SEND Survey 2023

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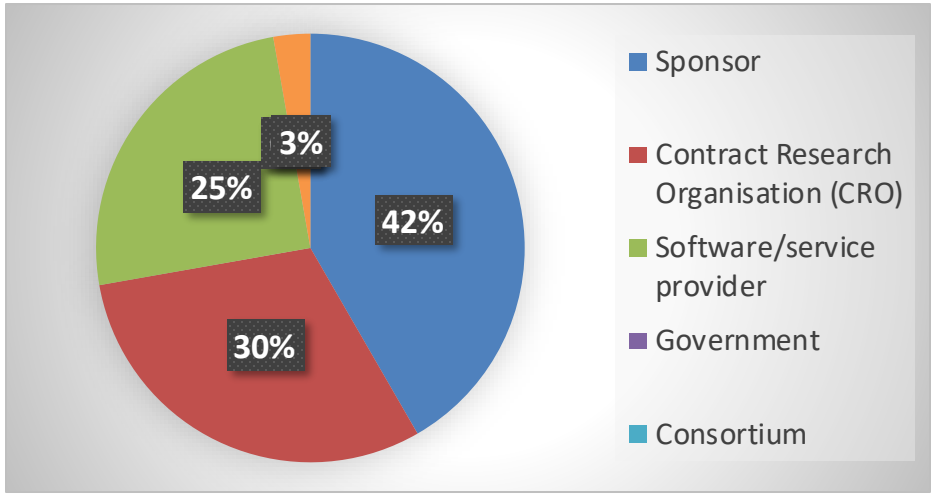
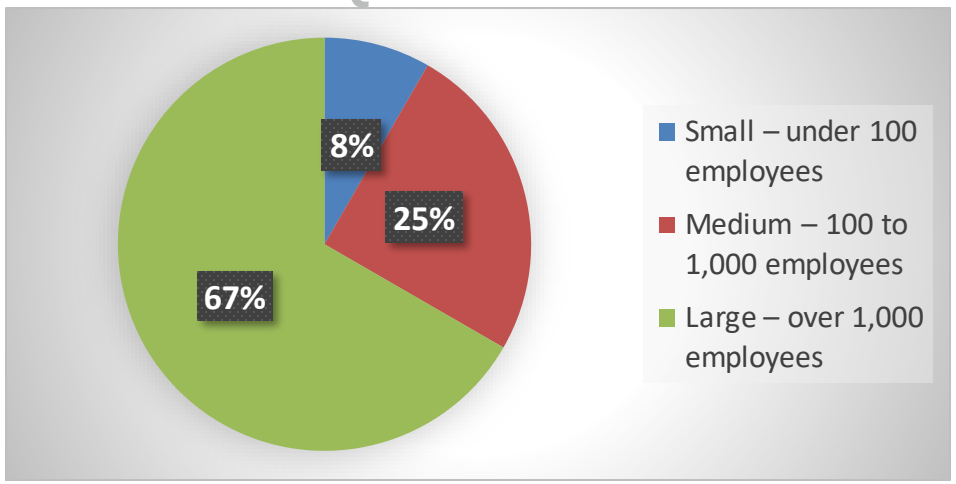
Demographics

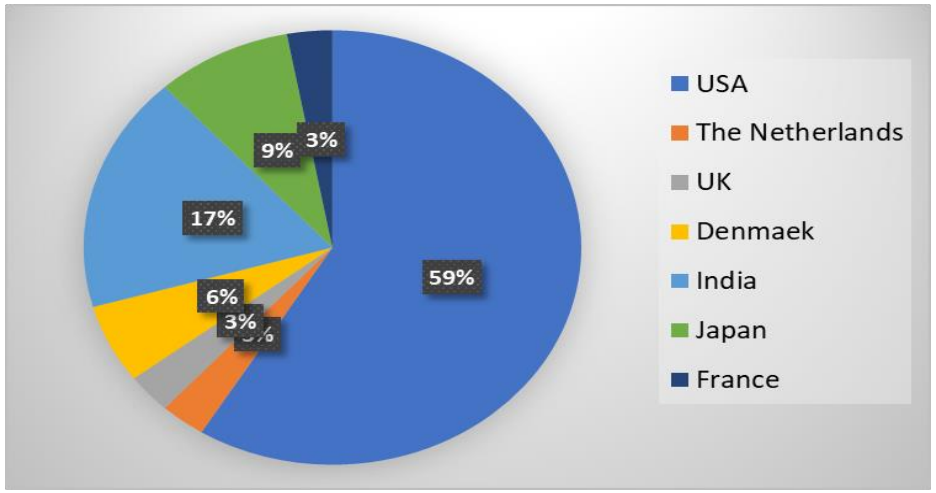
Q1 - Organisation



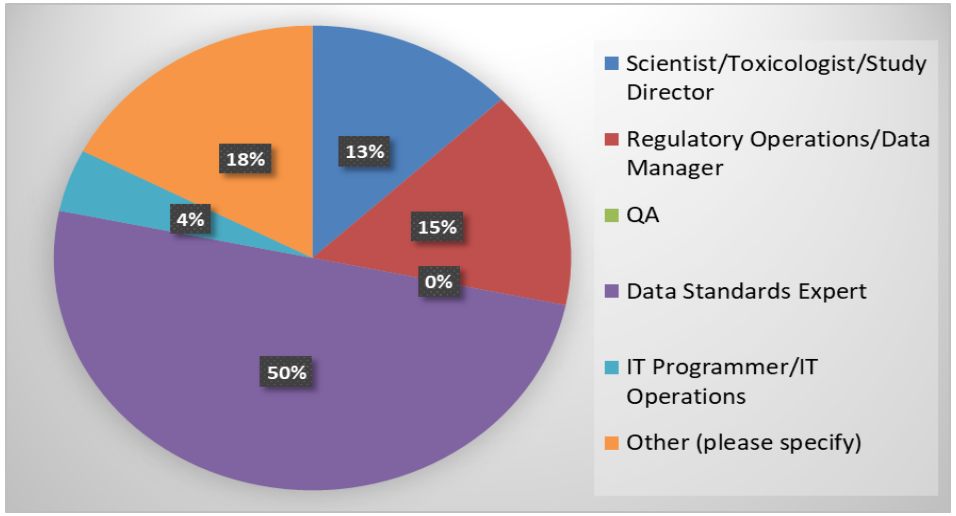
Q2 - Size



Q3 - Location

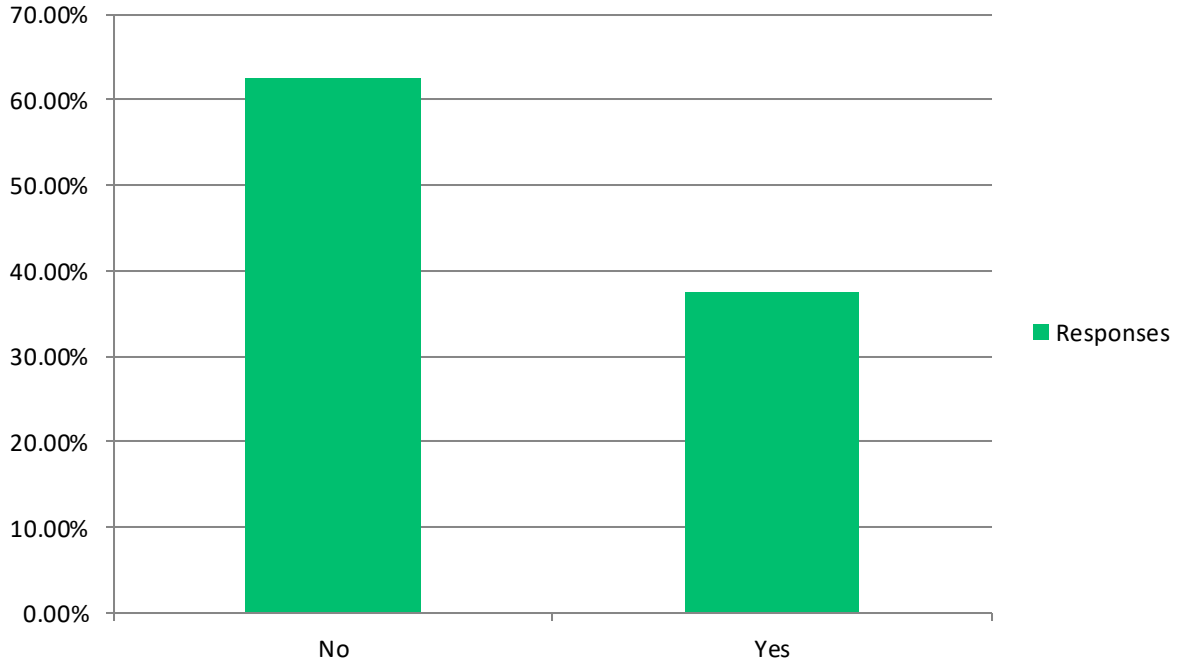


Q4 – Role



In Scope?

Q7 - Are there any out-of-scope data types that you currently include in your SEND datasets?



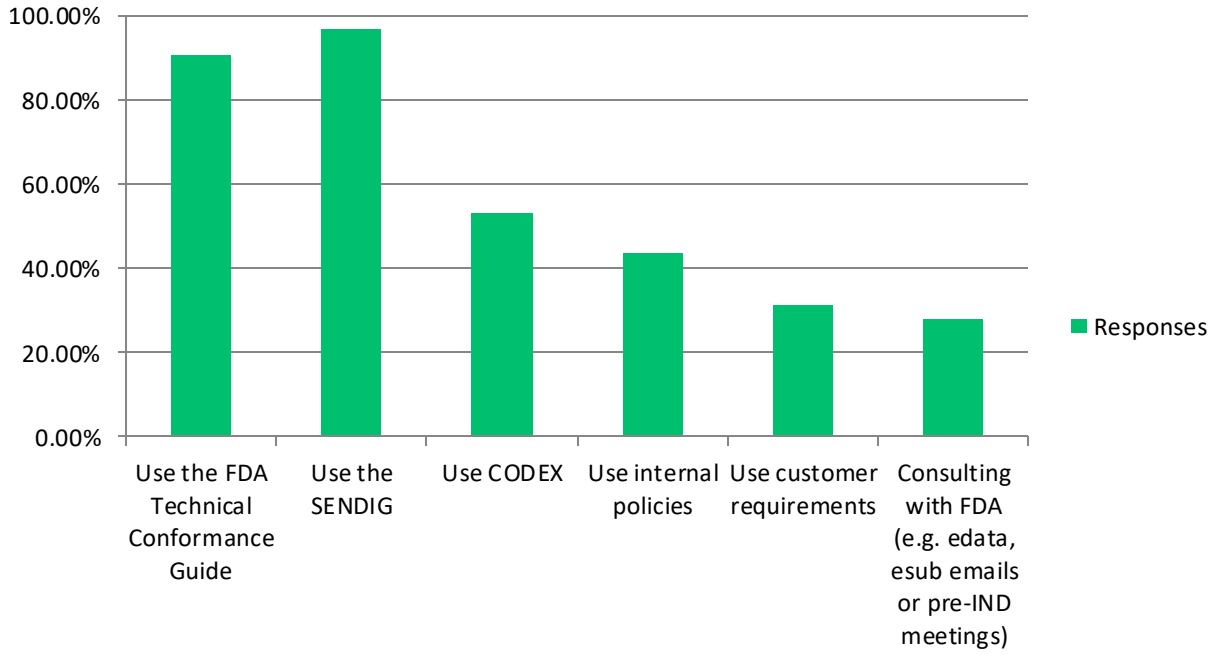
Out of Scope Data that is included:

- Any data that can be exchanged through the CP/LB/PC domain – such as cytokines, ADA, immunophenotyping, biomarkers
- Anatomical morphometric measurements
- CNS functional observational battery
- Immunotoxigenetics
- Local tolerance dermal scoring
- Male fertility (sperm analysis)
- Neurotox observations
- Ocular

Q5 - I am confident in my understanding of which data are in scope for SEND (1 being not very confident and 5 being very confident).

