ABSTRACT
The Study Data Standardization Plan (SDSP) is intended to aid in the conversation with the FDA when submitting a program. It seems like a very straight-forward document template which can easily be filled in by the study team. However, on closer analysis it has numerous places where the study team needs to reach out to its full membership including programming, regulatory, study statistician and drug program decision-maker.

INTRODUCTION
The purpose of this paper and poster is to provide a description of all the touchpoints among different groups and departments within a pharmaceutical company (Sponsor) that are involved in developing a clinical program’s data deliverables for submission to FDA. It also provides the recommended stage gates within a clinical program where information, within this document, is needed for discussion with a regulatory agency.

The SDSP is intended to provide agreement on the standards used throughout the lifecycle of the program and is beneficial both internally and with the FDA reviewer. This plan provides details about multiple studies within a single submission such as an Investigational New Drug (IND) Application or NDA. The FDA has confirmed in the Technical Conformance Guide, section 2 [1] that a document with all the information outlined in the SDSP is recommended for review meetings.

The SDSP acts as a tool to:
- Track discussions and agreements with the FDA on standards strategy
- Communicate the standards that will be used throughout the program lifecycle
- Drive legacy data conversion and up-versioning decisions

It provides an important reference for all functional area groups, which will be detailed below.

MANY FUNCTIONAL GROUPS
The information covered in the SDSP needs to be gathered from many functional groups. These may include: Data Management, Programming, Biostatistics, Regulatory Affairs, Clinical Scientists, Data Standards Specialists, Medical Writers and even others based on your organizational structure.

DATA MANAGEMENT
Data managers may be involved in data collection standards, transfers, data coding dictionaries, and SDTM.

PROGRAMMING
Programmers are in charge of SDTM transformations, ADaM datasets, and outputs for deliverables. They may be augmented by Standards members or have Subject Matter Experts (SME’s) on standards within the groups. They may lead the study teams or there may be a project manager that controls that task.

BIOSTATISTICIANS
These develop the Study Protocol, the SAP or any protocol amendments and review all the deliverables. They are instrumental in reviewing the sections that refer to these documents.

REGULATORY AFFAIRS
This group ensures that the regulatory requirements are met, are often in charge of QA, and a myriad of other oversight functions during the conduct and submission of a study. This role is typically the lead on communications with the FDA.

CLINICAL SCIENTISTS
These scientists begin with the concept of the program and individual trials.

DATA STANDARDS SPECIALISTS
This is a team or individuals who are very knowledgeable on the CDISC and other data standards. They may be full-time standards professionals or be in a role as part of another group such as Programming and Data Management. These SMEs provide guidance and documentation to other groups to inform on conformance with the latest requirements for a CDISC-compliant submission.

OTHER
Other groups involved in the SDSP might include project managers, consultants, and CROs.

ROLES FOR COMPLETION OF THE SDSP
As described in the PhUSE SDSP Completion Guide for Sponsors [3] there are several essential roles to govern and manage the completion of the SDSP and ensure incorporation of input from various groups in a timely manner. Depending on organizational needs, multiple individuals may contribute to or fill a given role. Do refer to the completion guide for additional recommended skillsets and responsibilities for these roles.

OWNER
The owner is someone who will take charge to ensure that the SDSP is moved along from group to group and filled out accordingly. The owner must have an overview of the entire clinical program for which the SDSP is being created. The owner does not, and should not be the only author filling in the contents of the SDSP. Some sponsor companies might pass ownership along during the study. For example, a Non-clinical Owner may start the SDSP and hand-off or coordinate with a Clinical Owner.

FDA LIASON
This role needs to be filled by someone who will be sitting at the table with the FDA representatives at each review meeting. The individual must be familiar with the whole program and set of studies, and also have read and understood the contents of the SDSP.

