Office of Minority Health and Health Equity

U.S. FOOD & DRUG ADMINISTRATION

Clinical Trial Recruitment Challenges

Precision, Personalized and Diverse: New Tools and Strategies

Disclaimer

- I do not have any financial relationships to disclose
- I will not discuss off label use and/or investigational use in this presentation
- The views expressed here are mine and not FDA

Outline

- Who are we?
- FDA's Role in Clinical Trials
- Representation in clinical trials
- Strategies to Improve Diverse Participation in Clinical Trials

OVERVIEW OF FOOD AND DRUG ADMINISTRATION & OFFICE OF MINORITY HEALTH AND HEALTH EQUITY (OMHHE)

Food and Drug Administration (FDA)

Mission

FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

FDA also regulates the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

Consumer protection agency

Provide information on regulated products to ensure safe and effective use to consumers/patients/health care providers

Regulatory agency

Intersection of commerce, laws and public health

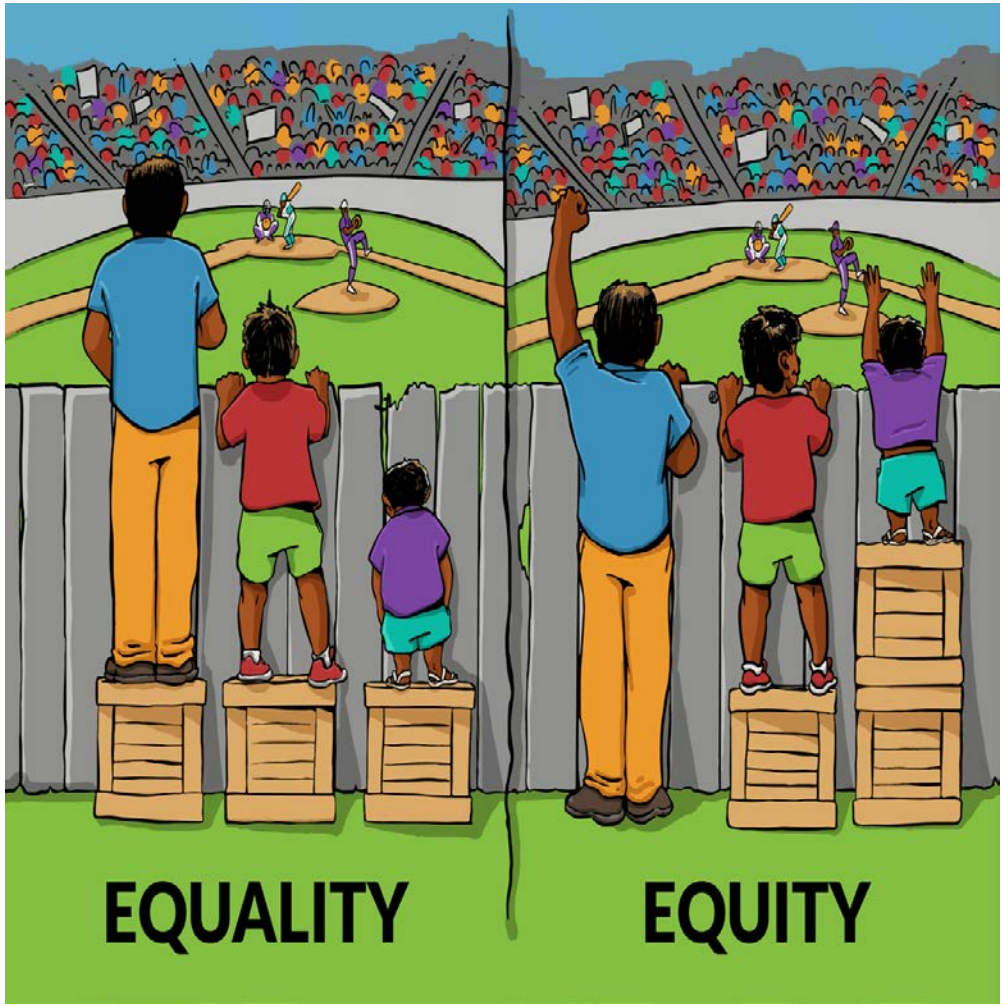
FDA Office of Minority Health and Health Equity

