American Kidney Fund®

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

Office of Minority Health and Health Equity

U.S. FOOD & DRUG ADMINISTRATION

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)

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

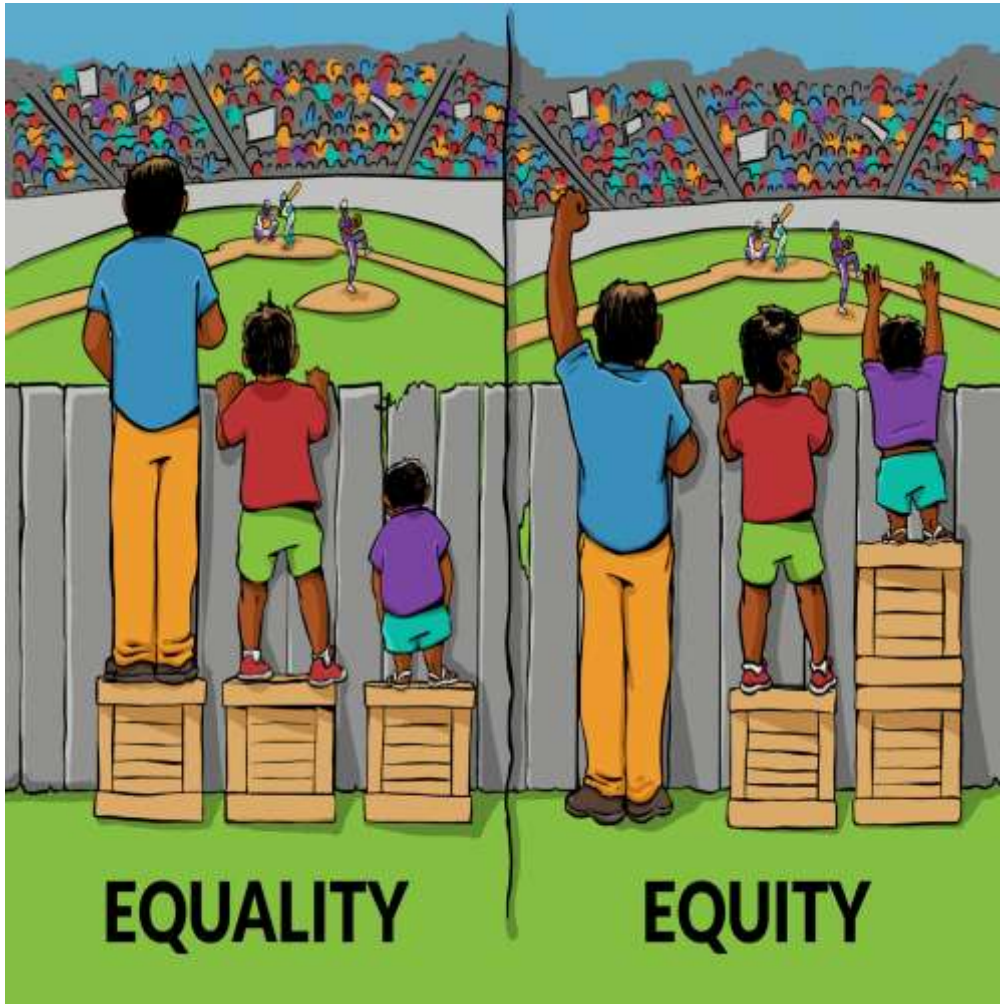
FDA Office of Minority Health and Health Equity (OMHHE)

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

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.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
  Comparative evaluation of U.S. brand and generic intravenous sodium ferric gluconate complex in sucrose injection: in vitro cellular uptake.
  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

- Clin Pharmacol Ther 2018 May;103(5):854-67
  Effect of chronic kidney disease on nonrenal elimination pathways: a systematic assessment of CYP1A2, CYP2C8, CYP2C9, CYP2C19, and OATP.
  Tan ML, Yoshida K, Zhao P, Zhang L, Nolin TD, Piquette-Miller M, Galetin A, Huang SM

