

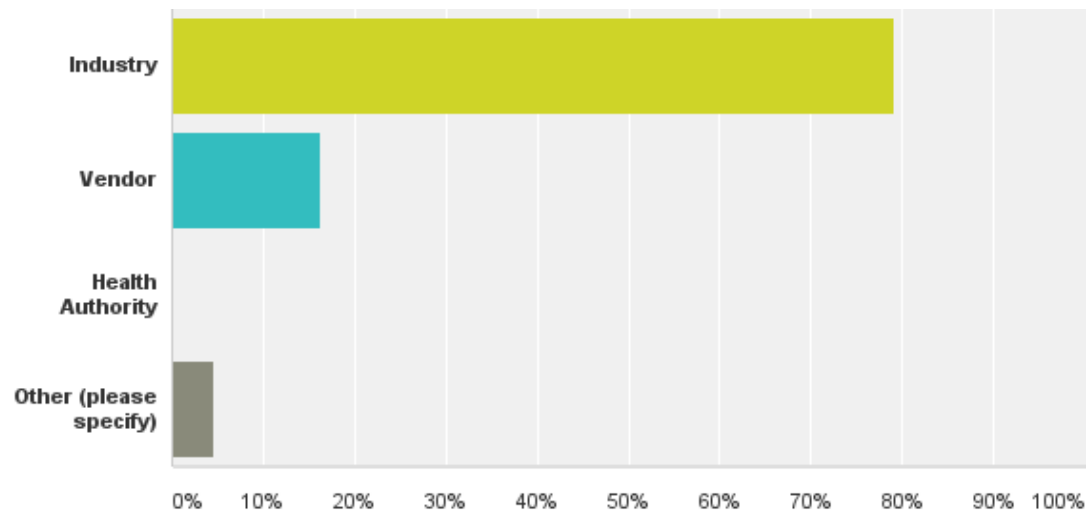
2016 Electronic Regulatory Submissions Survey

Tuesday, July 26, 2016

Powered by  SurveyMonkey

Q1: Which best describes your work affiliation?

