

PP03



Industry Survey On The Usability Of The SEND Standard (Submission Of Electronic Non-Clinical Data)

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Abstract

The utility of nonclinical data in the standardized format required by SEND is expanding beyond the original purpose for regulatory submissions. The PHUSE Nonclinical Group has undertaken a survey to understand the usability of the standard for submission, datamining, and other uses and to solicit feedback from sponsors and partners. Results of the survey, which are summarized in this poster, included focus on insight into the impact and drivers of manual edits, the implementation of the non-standard-driven harmonization initiatives, and machine-readability. PHUSE non-clinical group members will use the results to identify projects to help the industry maximize the value of SEND data. Selected data are presented here.

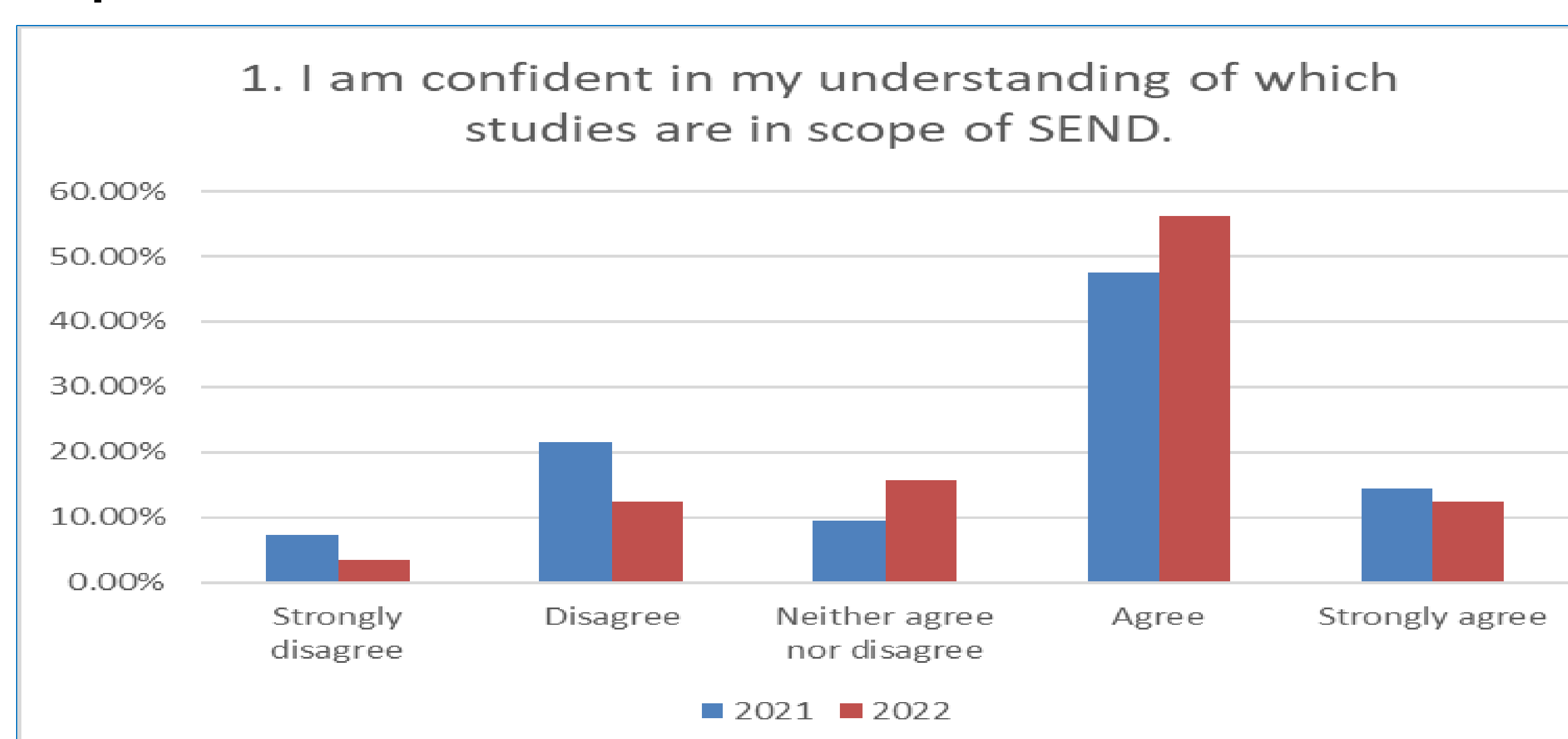
Methodology:

Twenty 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 03May2022 through 30May2022. The number of respondents increased from last year's survey by 33%, with a total of 60 participants.

