

2015 - 2016

GLOBAL PARTICIPATION IN CLINICAL TRIALS REPORT





Global Participation in Clinical Trials Report

2015-2016

JULY 2017



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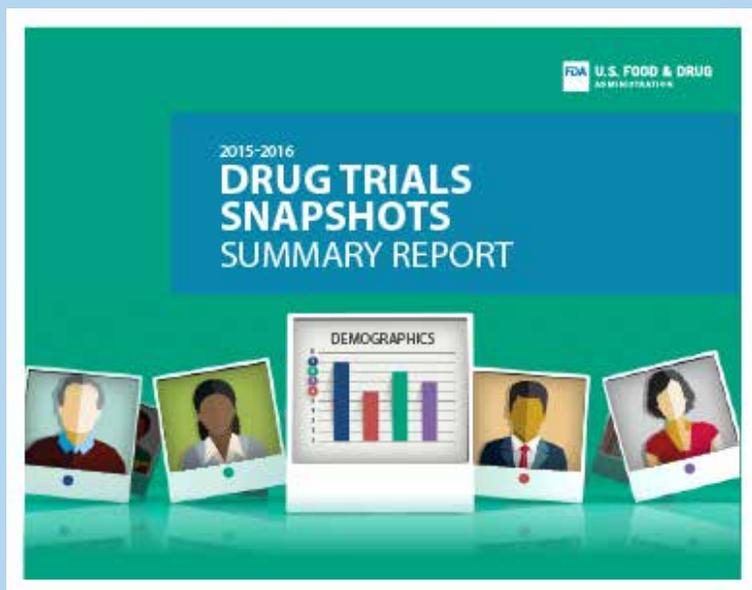
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Introduction

Welcome to the FDA's Center for Drug Evaluation and Research's (CDER's) Drug Trial Snapshots: Global Clinical Trials Report

Within the past two decades, clinical research has become more global and complex, with clinical trials increasingly being conducted in countries outside the United States. Every year, CDER approves a number of novel drugs based upon review of safety and efficiency measures in sponsor submitted clinical trial data from participants all over the world. Although the Center oversees approval of drugs to be marketed within the United States, these innovative new products come from drug development programs spanning multiple therapeutic areas, hundreds of clinical trial sites, and tens of thousands of people globally.

In recent years, there has been growing interest in stratifying different characteristics of clinical trial participants in an attempt to better understand variability in drug response. As part of the 2012 Food and Drug Administration Safety and Innovation Act (FDASIA 907), the U.S. Congress required the U.S. Food and Drug Administration (FDA) to report on the diversity of participants in clinical trials and the extent to which safety and effectiveness data is based on demographic factors such as sex, age, and race. The Center has responded with the **Drug Trials Snapshots program** to increase transparency of the demographic data of participants in pivotal clinical trials.



Complementing our recent two-year **Drug Trials Snapshots Summary Report**, this special report provides additional information on clinical trial participants by site location over the same two-year time frame (2015-16). Partnering with the FDA’s Office of Women’s Health (OWH), we combined site location data with demographic data of participants at those sites and summarize our results in three sections: Participants by Geography, Gender by Location, and Race by Location.

Drug development has become a global enterprise that relies on data from patients all over the world. We hope this information can provide more insight into the modern drug development paradigm and how new medicines are approved for human use is derived from humans around the globe.



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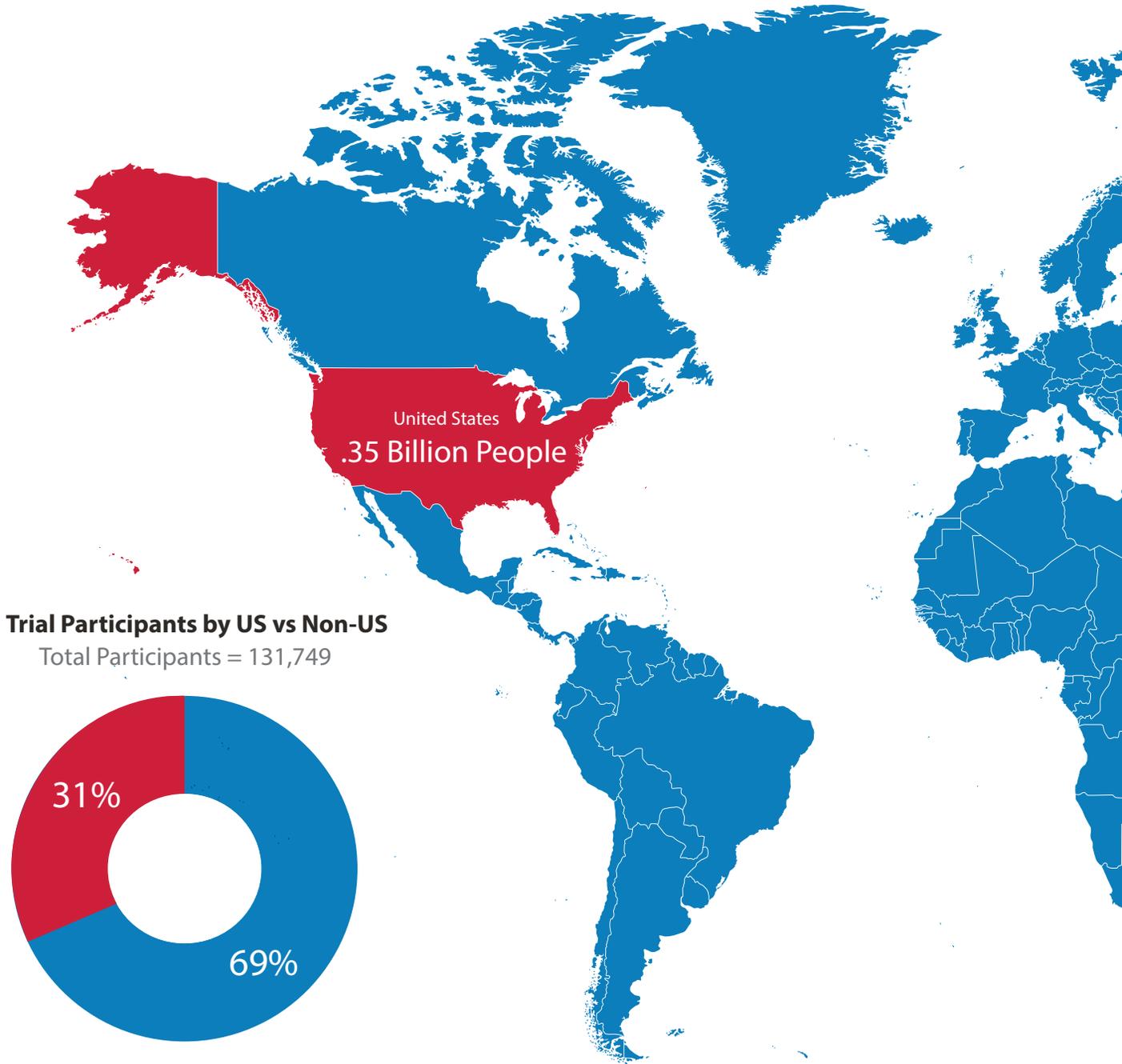


Marsha B. Henderson
Assistant Commissioner of Women’s Health,
FDA’s Office of Women’s Health (OWH)

Geography

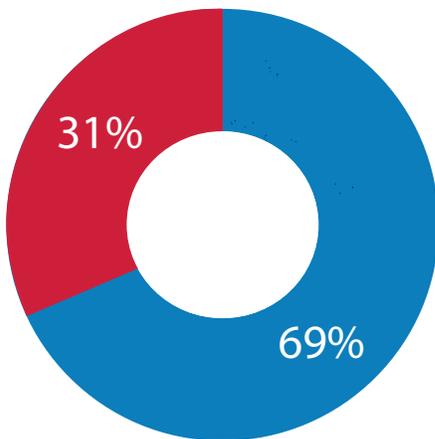
Where are Participants From?

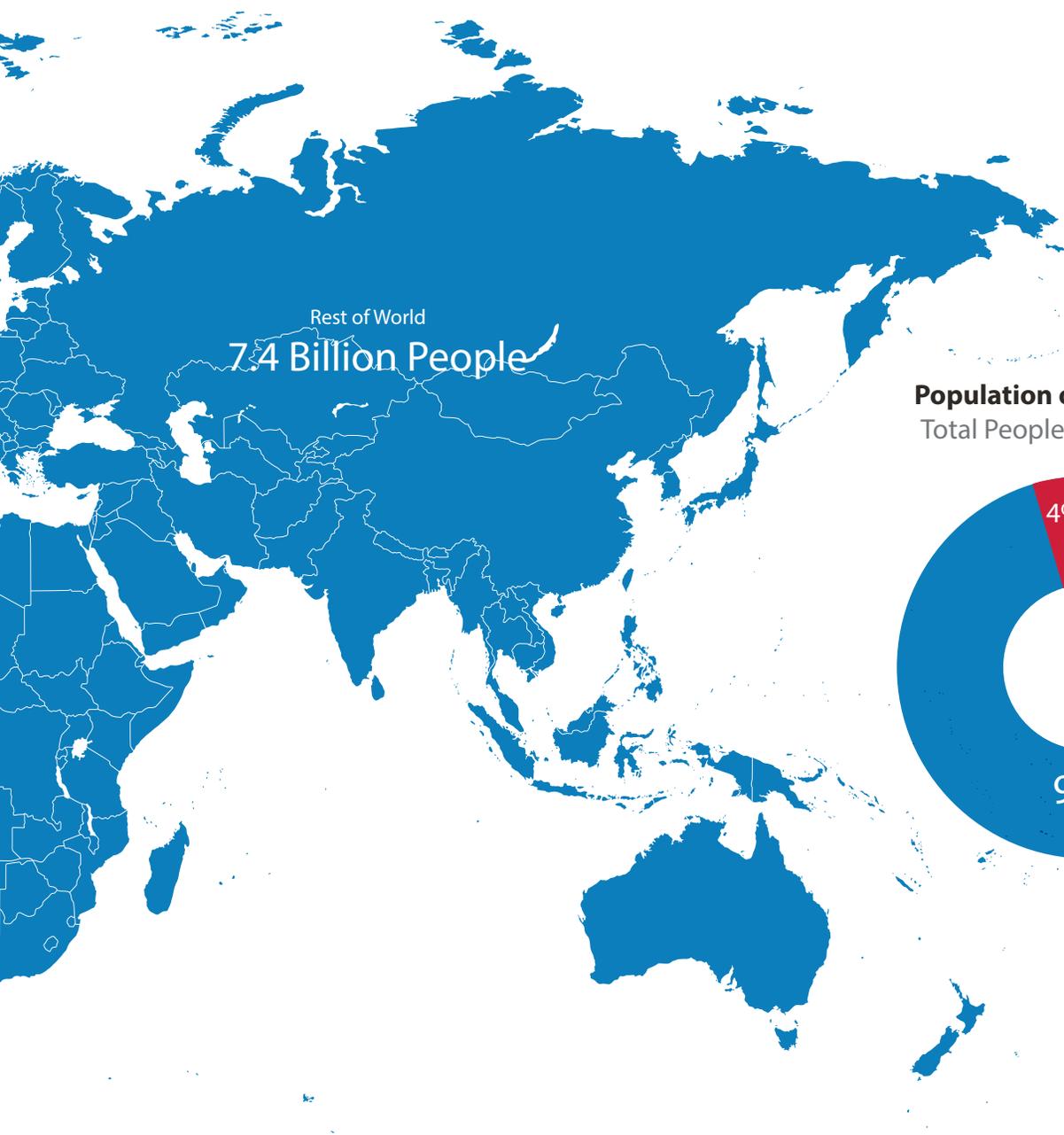
The country contributing the most clinical trial participants was the United States. Compared to the population of the entire world (7.4 Billion), the US (0.35 Billion) makes up a little more than 4% of the world population.



