

SEND data from Small/Medium Service Providers: How prepared are they to supply data in SEND format?

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Introduction

Service providers and commercial software systems that collect data necessary for SEND datasets are at different levels of SEND readiness. The Interorganizational SEND Team, part of the Nonclinical Working Group, prepared a survey for PhUSE members to assess the SEND readiness of their service providers and software systems, specifically focusing on small and medium service providers and small or specialized software systems. The results of the survey are presented along with specific conclusions regarding the data.

Methodology

A free online survey tool was used to create the survey, which was distributed via email to both the iSEND team as well as the PhUSE core non-clinical team.

Although the survey was brief and easily done in a matter of minutes, only thirteen respondents from eight organizations responded. While this does not paint a complete picture of the industry, it does offer some insights.

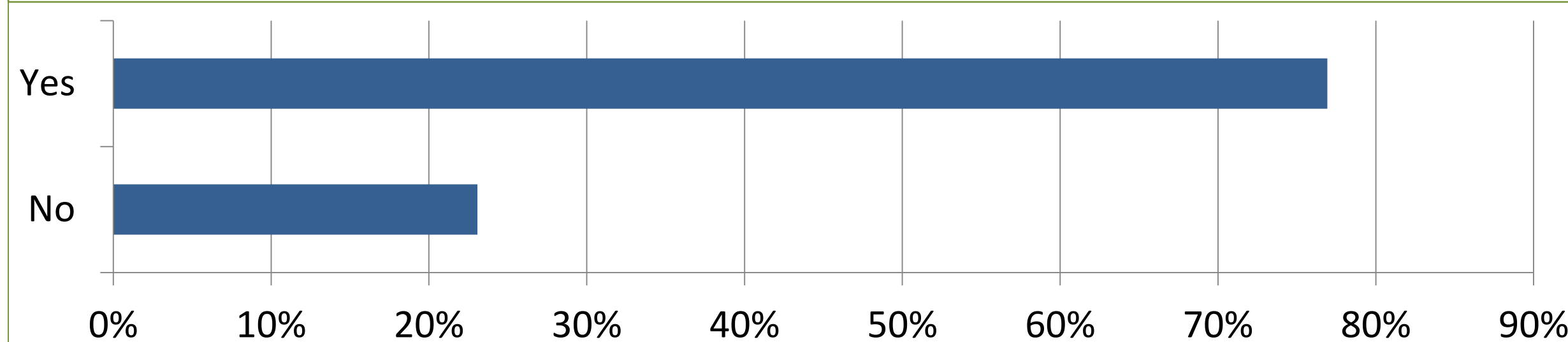
Survey Preface

The following text was the preface to the survey:

As our industry moves toward the submission of nonclinical study data to the FDA via SEND, the Interorganizational SEND Team is working to ensure all data is accounted for. This team, part of the PhUSE Nonclinical Working Group, has created this survey in an attempt to aid in the identification of what could be classified as smaller or specialized software providers to the non-clinical research industry. It is not intended to identify the obvious or well-known player in the field; instead it is to find those providers that can potentially be an issue when SEND becomes mandatory.

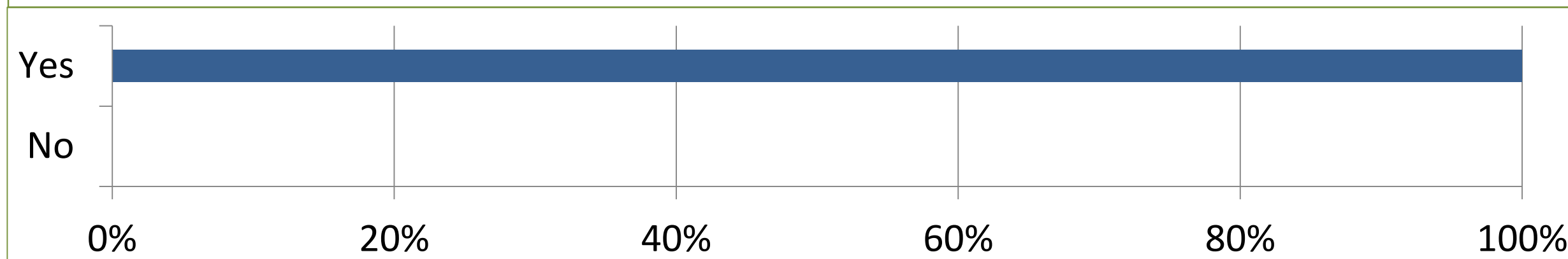
Questions, Answers and Analysis

Question 1: Are you using any small or specialized commercial software to collect or process data for a portion of a study?