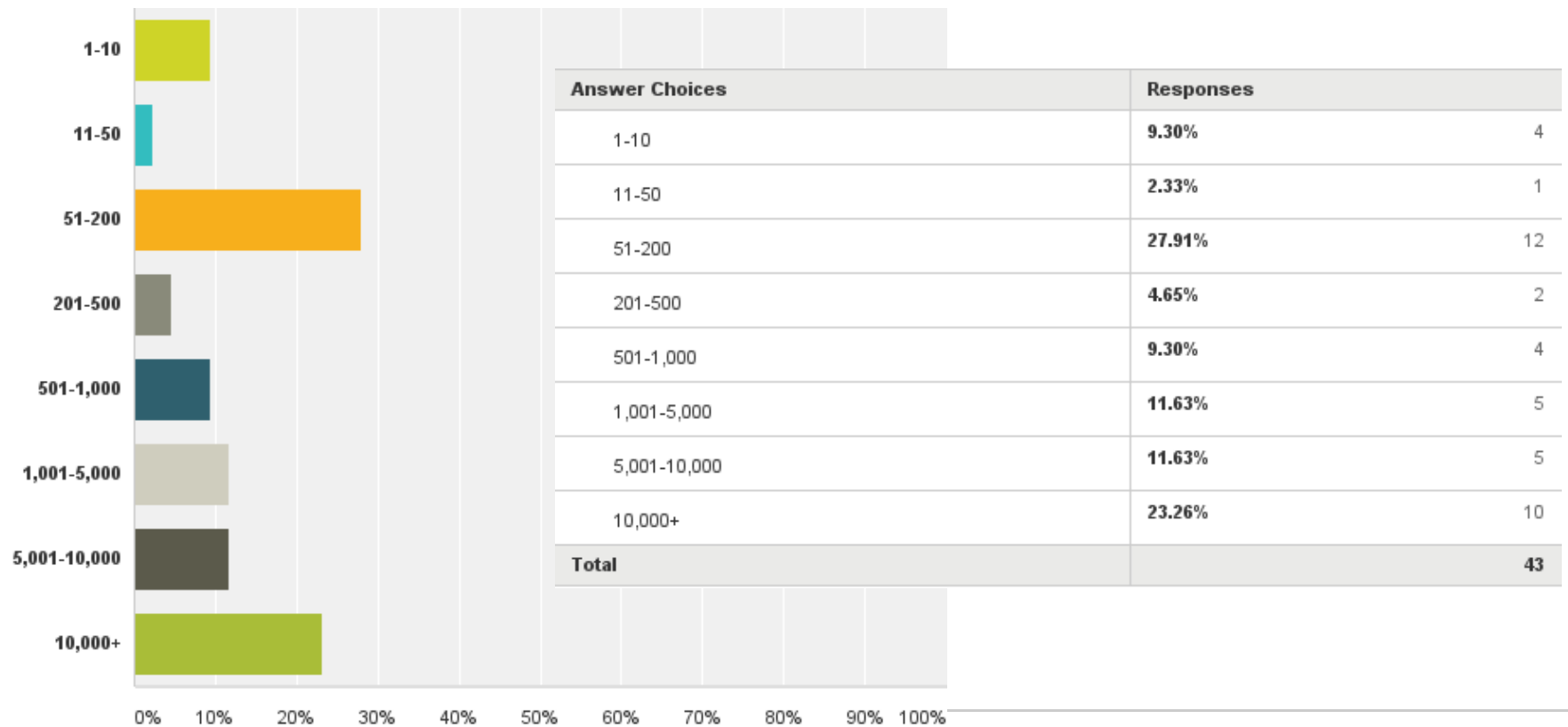
Answered: 43 Skipped: 0



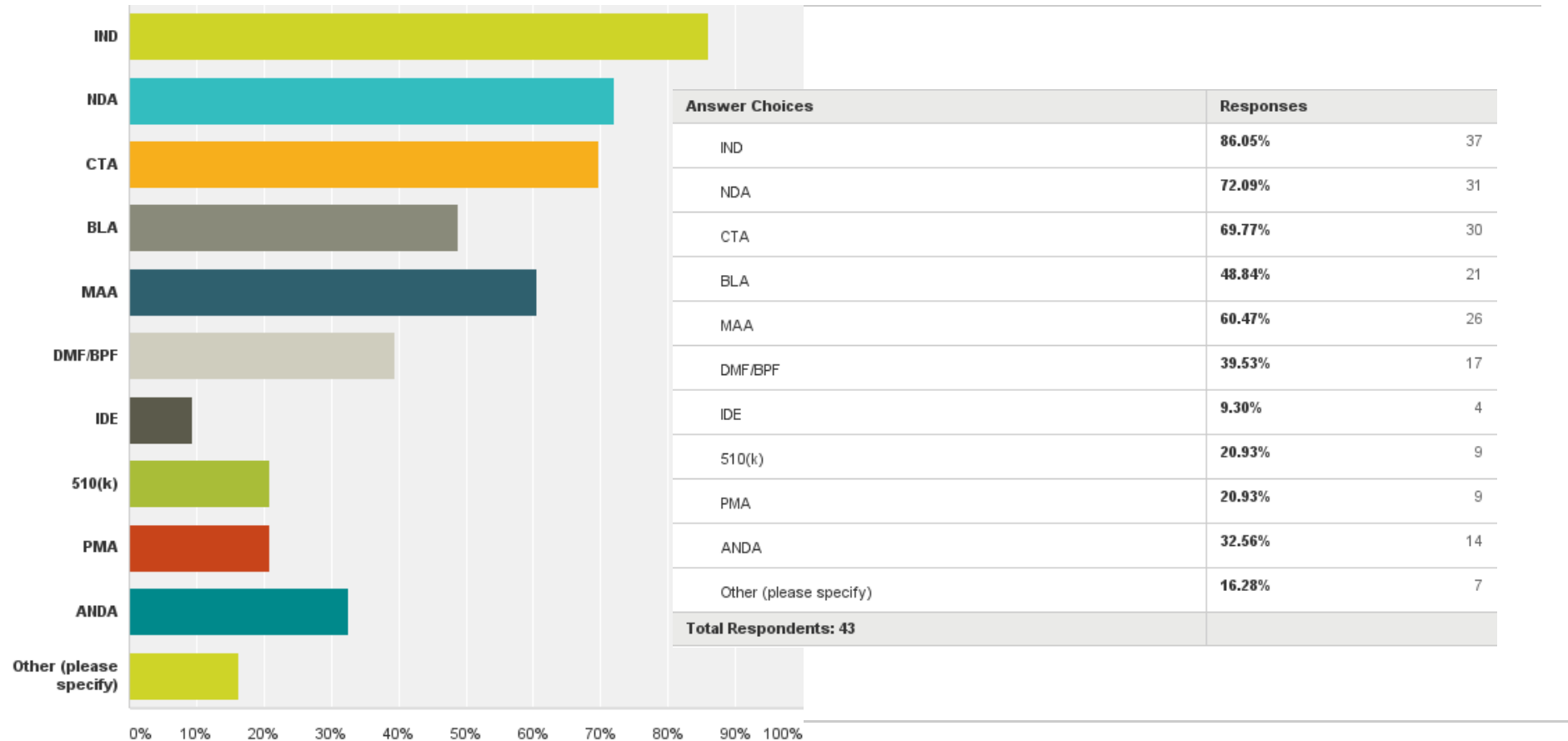
Answer Choices	Responses
Industry	79.07% 34
Vendor	16.28% 7
Health Authority	0.00% 0
Other (please specify)	4.65% 2
Total	43

Q2: What is the size of your organization?

Answered: 43 Skipped: 0

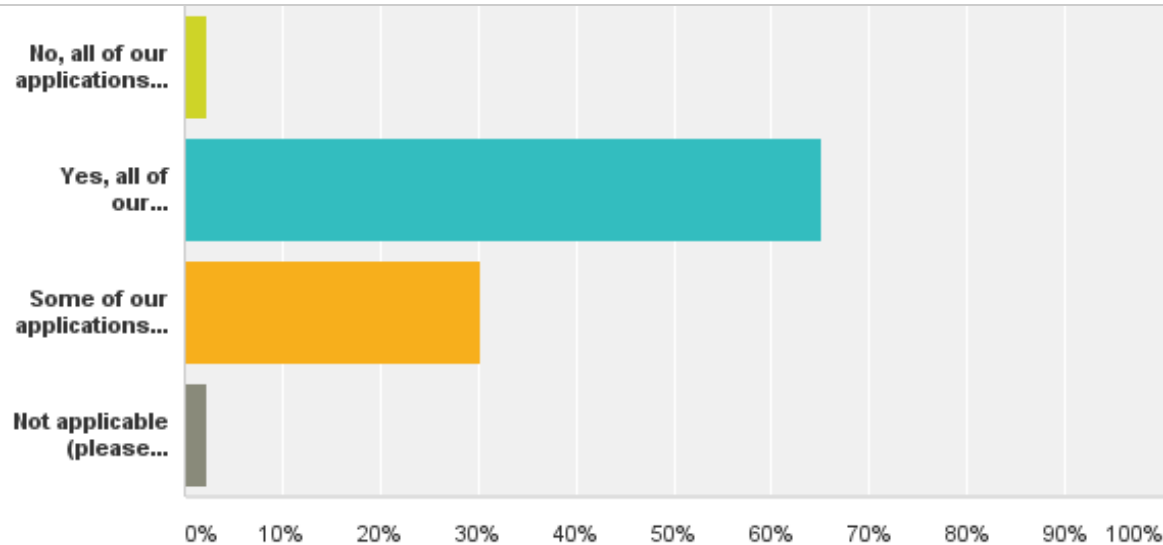


Q3: What type(s) of health authority applications does your company submit? (select all that apply)



Q4: Does your company already submit health authority applications in eCTD format?

