

Are You Concerned About Clinical Trial Enrollment and Representation?

SBIA Webinar

December 16, 2020

Presentation Outline

- Regulatory background on trial demographics

Milena Lolic

- The status of trials diversity per Drug Trials Snapshots

Melvyn Okeke

- Supporting future of diversity in clinical trials

Kaveeta Vasisht

Richardae Araojo

Disclaimer

- This presentation represents the personal opinions of the speakers and does not necessarily represent the views or policies of FDA
- No conflicts of interest to declare

Demographics in Clinical Trials

What's in the Regs?

Milena M. Lolic, M.D., M.S.
Lead Medical Officer
PASE/CDER

What Does FDA Approve?

Ultimately, the indication garnered represents the population studied and for whom safety and effectiveness has been established.

Participants in the Trials



- Healthy volunteers
- Patients with the condition in various stages of disease
- Patients in various stages of treatment
- Patients with various comorbidities
- Patients of different sex, age, race, ethnicity background

FDA/CDER 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

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- Draft Guidance: Inclusion of Older Adults in Cancer Clinical Trials, 2020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

Gender Guideline

Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs



- Lifts a restriction on participation by most women with childbearing potential from entering Phase 1 and early Phase 2 trials
- Requires sponsors to include a fair representation of both genders as participants in clinical trials so that clinically significant gender-related differences in response can be detected
- Identifies three specific pharmacokinetics issues to be considered when feasible

Race and Ethnicity Guideline

Collection of Race and Ethnicity Data in Clinical Trials

- Recommends the use of the standardized OMB race and ethnicity categories for data collection in clinical trials
- Recommends enrollment of participants who reflect the clinically relevant populations with regard to race, and ethnicity
- ICH-E5 describes how clinical data collected in one region can be used in the registration or approval in another region

Race and Ethnicity Categories

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White

- Hispanic or Latino
- Not Hispanic or Latino

Age Guideline

Studies in Support of Special Populations: Geriatrics E7

- Protocols should not ordinarily include arbitrary upper age cutoffs
- Geriatric patients should be included in the Phase 3 in meaningful numbers
- Recognition of important pharmacokinetic differences between younger and older patients related to renal/hepatic function or to drug-drug interactions

Data Reporting-Age Categories

- Infants <2 years
- Children..... 2-11 years
- Adolescents..... 12-17 years
- Adults..... ≥ 18 years
- Geriatrics ≥ 65 , 65-74, ≥ 75 years

Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs

Guidance for Industry

- Broadening eligibility criteria in later stages of drug development for the phase 3 population
- Broader population through adaptive trial design, enrichment strategies
- Less burdensome trial participation
- Expanded access
- Inclusion of pregnant women

Demographics Matter



- Alosetron: approved for irritable bowel syndrome in women
- Isosorbide dinitrate/hydralazine hydrochloride: approved for heart failure in Blacks
- Carbamazepine: boxed warning for Asians
- PI sections for special populations

Demographics Data Sharing

	Reviews	PI	DTS
Demographics in pivotal trials/subgroups	✓✓✓✓	✓✓	✓✓✓
Demographics in drug development program	✓✓✓✓	✓✓	
Consumer friendly information			✓✓✓✓

Challenge Question

True or False: Final Demographic Rule describes which demographic subgroups are expected to participate in the trials

TRUE

FALSE

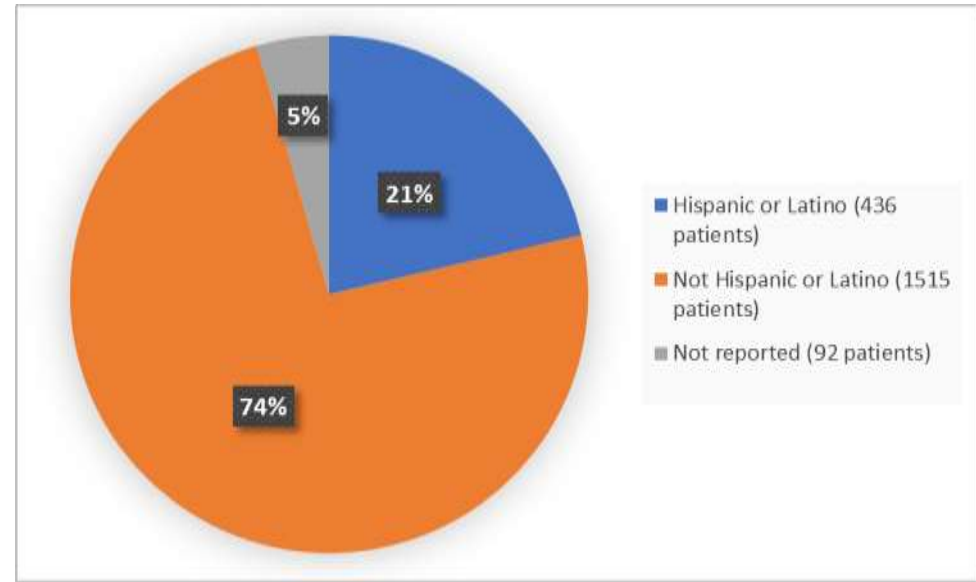
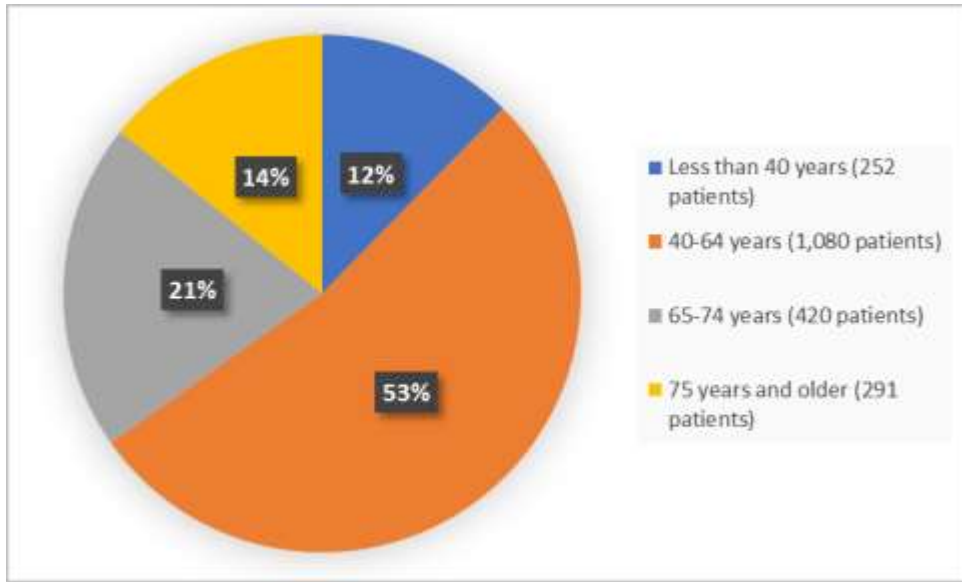
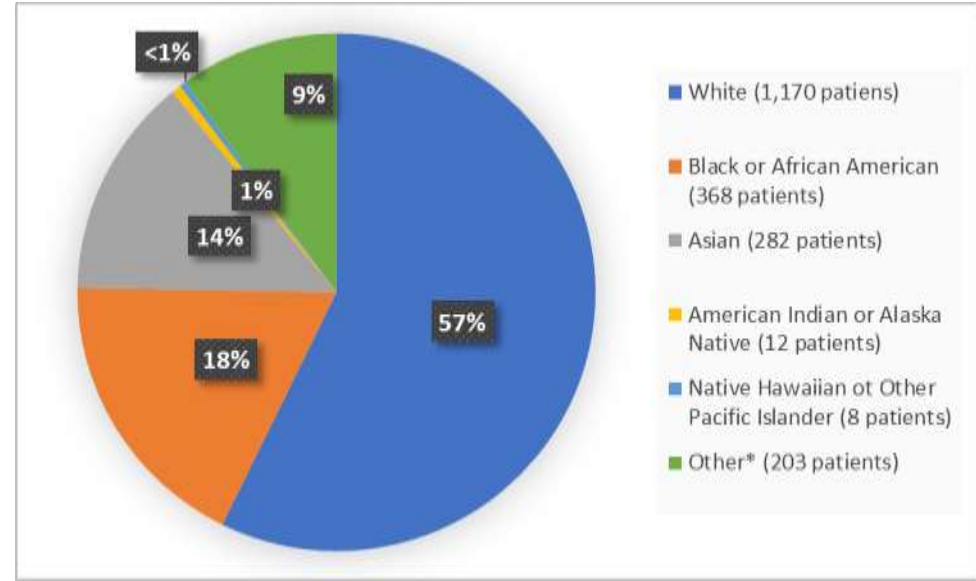
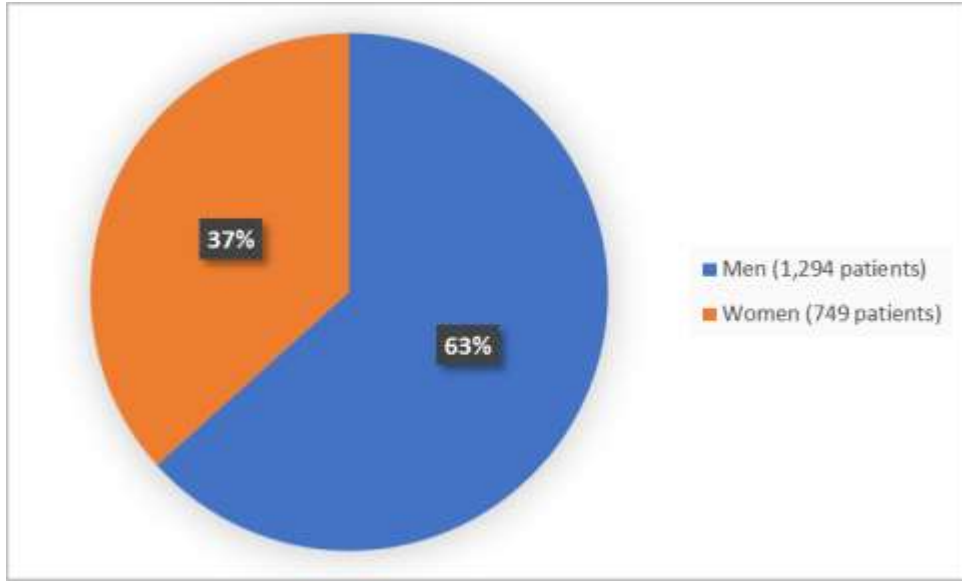
You can observe a lot by just watching.

Yogi Berra



Backup Slide

Remdesivir Trials



Diversity in Clinical Trials from Drug Trials Snapshots Perspective

Melvyn Okeke, M.P.H., ORISE Fellow

Drug Trials Snapshot

- Web-based information about participation in clinical trials that supported the FDA approval of new drugs*
- Includes trial demographic, trial design, overall and subgroup assessments of safety and efficacy

*New Molecular Entities and original Biologic Licensing Applications

DRUG TRIALS SNAPSHOTS



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

Drug Trials Snapshot Example

ADAKVEO (crizanlizumab-tmca)

ah dak vee oh

Novartis Pharmaceuticals Corporation

Approval date: November 15, 2019

DRUG TRIALS SNAPSHOT SUMMARY:

What is the drug for?

ADAKVEO is used to reduce the frequency of certain crises episodes (called vaso-occlusive crises) in patients 16 years of age and older who have sickle cell disease.

Sickle cell is an inherited blood disorder in which the red blood cells are abnormally shaped (in a crescent or "sickle" shape). Vaso-occlusive crisis (VOC) is a common and painful complication of sickle cell disease that occurs when blood circulation is obstructed by sickled red blood cells leading to severe pain and organ damage.

How is this drug used?

ADAKVEO is given by a healthcare provider directly into the vein (intravenous infusion) over 30 minutes. First two infusions are given 2 weeks apart followed by an infusion every 4 weeks thereafter.

What are the benefits of this drug?

Patients treated with ADAKVEO experienced fewer health care visits for VOC per year (about 1.63 visits), compared to patients who received a placebo (about 2.98 visits).

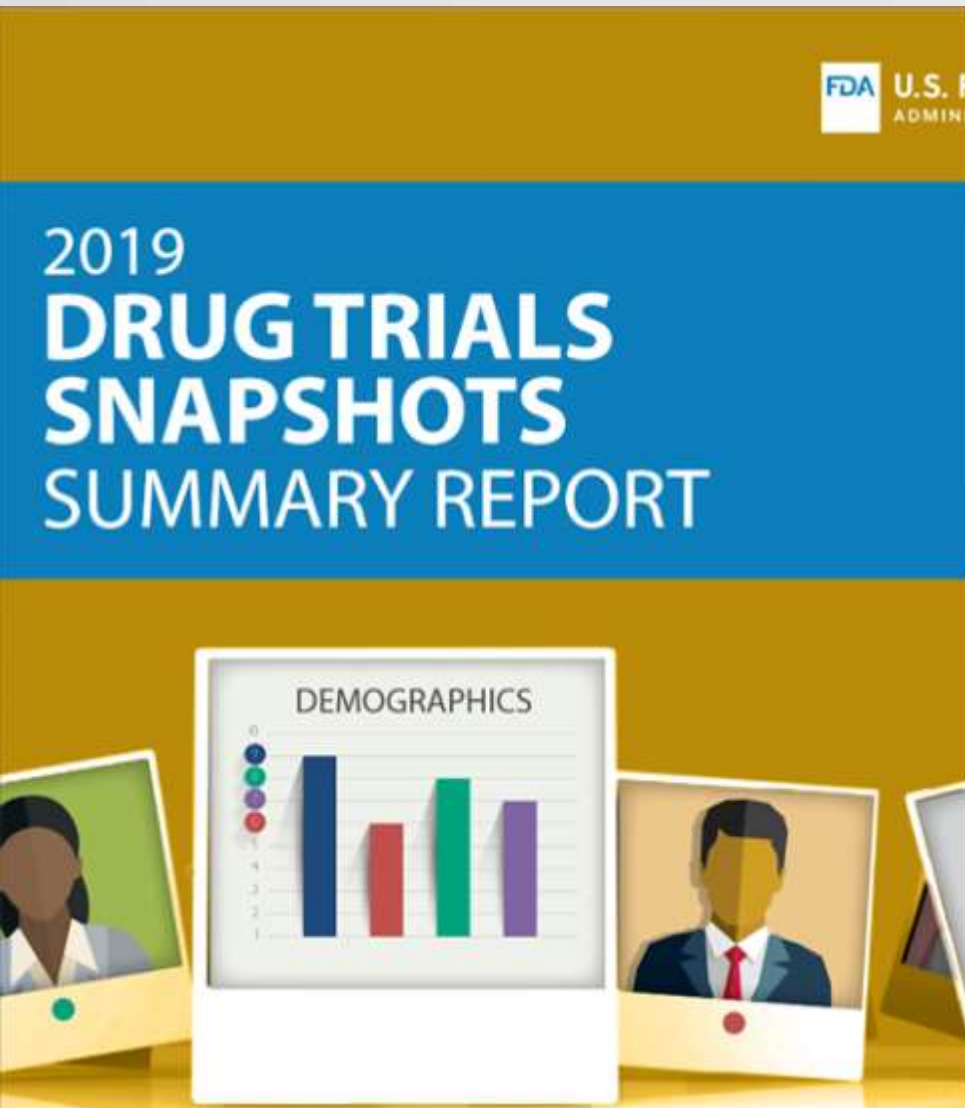
Who participated in the trials?