- Kidney Int 2018 Dec;94(6):1053-68
  Implementing core outcomes in kidney disease: report of the Standardized Outcomes in Nephrology (SONG) implementation workshop.
  Tong A, Manns B, Wang AYM, Hemmelgarn B, Wheeler DC, Gill J, Tugwell P, Pecoits-Filho R, Crowe S, Harris T, Van Biesen W, Winkelmayer WC, Levin A, Thompson A, Perkovic V, Ju A, Gutman T, Bernier-Jean A, Viecelli AK, O'Lone E, Shen J, Josephson MA, Cho Y, Johnson DW, Sautenet B, Tonelli M, Craig JC, SONG Implementation Workshop Investigators

- 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

- Clin Pharmacol Ther 2019 Mar;105(3):719-29
  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

- Eur Heart J 2019 Mar 14;40(11):880-6
  Cardiovascular outcome trials in patients with chronic kidney disease: challenges associated with selection of patients and endpoints.
  Rossignol P, Agarwal R, Canaud B, Charney A, Chatellier G, Craig JC, Cushman WC, Gansevoort RT, Fellstrom B, Garza D, Guzman N, Holtkamp FA, London GM, Massy ZA, Mebazaa A, Mol PGM, Pfeffer MA, Rosenberg Y, Ruilope LM, Seltzer J, Shah AM, Shah S, Singh B, Stefansson BV, Stockbridge N, Stough WG, Thygesen K, Walsh M, Wanner C, Warnock DG, Wilcox CS, Wittes J, Pitt B, Thompson A, Zannad F

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

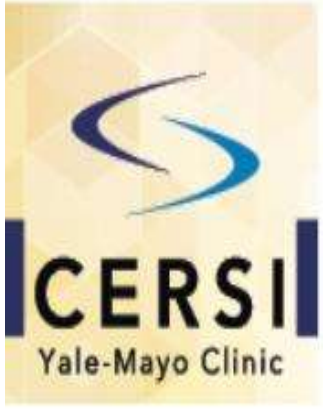
Research and Collaboration Program

Key Activities:

- Extramural Research
- Intramural Research
- Training and Fellowships
- FDA & HHS health disparities working groups
- Policy/Guidance Documents

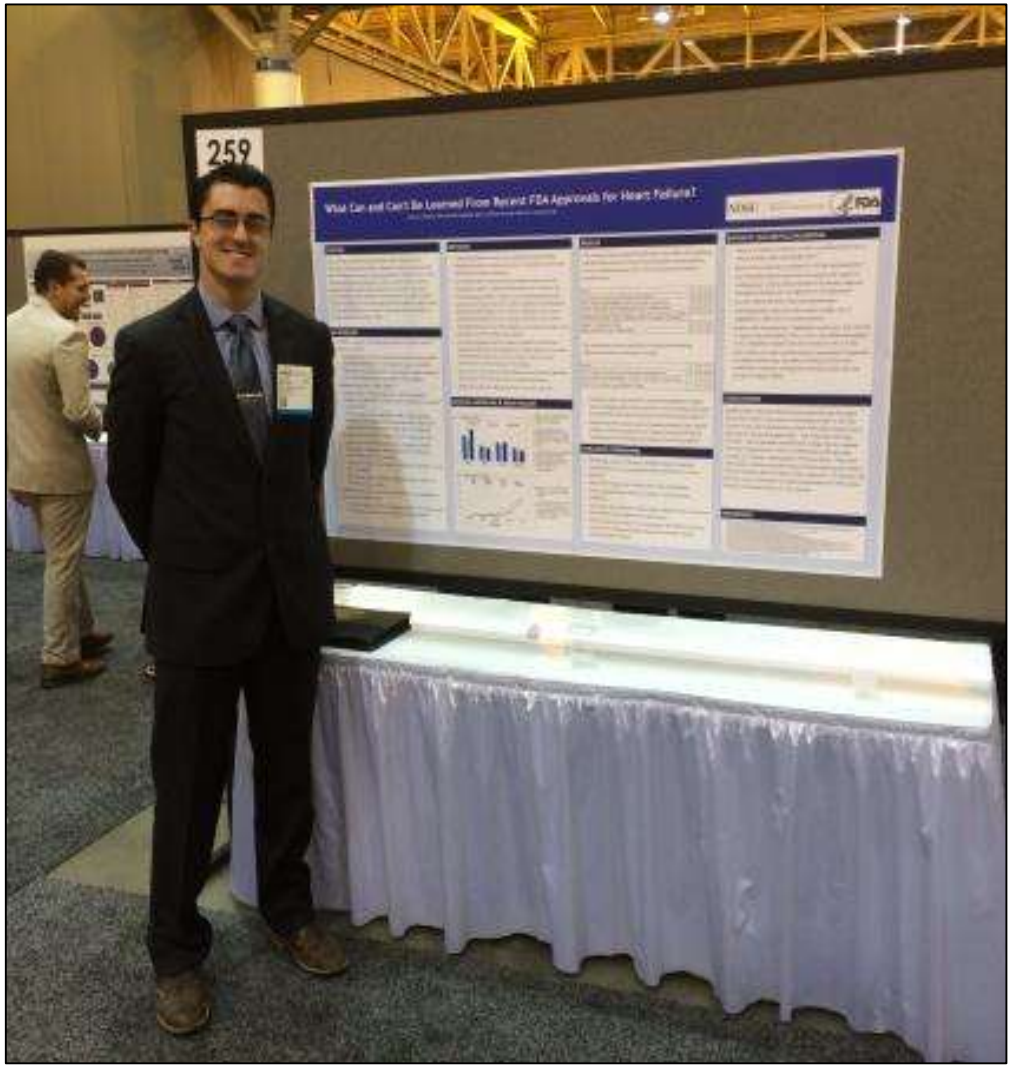
Extramural Research Program: Centers of Excellence in Regulatory Science & Innovation (CERSIs)

