

# SEND Survey 2026

Authors: Lindsay L. Eickhoff (Inotiv), Vanessa Chavez (Labcorp), Chloe Bosworth (Inotiv), Jamie Riggs (Merck & Co.)

# Demographics

---

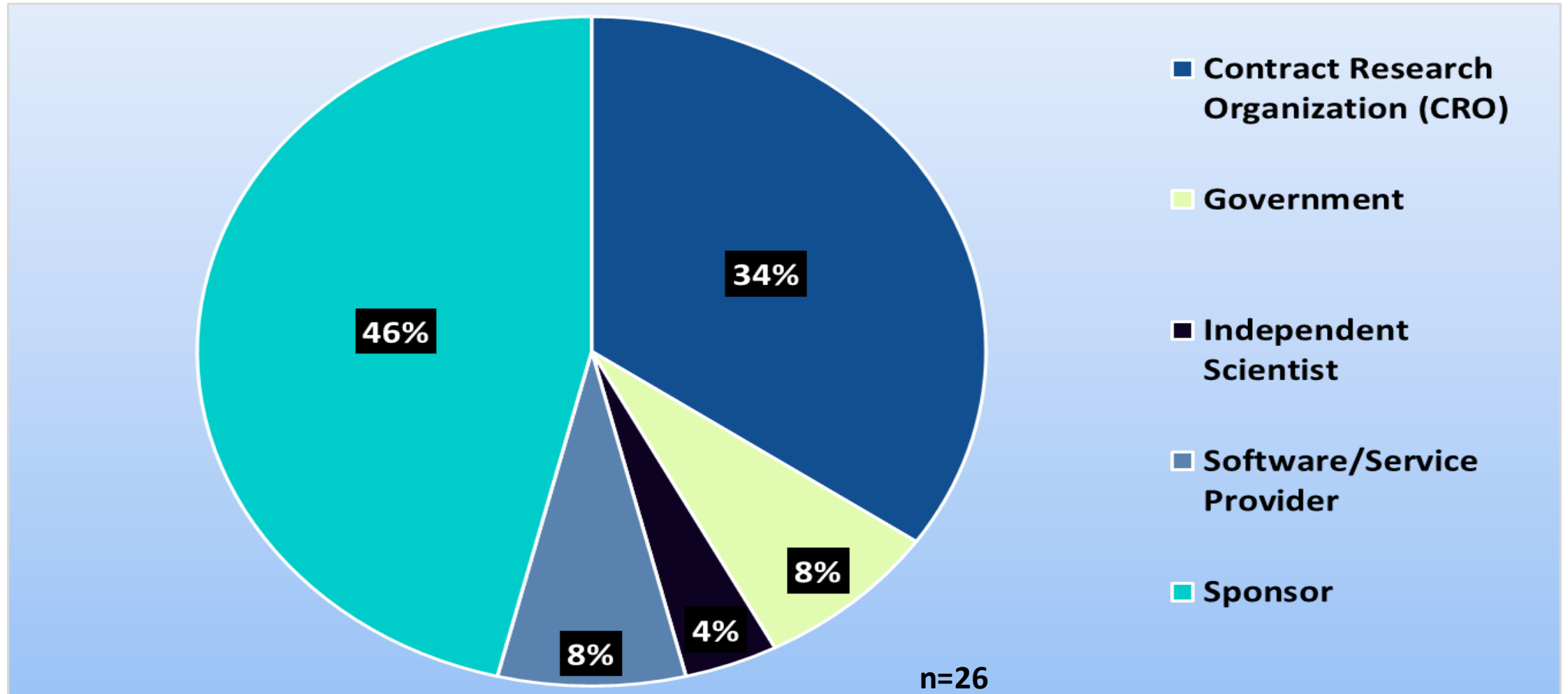


[phuse.global](https://phuse.global)

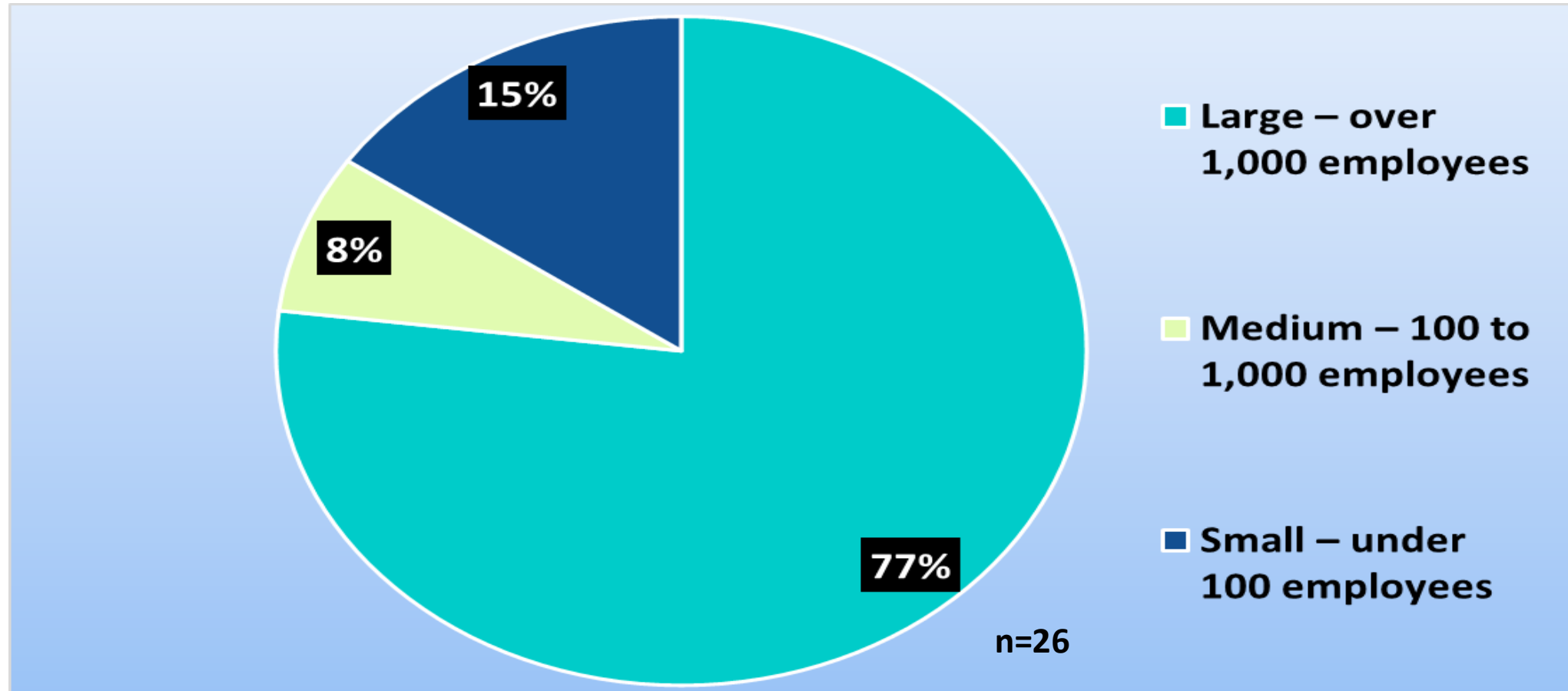
**Working  
Groups**



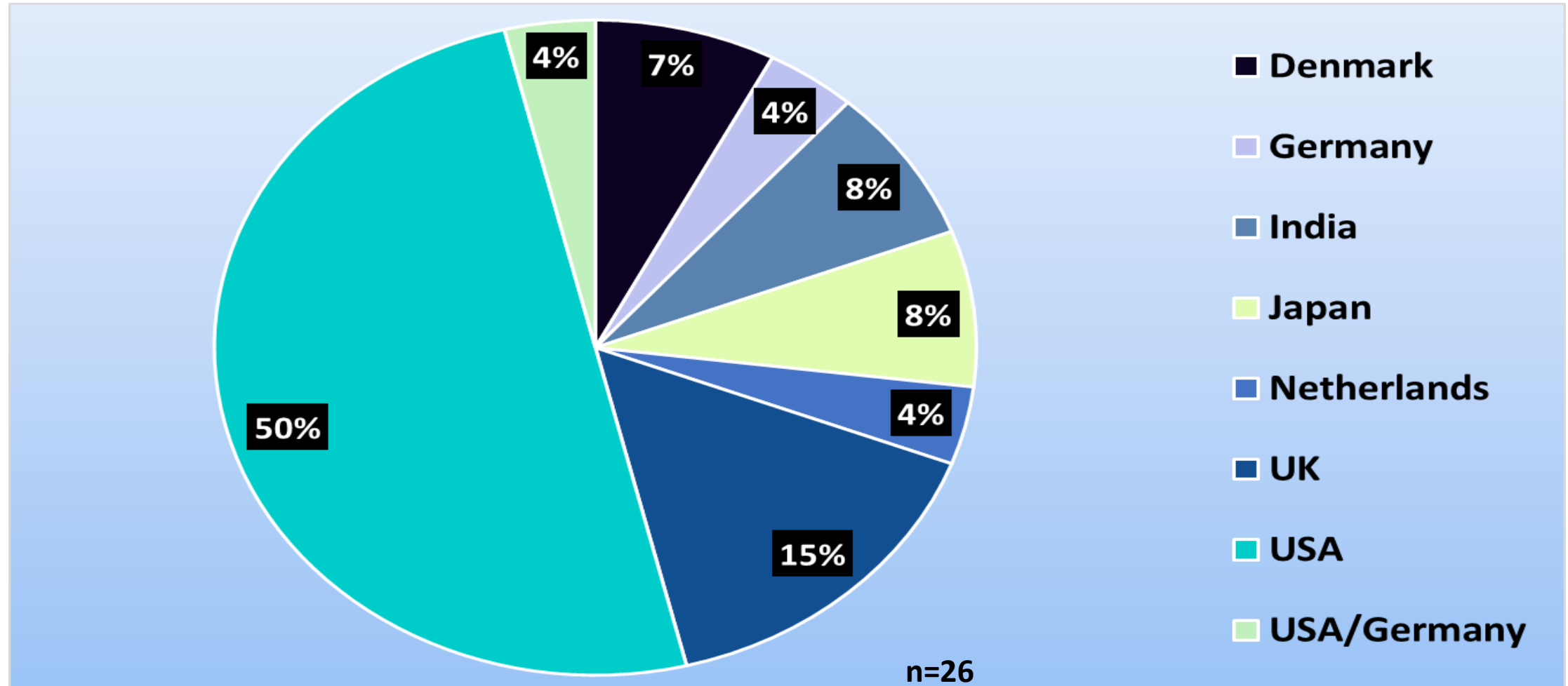
# What is Your Organization Type?



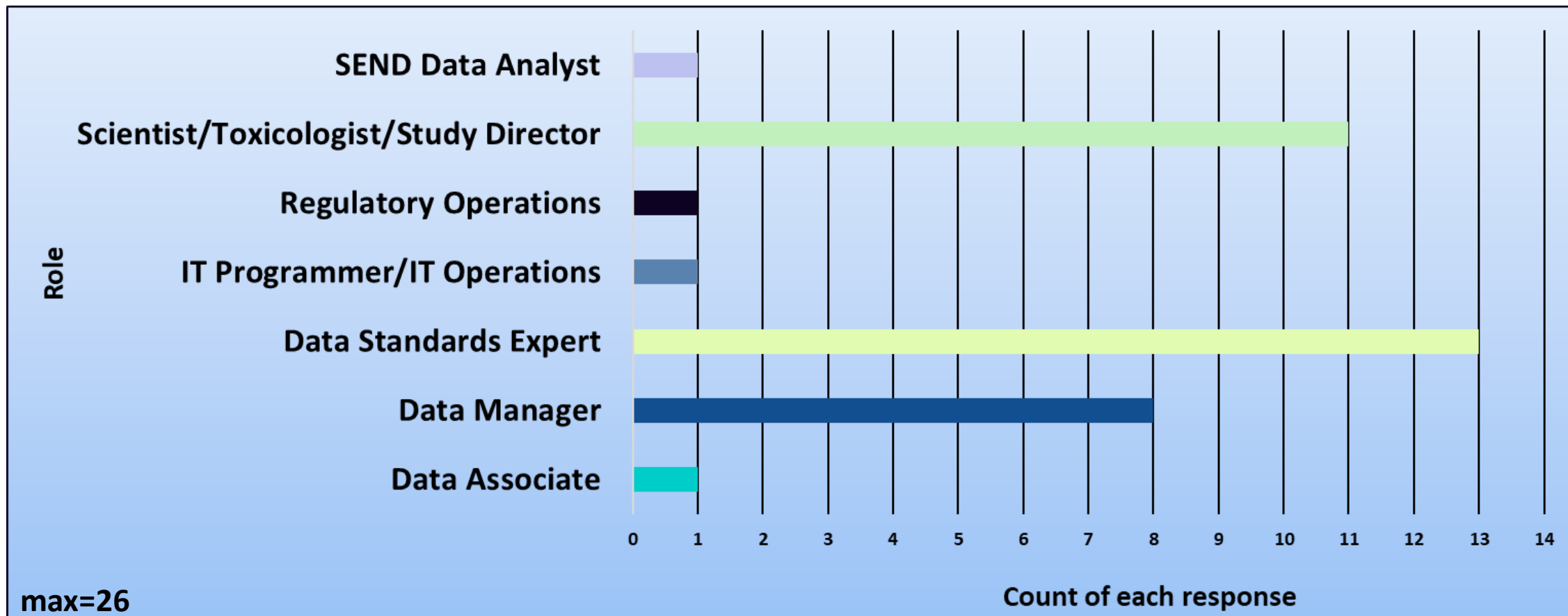
# How do you Characterize the Size of Your Organization?



