

The SEND Implementation WIKI - Crowd-Sourced Practical SEND Information

SEND Implementation Project Team

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Note: The opinions expressed in this poster are those of the authors and do not necessarily represent the opinions of their respective companies.

Introduction

The deadline for when the FDA will require submission of SEND datasets is fast approaching, and Industry is quickening its pace to implement processes and software that will allow them to meet the mandate. As companies gain experience with SEND, many questions arise related to the standard and/or intent of the standard. The vast array of existing data types and collection processes also adds to the challenge. The PhUSE SEND Implementation Project Team was created to address the gap between concept and reality. To assist the industry, the group assembled a PhUSE Wiki site that contains both a Discussion Forum and an FAQ section. As questions are asked via the Forum, individuals familiar with the SEND standard offer real-time responses based on experience. The Implementation team meets monthly to moderate the Forum and transfer any necessary Q&A to the FAQ site. This poster outlines the process and provides a glimpse into several significant Forum topics.

A Collaborative Approach

The SEND Implementation Wiki leverages the expertise of SEND experts to help close the gap between the concept of SEND standards and the challenges of implementation. The Wiki is designed to help both the person new to SEND trying to navigate the standards and implementation guides, as well as the SEND expert who when faced with an ambiguous situation wants to discuss potential solutions with other SEND implementers. A dedicated group of individuals ensures that accurate, up to date information is available on the FAQ and Implementation News sites and that questions on the Implementation Forum are answered in a timely manner.

Valuable Resources for New SEND Implementers

The wiki offers a comprehensive list of resources to help users gain a better understanding of SEND and how to approach implementation.

http://www.phusewiki.org/wiki/index.php?title=SEND_Implementation_Forum



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SEND Implementation Wiki

Welcome to the SEND Implementation Wiki!

The SEND Implementation Wiki is a knowledge base on implementing SEND - a series of articles designed to help you understand and implement SEND, including modeling basics, useful links, FAQs, and more.

In addition to the wiki, the companion SEND Implementation Forum is a place for active discussion and to ask questions not already answered in the wiki.

What Is SEND?

SEND, or the Standard for Exchange of Nonclinical Data, is an implementation of the CDISC Standard Data Tabulation Model (SDTM) which specifies a way to present nonclinical data in a consistent format.

By having a common model to which the industry can conform, many benefits can be realized, such as inter-company exchange that is consistent in format regardless of the parties involved, the ability for vendors to develop tools, and many others.

A SEND package consists of a few parts, but the main focus is on individual endpoint data. Endpoints typically map to domains (essentially, datasets), with a number of variables (a.k.a., columns or fields).

Pages

News

Keep up to date with SEND developments!

SEND Implementation News

Fundamentals

New to SEND? These pages will introduce you to the model:

SEND Fundamentals - Basics on SEND, such as what it is, where to find the implementation guide, and how to use it

CT Fundamentals - Basics on Controlled Terminology, such as what it is and where to find it

Define.xml Fundamentals - Basics on the define.xml, such as what it is and key links and preparation information

Implementation

Ok, so you need to implement SEND. Here are some pages that will help:

Getting SEND-ready - A guide for new implementers, with such information as where to start, things to consider, etc.

FAQ - Frequently Asked Questions, with answers to many questions

Known Issues - A list of key known issues

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Implementation Forum Discussion

The SEND Implementation Forum is a place to ask questions and receive answers from SEND experts. SEND implementers also share knowledge on the standard that they feel will be helpful to the industry.

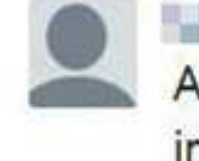
The forum is an ideal place to get answers to basic implementation questions.



5 months ago

Would anyone be able to advise on whether the SDRG is required for a SEND test submission with the FDA? It would be much appreciated!

1 ^ | v · Reply · Share ·



5 months ago

At a face to face meeting yesterday with FDA and members of the CDISC SEND team, an FDA representative stated that inclusion of an SDRG with SEND test submissions is helpful to them.

