FDA Efforts to Advance Racial and Ethnic Minority Participation in Clinical Trials

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• No conflicts of interest to declare
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
What We Do

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
Initiatives to Advance Racial and Ethnic Minority Participation in Clinical Trials

• FDA Guidance Documents for Industry

• OMHHE Diversity in Clinical Trials Initiative

• OMHHE Enhance Equity Initiative
Collection of Race and Ethnicity Data in Clinical Trials

Guidance for Industry and Food and Drug Administration Staff

Document issued on October 26, 2016

For questions about this document, contact the FDA Office of Minority Health at 240-402-3084 or

Evaluation and Reporting of Age-, Race-, and Ethnicity-Specific Data in Medical Device Clinical Studies

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 12, 2017

The draft of this document was issued on June 20, 2016.

For questions about this document regarding CDRH-regulated devices, contact CDRH at 301-796-5900 or CDHRPmce@fda.hhs.gov or CDHRPmce@fda.hhs.gov.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-857-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

October 2016
Clinical Medical
Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs
Guidance for Industry

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: http://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-301), 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 Fasihayo-Abg, 240-402-8205, (CDER) Office of Communication, Outreach, and Development, 880-835-4709, or 240-402-8018, or CDER/perstf@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
November 2020
Clinical/Medical

Center for Biologics Evaluation and Research (CBER)
Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Oncology Center of Excellence (OCE)
Center for Drug Evaluation and Research (CDER)
April 2022
Clinical/Medical

Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Office of Minority Health and Health Equity (OMHHE)
An ongoing *multi media campaign* to raise awareness around the importance of *diverse participation* in clinical trials.
OMHHE Diversity in Clinical Trials Campaign

BE A #CLINICALTRIALSCHAMPION

Videos

Newsletters & E-alerts

Webpage

Stakeholder Collaboration

Podcasts

Social Media

Educational Materials Translated into 11 Languages

Culturally & Linguistically Tailored Materials
OMHHE Diverse Participation in Clinical Trials
Podcast I Videos I Social Media

Let’s Take Charge!
Help make lupus research more diverse

Shanelle Gabriel
Poet & Lupus Advocate

FDA Minority Health and Health Equity
Let’s undo underrepresentation!
By choosing to join a clinical trial, we make sure that new medicines and treatments will work for us, our family, and our communities.
Learn more about #diversity in ClinicalTrials: fda.gov/consumers/mino...
OMHHE Clinical Trial Diversity Resources
Engaging Community Providers in Clinical Research

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.
## OMHHE Equity in Clinical Trials

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<th>Project</th>
<th>Awarded To</th>
<th>Fiscal Year</th>
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<td>Co-creation of digital tools to enhance young adult minority participation in COVID-19 trials</td>
<td>California State University, Fullerton</td>
<td>2022</td>
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<tr>
<td>Hispanic, black and pacific islander perspectives on COVID-19 outreach Strategies and patient centered outcomes (HeAR US)</td>
<td>Queens Medical Center</td>
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<td>COMMunity Mistrust and Institutional Trustworthiness to advance health Equity research (COMMIT-EQ)</td>
<td>University of Maryland, Baltimore</td>
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<td>RFA</td>
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<tr>
<td>Center for Advancing COVID-19 Health Equity Research</td>
<td>Florida Agricultural and Mechanical University</td>
<td>2022</td>
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<td>Utilizing the Pharmacy Advances Clinical Trials (PACT) Network to Achieve Diversity in COVID Clinical Trials: A Strategic Framework</td>
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<td>Bridging Gaps: Recruiting African American and Asian American Participants for COVID-19 Clinical Trials and</td>
<td>Howard University</td>
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OMHHE Equity In Clinical Trials

Journal of Translational Science

Research Article

Attitudes towards clinical trial participation among people living with chronic hepatitis B

Yasmin Ibrahim1, Chari Cohen2, Richard De Azevedo2, Christine Merenda3, Sarah Dykstra4 and Christine Lee5
Public Health Manager, Hepatitis B Foundation, 3805 Old Easton Road, Doylestown, PA, USA

Abstract

Background: Inclusion of diverse populations in clinical trials for chronic hepatitis B (CHB) is an integral part of development of new treatments. However, the assessment of the willingness of diverse patients to participate in hepatitis B clinical trials is understudied.

Methods: The Hepatitis B Foundation conducted an online survey regarding the willingness to participate in clinical trials among people living with CHB in the U.S. and outside the U.S. Descriptive demographic and bivariate analyses were conducted to identify relationships between willingness to participate and demographic characteristics.

Findings: Among all respondents, the overall willingness to participate in clinical trials was high. 73% were willing to participate in clinical trials, 21% were undecided, and only 6% were unwilling to participate. Among all respondents, Black or African American respondents showed the highest rate of willingness to participate in clinical trials (83%), compared with White respondents (68%) or Asian (63%) (p<0.001). Among all respondents, higher willingness to participate in clinical trials was observed among those living outside of the U.S. (77%), those who identified as Black (83%) or identified as male (77%) (p<0.001). Respondents from the U.S. were more likely to be undecided about their participation (34%), compared with international respondents (17%) (p<0.001).

Interpretations: This study showed there was a lower overall willingness to participate in clinical trials among those living outside the U.S. compared to those outside of the U.S. This highlights the need to increase the engagement with patients living with CHB within the U.S. and in particular with Black or African American and Asian U.S. populations.

Keywords: chronic hepatitis B, clinical trial participation, diversity, under-represented population, willingness to participate

Disclaimer: This publication reflects the views of the authors and should not be construed to represent FDA’s views or policies.
OMHHE Initiatives to Advance Racial and Ethnic Minority Participation in Clinical Trials

Looking Forward...
OMHHE Funding Opportunities

The Office of Minority Health and Health Equity (OMHHE) continues to promote and protect the health of racial and ethnic minorities and tribal populations through research and communication that addresses health disparities. Through OMHHE’s Enhance Equity Initiative Funding Opportunities.

OMHHE’s Enhance Equity Initiative Funding Opportunities enables OMHHE to advance minority health and health equity through regulatory science research by engaging across a broad range of stakeholders, including academic, minority-serving institutions, government agencies, and non-profit organizations.

Please sign up for our newsletter to learn about future funding opportunities.

Now Accepting Applications:

As part of OMHHE’s Enhance Equity Initiative, OMHHE is announcing two new funding opportunities:

- FDA OMHHE Health Equity Innovation Award: Enhance Equity Funding Opportunity

The purpose of this funding opportunity announcement (FOA) is to fund innovative research that will strengthen and advance minority health and health equity research.
FDA OMHHE & NHGRI Genomic Science and Health Equity
Postdoctoral Fellowship

Postdoctoral Fellowship in Genomic Science and Health Equity

Joint Fellowship Program
National Institutes of Health
National Human Genome Research Institute

Food and Drug Administration
Office of Minority Health and Health Equity

Apply Starting
February 15, 2021

Expected Start Date
Summer 2023

genome.gov/NHGRIFDA-fellowship
Thank You!

Follow us at: @FDAHealthEquity

Email us at: healthequity@fda.hhs.gov

Visit us at: FDA.gov/HealthEquity

Join OMHHE listserv for info on webinars and stakeholder calls