

Scientific Equity: Navigating the challenges of including diverse participants in pragmatic trials

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**NIH PRAGMATIC TRIALS
COLLABORATORY**

Rethinking Clinical Trials®

Objectives

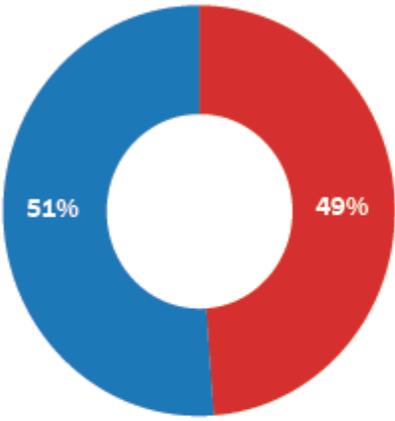
- Introduce the importance of diverse participation in pragmatic clinical trials from an equity perspective
- Discuss barriers and solutions to engaging diverse participants in pragmatic clinical trials from the patient, community, system, and federal perspectives
- Develop a comprehensive roadmap for translation to participants' context

ePCTs are motivated by ethical imperatives to help the population with urgent health needs



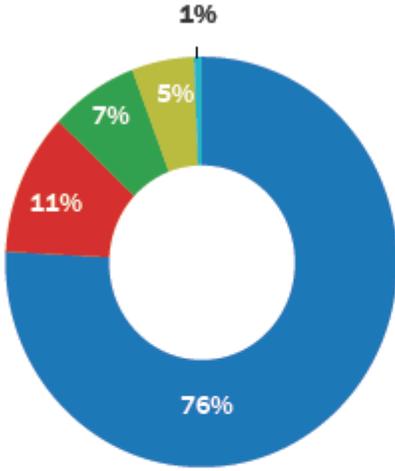
Clinical Trial Participation 2015-2019

Sex Distribution



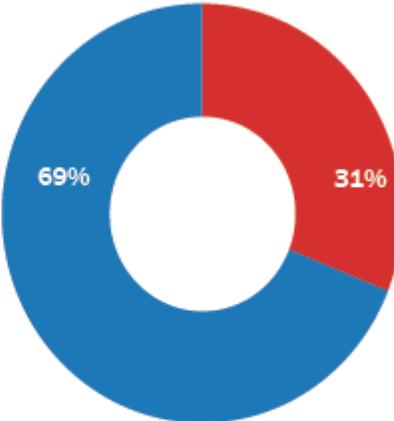
Female ■
Male ■

Race Distribution



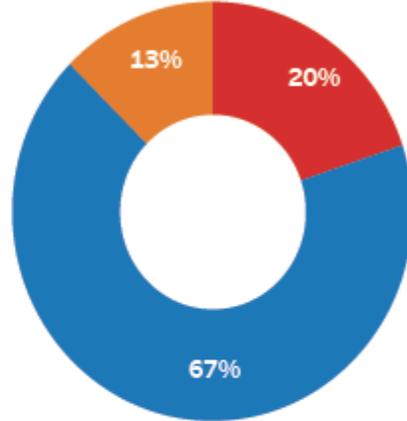
White ■
Asian ■
Black or African American ■
Other ■
American Indian or Alaska Native ■

