U.S. FOOD & DRUG ADMINISTRATION

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

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- Draft Guidance: Inclusion of Older Adults in Cancer Clinical Trials,2020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


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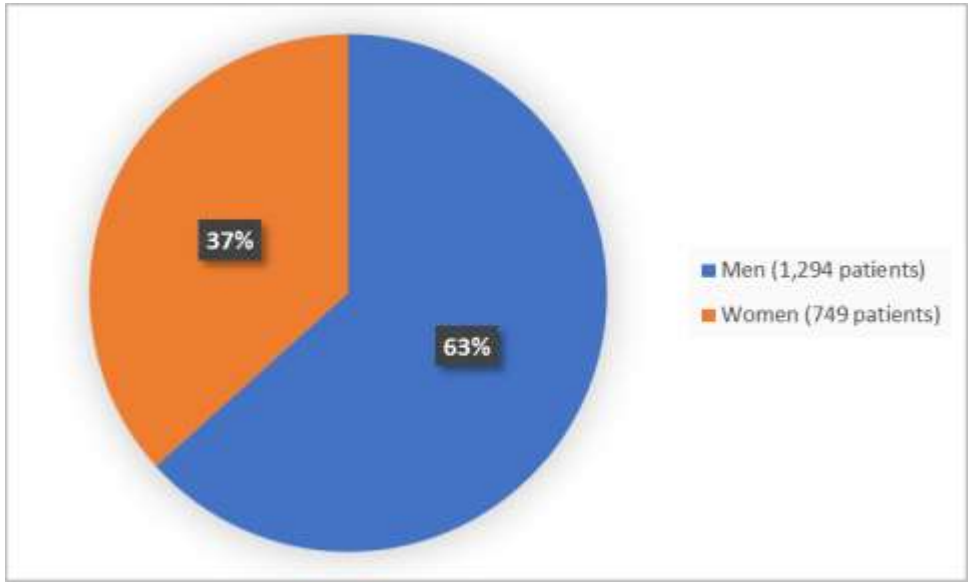
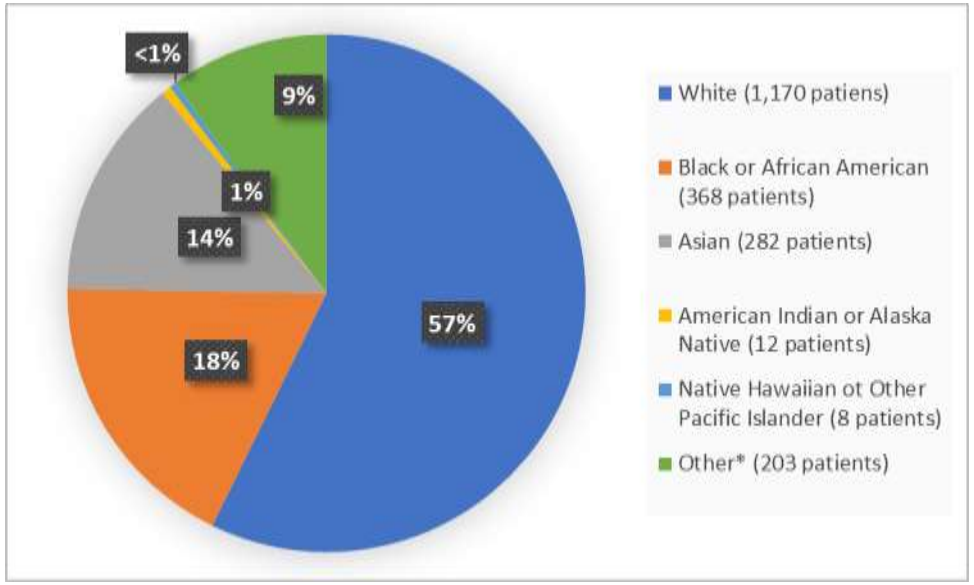
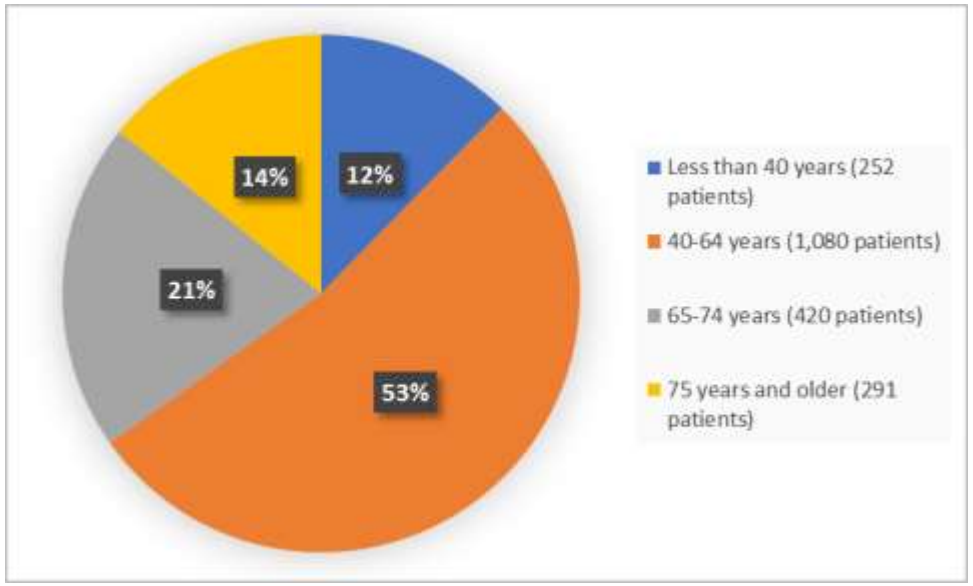
ADMINISTRATION

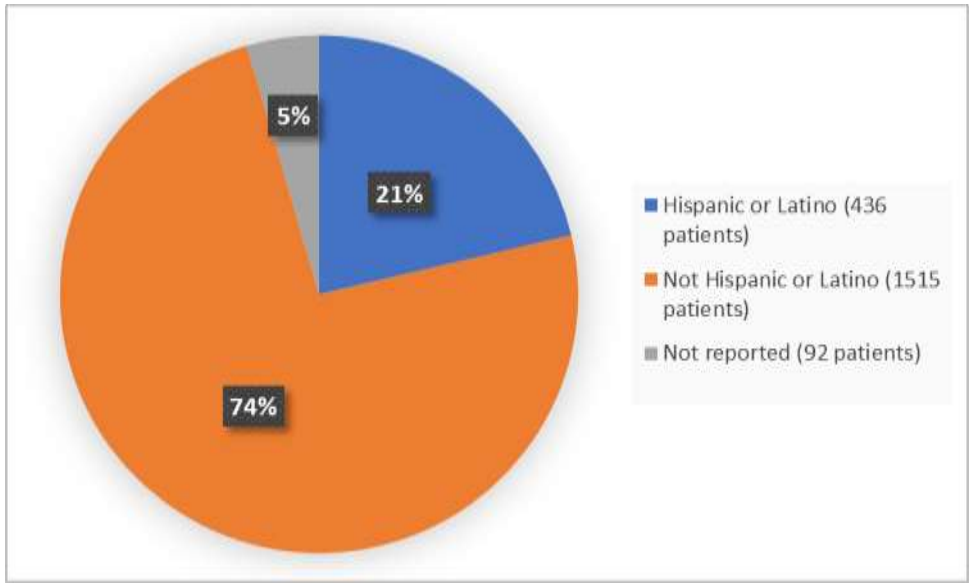
Backup Slide

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 vasooclusive 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

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

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-oclusive 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-oclusive 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).

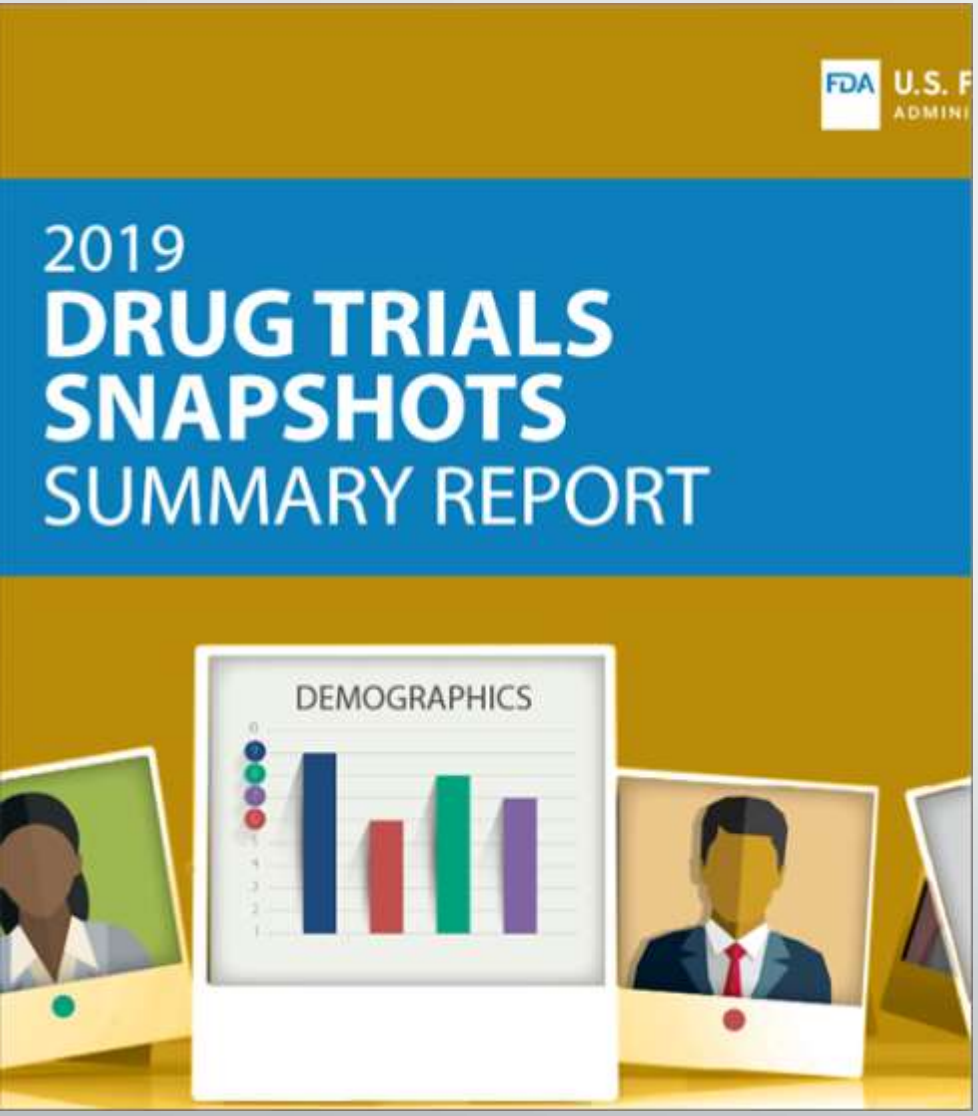
Who participated in the trials?

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



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%

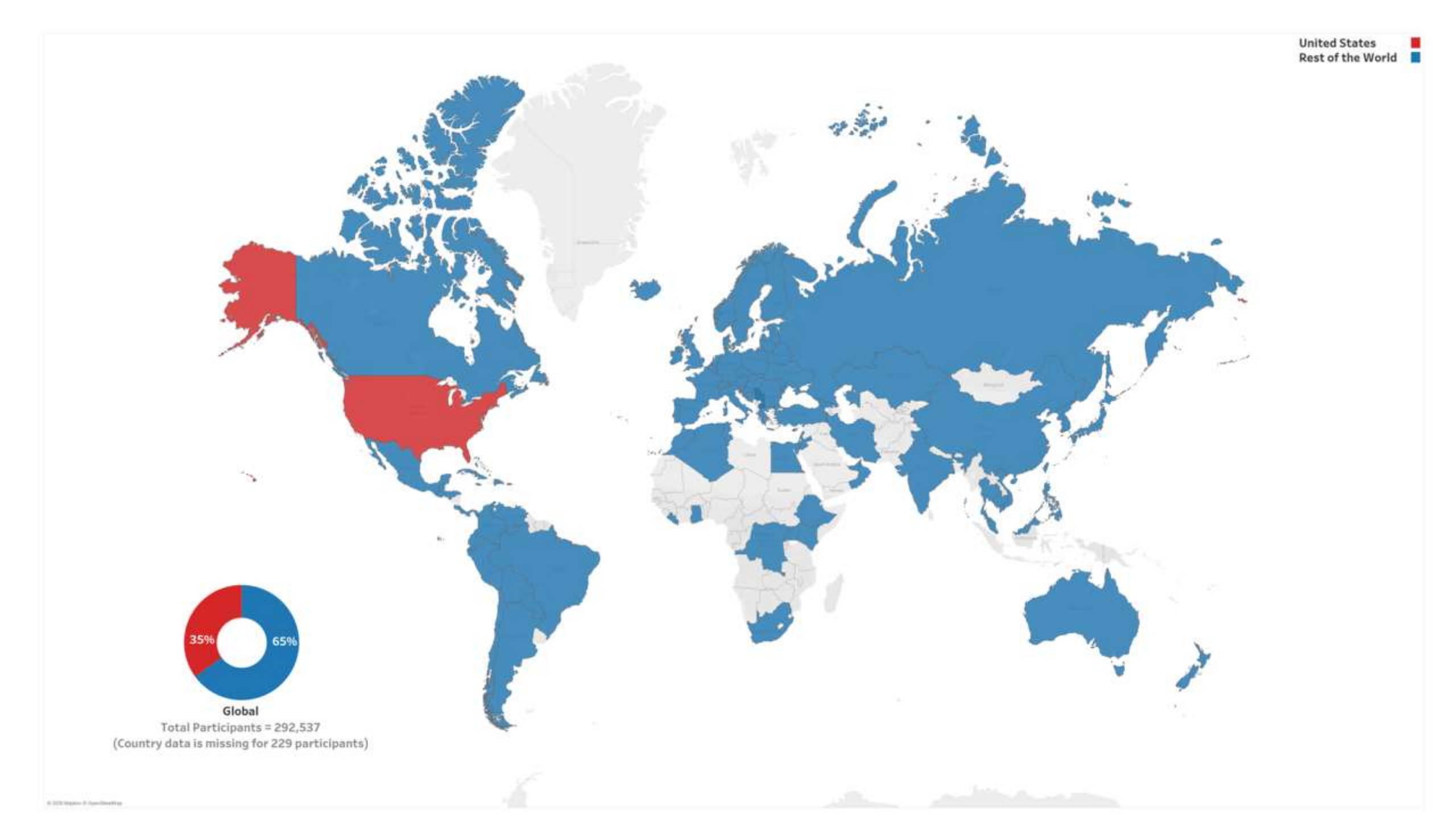
*Data presented in this report are from 49 snapshots as one drug was approved for two indications.

