Tight budgets lead to fewer language-diverse participants in academic than industry trials

Individuals with limited English proficiency were less likely to participate in, and sign consent documents in their primary language for, clinical trials led by academia than those led by industry. This retrospective analysis shows that inadequate funding for translation is a barrier to equitable trial enrolment and appropriate informed consent in academic trials.

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At a glance

Study design: retrospective analysis of trial-consent events at a single cancer centre.

Population: 12,082 consent events involving 9,213 individuals.

Analysis: statistical modelling of consent events and covariables in industry and academic trials.

Conclusion: academic trials had fewer consent events with translated documents than did industry trials.

The unmet medical need

Data from cancer-related clinical trials reveal clear and striking disparities in the enrolment of individuals according to race and ethnicity (see go.nature.com/3xn82ba). Numerous factors contribute to this problem, including systemic clinical-trial practices[1]. Our group at the Jonsson Comprehensive Cancer Center at the University of California, Los Angeles, studies lung cancer and is in a diverse catchment area. We applied a mechanistic lens to our cancer centre's clinical trial practices to assess the impact of a well-known disincentive against language-diverse trial participation: the cost of translating consent documents.

Industry and academic clinical trials vary greatly in their access to funding and resources[2]. Whereas budgets for industry trials are typically flexible, academic ones are not. This is because an academic trial's budget is negotiated per participant up-front and delivered to an account generally managed by the investigator throughout the study. We proposed that the unexpected cost or financial penalty for obtaining translated consent documents, although relatively modest, would lead to decreased enrolment of individuals with limited English proficiency in academic trials compared with those led by industry.

The study and its findings

We evaluated 12,082 consent events in clinical trials at the Jonsson Comprehensive Cancer Center between 2013 and 2018. Industry-led studies listed a biopharmaceutical company as the principal sponsor. Primary language and English proficiency were determined through electronic health records. We used timestamps on regulatory documents to determine whether concomitant translated documents were signed by the participant. Statistical models of consent events and of various covariables, such as study type and participant insurance type, assessed the likelihood of consent events including documents in participants' primary language on the basis of the presence or absence of industry sponsorship.

Relatively few (6.1%) consent events involved individuals whose primary language was not English, and even fewer (4.0%) included people with limited English proficiency. Compared with industry trials, academic ones had roughly half as many consent events for individuals with primary languages other than English and those with limited English proficiency (Fig. 1). Although the proportion of discordant consent events — in which translated documents were not available in a participant's primary language — was similar for both types of trial, industry trials had three to four times the number of events with appropriately translated documents than academic ones did. Several analyses showed that these differences were unlikely to be driven mainly by confounding factors.

Limited English proficiency is a recognized barrier to clinical-trial participation, and we have evaluated a systemic process contributing to this. By identifying impediments — such as funding for translation in academic trials — that can be overcome, this work offers an opportunity for intervention to help address this disparity.

Outlook for the future

- The Jonsson Comprehensive Cancer Center and some industry partners have pledged funds to cover future translation costs in academic trials.
- This study evaluates a single centre's experiences, which might not be representative. Confirming the generalizability of our findings to further clinics and diseases other than cancer will be important.
- We hope our study inspires pragmatic solutions to other factors impeding the recruitment of fully representative pools of participants into clinical trials.

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EXPERT OPINION

"The authors present a single-site study of consent rates among non-English-speaking and limited-English-proficiency individuals in industry-funded and non-industry-funded studies. This work is important for understanding whether using different funding mechanisms might be an actionable strategy to address the under-representation of these groups in clinical trials for cancer and beyond. Many studies document the problem of low enrolment rates by under-represented groups, but this study is novel in its approach of using existing data and differentiating by funding source." (CC BY 4.0)

Andrea Ramirez is at the All of Us Research Program, National Institutes of Health, Bethesda, Maryland, USA.

FIGURE

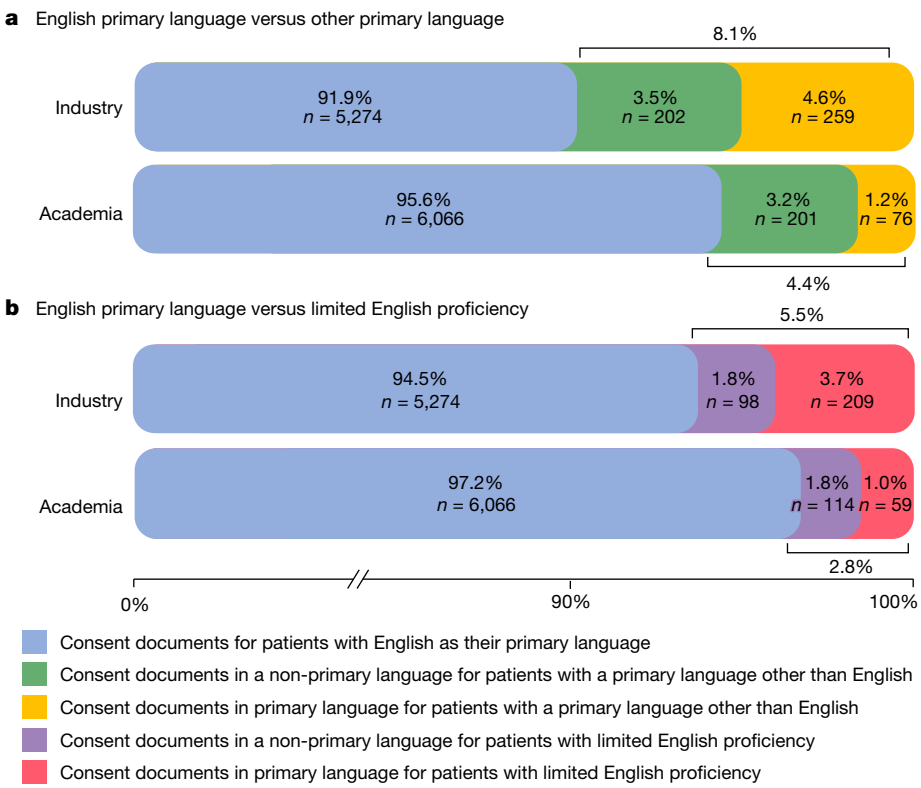

Figure 1 | Consent events in industry and academic trials. Summary of the consent events in academic trials and in those led by industry, including events in participants' primary language or for those with limited English proficiency. **a**, **b**, The number of consent events that included participants with a primary language other than English (**a**) and those with limited English proficiency (**b**) were greater in industry than in academic trials. The numbers of discordant consent events were similar in both types of trial, but appropriately translated consent documents were available three to four times more often in industry trials than in academic ones. **a**, Blue, consent events for participants whose primary language is English. Green, discordant consent events in which the primary language did not match that of the translated documents. Yellow, consent events in which the primary language matched that of the translated documents. **b**, Purple, consent events for individuals with limited English proficiency and whose primary language did not match that of the translated documents. Red, consent events for individuals with limited English proficiency but whose primary language matched that of the translated documents.

REFERENCES

1. Gerber, D. E., Lakoduk, A. M., Priddy, L. L., Yan, J. & Xie, X.-J. *Oncologist* **20**, 674–682 (2015).

2. Seow, H.-Y. *et al. J. Clin. Oncol.* **30**, 1456–1461 (2012).

FROM THE EDITOR

This study analyses how the availability of translated consent documents can be a barrier for clinical-trial enrolment of people from under-represented minority groups whose members often have limited English proficiency. Acknowledging and addressing such hurdles is important to increase diversity and representation in trial populations.

Victoria Aranda, Team Manager and Senior Editor, *Nature*