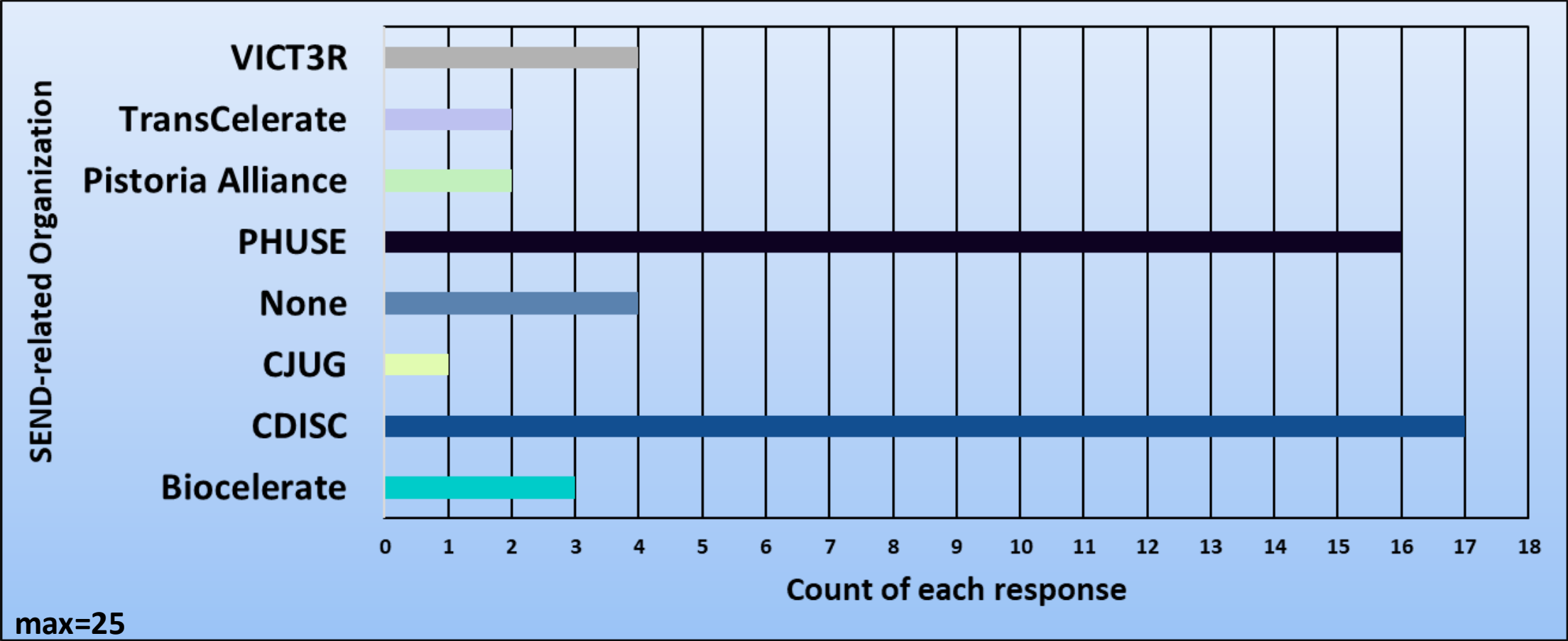
# What Country Are You Located In?



# How Do You Characterize Your Role In Your Organization?



# Select the SEND-related Industry Organizations that You're Involved With



# Responses

---



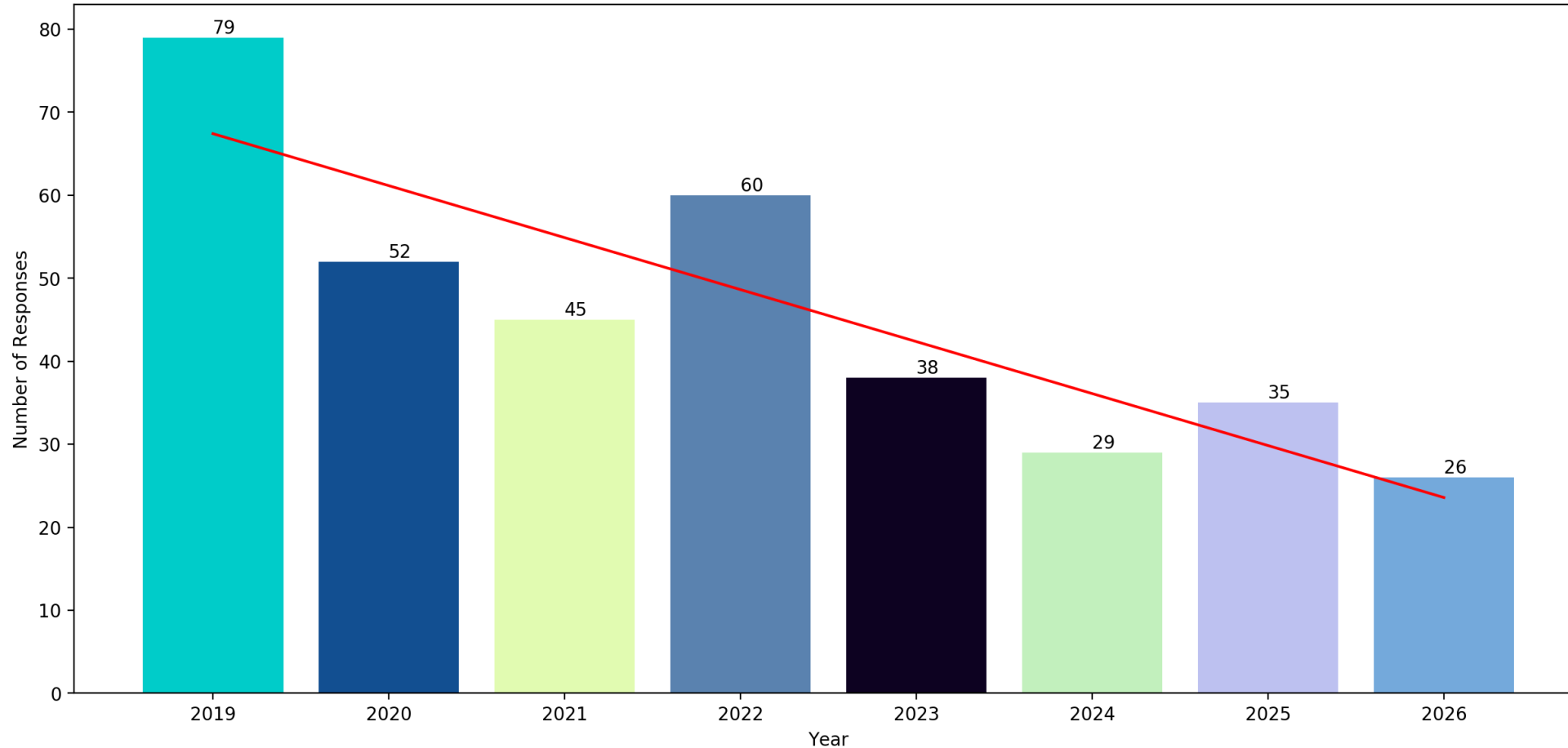
[phuse.global](https://phuse.global)

**Working  
Groups**



# Response Rate through the years

Number of Responses through years 2019-2026



## Trend

- Steady **decline** of responses through the years

## Discussion

- **9 less** responses than previous year
- Some responses are entered on a company-level rather than an individual-level



phuse.global

Working  
Groups

# Regulatory

---

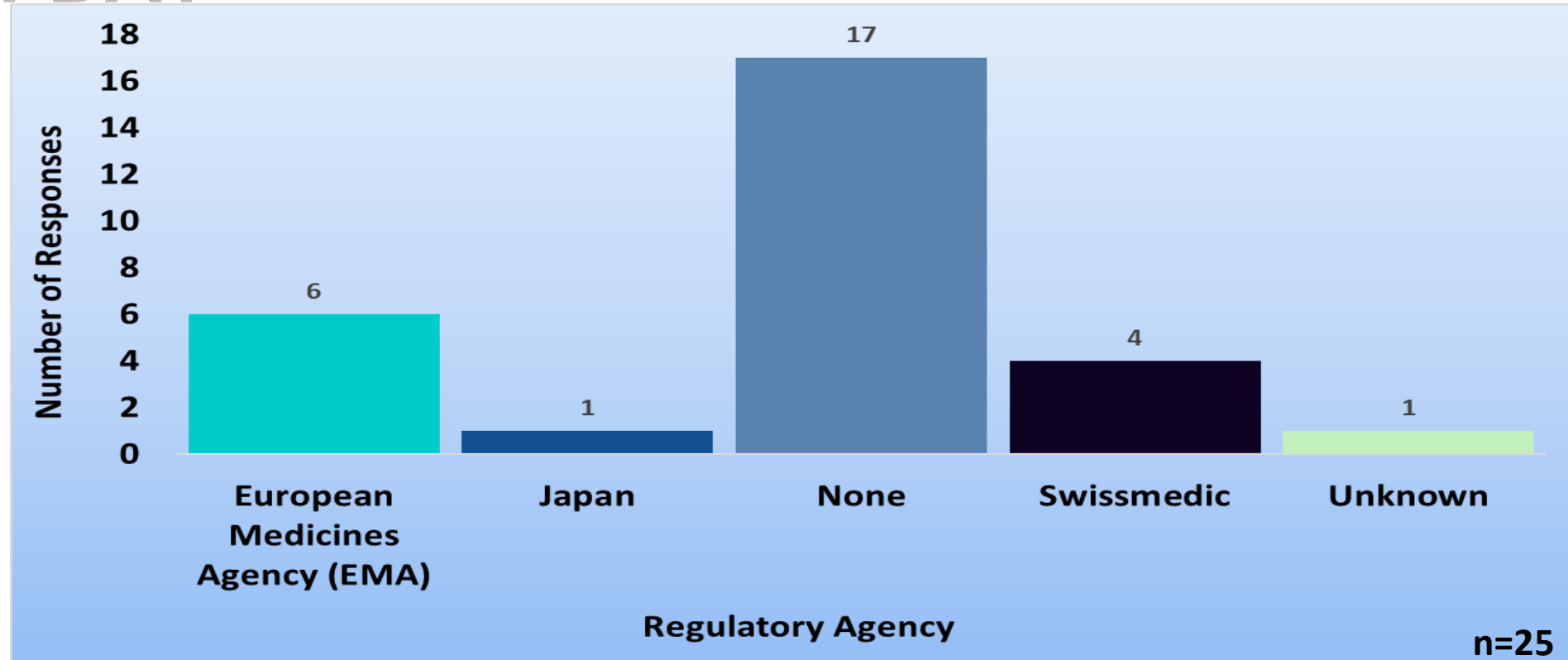


phuse.global

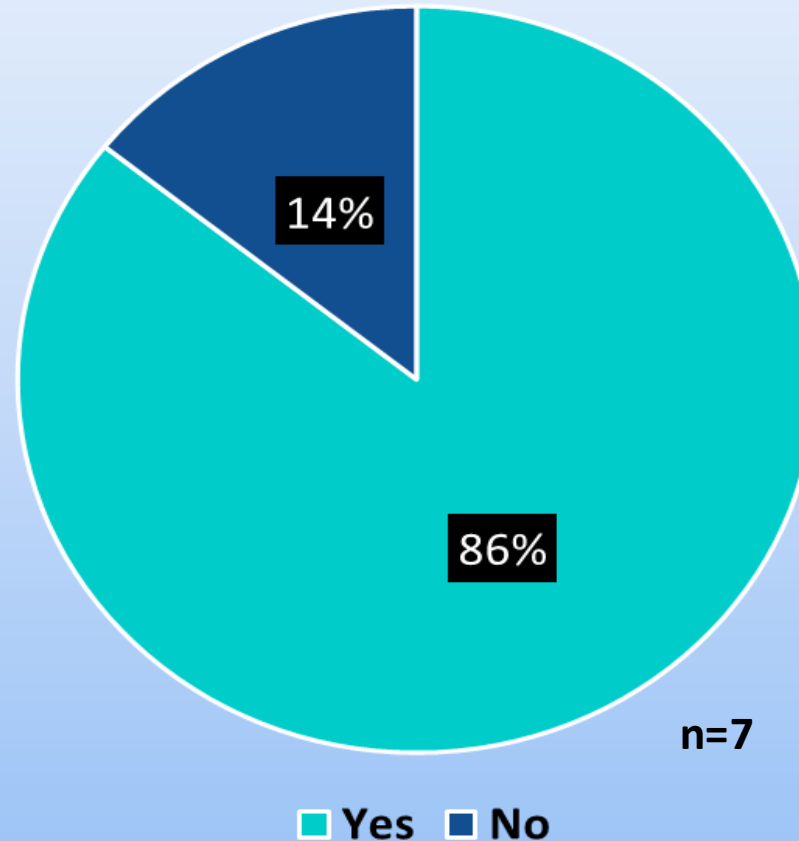
**Working  
Groups**



# Has your company been contacted to provide SEND data to regulatory agencies outside of the US/the FDA?



# If you selected an agency, did you provide the data?



**Note-**  
11 responses  
selected an agency in  
the previous  
question, of those  
11, 7 answered this  
question. Of the 7, 5  
submitted to EMA  
and 3 to Swissmedic.

