

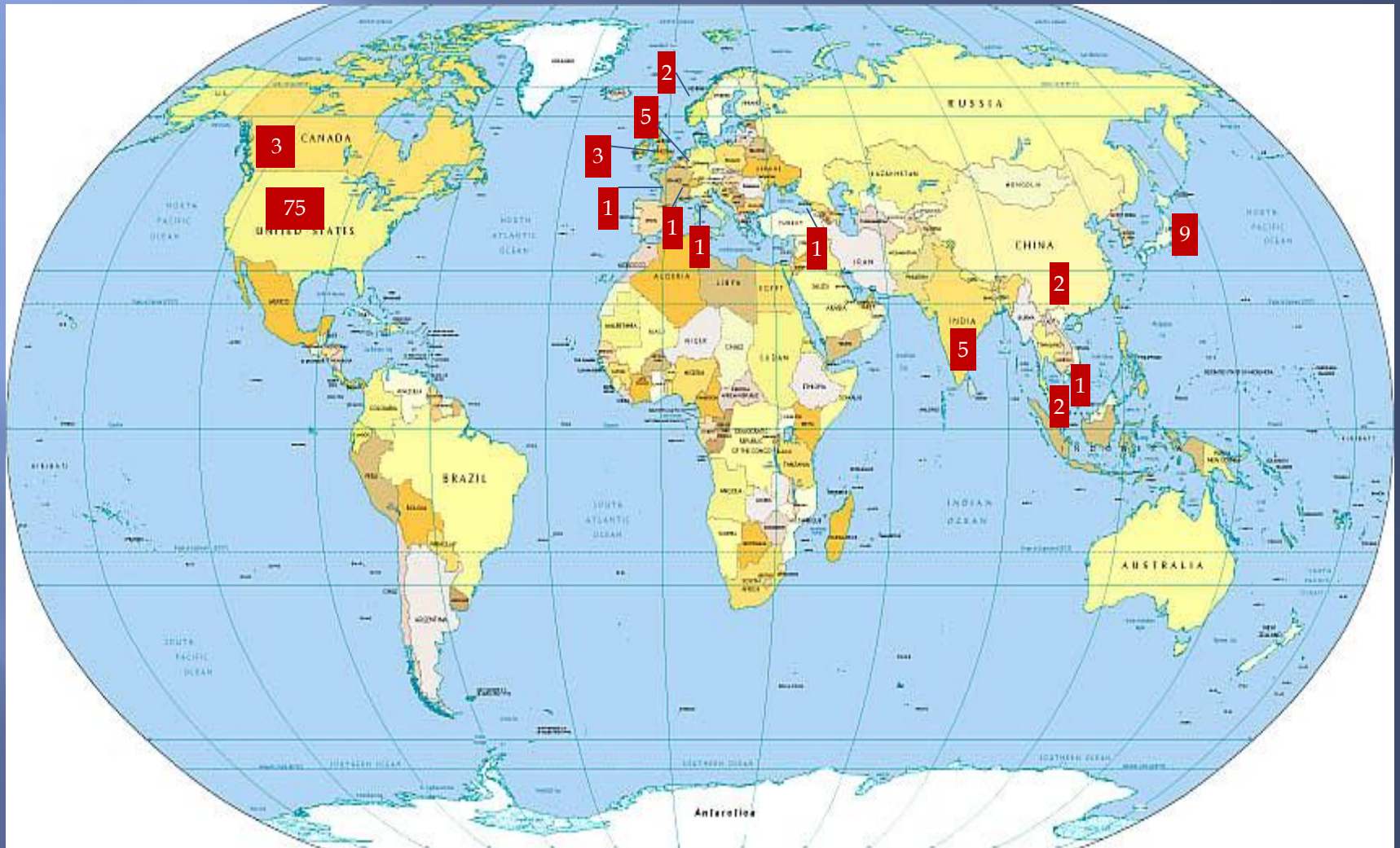
PHUSE/SQA SEND READINESS SURVEY

George Kahlbaugh, Lou Ann Kramer,
William Houser

PhUSE CSS Meeting, March 13-15, 2016

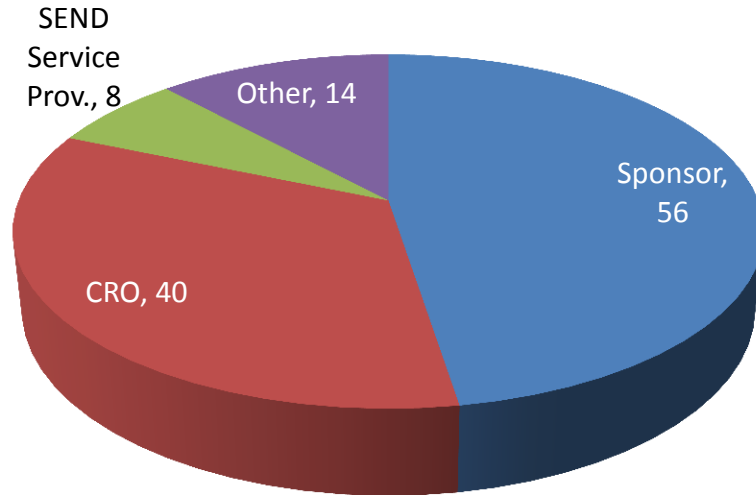
One Hundred Eleven Respondents !

