SEND Survey 2024

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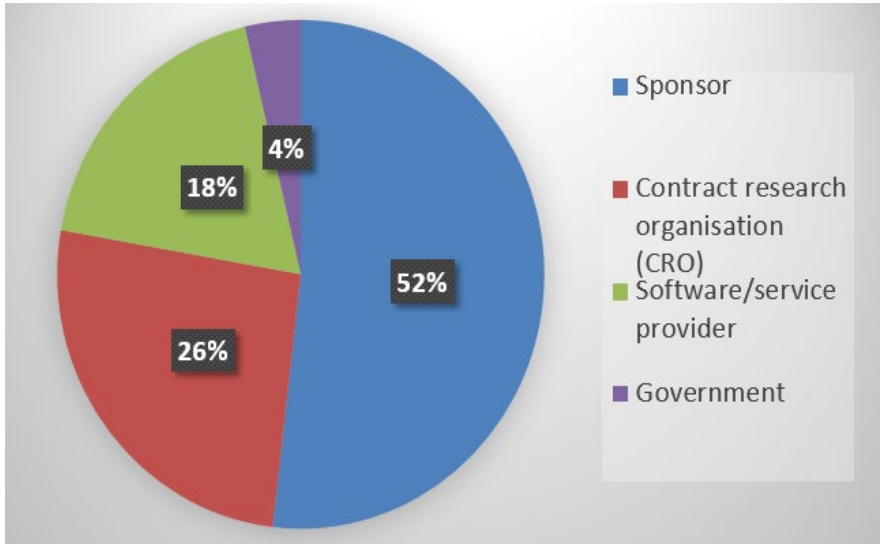
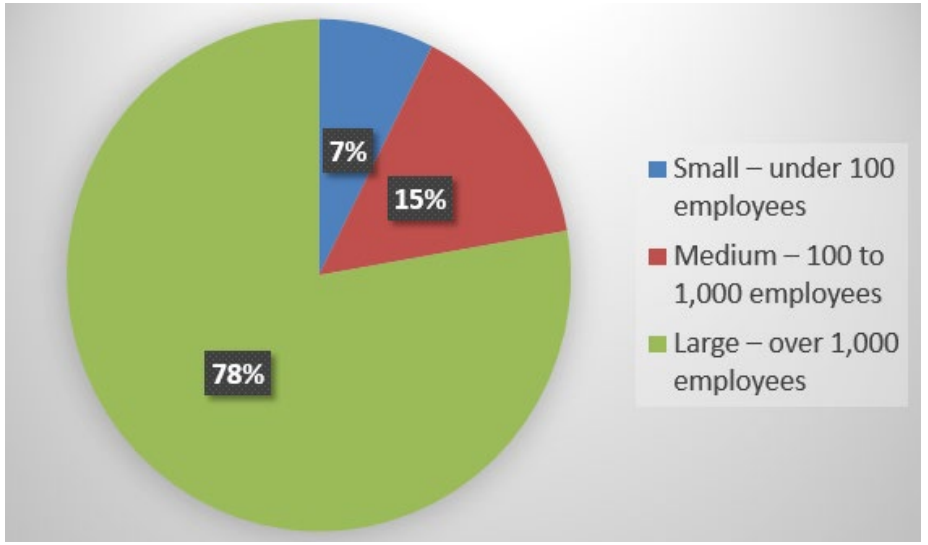
Demographics

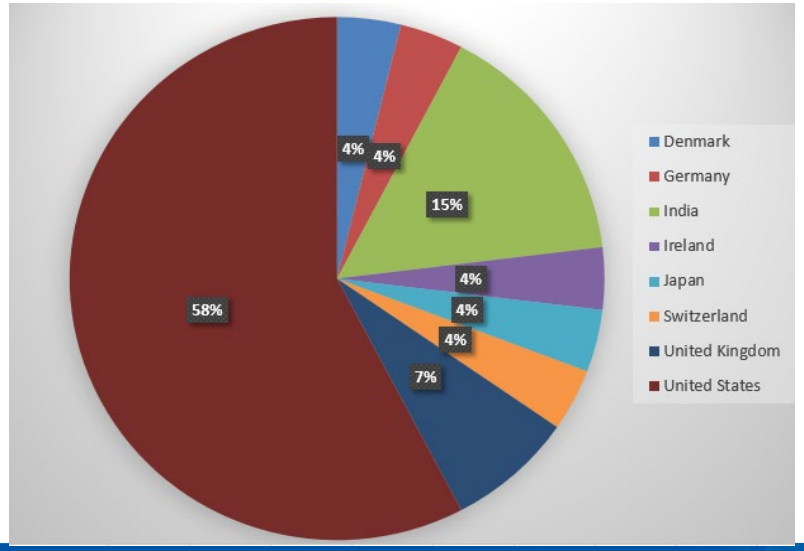
Q1 – Is your organisation a:



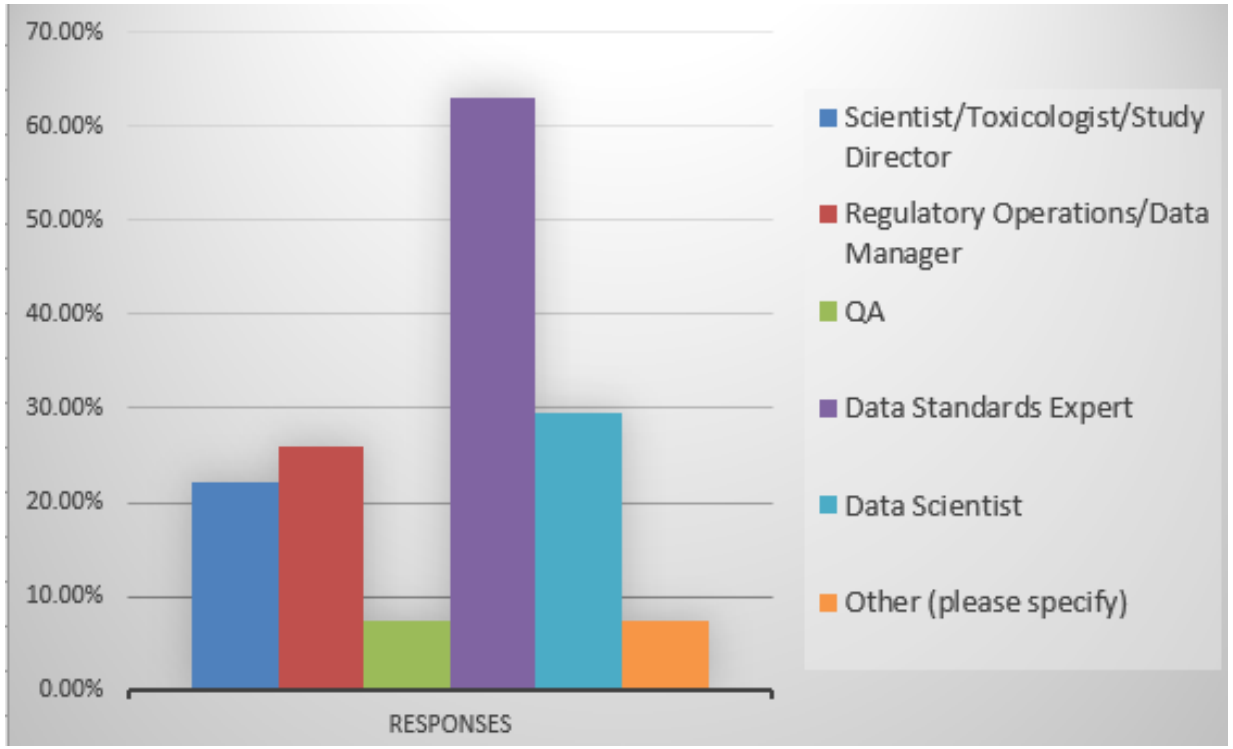
Q2 - Size



Q3 - Location



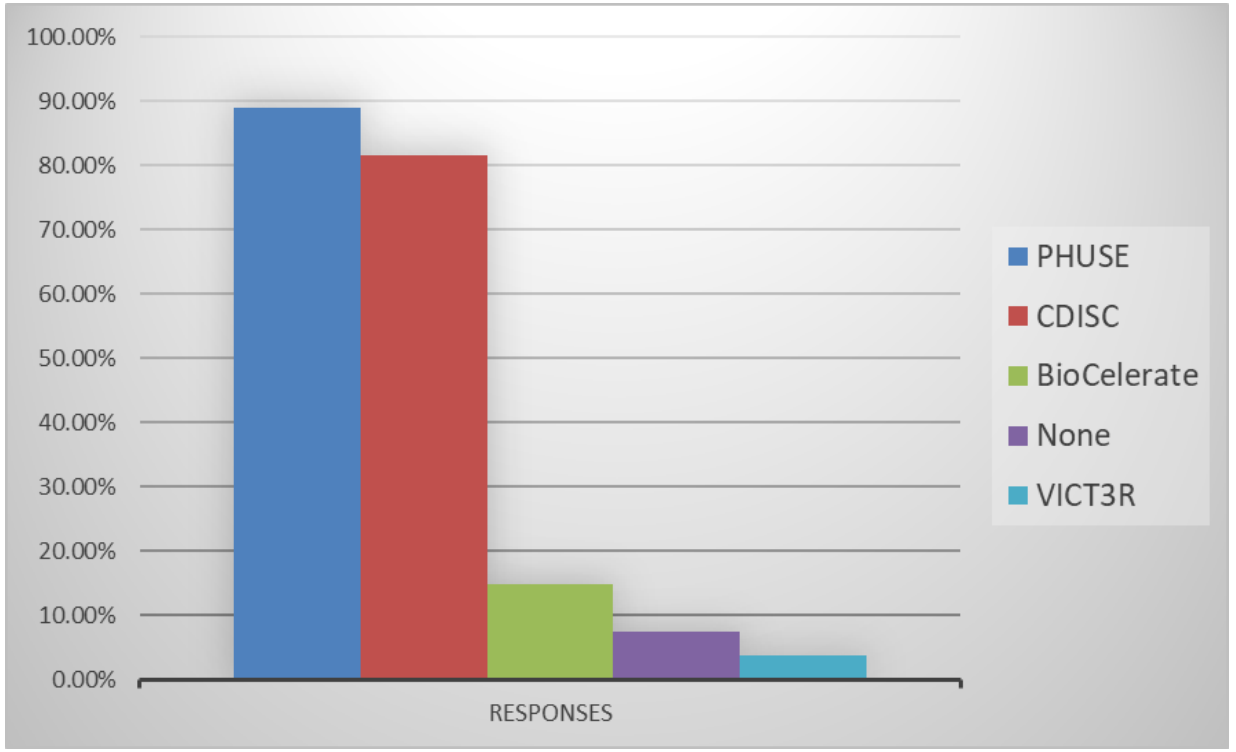
Q4 – How do you characterise your role in your organisation? (select all that apply)



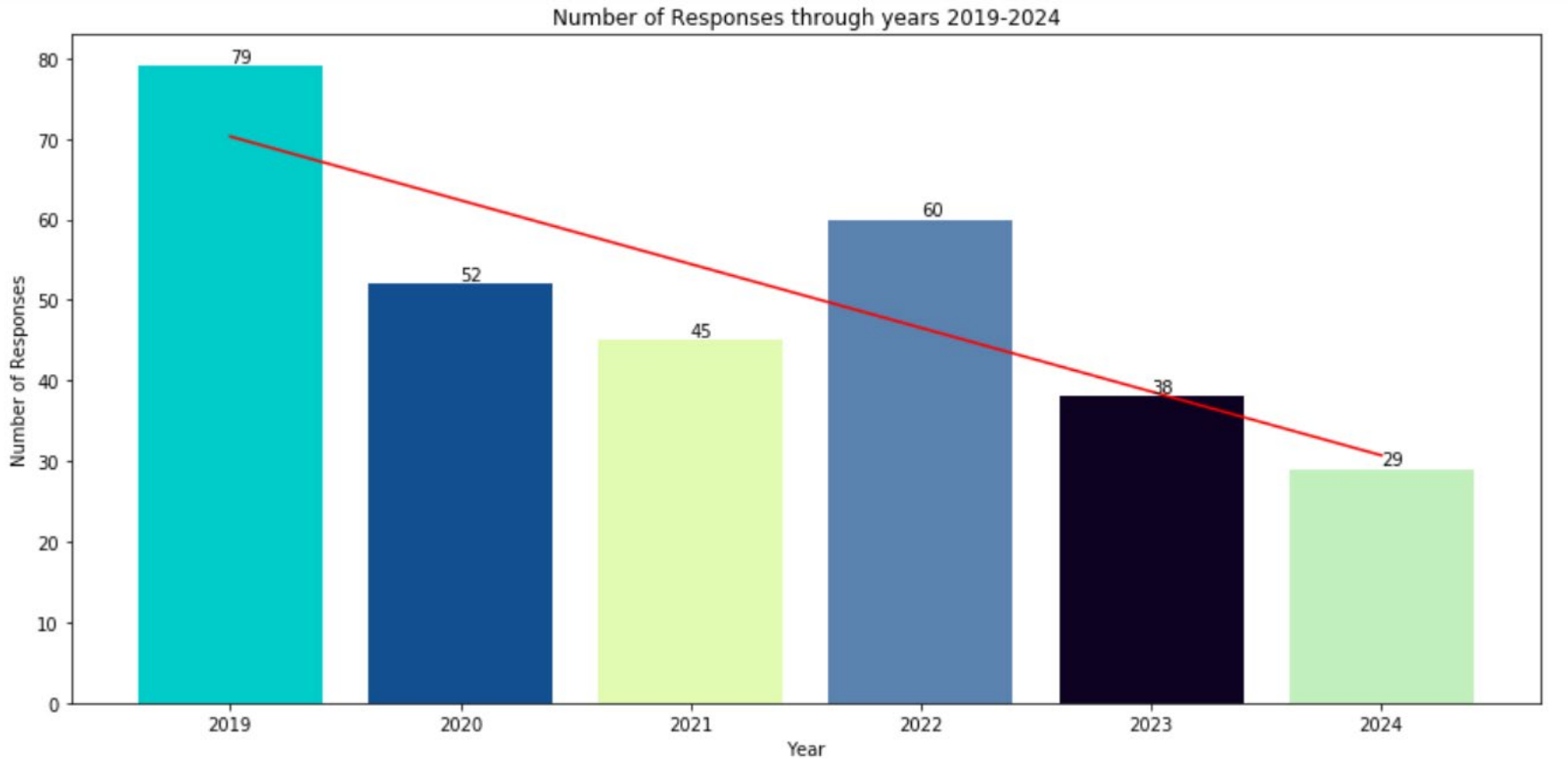
'Other' Responses:

- Management
- Statistician

Q5 – Please select the SEND-related industry organisations you're involved with (select all that apply):



Responses



Trend

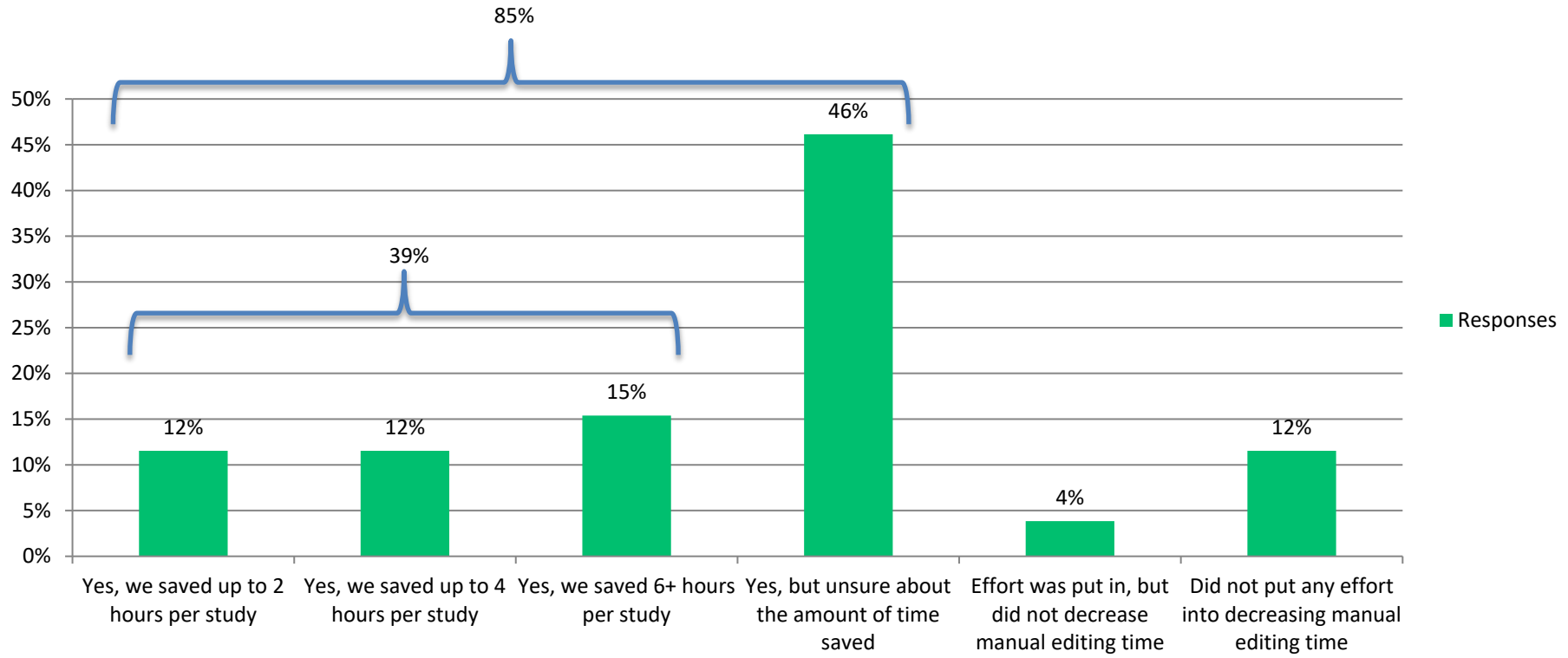
- Steady decline of responses through the years

