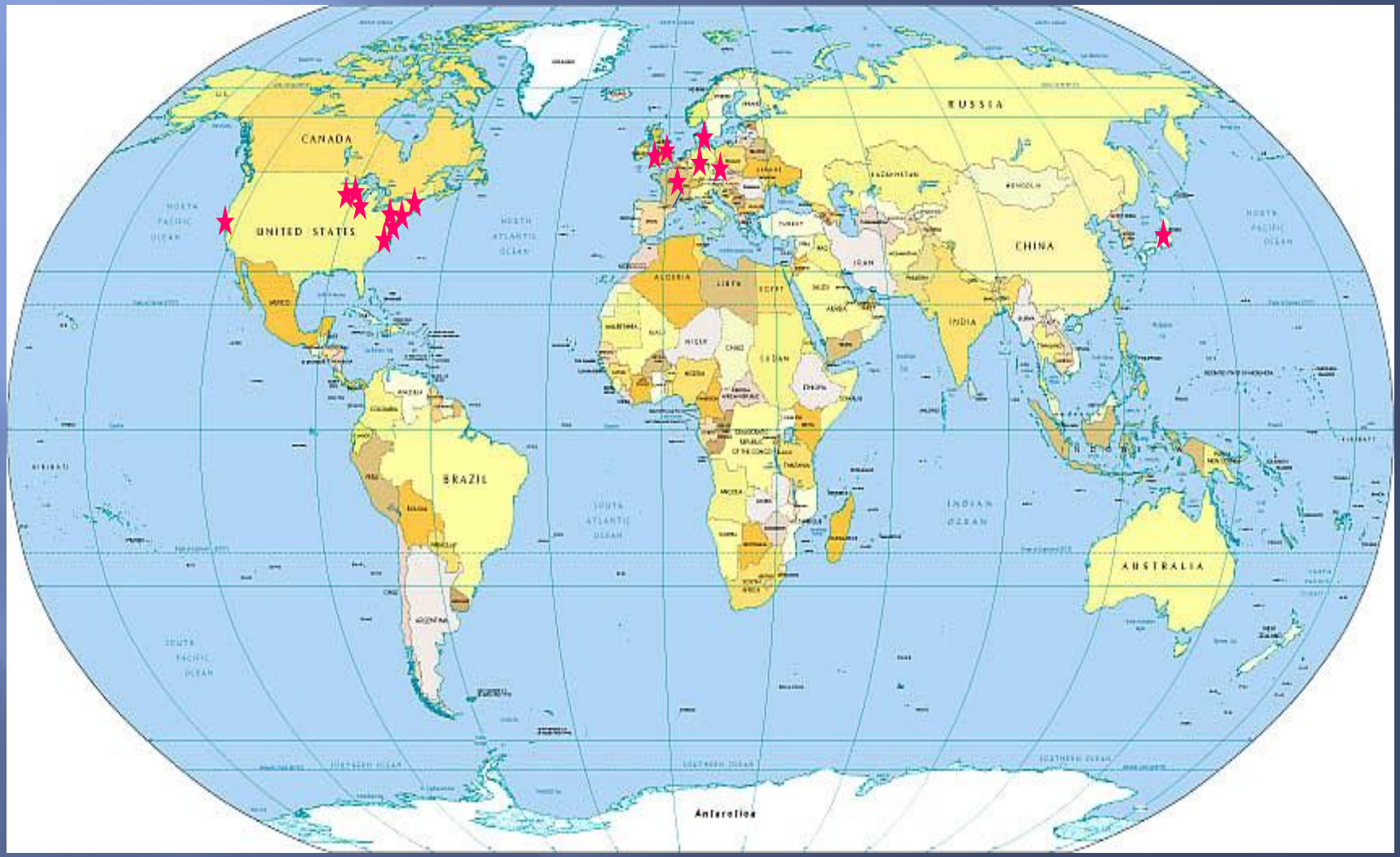
# PHUSE/SQA SEND READINESS SURVEY

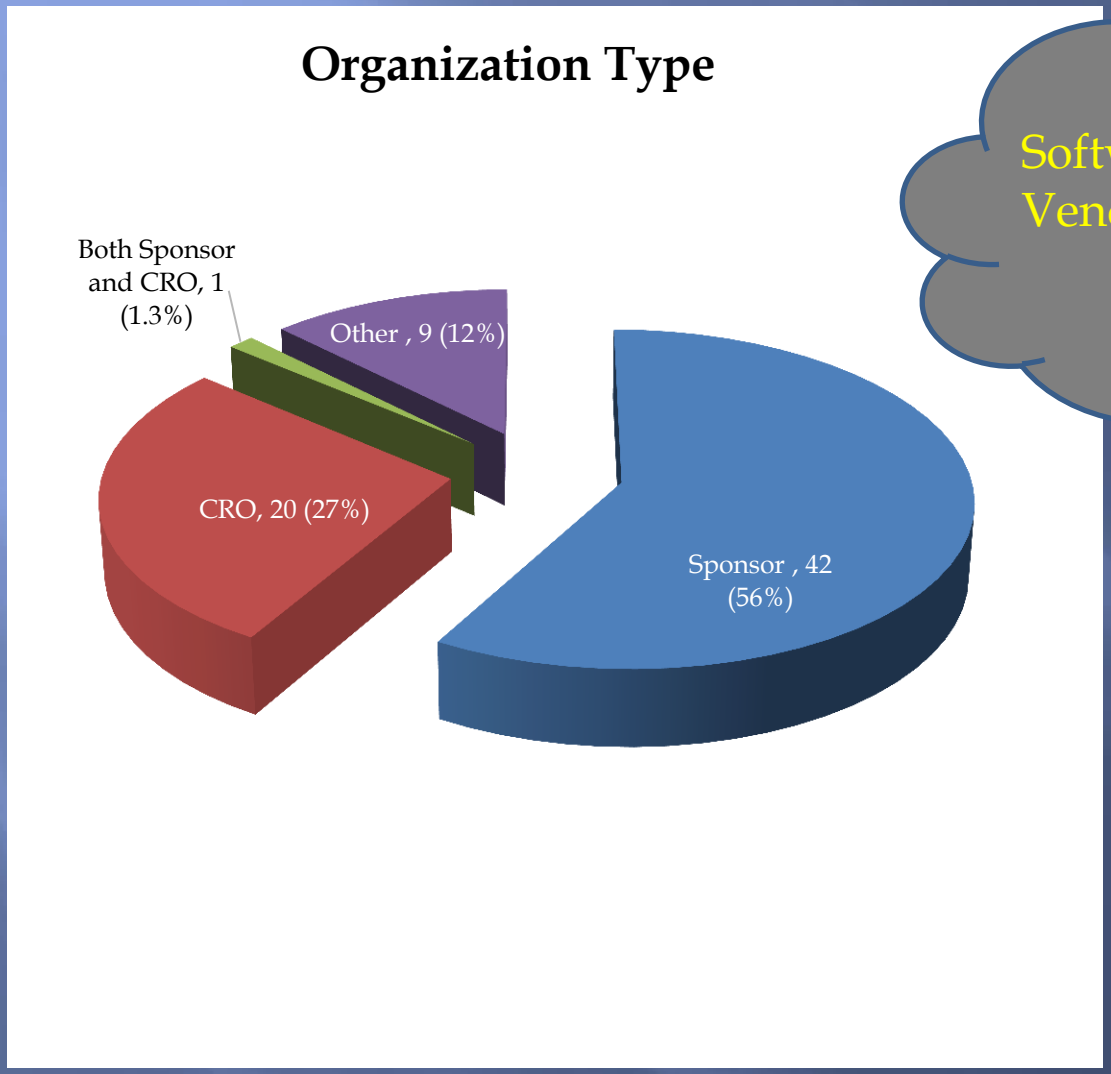
George Kahlbaugh, Lou Ann Kramer,

PhUSE CSS Meeting, March 19-21, 2017

# 72 Respondents !
# What country are you located in?



# Demographics




Service or Solution Provider

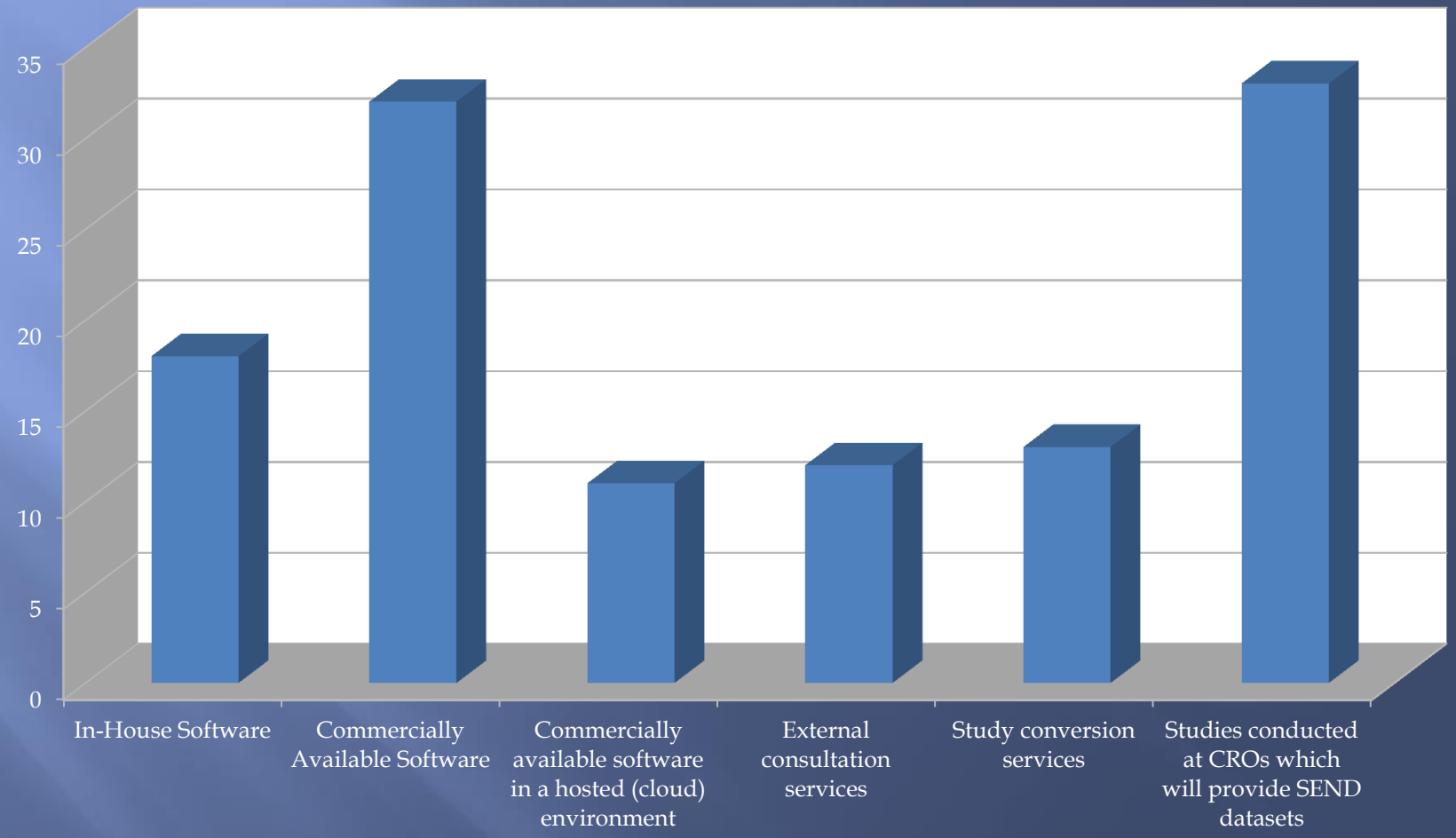
