

2015-2019

DRUG TRIALS SNAPSHOTS SUMMARY REPORT

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

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Introduction

Welcome to the FDA's Center for Drug Evaluation and Research (CDER) Drug Trials Snapshots Summary Report 2015–2019.

Beginning in 2015, and in response to the 2012 Food and Drug Administration Safety and Innovation Act (FDASIA 907), the FDA's Center for Drug Evaluation and Research (CDER) has been reporting clinical trial demographic data for new molecular entities and original biologics through the Drug Trials Snapshots (DTS) program. We have provided individual drug trial snapshots and annual summaries on the FDA website for the past five years. This summary report aggregated demographic data from DTS snapshots published between 2015 and 2019.

The report is organized into five sections:

1. Clinical Trials Global Report
2. Demographics of Trial Participation
3. U.S. Clinical Trial Participant Distribution by Race and Ethnicity Categories
4. Clinical Trial Participation by Therapeutic Area
5. Demographics of Trial Participants in Rare Diseases

Within each section, trial participation is divided into four demographic categories: sex, race, age, and ethnicity. Careful analysis of each category is enhanced with data visualization in order to relay important metrics and trends over time. A brief overview highlights the key findings for each graphic representation. The goal of the DTS five-year report is to provide insight into the aggregate trial data spanning five years.

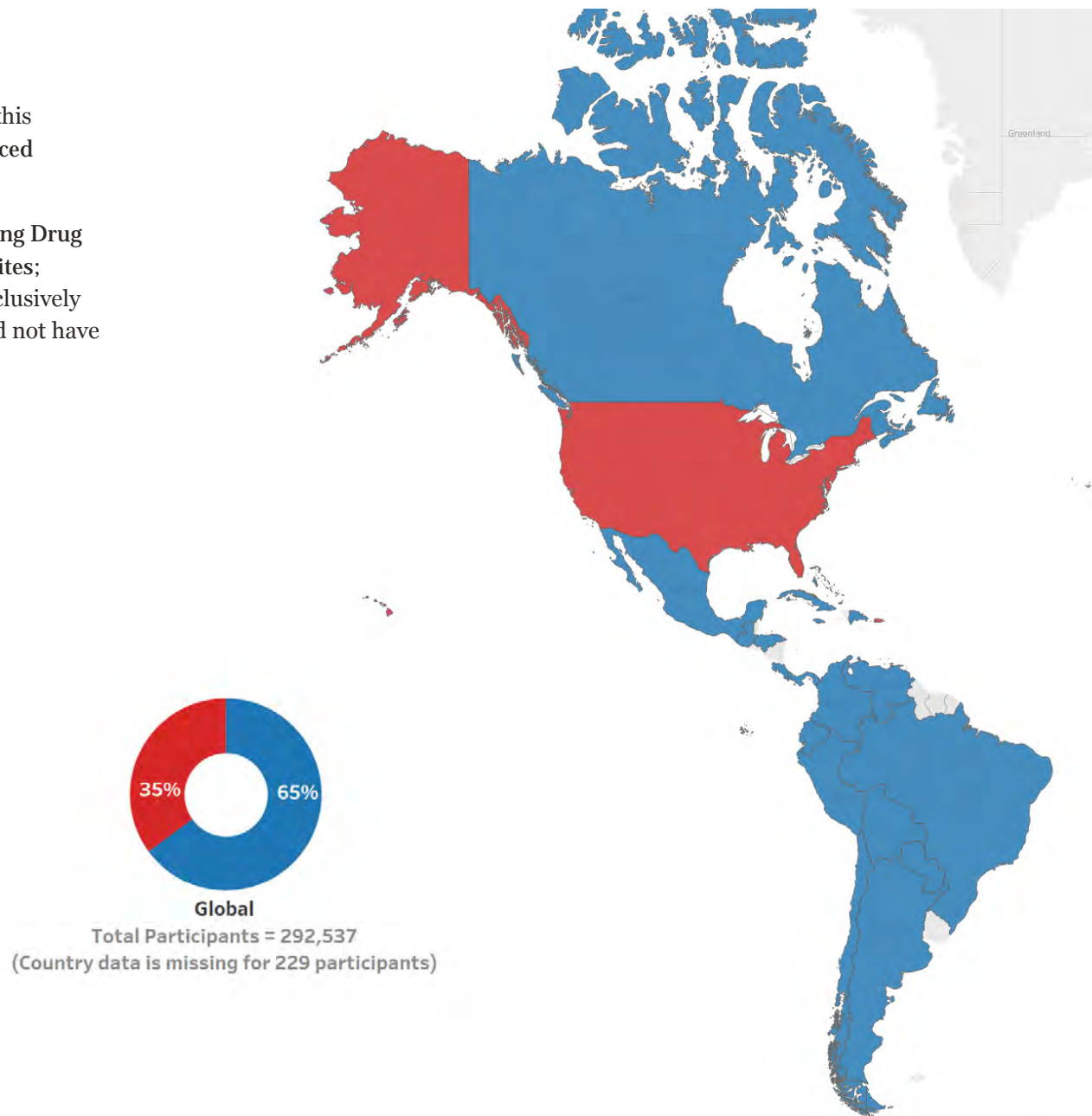
We hope the report conveys valuable information and insight into the diversity of clinical trial participation. Through the collective effort of participants, sponsors, and regulators, we aim to achieve the goals of safe and effective medicines for all. We welcome comments and feedback at CDERDrugTrialSnapshots@fda.gov.

