NASEM Workshop on the Use of Race and Ethnicity in Biomedical Research

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FDA Push for Increased Diversity in Clinical Trials

Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry

Docket Number:FDA-2021-D-0789, Oct 2022

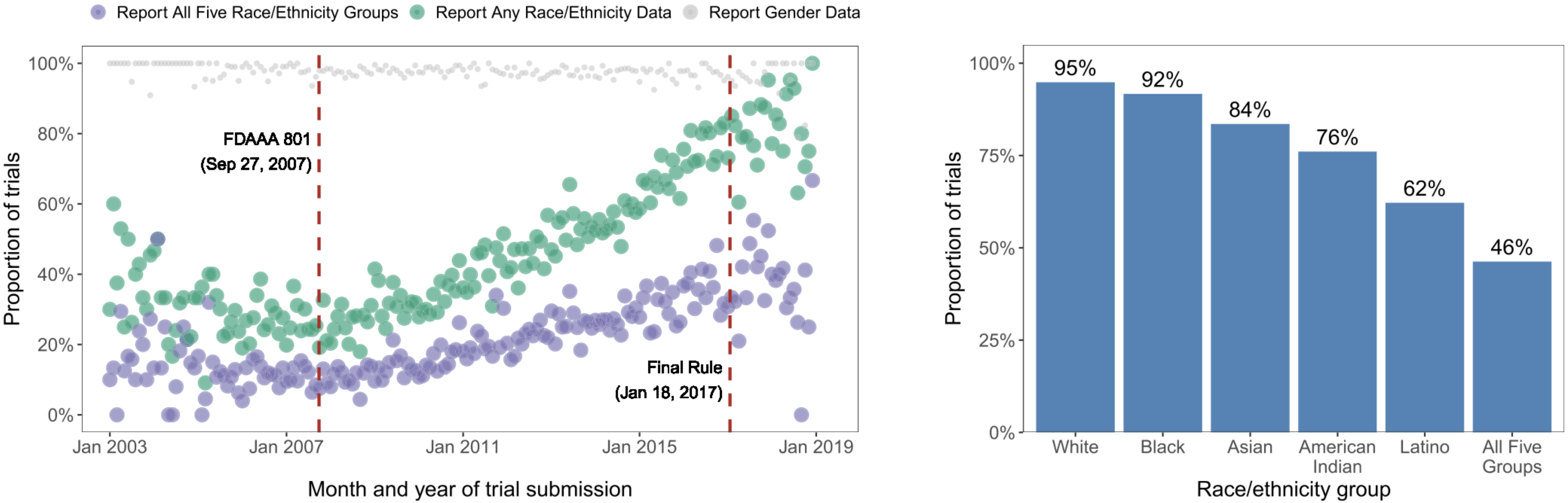
FDA guidance documents define a diverse population, when applicable, to be inclusive of all populations as defined by demographic factors such as **race, ethnicity, sex, gender identity, age, pregnancy status, lactation status**, and by the presence of certain clinical characteristics such as multiple **comorbidities**”

Clinical trial participants should be representative of the population that the product is intended to treat

Post-marketing Approaches to Obtain Data on Populations Underrepresented in Clinical Trials for Drugs and Biological Products

