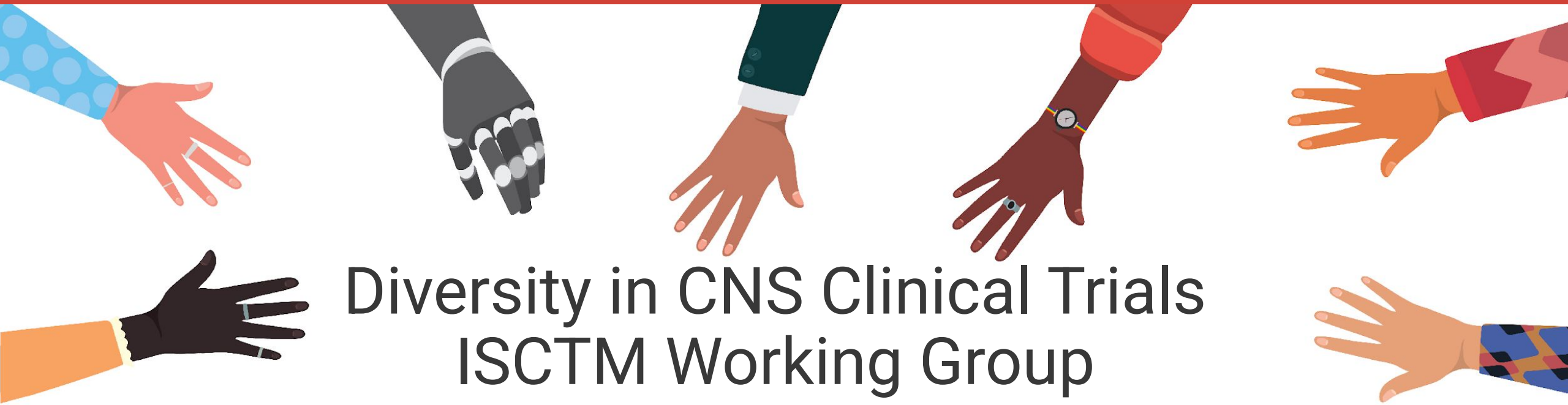
ISCTM

International Society for CNS Clinical Trials and Methodology



Diversity in CNS Clinical Trials
ISCTM Working Group

Feb 19 | 4.25-6 PM

Agenda

Introductions

Quick Recap

Key Discussion Today

- Representativeness beyond Recruitment - Latest learnings from AllofUS
- FDA Guidance - Discussion
- ISCTM’ 26 Session on Diversity in Clinical Trials - Discussion

Disclosures

Sian Ratcliffe

- Head of Global Clinical Operations, Analytics, Technology & Data Sciences
- Employee and shareholder of Biogen
- Shareholder of Pfizer
- Data presented today is not linked to any Biogen studies/trials
- Opinions = mine

Abhi Pratap

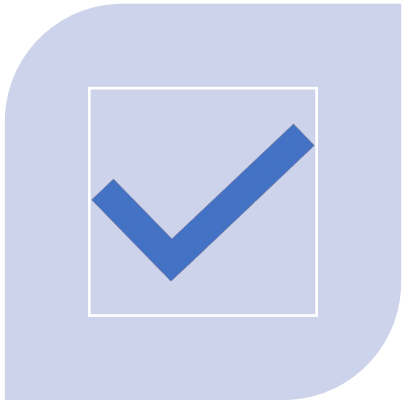
- Executive Director, Global Evidence Lead - CNS
- Employed by Boehringer Ingelheim
- Data presented today is not linked to any Boehringer Ingelheim studies/trials

Academic Affiliations

- Visiting fellow, Kings College London, UK
- Adjunct Faculty, University of Washington, USA

