Office of Minority Health and Health Equity

U.S. FOOD & DRUG ADMINISTRATION

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Office of Minority Health and Health Equity

2020

Disclaimer

- 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

Overview

- Overview of the U.S. Food and Drug Administration's Office of Minority Health and Health Equity
- FDA Policy Strategies to Support Diverse Participation in Clinical Trials
- Communication & Outreach Strategies to Improve Diverse Participation in Clinical Trials

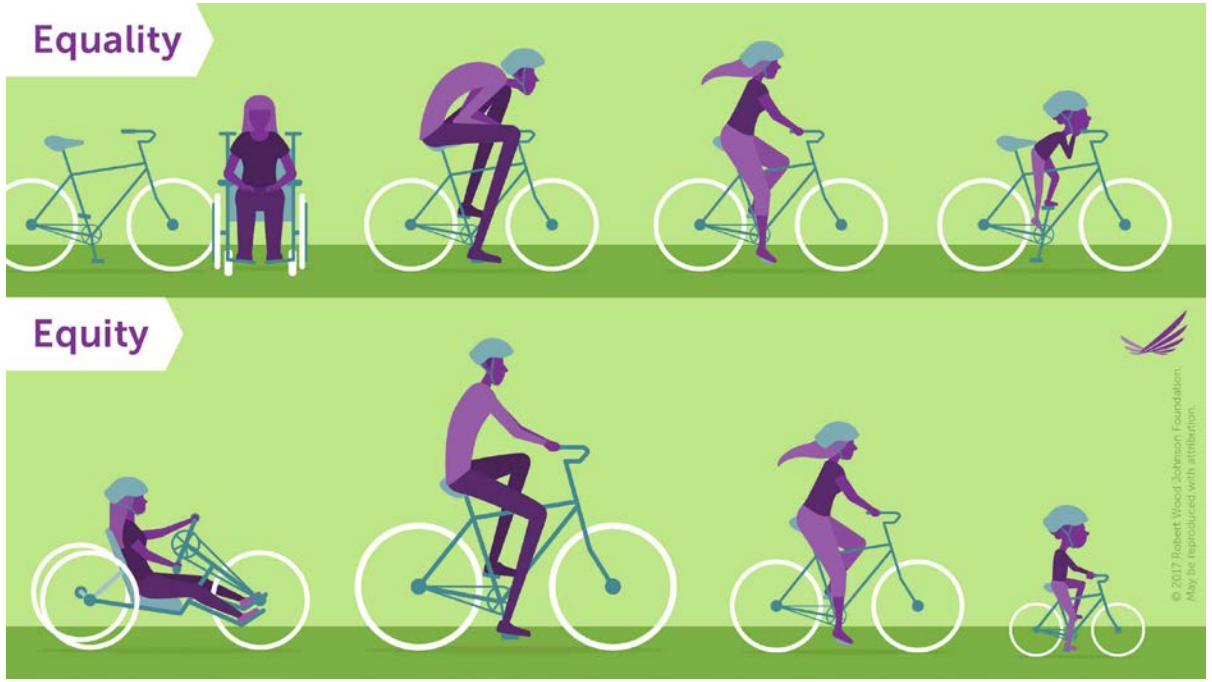
FDA Office of Minority Health and Health Equity (OMHHE)

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

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, Podcasts
- FDA & HHS Working Groups
- Stakeholder Meetings/Symposiums/Exhibits
- Foster collaboration between FDA & stakeholders

Priority Areas

- Opioids
- Tobacco
- Rare Diseases
- Cardiovascular Disease
- Language Access
- Diabetes & Kidney Health
- Nutrition & Food Safety
- Hepatitis
- HIV/AIDS
- Clinical Trial Diversity
- Men's Health