^ | v · Reply · Share ·



5 months ago

As a test submission, nothing would be required per se. You decide what you wish to submit for a technical check, and you will not get any feedback on something you didn't submit. With that said, the SDRG is described in the Technical Conformance Guide as an integral part of any standards submission, so I would probably include it, at least in an abbreviated form with the technical clarifications. Depending on how good your datasets are, the SDRG may be the difference between acceptance and a do-over.

^ | v · Reply · Share ·

The forum is also an ideal place to share information that you have learned.



7 months ago

Sharing some information from the CDER standards Questions Team via edata@fda.hhs.gov. I asked two related questions about ADA data, their answers are in caps after the two questions.

1. If anti-drug antibody (ADA) tests are performed as part of a single-dose, repeat dose or carcinogenicity study, must that data be included in the SEND dataset included in a submission, once the guidance takes affect? YES

2. If so, that data could reasonably be included in the LB domain. Is that correct? THAT IS CORRECT

^ | v · Reply · Share ·



7 months ago

To comply with this response, many companies will require a significant amount of additional work beyond what they though was going to be required.

^ | v · Reply · Share ·

The forum is an ideal place to discuss questions regarding the details of implementation with other SEND experts.



2 months ago

We have recently seen some datasets with EXCLFL=Y and STAT=NOT DONE (and no ORRES/STRESC/STRESN) on one row. Based on the description of EXCLFL, we don't believe that combination is valid - you should only exclude rows where there is a result to be excluded from calculations. However the companies who have supplied these data say our interpretation is incorrect - that the entry should be excluded because it was not done. I would like to get other opinions on this matter.

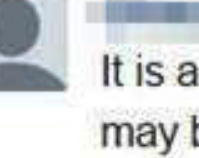
^ | v · Reply · Share ·



2 months ago

Thanks for the SDTM reference, I hadn't seen that. I wonder why that clause was dropped from the SENDIG? The full text in SDTM 1.4 includes "Not to be used with human clinical trials." which implies that the variable was specifically added for SEND.

^ | v · Reply · Share ·



2 months ago

It is a bit odd, however I wouldn't go so far as to say that the combination is invalid. It would be like a double negative (not giving a positive!). There may be systems that rely on the exclusion flag for visualization and analysis. It makes no difference for the SEND dataset if you are excluding a "NOT DONE" record, i.e. it doesn't give more information, but it doesn't brake the model, in my opinion. Making a validation rule to prevent this, would give just as little value as allowing the combination, as long as people don't think that exclusion flag gets a different meaning when used under these circumstances.

^ | v · Reply · Share ·

When difficult questions are asked, the team of SEND experts will collaborate to provide a response.



5 months ago

Hi SEND experts - Here's a question about test substance characterization. Have you ever come across studies, where you had to map test substance characteristics? If so, where did you put that?

What I'm looking at right now is inhalation tox studies and they are reporting not only means of constituent concentrations, humidity, temperature and what not, but also collecting this information on a daily or weekly basis through the study.

* EX can't handle this, and it will make for a nasty SUPPEX dataset.

* I was also thinking of just putting the mean concentrations for the entire study into TX (since it is reported per group), but it seems insufficient compared to how extensive the sponsor is documenting this for the study.

* Ideally, I would think that this belongs in a new domain, but what would this domain be? It's related to dose administration (intervention), but it resembles collected data (findings). Oh, and it is reported not per subject, but per inhalation chamber, i.e. dosing group (POOLS?)

I would greatly value any thoughts on this before I venture down one of these paths.

^ | v · Reply · Share ·



4 months ago

The team discussed this and:

- Because these data aren't usually tabulated

- These data usually show up in text of the report

- No consuming bodies are asking for this in a rigid format

Then our recommendation is there is no recommendation - any of the options you suggested would work, and all would have to be described to the organization receiving the data. So go for the one that is a combination of easiest to implement while still meeting the requirements of the organization asking for the information to be in a dataset. It could be a candidate for later standardization, but it will likely be low priority.

Conclusion

The SEND Implementation Wiki uses the power of crowdsourcing to create a comprehensive resource for SEND implementation that benefits both SEND beginners and experts.