Demographics of trial participants are presented below.

Table 5. Baseline Demographics (Efficacy Population-ITT)

Demographic Parameters	ADAKVEO (N= 67) n (%)	Placebo (N=65) n (%)	TOTAL (N=132) n (%)
Sex			
Male	32 (47.8)	27 (41.5)	59 (44.7)
Female	35 (52.2)	38 (58.5)	73 (55.3)
Race			
Black or African American	60 (89.5)	60 (92.3)	120 (91)
White	4 (6)	3 (4.6)	7 (5.3)
Other ¹	3 (4.5)	2 (3.1)	5 (3.7)
Age			
Mean years (SD)	30.9 (10.89)	29.3 (10.36)	30.1 (10.6)
Median (years)	29	26	28
Min, max (years)	16, 63	16, 56	16,63

Annual Summary Report Example



Drug Trials Snapshots Report (2019)

2019 Summary Statistics

(Jan 1, 2019 - Dec 31, 2019)

In 2019, CDER approved 48 novel drugs*, either as New Molecular Entities (NMEs) under New Drug Applications (NDAs) or as new therapeutic biologics under Biologics License Applications (BLAs). Overall, 46,391 patients participated in these trials. Subpopulation demographics from these trials are presented below.

Table 1. Demographic Subgroups In 2019

DEMOGRAPHIC SUBGROUPS	WOMEN	WHITE	BLACK or AFRICAN AMERICAN	ASIAN	HISPANIC	AGE 65 AND OLDER	UNITED STATES
AVERAGE	72%	72%	9%	9%	18%	36%	40%

*Data presented in this report are from 49 snapshots as one drug was approved for two indications.

More insight into demographics for all 49 CDER approved NMEs are provided below in Table 2.

Table 2. Percentage of Subpopulations* - All Approvals

BRAND NAME	INDICATION	WOMEN	WHITE	BLACK or AFRICAN AMERICAN	ASIAN	HISPANIC	AGE 65 and OLDER	UNITED STATES
ACCRUFER	Treatment of iron deficiency	68	83	12	2	14	41	57
ADAKVEO	Treatment of vasoocclusive crisis in sickle cell disease	55	5	91	NR	24	0	75
AKLIEF	Treatment of acne vulgaris	55	87	7	3	17	0	45



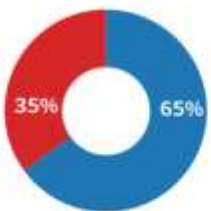
2015-2019

DRUG TRIALS SNAPSHOTS SUMMARY REPORT

Five-Year Summary and Analysis of Clinical Trial Participation and Demographics

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

United States ■
Rest of the World ■



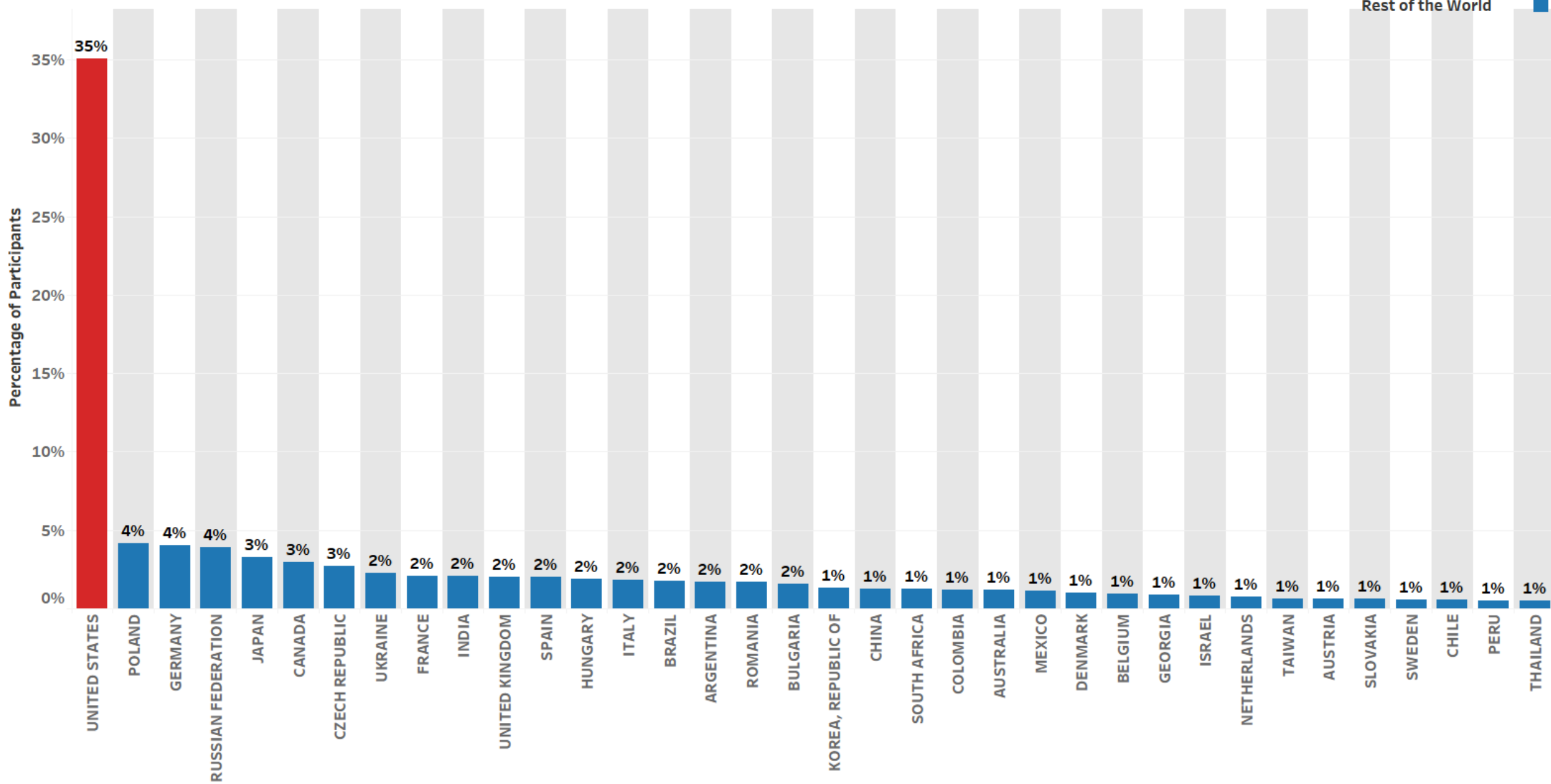
Global

Total Participants = 292,537

(Country data is missing for 229 participants)