The problem…


SCIENTIFIC AMERICAN

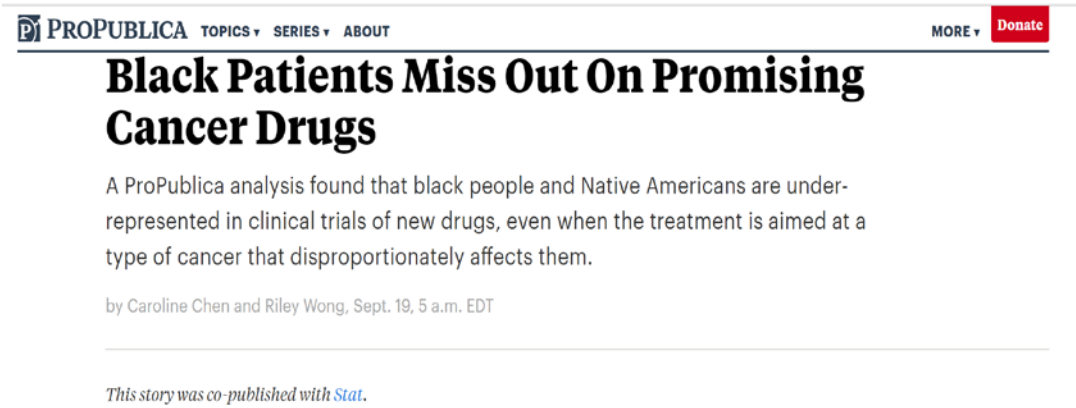
English Cart Sig

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

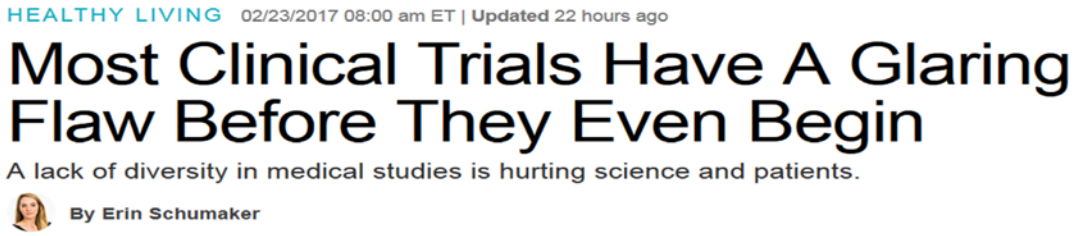
Addressing the key challenges in the global clinical trial space

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

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

The Need for Diverse Participation

- Racial and ethnic minorities have been historically and remain under-represented in clinical trials
- Need representation to study the effects of medical products in the people who will ultimately use them
- Racial/ethnic minority populations may respond differently to certain medical products (i.e., heart failure medications)
- To understand health disparities - diseases that occur more frequently or appear differently in diverse populations

Research Shows….

- In general, minorities will participate if asked. For example…..
  - 91% of African Americans who were surveyed in one study would consider participating in a clinical trial and that mistrust is becoming less of an issue
  - Among immigrant Latinos, 71% of those surveyed who knew what a clinical trial was would consider participating in a cancer clinical trial
  - One study showed there is no difference between African-Americans and Hispanics willingness to participate in research compared to Whites

Sources:
Wallington, SF, Assessing the Awareness of and Willingness to Participate in Cancer Clinical Trials Among Immigrant Latinos. *J Community Health* (2012) 37:335–343.
Wendler D, Kington R, Madans J, Van Wye G, Christ-Schmidt H, et al. Are racial and ethnic minorities less willing to participate in health research? (2006) PLoS Med 3(2):e19.

Take home message:
Ask patients to participate!

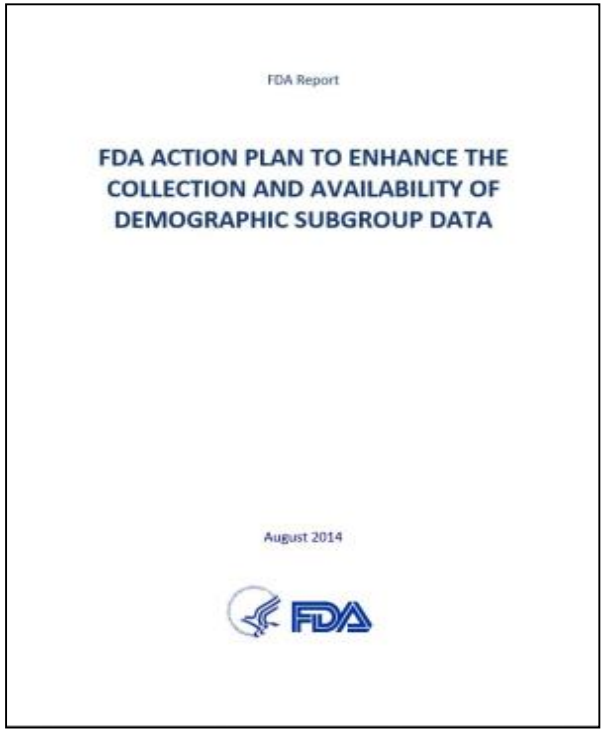
FDA'S ROLE IN CLINICAL TRIALS

2012 FDA Safety and Innovation Act (FDASIA)

- **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 publicly 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, quality and availability of demographic subgroup 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