# Please give your reasoning for providing or not providing the data

## Responses

- **EMA pilot** - internal recommendation to not participate in the pilot because of outstanding concerns regarding the protection of commercial confidential information within full datasets and the potential post-authorization data requests from third parties (EMA Policy 43.).
- **Swissmedic** - no applicable submissions containing datasets have occurred since the guidance was issued.

# European Medicines Agency (EMA)

---

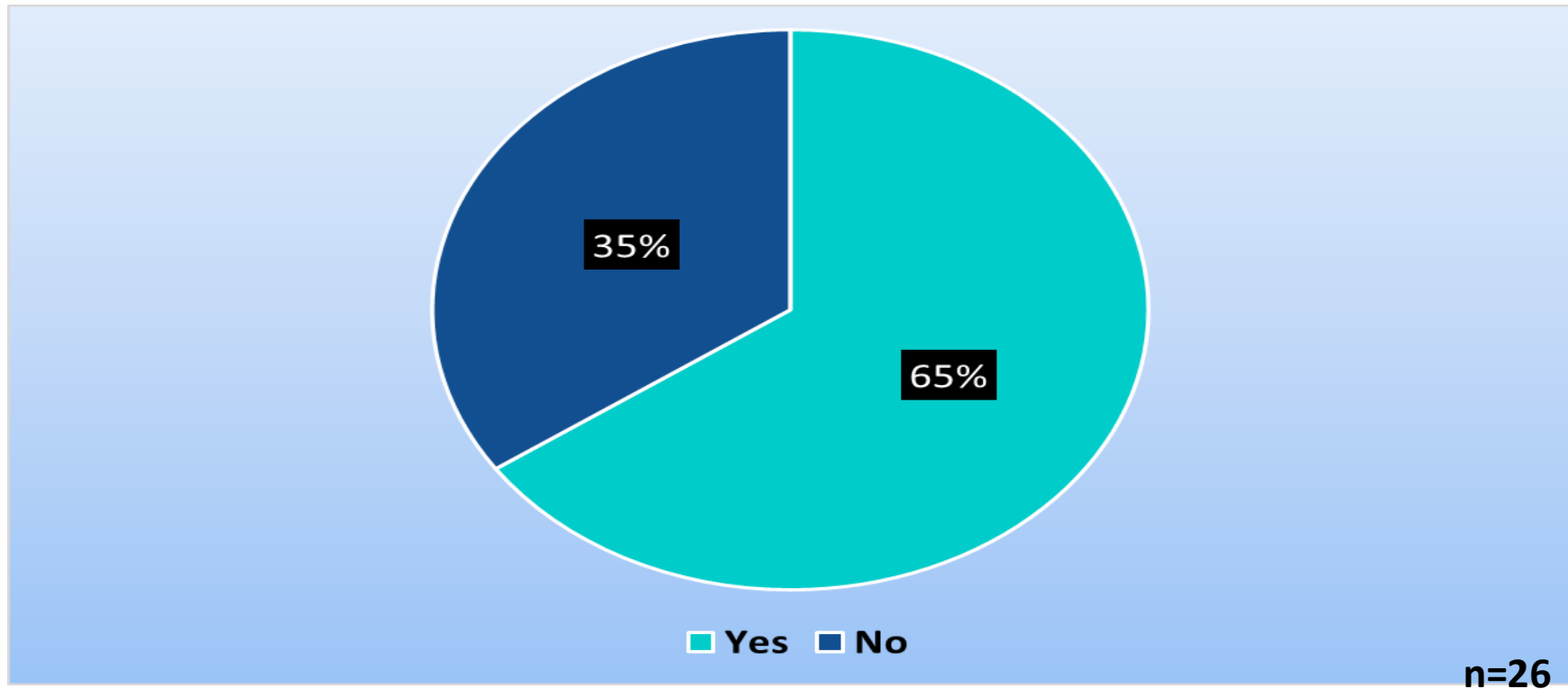


phuse.global

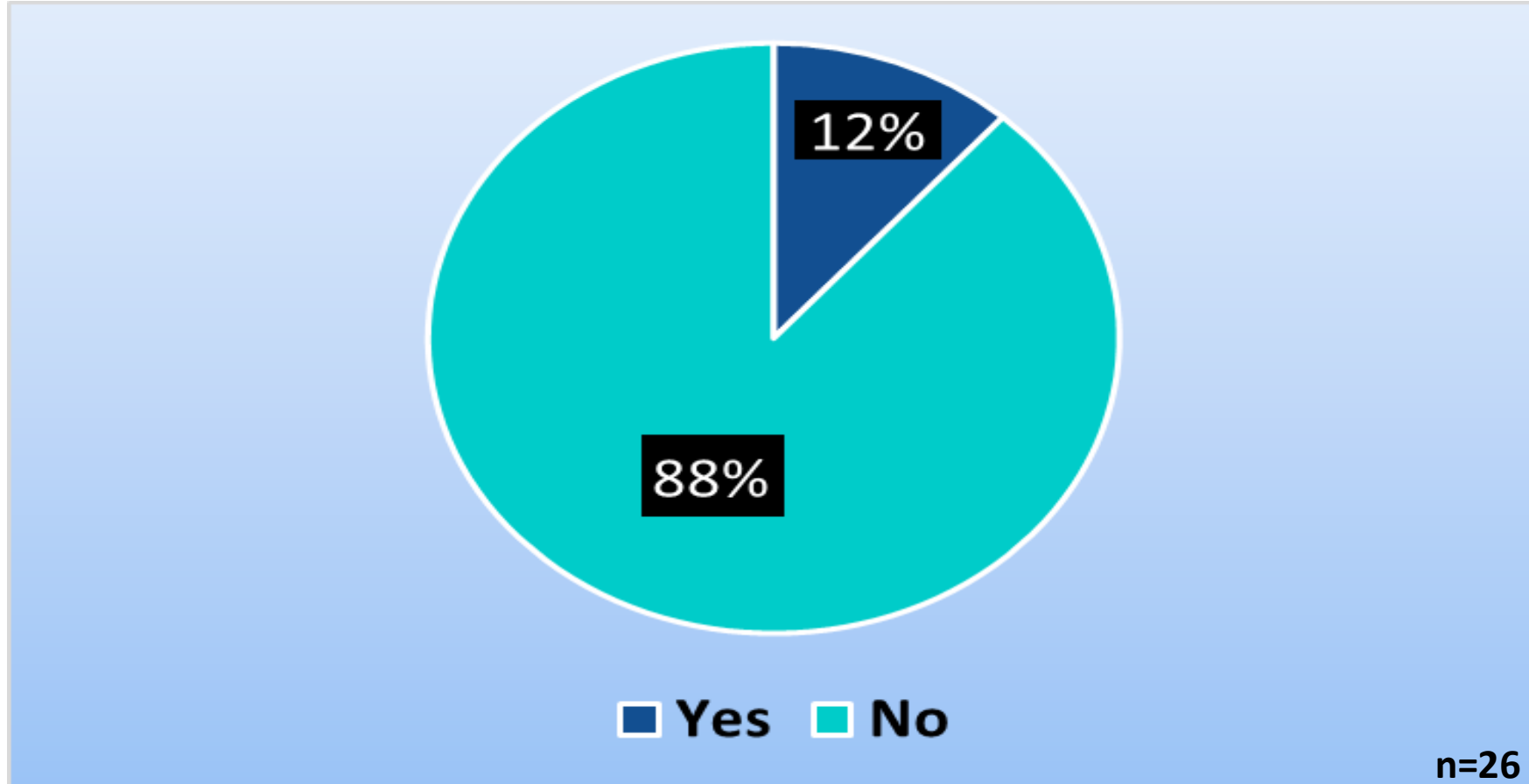
**Working  
Groups**



# Are you aware of the EMA's proof of concept pilot that started in January 2024 to test the feasibility of using SEND datasets?



# Are you currently submitting SEND datasets to the EMA?



# What trigger(s) would lead you to submit SEND data to the EMA?

## Responses

- Collaborative reviews with FDA. If your submission involves parallel scientific advice or work-sharing between EMA and FDA, SEND datasets might be requested for consistency.
- EMA request to sponsor to provide SEND datasets.
- Future regulatory changes EMA has shown interest in data standardization. If EMA adopts SEND in the future (similar to FDA), triggers could include: Marketing Authorization Applications (MAA), extensions or variations requiring detailed nonclinical data.
- Voluntary Submission Sponsors may choose to submit SEND datasets to EMA to: facilitate data transparency, support advanced analytics or data re-use.