Software Vendor

Consulting

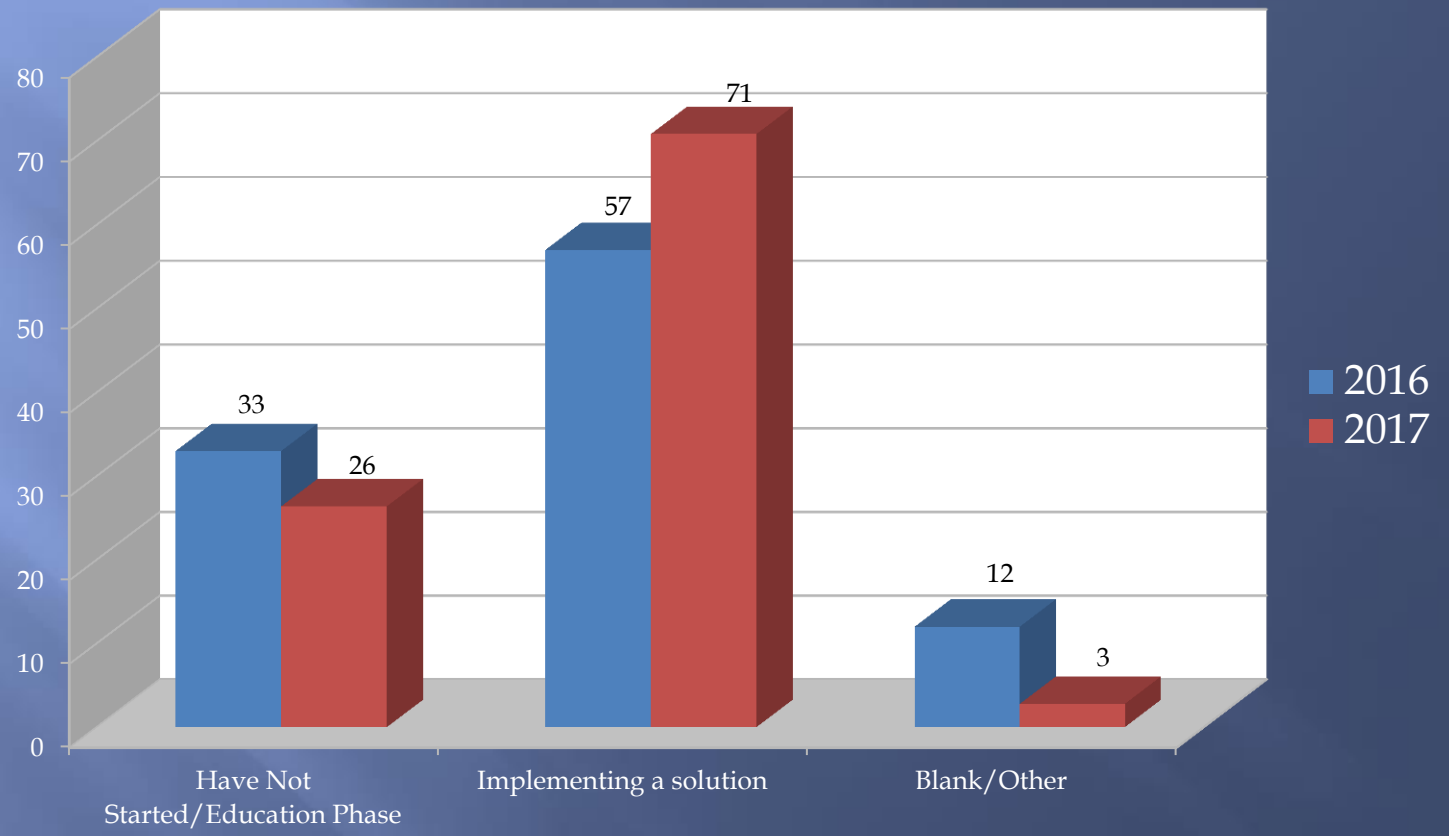
## Background

- 13 Scientists
- 7 Regulatory
- 12 Consultants
- 3 QA
- 9 IT
- 24 Other

# What Type Of SEND Solutions Do You Use? (n)



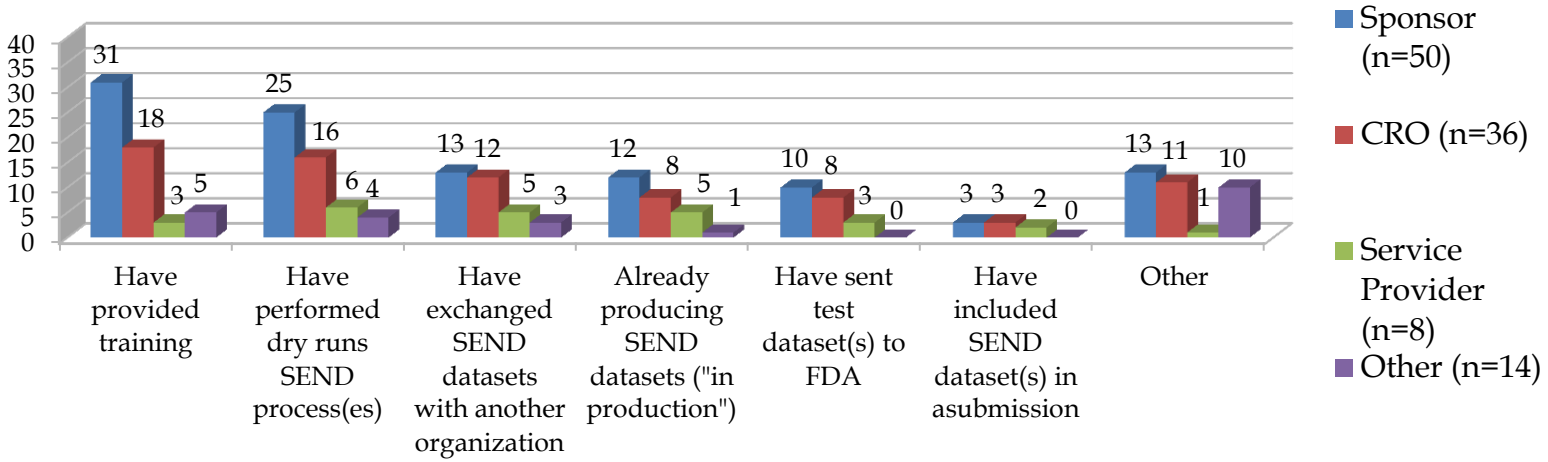
# What Stage Of Send Readiness Are You In? (% of Respondents)