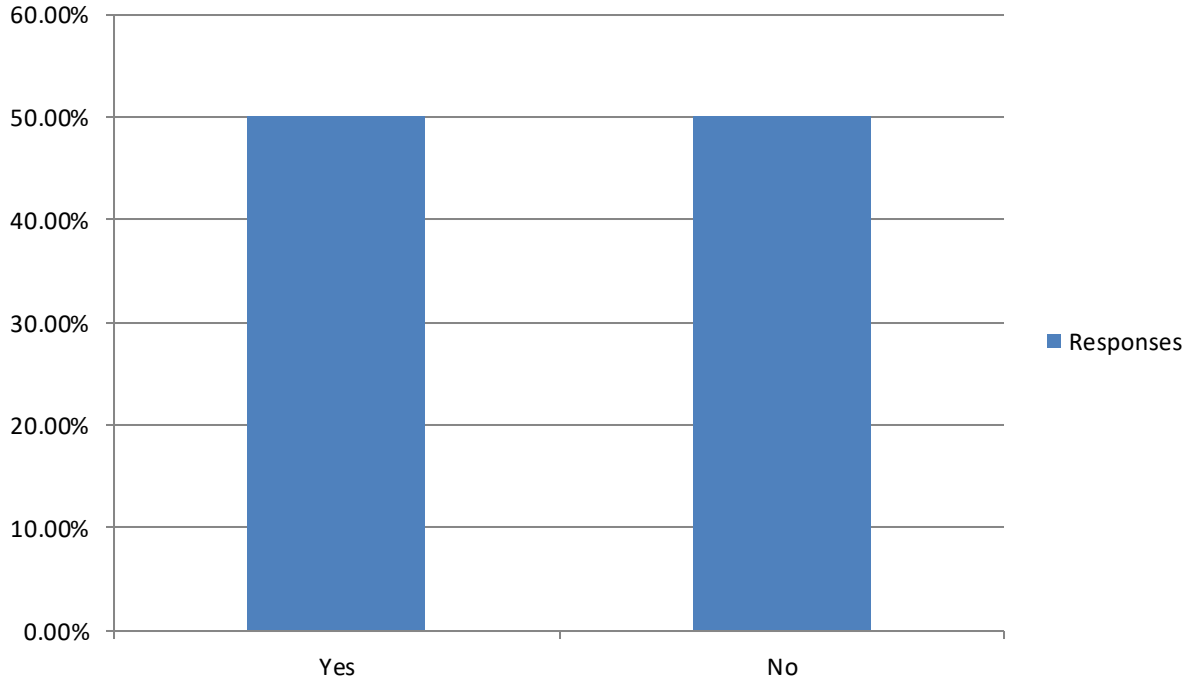
- Overall, the confidence level in the understanding of which data are in scope averages out to be ~75%. This value holds consistent with the results that we found last year.
- Of the total respondents, 64% of people ranked their confidence level at a 4 or 5.
- A total of 12% of the total respondents ranked their confidence level at a 1. Of these respondents, all identified as data standard experts.

Q6 - How do you decide what measurements are in scope for your SEND data? Check all that apply:

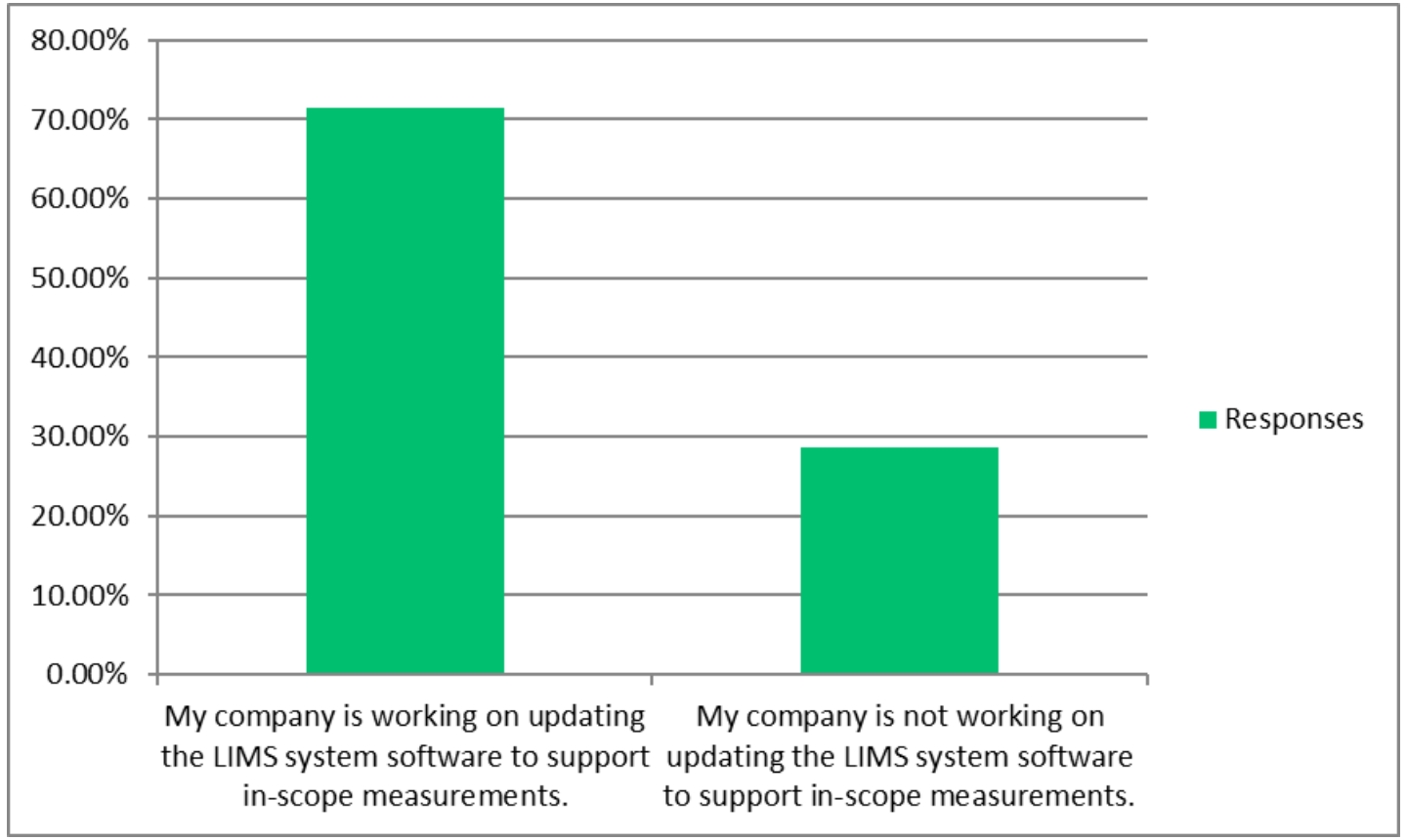


Manual Edits

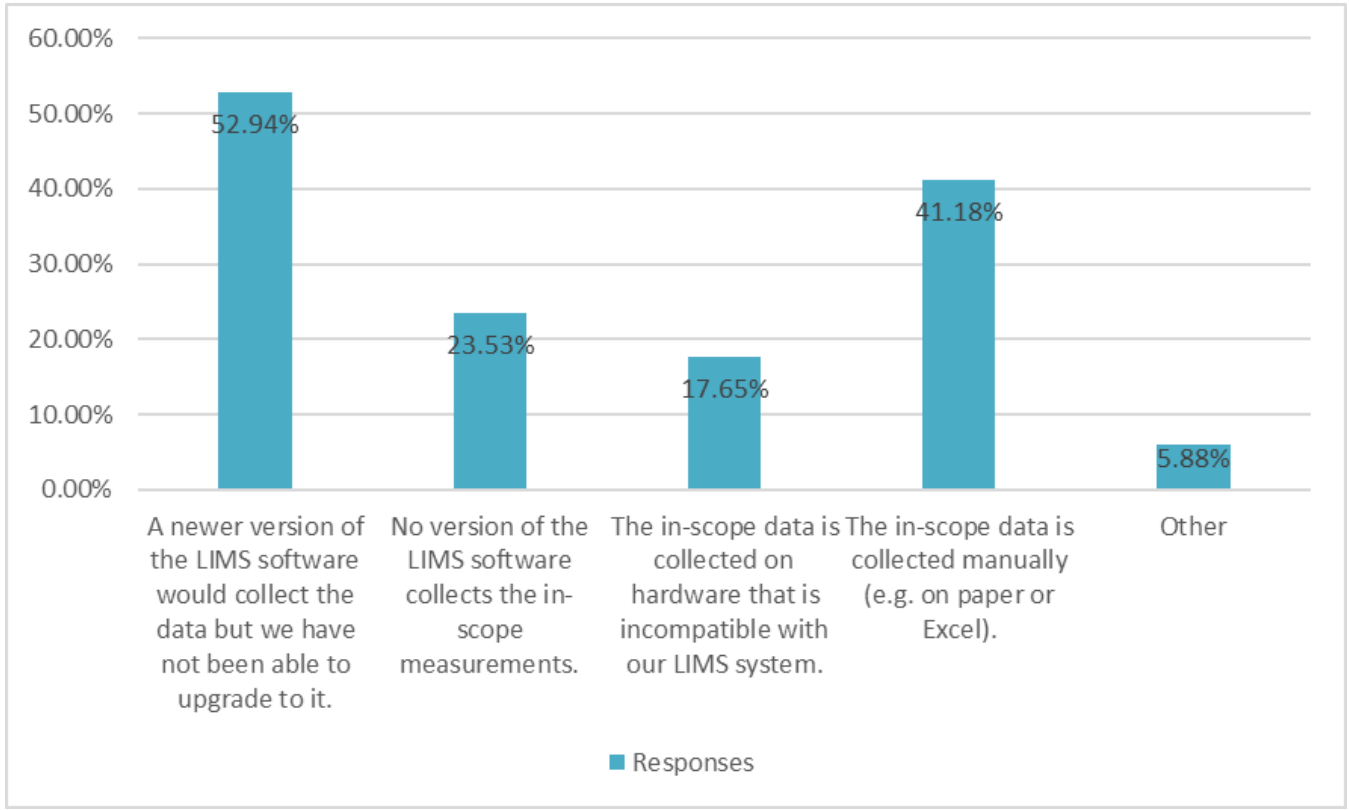
Q8 - Are there in-scope measurements in SEND that your LIMS systems do not have the ability to collect?



