


## The FDA Office of Minority Health and Health Equity

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**Acting Associate Commissioner for Minority Health**  
FDA Office of Minority Health and Health Equity

[www.fda.gov/healthequity](http://www.fda.gov/healthequity)



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- This presentation represents the personal opinions of the speaker and does not necessarily represent the views or policies of FDA
  - No conflicts of interest to declare
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# FDA Office of Minority Health and Health Equity (OMHHE)

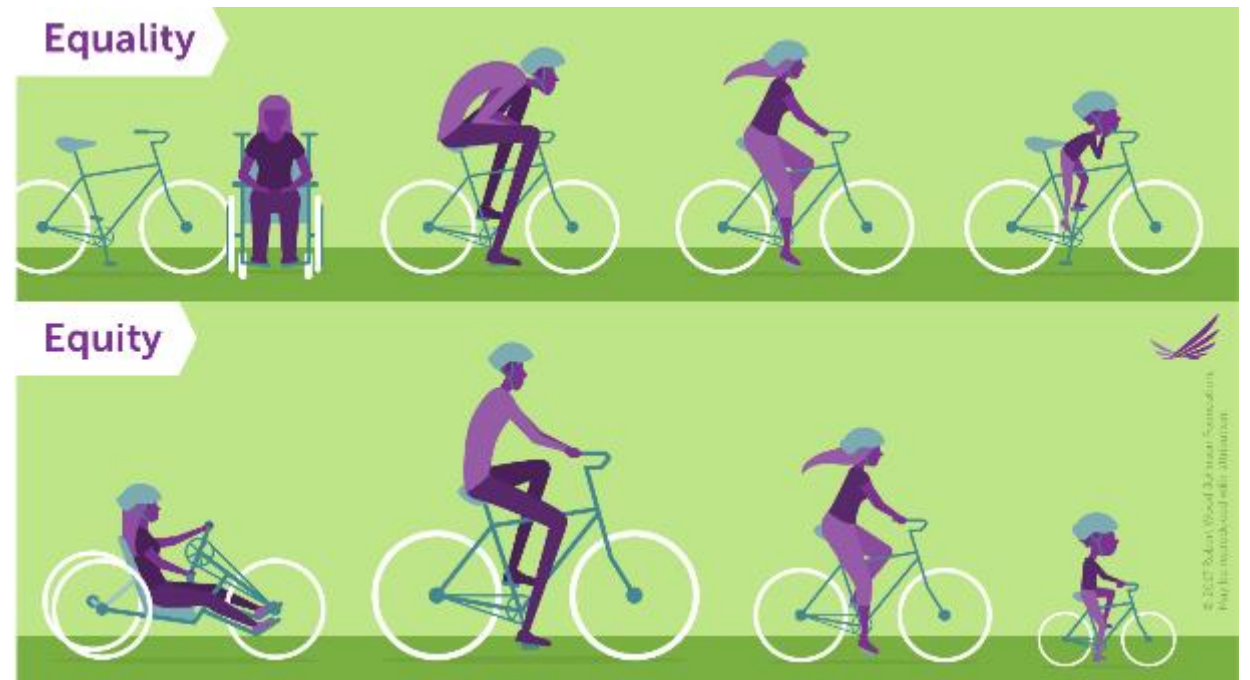


## Mission

To promote and protect the health of diverse populations through research and communication that addresses health disparities.

## Vision

To create a world where health equity is a reality for all.



# What We Do



## Research and Collaboration

- Intramural Research
- Extramural Research
- FDA Centers of Excellence in Regulatory Science and Innovation (CERSI) Projects
- Broad Agency Announcement (BAA)
- Other research opportunities
- Internships and Fellowships
- Academic Collaborations
- Stakeholder Input into Research Agenda



## Outreach and Communication

- Culturally and Linguistically Tailored Programs/Initiatives/Campaigns
  - Diversity in Clinical Trials Initiative
  - Language Access Program
- Health Education Materials
- Social Media
- Newsletter & E-alerts
- Website
- Health Equity Lecture Series & Webinars
- Stakeholder Meetings/Symposiums/Exhibits
- Collaborations and Partnerships

# Equity in ACTION

Sept 2021:  
**OMHHE Enhance Equity Initiative**



March 2023:  
**OMHHE Enhance Equity Research Hub**



June 2023:  
**OMHHE Racial and Ethnic  
Minority Acceleration Consortium  
for Health Equity (REACH)**





