U.S. FOOD & DRUG ADMINISTRATION

CERSI University of Maryland

Collaborating to Advance Health Equity for Diabetes and Chronic Kidney Disease (CKD)

Wednesday, February 10, 2021
10:00 am - 3:00 pm ET

Information

- Webex “panelists”: Please mute your microphone
- Webex “attendees”: Please ask questions via Q&A function in Webex
- This event will be recorded and posted (with slides, after the event) at: www.pharmacy.umaryland.edu/health-equity
- Biographies available at above website
- Questions: aanonsen@umd.edu
- Lunch break: 11:15-12:30 pm ET
- Break: 1:45-2:00 pm ET

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Opening Remarks

10:00 – 10:15 a.m.

Opening Remarks
RADM Richardae Araojo, PharmD, MS
FDA Associate Commissioner for Minority Health and Director of the Office of Minority Health and Health Equity

Keynote
Lashawn McIver MD, MPH
Director, CMS Office of Minority Health

U.S. FOOD & DRUG ADMINISTRATION

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SESSION 1: 10:15 - 11:30 a.m.

Using Patient Experience Data and Community/System Approach to Inform Care, Drug Development and the Overall Research Agenda

Moderator

Chanel F. Whittaker, PharmD, BCPS, CGP, FASCP

Associate Professor, University of Maryland School of Pharmacy

Richard Knight, MBA

President of the American Association of Kidney Patients (AAKP) Board of Directors

Rich Knight, MBA - President
The Largest Kidney Patient Organization

- Lecturer – Bowie State University College of Business
- **Personal Opportunities Afforded to Me to Impact Policy**
  - NIH/NIDDK Advisory Council Member
  - Co-Chair NIDDK Strategic Plan - Participant Engagement Subgroup
  - Co-Chair – CEC – Kidney Precision Medicine Project (NIH/NIDDK)
  - Member – HHS/Scientific Registry Transplant Recipients (SRTR) – Review Committee
  - Co-Chair – HHS/SRTR Patient & Family Sub-Committee
  - Founding Member – Making Dialysis Safe Coalition (CDC)
  - Kidney Health Initiative (ASN/FDA)
  - Clinical Trial Transformation Initiative (Duke/FDA)
  - Acute Kidney Injury Workgroup
  - Rare Disease Diversity Coalition
  - Diabetic Kidney Disease with Industry – Clinical Trials/Advisory Committees

AAKP Priorities

- **Respect** and **preserve** the relationship between kidney patients and the doctors they choose.

- **Protect** and **expand** kidney patient **consumer care choice** in all policies that impact access to patient care, treatment and health outcomes.

- **Accelerate** and **enhance innovation** in diagnostics, biologics and devices through substantive inclusion of patient insights across the product development lifecycle and payment decisions.

Patrick Gee, PhD

Kidney Health Initiative (KHI) Patient Family Partnership Council (PFPC) Members

Rana Malek, MD

Clinical Associate Professor, University of Maryland School of Medicine

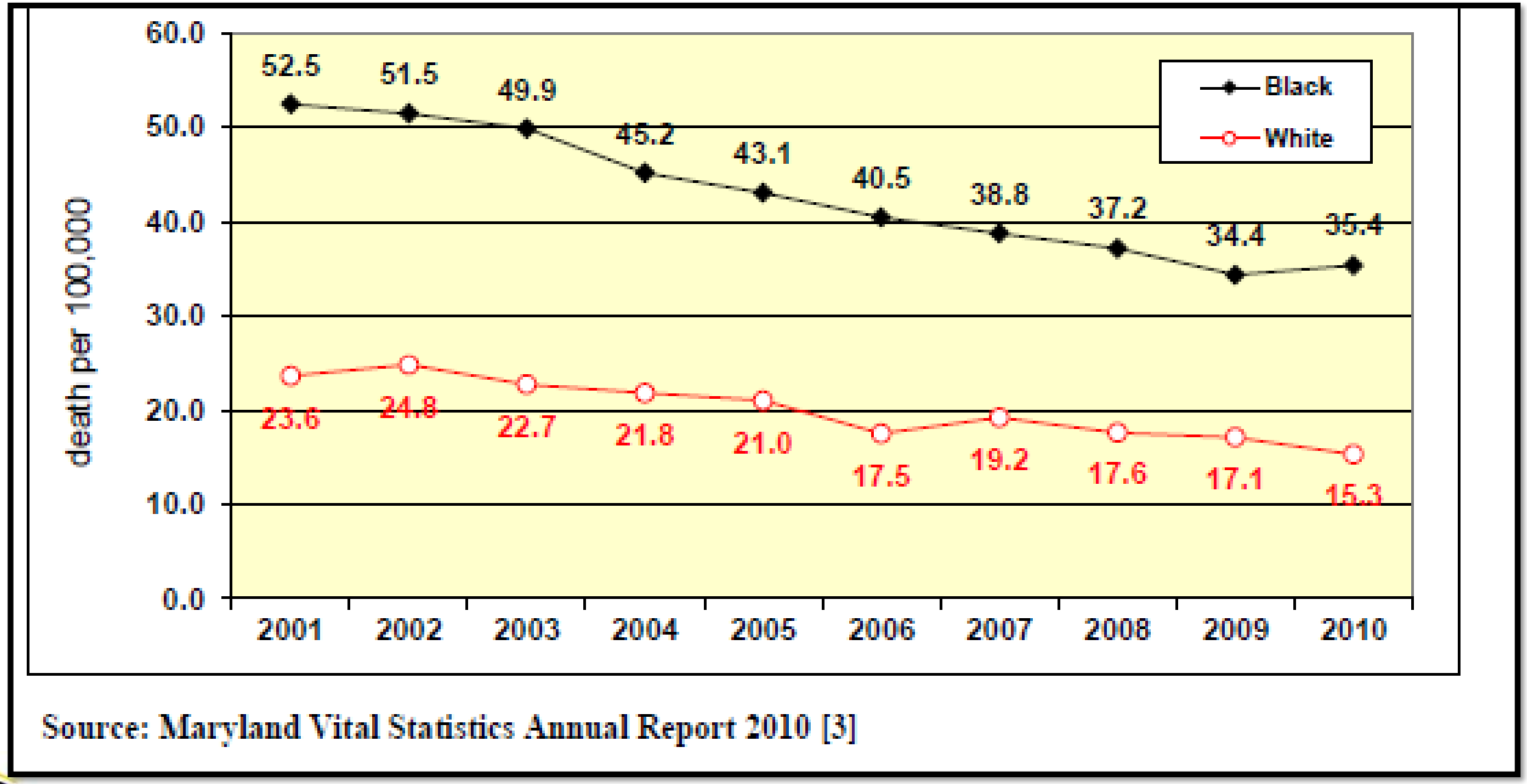
Collaborating to Advance Health Equity for Diabetes and Chronic Kidney Disease (CKD)

Rana Malek
Associate Professor
Endocrinology and Diabetes Fellowship Program Director
University of Maryland School of Medicine

Disclosures

- Nothing to disclose

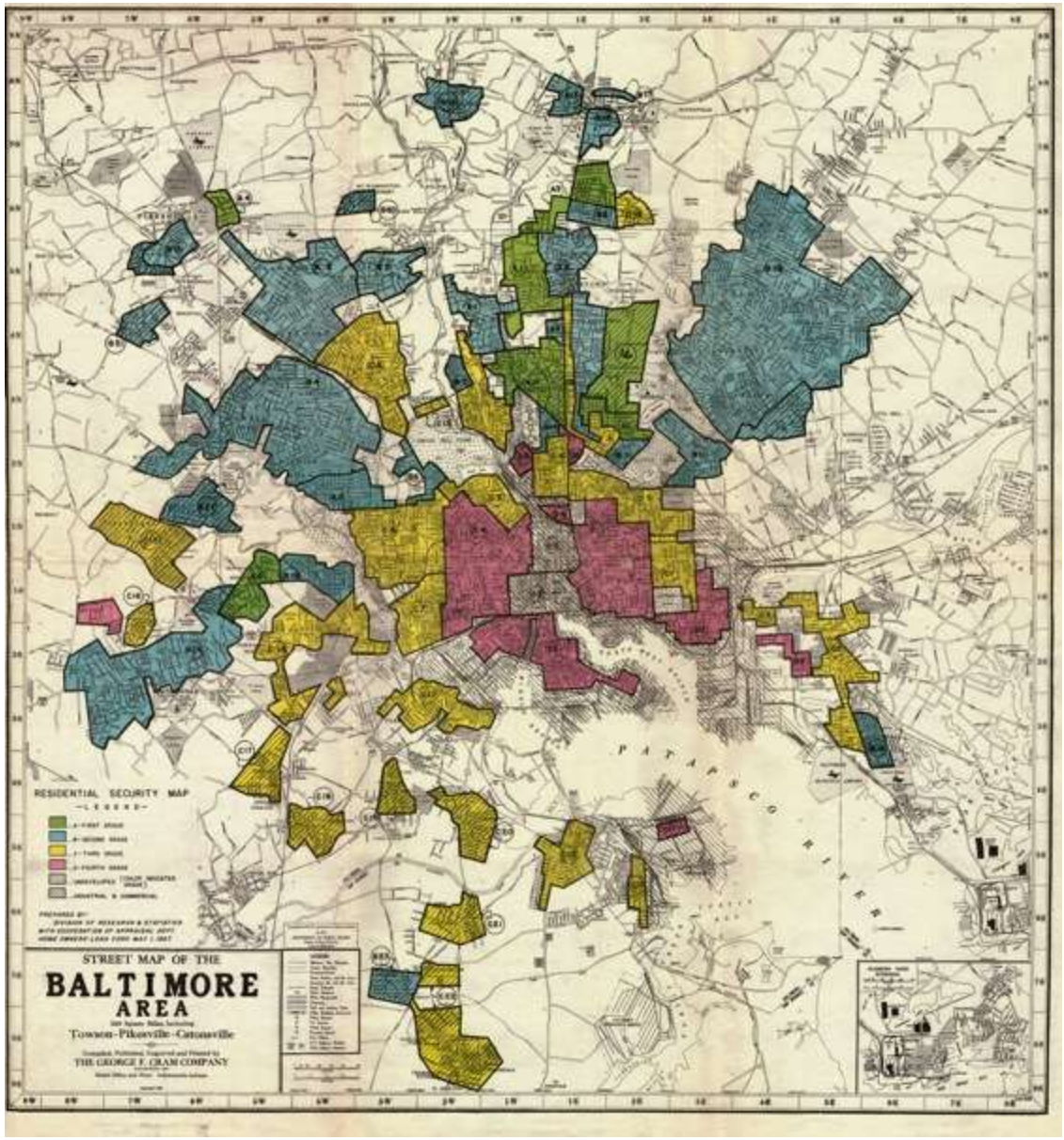
Age-adjusted Diabetes Mortality Rate, Maryland 2001-2010



Source: Maryland Vital Statistics Annual Report 2010 [3]

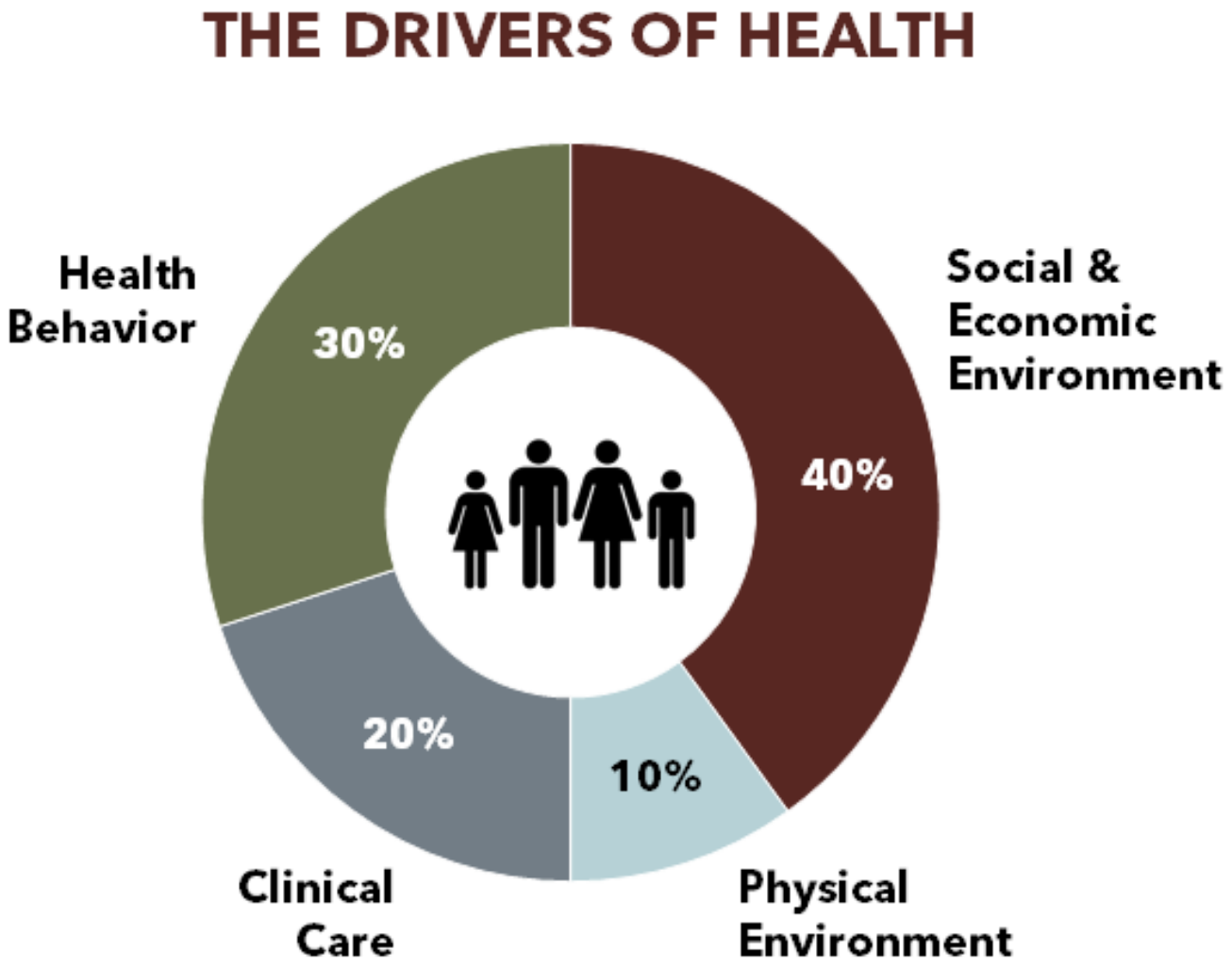
Redlining as a Tool of Segregation

- 1933: U.S. housing shortage
- 1934: **F**ederal **H**ousing **A**dministration established to provide housing to white, middle-class, lower-middle-class families
- FHA subsidized entire housing subdivisions for whites — with the requirement that none of the homes be sold to African-Americans
- FHA refused to insure mortgages in and near Black neighborhoods (red-lining)
- Resulted in generational wealth gap



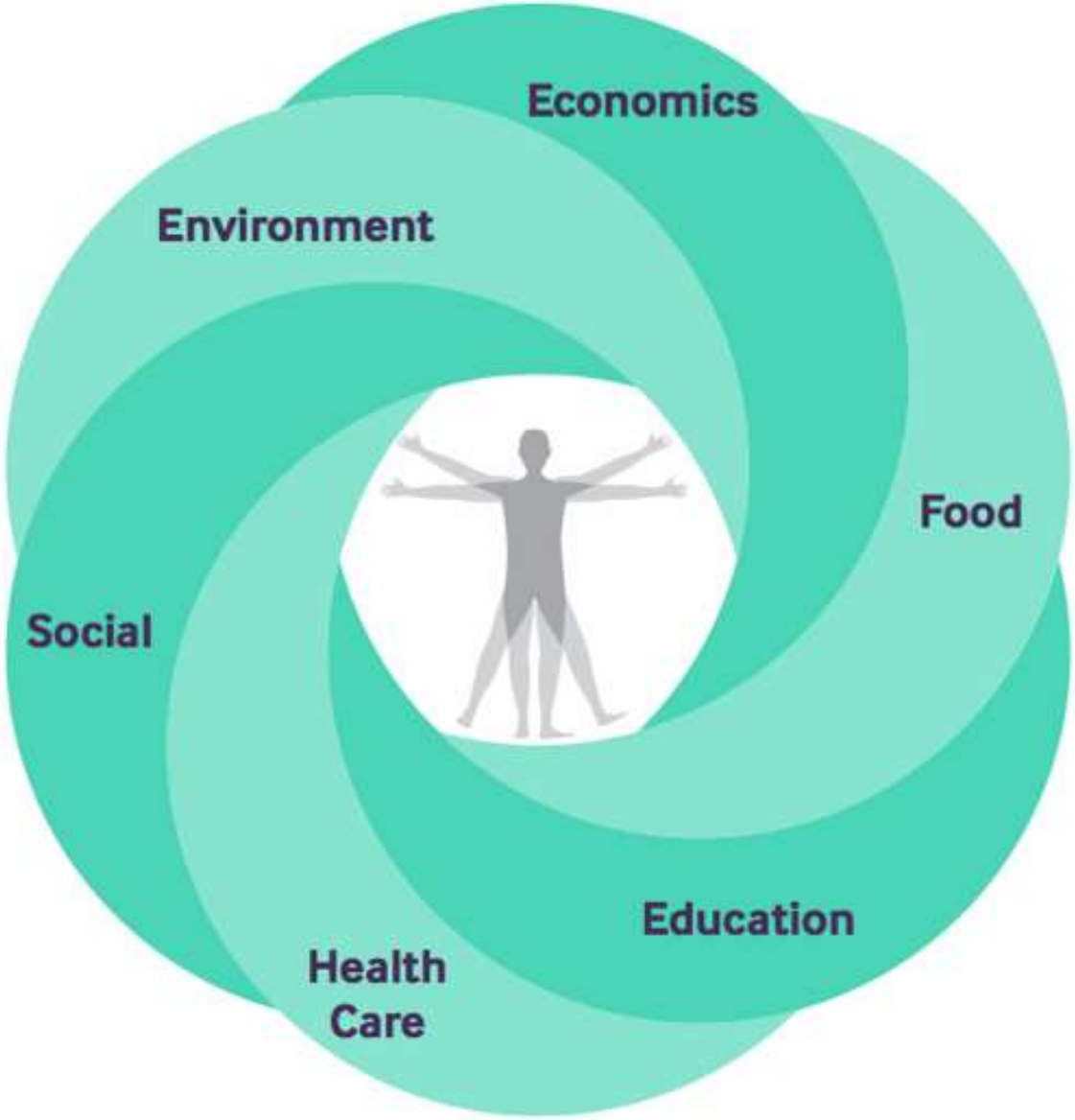
The Drivers of Health

"Health is the product of the interactions among biology, genetics, behavior, relationships, cultures, and environment"

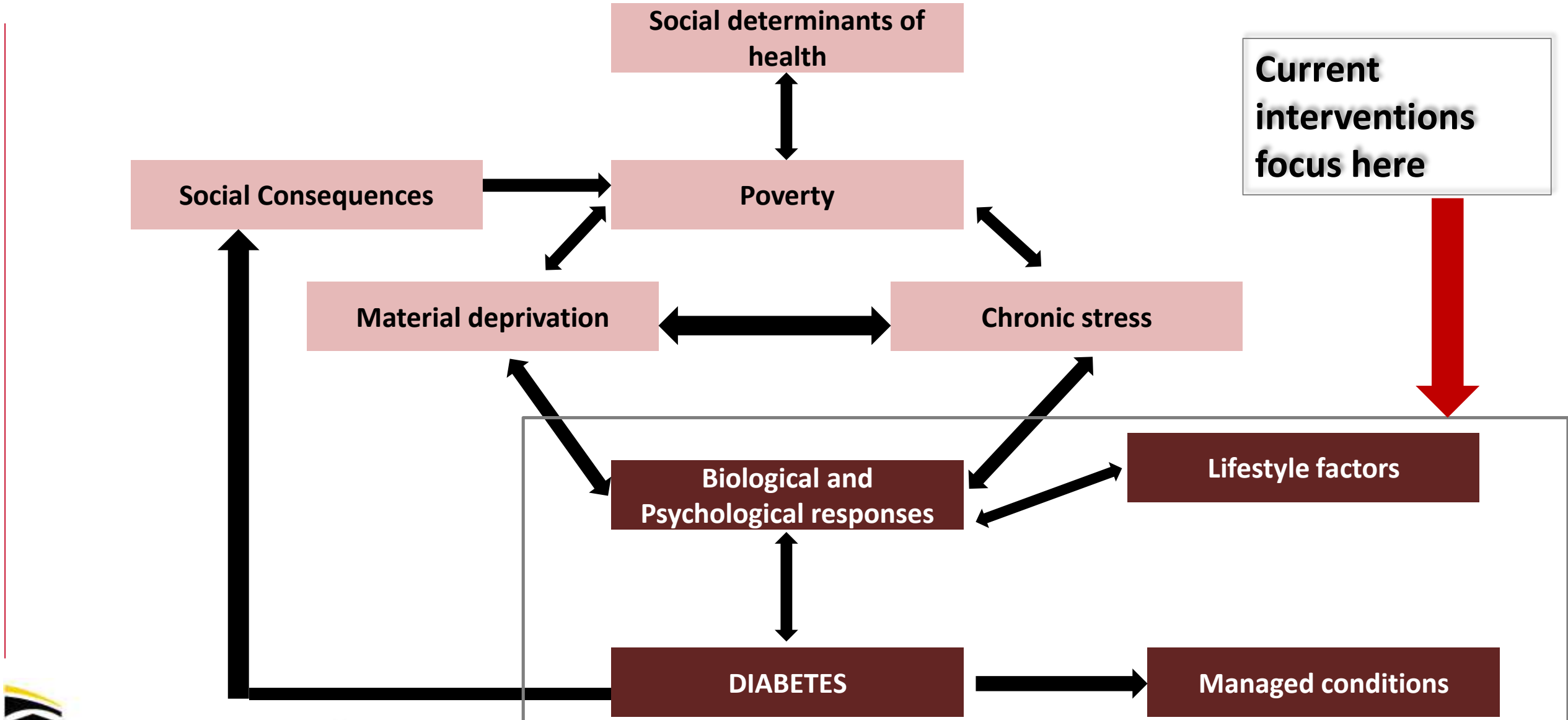


Note: Excludes the role of genetics.
Source: McGovern, Laura, Miller, George and Hughes-Cromwick, Paul. Health Policy Brief: The Relative Contributions of Multiple Determinants to Health Outcomes. *Health Affairs*. August 21, 2014.

What are the Social Determinants of Health?



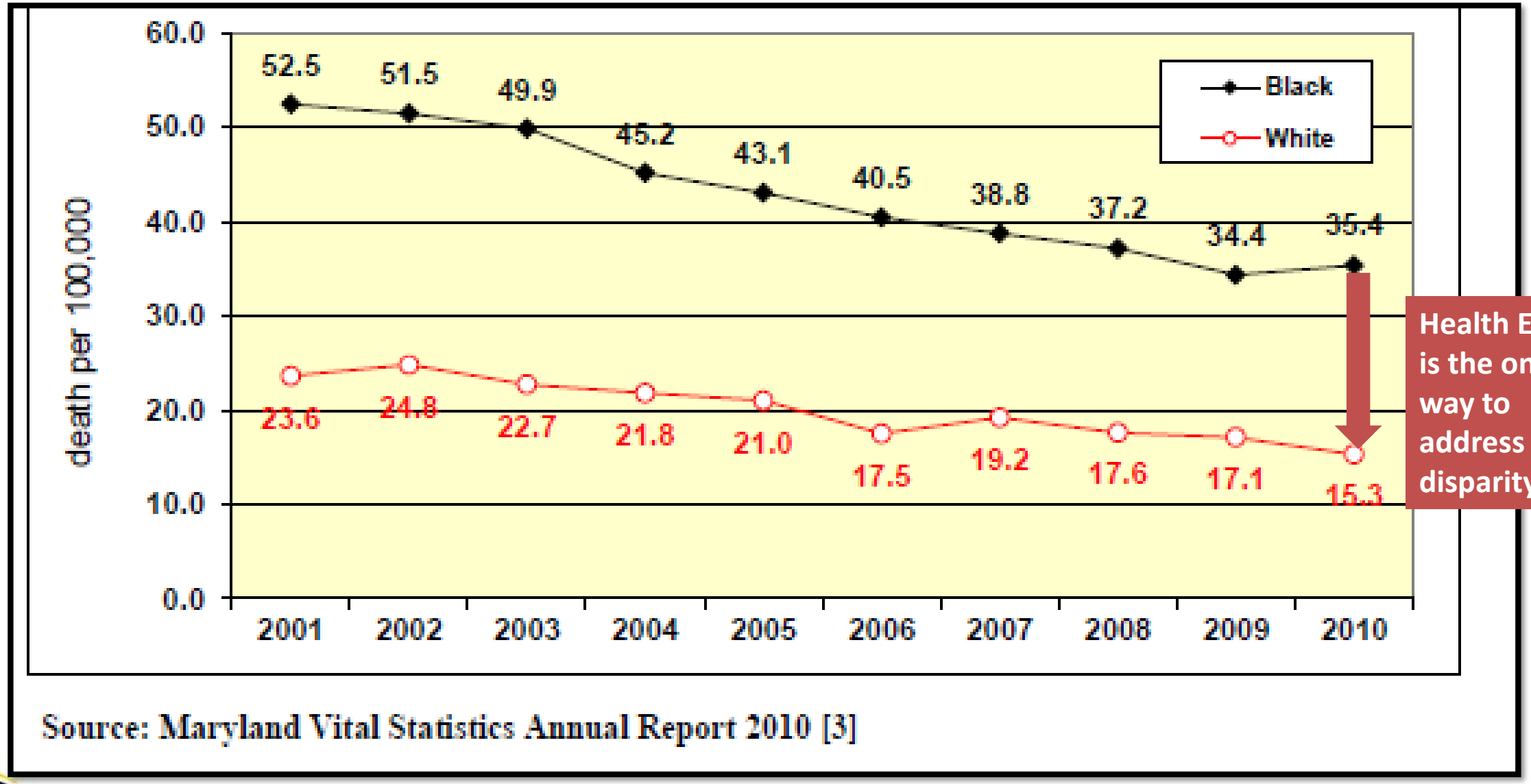
The Socio-Biologic Cycle of Diabetes



UNIVERSITY of MARYLAND SCHOOL OF MEDICINE

Hill et al. Perm J 2013 Spring; 17 (2):67-72

Age-adjusted Diabetes Mortality Rate, Maryland 2001-2010



Source: Maryland Vital Statistics Annual Report 2010 [3]

Health Equity is the only way to address this disparity

Ann Bullock, MD

Director, Division of Diabetes Treatment and Prevention, Indian Health Service

Diabetes and CKD in the Indian Health System

Ann Bullock, MD
Director
Division of Diabetes Treatment and Prevention
Indian Health Service

Indian Health Service (IHS)

- Agency within the Dept. of Health and Human Services
- Serves members of 574 federally-recognized Tribes in 37 states
  - 2.56 million American Indians and Alaska Natives (AI/AN)
- IHS/Tribal/Urban (I/T/U) Health System
  - **IHS** provides direct health care services at many sites
    - 26 Hospitals, 55 Health Centers, 21 Health Stations
  - **Tribes** have the right to assume control and management of programs—over 60% of the IHS appropriation is administered by Tribes
    - 19 Hospitals, 280 Health Centers, 62 Health Stations, and 134 Alaska Village Clinics
  - 43 **Urban** Indian Organizations provide various levels of clinical and resource services

Diabetes in AI/AN People

- Prevalence of type 2 diabetes was rising in AI/ANs
- In response, IHS:
  - Established the National Diabetes Program: 1979
  - IHS Diabetes Standards of Care: 1986
  - Started the Diabetes Care and Outcomes Audit: 1986
  - Promoted comprehensive team-based approaches to diabetes care in primary care settings
- Special Diabetes Program for Indians (SDPI)
  - Established by Congress in 1997
  - Today provides funds to 301 I/T/U grant programs for diabetes prevention and treatment
- IHS Division of Diabetes provides national support

