PP02

SEND (Standard for Exchange of Nonclinical Data) Industry Feedback Survey: 2025 Results

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Abstract

As the scope of SEND continues to expand, sponsors and vendors must continuously evolve to keep pace with updated regulatory specifications. The 2025 Industry Feedback Survey will provide a snapshot of the SEND industry, focusing on three main topics: Implementation of New Standards, Virtual Control Groups and Dataset-JSON. The responses received were analysed to report any trends seen across the industry. PHUSE Working Groups will use the summarised results of this survey to examine possible initiatives and discussions for effective SEND standard operations.

Methodology

29 survey questions were developed and the survey was created using SurveyMonkey. Mailing lists of the CDISC and PHUSE working groups were emailed with announcements of this survey. The survey was open from 16 Dec 2024 - 29 Jan 2025. All answers were anonymous and each respondent had an option of skipping.

Results

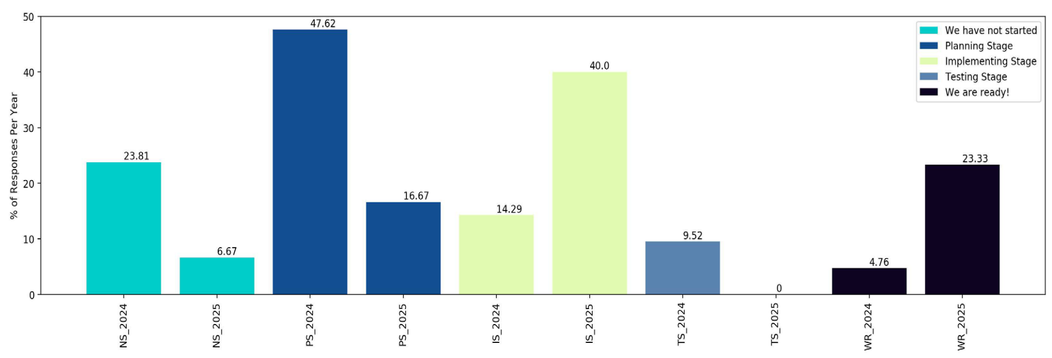
Selected results are shown here; please see for the full results.

Responses

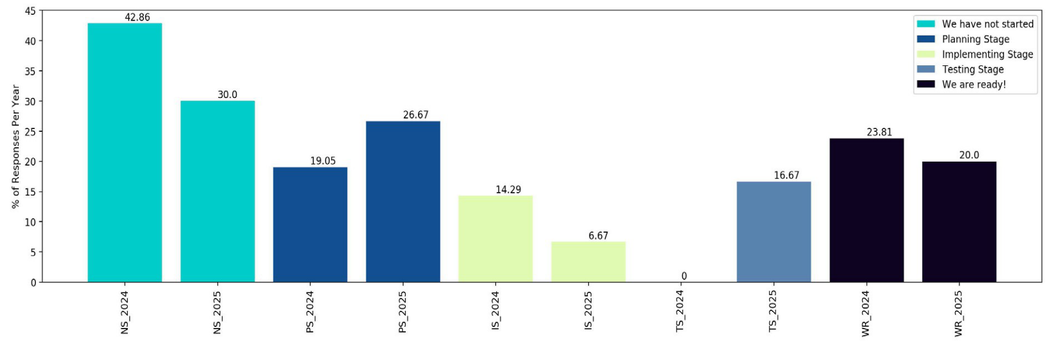
The total number of respondents was 37, which is 6 more responses than the previous year. This increase was attributed to an extended open period for the survey and a wider distribution group.

Implementation

Q6 Analysis - The implementation stage level results of SENDIG-Genetox v1.0 between 2024 and 2025 illustrated an industry trend with a decrease in early-stage preparedness ("not started" and "planning") and an increase in later-stage preparedness ("implementing" and "ready"). This aligns with the FDA requirement of the standard (2025-03-15).

