

# Identifying Hurdles for Submission of Electronic Non- Clinical Data (SEND) slides

Janice Fiori, Eli Lilly

Bob Friedman, Xybion Medical Systems

Lou Ann Kramer, CDISC

Lauren White, PhUSE

Survey

Respondents

Results:

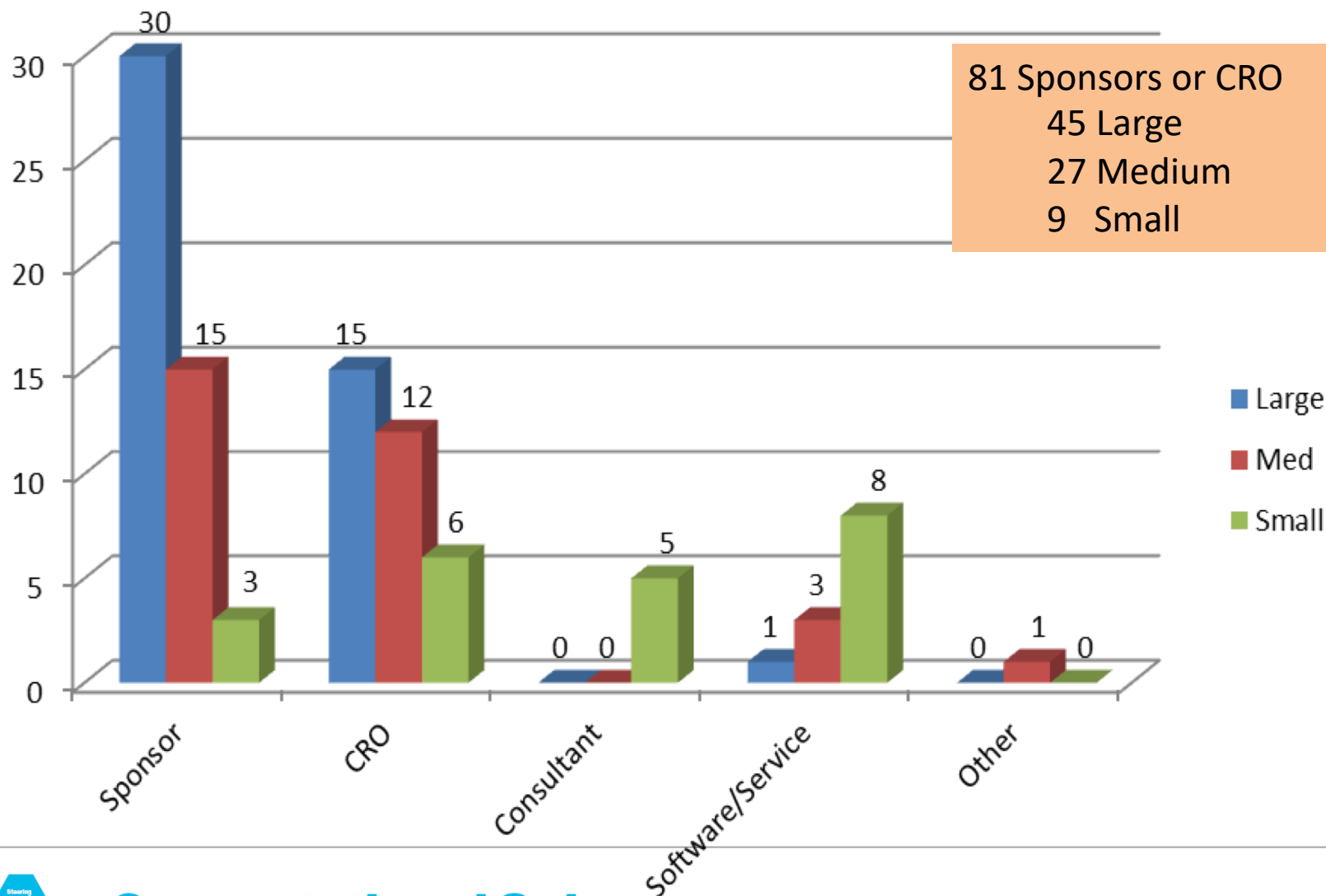
- SEND Readiness
- SEND Planning
- Submission mechanics
- Hurdles/stumbling blocks

Next steps

# Survey

- **The PhUSE Non-clinical working group**
- **Annual SEND readiness survey (5<sup>th</sup> year)**
  - To understand
  - To inform
  - Stakeholder comparisons
  - Offer possible solutions

# Respondent Business Type By Size



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# Demographics of Respondents

(n=99)

