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.
<table>
<thead>
<tr>
<th>Research and Collaboration</th>
<th>Outreach and Communication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intramural Research</td>
<td>Programs/Initiatives/Campaigns</td>
</tr>
<tr>
<td>Extramural Research</td>
<td>- Language Access Program</td>
</tr>
<tr>
<td>Participate in FDA Centers of Excellence in Regulatory Science and Innovation (CERSI) Projects</td>
<td>- Diversity in Clinical Trials Initiative</td>
</tr>
<tr>
<td>Summer Science Teacher Training Program</td>
<td>- Health Education Materials</td>
</tr>
<tr>
<td>Pharmacy Internships</td>
<td>- FDA Spokesperson; Speaking Engagements</td>
</tr>
<tr>
<td>Academic Collaborations/Fellowships</td>
<td>- Social Media</td>
</tr>
<tr>
<td>Congressional Mandates</td>
<td>- Newsletter &amp; E-alerts</td>
</tr>
<tr>
<td>FDA &amp; HHS Working Groups &amp; Collaborations</td>
<td>- Website</td>
</tr>
<tr>
<td>Stakeholder Input into Research Agenda</td>
<td>- Lecture Series, Webinars, Podcasts</td>
</tr>
<tr>
<td>Guidance Documents</td>
<td>- FDA &amp; HHS Working Groups</td>
</tr>
<tr>
<td></td>
<td>- Stakeholder Meetings/Symposiums/Exhibits</td>
</tr>
<tr>
<td></td>
<td>- Foster collaboration between FDA &amp; stakeholders</td>
</tr>
</tbody>
</table>
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
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

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

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

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

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

By Erin Schumaker
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 underrepresented 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:
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*)

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

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

- **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

- **Public Meetings**
  - Tools to support diverse clinical trial participation

- **Drug Trials Snapshot**
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.
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
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

BE A #CLINICALTRIALSCHAMPION

www.fda.gov/healthequity
Latinos Can Make a Difference in Clinical Trials

www.fda.gov/healthequity
Shirley’s Story

Shirley’s Story: How to Find Information about Clinical Trials

Shirley’s Story: You Don’t Have to be Sick to Participate

Shirley’s Story: Getting Access to Cutting Edge Therapies

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

www.fda.gov/healthequity
Partnering for Health Equity: Veterans in Clinical Trials

Zulma Santiago
Command Sergeant Major (US Army Ret.)

Quinyardo McClain
Staff Sergeant (US Army Ret.)

www.fda.gov/healthequity
Diversity in Clinical Trials Resources

Las minorías en los estudios clínicos

La investigación necesita de Usted.

Es SU decisión.

Participe en una investigación como voluntario(a)

Minorities in Clinical Trials

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 participation in Clinical Trials

1. The studies are open to all individuals with a specific condition, regardless of race or ethnicity.

2. The results are shared with everyone, regardless of race or ethnicity.

3. The research community values diversity and inclusion.

4. The FDA requires that studies include participants from diverse backgrounds.

Minorities in Clinical Trials

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 participation in Clinical Trials

1. The studies are open to all individuals with a specific condition, regardless of race or ethnicity.

2. The results are shared with everyone, regardless of race or ethnicity.

3. The research community values diversity and inclusion.

4. The FDA requires that studies include participants from diverse backgrounds.

Minorities in Clinical Trials

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 participation in Clinical Trials

1. The studies are open to all individuals with a specific condition, regardless of race or ethnicity.

2. The results are shared with everyone, regardless of race or ethnicity.

3. The research community values diversity and inclusion.

4. The FDA requires that studies include participants from diverse backgrounds.

Minorities in Clinical Trials

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 participation in Clinical Trials

1. The studies are open to all individuals with a specific condition, regardless of race or ethnicity.

2. The results are shared with everyone, regardless of race or ethnicity.

3. The research community values diversity and inclusion.

4. The FDA requires that studies include participants from diverse backgrounds.

Minorities in Clinical Trials

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 participation in Clinical Trials

1. The studies are open to all individuals with a specific condition, regardless of race or ethnicity.

2. The results are shared with everyone, regardless of race or ethnicity.

3. The research community values diversity and inclusion.

4. The FDA requires that studies include participants from diverse backgrounds.

Minorities in Clinical Trials

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 participation in Clinical Trials

1. The studies are open to all individuals with a specific condition, regardless of race or ethnicity.

2. The results are shared with everyone, regardless of race or ethnicity.

3. The research community values diversity and inclusion.

4. The FDA requires that studies include participants from diverse backgrounds.

Minorities in Clinical Trials

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 participation in Clinical Trials

1. The studies are open to all individuals with a specific condition, regardless of race or ethnicity.

2. The results are shared with everyone, regardless of race or ethnicity.

3. The research community values diversity and inclusion.

4. The FDA requires that studies include participants from diverse backgrounds.

Minorities in Clinical Trials

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 participation in Clinical Trials

1. The studies are open to all individuals with a specific condition, regardless of race or ethnicity.

2. The results are shared with everyone, regardless of race or ethnicity.

3. The research community values diversity and inclusion.

4. The FDA requires that studies include participants from diverse backgrounds.

Minorities in Clinical Trials

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 participation in Clinical Trials

1. The studies are open to all individuals with a specific condition, regardless of race or ethnicity.

2. The results are shared with everyone, regardless of race or ethnicity.

3. The research community values diversity and inclusion.

4. The FDA requires that studies include participants from diverse backgrounds.

Minorities in Clinical Trials

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 participation in Clinical Trials

1. The studies are open to all individuals with a specific condition, regardless of race or ethnicity.

2. The results are shared with everyone, regardless of race or ethnicity.

3. The research community values diversity and inclusion.

4. The FDA requires that studies include participants from diverse backgrounds.

Minorities in Clinical Trials

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 participation in Clinical Trials

1. The studies are open to all individuals with a specific condition, regardless of race or ethnicity.

2. The results are shared with everyone, regardless of race or ethnicity.

3. The research community values diversity and inclusion.

4. The FDA requires that studies include participants from diverse backgrounds.

Minorities in Clinical Trials

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 participation in Clinical Trials

1. The studies are open to all individuals with a specific condition, regardless of race or ethnicity.

2. The results are shared with everyone, regardless of race or ethnicity.

3. The research community values diversity and inclusion.

4. The FDA requires that studies include participants from diverse backgrounds.

Minorities in Clinical Trials

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.
Our Health Equity Stakeholders
Take home message:
Ask patients to participate!
Priority III: Transparency

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

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

* 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.

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

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

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

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
Connect with OMHHE

Follow us on twitter @FDAHealthEquity

healthequity@fda.hhs.gov

www.fda.gov/healthequity

Join webinars and stakeholder calls