Percent of SDPI Programs Reporting Diabetes Services

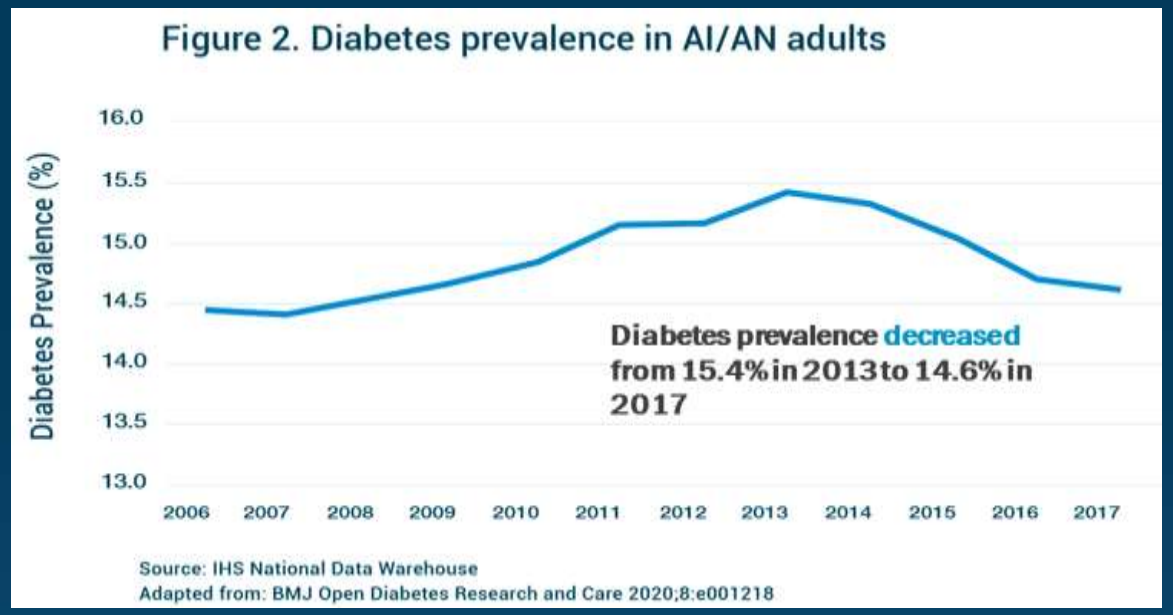
Intervention	1997	2019
Diabetes clinical teams	30%	95%
Diabetes patient registries	34%	96%
Nutrition services for adults	39%	94%
Access to registered dietitians	37%	85%
Access to physical activity specialists	8%	84%
Access to culturally tailored diabetes education materials	36%	96%
Adult weight management programs	19%	76%
Nutrition services for children and youth	65%	90%
Community-based physical activity programs for children and youth	13%	85%
Physical activity programs for school-age youth	9%	83%

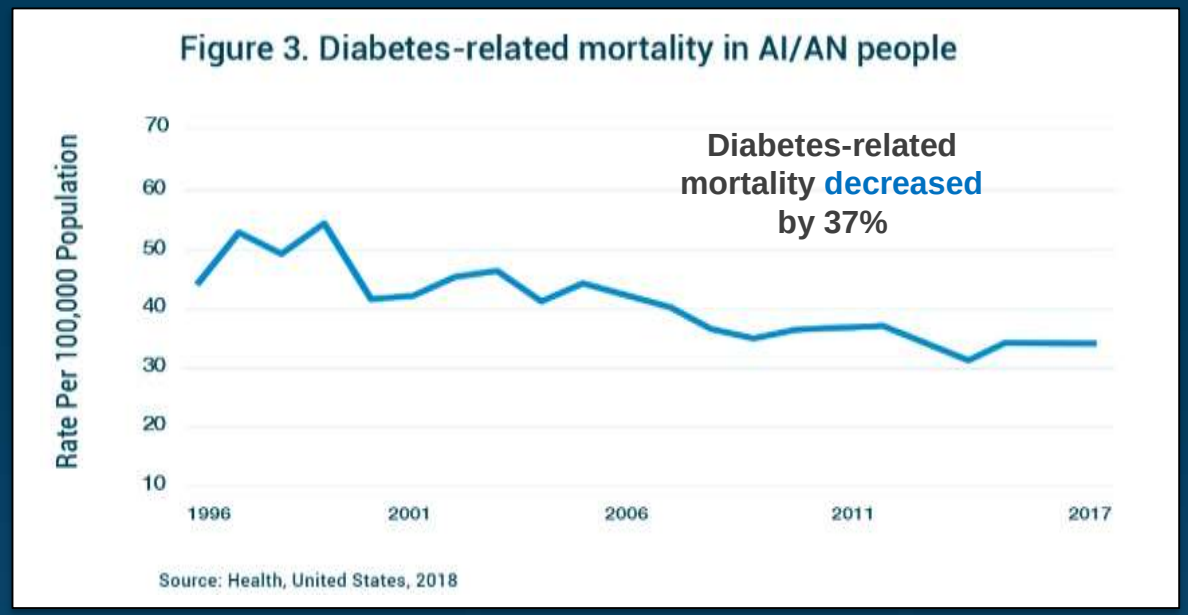
Source: Evaluation of the SDPI Community-Directed Diabetes Programs

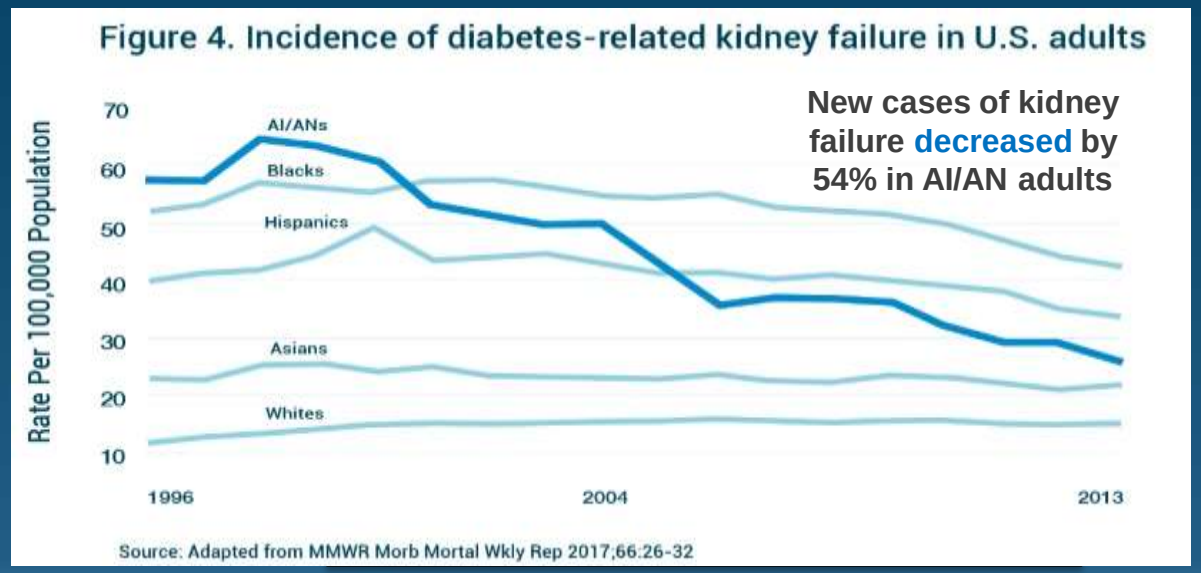
Context of Diabetes

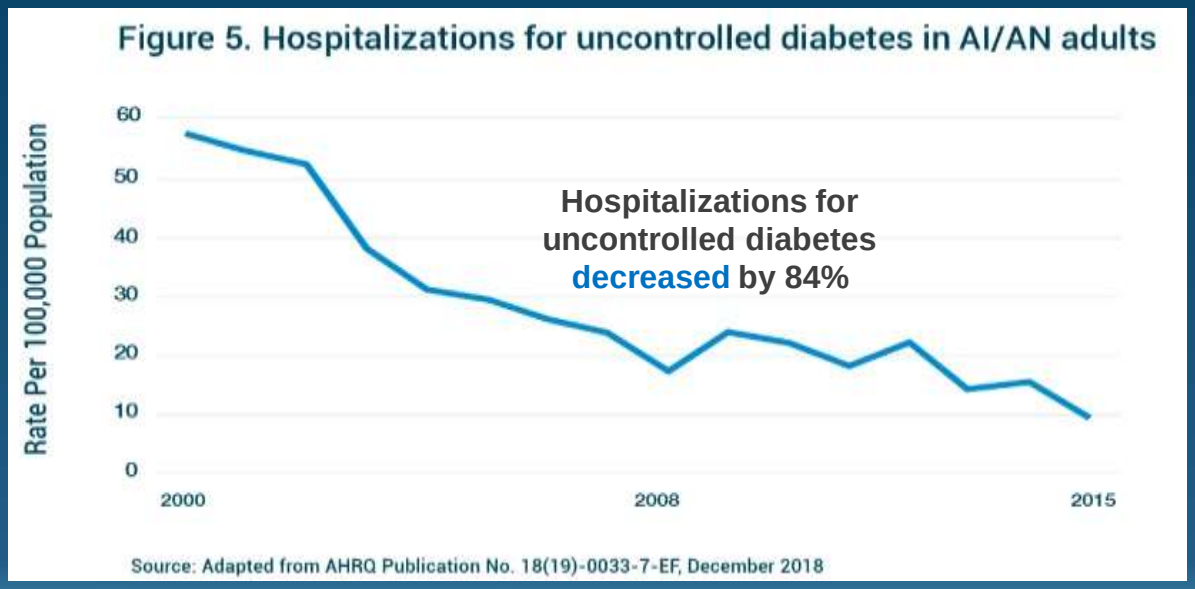
- Many life factors can make it difficult for patients to control diabetes and access healthcare
  - Poverty, food insecurity
  - Lack of transportation, child care, elder care, sick leave, housing
  - Chronic stress directly affects diabetes
- Diabetes care is a marathon, not a sprint
  - Preventing/delaying complications, (e.g., kidney failure) requires control of risk factors over many years
  - To reduce kidney failure rates, health care systems need to:
    - Take the long view on costs, outcomes
    - Work with *all* patients, including those who have challenges with clinic attendance, affording medicines, achieving targets
    - Actively engage communities as partners, value cultures as strengths
    - Go beyond medical care
      - Assess the communities where patients live, work with local governments and community organizations to make improvements

SDPI 2020 Report to Congress









Andrea Furia-Helms, MPH

Director, Office of Patient Affairs, FDA

U.S. FOOD & DRUG ADMINISTRATION

How FDA Involves Patients and Advocates

Andrea Furia-Helms, MPH
Office of Patient Affairs
Office of Clinical Policy and Programs

Collaborating to Advance Health Equity for Diabetes and Chronic Kidney Disease (CKD)
February 10, 2021

Overview

Understanding patient engagement at FDA

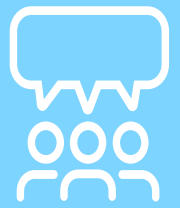
The Importance of the Patient Voice

- Insights on issues, needs and priorities that are important to patients and caregivers
- Diverse opinions and experiences
- Insights on risk tolerance and potential benefit
- Real world experience

Patients are at the heart of FDA's work!

Patient Affairs

Who we are



What we do

- Small team in the Office of the Commissioner dedicated to providing an inviting, welcoming and meaningful experience for patient communities to engage with the FDA

- Lead patient engagement activities across the medical product Centers through:
  - Cross-cutting programs and activities
  - Public-private collaborations and partnerships
  - Enhance external communication platforms

Patient Affairs initiatives

Cross-center patient activities

What is an FDA Patient Listening Session?

- One of the many ways that patients can **share their experience** living with and managing a disease or condition
- Patients & caregivers can **talk directly with FDA** scientific staff
- A **resource** for FDA's medical product Centers to **quickly engage** with patients or their advocates

Patient Engagement Collaborative

FDA U.S. FOOD & DRUG ADMINISTRATION

CLINICAL TRIALS TRANSFORMATION INITIATIVE

- FDA & Clinical Trials Transformation Initiative (CTTI)
- EMA's Patients' and Consumers' Working Party (PCWP) model
- Purpose: Discussions about engaging patients in medical product development and regulatory discussions

Resources

Tools and resources for engagement

Questions & Meeting Requests

U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

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Patients: Ask FDA

This form is for:

- Patients
- Caregivers
- Advocates
- Health Care Professionals

*This form **is not** for industry stakeholders.*

Please use this form to:

- Ask a question to FDA
  or
- Request a meeting with FDA

To report adverse events that you observe or suspect for human medical products please use the **MedWatch reporting form.*

This form is for requests about:

- Diseases or Health Conditions
- Drugs
- Devices
- Vaccines/Blood/Biologics

*For other requests please visit the **FDA contacts page**.*

Please tell us who you are (required):

○ Individual Patient, Caregiver or Advocate ○ Patient Group ○ Health Professional ○ Other

Question or Meeting Request (required):

○ Question ○ Meeting Request

What is your request about? (required):

○ a drug ○ a medical device ○ a vaccine, blood or biologic ○ disease or health condition ○ multiple or unknown

Is your request about a specific FDA program? (required):

○ Yes ○ No, or I do not know

Name of Disease or Condition (if applicable):

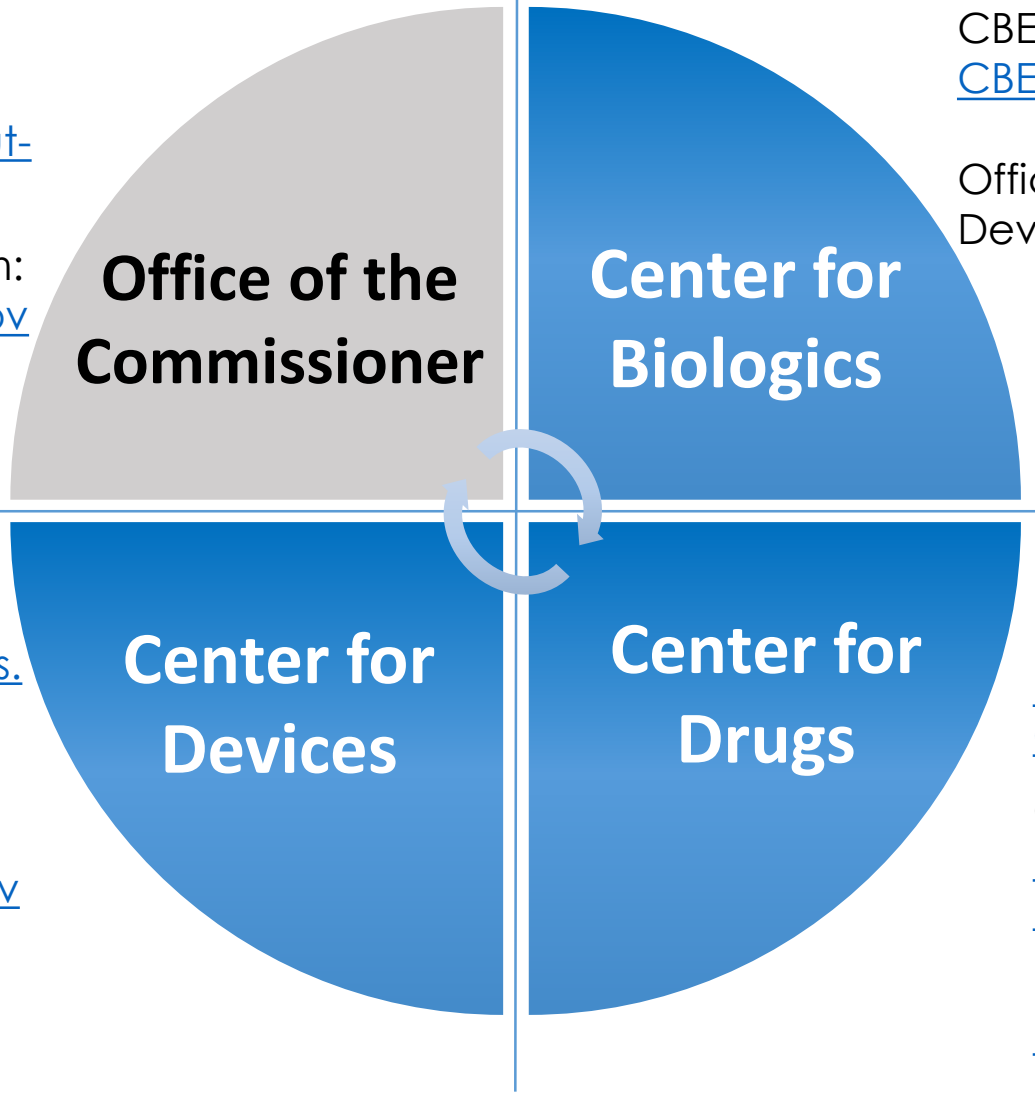
Enter Name of Disease or Condition (if applicable)

www.fda.gov/PatientsAskFDA

Patient Engagement Across FDA

FDA Office of Patient Affairs:
PatientAffairs@fda.gov
https://www.fda.gov/patients/about-office-patient-affairs

FDA Patient Representative Program:
FDAPatientRepProgram@fda.hhs.gov
https://go.usa.gov/xfB4h



CBER's Patient Engagement Initiatives:
CBERPatientEngagement@fda.hhs.gov

Office of Communication, Outreach and Development: OCOD@fda.hhs.gov

Patient Engagement Initiatives:
https://go.usa.gov/xfBdx
CDRH_PatientEngagement@fda.hhs.gov

Patient Engagement Meeting Requests:
CDRH_PatientMeetings@fda.hhs.gov

CDRH's Division of Industry and Consumer Education:
DICE@fda.hhs.gov

Professional Affairs and Stakeholder Engagement:
https://go.usa.gov/xfBpG
CDERPASE@fda.hhs.gov

CDER Division of Drug Information:
https://go.usa.gov/xfBpM
DrugInfo@fda.hhs.gov

Patient Focused Drug Development:
https://go.usa.gov/xfBph
patientfocused@fda.hhs.gov

Office of Patient Affairs

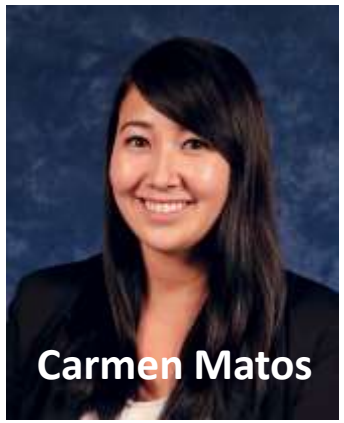
PatientAffairs@fda.gov

301-796-8460

www.fda.gov/Patients

@FDAPatientInfo

www.fda.gov/PatientsAskFDA



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Questions and Answers

FDA U.S. FOOD & DRUG ADMINISTRATION

CERSI University of Maryland

Lunch Break

11:30 – 12:30 p.m.

FDA U.S. FOOD & DRUG ADMINISTRATION

CERSI University of Maryland

SESSION 2: 12:30-1:45 p.m.

Diversity in Clinical Trials in Diabetes and Chronic Kidney Disease (CKD)

Moderator

Christine Lee, PharmD, PhD

Strategic Research Engagement Lead, FDA OMHHE

Milena Lolic, MD, MS
Lead Medical Officer, FDA

FDA and Diversity in Clinical Trials

FDA Encourages Diversity

- Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs, 1993
- Studies in Support of Special Populations: Geriatrics, 1994
- Collection of Race and Ethnicity Data in Clinical Trials, 2016
- Evaluation and Reporting of Age-,Race-,and Ethnicity-Specific Data in Medical Device Clinical Studies, 2017
- Pediatric Information Incorporated Into Human Prescription Drug and Biologic Product Labeling, 2019
- Enhancing the Diversity of Clinical Trial Populations— Eligibility Criteria, Enrollment Practices, and Trial Designs, 2020
- Draft Guidance: Inclusion of Older Adults in Cancer Clinical Trials, 2020
- Development and Licensure of Vaccines to Prevent COVID-19, 2020
- On COVID-19: Developing Drugs and Biological Products for Treatment or Prevention,2020

FDA Requires Reporting

Final Demographic Rule 1998

- IND: tabulate the trial population by age, gender, and race in annual reports per 21 CFR § 312.33(a)(2) -IND annual report regulations

- NDA: tabulate and analyze safety and efficacy by age, gender, and race per 21 CFR §314.50 (d)(5)- NDA content and format

Drug Trials Snapshots

Commitment to Transparency

- Transparency effort that provides the public with **information about who participated in clinical trials** that supported the FDA approval of new drugs
- Newly-approved drugs and biologics (NMEs and BLAs)*
- Published within 30 days of approval
- Highlight any differences in the benefits and side effects among sex, race, and age groups

*New Molecular Entities and original Biologic Licensing Applications

Search:

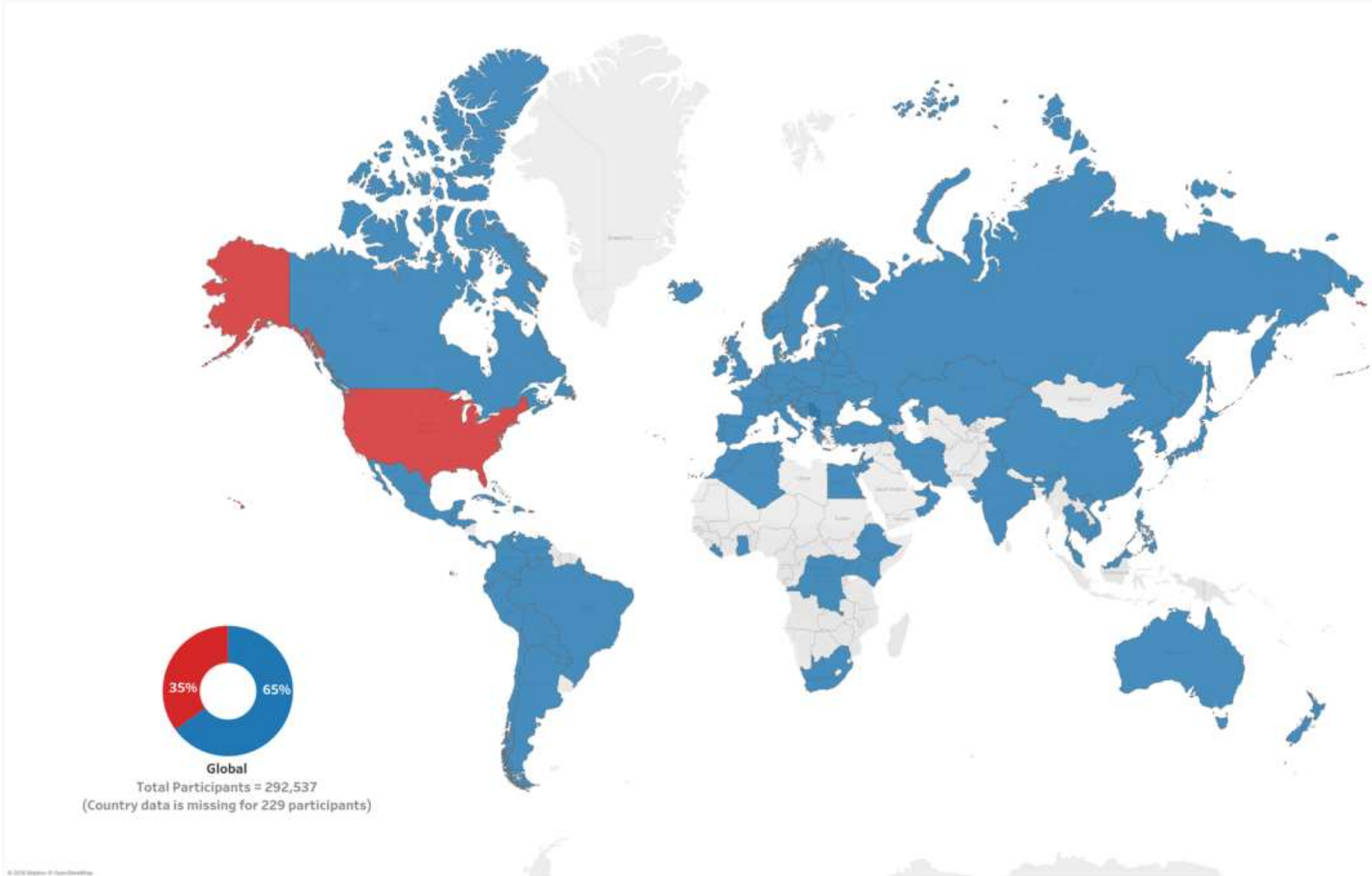
Export Excel | Show 10 entries

Drug Trials Snapshot	Active Ingredient	Date of FDA Approval	What is it Approved For	Prescribing Information
ACCRUFER	ferric maltol	July 25, 2019	Treatment of low iron stores	Accrufer
ADAKVEO	crizanlizumab-tmca	November 15, 2019	Treatment of vasoocclusive crises in patients with sickle cell disease.	Adakveo
ADDYI	flibanserin	August 18, 2015	Treatment of acquired, generalized hypoactive sexual desire disorder (HSDD) in premenopausal women	Addyi
ADLYXIN	lixisenatide	July 27, 2016	Improvement of blood sugar control in adults with diabetes mellitus (DM) type 2 when used in addition to diet and exercise	Adlyxin
AEMCOLO	rifamycin	November 16, 2018	Treatment of traveler's diarrhea in adults	Aemcolo
AIMOVIG	erenumab-aooe	May 17, 2018	Preventive treatment of migraine in adults	Aimovig
AJOVY	fremanezumab-vfrm	September 14, 2018	Preventive treatment of migraine in adults	Ajovy
AKLIEF	trifarotene	October 4, 2019	For the topical treatment of acne vulgaris in patients 9 years of age and older	Aklief
AKYNZEO	fosnetupitant and palonosetron	April 19, 2018	Prevention of the nausea and vomiting that happens right away or later in adults receiving certain anticancer medicines (chemotherapy)	Akynzeo
ALECENSA	alectinib	December 11, 2015	Treatment of metastatic non-small cell lung cancer	Alecensa

Showing 1 to 10 of 275 entries

Previous 1 2 3 4 5 ... 28 Next


FDA U.S. FOOD & DRUG ADMINISTRATION
2015-2019
DRUG TRIALS SNAPSHOTS
SUMMARY REPORT
Five-Year Summary and Analysis of Clinical Trial Participation and Demographics

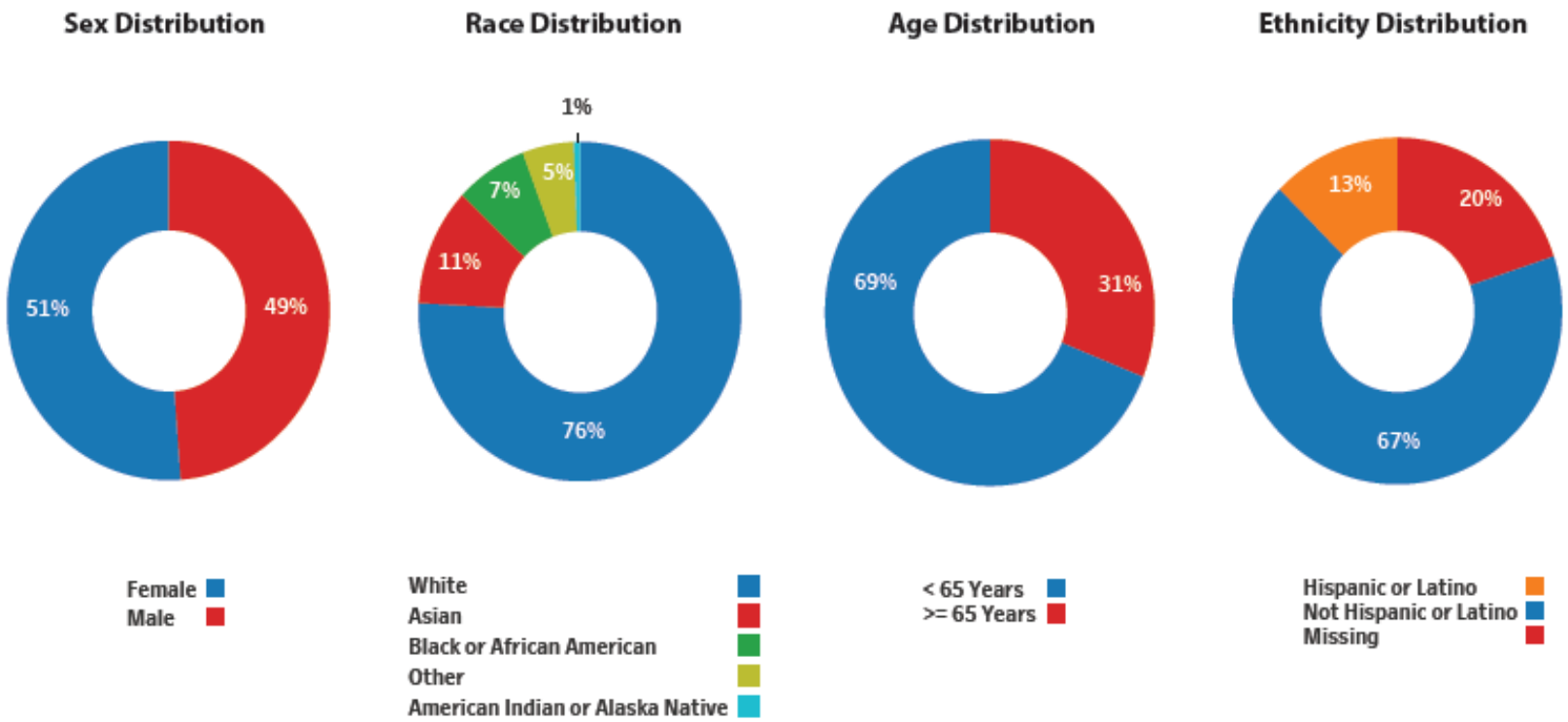


Global

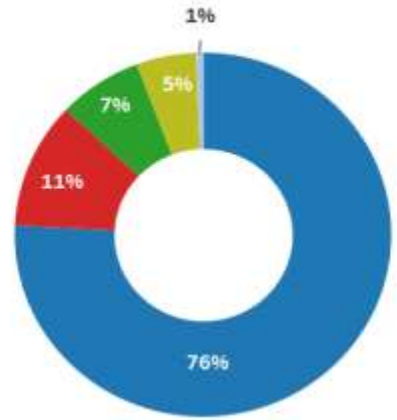
Total Participants = 292,537

(Country data is missing for 229 participants)

