2017 SEND Survey Results

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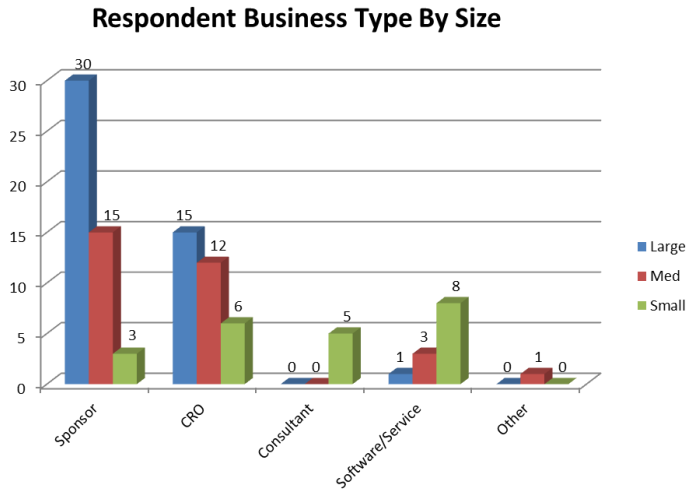
Demographics (n=99)



81 Sponsors or CRO
- 45 Large
- 27 Medium
- 9 Small

Responder Roles

60 % - Nonclinical scientist, regulatory scientist or operations, data managers, biostatistician