# OMHHE Enhance Equity Initiative

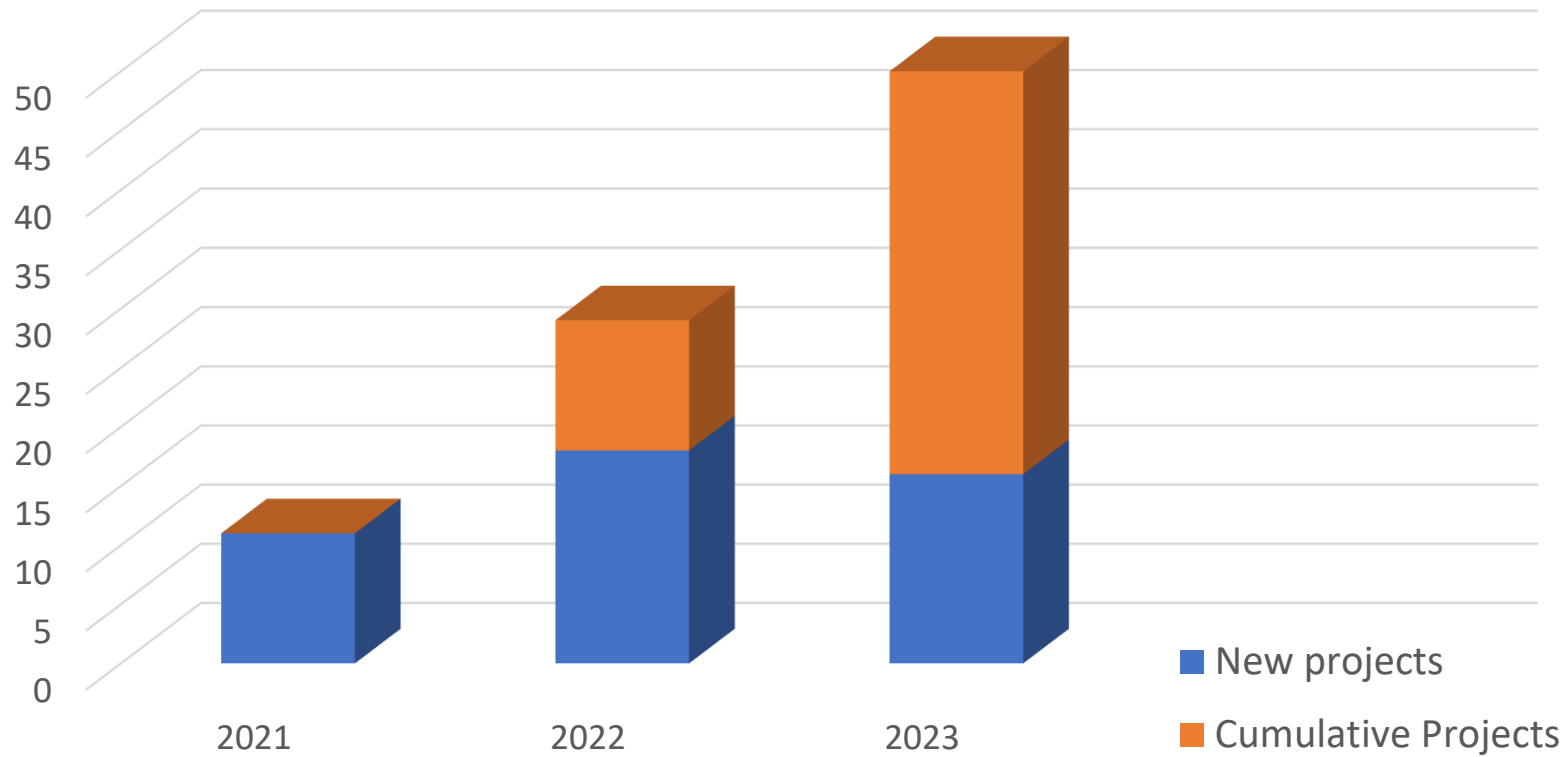


The FDA Office of Minority Health and Health Equity Enhance Equity Initiative highlights research projects and communication resources to enhance:

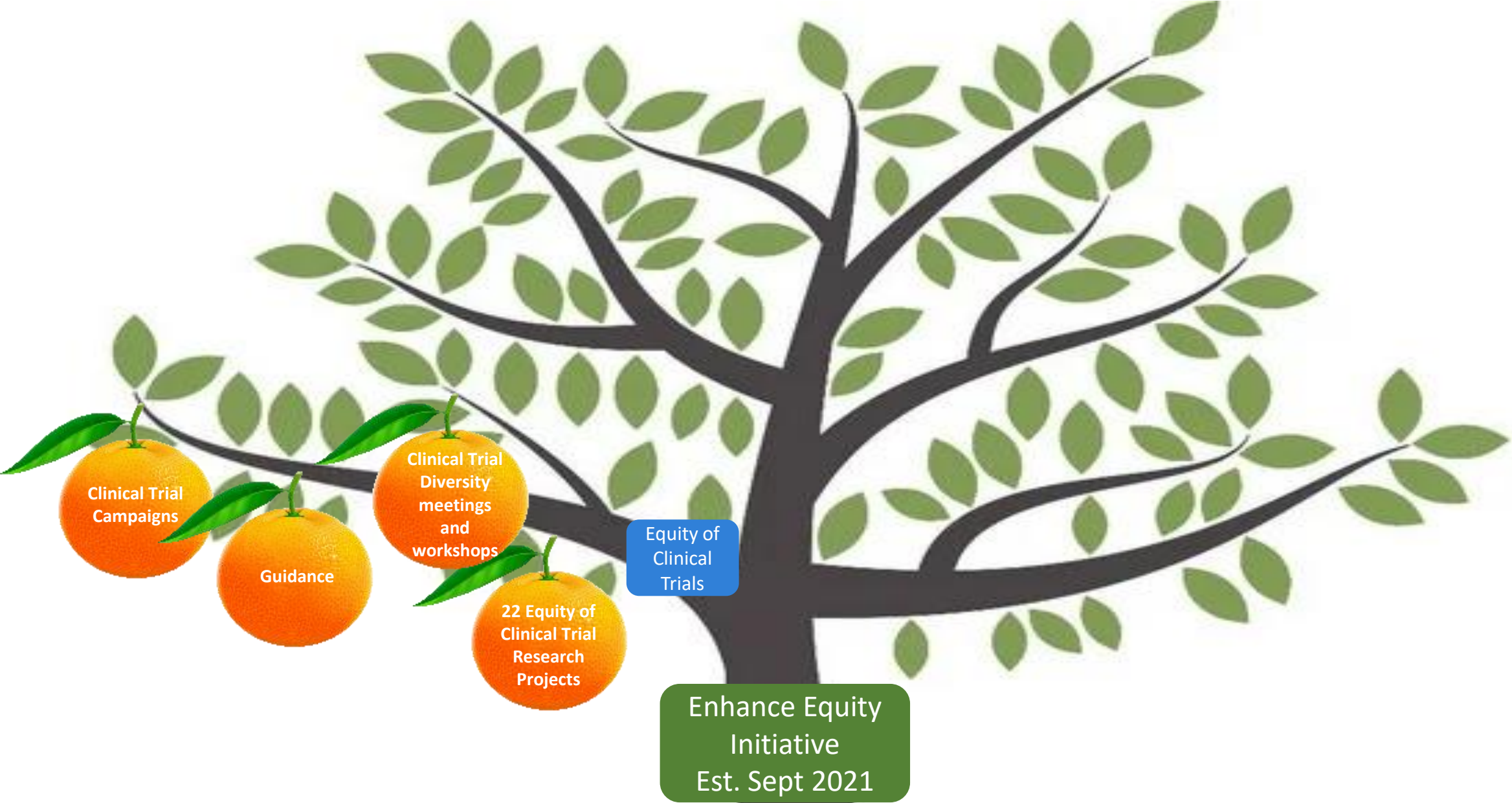
- [EQUITY in clinical trials](#) by supporting efforts to advance diversity in clinical trials
- [EQUITABLE data efforts](#) by increasing data available on diverse groups including, but not limited to, ethnicity, race, age, disability and geography
- [EQUITY of voices](#) by amplifying FDA’s communication with diverse groups to ensure stakeholders, including consumers, are informed about FDA’s efforts, and to understand diverse patient perspectives, preferences and unmet needs.



# Growth of OMHHE Enhance Equity Initiative



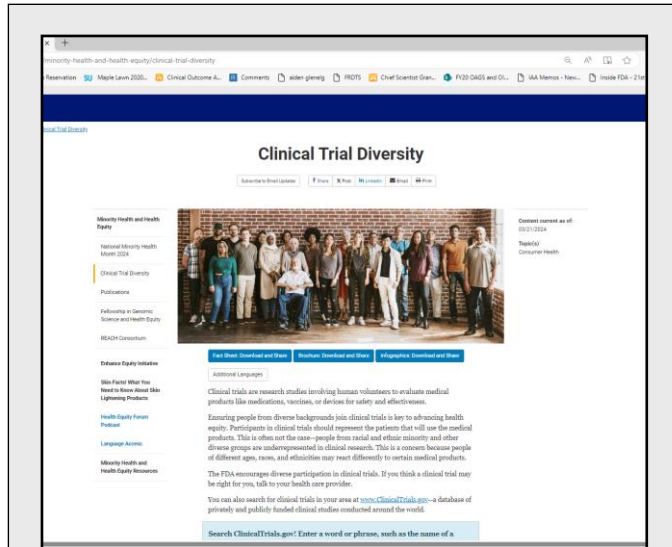
# Growth of OMHHE Enhance Equity Initiative