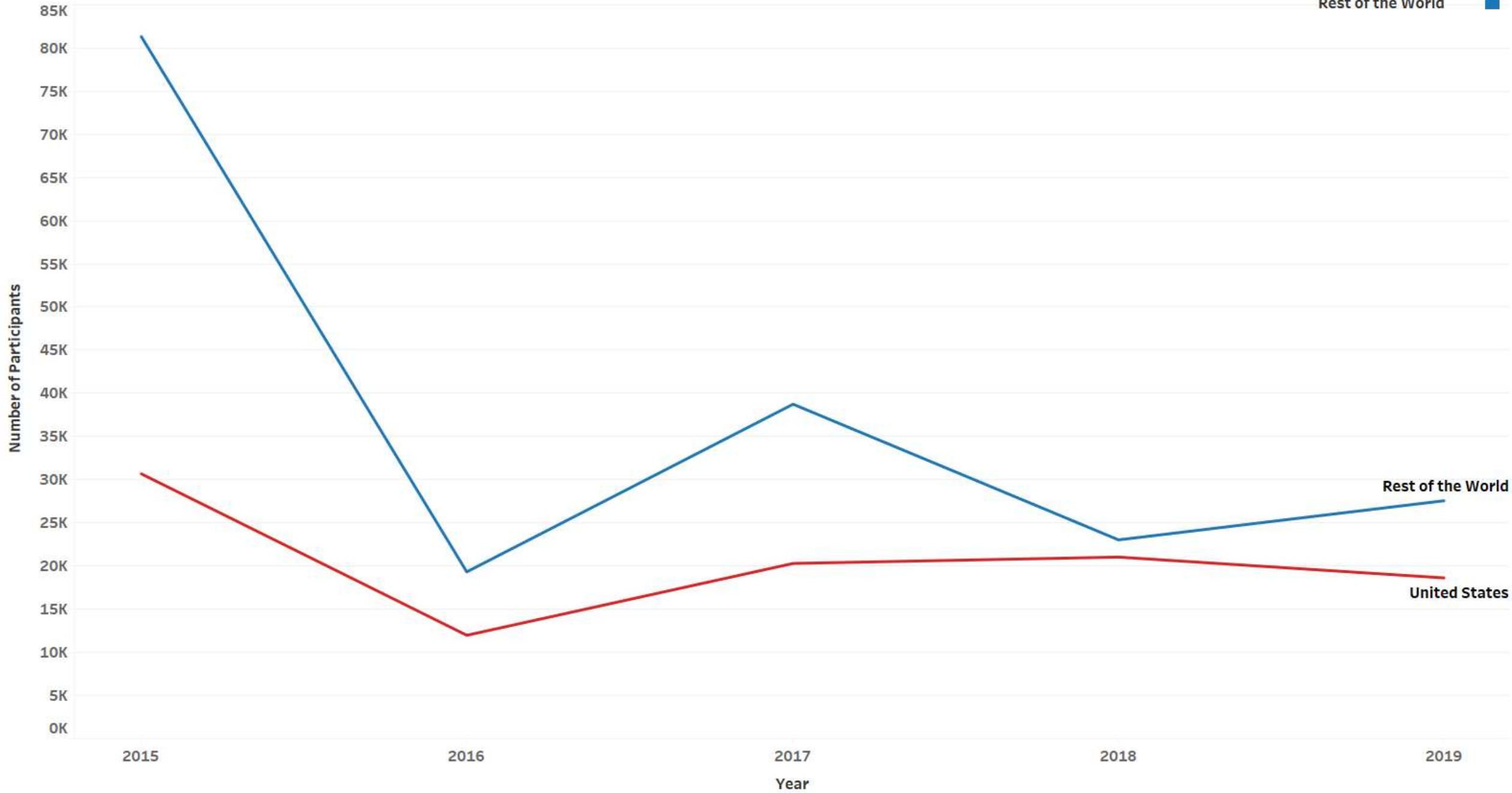
Trial Participants by Country

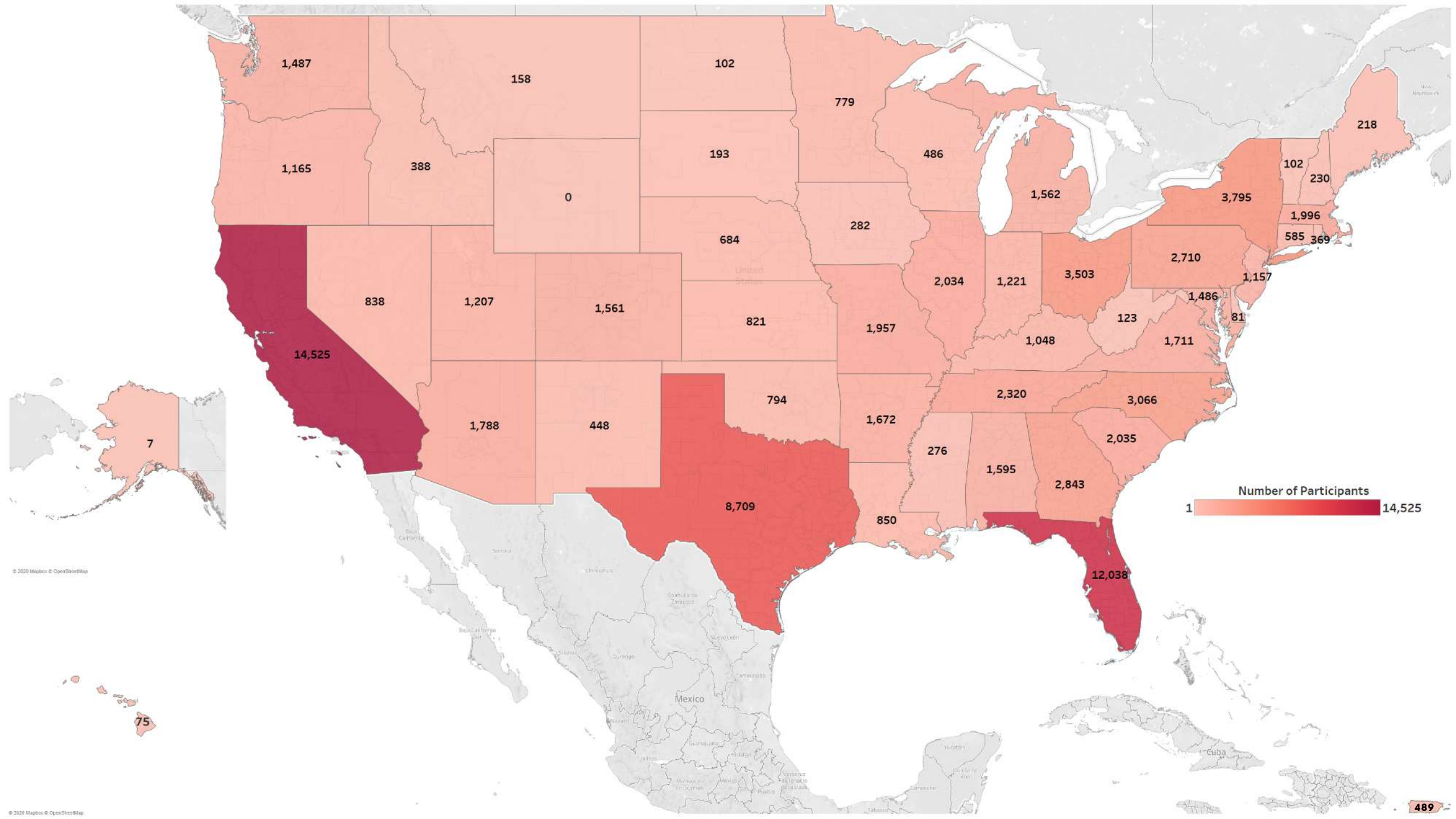
United States ■
Rest of the World ■



Participation by Year

United States ■
Rest of the World ■



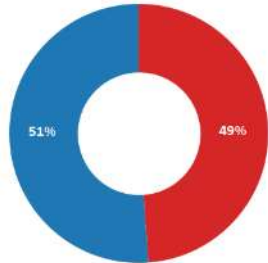


Number of Participants

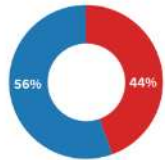
1 14,525

Trial Participants by Sex

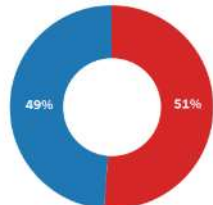
Sex Distribution



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



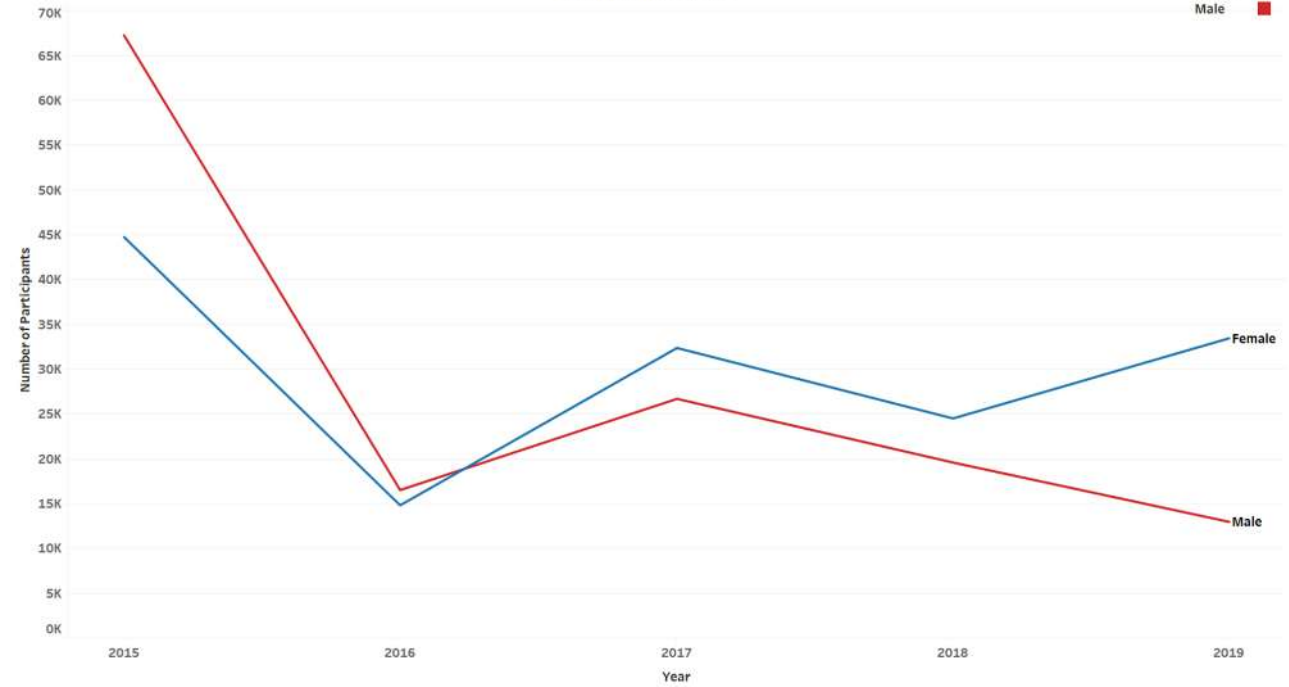
United States
Total Participants = 102,596



Rest of the World
Total Participants = 189,941

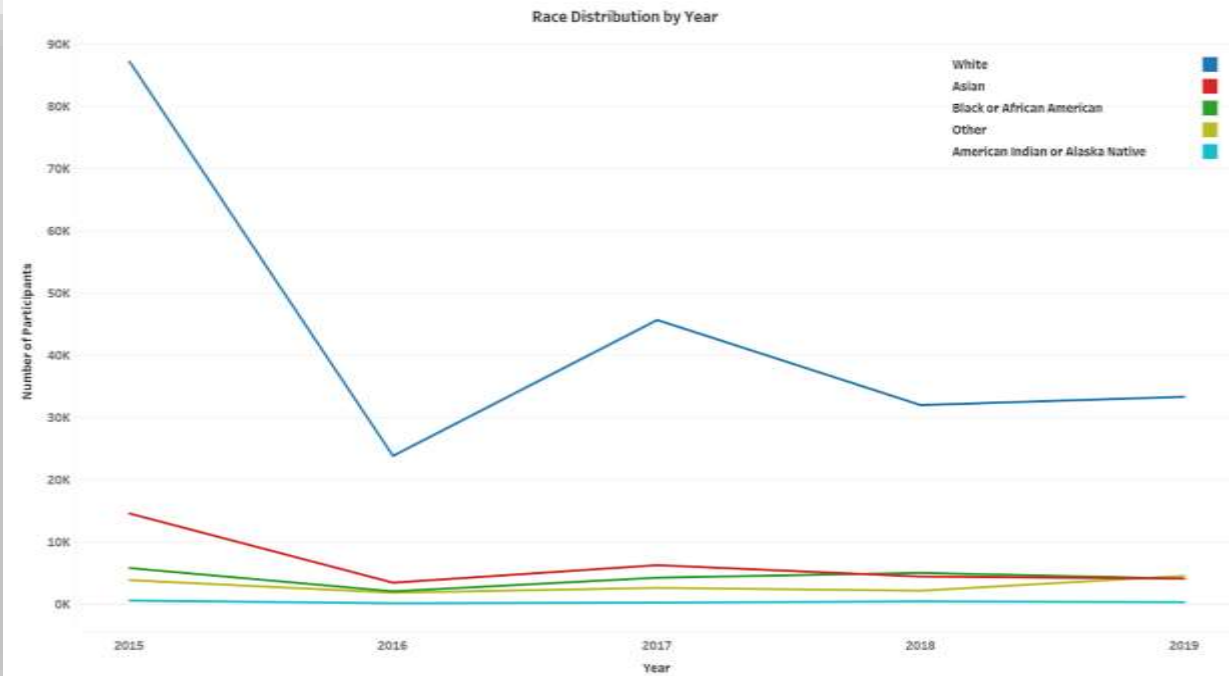
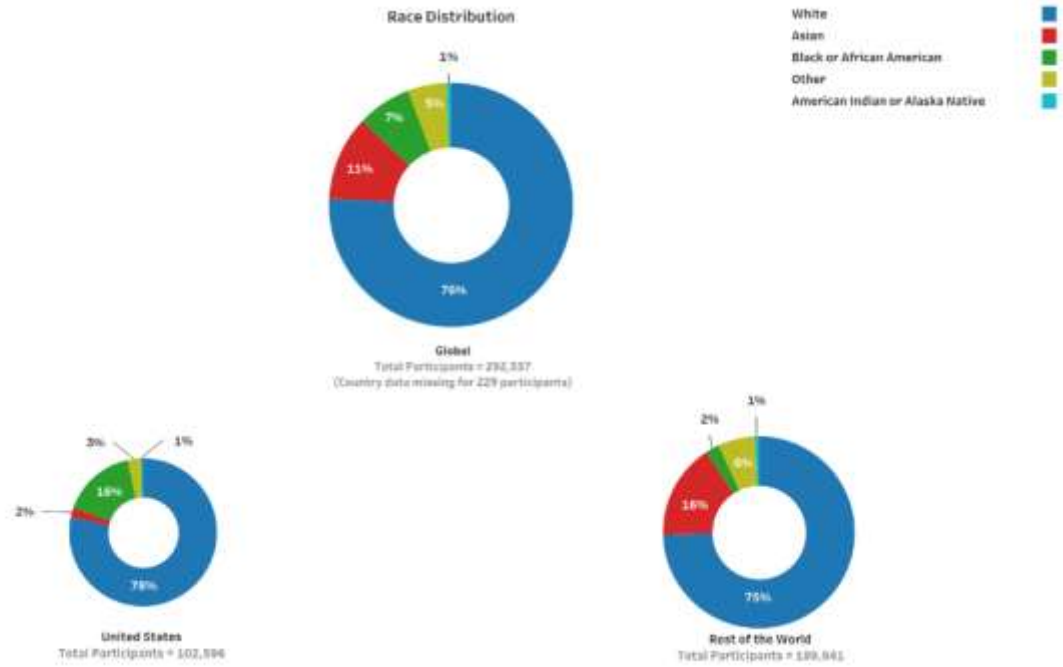
Female ■
Male ■

Sex Distribution by Year



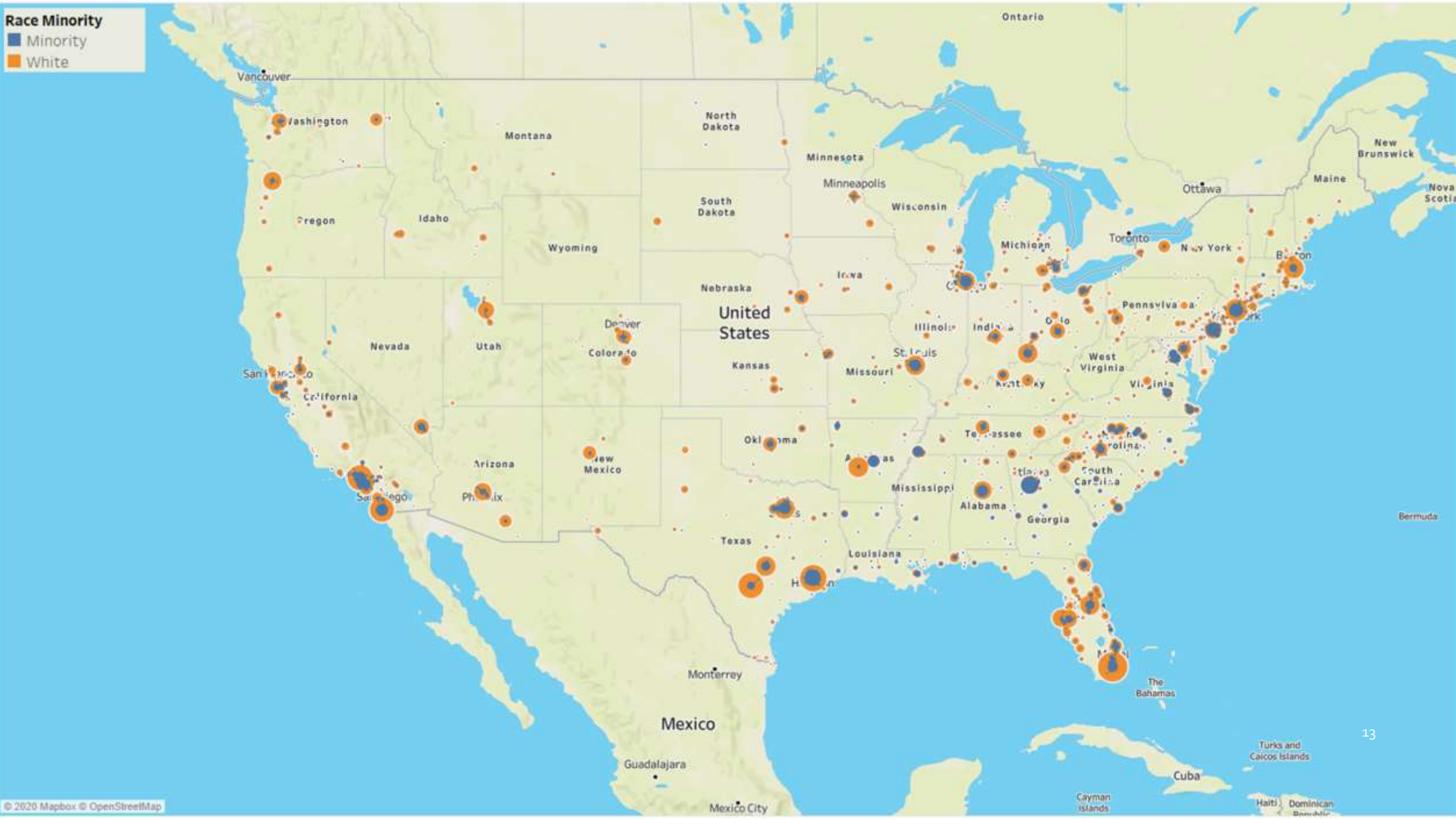
Female ■
Male ■

Trial Participants by Race



Race Minority

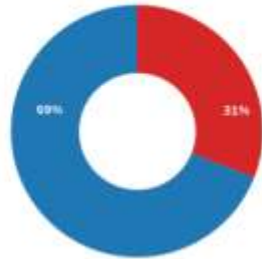
- Minority
- White



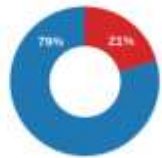
Participants by Age Group

Age Distribution

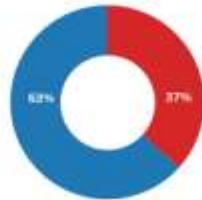
< 65 Years
>= 65 Years



Global
Total Participants = 292,533
(Age group is missing for 8 participants)
(Country is missing for 229 participants)