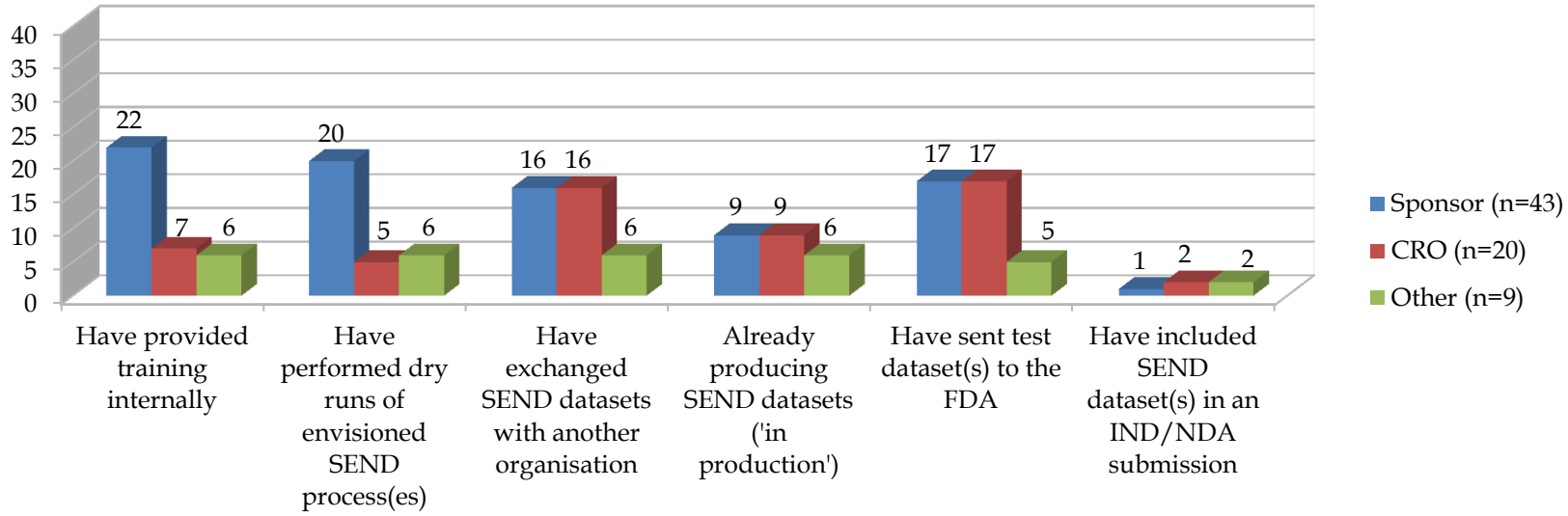

There has been a 14 percent increase in the number of respondents implementing a solution and a 7-9 percent decrease in the number of respondents who have not started or responded with Other