What country are you located in?



One Hundred Eleven Respondents !

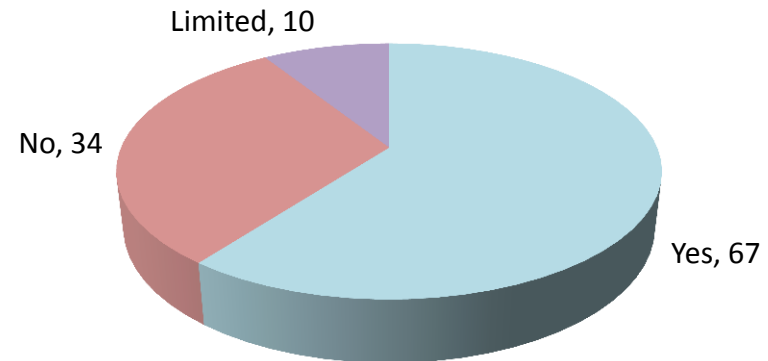
Organization Type



Background

- 29 Scientists
- 11 Regulatory
- 10 Consultants
- 41 QA
- 15 IT
- 15 Other

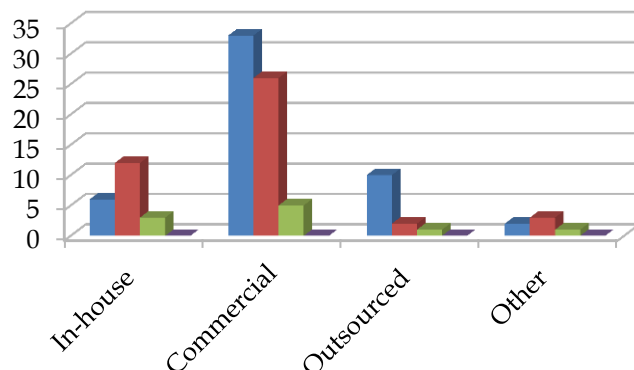
Run Studies That Will Be Submitted



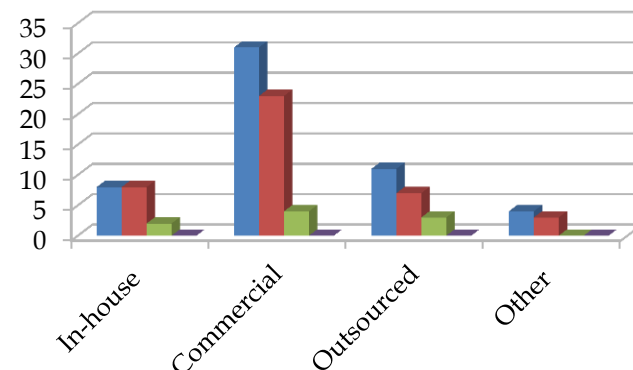
What Type Of Systems Do You Use?

■ Sponsor (n)
 ■ CRO (n)
 ■ Send Service Provider (n)
 ■ Other (n)