Introductions

NAME, AFFILIATION



CURRENT FOCUS IN CNS & DEI

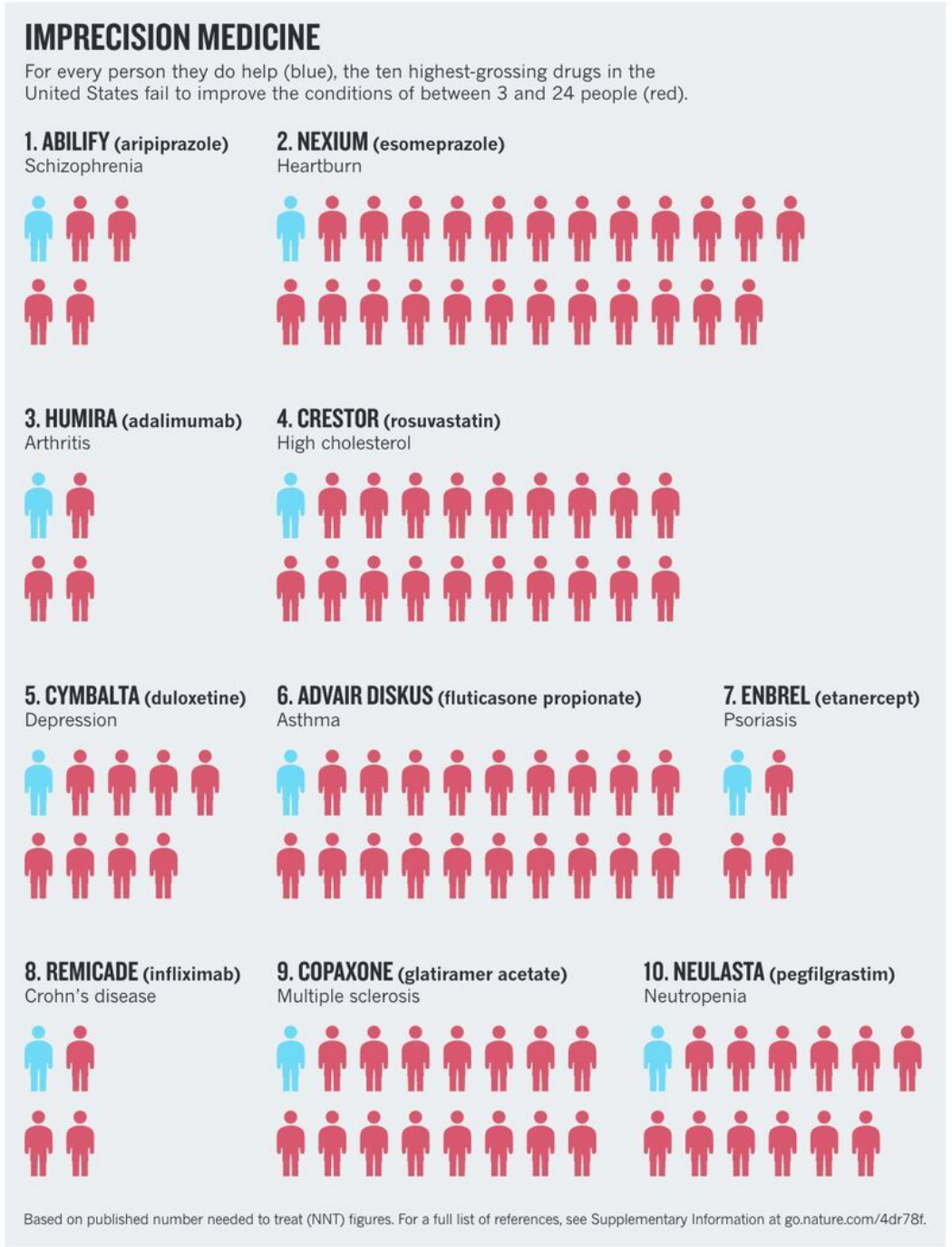
Being Truly Inclusive in CNS Clinical Trials? 🧠🌍

1. Expanding Patient Reach: Breaking Down Barriers 🌐
2. Recruitment Strategies: Moving Beyond One-Size-Fits-All 📝
3. Retention Efforts: Ensuring Ongoing Engagement 🔄
4. Representative Data Analysis: Achieving True Inclusivity 📊

"Underrepresentation" of target population in medical product development can make generated evidence inapplicable to those who weren't included in the trials and, therefore, biased

Imprecision Medicine

“For every person they do help (blue), the ten highest-grossing drugs in the United States fail to improve the conditions of between 3 and 24 people (red).”



GUIDANCE DOCUMENT

Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials; Draft Guidance for Industry; Availability

Draft Guidance for Industry

APRIL 2022

Download the Draft Guidance Document | Read the Federal Register Notice

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

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (OCE/CDER) Lola Fashoyin-Aje, 240-402-0205, (CBER) Office of Communication, Outreach, and Development, 800-835-4709, or 240-402-8010, or CDRHClinicalEvidence@fda.hhs.gov.