28 % - IT

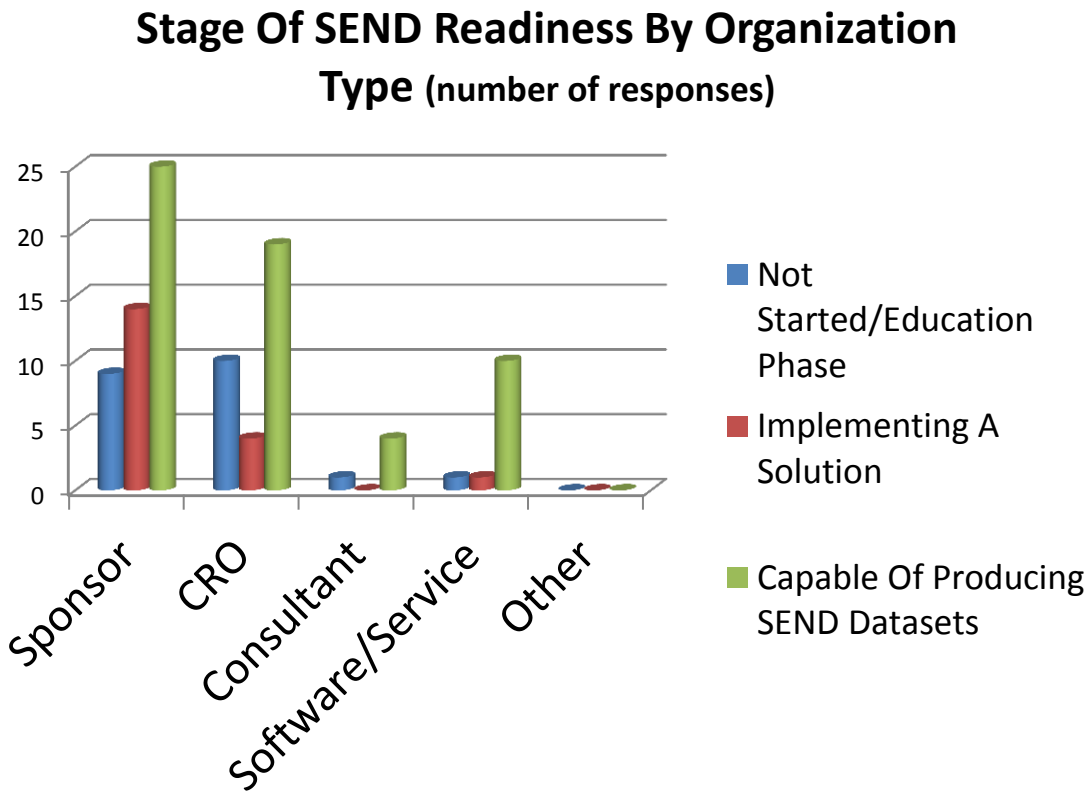
12 % - QA or Consultant

Type of Solutions

87.5 % use commercial software locally or cloud

47.5 % conduct studies at CRO's who produce the SEND dataset

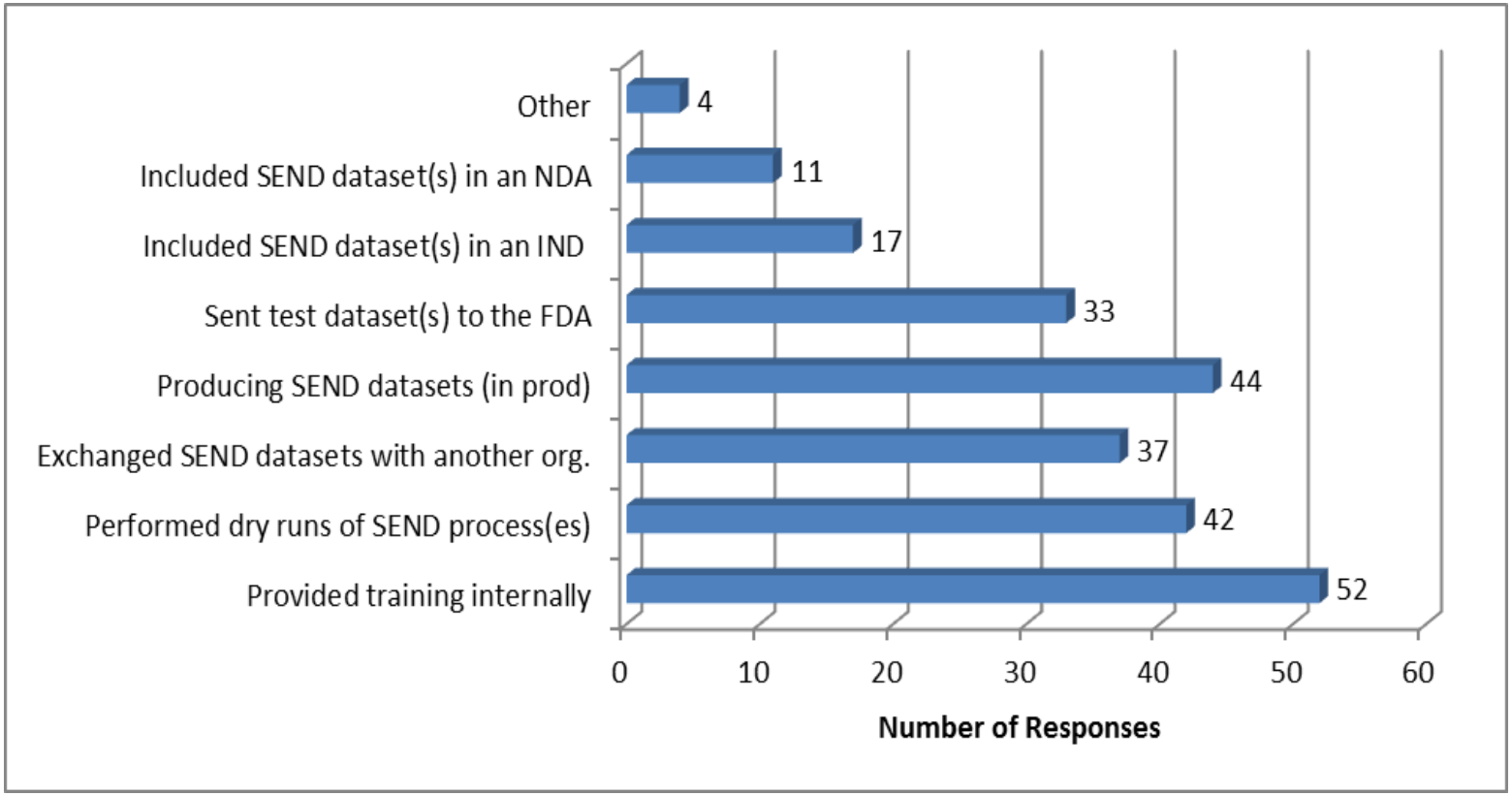
What stage of SEND readiness are you in?