## Responder Roles

60 % - Scientists

28 % - IT

12 % - QA or Consultant

## Type of Solutions

87.5 % In-house

47.5 % Obtain from CROs



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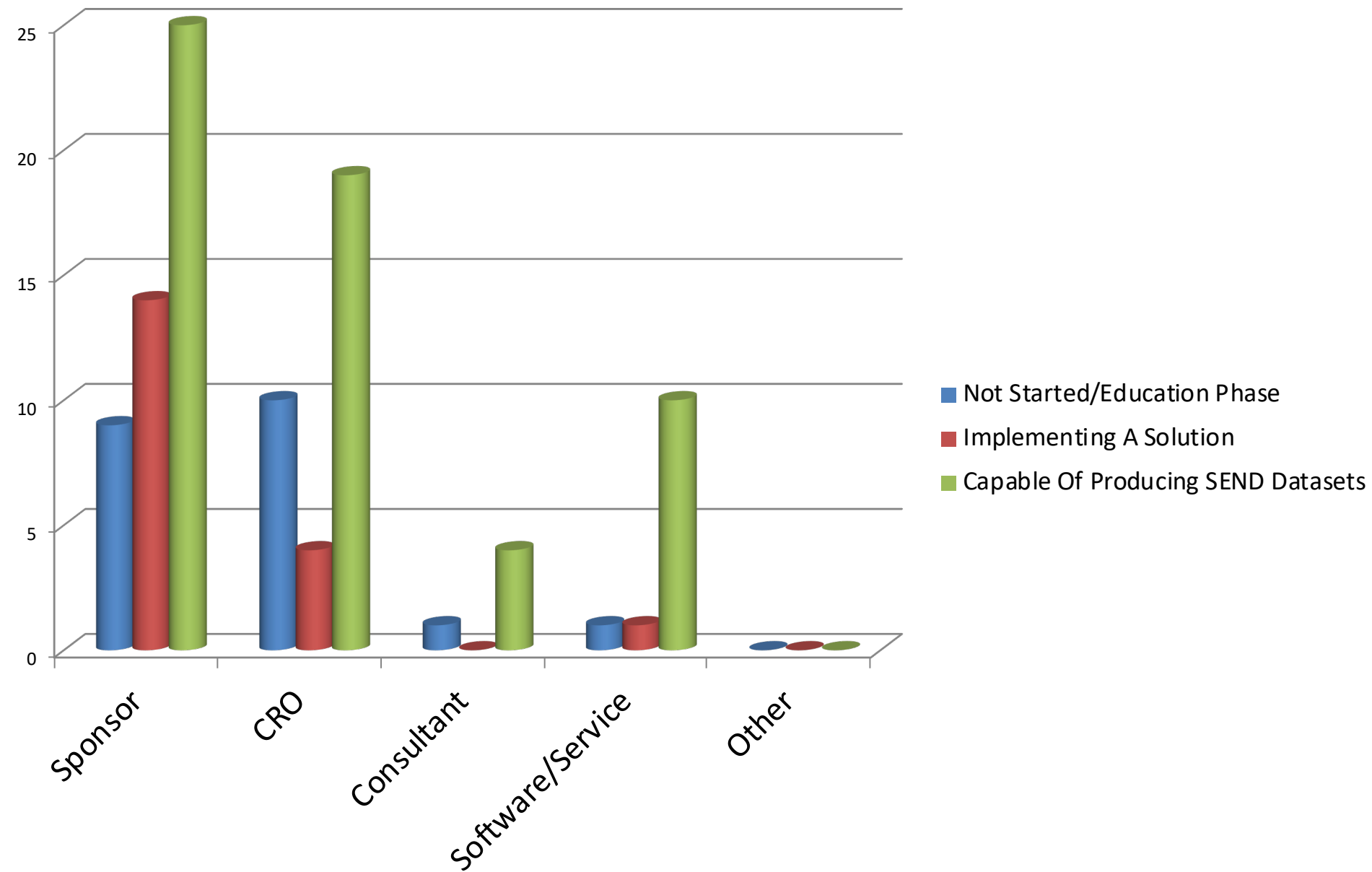
# Readiness and Planning



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**Stage Of SEND Readiness By Organization Type (number of responses)**



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# What stage of SEND readiness are you in?