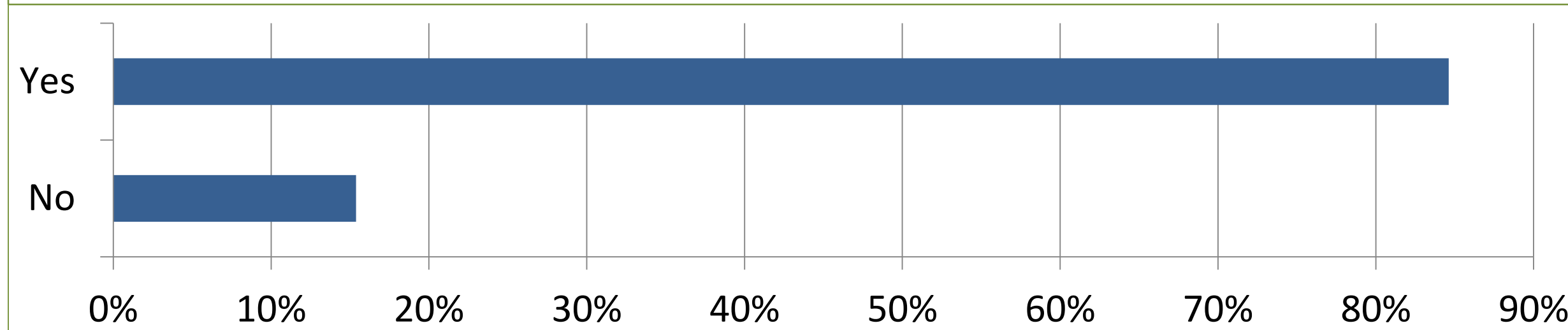
Analysis: The authors believe that much fewer than 20% (probably 0%) of the responding companies conduct studies without any of the systems mentioned in answers to question 2. So, our conclusion is that the variation in the answers is mostly an indication of the differing views on what this question meant to the respondents.

Question 4: Have you asked any of your providers if they are aware of SEND?



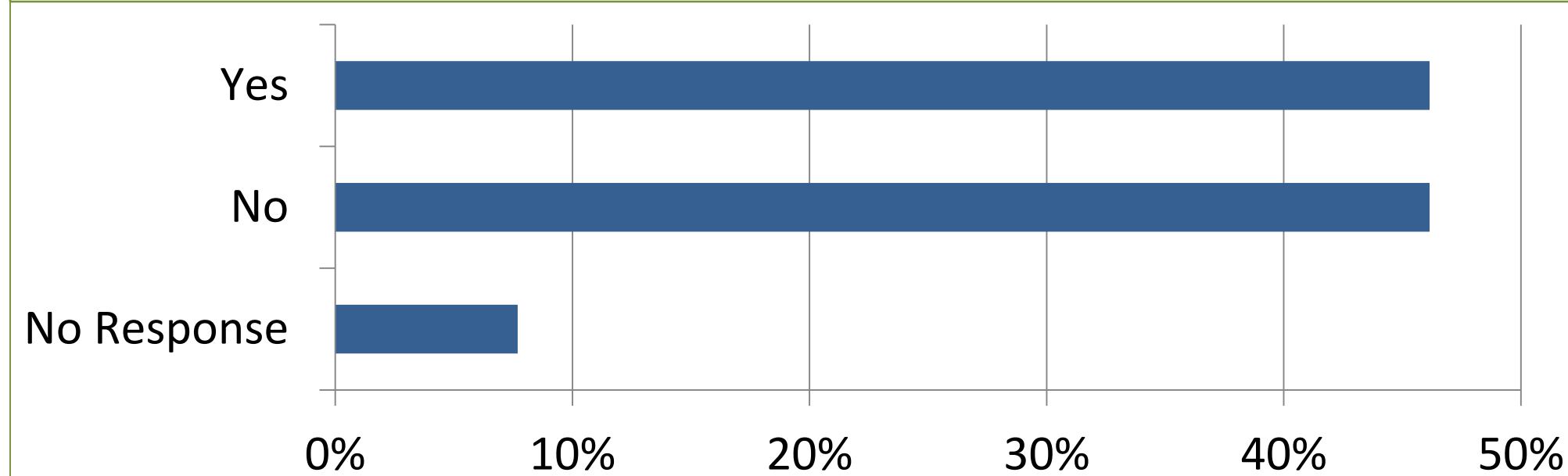
Analysis: Clearly everyone has some level of SEND awareness.

Question 5: Are any of your vendors planning on providing SEND formatted data?