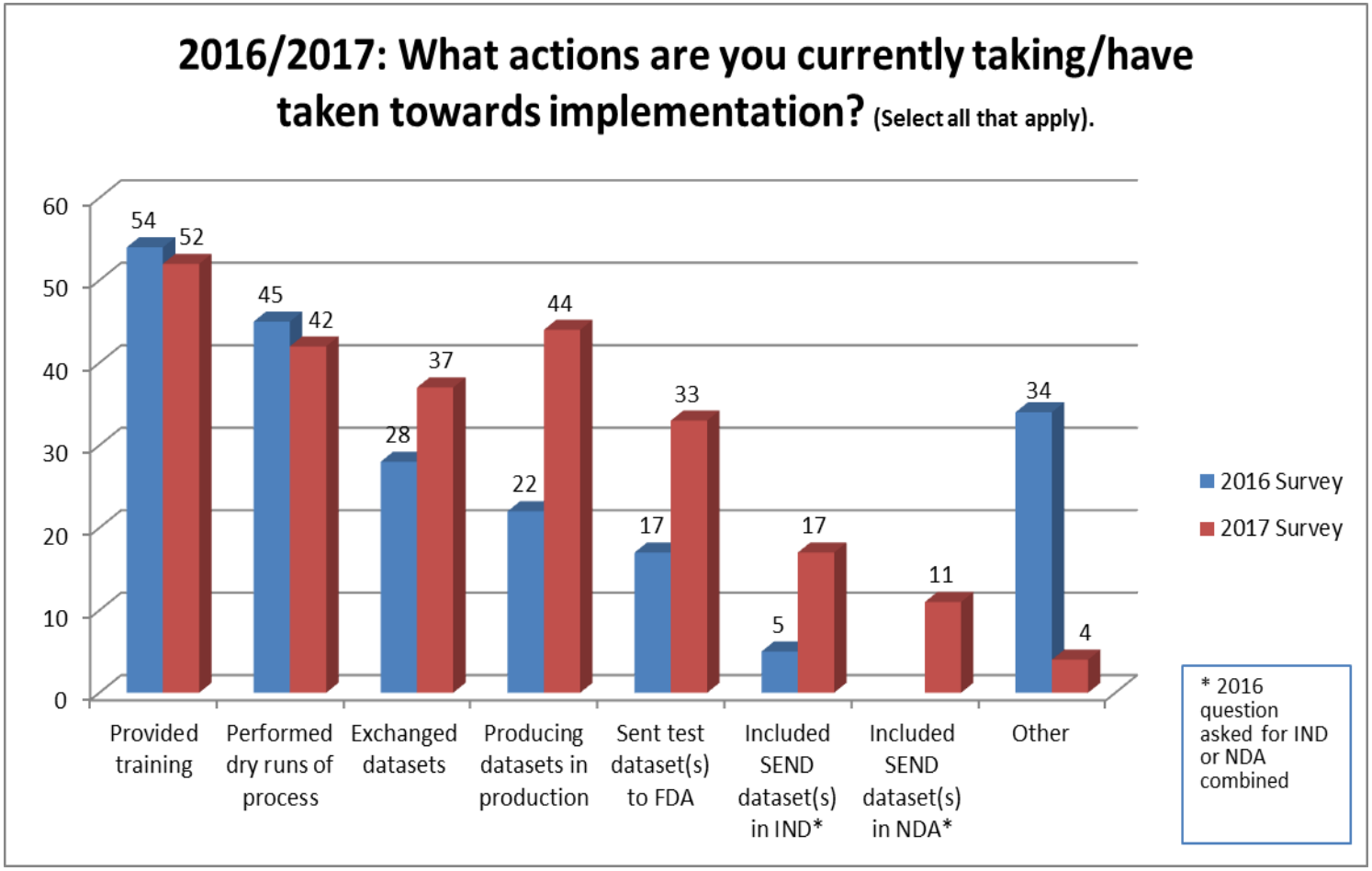
59% of respondents are capable of producing SEND datasets

20% of respondents have not started

What actions are you currently taking/have taken towards implementation? (Select all that apply).



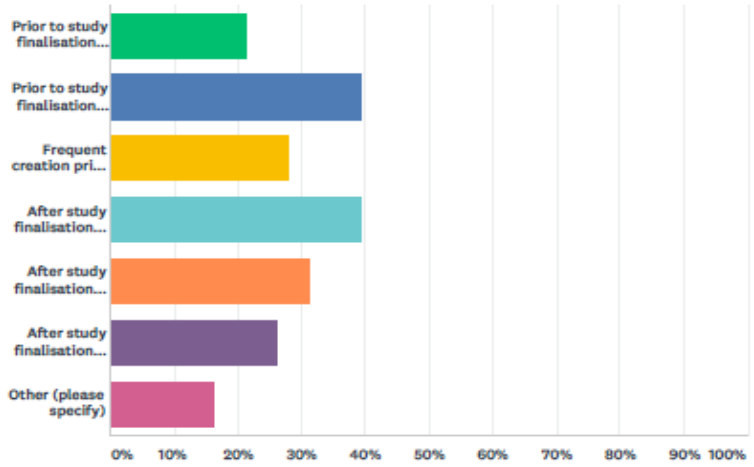
Comparison Of 2016/2017 Results



Timing For SEND Generation

Q8 At what point related to study finalisation (report signed by the Study Director) does your company plan to generate SEND datasets? (Select all that apply).