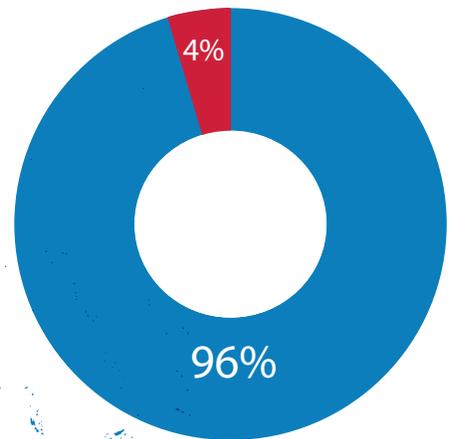
Trial Participants by US vs Non-US

Total Participants = 131,749



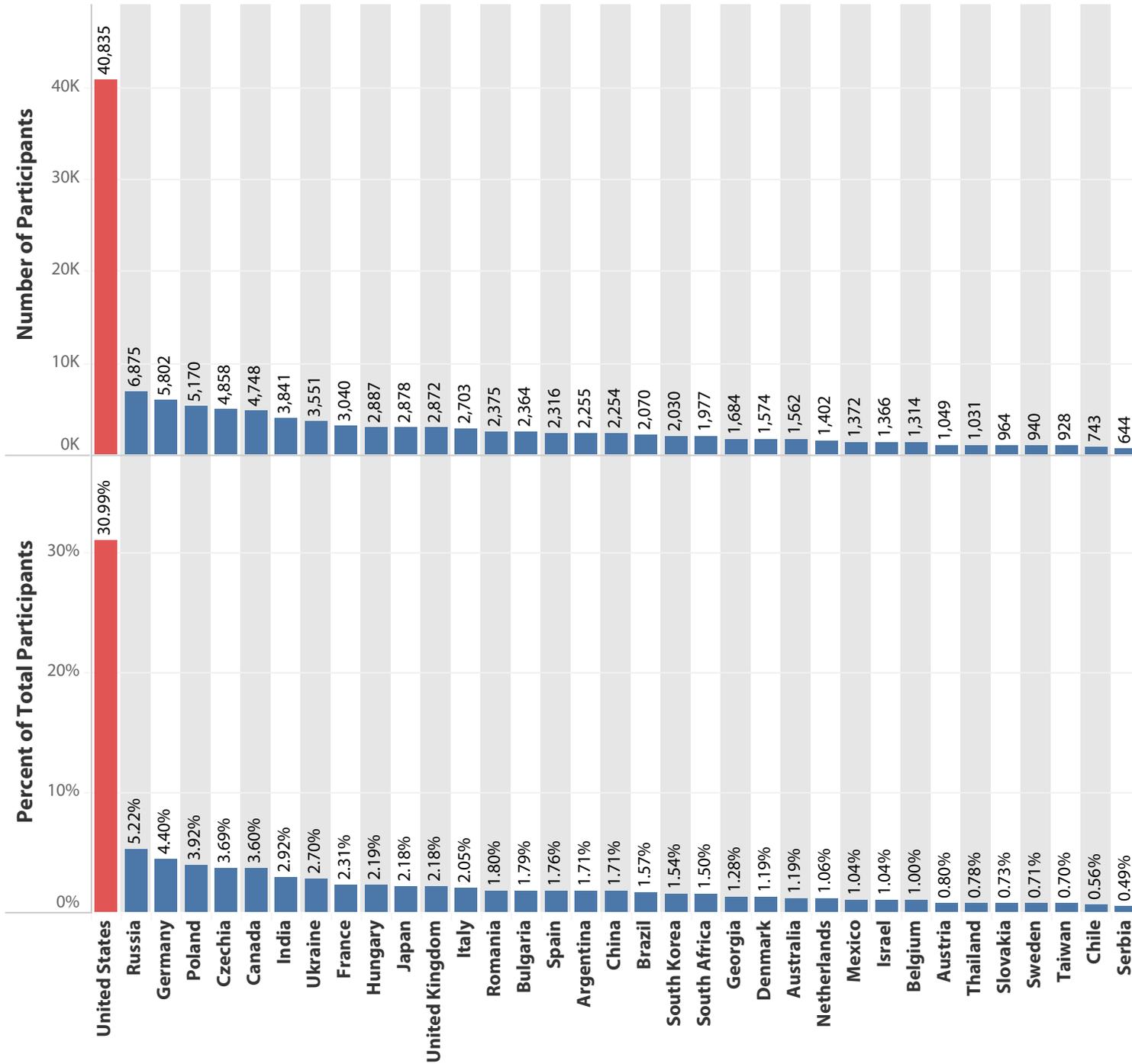


Population of US vs Non-US
Total People = 7,403,227,777

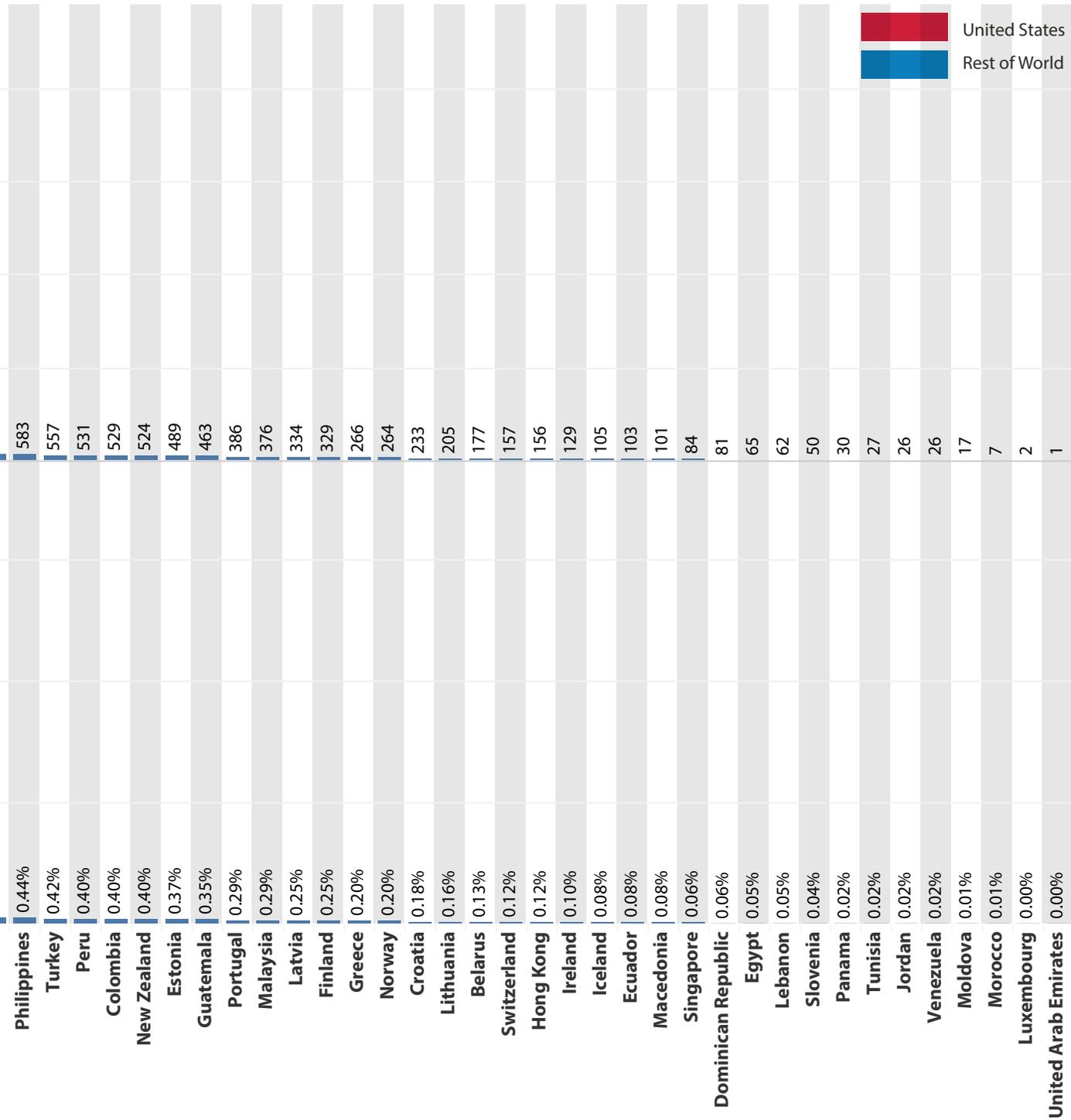


Trial Participants by Country

The top ten countries enrolling clinical trial participants are the United States (40,835), Russia (6,875), Germany (5,802), Poland (5,170), Czechia (4,858), Canada (4,748), India (3,841), Ukraine (3,551), France (3,040), Hungary (2,887), Japan (2,878), United Kingdom (2,872), Italy (2,703), Romania (2,375), Bulgaria (2,364), Spain (2,316), Argentina (2,255), China (2,254), Brazil (2,070), South Korea (2,030), South Africa (1,977), Georgia (1,684), Denmark (1,574), Australia (1,562), Netherlands (1,402), Mexico (1,372), Israel (1,366), Belgium (1,314), Austria (1,049), Thailand (1,031), Slovakia (964), Sweden (940), Taiwan (928), Chile (743), Serbia (644).

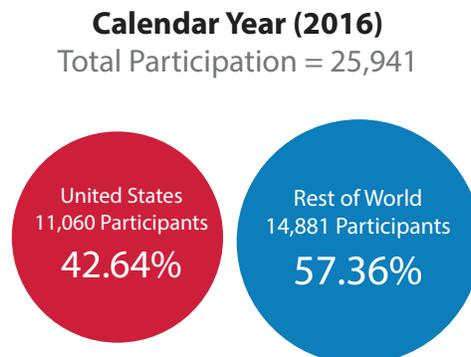
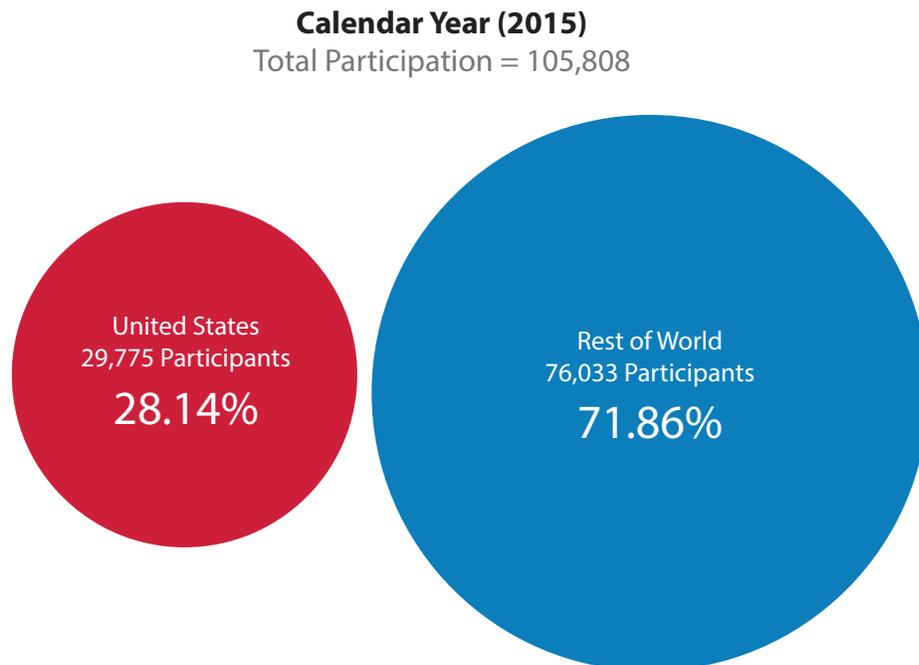


l (5,170), Czechia (4,858), Canada (4,748), India (3,841), Ukraine (3,551), France (3,040), and Hungary (2,887).