# Challenges with SEND

---

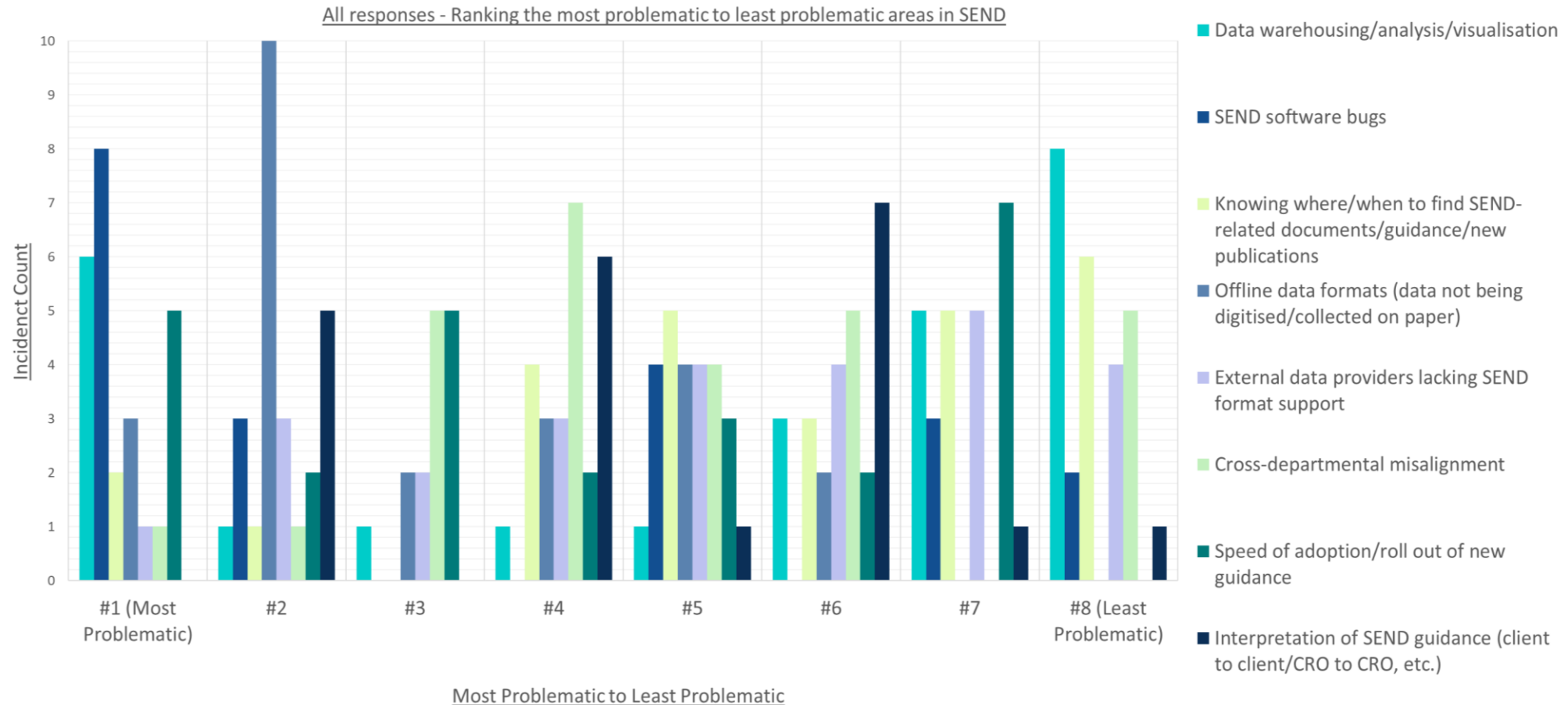


phuse.global

**Working  
Groups**



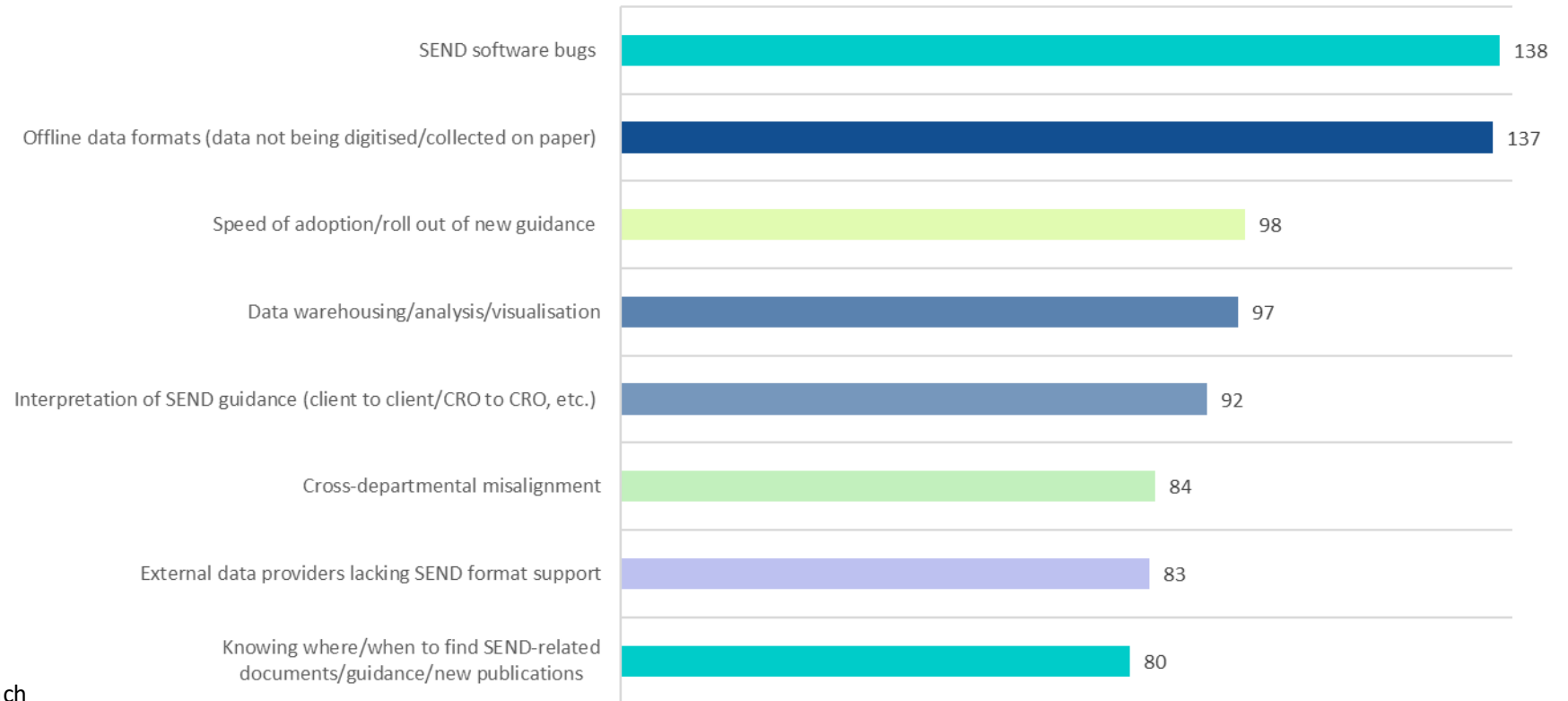
# All Responses - Ranking of Problem Areas in SEND



# Overall Ranking of Problem Areas in SEND

Total Score - Most Problematic to Least Problematic

Ranking



Total of ranked calculated value

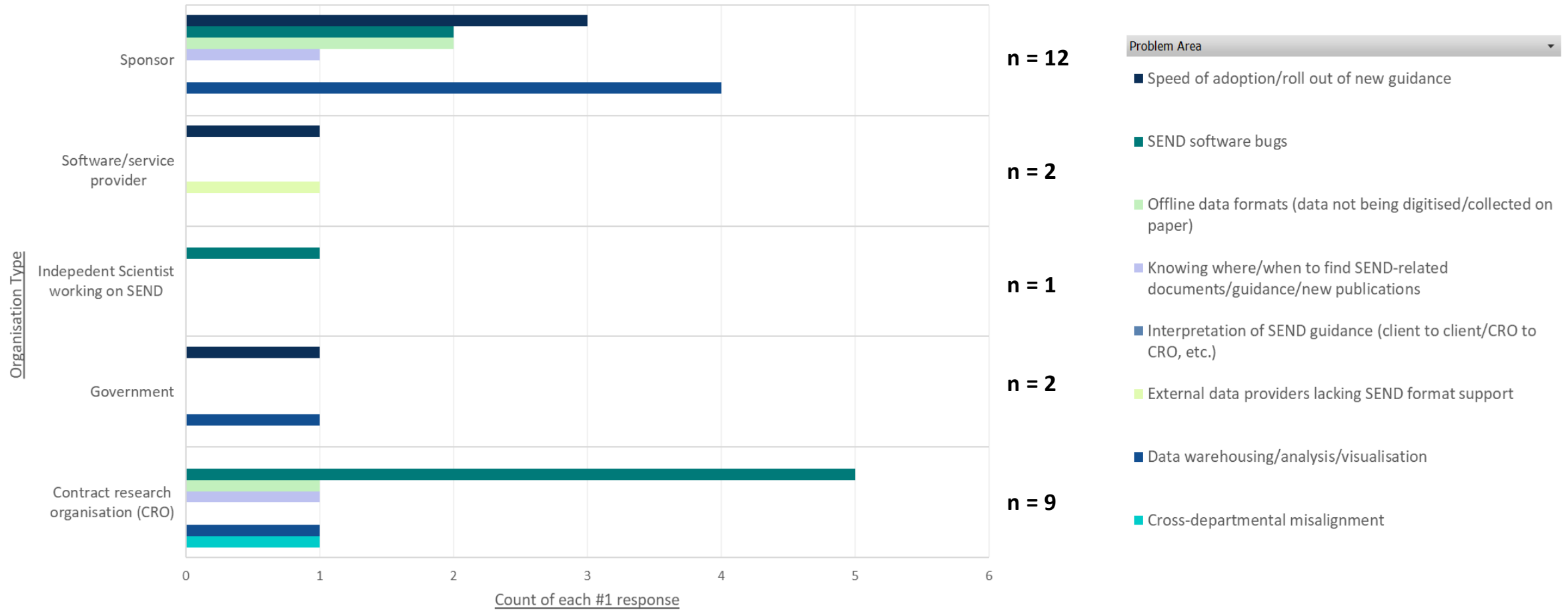
**n = 26**

The top 3 overall problem areas identified:

1. SEND software bugs
2. Offline data formats
3. Speed of adoption/roll out of guidance

Ranking was determined by assigning a value to each ranked slot (#1 - #8), then the assigned value was multiplied by the count of each problem area identified within that slot.

# #1 Problem Areas in SEND by Organization Type



Count of the number 1 ranked issue per response, per organization type

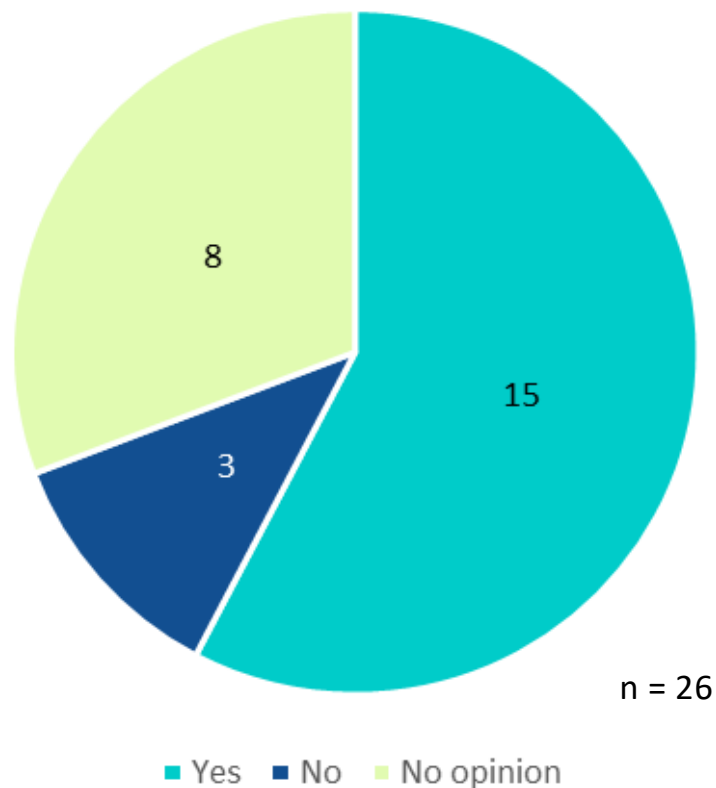
# Are there any other areas that you feel are problematic?

## Responses

- From CRO's
  - Additional Guidance on Tumor.xpt - Current guidance is not clear
  - The use of non-standard terminology
- From Sponsor's
  - Lots of study types, endpoints and results yet to be standardized
  - Lack of communication from FDA on SEND data quality
  - Lack of interpretative data (compound-related effects, NOAEL, etc.)
  - Long timelines for SEND software development by vendors and internal implementation (project planning, approval/funding, validation/testing)
  - Lack of software vendor options
    - Due to lack of options, this can hinder the adoption of SEND/SDTM in nonclinical areas that are not prioritized by a small group of decision-makers
    - Longstanding limitations and bugs in hardcoded systems have restricted global adoption and improvement of SEND implementations
  - Parallel workflows for study reports and SEND datasets often create discrepancies, requiring significant manual effort to reconcile