Answered: 61 Skipped: 38

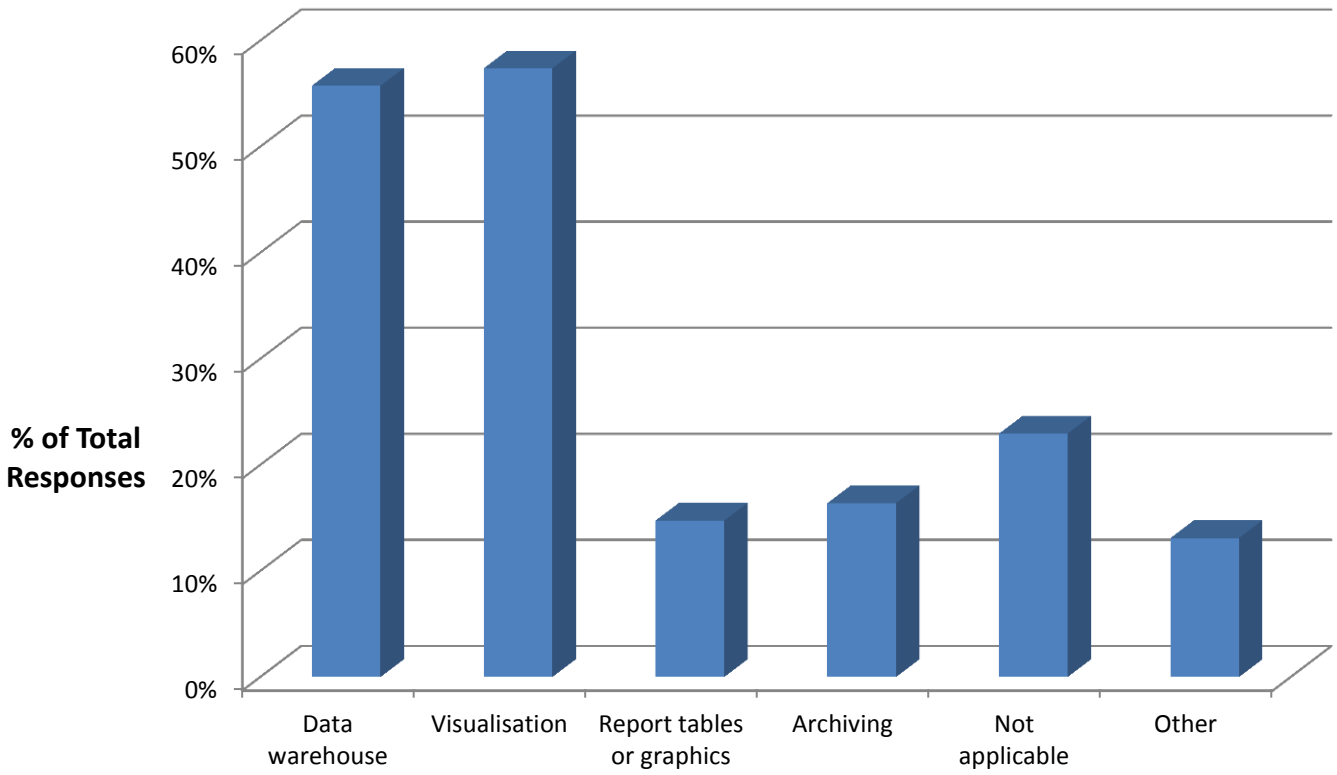


ANSWER CHOICES	RESPONSES	
Prior to study finalisation, for all studies	21.31%	13
Prior to study finalisation, upon sponsor/internal request (eg, for data visualisation/warehouse purposes)	39.34%	24
Frequent creation prior to study finalisation for study monitoring or interim submission	27.87%	17
After study finalisation, upon sponsor/internal request	39.34%	24
After study finalisation, for all studies	31.15%	19
After study finalisation, only if needed for a submission	26.23%	16
Other (please specify)	16.39%	10
Total Respondents: 61		

- 26% will generate SEND only if needed for submission after study is concluded.
- 103 responses, so some with multiple selections.

Will SEND datasets be used for purposes other than submission to the FDA or return of the data to the sponsor?

(Select all that apply).



- Not determined
- For Biocelerate exchange
- Comparison to internal dataset
- Consistency checking

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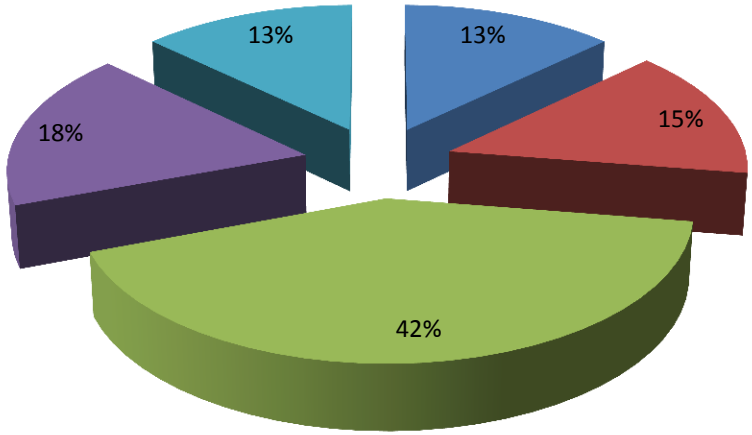
How do you ensure that your datasets completely and accurately represent the study data so that such a statement to the FDA can be supported?