How does Global Participation Change by Year?

Participation in clinical trials varies by year. In calendar year 2015, there were 105,808 participants in pivotal clinical trials. In calendar year 2016, there were 25,941 participants in pivotal clinical trials.



How many CDER NME Approvals had Foreign Data?

In 2015, CDER approved 45 novel drugs, either as new molecular entities (NMEs) under New Drug Applications (NDAs) or as new therapeutic biologics under Biologics License Applications (BLAs).

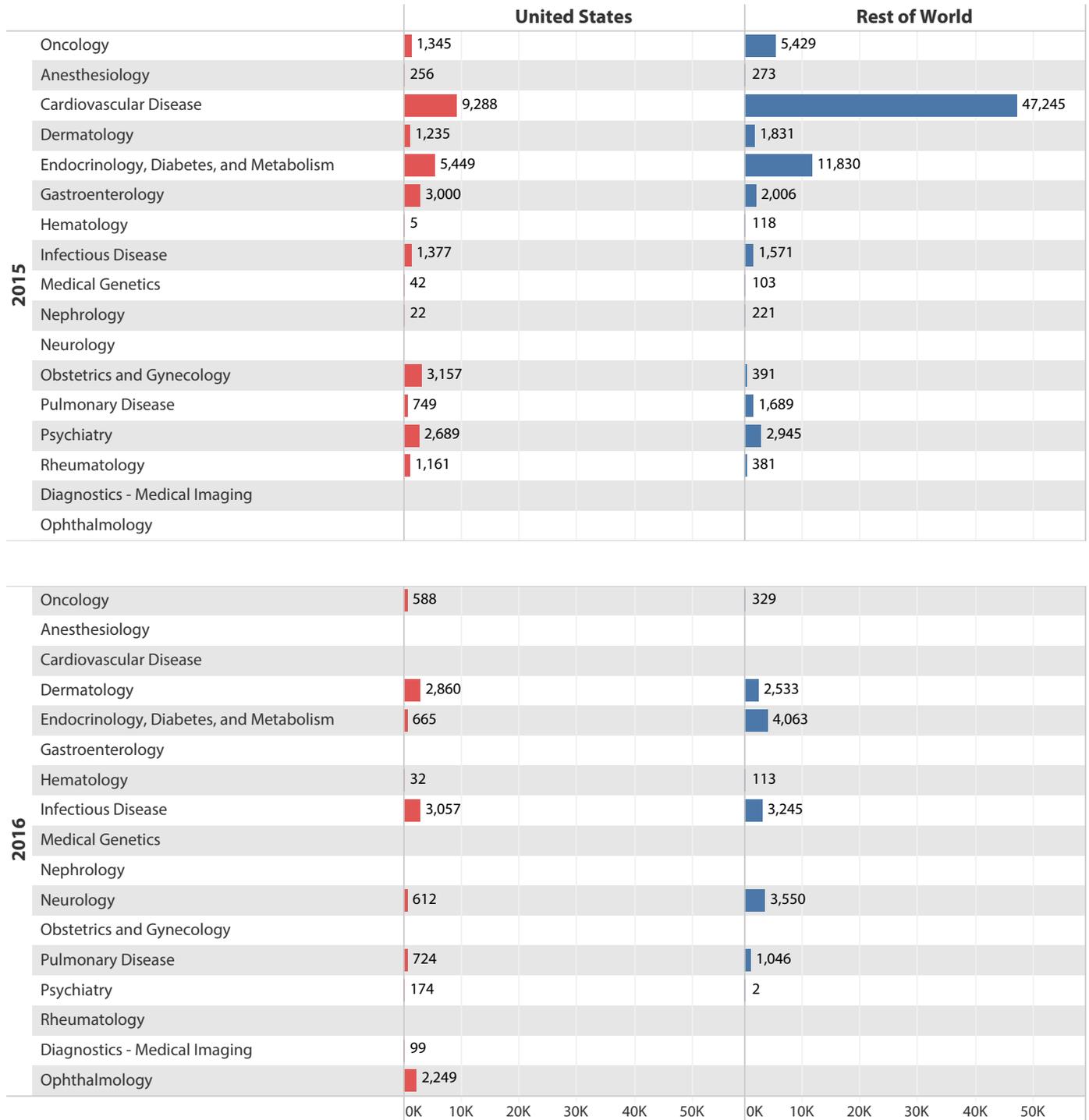
In 2016, CDER approved 22 novel drugs, either as new molecular entities (NMEs) under New Drug Applications (NDAs) or as new therapeutic biologics under Biologics License Applications (BLAs).

YEAR	NME Approvals (N)	NMEs (%) WITH ANY PARTICIPANTS OUTSIDE US
2015	45	42 (93%)
2016	21*	15 (71%)

*Site location data was not available for one new molecular entity

Trial Participants by Year Approved, Therapeutic Area, and Geography

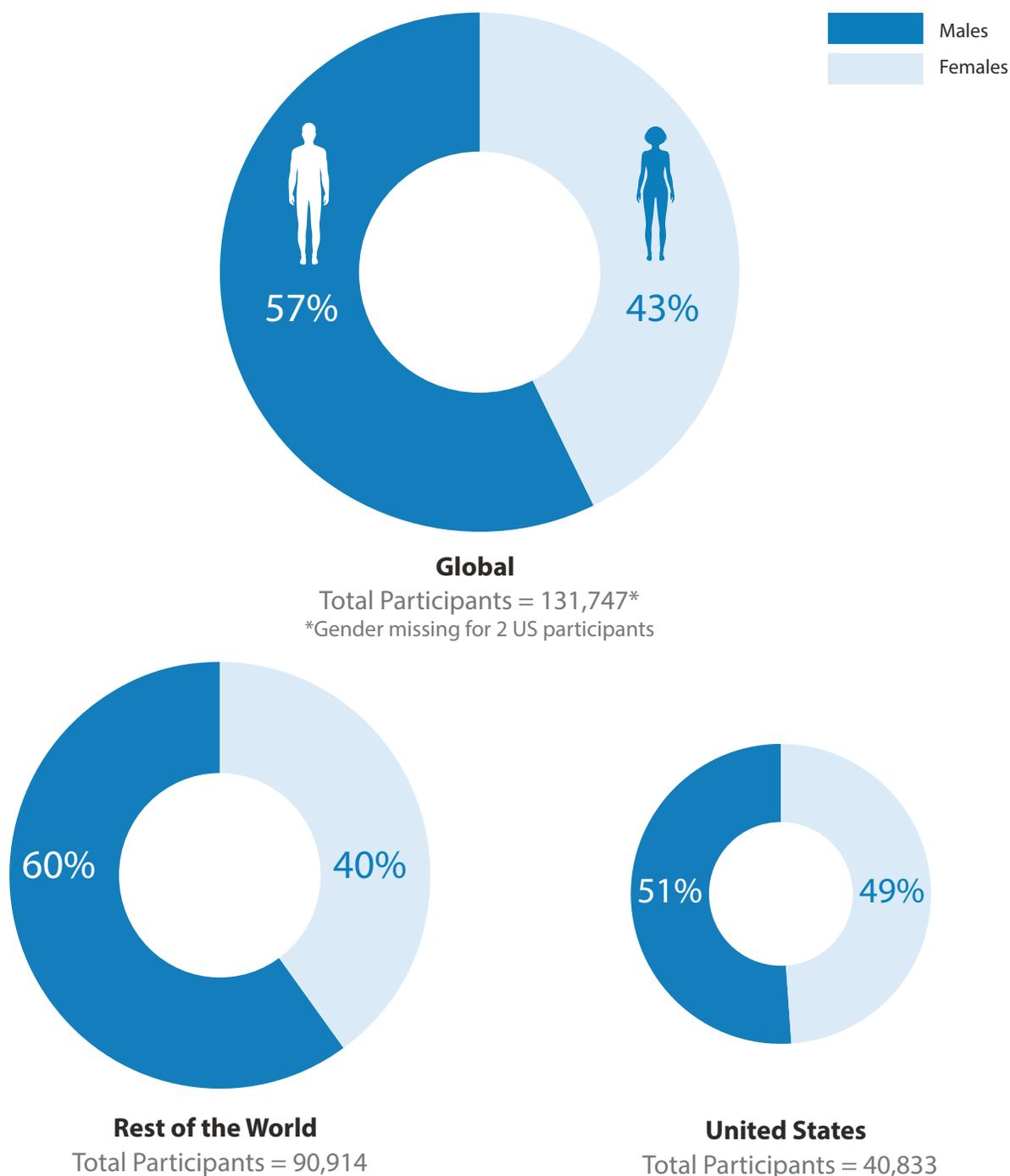
More insight into pivotal trial participants are provided below by year approved, therapeutic area, and geography.



Gender

How does Gender Participation differ by Geographic Location?

Gender composition at non-US sites was majority male, whereas gender composition at US sites was closer to 50:50.

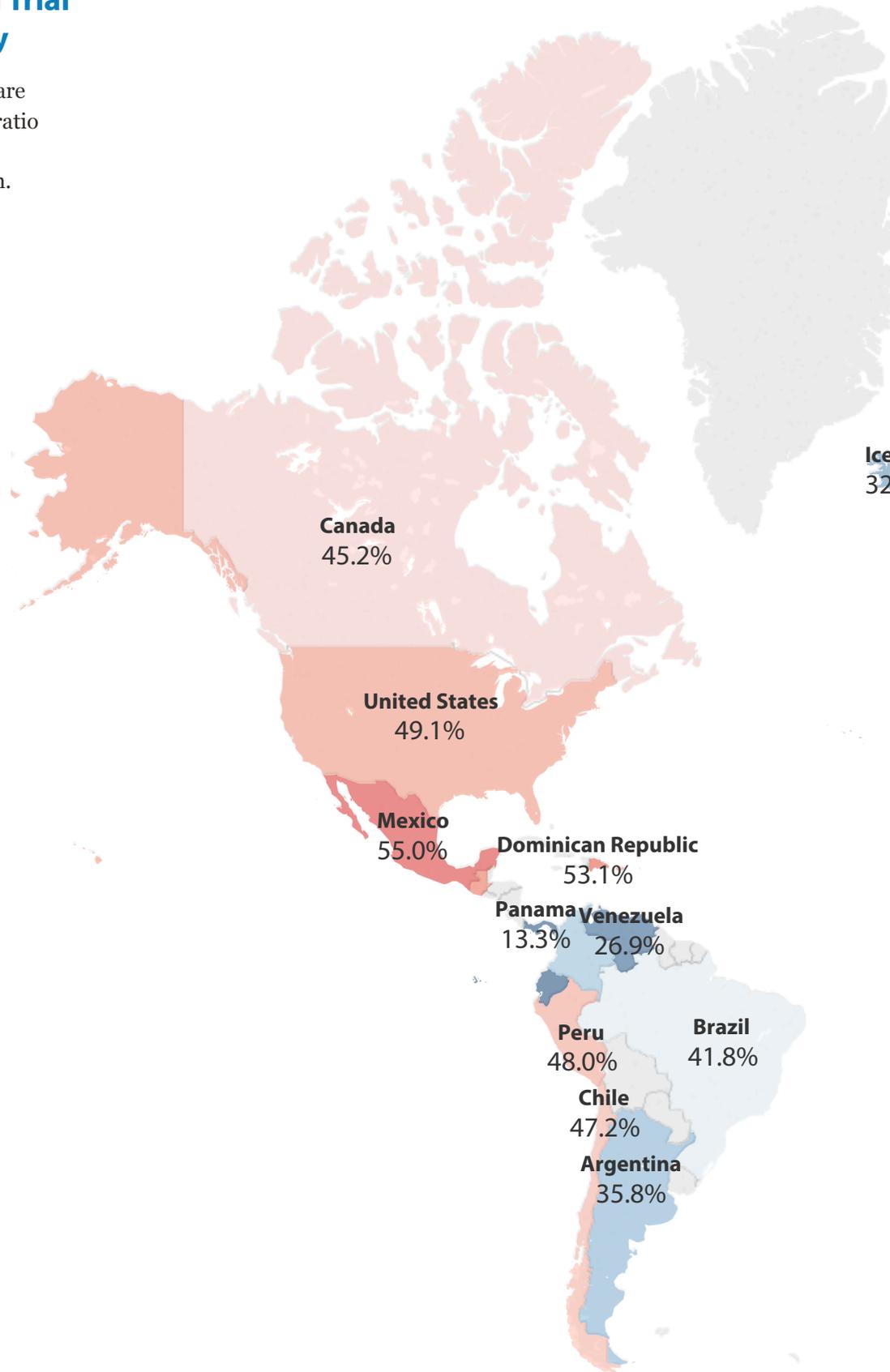
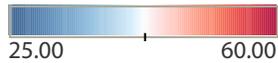