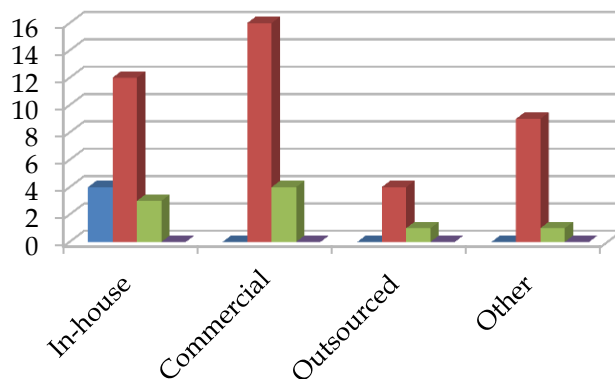
Tox System Type



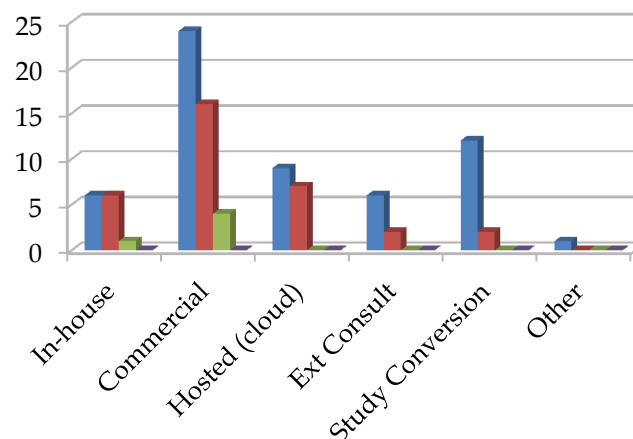
DMPK System Type



Repro/DART System Type



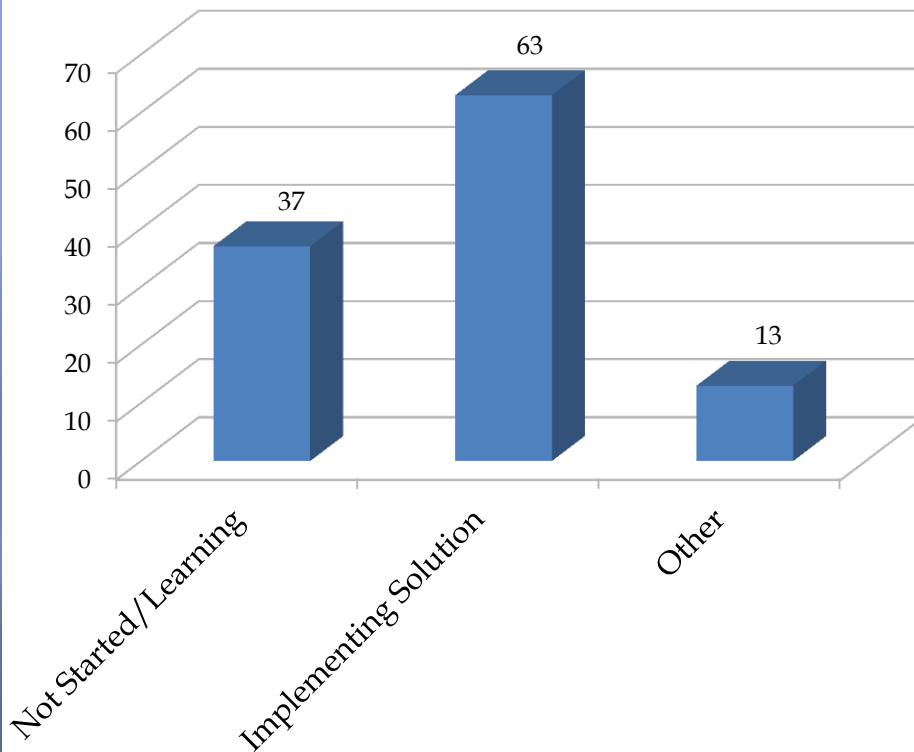
SEND Solution Type



SEND, Tox
 and DMPK
 Systems Are
 Primarily
 Commercial
 Systems For
 Sponsors
 and CRO's