https://www.fda.gov/media/170899/download, Aug 2023

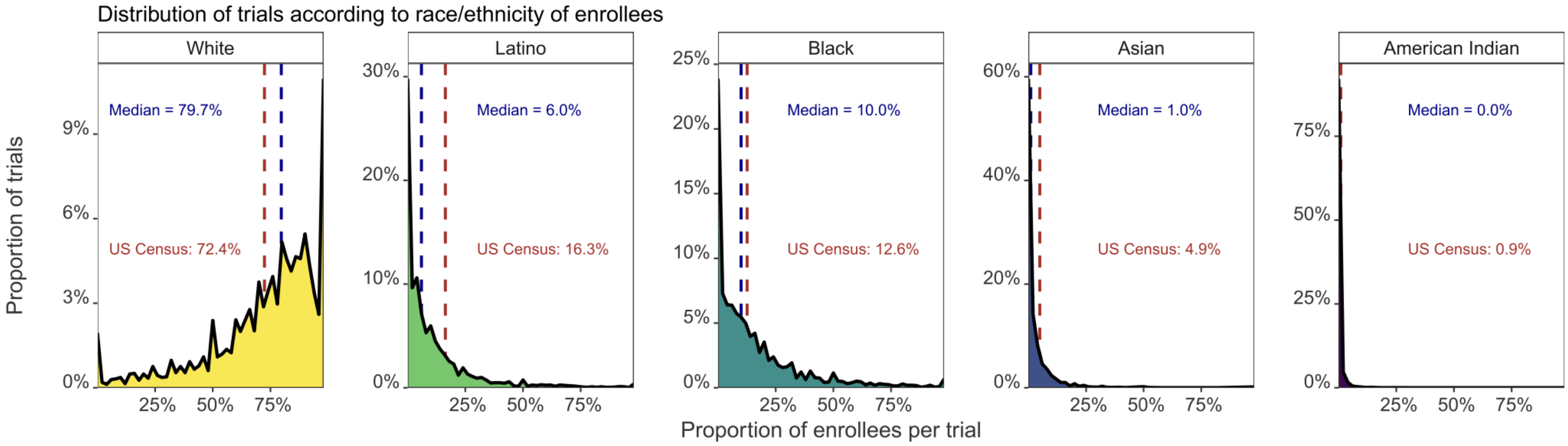
Progress in reporting race and ethnicity data in clinical trails – 2000 to 2020



US clinical trials registered in ClinicalTrials.gov from March 2000 to March 2020.

Turner BE, Steinberg JR, Weeks BT, Rodriguez F, Cullen MR. **Race/ethnicity reporting and representation in US clinical trials: a cohort study.** *Lancet Reg Health Am. 2022 Jul;11:100252. doi: 10.1016/j.lana.2022.100252. Epub 2022 Apr 10. PMID: 35875251; PMCID: PMC9302767.*

Race and Ethnicity Distributions in US Clinical Trials– 2000 to 2020



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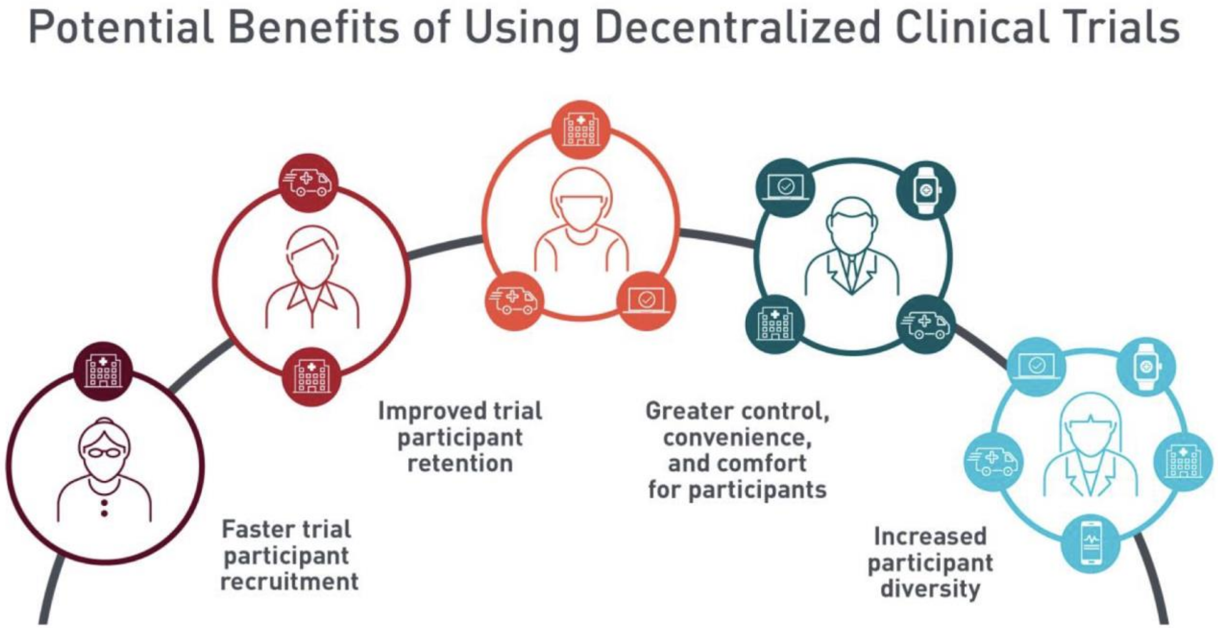
Decentralized Clinical Trials Could Drive Increased Diversity

"As we seek to improve our evidence generation system, decentralized clinical trials may enhance convenience for trial participants, reduce the burden on caregivers, <u>expand access to more diverse populations</u>, improve trial efficiencies, and facilitate research on rare diseases and diseases affecting populations with limited mobility."