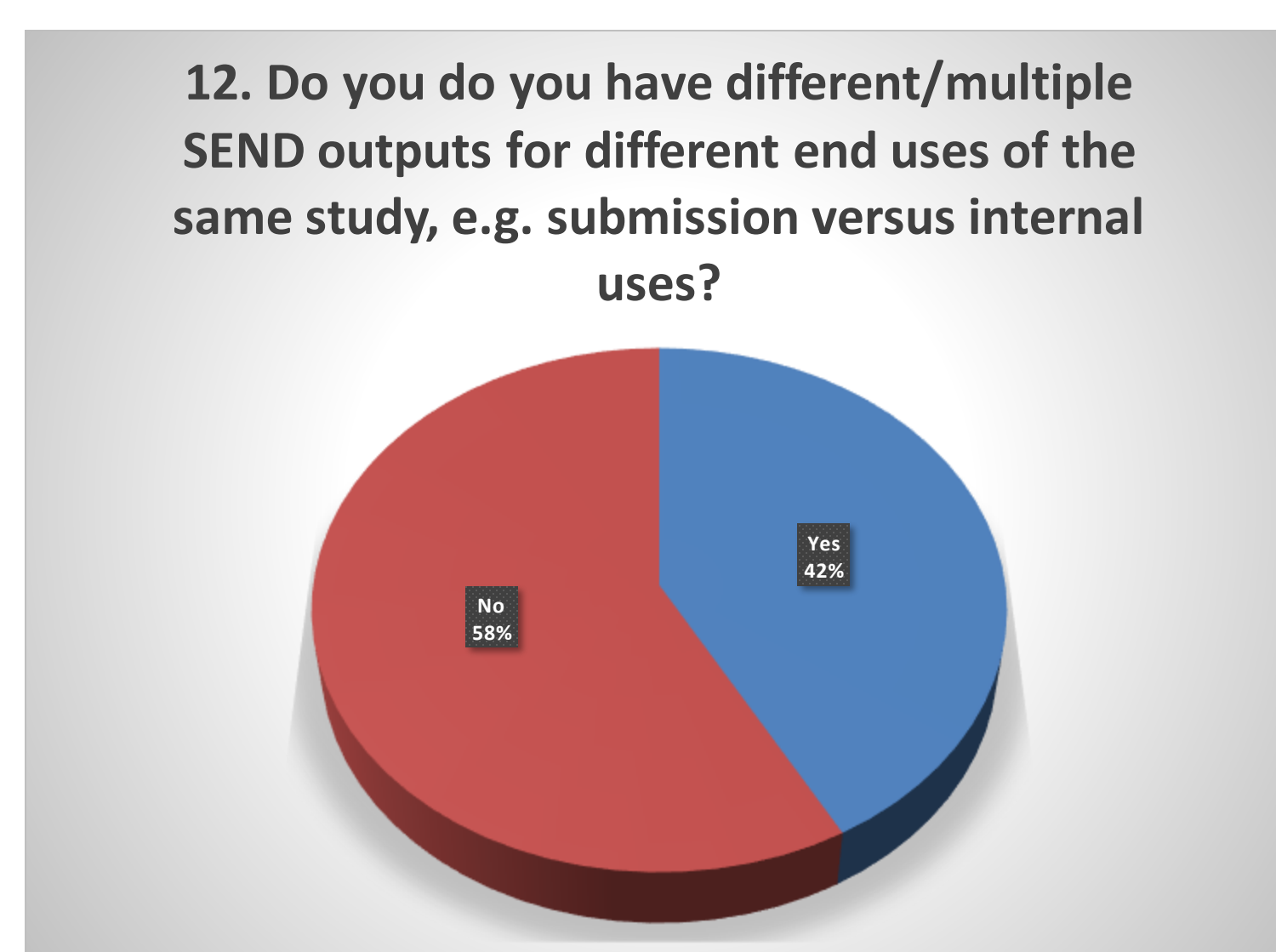
Results:

Selected results are shown here, see this website for the full results:
<https://advance.phuse.global/display/WEL/SEND+Industry+Feedback+Survey>

Scope of SEND



Q1. While 60% of respondents expressed more confidence in their understanding of the scope of SEND following the publication of the extended text on scope in the TCG by the FDA in Sept 2021, there are still 15% who are not confident in their understanding of the scope.