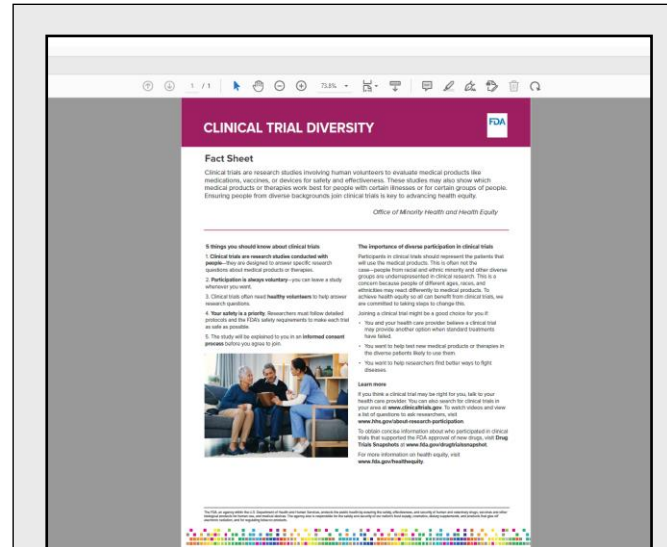
# Clinical Trial Campaigns

Available in 12 languages  
7/13/22 - 2/8/24 | 41,511 total page views



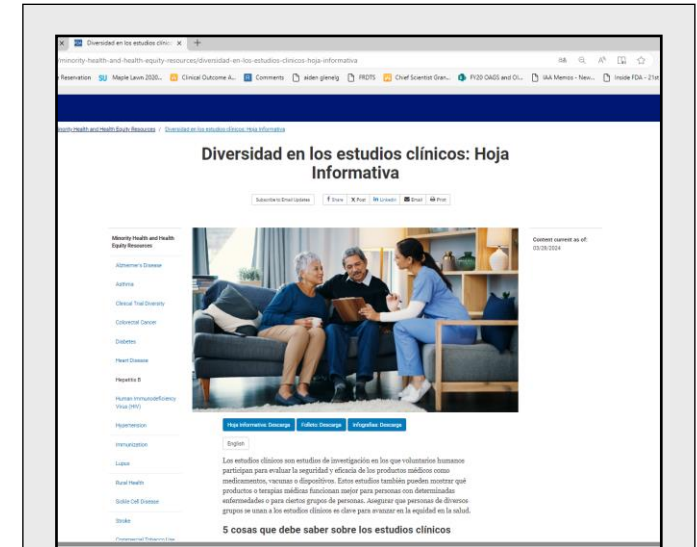
33,321 page views

[Clinical Trial Diversity Webpage](#)



8,182 page views

[Fact Sheet page](#)



48 page views

[Fact Sheet page - Spanish](#)

# FDA Guidance

## Collection of Race and Ethnicity Data in Clinical Trials

- The purpose of the Guidance on the Collection of Race and Ethnicity Data in Clinical Trial and Clinical Studies is to provide recommendations on a standardized approach for collecting and reporting race and ethnicity data in submissions for clinical trials for FDA regulated medical products.
- Using standard terminology for race and ethnicity helps ensure that data is collected consistently and supports demographic data analysis including evaluation potential difference in safety and effectiveness of medical products.



Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products

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 90 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 (CDER) [CDEROMP@fda.hhs.gov](mailto:CDEROMP@fda.hhs.gov), 301-796-2500; (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010; or (OMHHE) Office of Minority Health and Health Equity, [healthequity@fda.hhs.gov](mailto:healthequity@fda.hhs.gov).

U.S. Department of Health and Human Services  
Food and Drug Administration  
Office of the Commissioner (OC)  
Office of Minority Health and Health Equity (OMHHE)  
Office of Women's Health (OWH)  
Office of Clinical Policy (OCLiP)  
Office of Pediatric Therapeutics (OPT)  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)  
Center for Devices and Radiologic Health (CDRH)  
Oncology Center of Excellence (OCE)

January 2024  
Clinical/Medical  
Revision 1



# National Minority Health Month 2024



FDA Office of Minority Health and Health Equity Presents

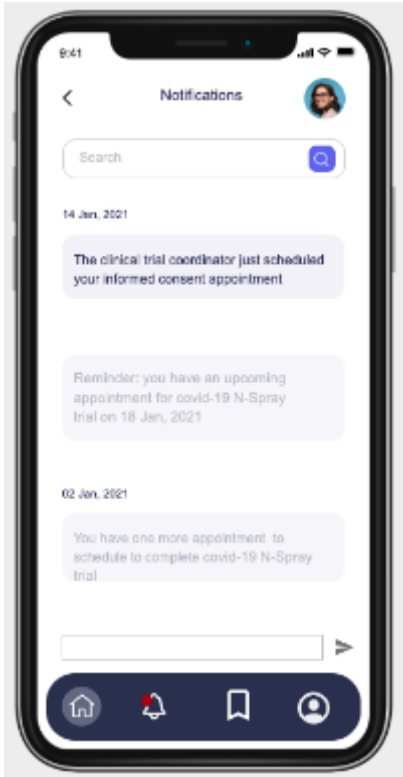
**Strategies to Increase Clinical Trial Participation for Diverse Communities**  
A Panel Discussion

April 17, 2024 | 11 am ET | Virtual

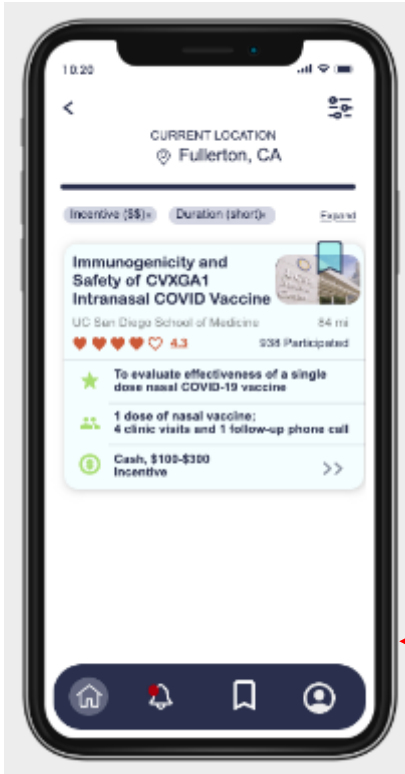




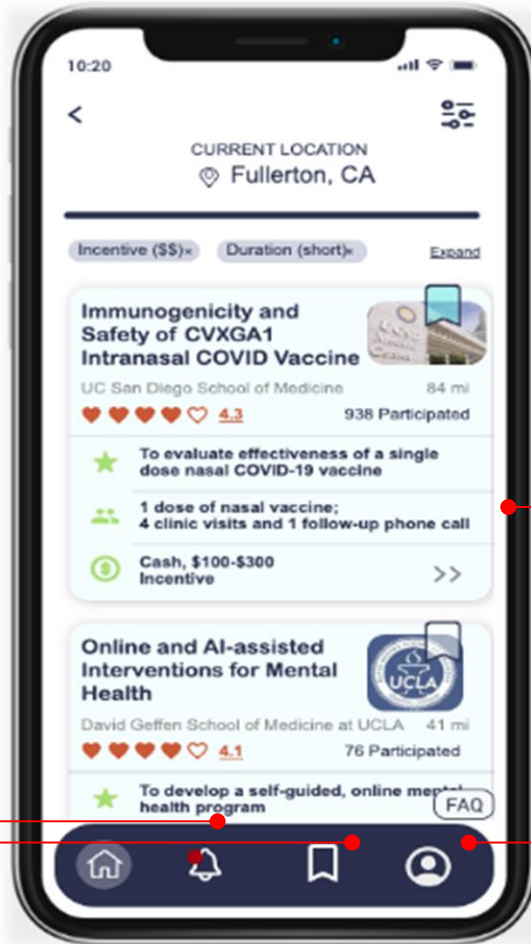
# Co-creation of digital tools to enhance young adult minority participation in COVID-19 trials -California State University, Fullerton