# Actions Towards Implementation

## 2016 Activity By Organization Type - Absolute

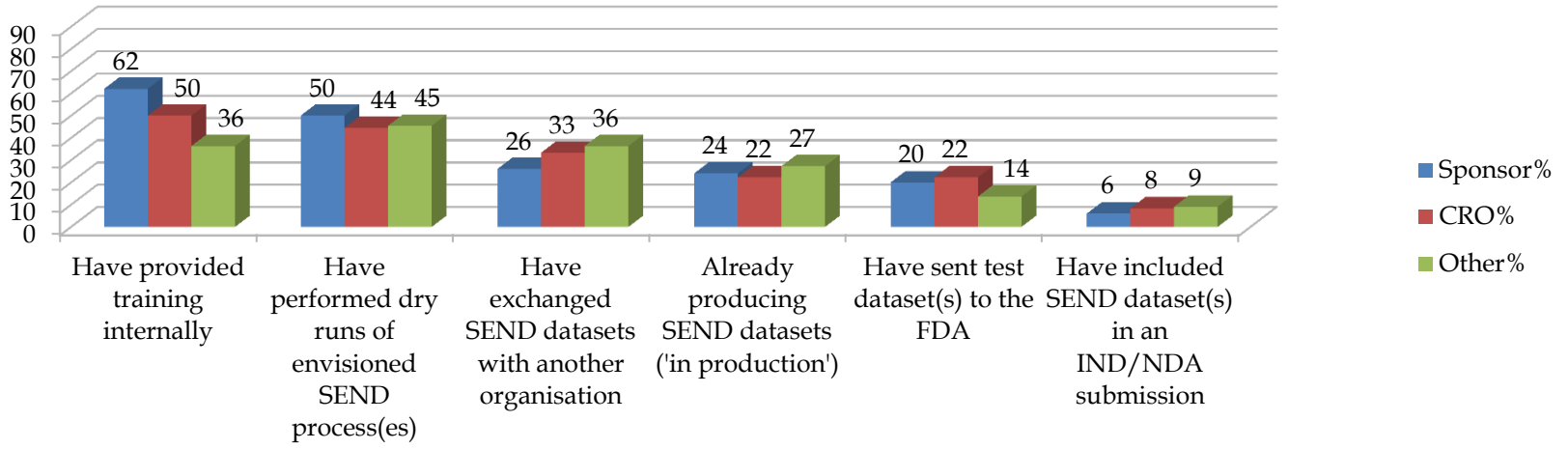



## 2017 Activity By Organization Type -Absolute

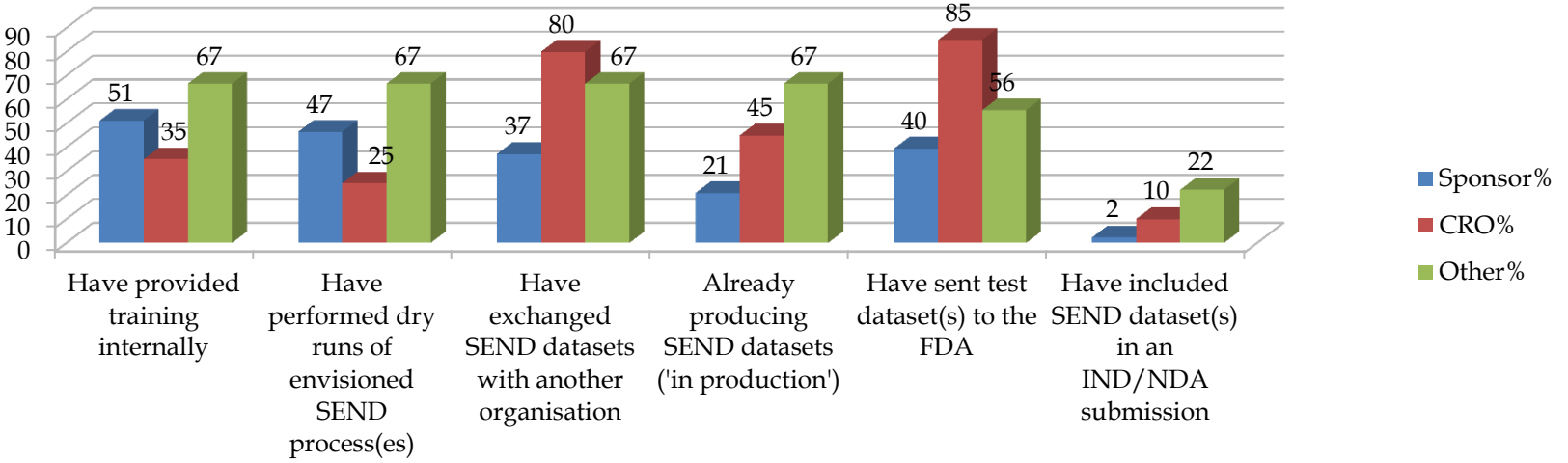


# Actions Towards Implementation

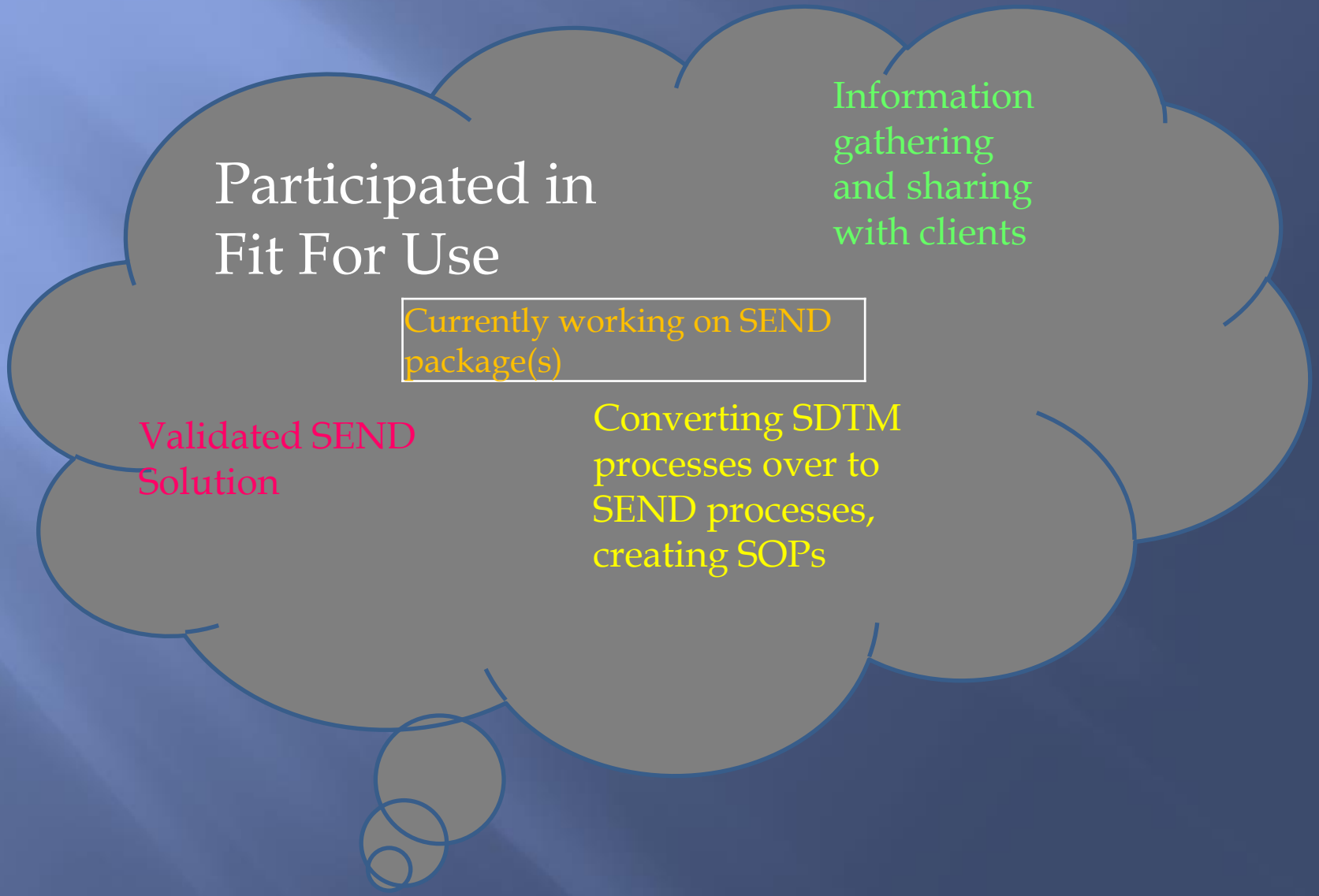
## 2016 Activity By Organization Type - Percentage




## 2017 Activity By Organization Type - Percentage

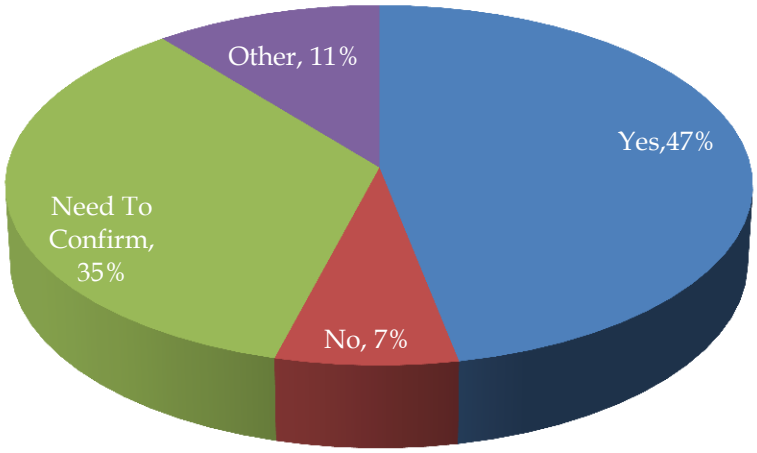


# 4. Actions Taken - Other

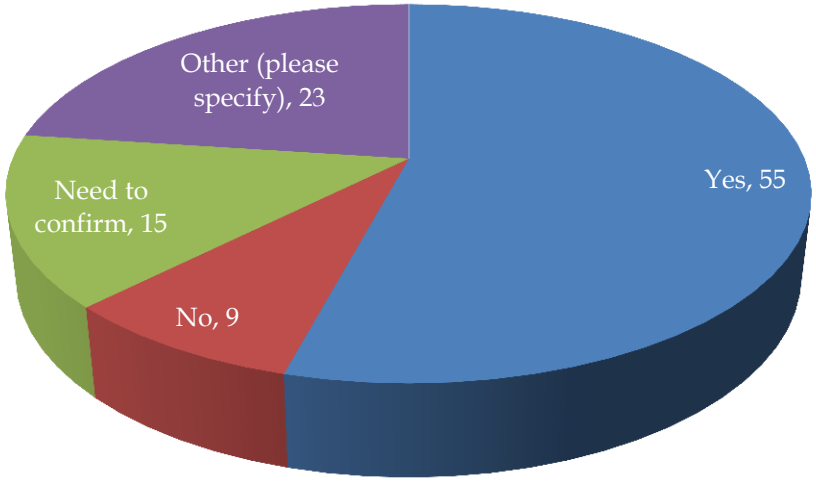


# Are your service providers able to create SEND datasets?

**2016** (n=111)

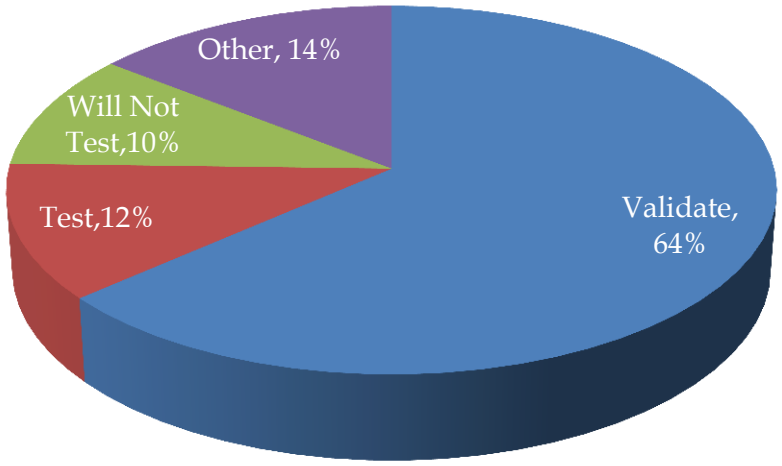


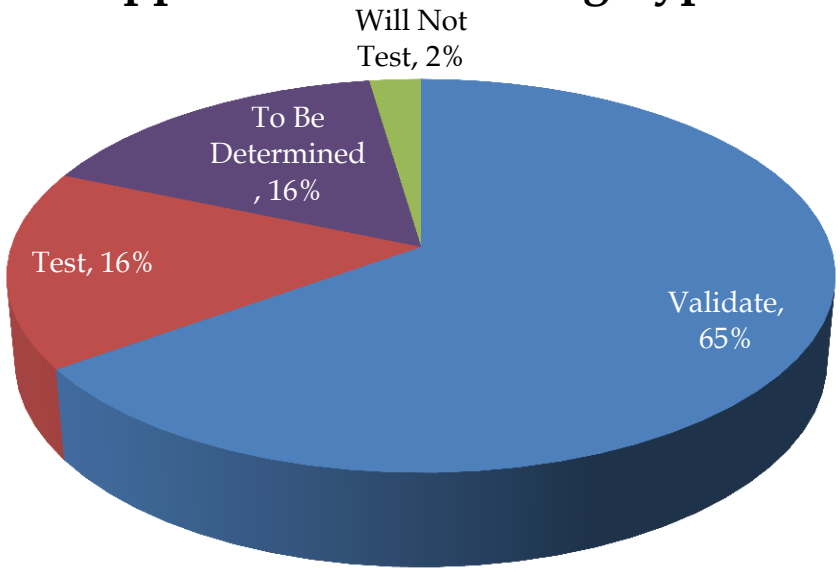

**2017** (n=72)




The percentage of respondents that need to confirm has dropped by 20%. The percentage of respondents who know their CRO capabilities increased by 10%.

