



Vaccines Study Data Standardization Plan Experience (PP #10)

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Background

- The Study Data Technical Conformance Guide published (section 2) by FDA recommends that sponsor plan for the submission of standardized data through the use of Study Data Standardization Plan (SDSP).
- In March 2018, PhUSE released SDSP template that incorporated a CBER appendix.
- While CDER wants to be informed on the development and adoption of data standards at major stage gates, CBER seeks additional detailed information and may propose sponsor to reconsider certain mapping.

Introduction

- FDA requested that SDSP be submitted for the a vaccine program during the phase 3 study conduct.
- The program at that time had multiple clinical studies that were planned to be included in the submission.
- Types of studies
 - Completed studies - need SDTM up versioning
 - Ongoing studies
 - Planned studies
 - Completed studies with no – electronic data
- The PhUSE template was used to build the SDSP.

Primary Sections

- Primary sections in the PhUSE template,
 - List of studies and standards used.
 - Non-conformance to standards.
 - FDA Standards discussion.
 - CBER Appendix.
 - SDTM data and SUPP qualifiers.
 - ADaM datasets.
 - Pooling strategy (ISS/ISI/ISE).

List of Studies and standards

- List all non-clinical studies
- List all Clinical
- List the studies used in pooling
 - Integrated Summary of Safety (ISS)
 - Integrated Summary of Immunogenicity (ISI)
 - Integrated Summary of Efficacy (ISE)

Non-conformance to standards

- A few studies that were terminated early for which we were only providing SDTM data and no ADaM data were listed in this section with appropriate justification.
- No electronic data was to be submitted for the non-clinical studies and methodology clinical studies.
- FDA agreed to above non-conformance items.

FDA standards Discussion

- Feedback from FDA and any subsequent discussion were recorded in this section.
- A means of tracking the communications and agreements of the data standards which happen over time with FDA.

CBER Appendix

- Detailed section to list all studies, datasets and variables utilized.
 - SDTM datasets
 - Supplemental qualifier variables
 - ADaM datasets

SDTM Datasets

- All the domains for every study are expected to be listed.
- Challenging to know all the variables to list for ongoing studies and planned studies.
- Did the best we could based on available information with understanding that this can be updated later to include more details.

SDTM Supplemental Qualifiers

Very detailed section to list the supplemental qualifiers for all studies.

- Supplemental qualifier variables and source of the data.
- Can be hard to nail down all the details for planned studies.

ADaM Datasets

Not as detailed information expected.

- All ADaM datasets (no variable details are needed).
- List ADaM dataset structures like Subject Level Data structure, BDS and OCCDS
- List the datasets in each study that fall into above categories of data structure.

CBER-Office of Vaccines RR Feedback

- Very positive feedback on SDSP and agreed to the standardization approach presented in the SDSP
- Suggestion to include TAETORD variables in DS domain for all studies
- Suggested to provide only exposure (EX) and not EC domain
- Suggested to provide the Death Details (DD) domain

PhUSE SDSP Template

- The template and instructions provided by PhUSE SDSP working group were an excellent resource. The instructions provided are very detailed and the example SDSP for Vaccines was an excellent starting place.
- The SDSP has pertinent bookmarks to various sections and is useful for navigating the SDSP. However, there are no bookmarks to get to an individual study within the appendix section. It would make it much more easier to navigate if bookmarks can be added to get to each individual study from the TOC.

Summary

- The PhUSE template was used to create the SDSP for Vaccine program and the overall feedback from FDA was very valuable.
- It is important that accurate and complete information is provided in the CBER appendix as FDA conducted a very thorough review and suggested that we provided additional domains and asked to make specific changes to SDTM mapping.
- Careful planning is required to make SDSP as detailed as possible, so that we can seek accurate FDA feedback and act appropriately on any changes suggested by CBER.