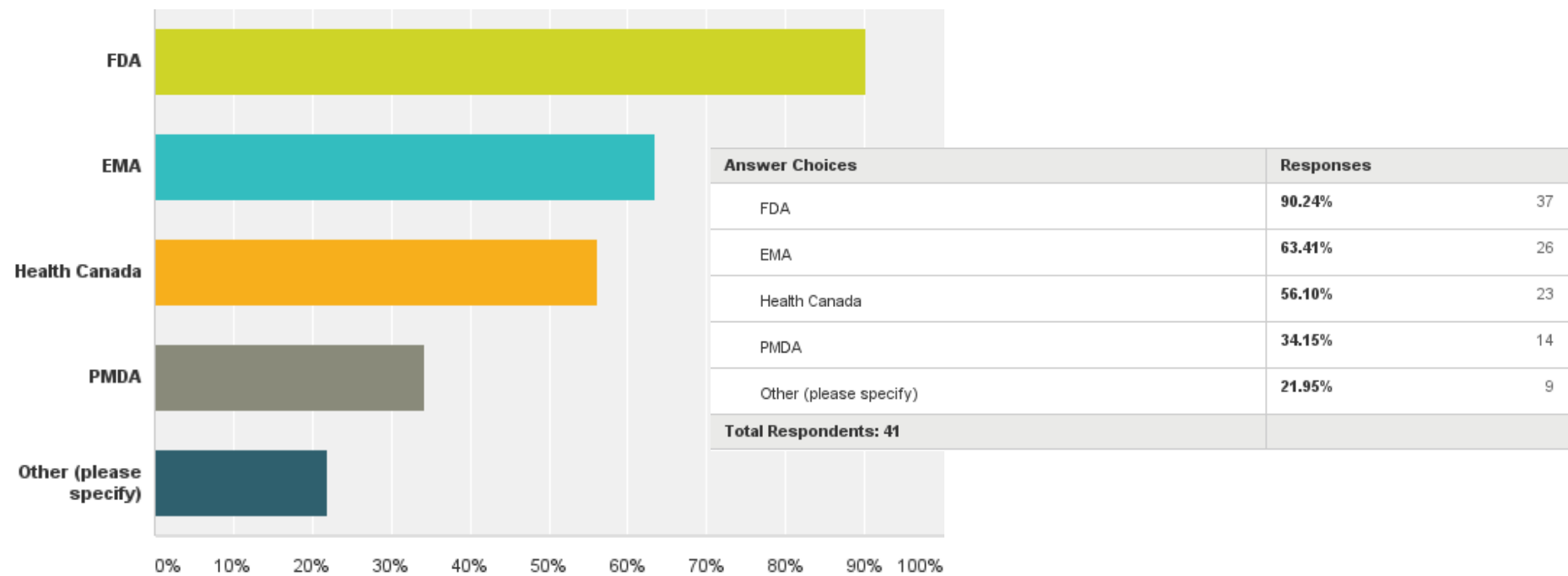
Answered: 43 Skipped: 0



Answer Choices	Responses	
No, all of our applications are in paper format.	2.33%	1
Yes, all of our applications are in eCTD format.	65.12%	28
Some of our applications are in eCTD format and some are still in paper format.	30.23%	13
Not applicable (please specify)	2.33%	1
Total	43	

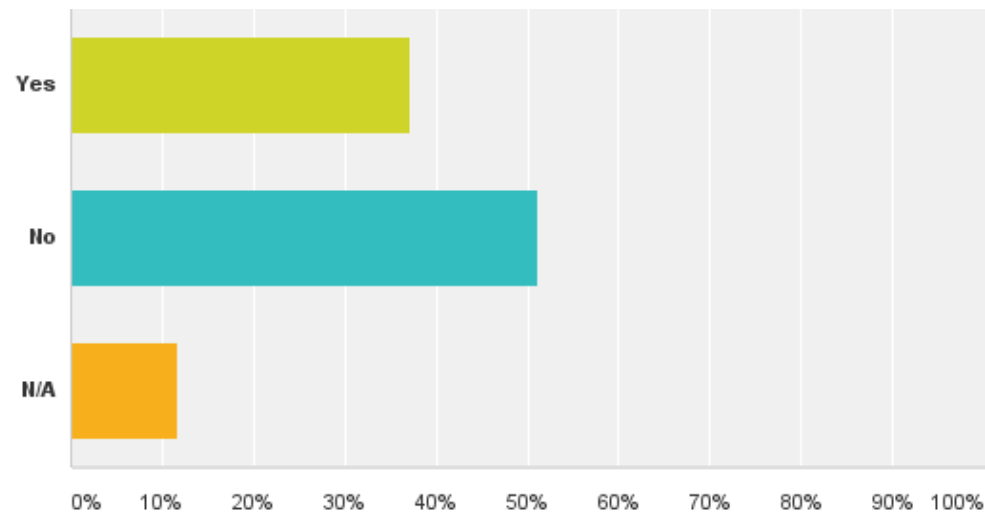
Q5: To which health authorities does your company submit applications in eCTD format?

Answered: 41 Skipped: 2



Q6: Have you submitted a sequence using the new module 1 (v2.3)?