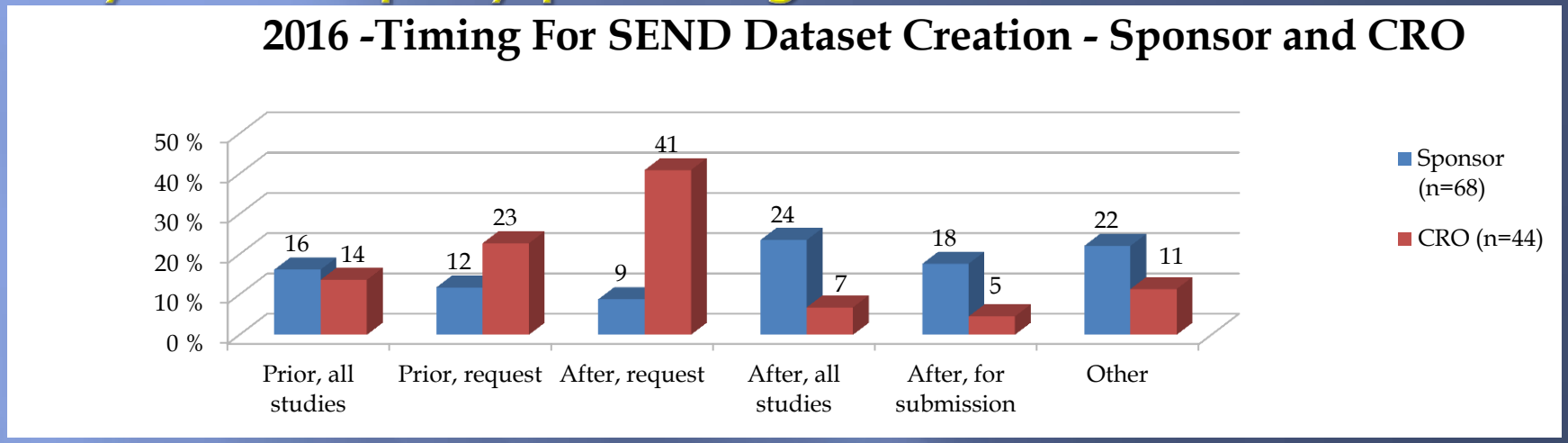
# At what level do you intend to test the SEND system?

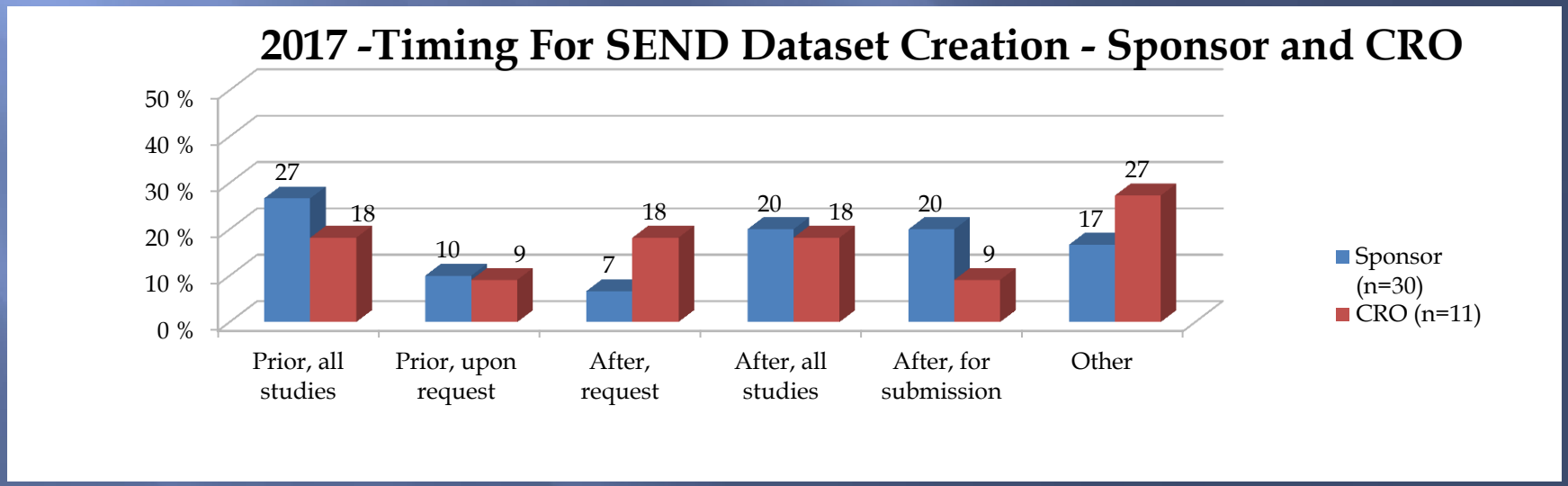



A majority are validating their SEND solution, while a small fraction is planning to do no testing. 81 % of respondents will validate or test.

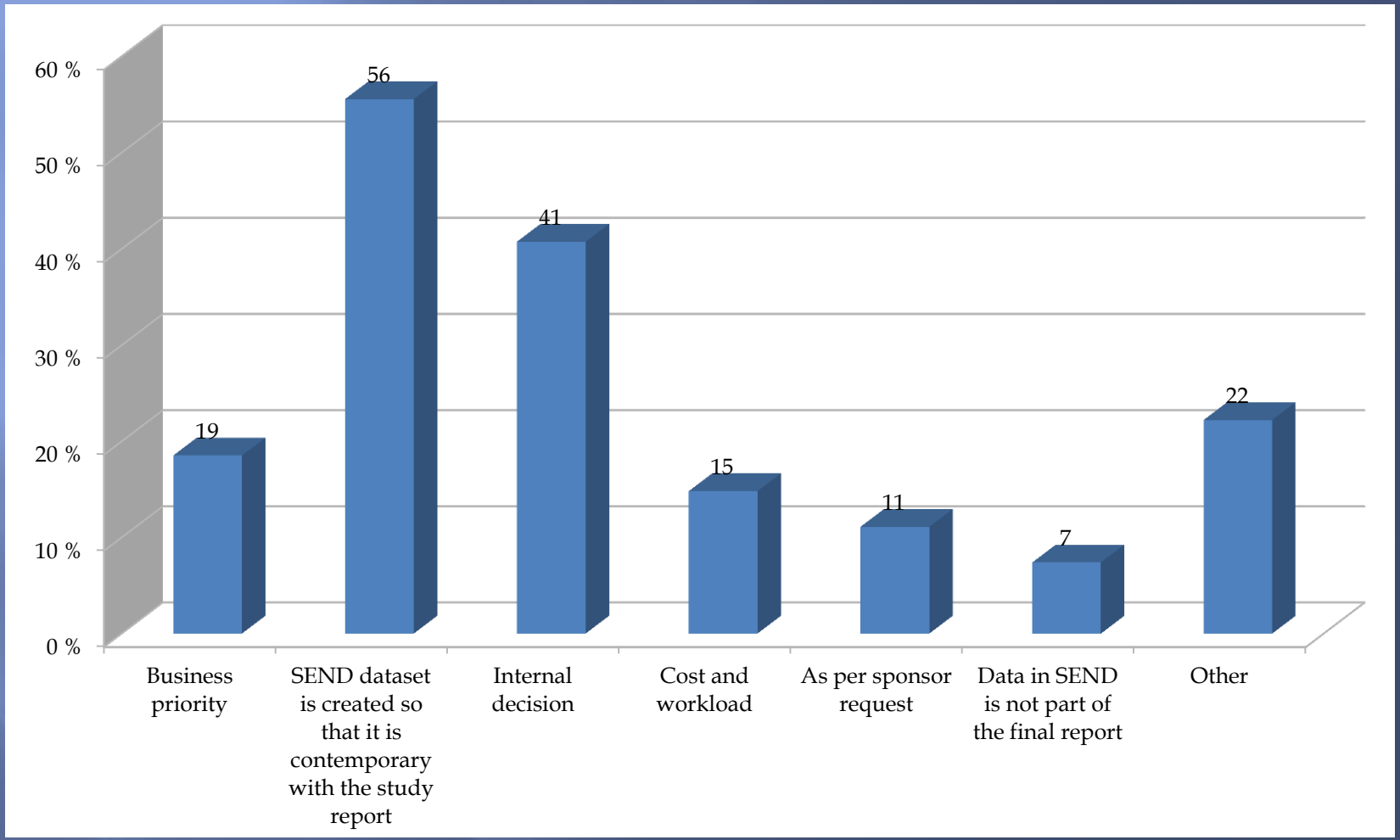
# At what point related to study finalization does your company plan to generate SEND datasets?