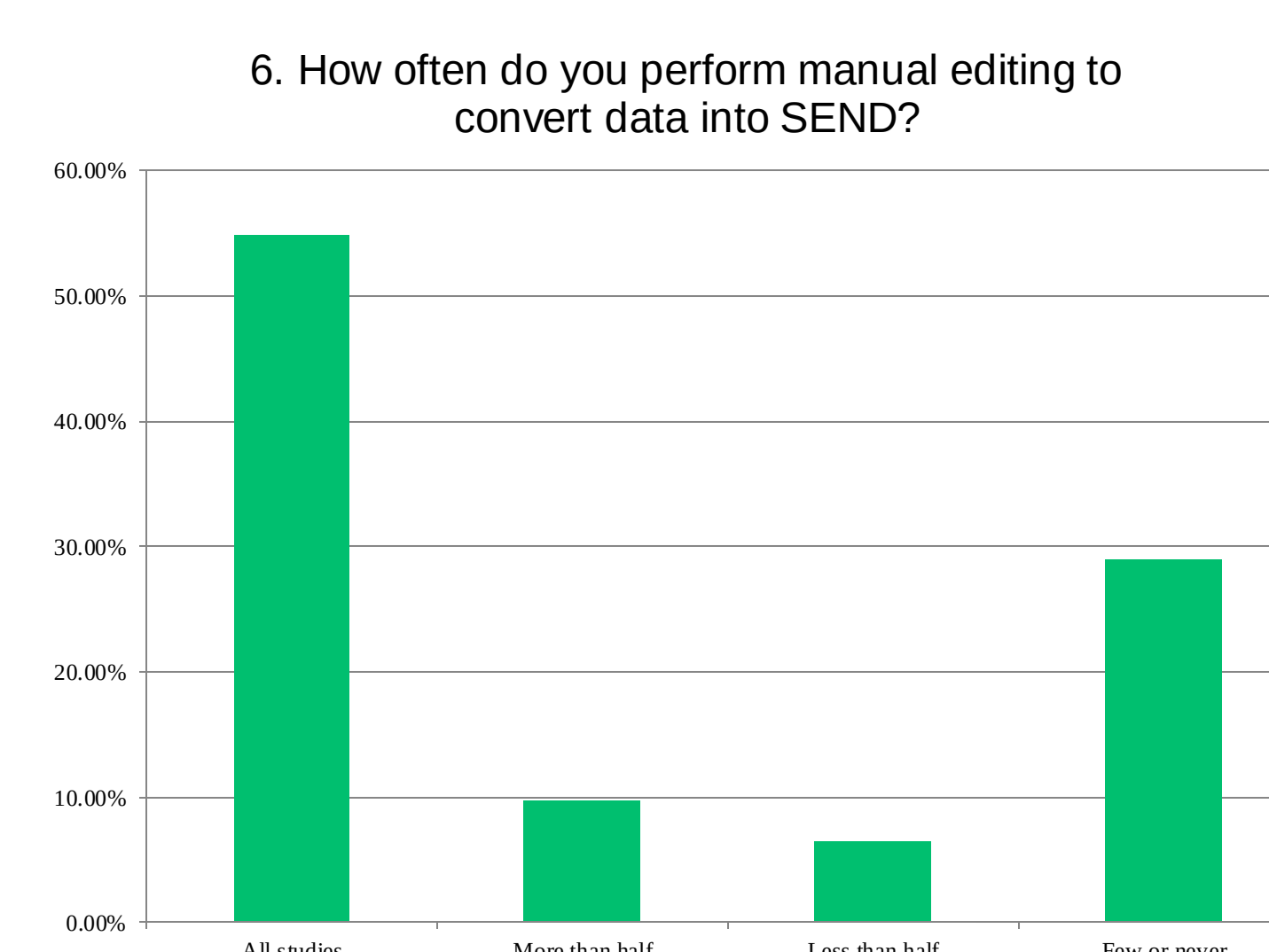


Multiple SEND Outputs:

Q12. Forty-two percent of respondents vary the SEND output for different end uses. This suggests that flexibility in the processes may be beneficial to some, while for others, increased consistency is desired.