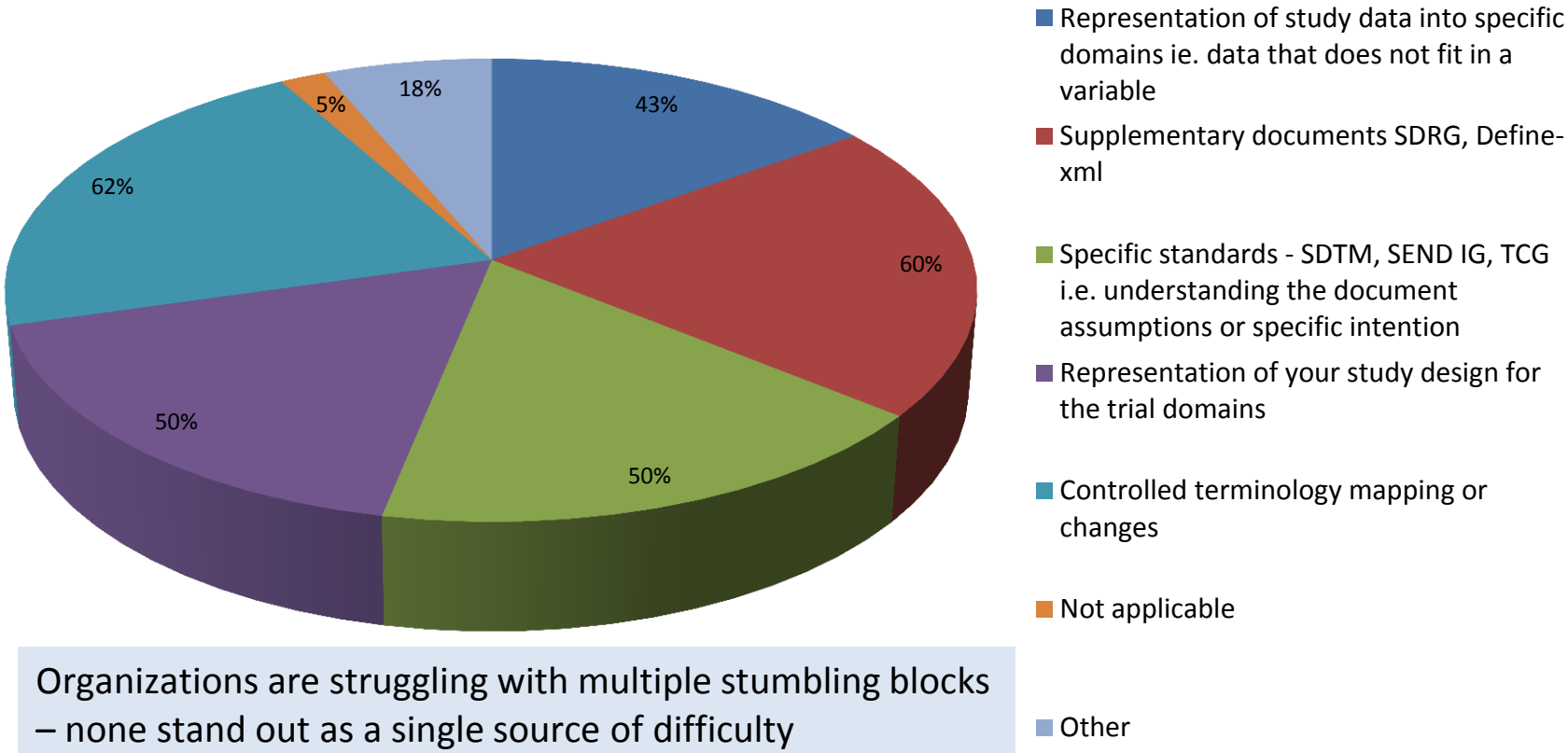


- 100% datapoint QC of all datasets in a submission
- Less than 100% datapoint QC of all datasets (i.e. military standard)
- System testing/validation and then random data checks for all datasets
- Still undecided
- Other (please describe)

- Full QC for the first studies then random checks
- QC performed by the CRO
- Automated 100% comparison of data against Study Report; and use of machine learning algorithms
- Visualization tables based on SEND datasets are compared to the study report