Q10 - Which is true?



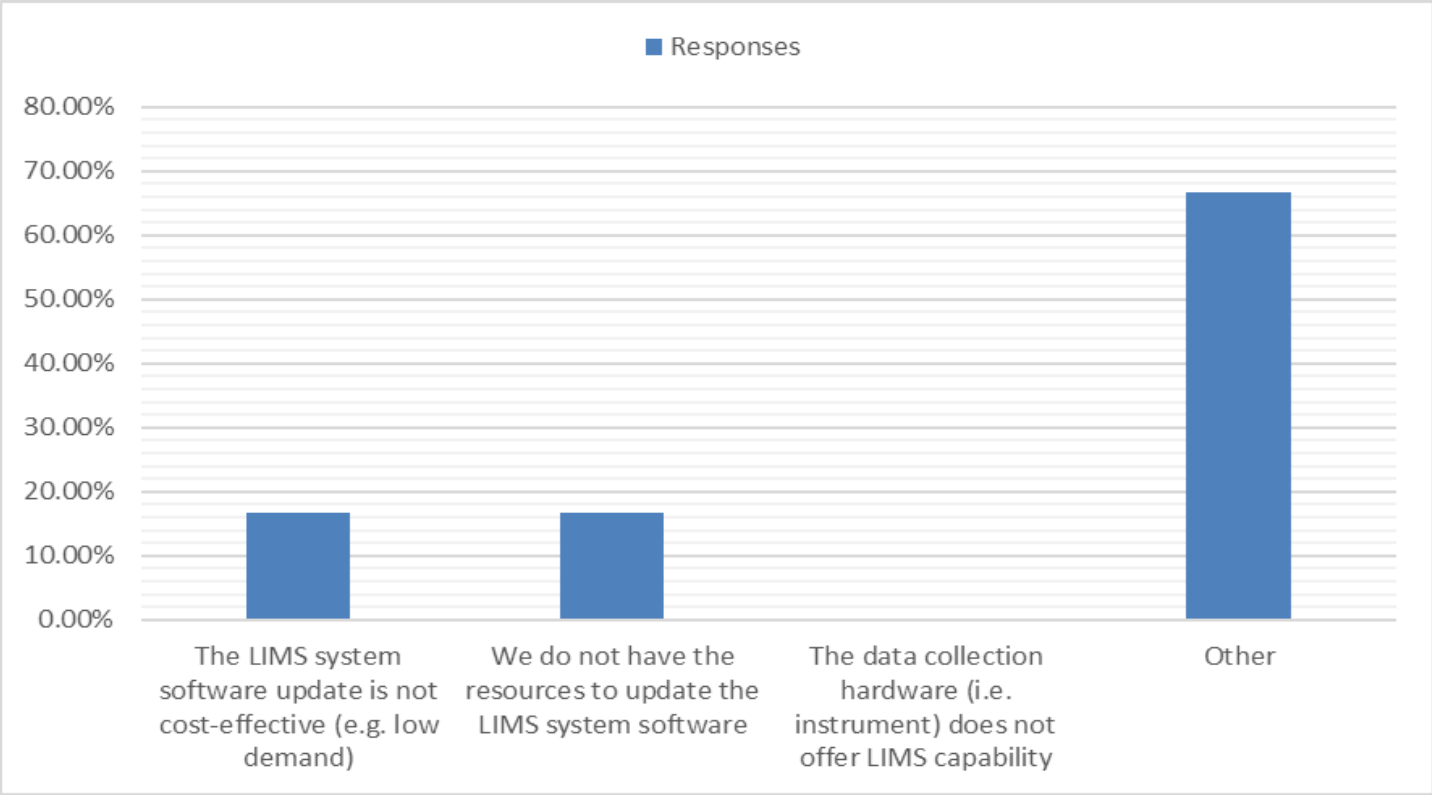
Q9 - If you answered yes, please choose all of the options that apply:



Comments:

- LIMS are often not designed with SEND in mind. Nor are they updated in a timely manner to meet SEND-related requirements. For this reason, it is not possible to require LIMS to retain all of the data that would be in-scope data.
- there are a large number of sub-studies associated with nonclinical studies that are not covered by the LIMS data collection capability.

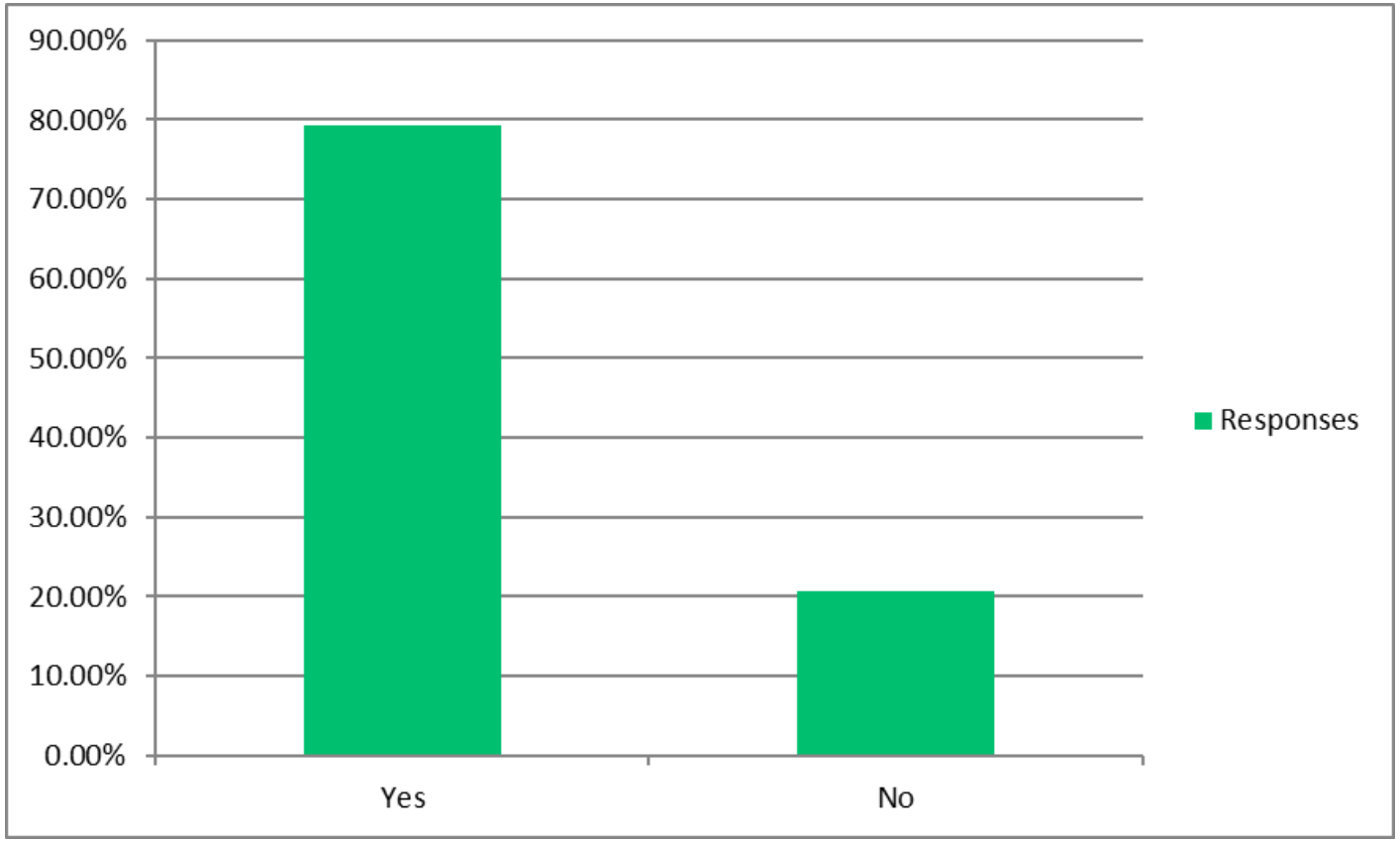
Q11 - If you answered “My company is not working on updating the LIMS system software to support all in-scope measurements”, which of the following are true?