Global Demographics

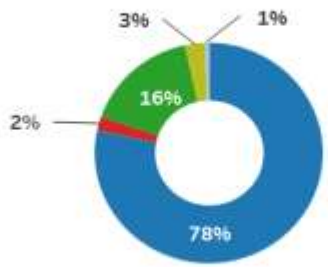


Race Distribution

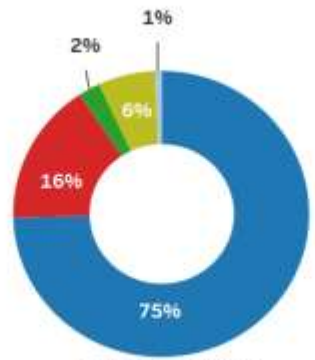


White
Asian
Black or African American
Other
American Indian or Alaska Native

Global
Total Participants = 292,537
(Country data missing for 229 participants)

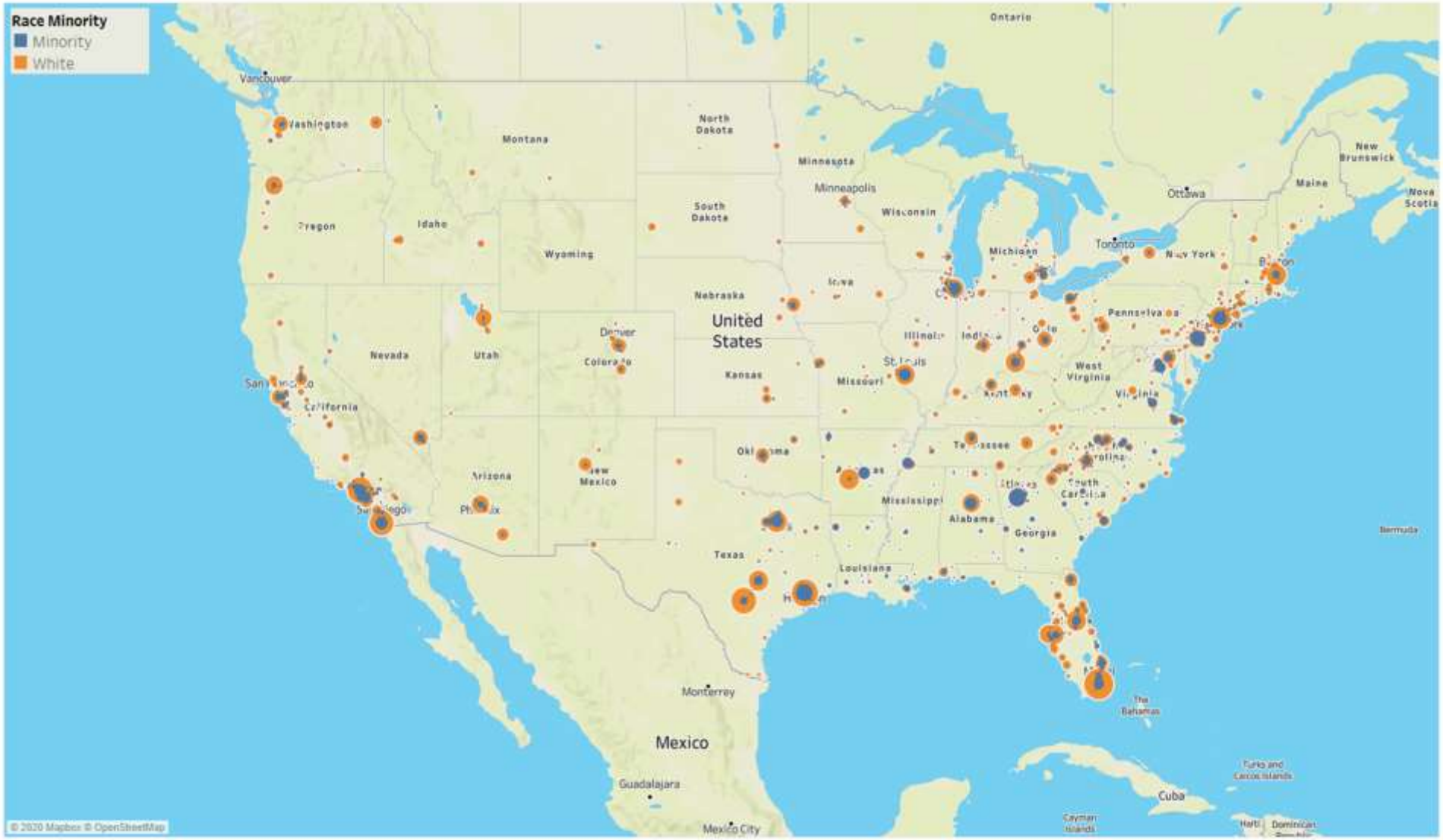


United States
Total Participants = 102,595



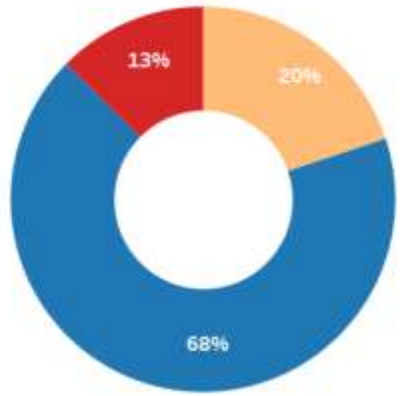
Rest of the World
Total Participants = 189,942

US Participation by Race



Ethnicity Distribution

Not Hispanic or Latino
Hispanic or Latino
Missing



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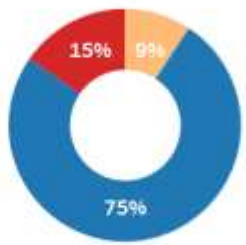

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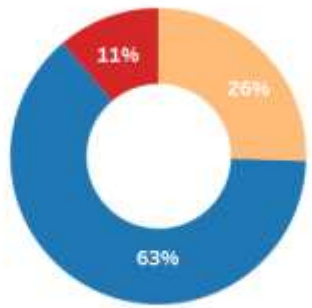
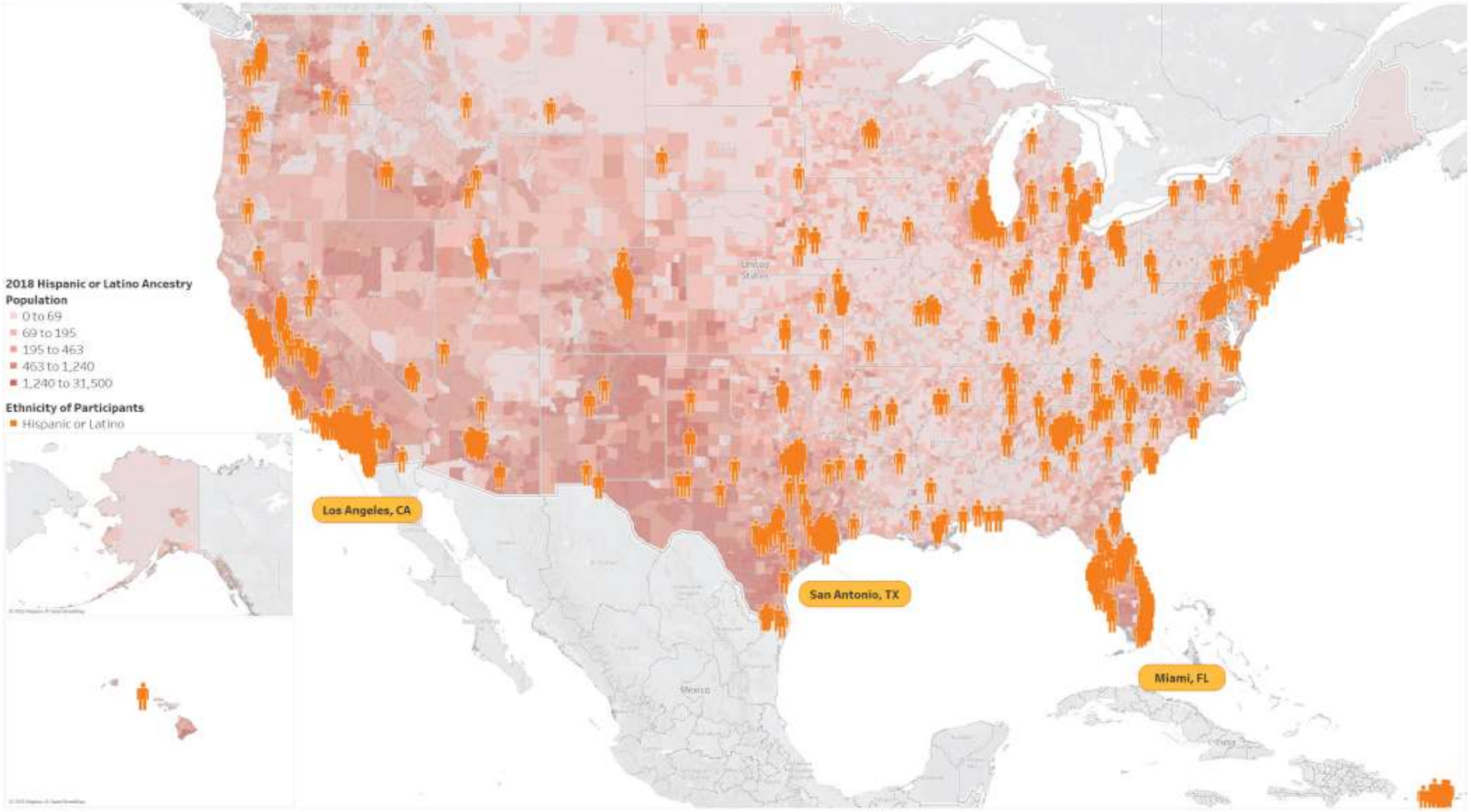


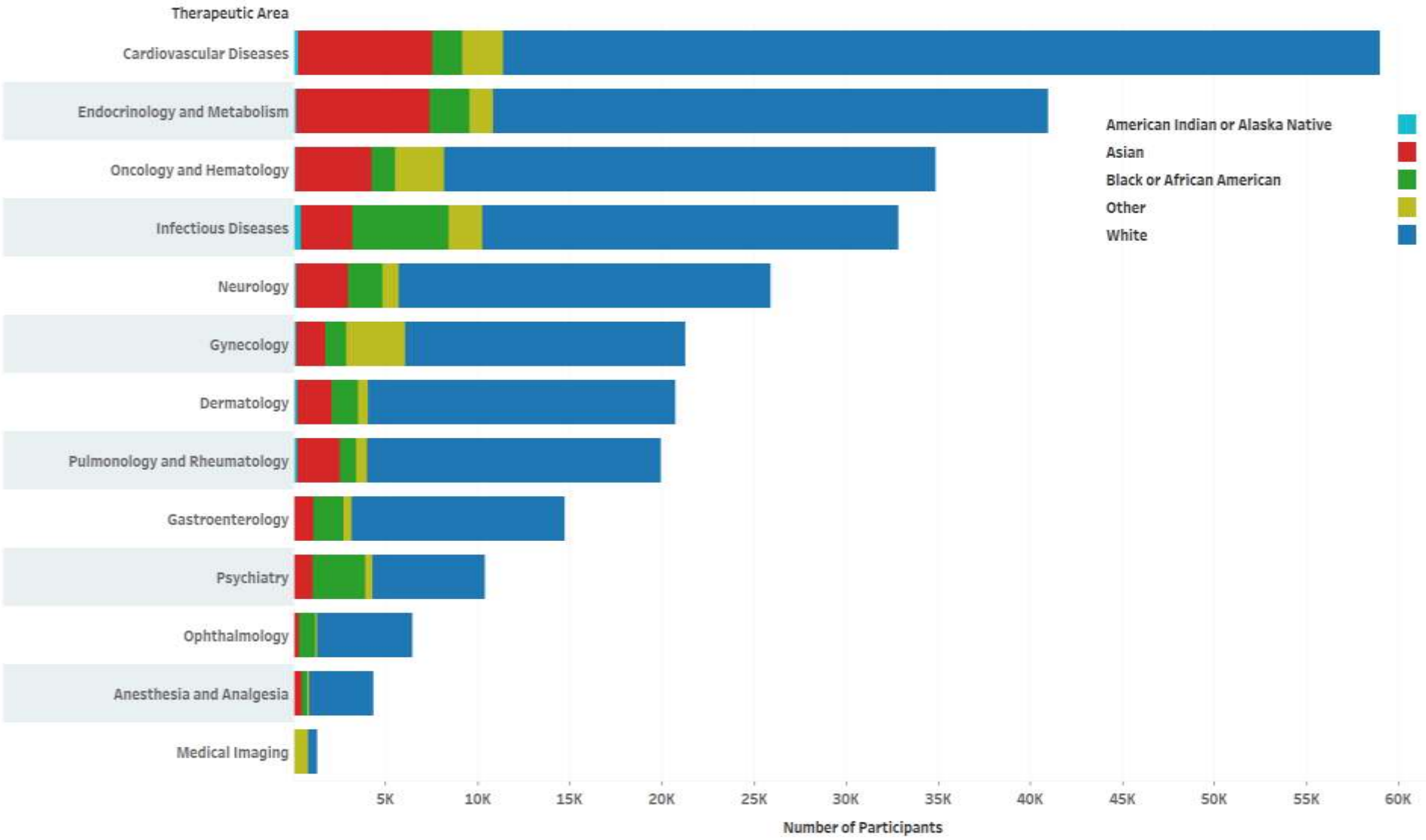
Rest of the World
Total Participants = 189,942

US Participation by Ethnicity

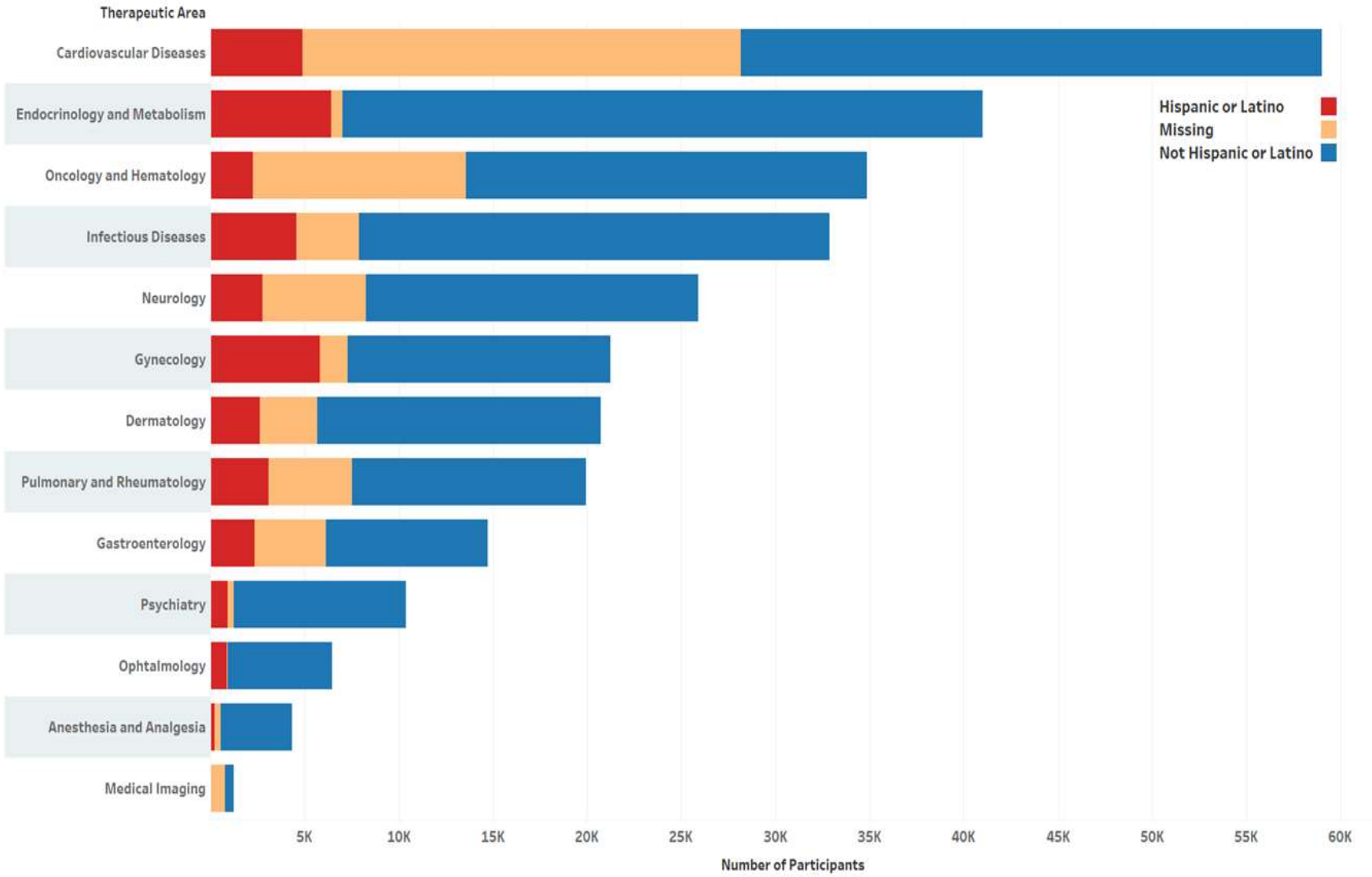


2015-2019 Drug Trials Snapshots Summary Report

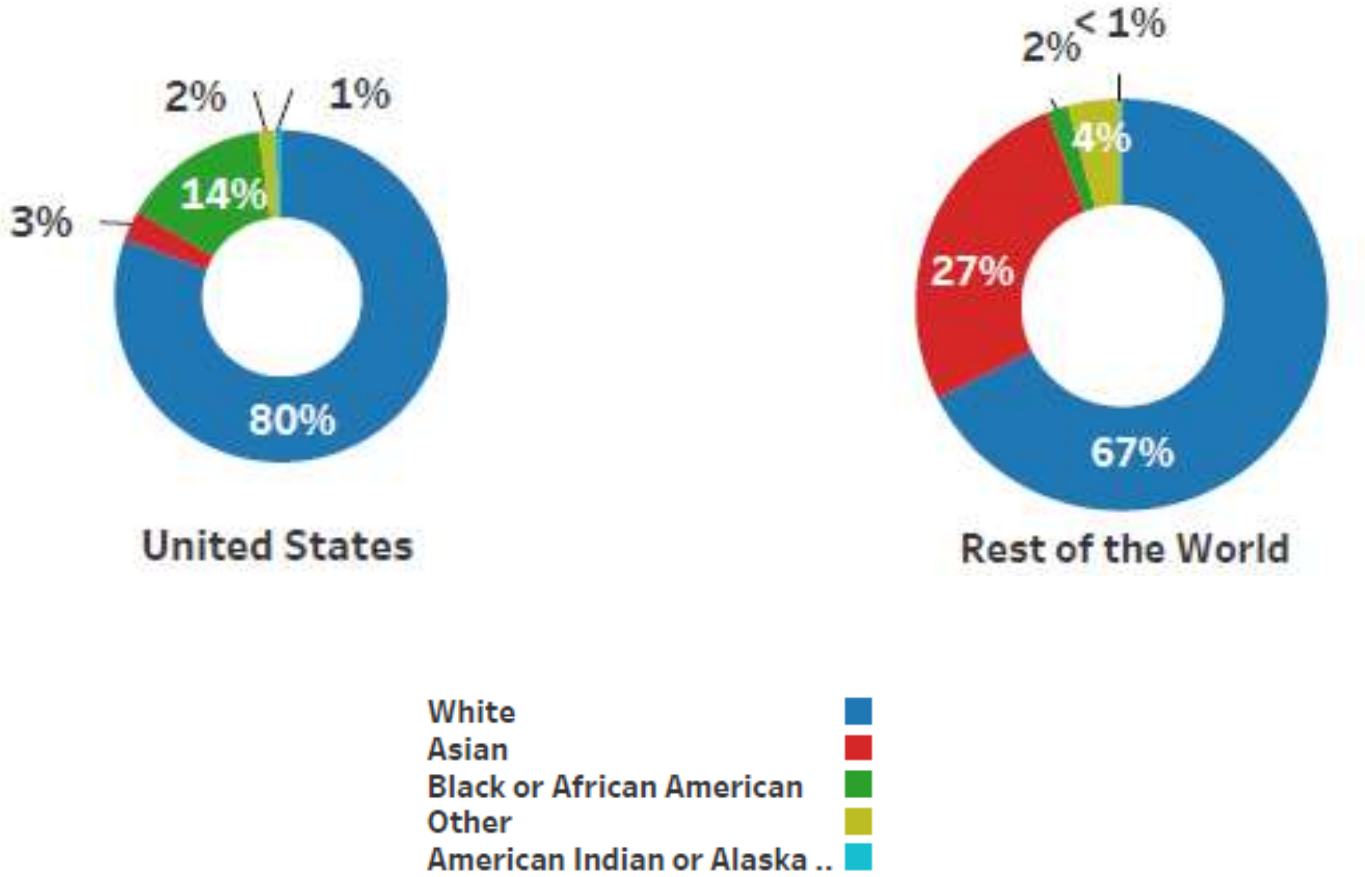
Race Breakdown Across Therapeutic Areas



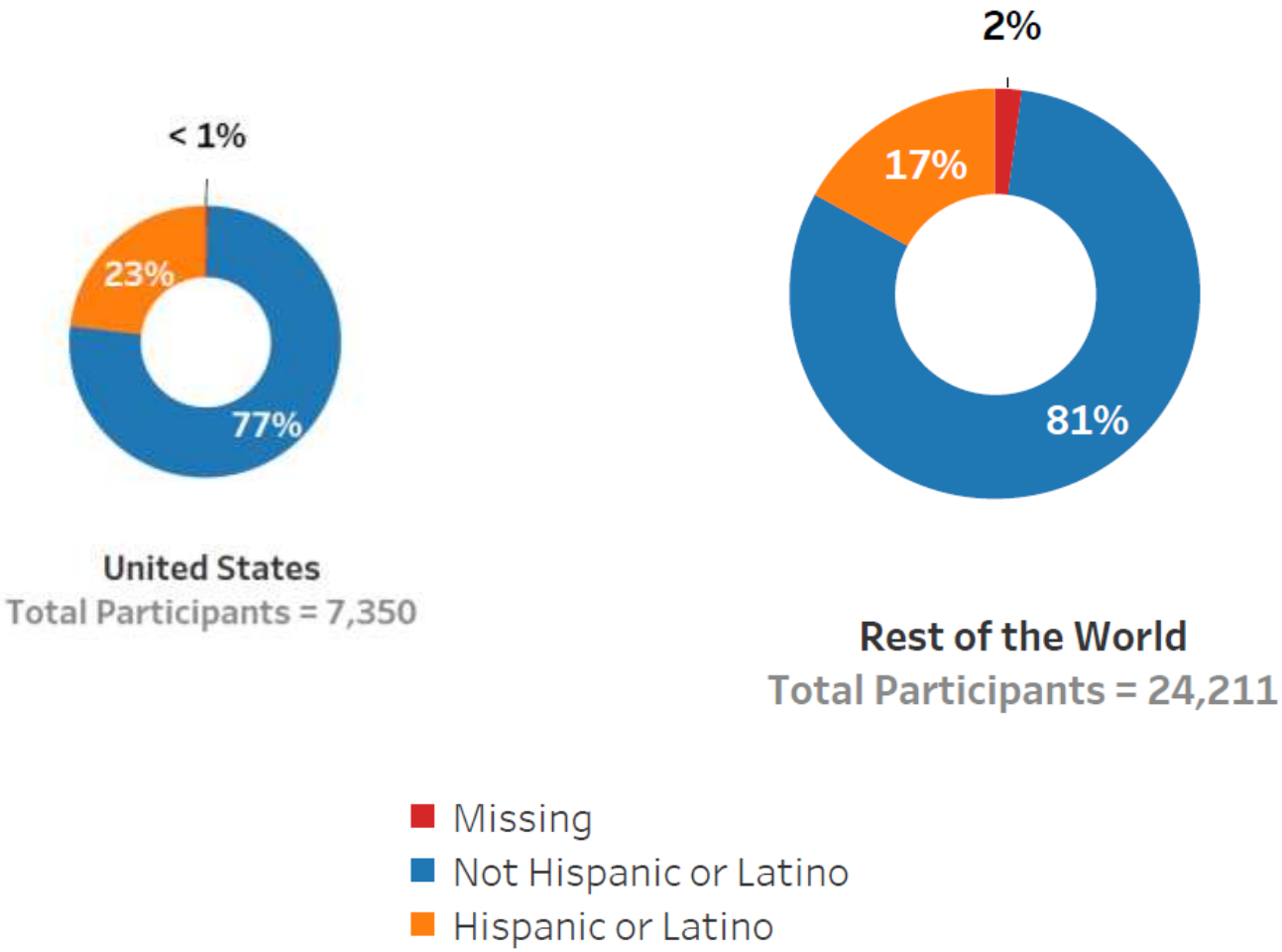
Ethnicity Breakdown Across Therapeutic Areas



Race Distribution in DM Trials



Ethnicity Distribution in DM Trials



Rekha Kambhampati, MD, MHS
Medical Officer, FDA

Diversity in Kidney Disease Trials

Rekha Kambhampati, MD, MHS
FDA, CDER, Office of New Drugs
Division of Cardiology and Nephrology

Outline

- Why is Diversity in Clinical Trials Important?
- African Americans and CKD
- Global Nature of Drug Development
- African American Enrollment in U.S. Trials
- Barriers to Enrollment in Kidney Clinical Trials
- Regulatory Initiatives to Address Diversity
- Enrichment in Clinical Trials

FDA Encourages More Participation, Diversity in Clinical Trials

Why is diversity in clinical trials important?

"Clinical trials, and the people who volunteer to participate in them, are essential to help the development of ways to fight illnesses.
To make sure that the FDA has a full picture of the risk or benefit of a medical product, **patients enrolled in a trial should be representative of the types of patients who are likely to use the medical product if it is approved or cleared by the FDA…**

…**experience has shown that there can be important differences in how people of diverse groups respond to medical products.** Information on those differences can then be included in the product labeling to help doctors and patients make treatment decisions.