Discussion

- SEND as a standard has matured, there are fewer large updates
- Used to have 10 people/company answer now we have 1-2/company answer to represent company
- Goal for 2025: Ask survey questions that push the Boundaries of SEND

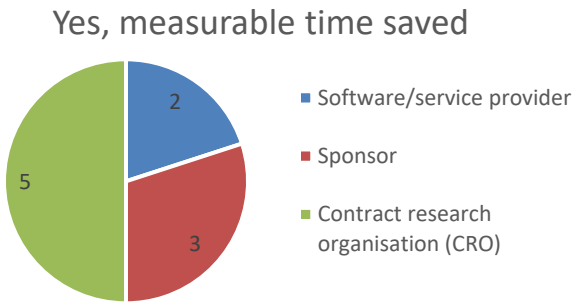
Manual Edits

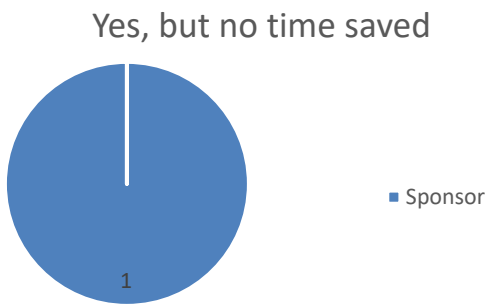
Q6 - Have you put effort into decreasing manual editing time in the past 2 years? If so, how much time have you saved?

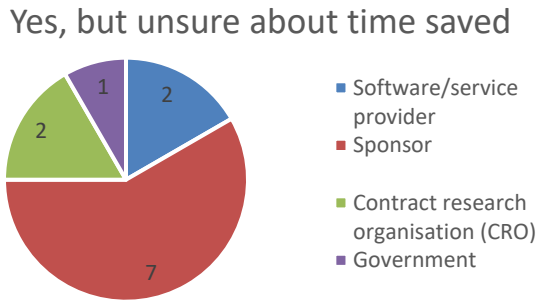


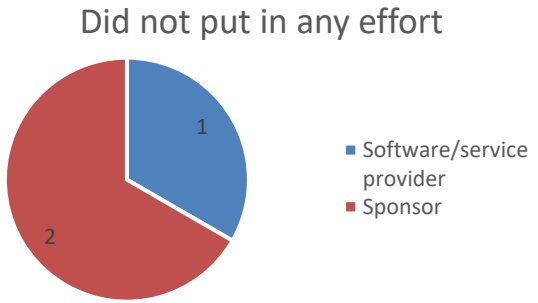
Q6 - Have you put effort into decreasing manual editing time in the past 2 years? If so, how much time have you saved? (cont.)

Responses Demographics:

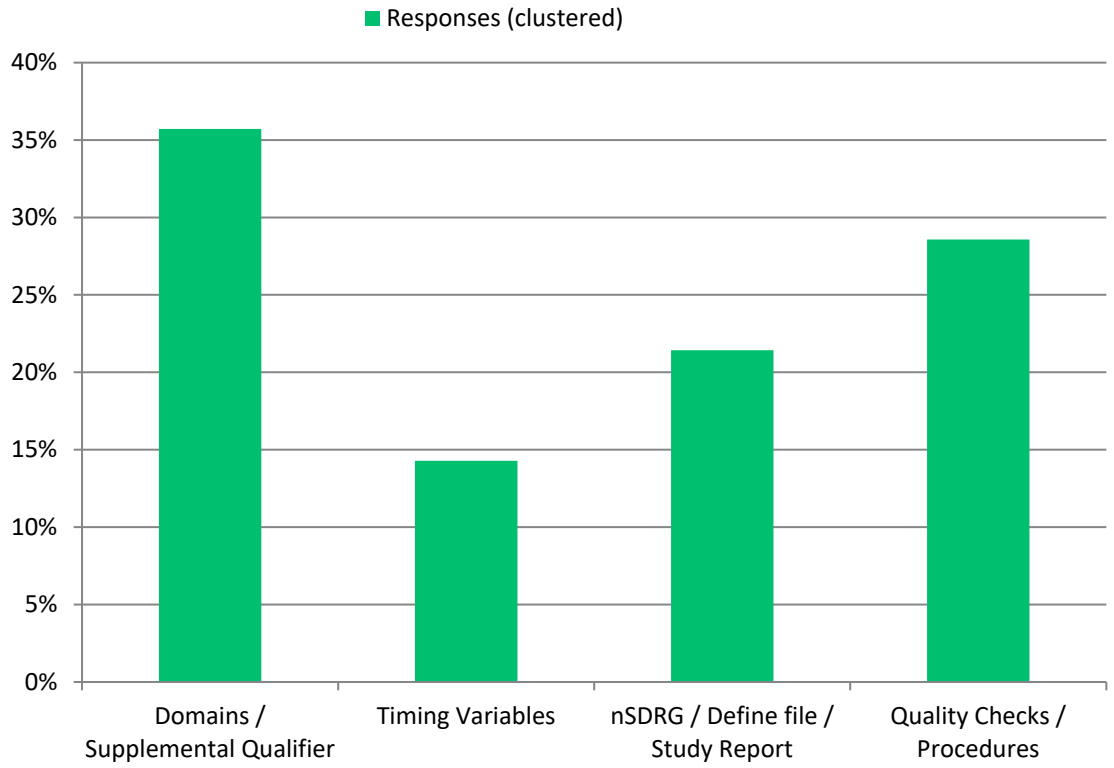








Q7 - In which area did you see the most significant impact? Any other comments?



Cluster methodology:

- Answered: 15 / Skipped: 13
- 2 participants responded ‘NA’
- 3 responses were comments only and could not be clustered
- 10 valid responses were clustered based on buzz words, resulting in 13 individual cluster counts

Q7 - In which area did you see the most significant impact? Any other comments? (cont.)

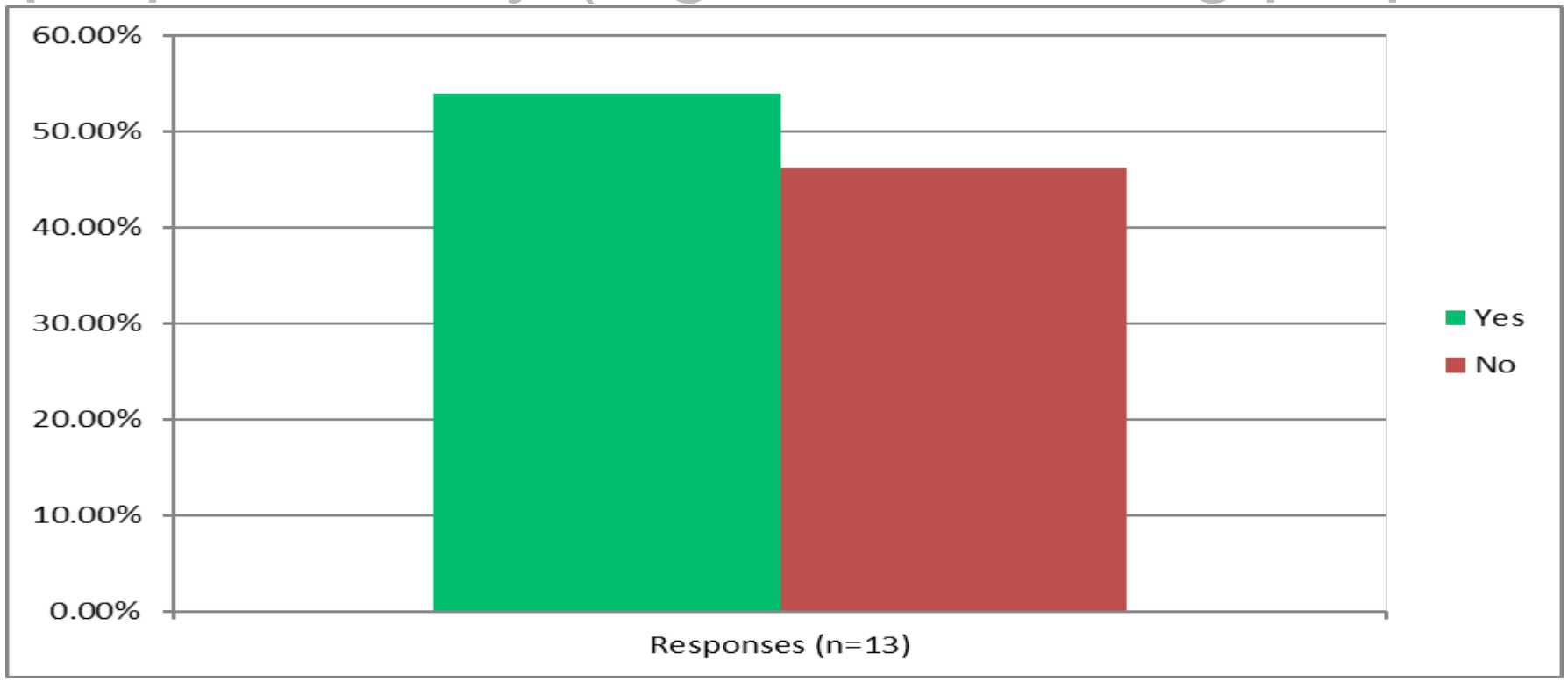
Un-clustered comments:

- FDA keep on accepting data submitted by all the sponsors and don't provide any critical feedback about quality of every submission. Even if substandard data is submitted no rejection or feedback given by FDA.
- My manual editing is done to fix errors in submission files. The amount of time spent doing manual edits is based on the number and types of errors made by sponsors and CROs.
- Not many opportunities for change due to internal validated system limitations.

Q7 - In which area did you see the most significant impact? Any other comments? (cont.)

	Domains / Supplemental Qualifier	Timing Variables	nSDRG / Define file / Study Report	Quality Checks / Procedures
Correcting information in SUPP-- qualifier, removing redundant information from finding domains (e.g., --TPT/--TPTNUM where there is only one value (one session))	x	x		
pathology domans	x			
Quality checks				x
Trial design, study metadata present in report (methods, baseline, fasting flags, comments, etc.)	x		x	
Programs/Software/Application used to process data not originally recorded in system that outputs data in SEND format.				x
Define file, findings domains, nSDRG, domains from external sites (like PC, PP)	x		x	
Dose levels				x
nSDRG			x	
LB, PC, and PP domains	x			
Timing variable population.		x		

Q8: As a sponsor, do you make any edits to the third-party generated SEND dataset for non-submission purposes only (e.g. warehousing purposes)?



Note- "I am not a Sponsor" responses were not included in the analysis.

Q9: Sponsor-only question: If you answered yes to the previous question, what types of edits are you making for non-submission purposes?

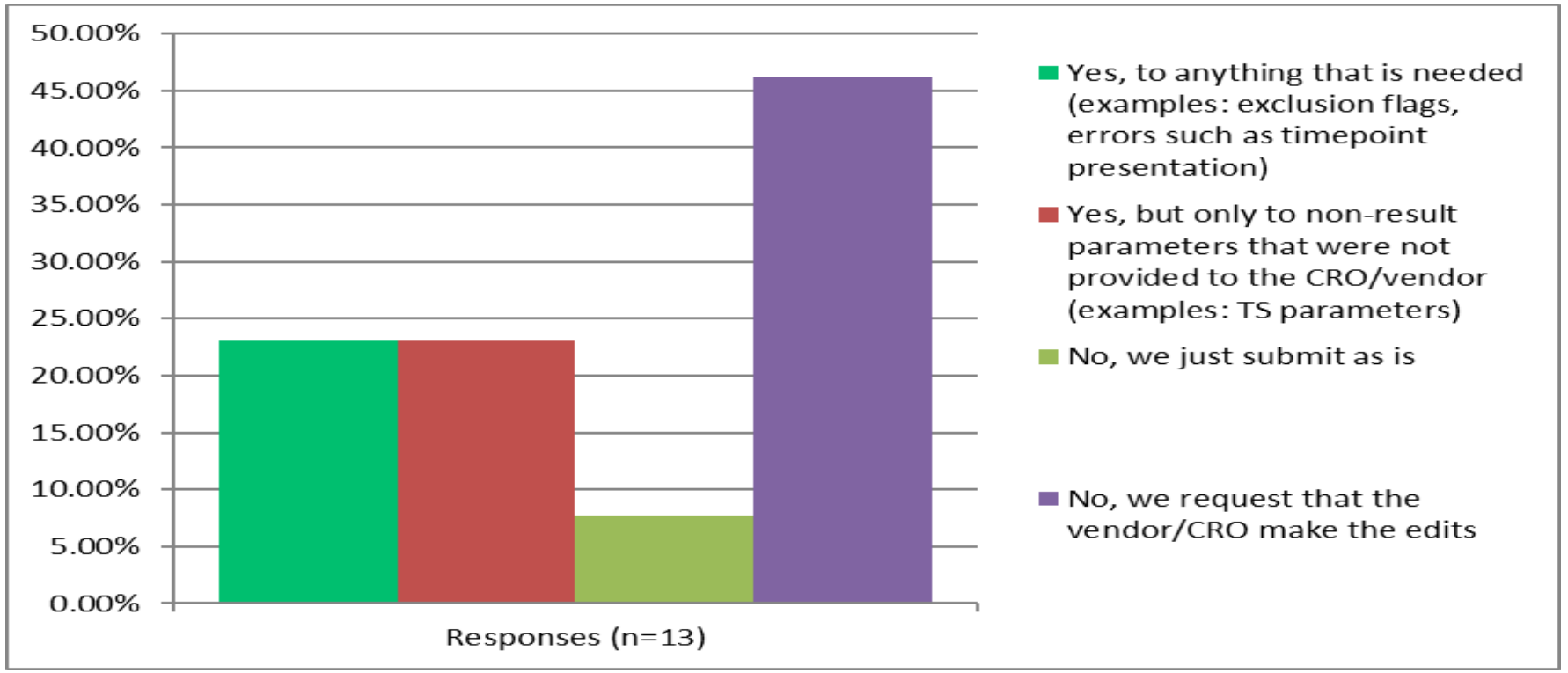
Responses

- Enrich the dataset with company / project specific identifiers and metadata
- Non-result parameters
- Occasional corrections/additions to TS domain
- Edit to the STUDYID and SPREFID
- If proper population of variables, e.g LBSTRESC is not decoded correctly, MISTRESC OR SUPPMI entry are incorrect, timing variables are incorrectly populated

Q10: Sponsor-only question: What (if any) are your concerns about making edits to the third-party generated SEND dataset?

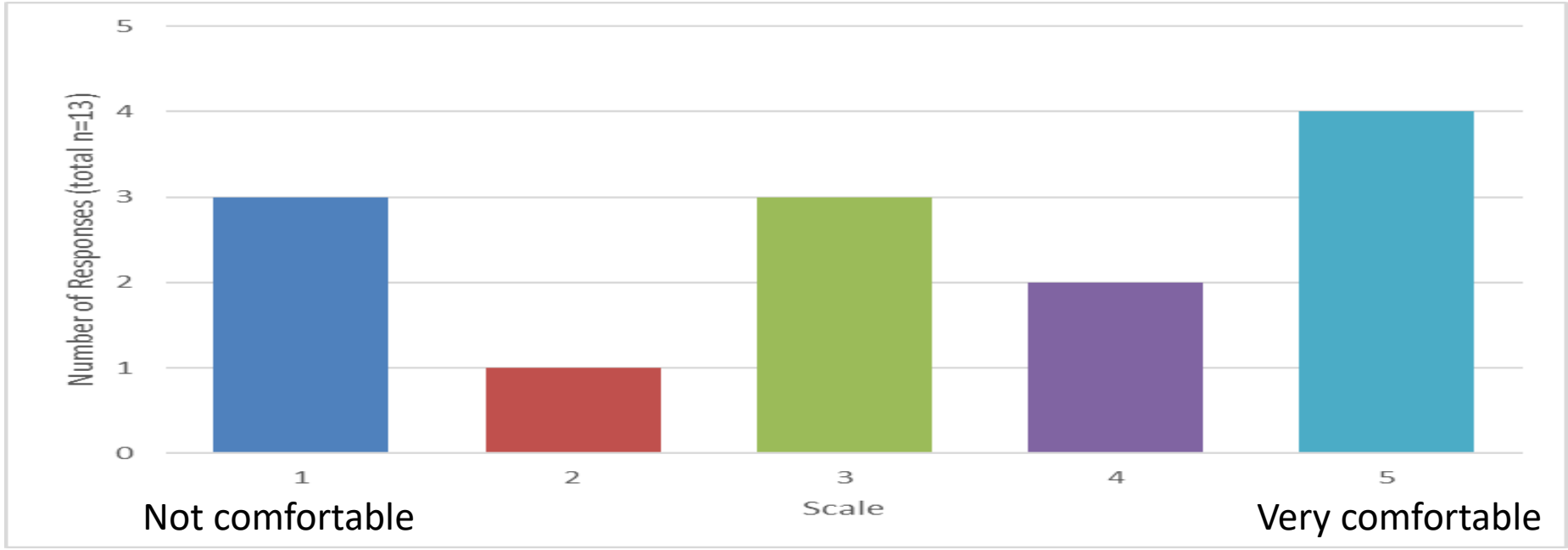
- **Concerns**
  - Responsibility of the SEND datasets should remain with the dataset generator
  - Loss of consistency
  - Data integrity, manual effort
  - Having to use a third-party editing tool to make edits and creating additional issues.
- **Little/No Concerns**
  - Will request third-party to make corrections if needed
  - Minimal concern because edits we propose to do are first vetted by a small group of about 3 people.
  - None because from FDA perspective the submitting sponsor is ultimately responsible for the quality of the filed datasets.