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

Outreach and Communication

- Programs/Initiatives/Campaigns
  - Language Access Program
  - Diversity in Clinical Trials Initiative
- Health Education Materials
- FDA Spokesperson; Speaking Engagements
- Social Media
- Newsletter & E-alerts
- Website
- Lecture Series & Webinars
- FDA & HHS Working Groups
- Stakeholder Meetings/Symposiums/Exhibits
- Foster collaboration between FDA & stakeholders

Research and Collaboration

- Intramural Research
- Extramural Research
- Participate in FDA Centers of Excellence in Regulatory Science and Innovation (CERSI) Projects
- Summer Teacher Training Program
- Pharmacy Internships
- Academic Collaborations/Fellowships
- Congressional Mandates
- FDA & HHS Working Groups & Collaborations
- Stakeholder Input into Research Agenda
- Guidance Documents

Research and Collaboration Program Goals

Goal 1: Advance minority health-focused research and increase the amount of clinical trial data available on racial/ethnic minority populations.

Goal 2: Reduce health disparities by advancing minority health-focused education and scientific exchange.

Outreach and Communication Program Goals

Goal 1: Strengthen FDA outreach to racial and ethnic minority populations and underserved populations that often experience low health literacy and speak English as a second language or not at all.

Goal 2: Partner with external stakeholders to identify and reduce health disparities.

FDA'S ROLE IN CLINICAL TRIALS

FDA's Role in Clinical Trials

- FDA is the only agency in the world that does primary review of data ranging from pre-clinical to clinical.
- FDA establishes regulations and guidance about the data in trials for product applications.
- FDA helps raise awareness about clinical trials participation.

Legislation: FDA Safety & Innovation Act of 2012, Section 907

- **Section 907** - *Reporting of Inclusion of Demographic Subgroups in Clinical Trials and Data Analysis in Applications for Drugs, Biologics, and Devices*
  - Report to determine the extent of demographic subgroups in applications, in FDA reviews for safety and efficacy; if information is publically available on FDA website or in labeling; **report posted August 2013**
  - Publish and provide to Congress an action plan outlining recommendations for improving the completeness and quality of analysis of data; **action plan posted August 2014**

FDASIA Section 907 Action Plan Priorities & Sample Strategies

Priority One: Improve the completeness and quality of demographic subgroup data collection, reporting and analysis (**Quality**)

FDA Guidance Documents:

Collection of Race and Ethnicity Data in Clinical Trials

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

Priority Two: Identify barriers to subgroup enrollment in clinical trials and employ strategies to encourage greater participation (**Participation**)

Public Meetings

Tools to support diverse clinical trial participation

Priority Three: Make demographic subgroup data more available and transparent (**Transparency**)