Source: https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm535306.htm

African Americans and CKD

- There is a disproportionate burden of kidney disease in African Americans
- In the U.S., the risk for kidney failure is 3-fold higher in African Americans compared to the general population
  - African Americans account for about 35% of U.S. dialysis patients
- The difference in risk may be due in part to genetic contributions to disease progression

Apolipoprotein L1

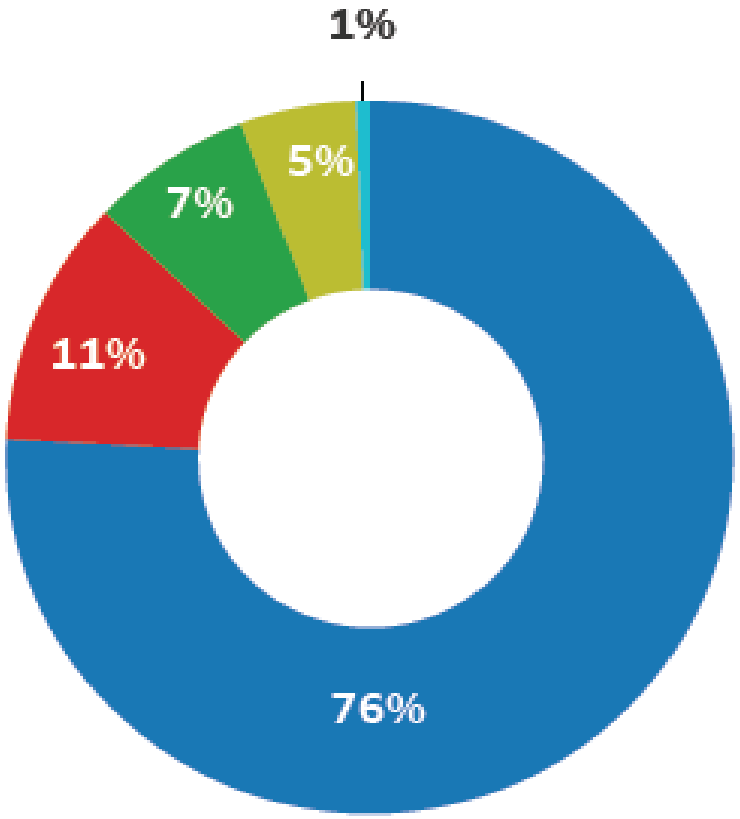
- Apolipoprotein L1 (*APOL1*) gene risk variants have been reported in African-derived chromosomes
- *APOL1* may play a role in kidney disease
  - E.g., increased severity of kidney disease compared to the general population

Global Nature of Drug Development

- Data supporting the efficacy and safety of drugs is often provided by international trials
- In European and Asian countries, blacks constitute a lower proportion of the population, compared to the U.S.
- This global race distribution is often reflected in clinical trials with a majority of international sites

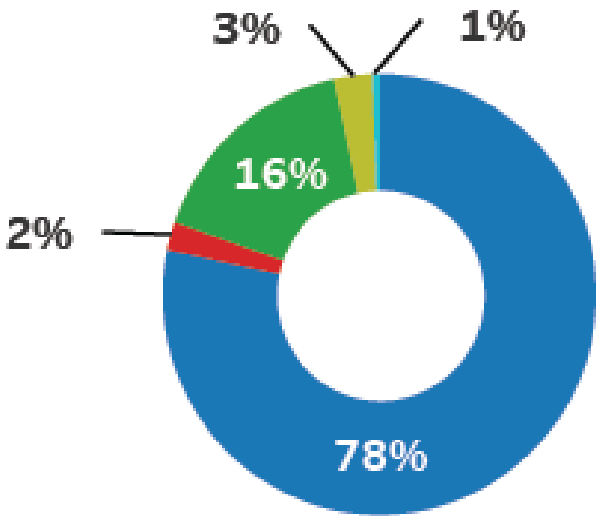
Race Distribution for all New Molecular Entities Approved by CDER from 2015-2019

Global



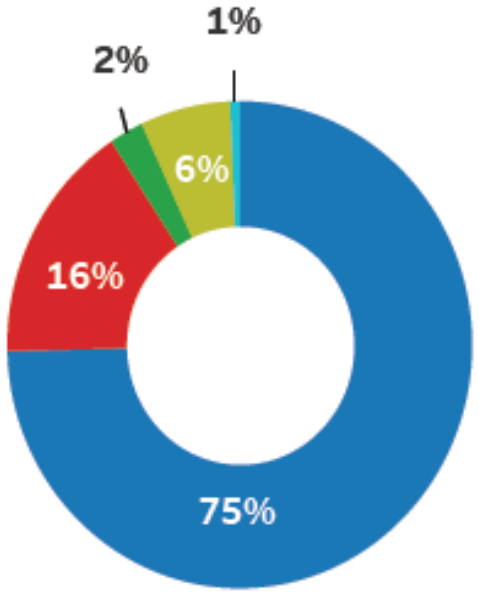
Total Participants: 292,537

United States

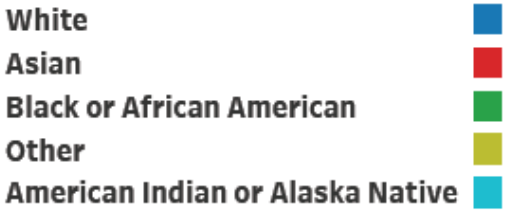


Total Participants: 102,596

Rest of the World



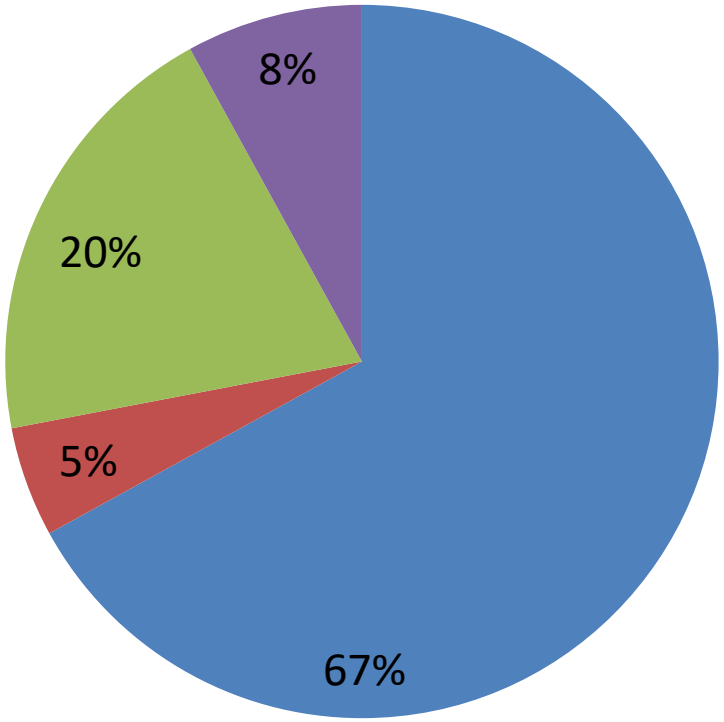
Total Participants: 189,941



Source: Drug Trial Snapshots

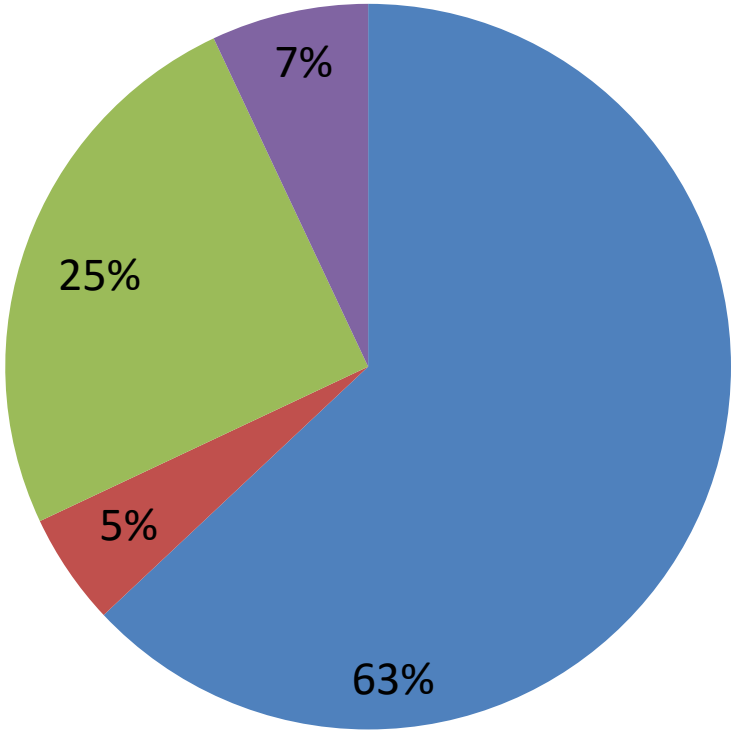
Snapshot of Recent Trials for Diabetic Kidney Disease

Invokana



Total Participants: 4401
5% Black or African American
16% enrollment from United States

Finerenone

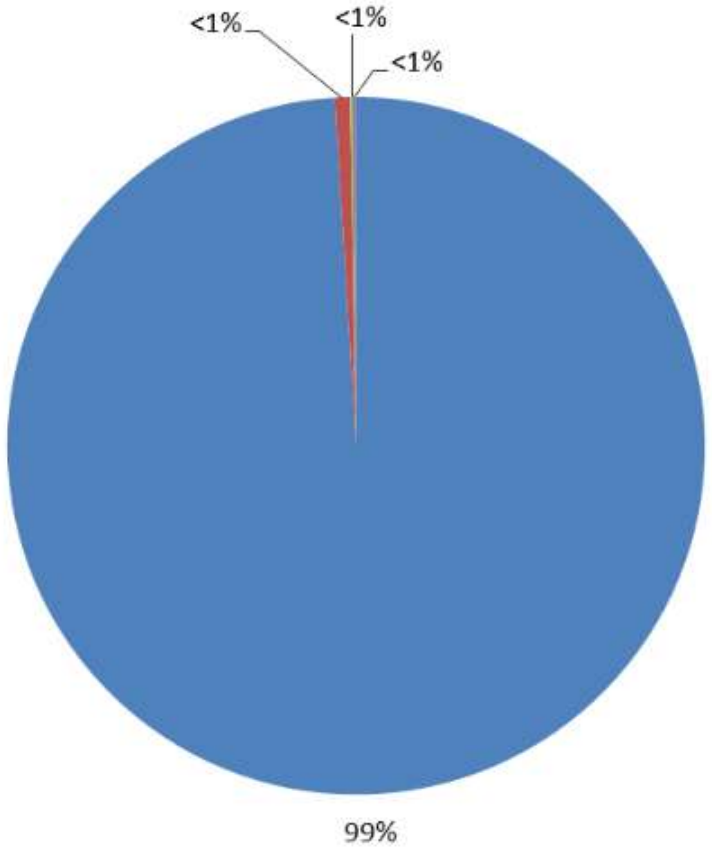


Total Participants: 5658
5% Black or African American
15% enrollment from United States

White Black or African American Asian Other

A Tale of Two Different Trials for Hyperkalemia

Veltassa

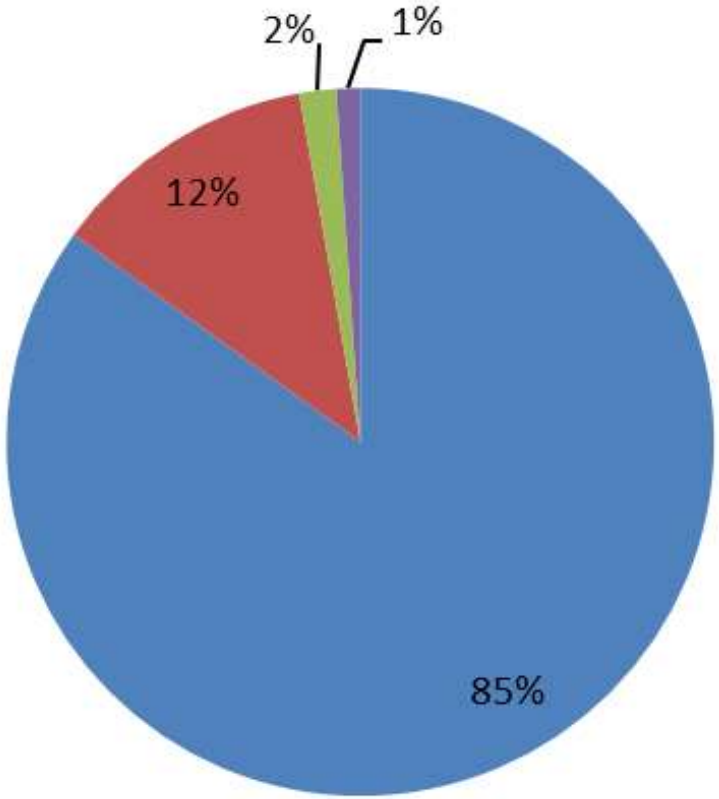


Total Participants: 715

<1% Black or African American

9% enrollment from United States

Lokelma



Total Participants: 1011

12% Black or African American

90% enrollment from United States

White Black or African American Asian Other

Source: Drug Trial Snapshots

African American Enrollment in U.S. Trials

- A goal of development programs is to have the study population inform the patient population likely to use the drug in clinical practice
- African Americans constitute about 13% of the total US population
- However, African Americans constitute a higher proportion of total patients with CKD in the United States
  - Most kidney clinical trials do not reflect this distribution

Barriers to Enrollment of African Americans in Clinical Trials

- Participants not asked/unaware of trials
- Mistrust in clinical trials
- Logistical barriers (e.g., transportation)
- Challenge for CKD trials:
  - Lack of awareness of kidney disease
    - Motivation to participate in clinical trials can be low

Regulatory Initiatives to Address Diversity

- Requirement that sponsors analyze clinical trial data by race
- Guidance for Industry*
- Post-marketing requirements

*Enhancing the Diversity of Clinical Trial Populations, www.fda.gov

Post-Marketing Requirement Example: Entresto

- Combination neprilysin inhibitor and angiotensin II receptor blocker approved to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure with a reduced ejection fraction
- Warning and Precaution indicates that the drug is associated with a **higher rate of angioedema in Black** than in non-Black patients
- Post-marketing requirement for “an epidemiologic study…to evaluate the incidence of angioedema in Black patients treated with Entresto compared to a control drug”

Closing Point: Enrichment

- There can be important differences in how people of diverse groups respond to medical products
- When a difference in treatment response is an a priori concern, the trial should ensure adequate enrollment of this group so that treatment differences can be detected if they exist

Summary

- There is a significant unmet need for safe and effective therapies for kidney disease
- African Americans have a high burden of kidney disease
- International clinical trials often reflect the global race distribution
- Enrichment of trials should be considered when there is an a priori concern that response to treatment may differ for different groups

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Andreea Lungu, MD
Medical Officer, FDA

Diversity in Diabetes Clinical Trials

Andreea Lungu, M.D.
Division of Diabetes, Lipids and Obesity
Office of New Drugs
Center for Drug Evaluation and Research

Disclaimers and Disclosures

- The views expressed in this talk represent my opinions and may not represent the views of the FDA

- I have no financial relationships to disclose

Overview

- Diabetes statistics
- Drug development in diabetes
- Demographic information in recent FDA approved drugs
- Potential barriers to enrollment of minorities in diabetes clinical trials

Diabetes statistics

National Diabetes Statistics Report 2020 (CDC)

- 34.1 million adults have diabetes (13% of US adult population)

- 7.3 million adults who met the laboratory criteria for diabetes did not report having diabetes (21.4% of all adults with diabetes)

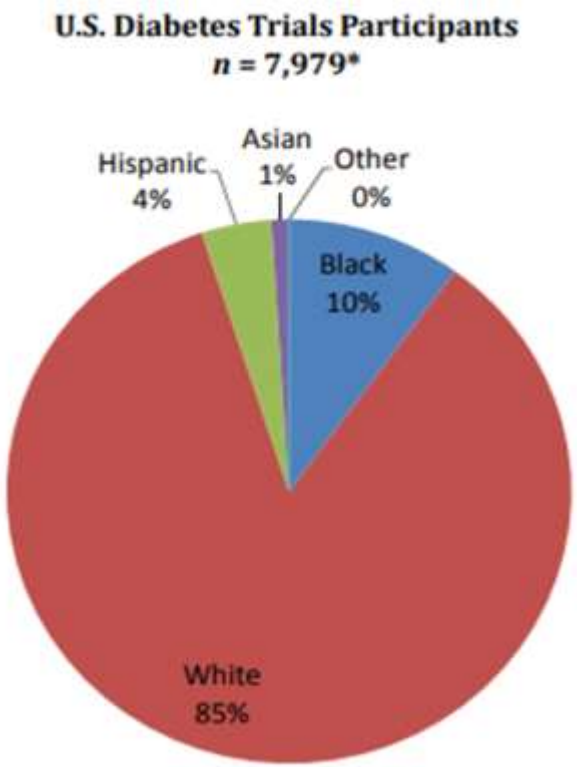
- Prevalence of diagnosed diabetes was highest among American Indians/Alaska Natives (14.7%), people of Hispanic origin (12.5%), and non-Hispanic blacks (11.7%), followed by non-Hispanic Asians (9.2%) and non-Hispanic whites (7.5%)

- Prevalence varied significantly by education level, which is an indicator of socioeconomic status - 13.3% of adults with less than a high school education had diagnosed diabetes versus 9.7% of those with a high school education and 7.5% of those with more than a high school education

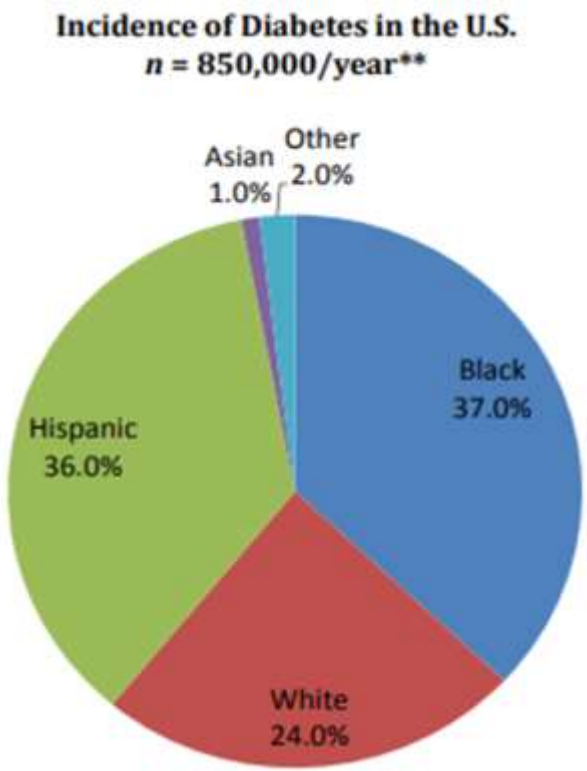
Source: https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf

Drug Development in Diabetes

FDA data 1998-2001



New diabetes diagnosed 2005



Source: White Paper on the Dialogue on Diversifying Clinical Trials Conference – 2011

Drug Development in Diabetes

- FDA has promoted enrollment practices that would lead to clinical trials that better reflect the population most likely to use the drug if the drug is approved
  - Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs 2020
  - Type 2 Diabetes Mellitus: Evaluating the Safety of new Drugs for Improving Glycemic Control 2020
  - Collection of Race and Ethnicity Data in Clinical Trials 2016

- CFR 314.50 The effectiveness and safety data must be presented by gender, age, and racial subgroups.

Drug Development in Diabetes

- Diabetes clinical trials
  - Large, multicenter, multinational trials
  - Usually less than half of patients are from the US
  - Majority of patients are white
  - Cardiovascular outcomes trials tend to enroll older patients, with more comorbidities compared to glycemic efficacy trials

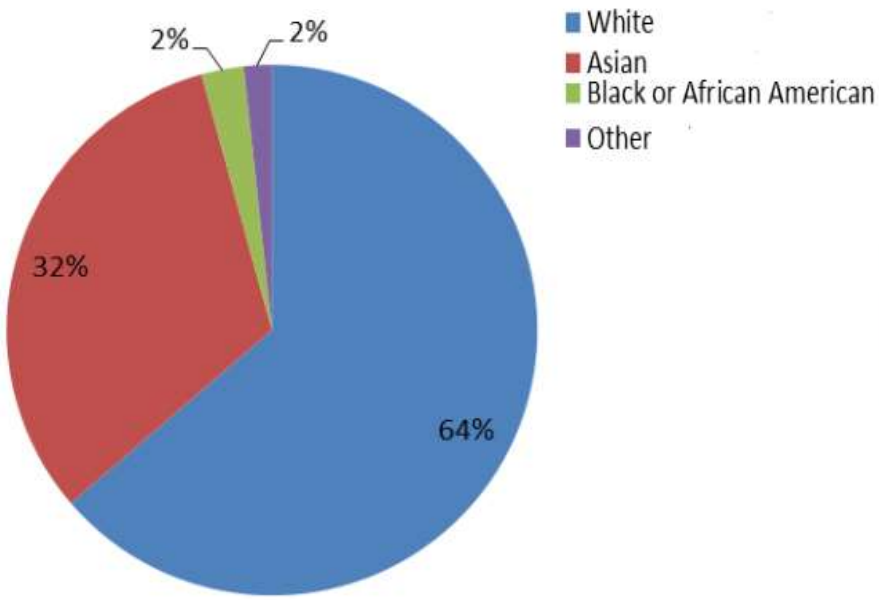
Diabetes Drug Approvals 2010-2020

DPP4-Inhibitors	SGLT2i	GLP1-RA	Insulins
Linagliptin 2011	Canagliflozin 2013	Liraglutide 2010	Insulin degludec 2015
Alogliptin 2013	Dapagliflozin 2014	Lixisenatide 2016	Insulin degludec/aspart 2015
	Empagliflozin 2014	Semaglutide sc 2017	
	Ertugliflozin 2017	Semaglutide oral 2019	
T2DM			T1 and T2DM

Cardiovascular outcomes trials for most of these drugs were completed and reviewed

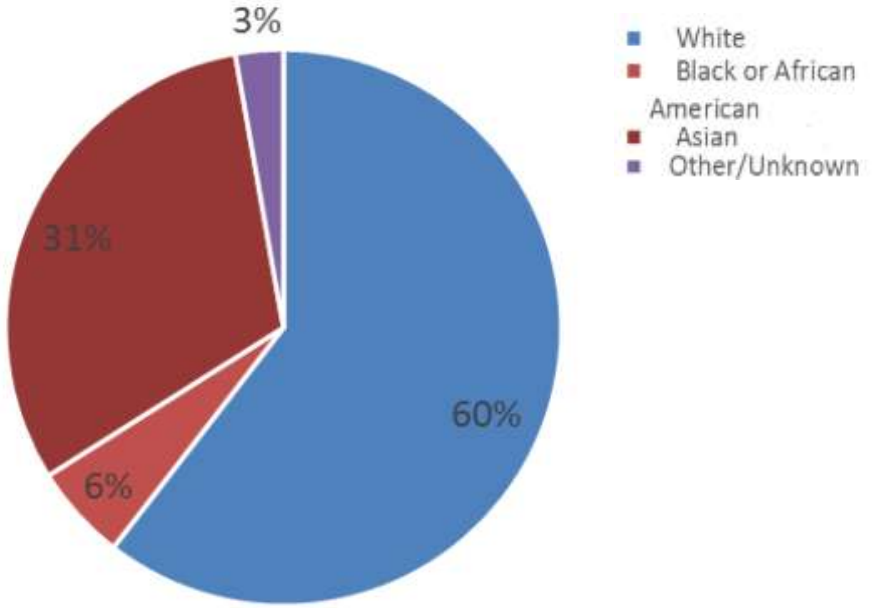
Demographic Information - Glycemic Control Trials

Lixisenatide



4508 subjects
14.9% US
19.3% Hispanic

Semaglutide

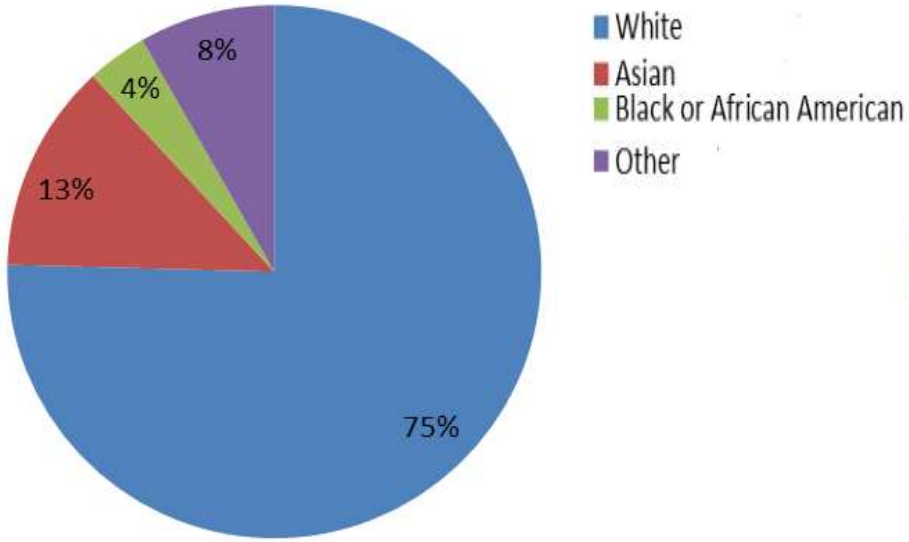


4087 subjects
27% US
19% Hispanic

Source: FDA Drug Snapshots, drugs@FDA

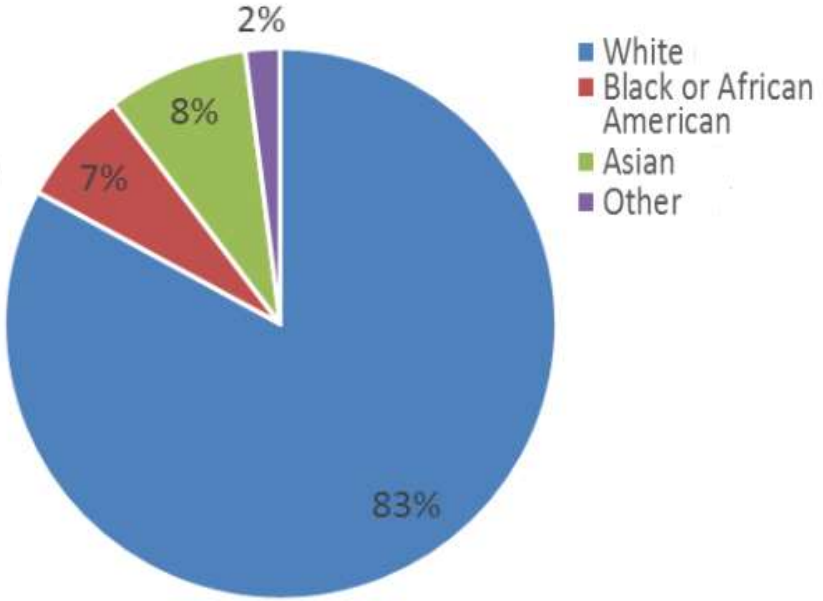
Demographic Information - Cardiovascular Outcomes Trials

Lixisenatide



6068 subjects
13.3% North America
29% Hispanic

Semaglutide

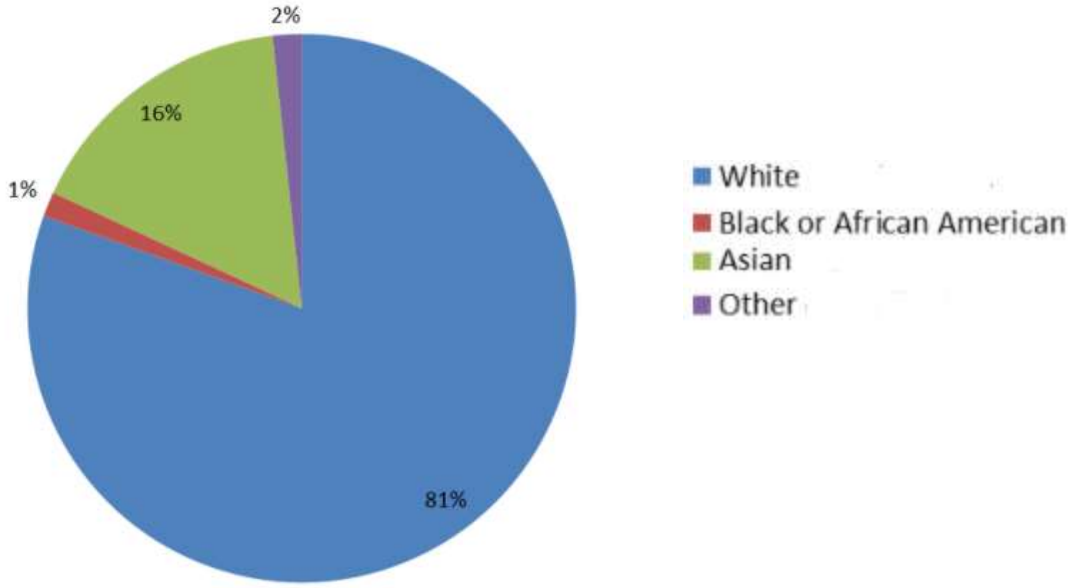


3297 subjects
34.5% US
15.5% Hispanic

Source: FDA Drug Snapshots, drugs@FDA

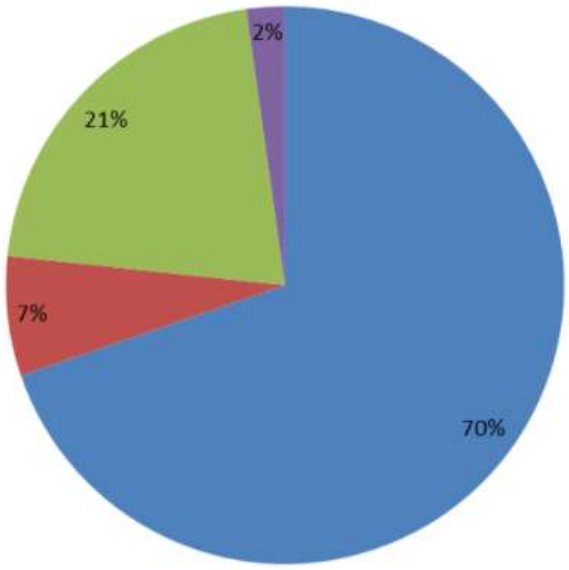
Demographic Information - Insulin Degludec

T1DM



1577 subjects
62% US
4% Hispanic

T2DM



4048 subjects
32% US
12% Hispanic

Source: FDA Drug Snapshots, drugs@FDA

Demographic Information in Prescribing Information

- **Section 12.3 Pharmacokinetics**
  - The impact of age, sex, race, ethnicity and other intrinsic factors as applicable on the pharmacokinetics of the drug
- **Section 14 Clinical Trials**
  - Statement regarding whether efficacy was impacted by age, gender, race, ethnicity, other variables
  - Study description includes demographic information
  - Efficacy data by subgroups is not usually presented as it is an exploratory analysis

Potential Barriers to Enrollment of Minorities in Diabetes Trials

- Cultural (lack of trust) and socioeconomic differences
- Access to information/language barrier
- Location of clinical trial sites
- Lack of awareness that they have diabetes

Summary

- Diabetes in the US occurs in a higher proportion of minority populations compared to non-Hispanic whites

- Clinical trials in diabetes are multinational, more patients are enrolled outside of US vs US, and a high proportion of participants are white, with no major differences between recent drug programs

- The impact of race/ethnicity on safety and efficacy is evaluated in the FDA review of new drugs, and no issues have been identified to impact indication or safety in specific subpopulations, although the size of certain subgroups limits our conclusions

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Jovonni Spinner, DrPH, MPH, CHES
Senior Public Health Advisor, FDA

The FDA Office of Minority Health and Health Equity: Clinical Trial Diversity Campaign

Dr. Jovonni Spinner, MPH, CHES
February 10, 2021

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

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.

