

SEND Implementation FAQ - SEND Between Organisations

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This page discusses several considerations related to the production and handling of SEND across organizations, such as between Sponsor and CRO.

Types of Interorganizational Partnerships

While not an extensive list, the following are some typical cases seen where multiple organizations might collaborate to create a SEND package, along with when they might use the Points to Consider lists provided further below:

Sponsor and CRO - CRO creates full package

In this case, the production and packaging work is all done by the CRO; however, the sponsor may have inputs into the creation, especially in cases where there are multiple ways to accomplish the same thing. For this case, the Sponsor would potentially first engage the CRO using the Partnership-level Points to Consider (Initial Survey) below, followed by the Partnership-level Points to Consider (Detailed) list. Once down to the study level, for each study, the Study-level Points to Consider would be filled out.

Sponsor and CRO - CRO creates most datasets

In this case, most of the work is done by the CRO, but the sponsor creates some or part of the datasets (e.g., sponsor doing PK, pathology, or some of the lab work), with the CRO being responsible for compiling the package. For this case, the Sponsor would potentially first engage the CRO using the Partnership-level Points to Consider (Initial Survey) below, followed by the Partnership-level Points to Consider (Detailed) list. In addition, the CRO may have an additional stake in understanding the format of the datasets it will receive and thus in turn ask questions of what the Sponsor would provide as if the Sponsor were a subcontractor. Once down to the study level, for each study, the Study-level Points to Consider would be filled out.

Sponsor, CRO, and Subcontractor - CRO creates most datasets, subcontractor creates remaining datasets

In this case, most of the work is done by the CRO, but a subcontractor is utilized to create some of the dataset contents (e.g., subcontractor doing some lab work or PK), with the CRO being responsible for compiling the package. For this case, the Sponsor would potentially first engage the CRO using the Partnership-level Points to Consider (Initial Survey) below, followed by the Partnership-level Points to Consider (Detailed) list. The CRO may then also independently do the same with the subcontractor. Once down to the study level, for each study, the Study-level Points to Consider would be filled out.

Third Party Assembly - A third party creates datasets for any of above

In this case, a contracted organization provides dataset preparation and assembly as a service. This ends up acting just like the case above (as a subcontractor).

Points to Consider

Several considerations must be established before initiating a partnership for the assembly of SEND datasets, including determining capabilities, costs, specific needs, and so on. The following Points to Consider lists are intended to help smooth that process.

Note:

- Some questions are at the partnership level and some are at the study-to-study level. Anything that can be ironed out earlier should be, to avoid affecting the critical path of a study or submission timeline.
- The abilities of some parties may be less than ideal, especially early on as more companies begin to adopt SEND and stand up or enhance their SEND capabilities. Thus, it may be useful to establish not only current state but also future state.
- These lists are primarily written for the classic case of a Sponsor engaging a CRO. For other interactions, such as CRO with subcontractor, the same question list may be employed, but fewer items may be of interest.
- These lists talk to establishing a partnership. Individually, within organizations, first implementing SEND is its own (usually quite large) project. See the [Getting SEND-ready](#) page for more information on getting started on standing up SEND in your organization.

Partnership-level Points to Consider

The following are lists of questions and discussion items to vent with a potential partner for the production of SEND or other datasets at the partnership-level. These questions are especially valuable to establish early on to avoid affecting study timelines, as well as periodically re-assess as needs and capabilities change.

Note that some questions may be more definitively addressed at the study level, such as cost, but may have a general understanding to be reached at the partnership level. See the Study-level Points to Consider section below for those questions.

There are two lists provided below:

- **Initial Survey** - a high-level list to assess very basic information about capabilities
- **Detailed** - an in-depth list of discussion points regarding overall and specific capabilities

Partnership-level Points to Consider (Initial Survey)

The following is a very basic, high-level list of questions for the partnership level, at first contact, to assess very basic information about capabilities. As a partnership evolves past this

first cut, the "Partnership-level Points to Consider (Detailed)" list further below has more detailed considerations to iron out.

- Do you have SEND capabilities? (what endpoints are and are not covered? what study types are covered?)
- Do you have example datasets for review?
- What portion of your capabilities are automated and/or validated?
- Do you outsource any of these capabilities?
- Roughly how many studies have you created SEND datasets in the last year?
- Do you have alternate means of providing data other than XPT files (e.g., Excel, CSV)?