Q11: As a sponsor, do you make any edits to the third-party generated SEND dataset prior to submission to the FDA?

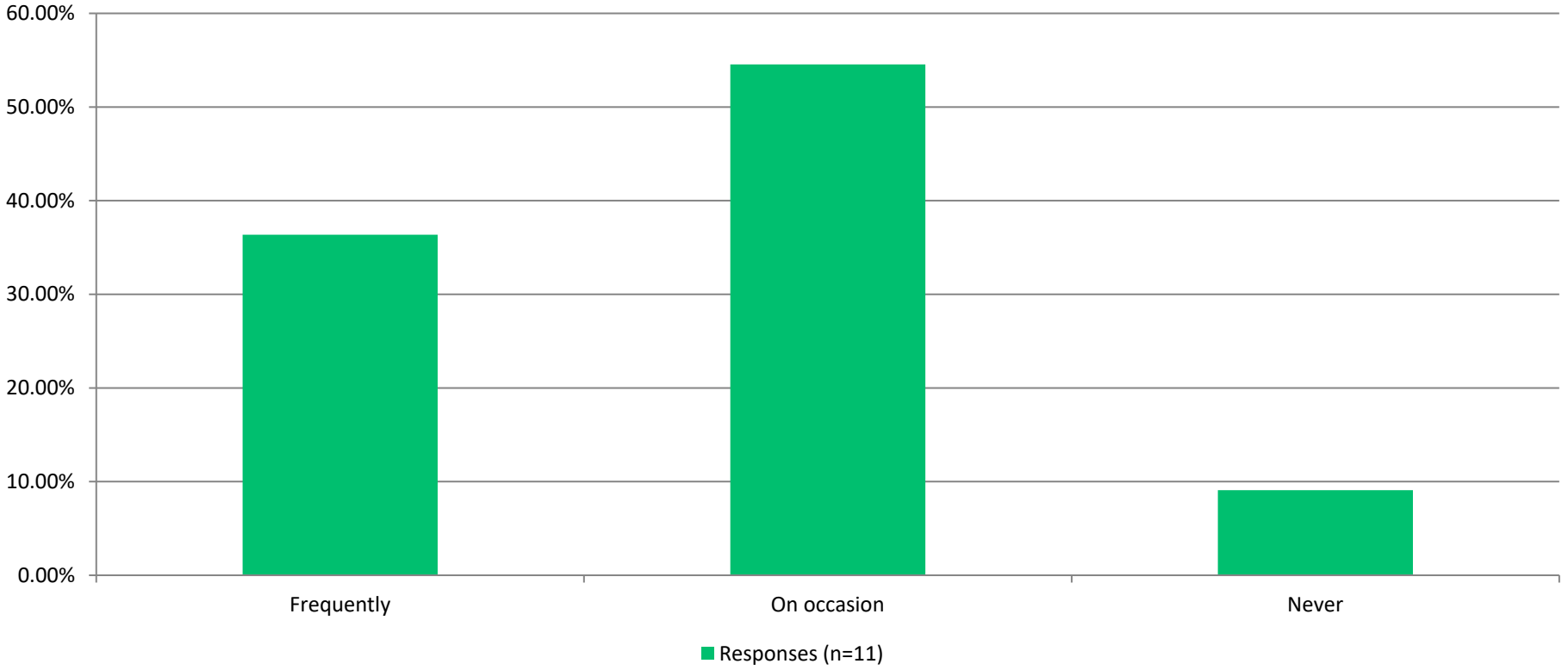


Note- "I am not a Sponsor" responses were not included in the analysis.

Q12: Sponsor-only question: On a scale from 1 to 5, how comfortable are you with making edits to the third-party generated SEND datasets (non-findings variables) needed for submission?

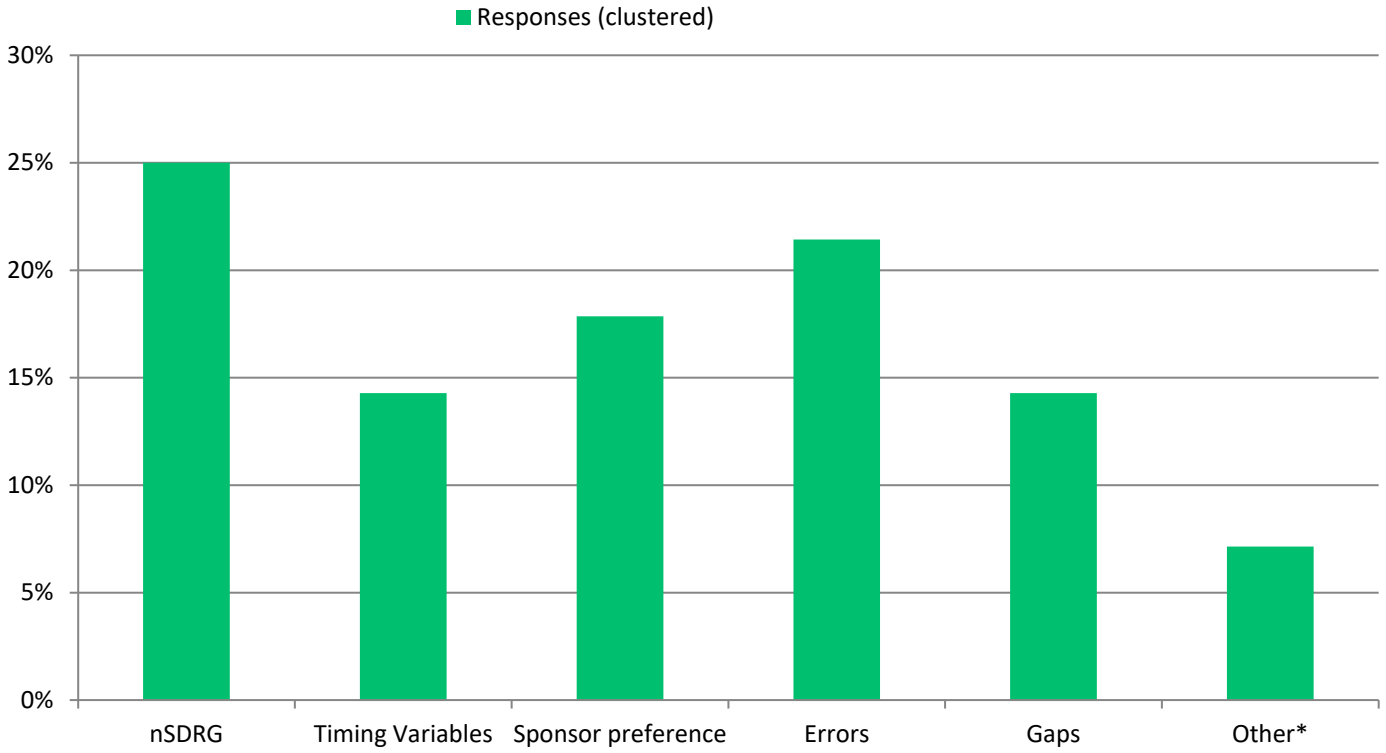


Q13 - As a CRO/vendor, how often are you asked by the sponsor to make SEND dataset edits?



Note- "Not a CRO/Vendor" responses were not included in the analysis.

Q14 - If you answered ‘Frequently’ or ‘On occasion’ to the previous question, what changes are you asked to make (e.g. nSDRG updates/explanations, timepoint updates, sponsor preference, errors, gaps)?