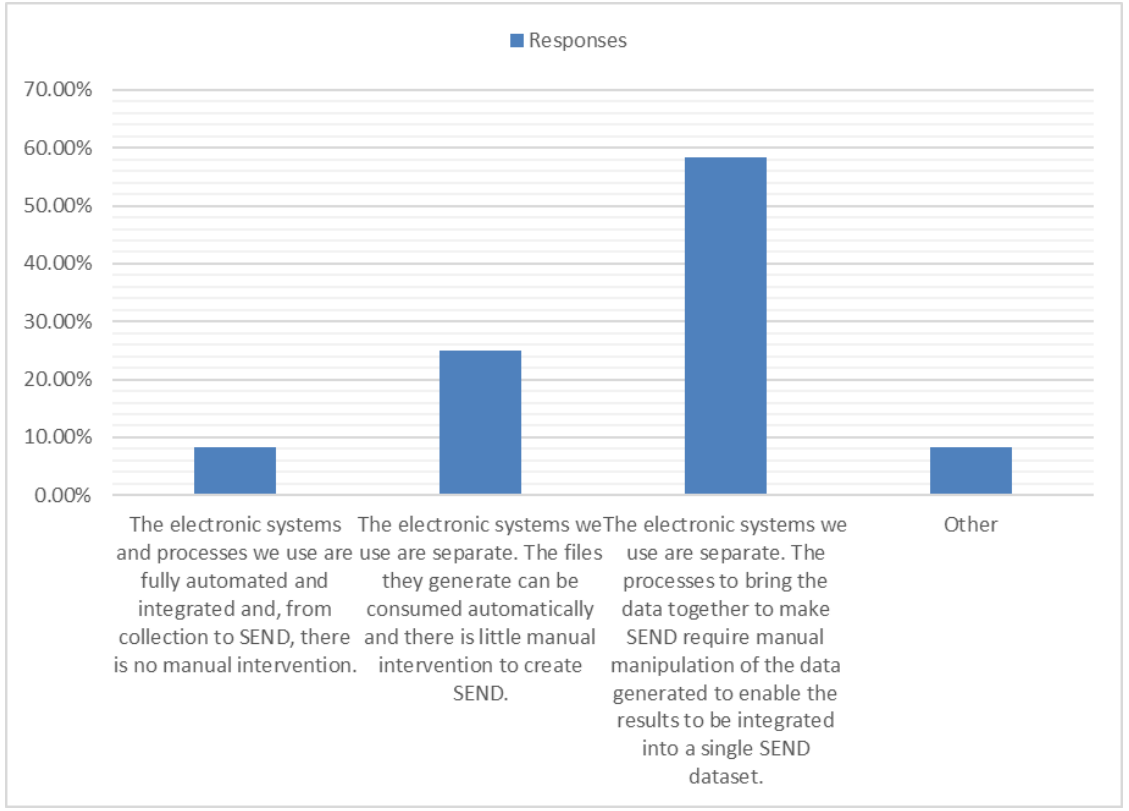
Comments:

LIMS lack the flexibility to add data collection methods, procedures, measurements as often as studies get updated and methods get changed.

Q12- Do you use more than one LIMS system to collect your study measurements?



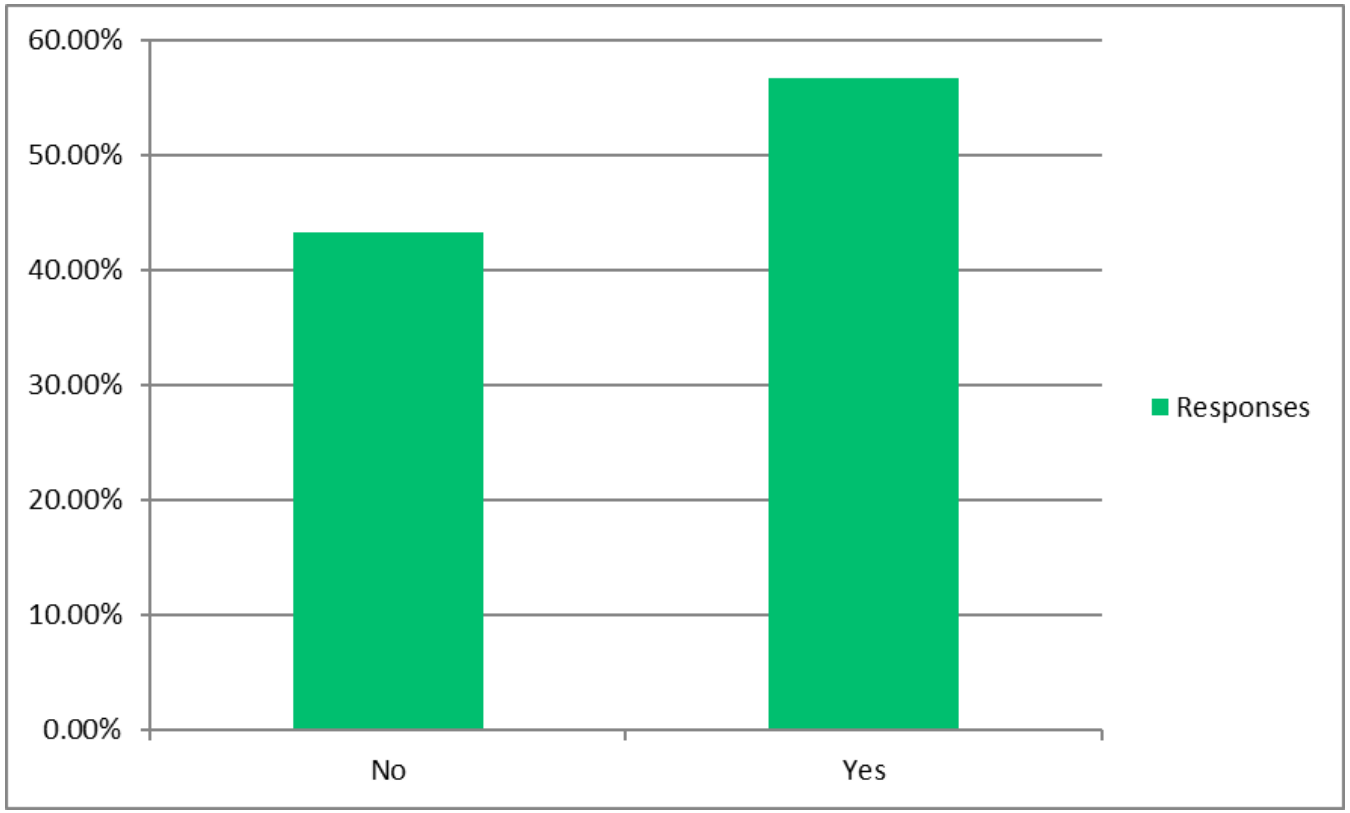
Q13 - If Yes, which of the following statements is true?



Comments:

- LIMS are fully automated, but some departments prefer not to use them fully - leaving gaps for dosing, TK and subject elements, that need to be manually compensated.
- the amount of manual effort varies across our systems

Q14 - Do you collect some measurements in LIMS and some manually?



Organisation Type	Yes Responses
Contract Research Organisation (CRO)	6
Software/service provider	4
Sponsor	7

Organisation Size	Yes Responses
Large	11
Medium	5
Small	1

Q14 - Do you collect some measurements in LIMS and some manually? (continued)

Reduces efficiency/LIMs unable to collect
Reduces efficiency, adds to QC processing and adds to customer price
This necessitates a manual process to create csvs to feed into our main LIMS. It can take a lot of time and adds a layer of complexity to the process.
The metadata required for TS.xpt, as well as creating the most complete SEND dataset, cannot be recorded in a LIMS, or is not currently recorded in CRO practices. External data such as this which is recorded manually/in the study report needs to be implemented via manual creation, impacting the timeline of creating a complete dataset.
A significant amount of metadata is extracted from the digitized Study Report or the Protocol for trial design, including all the metadata variables in data domains. All of these are outside the scope of LIMS as a source.

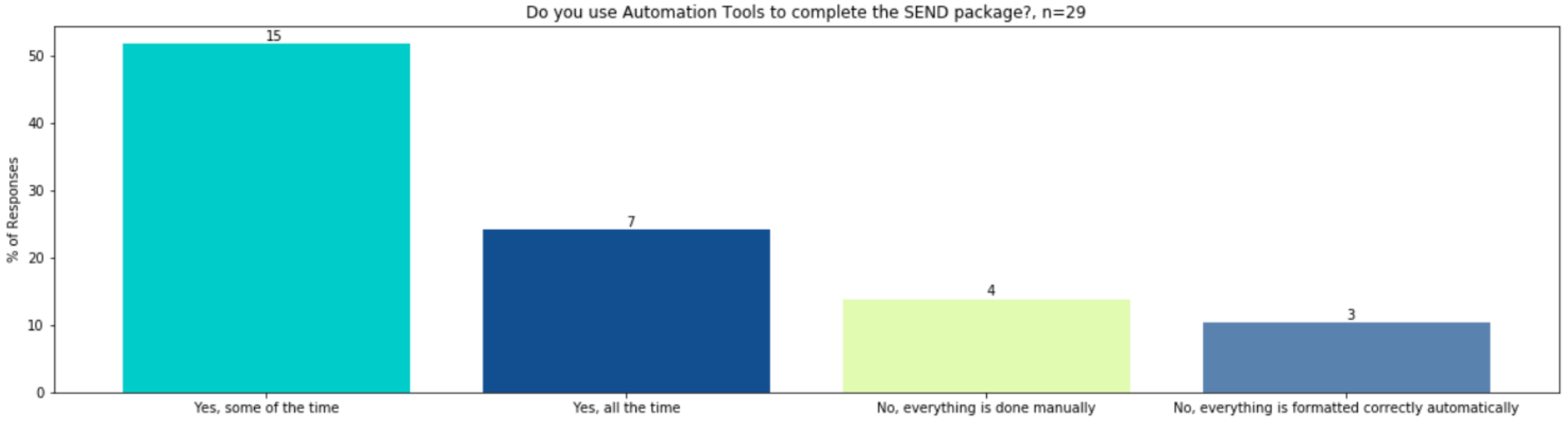
Q14 - Do you collect some measurements in LIMS and some manually? (continued)

Types of data not in LIMS - PC/PP/Safety Pharm
PK/PD data (current IG) and In-vitro data (gene tox, biomarkers, ADA and certain bioanalytical data, that are expected in future version of IG)
some PK and ECG results are recorded in Excel instead of LIMS
The most common example are date/time stamps on toxicokinetic data. TK blood collection dates and clock times are recorded manually, mainly because of the impracticality of recording such on our primary LIMS while doing the actual collection procedure. The secondary LIMS system used to analyze the samples either would require manual transcription of such "time stamps" or it cannot accommodate them at all.
Some parameters related to safety pharmacology (eg, ECG measurement, which is an independent instrument).

Other
In these cases we retrospectively enter the data into one of the LIMS.
results in some data not being entered into SEND
Minimal impact as data are easily converted

Automation

Q15 - Do you use locally applied automation tools (R scripts, Python scripts, etc.) to complete your SEND package?