59% of respondents are capable of producing SEND datasets

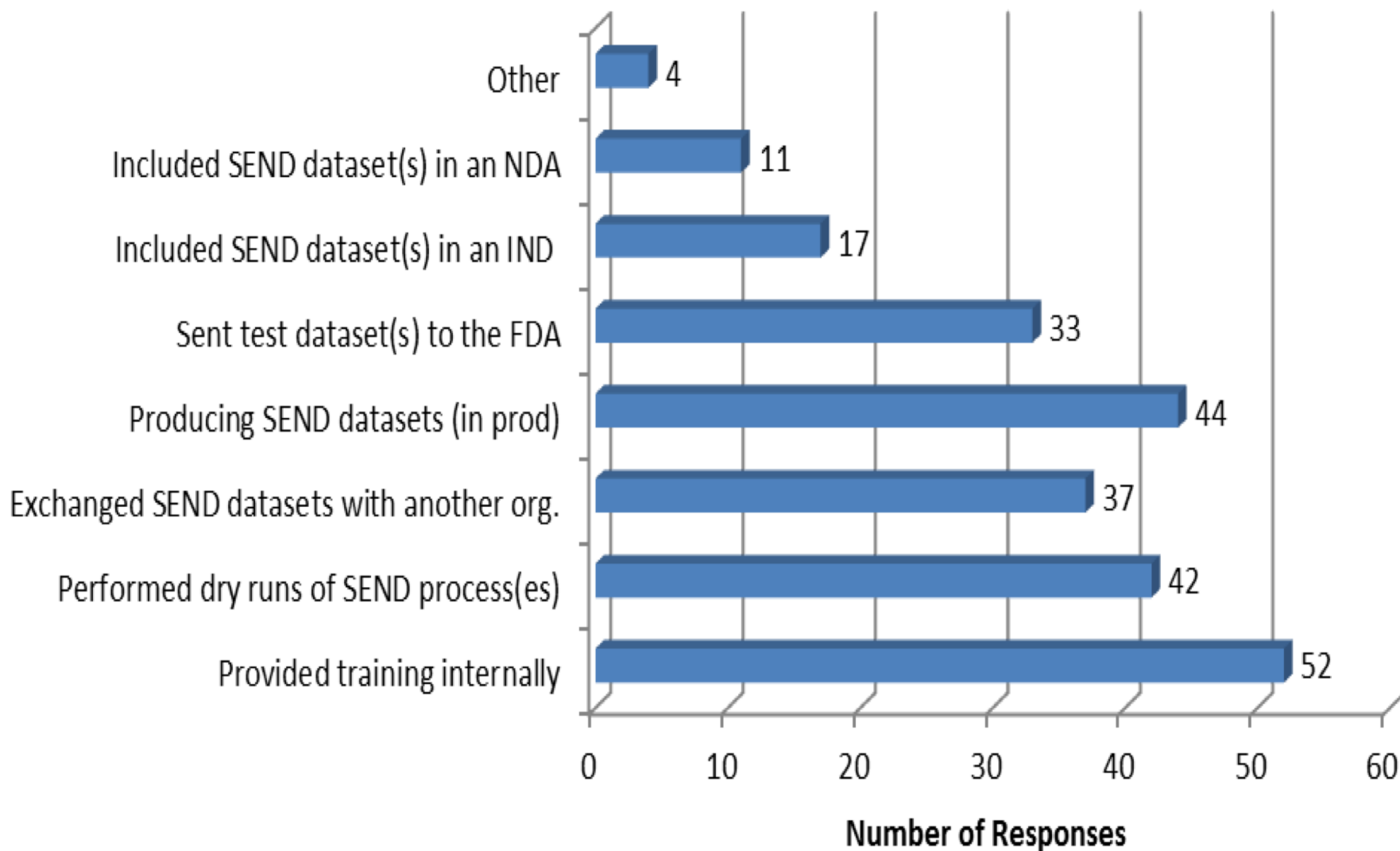
20% of respondents have not started



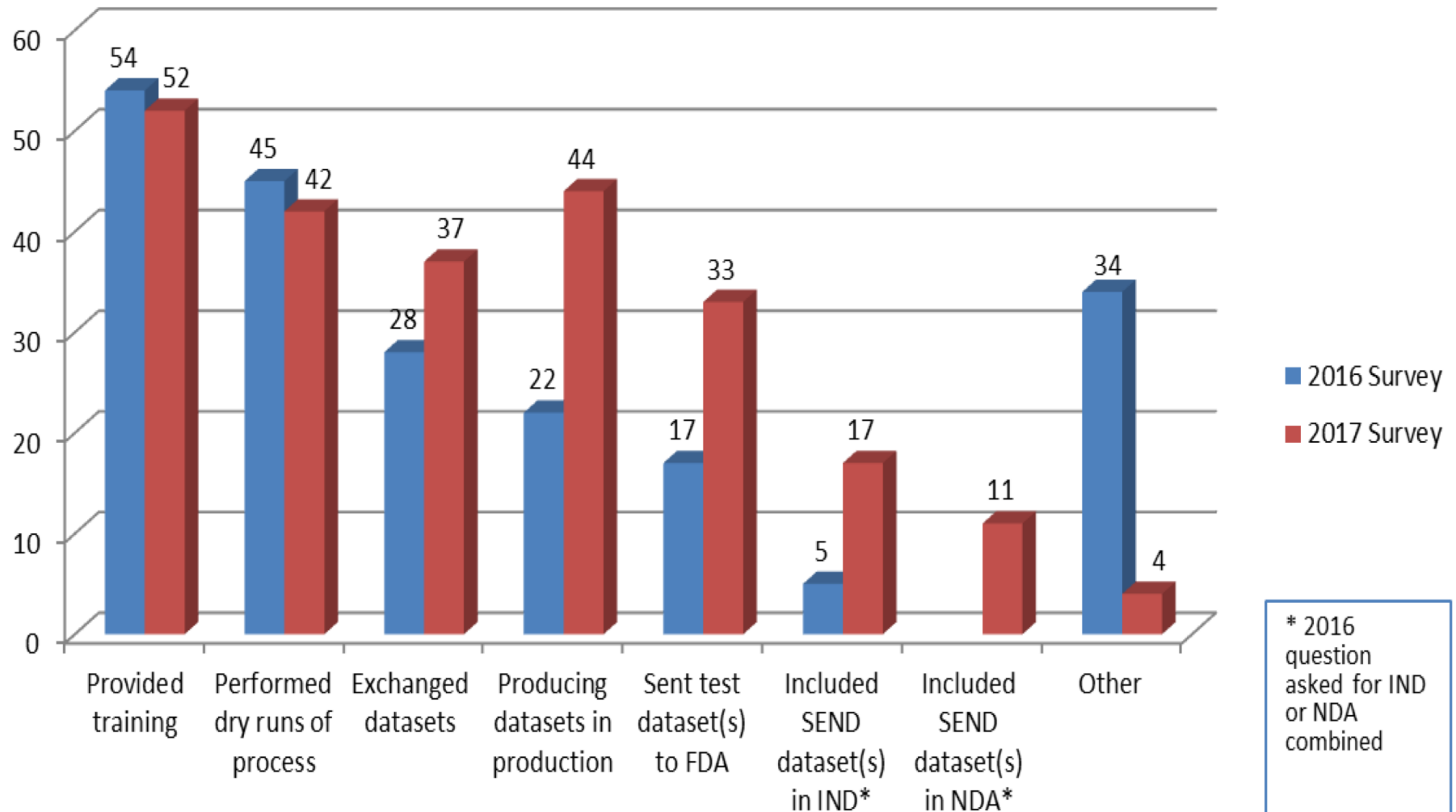
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# Implementation Actions