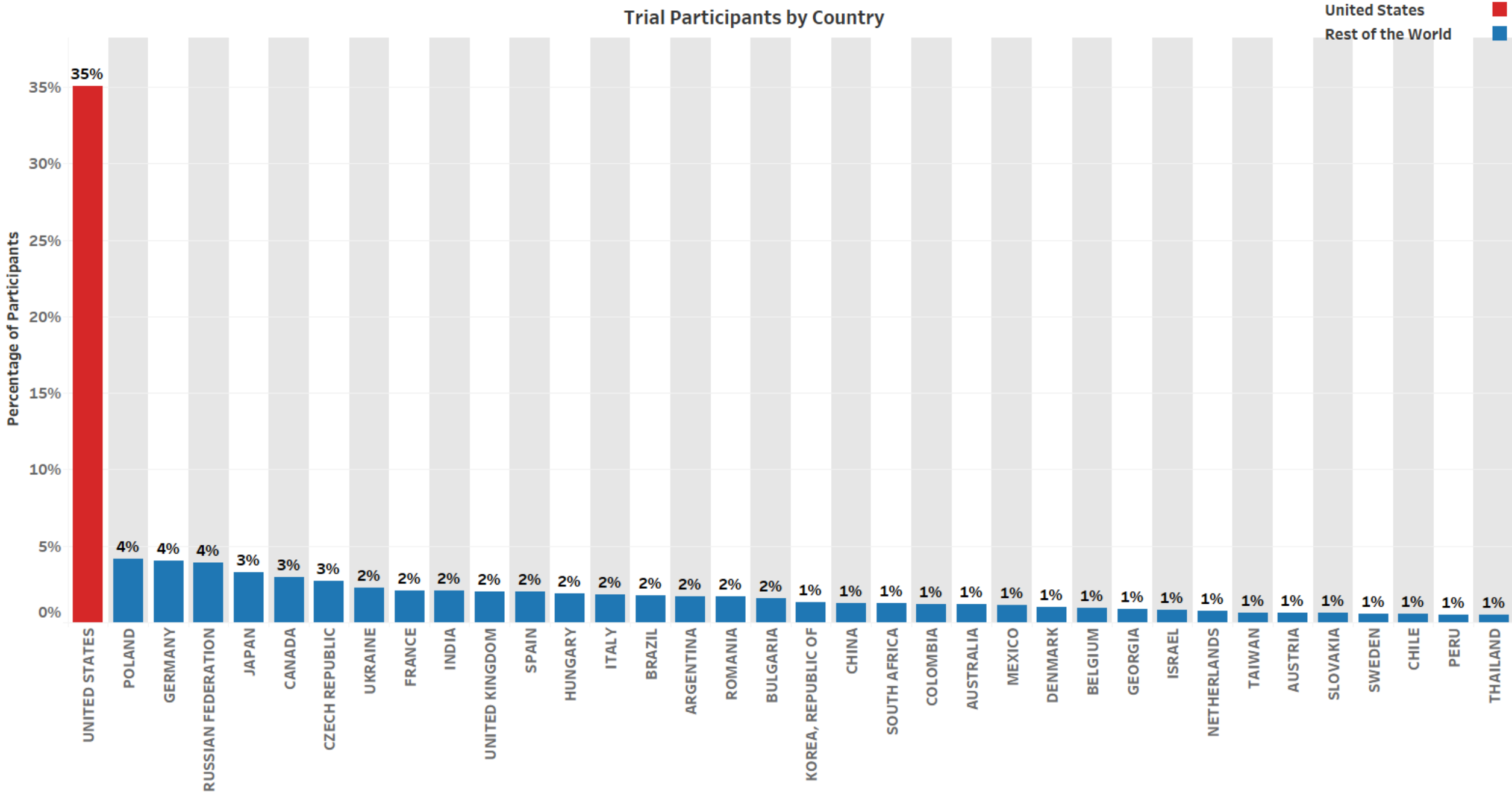
More insight into demographics for all 49 CDER approved NMEs are provided below in Table 2.

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

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


United States
Rest of the World
35%
65%
Global
Total Participants = 292,537
(Country data is missing for 229 participants)


Trial Participants by Country
United States
Rest of the World
Percentage of Participants
35%
30%
25%
20%
15%
10%
5%
0%
35%
4%
4%
4%
3%
3%
3%
2%
2%
2%
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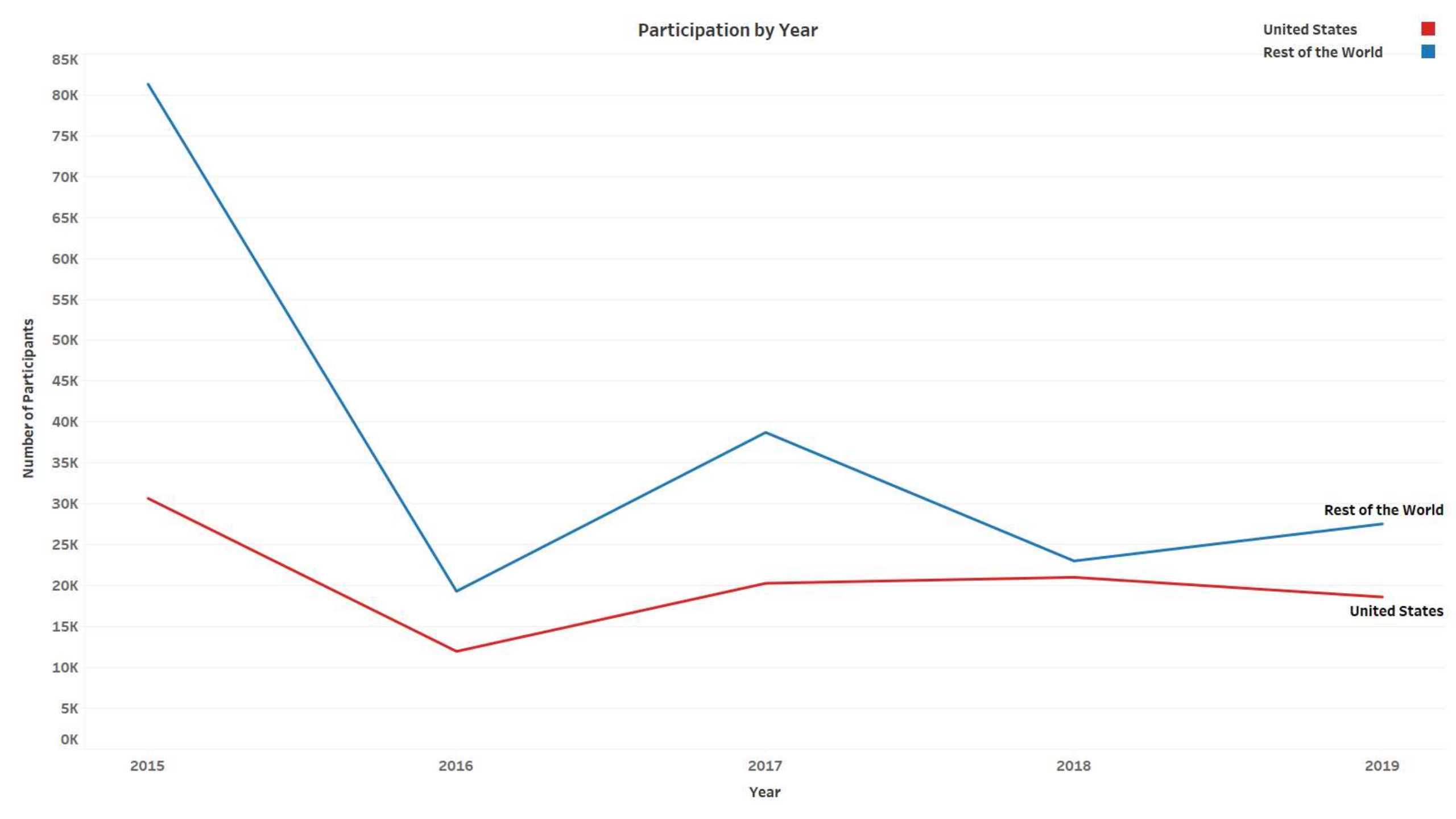
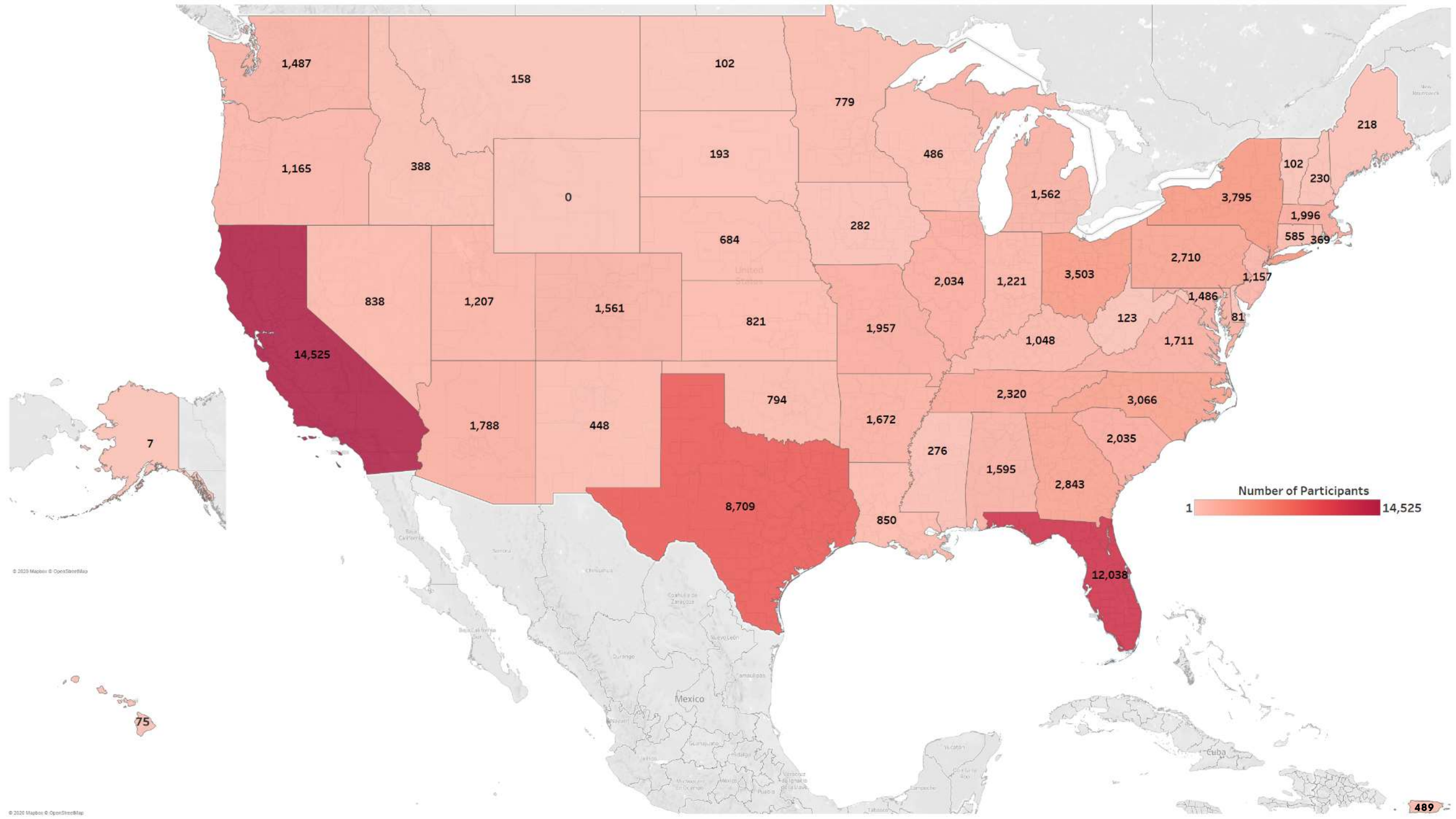
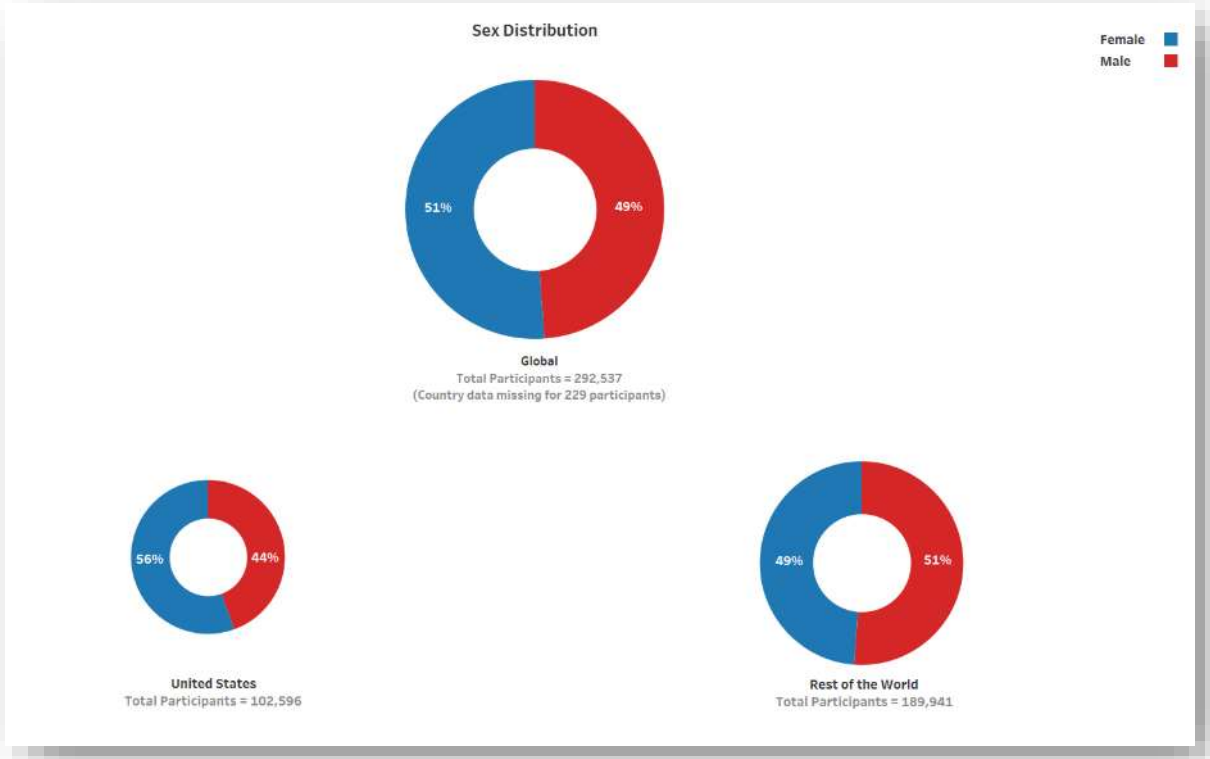
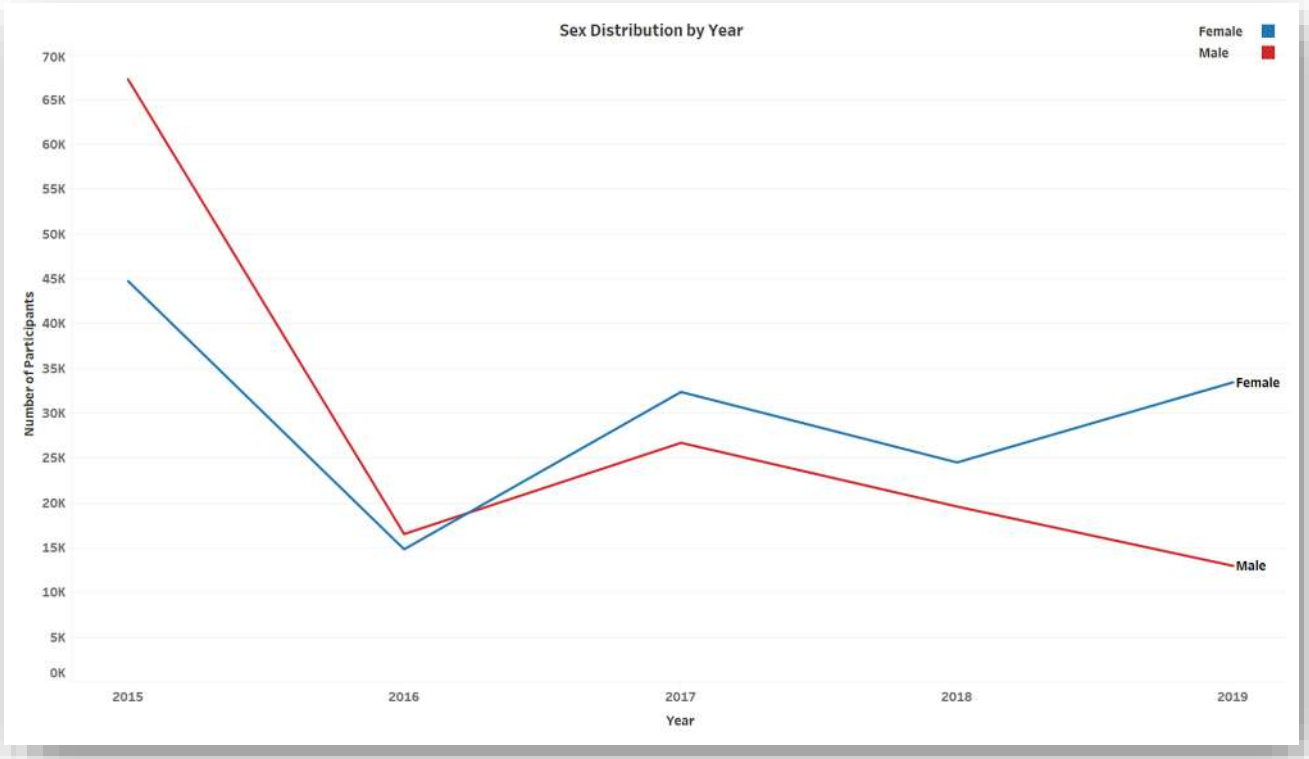
UNITED STATES
POLAND
GERMANY
RUSSIAN FEDERATION
JAPAN
CANADA
CZECH REPUBLIC
UKRAINE
FRANCE
INDIA
UNITED KINGDOM
SPAIN
HUNGARY
ITALY
BRAZIL
ARGENTINA
ROMANIA
BULGARIA
KOREA, REPUBLIC OF
CHINA
SOUTH AFRICA
COLOMBIA
AUSTRALIA
MEXICO
DENMARK
BELGIUM
GEORGIA
ISRAEL
NETHERLANDS
TAIWAN
AUSTRIA
SLOVAKIA
SWEDEN
CHILE
PERU
THAILAND