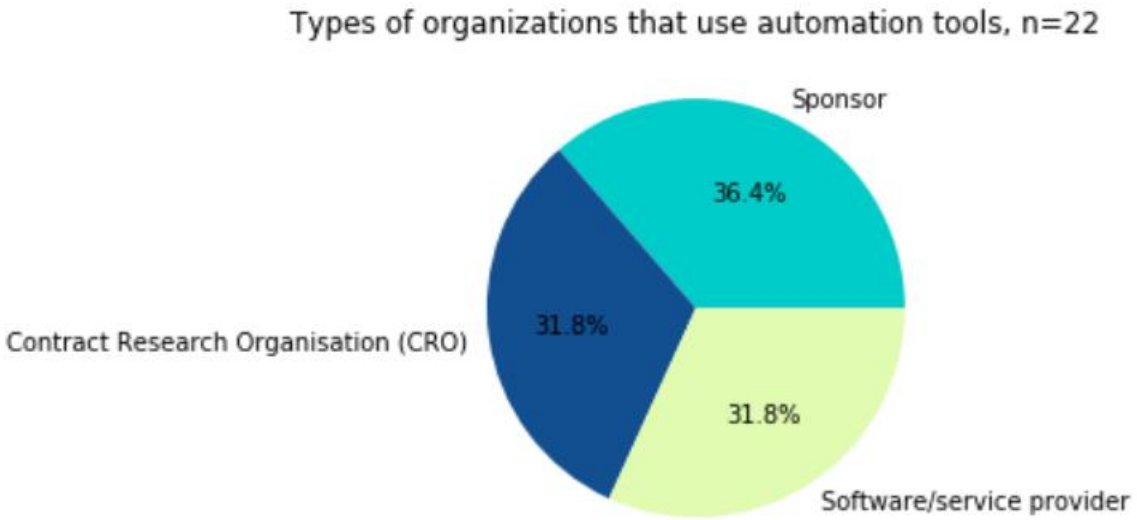


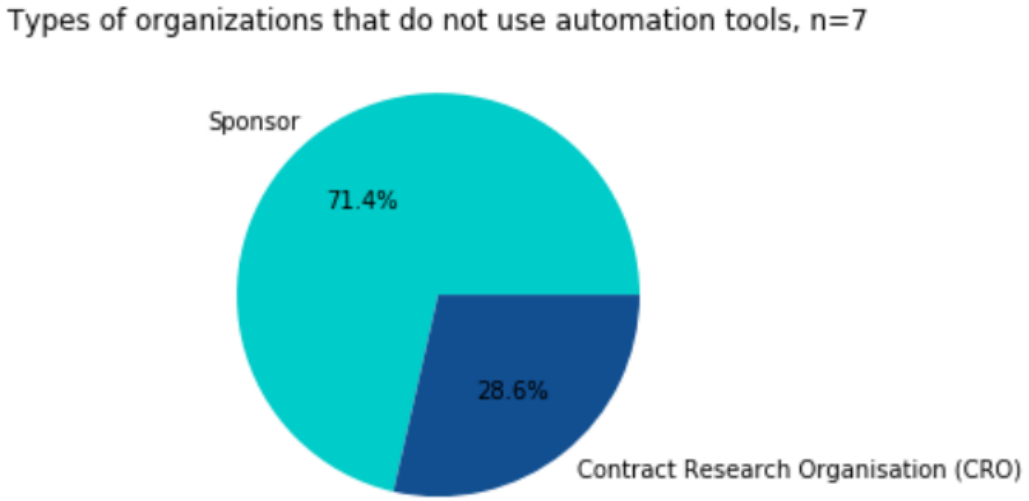
Q15 - Key points from comments

- **Uses:**
  Create trial sets
  Simplified TS files
  Data extraction
  Editing .xpt files
  Transforming data not from LIMS (e.g. cytokine, ADA)
  EG, CV, RE, VS datasets

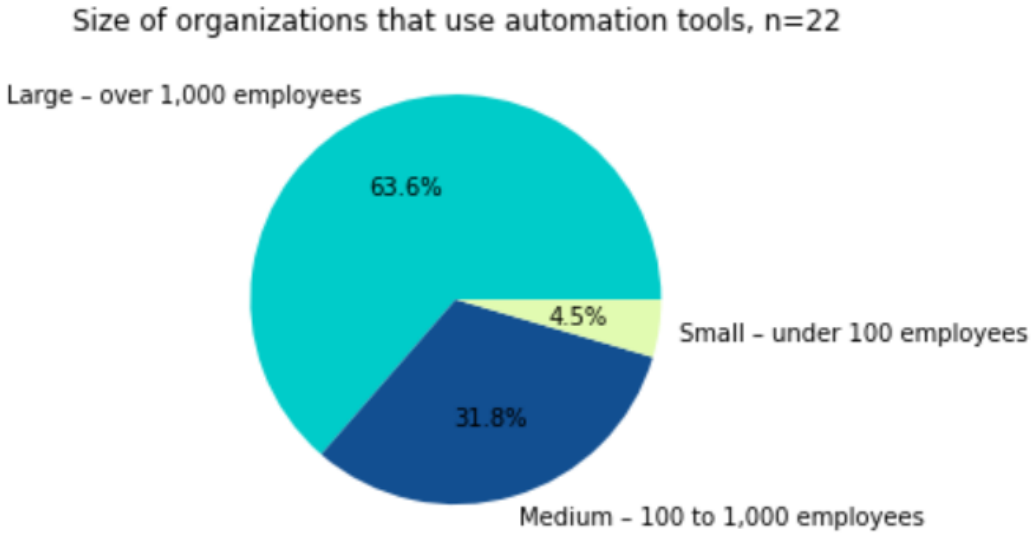
- **Languages Used:**
  R
  Excel macros
  Flat File data adapters
  Python
  SAS-based software