Validation/Qualification is the most common choice for system testing – 42 %

What did you find were stumbling blocks or barriers during your implementation efforts for SEND? **(select all that apply)**



Organizations are struggling with multiple stumbling blocks – none stand out as a single source of difficulty

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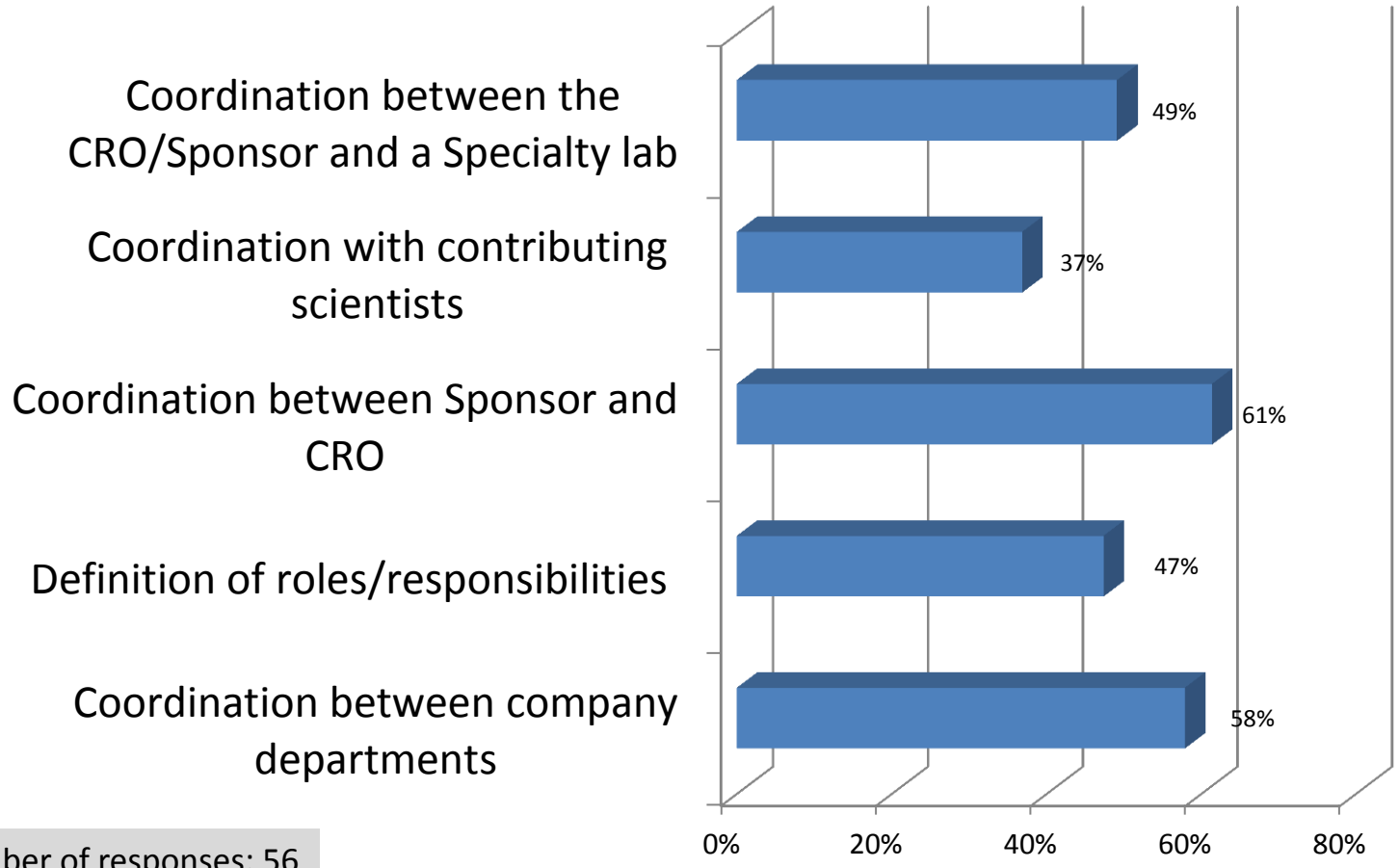
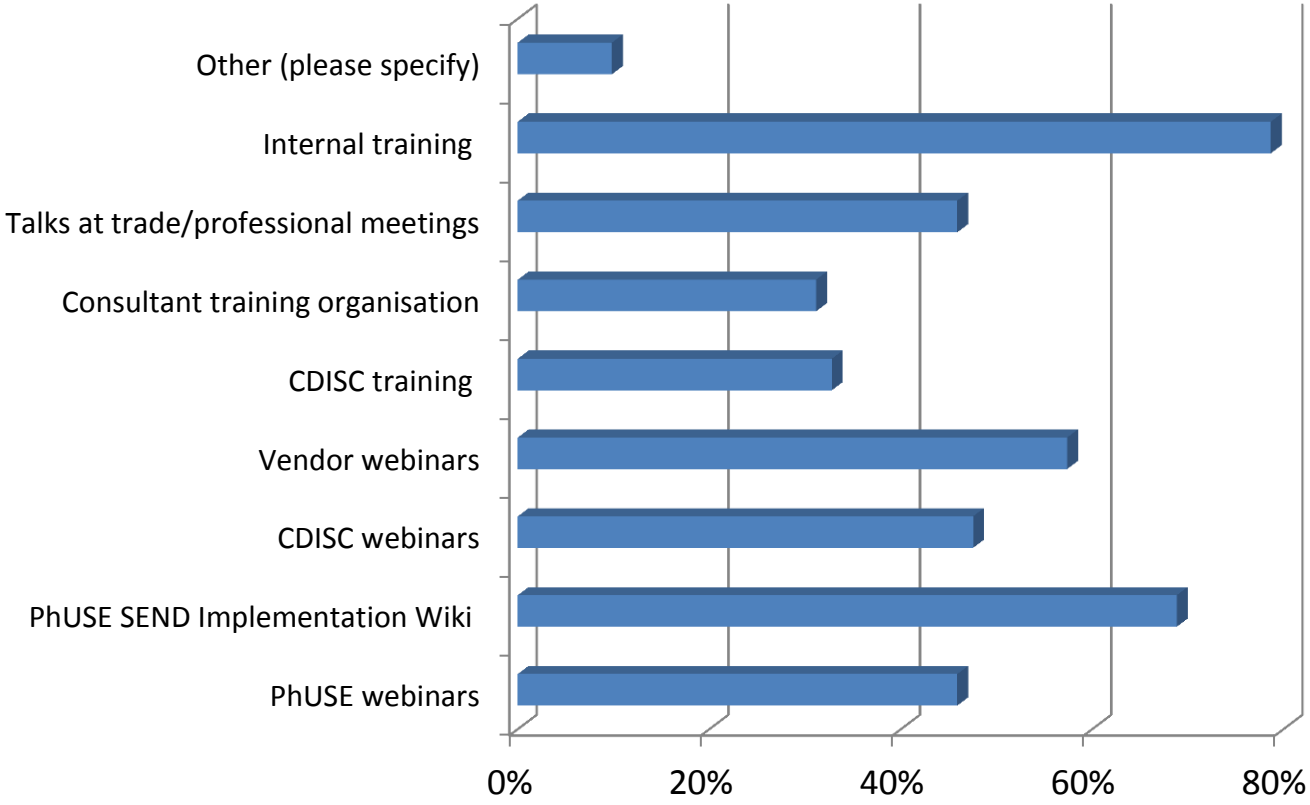
What were the process problem areas that you encountered during the implementation of SEND? (Select all that apply).