Clinical Trials Global Report

Global Map of Trial Participants

A total of 292,766 clinical trial participants were included in this analysis, representing populations from 231 snapshots produced between 2015 and 2019.

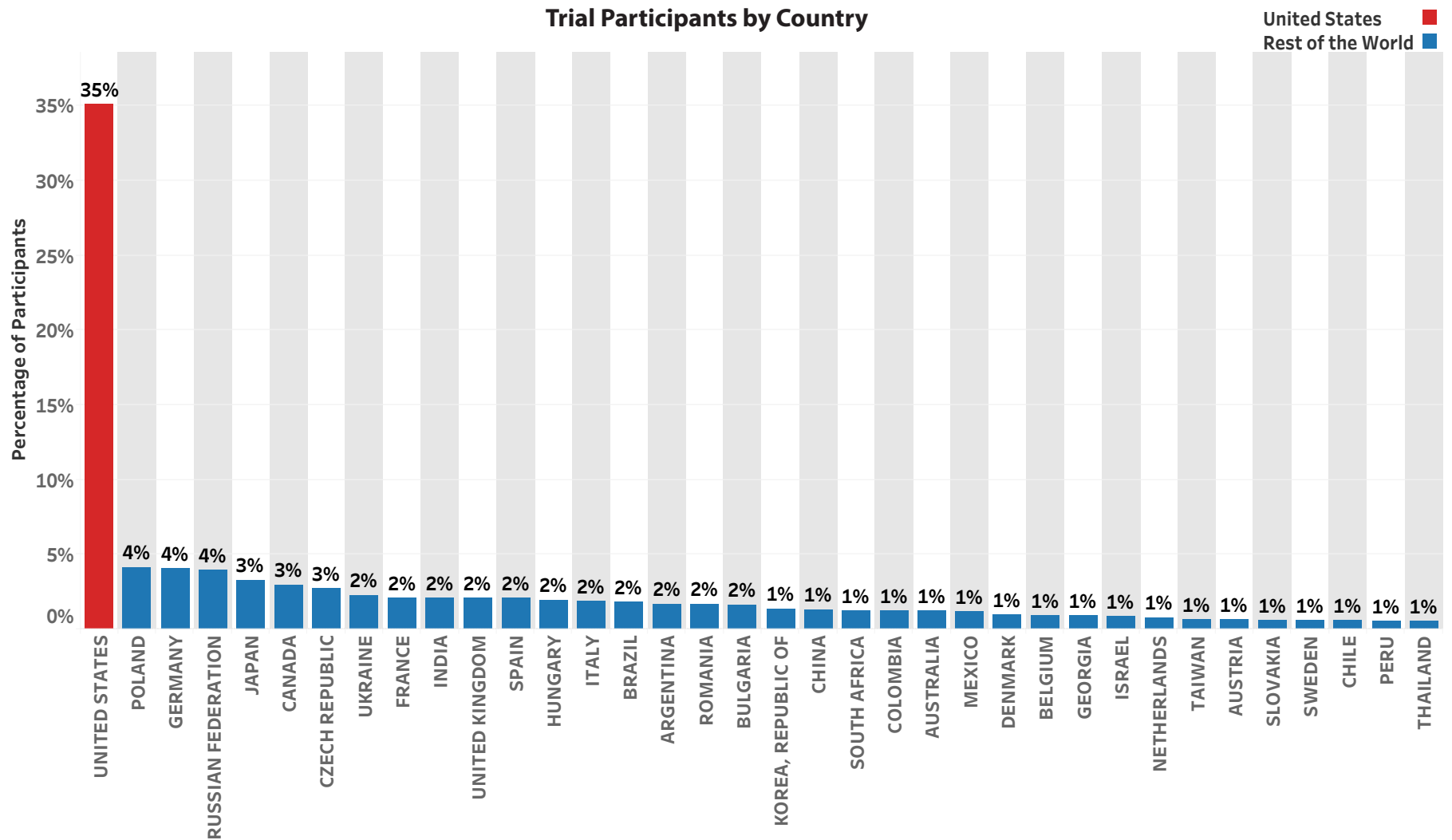
The majority of applications which were the basis for producing Drug Trials Snapshots contained data both from U.S. and foreign sites; however, 10.3% had data exclusively from U.S. sites, 5.4% exclusively from foreign sites, and 0.4% of the submitted applications did not have any site location data.