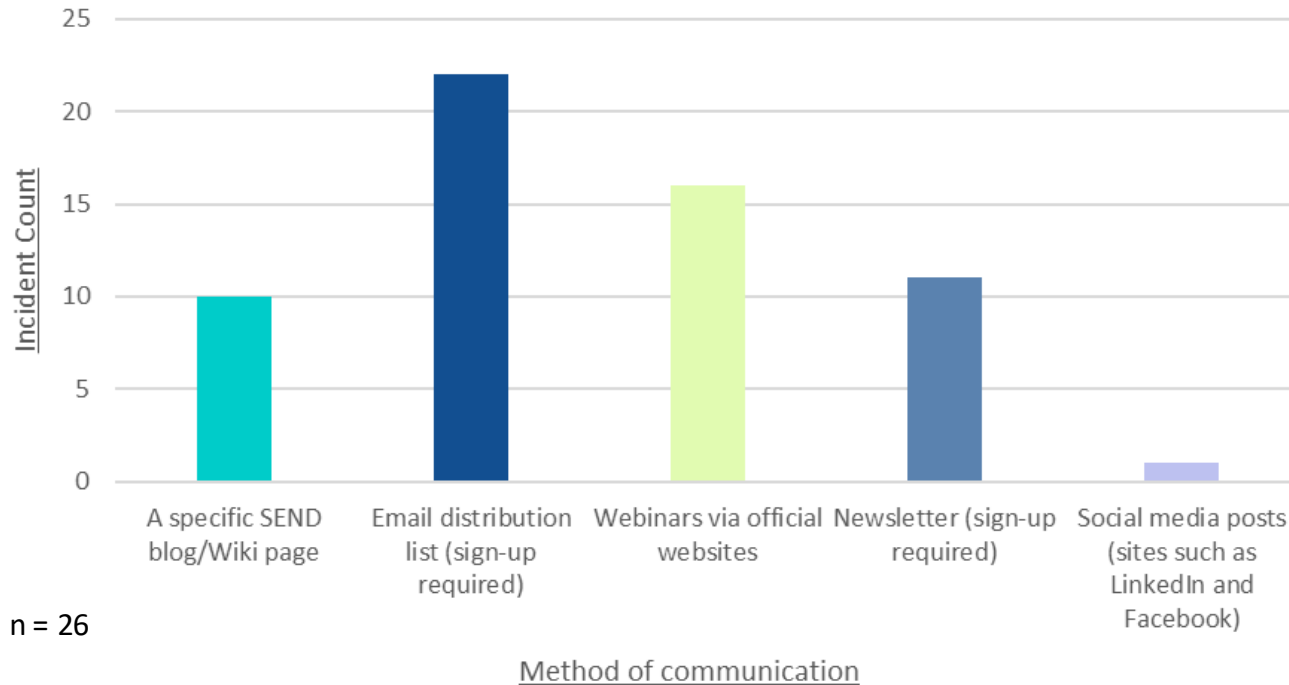


# Do you feel that SEND is supported within the industry compared with other CDISC standards such as SDTM and ADaM?



- 15 responded that SEND is supported within industry
- 3 responded that SEND is not as supported
  - Note - All responses were Sponsors
- 8 had no opinion

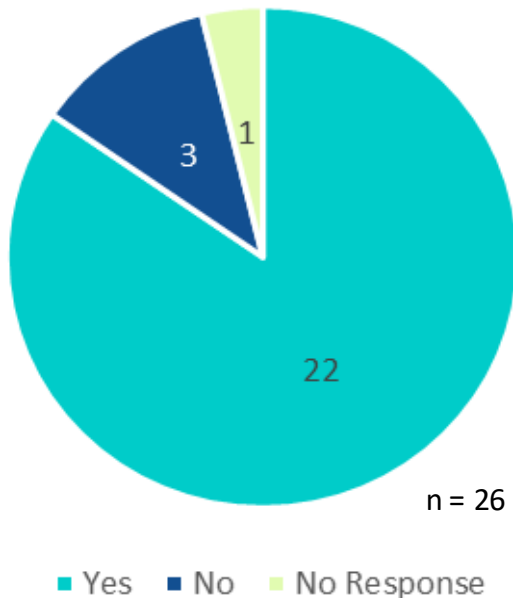
# How would you prefer to have information on SEND industry topics reach you?



- From the responses, an email distribution list (sign up required) is the preferred method requested, closely followed by official webinars, then a newsletter.
- Social Media posts were not desired with only one response.
- Furthermore, one respondent suggested to have more interactive sessions on SENDIGs.

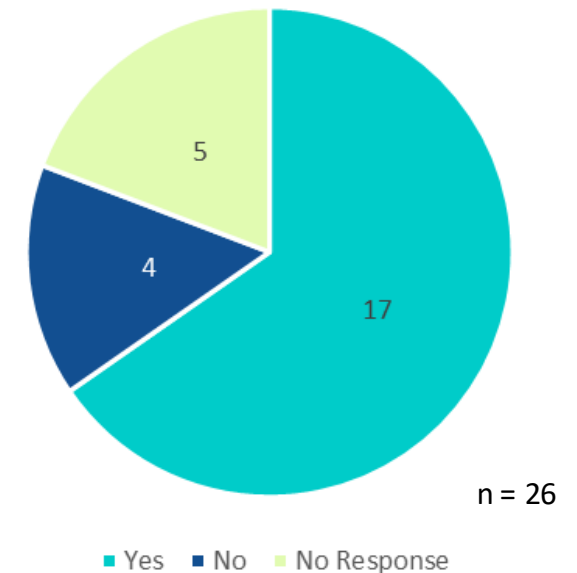
# Is there value in creating a PHUSE SEND information group?

Is there value in creating a PHUSE SEND information group

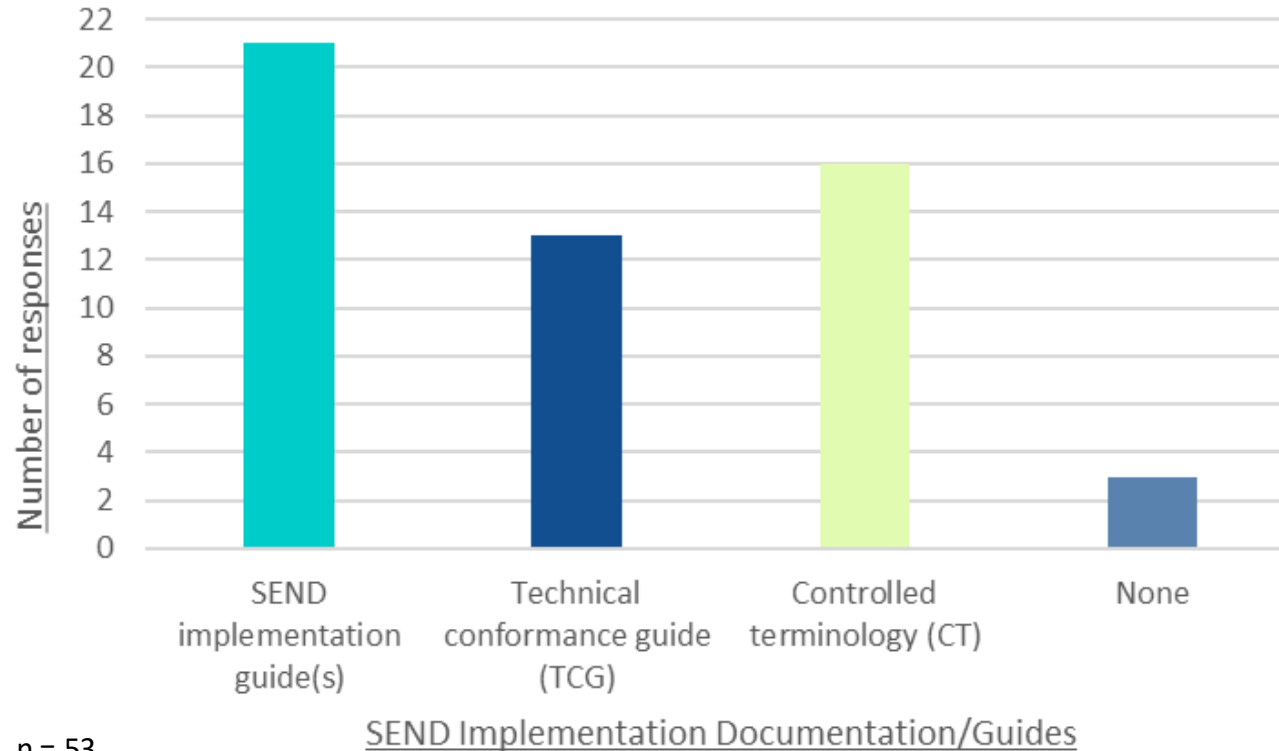


- There was an 85% agreement rate on having a PHUSE SEND group, with the aim being to create/manage/distribute the latest SEND information.
- Of those that responded "Yes", 65% of responders said their organization will allocate time for participation.

Is your organisation willing to allocate time for participation in a SEND information group?



# Which of the following do you feel your software provider keeps up to date?



- 3 responses of "None" were received indicating that the applicable organization feel the vendor used does not keep up to date with the available supporting documents/files.
- CT and TCG responses were reasonable but there is room for improvement.
- Overall, there was a good response on vendors keeping up to date with the SENDIGs.

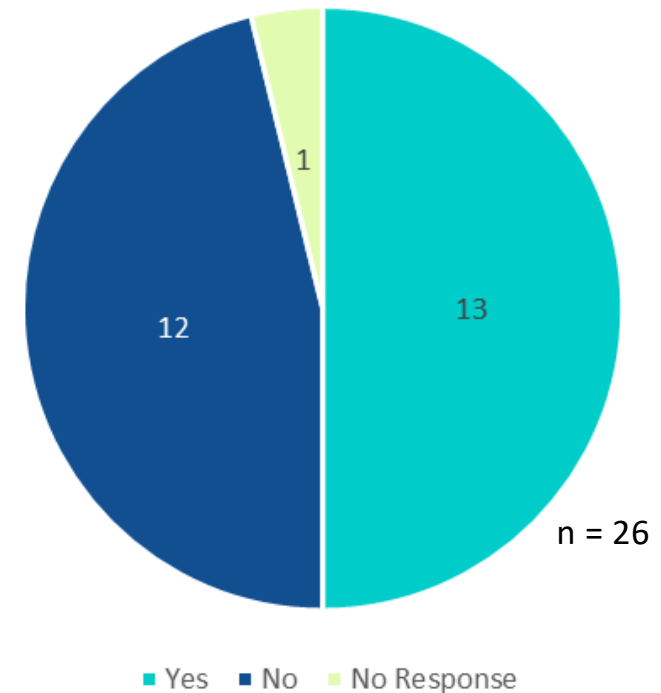
# What would you like SEND software providers to prioritize?

## Responses

- Coding:
  - Bug fixes
  - Robust coding so the application can handle cases outside of the simplest standard scenarios.
  - Correcting software bugs and testing to minimize number of bugs in future releases.
- Keeping us (vendor client) updated with information more efficiently (fixes/new releases/etc.)
- Being proactive:
  - Starting development earlier in the IG publication lifecycle to better support piloting of new standards.
  - Have new published SENDIG's available even before requirement kicks in.
  - Implement TCG guidance quicker.
  - Keeping controlled terminology and validator engines up to date.
  - Having production software match the current IG requirements.
- Ease of SEND generation:
  - Automate more to drive down costs of dataset creation: therefore, lowering drug cost for consumers.
  - Improving/expanding automated data flow from collection/electronic protocol to SEND.
- Visualization of data and data integrity

# Have you discussed with a SEND software provider the changes that are coming with SENDIG v4.0 and what their adoption process looks like?

- 50% of responses indicated to having discussed with their software supplier the upcoming SENDIG v4.0 changes.



# Without naming specific applications, what areas in SEND software could be improved?

## Responses

- SENDIG Compliance / Proactiveness:
  - With new guidance/IG/TCGs, White Papers, etc. (Go live readiness).
  - JSON dataset readiness.
- Automation:
  - Integrated validation/business rule checks.
  - Controlled Terminology handling / updates.
  - Mappings, multiple software applications have incorrect mappings, or rely heavily on custom coding to correct mapping errors.
  - Automated baseline flag population.
  - Trial domain curation.
  - Batch manual edits.

# Without naming specific applications, what areas in SEND software could be improved?

## Responses - Continued

- Performance:
  - More rigorous QC by the vendor to ensure the application can handle more complex studies, not just the simplest standard ones.
- Data visualization:
  - Analysis of SEND data while the study is ongoing.
  - Better comparison of changes between different versions of the same dataset.
- More providers within the industry.
- System validation processes being subpar and complicated. This should be easier on customers.
- Supporting custom domains.
- More logical User Interface/ intuitive user interface.
- Define creation, appears to be so much of an afterthought that it is created in applications outside SEND software.



