

PP03



SEND (Standard for Exchange of Nonclinical Data) Industry Feedback Survey: 2024 Results

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Abstract

As the scope of SEND broadens, sponsors must continuously evolve to keep pace with updated regulatory specifications. The 2024 Industry Feedback Survey will provide a snapshot of the SEND industry focusing on three main topics: Manual edits pre- and post- tabulation with a focus on confidence-levels, harmonization of industry-wide project initiatives, and implementation efforts for future SEND standards. The collected responses provide commentary on these topics and were analyzed to report any result trends seen across the trade. PHUSE working groups will use the summarized results of this survey to examine possible future initiatives and discussions for effective SEND standard operations.

Methodology

Twenty-two 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 05 Feb 2024 through 23 Feb 2024. All answers were anonymous and each respondent had an option of skipping.

Results

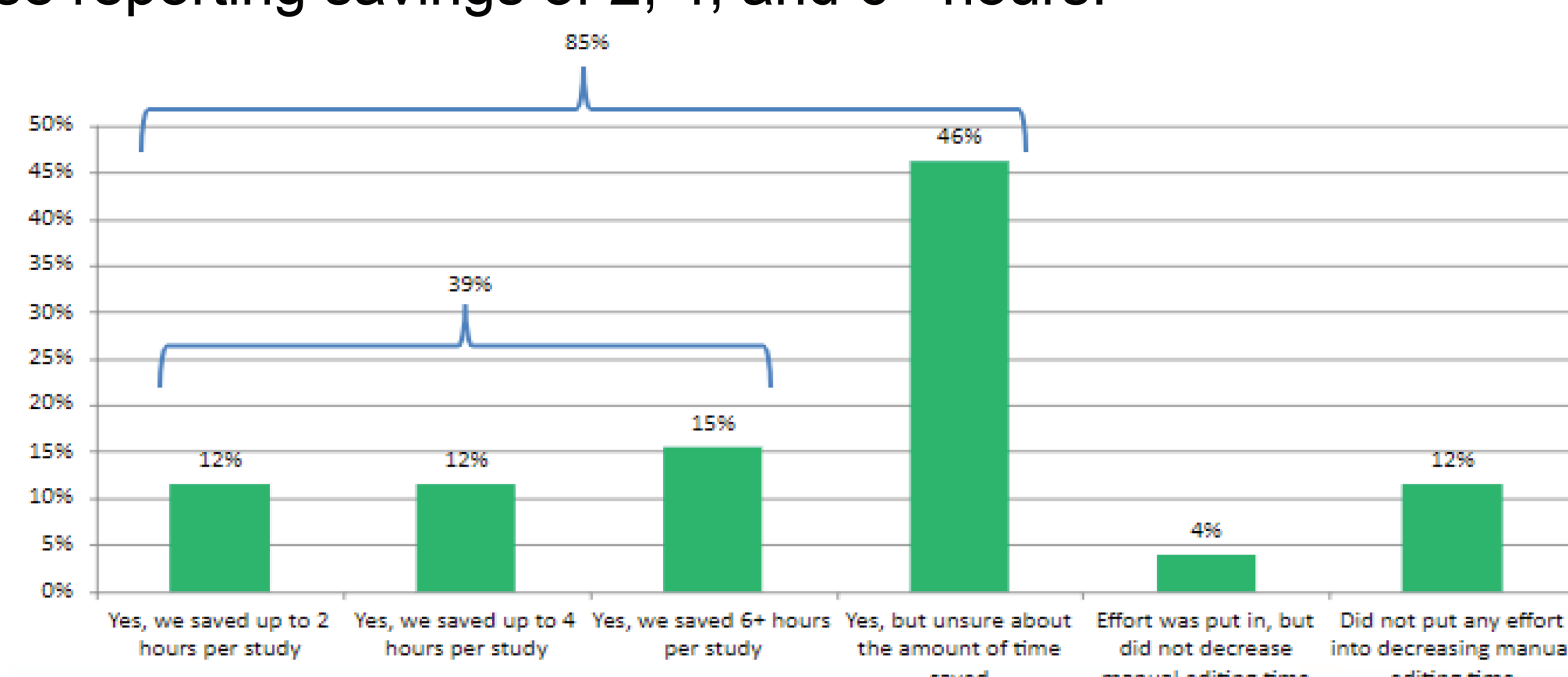
Selected results are shown here, please see the PHUSE website for the full results.