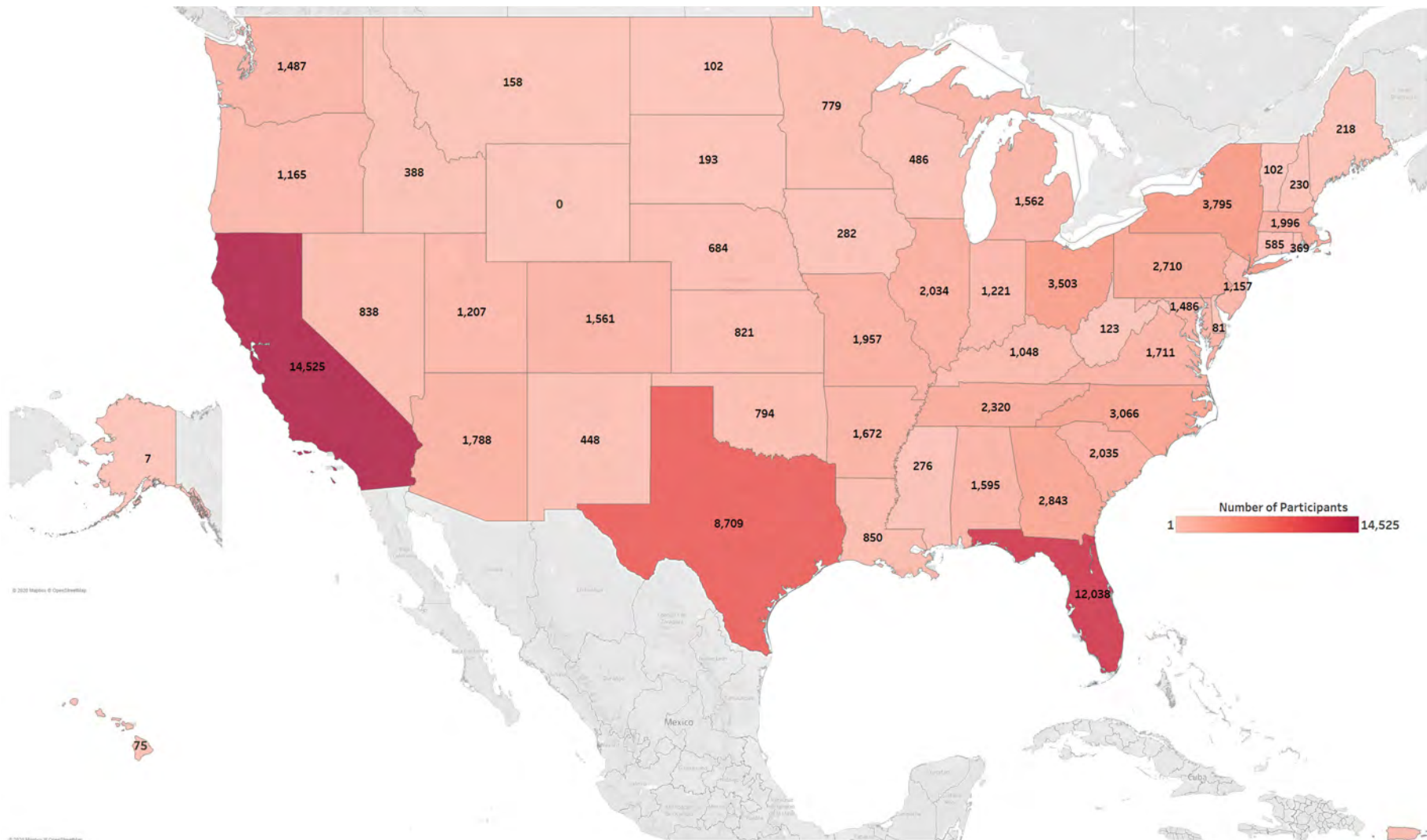
Trial Participants by Country

The countries that enrolled at least 1% of the total number of trial participants are presented below. These countries account for 96% of all trial participants. The remaining 4% of participants were distributed across 59 countries.