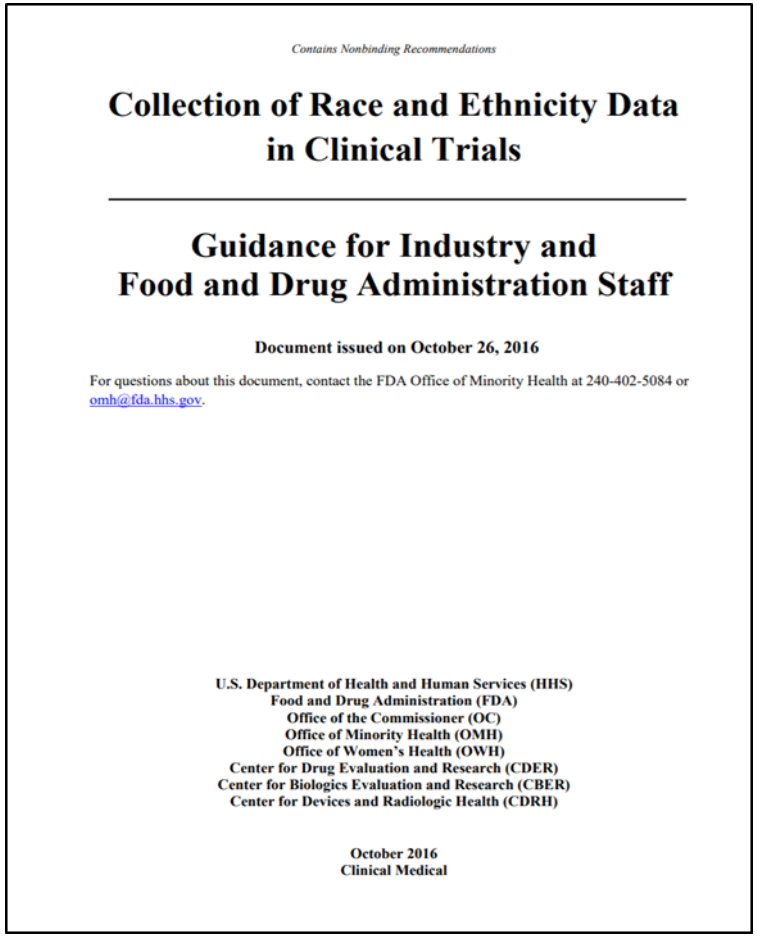
Drug Trials Snapshot

Guidance Document- Main Points

- FDA expectations are that sponsors enroll participants who **reflect the demographics for clinically relevant populations** with regard to age, gender, race, and ethnicity

- **A plan to address inclusion of clinically relevant subpopulations** should be submitted for discussion to the Agency at the earliest phase of development and, for drugs and biologics, no later than the end of the phase 2 meeting

- Inadequate participation and/or data analyses from clinically relevant subpopulations can lead to insufficient information pertaining to medical product safety and effectiveness for product labeling



Contains Nonbinding Recommendations

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 240-402-5084 or 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

Points to Consider: Subgroup Differences

For potential race and ethnicity differences relevant to the evaluation of the medical product for the disease/condition, consider:

- Prevalence
- Diagnosis and treatment patterns
- Previous subgroup inclusion in past studies for target indication
- Any clinically meaningful subgroup differences in safety or efficacy

REPRESENTATION IN CLINICAL TRIALS

The continuing conversation…


SCIENTIFIC AMERICAN

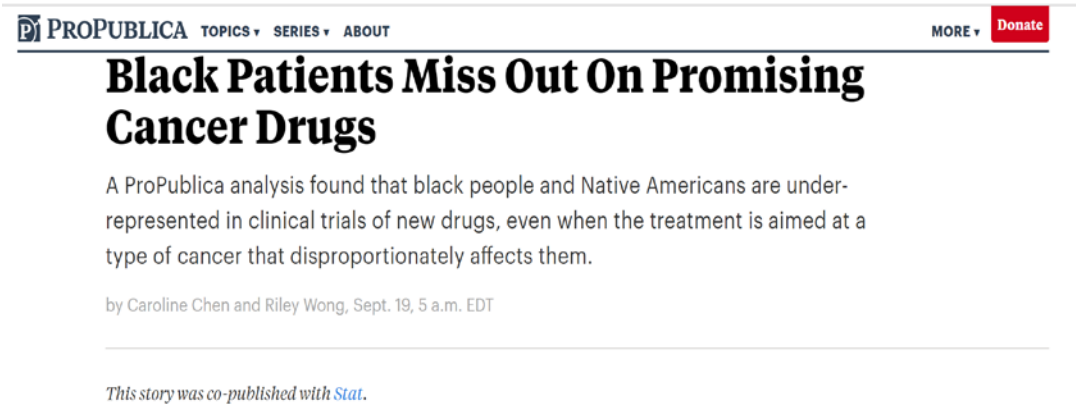
English Cart 0 Sig

POLICY & ETHICS

Clinical Trials Have Far Too Little Racial and Ethnic Diversity

It's unethical and risky to ignore racial and ethnic minorities

By THE EDITORS on September 1, 2018


PROPUBLICA TOPICS SERIES ABOUT MORE Donate

Black Patients Miss Out On Promising Cancer Drugs

A ProPublica analysis found that black people and Native Americans are under-represented in clinical trials of new drugs, even when the treatment is aimed at a type of cancer that disproportionately affects them.

by Caroline Chen and Riley Wong, Sept. 19, 5 a.m. EDT

This story was co-published with Stat.