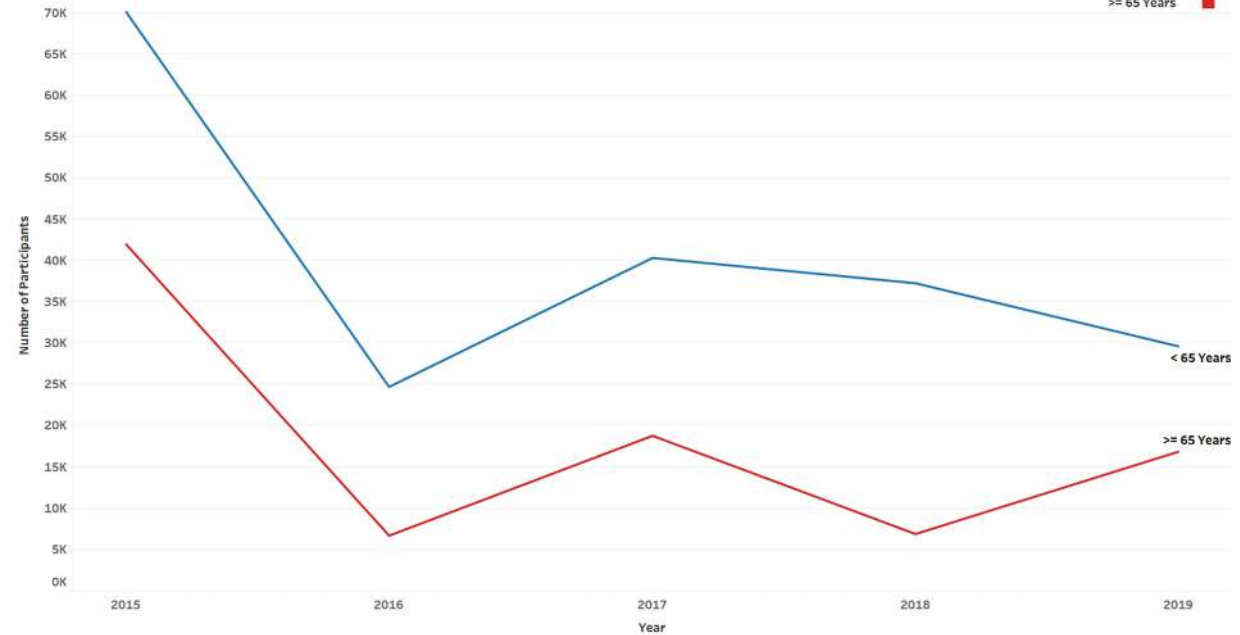
United States
Total Participants = 102,592



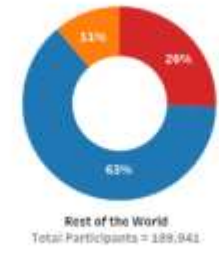
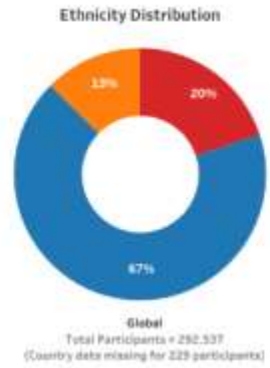
Rest of the World
Total Participants = 189,941

Age Distribution by Year

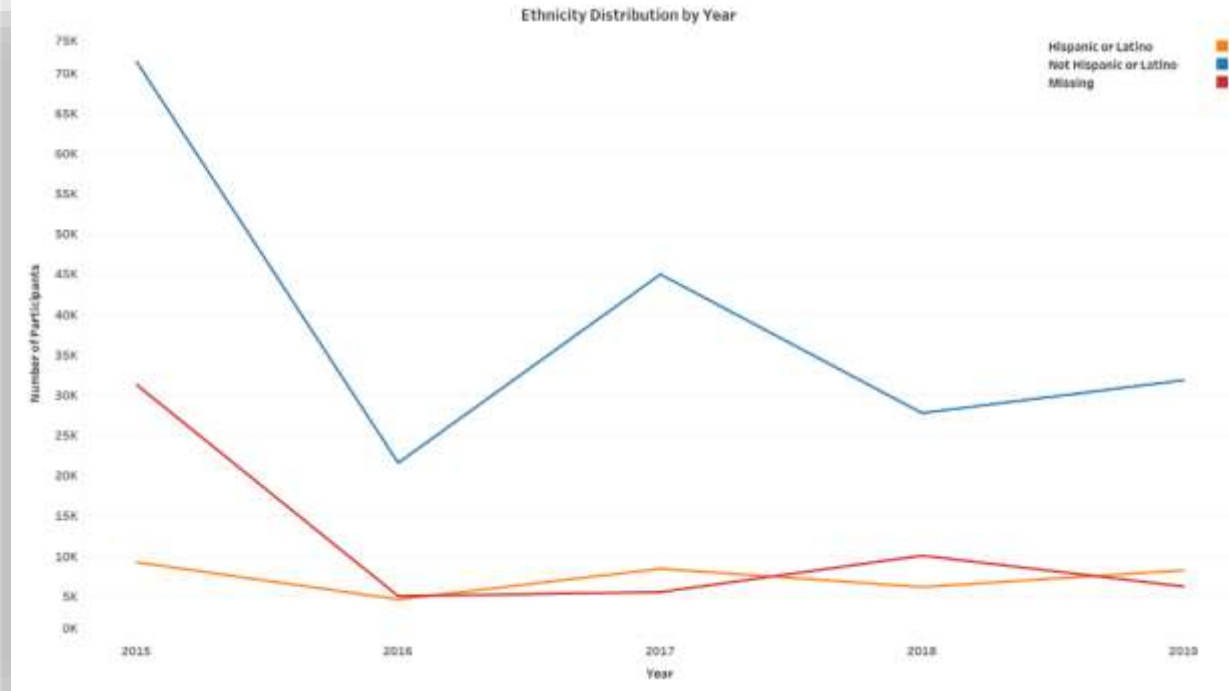
< 65 Years
>= 65 Years



Participants by Ethnicity



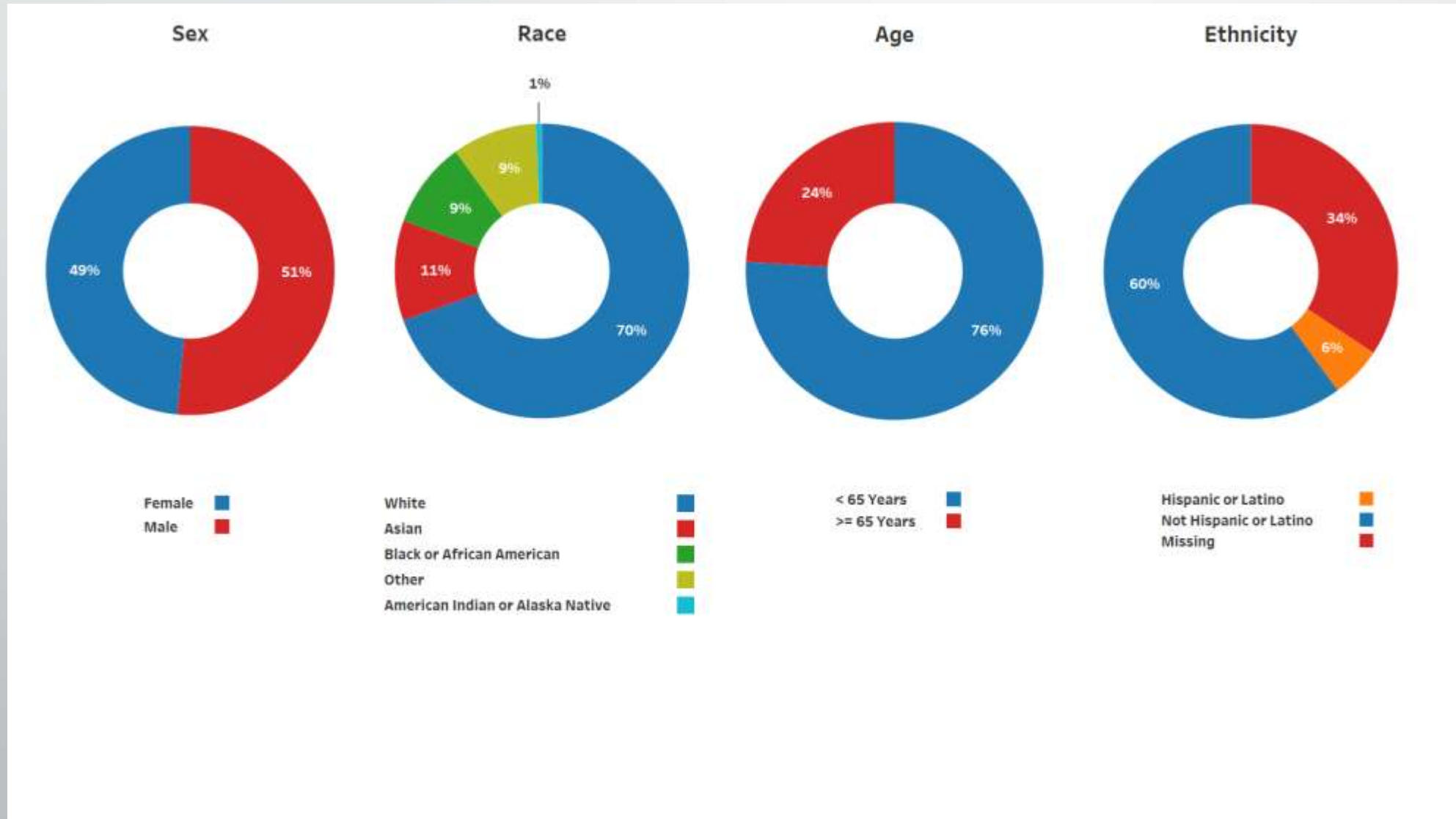
Hispanic or Latino
Not Hispanic or Latino
Missing



Hispanic or Latino
Not Hispanic or Latino
Missing



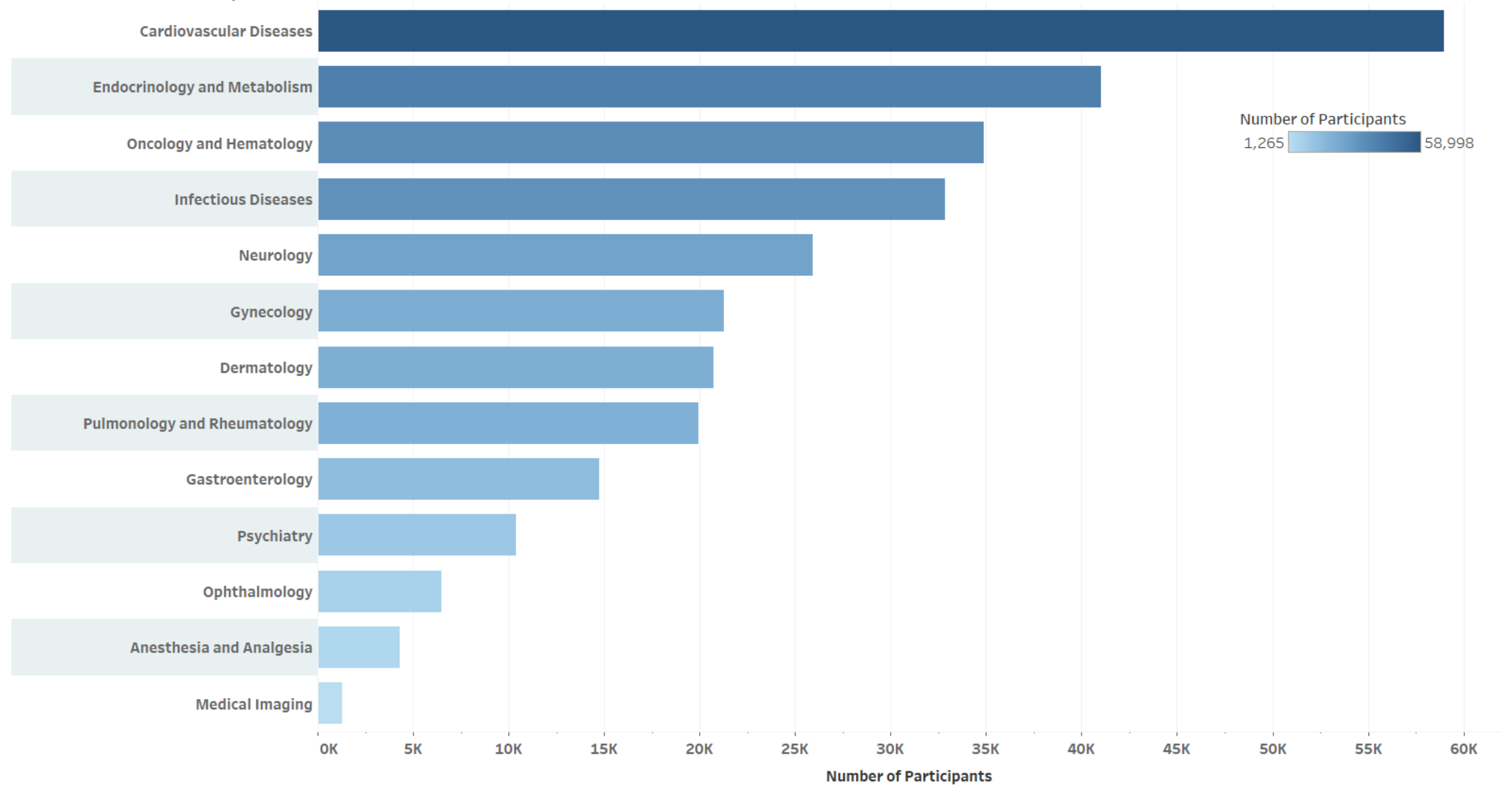
Rare Disease Population by Demographic Subgroups



