Results of the Fourth Annual SEND Industry Readiness Survey

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Abstract

The first year of SEND requirements for non-clinical general toxicity studies for IND submission has recently concluded. The industry has been implementing SEND 3.0 while preparing for the addition of safety pharmacology studies and the requirements of SEND 3.1 in March 2019. The PhUSE Nonclinical Group has undertaken an annual survey to understand the status of industry readiness and the issues that sponsors and partners are encountering. The results of the fourth annual survey are summarized in this poster, including insight into implementation approaches, staff training, stumbling blocks, and FDA feedback. PhUSE collaboration members will use the results to identify problem areas where they can focus their efforts to best help the industry meet this regulatory obligation.

Methodology:

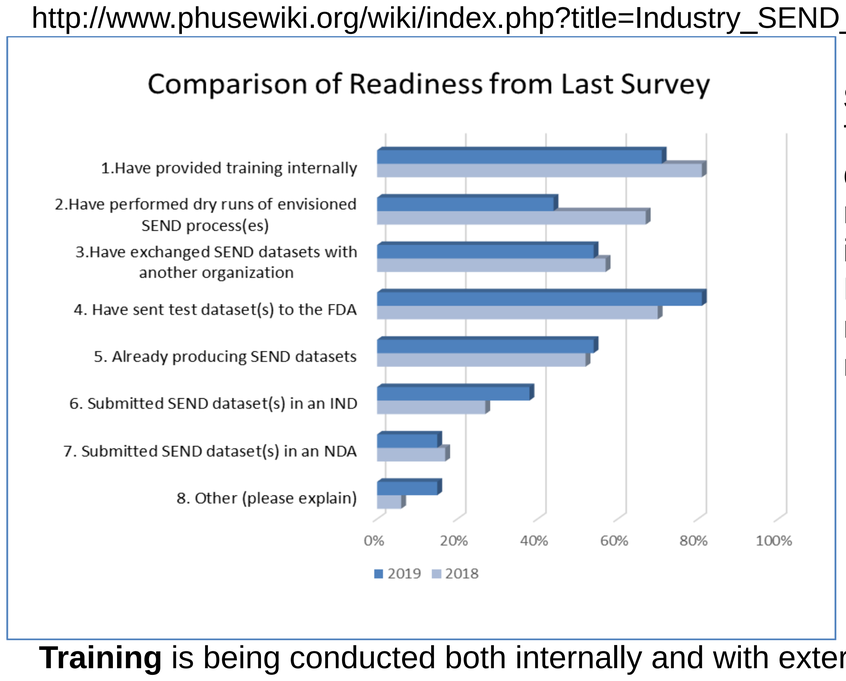
Fifteen survey questions were developed and the survey was implemented using SurveyMonkey.co.uk.

Announcements of the survey were 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 open from 01/18/2019 through 3/13/2019. The number of respondents decreased from last year's survey by 20%, with a total of 79 participants.

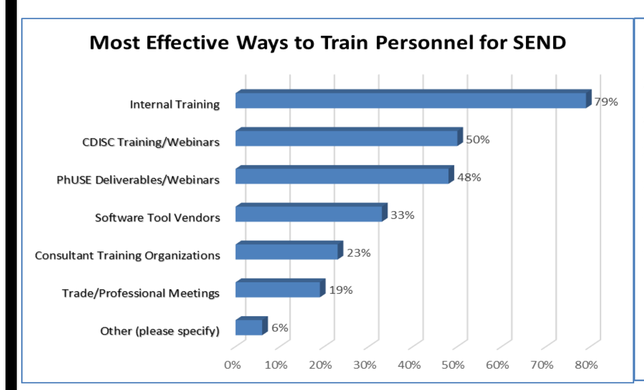
Results:

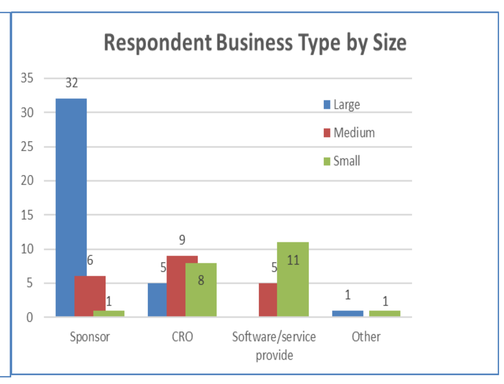
Selected results are shown here, see this website for the full results:
http://www.phusewiki.org/wiki/index.php?title=Industry_SEND_Progress_Survey



SEND Readiness: There were no dramatic shifts in readiness and implementation. Programs are maturing at a methodical pace.