AAMC Association of American Medical Colleges

ABOUT MISSIONS ADVOCACY DATA

AAMCNEWS

DIVERSITY & INCLUSION

Tuesday, December 20, 2016 | by David Levine and Rebecca Greenberg

More Minorities Needed in Clinical Trials to Make Research Relevant to All


MEETING NEWS

Highlights from AACR Annual Meeting

Survey: Minorities underrepresented in clinical trials, but want to participate

March 15, 2018


Clinical Trials ARENA

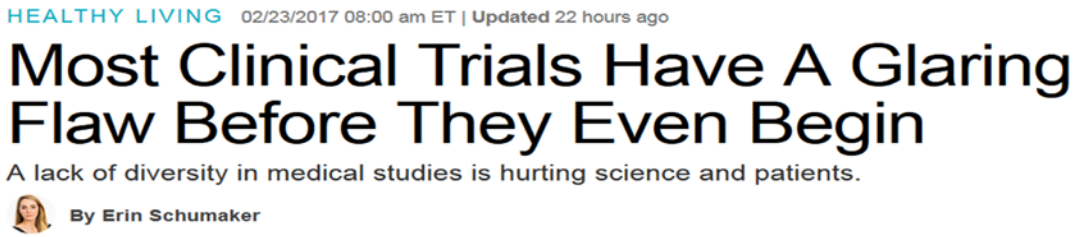
Addressing the key challenges in the global clinical trial space

Search

OPERATIONS SUPPLY CHAIN DATA OUTSOURCING ONCOLOGY TECHNOLOGY MEDICAL DEVICES COLD CHAIN RESOURCES SUPPLIERS EVE

13 JUNE 2018 NEWS

We Need to Talk About Race: Lack of Diversity in Clinical Trials is a Public Health Issue


HEALTHY LIVING 02/23/2017 08:00 am ET | Updated 22 hours ago

Most Clinical Trials Have A Glaring Flaw Before They Even Begin

A lack of diversity in medical studies is hurting science and patients.

By Erin Schumaker


CONQUER the patient voice

Home Issues Browse by Topic Patient Stories Financial Support Survivorship Wellness Corner Interactive Media

CLINICAL TRIALS MULTIPLE MYELOMA

Lack of Diversity in Clinical Trials Hurts Patients and Drug Development

Huffington Post 2/23/17

HEALTHY LIVING 02/23/2017 08:00 am ET | **Updated** 22 hours ago

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By Erin Schumaker

Why do we need minorities in clinical trials?

- Minorities have been historically under-represented in clinical trials
- Need representation to study the effects of medical products in the people who will ultimately use them
- Minorities may respond differently to medical products (ex: cancer treatment, heart failure medications)
- To understand health disparities—diseases that occur more frequently or appear differently in diverse populations.

Drug Trials Snapshots: Summaries (2016-2018)

	WOMEN	BLACK or AFRICAN AMERICAN	ASIAN	WHITE	OTHER*	AGE 65 AND OLDER
2016	48%	7%	11%	76%	7%	21%

	WOMEN	BLACK or AFRICAN AMERICAN	ASIAN	WHITE	HISPANIC	AGE 65 AND OLDER
2017	55%	7%	11%	77%	14%	32%

	WOMEN	BLACK or AFRICAN AMERICAN	ASIAN	WHITE	HISPANIC	AGE 65 AND OLDER
2018	56%	11%	10%	69%	14%	15%

** The percentages of the categories "American Indian or Alaska Native (AI/AN)," "Native Hawaiian or Other Pacific Islander (NH/OPI)," and "Unknown/Unreported" were small enough that we combined them into the "Other" category for the purposes of this review.*
***These particular subgroups were calculated as part of a Geriatrics Report and are not a regular feature of the Drug Trial Snapshots*
https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots

Barriers to Diverse Participation

- Mistrust and distrust of the medical system due to historical abuses
- Lack of awareness on the patient's part
- Inadequate recruitment and retention efforts
- Lack of minority physicians, researchers, and clinical investigators
- Misunderstanding of racial/ethnic minorities' beliefs and values that contribute to their decision making process
- Lack of culturally/linguistically appropriate communication
- Perception that minorities do not want to participate
- Physicians/providers may not talk to their patients about clinical trials
- Enrollment criteria
- Return of Results
- Privacy concerns
- Lack of access

Research Shows….

- Asian American communities have low knowledge of and negative attitudes toward clinical trials.[10, 11]

- In one study of Asian American cancer patients, 62% reported no knowledge of clinical trials.[12]

- In a survey study of cancer patients and healthcare providers, Asian Americans were **less likely** than other groups:[13]
  - to have heard the term "clinical trials,"
  - to know someone who had participated in a Randomized Clinical Trial (RCT),
  - to be willing to participate in a RCT.
  - were more likely to think of RCTs as experiments
  - were concerned about insurance coverage and costs of care.