STUDY CONTACT
The Study Contact is in charge of questions relating to a single study. The contact may be anyone within the team that has been assigned that role, usually someone from programming or data management. A Study Contact may interact with other subject matter experts (SMEs) to provide complete and accurate information.

CONSIDERATIONS
• There will be multiple study contacts per SDSP (one per study)
An SDSP may have one or multiple studies, and a study may be present in one or more SDSPs (i.e. an ISS and an initial submission, or same study in different indications)

Multiple SDSPs are permissible for a single compound in the event of multiple Indications (INDs)

**SHARING THE SDSP WITH THE FDA**

The diagram below shows the potential stage gates for the clinical program. Sponsors should share the SDSP with the FDA reviewers at these key stage gate timepoints.

**PRE-IND MEETING**

At this meeting all known studies and proposed data standards to be used should be discussed.

**SUBMIT IND**

The SDSP should be presented in the IND within the general investigational plan and should be updated in subsequent annual IND submissions.

**EOP II MEETING**

The SDSP should include all studies conducted for the compound. By this meeting studies for submission and standards for any integration plans should be identified. Note that for CBER, there is an additional Appendix, which resembles an SDRG. Note: while the SDSP should include all studies conducted for the compound, the CBER Appendix should include only those studies that will be include in the submission.

**TYPE C MEETING**

A Type C meeting should be requested to discuss technical concerns or if there are questions about data standards. The SDSP should be shared and updated with agreements reached at the meeting.

**PREnda/BLA MEETING**

The pNDA/BLA (Type B) meeting is generally held prior to the submission. Provide the latest available SDSP in the briefing document package to confirm plans and agreements around data standards. Note that on section 6 of the SDSP is a log of all the discussions that have occurred with the FDA. This should be kept current.

**SUBMIT NDA**

The completed and final SDSP is included in the electronic Common Technical Document (eCTD).

**SDSP COMPLETION GUIDELINES**

As seen in the discussion above, the SDSP is a living document. It can provide added value during the Clinical Program to keep track of studies and standards.

- The SDSP Template from PhUSE provides a starting framework which is recommended by FDA. (Note: other formats may be used as long as all information is included.)
- Each section has to be included in a Sponsor’s SDSP. If values are unknown, leave blank or specify TBD. Then update as soon as new information becomes available.
- Updates to the SDSP should not be communicated each time a study is started. The SDSP is a living document and version dates should correspond with communication to the FDA.
- The CBER appendix is only applicable for submissions to CBER and helps reviewers to understand the metadata for the study. It resembles an abbreviated version of an SDRG for SDTM [6]
- The final version has a statement in the cover letter describing the extent to which the latest version of the SDSP was executed.
The template developed by PhUSE is an easy-to-fill-in Word document [1]. It is available at the PhUSE website as a zipped package with multiple components. The primary template is highlighted below, with ancillary documentation provided; including sample SDSPs that have been filled out for asthma and oncology (CDER) and for vaccine (CBER) indications. The two pdf documents are an SDSP completion guideline, and a sponsor implementation guide.

Below is a picture of all the sections in the SDSP. They are fully described in the SDSP completion guideline [2] and are therefore out of scope for this paper. Please do refer to this document for details on how to fill out each section.

CONCLUSION
The SDSP is a living document that aids in the discussions with the FDA. It requires input from and coordination with various departments. In the poster and paper forms, we showed a visualization of the Stage Gates for submitting the SDSP to the FDA. We also provided details for the process and ownership of the various items that are required to fill in an SDP. The PhUSE template is not the only format that this information can be provided. In the initial IND’s the information is located in the general investigational plan. The PhUSE template is acceptable for the FDA and has been designed with FDA input. The SDSP brings internal value to the sponsor by providing an authoritative inventory of data standard use of studies within a program. The SDSP encourages proactive planning and discussion of data standard decisions with FDA reviewers which can ultimately lead to a smoother submission process. Therefore we highly recommend this instrument for tracking all the various data standards throughout a clinical program.

REFERENCES
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