Distribution of Therapeutic Areas

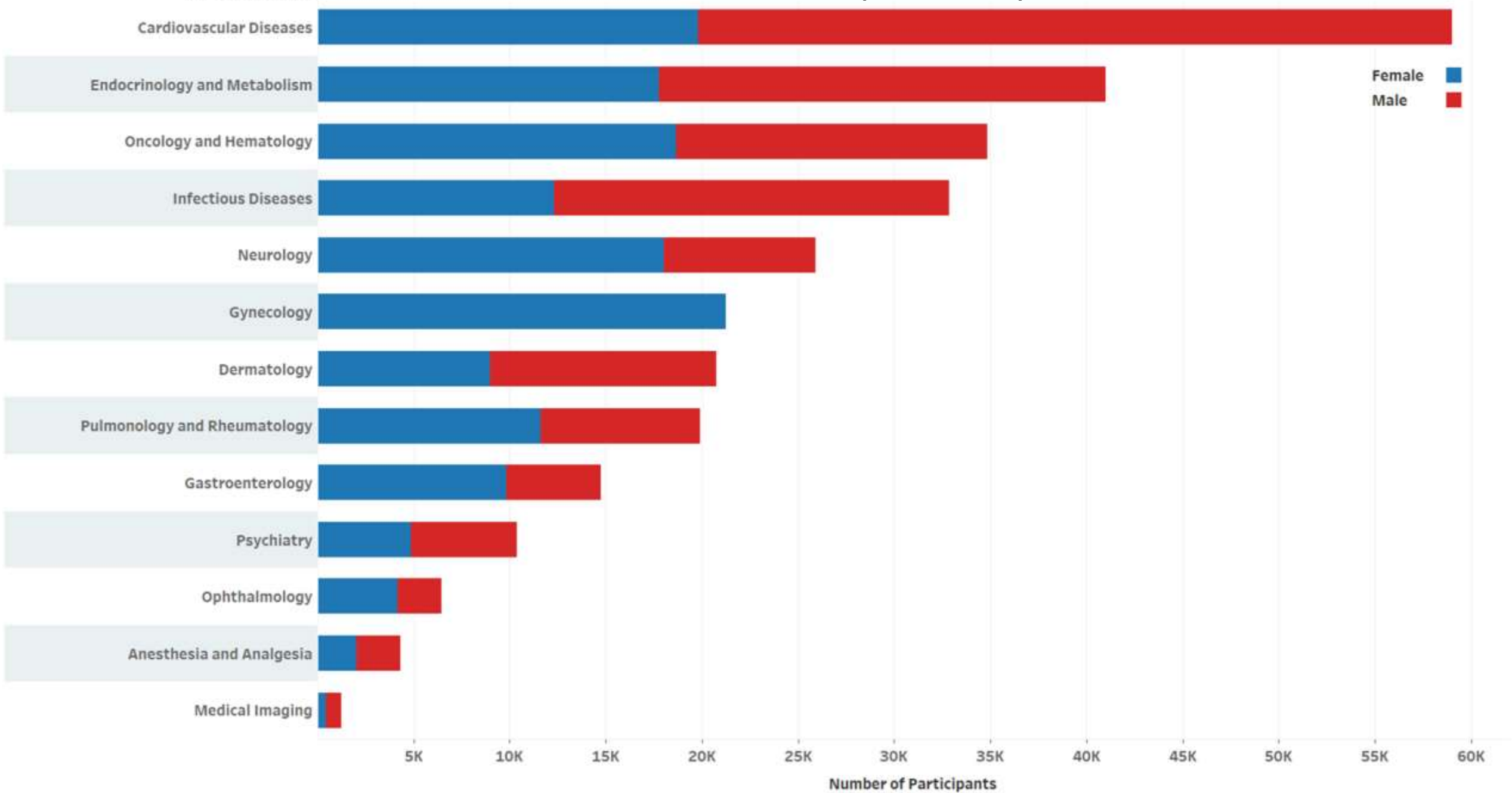
Therapeutic Area

Number of Participants
1,265 58,998



Distribution of Therapeutic Areas by Sex

Female 
Male 



Distribution of Therapeutic Areas by Race

Therapeutic Area

Cardiovascular Diseases

Endocrinology and Metabolism

Oncology and Hematology

Infectious Diseases

Neurology

Gynecology

Dermatology

Pulmonology and Rheumatology

Gastroenterology

Psychiatry

Ophthalmology

Anesthesia and Analgesia

Medical Imaging

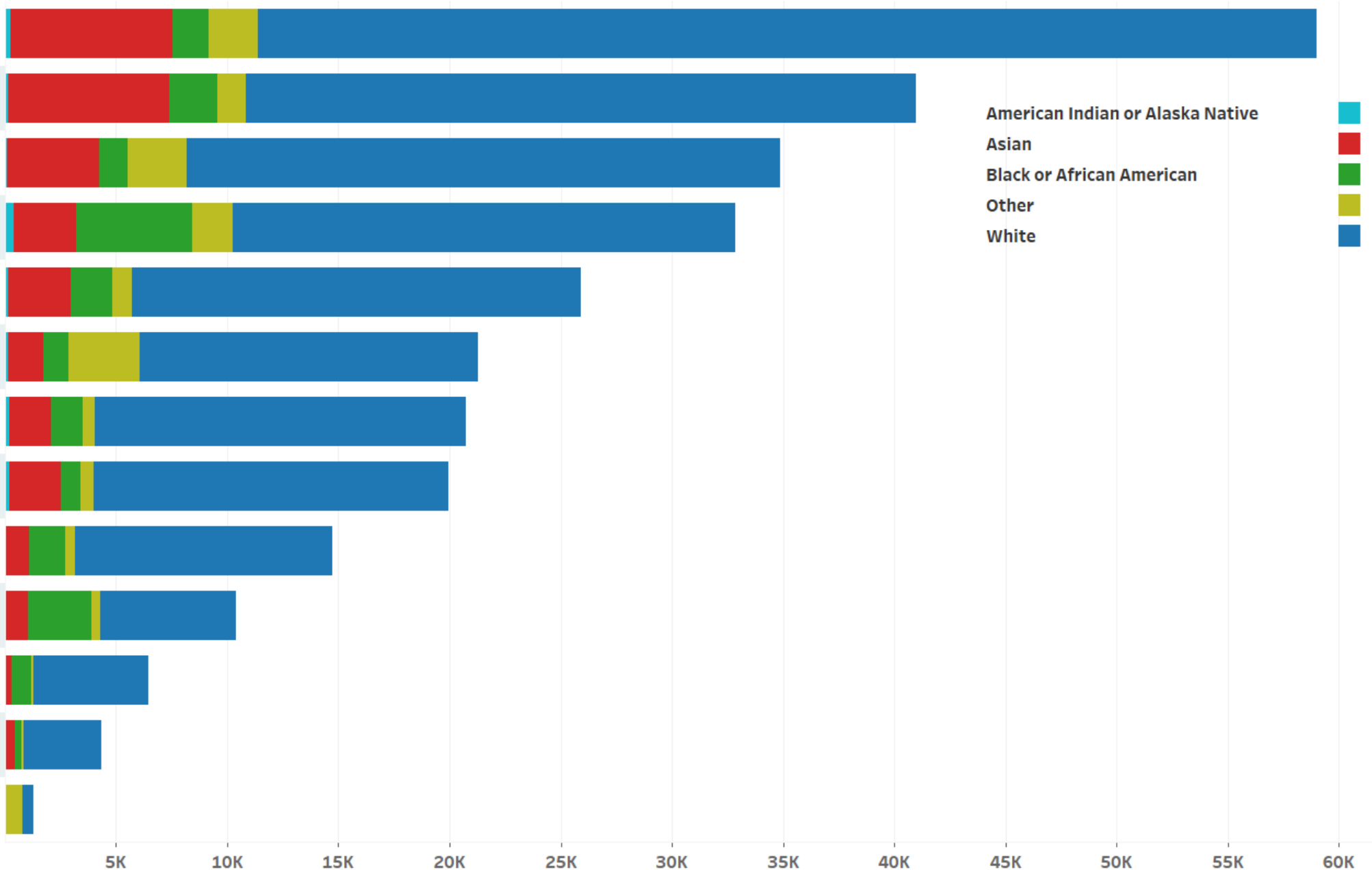
American Indian or Alaska Native

Asian

Black or African American

Other

White



Number of Participants

CE Question 1:
**Which 3 states within US had the highest numbers
of participants enrolled?**

- A. New York, Texas, Florida
- B. California, NY, Texas
- C. Texas, California, Florida
- D. Texas, California, Georgia

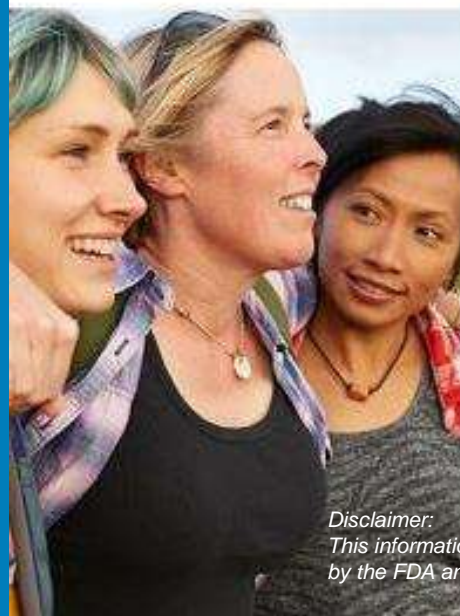
Closing Remarks

- Participants are characterized with a predominantly younger white population.
- Need better reporting of race & ethnicity
- Observed therapeutic areas with equitable distribution
- Visit the Drug Trial Snapshot website to view the full Summary Report

FDA Office of Women's Health (OWH)

Kaveeta P. Vasisht, MD PharmD
Associate Commissioner for Women's Health
Director, Office of Women's Health
U.S. Food and Drug Administration

DECEMBER 2020

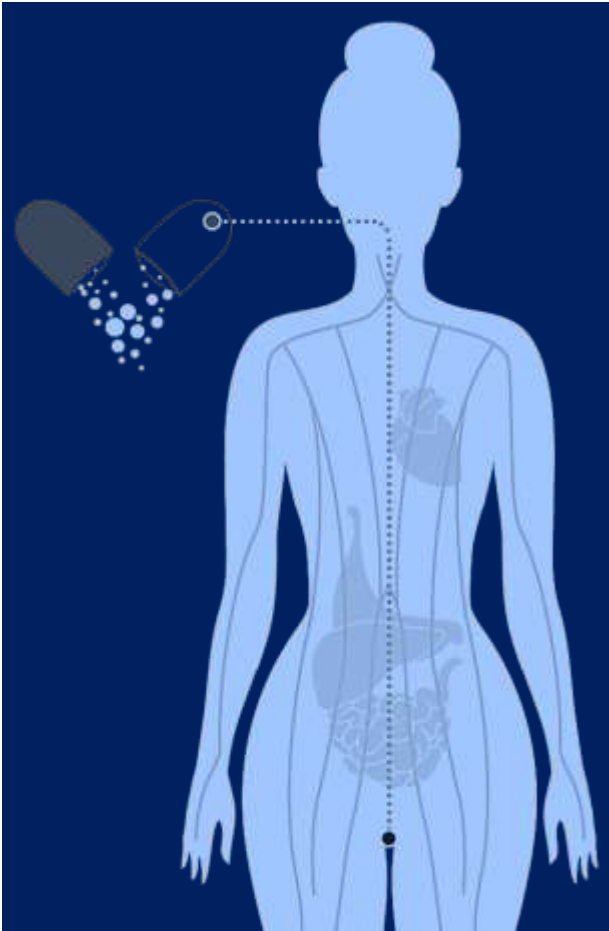


Disclaimer:
This information is not a formal dissemination of information
by the FDA and does not represent Agency position or policy.



**U.S. FOOD & DRUG
ADMINISTRATION**

Our Mission



- **Promote the inclusion of women in clinical trials** and the implementation of guidelines concerning the representation of women in clinical trials and the completion of sex/gender analysis
- **Identify** and monitor the progress of **crosscutting** and multidisciplinary women's health initiatives including **changing needs, areas that require study, and new challenges** to the health of women as they relate to FDA's mission
- **Serve** as the **principal advisor to the Commissioner** and other key Agency officials on **scientific, ethical, and policy** issues relating to women's health

Office of Women's Health

SCIENCE



EDUCATION



ENGAGEMENT



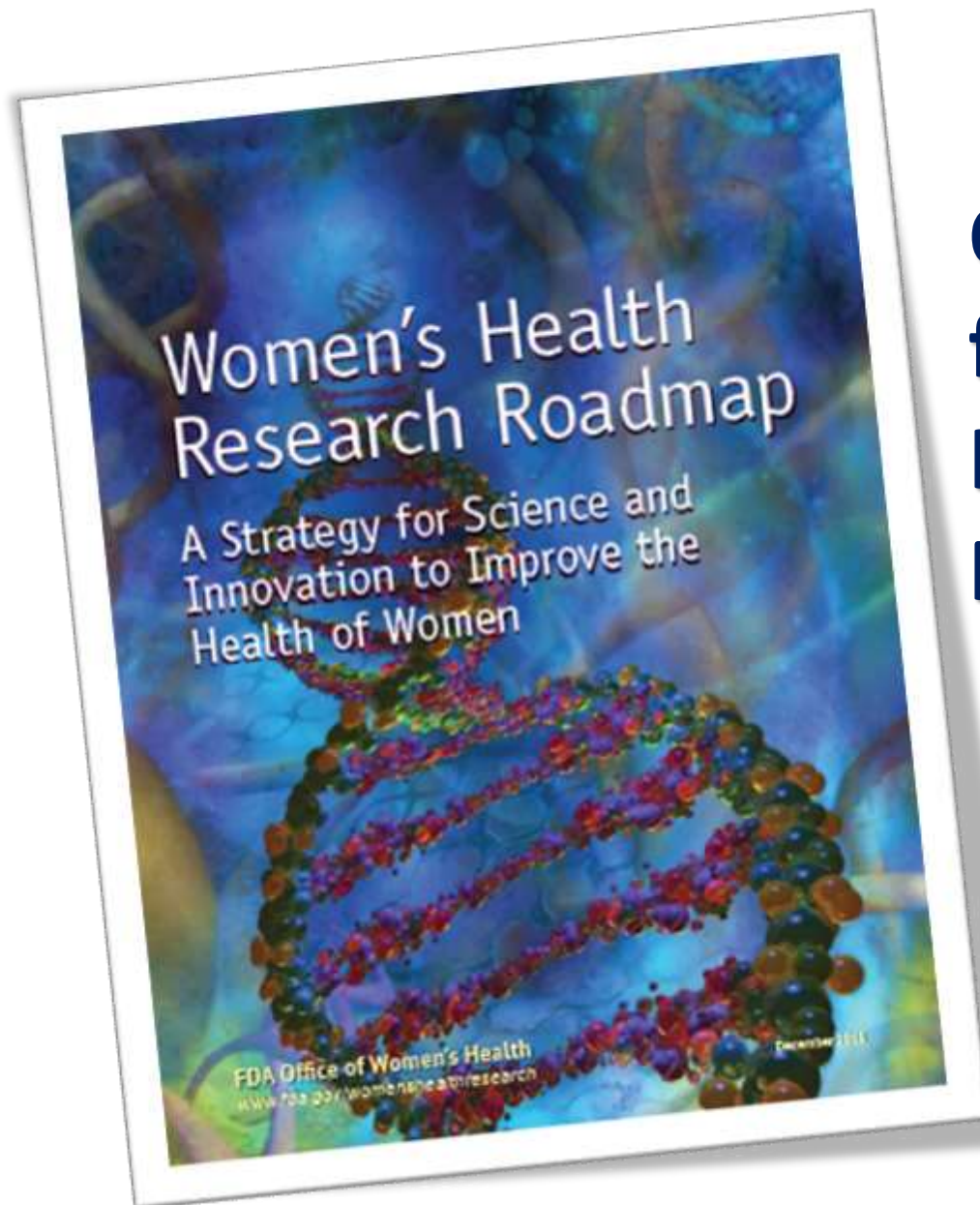
OWH achieves its mission through the foundational principle that Sex is a Biological Variable (SABV)

Sex ≠ Gender

Sex is the classification of living things, generally as male or female according to their reproductive organs and functions assigned by the chromosomal complement.