Priority I: Quality

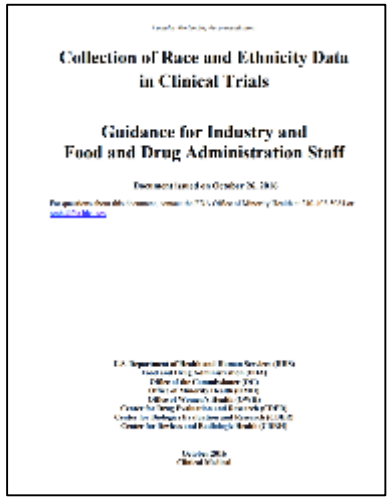
Guidance for Industry

Guidance Documents for Industry

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

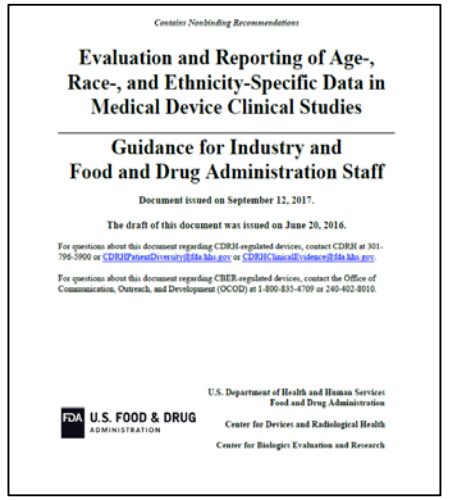
- **A plan to address inclusion of clinically relevant subpopulations** should be submitted for discussion to the Agency at the earliest phase of development and, for drugs and biologics, no later than the end of the phase 2 meeting

- 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


Collection of Race and Ethnicity Data in Clinical Trials

Guidance for Industry and Food and Drug Administration Staff

2016


Contains Nonbinding Recommendations

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 CDRHPatientDiversity@fda.hhs.gov or 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

2017

Points to Consider: Subgroup Differences

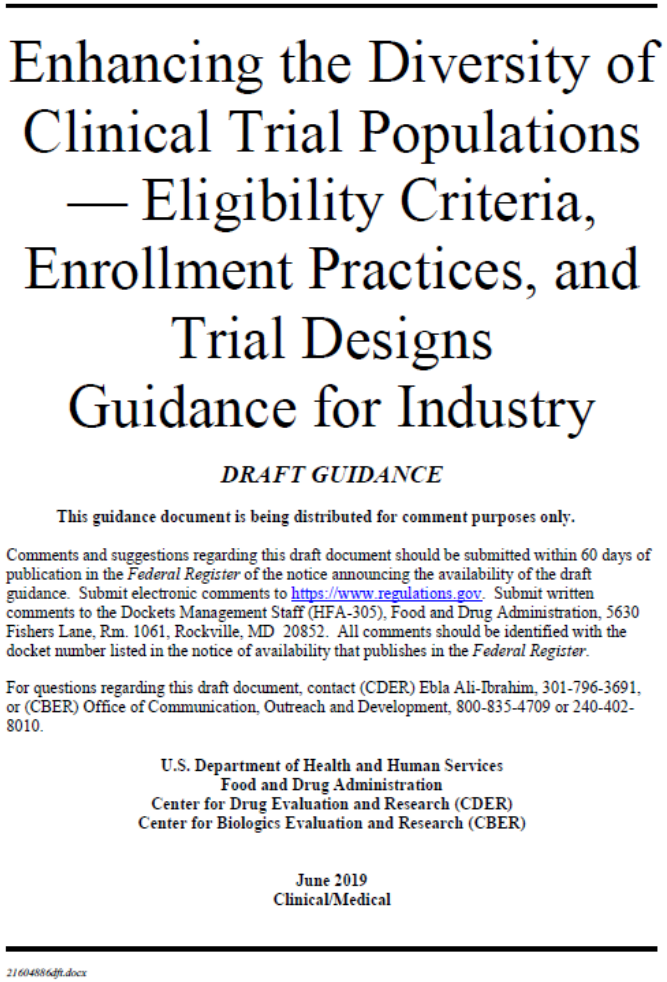
For potential race and ethnicity differences relevant to the evaluation of the medical product for the disease/condition, consider:

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

Guidance Documents for Industry

June 2019 Draft Guidance Issued by CDER & CBER

- Broaden eligibility criteria to increase diversity in enrollment
- Other study design and conduct considerations for improving enrollment
- Broadening eligibility criteria and encouraging recruitment for clinical trials of investigational drugs intended to treat rare disease or conditions



Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs
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 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) Ebla Ali-Ibrahim, 301-796-3691, or (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