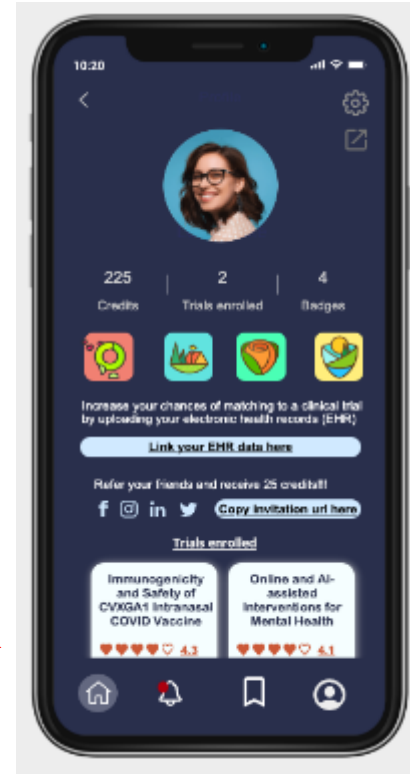
Notification page



"Saved" page



Search results page



Profile page



Trial detail page



# OMHHE Intramural Grant: Race & Ethnicity in Pediatric Trials Submitted under BPCA & PREA

Investigators: Ann W McMahon, Clement Acheampong, GT Wharton, James Travis, Carla Epps, Dionna Green, Prabha Viswanathan, Lily Mulugeta, Carrie Bryant

## **Purpose:**

This study aims to test the hypothesis that children from racial and/or ethnic minority populations are underrepresented in pediatric clinical trials.

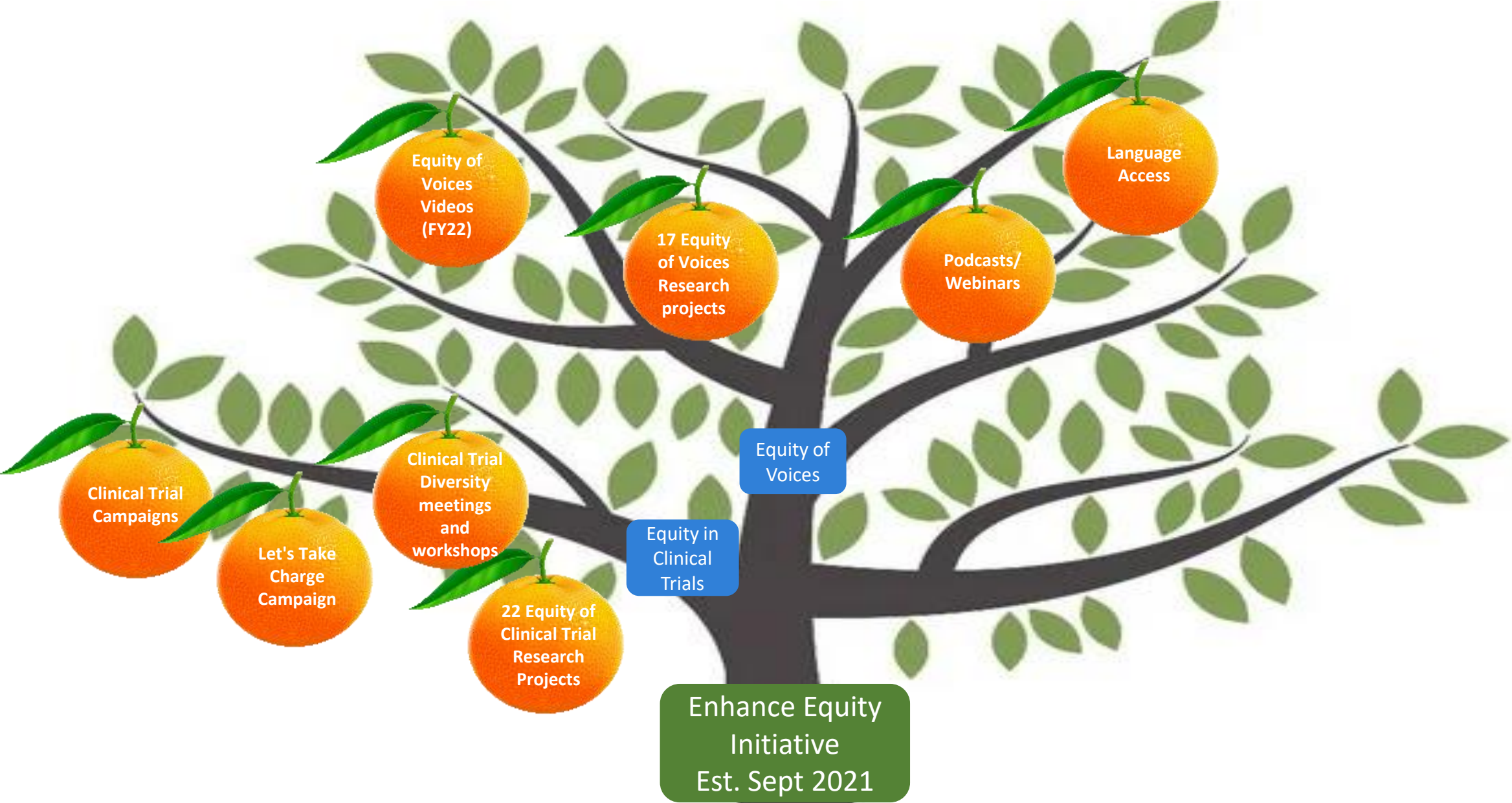
## **Objective:**

To test whether observed pediatric racial and ethnic minority populations enrollments are significantly different from predictions based on overall racial and ethnic populations estimates.





# Growth of OMHHE Enhance Equity Initiative



# Equity of Voices

## Health Equity Forum Podcast

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The FDA Office of Minority Health and Health Equity Forum podcast series is a platform for experts to come together and have meaningful conversations around health topics that impact the lives and well-being of diverse communities. The series will also help to raise awareness about health issues and disparities impacting the health of diverse populations including minority consumers/patients and spark conversations of your own.



