Results of the Fifth Annual SEND Industry Readiness Survey

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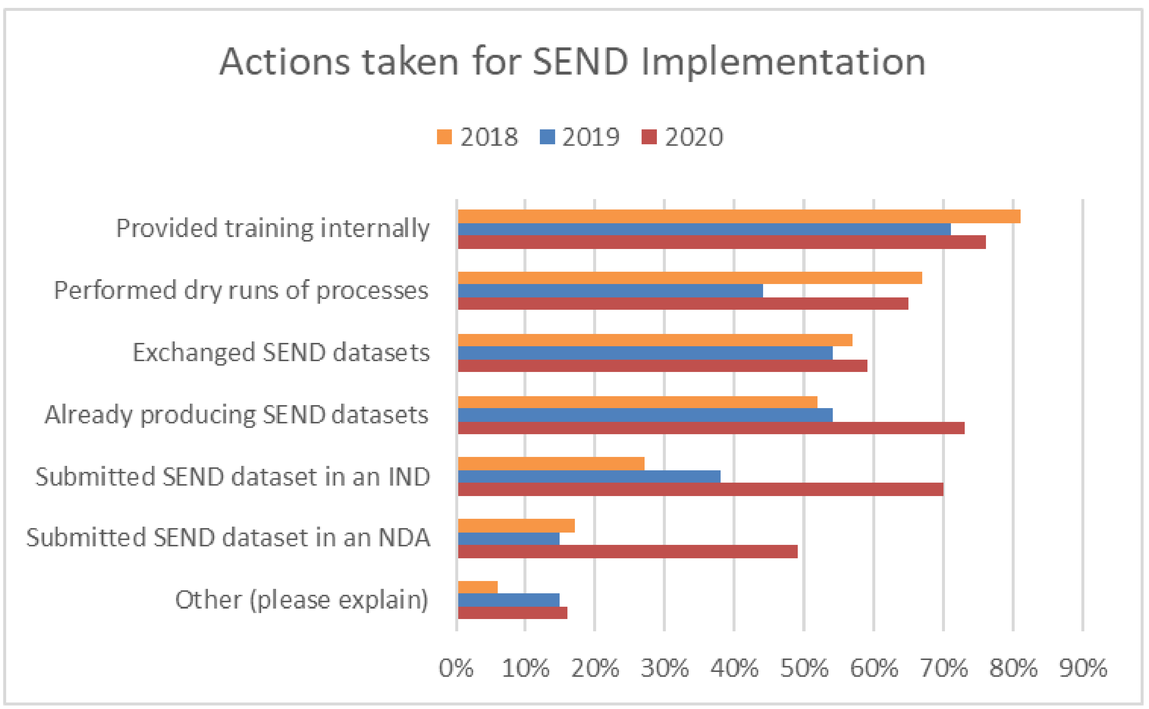
PHUSE US CSS 2020: PP07

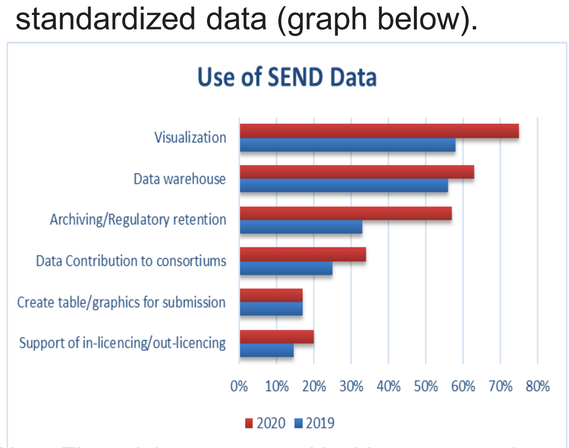
Abstract
SEND requirements for non-clinical general toxicity studies for IND submissions are in the second year of implementation. Safety pharmacology studies are now in scope with the beginning of SEND 3.1 in March 2019. The PHUSE Nonclinical Group has undertaken an annual survey to understand the status of industry readiness and the issues that sponsors and partners are encountering. The results of the annual survey are summarized in this poster, including insight into implementation approaches, execution challenges, and FDA feedback on submissions. PHUSE collaboration members will use the results to identify opportunities where they can focus their efforts to best help the industry meet this regulatory obligation.

Methodology
Seventeen 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. The survey was open from 01/21/2020 through 3/30/2020. A total of 52 participants, from 10 countries, representing sponsors, CROs, software & service providers, and consultants responded.

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



There was a big increase in late-stage activities, i.e, the submission of datasets to FDA, over previous years (graph above). Innovation in use of SEND data is expanding and is expected to increase the value of the standardized data (graph below).