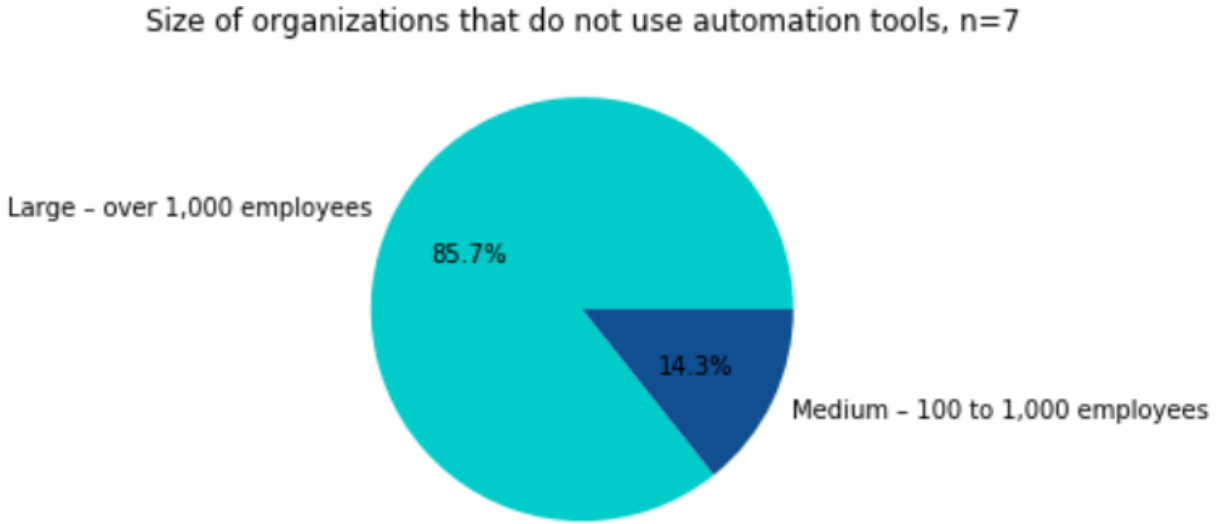
Comparing Q15 - Types





Comparing Q15 - Size

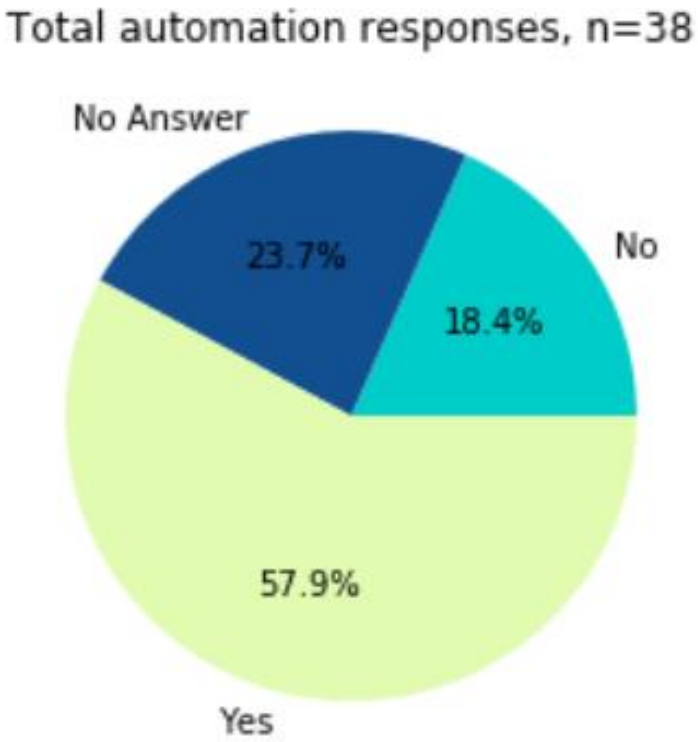




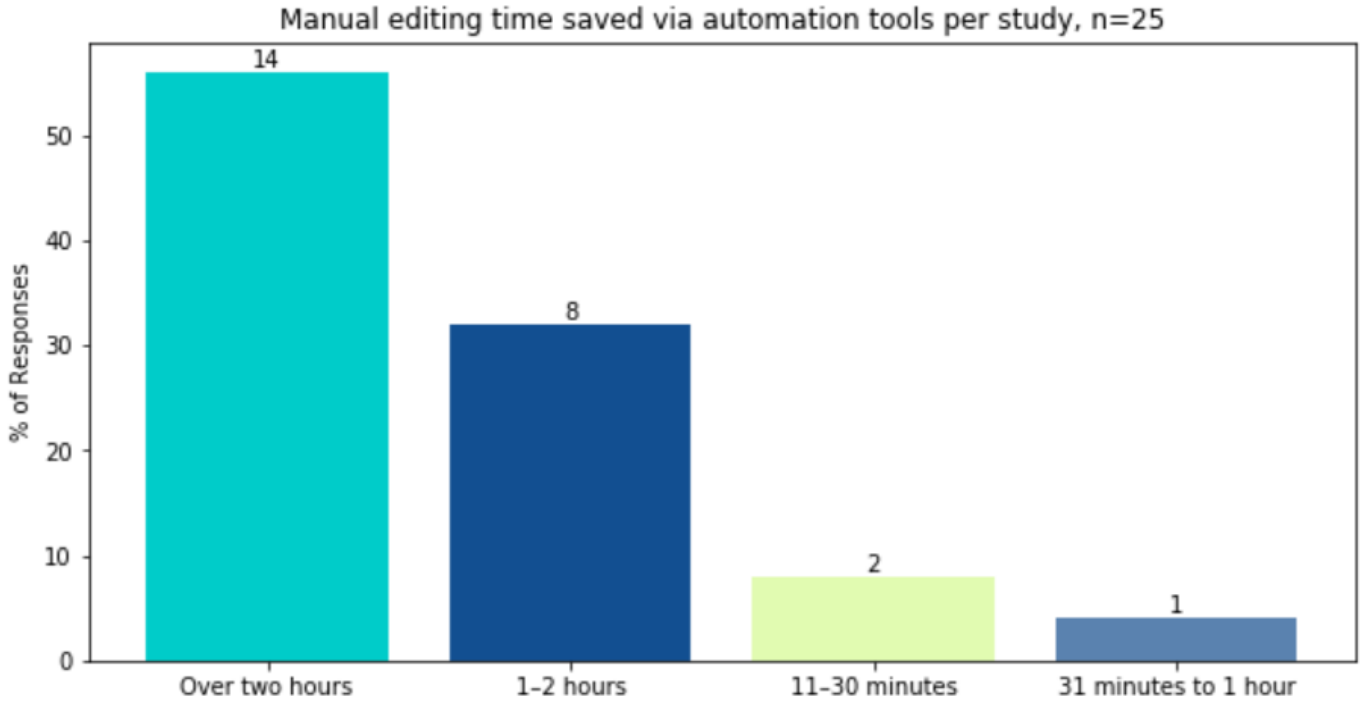
Comparing Q15 - Total Responses

Breaking down the data in Q15, we found that 57.9% of organisations do use automation as part of their SEND processes at some capacity

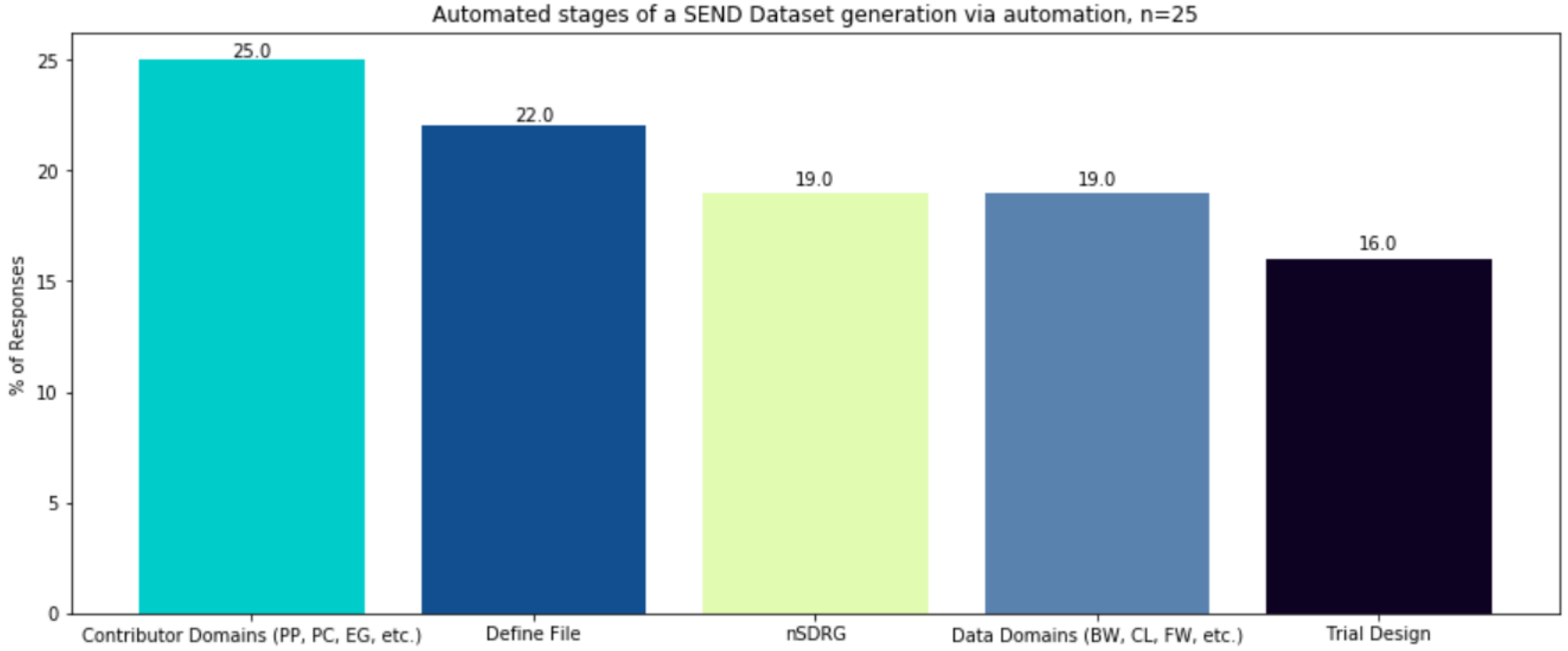
Category	Q15 Response
Yes	Yes, some of the time Yes, all of the time
No	No, everything is done manually No, everything is formatted correctly automatically
No Answer	Skipped



Q16 - Estimate how much manual editing time (touch time) using these automation tools saves you per study?



Q17 - What parts of the SEND dataset generation process are being automated by locally applied automation tools? Choose all that apply:



Q17 - Comments of Interest

Comments

Our SEND system is capable of preparing an nsdrg template with some of the study-specific detail derived from primary LIMS system.

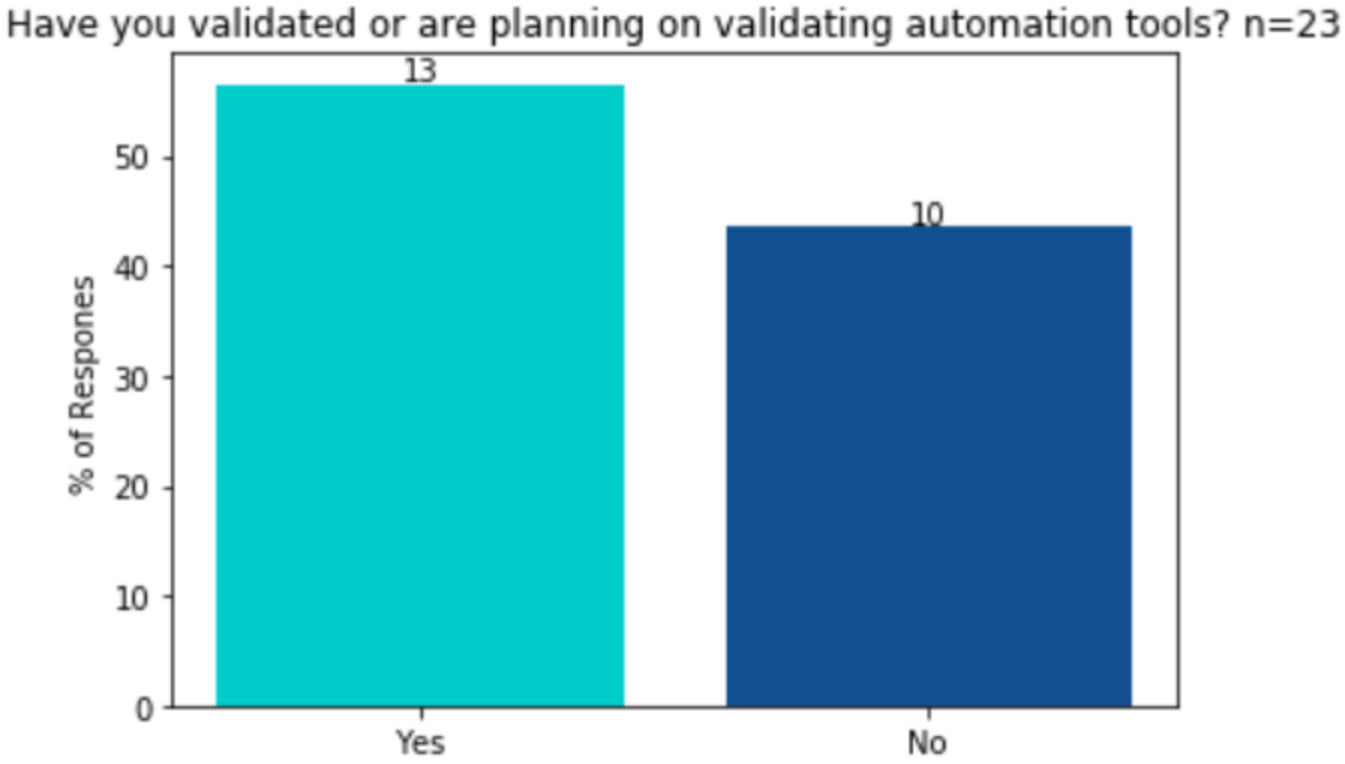
Note that for nSDRG we are still implementing a new automation tool, but once live, will automate the majority of the document

Any collected data that is not formatted as SEND is processed through automation tools that read the source format, mapping from source format is then manual. Finally, there is an automated reading of the mapping to generate SEND formatted data. The define file is 95% automated from the datasets and our metadata repository.

Key-Point

- Comments suggest that there is interest and current development in nsdrg automation

Q18 - Have you validated or are planning on validating automation tools?



Q18 - Comments of Interest

Comments

All tools are validated before entering production.