June 2019
Clinical/Medical

21604886dft.docx

Research Areas of Interest

- OMHHE seeks innovative pilot projects or funding of projects that contribute to identifying and understanding racial/ethnic differences with respect to safety, efficacy, and effectiveness of FDA-regulated products

- **Examples:**
  - Relationship between PK/PD and treatment outcomes for diseases with disparity in minority populations (i.e. hepatitis B and/or C, asthma, and diabetes)
  - Investigation of physical characteristics (e.g. BMI or adipose distribution) and/or clinical measures (i.e. biomarkers, co-morbidities, or bone density) that may contribute to differences in response in treatment outcomes for drugs and devices
  - Advancing understanding of human genetic variation to susceptibility and severity of diseases (i.e. cardiovascular disease (heart failure and stroke), prostate cancer, colorectal cancer, diabetes, chronic kidney disease, non-alcoholic fatty liver disease)
  - Analysis of demographic data from clinical trials for FDA-regulated products to determine clinical comparability of non-U.S. data to the U.S. population
  - Advancing new methodologies for analyzing treatment outcomes by race and ethnicity using diverse data sources (i.e. CMS data, VA data, and/or IHS data)
  - Post-market assessment of adverse events and treatment outcomes in minority populations
  - Assessments of FDA communications among racial and ethnic subgroups and/or their providers for comprehension and usability

Priority II: Participation

Clinical Trials Multi-Media 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/healthequity

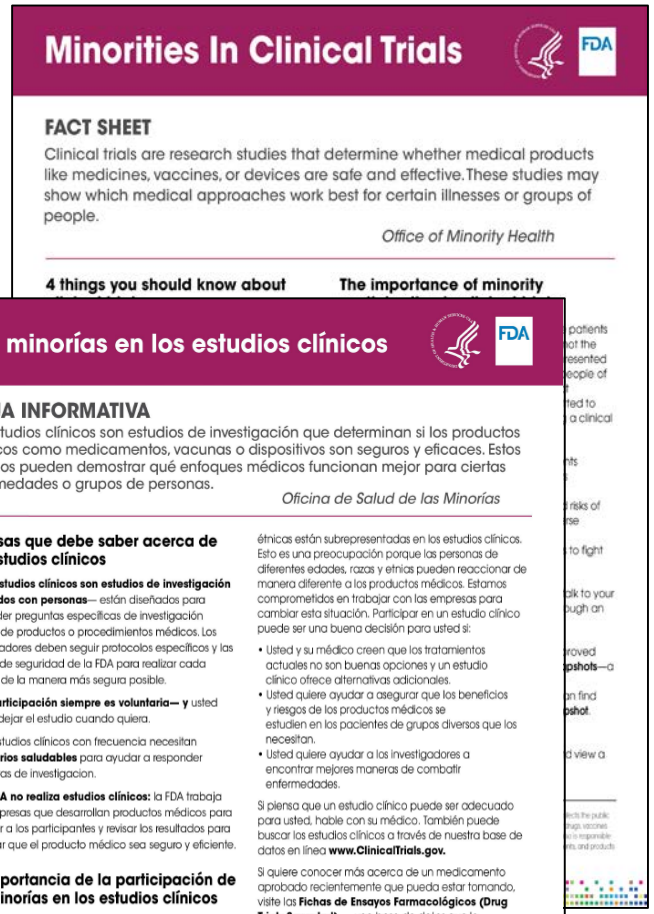
Latinos Can Make a Difference in Clinical Trials

Shirley's Story

Partnering for Health Equity: Veterans in Clinical Trials

Veterans Health Administration
Office of Health Equity

Diversity in Clinical Trials Resources



Minorities In Clinical Trials

FACT SHEET

Clinical trials are research studies that determine whether medical products like medicines, vaccines, or devices are safe and effective. These studies may show which medical approaches work best for certain illnesses or groups of people.

Office of Minority Health

4 things you should know about

The importance of minority

Las minorías en los estudios clínicos

HOJA INFORMATIVA

Los estudios clínicos son estudios de investigación que determinan si los productos médicos como medicamentos, vacunas o dispositivos son seguros y eficaces. Estos estudios pueden demostrar qué enfoques médicos funcionan mejor para ciertas enfermedades o grupos de personas.

Oficina de Salud de las Minorías

4 Cosas que debe saber acerca de los estudios clínicos

1. Los estudios clínicos son estudios de investigación realizados con personas— están diseñados para responder preguntas específicas de investigación acerca de productos o procedimientos médicos. Los investigadores deben seguir protocolos específicos y las pautas de seguridad de la FDA para realizar cada estudio de la manera más segura posible.