Participation by Year
United States
Rest of the World
85K
80K
75K
70K
65K
60K
55K
50K
45K
40K
35K
30K
25K
20K
15K
10K
5K
0K
Number of Participants
2015
2016
2017
2018
2019
Year
Rest of the World
United States

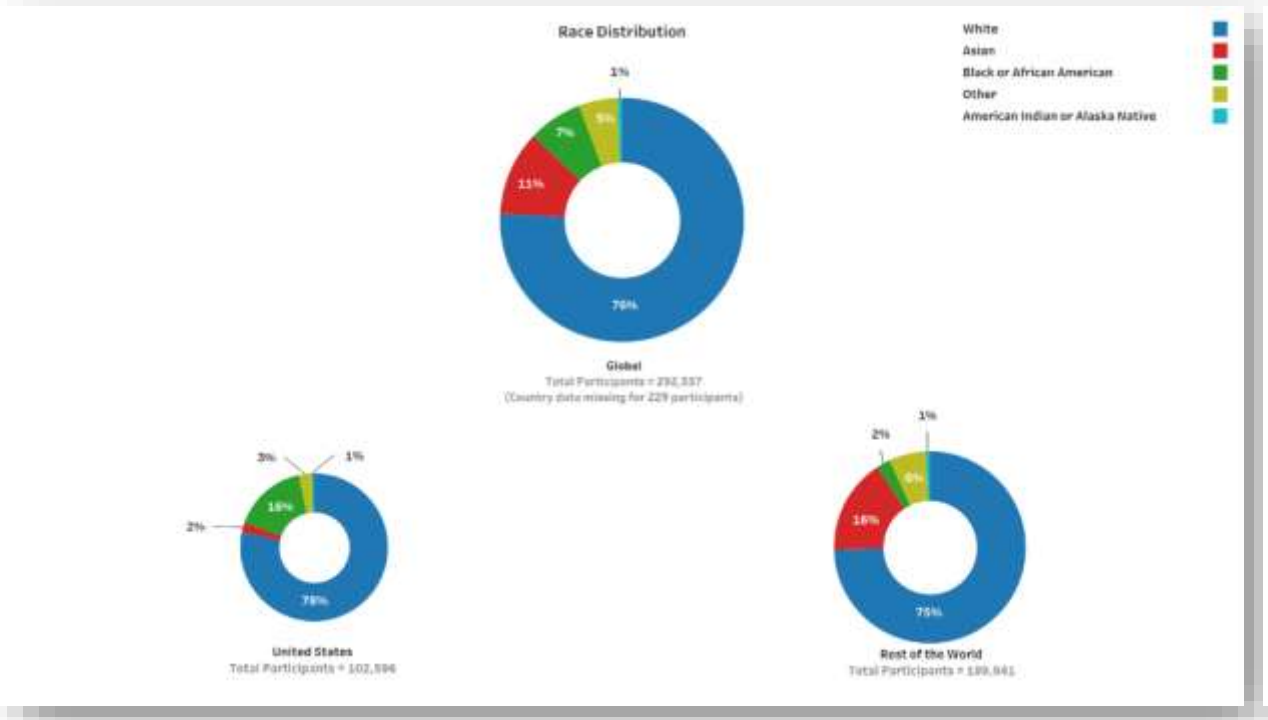

1,487
158
102
779
218
1,165
388
0
193
486
1,562
3,795
102
230
1,996
585
369
684
282
2,710
838
1,207
1,561
821
2,034
1,221
3,503
1,157
1,486
81
123
1,957
1,048
1,711
14,525
794
2,320
3,066
1,788
448
1,672
276
1,595
2,843
2,035
8,709
850
12,038
7
75
Number of Participants
1
14,525
Mexico
Cuba
© 2020 Mapbox © OpenStreetMap
489