3. What Stage Of Send Readiness Are You In?

Stage Of SEND Readiness -
Percent



Tool
Validated

Education
For Client
Advisement

Validation

SEND
Implementation
Complete

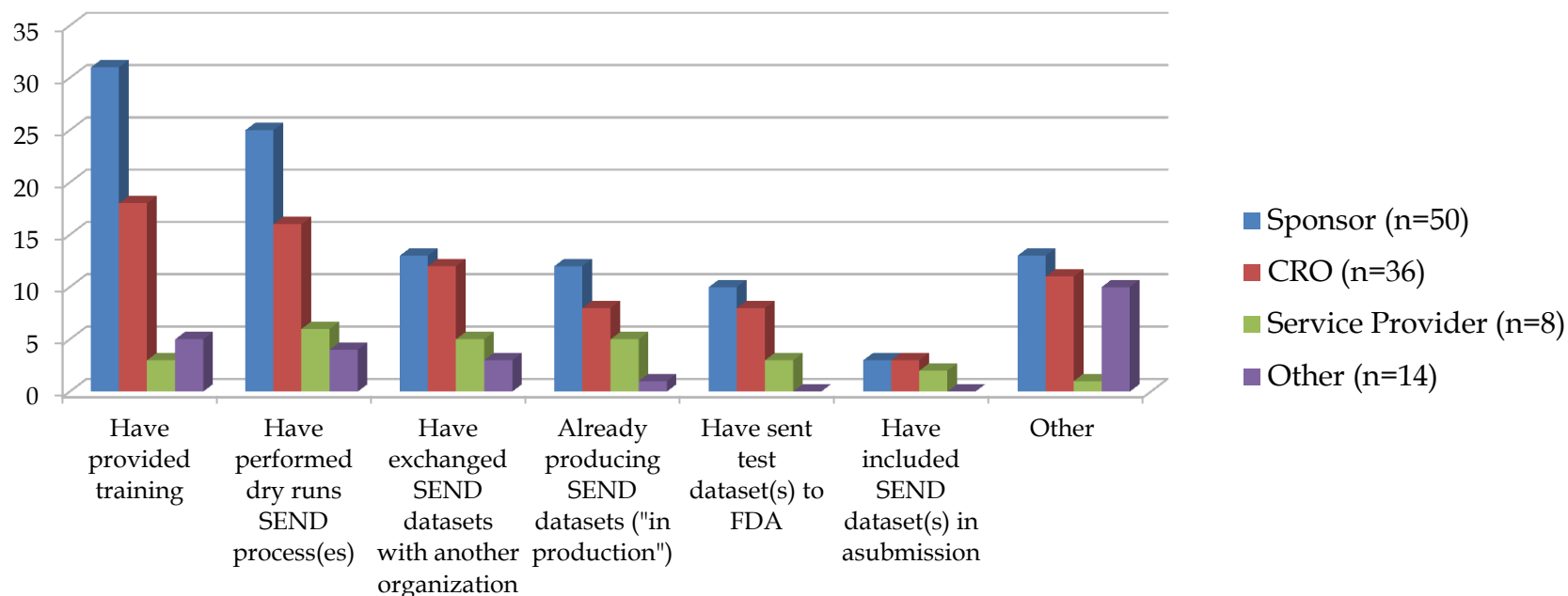
Piloting A
Commercial
System

Solution Implmented –
Refining And Enhancing

Looking At Options

4. What Actions Are You Currently Taking / Have Taken Towards Implementation?

Activity By Organization Type - Absolute

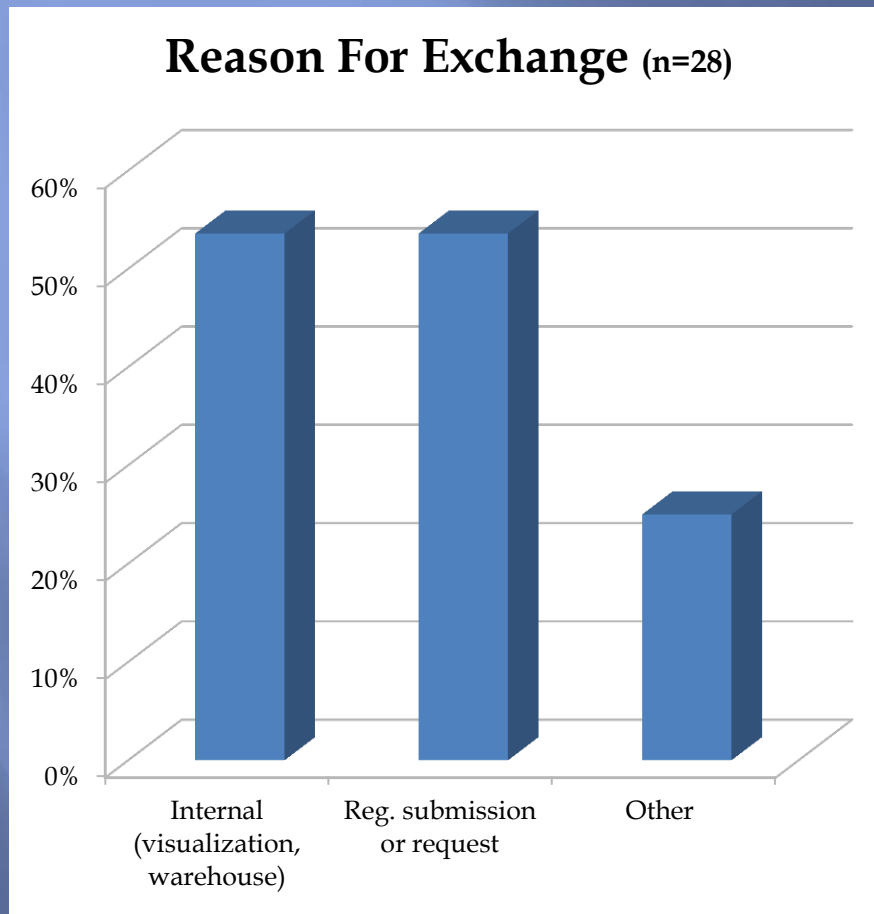


Generally it appears the sequence of steps for implementing SEND are as shown in the graph.

4. Actions Taken - Other



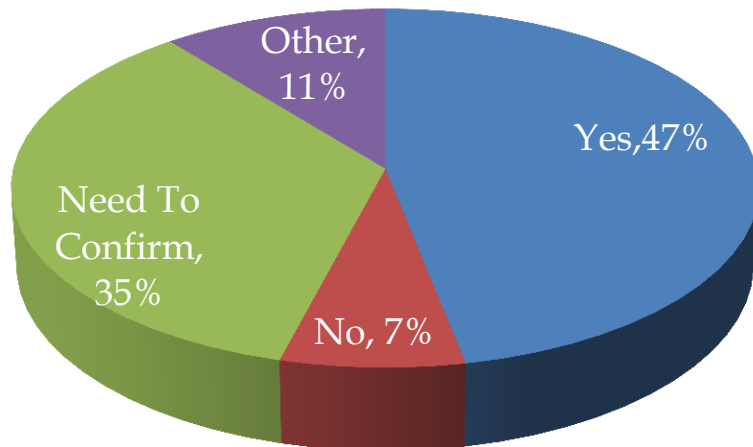
4a. What was the purpose of the dataset exchange?



Pilot Submission
Sharing *Testing*
Test Submission
Send To Consultant

5. Are your service providers able to create SEND datasets or have a plan in place to do this in the right timeframe?

Service Provider - Create Dataset? (n=111)