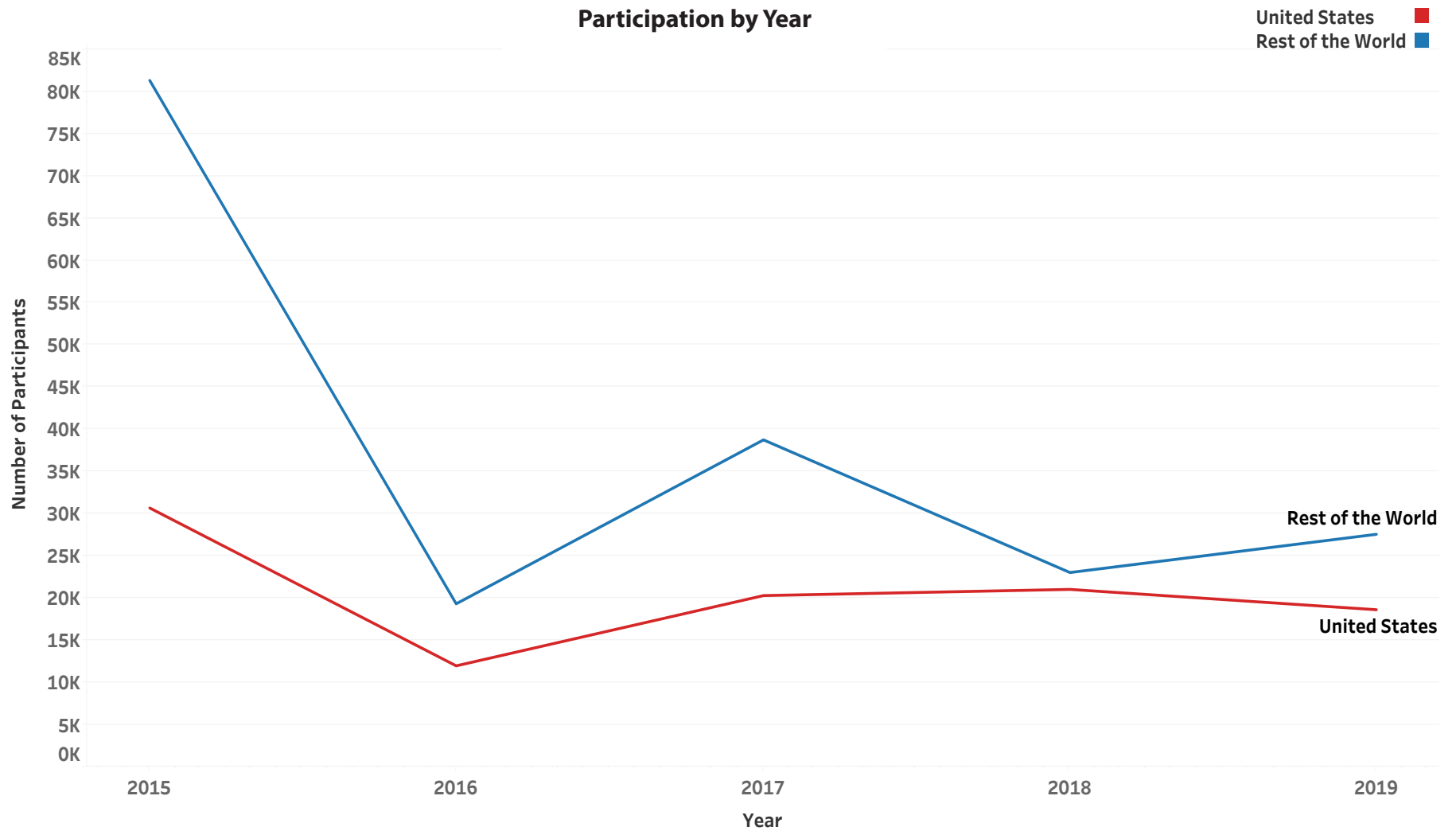


Clinical Trial Participation in the United States by State

The overall distribution of trial participants in the U.S. is presented on the map below.



How Does Global Participation Change by Year?

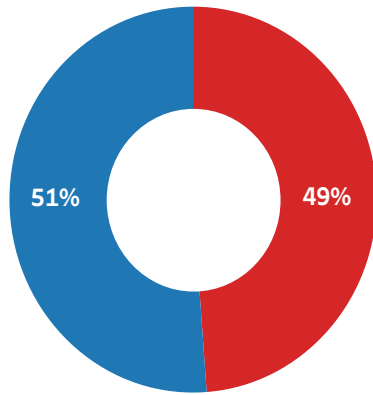


Demographics of Trial Participation

Demographic Categories