* Trial Design, Flags (e.g., --EXCLFL, --USCHFL), clarifications from report, translate comments and abbreviations

Cluster methodology:

- Answered: 10 / Skipped: 18
- 1 participant responded ‘NA’
- 9 valid responses were clustered based on buzz words, resulting in 28 individual cluster counts

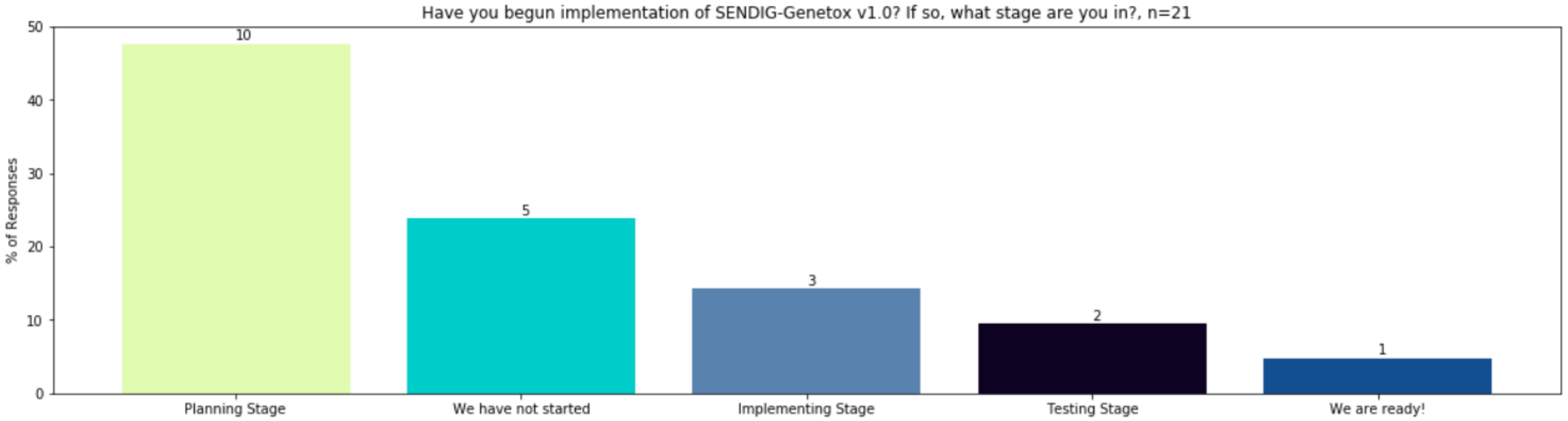
Q14 - If you answered 'Frequently' or 'On occasion' to the previous question, what changes are you asked to make (e.g. nSDRG updates/explanations, timepoint updates, sponsor preference, errors, gaps)? (cont.)

	nSDRG	Timing Variables	Sponsor preference	Errors	Gaps	Other*
nsdrg may some time variables	x	x				
Create nsdrg and define.xml, update Trial Design, adjust timing variables, populate flags (exclusion, unscheduled), translate comments and abbreviations, any issues that we find.	x	x		x	x	x
nSDRG updates, sponsor preference, gaps	x		x		x	
errors, nsdrg statements, clarifications from report, nitpicky items	x		x	x		x
Updates made to dataset domains generated from data recorded by us, the CRO, for studies conducted at an external site (other CRO or Sponsor).				x	x	
Add in nSDRG explanations about items that are system limitations / items that cannot be fixed in the SEND datasets due to various reasons, Sponsor preference changes that were either missed or not communicated before SEND Dataset was delivered	x		x			
Mostly nSDRG updates/explanations, timing variable updates, sponsor preference. Occasional error updates.	x	x	x	x		
All of the above.	x	x	x	x	x	
errors - data in SEND xpt files not compliant with standard and/or not consistent with study report				x		

* Trial Design, Flags (e.g., --EXCLFL, --USCHFL), clarifications from report, translate comments and abbreviations

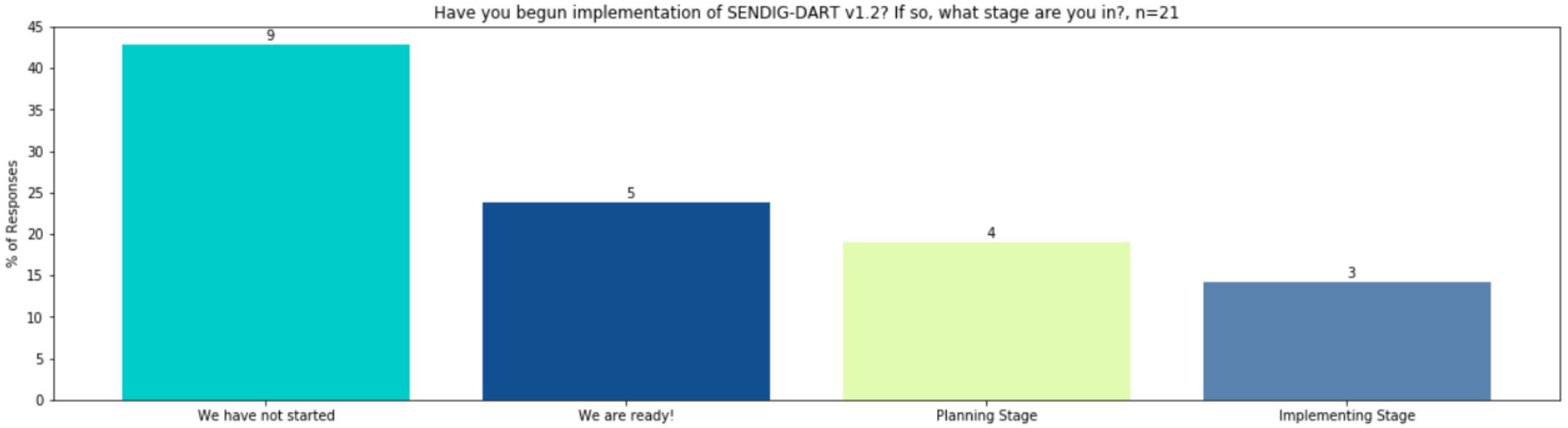
Implementing SEND

Q15 - Have you begun implementation of SENDIG-Genetox v1.0? If so, what stage are you in?

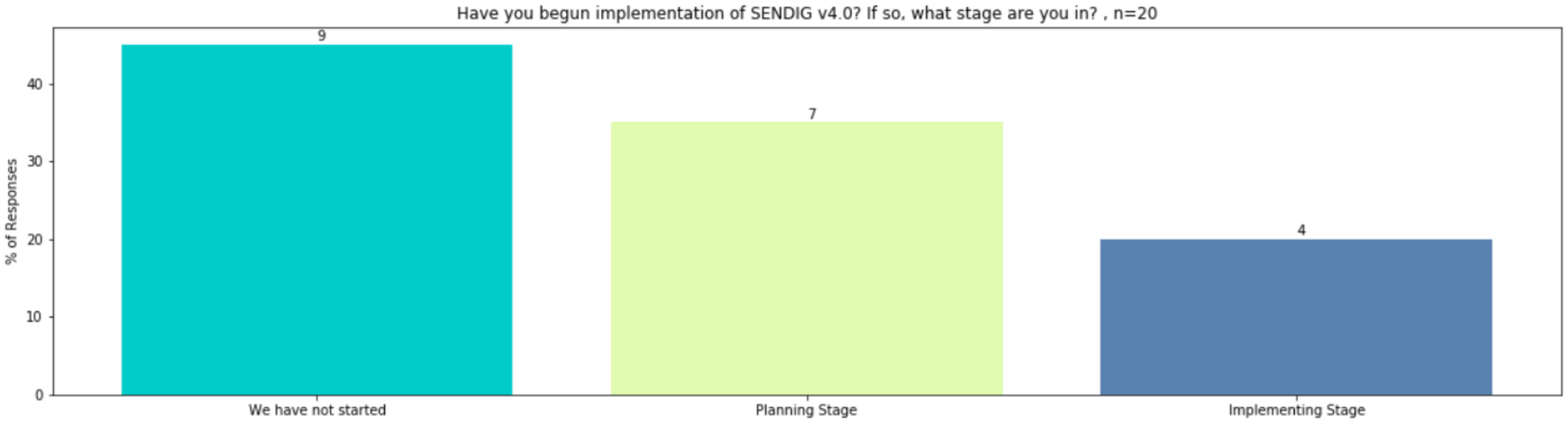


Consideration: 'We have not started' could include organisations that do not run genetox studies

Q16 - Have you begun implementation of SENDIG-DART v1.2? If so, what stage are you in?



Q17 - Have you begun implementation of SENDIG v4.0? If so, what stage are you in?