Responses

The total number of respondents was 27, which was a decrease from last year's 38 respondents. We related this to the shorter period of time that the survey was open. This is a continuation in the trend of decreasing participation.

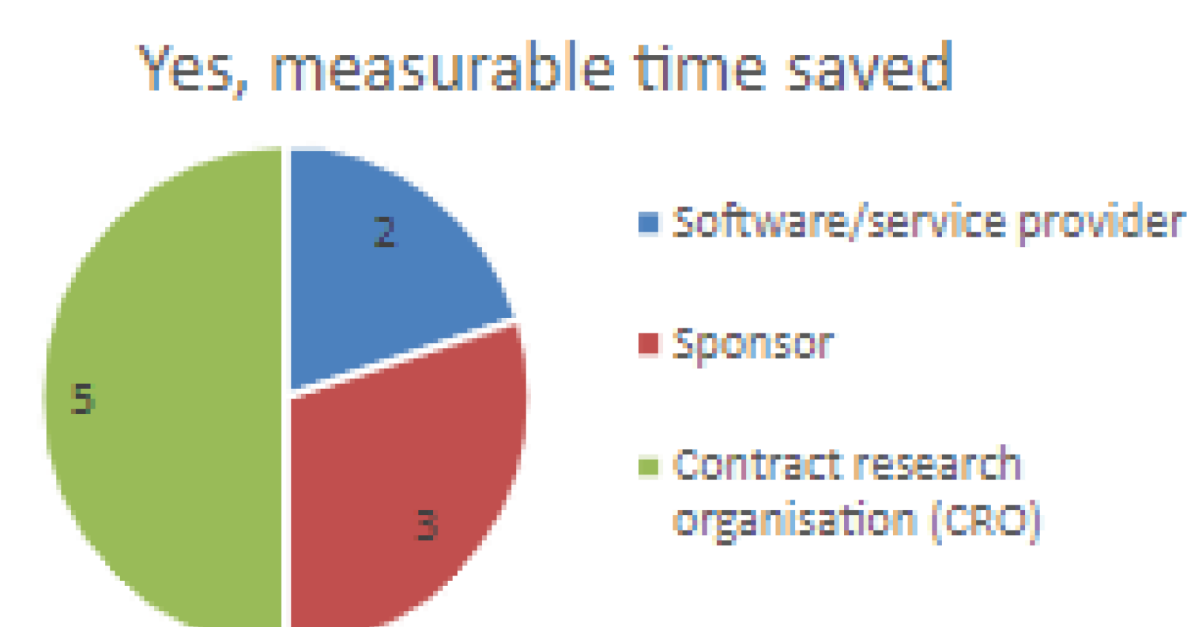
Manual Edits

Q6 - 85% of respondent's organisations have made an effort to decrease manual editing time within the past two years, with 39% of those reporting savings of 2, 4, and 6+ hours.



Results of the survey show that the most time saved by automation to decrease manual editing time is made by CRO and Sponsors.

