

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

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



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- No conflicts of interest to declare

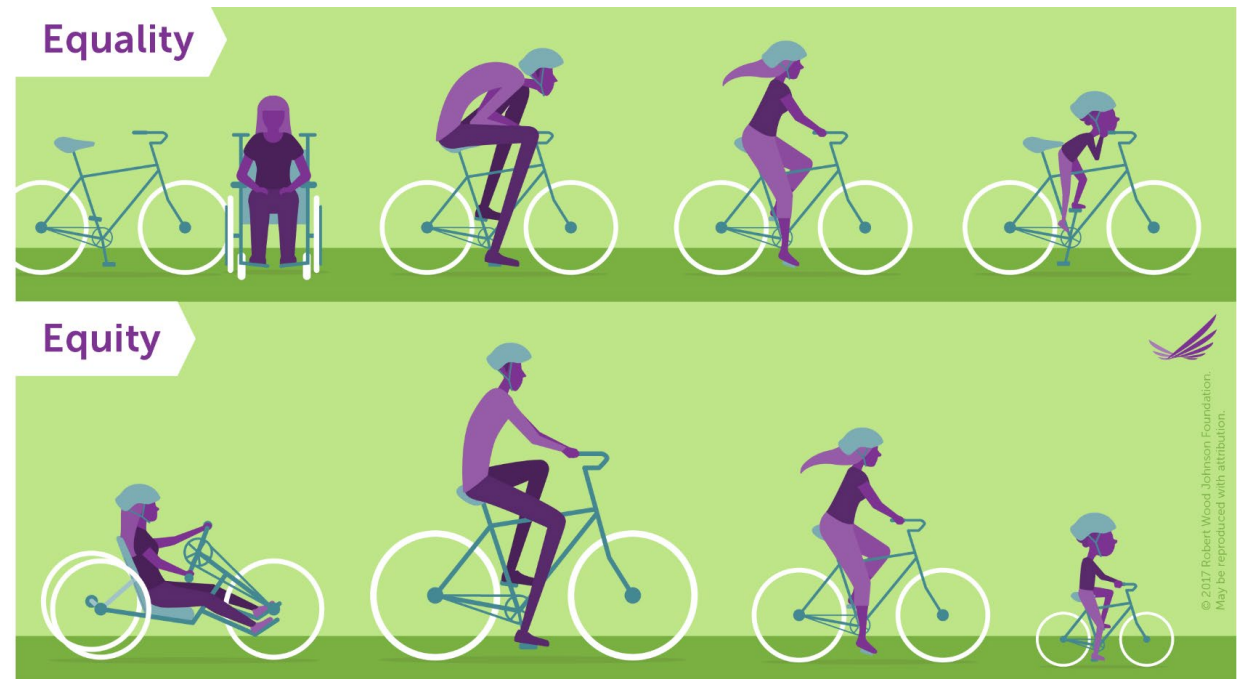
# FDA Office of Minority Health and Health Equity (OMHHE)

## 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

# FDA Guidance for Industry

*Contains Nonbinding Recommendations*

## Collection of Race and Ethnicity Data in Clinical Trials

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### 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 240-402-5084 or [omh@fda.hhs.gov](mailto:omh@fda.hhs.gov).

U.S. Department of Health and Human Services (HHS)  
Food and Drug Administration (FDA)  
Office of the Commissioner (OC)  
Office of Minority Health (OMH)  
Office of Women's Health (OWH)  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)  
Center for Devices and Radiologic Health (CDRH)

October 2016  
Clinical Medical

*Contains Nonbinding Recommendations*

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

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### 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 [CDRHPatientDiversity@fda.hhs.gov](mailto:CDRHPatientDiversity@fda.hhs.gov) or [CDRHClinicalEvidence@fda.hhs.gov](mailto:CDRHClinicalEvidence@fda.hhs.gov).

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 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



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ADMINISTRATION





# OMHHE Diversity in Clinical Trials Initiative

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 | Videos | Social Media

FDA



FDA Minority Health and Health Eq... @FDAHealthEq... · Feb 16  
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...](https://fda.gov/consumers/minority-health)





# OMHHE Clinical Trial Diversity Resources



## Fact Sheet (Spanish)

### DIVERSIDAD EN LOS ESTUDIOS CLÍNICOS

**Hoja informativa**

Los estudios clínicos son estudios de investigación en los que voluntarios humanos participan para evaluar la seguridad y eficacia de los productos médicos como medicamentos, vacunas o dispositivos. Estos estudios también pueden mostrar qué productos o terapias médicas funcionan mejor para personas con determinadas enfermedades o para ciertos grupos de personas. Asegurar que personas de diversos grupos se unan a los estudios clínicos es clave para avanzar en la equidad en la salud.

*Oficina de Salud de las Minorías y Equidad en la Salud*

**5 cosas que debe saber sobre los estudios clínicos**

1. Los estudios clínicos son estudios de investigación realizados con personas. Están diseñados para contestar preguntas de investigación específicas sobre productos o terapias médicas.
2. La participación es siempre voluntaria. Usted puede salir de un estudio cuando lo desee.
3. Los estudios clínicos a menudo necesitan voluntarios sanos para ayudar a contestar preguntas de investigación.
4. Su seguridad es una prioridad. Los investigadores deben seguir protocolos detallados y los requisitos de seguridad de la FDA para que cada estudio sea lo más seguro posible.
5. Se le explicará el estudio en un proceso de consentimiento informado antes de que acepte participar.