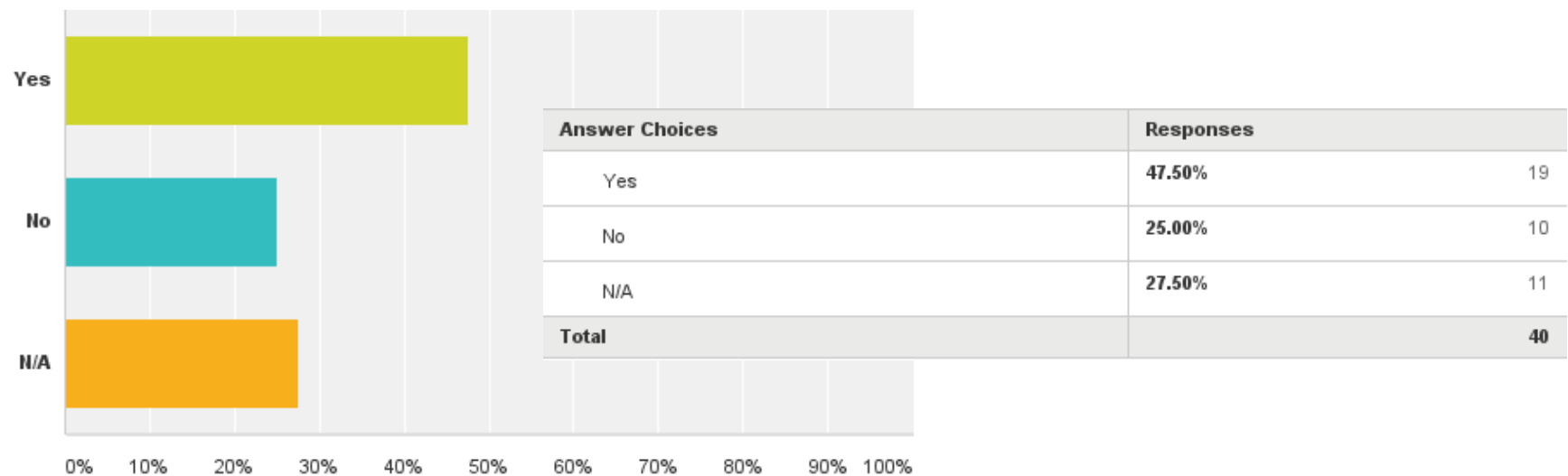
Answered: 43 Skipped: 0



Answer Choices	Responses	
Yes	37.21%	16
No	51.16%	22
N/A	11.63%	5
Total		43

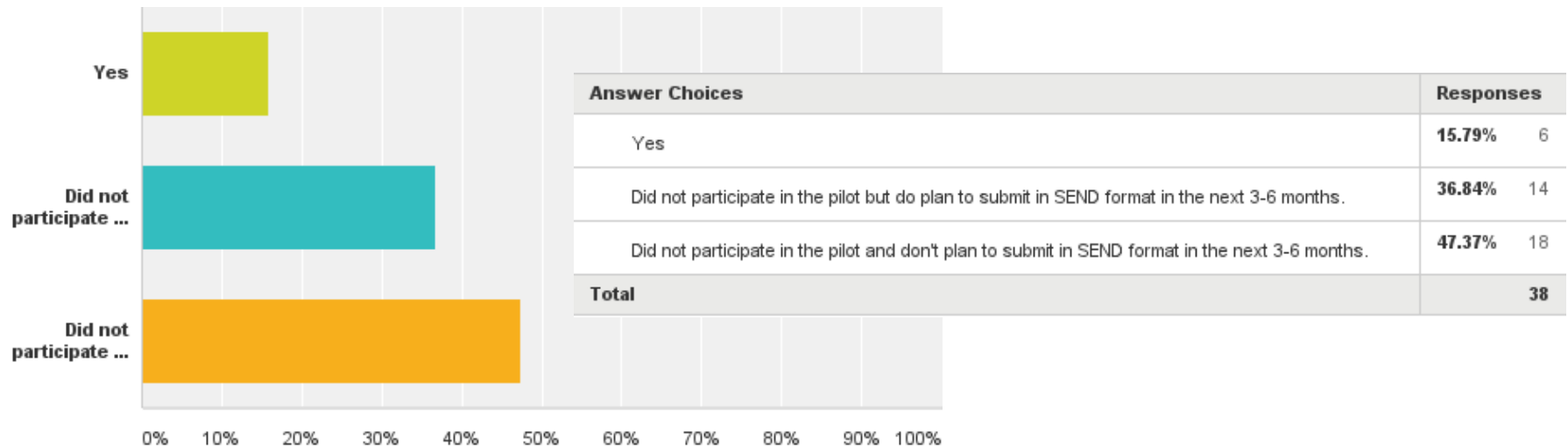
Q8: Has your company started to prepare for the mandated SEND dataset requirements?