Manual Edits

One of the focuses of the survey was on manual editing, including the time that manual edits add to the production of SEND and the triggers of the manual edits.

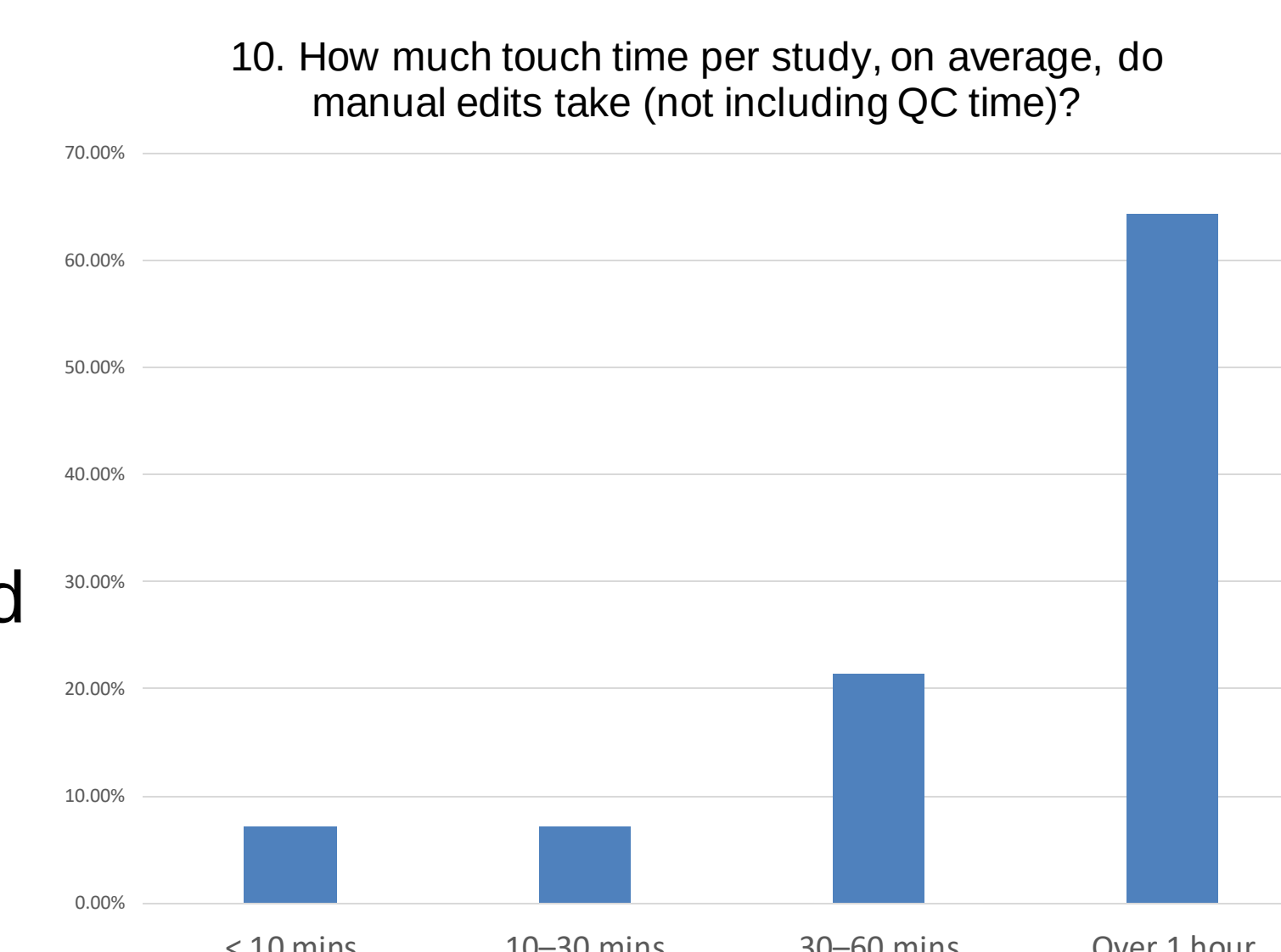


Q6.Frequency

Sixty-four percent responded that all studies (54%) or more than half of studies (10%) require manual edits. Twenty nine percent replied that manual edits are required for “few studies or never.”