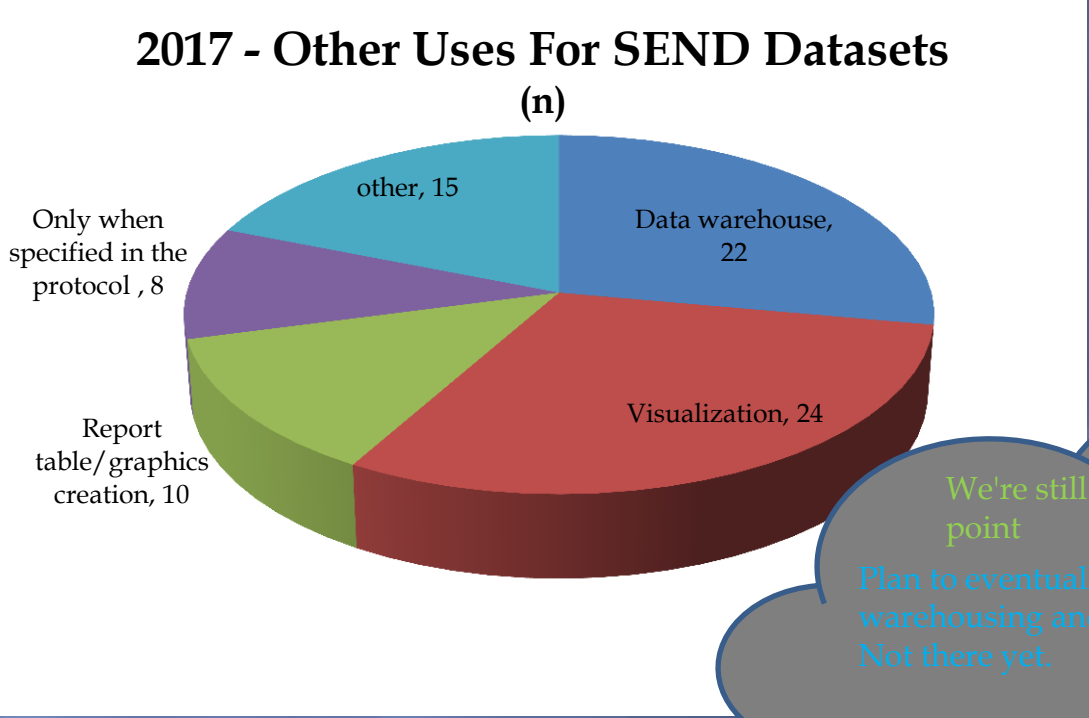




SEND datasets will be prepared at all the timings that were available choices in the survey.

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



# Will SEND datasets be used for purposes other than submission to the FDA. ie, data warehouse, reporting? (Select all that apply.)




Using SEND datasets for a Data Warehouse or Visualization are the leading additional uses of the dataset.

We're still discussing this point

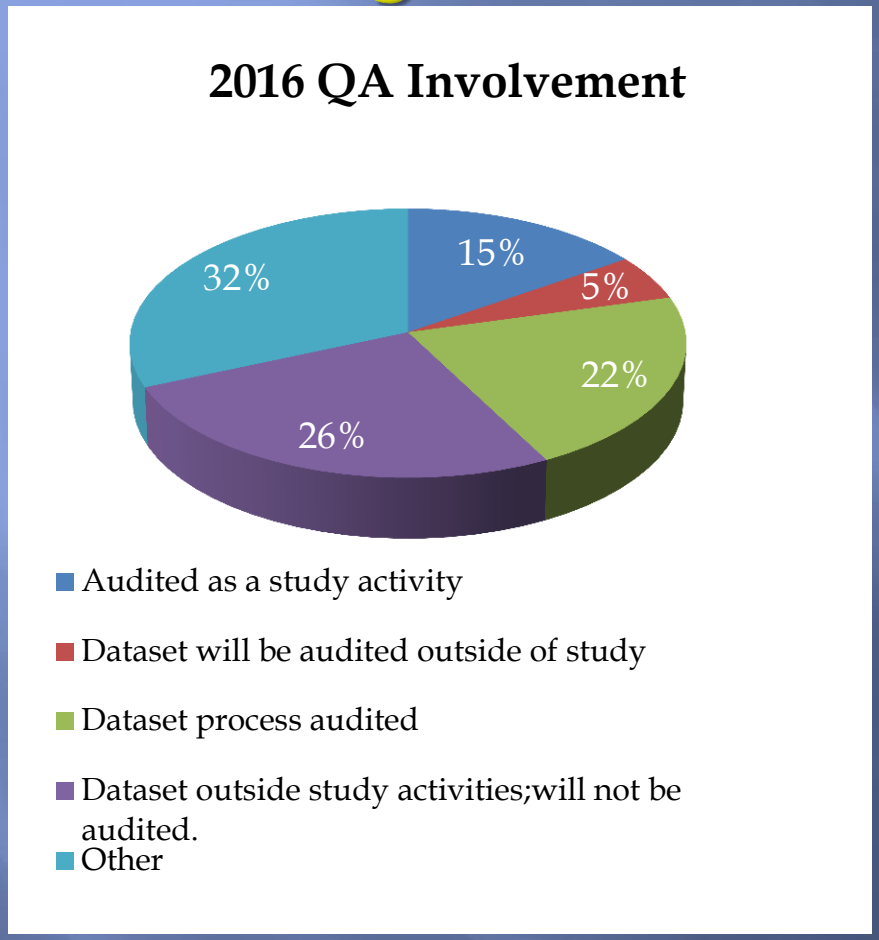
Internal use and comparison of data

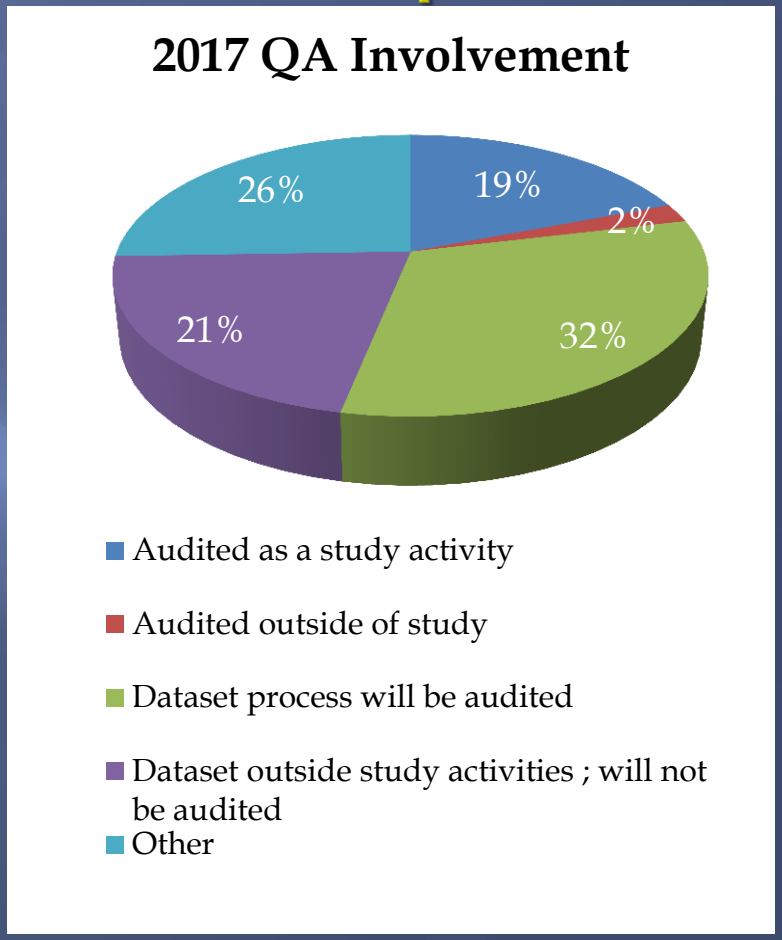
Plan to eventually use for warehousing and visualization. Not there yet.

Meta-analysis of preclinical information

Our organization is not using SEND datasets for purposes other than to generate and supply to clients.