U.S. Department of Health and Human Services

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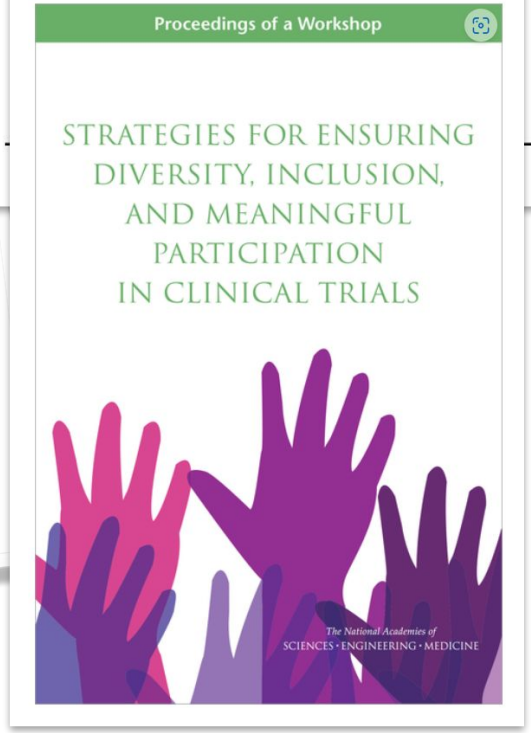
NEWS | 16 February 2023

FDA to require diversity plan for clinical trials

US regulatory agency makes 'big change' to increase the number of participants from under-represented groups in drug testing.



Patient-Focused Drug Development: Methods to Identify What Is Important to Patients

Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

February 2022
Procedural

Less than half of trials assessed (N=20k+) reported data from all five race/ethnicity groups

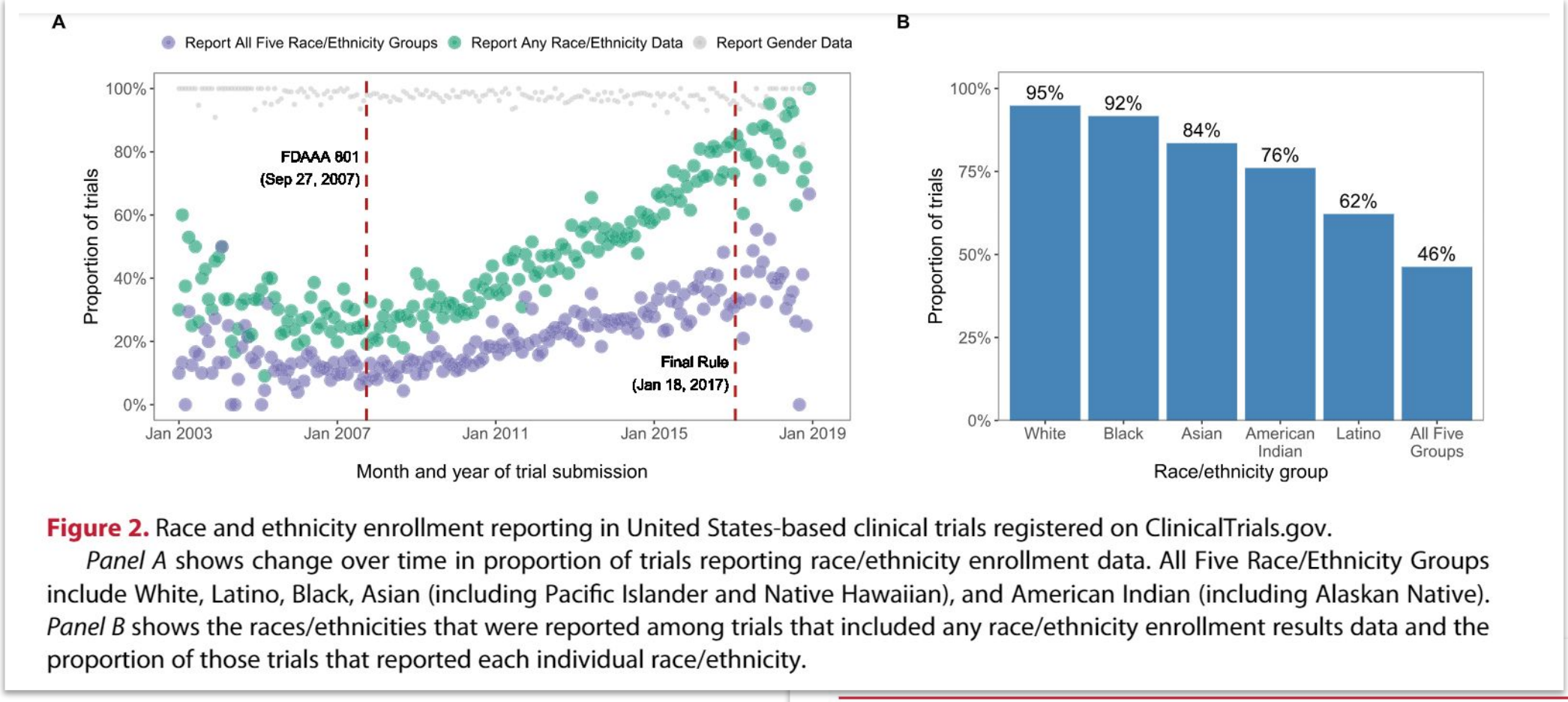


Figure 2. Race and ethnicity enrollment reporting in United States-based clinical trials registered on ClinicalTrials.gov.

