*.

2.1. SDTM Version

Indicate the published version of SDTM used by the study. Be consistent with the information provided in Section 4.2 of the SDSP.

2.2. STUDY ID

Provide the protocol number or identifier. When applicable, be consistent with regulatory documents. All listed studies should be included in Section 4 of the SDSP.

2.3. TITLE

Provide an abbreviated summary of the protocol title to highlight its overall purpose. Be consistent with the information provided in Section 4.2 of the SDSP.

2.4. DOMAIN

The template contains SDTM domains defined by CDISC and released for publication, using the domain long name and corresponding domain abbreviation. For transparency with the agency, include all available domains within the relevant SDTM publication. Do not delete rows from the template. Add rows as necessary for additional SDTM domains (e.g., Sponsor-defined custom domains, draft SDTM domains applied to the study, etc.), providing the domain long name and abbreviation of the associated domain.

2.5. Select Domains to be Submitted

Specify with a "X" if the domain is intended to be included in the exchange with CBER. Otherwise, leave blank.

2.6. Variables to be utilized

List the variables that will be exchanged. Do not include required SDTM variables. This list is a *minimal* set of expected and/or permissible variables; the potential exists that more standard variables associated with the observation class may be included in the eventual submission.

2.7. Additional Comments

Include a description of the type of data mapped to the domain as appropriate. This specification is particularly important for data supporting key safety and efficacy endpoint (i.e., reactogenicity data). Comments are *minimally* expected for custom domains.

3. Supplemental Qualifiers

If a study uses Supplemental Qualifiers (SUPPQUAL), complete one CBER Appendix SUPPQUAL table per clinical trial, even if the same supplemental qualifiers are utilized across multiple studies. Specify one SUPPQUAL variable per row.

3.1. SDTM Version

Indicate the published version of SDTM used by the study. Be consistent with the information provided in Section 4.2 of the SDSP.

3.2. STUDY ID

Provide the protocol number or identifier. When applicable, be consistent with regulatory

documents. All listed studies should be included in Section 4 of the SDSP.

3.3 TITLE

Provide an abbreviated summary of the protocol title to highlight its overall purpose. Be consistent with the information provided in Section 4.2 of the SDSP.

3.4 Supplemental Qualifier Domain

Provide the two character abbreviation of the associated parent SDTM domain. This information will appear in the SUPPQUAL dataset in the RDOMAIN variable.

3.5 Qualifier Variable Name

The short name of the Qualifier variable, abbreviated as QNAM.

3.6 Qualifier Variable Label

The long name or label associated with the QNAM, abbreviated as QLABEL.

3.7 Corresponding CRF Question or Derivation

Provide the source of this value by naming the originating CRF question or derivation logic.

4. ADaM Datasets

If analysis is planned or was performed on an individual study, complete one CBER Appendix ADaM table per clinical study, even if the same datasets are utilized across multiple studies.

4.1. ADaM Version

Indicate the published version of ADaM used by the study. Be consistent with the information provided in Section 4.2 of the SDSP.

4.2. STUDY ID

Provide the protocol number or identifier. When applicable, be consistent with regulatory documents. All listed studies should be included in Section 4.2 of the SDSP.

4.3. TITLE

Provide an abbreviated summary of the protocol title to highlight its overall purpose. Be consistent with the information provided in Section 4.2 of the SDSP.

4.4. TYPE

For transparency with the agency, include all available domains within the relevant ADaM publication applied to the study.

4.5. DOMAIN

The template contains ADaM domains defined by CDISC and released for publication, using

the domain long name and corresponding domain abbreviation. Do not delete rows from the template. Add rows as necessary for additional ADaM domains, providing the domain long name and abbreviation of the associated domain.

4.6. Select Domains to be Submitted

Specify with a “X” if the domain is intended to be included in the exchange with CBER. Otherwise, leave blank.

4.7. Comments

Include a description of the type of data mapped to the domain as appropriate. This specification is particularly important for data supporting key safety and efficacy endpoint (i.e., reactogenicity data). Comments are *minimally* expected for custom domains.

5. ISS and ISE

If integrated analysis is planned or was performed for safety and/or efficacy, list the ADaM domain(s) and associated information.

5.1. Dataset Label

This item provides the ADaM domain name.

5.2. Efficacy/Safety/Other

These items indicate the content of the dataset as ISS and/or ISE and/or other. In Section 4 of the SDSP, the Sponsor may also elaborate in free text any additional information critical to the pool or describe the domains pooled. Specify with a “X” if the domain is associated with ISS/ISE/other. Otherwise, leave blank.

5.3. Included Studies

This item provides a list of studies to be included/planned in the ADaM domain. Provide the Study Identifier(s) for all studies in each domain. All listed studies should be included in Section 4 of the SDSP. If the list of studies is unknown (i.e., the pool is PLANNED), provide a brief description to provide context for the pool.

5.4. Phase

This item identifies the phase(s) of the included studies.

5.5. Contributing Datasets

This item contains the SDTM and/or ADaM datasets used/planned to create the ADaM domain.