Mixed Responses
From Vendors

Don't
Know

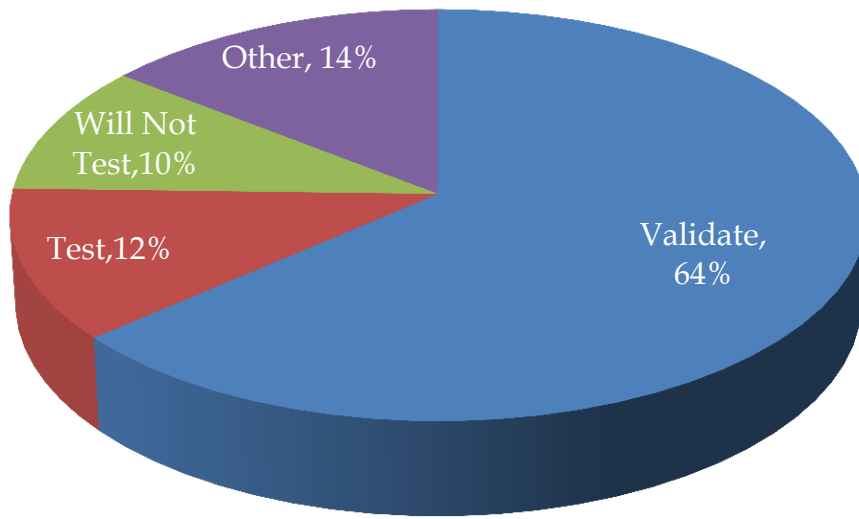
Most Are Ready

Yes For Larger
CRO's

We Are A Service Provider –
Plan To Do This In The Right
Time Frame

6. With regard to your company's implementation of a SEND computer system(s), at what level do you intend to test the system?

Type Of Testing Of SEND Application For All Org Types

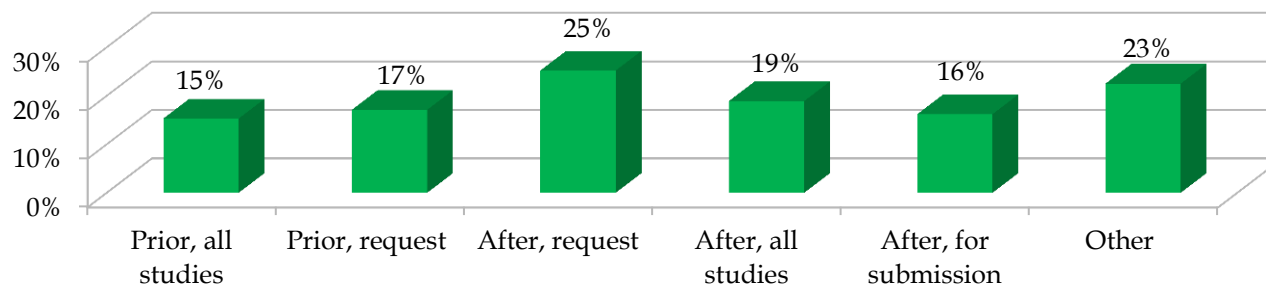


A majority are validating their SEND solution, while a small fraction is planning to do no testing.

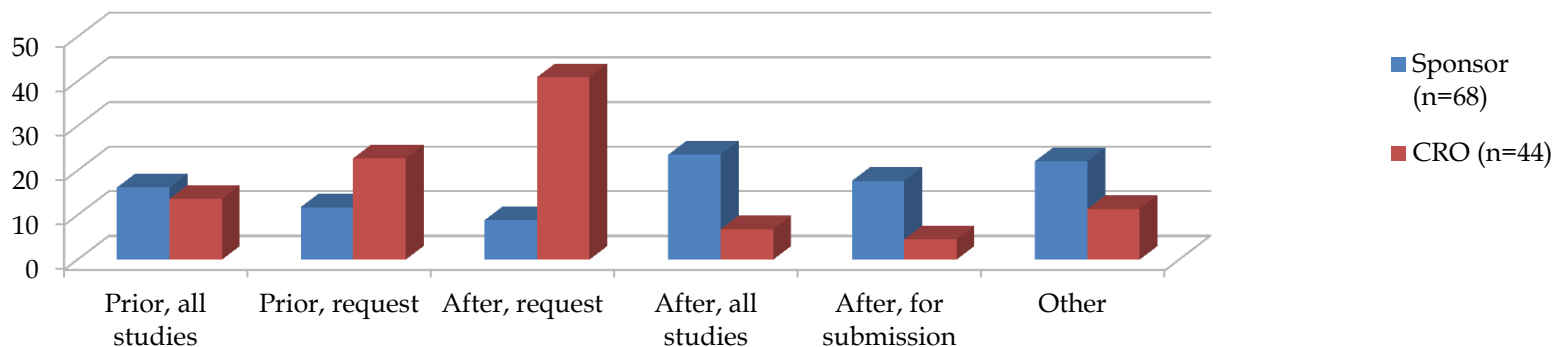


7. At what point related to study finalization does your company plan to generate SEND datasets?

Timing For Dataset Creation (n=112)



Timing For SEND Dataset Creation - Sponsor and CRO



SEND datasets will be prepared at all the timings that were available choices in the survey.