Age Distribution



< 65 Years ■
>= 65 Years ■

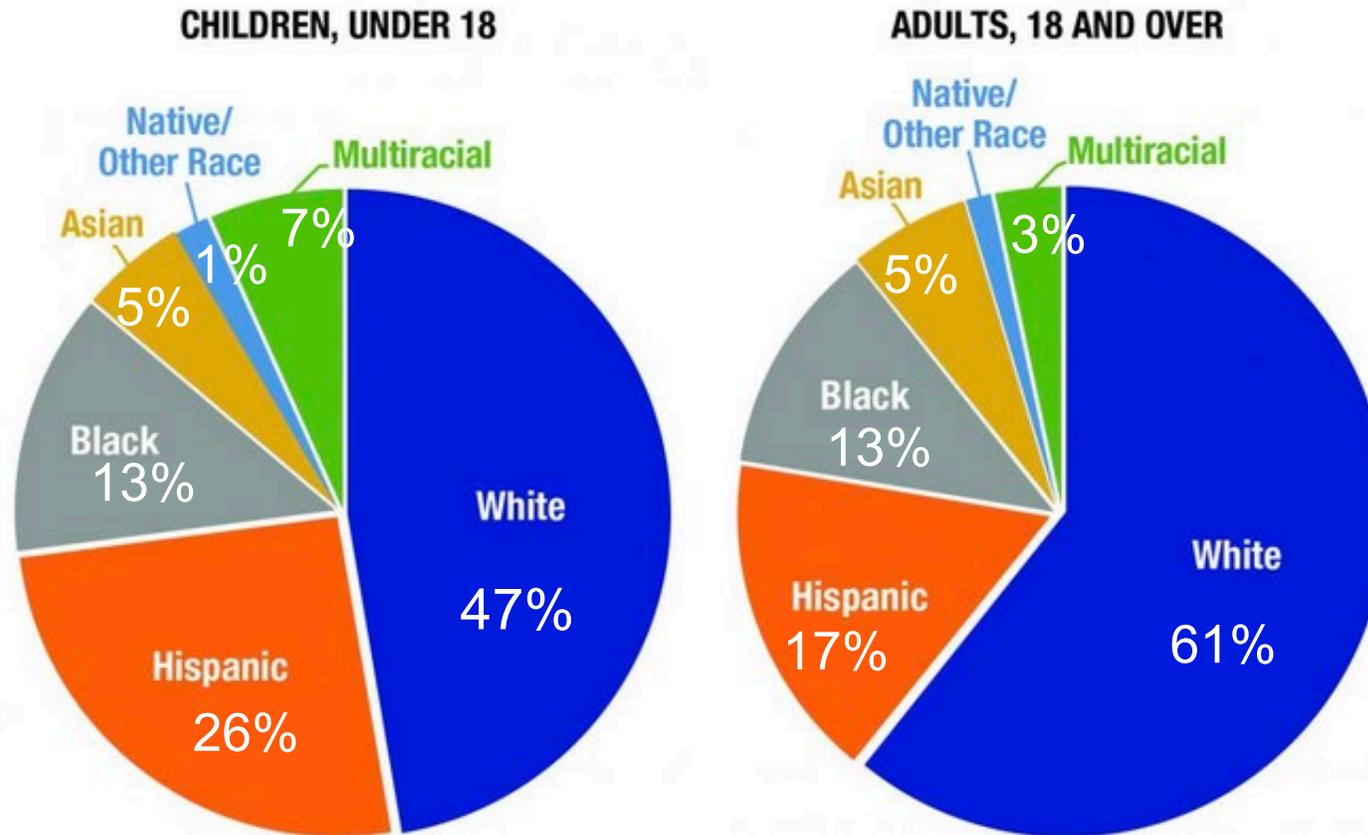
Ethnicity Distribution



Hispanic or Latino ■
Not Hispanic or Latino ■
Missing ■

(FDA, 2020; <https://www.fda.gov/media/143592/download>)

US Census 2020



<https://carsey.unh.edu/publication/new-census-reflects-growing-US-population-diversity>
<https://www.census.gov/quickfacts/fact/table/US/AGE295220>