FDA Commissioner Robert M. Califf, M.D.



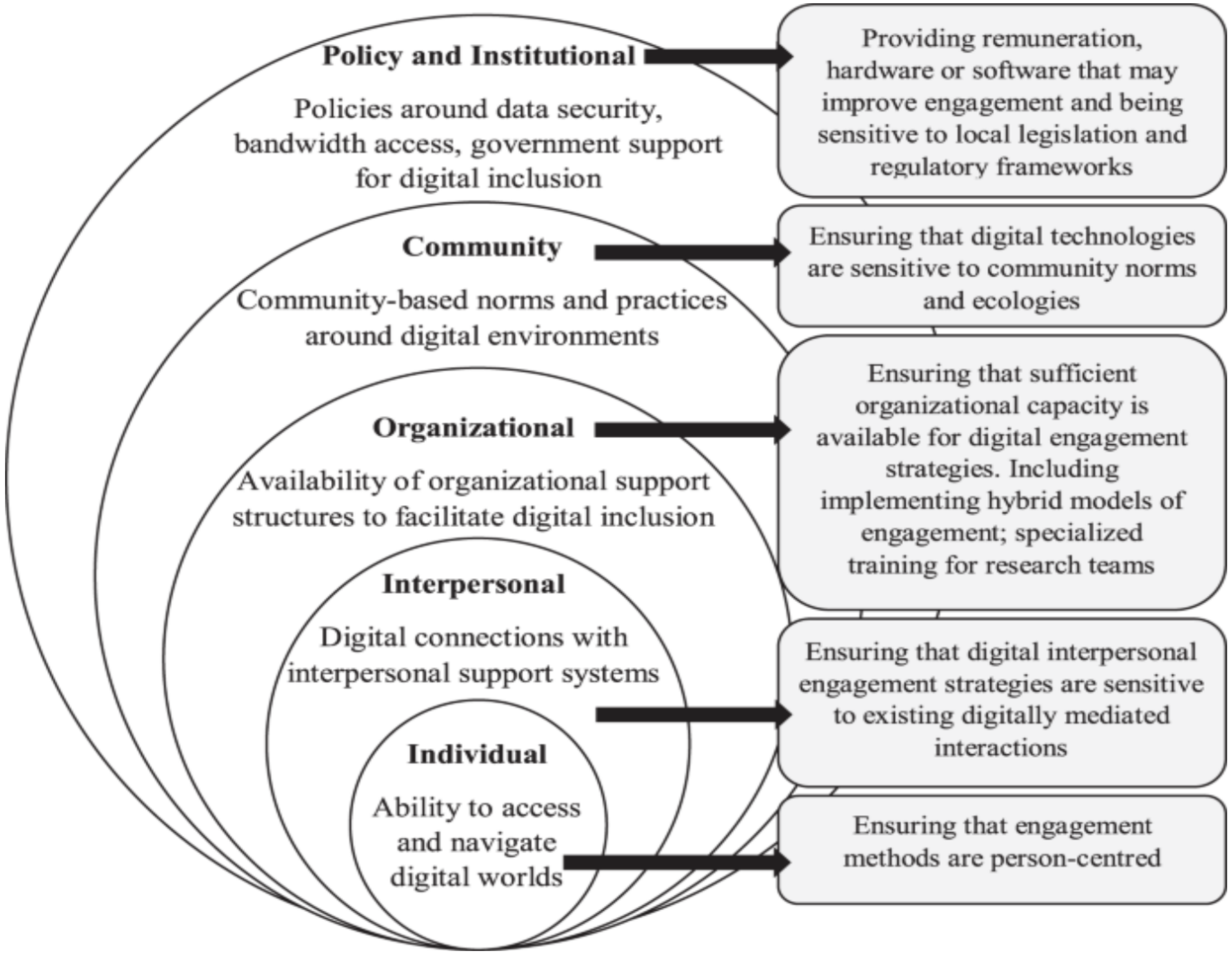
Clinical Trials Transformation Initiative. Decentralized Clinical Trials. Published September 2018. https://ctti-clinicaltrials.org/our-work/digital-health-trials/original-digital-health-trials-projects/.