Answered: 40 Skipped: 3



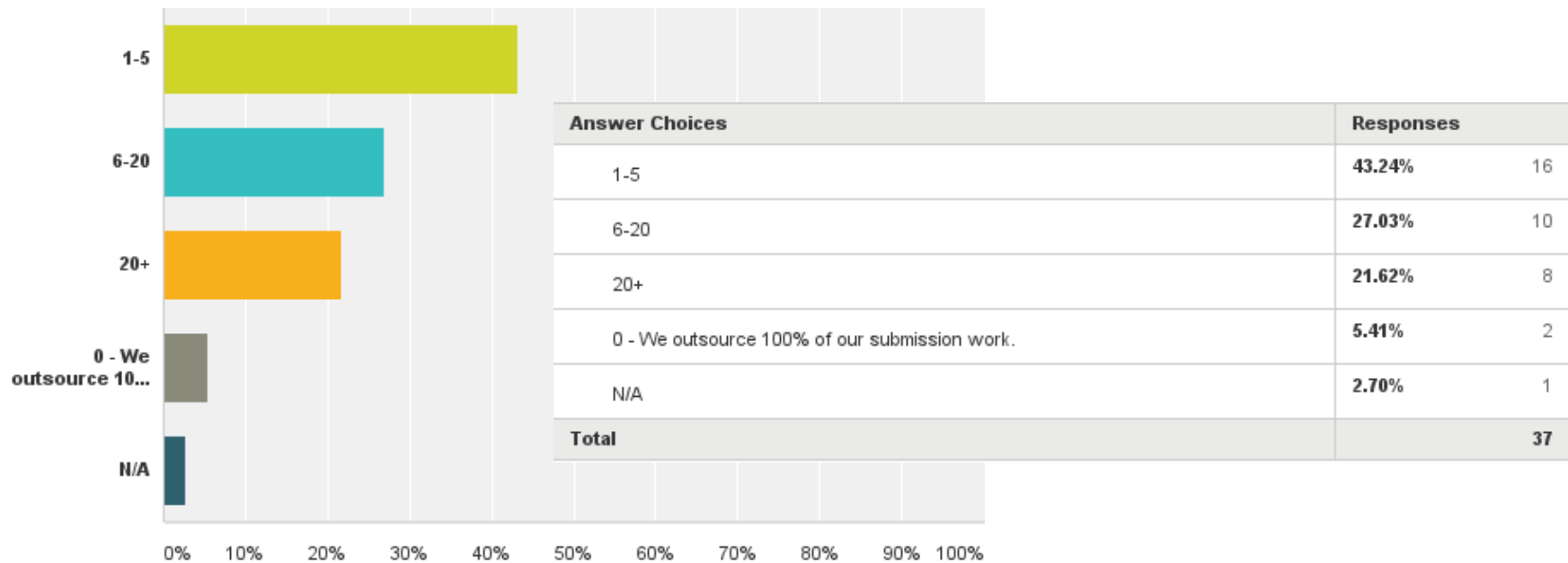
Q9: Have you participated in the SEND pilot? If not, do you plan to submit in SEND format in the next 3-6 months?

Answered: 38 Skipped: 5



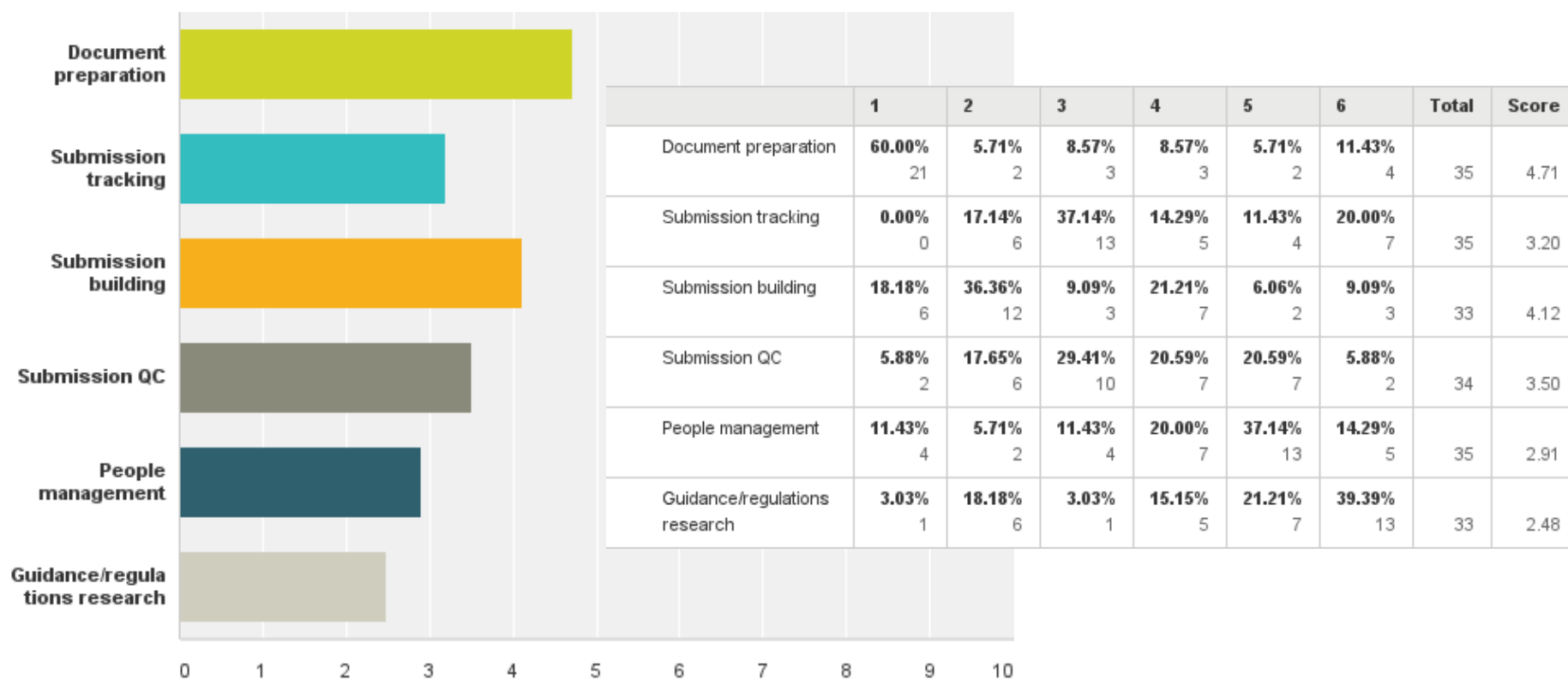
Q10: How many people comprise your Regulatory Operations/Publishing team?