8. What Is The Rationale For Your Timing Decision In Question #7 Above?

Sponsor Request

Leverage Dataset For Data Review During Report Writing

Data Avail To Internal Scientists ASAP

Still Considering

Buisness Priority

Less Chance Of Data Changing

Dataset Needed For Clin. Decision

Cost And Workload

Must Be Extracted Before Finalizations

Verify Data Before Finalization

Data Warehouse

Not Sure

Before For Interim Filing/Testing The Dataset

Safest Timeline Best Guess

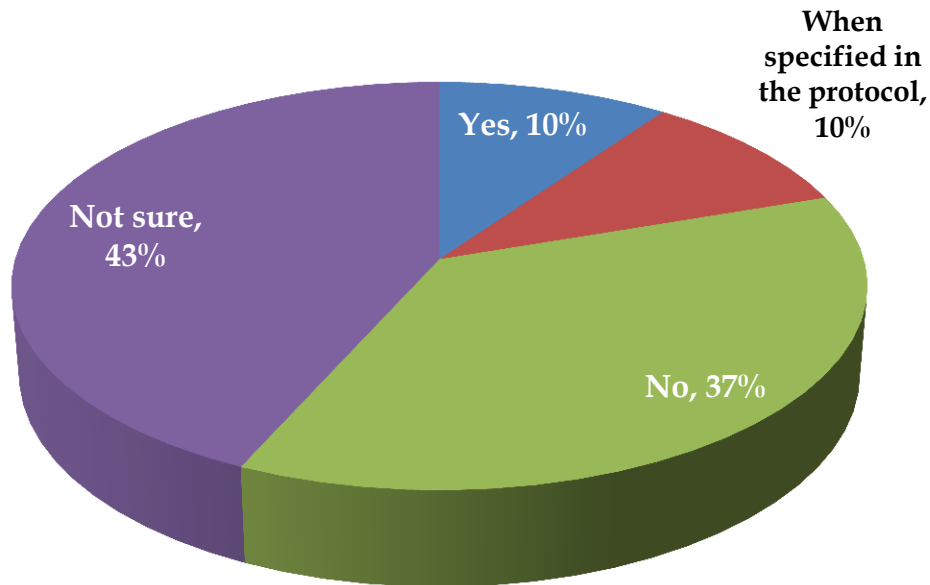
As Completed In The LIMS

Based On Protocol

Study Needs To Be Finished Before SEND

9. Will SEND datasets be used by the study director to interpret and analyze the data collected and to draw conclusions that are included in the final report?

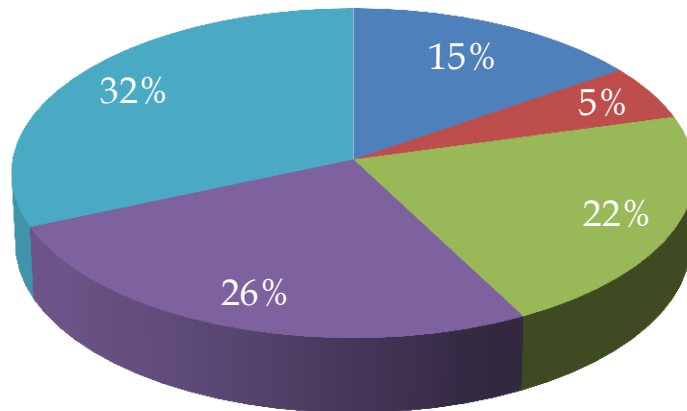
Datasets Used As Part Of Study



Many people are not sure if study directors will use SEND for study report conclusions.

10. How will your company provide QA oversight of the SEND dataset process?

QA Involvement (n=111)



- Audited as a study activity
- Dataset will be audited outside of study
- Dataset process audited
- Dataset outside study activities; will not be audited.
- Other

QA oversight varies significantly.

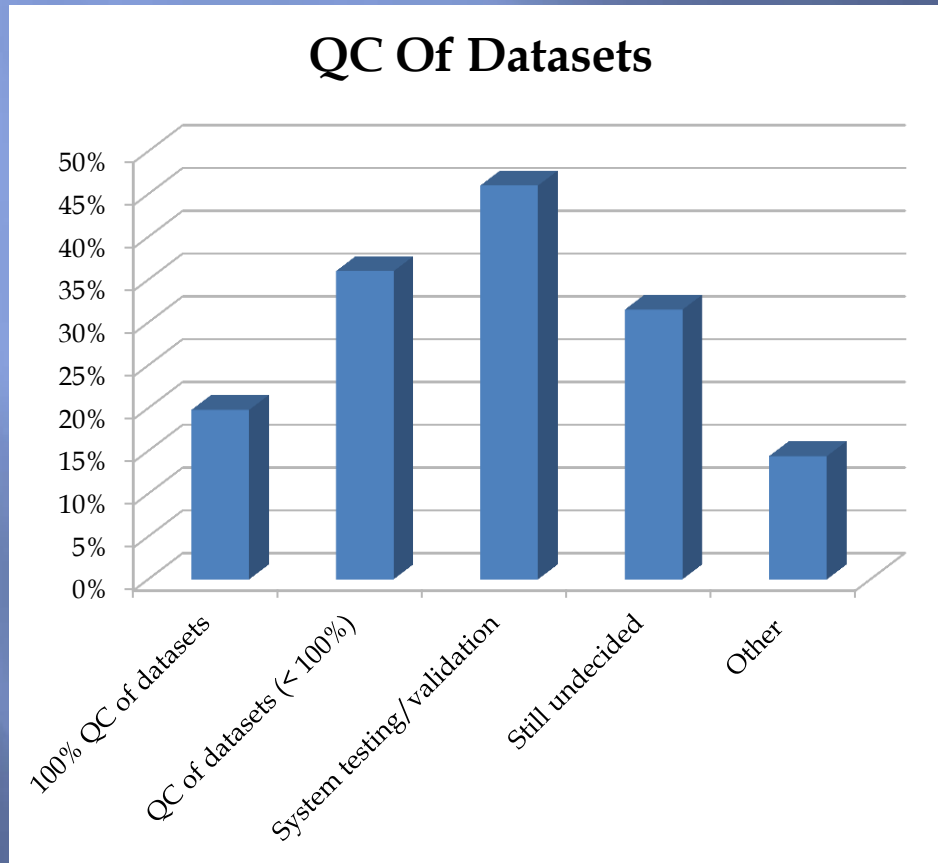
An Audit Is Envisioned

Only Validation Process

Not Decided

Will Not Audit Datasets – Will Audit Vendor And Process

11. How do you ensure that your datasets completely and accurately represent the study data?



Comparing this with question 6, we see that 10.2% will not test, and 15% will do 100% QC, but a majority will validate and perform some level of QC.