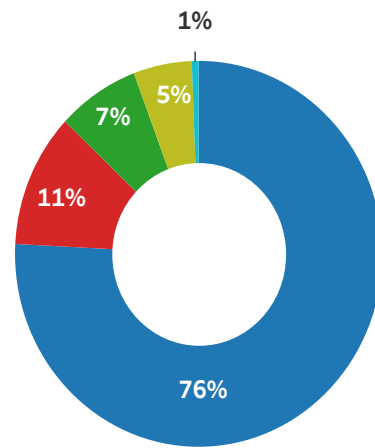
Clinical trial participation is broken down into four categories: sex, race, age, and ethnicity. *

Sex Distribution



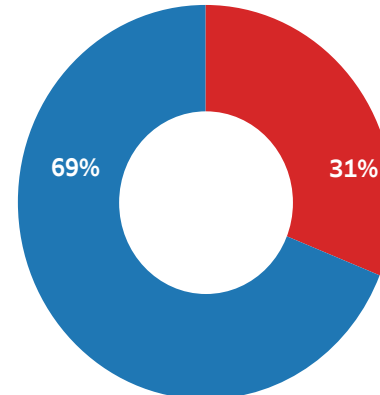
Female ■
Male ■

Race Distribution



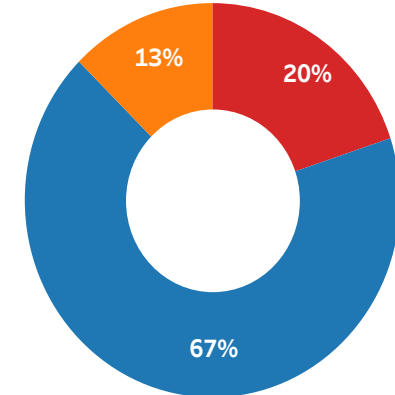
White ■
Asian ■
Black or African American ■
Other ■
American Indian or Alaska Native ■