2. La participación siempre es voluntaria— y usted puede dejar el estudio cuando quiera.

3. Los estudios clínicos con frecuencia necesitan **voluntarios saludables** para ayudar a responder preguntas de investigacion.

4. La FDA no realiza estudios clínicos: la FDA trabaja con empresas que desarrollan productos médicos para proteger a los participantes y revisar los resultados para asegurar que el producto médico sea seguro y eficiente.

La importancia de la participación de las minorías en los estudios clínicos

Los participantes de estudios clínicos deben representar a los pacientes que utilizarán los productos médicos. Esto con frecuencia no es el caso-- las minorías raciales y étnicas están subrepresentadas en los estudios clínicos. Esto es una preocupación porque las personas de diferentes edades, razas y etnias pueden reaccionar de manera diferente a los productos médicos. Estamos comprometidos en trabajar con las empresas para cambiar esta situación. Participar en un estudio clínico puede ser una buena decisión para usted si:

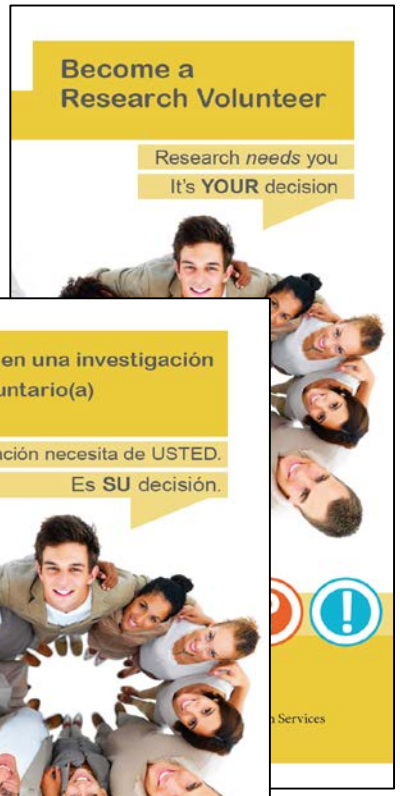
- Usted y su médico creen que los tratamientos actuales no son buenas opciones y un estudio clínico ofrece alternativas adicionales.
- Usted quiere ayudar a asegurar que los beneficios y riesgos de los productos médicos se estudien en los pacientes de grupos diversos que los necesitan.
- Usted quiere ayudar a los investigadores a encontrar mejores maneras de combatir enfermedades.

Si piensa que un estudio clínico puede ser adecuado para usted, hable con su médico. También puede buscar los estudios clínicos a través de nuestra base de datos en línea **www.ClinicalTrials.gov.**

Si quiere conocer más acerca de un medicamento aprobado recientemente que pueda estar tomando, visite las **Fichas de Ensayos Farmacológicos (Drug Trials Snapshot)** — una base de datos que le proporciona información sobre quiénes participaron en un estudio para la aprobación de medicamentos. Puede encontrar más información en **www.FDA.gov/DrugTrialsSnapshot**.

Para obtener más información sobre la salud de las minorías, vaya a www.fda.gov/minorityhealth. Para ver videos y ver una lista de preguntas para hacer a los investigadores, vaya a **www.hhs.gov/about-research-participation**.

La FDA es una agencia dentro del Departamento de Salud y Servicios Humanos de EE. UU., que protege la salud pública al asegurar la seguridad y eficacia de los medicamentos humanos y veterinarios, vacunas y otros productos biológicos para uso humano y dispositivos médicos. La agencia también es responsable de la seguridad y protección del suministro de alimentos, cosméticos, suplementos nutricionales y productos que emiten radiación electrónica y de la regulación de productos de tabaco de la nación.