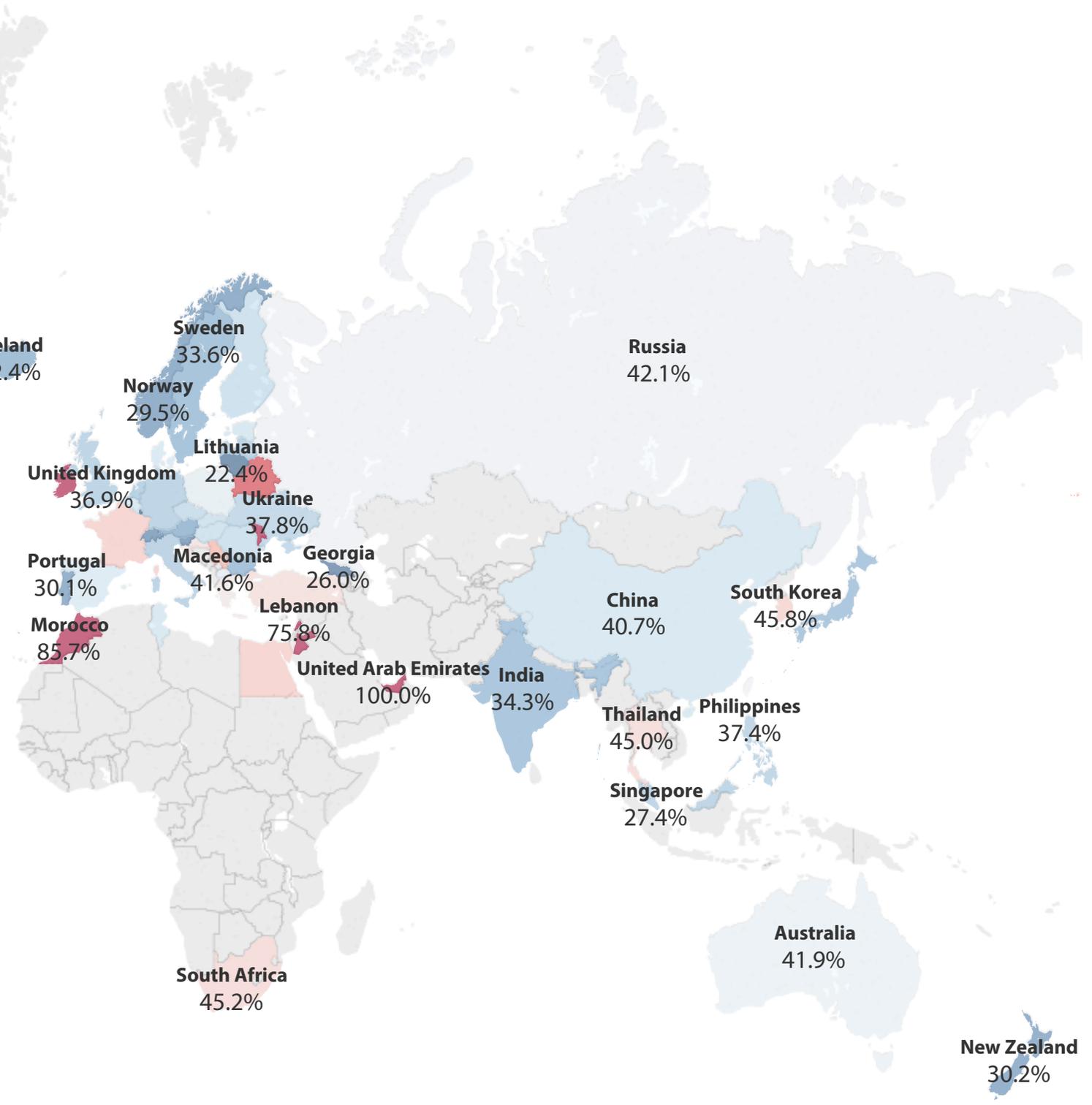
Percent Women among Trial Participants by Country

Globally, 43% of trial participants are women. Overall, the female:male ratio was between 30:70 and 45:55, consistent with global participation.



Percentage of Women Participation

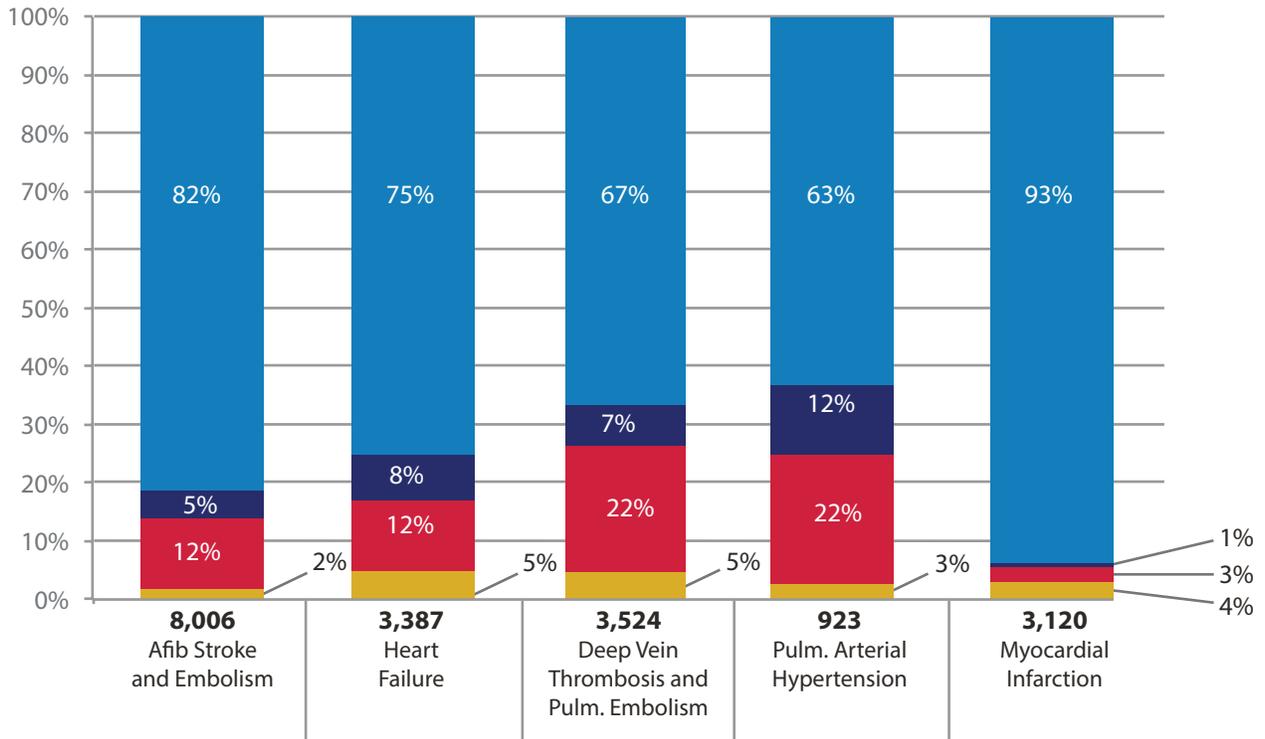
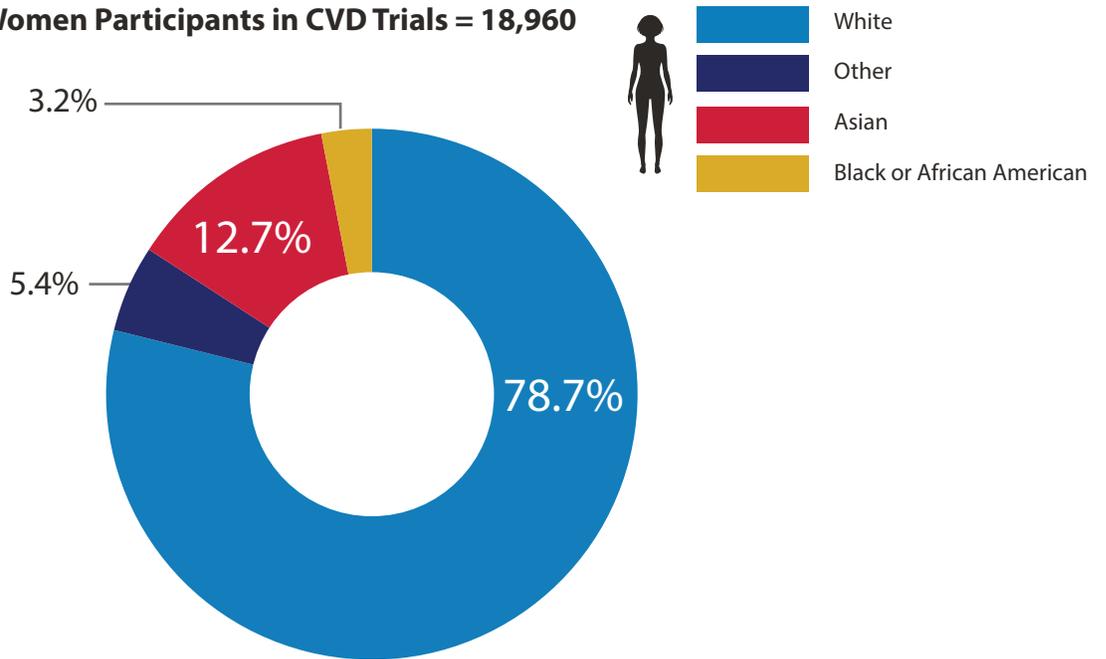




Of the Women Trial Participants in Cardiovascular (CVD) Trials, what was the Racial composition?

More insight into the races of women participating in cardiovascular trials is provided in the figures below.