Number of responses: 56

What type of training did you conduct or take advantage of? (Select all that apply).

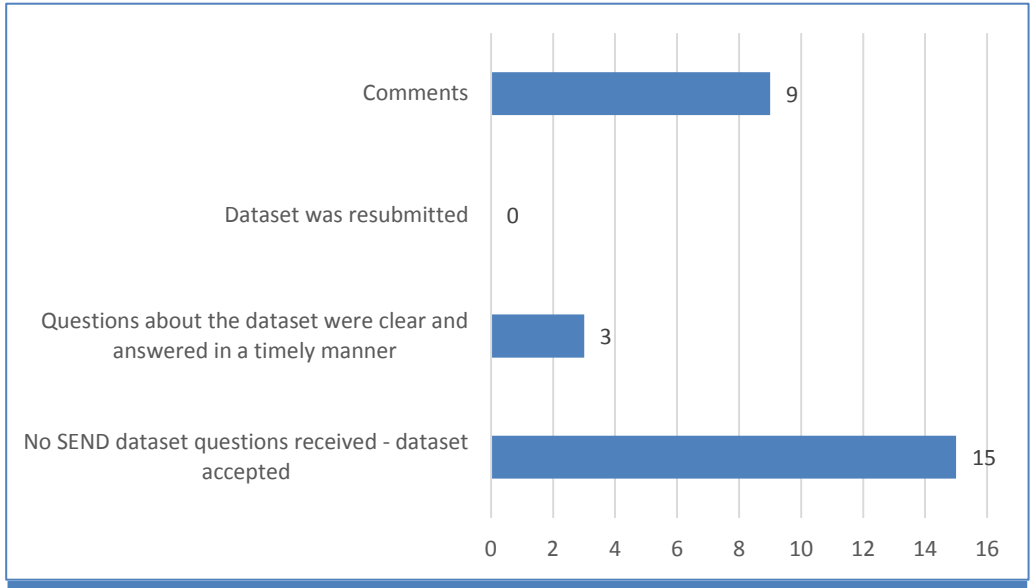


- Most popular training is internal
- PhUSE Wiki is a valuable resource
- Webinars are also widely used