# Defining a Data Standards Expert

---

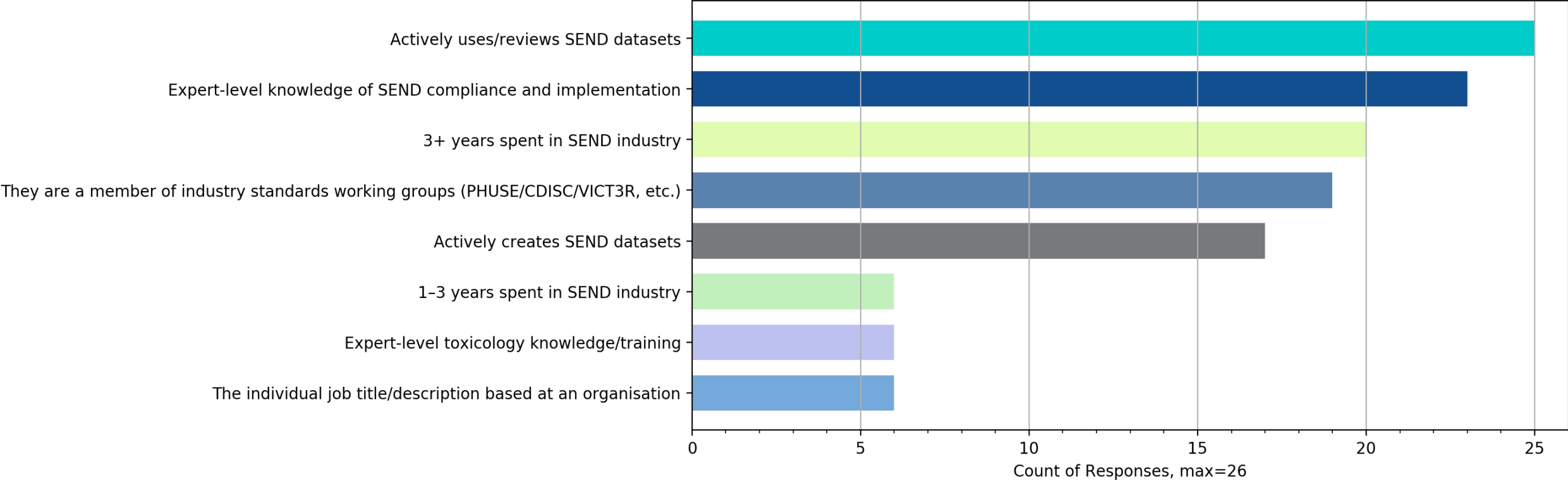


phuse.global

**Working  
Groups**



# When defining an "SEND Data Standards Expert", which of the following attributes would you say applies to this title? Select all that apply.



phuse.global

Working  
Groups

Cross-functional  
knowledge in  
industry

Documented  
official CDISC or  
company-specific  
training in CDISC  
SEND

Expert-level  
problem solver

## What other attributes define an "SEND Data Standards Expert"?

Experience guiding  
data scientists  
leveraging SEND  
data

Quality of  
understanding vs.  
time spent in  
industry

Knowledge of data  
collection and  
submission  
processes



phuse.global

**Working  
Groups**

# Post-Publication Preparation of SENDIG v 4.0

---



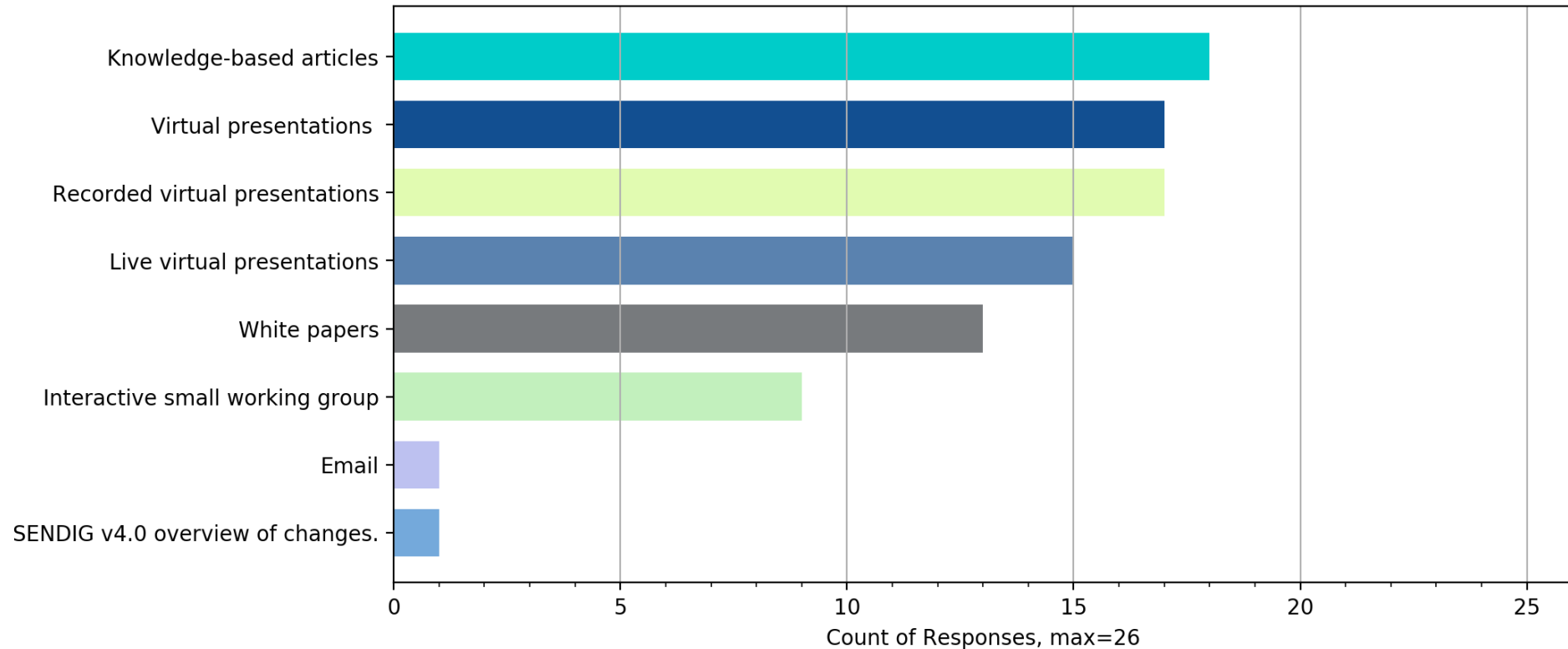
phuse.global

**Working  
Groups**

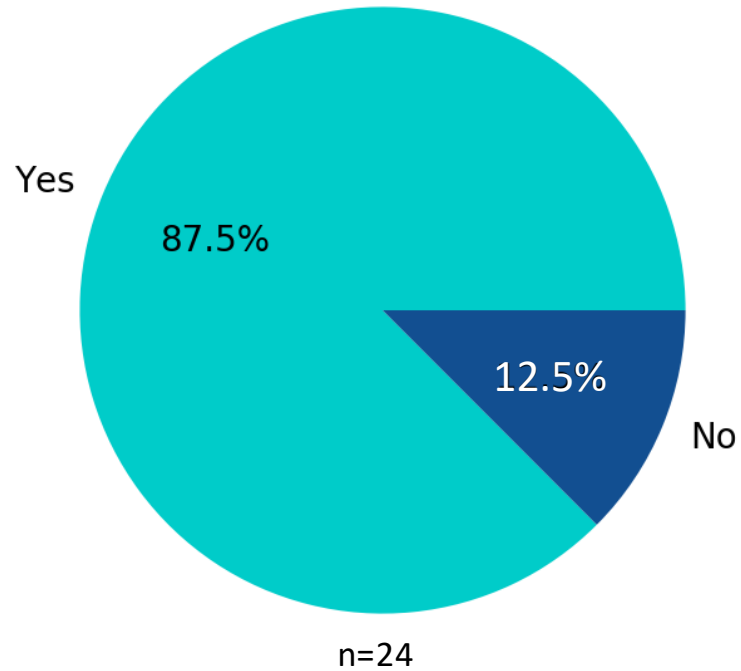


# How would you like to receive resources for the new material that has been added to the SEND IG v4.0?

Select all that apply.



# Would you like a platform to be developed to submit questions/concerns that arise regarding SEND v4.0 (potential new PHUSE team)?



- The data suggests that action should be taken to provide a platform to prepare for SEND v4.0 questions
  - This could be due to the large number of changes that will be seen in SENDIG v4.0

# Implementation Comparisons

---



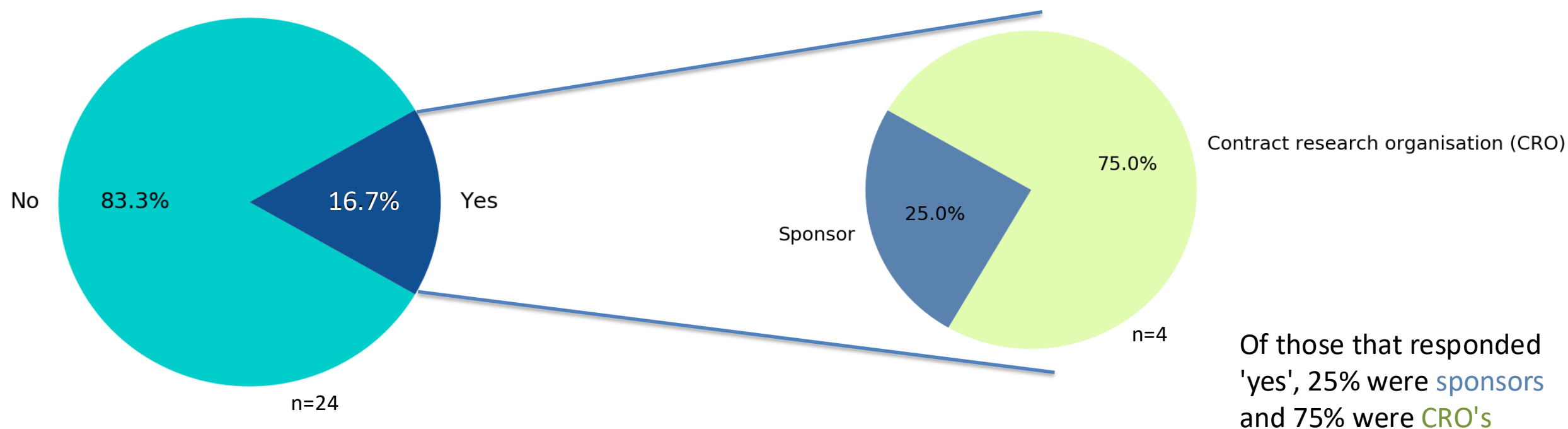
phuse.global

**Working  
Groups**



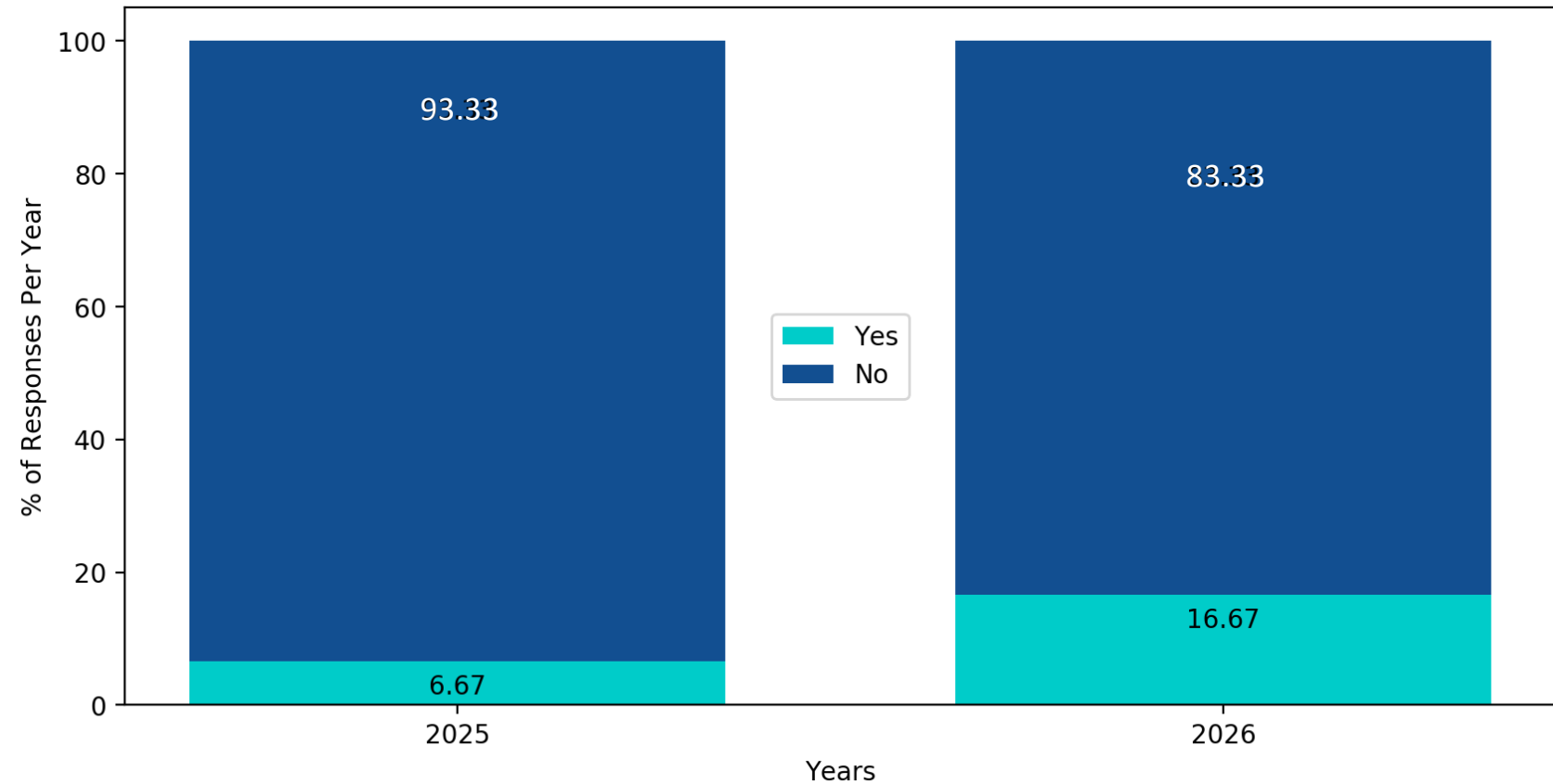
# Is your company using Virtual Control Groups (VCG's)?

