

SEND Implementation User Group



Project Scope

New users implementing SEND start out with only the implementation guide as a resource. Having additional places to turn to for assistance (eg forums, Advance Hub, FAQ and PHUSE website) substantially helps new users navigate the pitfalls of SEND implementation, offering them the opportunity to ask questions, receive answers and to discuss and learn more about common implementation issues.

Project Leads	Email
Debra Oetzman, <i>Instem</i>	debra.oetzman@instem.com
Troy Smyrnios, <i>Zoetis</i>	troy.c.smyrnios@zoetis.com
Alex Pearce, <i>PHUSE Project Assistant</i>	Alexandra@phuse.global

Objectives & Deliverables

Provide and maintain [SEND Implementation Wiki](#)

Provide and maintain [SEND Implementation Forum](#)

Provide and maintain [SEND Implementation News](#)

Timelines

Ongoing

Ongoing

Ongoing

CURRENT STATUS Q1 2024

- The project is inactive and shifting to an on-demand type of mechanism until greater needs potentially arise with implementations of latest nonclinical Study Data Catalog requirements from the FDA.

Resources	Description
SEND Implementation Wiki	A collection of pages for new and current implementers
SEND Implementation Forum	A place for people to ask questions and get answers from experts in the community (and us). We provide review and ensure that every question is answered (although many are answered before our regular meeting) and considered beyond the forum.
SEND Implementation News	A simple updates feed of noteworthy events in the SEND space, e.g., release of guide versions, registry notices, etc.
SEND Implementation FAQ	This page covers a knowledge base of Frequently Asked Questions regarding SEND.

Volunteer Today

The team is formed, but we have room for those interested in continually improving the Advance Hub or fielding questions on the forum. We are looking for individuals with the following areas of expertise to contribute to this effort:

- SEND SMEs (experienced with SEND)
- Submission SMEs (experienced with submissions)
- New SEND Implementers (those with fresh questions run into during implementation)

What is the commitment?

- Time (minimum of 1 hour every four weeks for team meetings, plus action items - totalling 1-2 hours / month)
- Expected to contribute, not just be a spectator
- Contribution of viewpoints and content
- Advance Hub - creating/reviewing wiki content
- Forum - participating in discussion

If you would like to participate, please contact either Lead for this group as seen above.

Meeting Schedule

The team meets 1 hour every 4 weeks in the following structure;

- BAU:**
 - Address any open items on the **forum** page (and consider additions to the FAQ page)
 - Add any news to the **news** page
- CI:**
 - Update/refine/create various wiki pages per version releases, guidance changes, etc.
 - Special topics