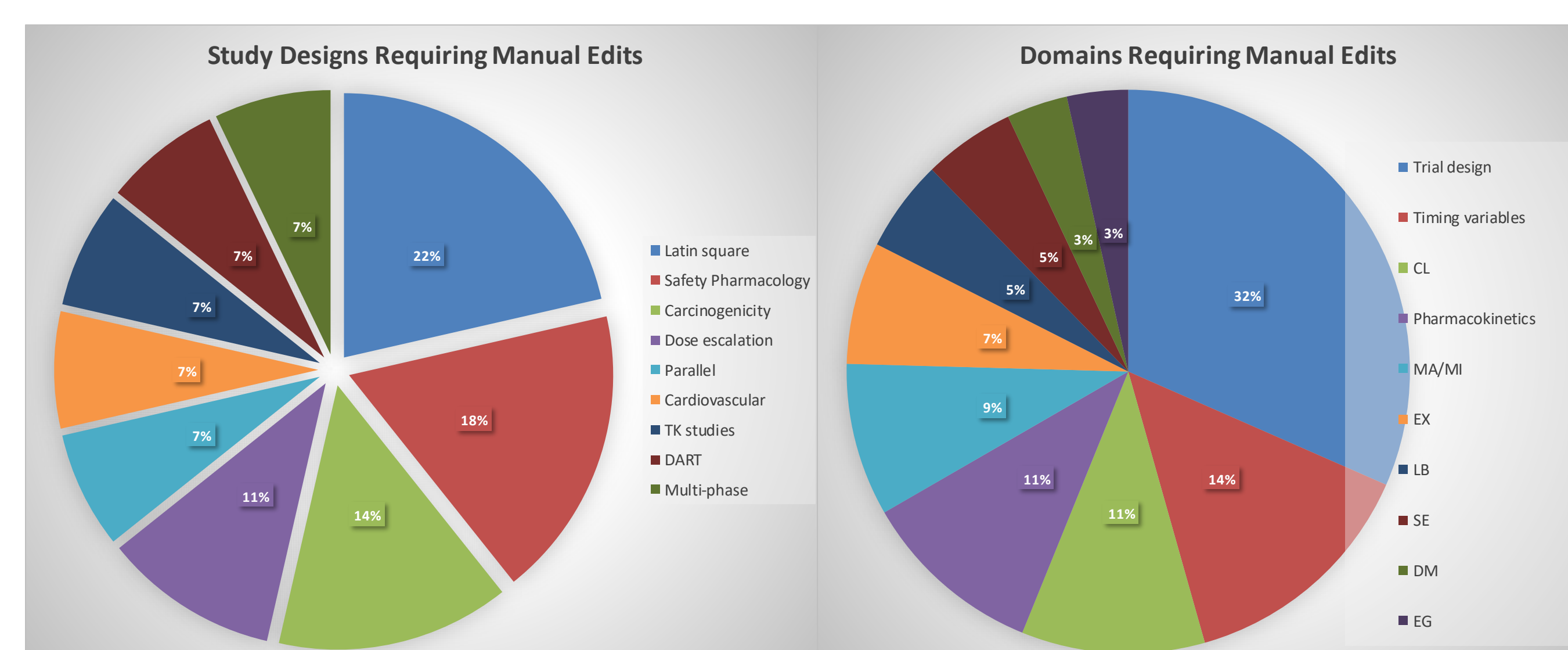
Q10, Q11. Touch time and cycle time.

Manual edits added more than an hour of touch time per study on average for 64% of respondents. Cycle time is impacted by days and weeks for 65% of responders (data not shown).



Q7-8. Causes

The trial design domains were the most frequently cited trigger for manual editing, followed by timing variables. Among study types requiring manual edits, Latin Square designs and Safety Pharmacology studies were the top two, accounting for 39% of responses.



Conclusion: The results of the survey demonstrate significant effort is being expended on manual edits to ensure SEND compliance and completeness. Responses to questions regarding the development of extensions and refinements to SEND outside of CDISC suggests that the industry is not yet ready to adopt these options and more work is needed. Increasing machine readability is compelling for many, with a rich set of features being proposed. The results point to the need for sustained efforts by the PHUSE non-clinical group to develop and promote productivity solutions for more efficient SEND generation.

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: jfiori@lilly.com; mike.harwood@instem.com; tania.smith@labcorp.com