What upcoming expansions to SEND are your priority? (In order of priority with 1 being the highest, 6 being the lowest)

Rank:	1	2	3	4	5	6	Total Responses	Priority Score
SEND 3.1	58.49%	35.85%	0.00%	3.77%	0.00%	1.89%	53	5.43
Define XML 2.0	32.73%	30.91%	9.09%	9.09%	7.27%	10.91%	55	4.40
Safety Pharm	5.66%	32.08%	33.96%	18.87%	7.55%	1.89%	49	4.04
DART 1.1	2.04%	4.08%	34.69%	34.69%	16.33%	8.16%	53	3.16
Gene Tox	2.04%	0.00%	12.24%	16.33%	42.86%	26.53%	49	2.22
Dermal Ocular	0.00%	0.00%	9.80%	13.73%	27.45%	49.02%	51	1.84

If you have submitted a SEND dataset as part of an IND or NDA, what experience have you had? (Select all that apply).



Comments
Dataset submitted but no information
Feedback pending on several submimssions
Have only provided ts.xpts for legacy studies.
No application experience
No communication received on acceptability or fit-for-use acceptability.
Submitted datasets for voluntary sumbission and have not received any feedback yet
Too early for any feedback
We did test submissions to FDA
We do not know if any of our SEND datasets have been part of a submission

Conclusion:

- Relatively few respondents have submitted datasets (18 affirmations of 99 participants).
- Of these, 3 have received questions.
- Low levels of submission may contribute to limited opportunity for the FDA to review the datasets and assess acceptability.

The Stumbling Block Question Resulted In A Wide Variety Of Comments

Stumbling blocks: Submission mechanics

File format as proprietary SAS transport binary file format.

Unclarity on where to place legacy TS domain file during submissions

Timing of the SEND sets relative to final report.

Where to put the TUMOR dataset of carcinogenicity studies in the eCTD as it is not a standard SEND dataset?

Stumbling blocks: FDA Feedback

Lack of FDA feedback and expectations and guidance.

Without regular feedback from the FDA, it is challenging to know if, i.e., the trial design and/or define file represents the study as expected.

Stumbling blocks: SEND vs Study data (1/2)

Found it very challenging to extract sufficient protocol information with the source data.

The best approach for legacy data conversion, etc.

Representing collected data that does not fit in SEND variables & data expected in SEND but not collected

Sponsors mapping 4 to 5 grades and then reports not matching SEND data, incorrect legacy data output when compared to report

PhUSE wiki page for SEND is very helpful … regarding PC and PP datasets in the SEND IG. … need any additional info on these datasets.

Stumbling blocks: SEND vs Study data (2/2)

Commercial IT hard coded to SENDIG variable structure.

SENDIG timing variables are scarce, in conflict with GLP leading to unfortunate implementations where variables must work together in unintended ways.

… conflict between the core intention to just tabulate data and the inherent need to have analysis grade data - leading to basic conflicts in degree of processing from original data capture system designed for creating pdf tables versus the SEND data - while maintaining traceability...

Stumbling blocks: Guidelines and standards

With issuance of the various documents, there are sometimes conflicts in requirements/recommendations

Differentiation of IG interpretations by many sponsors

Learning how to decipher through validation report, data, standards and guidelines.

Follow the CT changes every 3 months

There are so many "rules" in addition to SENDIG, including FDA validator rule, TCG, Business Rule, etc. … hard to … follow all of them, especially for … non-English speaking country.

Gray areas on rigor of implementation of standards.

Learning curve for people new to SEND. Poor examples in SENDIG. Constant changing nature of SEND.

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Stumbling blocks: Software and systems

Even with a software system made by the same company that makes our data collection and reporting systems, there are big gaps that require much manual effort

Limitations of data capture systems to align with SEND format.

Software vendor issues with their assumptions made for the SEND system. We did not find barriers but definitely encountered a few stumbling blocks.

Assessing different SEND conversion service providers and software providers.

Stumbling blocks: Management complexities

The biggest stumbling block was the inability of upper management to comprehend the intricacy of SEND

There are 3 elements that have been challenging:

- 1) Get our internal studies SEND compliant (technical component)
- 2) Get SEND data from CRO
- 3) Process from start to submission involves many parties

Limited pre-clinical budgets,SEND requirements are not sufficiently clear yet to set aside budgets

Thank You!

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