Take home message:
Ask patients to participate!

COMMUNICATION & OUTREACH STRATEGIES TO IMPROVE DIVERSE PARTICIPATION IN CLINICAL TRIALS

Building the Case for FDA

- **Issue**- FDA communications may not reach the intended audiences in a manner they can understand

- **Key Strategies-**
  - We meet people at their place of need/comfort level
    - Example: minorities are early adopters of technology
  - We are **spokespersons** to raise the profile of FDA's minority health activities

Clinical Trials Clinical Trials Diversity Campaign

Developed a multi media campaign to raise awareness around the importance of diverse representation in clinical trials to ensure medical products are safe and effective for everyone.

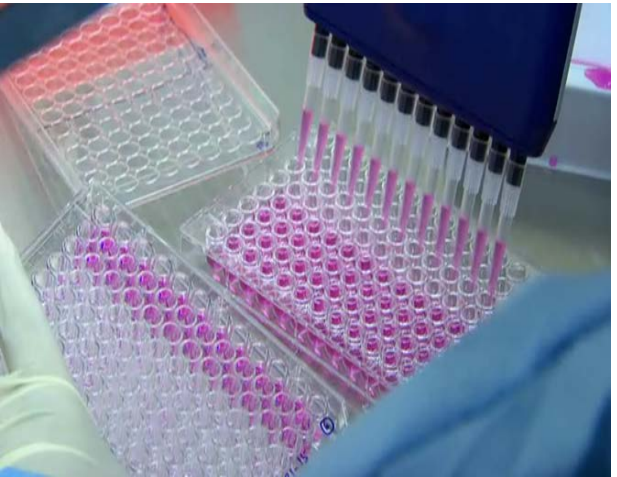
Motivators for Campaigns

- Add positive reinforcement as to why minority health issues matter
- Educate consumers about key issues
- Help stimulate dialogue among peers and patient-provider

Minorities and Clinical Trials Campaign

- Videos
- Newsletters & E-alerts
- Webpage
- Stakeholder Collaboration
- Podcasts
- Social Media
- Communications Toolkit
- Graphics