- 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



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

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**)

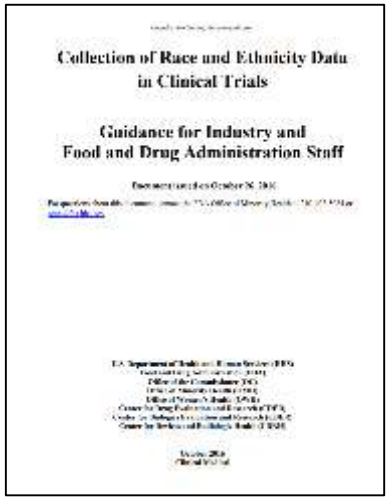
Drug Trials Snapshot

Guidance Documents for Industry

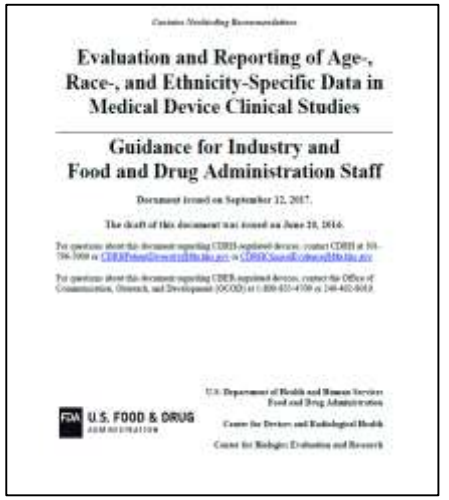
- FDA expectations are that sponsors enroll participants who **reflect the demographics for clinically relevant populations** with regard to age, gender, race, and ethnicity

- **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



2016



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

REPRESENTATION IN CLINICAL TRIALS

What's Being Said…


SCIENTIFIC AMERICAN.

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 ABOUT MISSIONS ADVOCACY DATA

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

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


Clinical Trials ARENA

Addressing the key challenges in the global clinical trial space

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

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

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CLINICAL TRIALS MULTIPLE MYELOMA

Lack of Diversity in Clinical Trials Hurts Patients and Drug Development

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.

Examples of 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.

Snapshots in Diabetes 2015-2017

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

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

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:
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 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