Partnership-level Points to Consider (Detailed)

The following is an in-depth list of questions and discussion points at the partnership level. Most commonly, this pertains to a Sponsor with a CRO (or third party assembler) which will be providing SEND datasets, although it could also apply to a CRO and a subcontractor.

Process Questions

- Can you provide a sample study data package (including sample define file), to review capabilities?
- Will production of SEND datasets be included in master service agreement for all applicable study types or contracted study by study?
- Is there an impact to the delivery timelines for completed studies, if SEND datasets are requested as part of the process to finalize a study?
- Can you provide interim/draft SEND datasets?
- If any data will be commonly collected by organizations other than the CRO (e.g., if the Sponsor will always do some of the lab work), who will merge the datasets (e.g., LB, CO, RELREC, etc)? (Note that this may also be defined on a study-by-study basis)
- When integrating sponsor and/or subcontractor generated data in SEND format...
 - Who is responsible for each record in SEND for domains which have sponsor and/or subcontractor data?
 - How will the define file be created/merged?
 - How will the Reviewer's Guide be created?

Cost Questions

- What are standard costs for producing SEND datasets for current studies?
- What parts of the assembly incur additional cost?
- What is the cost for multiple sets of datasets produced for one study (interim/draft and final, for example)?
- What are the costs associated with production of SEND datasets for legacy studies, if this capability is available? (*e.g., for special requests for transcription from study report, sponsor warehousing, etc.*)

- What are the costs associated with production of specific versions of SEND or CT, if this capability is available? (*this is less common, e.g., for special requests where the receiving organization can only handle specific versions*)

Compliance Questions

- What is the validation status for 21 CFR Part 11 compliance of the system(s) producing SEND datasets?
- Do you have processes in place to ensure the quality and regulatory adherence?
- Do you use a tool to validate SEND datasets before delivering to sponsors? If yes, what tool/ruleset is used?

Fundamental Content Questions

- Which SEND version(s) are supported?
- Which CT version(s) are supported?
- Which define.xml version(s) are supported?
- How does your organization handle Permissible variables?
- How will null Expected variables be handled (if applicable)?
- What output formats do you support, including XPT (e.g., *.xpt, *.xml, *.xls, *.csv, etc.)?

Specific Content Questions

- What naming convention is used for USUBJID (e.g., Study+underscore+subject, a numeric ID, etc.)?
- What naming convention is used for STUDYID (e.g., study number, a numeric ID, etc.)?
- Are there situations where EX is not populated with 1 record per dose?
- What conventions are used for creating/naming trial design components (e.g., ARM, ELEMENT, etc.)?
- Which variables are provided in SUPPQUAL datasets? (e.g., RESMOD in MI, CALCN in LB/PC, custom variables, etc.)
- Which parameters are included in the Trial Summary and Trial Sets domains?

Define file

- Is the define file study-specific or generic across studies?
- Is the controlled terminology only those terms used during data collection or entire list?
- Are extended controlled terminology terms indicated in the define file?

Transfer Logistics

- What methods/tools do you use for transferring files? (e.g., SFTP or other secure file exchange)
- Are there any stipulations on either side for maximum file size?
- When are the datasets need to be available versus when can they be available? What should trigger their creation (e.g., X days after data archival; send with draft report; etc.)?

Study-level Points to Consider

At the study-level, some additional considerations may be necessary to define or refine for the study, points which might differ from the general decisions made at the partnership level.

Process Questions

- What version of SENDIG will be used for this study?
- What data exchange intervals are desired for the study (At end? Interim? Draft?)?
- If any data are collected by multiple parties (e.g., if the Sponsor does some of the LB work), who will merge the datasets (other examples include LB, CO, RELREC, etc.)?
- What process will be used for integrating sponsor and/or subcontractor generated data in SEND format?
- How will the define file be created (esp. if multiple parties are involved)?
- What are the costs for the study?

Compliance Questions

- Will QA be involved for the study?

Fundamental Content Questions

- Will any domains be specifically included or excluded for the study?
- Will any variables beyond the CRO's sample SEND package be desired?
- Will any domains not be transmitted in SEND format?
- File format for exchange (samples maybe very helpful in *.xml, *.xls, *.csv, etc.)

This content was originally prepared by the now adjourned [Interorganizational SEND](#) team.