## 2016/2017: What actions are you currently taking/have taken towards implementation? (Select all that apply).



# Type of Training



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



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# Mechanics for Preparation

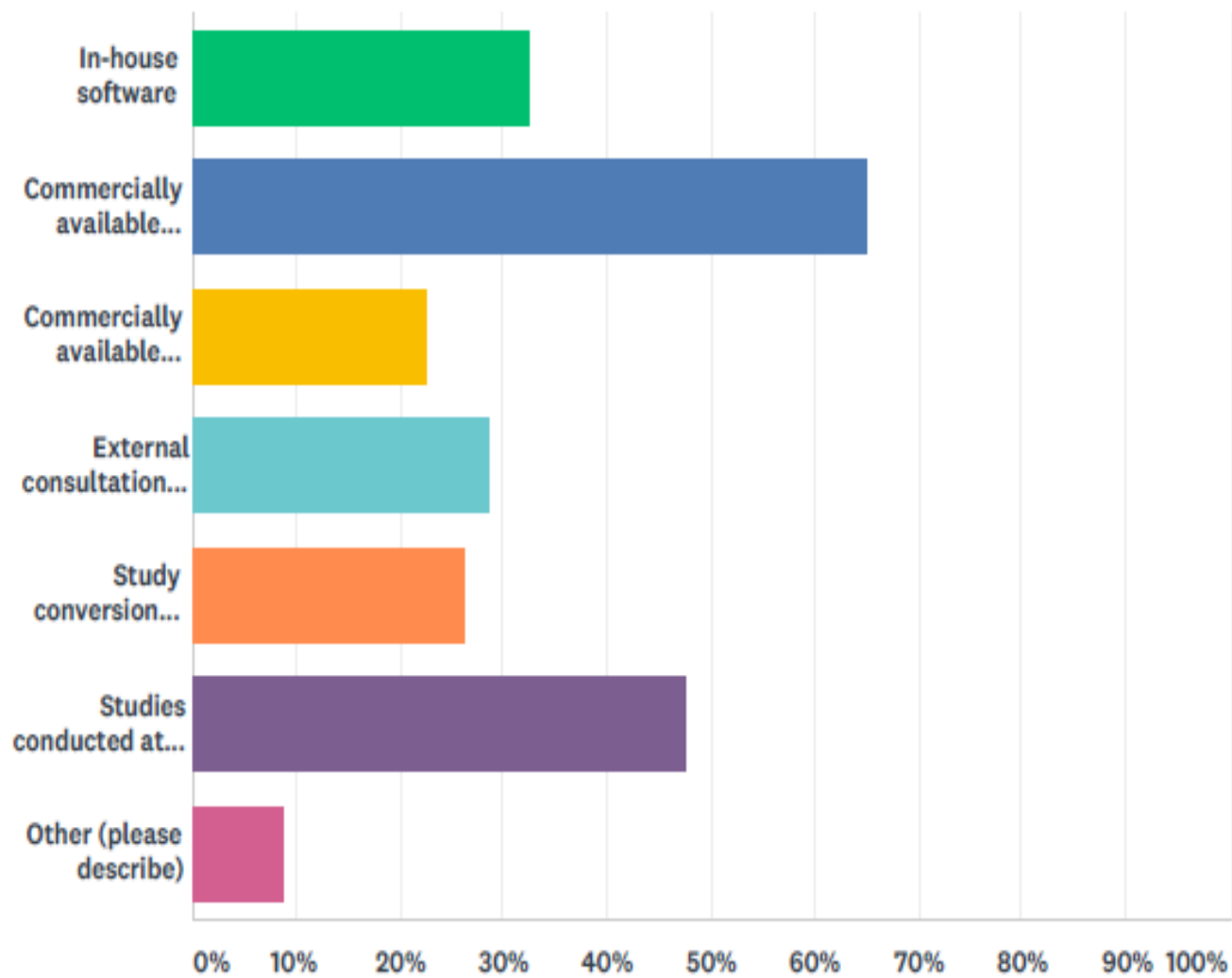


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Q6 Please tell us about the SEND solution(s) you have implemented or are considering (Select all that apply).