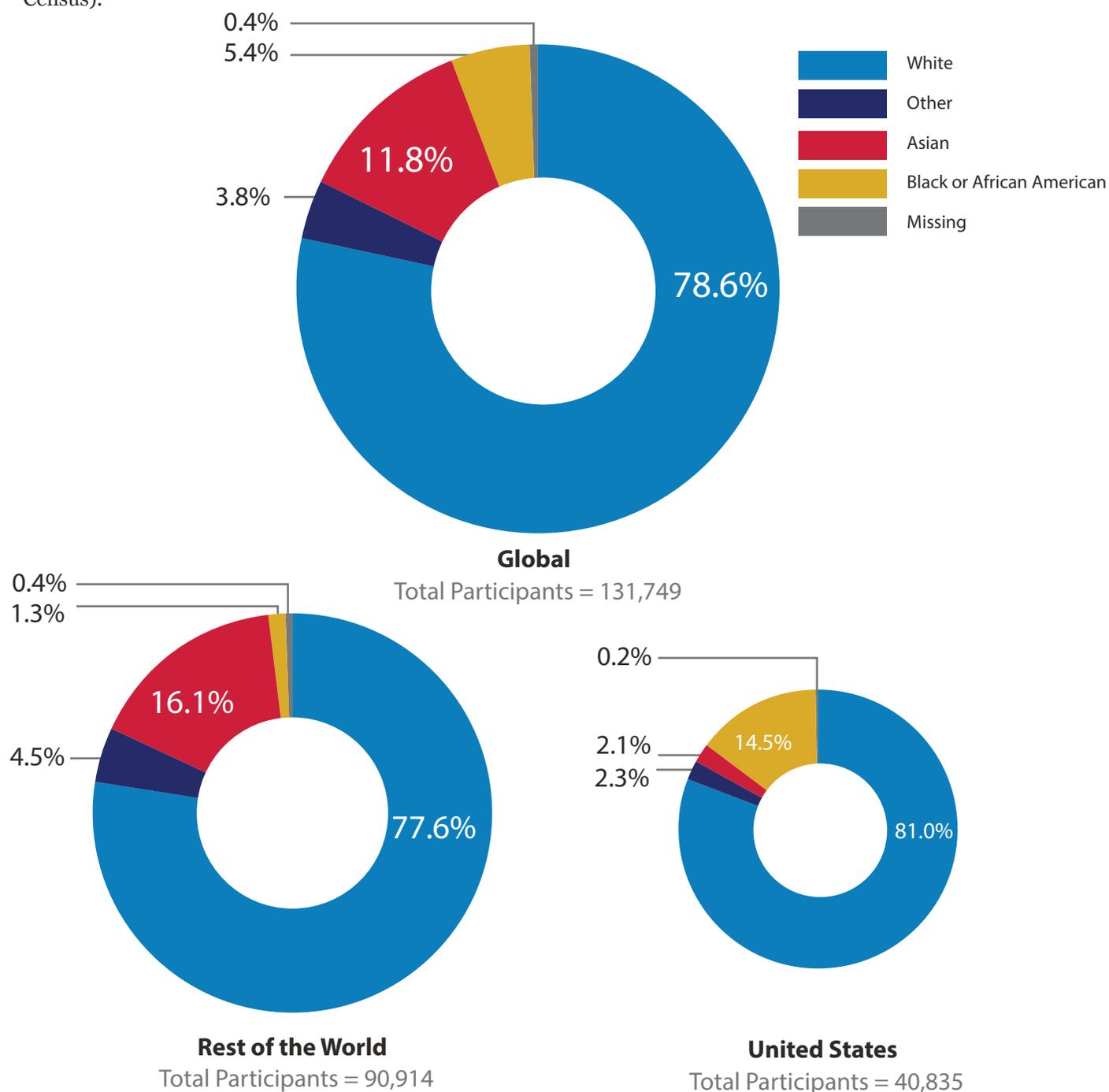
Women Participants in CVD Trials = 18,960



Race

How does Racial Participation differ by Geographic Location?

The majority of Asian trial participants were at non-US sites. The representation of Black or African American participants at US sites is similar to the US general population, which is 13% Black or African American (2011-2015 Census).



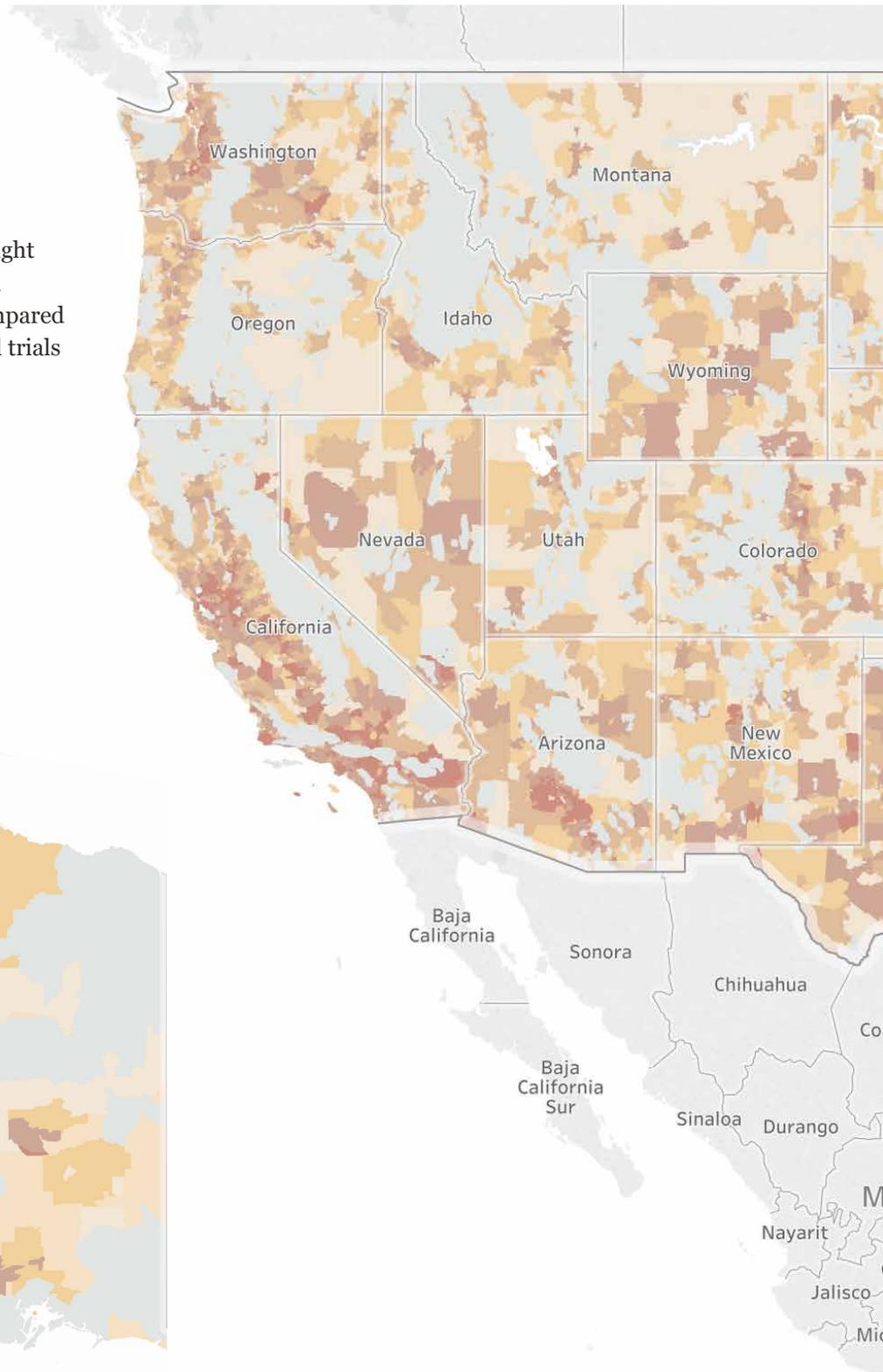
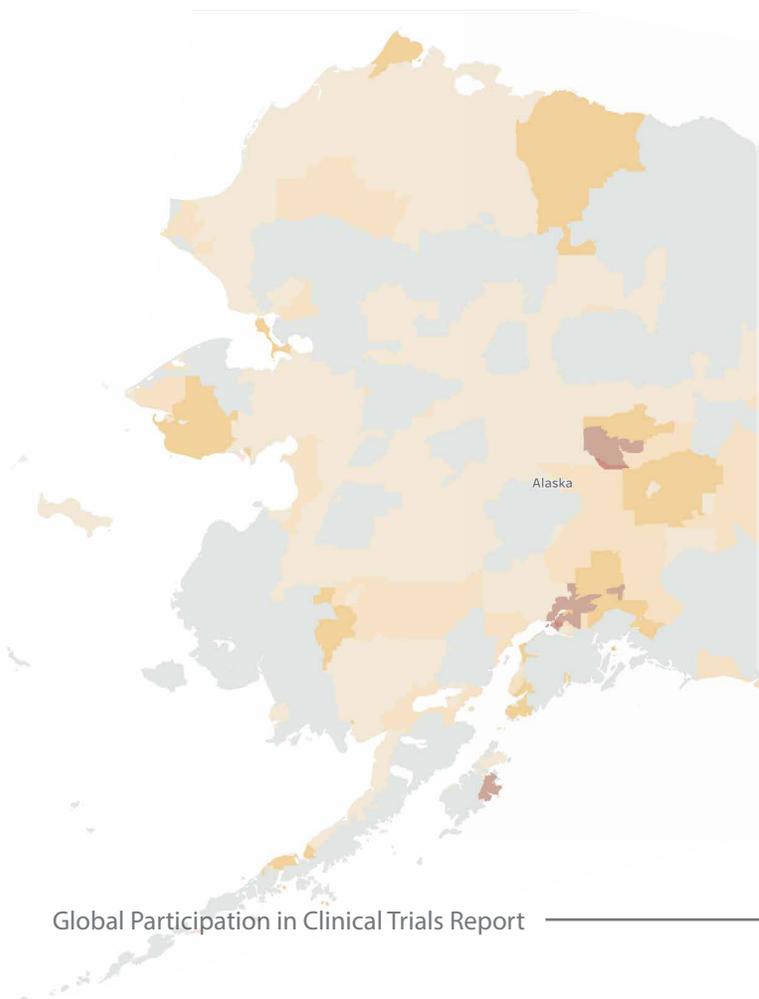
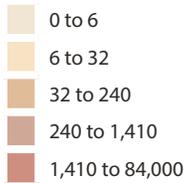
*Other includes American Indian/Alaskan Native (AI/AN), Native Hawaiian/Other Pacific Islander (NH/OPI), and Others

