Thanks to our speaker!

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- Senior Public Health Advisor at the U.S. Food and Drug Administration (FDA)
- Lead for the Outreach and Communications Team in the Office of Minority Health & Health Equity
- Has a deep passion for improving health equity across the lifespan through research, communication, multi-sector partnerships, and leadership coaching
Minorities and Clinical Trials: Why it Matters?
Jovonni R. Spinner, MPH, CHES
Senior Public Health Advisor
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 & HEALTH EQUITY (OMHHE)
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 (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

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

www.fda.gov/minorityhealth
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
Diabetes and Kidney Health

• Diabetes and kidney disease adversely impacts minorities
  – Racial and ethnic minorities have higher prevalence of end stage renal disease compared to non-Hispanic whites.
    – African-Americans/Blacks: 3.4X higher
    – American Indians/Native Americans: 2.7X higher
    – Hispanics: 2.6X higher

Source: [https://www.niddk.nih.gov/health-information/kidney-disease](https://www.niddk.nih.gov/health-information/kidney-disease)
[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3983362/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3983362/)
Kidney Related Activities

• Featured on “Healthy Moments” Radio Broadcast
  – Automatic insulin dosing devices
  – Diabetes management
  – Medication and device approvals
• Diabetes Town Hall Meeting
• Health Education Materials
• Social Media Outreach
• Kidney Health Initiative (FDA & ASN)
• Patient Engagement
Sample of Kidney Related Publications (2017-2019)

- Nanomaterials 2017 Dec 15;7(12):451
  Wu M, Sun D, Tyner K, Jiang W, Rouse R

- Clin Pharmacol Ther 2017 Sep;102(3):436-49
  The role of the kidney in drug elimination: transport, metabolism and the impact of kidney disease on drug clearance.
  Miners JO, Yang X, Knights KM, Zhang L

  Effect of chronic kidney disease on nonrenal elimination pathways: a systematic assessment of CYP1A2, CYP2C8, CYP2C9, CYP2C19, and OATP.

- Kidney Int 2018 Dec;94(6):1053-68
  Implementing core outcomes in kidney disease: report of the Standardized Outcomes in Nephrology (SONG) implementation workshop.

- Environ Res 2018 Oct 22;169:72-8
  Global burden of late-stage chronic kidney disease resulting from dietary exposure to cadmium, 2015.
  Zang Y, Devleesschauwer B, Bolger PM, Goodman E, Gibb HJ

  Use of physiologically-based pharmacokinetic (PBPK) modeling to evaluate the effect of chronic kidney disease on the disposition of hepatic CYP2C8 and OATP1B drug substrates.
  Tan ML, Zhao P, Zhang L, Ho YF, Varma MVS, Neuhoff S, Nolin TD, Galetin A, Huang SM

  Cardiovascular outcome trials in patients with chronic kidney disease: challenges associated with selection of patients and endpoints.

Source: https://www.accessdata.fda.gov/scripts/publications/
RESEARCH AND COLLABORATION PROGRAM
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
Research and Collaboration Program

Key Activities:
• Extramural Research
• Intramural Research
• Training and Fellowships
• FDA & HHS health disparities working groups
• Policy/Guidance Documents
Extramural Research Program: Centers of Excellence in Regulatory Science & Innovation (CERSIs)

- Research Projects:
  - Safer Labeling of Pediatric Medication (Stanford)
  - The Impact of Race and Ethnicity on Responses to Heart Failure Patient-Reported Outcome Measures (UCSF)

- Workshops:
  - Assessing and Communicating Heterogeneity of Treatment Effects for Patient Subpopulations (Johns Hopkins; Nov 2018)

- Visiting Scientist Program:
  - Mayo Clinic Lecture: FDA Perspective on Clinical Trial Inclusion - Challenges and Opportunities

www.fda.gov/minorityhealth
OMHHE Fellowships and Training

- FDA Pharmacy Experiential Program
- NCTR Summer Student Research Program
- CFSAN Teachers Academy in Food Science (collaboration with National Science Teachers Association)
OMHHE Intramural Research Program: Office of the Chief Scientist Challenge Grants

• Alzheimer’s Disease in African Americans and Caucasians: Comparisons of Biomarkers of Inflammation in Human Tissues; PI: Sherry Ferguson, NCTR

• Molecular Characterization of Racial Disparities and Outcome in Multiple Myeloma; PI: Dickran Kazandjian, CDER

• An Examination of Advertising and Promotional Labeling in Adult Immunization Disparities; PI: Oluchi Elekwachi, CDER

• Rapid Message Testing with Consumer Panels; PI: Brian Lappin, OC

• Structuring Stakeholder Data into Meaningful Information and Analyzable Datasets; PI: Christine Lee, CDER

• Interactions Between Hepatitis B Vaccines and Hepatitis B Immune Globulin; PI: Marian Major, CBER

• Testing Near-infrared Tissue Oximeters Sensitivity to Melanin for Disparities in Performance; PI: Joshua Pfefer, CDRH
OUTREACH AND COMMUNICATION PROGRAM
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
# Outreach and Communication Program

## Activities & Implementation Strategies

### Programs/Initiatives/Campaigns
- Language Access Program
- Diversity in Clinical Trials Initiative
- Multi-Lingual Dietary Supplements/Health Fraud Campaign
- ORA/PAS Outreach and Internship Program
- #ilovemyheart Social Media Campaign