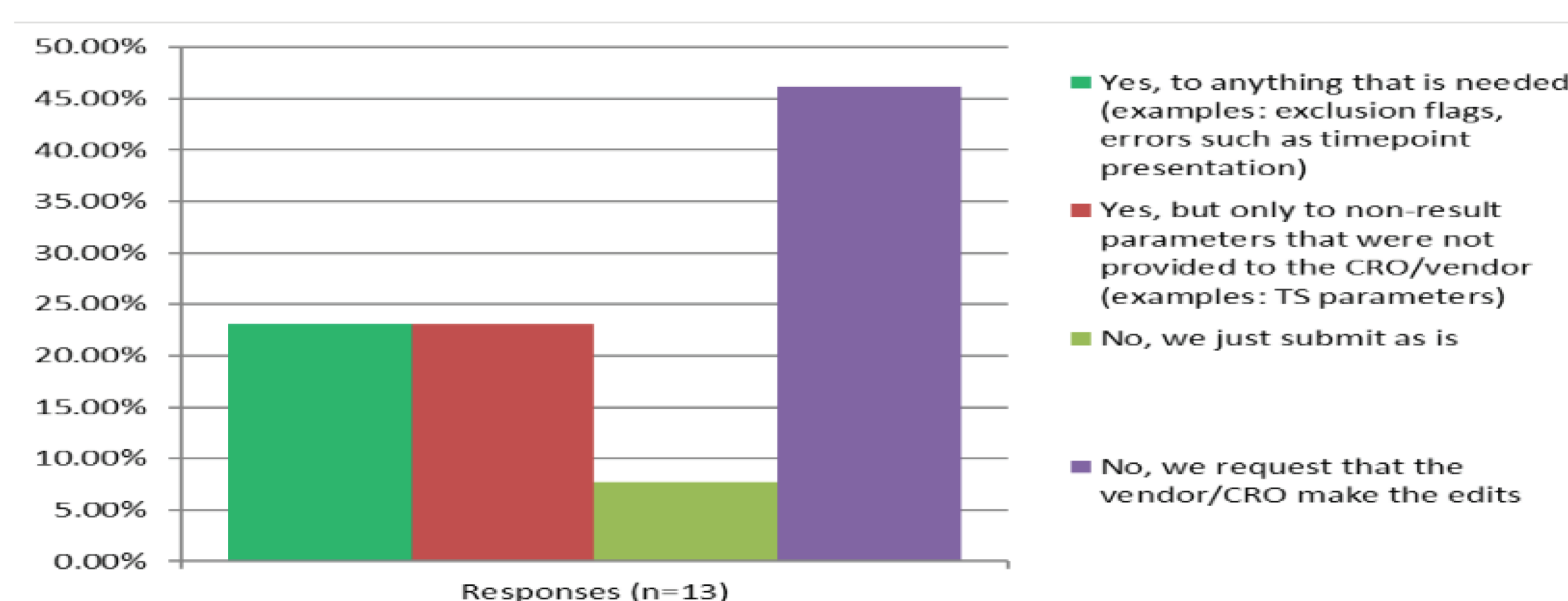
The data suggest that organisations generating SEND data directly (e.g., CROs), prioritize efforts to reduce manual editing, as compared to other organisations.



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: leickhoff@inotivco.com; vanessa.chavez2@labcorp.com; tania.smith@labcorp.com; mike.harwood@instem.com; fiori_janice_m@lilly.com; michael.rosentreter@bayer.com; RThompso@its.jnj.com

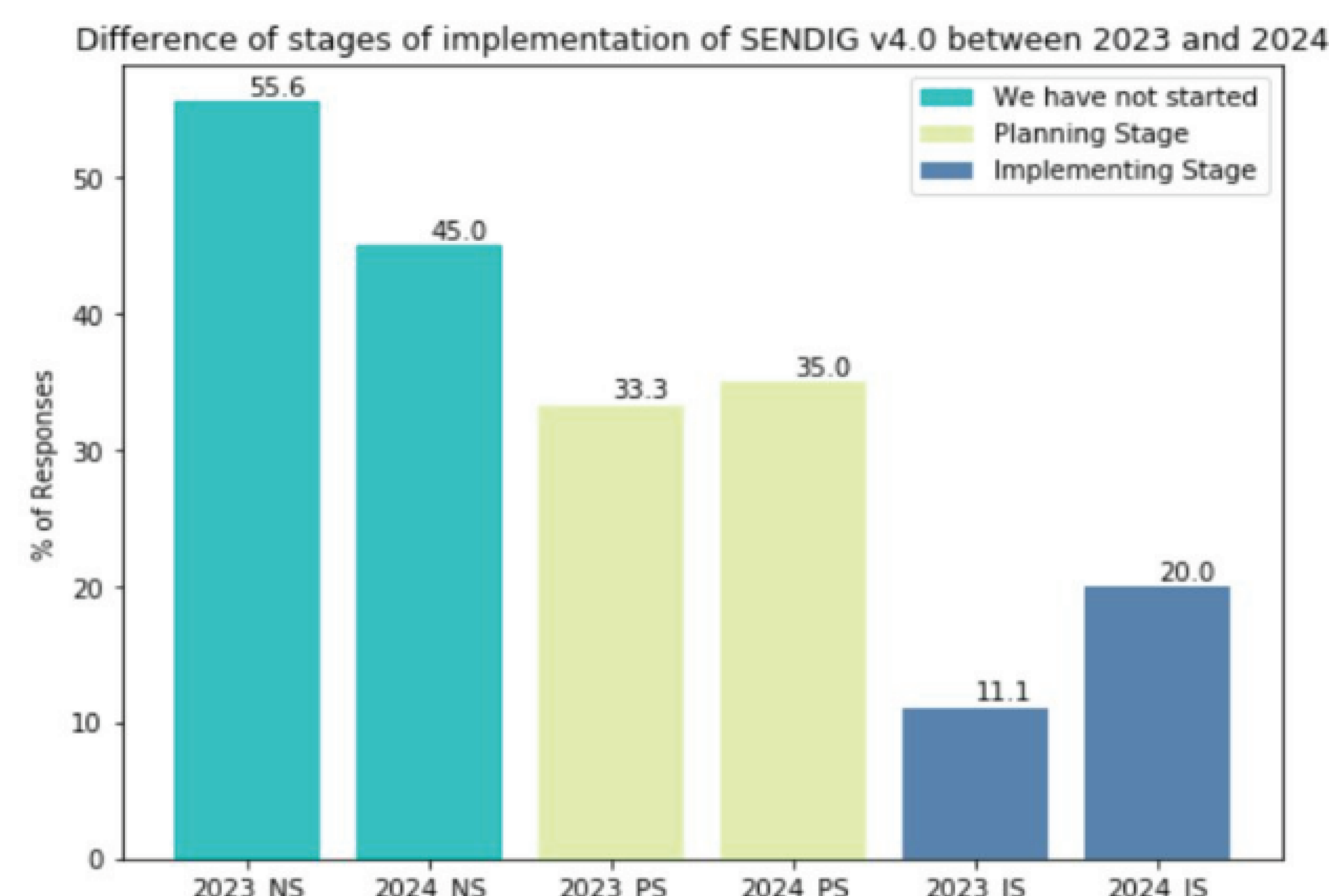
Manual Edits Cont.