Answered: 37 Skipped: 6



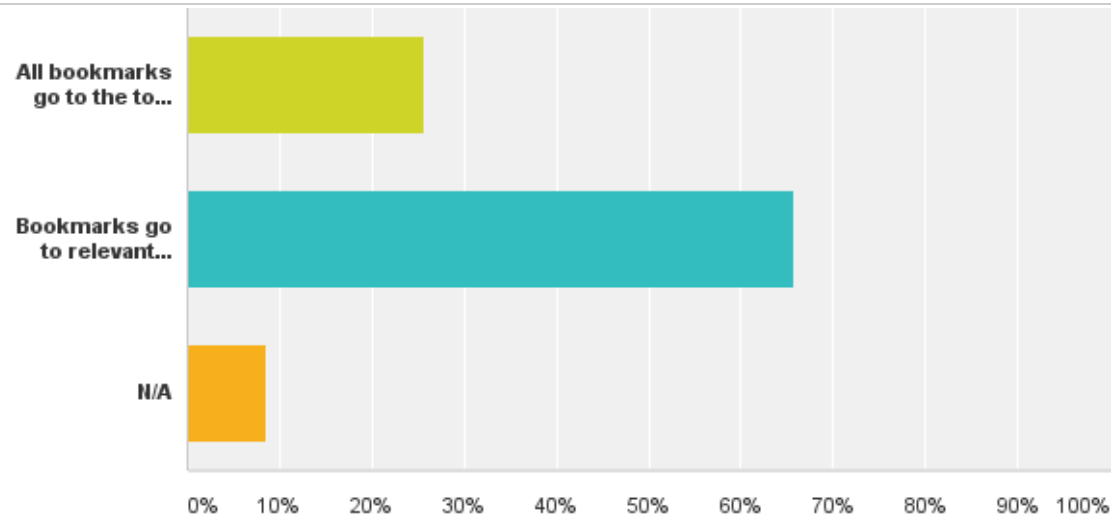
Q11: Please rank in order of time spent on each task:

Answered: 35 Skipped: 8



Q12: Do you create bookmarks that go to the top of the page or more directly to the beginning of the section (further down on the page)?