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

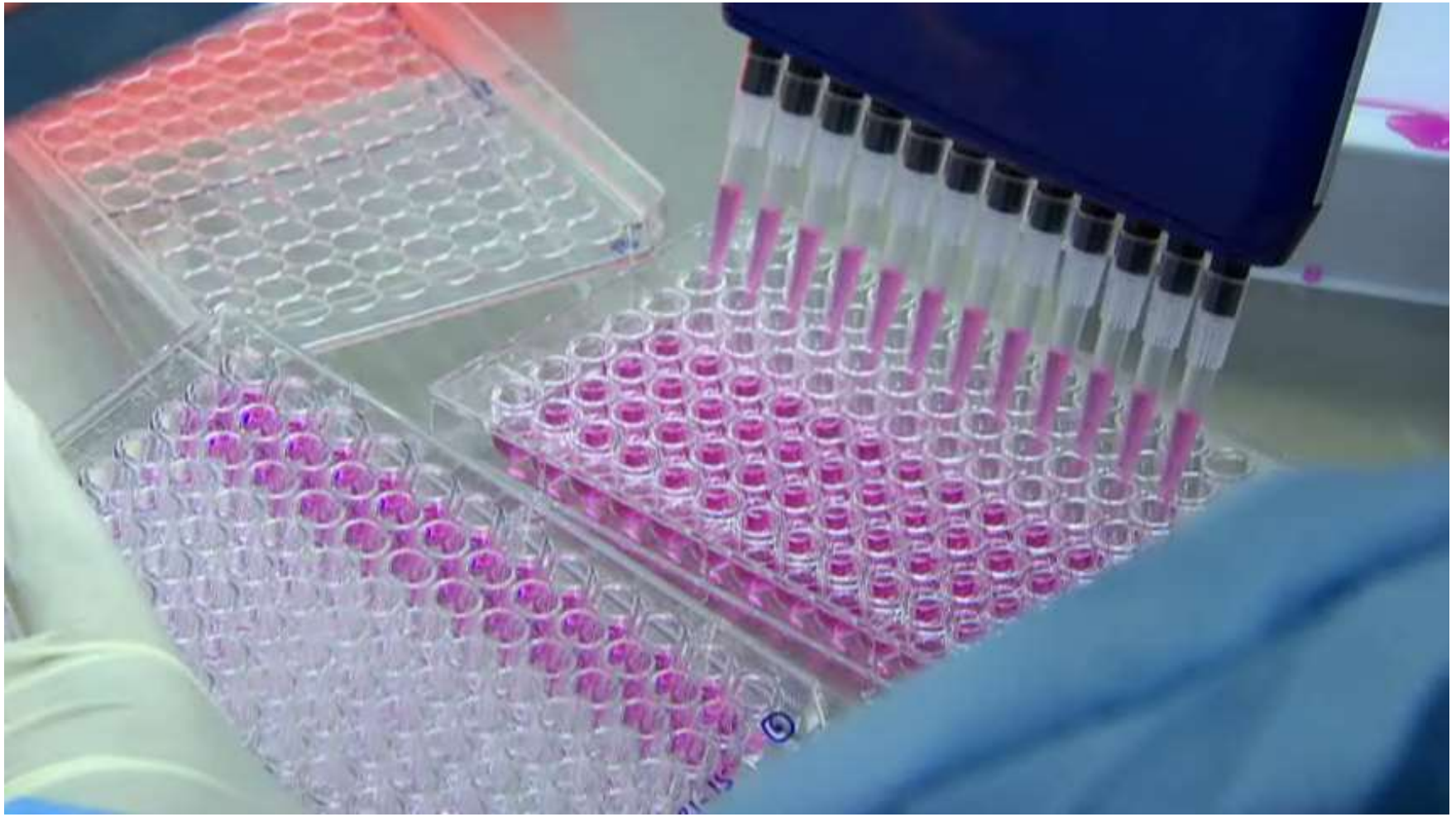
- Videos
- Newsletters & E-alerts
- Webpage
- Stakeholder Collaboration
- Podcasts
- Social Media
- Communications Toolkit
- Graphics

