PP07

# SEND (Standard for Exchange of Nonclinical Data) Industry Feedback Survey: 2023 Results

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**Abstract**
As the scope of SEND broadens, contract research organizations and sponsors must continuously evolve to keep pace with updated regulatory specifications. The 2023 Industry Feedback Survey will provide a snapshot of the SEND industry focusing on three main topics: Manual edits stemming from gaps within data collection systems, automation practices and the frequency of scripting-solutions, and readiness 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-five survey questions were developed and the survey was created using SurveyMonkey. Mailing lists of the CDSIC and PHUSE working groups were emailed with announcements of this survey. The survey was open from 22 May 2023 through 19 June 2023. All answers were anonymous and each respondent had an option of skipping or providing further commentary for analysis. The total number of respondents was 38, which was a decrease from last year's 60 respondents.

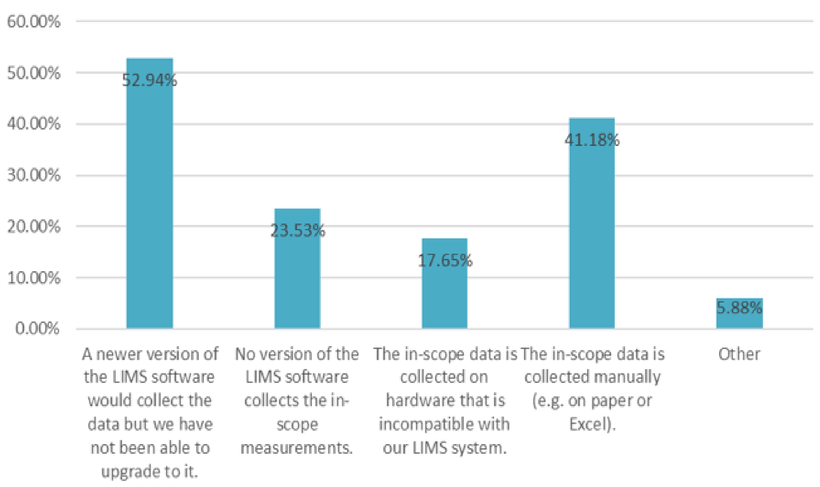
**Results**
Selected results are shown here, please see the PHUSE website for the full results.

**Manual Edits**
Most respondents stated they are using multiple LIMS systems and most have limitations in collecting data.

**Q8:** 50% of respondents answered that there are some types of in-scope data that are not captured by their LIMS.

**Q9:** Out of this data, ~53% responded that LIMS upgrades would give the ability to collect the data, and ~42% responded that the in-scope data are captured manually.

Eliminating some of these manual steps may lead to increased efficiency.

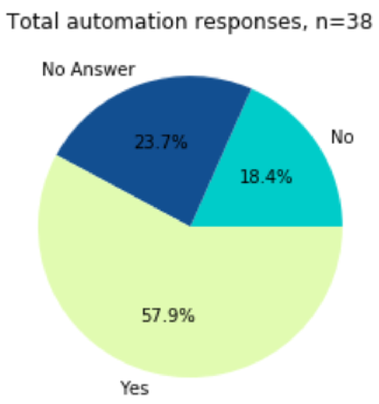



**Q14:** The majority of organisations impacted by manual data collection processes are large (over 1,000 employees) Contract Research Organizations (CROs).

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

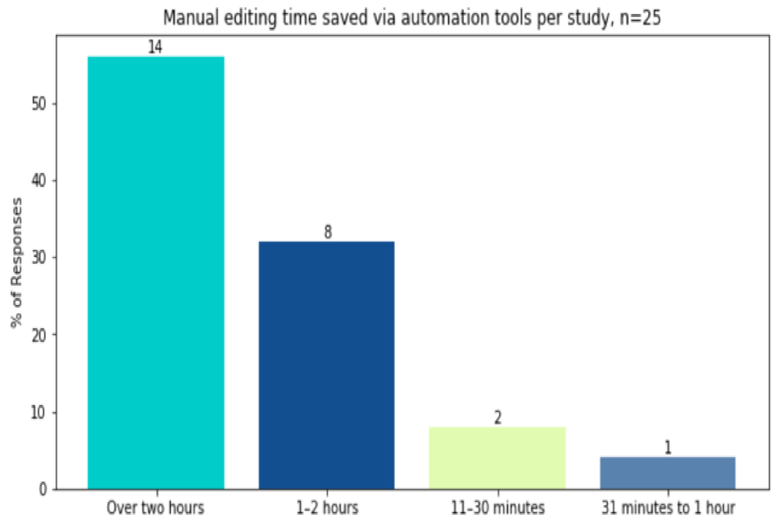
**Automation**
Previous surveys indicated many respondents were spending time on manual edits. These results report on efforts to automate deliverables, thereby reducing manual edits.

**Q15:** ~58% of organisations use automation tools either some or all of the time. This suggests that a high number of organisations have already invested in developing tools to complete SEND packages.




| Category | Q15 Response |
|---|---|
| Yes | Yes, some of the time<br>Yes, all of the time |
| No | No, everything is done manually<br>No, everything is formatted correctly automatically |
| No Answer | Skipped |

Of those that fall into the "Yes" category from Q15, **Q16** explored the time that is saved using those tools. The data found that >50% of organisations are saving over 2 hours of manual editing time per study. The next highest occurrence at ~30% saved 1-2 hours of time using automation tools.




**Future Standards**
The majority of respondents appear to be prepared or already generating SEND datasets for DART studies, with a significantly lower percent generating datasets for submission to CBER.
An average of ~71% of respondents were aware of all proposed topics for SENDIG v4.0.

**Conclusion**
The results of the survey show that manual data collection still seems to be a big issue for most large companies. Many of these gaps seem to be due to LIMS and resource limitations. Automation is one solution that is being implemented to save time in the SEND generation process.