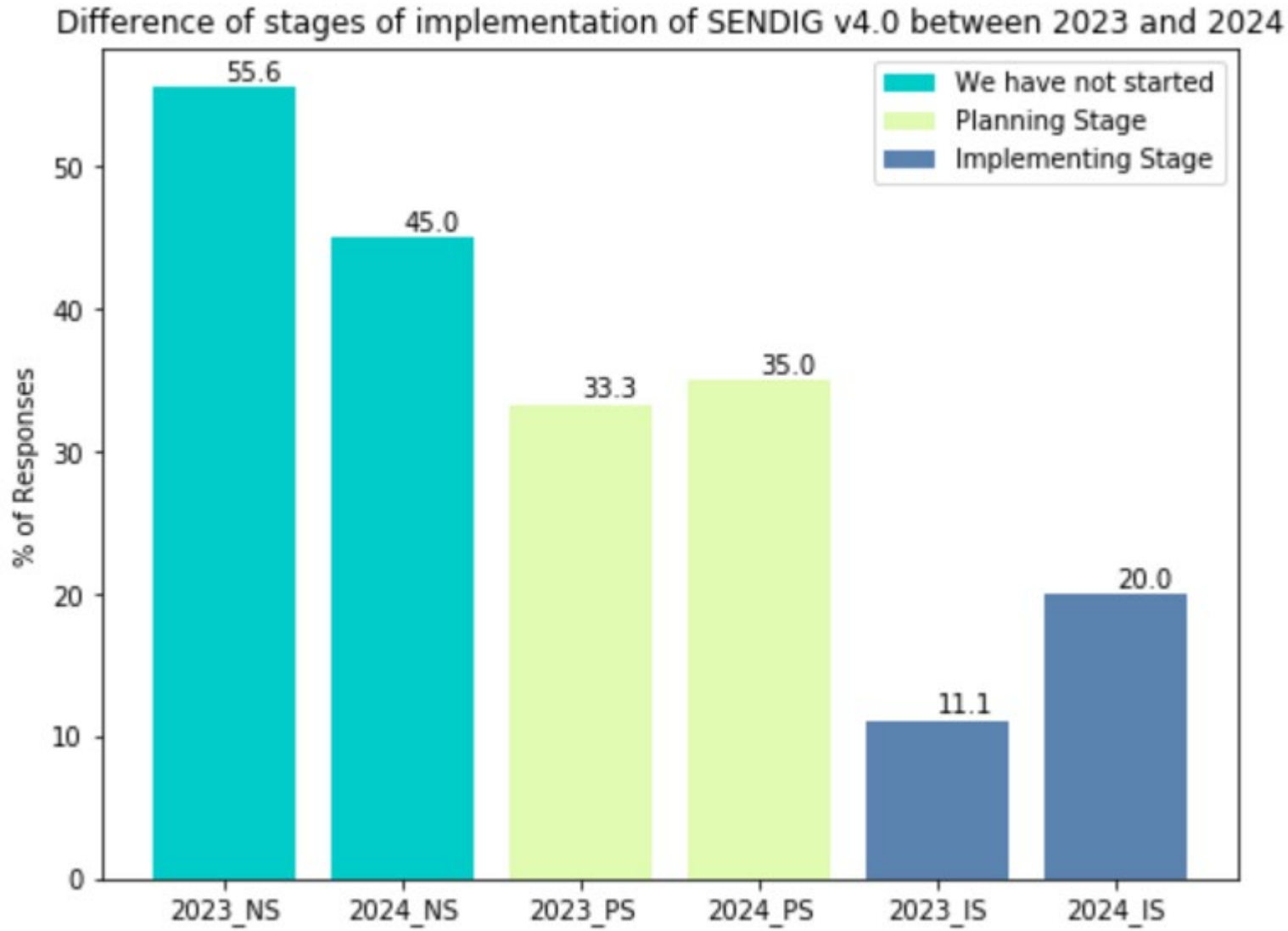
Q17 Analysis

Observations of Interest:

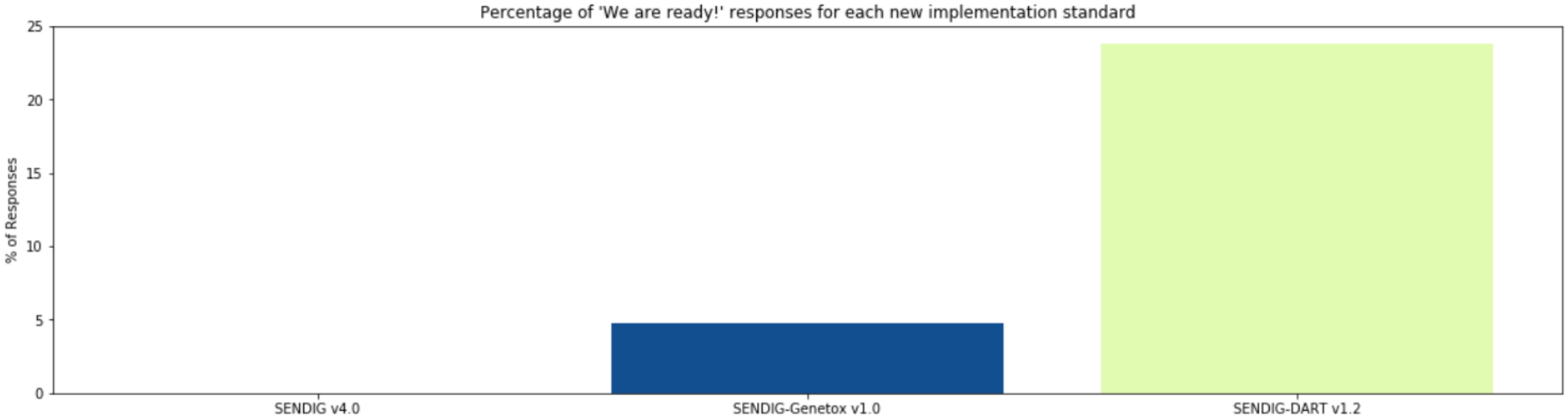
10.6% decrease of response “We have not started” from 2023 to 2024

8.9% increase of response “Implementing Stage” from 2023 to 2024

Gentle movement



Q15-17 Analysis



Observations of Interest:

Organisations are most ready for DART v1.2 at ~25%

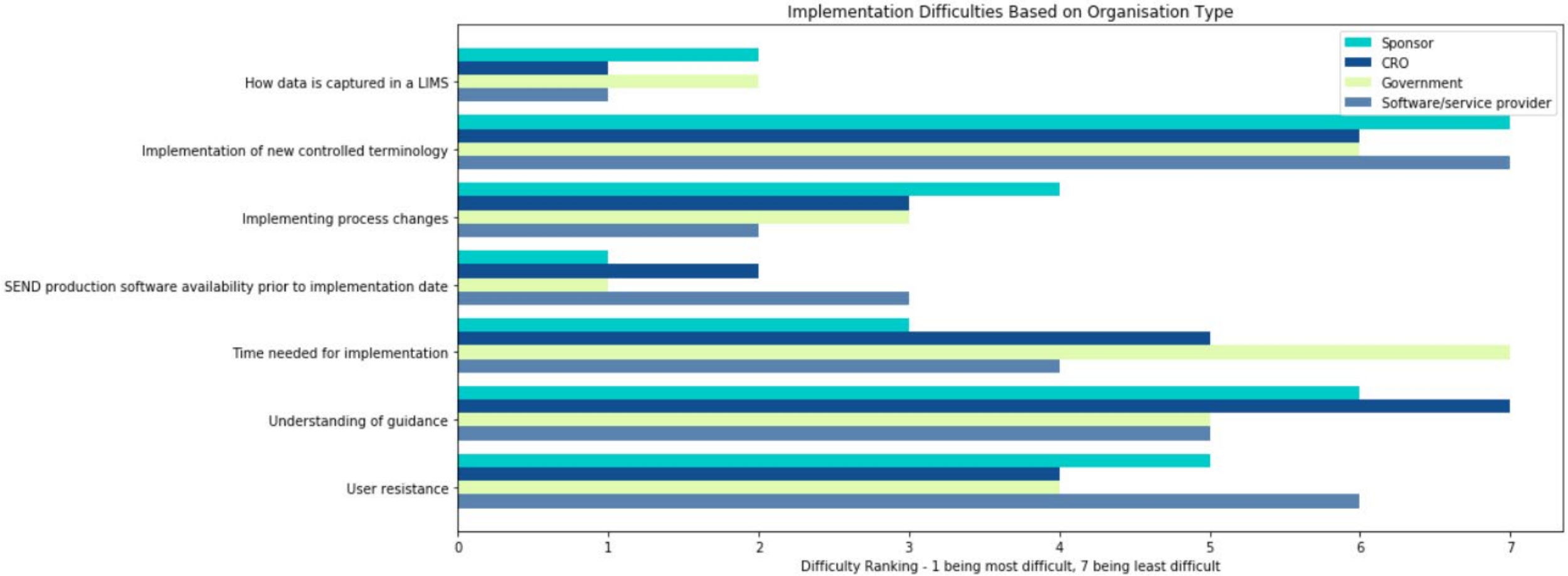
Organisations are least ready for SEND v4.0 at a 0%

Q18 - What difficulties are you facing in your efforts to implement the new and upcoming requirements?