www.fda.gov/minorityhealth

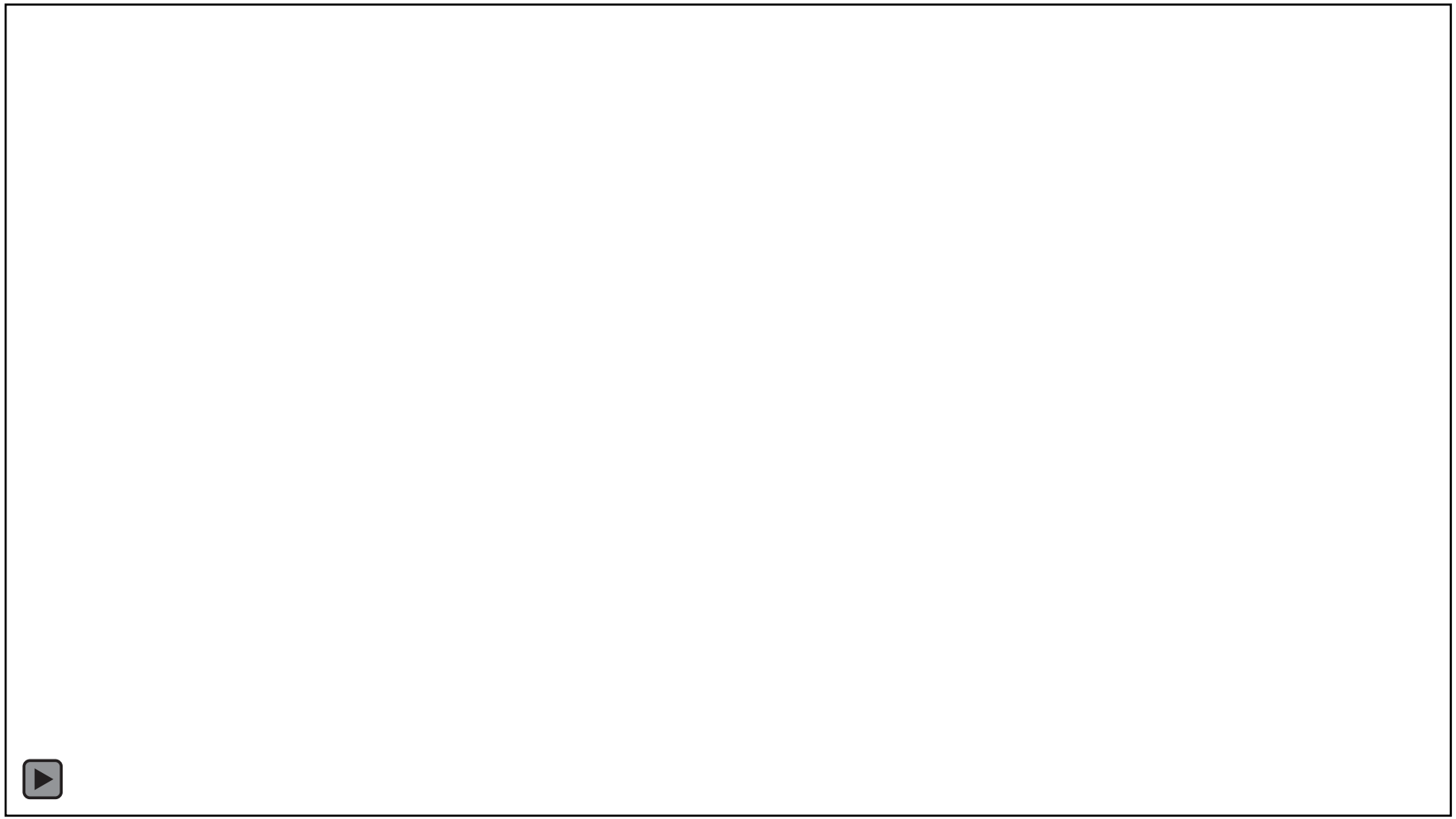


Minority Participation in Clinical Trials Videos

Videos highlighting the importance of minority participation in clinical trials.

Each video features a different theme and key message.

Shirley's Story



Shirley's Story: Diversity is Critical to Making Better Medical Products

Veterans Health Administration
Office of Health Equity

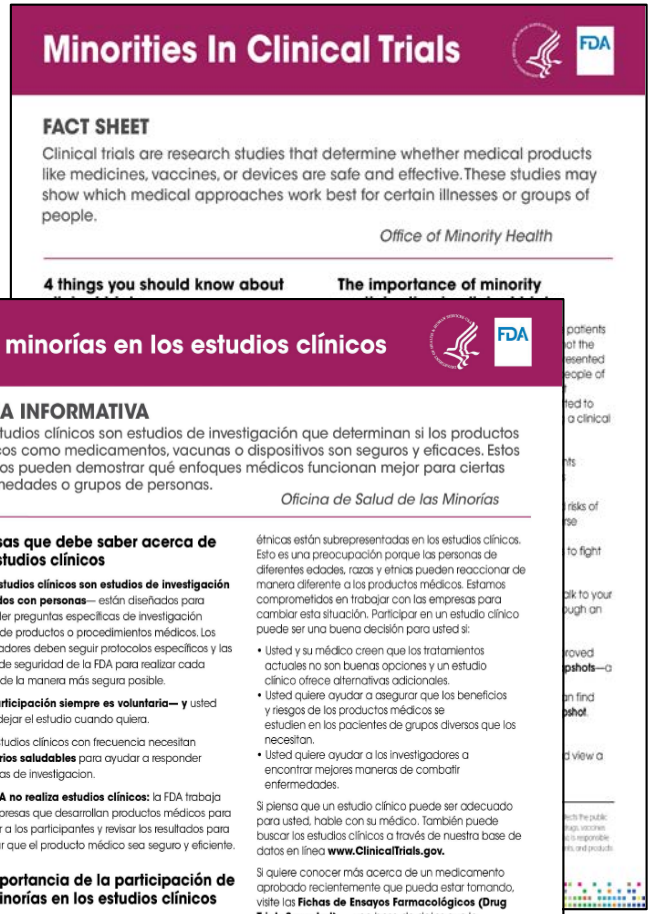
Veteran Participation in Clinical Trials Videos & Podcast