Gender is defined as a person's self-representation, or how that person is responded to by social institutions on the basis of the individual's gender presentation.

Source: [Exploring the Biological Contributions to Human Health: Does Sex Matter](#) (2001)



OWH created the first FDA Women's Health Research Roadmap

<http://inside.fda.gov:9003/downloads/scienceresearch/specialtopics/womenshealthresearch/ucm479681.pdf>

1.
Advance
Safety
and
Efficacy

5. Expand Data
Sources and
Analysis

7. Identify Sex
Differences
via Emerging
Technologies

6. Improve
Health
Communications

2. Improve
Clinical Study
Design and
Analysis

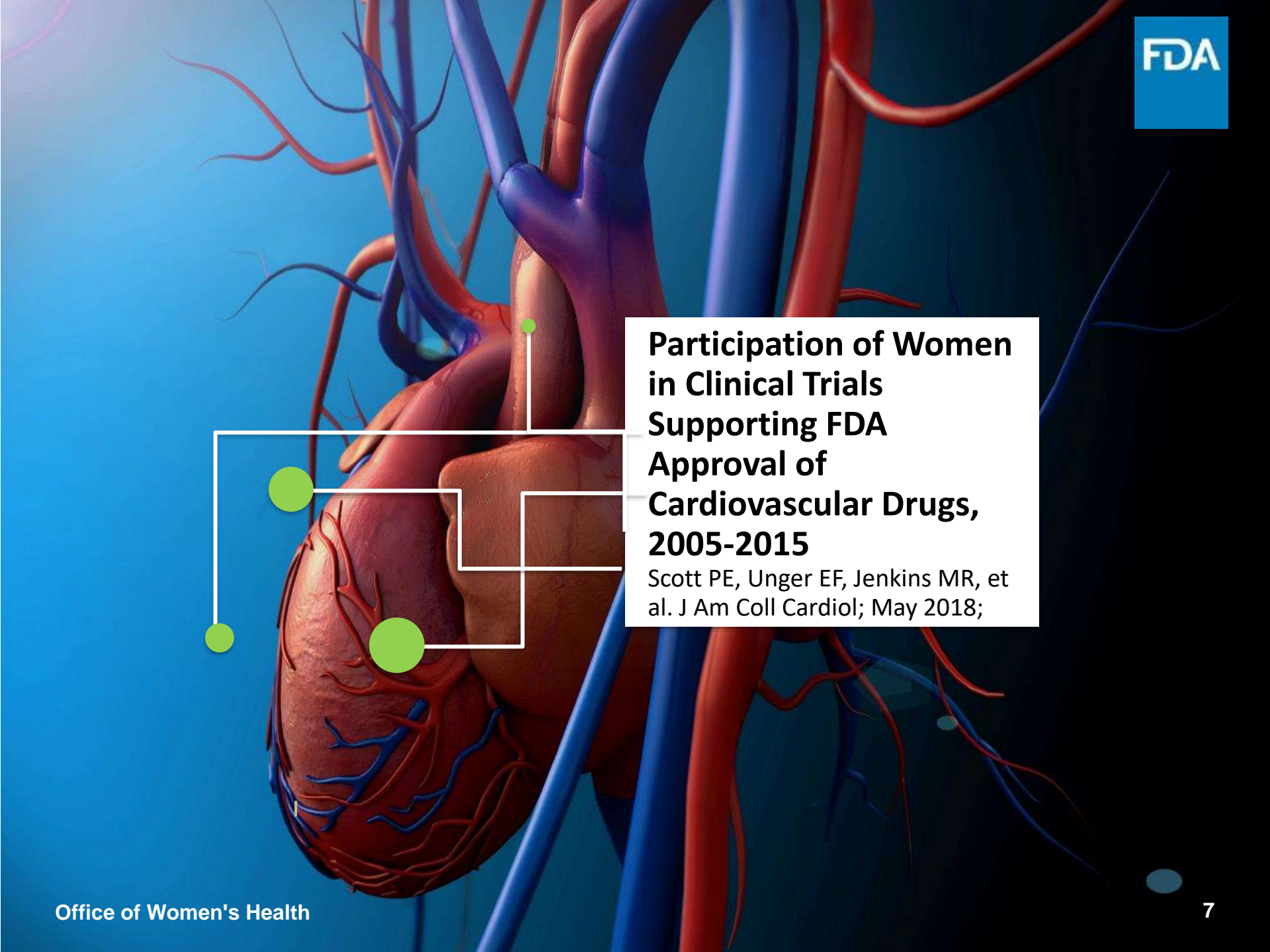
3. Evaluate New
Modeling and
Simulation
Approaches

4. Advance
Biomarker
Science

Priority Areas Outlined in OWH *Women's Health Research Roadmap*

Read the Women's Health Research Roadmap

<https://www.fda.gov/science-research/womens-health-research/womens-health-research-roadmap>

The background features a detailed anatomical illustration of the human heart and its major blood vessels. The heart is shown in a reddish-brown color, with blue arteries and red veins branching out. A white box with a black border is overlaid on the right side of the heart, containing text. Four green circles are connected to the white box by white lines, pointing to specific areas on the heart: one on the upper right, one on the left side, one on the lower left, and one on the bottom left.

Participation of Women in Clinical Trials Supporting FDA Approval of Cardiovascular Drugs, 2005-2015

Scott PE, Unger EF, Jenkins MR, et al. J Am Coll Cardiol; May 2018;

OWH Scientific Speaker Series



XX XY
FDA Office of Women's Health Scientific Series

**SEX DIFFERENCES IMPACT VACCINE EFFICACY:
What You Need to Know**

February 4, 2020
12:00 - 1:00 PM ET
CNE/CPE/CNE Available

Exploring Sex and Gender - Connections to Regulatory Science

Registration: <https://go.usa.gov/xpHpB>



Dr. Sabra Klein
Associate Professor, Molecular Microbiology and Immunology
Johns Hopkins Bloomberg School of Public Health



XX XY
FDA Office of Women's Health Scientific Series

SEX DIFFERENCES IN COVID-19

October 20, 2020 | 12:00 - 1:00 PM ET | Adobe

EXPLORING SEX AND GENDER - CONNECTIONS TO REGULATORY SCIENCE

Kathryn Sandberg, PhD
Director, Center for the Study of Sex Differences in Health, Aging, and Disease



XX XY
FDA Office of Women's Health Scientific Series

COVID-19 AND PREGNANCY
What We Know


August 6, 2020 • 12:00 - 1:00 PM ET
Available via Adobe Connect

EXPLORING SEX AND GENDER - CONNECTIONS TO REGULATORY SCIENCE

Vincenzo Berghella, MD
Director, Division of Maternal-Fetal Medicine
Thomas Jefferson University



OWH Scientific Workshops and Public Meetings



Opioid and Nicotine Use,
Dependence, and Recovery:
Influences of Sex and Gender

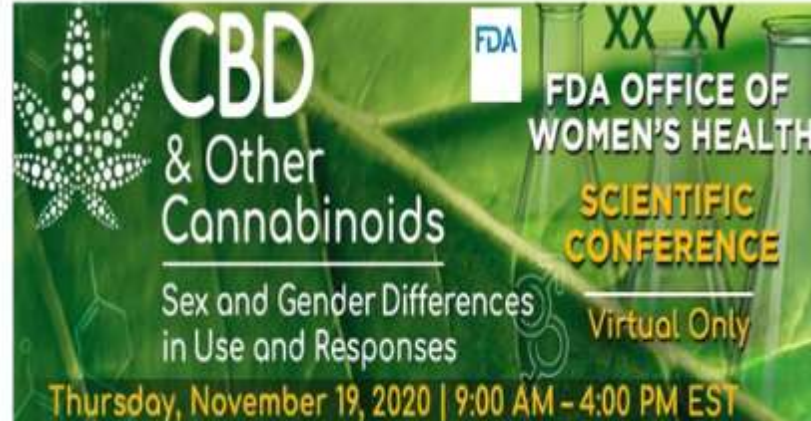
Was held on September 27-28, 2018 at the US FDA White Oak Campus and via Webcast

FDA Office of Women's Health and
CDER Division of Pediatric and Maternal Health
invite you to:

**The Safety of Asthma Medications During
Pregnancy: Research Priorities
and Methodology**

Nov 8, 2019, White Oak Great Room A, 8:00 AM - 5:00 PM

Registration not required. Webcast not available.



**CBD
& Other
Cannabinoids**
Sex and Gender Differences
in Use and Responses
Thursday, November 19, 2020 | 9:00 AM - 4:00 PM EST

FDA
XX XY
FDA OFFICE OF
WOMEN'S HEALTH
SCIENTIFIC
CONFERENCE
Virtual Only

Bench to Bedside

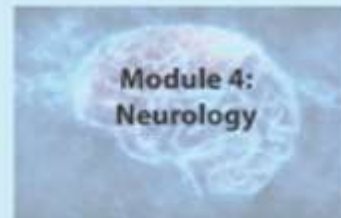
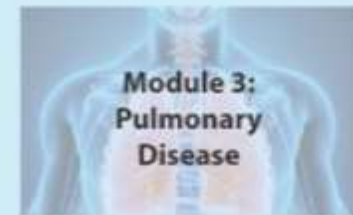
Integrating Sex and Gender to Improve Human Health Course

Available NOW: Free Online Courses Addressing Sex and Gender

Developed by the NIH Office of Research on Women's Health in partnership with the FDA Office of Women's Health

Bench to Bedside: Integrating Sex and Gender to Improve Human Health

Explore sex- and gender-related differences in human health and disease.



Register at <https://go.usa.gov/xvGwn>.



NIH National Institutes of Health
Office of Research on Women's Health



nih.gov/women



<https://orwh.od.nih.gov/career-development-education/e-learning/bench-bedside>

Diverse Women in Clinical Trials

www.fda.gov/womeninclinicaltrials



WOMEN IN CLINICAL TRIALS
= HOPE

Ask your healthcare provider if a clinical trial is right for you.

Office of Women's Health www.fda.gov/womeninclinicaltrials

The graphic features a central DNA double helix with various icons (heart, brain, gear, etc.) around it. On either side of the DNA are silhouettes of diverse women representing different ages, abilities, and ethnicities. The text 'WOMEN IN CLINICAL TRIALS = HOPE' is prominently displayed above the silhouettes. The FDA logo is in the top right corner of the graphic area.

Diverse Women in Clinical Trials

Print and Electronic Publications Available

15 Things You Should Know Before You Join a Clinical Trial

Being in a clinical trial is your choice. You should not feel pressured to join. You have the right to quit at any time. There are rules to protect people in clinical trials. Informed consent is the process of learning the key facts about the clinical trial before you join. This list is not everything you need to know, but it will help you start the conversation. Make sure that you have your questions answered before you agree to participate. Find out:

The Purpose and What Will Happen

1. The purpose of the study
2. The drugs, tests, and treatments you may receive
3. How long the study will last and how many times you will have to come
4. How they will keep your information private
5. What happens when the study ends

The Possible Risks and Benefits

- The trial may provide treatments or screenings, but there is no promise that your health will get better. The medicine, test, or treatment may not work for you.
6. The benefits of the treatments
 7. The risks and side effects of the treatments

8. Any treatments or other options for people with your disease
9. If you can take your other medicines

Any Other Support or Possible Costs

10. What treatment or services the study will pay for
11. If the study offers child care or transportation
12. The costs you may have to pay
13. What your insurance will cover

How to Get More Information

14. Who you should contact if you have questions or problems
15. How you will get the results

What is FDA's Role?

The U.S. Food and Drug Administration (FDA) makes sure medical treatments are safe and effective for people to use. FDA does not develop new treatments or conduct clinical trials.

The FDA Office of Women's Health is partnering with the NIH Office of Research on Women's Health on an initiative to promote the participation of diverse women in clinical trials. To learn more about these activities, go to:

www.fda.gov/womeninclinicaltrials



FDA U.S. FOOD & DRUG ADMINISTRATION

[Download the Fact Sheet](#)



Sample Tweets

1. Clinical trials = Hope. Learn how to make a difference for yourself and women like you: <http://go.usa.gov/x8Eyu>
2. Play a part in the future of women's health. Find out how joining a clinical trial can make a difference: <http://go.usa.gov/x8Eyu>
3. Have you considered participating in a clinical trial? Ask your healthcare provider if a clinical trial is right for you. Clinical trials = Hope: <http://go.usa.gov/x8Eyu>
4. When diverse women join clinical trials, doctors learn more about how meds affect all people. Learn more: <http://go.usa.gov/x8Eyu>
5. Help doctors learn about women's health by joining a clinical trial. Search by city, medical condition, or treatment: <https://go.usa.gov/x8Eyu>
6. DYK clinical trials can be a treatment option for many health conditions? Ask your healthcare provider if a clinical trial is right for you: <http://go.usa.gov/x8Eyu>
7. Diverse women make a difference in clinical trials. Find out why: <http://go.usa.gov/x8Eyu>
8. Provide hope for a healthier future. Ask your healthcare provider about participating in a clinical trial: <http://go.usa.gov/x8Eyu>
9. Make a difference. Join a clinical trial and help doctors learn more about women's health: <http://go.usa.gov/x8Eyu>
10. Do you know who should think about joining a clinical trial? Women of all ages, racial, and ethnic groups. Women with disabilities or chronic health conditions. When diverse people join, clinical trials can help improve health for all. <http://go.usa.gov/x8Eyu>
11. Healthy women can participate in clinical trials too! Talk to your doctor about finding the right one for you: <http://go.usa.gov/x8Eyu>
12. Thinking about joining a clinical trial? It's a great way to make a difference for women like you. 15 things you should know before joining a clinical trial: <http://go.usa.gov/x8Eyu>

[Download the Social Media Toolkit](#)

Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)

The 21st Century Cures Act P.L. 114-255

- Advise the Secretary of Health and Human Services (HHS) regarding gaps in knowledge and research on safe and effective therapies for pregnant women and lactating women
 - 15 recommendations
 - Implementation of recommendations report

<https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAAct/21stCenturyCuresAct/default.htm>

Related Guidances

Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact the Division of Pediatric and Maternal Health (CDER) at (301) 796-2200 or the Office of Communication, Outreach, and Development (CDER) at 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

April 2018
Clinical/Medical
Revision 1

Postapproval Pregnancy Safety Studies Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Denise Johnson-Lyles at 301-796-6169 or (CBER) the Office of Communication, Outreach, and Development at 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

May 2019
Clinical/Medical

20190509plh/aw
05/16/19

Clinical Lactation Studies: Considerations for Study Design Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Jian Wang at 301-796-2846 or (CBER) the Office of Communication, Outreach, and Development at 800-835-4709 or 240-402-8010.