### Materials Development
- Fact sheets
- Blogs
- Infographics
- Post Cards
- Brochures
- PSAs
- Podcasts

### Outreach
- FDA Spokesperson/Speaking Engagements
- Social Media
- Newsletter & E-alerts
- Website
- Webinars
- OMH Health Equity Lecture Series
- Coordinate HHS Reports
- FDA & HHS Working Groups
- Trainings
- Building relationships with external organizations
Language Access Program (LAP)

• 65 million Americans speak a language other than English at home

• FDASIA Section 1138 and Executive Order 13166

• Program goals:
  – provide access to translation services
  – offer easy to read materials in other languages
  – oversee volunteer’s program

www.fda.gov/minorityhealth
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)*

**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
REPRESENTATION IN CLINICAL TRIALS
Clinical Trials Have Far Too Little Racial and Ethnic Diversity

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

AAMC NEWS

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

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

Healthy Living

Most Clinical Trials Have A Glaring Flaw Before They Even Begin

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

Black Patients Miss Out On Promising Cancer Drugs

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

We Need to Talk About Race: Lack of Diversity in Clinical Trials is a Public Health Issue
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 (e.g., cancer treatment, heart failure medications).
- To understand health disparities—diseases that occur more frequently or appear differently in diverse populations.
Examples of 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>Pathophysiological, 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></td>
<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>
</tr>
</tbody>
</table>

G6PD: glucose-6-phosphate dehydrogenase; HLA: human leukocyte antigen B; ACE: angiotensin-converting enzyme; CYP3A5: Cytochrome P450 3A5.
## Snapshots in Diabetes 2015-2017

<table>
<thead>
<tr>
<th>BRAND NAME</th>
<th>INDICATION</th>
<th>WOMEN</th>
<th>AFRICAN AMERICAN/BLACK</th>
<th>WHITE</th>
<th>ASIAN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adlyxin (2016)</td>
<td>Improvement of blood sugar control in adults with diabetes mellitus (DM) type 2 when used in addition to diet and exercise.</td>
<td>52%</td>
<td>2%</td>
<td>64%</td>
<td>32%</td>
</tr>
<tr>
<td>Ozempic (2017)</td>
<td>Improvement of blood sugar control in adults with type 2 diabetes mellitus (DM) when used in addition to diet and exercise.</td>
<td>43%</td>
<td>6%</td>
<td>60%</td>
<td>31%</td>
</tr>
<tr>
<td>Ryzodeg (2015)</td>
<td>Improves blood sugar control in adults with diabetes mellitus (DM)</td>
<td>46%</td>
<td>4%</td>
<td>47%</td>
<td>48%</td>
</tr>
<tr>
<td>Steglatro (2017)</td>
<td>Improvement of blood sugar control in adults with type 2 diabetes when used in addition to diet and exercise.</td>
<td>48%</td>
<td>5%</td>
<td>77%</td>
<td>13%</td>
</tr>
<tr>
<td>Tresiba (2015)</td>
<td>Improve glucose control in adults with diabetes mellitus</td>
<td>44%</td>
<td>7%</td>
<td>70%</td>
<td>21%</td>
</tr>
</tbody>
</table>

Reasons for Decreased Participation

- Mistrust and distrust of the medical system due to historical abuses
- Inadequate recruitment and retention efforts
- Misunderstanding of minorities’ beliefs and values that contribute to their decision making process
- Perception that minorities are ineligible for enrollment
- Perception that minorities do not want to participate
- Lack of awareness on the patient’s part
- Privacy concerns
- Return of Results
- Physicians may not talk to their patients about clinical trials
- Language barriers
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 your doctor about joining a clinical trial!
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

www.fda.gov/minorityhealth
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.

www.fda.gov/minorityhealth
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

www.fda.gov/minorityhealth
Shirley’s Story: How to Find Information about Clinical Trials
Shirley’s Story

Shirley’s Story: Getting Access to Cutting Edge Therapies
Shirley’s Story

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

Shirley’s Story: Diversity is Critical to Making Better Medical Products
Latinos Can Make a Difference in Clinical Trials
Partnering for Health Equity: Veterans in Clinical Trials

Hi, My name is Quinyardo McClain
Staff Sergeant (US Army Ret.)

Hi, My name is Zulma Santiago Ortiz
Command Sergeant Major (US Army Ret.)
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, aging adults, translate into other languages
FDA OMHHE Resources

Health Equity for All
FDA OMHHE Clinical Trials Resources

Minorities In Clinical Trials

FACT SHEET
Clinical trials are research studies that determine whether medical products or medical devices are safe and effective. These studies may also determine the best way to use these products and devices.

Become a Research Volunteer
Research needs you. It’s YOUR decision

Participate in a research study.

La investigación necesita de USTED. Es SU decisión

Minorities in Clinical Trials

www.fda.gov/minorityhealth
FDA OMHHE Clinical Trials Resources

Hi, My name is Zulma Santiago
Command Sergeant Major (US Army Ret.)

Hi, My name is Quinyardo McClain
Staff Sergeant (US Army Ret.)
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 @FDAHealthEquity

OMH@fda.hhs.gov

www.fda.gov/healthequity

Join webinars and stakeholder calls
Questions?
Join us for our next webinar!

Kidney Chat: Ask a Social Worker
Wednesday, October 23, 2019 from 2:00 – 3:00 p.m. EDT

Join us to hear more about:
• The role of a social worker
• Financial support when you have kidney disease
• Emotional support when you have kidney disease
• Other resources for people with kidney disease

Go to www.KidneyFund.org/webinars to learn more and register!

Kathy Merritt, LCSW