www.fda.gov/minorityhealth

Shirley's Story

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

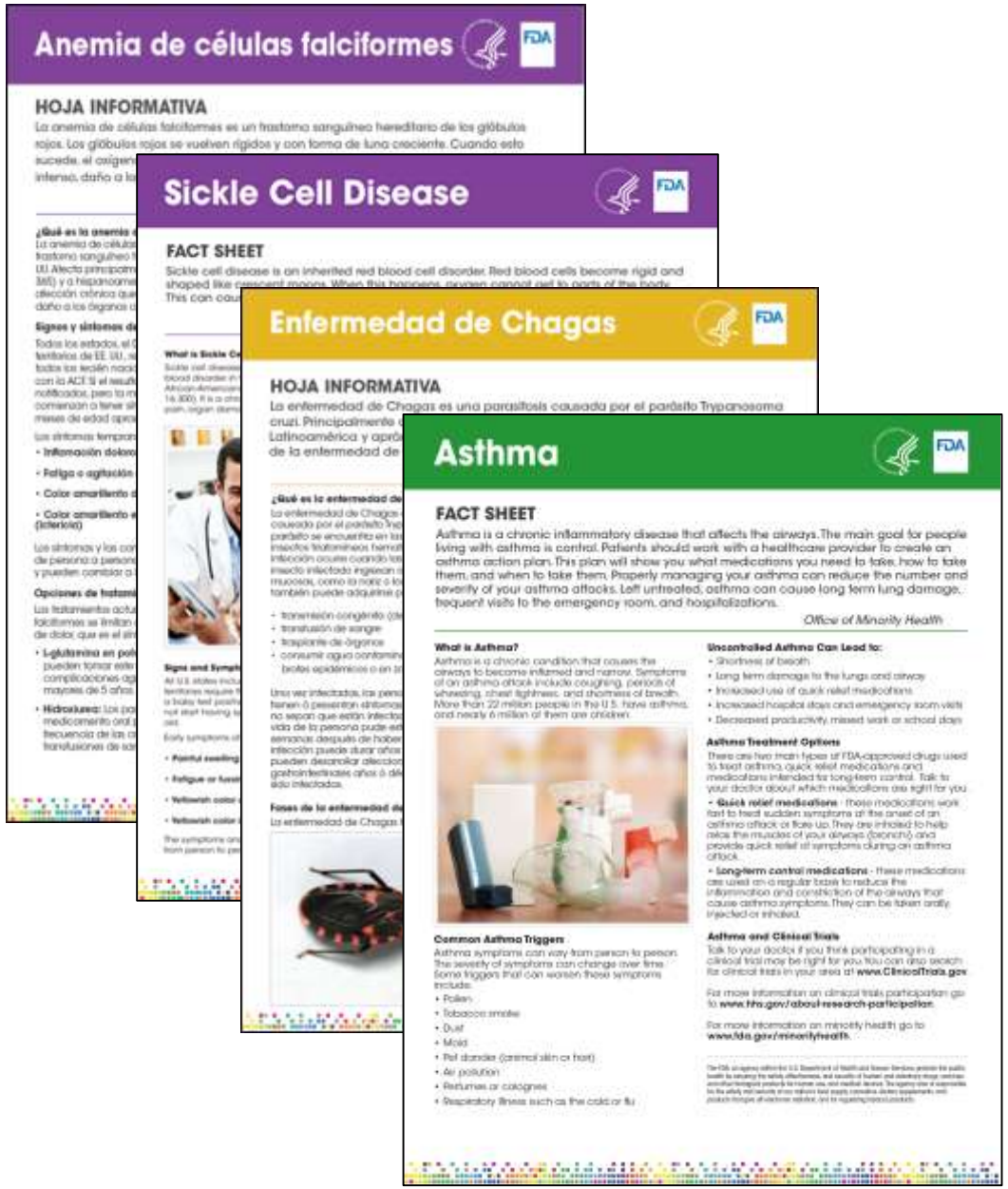
Partnering for Health Equity: Veterans in Clinical Trials