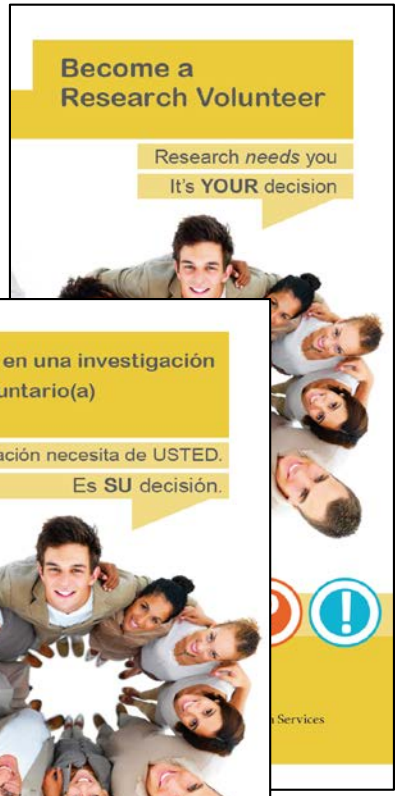
Videos highlighting the importance of veteran participation in clinical trials.

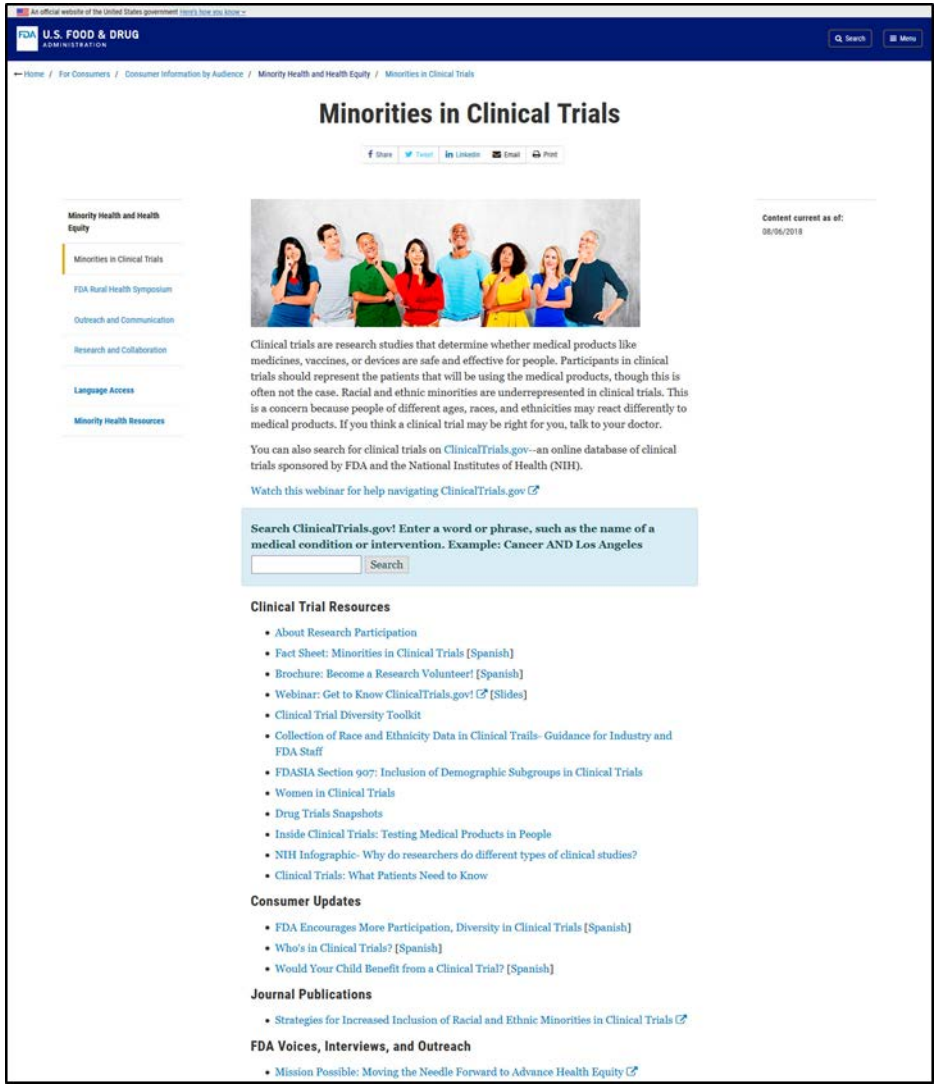
Launched a new podcast series to discuss minority health issues.