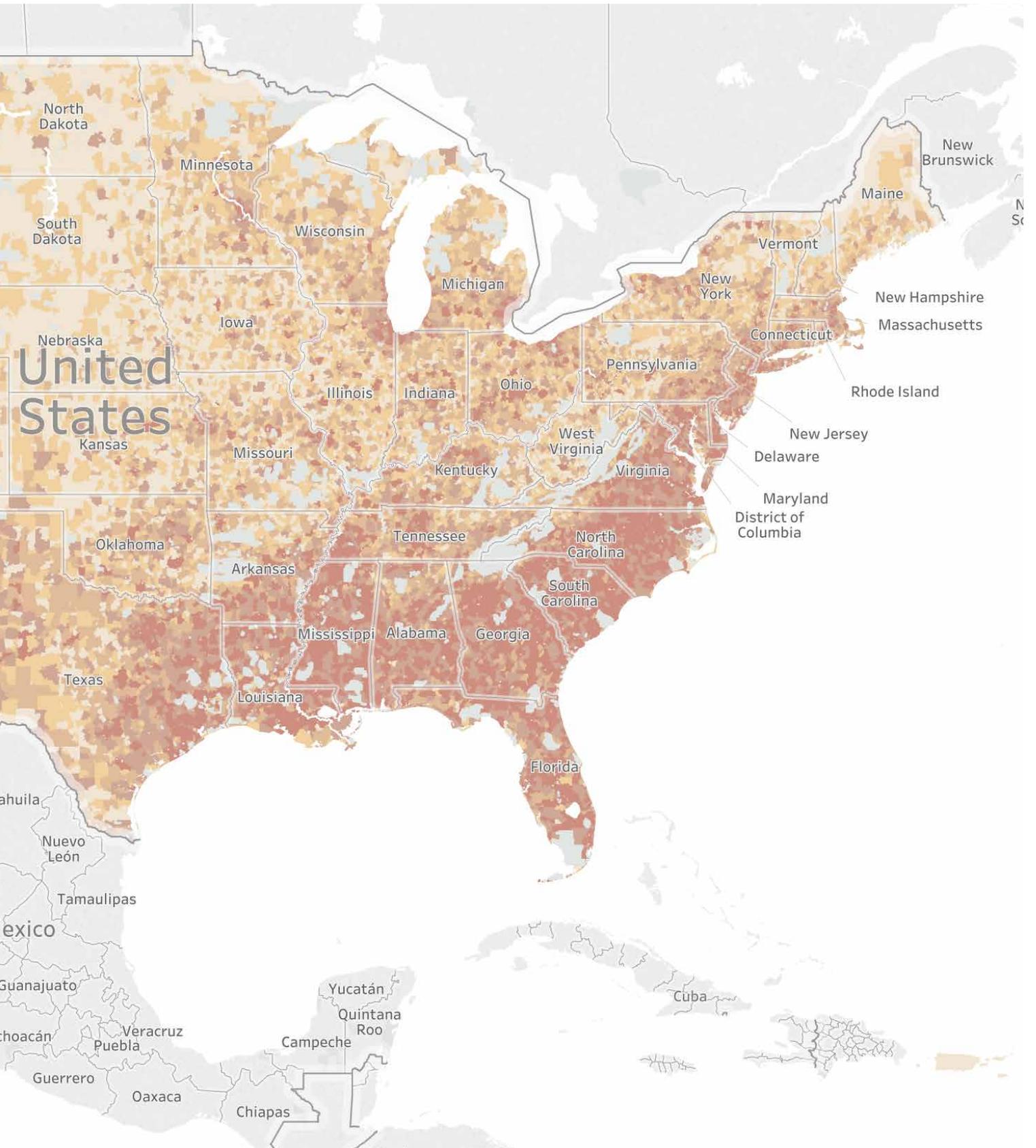
Black or African American (Black/AA) Clinical Trial Participation in the United States

The next series of maps provides more insight into where the majority of Black or African American (Black/AA) participants live compared to where Black/AAs participated in clinical trials at the US Zip-Code level.

Where do Black or African Americans Live?

2017 Black/African American Population





Where do Black or African American participate in Clinical Trials? (Based on NMEs from 2015-16)

This map shows where Black/AAs participated in clinical trials. Red icons represent zip codes in which at least one Black/AA participated in a clinical trial.

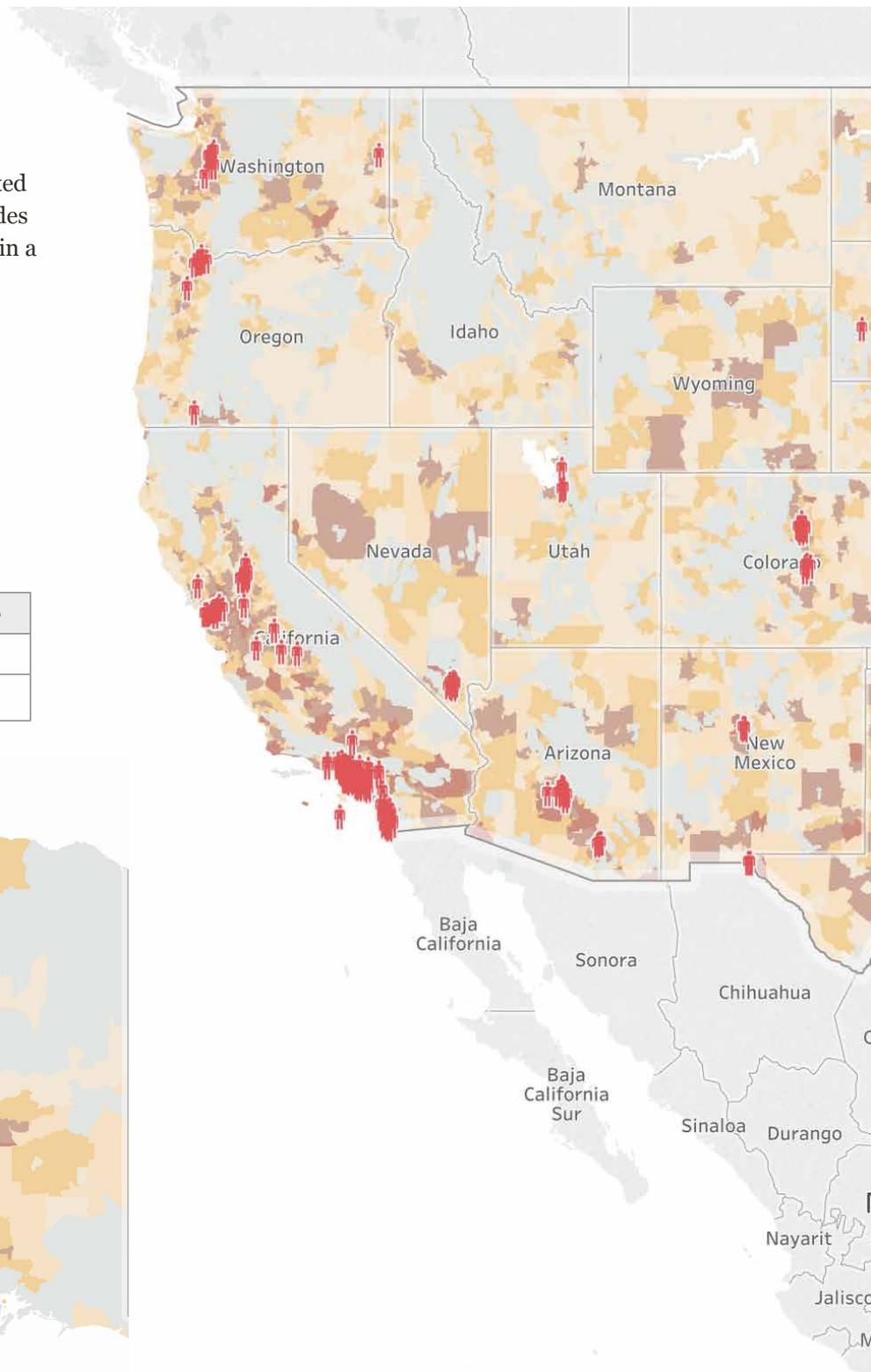
2017 Black/African American Population

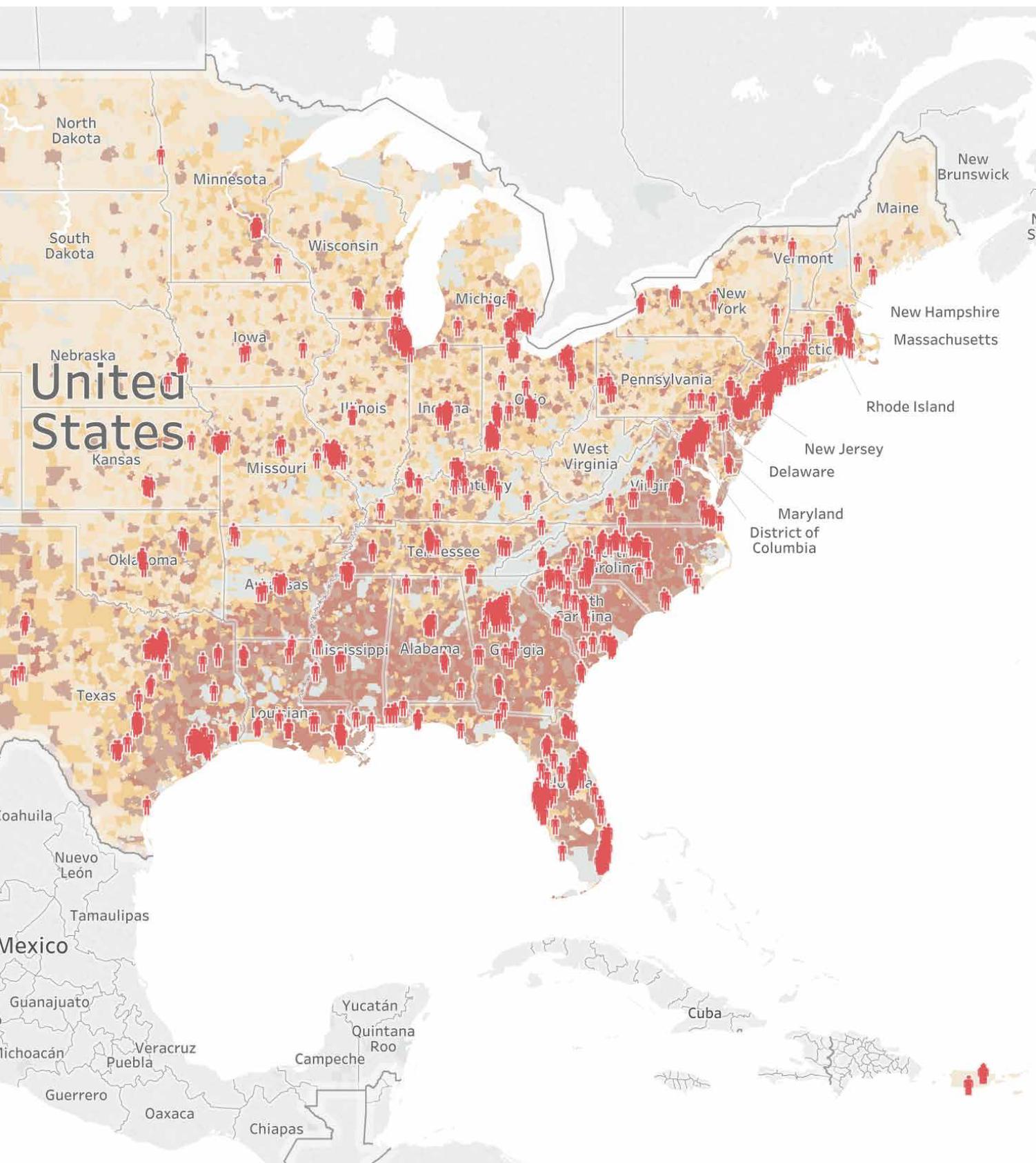
- 0 to 6
- 6 to 32
- 32 to 240
- 240 to 1,410
- 1,410 to 84,000

Race of Participant

- Black/AA

	Participants	Percentage
Black/AAs	5,913	14.48%
Some Other Race	34,922	85.52%





Where do non-Black or African American participate in Clinical Trials? (Based on NMEs from 2015-16)

This map shows where non-Black/AAs participated in clinical trials. Blue icons represent zip codes in which non-Black/AAs participated in trials.