**La importancia de la participación diversa en los estudios clínicos**

Los participantes en los estudios clínicos deben representar a los pacientes que utilizarán los productos médicos. A menudo esto no es así. Las personas de minorías raciales y étnicas, y otros grupos diversos están poco representados en la investigación clínica. Esta es una preocupación porque las personas de diferentes edades, razas y etnias pueden reaccionar de manera diferente a los productos médicos. Para lograr la equidad en la salud y que todos puedan beneficiarse de los estudios clínicos, nos comprometemos a tomar medidas para cambiar esto.

**Participar en un estudio clínico puede ser una buena opción para usted si:**

- Usted y su proveedor de salud creen que un estudio clínico puede proporcionar otra opción cuando los tratamientos estándar han fracasado.
- Usted quiere ayudar a evaluar nuevos productos o terapias médicas en los diversos pacientes que probablemente los utilicen.
- Usted quiere ayudar a los investigadores a encontrar mejores formas de combatir enfermedades.

**Aprenda más**

Si cree que un estudio clínico puede ser adecuado para usted, hable con su proveedor de salud. También puede buscar estudios clínicos en su zona en [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Para ver videos y una lista de preguntas para los investigadores, visite [www.hhs.gov/about-research-participation](http://www.hhs.gov/about-research-participation).

Para obtener información precisa sobre quiénes participaron en los estudios clínicos que apoyaron la aprobación de la FDA de nuevos medicamentos, visite [DrugTrials.Snapshots](http://DrugTrials.Snapshots).

Para obtener más información sobre la equidad en la salud, visite [www.fda.gov/healthequity](http://www.fda.gov/healthequity).

La FDA, una agencia del Departamento de Salud, Servicios Humanos de EE. UU. protege la salud pública garantizando la seguridad, la eficacia, la producción de los medicamentos humanos y veterinarios, los dispositivos médicos y otros productos biológicos para uso humano, y los dispositivos médicos. La agencia también es responsable de la seguridad de los alimentos, los cosméticos, los suplementos dietéticos y los productos que controla. Para obtener más información, visite [www.fda.gov](http://www.fda.gov).

## Brochure

### RESEARCH NEEDS YOU

**FDA Office of Minority Health and Health Equity**

## Infographic

### 4 WAYS TO BE A #ClinicalTrialsChampion

Clinical trials are research studies involving human volunteers to evaluate medical products like medications, vaccines, or devices for safety and effectiveness.

In order to represent the patients that may use a medical product or therapy, research studies need diverse participants, including people of all races and ethnicities.

- SHARE** the #ClinicalTrialsChampion videos
- TALK** to your friends and family about clinical trials
- LOOK** on ClinicalTrials.gov for open research studies
- ASK** your health care provider if a clinical trial is right for you

Search for clinical trials at [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

For more information on health equity, visit [www.fda.gov/healthequity](http://www.fda.gov/healthequity)

**Ensuring diversity in clinical trials is key to advancing health equity**

## Webpage

### Clinical Trial Diversity

**Minority Health and Health Equity**

**National Minority Health Month (NMHM) 2021**

**Clinical Trial Diversity**

**FDA Office of Minority Health and Health Equity 10 Year Anniversary**

**FDA Race and Health Symposium**

**Outreach and Communication**

**Health Equity from Patient Education (HETP) Initiative**

**Language Access**

**Minority Health and Health Equity Resources**

**Fast Fact Download and Share**

**Brochure Download and Share**

**Infographic Download and Share**

**Clinical trials are research studies involving human volunteers to evaluate medical products like medications, vaccines, or devices for safety and effectiveness.**

**Ensuring people from diverse backgrounds join clinical trials is key to advancing health equity. Participants in clinical trials should represent the patients that will use the medical products. This is often not the case—people from racial and ethnic minority and other diverse groups are underrepresented in clinical research. This is a concern because people of different ages, sexes, and ethnicities may react differently to certain medical products.**

**The FDA encourages diverse participation in clinical trials. If you think a clinical trial may be right for you, talk to your health care provider.**

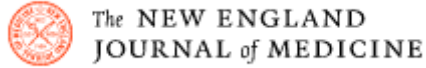
**You can also search for clinical trials in your area at [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov)—a database of privately and publicly funded clinical studies conducted around the world.**

**Search ClinicalTrials.gov:** Enter a word or phrase, such as the name of a medical condition or intervention. Example: Cancer AND Los Angeles

**Clinical Trial Resources**

- [About Research Participation](#)
- [Fast Fact: Clinical Trial Diversity \(Spanish\)](#)
- [Brochure: Research Needs You \(Spanish\)](#)

# Engaging Community Providers in Clinical Research



## Integrating Research into Community Practice — Toward Increased Diversity in Clinical Trials

Janet Woodcock, M.D., Richardae Araujo, Pharm.D., Twyla Thompson, Pharm.D., and Gary A. Puckrein, Ph.D.