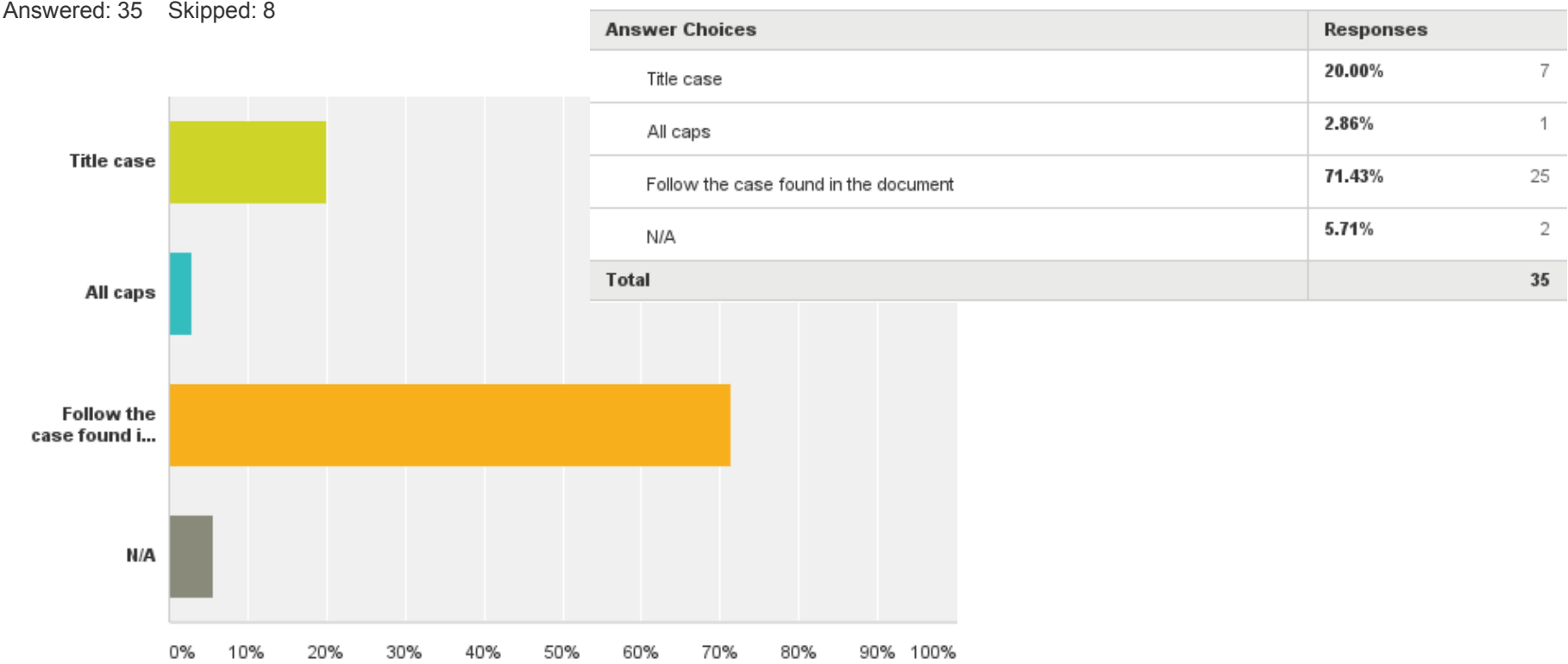
Answered: 35 Skippe



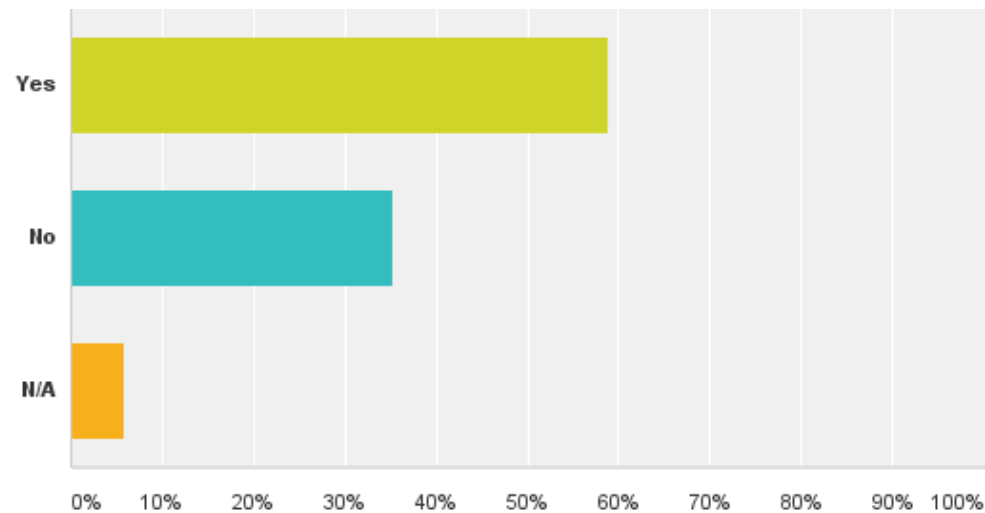
Answer Choices	Responses	
All bookmarks go to the top of the page	25.71%	9
Bookmarks go to relevant section	65.71%	23
N/A	8.57%	3
Total		35

Q13: Do you create bookmarks in title case, upper case, or follow the case found in the document?

Answered: 35 Skipped: 8



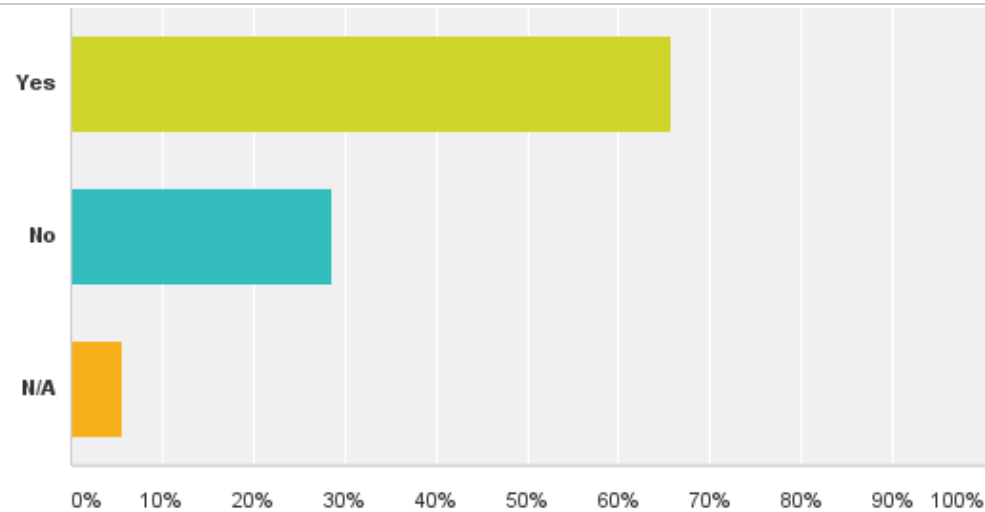
Q15: Do you link superscripts within tables to the footnote/legend section at the end of the table if the footnote/legend section is on a different page from the superscripts?



Answer Choices	Responses	
Yes	58.82%	20
No	35.29%	12
N/A	5.88%	2
Total		34

Q16: Do you externally link to literature references from the references page of summary documents/the investigator's brochure in submissions that are not the original application (e.g. amendments)?