Representation within the context of disease burden

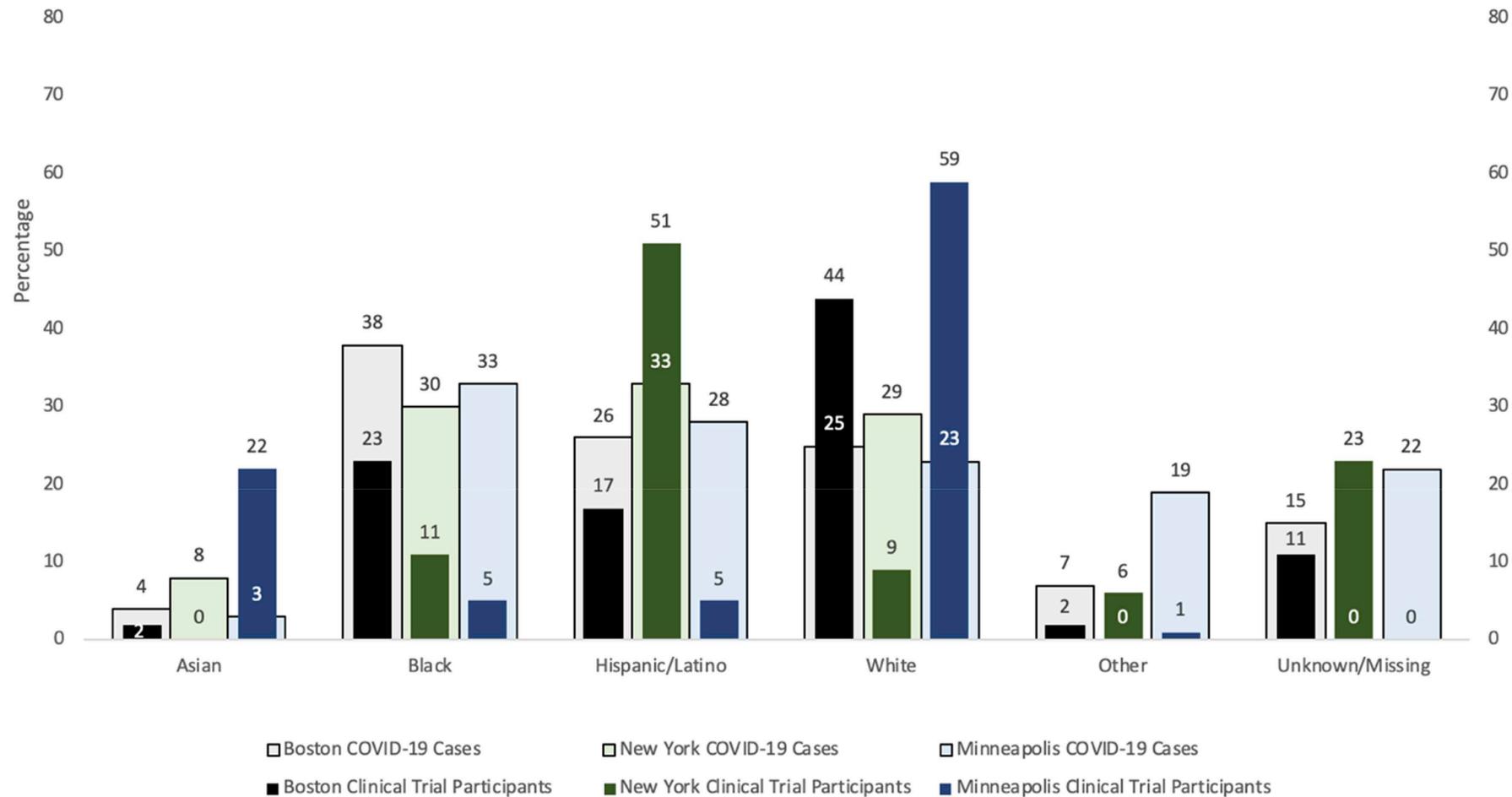


Fig. 1. City burden of COVID-19 cases and clinical trial participant demographics.

(Borno et al., 2020; <https://doi.org/10.1016/j.conctc.2020.100630>)

Scientific Equity

Equality



The assumption is that **everyone benefits from the same supports**. This is equal treatment.

Equity



Everyone gets the supports they need (this is the concept of "affirmative action"), thus producing equity.

Justice



All 3 can see the game without supports or accommodations because **the cause(s) of the inequity was addressed**. The systemic barrier has been removed.

https://www.ynpntwincities.org/your_equity_statement_is_not_enough

ePCT Ecosystem is interconnected



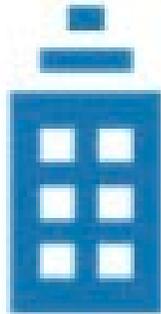
Patients



Clinics



Providers



Hospitals

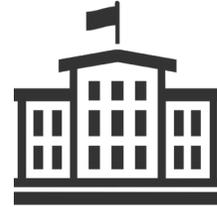
ePCT Ecosystem



Patients live in communities



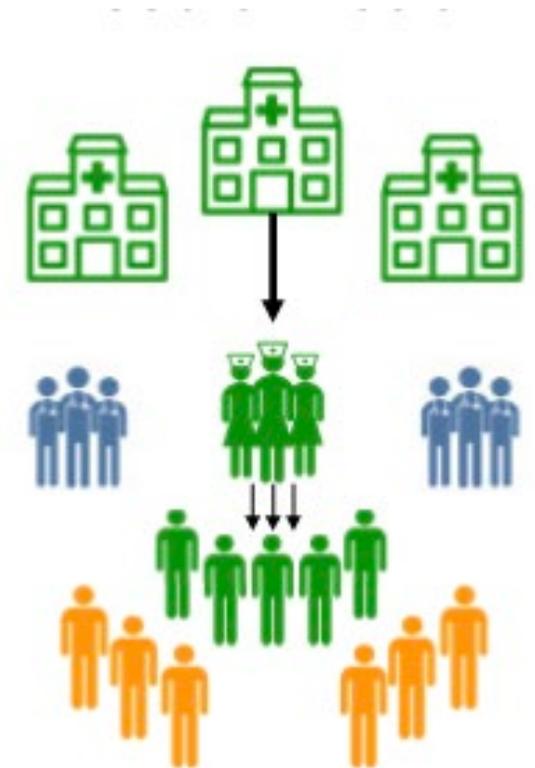
Providers are trained in schools



Clinics and hospitals are part of systems



Federal Policy and Regulations Apply





Achieving Scientific equity is a big challenge

Lack of Representation

- Compromises generalizability of clinical research findings to the whole US population.
- Costs hundreds of billions of dollars.
- May hinder innovation and new discoveries.
- May compound low accrual that causes many trials to fail.
- May lead to lack of access to effective medical interventions.
- May undermine trust of the clinical research enterprise and the medical establishment.
- Compounds health disparities in the populations currently underrepresented and excluded in clinical trials and clinical research.

IMPROVING REPRESENTATION IN CLINICAL TRIALS AND RESEARCH

Building Research Equity for Women and Underrepresented Group

Kirsten Bibbins-Domingo and Alex Helman, Editors



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