The Covid-19 pandemic has underscored health inequities affecting racial and ethnic minority and other underserved communities in the United States, highlighting, among other critical needs, the importance of increasing the diversity of participants in clinical trials. Clinical trials provide evidence of medical products' safety and effectiveness (or lack thereof). Physicians' ability to extrapolate from trial results to their own patients would be dramatically improved if a trial's participants reflected the product's intended patient population as accurately as possible. Yet in 2020, industry-sponsored clinical trials that supported Food and Drug Administration (FDA) approval of new molecular entities and original therapeutic biologics included 8% Black or African American, 6% Asian, and 11% Hispanic or Latino participants.<sup>1</sup>

Many strategies have been developed to increase enrollment of diverse populations, but they have produced mixed results. One strategy that has not been scaled up in a sustainable way is engaging community clinicians in research.

There is considerable evidence that clinician recommendations play an important role in helping patients to consider participating in clinical trials.<sup>2</sup> Yet such engagement is not widespread. Multiple barriers impede clinician engagement in research, starting with a lack of awareness and knowledge about clinical research. Many U.S. clinicians are not affiliated with large academic medical centers or research institutions and may therefore be unaware of current research efforts, even if research is being conducted at nearby sites. Additional barriers are lack of time and compensation for discussing trial participation with patients, failure to see clinical trials as an integral part of the care continuum, concerns that participation may interfere with established patient-clinician relationships, and lack of recognition for referring patients to trials.<sup>2</sup> Community clinicians are usually not offered the training, mentorship, ongoing support, and resources they need to enable sustained participation in research.

Lack of trial access is a particularly problematic barrier for both clinicians and patients. For

example, less than 8% of patients with cancer participate in clinical trials, even though more than 50% will participate when offered the opportunity.<sup>3</sup> Community clinicians can't present these opportunities to their patients if the trials are not accessible.

Typical site-selection practices create another substantial barrier: often, to meet recruitment goals and timelines, industry sponsors repeatedly use the same large sites and investigators to conduct clinical research. These sites and investigators generally do not provide care to underserved populations and are often not easily accessible to diverse communities. In addition, much research that is sponsored by the U.S. government is conducted at major medical centers, which may serve patients in their local communities but often do not engage community-based clinicians.

Engaging community clinicians in clinical research could have multiple benefits. These clinicians are dedicated to the populations they serve and committed to addressing the health issues of those populations. The clinicians' established, trusting pa-

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The New England Journal of Medicine

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Woodcock J, Araujo R, Thompson T, Puckrein GA. Integrating Research into Community Practice - Toward Increased Diversity in Clinical Trials. *N Engl J Med*. 2021 Oct 7;385(15):1351-1353.



# 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



Project	Awarded To	Fiscal Year	Funding Mechanism	Status
Co-creation of digital tools to enhance young adult minority participation in COVID-19 trials	California State University, Fullerton	2022	RFA	On Going
Hispanic, black and pacific islander perspectives on COVID-19 outreach Strategies and patient centered outcomes (HeAR US)	Queens Medical Center	2022	RFA	On Going
COMMunity Mistrust and Institutional Trustworthiness to advance health EQUity research (COMMIT-EQ)	University of Maryland, Baltimore	2022	RFA	On Going
Center for Advancing COVID-19 Health Equity Research	Florida Agricultural and Mechanical University	2022	RFA	On Going
Utilizing the Pharmacy Advances Clinical Trials (PACT) Network to Achieve Diversity in COVID Clinical Trials: A Strategic Framework	Texas A&M University Health Science Center	2022	RFA	On Going
Bridging Gaps: Recruiting African American and Asian American Participants for COVID-19 Clinical Trials and	Howard University	2021	BAA	On Going

Journal of Translational Science



Research Article

ISSN: 2059-268X

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

Yasmin Ibrahim<sup>1\*</sup>, Chari Cohen<sup>1</sup>, Richardae Araujo<sup>2</sup>, Christine Merenda<sup>2</sup>, Sarah Dykstra<sup>3</sup> and Christine Lee<sup>2</sup>

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 (64%) or Asians (63%) ( $p < 0.001$ ). Among all respondents, higher willingness to participate in clinical trials was observed among those living outside 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 from 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

[OMHHE Enhance Equity Initiative Funding Opportunities](#)

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### Enhance EQUITY Initiative

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[Enhance EQUITABLE Data Efforts](#)

[Enhance EQUITY of Voices](#)

[OMHHE Enhance Equity Initiative Funding Opportunities](#)



Content current as of:  
03/10/2023

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 focused regulatory science research by engaging across a broad range of stakeholders, including academia, minority-serving institutions, government agencies, and non-profit organizations.

**Please sign up for our listserv 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

FDA

## 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

[genome.gov/NHGRIFDA-fellowship](https://genome.gov/NHGRIFDA-fellowship)

**Apply Starting**  
February 15, 2021

**Expected Start Date**  
Summer 2023



# Thank You!



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