2012 FDA Safety and Innovation Act (FDASIA) Section 907 Action Plan Priorities & Strategies

PRIORITY 01

(QUALITY)

Improve the completeness and quality of demographic subgroup data collection, reporting and analysis

FDA Guidance Documents

PRIORITY 02

(PARTICIPATION)

Identify barriers to subgroup enrollment in clinical trials and employ strategies to encourage greater participation

Public Meetings

Tools to support diverse clinical trial participation

PRIORITY 03

(TRANSPARENCY)

Make demographic subgroup data more available and transparent

Drug Trials Snapshots

(Center for Drug Evaluation and Research)

Clinical Trial Diversity: Why it matters?

- Racial and ethnic 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
- Persons of different ages, races, and ethnicities could react differently to certain medical products
- To understand health disparities - diseases that occur more frequently or appear differently in diverse populations

Diversity in Clinical Trials Initiative

Developed an ongoing multi-media public education and outreach campaign to raise awareness around the importance of diverse participation in clinical trials.

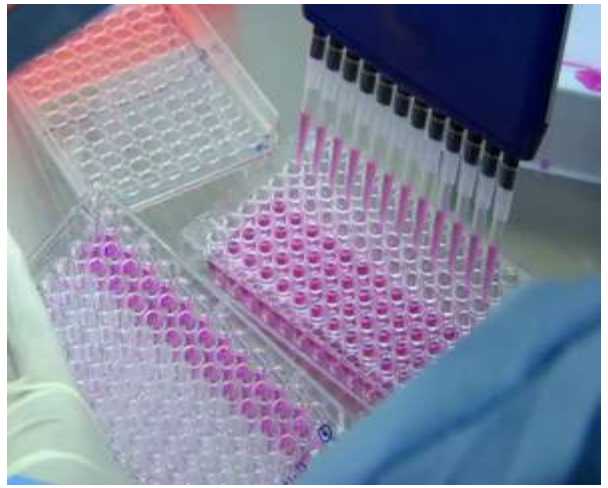
Motivators for Campaign

- Add positive reinforcement as to why minority health issues matter
- Educate consumers about key issues
- Help stimulate dialogue among peers and patient-provider

Diversity in Clinical Trials Campaign

- Videos
- Newsletters & E-alerts
- Webpage
- Stakeholder Collaboration
- Podcasts
- Social Media
- Communications Toolkit
- Culturally & Linguistically Tailored

Diverse Participation in Clinical Trials
Videos and Podcast



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

Veterans in Clinical Trials

Veterans Health Administration
Office of Health Equity

Diversity in Medical Device Clinical Trials Video

Clinical Trial Diversity Resources

Clinical Trial Diversity

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 and Health Equity

4 things you should know about clinical trials

1. Clinical trials are research studies conducted with people—They are designed to answer specific research questions about medical products or procedures. Researchers must follow detailed protocols and the FDA's safety guidelines to make each trial as safe as possible.

2. Participation is always voluntary—and you can leave a study whenever you want.

3. Clinical trials often need **healthy volunteers** to help answer research questions.

4. FDA does not conduct clinical trials—FDA works with companies that develop medical products to protect participants and review the results to ensure that the medical product is safe and effective.

The importance of diverse participation in clinical trials

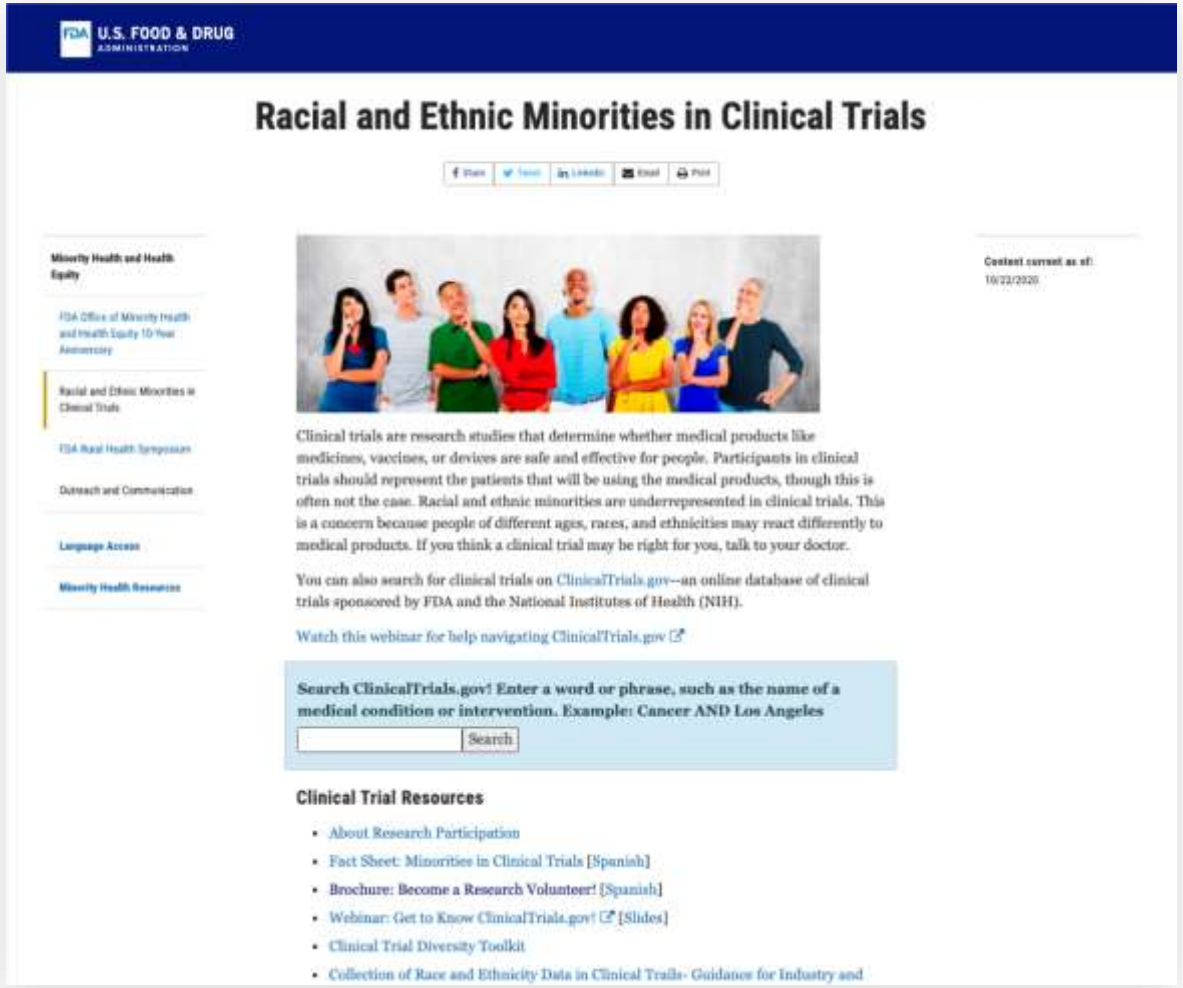
Participants in clinical trials should represent the patients that will use the medical products. This is often not the case—racial and ethnic minorities are underrepresented in clinical research. This is a concern because people of different ages, races, and ethnicities may react differently to medical products. Talking to your doctor is the best way to find out if joining a clinical trial might be a good choice for you. If:

- You and your doctor believe current treatments aren't good options and a clinical trial offers additional alternatives.
- You want to help ensure that the benefits and risks of new medical products are studied in the diverse patients likely to need them.
- You want to help researchers find better ways to fight illnesses.

If you think a clinical trial may be right for you, talk to your doctor. You can also search for clinical trials through an online database, **www.ClinicalTrials.gov**.

If you want to know more about a recently approved drug you may be taking, visit the **Drug Trials Snapshots**—a database that gives you information on who participated in a trial for drug approval. You can find more information at **www.FDA.gov/DrugTrialsSnapshot**.

For more information on minority health go to **www.fda.gov/healthequity**. To watch videos and view a list of questions to ask researchers go to **www.hhs.gov/ohrp/research-participation**.



U.S. FOOD & DRUG ADMINISTRATION

Racial and Ethnic Minorities in Clinical Trials

Share | Tweet | LinkedIn | Email | Print

Minority Health and Health Equity

- FDA Office of Minority Health and Health Equity 10 Year Anniversary
- Racial and Ethnic Minorities in Clinical Trials
- FDA Rural Health Symposium
- Outreach and Communication
- Language Access
- Minority Health Resources

Content current as of: 10/22/2020

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 Trials- Guidance for Industry and

Social Media Outreach

Examples of Stakeholder Engagement Activities

- The Alliance of Multicultural Physicians and FDA OMHHE Memorandum of Understanding
  - Collective of the Association of American Indian Physicians (AAIP), Association of Black Cardiologists (ABC), National Council of Asian Pacific Islander Physicians (NCAPIP), National Hispanic Medical Association (NHMA), and National Medical Association (NMA). Opportunities to collaborate on developing educational, outreach, and training initiatives for physicians and the patients they serve to advance health equity.

- Yale and FDA OMHHE Memorandum of Understanding
  - To advance the Yale Cultural Ambassadors Program, an engagement of community partners to increase diverse participation in clinical research

Thank You!

Follow us at: @FDAHealthEquity

Email us at: HealthEquity@fda.hhs.gov

Visit us at: FDA.gov/HealthEquity

Join webinars and stakeholder calls

Tesheia Harris, MBA, MHS
Deputy Director and Chief Operating Officer of YCCI and the Associate Director for Clinical Research for Yale School of Medicine

Explore barriers to diversity in clinical trials for CKD and diabetes and describe strategies to improve clinical trial diversity

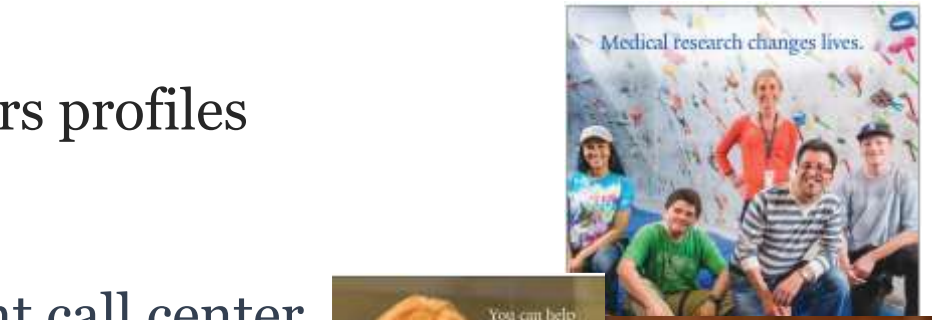
The Yale Model: Community and Participant Engagement

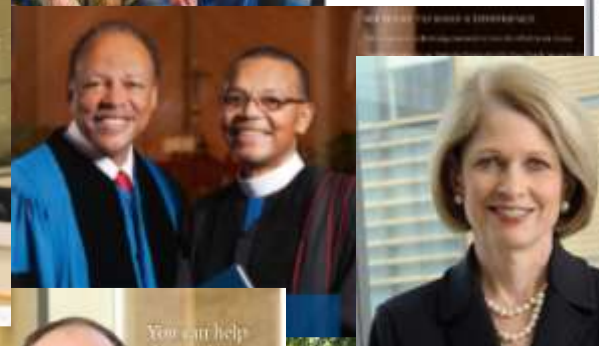
Tesheia Harris, MBA, MHS (formerly Johnson)

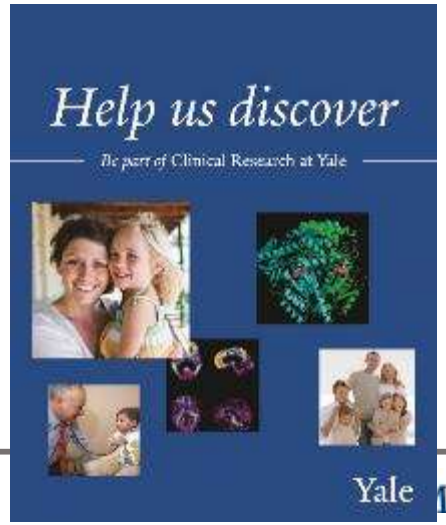
Chief Operating Officer and Deputy Director , Yale Center for Clinical Investigations
Director of Clinical Research , Yale University School of Medicine

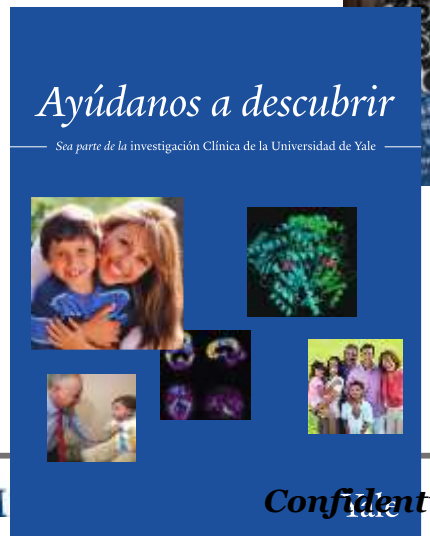
Integrated Approaches to Recruitment:
"Help us discover" clinical research awareness campaign

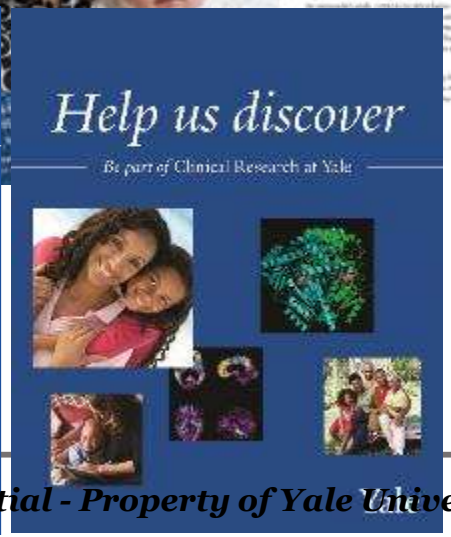
- *"Help us discover"* volunteers profiles
- Cultural Ambassadors
- Advertising and media
- Clinical research recruitment call center
- Integrate community practices
- Epic telehealth engagement







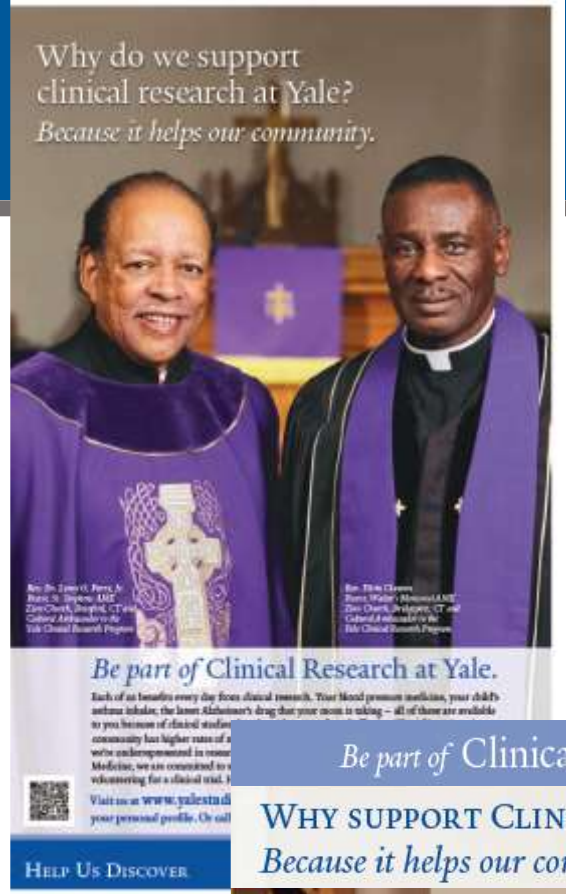


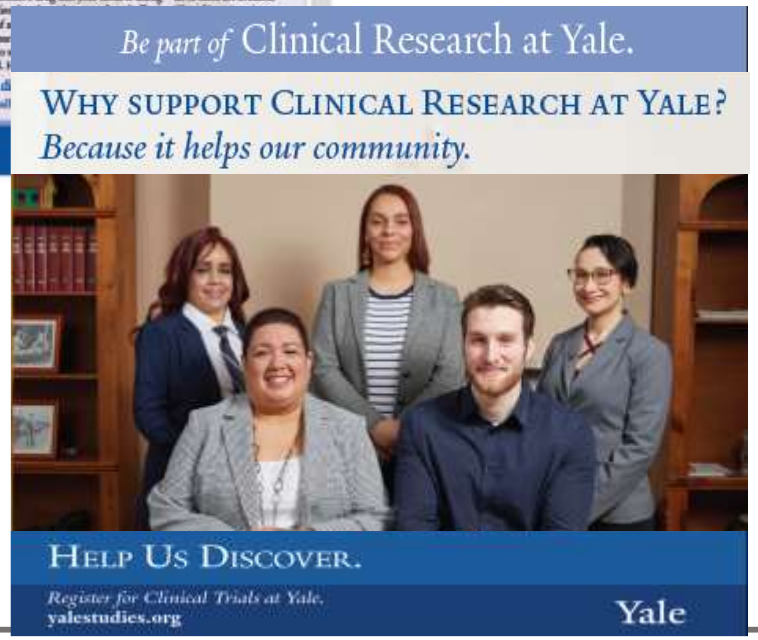


Cultural ambassador

Ambassador program role include:

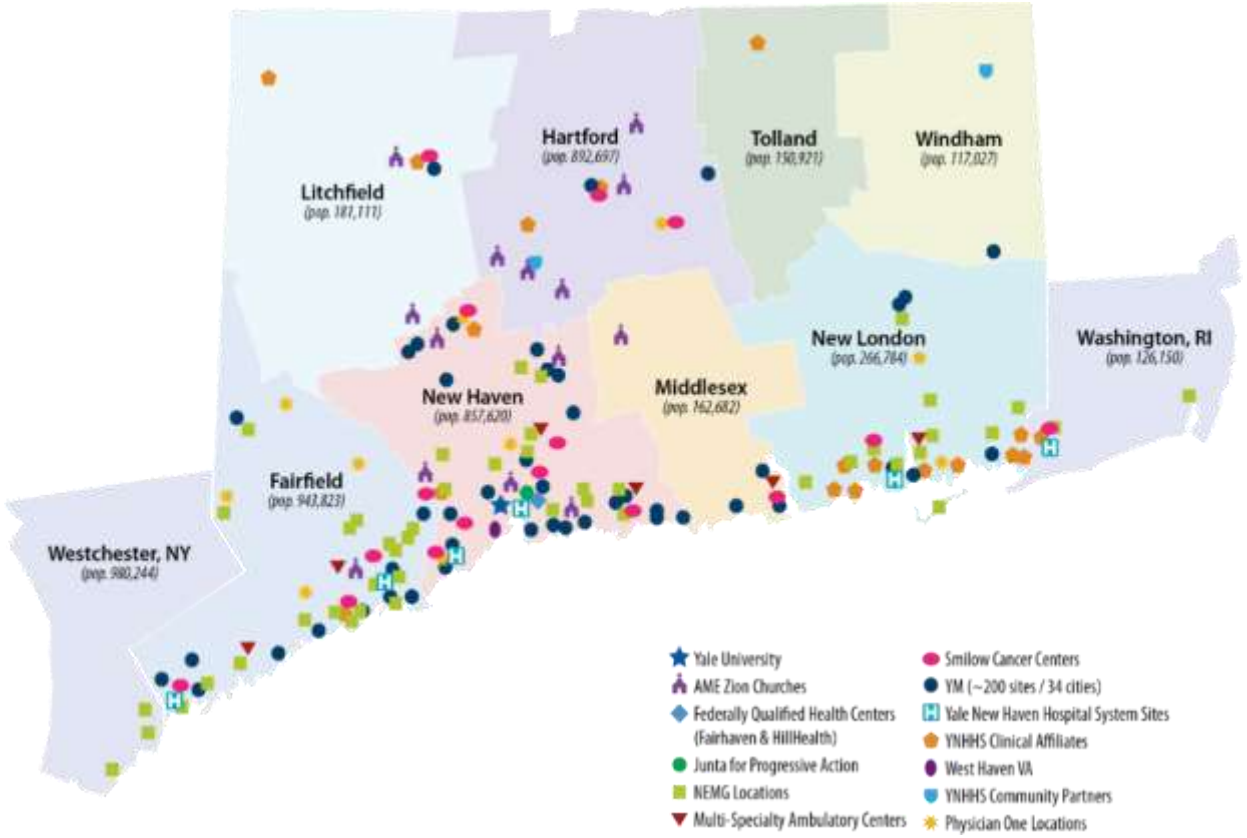
- ✓ **Bidirectional collaboration**
- ✓ Express community needs, ideas, and interest
- ✓ Recruitment campaign development advice
- ✓ Recruitment plan development
- ✓ Recruitment support for special populations
- ✓ Study design support
- ✓ Translations of study material and informed consent
- ✓ Community Grand Rounds held monthly





Clinical Research Growth

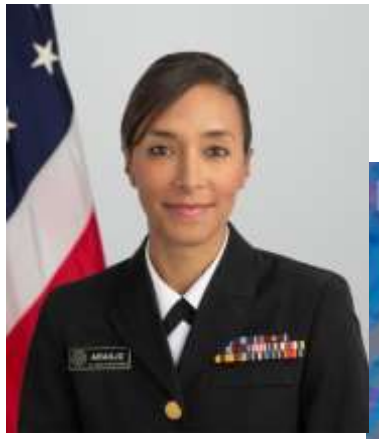
- 8% of new patients come to Yale initially for RESEARCH
- 950% Increasing in industry research
- **In FY20, more than *30%* of all accrual across Yale studies was historically underrepresented populations**



FDA Office of Minority Health Equity and Yale University

https://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/AcademiaMOUs/ucm603678.htm

1. Collaborations to cultivate and advance **the Yale Cultural Ambassadors Program** and the engagement of community partners to increase participation of diverse and historically under represented or underserved populations in clinical research.



Bi-directional – Community priority list

The community 2018-2019 priority list

1. Access to health care
2. Addressing health disparities
3. Substance abuse prevention and interventions
4. Violence and crime prevention
5. Cancer care
6. Asthma prevention and treatment
7. Obesity and related chronic medical conditions
8. Diabetes
9. Violence and crime prevention
10. Health promotion/activity/exercise
11. Infant mortality and health disparities
12. Mental health issues
13. HIV/aids prevention and treatment
14. Teen pregnancy and STI prevention
15. Community involvement in research and dissemination of results

Reprioritized the work FY21

- COVID19 / Vaccine uptake
- FDA partnership
- Health access
- Other health issues
  - Depression
  - Substance abuse
  - Cancer
  - Heart disease

Important lessons: Community partners input

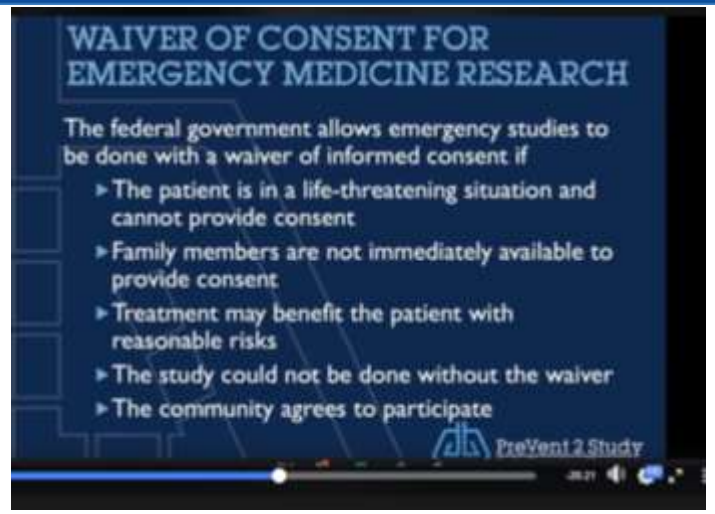
Big wins for the community and research:

- ✓ Expressed community needs, ideas, and interest
- ✓ Better studies with better participation.
  - ✓ Think about the participant: appropriate messaging, access issues (hours, research stipend, # of study visits, transportation), recruitment strategies.

You should expect the following with engagement:

- ✓ Hard questions will be asked: This might be interesting science, but should we do this study in the community?
- ✓ Is this additional survey really necessary?
- ✓ Recruitment approaches – How does the ad look to the community?
  - ✓ Examples: HIV, single parent, words “trial vs research” and “drug vs potential medicine”

Community Engagement during pandemic



https://medicine.yale.edu/ycci/researchspectrum/cer/research/ambassadors/tfrs/

U.S. FOOD & DRUG ADMINISTRATION

CERSI University of Maryland

Questions and Answers

Break

1:45-2:00 p.m.

FDA U.S. FOOD & DRUG ADMINISTRATION

CERSI University of Maryland

SESSION 3: 2:00 - 3:00 p.m.