**16.7%** of respondents confirmed use of VCG's

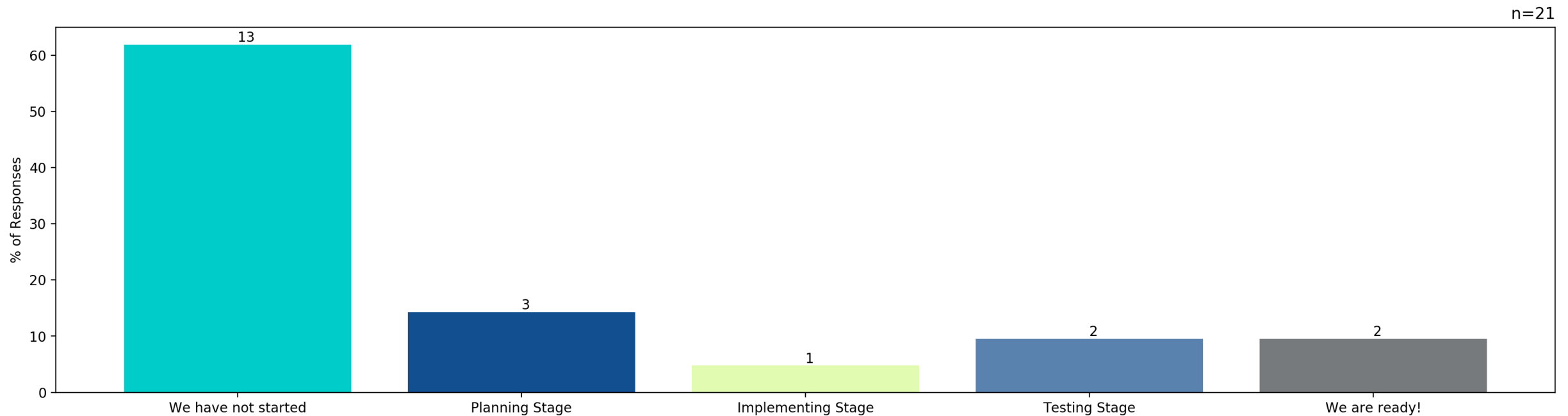


# Reported VCG use between 2025-2026

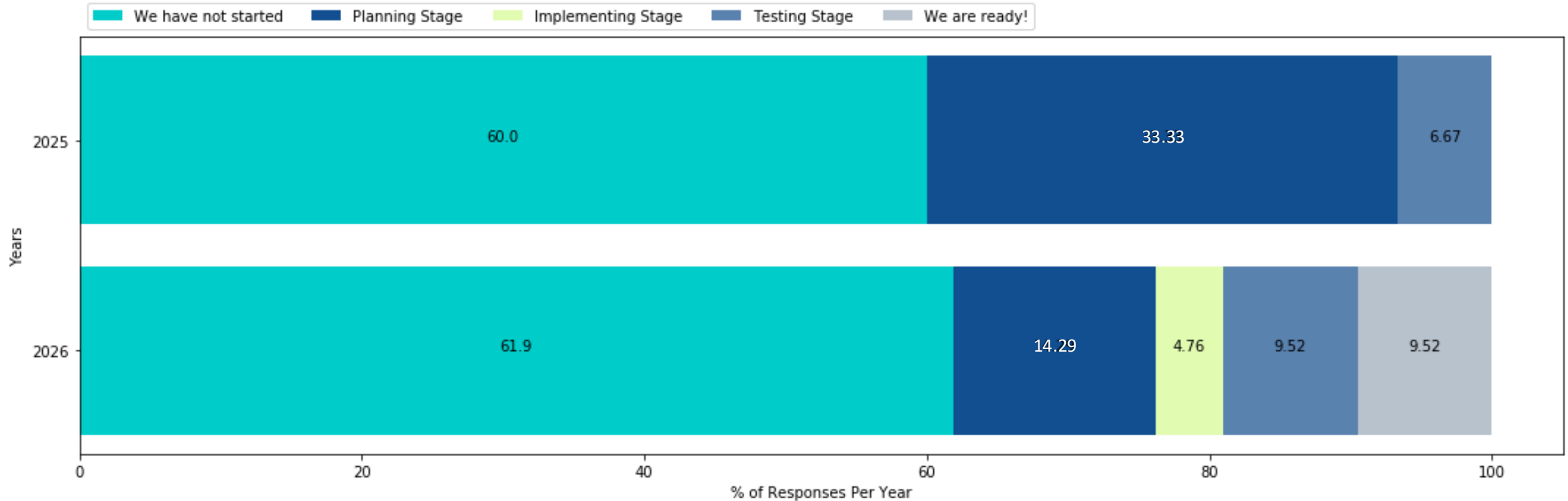
- Decrease in “**No**” responses by 10% between 2025 and 2026
- Increase in “**Yes**” responses by 10% between 2025 and 2026
- This change suggests there are organizations that are beginning to implement VCGs



# To SEND VENDORS/CROs/Sponsors - What stage of implementation are you in with Dataset-JSON for importing, exporting, and/or visualizing data?

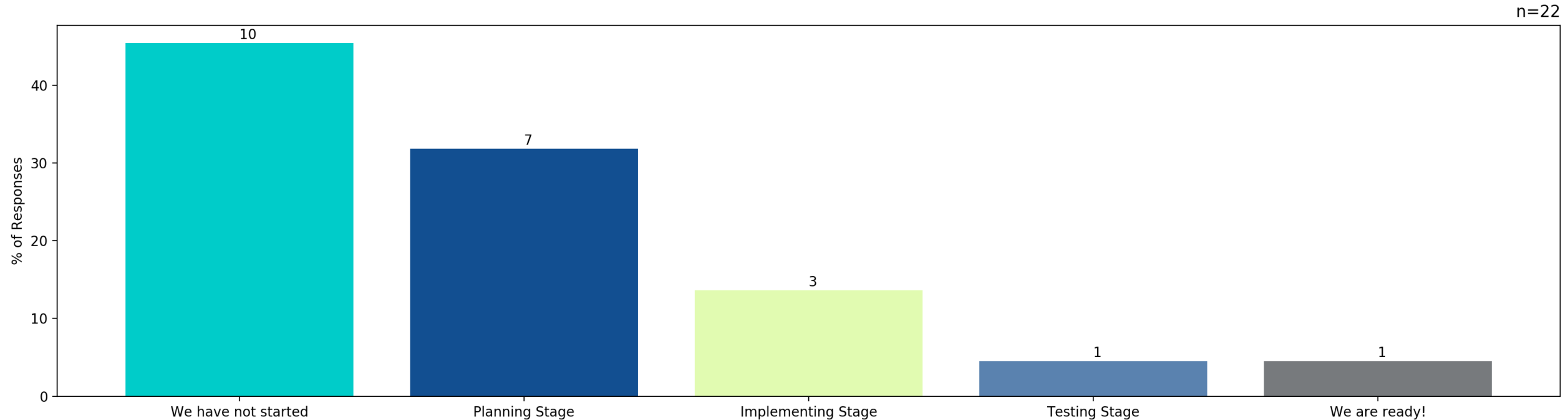


# Implementation of Dataset-JSON between 2025-2026

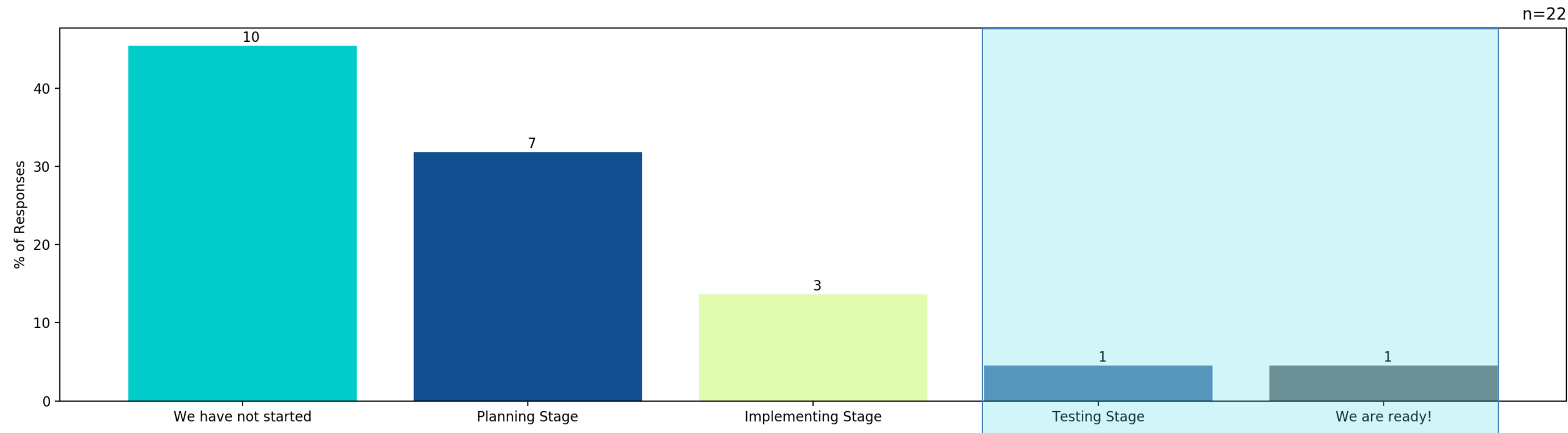


- Similar percentages of 'We have not started' between 2025 and 2026.
- 'Planning Stage' have started shifting towards **Implementing**, **Testing**, and **Ready** stages.