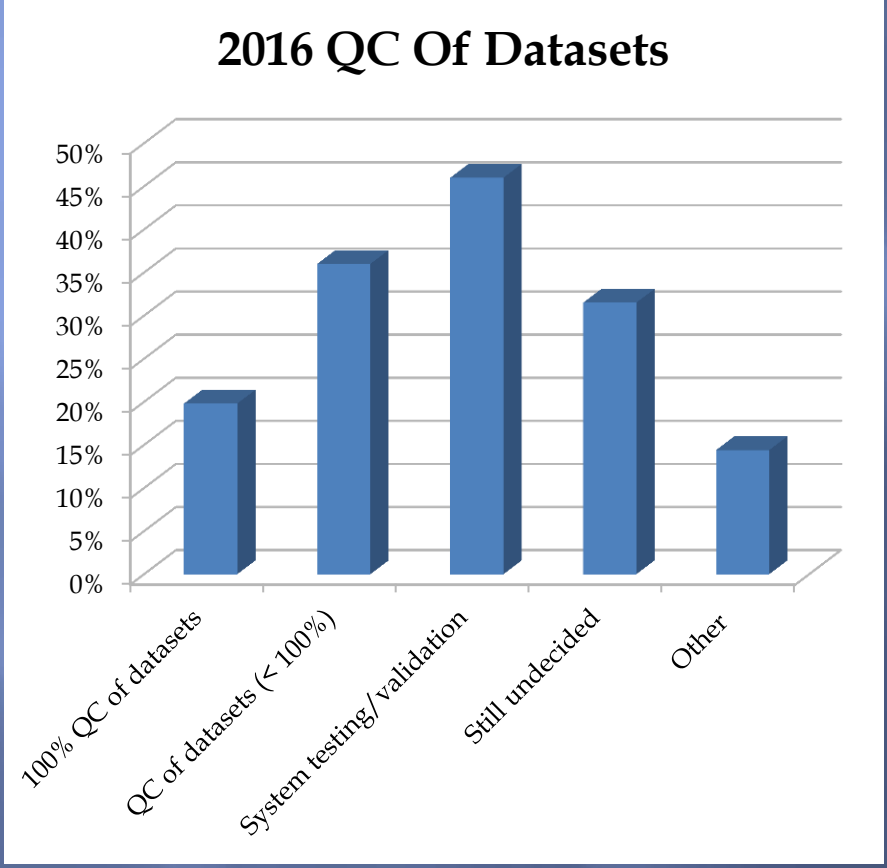
# How will your company provide QA oversight of the SEND dataset process?

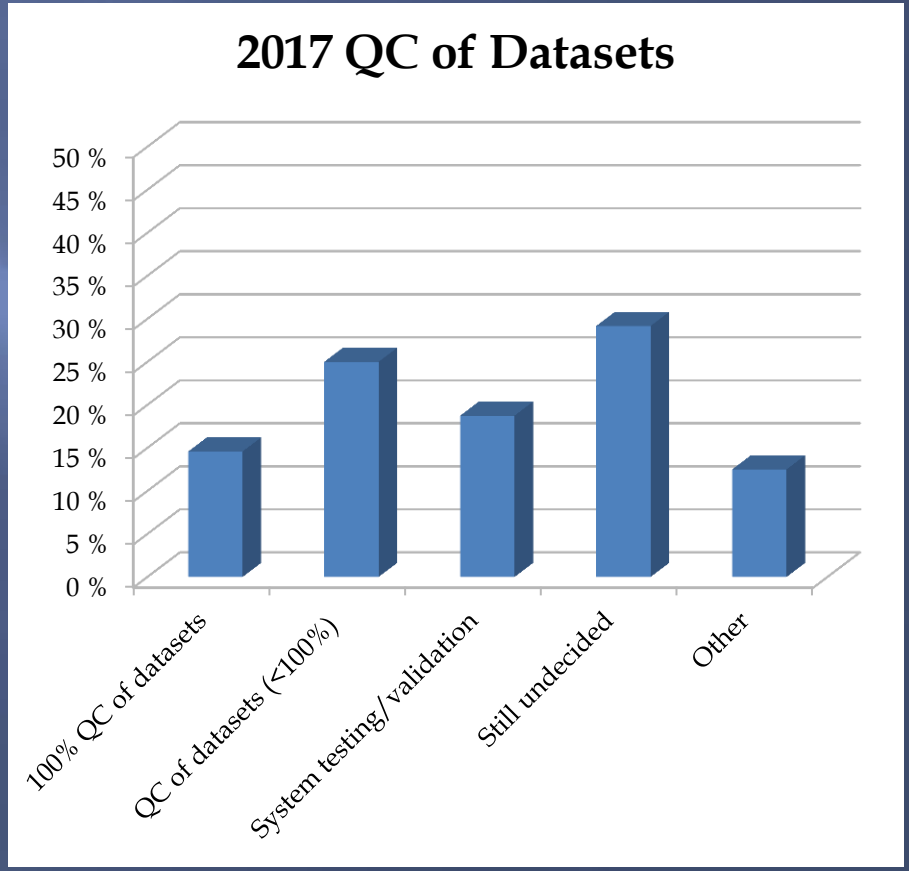


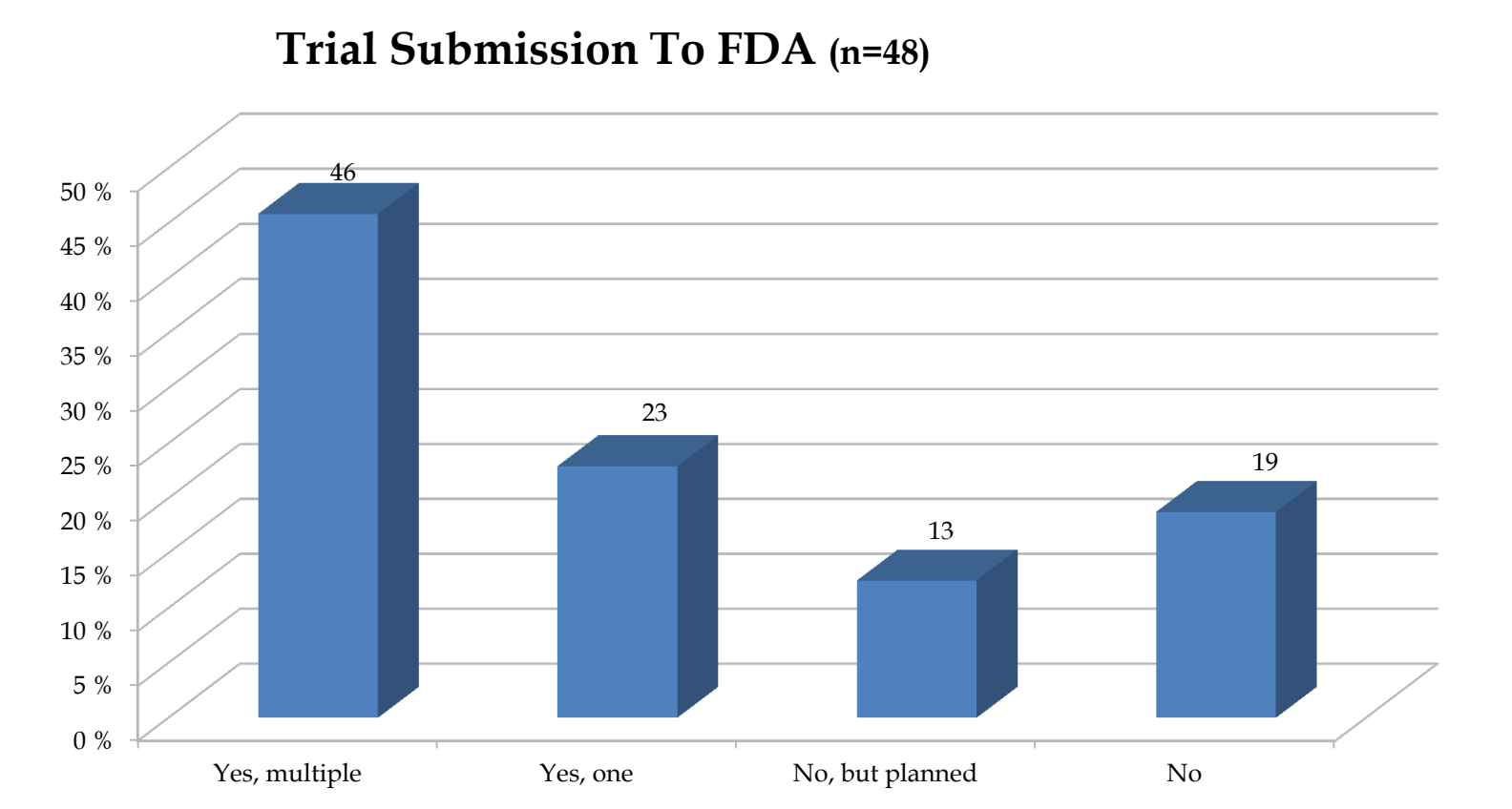

55% of respondents will audit the SEND process or not audit. 19% will audit as a study activity