## Language Access

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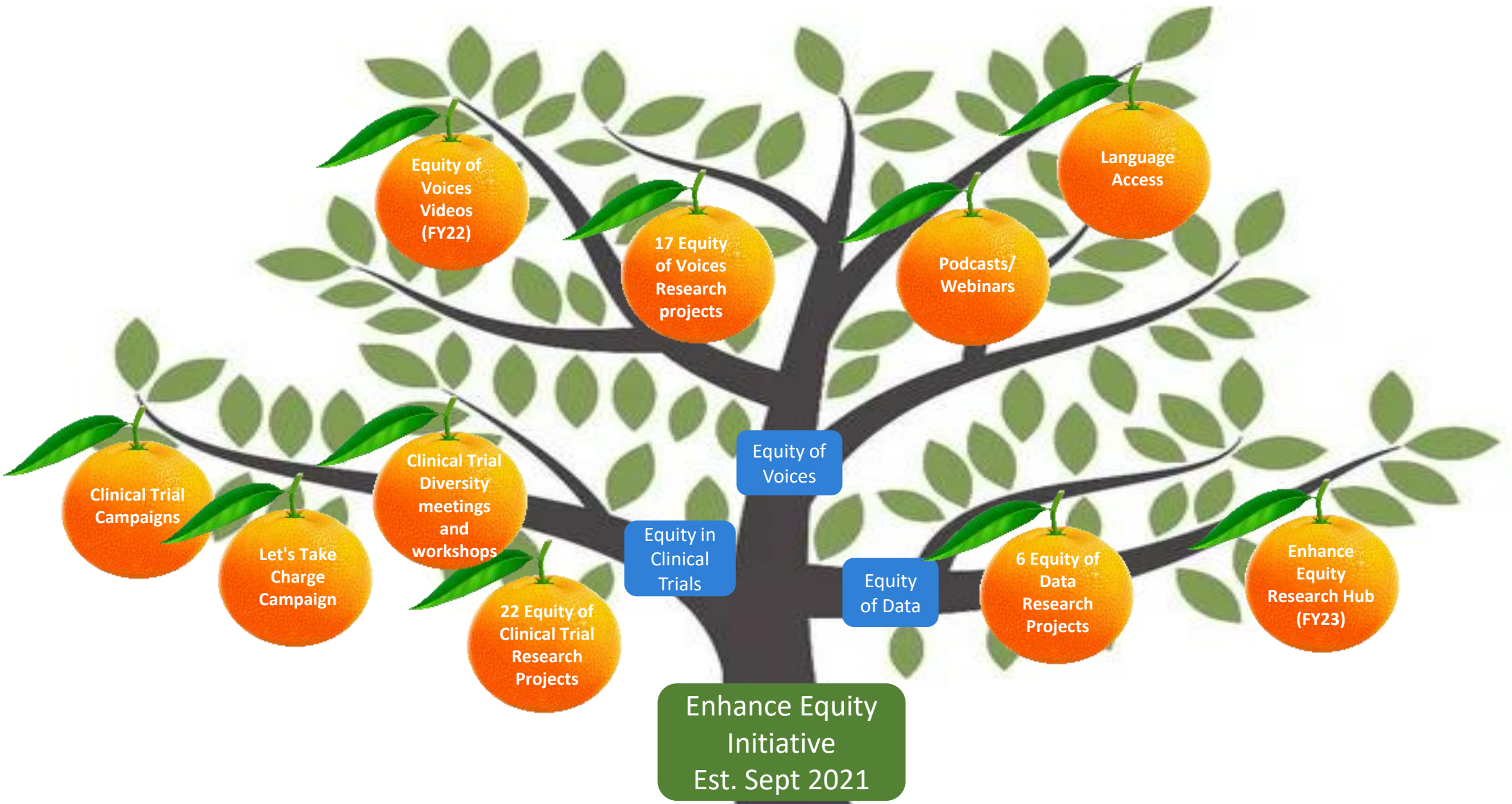
Print



- FDA Language Access Plan 2024
- 中文
- 한국어
- Tagalog
- Tiếng Việt
- Français
- عربي



# Growth of OMHHE Enhance Equity Initiative



# Equity of Data:



## Challenges Specific to Racial and Ethnic Minority Population – Real World Data

- Lack of attention and awareness to challenges of racial and ethnic minority data in real world data
- Lack of additional potential covariate and demographic variables that could contribute to confounding outcomes
- Lack of attention to barriers that prevent reporting from racial and ethnic and other underserved populations
- Address Missingness
- Oftentimes, prevalence estimate of the disease population is unavailable by race, ethnicity, age, and/or geography to determine if clinical trial population is representative of the disease population



# OMHHE Equitable Data Efforts

## Exploring Additional Data Sources

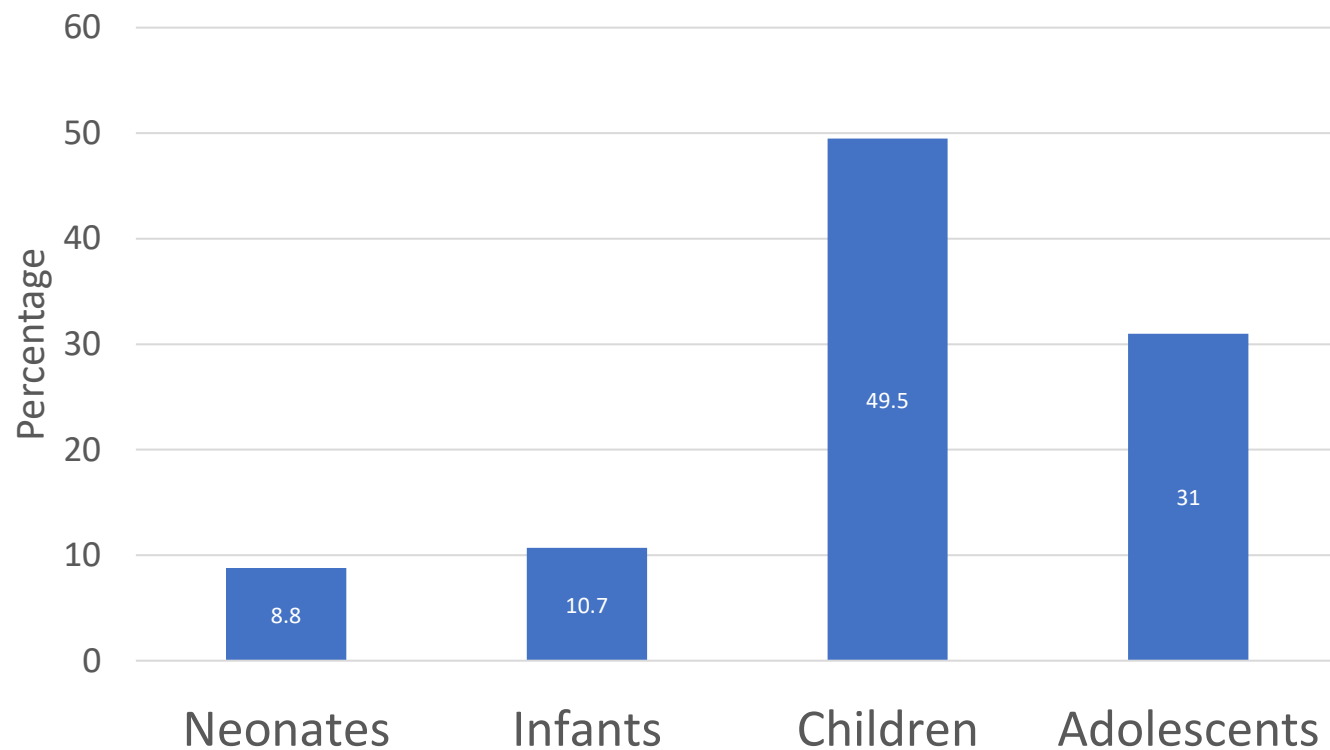
- **American Family Cohort** database (PI: Dr. David Rehkopf, Stanford University)
- **Some Highlights of the American Family Cohort database**
  - Largest set of Electronic Health Records (EHR) data that we are aware of on primary care in the U.S.
    - Primary care – where most individuals first see a provider for health problems, and where many chronic conditions are managed
  - Good representation
    - Includes all 50 states and proportional to state population
    - Includes rural population
  - Racially and ethnically diverse
    - Disaggregation of data possible via free text collection method
  - **Includes pediatric population (ages <18 years)**
    - Allowing for analyses across the life course, and across generations in diverse groups





