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.

www.fda.gov/minorityhealth
## 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/Symposia/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

[www.fda.gov/minorityhealth](http://www.fda.gov/minorityhealth)
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 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 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)**

**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
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.

[Image: Collection of Race and Ethnicity Data in Clinical Trials]

For questions about this document, contact the FDA Office of Minority Health at 240-402-8084 or cmhc@fda.hhs.gov.
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...

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

AAMC NEWS

DIVERSITY & INCLUSION

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

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

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

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

March 15, 2011

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. 10, 5 a.m. EDT

This story was co-published with Wix.

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

Lack of Diversity in Clinical Trials Hurts Patients and Drug Development
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
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)**

<table>
<thead>
<tr>
<th></th>
<th>WOMEN</th>
<th>BLACK or AFRICAN AMERICAN</th>
<th>ASIAN</th>
<th>WHITE</th>
<th>OTHER*</th>
<th>AGE 65 AND OLDER</th>
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<td>2016</td>
<td>48%</td>
<td>7%</td>
<td>11%</td>
<td>76%</td>
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<tr>
<td>2017</td>
<td>55%</td>
<td>7%</td>
<td>11%</td>
<td>77%</td>
<td>14%</td>
<td>32%</td>
</tr>
<tr>
<td>2018</td>
<td>56%</td>
<td>11%</td>
<td>10%</td>
<td>69%</td>
<td>14%</td>
<td>15%</td>
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</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 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

BE A #CLINICALTRIALSCHAMPION

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

www.fda.gov/minorityhealth
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

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 participation in clinical trials.

1. Clinical trials need people from different backgrounds to help make sure drugs and medical products are safe and effective for everyone.
2. Participating in a clinical trial may provide treatment options not available through routine medical care.
3. Participating in a clinical trial provides valuable research information that may lead to improved treatments for others.
4. Participating in a clinical trial can be an important way to help improve health care for future generations.

Become a Research Volunteer

Research needs you. It's your decision.

Participate in a Research Study

La investigación necesita de USTED. Es su decisión.

Research Participation Resources

- About Research Participation
- Fact Sheet: Minorities in Clinical Trials (Spanish)
- Brochure: Become a Research Volunteer (Spanish)
- Webinar: Clinical Trials: Clinical Trials for Kids (Spanish)
- Clinical Trial Diversity Toolkit
- Collections of Rare and Minority-Diverse Clinical Trials: Databases for Industry and High Staff
- Inclusion 2020: Frontiers of Diversity and Inclusion in Clinical Trials
- Women in Clinical Trials
- Drug Trials Open
- Underserved Clinical Trials: Testing Medical Products in People
- NIH Toolbox: Why do researchers do different types of clinical studies?
- Clinical Trials: What Patients Need to Know

Consumer Updates

- NIH News about Clinical Trials Diversity
- What is a Clinical Trial? (Spanish)
- Would Your Child Benefit from a Clinical Trial? (Spanish)

Journals and Publications

- Magazines and Periodicals of Social and Ethical Minorities in Clinical Trials
- FDA Views, Interviews, and Outreach
- Minority Outreach: Moving the Needle Forward to Advance Health Equity

For more information please visit the following websites:

- www.fda.gov/clinicaltrials
- www.clinicaltrials.gov
- www.clinicalresearchhospitalpartnershipfoundation.org
- www.fda.gov/drugtrialsopen
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
Asian Americans and Hepatitis B

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.

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: see 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
• Intramuscular (IM) (intravenous administration): Patients with chronic hepatitis B 1 year of age or older with compensated liver disease.
• Nucleic acid (NAR): Patients with chronic hepatitis B aged 12 years or older.

For Adults
• Intramuscular (IM) (intravenous administration): Patients with chronic hepatitis B.
• Nucleic acid (NAR): Patients with chronic hepatitis B with compensated liver disease.
• Entecavir (entecavir): Patients with chronic hepatitis B with evidence of active viral replication.
• ETV (etavir): Patients with chronic hepatitis B with evidence of active viral replication.
• Pegente (peginterferon): Patients with hepatitis B with evidence of viral replication and liver inflammation.

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

Additional Resources
For more information on hepatitis B, visit FDA's Hepatitis B Resources page at www.fda.gov/minorityhealth
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

www.fda.gov/minorityhealth
Connect With Us

Follow us on twitter @FDAOMH

OMH@fda.hhs.gov

www.fda.gov/minorityhealth

Join webinars and stakeholder calls
• Additional slides
## Minorities and Clinical Trials

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<th></th>
<th>US Population</th>
<th>Clinical Trial Participation</th>
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<tbody>
<tr>
<td>African-Americans</td>
<td>12%</td>
<td>5%</td>
</tr>
<tr>
<td>Hispanics</td>
<td>17%</td>
<td>1%</td>
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Note: NIH clinical trials have 30% minority representation overall