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
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 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 Implementati on Wiki	A collection of pages for new and current implementers
SEND_ Implementati on 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 Implementati on News	A simple updates feed of noteworthy events in the SEND space, e.g., release of guide versions, registry notices, etc.
SEND Implementati on FAQ	This page covers a knowledge base of Frequently Asked Questions regarding SEND.

Objectives & Deliverables	Timelines
Provide and maintain <u>SEND</u> <u>Implementation Wiki</u>	Ongoing
Provide and maintain <u>SEND</u> <u>Implementation Forum</u>	Ongoing
Provide and maintain <u>SEND</u> <u>Implementation News</u>	Ongoing

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