First podcast featured three U.S. Army Veterans talking about the importance of clinical trial participation.

Diversity in Clinical Trials Resources







What's the Impact?

- Stimulated dialogue around clinical trial diversity
- Increased utilization of our materials
- Next Steps:
  - Further research can assess the effectiveness of our materials and outreach strategies through cognitive testing and focus group testing.
  - PSA targeting physicians and engaging their patients in participating in clinical trials

Sample of OMHHE Resources

Asian Americans and Hepatitis B

FDA

FACT SHEET

Hepatitis B is a viral infection that causes inflammation of the liver. 1 out of 12 Asian Americans are chronically infected with hepatitis B. 2 out of 3 Asian Americans that are infected and don't know it.

Office of Minority Health

What is Hepatitis B?

Hepatitis B is a liver infection caused by the Hepatitis B virus (HBV). Hepatitis B is transmitted by:

- Having unprotected sex with an infected person
- Sharing contaminated razors, toothbrushes, or needles
- Coming in contact with infected blood (e.g. transfusion, open wounds)
- Mother to baby during vaginal or cesarean birth

If left untreated, hepatitis B can cause scarring of the liver, liver failure, cancer, or even death.

Hepatitis B Signs and Symptoms

- Fatigue
- Fever
- Loss of appetite
- Nausea and vomiting
- Yellow eyes and skin (jaundice)
- Clay-colored bowel movement and dark urine
- Pain on the right side of the stomach
- Joint pain

Key Facts

- Hepatitis B is preventable. You can prevent the infection by getting vaccinated before being exposed to the virus.
- Know your status. If you think you've been exposed: ask your doctor to get tested.
- If you have hepatitis B, talk to your doctor about starting an FDA-approved treatment regimen.

Hepatitis B Treatment Options

For Children

- **Intron A** (interferon alpha-2b): Patients with chronic hepatitis B 1 year of age or older with compensated liver disease.
- **Hepsera** (adefovir dipivoxil): Patients with chronic hepatitis B aged 12 years or older.

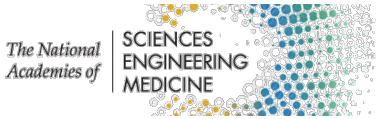
For Adults

- **Viread** (tenofovir): Patients with chronic hepatitis b.
- **Vemlidy** (tenofovir alafenamide): Patients with chronic hepatitis B with compensated liver disease.
- **Baraclude** (entecavir): Patients with chronic hepatitis B with evidence of active viral replication.
- **Epivir HBV** (lamivudine): Patients with chronic hepatitis B associated with HBV replication and active liver inflammation.
- **Pegasys** (pegylated inteferon): Patients with HBeAg positive and HBeAg negative chronic hepatitis B who have compensated liver disease and evidence of viral replication and liver inflammation.
- **Tyzeka** (telbivudine): Patients with chronic hepatitis B with evidence of viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease.

Additional Resources

For more information on Hepatitis B, visit FDA's Hepatitis B Resources page at **www.fda.gov/forpatients/illness/hepatitisBC**.
For more information on minority health go to **www.fda.gov/minorityhealth**.

Our Health Equity Stakeholders



Call To Action

- **Talk to your network or stakeholders about clinical trials**
  - Distribute FDA materials (display posters in your office, clinic, or hospital)
  - Send out announcements via your newsletter or social media

- **Stay Up to Date**
  - Visit the website and follow us on social media
  - Sign-Up for email alerts

- **Get Engaged: Make Your Voice Heard**
  - Communicate your issues and ideas to FDA at public meetings and respond to dockets
  - Patient Engagement Collaborative
  - Patient Representative Program

Connect With Us

Follow us on twitter @FDAOMH

OMH@fda.hhs.gov

www.fda.gov/minorityhealth

Join webinars and stakeholder calls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- Additional slides

Minorities and Clinical Trials

	US Population	Clinical Trial Participation
African-Americans	12%	5%
Hispanics	17%	1%

Note: NIH clinical trials have 30% minority representation overall