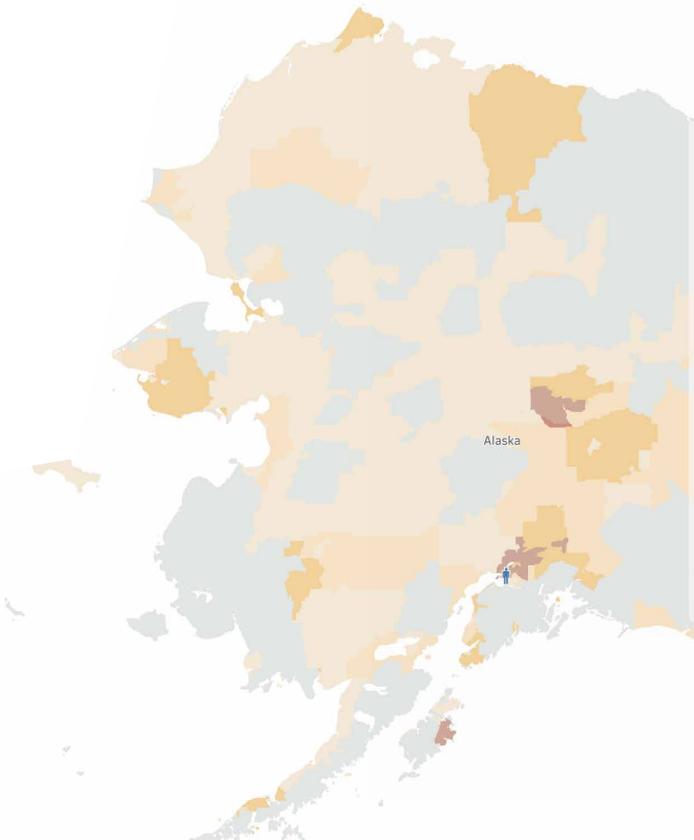
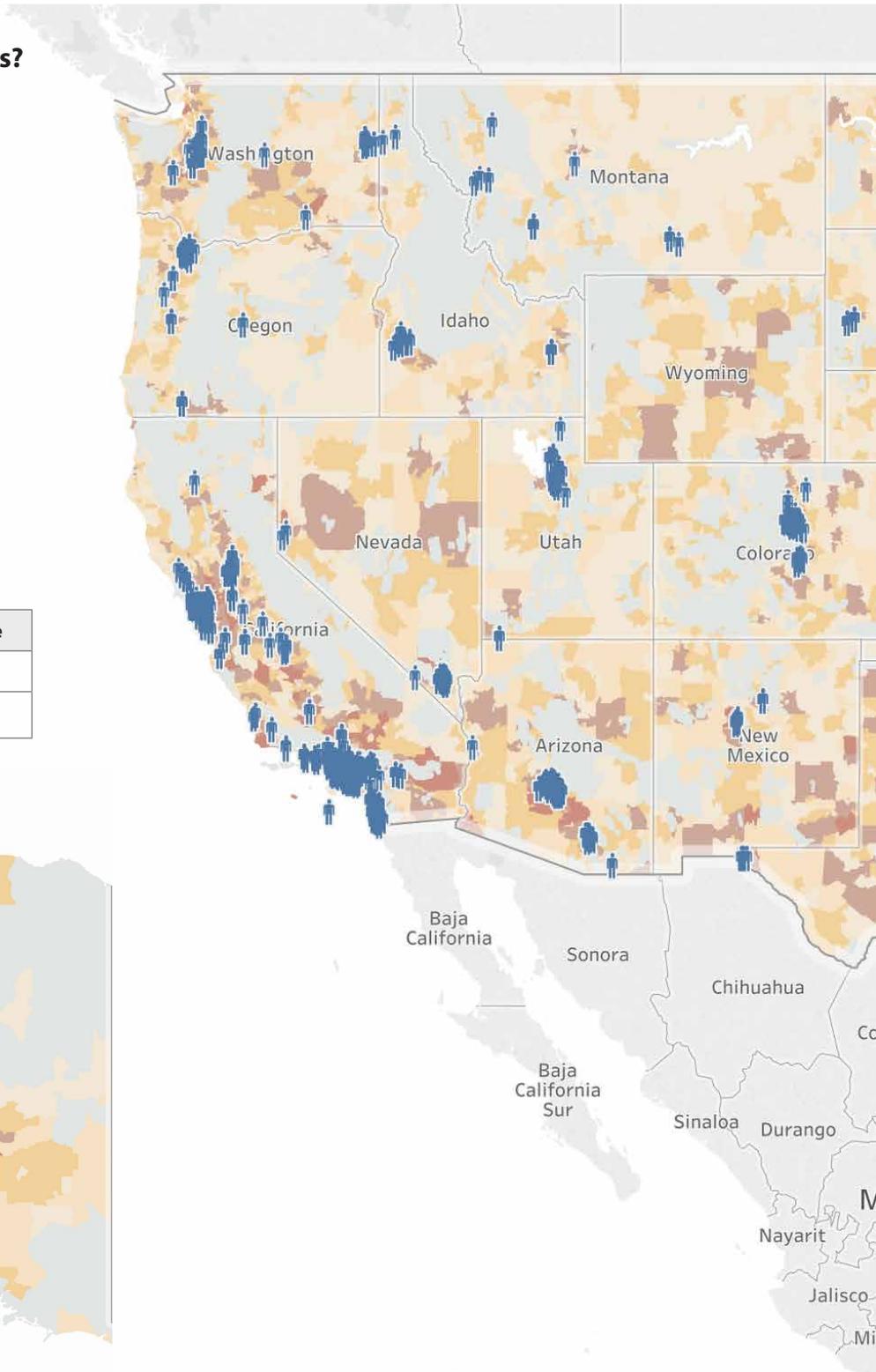
2017 Black/African American Population

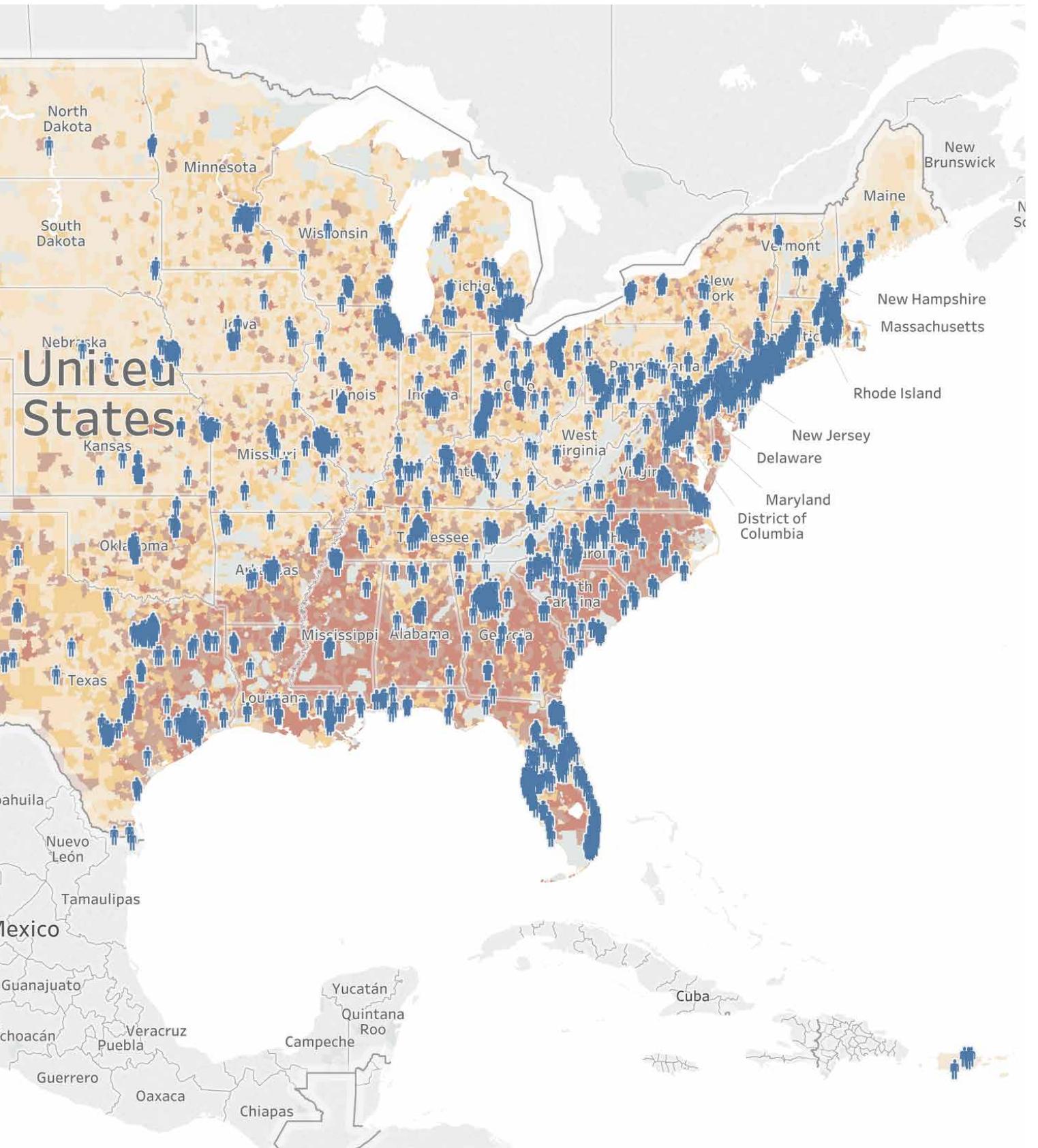
- 0 to 6
- 6 to 32
- 32 to 240
- 240 to 1,410
- 1,410 to 84,000

Race of Participant

- Some Other Race

	Participants	Percentage
Black/AAs	5,913	14.48%
Some Other Race	34,922	85.52%

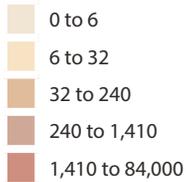




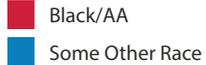
Where do Black/AAs participate in Clinical Trials compared to Non-Black/AA Races? (Based on NMEs from 2015-16)

This map shows where Black/AAs participate in clinical trials compared to Non-Black/AA races. Roughly comparing the sites with Black/AA participants and sites with non-Black/AA participants, it seems to suggest clinical trials in the US are being conducted where Black/AAs live.