Panel A shows change over time in proportion of trials reporting race/ethnicity enrollment data. All Five Race/Ethnicity Groups include White, Latino, Black, Asian (including Pacific Islander and Native Hawaiian), and American Indian (including Alaskan Native). *Panel B* shows the races/ethnicities that were reported among trials that included any race/ethnicity enrollment results data and the proportion of those trials that reported each individual race/ethnicity.

Race/ethnicity reporting and representation in US clinical trials: A cohort study

Brandon E. Turner,[a,b,*] Jecca R. Steinberg,[a] Brannon T. Weeks,[a] Fatima Rodriguez,[c] and Mark R. Cullen [d]

Virtual Public Workshop to Enhance Clinical Study Diversity (FDORA) - CTTI (ctti-clinicaltrials.org)

Advancing the Landscape: Increasing Diversity in Clinical Trials

CLINICAL TRIALS TRANSFORMATION INITIATIVE

Key Takeaways

FDA

- FDA has a longstanding commitment to promote diversity and inclusion of underrepresented populations in clinical trials.
- Enrollment in clinical trials should, to the extent possible, reflect the diversity of the population that will use the medical product, if approved.
- A pragmatic approach that balances FDA's intent to increase diversity in clinical trials with bringing urgent medical treatments to patients as soon as possible is needed.
- To achieve meaningful representation in clinical studies, it takes the combined effort of all interested parties in the clinical trials enterprise.

Various Potential for Biases in Clinical Trials

- Site selection
- Patient Reach
- Recruitment
- Retention
- Data analysis
- Inference
- ……..