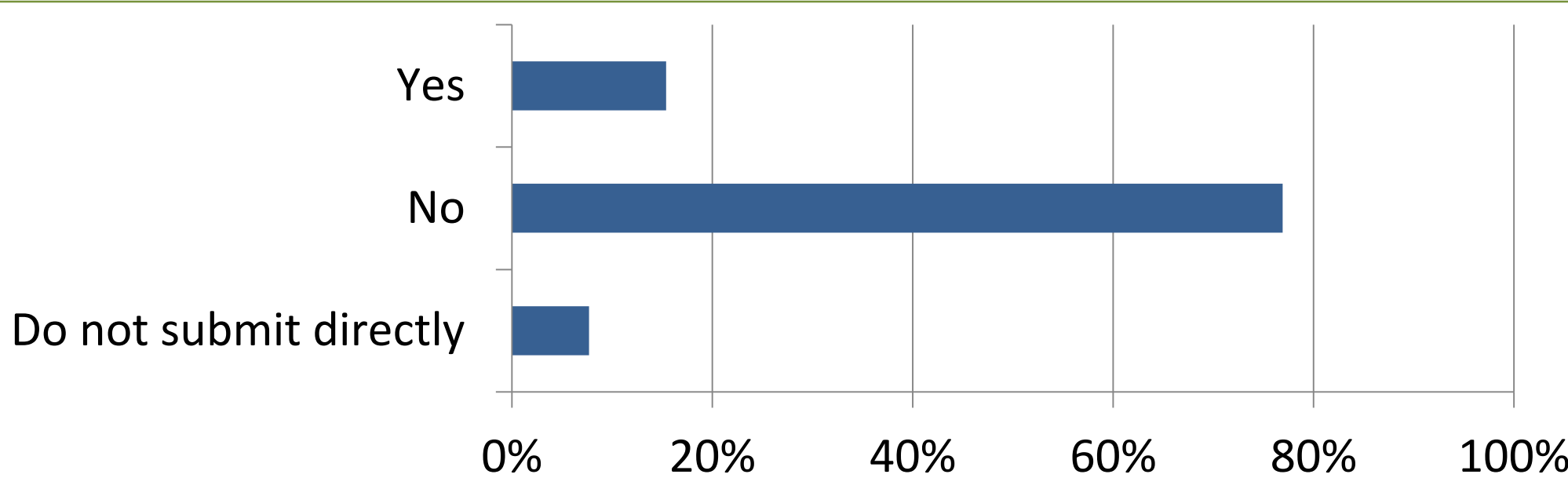
Analysis: The authors wondered about which vendors would not be working on providing SEND formatted data. There was also discrepancy between several responders from within the same company.

Question 6: Have you verified they actually do have SEND capability?



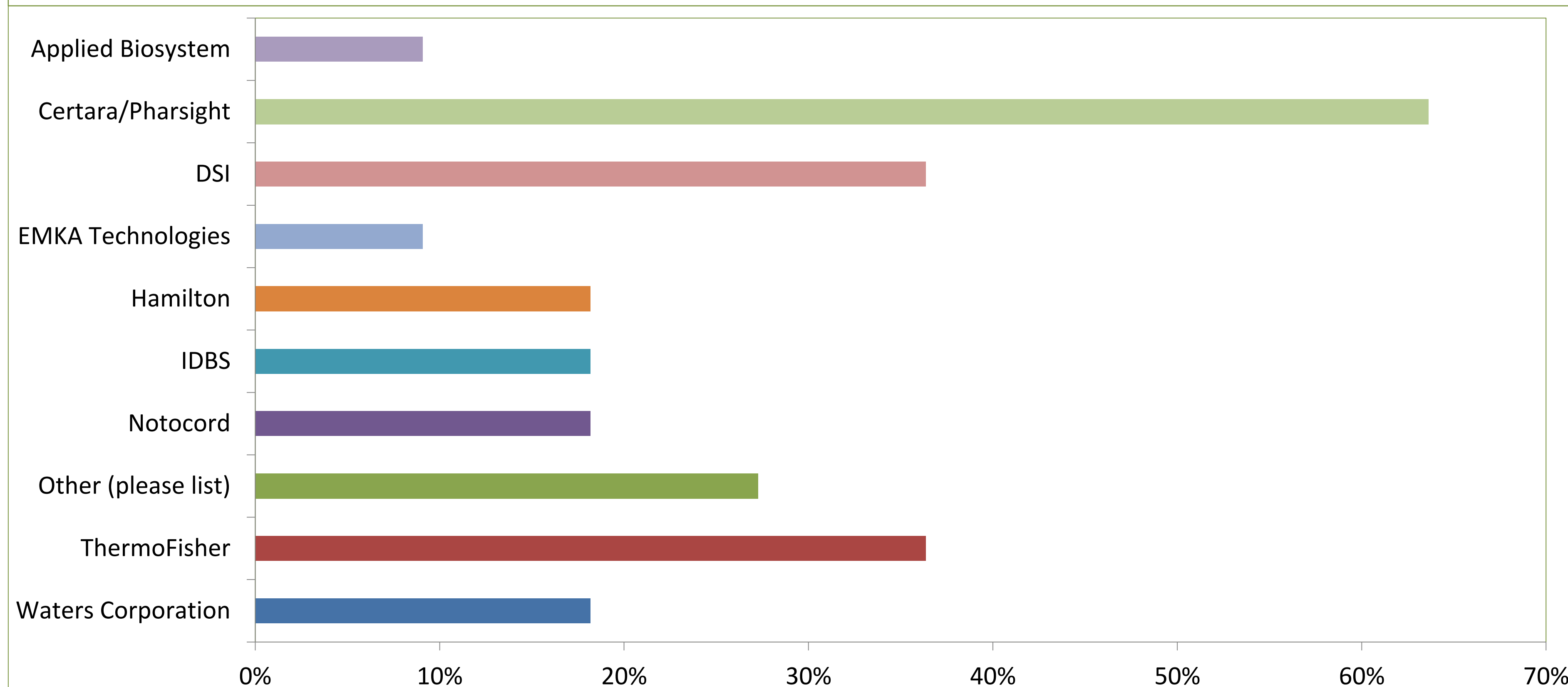
Analysis: Verification of actual capabilities is underway. Comments associated with this question indicated that actual verification (e.g. trial submission or dataset) make up a low percentage.