Answered: 80    Skipped: 19



| ANSWER CHOICES                                                  | RESPONSES |    |
|-----------------------------------------------------------------|-----------|----|
| In-house software                                               | 32.50%    | 26 |
| Commercially available software                                 | 65.00%    | 52 |
| Commercially available software in a hosted (cloud) environment | 22.50%    | 18 |
| External consultation services                                  | 28.75%    | 23 |
| Study conversion services                                       | 26.25%    | 21 |
| Studies conducted at CROs who will provide SEND datasets        | 47.50%    | 38 |
| Other (please describe)                                         | 8.75%     | 7  |



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# Other responses

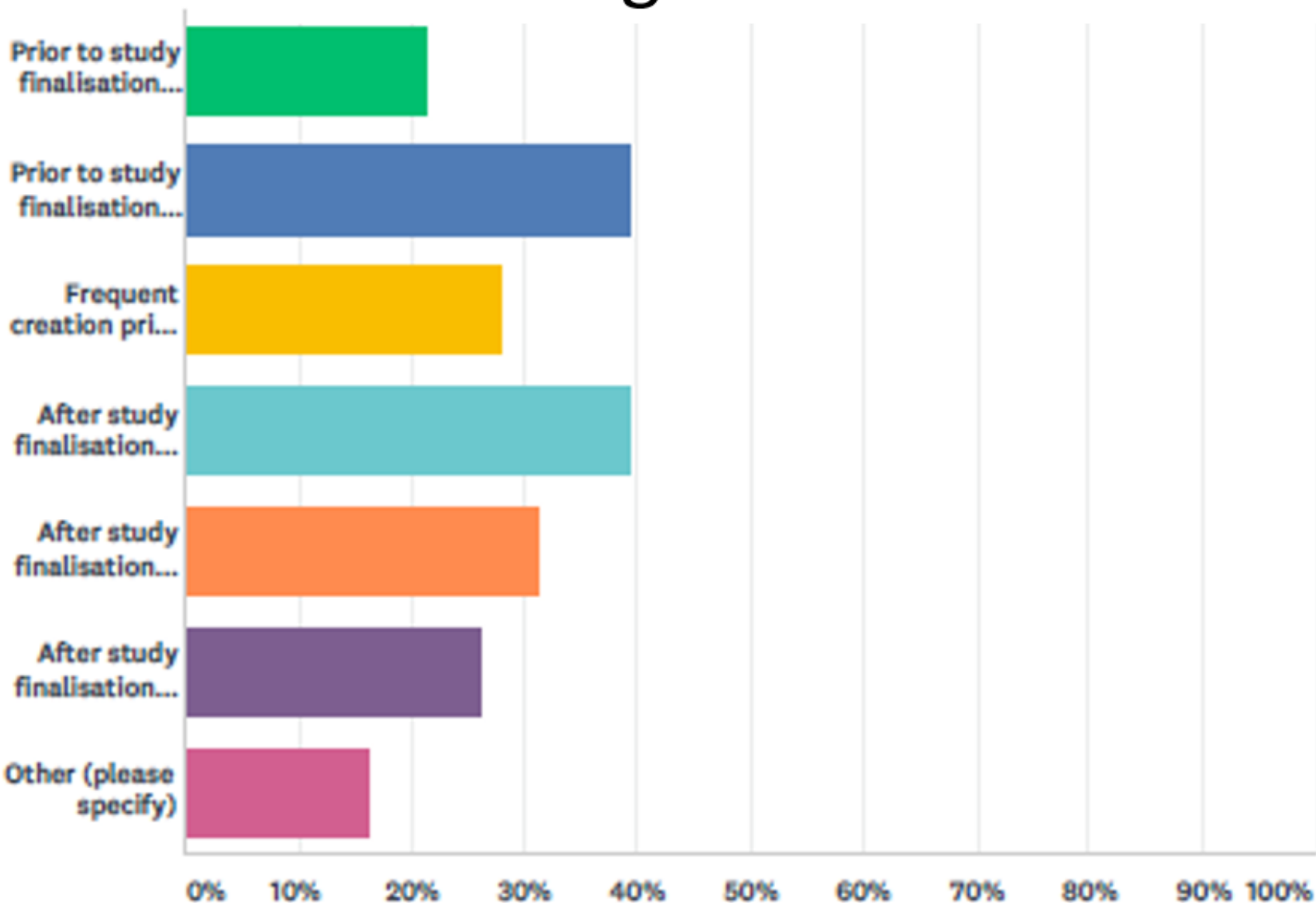
- Central team
- Custom tools
- Import of data in SEND to shared database
- Still solutioning
- Data warehouse with visualization
- Conversion services



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# Timing For SEND Generation