Group discussion

- What works
- How
- Real-world examples

Agenda

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AllofUS Recruitment Effort

The NEW ENGLAND JOURNAL of MEDICINE

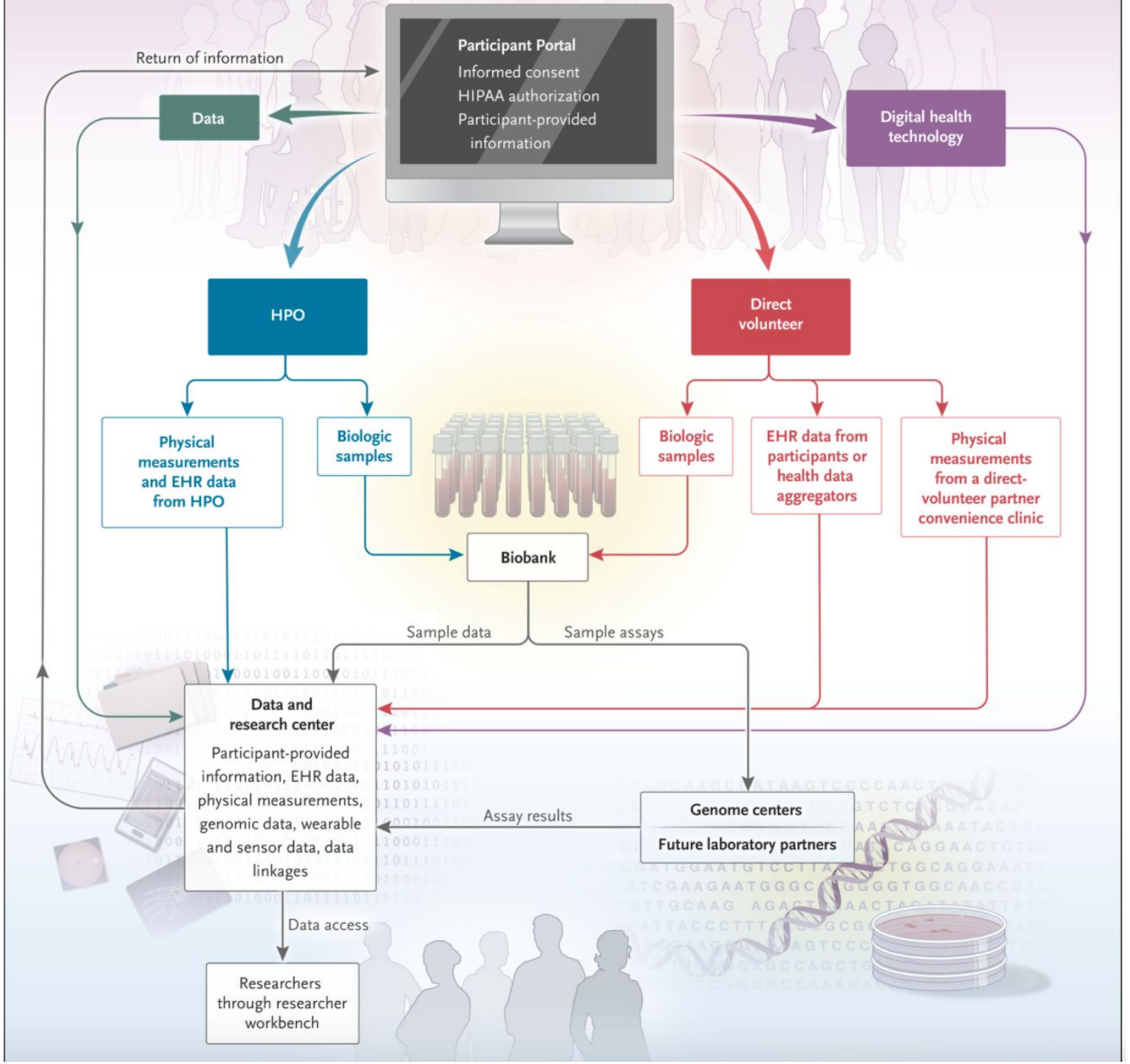
SPECIAL REPORT

The "All of Us" Research Program

The All of Us Research Program Investigators

mens. More than 80% of these participants are from groups that have been historically under-represented in biomedical research. EHR data

A wide variety of data, including full genome sequencing, EHR, and digital health data



AoU Program Investigators, *NEJM*, 2019

The Numbers

Participants

315,227 enrolled

314,994 completed all initial steps

Researchers

248 registered institutions

737 workspaces created

1,067 registered researchers

Researcher Workbench

By The Numbers

All of Us RESEARCH PROGRAM

Data Available from 314,000+ Participants

267,600+
Physical Measurements

214,200+
Electronic Health Records (EHR)

8100+
Fitbit Records

Survey responses from
314,000+ participants

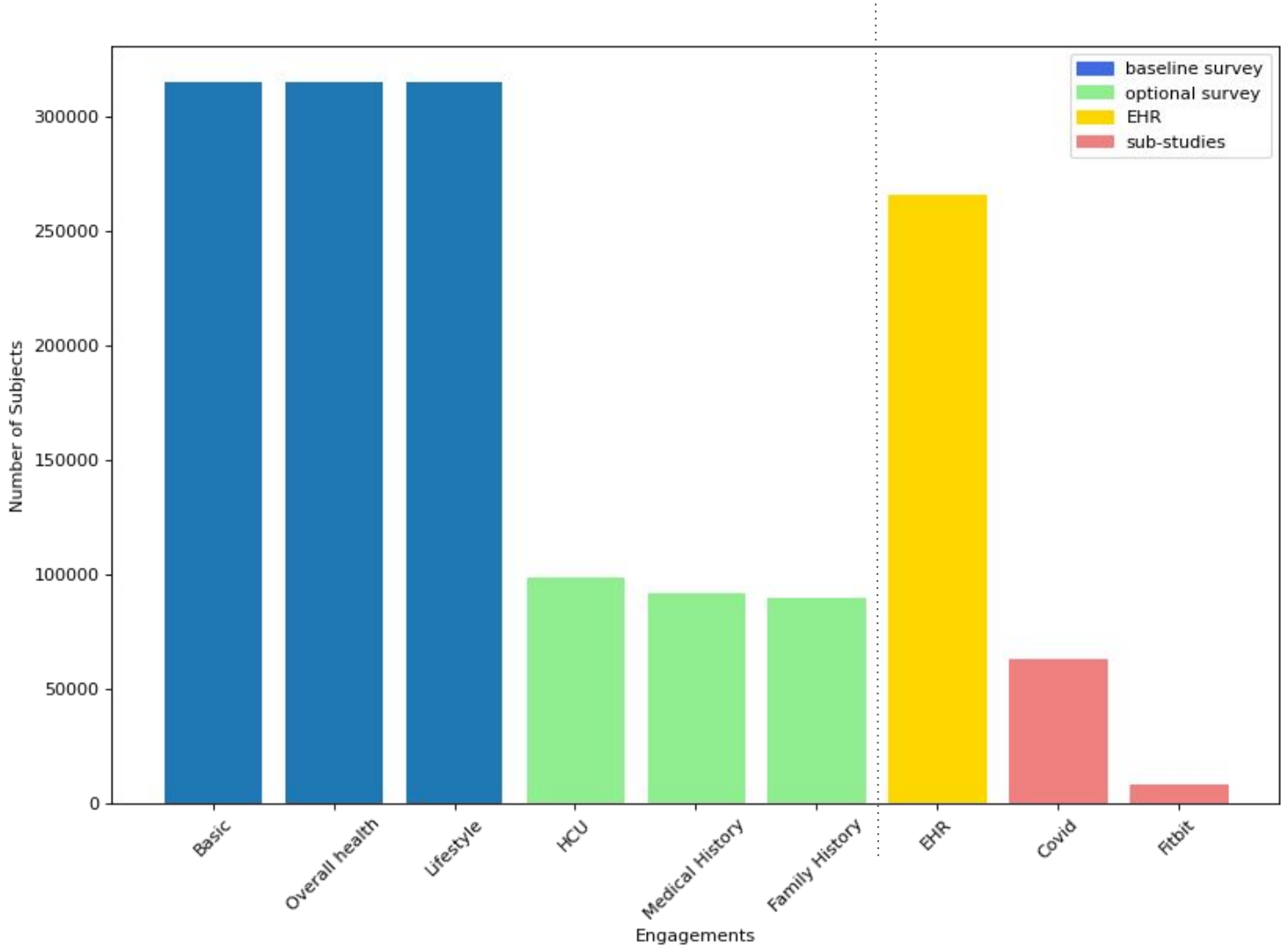
- Including lifestyle, access to care, and medical history
- Data from nearly 100,000 participants on their experiences during the COVID-19 pandemic