Question 7: Have you submitted SEND data to the FDA from one of these providers?



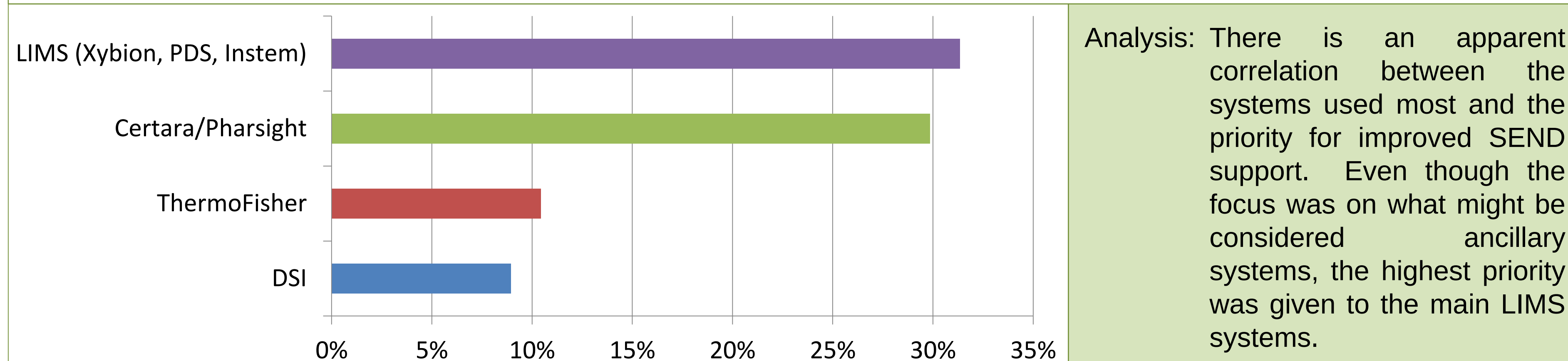
Analysis: This correlates with the observation based on the comments provided in response to Question 6. It also speaks to the level of SEND readiness on the part of the respondents.

Question 2. Please indicate which systems:



Analysis: The "others" listed within the response were largely LIMS vendors, including Xybion, PDS and Instem, indicating that LIMS vendors may be considered small. This question also clearly shows that Safety Pharmacology and DMPK are key parts of preclinical data systems.

Question 3. In order of priority, which providers are you most eager to have improved support for SEND?



Analysis: There is an apparent correlation between the systems used most and the priority for improved SEND support. Even though the focus was on what might be considered ancillary systems, the highest priority was given to the main LIMS systems.

Question 9: Please provide your company

Analysis: This question was added around the midpoint of the data collection period. However analysis of the source IP address attached to each response allowed determination of the company of each respondent. There were a total of 13 respondents from 8 companies, all of which would be considered large pharma.

Discussion

Even with the lower than desired response, there were several clear indications from the survey. Industry as a whole is working toward SEND readiness with some organizations being further along the continuum than others. Not everyone has addressed the need to get the data from the small or specialized vendors. It is not apparent from the responses whether the perceived lack of SEND readiness from vendors is real or an artifact of where people are in the process. It was also noted that responses from within the same companies (not shown here for confidentiality) were different for the same organization. This may indicate internal SEND awareness within an organization is not as mature as perhaps it should be. A highly similar or the same survey may be distributed next year to provide some benchmark on the industry's SEND readiness progress.

If you would like more information about SEND and the Interorganizational SEND Team, please visit the iSEND wiki page: http://www.phusewiki.org/wiki/index.php?title=Interorganizational_SEND

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