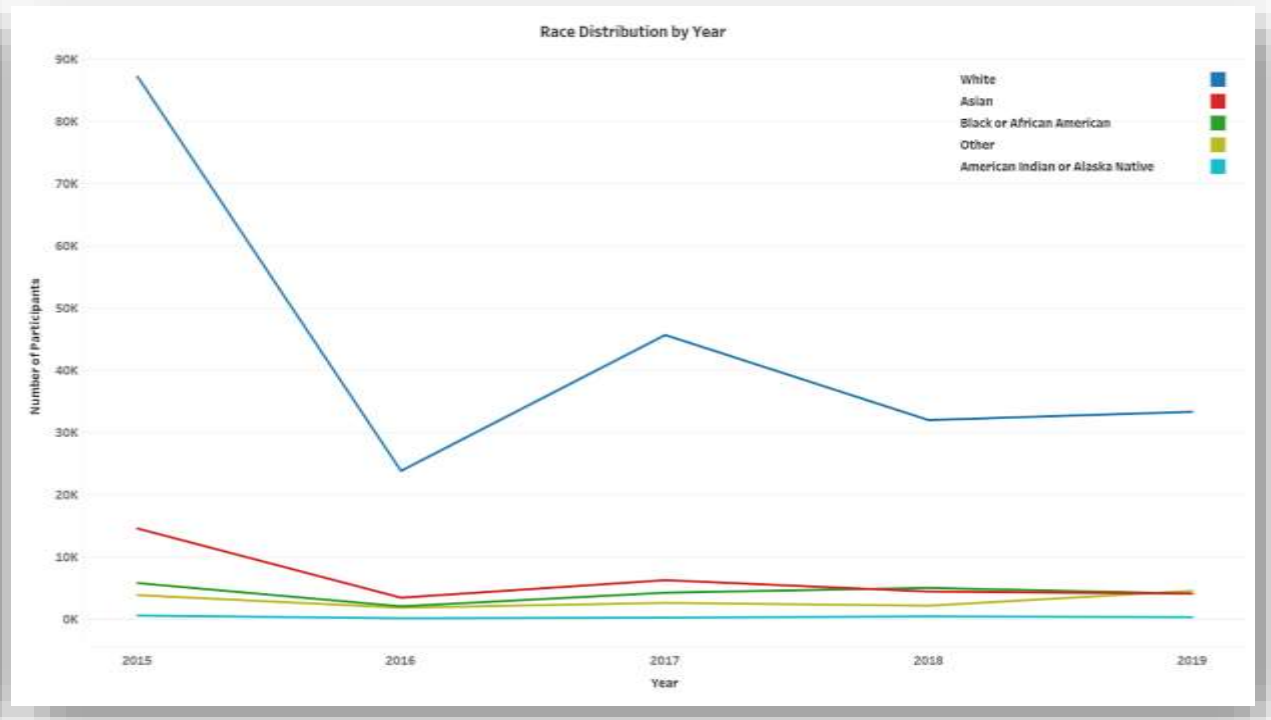
Trial Participants by Sex

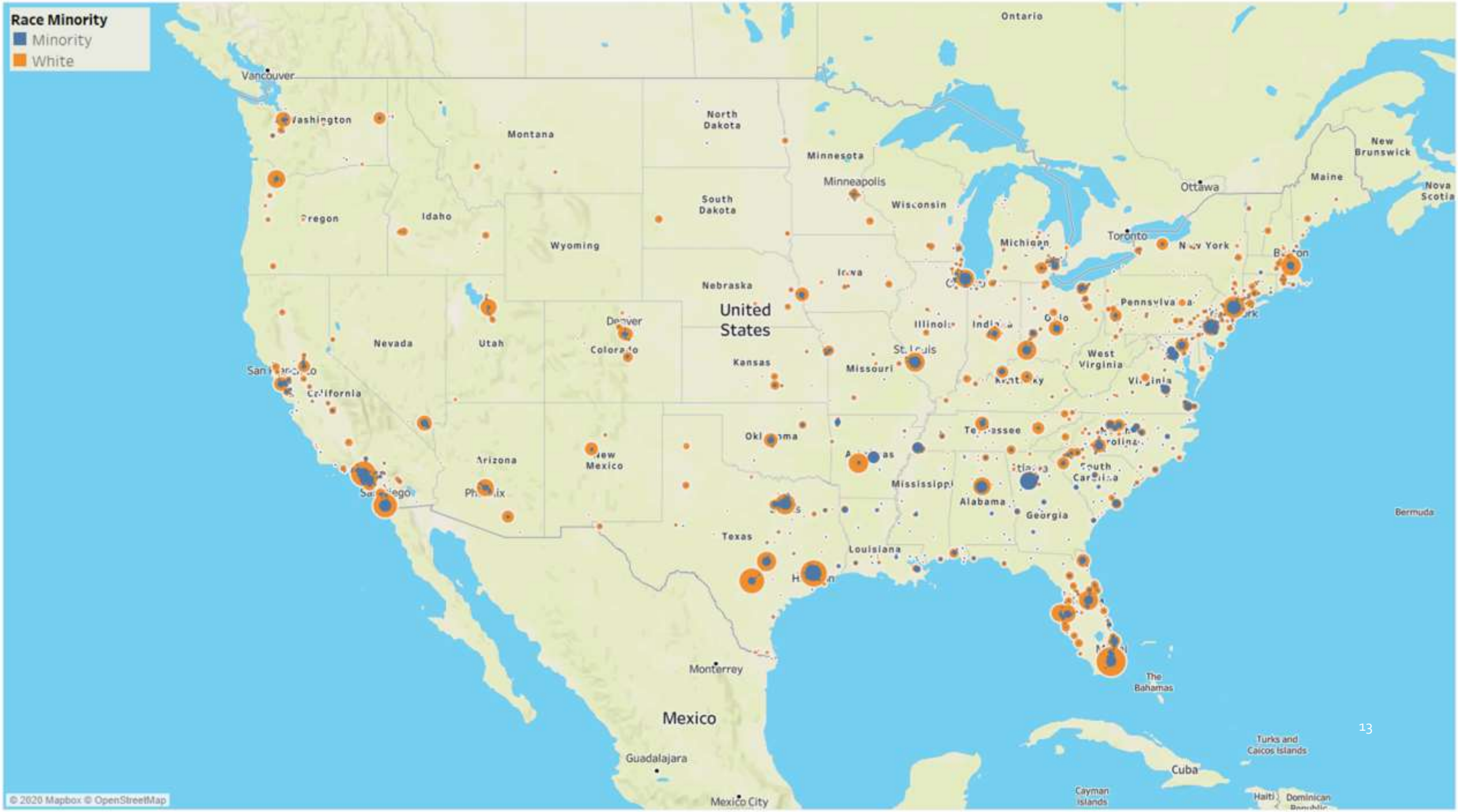




Trial Participants by Race






Race Minority
Minority
White
Ontario
Vancouver
Washington
Montana
North Dakota
Minnesota
Minneapolis
New Brunswick
Maine
Nova Scotia
Ottawa
Oregon
Idaho
South Dakota
Wisconsin
Toronto
Michigan
Wyoming
Nebraska
Iowa
Pennsylvania
Denver
Illinois
Indiana
Ohio
Nevada
Utah
Colorado
United States
St. Louis
Missouri
Kansas
West Virginia
Kentucky
Virginia
California
Tennessee
Oklahoma
Arizona
New Mexico
Mississippi
Alabama
Georgia
South Carolina
Texas
Louisiana
Bermuda
Monterrey
The Bahamas
Mexico
Guadalajara
Turks and Caicos islands
Cuba
Cayman Islands
Haiti
Mexico City
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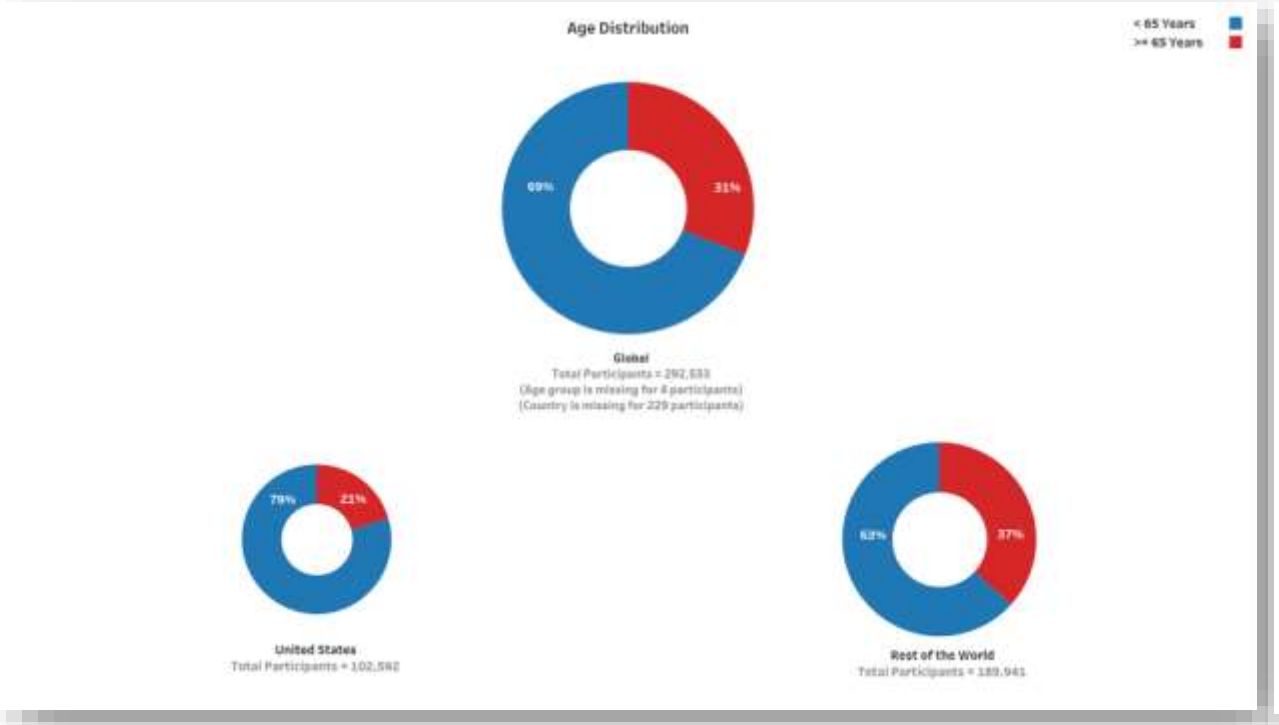
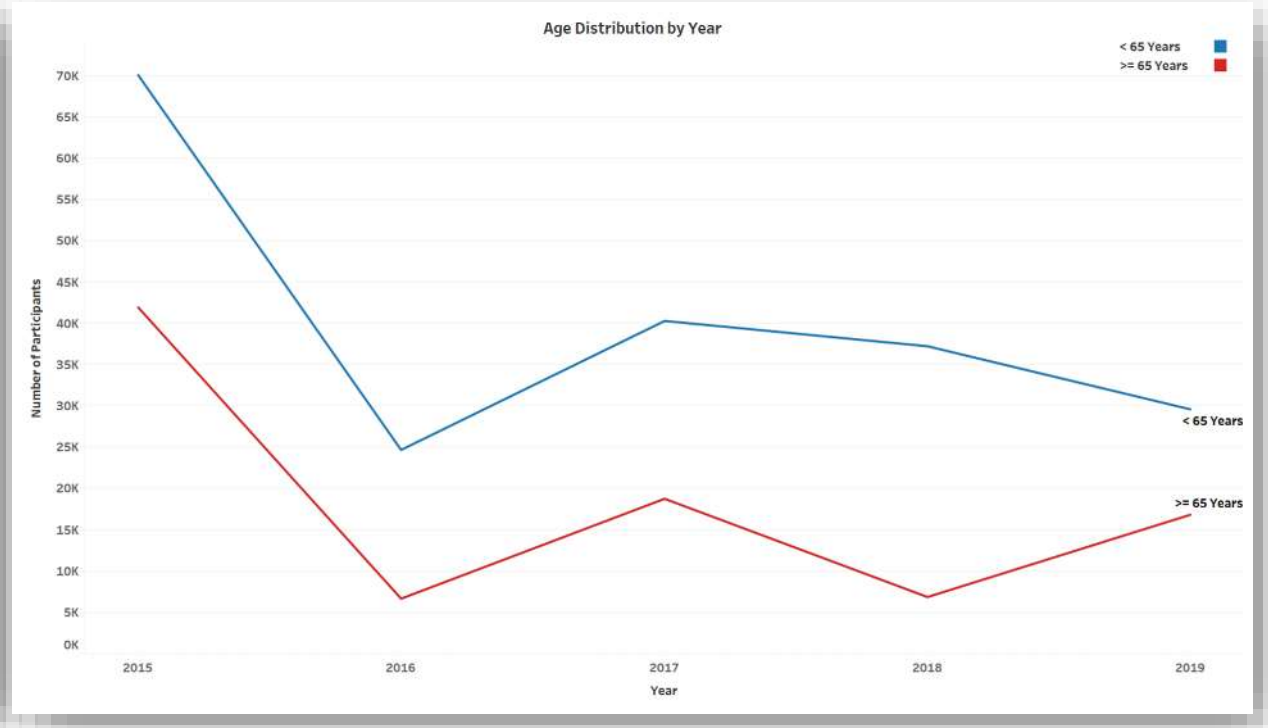
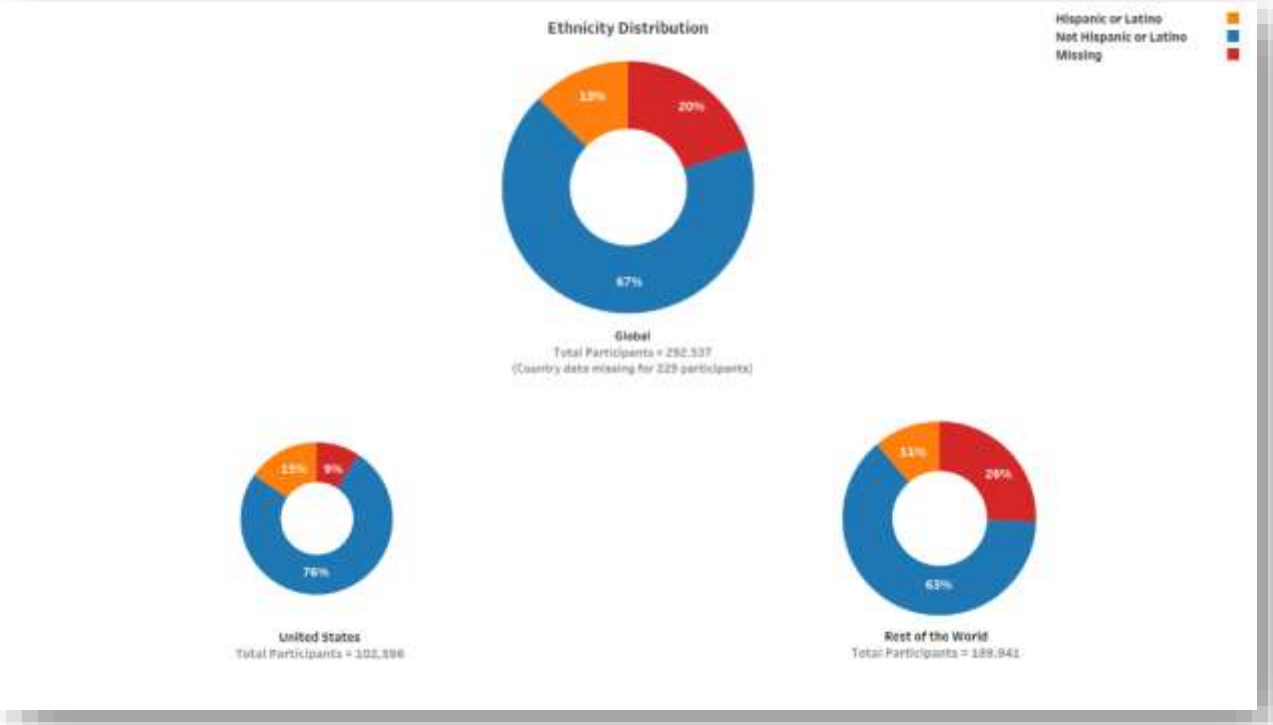
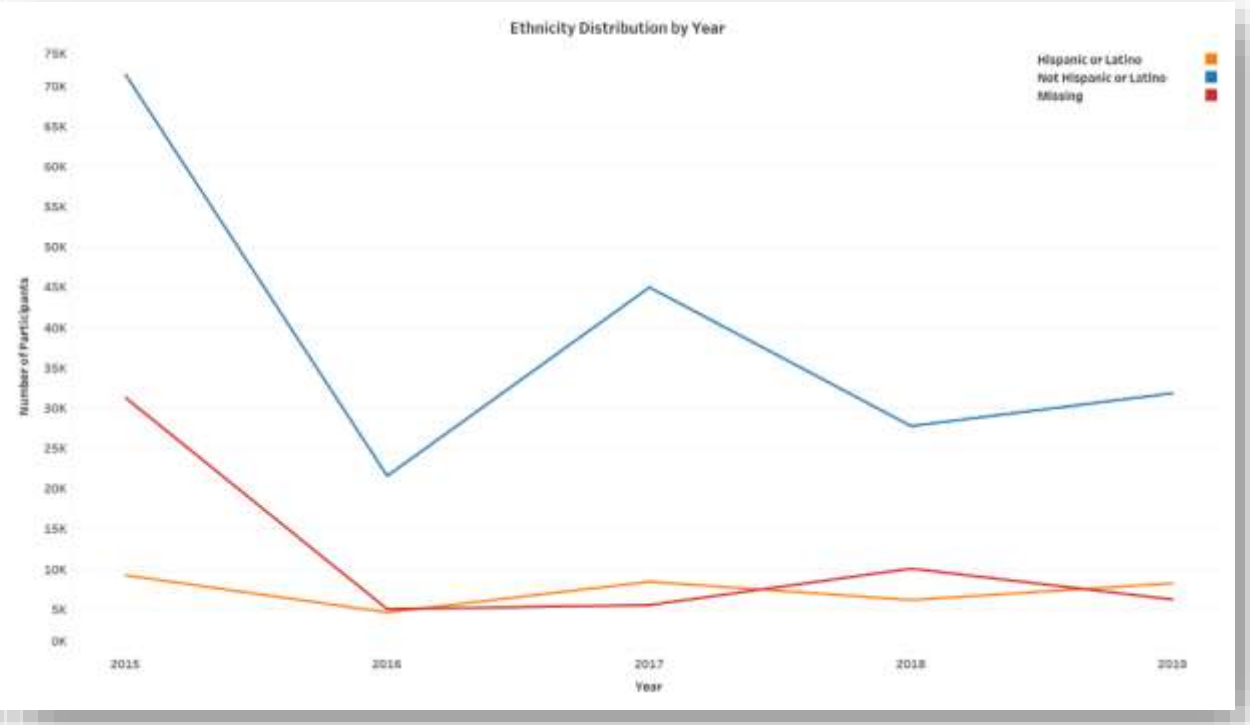
Participants by Age Group