# American Family Cohort – Pediatric Data

## By Age

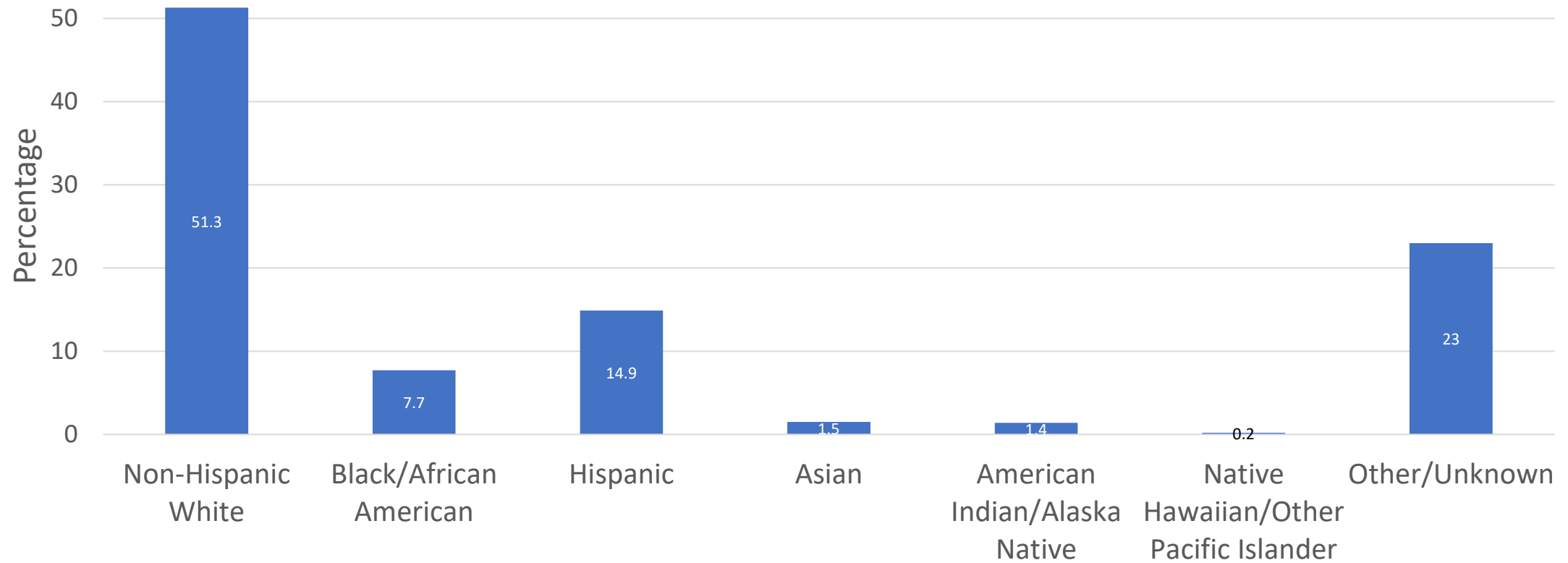


Age Group	Definition
Neonates	Within 28 days
Infants	29 days to less than 2 years
Children	2 years to less than 12 years
Adolescents	12 years to less than 17 years



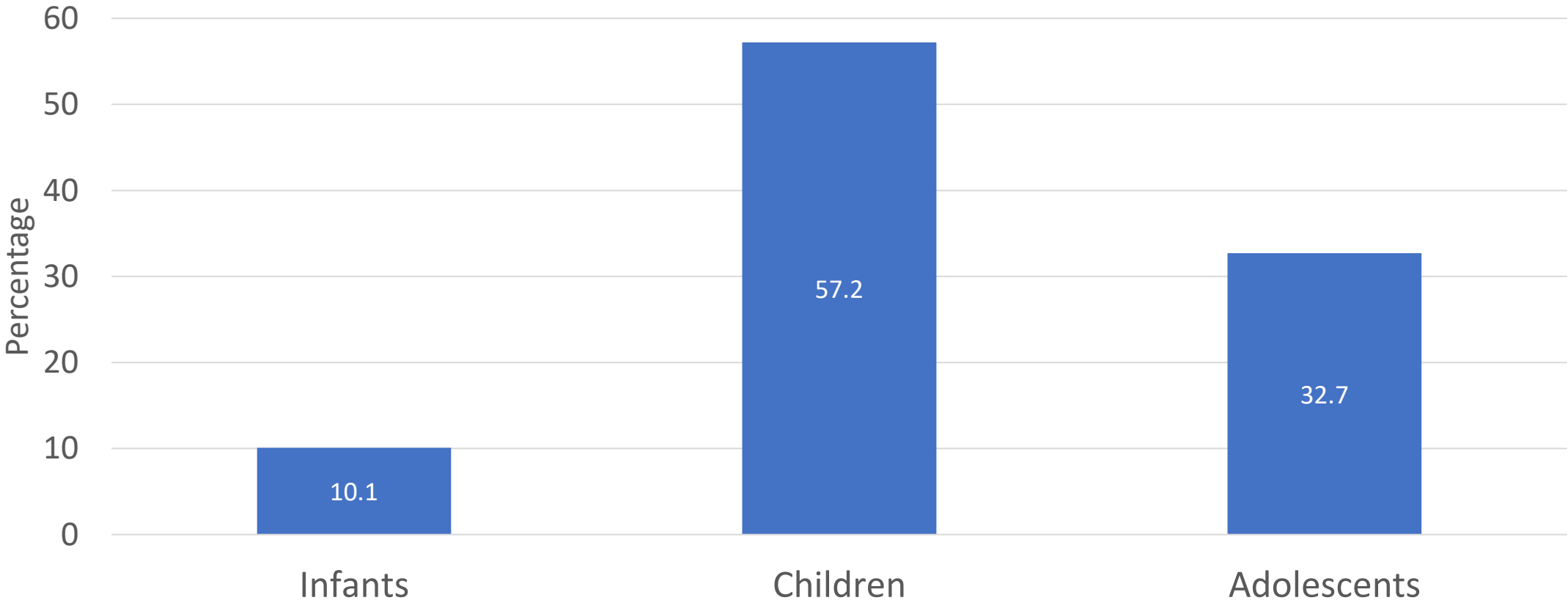
# American Family Cohort – Pediatric Data