Implementation Challenge	Difficulty Level
How data is captured in a LIMS	1
SEND production software availability prior to implementation date	2
Implementing process changes	3
Time needed for implementation	4
User resistance	5
Understanding of guidance	6
Implementation of new controlled terminology	7

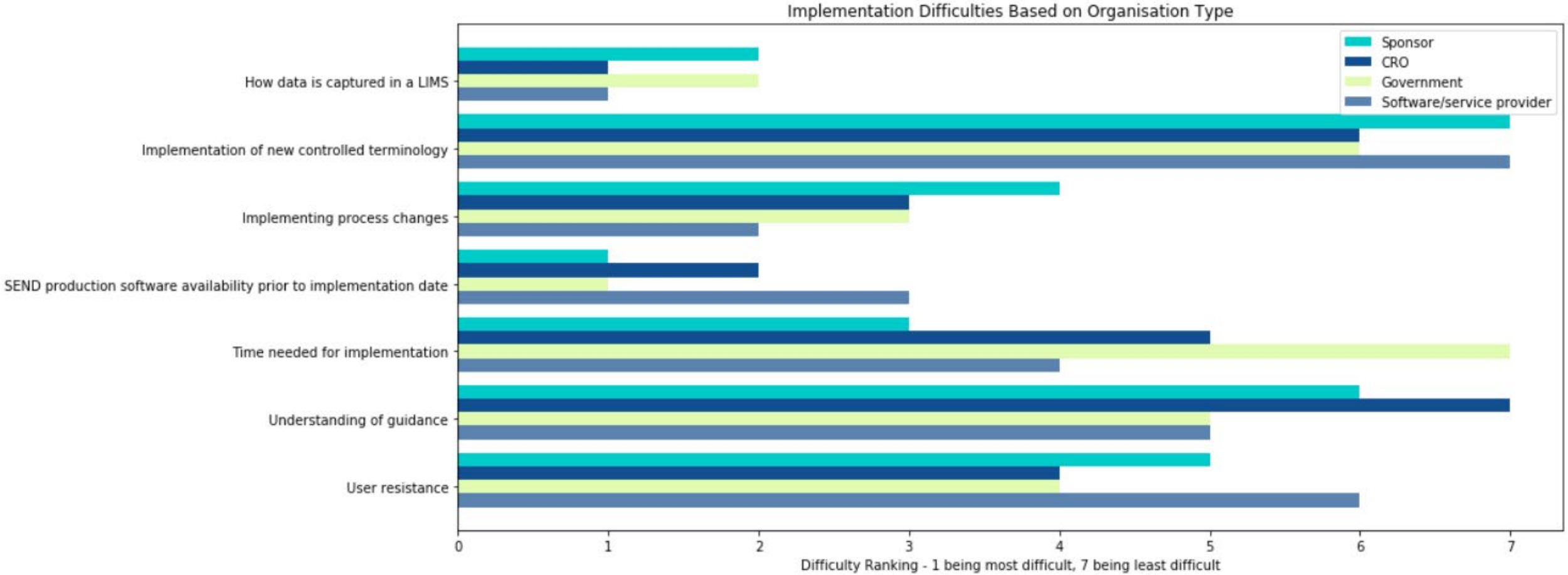
*Difficulty Level of 1 is the most difficult, 7 is the least difficult

Q18 - Analysis: Rankings based on Organisation Type



Most difficult for Software/Service Providers and CROs = ‘How data is captured in a LIMS’

Most difficult for Governments and Sponsors = ‘SEND production software availability’



Q19 - Comments of Interest

We face 3 challenges of potential equal importance/priority: 1) How we receive data (*eData availability and completeness*), 2) setting up our *internal custom views to perform semi-automated quality checks* using new SDTM variables (dependence on SDTM version, not SEND version) and 3) how much *time* we can allocate to the implementation and testing phase.

Biggest difficulties depend on how big *the process disrupts other areas/groups* outside of SEND team and how willing groups are to update their processes

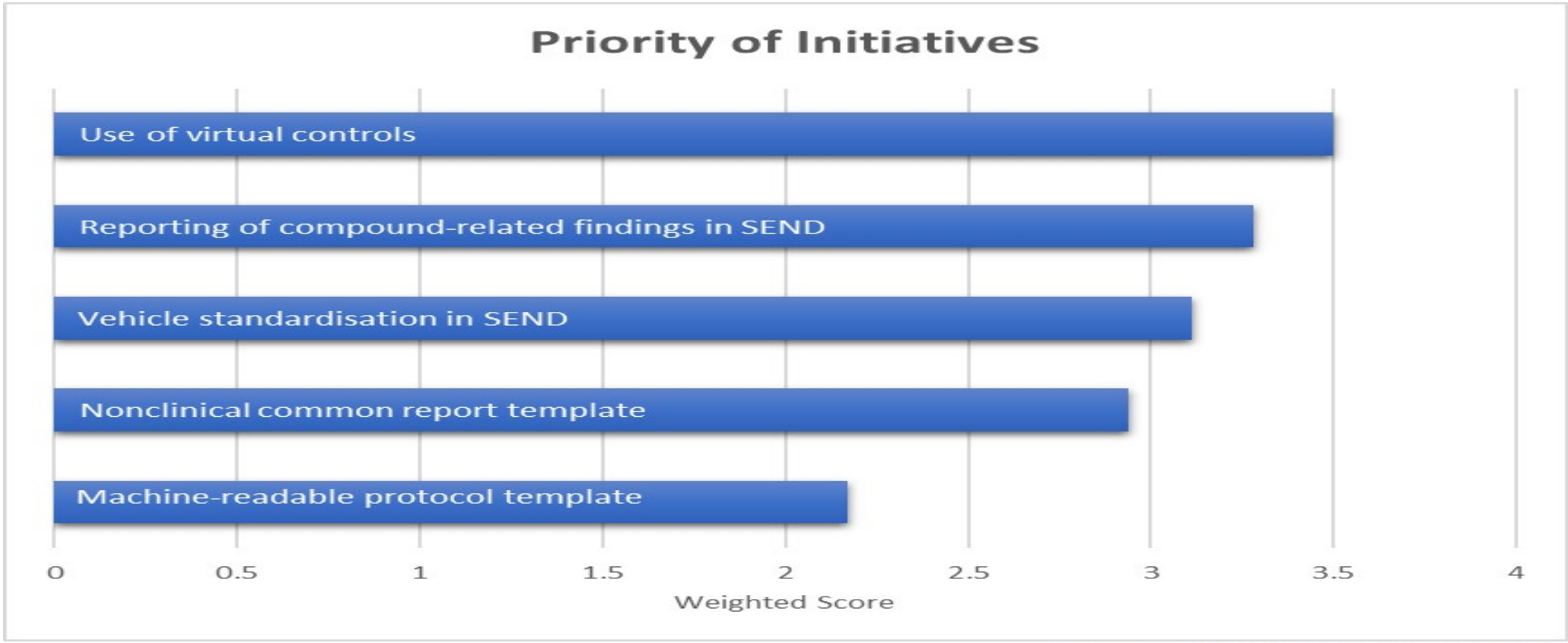
After the necessary software systems are available, 1 year may be needed to complete implementation due to validation, user acceptance testing, other evaluations, and documentation needed to complete the project before the system may be used for submission datasets. additional time may be needed if system deficiencies are identified during testing.

The guidance for the *new SENDIG v4.0 domains (ie., CP/IS) is going to be a big challenge to learn* and implement for non-scientific SEND datasets preparers.

Another difficulty would be *diminished IT support within an organization*, in terms of people available and cost to dedicate personnel and purchase new software.

Harmonization

Q20. Rank the following initiatives in order of priority for you/your organisation (1 being top priority, 5 being the lowest priority)



Next Steps

Q21: What are the next biggest gaps in SEND implementation standards that you would like to see developed by CDISC?

Responses

- Making a clear distinction as to what is in scope and what is out of scope
- Good example of dataset for all possible domains explaining how variables need to be populated
- Standardizing CL domain
- Addition of domains that allow us to identify all the content of non-clinical studies by SEND only dealing properly with combination tox / repro studies and adjusting the SENDIG-DART accordingly. Version 1.2 should be replaced ASAP.
- Additional DART study designs and aligning existing DART designs to SENDIG 3.1/4.0 (nominal not planned days)
- Multigeneration DART studies, EC for inhalation, Multiphase studies, In vitro Genetox, HERG Safety Pharmacology Studies
- SEND data to be used in virtual control animal selection and SEND data to include virtual control animals and data for those animals

Q22: What would you like PHUSE to work on?

Responses

- Continue researching VCGs, best practices for them and gaps for using them
- nSDRG examples for DART- we need a study design table template that accommodates the 'dual trial design' in a dart study with repro phases/stages as a second layer to the normal TA/TE/TX
- ADAM for SEND
- SR domain
- SEND 4.0 Education series, SEND visualization, SEND education for teams outside of SEND (like how study directors can leverage SEND)
- Include more in the nSDRG about verification
- Find ways for creators and their sponsors to verify that data is correctly formatted, consistent with the study report and usable for summarization in a manner consistent with the study report.

Questions/Comments?

Thank you!