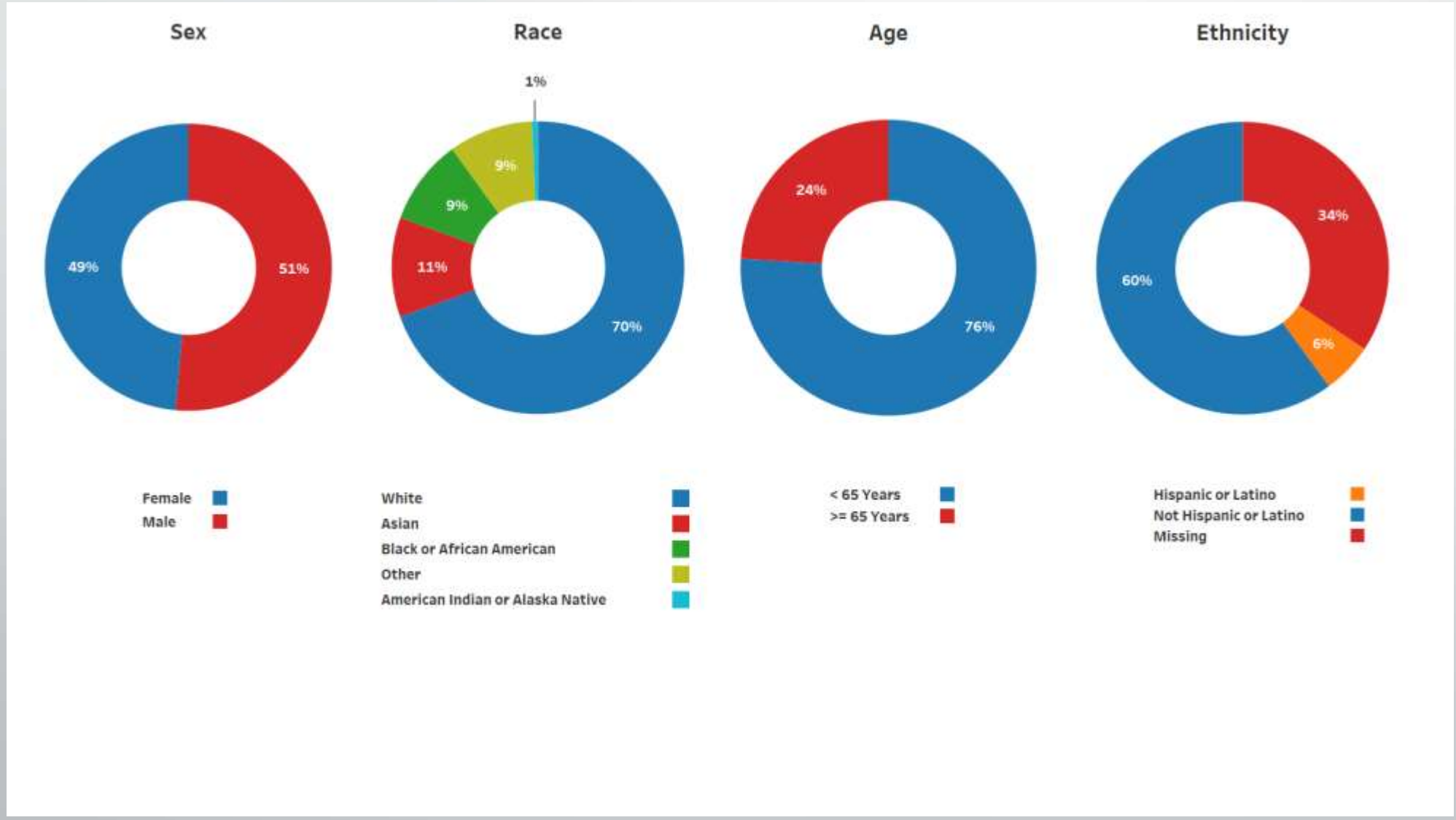


Participants by Ethnicity

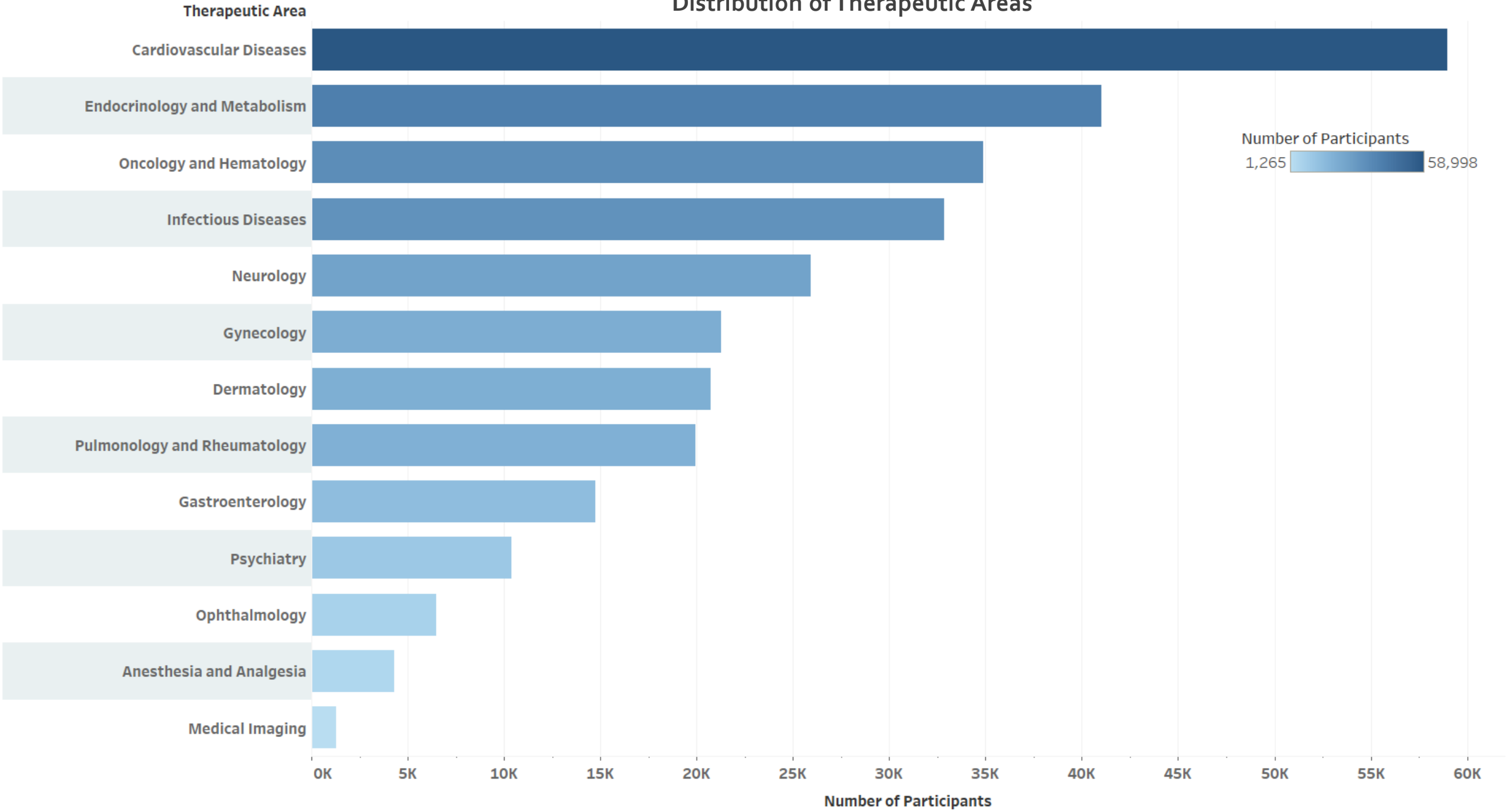




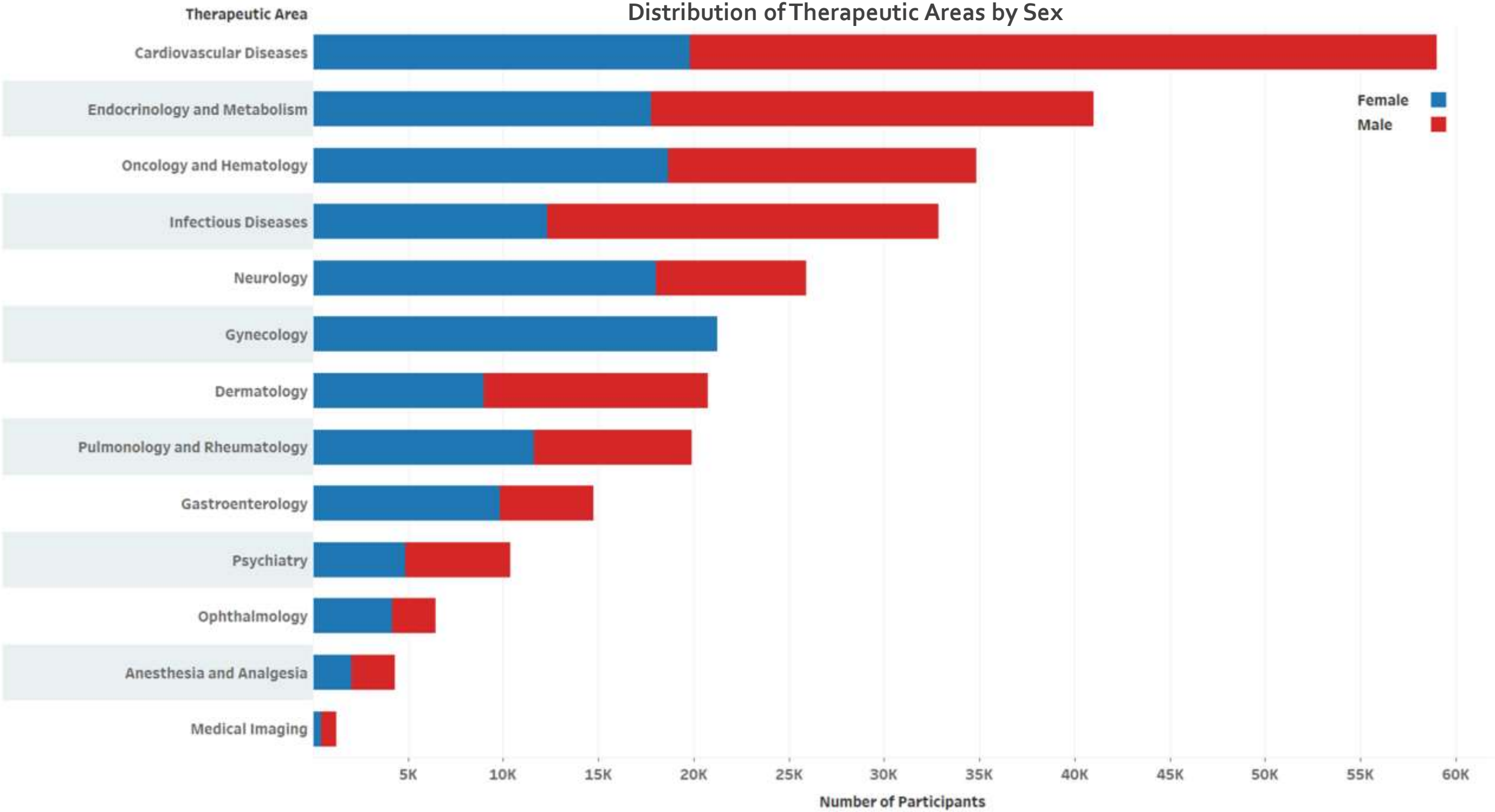
Rare Disease Population by Demographic Subgroups