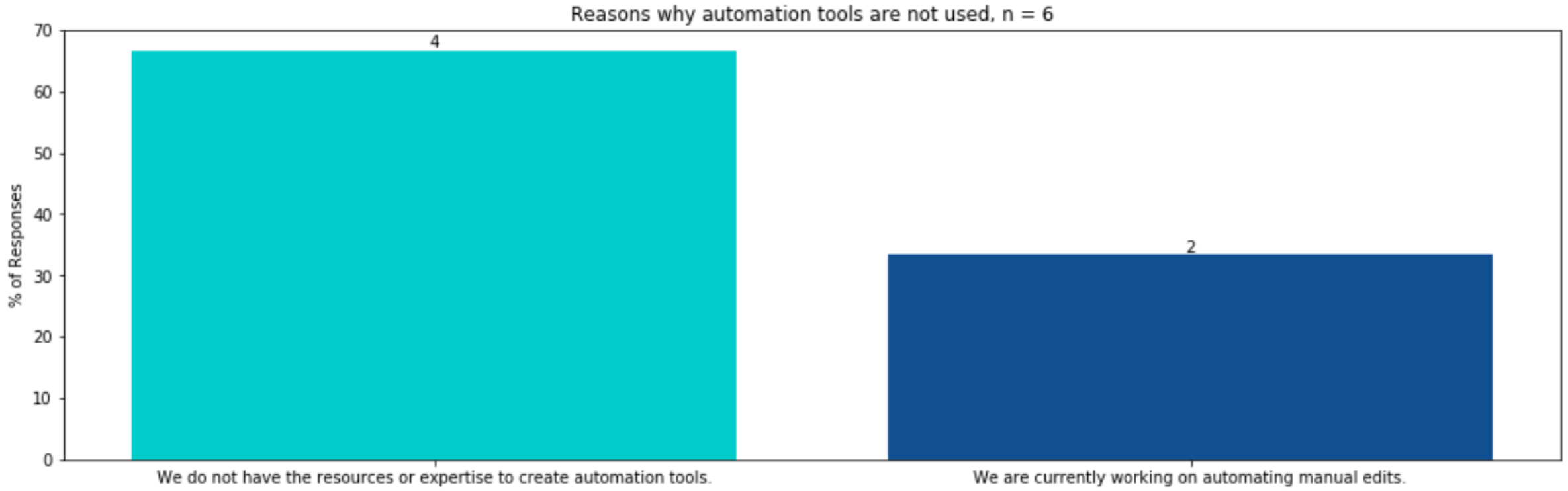
CDISC Japan User Group, SEND team prepare validating automation tools for SEND data and Define-XML .

Qualified. Regular testing.

The automation tool creates edit rules to are reviewed and imported into a validated tool that creates the records.

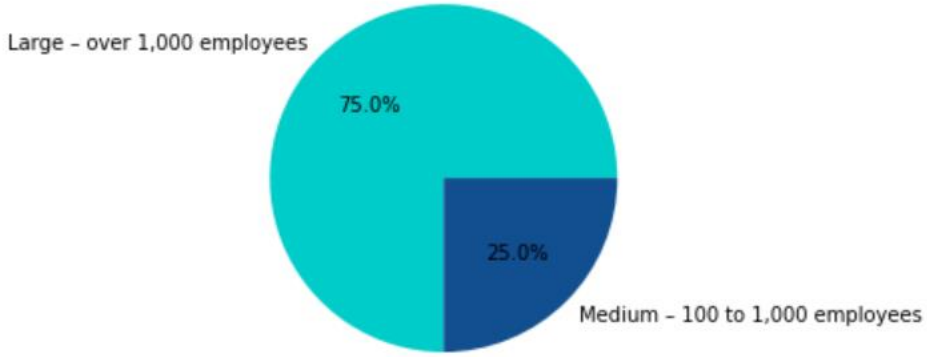
We are planning on validating automation tools but we do not have strong development infrastructure or hygiene. At this time, validation would be too resource intensive.

Q19 - If you answered No[to Q15], why not? Choose all that apply:

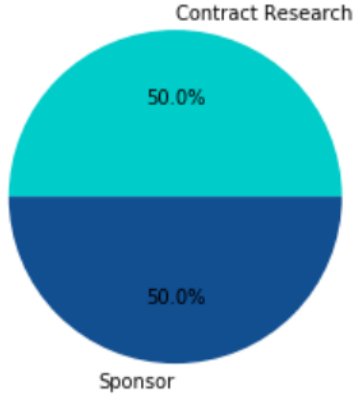


Comparing Q19 - Types & Size

Size of organizations who do not have the expertise or resources to develop automation tools for SEND, n=4

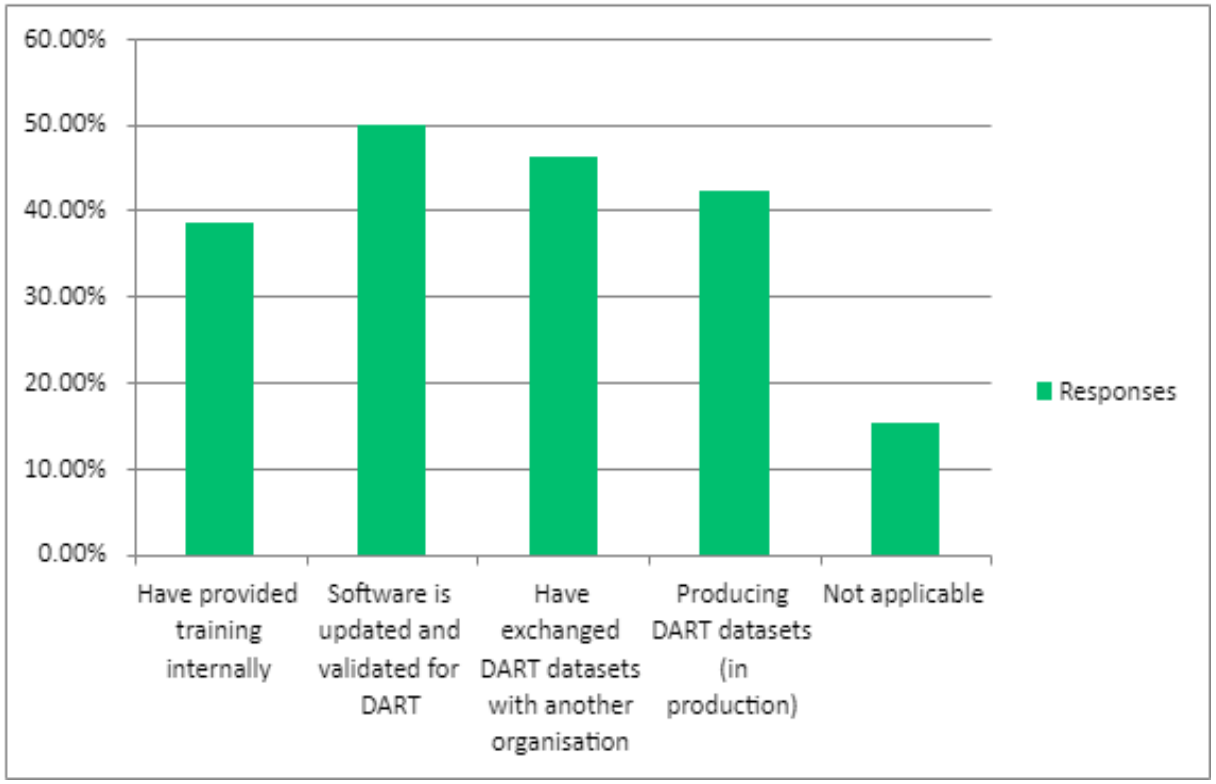


types of organizations that do not have expertise or resources to develop automation tools for SEND, n=4



Future Standards

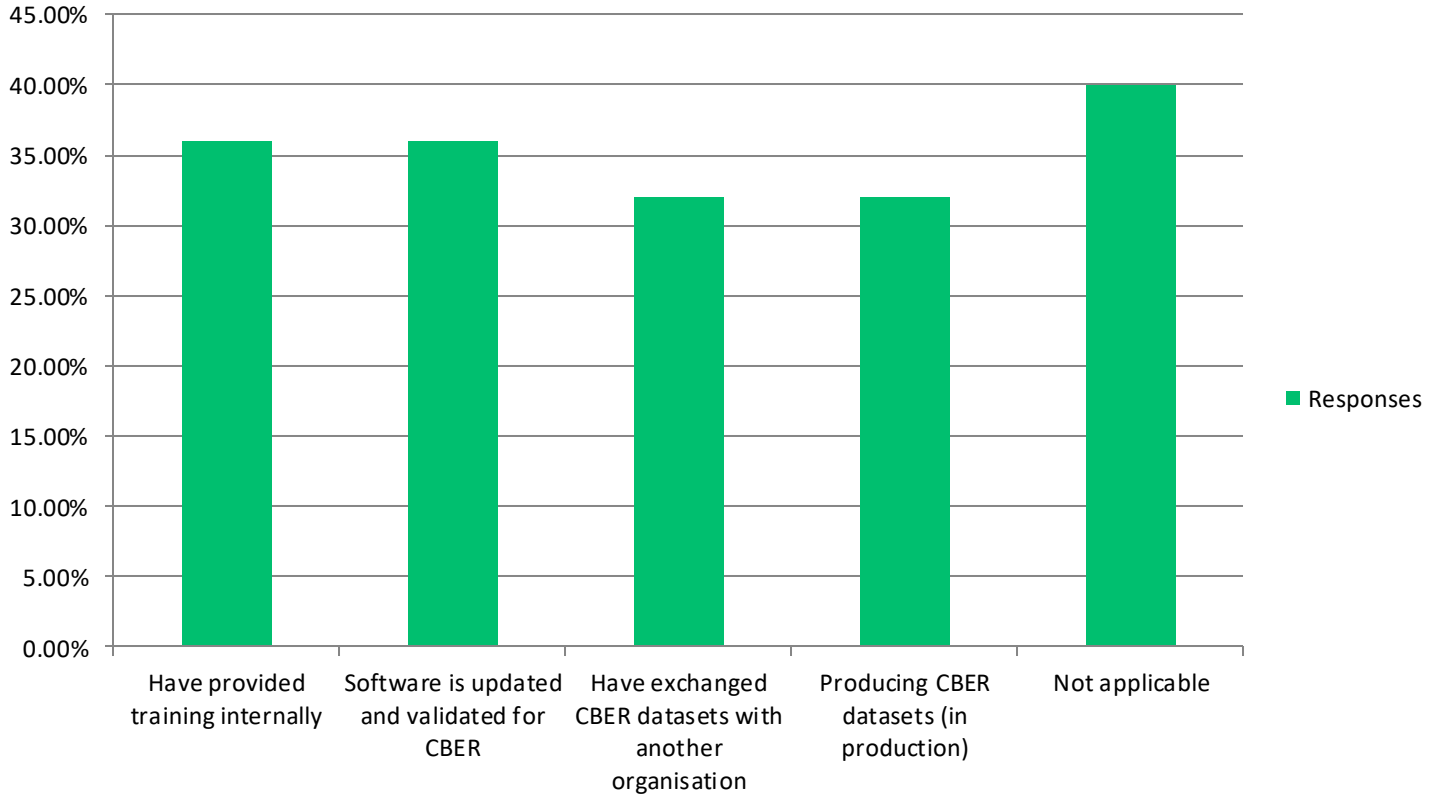
Q20 - What actions are you currently taking/have taken towards DART implementation? (Select all that apply.)