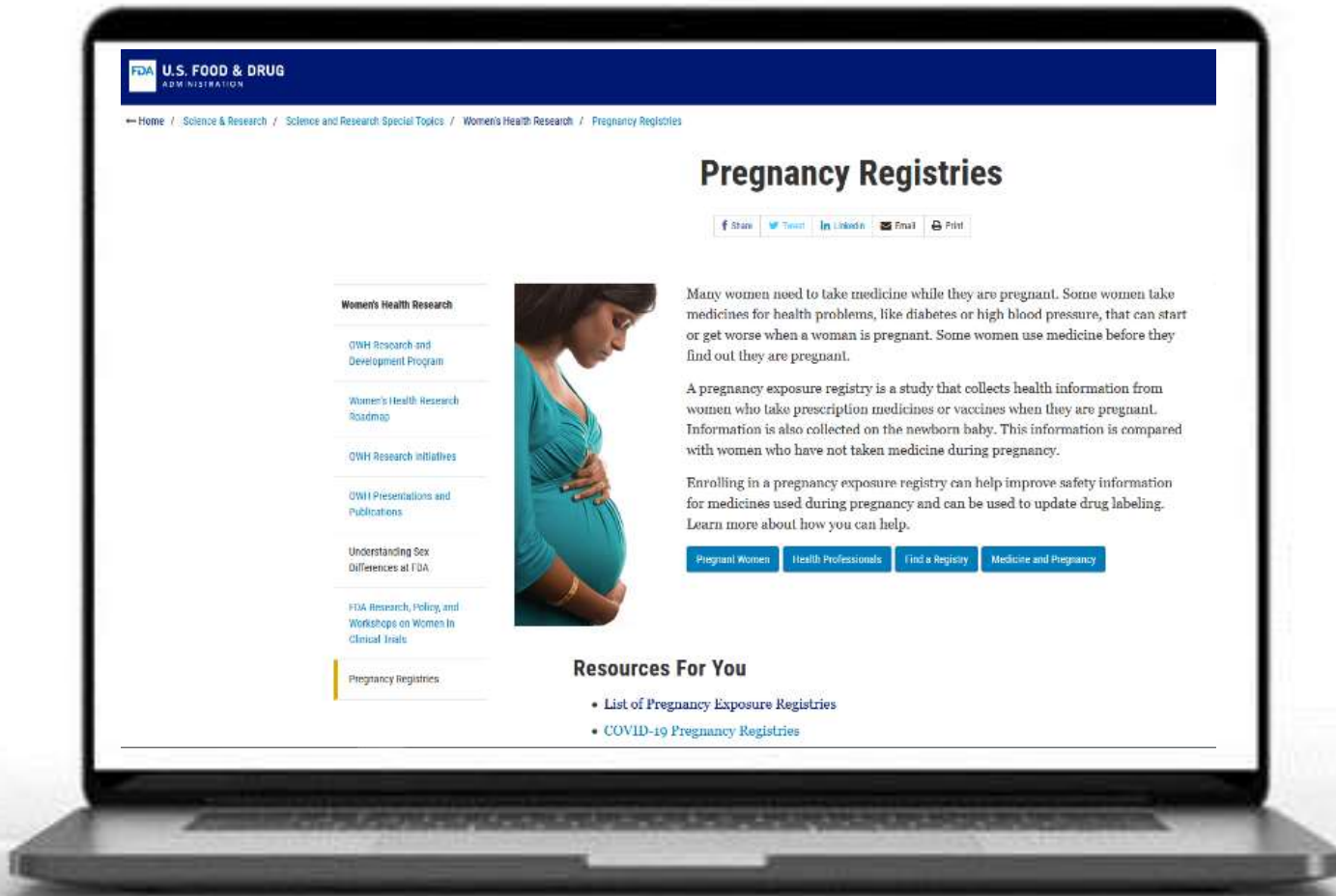
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

May 2019
Clinical/Medical

20190509plh/aw
05/16/19

- [Guidance for Industry: COVID-19: Developing Drugs and Biological Products for Treatment or Prevention \(May 2020\)](#)
 - FDA encourages the enrollment of **pregnant and lactating individuals** in the phase 3 (efficacy) clinical trials if appropriate.
- [Guidance for Industry: Development and Licensure of Vaccines to Prevent COVID-19 \(June 2020\)](#)
 - FDA encourages vaccine developers to consider early in their development programs data that might support **inclusion of pregnant women and women of childbearing potential** who are not actively avoiding pregnancy in pre-licensure clinical trials.

Pregnancy Registries



Pregnancy Registries

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Women's Health Research

[QWH Research and Development Program](#)

[Women's Health Research Roadmap](#)

[QWH Research Initiatives](#)

[QWH Presentations and Publications](#)

[Understanding Sex Differences at FDA](#)

[FDA Research, Policy, and Workshops on Women in Clinical Trials](#)

[Pregnancy Registries](#)



Many women need to take medicine while they are pregnant. Some women take medicines for health problems, like diabetes or high blood pressure, that can start or get worse when a woman is pregnant. Some women use medicine before they find out they are pregnant.

A pregnancy exposure registry is a study that collects health information from women who take prescription medicines or vaccines when they are pregnant. Information is also collected on the newborn baby. This information is compared with women who have not taken medicine during pregnancy.

Enrolling in a pregnancy exposure registry can help improve safety information for medicines used during pregnancy and can be used to update drug labeling. Learn more about how you can help.

[Pregnant Women](#)
[Health Professionals](#)
[Find a Registry](#)
[Medicine and Pregnancy](#)

Resources For You

- [List of Pregnancy Exposure Registries](#)
- [COVID-19 Pregnancy Registries](#)

Dynamic Social Media Content

on Twitter, Facebook & Pinterest



You can make a difference in [#WomensHealth](#). Women of all ages, racial & ethnic groups, and women with disabilities or chronic health conditions are needed for clinical trials. Ask your healthcare provider if a [#ClinicalTrial](#) is right for you. [fda.gov/womeninclinica...](https://www.fda.gov/womeninclinica...)



9:00 AM · Aug 14, 2020 · Hootsuite Inc.

OWH Strategic Priorities



FEDERAL REGISTER

The Daily Journal of the United States Government



Notice

Office of Women's Health Strategic Priorities; Establishment of a Public Docket; Request for Comments

A Notice by the [Food and Drug Administration](#) on [07/10/2020](#)

This document has a comment period that ends in 28 days. (09/08/2020)

[SUBMIT A FORMAL COMMENT](#)

[Docket Number FDA-2020-N-1391](#)

Knowledge and News on Women

Heart Health for Women

[Share](#) [Tweet](#) [LinkedIn](#) [Email](#) [Print](#)

Getting a Beat on What Women Know about Heart Health

Heart disease is the leading cause of death for women in the United States. Find out what other women like you know about heart health and get tips on how to keep your heart healthy!



En Español

OWH Blog: Knowledge and News on Women (July 2020)

[Share](#) [Tweet](#) [LinkedIn](#) [Email](#) [Print](#)

Knowledge and News on Women

July 21, 2020

July is Fibroid Awareness Month and the perfect time to shed light on this critical women's health condition that impacts a vast majority of women at some point in their lifetime. Uterine fibroids are non-cancerous tumors of the uterine muscle that can cause heavy menstrual bleeding, pain, bowel and/or bladder problems and infertility. This is a topic of personal interest to staff within the Office of Women's Health who have experienced firsthand the challenges of living with uterine fibroids. This month we are highlighting FDA's efforts to help expand the treatment options for women with fibroids. We also invite you to read about the personal journeys of two women whose experiences inspired them to bring broader awareness to this important topic.

The Division of Urology, Obstetrics and Gynecology (DUOG), Center for Drug Evaluation and Research (CDER), joins OWH in recognizing July as Fibroid Awareness Month. Fibroids are the most common benign tumors in women of reproductive age. When fibroid-related symptoms become severe, women often resort to surgical treatments, such

Consumer Resources

Women and Pain Medicines

Women experience pain differently than men.

- Action options such as heat
- Even general anesthesia doesn't quite do the job for some women, so women need more powerful pain relief options.
- Women are more likely to be prescribed pain medications, but given other doses, and use them for longer time periods than men.

Types of Pain Medicines

Osteoporosis

What is osteoporosis?

Osteoporosis is a disease that causes weak bones that break easily.

Who is at risk?

- Anyone can get osteoporosis, but we are more likely to get it than men. We may be more likely to get it if you:
 - Are over age 50
 - Smoke
 - Have a low body weight
 - Have family members who had osteoporosis or broken bones
 - Do not get enough exercise
 - Drink too much alcohol
 - Take certain medicines for a long time like certain medicines for osteoporosis

Diabetes Medicines

Diabetics can reduce their risk for control from made sugar (called glucose) in their blood.

There is hope!

Some people with diabetes can take medicines to help keep their blood sugar at a healthy level.

Use this booklet to help you talk to your healthcare provider about the right medicines that is right for you.

ACE YOUR HEALTH RESOURCES FOR COLLEGE WOMEN

FDA OFFICE OF WOMEN'S HEALTH

www.fda.gov/collegewomen

Virus del papiloma humano (VPH)

¿Qué es el VPH?

El VPH (virus de papiloma humano) es un virus de transmisión sexual que se transmite por contacto genital (como el contacto sexual vaginal y anal). También se transmite por contacto oral-genital. Como mínimo, un 80% de las personas que han tenido relaciones sexuales se infectan con el VPH en algún momento de su vida.

¿Por qué nunca he oído hablar acerca del VPH?

El VPH no es un virus nuevo, pero mucha gente no lo conoce. La mayoría de las personas que contraen el VPH no presentan síntomas. El VPH puede desaparecer solo, sin causar ningún trastorno de salud.

¿Qué debo saber acerca de los verrugas genitales?

Existen muchos tipos de tratamiento para las verrugas genitales. Sin embargo, incluso después del tratamiento de las verrugas, es posible que el virus siga presente y se transmita a otros. Si las verrugas genitales no se tratan, pueden dar lugar a verrugas más grandes, a verrugas más profundas, o a verrugas que cambian de color, pero no se convierten en cáncer.

My Medicines

Women's Health: Take Time To Care for Yourself for those who need you

Caring for Others: Tips for Medicines and Devices

Do you help care for a loved one at home or show up when you can't stand to see them? Help your loved ones take the best care they can. You can help by managing their medicines and medical devices. Changes in their treatment can also be a challenge. Use these four habits for better care, peace of mind, and your healthcare provider can create a plan for staying medicines ready.

Don't Rush
Follow Directions
Stay Organized
Stay Prepared

FDA OFFICE OF WOMEN'S HEALTH
www.fda.gov/womenshealth

PREGNANCY Social Media Toolkit

www.fda.gov/womenshealth

PREGNANCY Social Media Toolkit

www.fda.gov/womenshealth

www.fda.gov/womenshealthpubs

Stay Connected With OWH



twitter.com/FDAWomen



facebook.com/FDA/



fda.gov/consumers/consumer-information-audience/women

Challenge Question

Which of the following statements about sex and gender is correct?

- a) Sex is a biological variable
- b) The terms *male* and *female* are used to characterize gender
- c) Gender is a binary variable
- d) Sex and gender are synonymous terms

Thank you

www.fda.gov/womens

www.fda.gov/womenshealthresearch

@FDAWomen on Twitter

**The FDA Office of
Minority Health and Health Equity:
*Efforts to Diversify Clinical Trials***

www.fda.gov/healthequity



Speaker



RADM Richardae Araojo

Associate Commissioner for Minority Health
Director, Office of Minority Health and Health Equity



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



Objectives

- Provide an overview of the U.S. Food and Drug Administration's Office of Minority Health and Health Equity (OMHHE)
- Describe FDA OMHHE's Diversity in Clinical Trials Initiative
- Provide an overview of communication and outreach strategies to advance diverse participation in clinical trials



FDA Office of Minority Health and Health Equity (OMHHE)

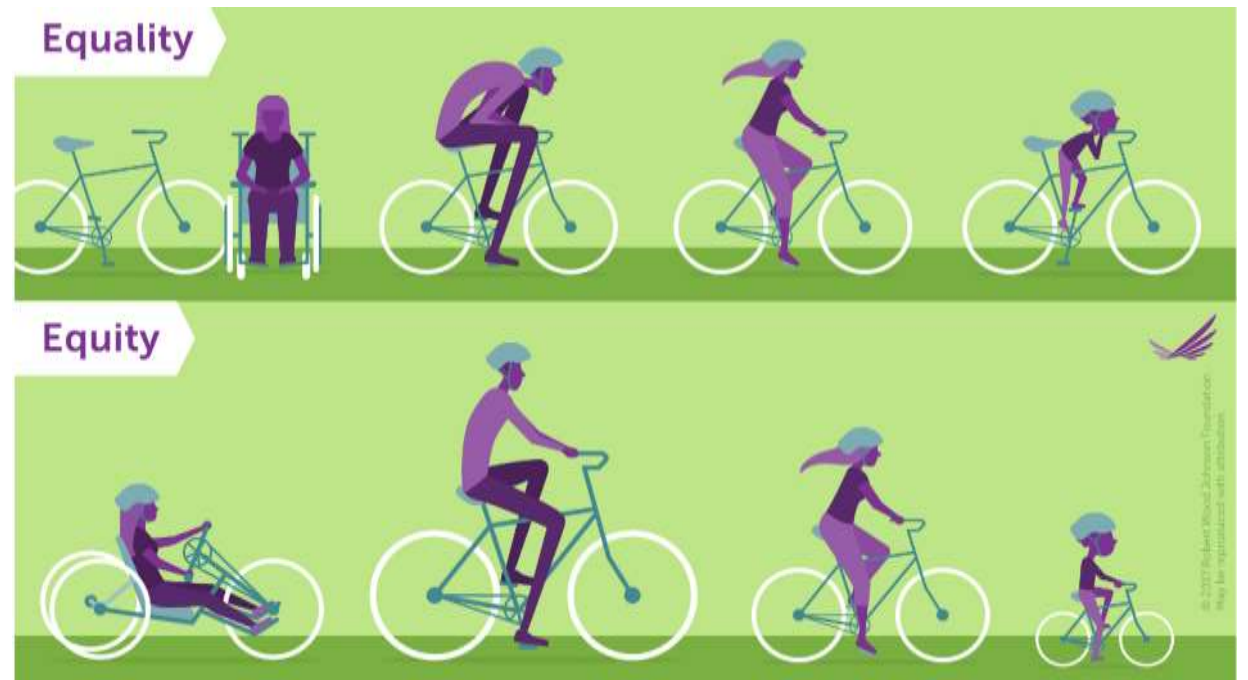


Mission

To promote and protect the health of diverse populations through research and communication that addresses health disparities.