# 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?



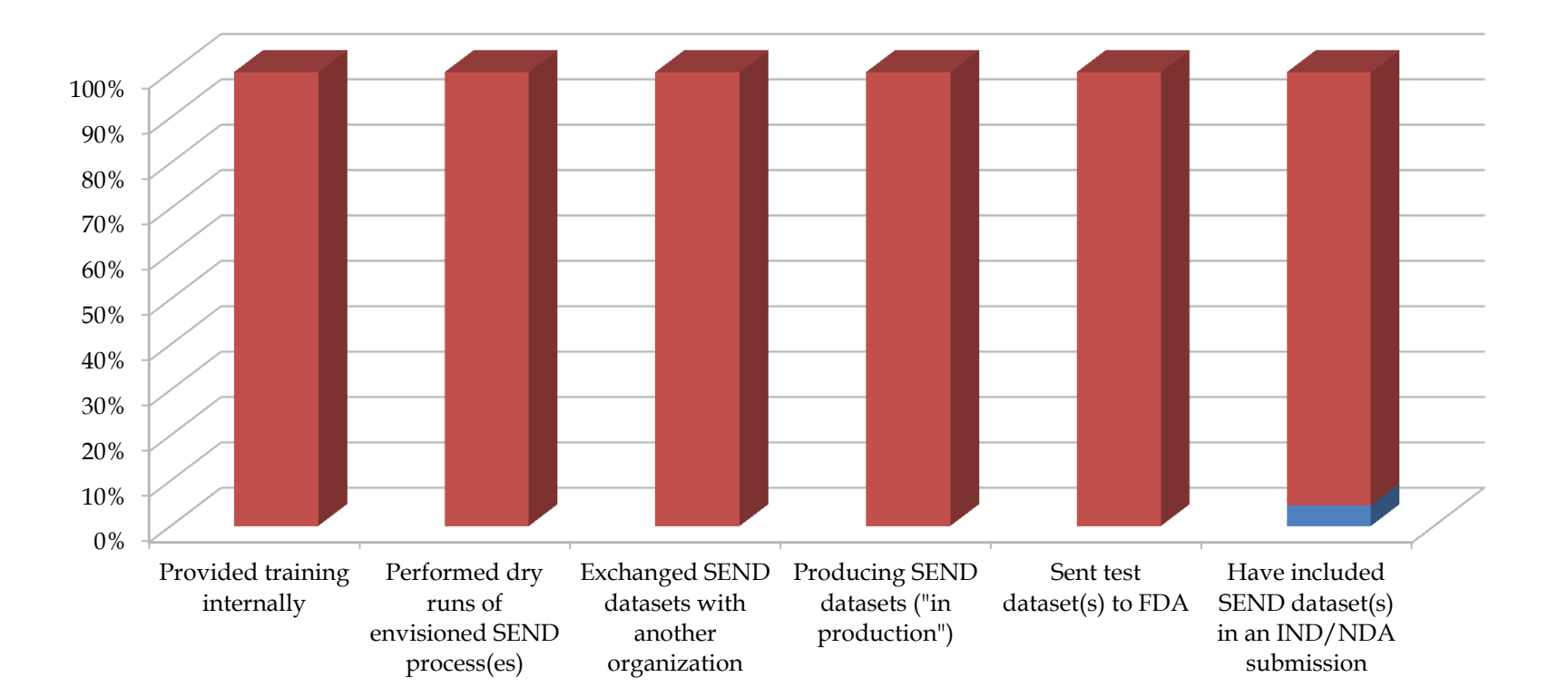



# Have you submitted a trial dataset to the FDA?




69 Percent of respondents have submitted at least one trial submission to FDA

# A Meter For Where We Want To Be




Working Toward The Final SEND Readiness Goal Of 100 Percent. How Can PhUSE Help All Of Us With SEND Readiness?

# Thank You To:

Wendy Dobson – PhUSE

All Survey Respondents

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

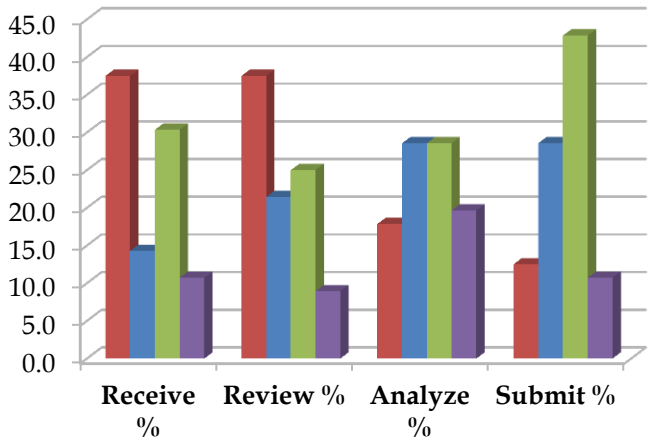
Yes

No

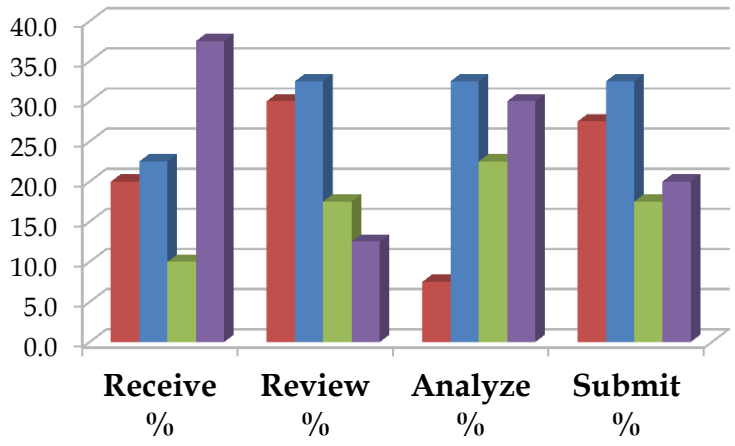
Partially

Not Applicable

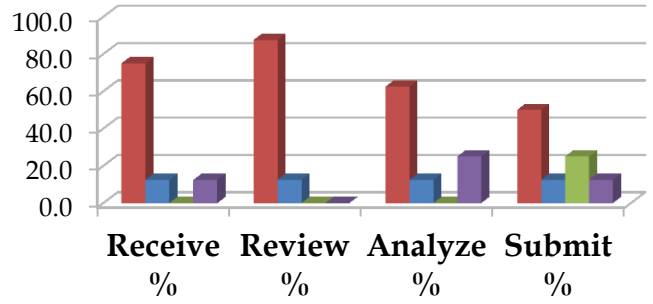
## Sponsor - Capabilities (N=56)



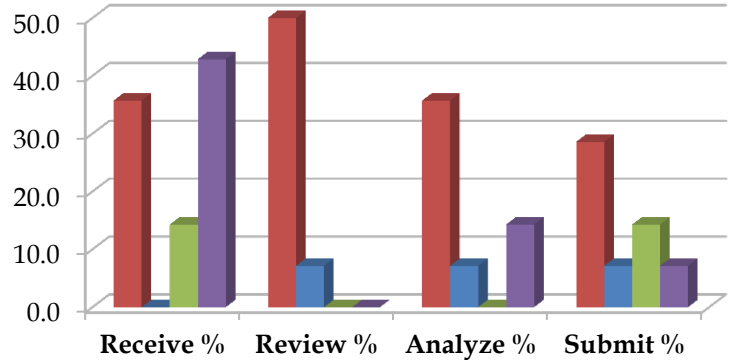

## CRO - Capabilities (N=40)




## SEND Service Provider - Capabilities (N=8)

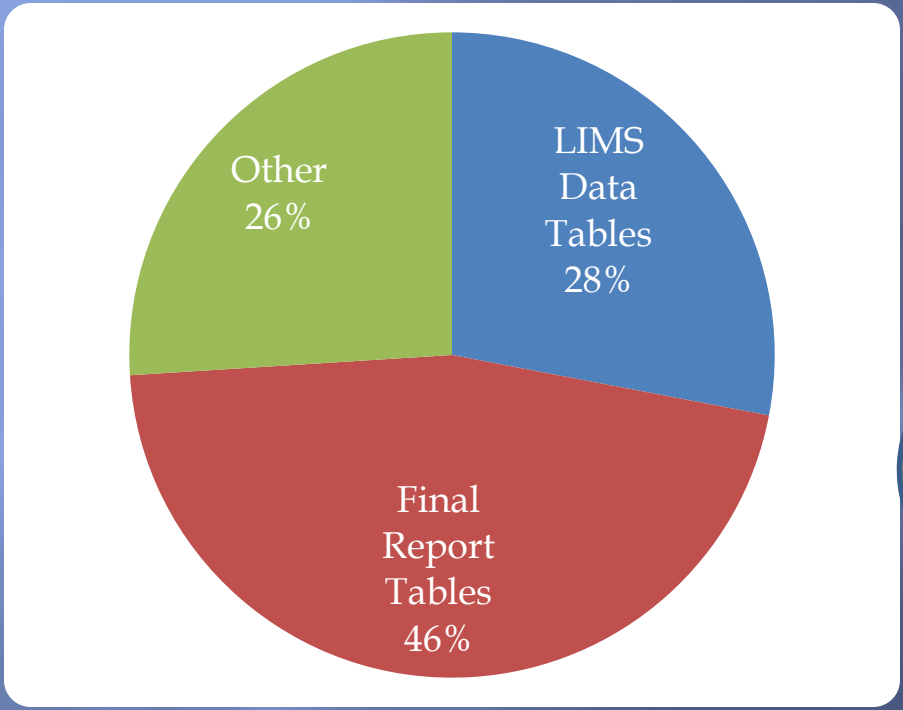



## Other - Capabilities (N=14)




Only SEND Service Providers are generally ready in all categories.

# 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