Don't Know/TBD

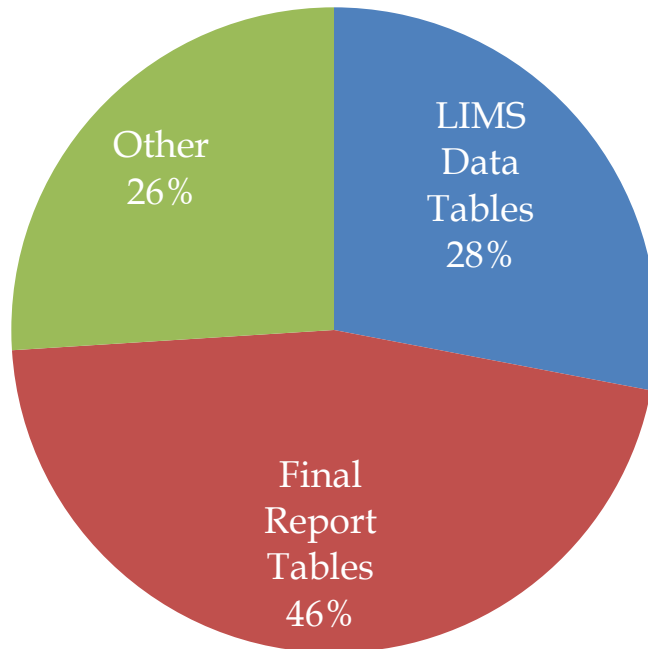
100% Of Manual

Rely On

Contract W/CRO

Team To Ensure Data Is Correct
System Is Validated

12. What will you use as the reference source to verify (QC) your datasets against?



Unknown At This Time

Original Raw Data

Report Tables

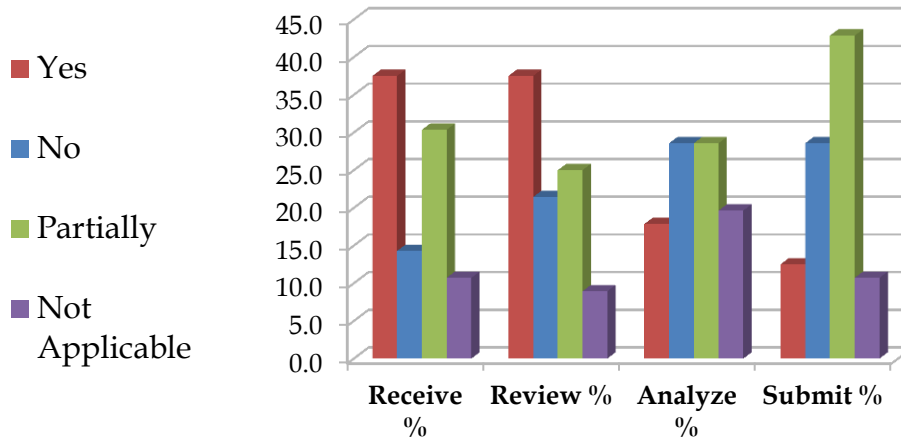
Along With Checks Against Study Plan, Schedule, And Report

Report Tables And LIMS If Needed

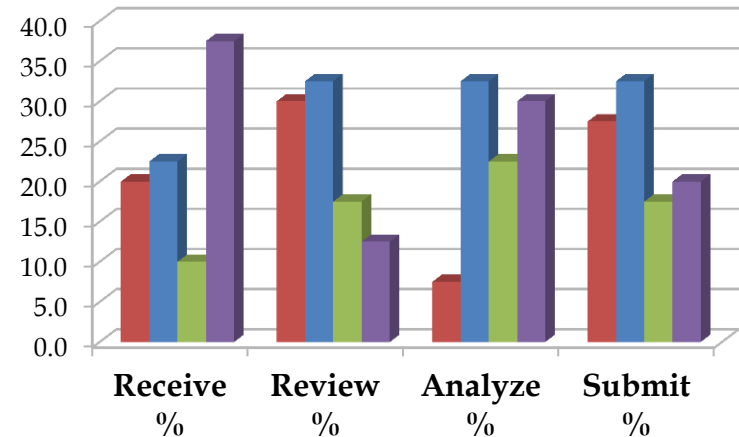
Final Report Tables Are The Most Commonly Used Source (2:1 to LIMS Data Tables. Other Have Not Decided

13. If applicable, are you ready to...

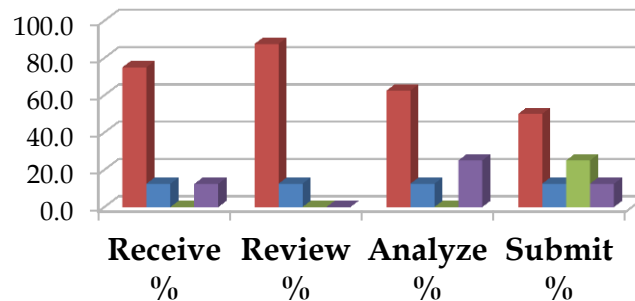
Sponsor - Capabilities (N=56)