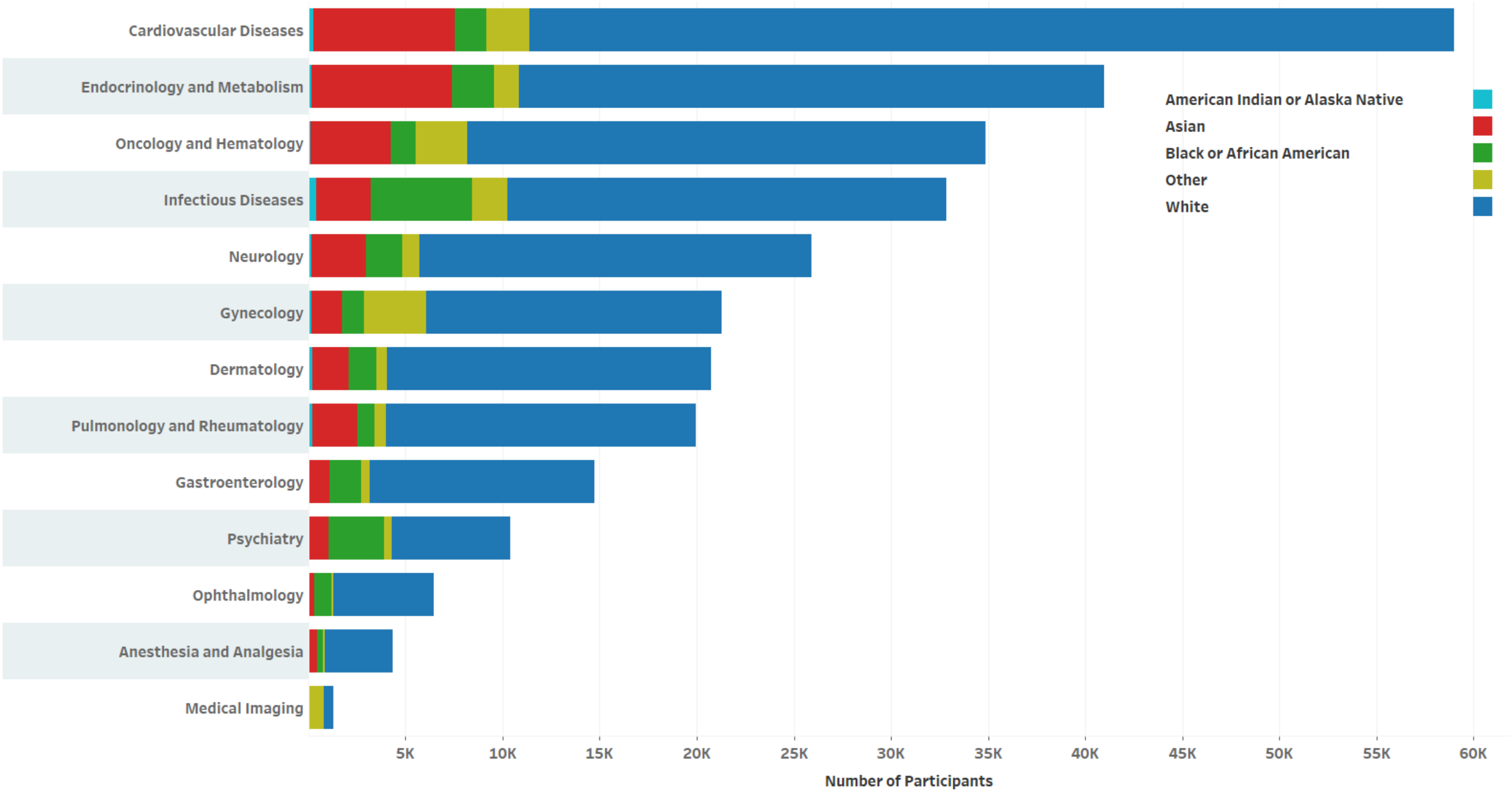
Distribution of Therapeutic Areas



Distribution of Therapeutic Areas by Sex



Distribution of Therapeutic Areas by Race



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

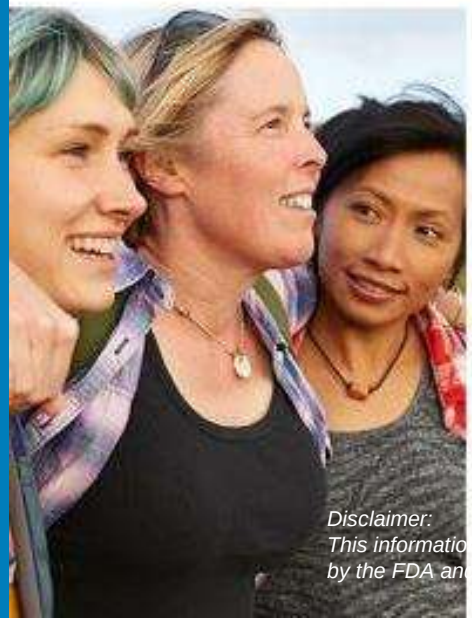
Closing Remarks

- 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



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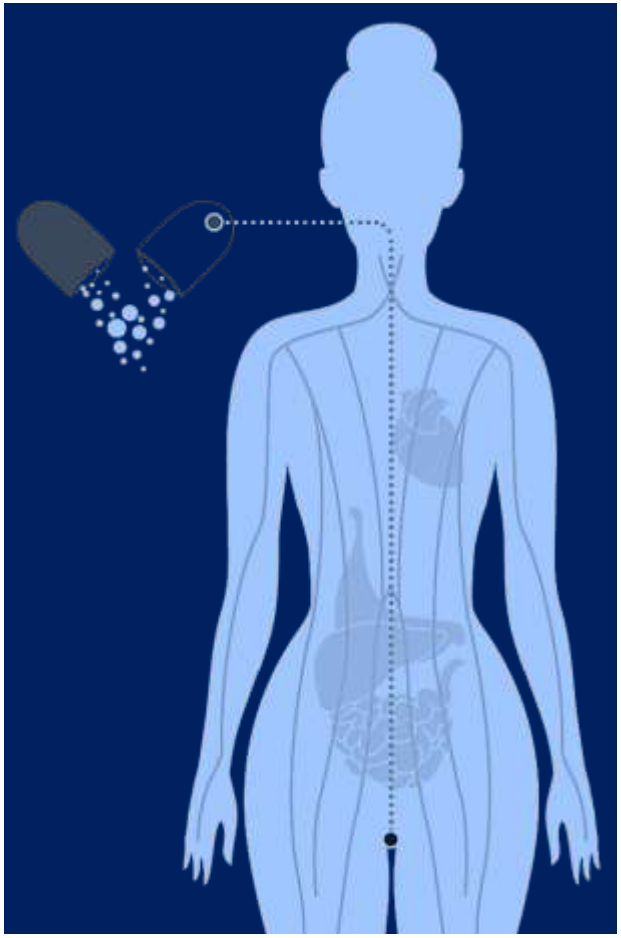
FDA U.S. FOOD & DRUG ADMINISTRATION

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

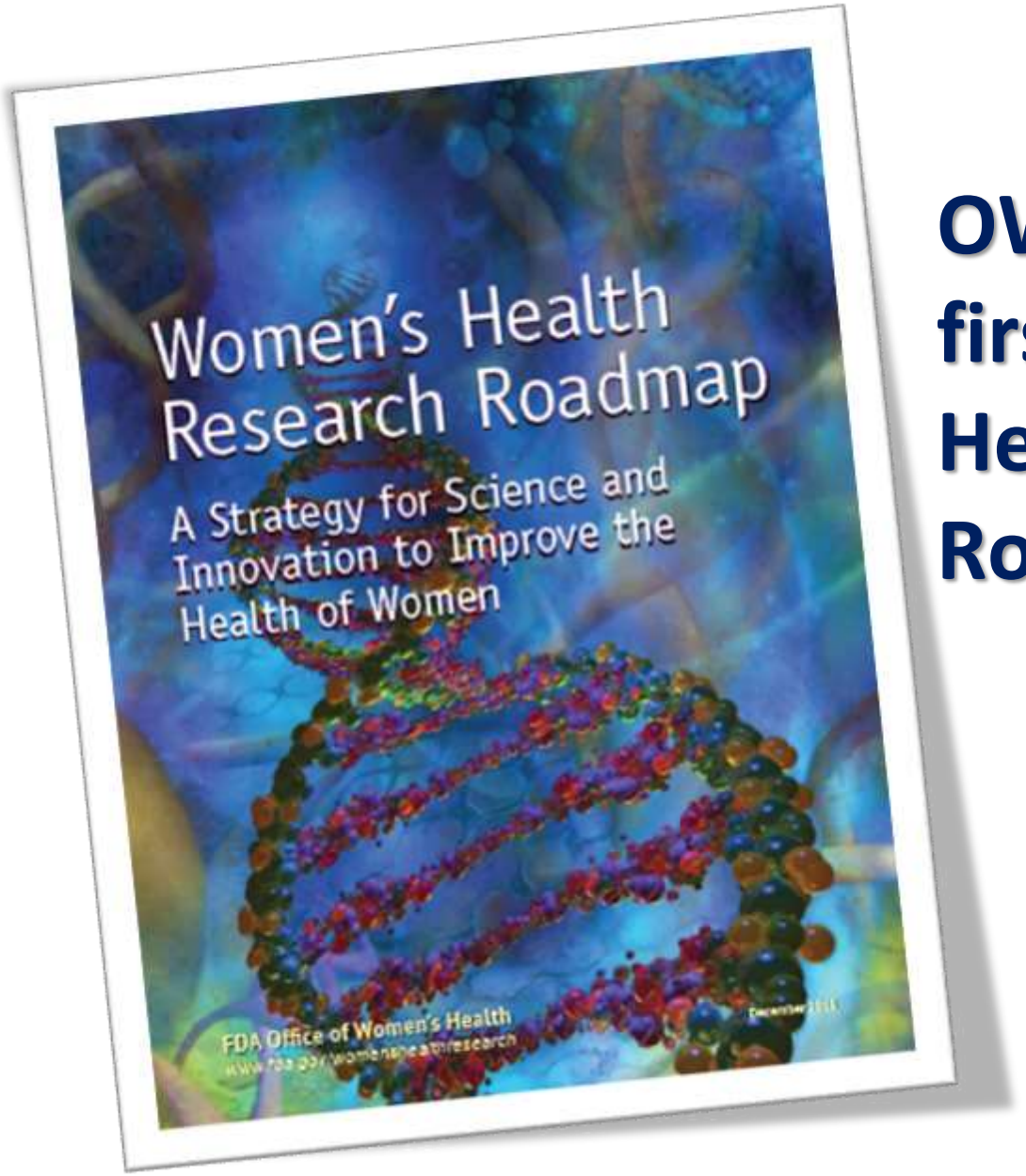
OWH achieves its mission through the foundational principle that Sex is a Biological Variable (SABV)

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)



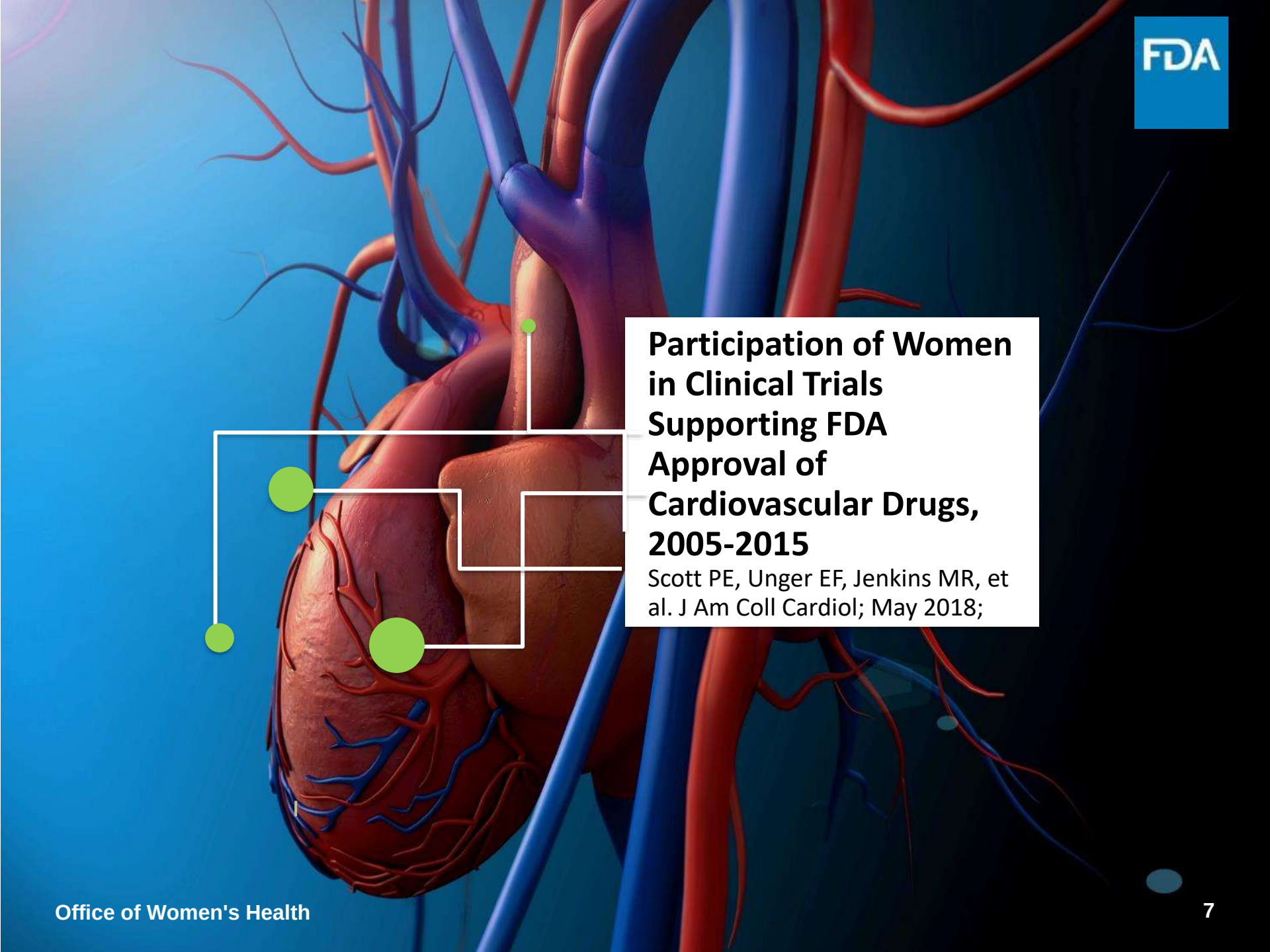
OWH created the first FDA Women's Health Research Roadmap