RWD Research in Diabetes and Chronic Kidney Disease (CKD)

Moderator

Charmaine Rochester -Eyeguokan, PharmD, CDCES (CDE), BCACP

Professor, University of Maryland School of Pharmacy

Clydette Powell MD, MPH, FAAP
Designated Federal Officer, National Clinical Care Commission, Medical Officer
Office of the Assistant Secretary for Health, US Department of Health and Human Services




National Clinical Care Commission

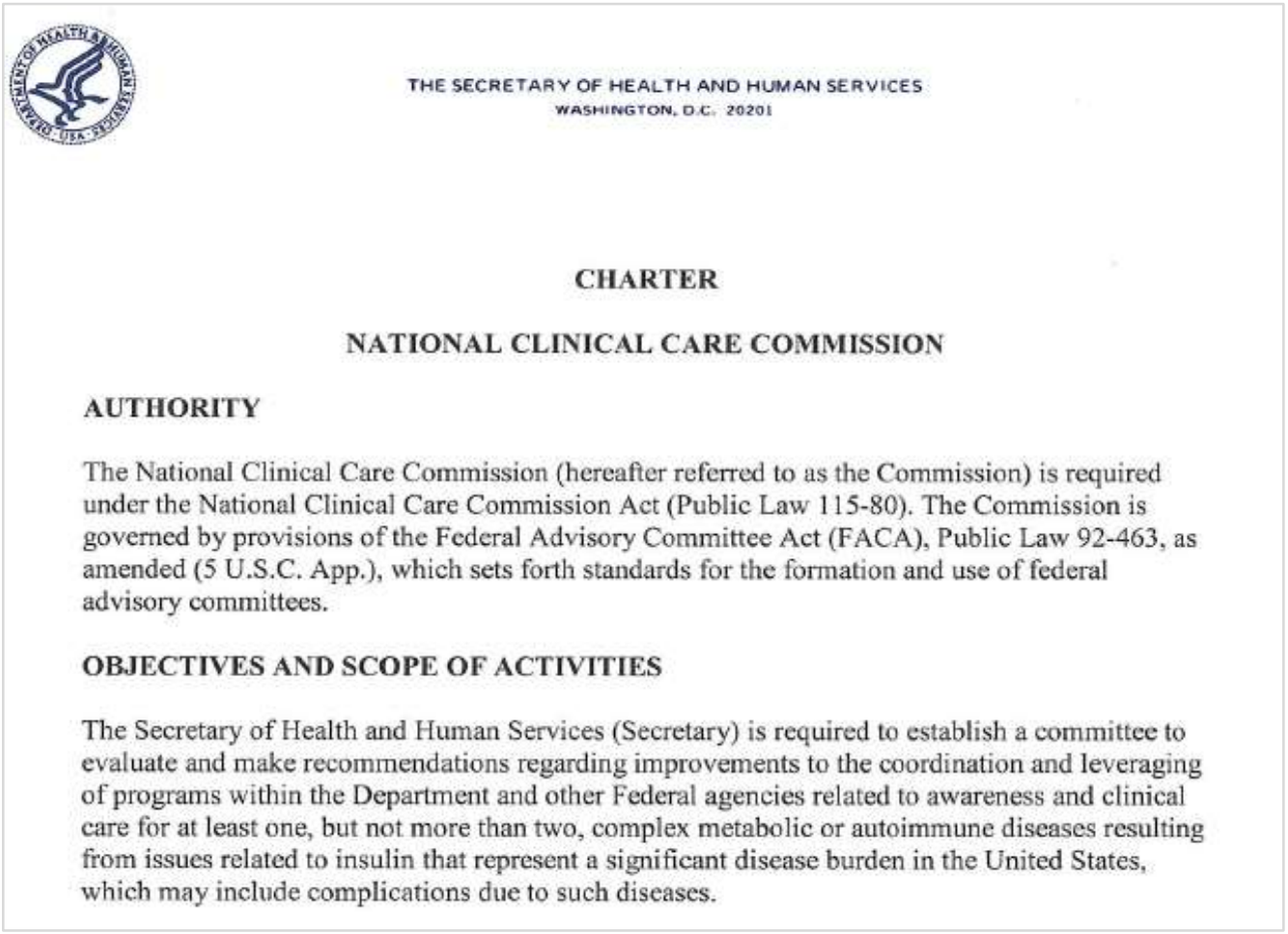
ODPHP | Office of Disease Prevention and Health Promotion

Welcome

Clydette Powell, MD, MPH, FAAP
Designated Federal Officer, NCCC
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services

Establishing the NCCC

- Mandated by Congress in November 2017
- ASH assigned management and support of the NCCC to ODPHP in 2018
- Secretary Azar signed the Charter - April 3, 2018



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

CHARTER

NATIONAL CLINICAL CARE COMMISSION

AUTHORITY

The National Clinical Care Commission (hereafter referred to as the Commission) is required under the National Clinical Care Commission Act (Public Law 115-80). The Commission is governed by provisions of the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

OBJECTIVES AND SCOPE OF ACTIVITIES

The Secretary of Health and Human Services (Secretary) is required to establish a committee to evaluate and make recommendations regarding improvements to the coordination and leveraging of programs within the Department and other Federal agencies related to awareness and clinical care for at least one, but not more than two, complex metabolic or autoimmune diseases resulting from issues related to insulin that represent a significant disease burden in the United States, which may include complications due to such diseases.

The Commission's Charge

1. Federal programs of DHHS that focus on preventing and reducing the incidence of diabetes and its complications
2. Current activities and gaps in Federal efforts to support clinicians in providing integrated, high-quality care
3. The improvement in, and improved coordination of, Federal education and awareness activities
4. Methods for outreach and dissemination of education and awareness materials that (1) address the diseases and complications; (2) are funded by the Federal Government; and (3) are intended for health care professionals and the public
5. Opportunities for consolidation of overlapping or duplicative Federal programs related to diabetes and its complications

Membership

Non-Federal

- Endocrinologists
- Primary care physicians
- Non-physician health care professionals
- Patient advocates
- National experts
- Health care providers with patients without health insurance coverage

Federal

Timeline

Nov 2017
PL 115-80

April-June 2018
Member search and selection

Oct 2018
Inaugural Meeting, commissioning ceremony and subcommittee formation

Jan 2019
3 year operating plan to Secretary and Congress

2019 4 Public Meetings

2020 4 Public Meetings

2021 4 Public Meetings

Oct 2021
Final report is signed by ASH/SoH, and sent to Congress

Prevention – General Population Recommendation Focus Areas

food supply, **healthy food** access, and **nutrition assistance programs**

sugar-sweetened beverage tax; sales in government offices, workplaces, healthcare facilities, and public spaces

trans-agency diabetes efforts

federal housing assistance and **secondhand smoke exposure**

Prevention – Targeted Population Recommendation Focus Areas

Screening & Diagnosis

for prediabetes/diabetes

Improve access to and utilization

of effective type 2 diabetes prevention intervention

Sustainability

of type 2 diabetes prevention over time

Develop new & more effective prevention strategies

for type 2 diabetes

Treatment & Complications Recommendation Focus Areas

Consider "**health equity** as a component of any new or revised federal policy related to diabetes"

Expand and improve federal **diabetes education and support**

Improve access to innovative diabetes **technologies**

Implement **team-based care**

Increase program integrity and utilization of **virtual care**

https://health.gov/our-work/health-care-quality

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Social media & email updates

Blog Archive

January 2020

2019

2018

Help Shape Federal Diabetes Prevention and Treatment Programs — Submit Your Comments!

Posted on January 15, 2020 by ODPHP

The National Clinical Care Commission (the Commission or NCCC) is seeking written comments about federal diabetes prevention and treatment programs.

The public comment period is open from January 15, 2020 through February 3, 2020. You're invited to review and comment on a set of questions about diabetes prevention and treatment — including questions about specific recommendations for federal agencies, best practices, and limitations and gaps in federal programs.

The Commission is charged with evaluating federal diabetes programs — including programs that focus on complications from diabetes. The Commission will work until October 2021, when it will submit a final report to Congress and the Secretary of Health and Human Services with its recommendations. Your comments will help inform this report.

Public comment is an essential part of the Commission's work. Members of the public — both individuals and organizations — are invited to review and submit their comments on federal diabetes prevention and treatment from **January 15, 2020 to February 3, 2020**.

Let's work together to improve federal diabetes prevention and treatment programs in the United States. Learn more about the questions available for comment and how to submit

Public Comments

01
Draft FRN

02
Federal Register

03
FDMS

04
Regulations.gov

OWH drafts FRN

- Notification of public meetings
- Request for comments

FEDERAL REGISTER
The Daily Journal of the United States Government

fdms.gov

Agencies use the Federal Docket Management System to post the FRN to regulations.gov and manage comments

Comments are reviewed by OWH

then posted to Regulations.gov

regulations.gov

Public can see the FRN, read comments and submit documents

National Clinical Care Commission

Register now!

10th Meeting of the National Clinical Care Commission

February 17, 2021 | 1:00- 5:30 pm EST (virtual)

Join us for the next round of **NEW** recommendations, discussion on access to care and making medications more affordable, and public comments.

Register at: https://adobe.ly/39JtSfj

Email OHQ@hhs.gov to submit comments and join the listserv!

Leonard Pogach, MD, MBA, FACP
National Program Director Diabetes and Endocrinology,
Specialty Care Services, Veterans Health Administration

VHA Data Driven Approach to Improve DM/CKD Care Organizational, Clinician Focused and Point of Care Strategies

Disclosure

- This presentation represents the perspective of the author and not that of the Veterans Health Administration. Dr. Pogach has no conflicts of interest to disclose

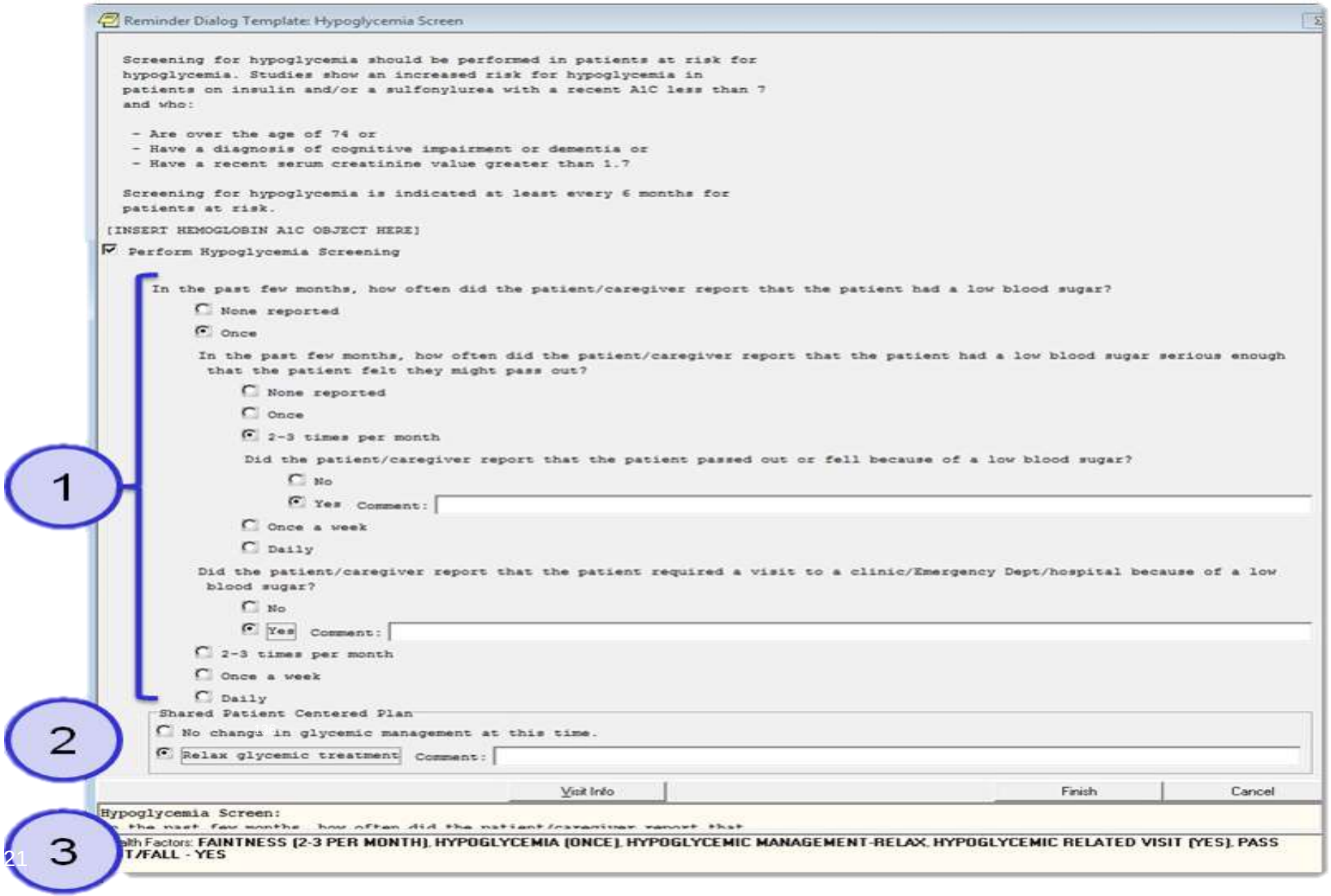
Specific VA Objectives to address DM-CKD

- **Key evidence-based strategies** to address DM-CKD management include: (1) **individualized goals** that target glycemic management, blood pressure control (2) **use of medications** angiotensin-converting-enzyme inhibitors (ACEi) or angiotensin receptor blockers (ARB) for patients with albuminuria and hypertension; and SGLT-2i for CKD
- **Utilization of National Reports** to evaluate disparities (age, race, mental health, co-morbid conditions) using current and longitudinal data.
- **Use of Organizational Structure to Implement Quality Improvement:** [Network level (Integrated Clinical Communities]); Academic Detailing [Pharmacy Benefits Management Program]; National Initiatives [**Choosing Wisely Hypoglycemic Safety Initiative**]

VA Choosing Wisely Hypoglycemic Safety Initiative/DHHS National Action Plan for Prevention Adverse Drug Events: A Case Study

Hypoglycemic Safety	• Provide patients with information on symptoms, management and ways to lower their risk
Shared Decision Making (SDM)	• Give both patients and providers the skills needed for SDM**, including health literacy & numeracy**
A1c Goals	• Disseminate information about A1c accuracy and **individualizing target ranges**
Food Insufficiency	• Educate both providers and patients about potential barriers and solutions to **food insufficiency**
Medication Safety	• Ensure providers and patients have an understanding of **potential risks of medications**

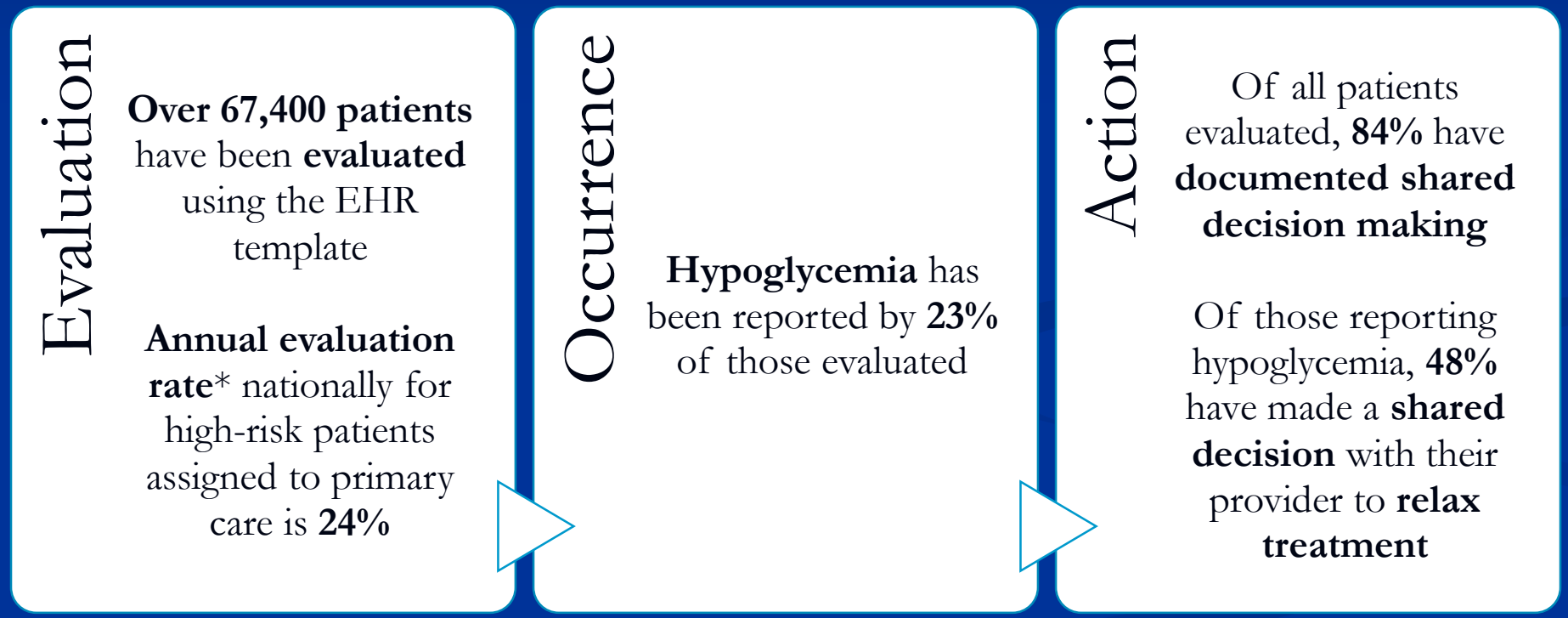
Ask About AND Document Hypoglycemia



Tom's Story: Be Aware
Ask About Low Blood Sugar

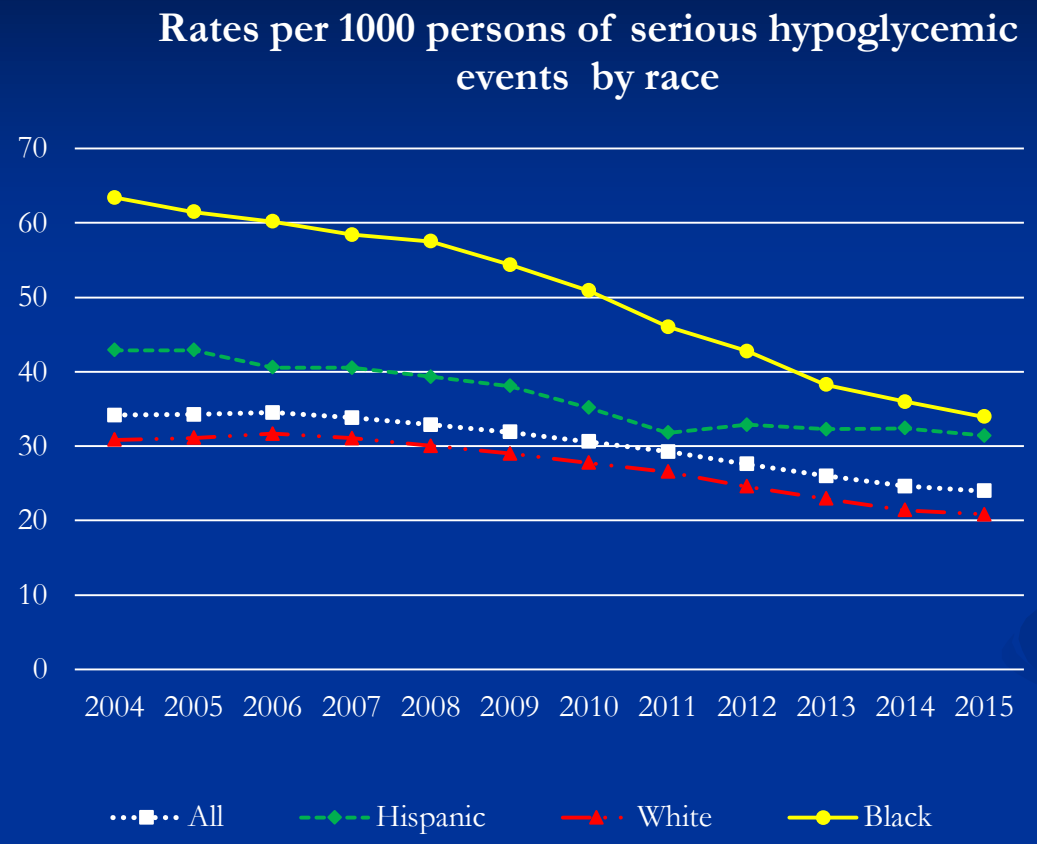
http://videos.va-ees.com/default.aspx?bctid=5476595850001

CW-HSI Findings (National; as of Oct 2020)



**The CW-HSI is a voluntary initiative and, as such, participation is not mandated. Measuring evaluation rates is dependent upon use of the Hypoglycemia Screening CPRS Tool, which is not a mandatory tool.*

Racial differences in trends of serious hypoglycemia among higher risk older adults in US Veterans Health Administration, 2004-2015: Tseng CL et al. Journal Diabetes Complications. 2020



% of patients with HbA1c <7% (53mmol/mol) decreased in all racial/ethnic groups (not shown):

- 44.2% to 32.9% (Blacks),
- 51.0% 32.6% (Whites),
- 41.3% to 28.4% (Hispanics).

The Black-White absolute rate differences among insulin users were 32.6 (63.4 vs. 30.8) in 2004 and 13.1 (33.9 vs. 20.8) in 2015;

- among non-insulin users, the differences were 25.7 (39.3 vs. 18.1) in 2004 and 10.1 (20.7 vs. 9.3) in 2015.

Study Design: Serial cross-sectional study using VHA and Medicare data. Study population: Ambulatory VA patients who received secretagogues (Sec) and/or insulin (Ins) within 120 days of calendar yrs 2004-2015 and who were Medicare enrolled for one yr prior to and during the study yr. Hba1c values (from VA source only): Baseline HbA1c within 120 days of each study yr; updated last value before the first event or end of study yr

Diabetes Quality Measures and for DM and CKD

- Current NCQA reported diabetes measures as apply to **all patients (18-75)** with a diagnosis of diabetes.

Measure: Effective FY21, will be e-measures
Quality
Endocrinology/Diabetes
Diabetes - CV Risk Management
DM: HbA1c poor control A1c>9%)
DM: BP LT <140/90

VA KIDNEY SPECIFIC METRICS

	Metric	Definition	Data Source
CKD Care	Awareness	% Pts with CKD Stages 3-5 w CKD ICD 10 code/eGFR	VSSC/DM Cube
	Screening	% Pts w DM w annual eGFR % Pts w DM w annual UACR	VSSC/DM Cube
	Treatment	% Pts w CKD w BP < 140/90 mm Hg; % Pts w CKD prescribed a statin % Pts w DM & HTN prescribed RAASi % Pts w T2DM & CKD stages 1-3 prescribed SGLT2i	VSSC/DM Cube
	Safety	% Pts w DM & CKD Stages 3-5 on insulin w A1c < 7%	VSSC/DM Cube
ESRD Care	Prevention	Hemodialysis unit BSI rate	IPEC/Dialysis Data Mart
	RRT Preparation	% ESRD pts on hemodialysis w permanent catheter	IPEC/Dialysis Data Mart

Data to Refine Population and Stratification

Stratification within Disease Cohort: Targeted Quality Improvement

- Age, Sex, Race, BMI
- Uses CPT, ICD, and stop codes for the last 24 months
- Key Laboratory Results (including A1c, BP, Cholesterol, eGFR)
- Diabetes Complications and common co-morbid conditions:

  Amputation, **cognitive impairment**, **chronic kidney disease**, ESRD, Fistula, Glaucoma, Heart Failure (HF**),** Ischemic Heart Disease (IHD), Macular Degeneration, Nicotine, PTSD, **Obesity/Morbid Obesity**, Peripheral Vascular Disease (PVD), Retinopathy **Serious Mental Illness,** Stroke, **Substance Abuse**, Ulcer, and **Vision Impairment**
- Medications related to glycemic management, hypertension management, cardiovascular disease
- Longitudinal time views at 12 or 24 months to identify trends

Diabetes Prevalence

DM Definition	#	%		Black		White	
Definite Diabetes	1,619,857	26%		322,738	30 %	1,141,801	27%
Possible Unrecognized Diabetes	176,976	3%		36,308	3%	119,761	3%
Possible Pre-diabetes	2,290,310	37%		395,178	37 %	1,658,566	39%
No Diabetes	2,116,359	34%		305,640	29 %	1,359,572	32%
Total	6,203,502						

Diabetes and Co-Morbid Conditions

Disease Cohorts	Total	%	Black		White
None	462,476	29%	85,513	26%	326,591
Amputation	50,175	3%	10,888	3%	35,220
Cognitive Impairment	19,863	1%	3,544	1%	14,623
Dementia	65,888	4%	13,030	4%	47,045
ESRD/CKD	**308,099**	**19%**	**67,933**	**21%**	**213,015**
HF	192,092	12%	37,780	12%	139,005
IHD	451,370	28%	57,655	18%	356,055
Macular Degeneraration	57,669	4%	7,861	2%	45,053
PTSD	274,717	17%	70,324	22%	176,456
PVD	159,833	10%	29,191	9%	118,602
SMI	78,462	5%	21,863	7%	49,952
Stroke	128,068	8%	26,318	8%	91,408
Subabuse	141,908	9%	44,552	14%	85,256
Ulcer	82,231	5%	14,498	4%	61,435
Vision Impairment	34,571	2%	8,152	3%	23,323

DM-CKD/BMI

BMI	Total		Black		White
<25	47,987	16%	12,513	18%	30,713
25-29.9	94,429	31%	20,399	30%	65,308
30-39.9	130,130	42%	27,507	40%	91,970
>=40	27,463	9%	5,839	9%	19,589
Not Done in Last 24 Mos	8,090	3%	1,675	2%	5,435
	308,099	100%	67,933		213,015

DM-CKD A1c Results

A1C	Total		Black		White	
<6.5	**81,535**	**26%**	**20,172**	**30%**	**54,370**	**26%**
6.5-6.9	**41,306**	**13%**	**8,522**	**13%**	**29,356**	**14%**
7.0-7.9	64,360	21%	11,950	18%	47,099	22%
8.0-8.9	33,394	11%	6,586	10%	24,261	11%
>=9.0	**28,673**	**9%**	**7,225**	**11%**	**18,794**	**9%**
Not recorded last 12 months	58,231	19%	13,478	20%	39,135	18%
	307,499		67,933		213,015	

DM-CKD Receiving Insulin A1c

A1C	Total	%	Black	%	White	%	<25	25-29.9	30-39.9	4(->=40
<6.5	**15,886**	**5%**	**3,878**	**6%**	**10,767**	**5%**	2,111	4,640	7,173	1,756
6.5-6.9	**14,818**	**5%**	**2,851**	**4%**	**10,790**	**5%**	1,471	4,122	7,235	1,833
7.0-7.9	35,423	11%	6,476	10%	26,029	12%	3,358	9,634	17,700	4,375
8.0-8.9	23,381	8%	4,681	7%	16,835	8%	2,255	6,091	11,804	3,010
>=9.0	**22,388**	**7%**	**5,755**	**8%**	**14,665**	**7%**	2,618	5,876	10,832	2,843
Not recorded last 12 months	13,712	4%	2,810	4%	9,658	5%	1,795	3,818	5,896	1,415

ACADEMIC DETAILING IN VHA

- Academic Detailing is an evidence-based intervention used to impact practice change for clinicians
  - In VHA, Academic Detailing leverages a multifaceted intervention which includes one-on-one educational outreach, audit and feedback, barrier resolution, and practice facilitation to support clinicians to make change effectively for improving Veterans health outcomes
- >10-year history in VHA
  - >100,000 educational outreach visits with >35,000 VA staff by predominantly clinical pharmacists (~70 FTEE in FY20)
- Demonstrated to improve AUD pharmacotherapy[1], increase naloxone prescribing[2], reduce BZD prescribing [3,4], and more!
- Resources are developed nationally by the VACO PBM Academic Detailing Service including training, educational materials, and daily updated data tools
  - Educational materials are designed to focus on clinical "key messages" rather than provide comprehensive disease state management
  - Dashboards & reports are designed to align with educational materials to identify specific actionable patients, their providers', and quarterly trends

TYPES OF DATA RESOURCES

Dashboard/Scorecard

- High level, aggregate of data
- Often in a scorecard/metric format
- Audience: Admin/leadership