Comments:

- Have evaluated our ability to review DART datasets.
- Internally we currently have no plans to generate datasets for these studies types and will get these datasets from CROs . Our tool is able to load DART studies.
- Have specified reliable CRO that can produce DART SEND datasets.
- Have worked with our CRO partner and received several DART study SEND packages, and have updated/modified our SEND database/warehouse as needed so that DART studies will be accepted for upload.

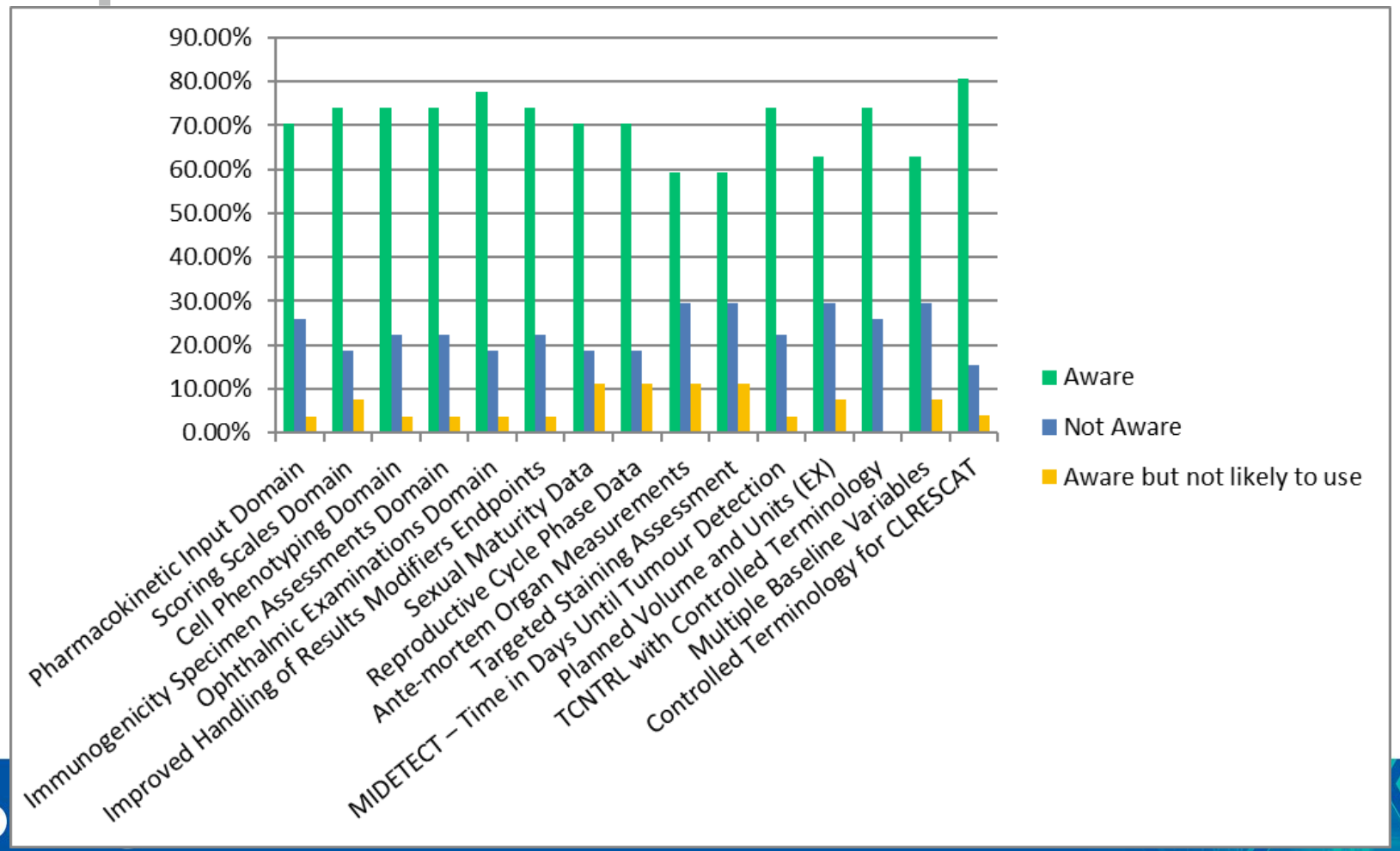
Q21 - What actions are you currently taking/have taken towards CBER implementation? (Select all that apply.)



Comments:

- Rarely submit to CBER.
- The current validated system fully supports for SENDIG 3.1, 3.1.1 and DART v1.1 for both CDER/CBER submissions, however the CBER specification domains are under development and will be ready shortly.
- We don't consider "CBER datasets" any different than those created for CDER. All are SENDIG 3.1.
- We have been submitting SEND to CBER for a number of years (before it became a requirement).

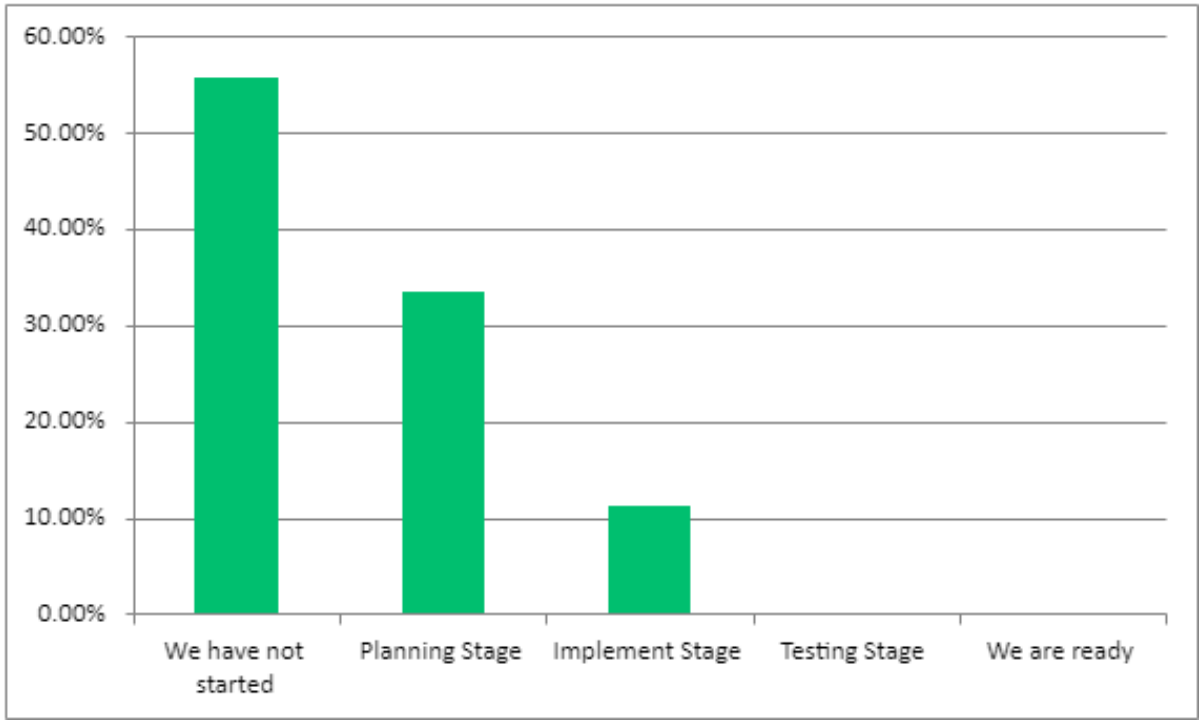
Q22 - Are you aware of the following elements that are proposed to be included in SEND 4.0?



The elements with the lowest awareness are:

- **Ante-Mortem Organ Measurements**
- **Targeted Staining Assessment**

Q23 - Have you begun implementation of SEND 4.0? If so, what stage are you in?



Comments:

- Planning to create adapters to bring new endpoints into LIMS
- As it is not even published, it's far too early to begin implementation. We are aware as we have staff on almost every CDISC SEND team.
- Under development
- waiting for publication of the new SENDIG and system upgrades

Q24 - What are the next biggest gaps in SEND implementation standards that you would like to see developed by CDISC?

Count	Topic	Comment
2	Ocular/Dermal	Ocular / Dermal Studies that have different doses per site.; skin sensitization (GPMT / LLNA) test results (Draize scoring).
2	genetox	In vitro GeneTox; In vivo GeneTox (mouse micronuclus tox assay)
2	neuro	FOB/CNS data; neuro and all repro findings endpoints.
2	immunology	Faster realization of immunology; PBMC for in-vivo studies
2	CT	Expanded CT (specifically CL)
2	exclusion flag	add exclusion flags to PP; exclusion flags in all domains
2	Multi-phase	To clarify or provide examples in SEND for more study design types and address multi-phase studies.
	LB	Urine Fluoride data
	codex	Updates to the codex for confirmed and clear data endpoints
	Usability	Continue to develop standards that facility the usability of the data for analysis by scientists.
	Define	Clarifying define.xml content
	in vitro	A huge gap is in vitro and ex vivo. With the release of the TIG, the SEND team have fallen way behind, and the pharmaceutical industry will now be stuck with what has been modeled for tobacco products. Highly problematic that use cases for in vitro has not been sought from the SEND team before this is vetted by SDTM.

Q25 - What would you like PHUSE to work on?

Topic	Comment
Knowledge mgnt-build capabilities	Identify use cases where changes in the standards would enable sponsors to extract scientific information from the data sets.
Knowledge mgmt	To discuss important issues for sponsors and CROs from the user's point of view and publish them as white papers, although they are not what CDISC should work on.
Knowledge mgmt	Overcoming operational and personnel barriers to using SEND data across drug projects.
Bridging preclin & clin-KM	Identifying and testing translational hypotheses using integrated SEND and SDTM data.
ID best practices	Promoting best practices of SEND implementation and use achievements across Industry.
Combo DART guidance	Work with the CDISC DART team who are currently working on examples to provide guidance on how to meet the FDA's current TCG requirement for combo repro studies (e.g. Fertility + EFD, and PPND + EFD). Develop best practices for implementation (data representation based on industry / CRO experience) of DART v1.1

Q25 - What would you like PHUSE to work on?

Topic	Comment
DART	Develop best practices for implementation (data representation based on industry / CRO experience) of DART v1.1
Automate/Trial design	how to automate more the creation of trial design data :)
Trial design	Trial design modeling for non-standard study types (more than just 4 week repeat dose tox)
CBER	managing upcoming CBER specific SEND domains and invitro gene tox data.
Visualization	more use cases for visualizing SEND data
New SEND members	Better communication to new members of the SEND community
Define/nSDRG	address common issues: define, nsdrg
focus to enable momentum	more single day events for non-clinical topics

Propose poll here on previous slide

Questions/Comments?