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

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



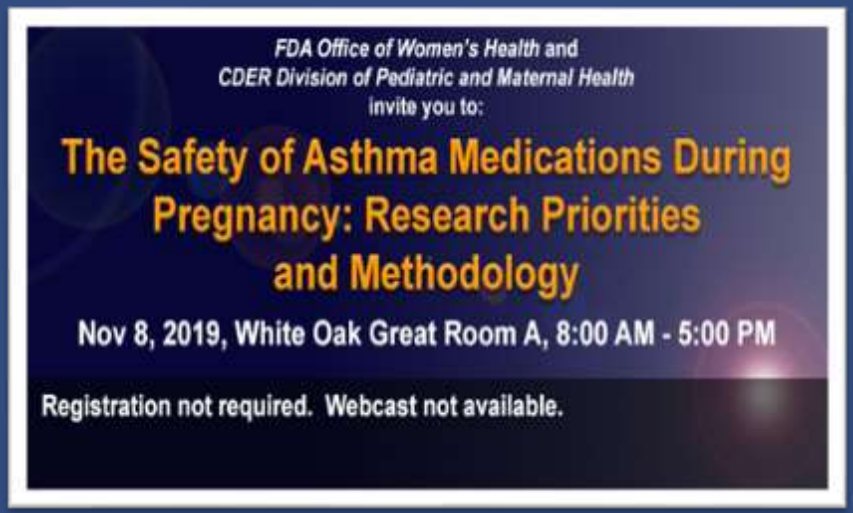
Participation of Women in Clinical Trials Supporting FDA Approval of Cardiovascular Drugs, 2005-2015

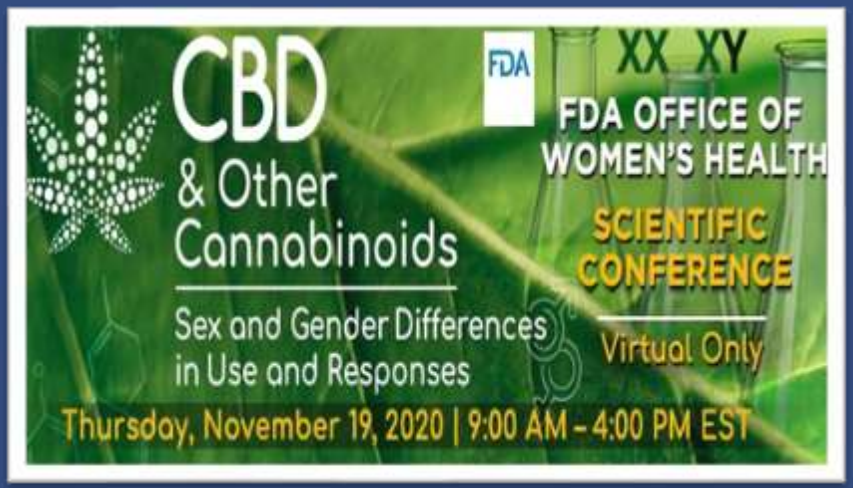
Scott PE, Unger EF, Jenkins MR, et al. J Am Coll Cardiol; May 2018;

OWH Scientific Speaker Series

OWH Scientific Workshops and Public Meetings

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





Bench to Bedside

Integrating Sex and Gender to Improve Human Health Course

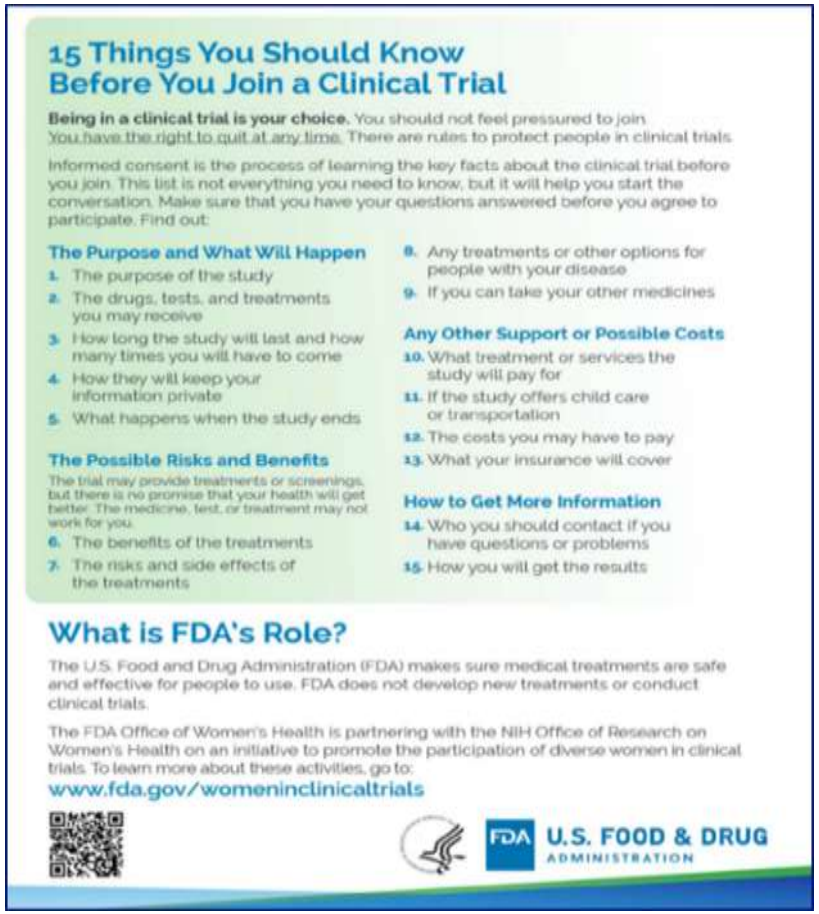
https://orwh.od.nih.gov/career-development-education/e-learning/bench-bedside

Diverse Women in Clinical Trials

www.fda.gov/womeninclinicaltrials

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?

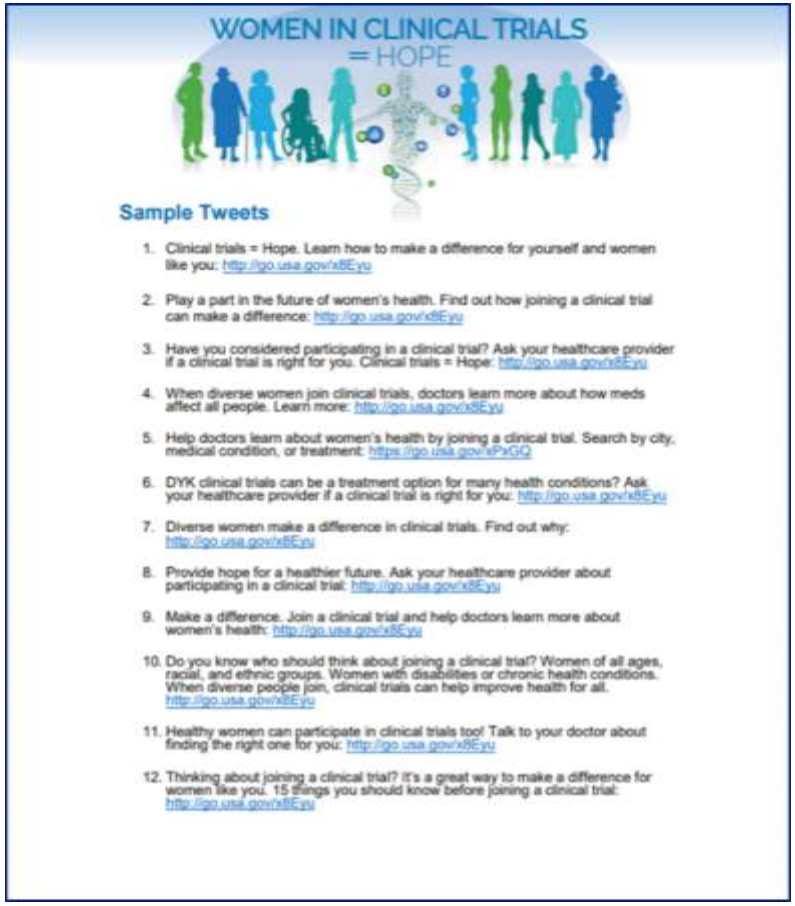
The U.S. Food and Drug Administration (FDA) makes sure medical treatments are safe and effective for people to use. FDA does not develop new treatments or conduct clinical trials.

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]



WOMEN IN CLINICAL TRIALS = HOPE

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/xPxGQ
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]

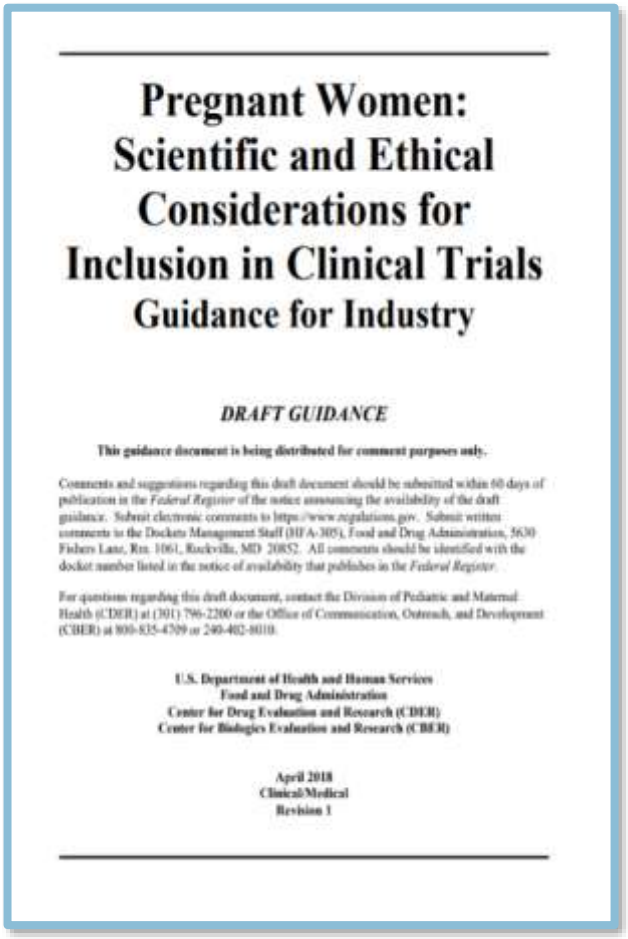
Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)

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/SignificantAmendmentstotheFDCAct/21stCenturyCuresAct/default.htm

Related Guidances



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

Guidance for Industry

DRAFT GUIDANCE

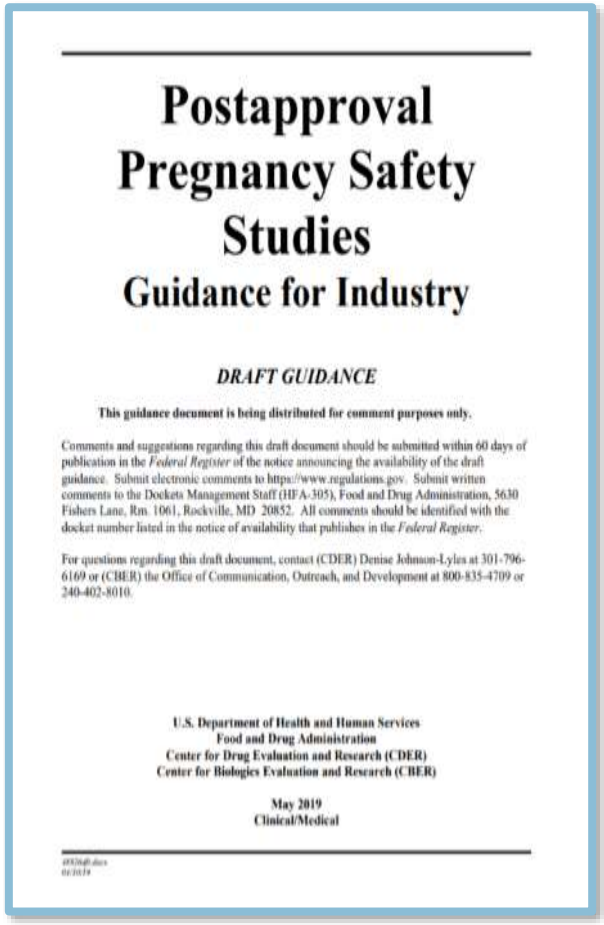
This guidance document is being distributed for comment purposes only.

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 (CBER) 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

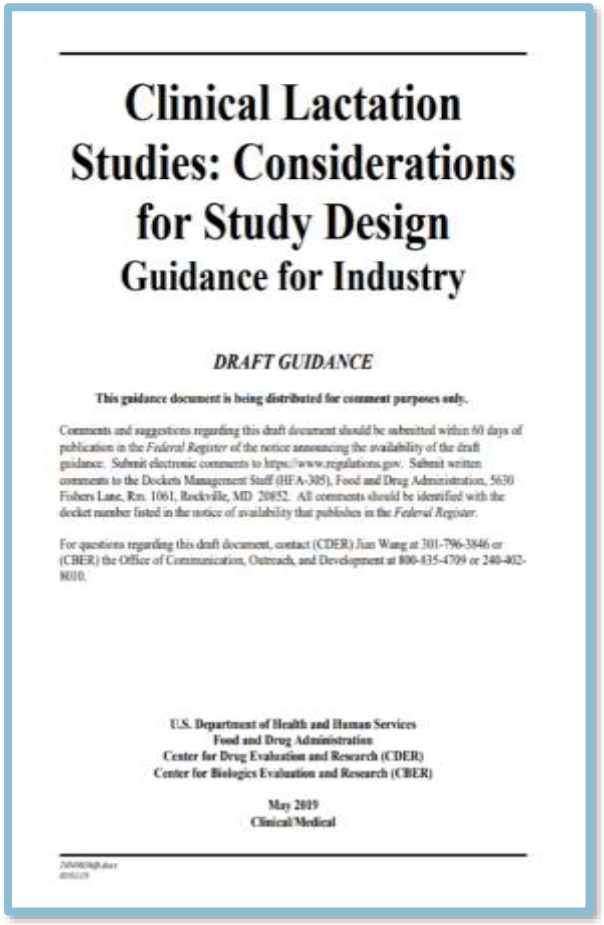
This guidance document is being distributed for comment purposes only.