Priority Panel Report

- Pivoted dashboard by clinician panels
- Audience: Detailers

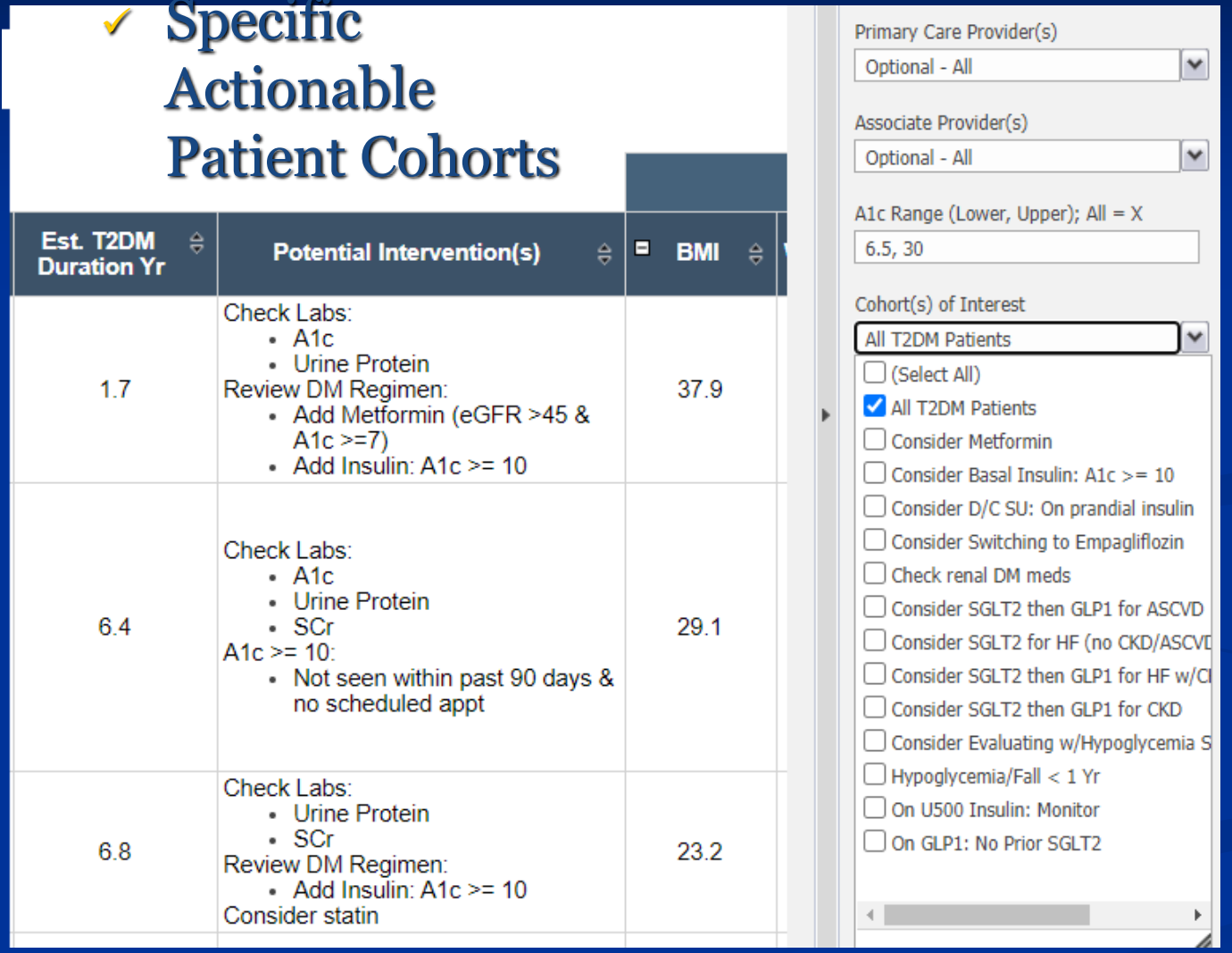
Patient Report

- Actionable, patient-centered data relevant to report's clinical focus; can be a simple summary or provide detailed information
- Audience: Clinicians/Detailers

Trend Reports

- Trends of metric progression over time
- Often can be viewed at National, VISN, Facility, and Provider levels
- Audience: Admin/Detailers

EXAMPLE DIABETES PATIENT REPORT



Academic Detailers utilize this to identify patients to discuss with providers.

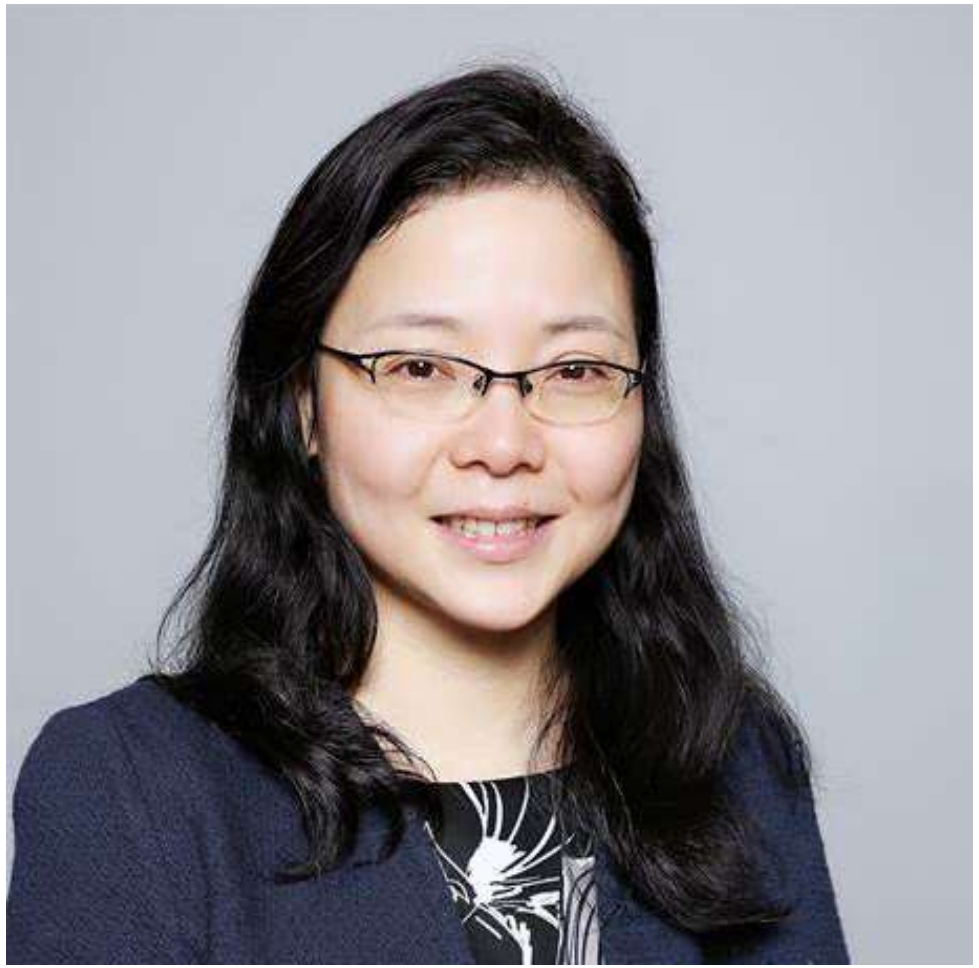
Providers may use it to manage their patient panel.

Administration may use it to identify other medication safety concerns.

Questions?

Contact Information:
Leonard.Pogach@va.gov

Qi Liu, PhD, MStat, FCP
Senior Science Advisor,
Office of Clinical Pharmacology, FDA



The Use of Real-World Data/Evidence to Improve Minority Health

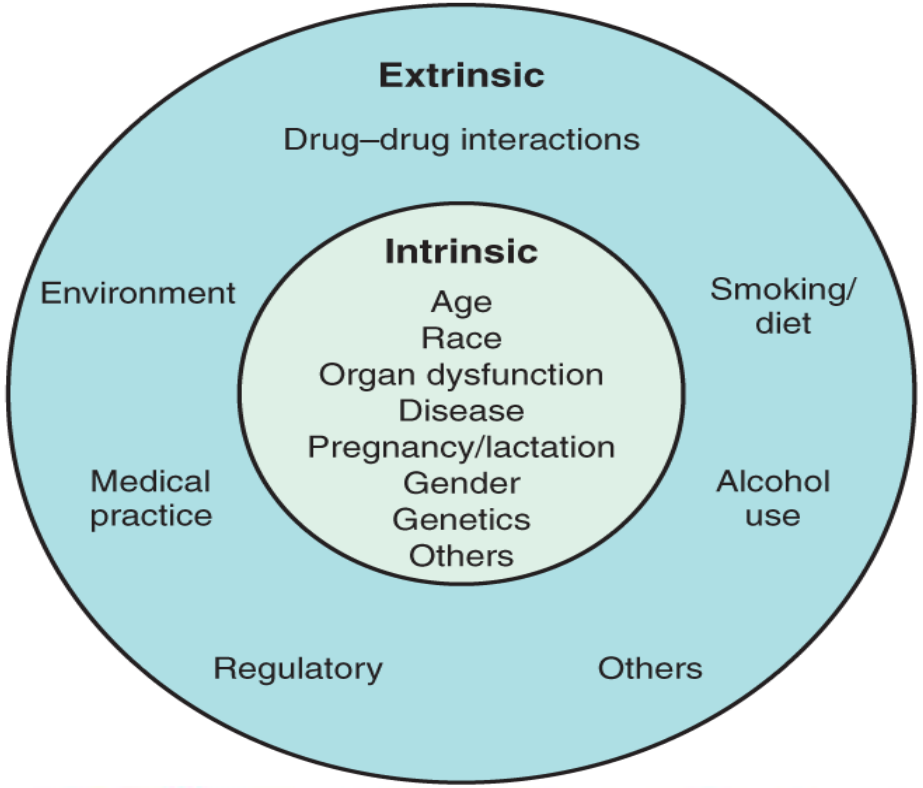
Disclosure

- Conflict of Interest: I have no competing interests for this work
- The views expressed are those of the author and do not reflect official policy of the FDA

Key Clinical Pharmacology Issue: Finding the Right Drug at the Right Dose at the Right time for Each Patient

Is This the Drug or Dose for You?: Impact and Consideration of Ethnic Factors in Global Drug Development, Regulatory Review, and Clinical Practice

S-M Huang[1] and R Temple[2]



CLINICAL PHARMACOLOGY & THERAPEUTICS | VOLUME 84 NUMBER 3 | SEPTEMBER 2008

- **Differences in response to medical products have been observed in racially and ethnically distinct subgroups of the US population.**

----------INDICATIONS AND USAGE----------

BiDil is a combination of isosorbide dinitrate, a nitrate vasodilator, and hydralazine hydrochloride, an arteriolar vasodilator, indicated for:

- the treatment of heart failure as an adjunct therapy to standard therapy in self-identified black patients to improve survival, prolong time to hospitalization for heart failure and to improve patient-reported functional status (1.1)

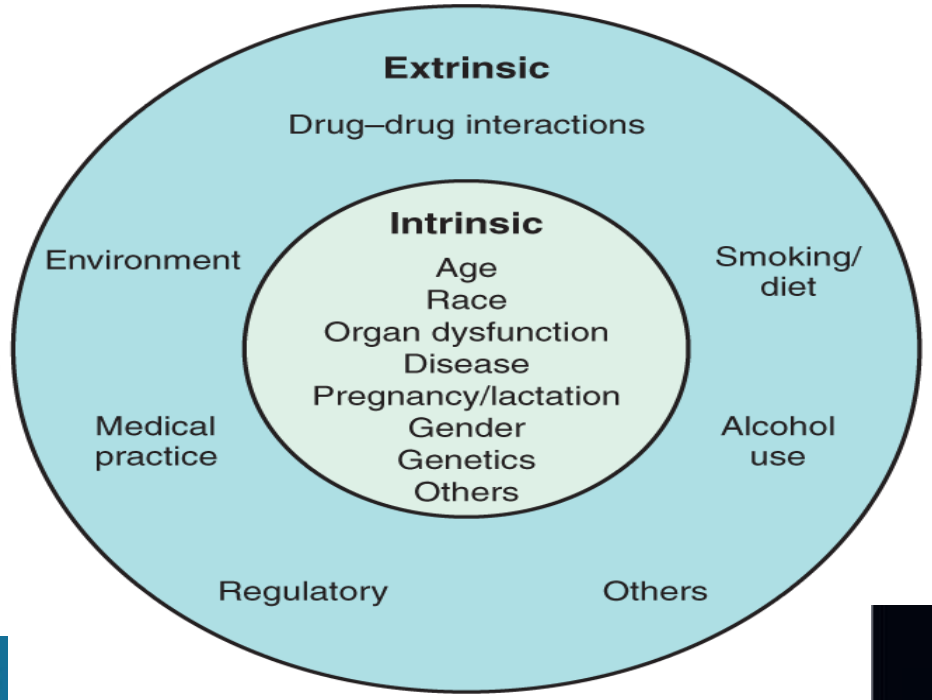
nature publishing group DEVELOPMENT

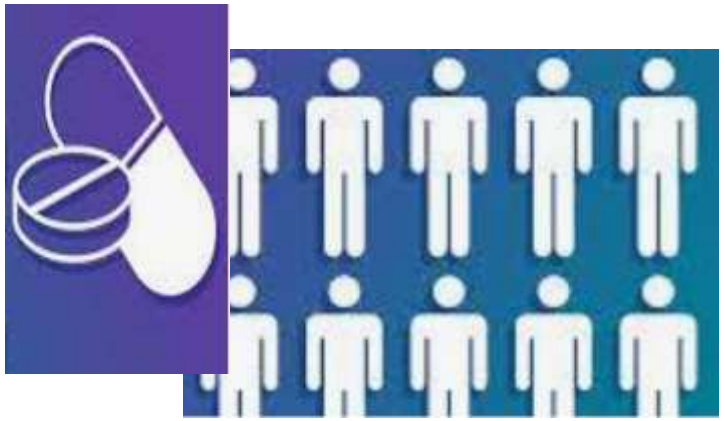
The Role of Ethnicity in Variability in Response to Drugs: Focus on Clinical Pharmacology Studies

SU Yasuda[1], L Zhang[2] and S-M Huang[2]

Clinical Pharmacology & Therapeutics (2009) **86** 6, 683.

Can RWD/E Augment Trial Data to Evaluate the Impact of Intrinsic and Extrinsic Factors on the Drug Response?





Clinical Trials

RWD/E

Challenges with the Use of Real-World Data

- Data quality and completeness
  - Many RWD sources were not built for research purpose
  - Various information for a patient may exist in different electronic systems that lack cross-communication
- Unstructured data
- Potential confounding and bias
  - Lack of randomization
- Need for common data platforms and data standards

- The research using RWD can be challenging
- Regulatory research is needed for us to learn where RWD can be helpful and to develop best practice

Clinical Pharmacology RWE Demonstration Projects

- **Case 1:** Renal/Hepatic Dysfunction and Clinical Outcomes in Cancer Patients Treated with Immune Checkpoint Inhibitors
- **Case 2:** Pneumonitis Incidence in Patients with Non-Small Cell Lung Cancer Treated with Immunotherapy or Chemotherapy in Clinical Trials and RWD

Common characteristics of the 2 cases:

- Collaboration projects
- Both clinical trial data and RWD were analyzed
- Analyses protocol discussed and developed upfront
- Generally consistent results from RWD and clinical trial data

https://ascopubs.org/doi/10.1200/JCO.2019.37.15_suppl.2569
AACR annual meeting 2020; https://www.ascopost.com/videos/aacr-virtual-annual-meeting-2020/qi-liu-on-pneumonitis-immunotherapy-and-chemotherapy-in-nsclc/

OCP Collaborates with OMHHE for Minority Health and Health Equity

- Common goal: optimizing the therapeutic outcome for minority populations

- Common interest: using **quality data from various sources** and **novel data analytics** to better characterize and predict treatment outcome for diverse population

- Current collaboration projects:
  - Diabetes
  - Cardiovascular disease
  - COVID19

Ongoing Project: Assessing Disparities in Occurrence and Outcomes of Type 2 Diabetes Adverse Drug Events in Minority Populations Using RWD

- An ongoing CERSI project: FDA in collaboration with Johns Hopkins University – Bloomberg School of Public Health (Drs. Hadi Kharrazi & Jonathan Weiner)
- African Americans and Hispanics are 70% more likely to be diagnosed with diabetes compared to non-Hispanic whites
- The National Action Plan for Adverse Drug Event Prevention (NAPADEP) identified 3 key drug classes as initial targets:
  - Anticoagulants (primary ADE of concern: bleeding)
  - **Diabetes agents** (primary ADE of concern: **hypoglycemia**)
  - Opioids (primary ADE of concern: accidental overdoses, oversedation, respiratory depression)
- Several patient populations may be especially vulnerable to ADEs, including
  - Pediatric patients
  - Older adults
  - individuals with low socioeconomic status or low health literacy,
  - those with limited access to health care services,
  - **certain minority races or ethnic groups**

https://health.gov/our-work/health-care-quality/adverse-drug-events/national-ade-action-plan

Ongoing Project: Assessing Disparities in Occurrence and Outcomes of Type 2 Diabetes Adverse Drug Events in Minority Populations Using RWD

- **Aim 1**: Improve the identification of severe hypoglycemia (SHG) events in ambulatory EHRs and claims.
- **Aim 2**: Compare SHG events across races/ethnicities and various social determinants of health (SDH) factors (e.g., housing instability, food insecurity, transportation challenges)
- **Aim 3**: Identify key disparity factors associated with increased likelihood of SHG among African American patients (after adjusting for clinical comorbidities).
- **Aim 4**: Discover contextual patterns (using EHR's free-text) associate with higher rates of SHG among different minority and special-need populations.
- **Aim 5**: Explore applicability of methods to other areas

Project is ongoing, report is expected in 2022.

Summary

- RWD/E can be used to augment clinical trial data in the evaluation of the impact of various intrinsic and extrinsic patient factors on treatment outcome.
- FDA is committed to using quality data from various sources and novel data analytics to better characterize and predict treatment outcome for minority population, and to improve health equity.

Acknowledgement

- Shiew-Mei Huang
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- Audrey Thomas
- Kinnera Chada
- Christine Lee
- RADM Richardae Araojo
- Christine Merenda
- Christian Hampp
- Yandong Qiang
- Yueqin Zhao
- Mahtab Niyyati
- Justin Penzenstadler
- Martin Bishop
- Jamie Heyward
- Hadi Kharrazi
- Jonathan Weiner
- Lauren Tansky
- Caleb Alexander
- Hsien-Yen Chang
- Thomas M Richards
- Elham Hatef
- Elyse Lasser
- Rachel Jones

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The e-Care Plan for People with Multiple Chronic Conditions Project: Opportunities to Advance Health Equity

Jenna Norton, MPH

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Agenda

- Race, place & health equity
- Overcoming challenges to health data infrastructure
- Multiple Chronic Conditions e-Care Plan Project
  - Applications for health equity

RACE, PLACE AND HEALTH EQUITY

Race & ethnicity: poor proxies for genetics

- Americans who identify as Black:
  - ~25% of ancestry informative markers reflect non-African origin
- Americans who identify as Hispanic/Latino:
  - ~65% European ancestry, ~18% Native American ancestry, ~6% African ancestry
- Diverse admixture reflects:
  - European colonization
  - Enslavement of Black Americans
  - Race classification structures perpetuated by the “one-drop rule”

Lee, et al. *J Genetics* 2010;**89**(4):417-23; Rotimi. *Nature genetics* 2004;**36**(11 Suppl):S43-7; Yudell, et al. *Science* 2016;**351**(6273):564-65; Jones & Bullock. Washington, DC: The U.S. Census Bureau, 2012; Bryc, et al. Bio Rxiv 2014; Liz. *Crit Philos Race* 2018;6(2):239–61; Williams & Sternthal. *J Health Soc Behav* 2010;51(Suppl):S15–27; Roberts. *J Law Med Ethics* 2008;36(3):537–45

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Racial/ethnic segregation perpetuates differential access to social determinants of health

- U.S. neighborhoods remain substantially segregated by race and ethnicity.
- Racial segregation and poverty often overlap
- **WHY are our communities segregated?**

Iceland et al. *Demography* 2013; Logan, et al. *Demography* 2004; Annie E. Casey Foundation. Baltimore, MD, 2014

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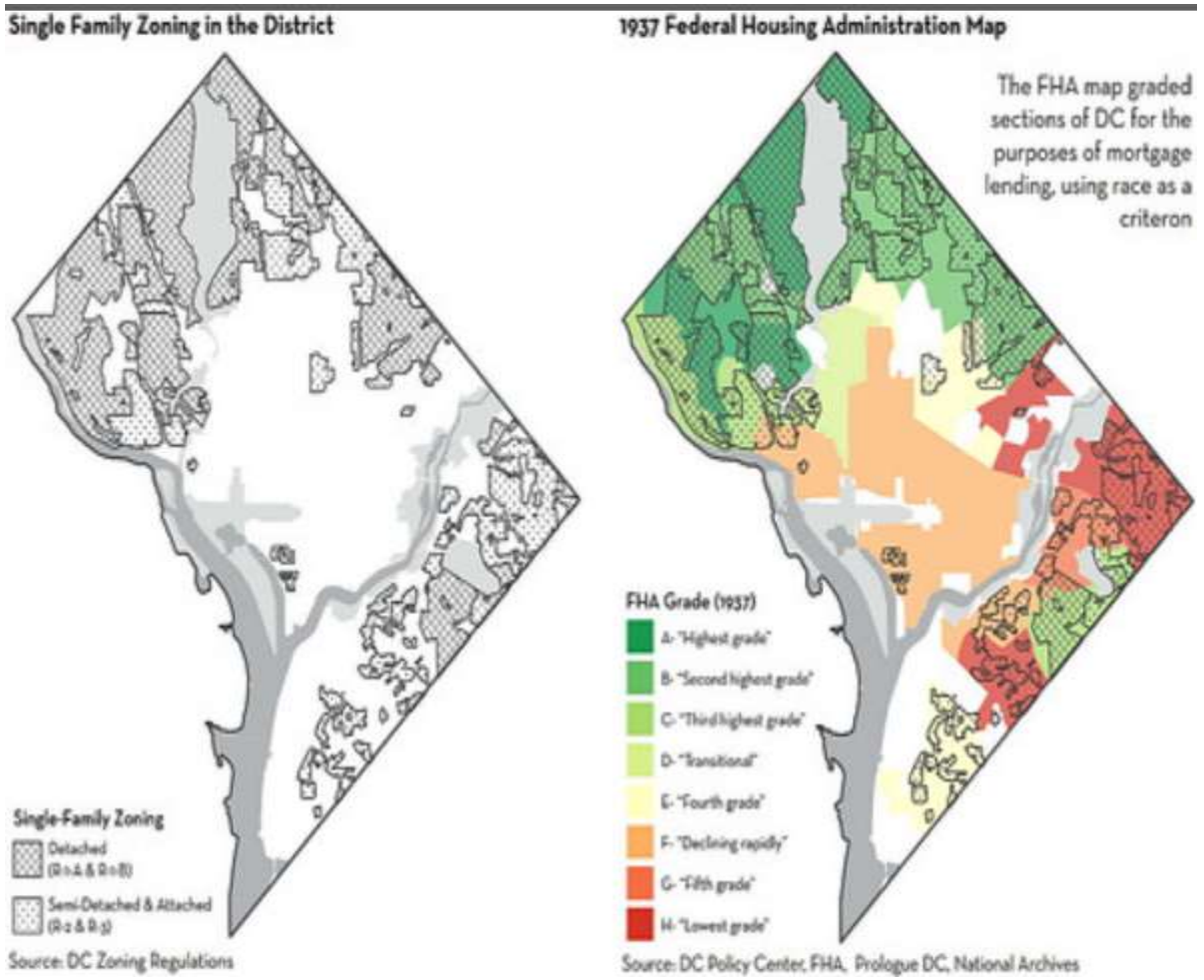
Place Matters: Legacy of Racial Segregation



Washington, DC - 1937

Government Policy and Segregation

- "Redlining"- federal policy that supported systematically denying mortgage loans to African Americans and excluding them from neighborhoods during a critical period of suburbanization
- Perpetuated residential segregation and poverty, inequitable access to opportunity and resources, and health inequities

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Place Matters: Legacy of Racial Segregation

Babies born to mothers in Maryland's Montgomery County and Virginia's Arlington and Fairfax Counties can expect to **live 6-7 years longer** than babies born to mothers in Washington, D.C. – –

just a few subway stops away

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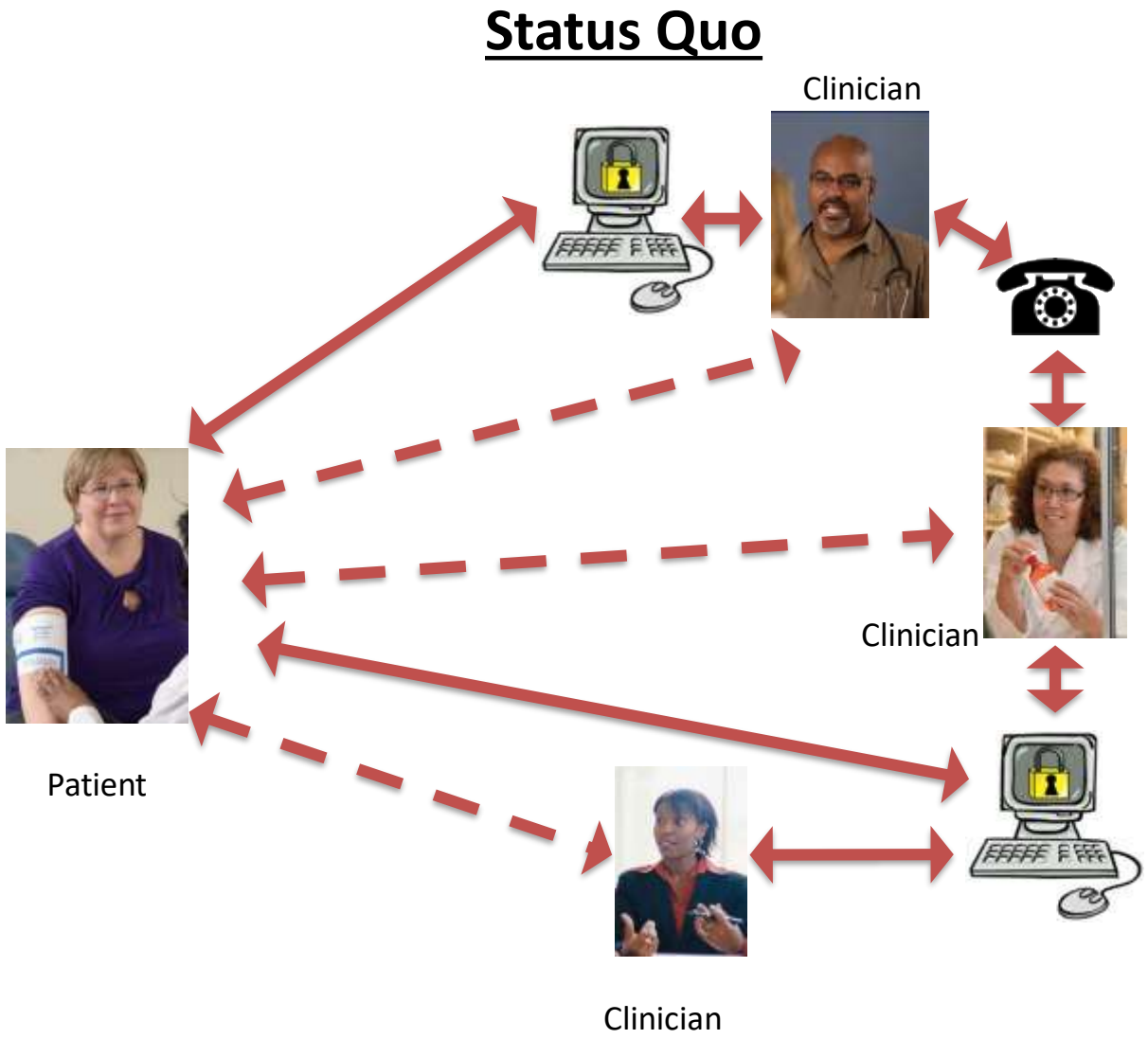
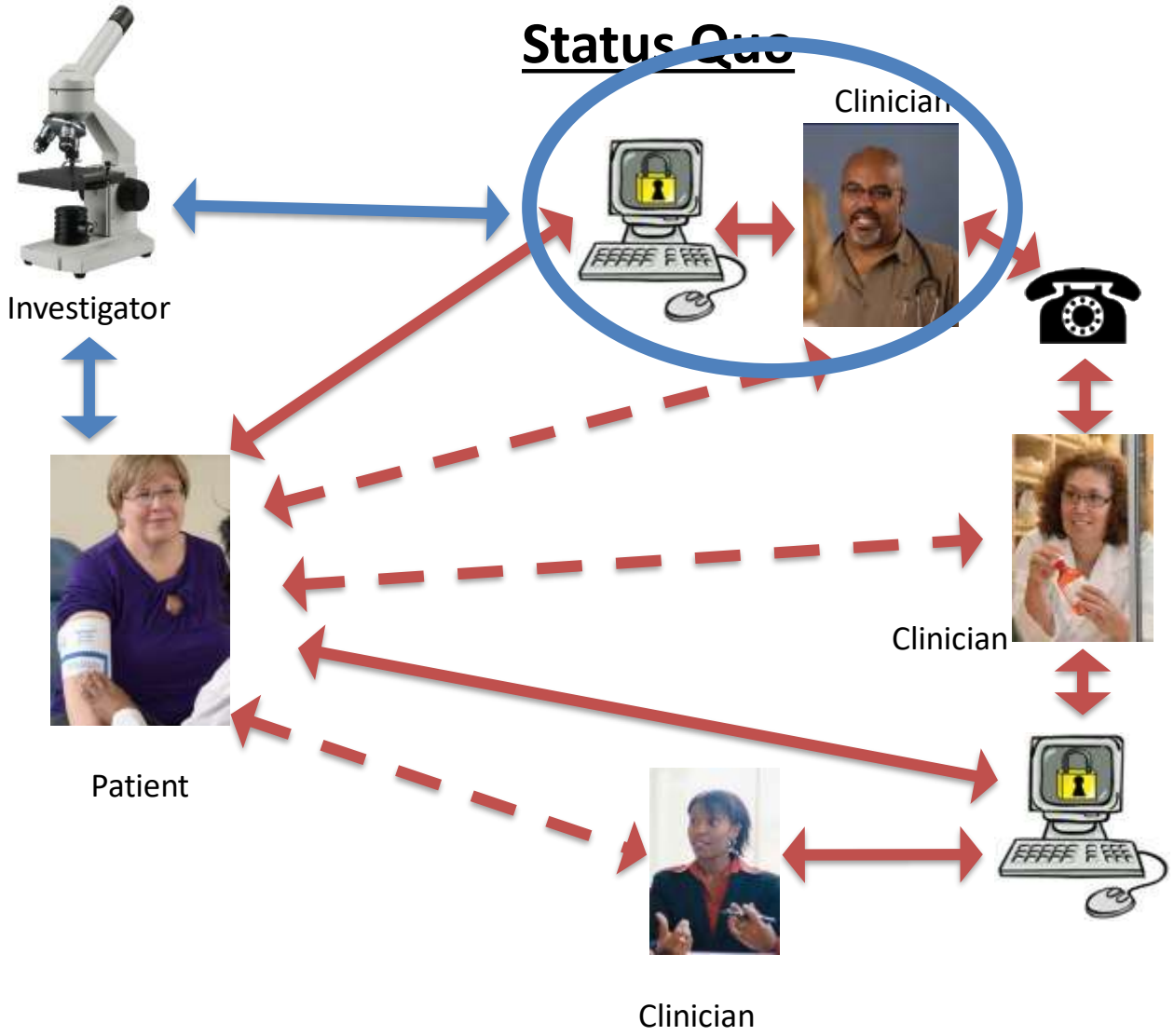
OVERCOMING CHALLENGES TO HEALTH DATA INFRASTRUCTURE