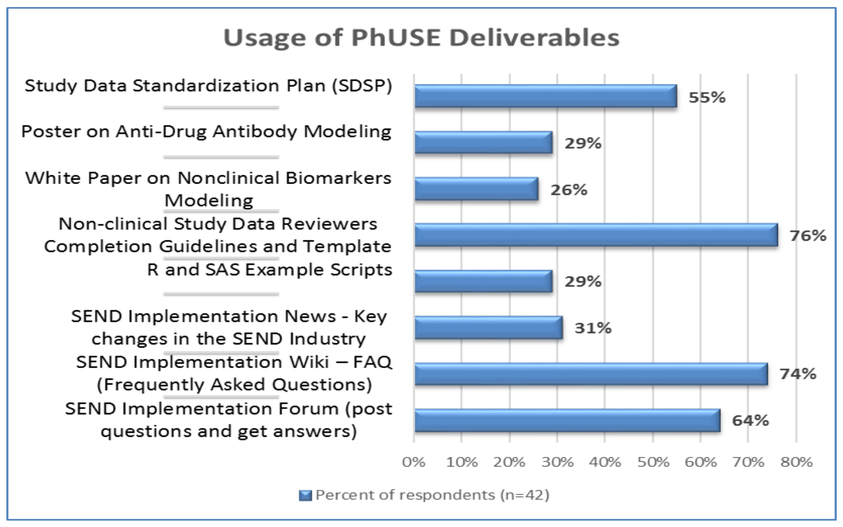
Training is being conducted both internally and with external resources. Training periods ranged from 1 month to 2 years depending on role and level of expertise.





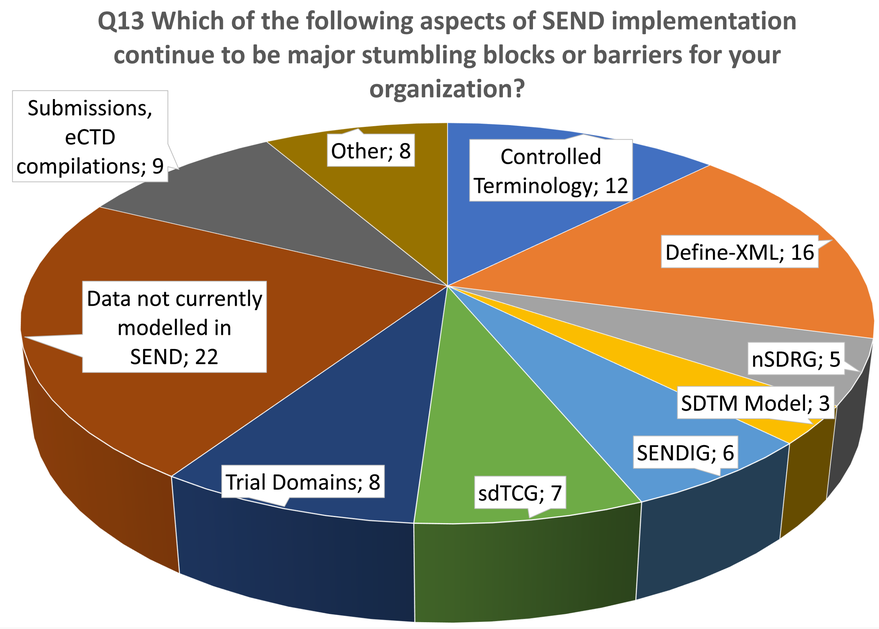
Note: The opinions expressed in this poster are those of the authors and do not necessarily represent the opinions of their respective organizations.

PhUSE: Over half of respondents indicated they have found one or more of the deliverables sponsored by PhUSE or developed by Nonclinical Working Group subteams useful. The available tools range from newsfeeds to domain-specific tips and programming scripts. These resources can be found on the PhUSE wiki.



Link for SDSP and SDRG

Link for SEND implementation wiki



Q15 - What FDA Feedback have you Received?

Dos:	**Don'ts:**
• Set fasting flags	• CLTPT for unscheduled
• Identify each dose location	• Generic time point names
• Accurate codelists and keys in define.xml	• Confuse Decodes and Codes
• Valid number of decimal places	• Generic validation explanations

Conclusion: The survey results suggest continued incremental SEND readiness across the industry. Implementation challenges remain, such as the data flow from multiple sources into SEND processes as well as the historic design of the data collection systems. However, challenges also remain in applying the specifics of the standard. The SENDIG is general so feedback from regulators on usability is desired. Topics such as the Define.xml file, the nSDRG, and common terminology top the concerns. This points to the need and importance for sustained efforts by the PhUSE non-clinical group to help overcome these challenges.