## By Race and Ethnicity



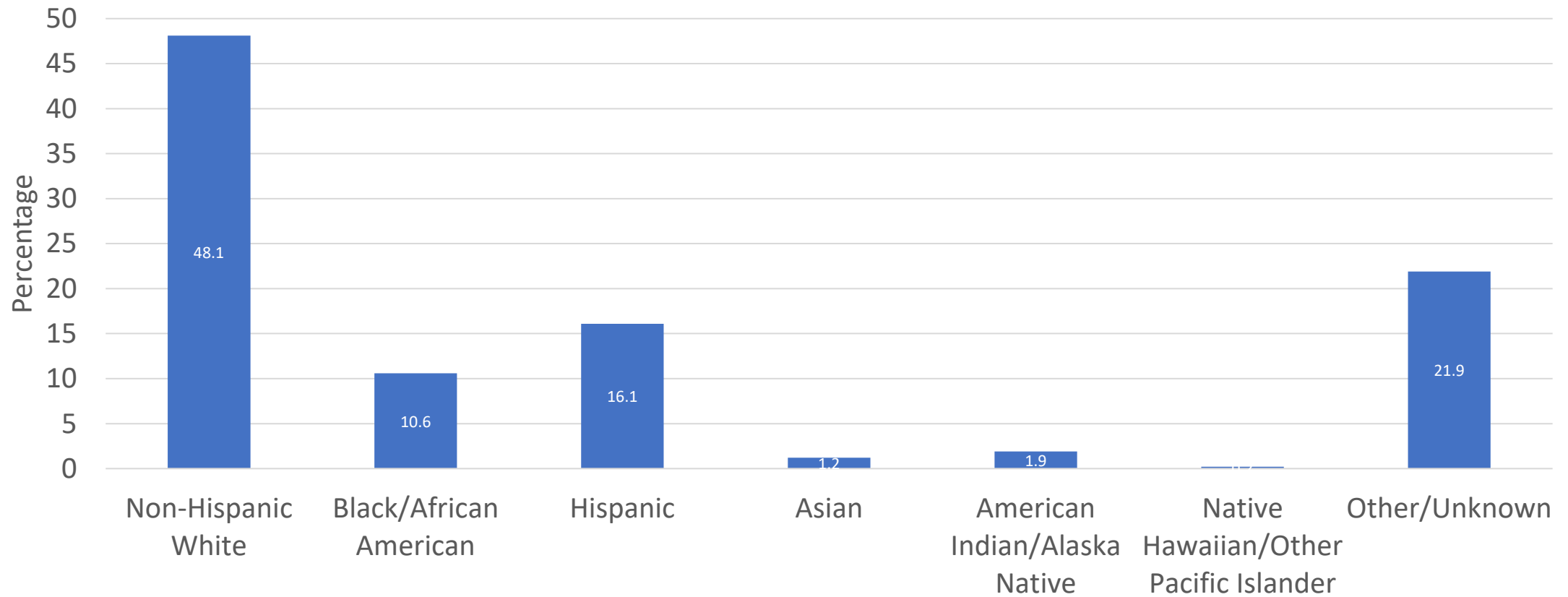
# Pediatric Asthma

## By Age




# Pediatric Asthma

## By Race and Ethnicity



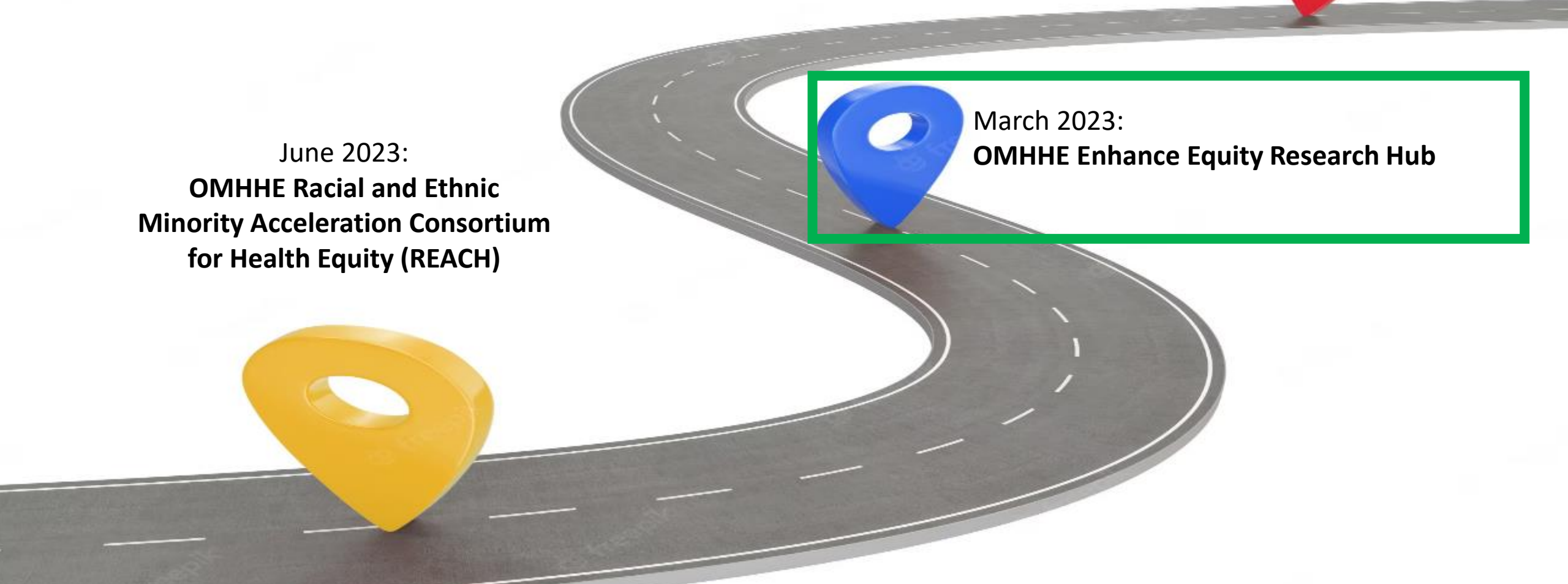
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# Enhance Equity Research Hub

## OMHHE Enhance Equity Research Hub

Overview of OMHHE funded research

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### Background

The FDA Office of Minority Health and Health Equity (OMHHE) [Enhance Equity](#) Research Hub provides information about OMHHE-funded research projects that are a vital part of achieving the OMHHE mission to promote and protect the health of diverse populations through research and communication of science that addresses health disparities.