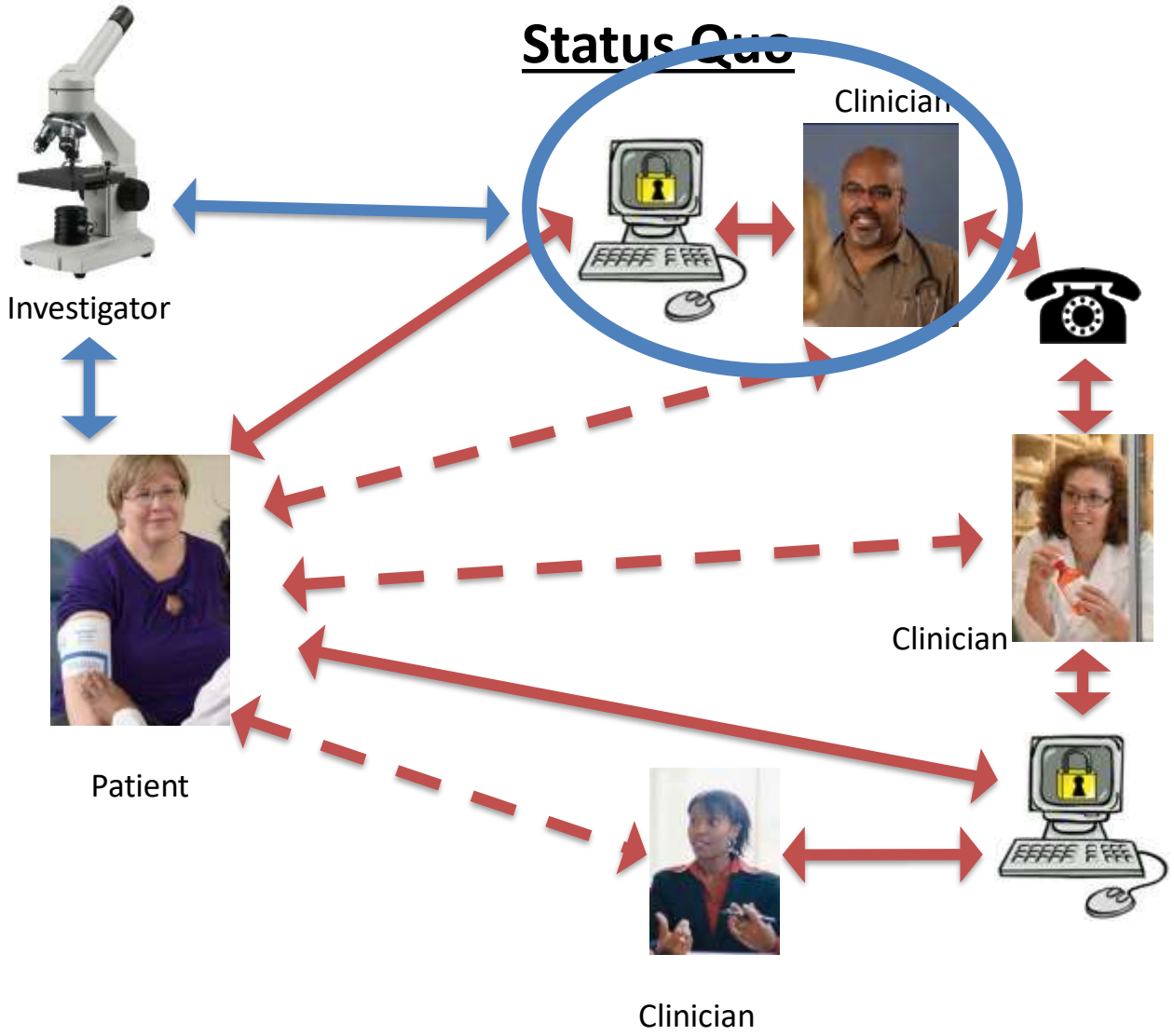
Lack of infrastructure to share patient data across settings impedes clinical care



Lack of infrastructure to share patient data across settings impedes clinical care and research



Lack of infrastructure to share patient data across settings impedes clinical care and research

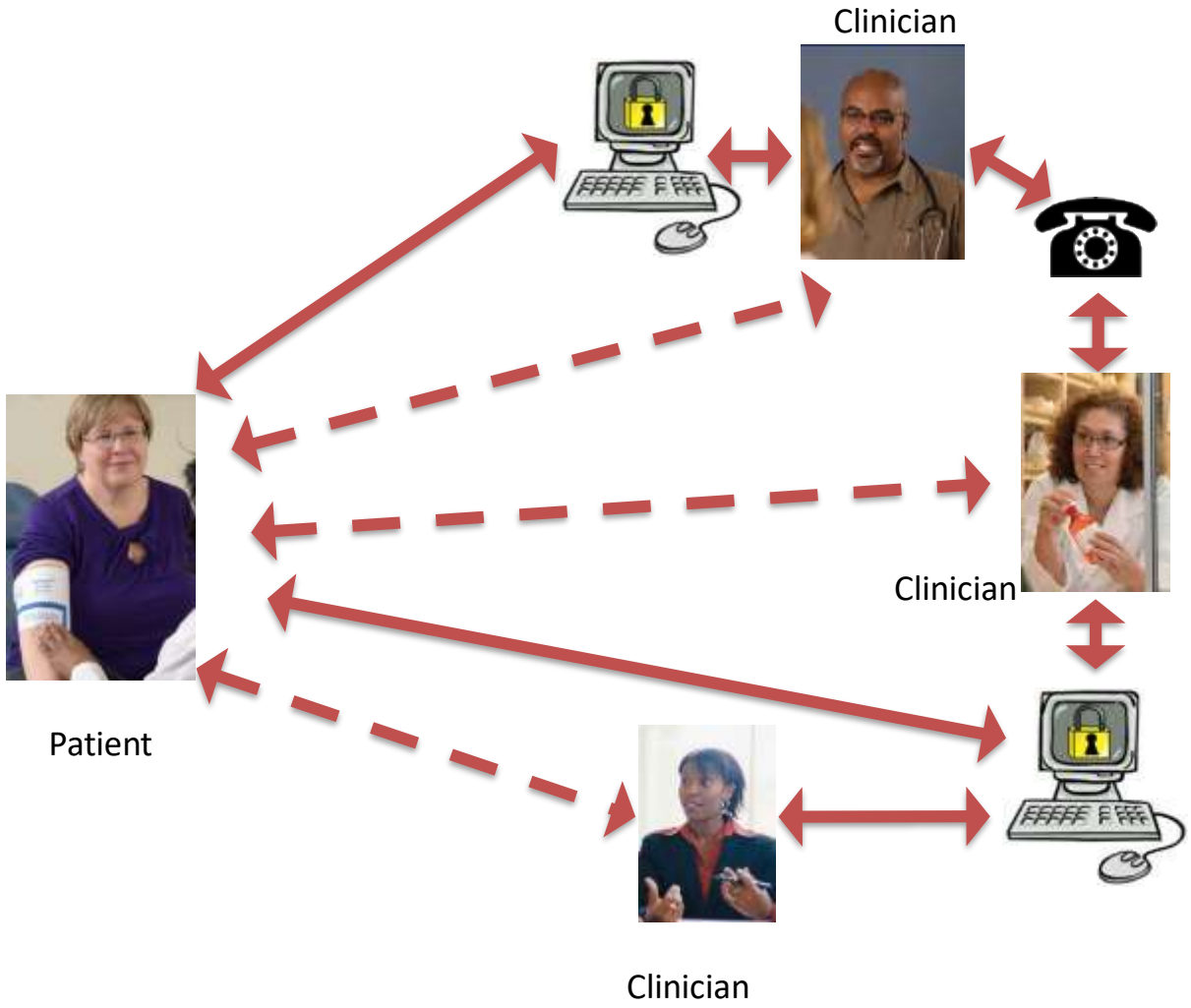


Challenges may be exacerbated in underserved communities due to:

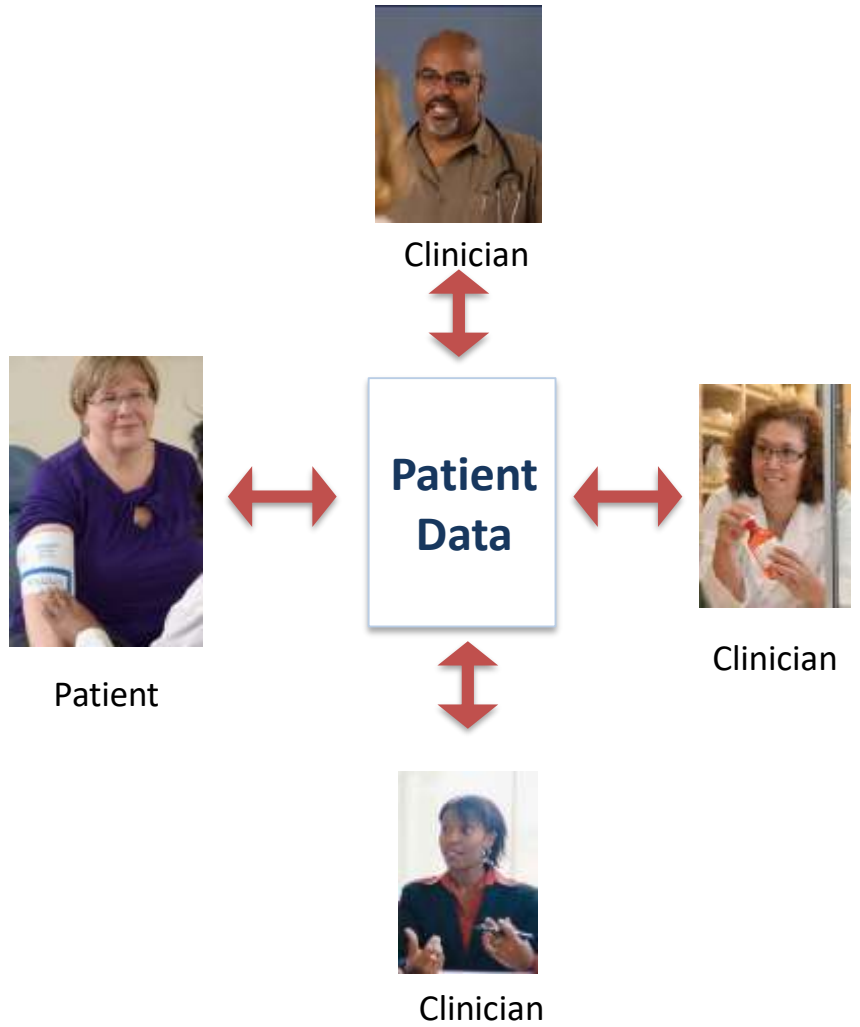
- Reduced access to primary care
- Inconsistent health coverage
- Housing insecurity & transiency
- Higher prevalence of multiple chronic conditions

The e-care plan uses data standards to enable access to/sharing of comprehensive, person-centered information

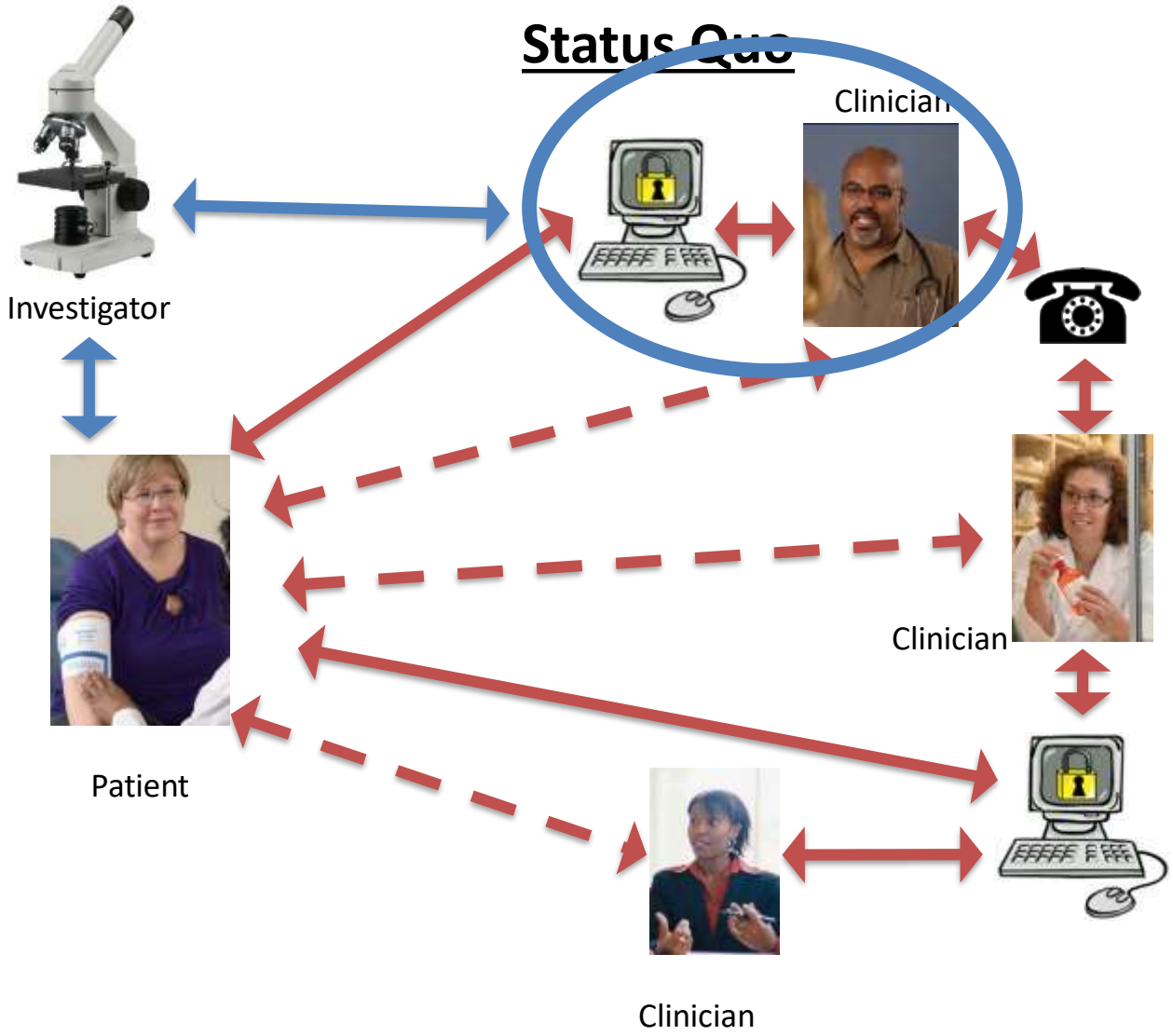
Status Quo

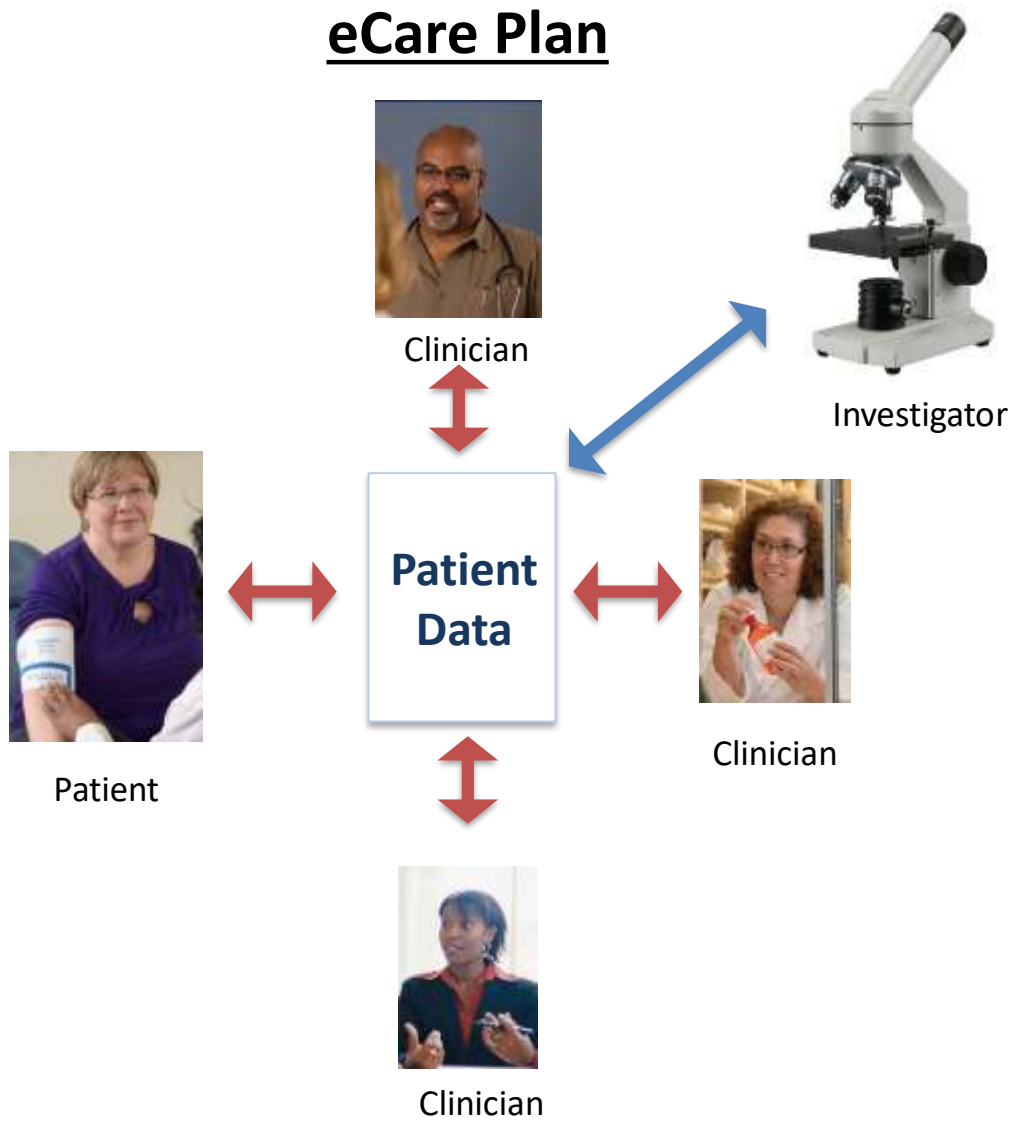


eCare Plan



The e-care plan uses data standards to enable access to/sharing of comprehensive, person-centered information





THE E-CARE PLAN FOR MCC PROJECT

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NIDDK/AHRQ e-Care Plan for Multiple Chronic Conditions Project

Build capacity for pragmatic, patient-centered outcomes research by developing an **interoperable electronic care plan** to facilitate aggregation and **sharing of critical patient-centered data** across **home-**, **community-**, **clinic-** and **research-** based settings for people with **multiple chronic conditions** (MCC)

ASPE

AHRQ

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NIDDK/AHRQ Project Deliverables

1. **Standardized data elements** for diabetes, chronic kidney disease, cardiovascular disease & chronic pain
2. **Clinical information models/FHIR profiles** to specify data structure & semantics for storing all data elements in health IT systems
3. **HL7 FHIR implementation guide** to support MCC e-Care Plan development & implementation activities -- balloted as a standard for trial use
4. **Pilot tested patient- & clinician-facing e-care plan applications** that integrates with the EHR to pull, share, display and collect key patient data

* All deliverables will be open-source & freely available

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Applications for health equity

- MCC disproportionately impact poor/underserved communities
- Heightened care coordination needs due to transitions in care providers
  - MCC requires multiple providers across multiple settings
  - Reduced access to primary care
  - Inconsistent health coverage
  - Housing insecurity & transiency
- Inclusion of social determinants of health data
  - Enable social risk informed and social need targeted care
- Limited application for populations without access to care

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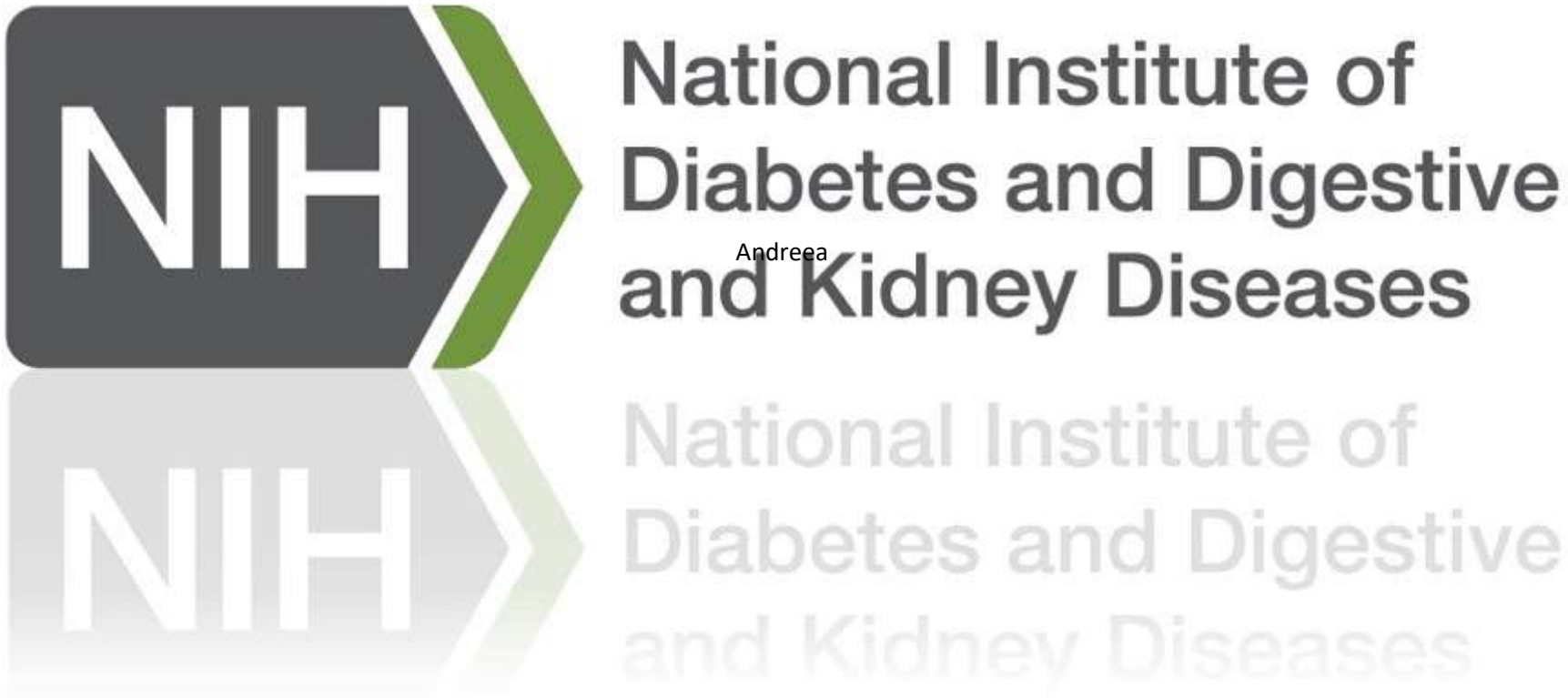
It takes a village!!

- **Contract Team**: Cognitive Medical Systems, EMI Advisors, RTI International, Oregon Health Services University
- **Technical Expert Panel**: Patients, caregivers, internal med/ primary care, nephrology, cardiology, pain medicine, addiction medicine, geriatrics, psychology, nursing, social work, pharmacy, public health/health policy, clinical/health informatics, developers/vendors
- **Federal partners**: Agency for Community Living, Centers for Medicare & Medicaid Services, Health Services & Research Administration, Indian Health Service, National Cancer Institute (PROMIS), National Heart Lung and Blood Institute, National Institute on Aging, National Library of Medicine, Office of the National Coordinator for Health IT, Patient-Centered Outcomes Research Institute, Veteran's Health Administration
- **Monitoring Board**: patients, clinicians, researchers, payers, informatics, policy, developers, vendors, health systems
- **HL7**: Patient Care Work Group (sponsor), Clinical Decision Support & Learning Health System (co-sponsors)
- **Complementary efforts**: Gravity, eLTSS, PACIO, MedMorph, Care Plan DAM, and many more!
- **You?** https://ecareplan.ahrq.gov/collaborate/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and Kidney Diseases

Andreea

U.S. FOOD & DRUG ADMINISTRATION

CERSI University of Maryland

Questions and Answers

U.S. FOOD & DRUG ADMINISTRATION

CERSI University of Maryland

Closing remarks
3:00 - 3:05 p.m.