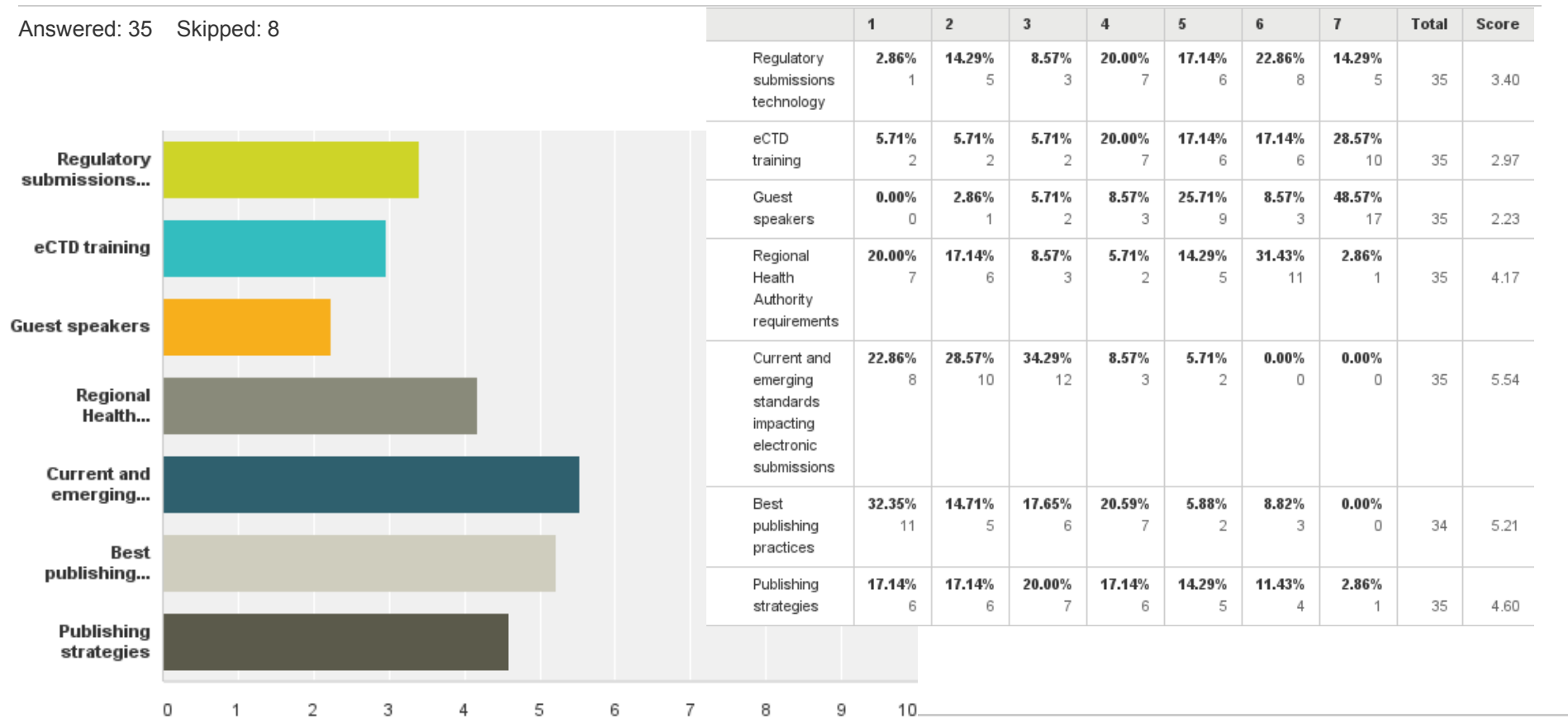
Answered: 35 Skipped: 8



Answer Choices	Responses	
Yes	65.71%	23
No	28.57%	10
N/A	5.71%	2
Total		35

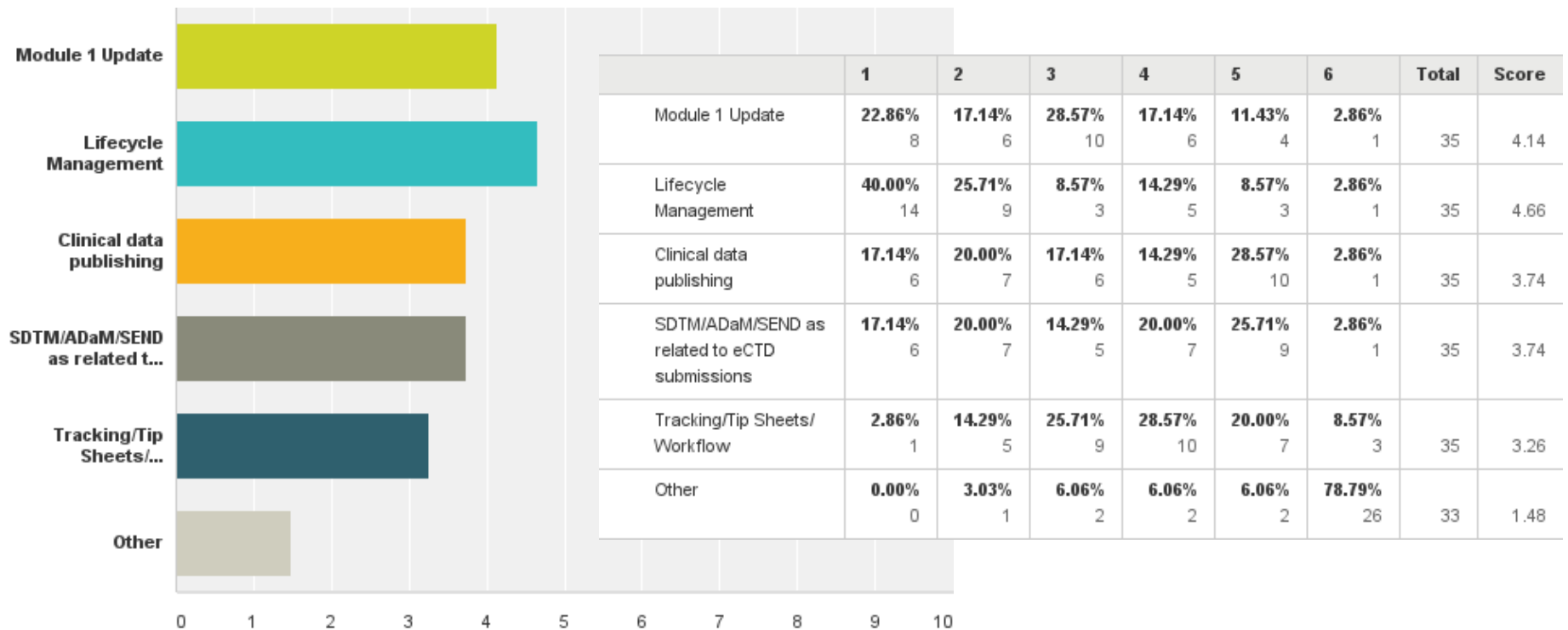
Q17: Rank, in order of importance to you, what you would like the ERS Community to focus on:

Answered: 35 Skipped: 8



Q18: Rank, in order of importance to you, the issues you would like discussed in ERS Community meetings:

Answered: 35 Skipped: 8



Overall Summary

- Respondents are mostly from industry 80%
- About half responders are from Organizations that are 1000 people and smaller.
- 65% of companies have only eCTD submission.
- 37% have submitted a sequence using the new Module 1.
- 50% have started to prepare to submit datasets in SEND format.
- 16% participated in SEND pilot.
- 6% outsource submissions and 43 % have only 1-5 publishers.
- Document preparation, submission building, and submission tracking take up most of respondent's time.
- 66% create bookmarks that go to the relevant section on page.
- 71% create bookmarks follow the case found in the document.
- 65% link superscripts within tables to the footnote/legend section at the end of the table if the footnote/legend section is on a different page.
- 66% externally link to literature references from the references page of summary documents in submissions that are not the original application.
- Community members are most interested in talking about current/emerging standards impacting electronic submissions, best publishing practices, and publishing strategies.
- The issues that community members want to discuss are lifecycle management and the Module 1 update.