# Timing For SEND Generation

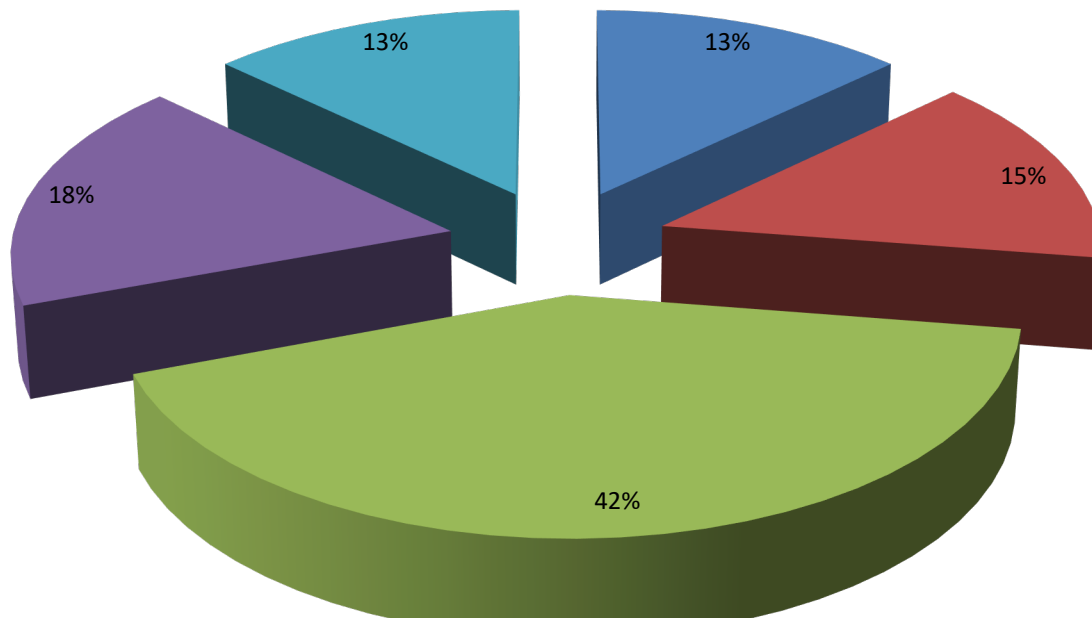
- 26% will generate SEND only if needed for submission after study is concluded.
- 103 responses, so some with multiple selections.



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# Dataset QC



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

- 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)



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# Dataset QC - Comments

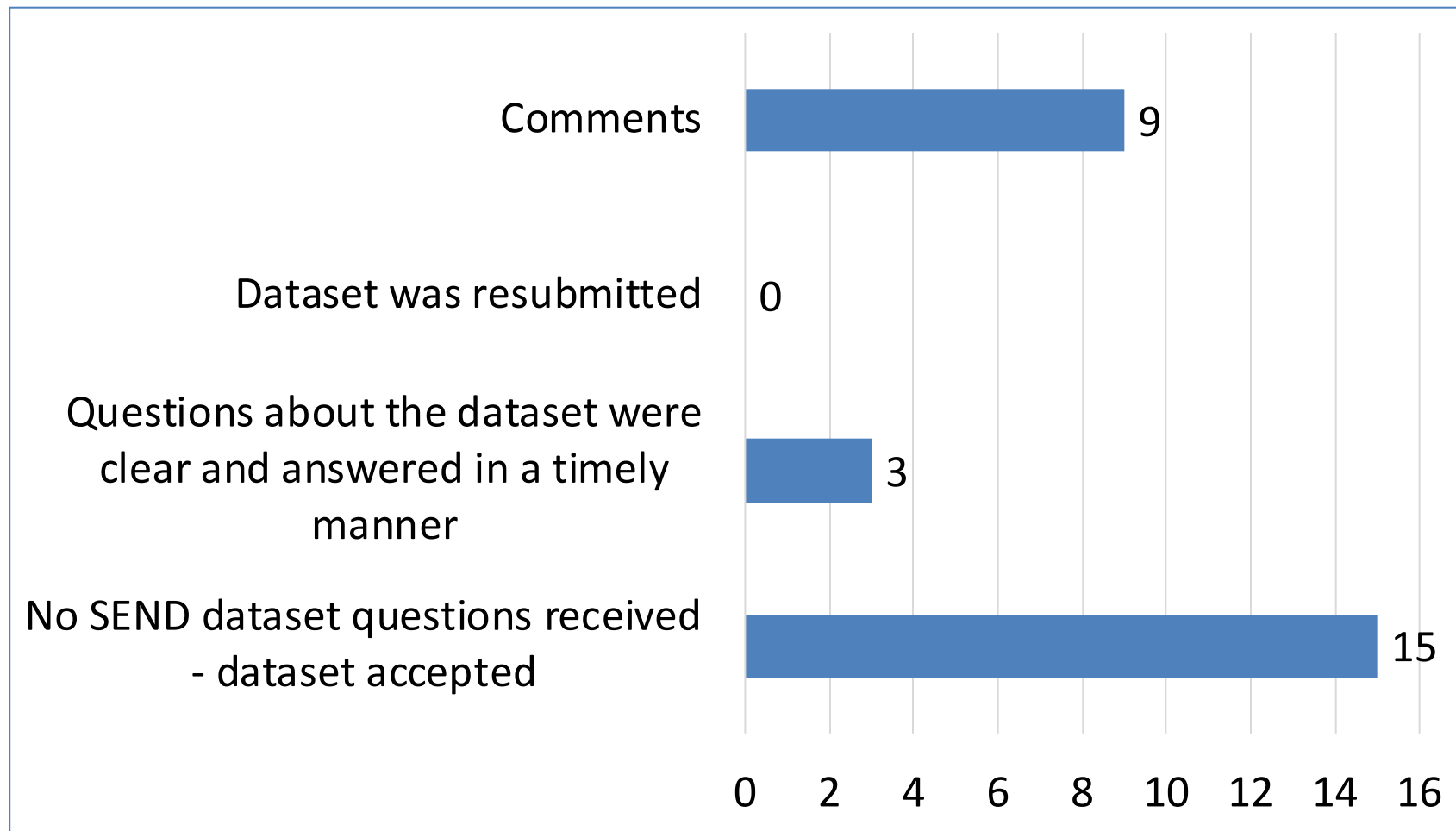
- Full QC for initial studies
- QC performed by the CRO
- Automated 100% comparison of data
- Compare SEND visualization against study reports