Become a Research Volunteer

Research *needs* you

It's **YOUR** decision

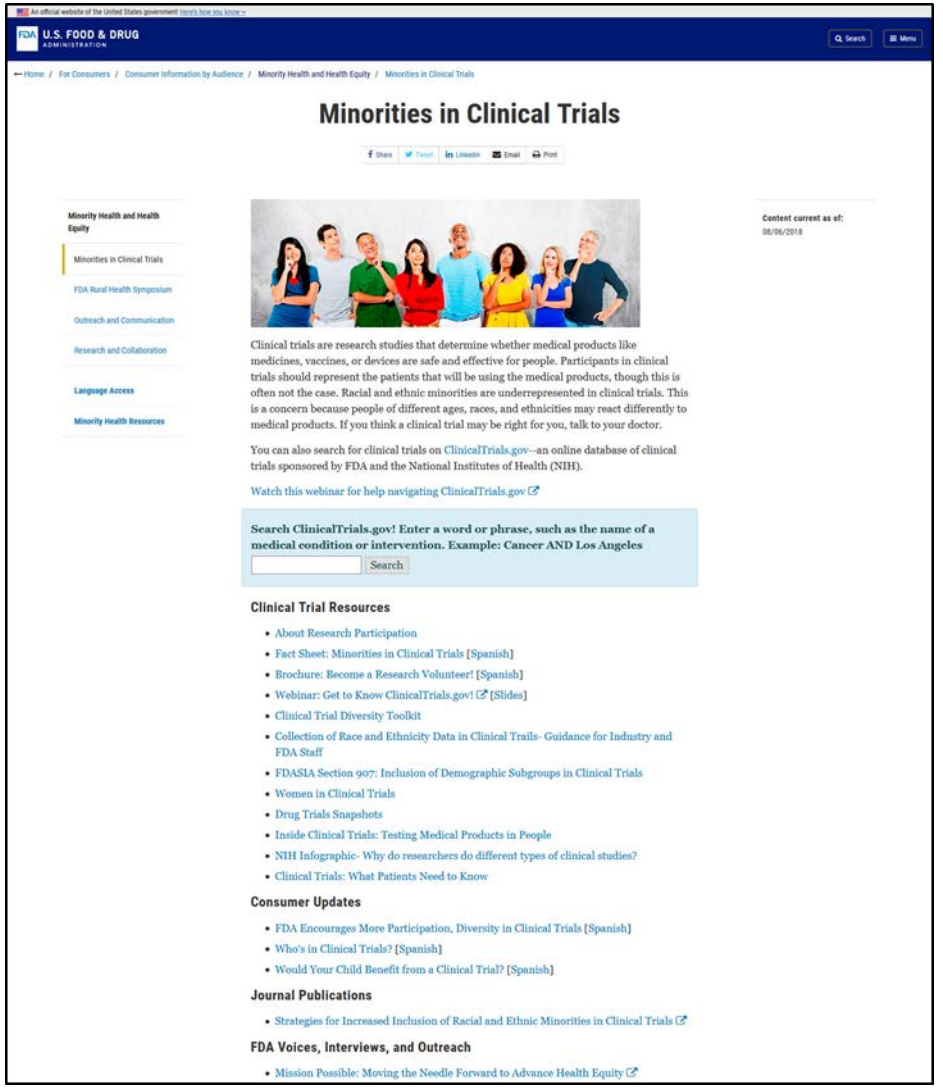
Participe en una investigación como voluntario(a)

La investigación necesita de USTED.

Es **SU** decisión.

FDA

Departamento de Salud y Servicios Humanos de los Estados Unidos
Administración de Alimentos y Medicamentos (FDA)
Oficina de Salud de la Minorías



U.S. FOOD & DRUG ADMINISTRATION

Home / For Consumers / Consumer Information by Audience / Minority Health and Health Equity / Minorities in Clinical Trials

Minorities in Clinical Trials

Minority Health and Health Equity

- Minorities in Clinical Trials
- FDA Rural Health Symposium
- Outreach and Communication
- Research and Collaboration
- Language Access
- Minority Health Resources

Content current as of: 08/06/2018

Clinical trials are research studies that determine whether medical products like medicines, vaccines, or devices are safe and effective for people. Participants in clinical trials should represent the patients that will be using the medical products, though this is often not the case. Racial and ethnic minorities are underrepresented in clinical trials. This is a concern because people of different ages, races, and ethnicities may react differently to medical products. If you think a clinical trial may be right for you, talk to your doctor.

You can also search for clinical trials on ClinicalTrials.gov--an online database of clinical trials sponsored by FDA and the National Institutes of Health (NIH).

Watch this webinar for help navigating ClinicalTrials.gov

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

Search

Clinical Trial Resources

- About Research Participation
- Fact Sheet: Minorities in Clinical Trials [Spanish]
- Brochure: Become a Research Volunteer! [Spanish]
- Webinar: Get to Know ClinicalTrials.gov! [Slides]
- Clinical Trial Diversity Toolkit
- Collection of Race and Ethnicity Data in Clinical Trails- Guidance for Industry and FDA Staff
- FDASIA Section 907: Inclusion of Demographic Subgroups in Clinical Trials
- Women in Clinical Trials
- Drug Trials Snapshots
- Inside Clinical Trials: Testing Medical Products in People
- NIH Infographic- Why do researchers do different types of clinical studies?
- Clinical Trials: What Patients Need to Know

