Results of the Third Annual SEND Industry Readiness Survey

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Abstract
Now that the Pharmaceutical Industry is under the regulatory mandate for submission of non-clinical study data using the SEND format, it is important to understand the status of industry readiness and the issues that sponsors are encountering.

A survey of sponsors and other involved parties was done to gather this information. The survey questions were based upon the two previous surveys and updated to include questions pertinent to current submissions. The results include information about what complications are being encountered in the data preparation process and the coordination amongst the parties responsible for different parts of the dataset in one submission.

This will inform PhUSE as to where they can focus their efforts to best help the industry in meeting this obligation and provide the stakeholders with metrics of how their progress compares with the industry and possible solutions to questions they have with their own processes.

Methodology:

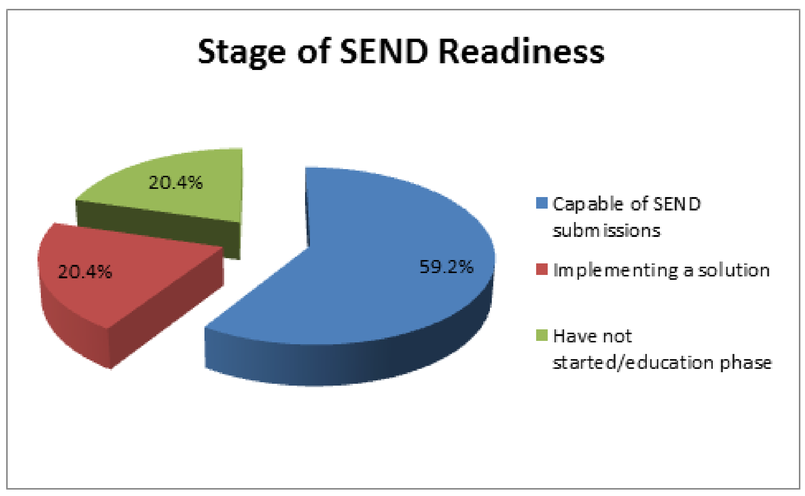
17 survey questions were developed and then the survey was implemented using SurveyMonkey.co.uk.

Invitations to complete the survey were then sent to members of the CDISC and PhUSE non-clinical mailing lists. Answers were anonymous with the opportunity to include the respondent's organization.

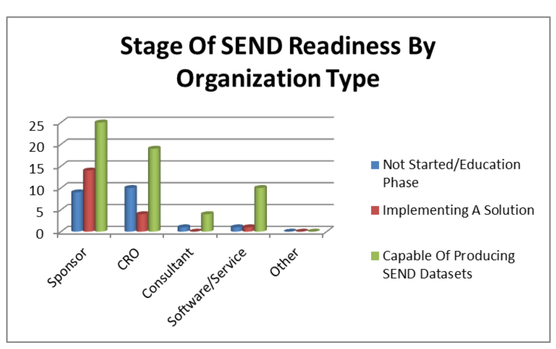
The survey was held open from 11/21/2017 through 1/19/2018. The number of respondents increased over last year's survey by 38%, with a total of 99 participants.

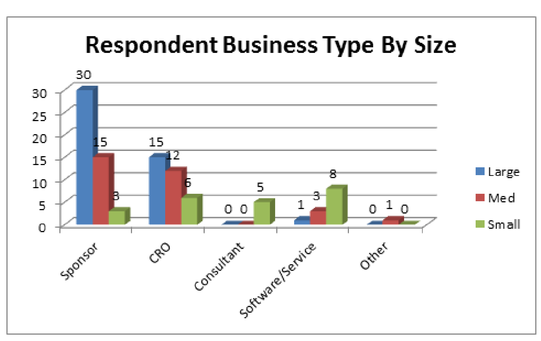
Results:

Selected results are shown here, see this website for the full results:
http://www.phusewiki.org/wiki/index.php?title=Industry_SEND_Progress_Survey