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



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*.

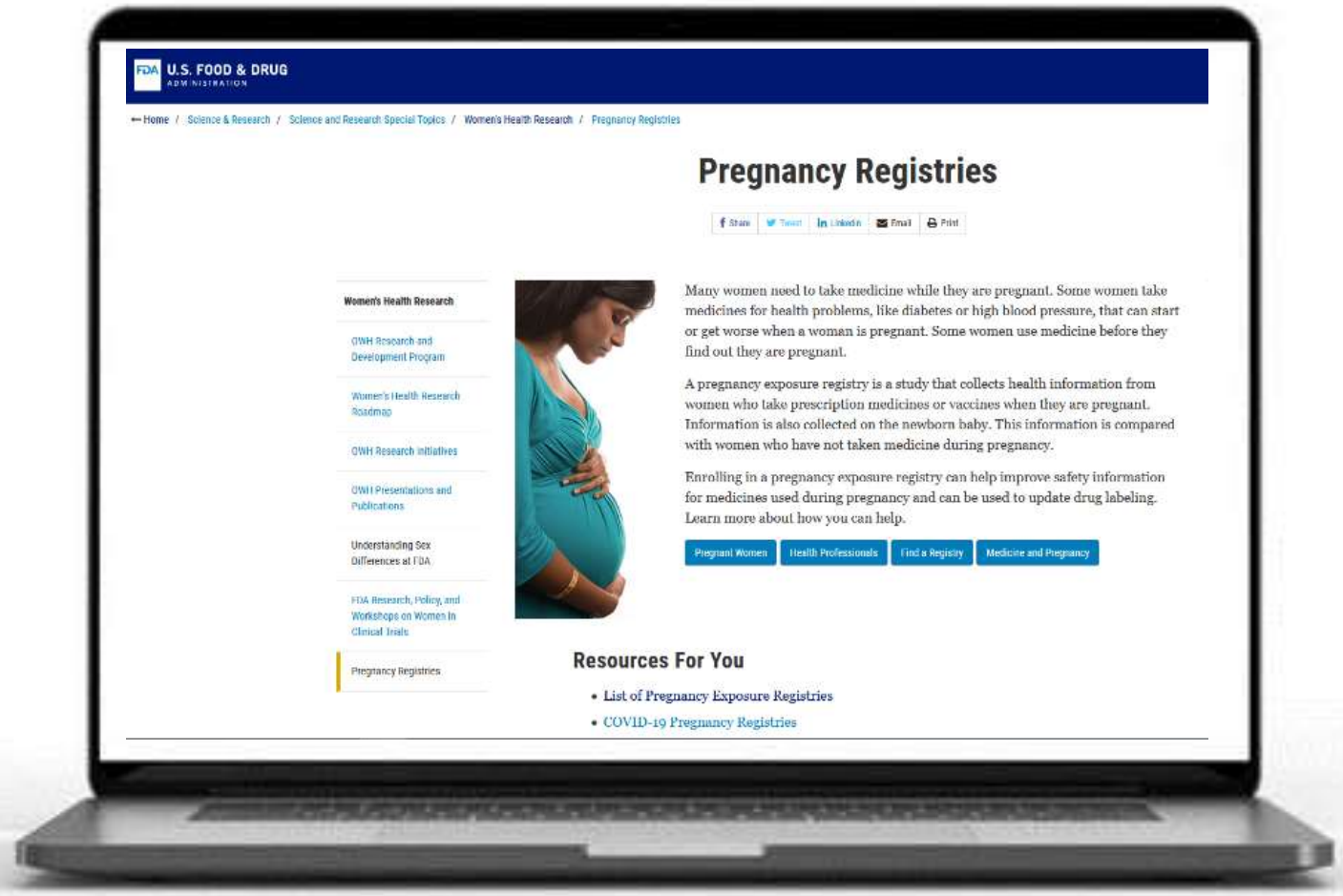
For questions regarding this draft document, contact (CDER) Jian Wang at 301-796-3846 or (CBER) the Office of Communication, Outreach, and Development at 800-835-4709 or 240-402-8010.

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

- **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



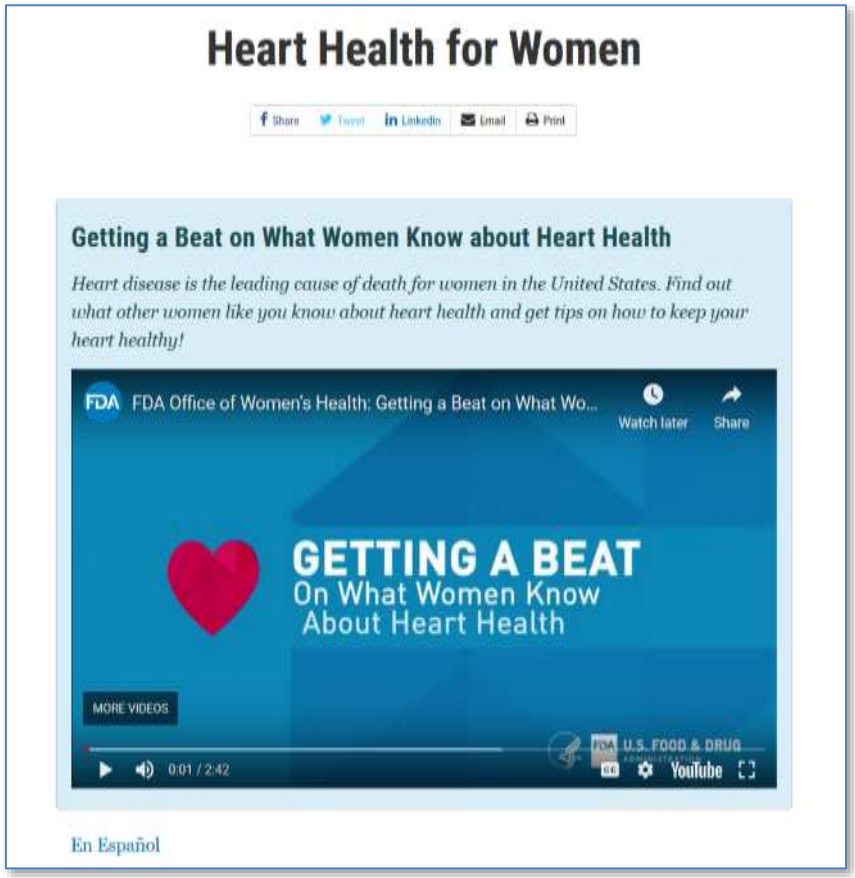
Dynamic Social Media Content

*on **Twitter, Facebook & Pinterest***

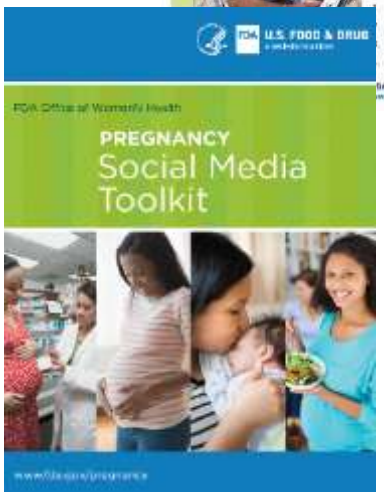
OWH Strategic Priorities

Docket Number FDA-2020-N-1391

Knowledge and News on Women



Consumer Resources



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

www.fda.gov/womens

www.fda.gov/womenshealthresearch

@FDAWomen on Twitter

U.S. FOOD & DRUG ADMINISTRATION

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

U.S. FOOD & DRUG ADMINISTRATION

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A Decade of FDA Advancing Health Equity

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

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04/22/2020

Regulated Product(s)
Biologics
Drugs
Medical Devices
Tobacco

Topic(s)
Consumer Health

Health Topic(s)
Coronavirus

By: RADM Richardae Araojo, 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

FEDERAL REGISTER
The Daily Journal of the United States Government

Notice

Office of Minority Health and Health Equity Strategic Priorities; Establishment of a Public Docket; Request for Comments

A Notice by the Food and Drug Administration on 01/03/2020

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)

COVID-19
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.

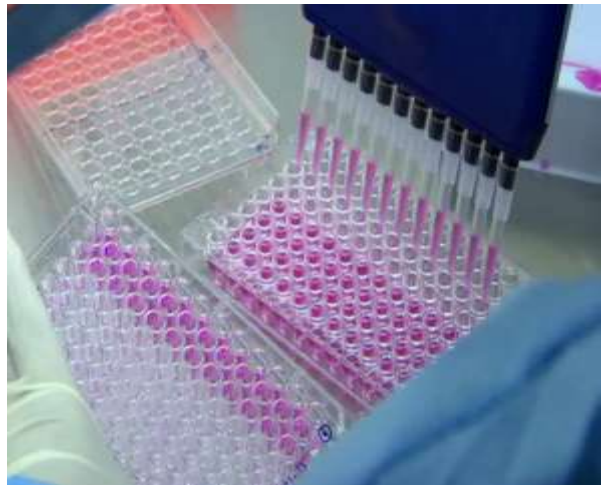
Motivators for Campaign

- 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



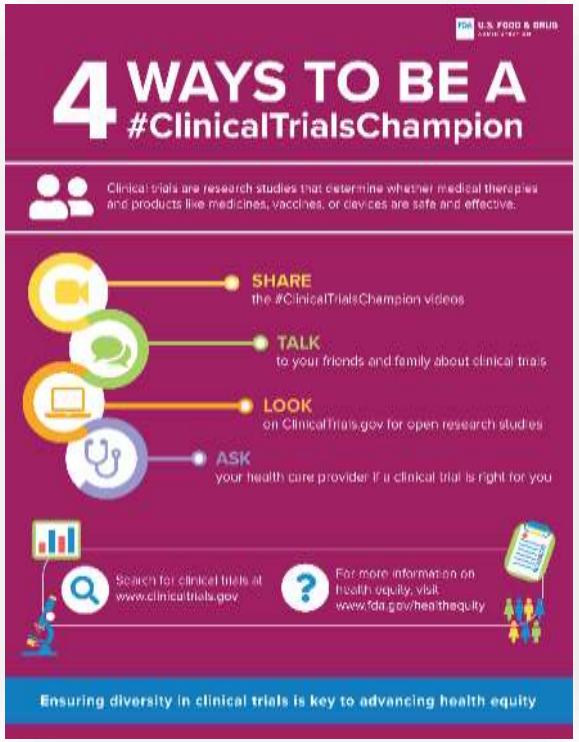
Shirley's Story: Diversity is Critical to Making Better Medical Products

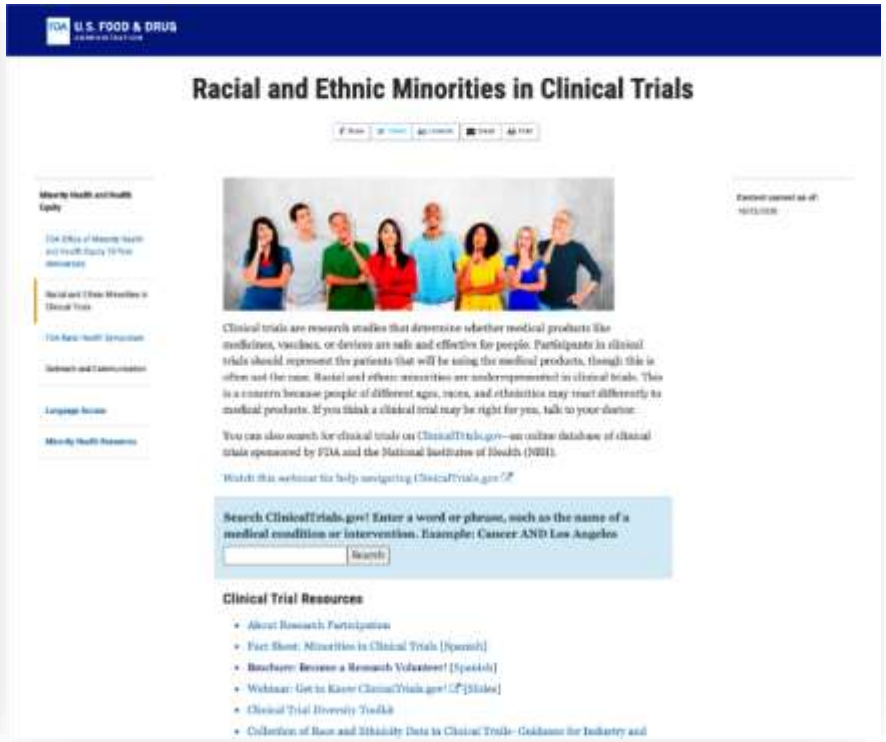
Veterans in Clinical Trials

Veterans Health Administration
Office of Health Equity

Diversity in Medical Device Clinical Trials Video

Clinical Trial Diversity Resources





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

Broad Agency Announcement (BAA)

CERSIs

University of Maryland
UCSF-Stanford
Johns Hopkins University
Yale-Mayo Clinic

Intramural Research

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

Social Media Outreach

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!

Follow us at: @FDAHealthEquity

Email us at: OMHHE@fda.hhs.gov

Visit us at: FDA.gov/HealthEquity

Join webinars and stakeholder calls