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# Dataset Submission



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# Dataset Submission

## Comments:

No feedback received

Feedback pending

Have only provided ts.xpts for legacy studies

No application experience

We did test submissions to FDA



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# Dataset Submission

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.



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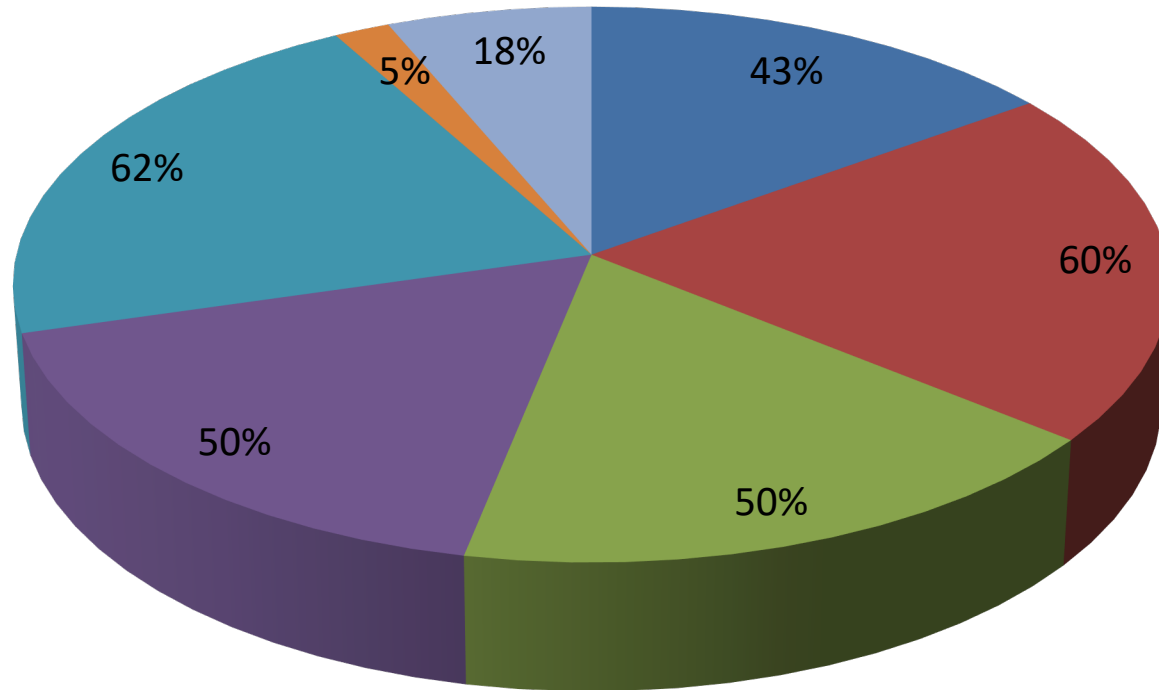
# Hurdles and Stumbling Blocks



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# Stumbling Blocks



■ Representation of study data into specific domains ie. data that does not fit in a variable

■ Supplementary documents SDRG, Define-xml

■ Specific standards - SDTM, SEND IG, TCG i.e. understanding the document assumptions or specific intention