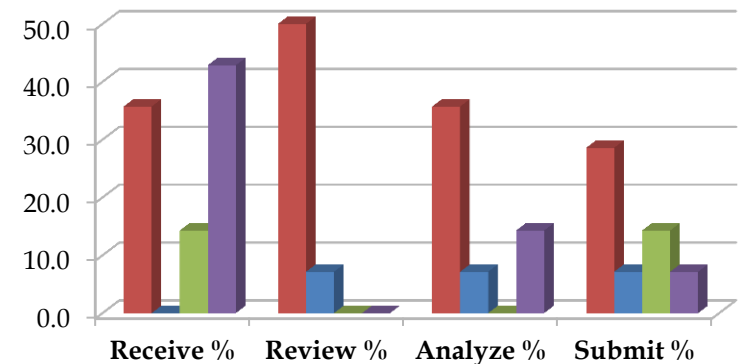
CRO - Capabilities (N=40)



SEND Service Provider - Capabilities (N=8)

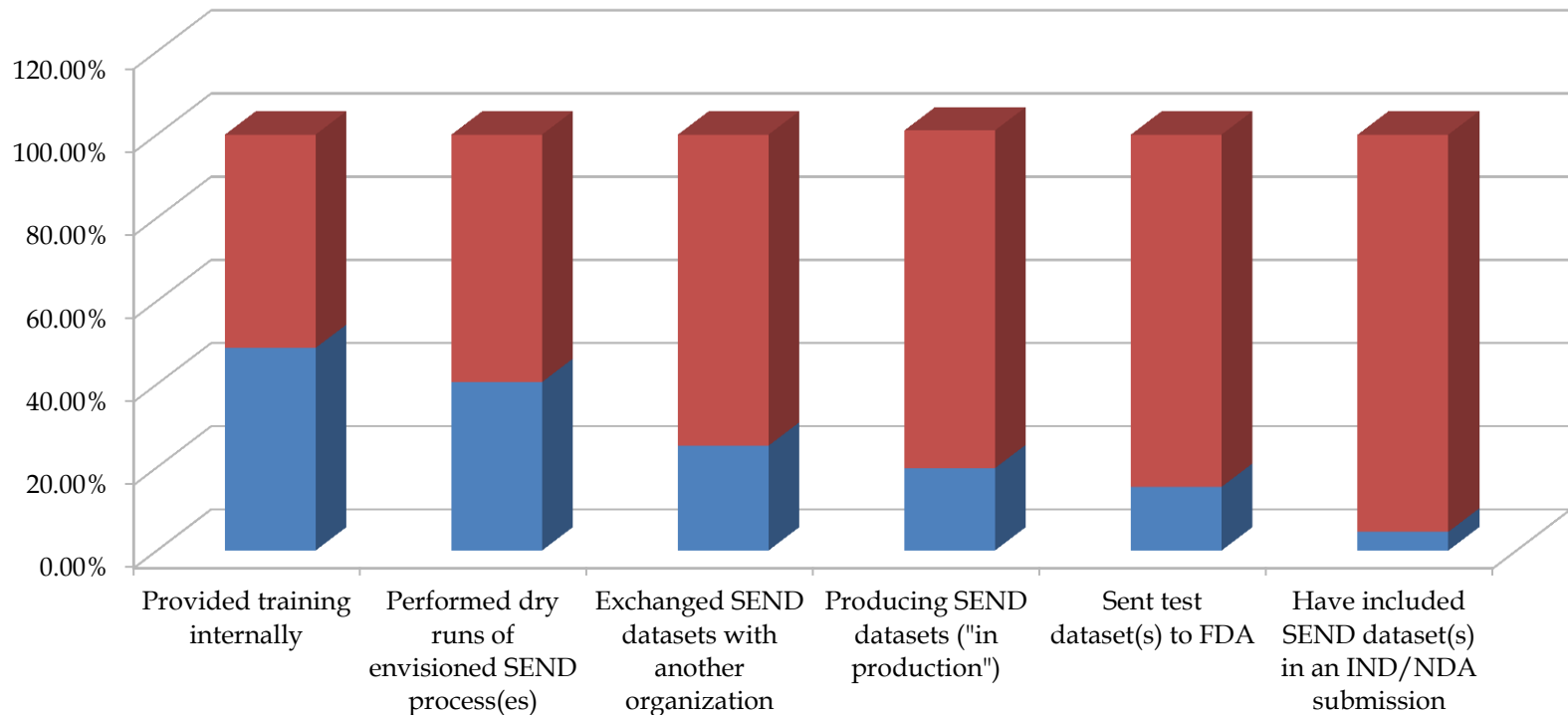


Other - Capabilities (N=14)



Only SEND Service Providers are generally ready in all categories.

A Meter For Where We Want To Be



If We Conduct This Survey Next Year And The Activity Data Shows The Change In Red, SEND Readiness Will Have Been Accomplished.

Overall Observations From The Survey

Thank You