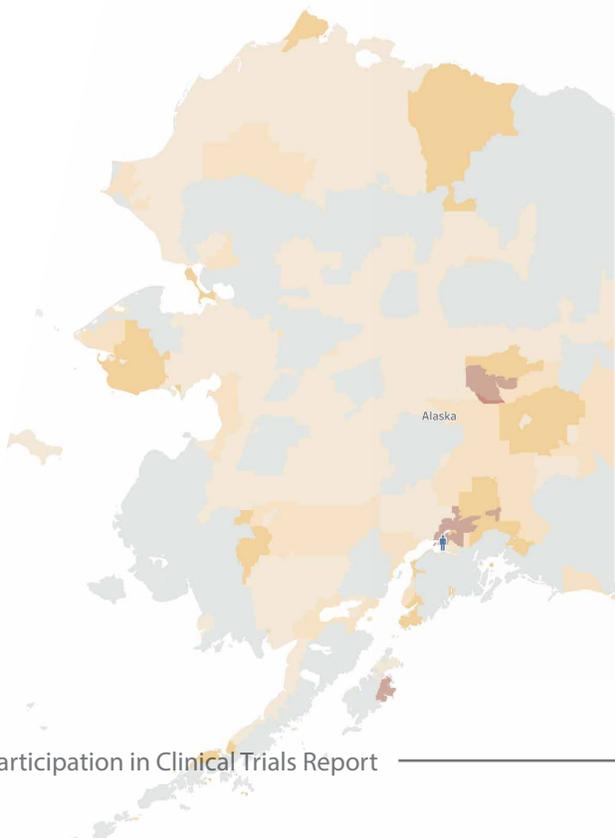
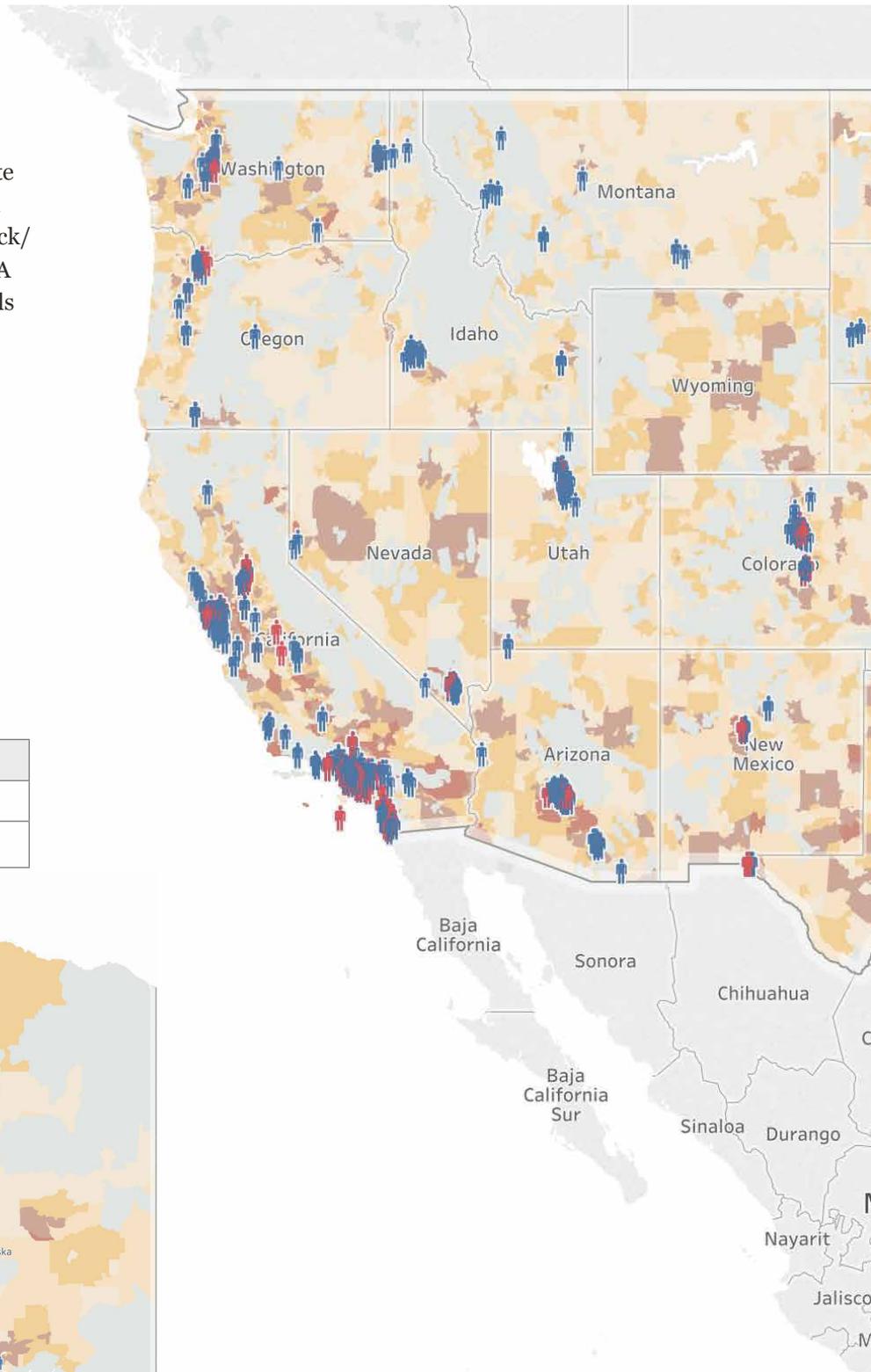
2017 Black/African American Population

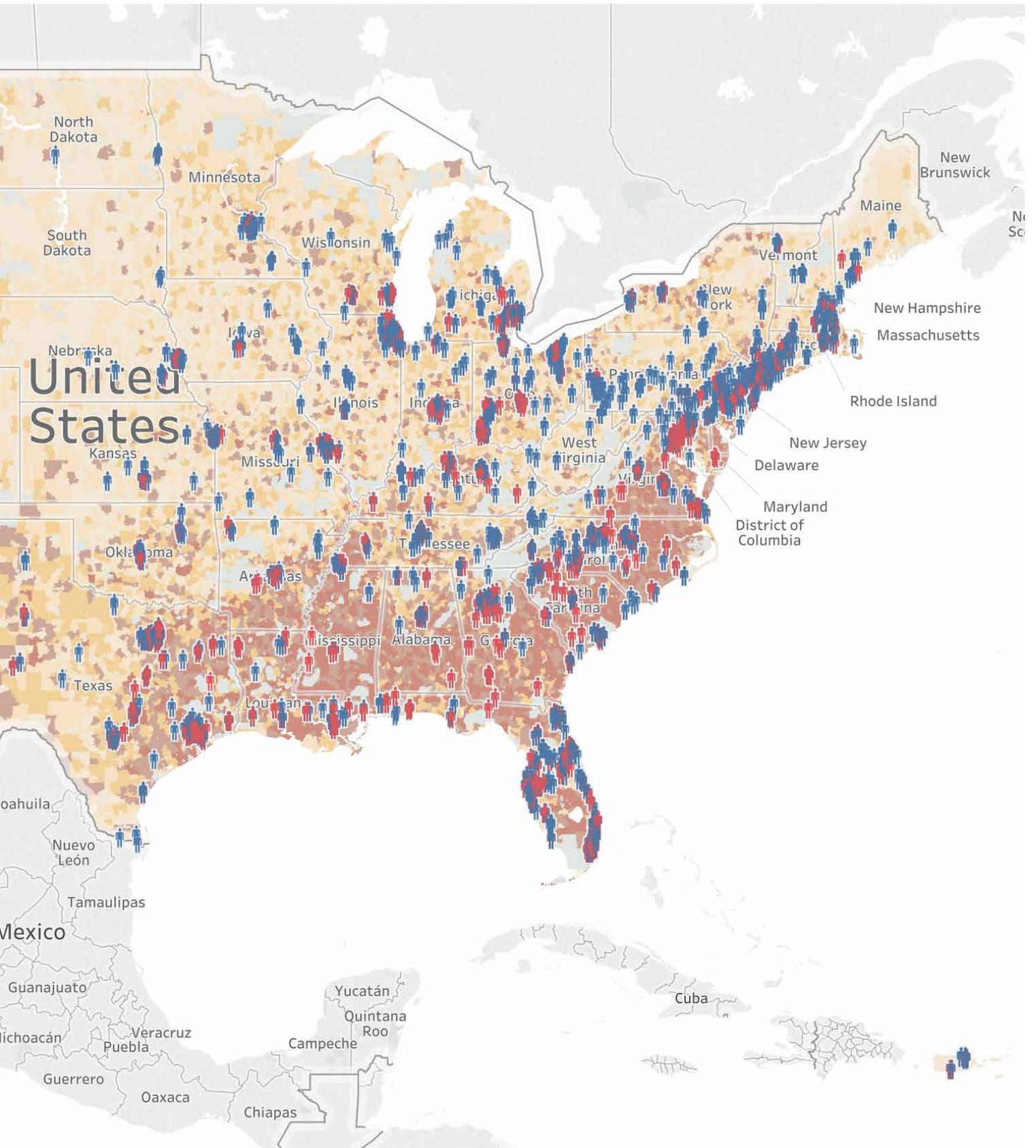


Race of Participant



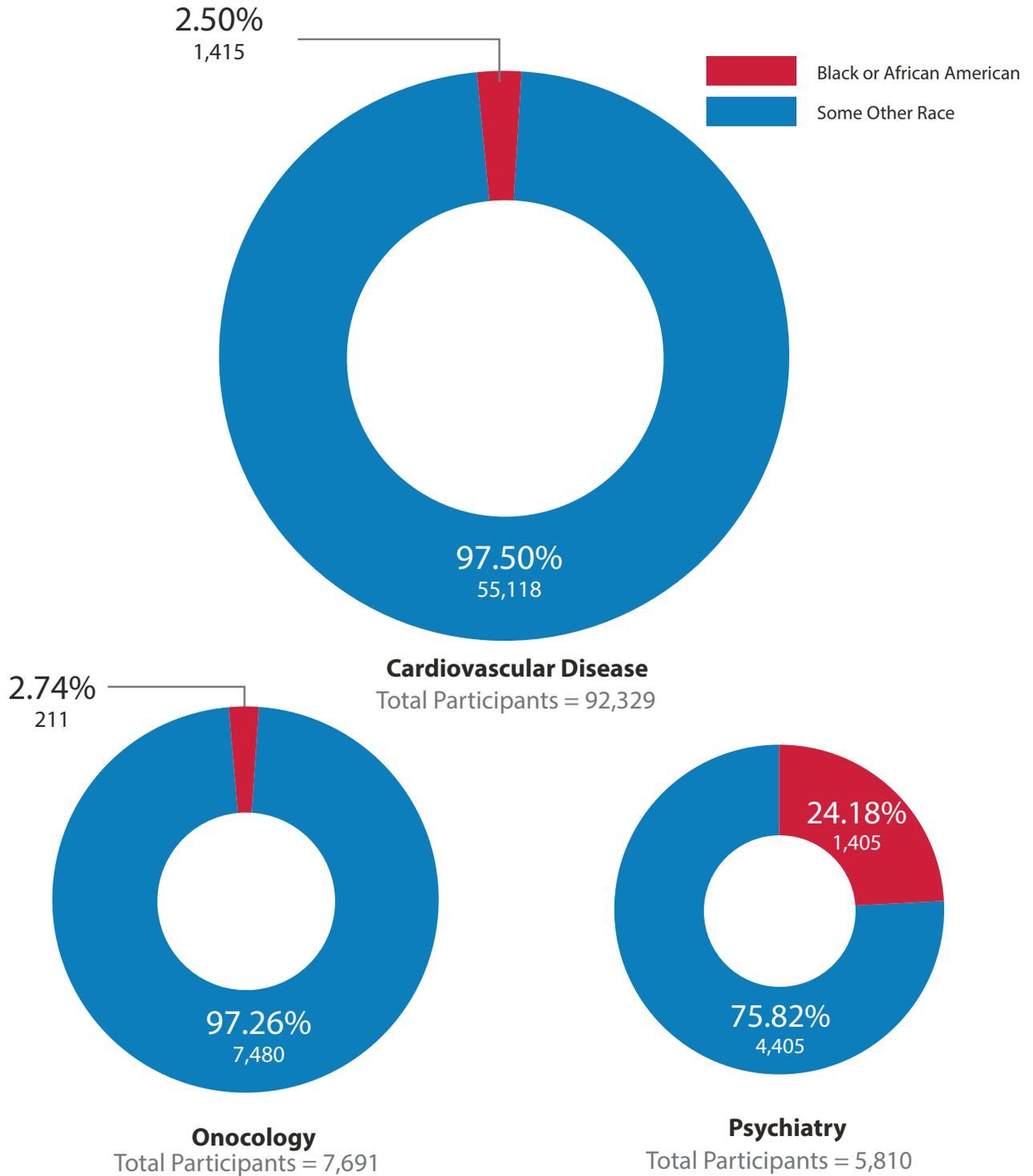
	Participants	Percentage
Black/AAs	5,913	14.48%
Some Other Race	34,922	85.52%





Participation of Black/AAs in Clinical Trials for Oncology, Cardiology, and Psychiatry

More insight into the participation rates of Black/AAs in clinical trials for Oncology, Cardiology, and Psychiatry are provided in the figures below.



Global Participation in Clinical Trials Project Team Members

We would like to acknowledge the hard work of the following offices and people in the creation of this Global Participation in Clinical Trials Report:

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