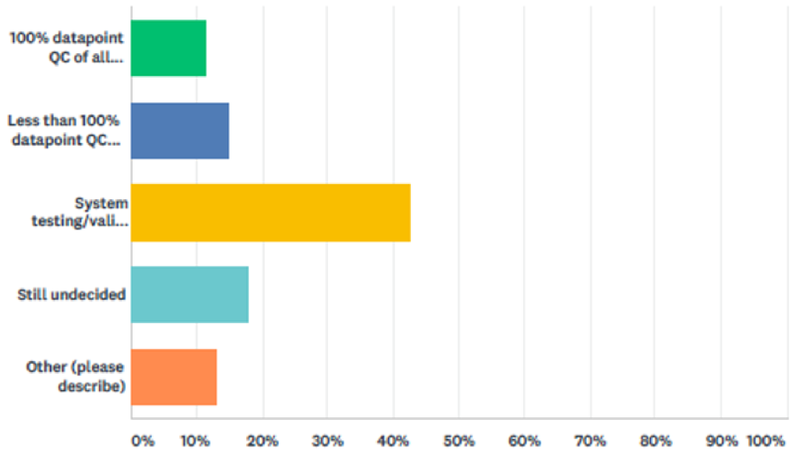
SEND Readiness: *79% indicated they have implemented or are implementing a solution. This is an increase over last year where 74% replied this way.*



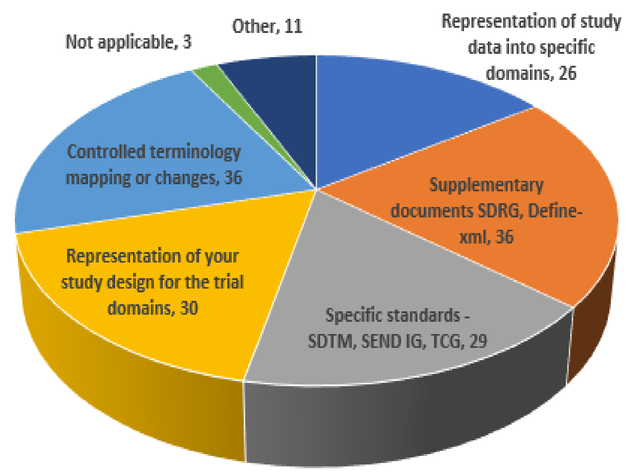


Note: The opinions expressed in this poster are those of the authors and do not necessarily represent the opinions of their respective organizations.

69% of those implementing a SEND computer system, are validating/qualifying the system (Q10). When asked how they ensure that their datasets completely and accurately represent the study data so that such a statement can be supported (Q11), the majority also relied on system testing and validation:



Q12 What did you find were stumbling blocks or barriers during your implementation efforts for SEND?



Q16. What upcoming expansions to SEND are your priority? (Please rank these in order of your priority with 1 being the highest and 6 being the lowest).

Rank:	1	2	3	4	5	6	Total Responses	Priority Score
SEND 3.1	58.49%	35.85%	0.00%	3.77%	0.00%	1.89%	53	5.43
Define XML 2.0	32.73%	30.91%	9.09%	9.09%	7.27%	10.91%	55	4.40
Safety Pharm	5.66%	32.08%	33.96%	18.87%	7.55%	1.89%	49	4.04
DART 1.1	2.04%	4.08%	34.69%	34.69%	16.33%	8.16%	53	3.16
Gene Tox	2.04%	0.00%	12.24%	16.33%	42.86%	26.53%	49	2.22
Dermal Ocular	0.00%	0.00%	9.80%	13.73%	27.45%	49.02%	51	1.84

Conclusion: The survey shows progress in SEND readiness and actual submissions from the previous year. However, most respondent organizations are experiencing challenges in both the technical aspects of preparing submissions and intra- and inter-company processes. This points to the need and importance for sustained efforts by the PhUSE non-clinical group to help companies overcome these challenges.