Consumer Updates

- FDA Encourages More Participation, Diversity in Clinical Trials [Spanish]
- Who's in Clinical Trials? [Spanish]
- Would Your Child Benefit from a Clinical Trial? [Spanish]

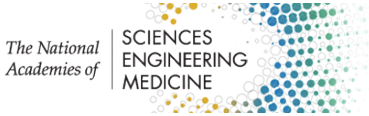
Journal Publications

- Strategies for Increased Inclusion of Racial and Ethnic Minorities in Clinical Trials

FDA Voices, Interviews, and Outreach

- Mission Possible: Moving the Needle Forward to Advance Health Equity

Our Health Equity Stakeholders



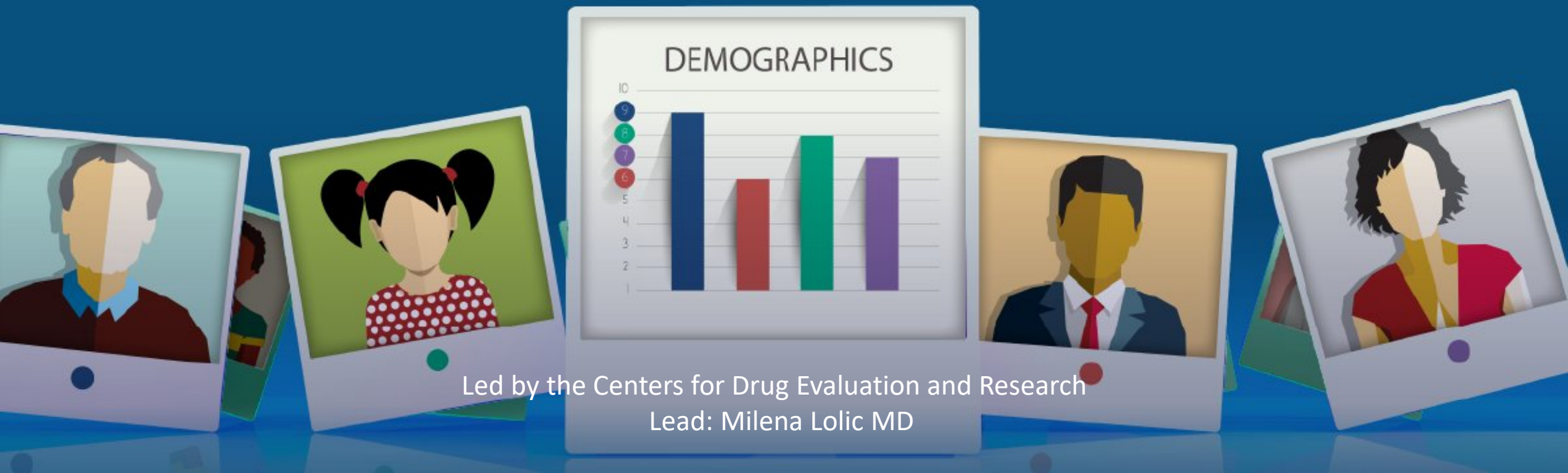
Take home message:
Ask patients to participate!

Priority III: Transparency

U.S. FOOD & DRUG ADMINISTRATION

DRUG TRIALS SNAPSHOTS

Learn who participated in clinical trials that supported FDA approval



Led by the Centers for Drug Evaluation and Research
Lead: Milena Lolic MD

DTS Summary Reports 2015-2019

	WOMEN	WHITE	ASIAN	BLACK or AA	HISPANIC	AGE 65 and OLDER	USA
2015	40%	79%	12%	5%	-	37%	28%
2016	48%	76%	11%	7%	-	21%	43%
2017	55%	77%	11%	7%	14%	32%	34%
2018	56%	69%	10%	11%	14%	15%	47%
2019	72%	72%	9%	9%	18%	36%	40%

** 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 report.*
https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots

Examples of Information Provided in FDA-Approved Product Labeling Directed at Specific Races/Ethnicities