Veterans Health Administration
Office of Health Equity

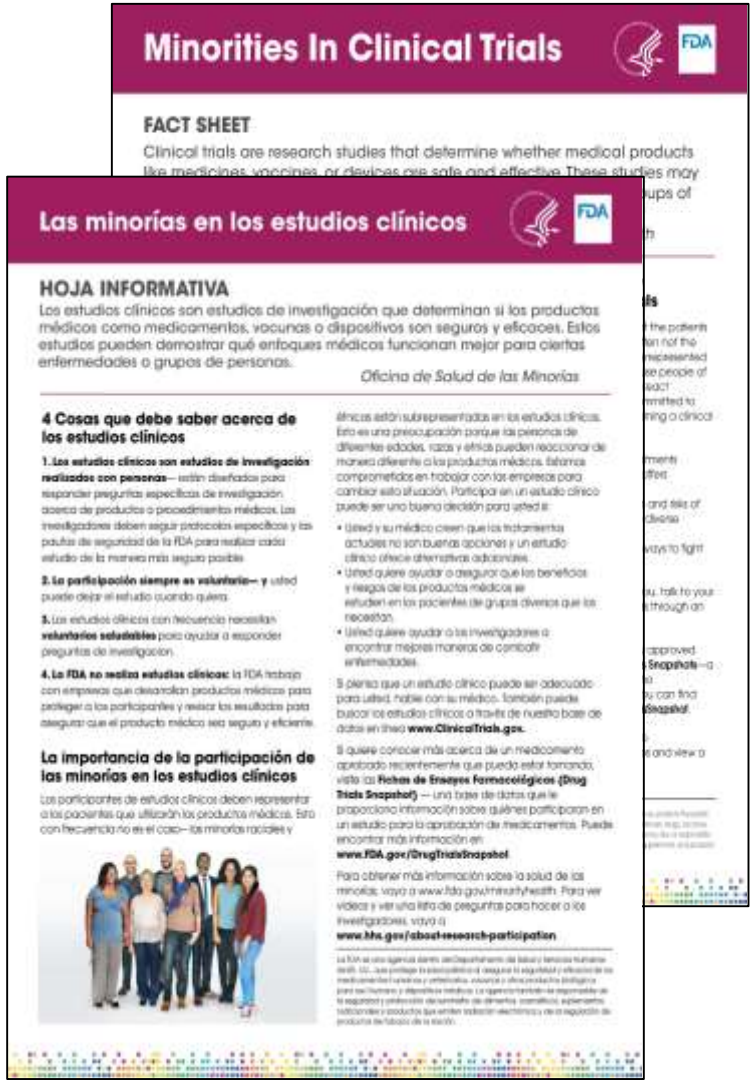
What's the Impact?

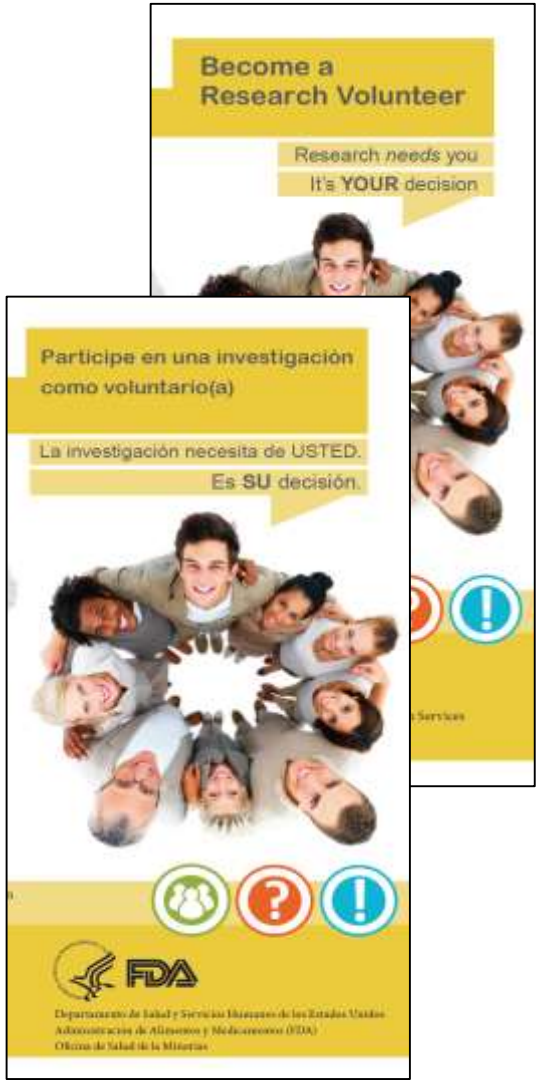
- Stimulated dialogue around clinical trial diversity
- Increased utilization of our materials
- Next Steps:
  - Further research can assess the effectiveness of our materials and outreach strategies through cognitive testing and focus group testing.
  - PSA targeting physicians and engaging their patients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

FDA OMHHE Resources



FDA OMHHE Clinical Trials Resources





FDA OMHHE Clinical Trials Resources

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 @FDAHealthEquity

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www.fda.gov/healthequity

Join webinars and stakeholder calls


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Questions?

American Kidney Fund®

Join us for our next webinar!

Kathy Merritt, LCSW

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!