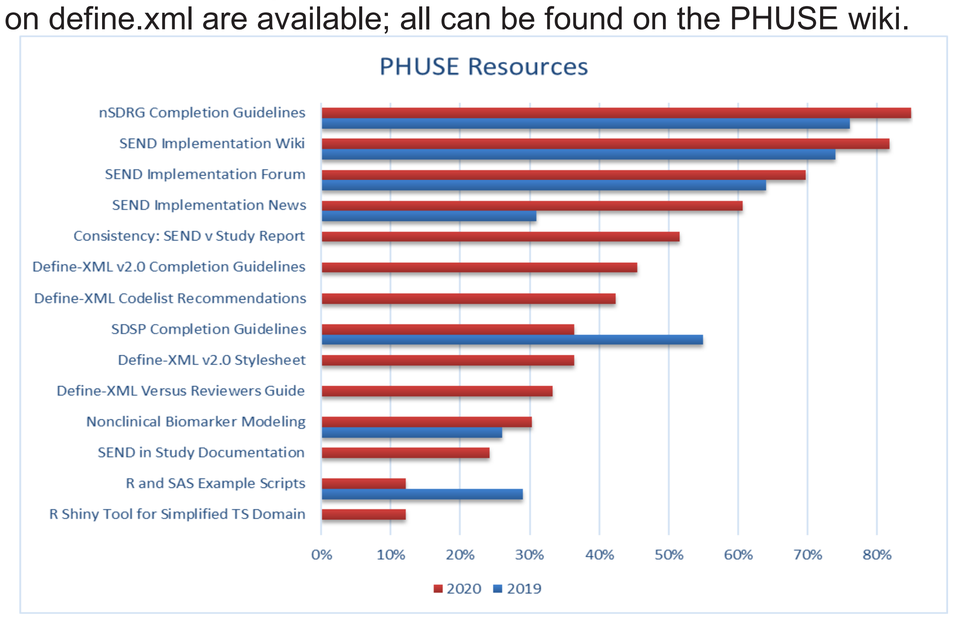


Other (22%):

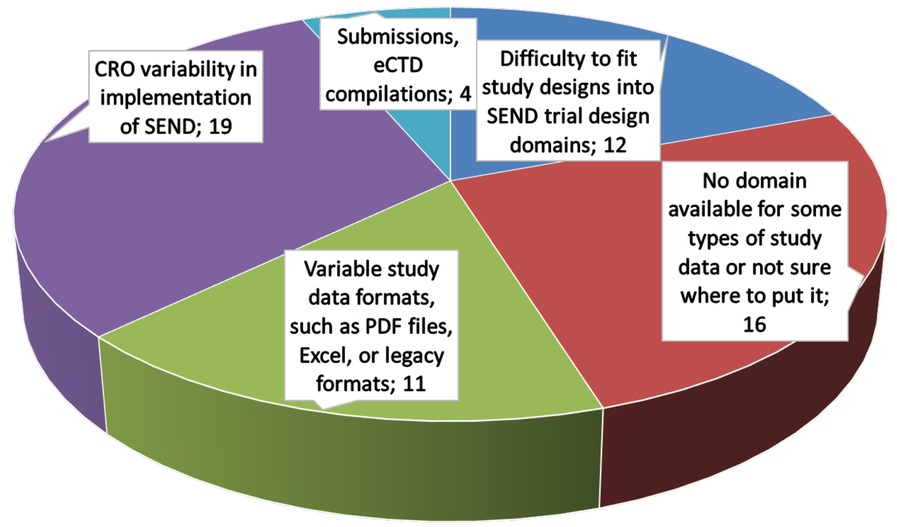
- adhoc **analyses**, exploratory **analyses**
- Data **analysis** of toxicology studies.
- Data **analysis** to support changes in Phase I clinical protocol.
- Report table/graphics creation for in-house **study result interpretation**
- Legacy study **conversion**,
- Only by specific acceptance of the sponsor, it may be used in consortiums or for **training** purposes.
- Developing SEND **Training** Sets for Toxicology Analysis and Review purposes for unusual or upcoming IGs
- Only for submission
- Potential **visualization** post-submission at this time.
- Interim SEND datasets for **Study Monitoring**

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

Over 60% of respondents indicated they have found one or more of the PHUSE deliverables sponsored by PHUSE or developed by Nonclinical Working Group subteams useful. Several new resources on define.xml are available; all can be found on the PHUSE wiki.



Challenging Aspects of SEND Implementation



Summary Lessons from the FDA Feedback (n=10)

Dos:	Don'ts:
Set fasting and baseline flags	Submit draft/interim reports without SEND data
Define file: Field level meta data	Use generic time point names
Define file: Trial domain codesets	Confuse Decodes and Codes
Define file: Code lists subset for study	Incorrect metadata lengths

Conclusion The survey results suggest good overall SEND readiness across the industry. However, challenges also remain in applying the specifics of the standard. Topics such as the Define.xml file, and continually evolving standards top the concerns. Feedback from regulators on usability helps focus the discussion on priority issues. This points to the need and importance of sustained efforts by the PHUSE non-clinical group to help overcome these challenges.