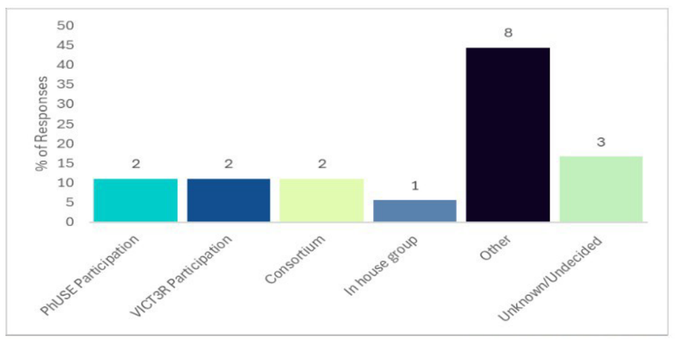


Q7 Analysis - When comparing SENDIG-DART v1.2 readiness levels between 2024 and 2025, the results show an overall trend towards greater levels of readiness for DART v1.2. The greatest difference in results was a jump from 0% to 16.67% between the years in the "testing stage".



Virtual Control Groups (VCGs)

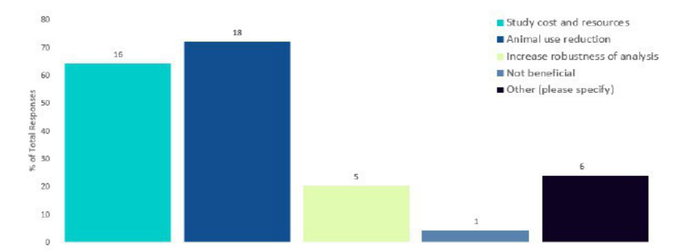
Q12 - Of the 18 responses that were received regarding pursuing VCGs, established groups (PhUSE, VICT3R, and Consortium) all had equal responses of 11% each, with ~44% of the total responses answering that they were using "Other" methods (see directly below).



"Other" consisted of listening stage, collaborating with CRO partners, researching, and involved in creating VCGs without running studies.

Q15 - A variety of reasons were given in relation to challenges/worries in using VCGs. A few of those reasons were animal traceability, data population issues, regulatory acceptance, validity, and risk of job loss.

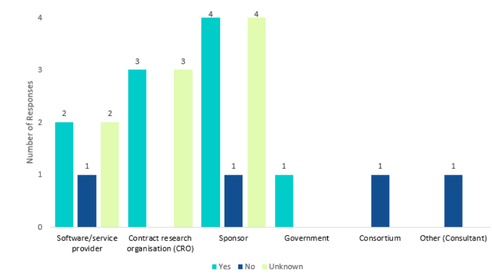
Q18/19/20 - When survey recipients were asked how VCGs would benefit their company, a majority of the responses believed that study cost and resources, as well as animal use reduction would be the greatest benefits.



Other/Not beneficial consisted of not knowing company policy, unknown/possibly other benefits, opportunity for software tool offerings and not relevant.

Dataset-JSON

Q22/23 - CROs, Sponsors, and service providers are equally split in determining whether or not there will be limitations when switching over to Dataset-JSON. Examples of their concerns are listed below.



Limitations
Commercially available solutions
Database architecture changes to accept JSON
Lack of confidence in tools
Lack of regulatory requirements
Large companies resistant to changes
Limited knowledge
Software support/upgrade
Unsure if define.xml will still be needed

Q25/26 - When asked what stage of implementing Dataset-JSON they were in, CROs shared equal responses between "we have not started" and "planning stage". All of the Sponsor responses were "we have not started" and the reasons attributed to this were unclear requirements. Software/service provider responses were split between "planning stage" and "testing stage".

Conclusion

The results of this survey show that in relation to **Genetox v1.0 and DART v1.2,** there has been a vast increase in readiness for the new implementations. For **virtual control groups**, there is a large interest, but only a few respondents have put them to use, and many are concerned with challenges that they may bring. **Dataset-JSON** is being widely discussed; however, it was found that minimal effort is being put towards implementation until required.

Note: The opinions expressed in this poster are those of the authors and do not necessarily represent the opinions of their respective organizations. Author emails: lindsy.eickhoff@inotiv.com; vanessa.chavez2@labcorp.com; fiori_janice_m@lilly.com; michael.rosentreter@bayer.com; RThompso@its.jnj.com; jamie_riggs@merck.com; chloe.bosworth@inotiv.com