### Citation

Please use the following to cite our webpage:

Full Citation: FDA Office of Minority Health and Health Equity, (2023). OMHHE Enhance Equity Research Hub | FDA. <https://www.fda.gov/science-research/minority-health-and-health-equity-research-and-collaboration/omhhe-enhance-equity-research-hub>

In-Text Citation: (Office of Minority Health and Health Equity Enhance Equity Research Hub, 2023)

[Background Search](#) | [Citation](#)

### Contact Us

FDA/OMHHE  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

[Email Us](#)

## OMHHE Enhance Equity Research Hub

Race

Ethnicity

Enhance Equity Aim

Disease/Condition of Interest

Age

Clear Filters

[OMHHE Enhance Equity Research Hub | FDA](#)

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# Still a MISSING Piece in Health Equity Action



Responsiveness





# Without the Core Concepts of REACH we cannot be RESPONSIVE



# Racial and Ethnic Minority Acceleration Consortium for Health Equity (REACH)



## REACH Consortium



In 2023, OMHHE established the Racial and Ethnic Minority Acceleration Consortium for Health Equity (REACH). REACH is a research consortium of organizations and institutions that aims to **timely and efficiently** help respond to health equity needs.



# REACH Consortium



FQHCs

Network:

- North Carolina Community Health Center Association
- FQHCs: Charlotte Community Health Clinic
- FQHCs: Rural Health group
- FQHCs: Med North Health Center



Puerto Rico

Network:

- University of Puerto Rico: Medical Science campus
- University of Puerto Rico: Carolina campus
- Universidad Central del Caribe
- Neo Medical Center



Hawaii

Network:

- The Queen's Health Systems (QHS)
- The Queen's Medical Center (QMC)
- The Queen's Medical Center – West O'ahu
- North Hawaii Community Hospital



Tribal Communities

Network:

- The United Tribes Technical College (UTTC), an accredited, land-grant tribal college located in Bismarck, North Dakota, that serves the five reservations in ND and tribal members across the U.S. UTTC has provided higher education support to over 10,000 AI students from over 75 tribes.



Community Centers

Network:

- Community Partnership: Compass LGBTQ Community Center, West Palm Beach, FL; Guatemalan Maya Center, West Palm Beach, FL; Social Science Research Institute (SSRI) at the University of Hawai'i at Mānoa
- (Virtual: Hawai'i), Center for Asian Health (CAH) at Temple University, Howard Brown Health (HBH)



HBCU's and Faith-Based

Network:

- UMD PATIENTS Program
- Pastor of Mt. Lebanon Baptist Church
- HBCU: Coppin State University Helene Fuld College of Nursing and College of Health Professions
- HBCU: Xavier University of Louisiana College of Pharmacy

REACH consortium serves diverse communities, including but not limited to the following populations:

- Black or African American
- Hispanic or Latino
- Asian
- Native Hawaiian or Other Pacific Islander
- American Indian or Alaska Native
- Sexual and Gender minorities
- Rural




# REACH- Investigators




**Becca Hayes, MD, MEHP**  
 Director of Health Equity Research, North Carolina Community Health Center Association

**FQHCs-REACH**



**Perla Nunes**  
 DEIA and Clinical Trial Research Expert




**Billie Jo Kipp, PhD**  
 Associate Director Center For Native American Youth




**Myra Parker, JD, MPH, PhD**  
 Director of Seven Directions

**Tribal-REACH**




**Stephine Poston, MA**  
 President & CEO — Poston & Associates, LLC



**Todd Seto, MD**  
 Director of Academic Affairs and Research, The Queen's Medical Center

**Hawaii-REACH**



**Deb Taira, ScD**  
 Professor, Department of Pharmacy Practice, University of Hawaii at Hilo



**Eugenia Millender, PhD RN**  
 Co-Founder & Co-Director, Center of Population Sciences for Health Equity



**Casey Hall MPH, PhD**  
 Assistant Director, Center of Population Sciences for Health Equity

**Community Centers -REACH**



**Frank Wong, PhD**  
 McKenzie Endowed Professor of Health Equity Research



**Darlene Quiñones, PhD, MSc**  
 Associated Professor School of Pharmacy University of Puerto Rico

**Puerto Rico-REACH**



**Karen Gonzalez, MD, MSc**  
 Associate Professor, Department of Psychiatry, University of Puerto Rico



**Claudia Baquet, MD, MPH, PhD**  
 UMD Professor



**Kathleen Kennedy, PharmD**  
 Dean Xavier College of Pharmacy



**Joan Tilghman PhD, RN**  
 Professor and Dean at Coppin State University



**Jasmine Cooper-Williams, PhD, MA**  
 Director of Qualitative Research UMD PATIENTS Program

**Faith-Based and HBCUs-REACH**

# REACH Consortium Past/Current projects

## FQHCs-REACH

- Increase awareness of clinical trials for diverse rural populations
- Provide education to FQHC providers and community health workers to advance clinical trials for diverse rural communities

## Puerto Rico-REACH

- Increase awareness of clinical trials for Hispanic or Latino populations
- Patient reported outcomes and unmet needs for substance use disorder

## Hawaii-REACH

- Increase awareness of clinical trials for Native Hawaiian or Other Pacific Islander (NHPI) populations
- Education to advance clinical trials for Clinical Trial Research Associates professionals
- Increase RWD efforts for NHPI communities

## Tribal-REACH

- In home use diabetes device communication and education
- Increase awareness of clinical trials for American Indian or Alaska Native (AIAN) populations
- Education to advance clinical trials for AIAN communities
- Gene therapy clinical trials education

## Community Centers-REACH

- Technology and devices
- Clinical trials for sexual and gender minority communities

## HBCU/ Faith-based-REACH

- Increase awareness of clinical trials for Black or African American populations
- Education to advance clinical trials for Black or African American communities
- Food allergy disparities and community engagement

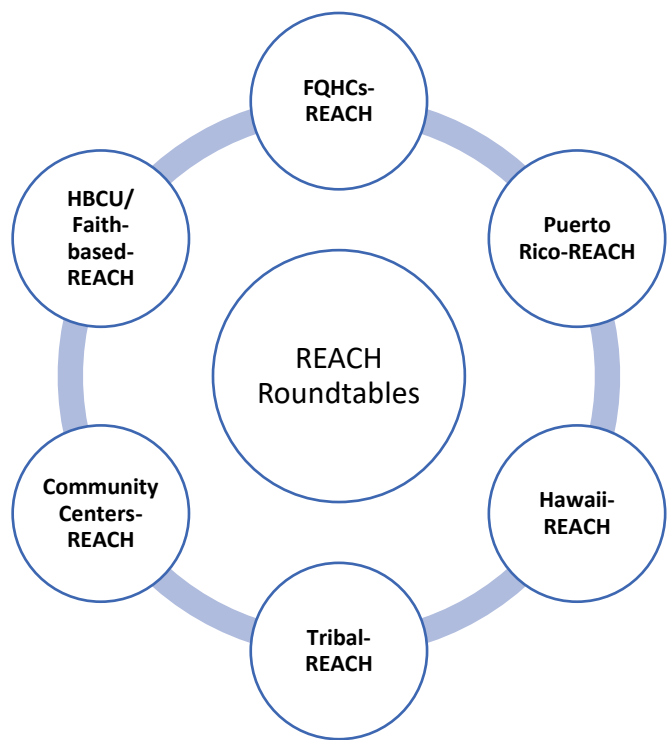




# REACH Panels



# REACH Roundtables



Date	Topic
Dec 2023	Engagement strategies
April 2024	Rural Clinical Trials
Sept 2024 (upcoming)	Informed consents



# REACH Connection with Centers





# Questions?



# Thank You!



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