Recommendation in FDA approved labeling	Example drug	Racial/ethnic information in the labeling	Rationale
Indicated for a specific racial population	Isosorbide dinitrate/ hydralazine	Indicated for self-identified blacks	Based on retrospective analyses, an effect on survival was reported in blacks, with little evidence to suggest an effect in the whites
Contraindicated in case of G6PD deficiency which is present in a higher frequency in specific racial populations	Rasburicase	Contraindicated in G6PD deficiency. Screen patients at a higher risk for G6PD deficiency (e.g., patients of African or Mediterranean ancestry) prior to starting therapy	Recommendations to screen patients at a higher risk for G6PD deficiency (e.g., patients of African or Mediterranean ancestry) prior to starting therapy because of the increased risk of hemolysis in patients with G6PD deficiency
Warnings and precautions directed at a specific racial population	Carbamazepine	Boxed warning for *HLA-B*1502* in Asian patients	Incidence of adverse event and prevalence of genetic factor are higher in Asian populations
Recommendations for considering alternative therapy for a specific racial population	ACE inhibitors or Angiotensin II antagonists, e.g., candesartan and losartan	A general statement for African-Americans/blacks in the labeling of a number of drugs belonging to this class because of the smaller effect size observed	Pathophysiologically, hypertension is driven less by the renin-angiotensin-aldosterone system in African-Americans/blacks
Different dosing recommendation for a specific racial population	Rosuvastatin	Lower initial starting dose in Asians	Based on clinical observation of ~2-fold higher exposure in Asians compared to Caucasians
	Tacrolimus	Higher dose in African-American transplant patients	Based on clinical observation; metabolized by CYP3A5 and African-American/black populations have low prevalence of reduced function variants compared to Caucasians

G6PD: glucose-6-phosphate dehydrogenase; HLA-B: human leukocyte antigen B; ACE: angiotensin-converting enzyme; CYP3A5: Cytochrome P450 3A5.

Ramamoorthy A, et al. Racial/ethnic differences in drug disposition and response: review of recently approved drugs. Clin Pharmacol Ther 2015;97:263–273.

Call To Action

U.S. FOOD & DRUG ADMINISTRATION

FDA Office of Minority Health and Health Equity

January 6, 2020

FDA OMHHE is Seeking Public Feedback on Strategic Priorities

The Food and Drug Administration (FDA or the Agency) is opening a public docket to solicit input and comments from interested stakeholders, including racial and ethnic minority, underrepresented, and underserved populations in establishing strategic priorities for the Office of Minority Health and Health Equity (OMHHE). This will help the Agency ensure that important health concerns are carefully considered in establishing priorities.

We encourage interested stakeholders to submit comments on the areas and types of engagement FDA's OMHHE should prioritize in the coming year(s), and potential mechanisms that can be used to implement them (e.g., through collaborations and partnerships).

Submit either electronic or written comments by February 28, 2020. You can find more information, and submit your comments, on the Federal Register website.

Visit the FDA OMHHE website and follow us on Twitter at

@FDAHealthEquity

"Creating a world where health equity is a reality for all."

www.fda.gov/HealthEquity

- **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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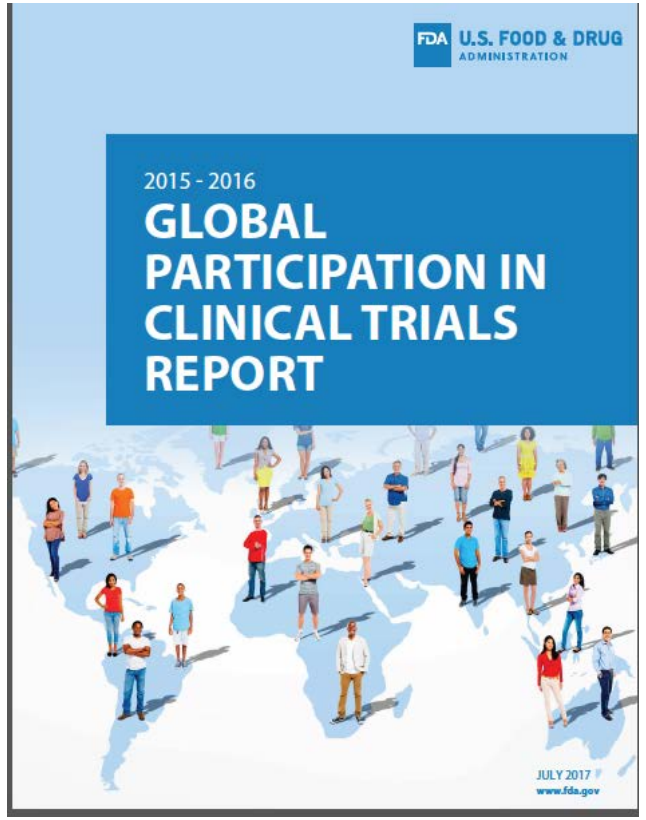
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REPORT
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www.fda.gov

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healthequity@fda.hhs.gov

www.fda.gov/healthequity

Join webinars and stakeholder calls


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