Q11 - ~45% of sponsor organisations responded that they do not make any updates to their SEND datasets prior to submission and instead send them back to the vendor or CRO to make updates. Another ~44% of sponsors stated that they do make updates with half of those responses stating that they only make updates to non-result parameters.

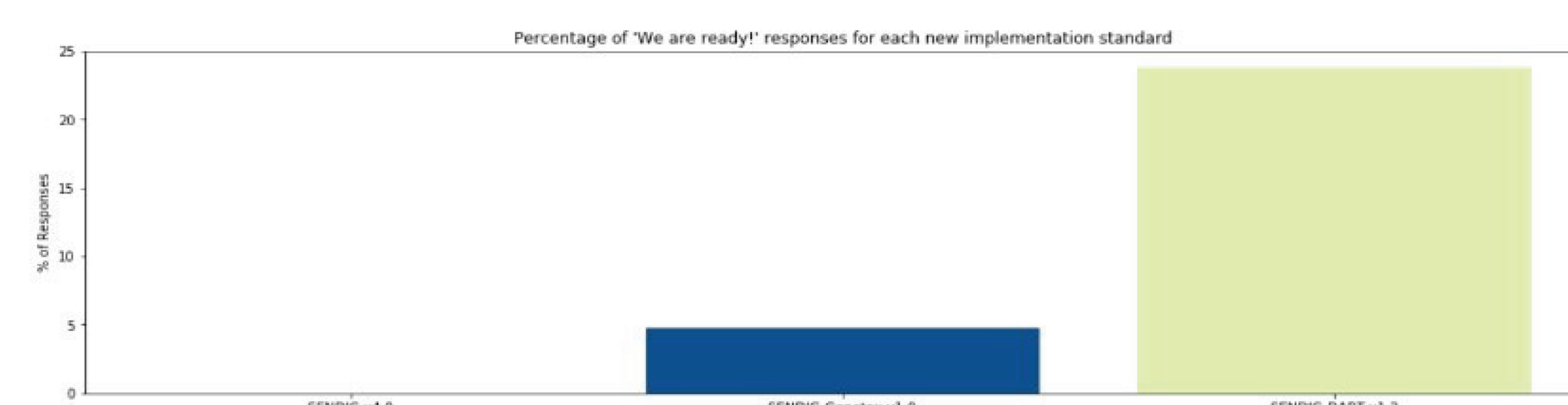


Implementing

Q15 Analysis - Between years 2023 and 2024, there's been an **8.9% increase** of "Implementing Stage", highlighting that organisations are taking proactive steps to establish processes for SENDIG v4.0.



Q15-17 Analysis- When asking for the status of implementation readiness, organisations are most ready at ~25% for DART v1.2, 5% for Genetox v1.0, and 0% for SENDIG v4.0.



Conclusion

The results of the survey show that 85% of organisations have made an effort to decrease manual editing. The majority of organisations moving towards automation are either CROs or Sponsors. The results also show that none of the SEND stakeholders are ready for SENDIG v4.0, however, they have shown great advancements towards preparing for DART v1.2. Implementation of SENDIG v4.0 is quickly approaching and will soon be a priority for everyone!