ResearchAllofUs.org

Data as of August 27, 2021

User Engagement Summary

Type of Engagement	Number of participants
Basic	314994
Overall Health	314994
Lifestyle	314994
Personal Medical History	89260
Health Care Utilization	98541
Family History	91695
Covid Survey	62651
EHR	265704
Fitbit	8152



Starting Cohort != Long Term

Table1: Demographics characteristics and percentage distribution of participants in each survey

	Groups (n)	Baseline Survey n %	HCA n %	Family History n %	Medical History n %	EHR n %	Covid Survey n in %	Fitbit n %
Age Group	18-44 (103192)	32.75	27.76	27.10	27.34	31.74	22.77	34.97
	45-64 (116662)	37.03	33.60	33.35	33.14	37.64	33.32	37.05
	65> (95140)	30.20	38.63	39.53	39.50	30.50	43.88	27.96
Sex	Male (119750)	38.01	33.52	33.44	33.53	38.90	33.76	28.65
	Female (191114)	60.67	65.79	65.87	65.79	59.61	65.56	70.86
	Others (4130)	1.31	0.67	0.68	0.67	1.37	0.65	0.47
Race	White (166917)	52.99	76.70	77.40	77.72	49.30	82.33	84.29
	African American (68112)	21.62	8.27	7.94	7.73	23.73	5.69	4.64
	Asian (10562)	3.35	3.42	3.38	3.42	3.16	2.89	3.12
	Others (69403)	22.03	11.59	11.26	11.12	23.69	9.05	7.92
Ethnicity	Non- Hisp (246637)	78.28	88.87	89.18	89.35	76.46	91.33	92.39
	Hisp (59283)	18.82	9.22	8.93	8.78	20.48	6.68	6.37
	Others (9074)	2.88	1.89	1.87	1.85	2.93	1.95	1.22