■ Representation of your study design for the trial domains

■ Controlled terminology mapping or changes

■ Not applicable

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

# Stumbling Blocks

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

# Process Problems

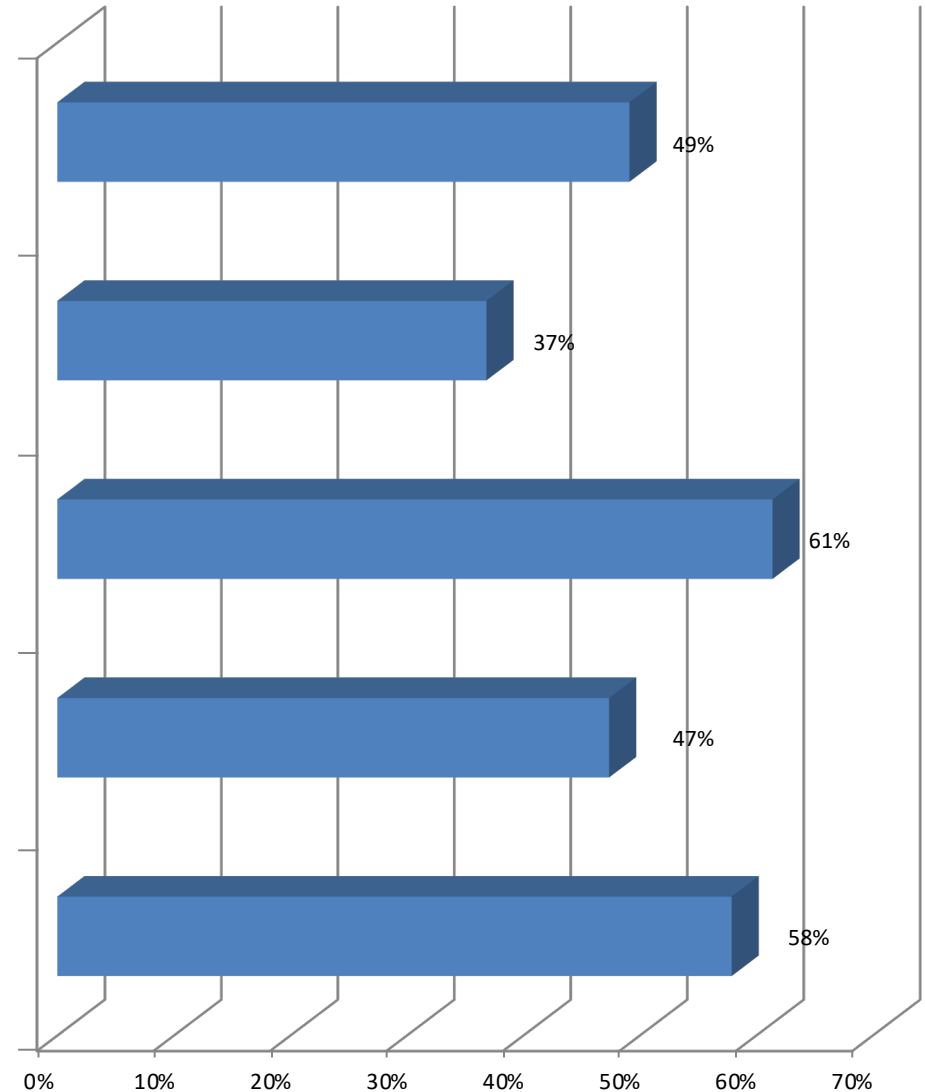
Coordination between the  
CRO/Sponsor and a Specialty lab

Coordination with contributing  
scientists

Coordination between Sponsor  
and CRO

Definition of roles/responsibilities

Coordination between company  
departments



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# The Stumbling Block Question Resulted In A Wide Variety Of Comments



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# Stumbling blocks: Submission mechanics

XPT format issues

Where to place legacy TS domain

Timing of the SEND sets relative to final report.

TUMOR dataset location



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# Stumbling blocks: FDA Feedback

Lack of FDA feedback and expectations and guidance.

Is the trial design and/or define file as expected



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

Protocol information representation

Legacy conversion

Data that does not fit in SEND variable

Data expected in SEND but not collected

Severity grade scale difference

Need info on PC and PP domain submission

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

Software hard coded to SENDIG variables

SENDIG timing variables not matching data collection

Conflict between tabulation data in SEND and analysis data in study report



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# Stumbling blocks: Guidelines and standards

Synthesizes info from various documents

Sponsors interpret the IG differently

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

CT changes every 3 months

# Stumbling blocks: Guidelines and standards

Hard to understand all for non-English speakers

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

Software gaps require much manual effort

Data capture systems not aligning to SEND

Software vendor assumptions

Assessing different providers.



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# Stumbling blocks: Management complexities

Upper management comprehending the intricacies of SEND

Getting internal studies SEND compliant

Get SEND data from CROs

Many parties involved

Pre-clinical budgets

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# Next Steps

**PhUSE non-clinical teams** – address hurdles through informational, exploratory or other projects.

**CDISC non-clinical group** - explore problem areas to identify where the standards need to be updated or expanded.

**FDA/CDISC** – pilot submissions projects for new study types.



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# CONCLUSION

The survey shows progress in SEND readiness and actual submissions from the previous year.

However, most respondent organizations are experiencing challenges in both the technical aspects of preparing submissions and intra- and inter-company processes.



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# Acknowledgements

## 2017 Survey Team:

George Kahlbaugh, Boehringer-Ingelheim

Bob Friedman, Xybion

Lou Ann Kramer, CDISC

Janice Fiori, Eli Lilly

Lauren White, PhUSE

## Team Site:

[www.phusewiki.org](http://www.phusewiki.org):

PhUSE wiki:CSS Working group ->

Nonclinical topics ->

Industry SEND progress survey

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# Questions?



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