Vision

To create a world where health equity is a reality for all.



FDA OMHHE Goals

- Goal 1: Improve regulatory science by increasing clinical trial data available on racial and ethnic minorities; improve data quality to determine how minorities react to medical products; and increase transparency and access to available data
- Goal 2: Strengthen FDA's ability to respond to minority health concerns
- Goal 3: Promote health and safety communication to minority populations who often experience low health literacy and/or speak English as a second language



What We Do

Research and Collaboration

- Intramural Research
- Extramural Research
- FDA Centers of Excellence in Regulatory Science and Innovation (CERSI) Projects
- Broad Agency Announcement (BAA)
- Other research opportunities
- Internships and Fellowships
- Academic Collaborations
- FDA & HHS Working Groups & Collaborations
- Stakeholder Input into Research Agenda

Outreach and Communication

- Programs/Initiatives/Campaigns
 - Diversity in Clinical Trials Initiative
 - Language Access Program
- Health Education Materials
- Social Media
- Newsletter & E-alerts
- Website
- Health Equity Lecture Series & Webinars
- FDA & HHS Working Groups & Collaborations
- Stakeholder Meetings/Symposiums/Exhibits
- Foster collaboration between FDA & stakeholders



Language Access Program

- Over 65 million Americans speak a language other than English at home
- Program goals:
 - provide access to translation services
 - offer easy to read materials in other languages
 - oversee volunteer’s program
- Language Access Services
 - provide flexible means for FDA centers and offices to acquire language services



OMHHE 10 Year Anniversary



A Decade of FDA Advancing Health Equity

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- FDA Voices on Policy
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- FDA Voices on Medical Products
- FDA Voices on Food
- FDA Voices on Tobacco



Content current as of: 04/22/2020

Regulated Product(s)
Biologics
Drugs
Medical Devices
Tobacco

Topic(s)
Consumer Health

Health Topic(s)
Coronavirus

By: RADM Richardae Araujo, Pharm.D., M.S., Associate Commissioner for Minority Health

The U.S. Food and Drug Administration is working around the clock with our U.S. government partners, medical product manufacturers and international partners to address the coronavirus disease 2019 (COVID-19) pandemic. As the FDA remains steadfast in our urgent response efforts to the pandemic for all Americans, including the nation's most vulnerable communities, I would be remiss not to pause for a moment to mark the importance of [National Minority Health Month](#), observed every April. The commemoration highlights advancements that have been made, and steps we can continue to take, to increase health equity and reduce health disparities among diverse populations. This year, the occasion is especially significant because it marks the 10-year anniversary of the FDA's [Office of Minority Health and Health Equity](#) (OMHHE), an office committed to reducing the health inequities minorities face that often contribute to reduced quality of life and premature death (watch the [OMHHE video](#) below to learn more).



Federal Register Notice: Strategic Priorities



The screenshot shows a Federal Register notice page. At the top, there are logos for the National Archives and the Federal Register, with the text "FEDERAL REGISTER The Daily Journal of the United States Government". A blue bar contains a circled 'N' and the word "Notice". The main title is "Office of Minority Health and Health Equity Strategic Priorities; Establishment of a Public Docket; Request for Comments". Below the title, it says "A Notice by the Food and Drug Administration on 01/03/2020". The page is divided into two main sections: "PUBLISHED DOCUMENT" and "DOCUMENT DETAILS".

PUBLISHED DOCUMENT

AGENCY:
Food and Drug Administration, HHS.

ACTION:
Notice; establishment of a public docket; request for comments.

SUMMARY:
The Food and Drug Administration (FDA or the Agency) is opening a public docket to solicit input and comments from interested stakeholders, including racial and ethnic minority, underrepresented, and underserved populations in establishing strategic priorities for the Office of Minority Health and Health Equity (OMHHE). This will help the Agency ensure that important health concerns are carefully considered in establishing priorities.

DOCUMENT DETAILS

Printed version:
[PDF](#)

Publication Date:
01/03/2020

Agencies:
[Food and Drug Administration](#)

Dates:
Submit either electronic or written comments by February 28, 2020.

Comments Close:
02/28/2020

Document Type:
Notice

Document Citation:
85 FR 316



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



Barriers to Clinical Trial Participation

- Mistrust and distrust of the medical system due to historical abuses
- Lack of awareness of what a clinical trial is and what it means to participate
- Inadequate recruitment and retention efforts
- Lack of minority physicians, researchers, and clinical investigators
- Misunderstanding of racial/ethnic minorities' beliefs and values that contribute to their decision making process
- Lack of culturally and linguistically appropriate communication
- Perception that racial/ethnic minorities do not want to participate
- Physicians/providers may not talk to their patients about clinical trials
- Enrollment criteria
- Return of Results
- Privacy concerns
- Lack of access
- Time and resource constraints for patients

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

(Center for Drug Evaluation and Research)



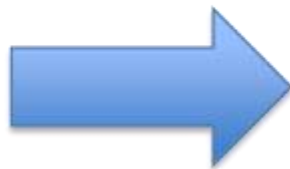
Inclusion of Diverse Populations

- FDA Guidance for Industry on Development and Licensure of Vaccines to Prevent COVID-19; June 2020
 - “FDA encourages the inclusion of diverse populations in all phases of vaccine clinical development. This inclusion helps to ensure that vaccines are safe and effective for everyone in the indicated populations.”
 - “FDA strongly encourages the enrollment of populations most affected by COVID-19, specifically racial and ethnic minorities.”
- FDA Guidance for Industry on COVID-19: Developing Drugs and Biological Products for Treatment or Prevention; May 2020
 - “Racial and ethnic minority persons should be represented in clinical trials. Sponsors should ensure that clinical trial sites include geographic locations with a higher concentration of racial and ethnic minorities to recruit a diverse study population.”



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

- Reinforce the importance of diverse participation
- 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



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 from diverse backgrounds and various ethnic and racial backgrounds. Clinical trials are conducted with people from various backgrounds and ethnicities to ensure that the results of the study can be applied to all people.
2. Participation in clinical trials is voluntary. You can choose to participate or not participate in a clinical trial.
3. Clinical trials are not always healthy. Some clinical trials are for new treatments that may have side effects.
4. FDA does not conduct clinical trials. It is up to the sponsor of the clinical trial to ensure that the study is conducted properly.

The importance of diverse participation in clinical trials

Research is a key to understanding the safety and effectiveness of new medicines, vaccines, and devices. Research is also a key to understanding the safety and effectiveness of new medicines, vaccines, and devices. Research is also a key to understanding the safety and effectiveness of new medicines, vaccines, and devices.

For more information, visit www.fda.gov/ohrt.

RESEARCH NEEDS YOU

FDA Office of Minority Health and Health Equity

4 WAYS TO BE A #ClinicalTrialsChampion

Clinical trials are research studies that determine whether medical therapies and products like medicines, vaccines, or devices are safe and effective.

- SHARE** the #ClinicalTrialsChampion videos
- TALK** to your friends and family about clinical trials
- LOOK** on ClinicalTrials.gov for open research studies
- ASK** your health care provider if a clinical trial is right for you

Search for clinical trials at www.clinicaltrials.gov

For more information on health equity, visit www.fda.gov/healthequity

Ensuring diversity in clinical trials is key to advancing health equity

Racial and Ethnic Minorities in Clinical Trials

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 to 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

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! [Spanish]
- Clinical Trial Diversity Toolkit
- Collection of Race and Ethnicity Data in Clinical Trials—Guidance for Industry and



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



Examples of Stakeholder Engagement Activities

- The Multi-Regional Clinical Trials Center and Harvard, “Achieving Diversity, Inclusion, and Equity in Clinical Research” Workgroup and Diversity Framework
 - Heterogeneity of Treatment Effects in Clinical Trials: Methods and Innovations; November 30 - December 1, 2020.
- Clinical Trials Transformation Initiative (CTTI) Diversity Project
 - CTTI is a Public-Private Partnership Co-founded by Duke University and FDA
- Society for Clinical Research Sites (SCRS) Diversity Awareness Program

Research Collaborations



Strategies to Support Diverse Participation

- There is not a one size fits all approach
- All actions should begin and end with the patient in mind
- A plan to address inclusion should be developed early on
- Consistent and continued community engagement
- Engage patients in trial design, logistics, and recruitment and retention practices
- Site locations where there are more racial and ethnic minorities
- Workforce diversity
- Engage providers
- Cultural sensitivity, competency, and awareness
- Eliminate language barriers
- Organizational goals that support diversity

Health Education

Brochures | Fact Sheets | Infographics | Podcast

FDA OFFICE OF MINORITY HEALTH AND HEALTH EQUITY

HEALTH EQUITY FORUM PODCAST

Listen on **Apple Podcasts** GET IT ON **Google Play**

Sickle Cell Disease

FACT SHEET

Sickle cell disease is an inherited red blood cell disorder. Red blood cells become rigid and shaped like crescent moons. When this happens, oxygen cannot get to parts of the body. This can cause fatigue, severe pain, organ damage, or stroke.

Office of Minority Health

What is Sickle Cell Disease?

Sickle cell disease (SCD) is the most common inherited blood disorder in the U.S. It primarily affects African Americans (1 in 363) and Hispanic Americans (1 in 16,300). It is a chronic condition that can cause anemia, pain, organ damage, or even stroke.

Key Facts

- Sickle cell disease (SCD) is the most common inherited blood disorder in the U.S.
- Chronic health may be an option for patients with SCD.
- There are many ways to prevent your child's safety during travel.

SCD Treatment Options

Current treatments for sickle cell disease are limited to preventing and managing complications, which is the most desirable symptom of SCD.

- L-glutamine oral powder:** Patients can take this oral medication to reduce acute complications in adults and children under age 5 years.
- Hydroxyurea:** Patients can take this oral medication to help reduce the frequency of pain crises and the need for blood transfusions.
- Pain Medication:** Patients can manage their pain with non-steroidal anti-inflammatory drugs (NSAIDs), opioids, anticonvulsants, and anticonvulsants.
- Chronic Transfusion Therapy:** Patients can get regular blood transfusions to help prevent complications, but they can experience a buildup of iron. Some patients or their care partners may need to take iron chelation therapy.

SCD and Clinical Trials

Clinical trials can be very important to developing new and better treatments for sickle cell disease. Your participation is voluntary. These are issues that protect your safety and your information is kept confidential. If you have a clinical trial that may be right for you, talk to your doctor. You can also search for clinical trials in your area at www.ClinicalTrials.gov.

For more information on minority health go to www.fda.gov/ohh/health. To learn if there are and see a list of questions to ask, visit www.fda.gov/ohh/researchparticipation.

Signs and Symptoms of SCD

In the U.S. states including District of Columbia (DC) and 12 territories include that all residents get screened for SCD as a baby test profile, usually age 6 months, but most infants do not start having symptoms until they are about 5 to 6 months old.

Early symptoms of SCD may include:

- Painful swelling of the hands and feet (dactylitis)
- Fatigue or weakness from anemia
- Yellowish color of the skin (jaundice)
- Yellowish color in white parts of the eye (sclera)

The symptoms and complications of SCD will vary in severity from person to person and can change over time.

Asthma

FACT SHEET

Asthma is a chronic inflammatory disease that affects the airways. The main goal for people living with asthma is control. Patients should work with a healthcare provider to create an asthma action plan. This plan will show you what medications you need to take, how to take them, and when to take them. Properly managing your asthma can reduce the number and severity of your asthma attacks. Left untreated, asthma can cause long term lung damage, frequent visits to the emergency room, and hospitalizations.

Office of Minority Health

What is Asthma?

Asthma is a chronic condition that causes the airways to become inflamed and narrow. Symptoms of an asthma attack include coughing, periods of wheezing, chest tightness, and difficulty breathing. More than 22 million people in the U.S. have asthma, and 8 million of them are children.

Uncontrolled Asthma Can Lead to:

- Shortness of breath
- Long term damage to the lungs and airways
- Increased use of quick relief medications
- Increased hospital visits and emergency room visits
- Decreased productivity missed work or school days

Asthma Treatment Options

There are two main types of FDA-approved drugs used to treat asthma: quick relief medications and medications intended for long-term control. Talk to your doctor about which medications are right for you.

- Quick relief medications:** These medications work fast to treat sudden symptoms of the onset of an asthma attack or flare-up. They are intended to help with the muscles of your airways (bronchi) and provide quick relief of symptoms during an asthma attack.
- Long-term control medications:** These medications are used on a regular basis to reduce the inflammation and control of the airways that cause ongoing symptoms. They can be taken daily, inhaled or injected.

Asthma and Clinical Trials

Talk to your doctor if you think participating in a clinical trial may be right for you. You can also search for clinical trials in your area at www.ClinicalTrials.gov.

For more information on clinical trial participation go to www.fda.gov/about-research-participation.

For more information on minority health go to www.fda.gov/ohh/health.

Common Asthma Triggers

Asthma symptoms can vary from person to person. The severity of symptoms can change over time. Some triggers that can worsen these symptoms include:

- Pollen
- Exhaustion
- Dust
- Moist
- Pet dander (animal skin or hair)
- Air pollution
- Perfumes or colognes
- Respiratory viruses such as the cold or flu

Steps to Control Your Asthma

FDA Office of Minority Health and Health Equity



Social Media Outreach

HISPANIC HERITAGE MONTH



YOUR BEST LEGACY IS YOUR HEALTH.

Did You Know?

About **800,000** Americans have a heart attack every year.



Be aware of warning signs like chest pain, nausea, or shortness of breath.

www.fda.gov/healthequity

NATIVE AMERICAN HERITAGE MONTH



DID YOU KNOW?

Some cancer survivors are at increased risk for lung cancer.



We all benefit from diversity in research

EAT FOR A healthy heart

Learn about the new Nutrition Facts label



Challenge Question

- One strategy to raise awareness on clinical trial diversity is to develop culturally and linguistically tailored health education materials.
 - a) True
 - b) False



Thank You!



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