n% : percentage distribution of subjects in each survey

FDA Draft Guidance

Study of Sex Differences in the Clinical Evaluation of Medical Products

Guidance for Industry

DRAFT GUIDANCE

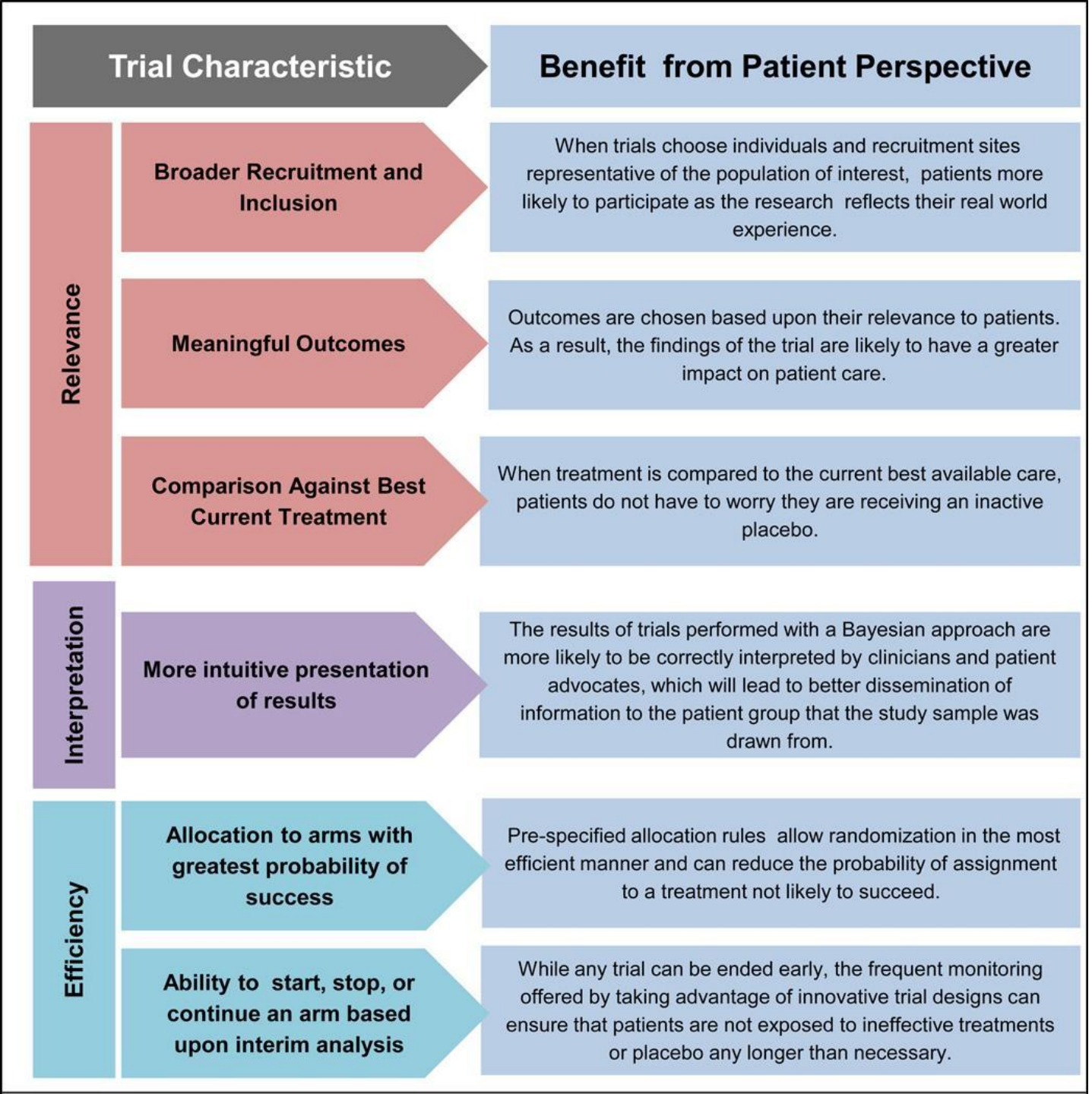
ISCTM'26 Diversity Sessoion

Discuss Agenda

Proposed Speakers

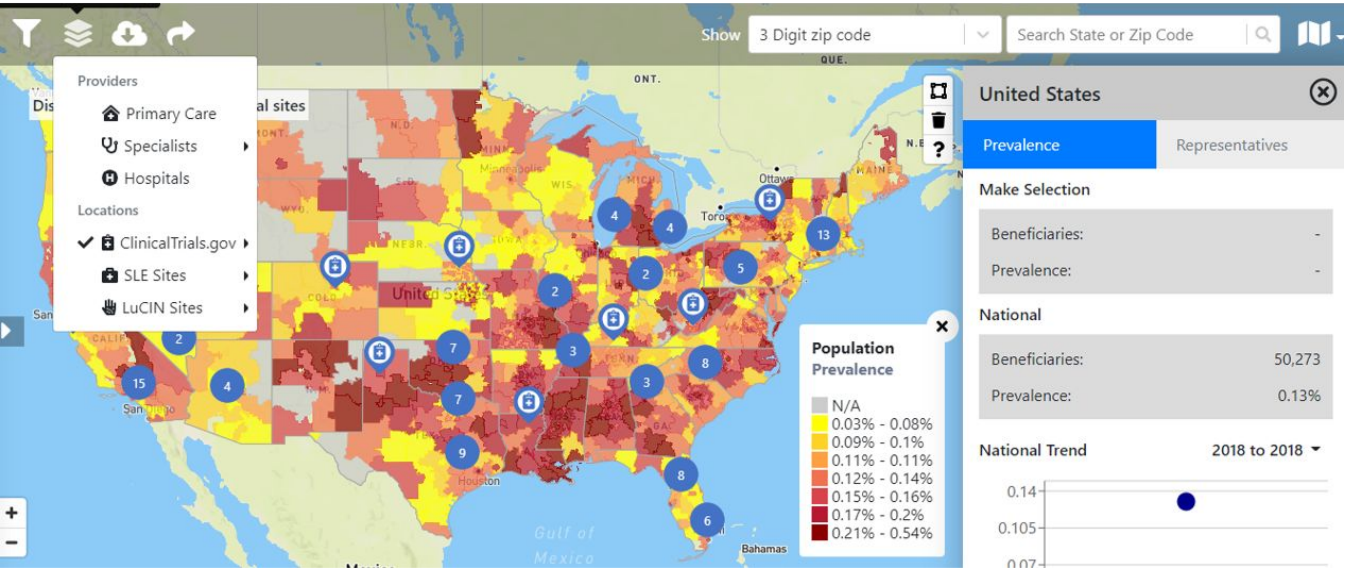
Availability of data/studies

Proposed Agenda - ISCTM'26 Session - Google Docs



Mullins CD, Vandigo J, Zheng Z, Wicks P. Patient-centeredness in the design of clinical trials. Value Health. 2014 Jun;17(4):471-5. doi: 10.1016/j.jval.2014.02.012. Epub 2014 May 5. PMID: 24969009; PMCID: PMC4497570.

Clinical Trial Index: Leveraging geographic and social determinants of health data to support clinical trial site selection



Purpose

The CTLC is designed to overcome the barriers that have historically plagued minority accrual in neurological clinical trials.

Visualizations

Users Identify treated populations by geography (zip code, county, state, metropolitan statistical areas, and state and congressional legislative districts), by demographic cohort (age, gender, race and ethnicity), and by provider (primary and specialty care, hospital, clinic and pharmacy).

Applications

Using data derived from the CT Index and advisors, an action plan was to help match clinical trial operations activities to the needs of the diverse patient populations at the community level. Initiatives may relate to site selection, clinical trial enrollment and retention.

Standardization for Health Equity Research

Circulation: Cardiovascular Quality and Outcomes
Volume 14, Issue 2. February 2021
https://doi.org/10.1161/CIRCOUTCOMES.121.007868

EDITORIAL

The Groundwater of Racial and Ethnic Disparities Research

A Statement From *Circulation: Cardiovascular Quality and Outcomes*

Khadijah Breathett, MD, MS, Erica S. Spatz, MD, MHS, Daniel B. Kramer, MD, MPH, Utibe R. Essien, MD, MPH, Rishi K. Wadhera, MD, MPP, MPhil, Pamela N. Peterson, MD, MSPH, P. Michael Ho, MD, PhD, and Brahmajee K. Nallamothu, MD, MPH