Key Issues to Address:

- Endpoints that are robust to remote or self administration
- Digital Divide

Goodson, N., Wicks, P., Morgan, J. et al. ***Opportunities and counterintuitive challenges for decentralized clinical trials to broaden participant inclusion****. npj Digit. Med.* ***5****, 58 (2022). https://doi.org/10.1038/s41746-022-00603-y*

Proactively Addressing Challenges of ‘Digital Divide’



Policy and Institutional

Policies around data security, bandwidth access, government support for digital inclusion

Providing remuneration, hardware or software that may improve engagement and being sensitive to local legislation and regulatory frameworks

Community

Community-based norms and practices around digital environments

Ensuring that digital technologies are sensitive to community norms and ecologies

Organizational

Availability of organizational support structures to facilitate digital inclusion

Ensuring that sufficient organizational capacity is available for digital engagement strategies. Including implementing hybrid models of engagement; specialized training for research teams

Interpersonal

Digital connections with interpersonal support systems

Ensuring that digital interpersonal engagement strategies are sensitive to existing digitally mediated interactions

Individual

Ability to access and navigate digital worlds

Ensuring that engagement methods are person-centred

Revised socio-ecological model providing considerations and potential solutions for digital incl Screenshot dividual, interpersonal, organizational, community, and policy levels.

Tan, R.K.J., Wu, D., Day, S. et al. ***Digital approaches to enhancing community engagement in clinical trials****. npj Digit. Med.* ***5****, 37 (2022). https://doi.org/10.1038/s41746-022-00581-1*

Patient Reported Outcomes in Diverse Populations

"A key barrier to PRO data collection in underserved groups is a lack of valid and reliable measures that have been developed in, or are salient to, the target population. ***Many PRO measures are developed with limited patient input and may not address concepts that matter to underserved groups***."

Calvert, M.J., Cruz Rivera, S., Retzer, A. et al. ***Patient reported outcome assessment must be inclusive and equitable****. Nat Med* ***28****, 1120–1124 (2022). https://doi.org/10.1038/s41591-022-01781-8*

"Non-responders to Breast Cancer PROs (BREAST-Q or Recovery Tracker) were significantly more often Black race and non-English speaking(p<0.001)."

Srour MK, Tadros AB, Sevilimedu V, Nelson JA, Cracchiolo JR, McCready TM, Silva N, Moo TA, Morrow M. ***Who Are We Missing: Does Engagement in Patient-Reported Outcome Measures for Breast Cancer Vary by Age, Race, or Disease Stage?*** *Ann Surg Oncol. 2022 Dec;29(13):7964-7973. doi: 10.1245/s10434-022-12477-1. Epub 2022 Sep 23. PMID: 36149608; PMCID: PMC10328095*

Patient Reported Outcomes in Diverse Populations

1) involving patient advocate representatives of the target population in the development of ***culturally sensitive questionnaires***
2) minimizing barriers that may limit a patient’s ability to complete PROs (issues of dexterity and technological awareness)
3) allowing caregivers to complete the questionnaires on behalf of the patient
4) ensuring availability of translators or interpreters for interviewer-led completion
5) ensuring that content is easy to understand for participants with different literacy levels and educational backgrounds
6) ***validation of the currently available PRO instruments in languages other than English.***

Calvert, M.J., Cruz Rivera, S., Retzer, A. et al. ***Patient reported outcome assessment must be inclusive and equitable****. Nat Med* ***28****, 1120–1124 (2022). https://doi.org/10.1038/s41591-022-01781-8*

Summary

- Progress being made in reporting and increasing diversity in clinical trials
- Decentralized trials an important opportunity, however potential barriers related to ‘digital divide’ must be addressed proactively
- Efforts need to be made to ensure that clinical endpoints and PROs customized for use by a diverse population

Thank You