# Have you begun implementation of SENDIG 4.0? If so, what stage are you in?

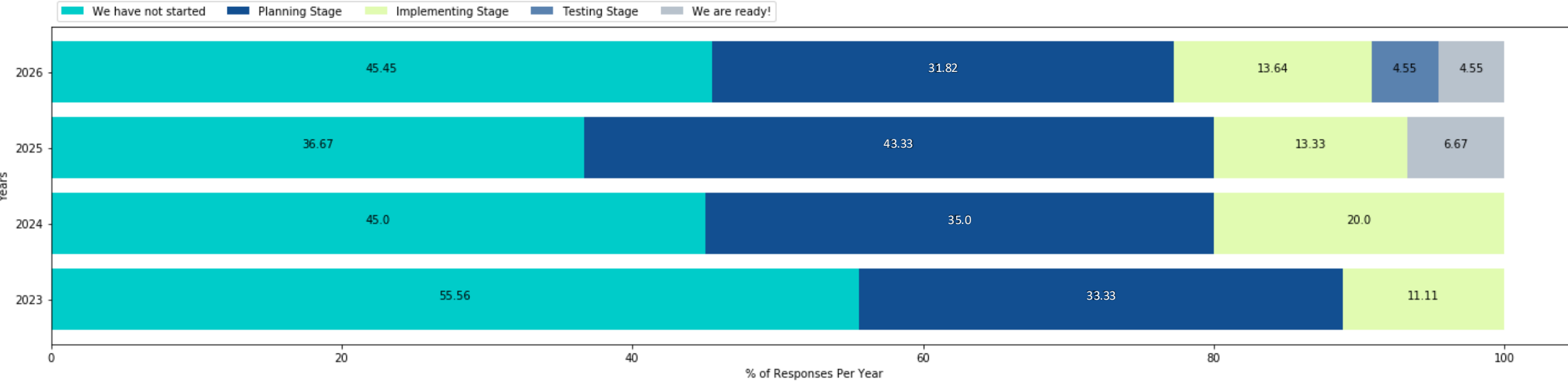


# Implementation of SENDIG 4.0 - Data Analysis

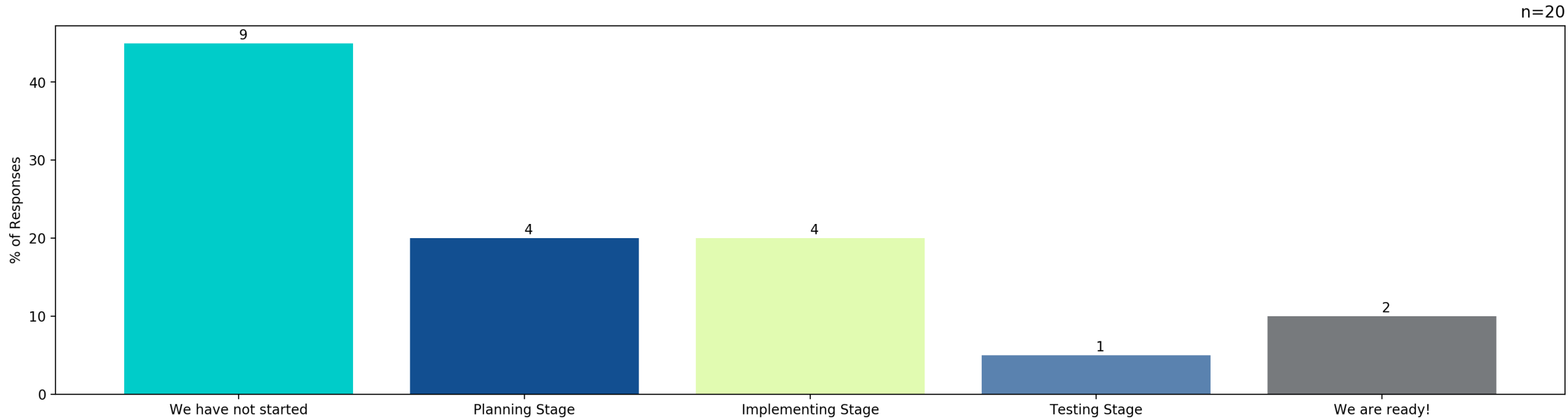


All responses labeled “Testing Stage” and “We are ready!” are from organizations classified as **CROs**.

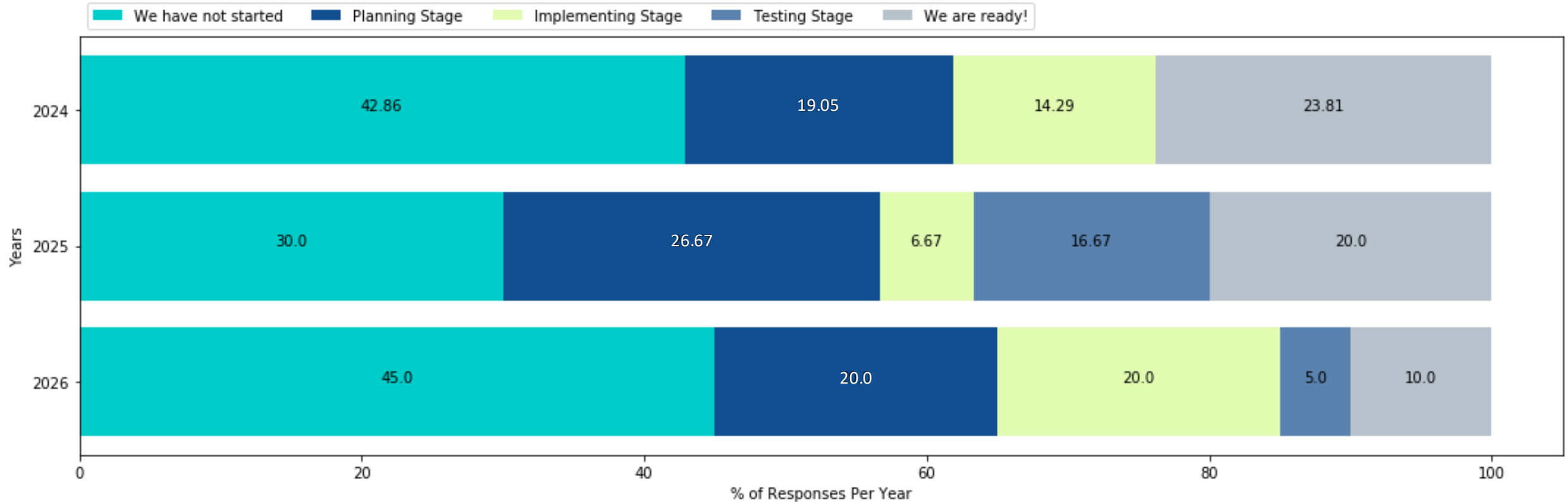
# Implementation of SENDIG 4.0 between 2023-2026



# Have you begun implementation of SENDIG DART 1.2? If so, what stage are you in?



# Implementation of SENDIG DART 1.2 between 2024-2026



# Future CDISC and PHUSE

---



[phuse.global](https://phuse.global)

**Working  
Groups**



# What are the next biggest gaps in SEND implementation standards that you would like to see developed by CDISC?

## Responses

- A way to represent test article related effects in a standard format/ Study Report domain (compound-related effects, NOAEL).
- Better handling of Dose Formulation and Analytical Data Gap: SEND does not fully capture formulation analysis or stability data. Need: Domains for: Dose preparation details, Analytical verification results.
- Complex study designs gap: Current SEND implementation struggles with non-standard study designs such as: Exploratory toxicology studies, Combination therapy studies, Adaptive or non-GLP studies. Need: Clear guidance on how to represent these in SEND datasets without forcing them into rigid structures.
- Digital pathology image algorithm result standardization.
- Harmonization with other standards gap: SEND is siloed compared to SDTM and ADaM. Need: Improved cross-standard mapping for integrated submissions and translational research.
- Integration with Omics and Biomarker Data Gap: Increasing use of genomics, proteomics, and biomarker data in nonclinical studies is not well supported. Need: CDISC should define: How to link omics datasets to SEND domains. Metadata standards for biomarker qualification.
- Metadata and traceability gap: Limited ability to trace back to raw data or study reports. Need: Enhanced metadata standards for: Data provenance, Audit trails.
- Unmodeled study designs such as: In Vitro NAMS data/Genotoxicity studies/Photo Tox.
- Veterinary observations and treatments.



phuse.global

**Working  
Groups**

# What are the next biggest gaps in SEND implementation standards that you would like to see developed by CDISC?

## Responses with supplied solutions

- Bridging between FDA business rules and validation of domains – This is a topic that is currently being discussed within the CDISC CORE program
- Dataset validation – Software Vendor Programs/CDISC CORE
- Open-source initiatives for SEND – CDISC CORE is an active project that promotes the use of open-source initiatives
- Dietary studies – Dietary studies can be modelled in SENDIG v3.1 & v3.1.1 (see example 5 in the EX domain). This example is being retained in SENDIG v4.0
- Fix some of the known deficiencies such as lack of standardization for clinical signs (CL) – This is a potential CDISC chartered item post SENDIG v4.0
- In vitro and ex vivo are a big gap for existing standards. More closely related to in vivo data are ADME and biodistribution studies. Omics data is increasingly becoming part of safety studies and may play a significant role in drug candidate selection as well as interspecies translation. – This is a potential CDISC chartered item post SENDIG v4.0
- Inclusion of Pig-A endpoints within the GV domain – This is a potential CDISC chartered item post SENDIG v4.0
- Virtual Control Groups – This is a potential CDISC chartered item post SENDIG v4.0
- Pharmacology and Safety Pharmacology Gap: SEND is primarily focused on toxicology. Pharmacology and safety pharmacology studies lack robust standards. Need: Development of domains and controlled terminology for: Primary pharmacodynamics, Secondary pharmacodynamics, Safety pharmacology endpoints – This is a potential CDISC chartered item post SENDIG v4.0 and new CT is able to be requested at any time, the resource link is available here: <https://nciternform.nci.nih.gov/nciternform/?version=cdisc>



# What are the next biggest gaps in SEND implementation standards that you would like to see developed by CDISC?

## Responses with supplied solutions - Continued

- Proper standard for dosing records (EX), which is rolled backwards/disappears in SENDIG 4.0 – The EX domain is moving to planned dosing information, if this is not desired, public review for SENDIG v4.0 is still open and accepting JIRA items for any concerns.
- Requirement to use controlled terminology for units in TE, TA, SE and Group Label in TX domains to give more consistency with the EX domain – Public review for SENDIG v4.0 is still open and accepting JIRA items, recommend adding a JIRA item to express this requirement.
- SEND for Non-Traditional Species Gap: Current controlled terminology is optimized for common lab species (rat, dog, monkey). Need: Expansion for: Emerging species (e.g., zebrafish, minipigs). In vitro models and organ-on-chip systems. – Known issue that is currently being discussed by the CDISC CT team on when/how/if to address



phuse.global

**Working  
Groups**

# What specific data needs or problems based on your scientific expertise, data analysis/interpretation experiences or submission experience, would you like to see as a PHUSE project?

## Responses

- Future-Focused Initiatives - Why: Regulatory expectations are evolving. Explore AI/ML applications for SEND data analytics. Work on data visualization standards for nonclinical data review.
- SEND + SDTM Integration - Why: Translational research and integrated submissions need seamless mapping. Publish mapping guides between SEND and SDTM domains. Provide examples for integrated datasets across nonclinical and clinical phases.
- Q&A Wiki for frequently asked questions, easily searchable (AI supported?)



phuse.global

## Working Groups

# What specific data needs or problems based on your scientific expertise, data analysis/interpretation experiences or submission experience, would you like to see as a PHUSE project?

## Responses with supplied solutions

- SEND Data Quality & Automation - Why: Data quality issues and manual processes slow down SEND adoption. Create open-source tools or scripts for SEND dataset validation. Develop automation frameworks for SEND dataset generation from LIMS or study reports. – **CDISC CORE is an active project that will include the ability to validate SEND datasets to CDISC conformance rules**
- Controlled Terminology Expansion - Why: Current terminology is limited for emerging study types and species. Collaborate with CDISC to propose new controlled terms for: Omics data, Novel species, In vitro models – **New CT terms can be requested at any time, the resource link is available here: <https://ncitform.nci.nih.gov/ncitform/?version=cdisc>**
- Implementation of SENDIG 4.0 working group – **There is planned CDISC training material to come post SENDIG v4.0.**
- More interactive sessions like webinars or workshops on different SENDIGs like DART, Genetox. – **Generalized training on SEND is available through CDISC, if more detailed training on specific endpoints is needed, this can be a discussion item along with the relevant subteams for collaboration.**
- SEND Conformance Rules in CORE – **This is an ongoing project, with CDISC prioritizing SDTM. The inclusion of SEND is a future item.**
- Virtual Control challenges/recommendations – **Phuse has an existing working group 'Supporting the Use of SEND for the Implementation of Virtual Control Groups' which is currently working on VCG's, this is also a proposed CDISC chartered item post SENDIG v4.0**

# What specific data needs or problems based on your scientific expertise, data analysis/interpretation experiences or submission experience, would you like to see as a PHUSE project?

## Responses with supplied solutions - Continued

- Education & Training - Why: Many sponsors and CROs lack SEND expertise. Offer training modules, webinars, and workshops. Develop case studies showing successful SEND implementation. – Phuse offers a range of public training, such as in-person single day events, online webinars, and conferences that can include non-clinical topics. If specific training on areas within SEND are wanted, this can be expressed to the Phuse team via [education@phuse.global](mailto:education@phuse.global) where discussions/arrangements can be made. See the Phuse education page for more details: <https://phuse.global/Education>.
- Practical Implementation Guides - Why: Many companies struggle with interpreting CDISC SEND standards for real-world scenarios. Develop step-by-step implementation guides for complex study types (e.g., exploratory tox, safety pharmacology). Provide best practices for SEND validation and QC. – While creating full implementation guides for every complex study design may not always be feasible due to the breadth of scenarios and the SDTM-based structure of SEND, we recognize the need for support in this area. If a new PHUSE SEND information team is created, questions could be submitted to address complex study designs
- SR (Study Report) Domain – Determine what level of detail is useful to put onto it, Explore how to cross validate with SEND, etc. – This was an initiative by eTRANSAFE, Phuse can investigate to see if this is still an ongoing project. (Not to be confused with the Skin Results 'SR' domain in SDTMIG)



phuse.global

## Working Groups

# Questions/Comments?



[phuse.global](https://phuse.global)

**Working  
Groups**



# Thank you!

---



phuse.global

**Working  
Groups**