AHAjournals.org/health-equity

Circulation

EDITORIAL

Creation of the American Heart Association Journals' Equity, Diversity, and Inclusion Editorial Board: The Next Step to Achieving the 2024 Impact Goal

Eldrin F. Lewis, MD, MPH; Christine Beaty; Johannes Boltze, MD, PhD; Khadijah Breathett, MD, MS; Walter K. Clair, MD, MPH; Lisa de las Fuentes, MD, MS; Utibe R. Essien, MD, MPH; Heather Goodell; H.E. Hinson, MD, MCR; Kiarri N. Kershaw, PhD, MPH; Joshua W. Knowles, MD, PhD; Sula Mazimba, MD, MPH; Mahasin Mujahid, PhD, MS; Henry E. Okafor, MD; Kyung Woo Park, MD, PhD, MBA; Jonathan Schultz

ELEVATING the focus on:

- **Disparities**
- **Anti-racism**
- **Health equity**
- **Community-engaged/community-based participatory research**
- **Implementation science**

COLLECTIONS include:

- **Disparities and health equity**
- **Race, ethnicity, and health**
- **Social determinants of health**
- **Women's health, sex, and gender**

Perspective

New Federal Incentives for Diversity in Clinical Trials

Thomas J. Hwang, M.D., and Otis W. Brawley, M.D.

In June 2022, the U.S. House of Representatives passed legislation intended to increase the diversity of the populations enrolled in clinical trials of new drugs. Under this bill, study sponsors would be required to submit a diversity action plan — including goals for study enrollment according to demographic group and steps for achieving those goals — for phase 3 or pivotal studies of new drugs. These diversity provisions, considered as part of a broader reauthorization of user-fee funding of the Food and Drug Administration (FDA), would codify recent FDA draft guidance recommending that clinical trial sponsors develop and submit diversity plans for enrolling participants from historically underrepresented racial and ethnic populations.[1]

Thank you!