Age Distribution



< 65 Years ■
>= 65 Years ■

Ethnicity Distribution



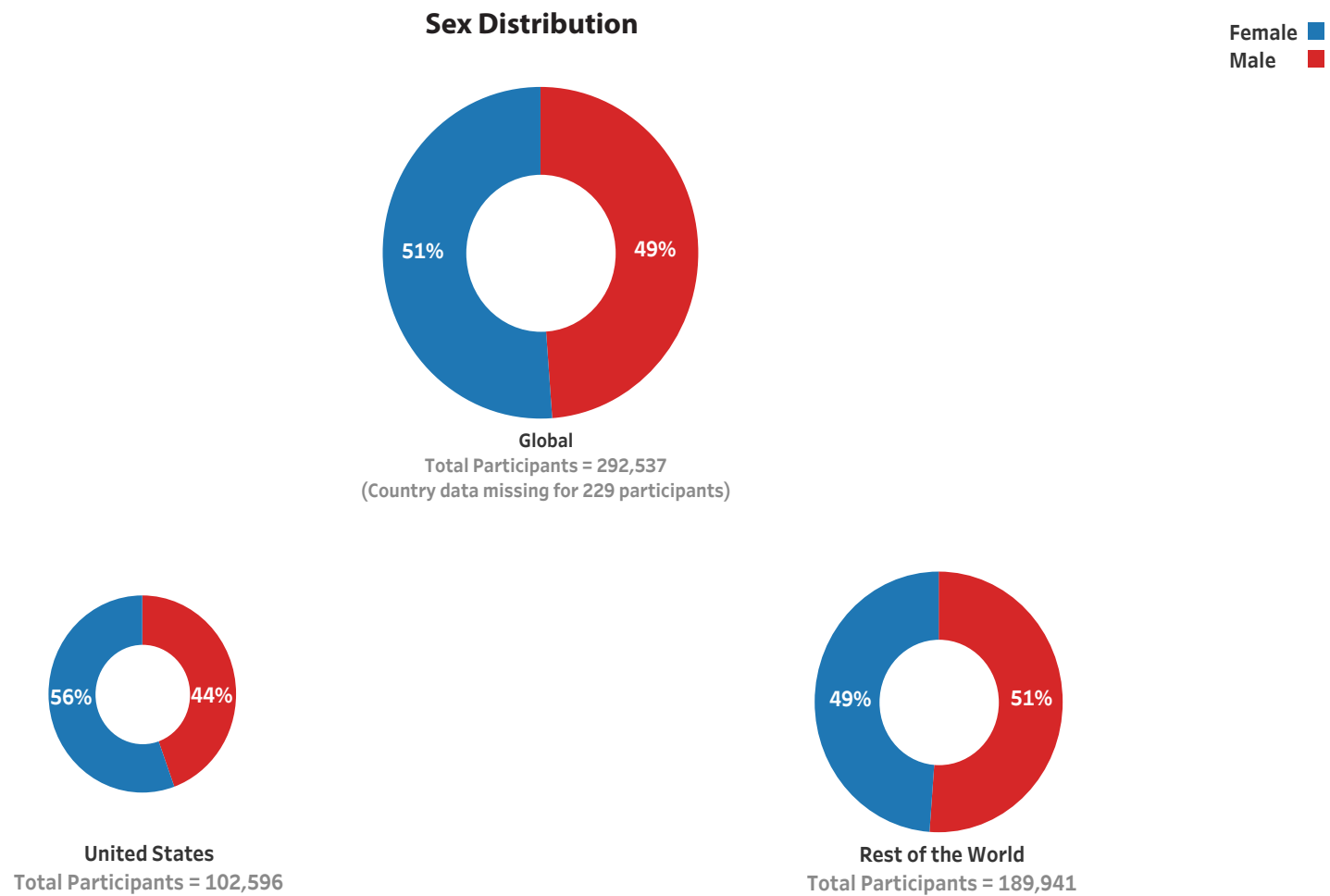
Hispanic or Latino ■
Not Hispanic or Latino ■
Missing ■

*Definitions for race and ethnicity used in the document can be found in the Terminology section.

Sex Composition

How Does Participation by Sex Differ by Geographic Location?

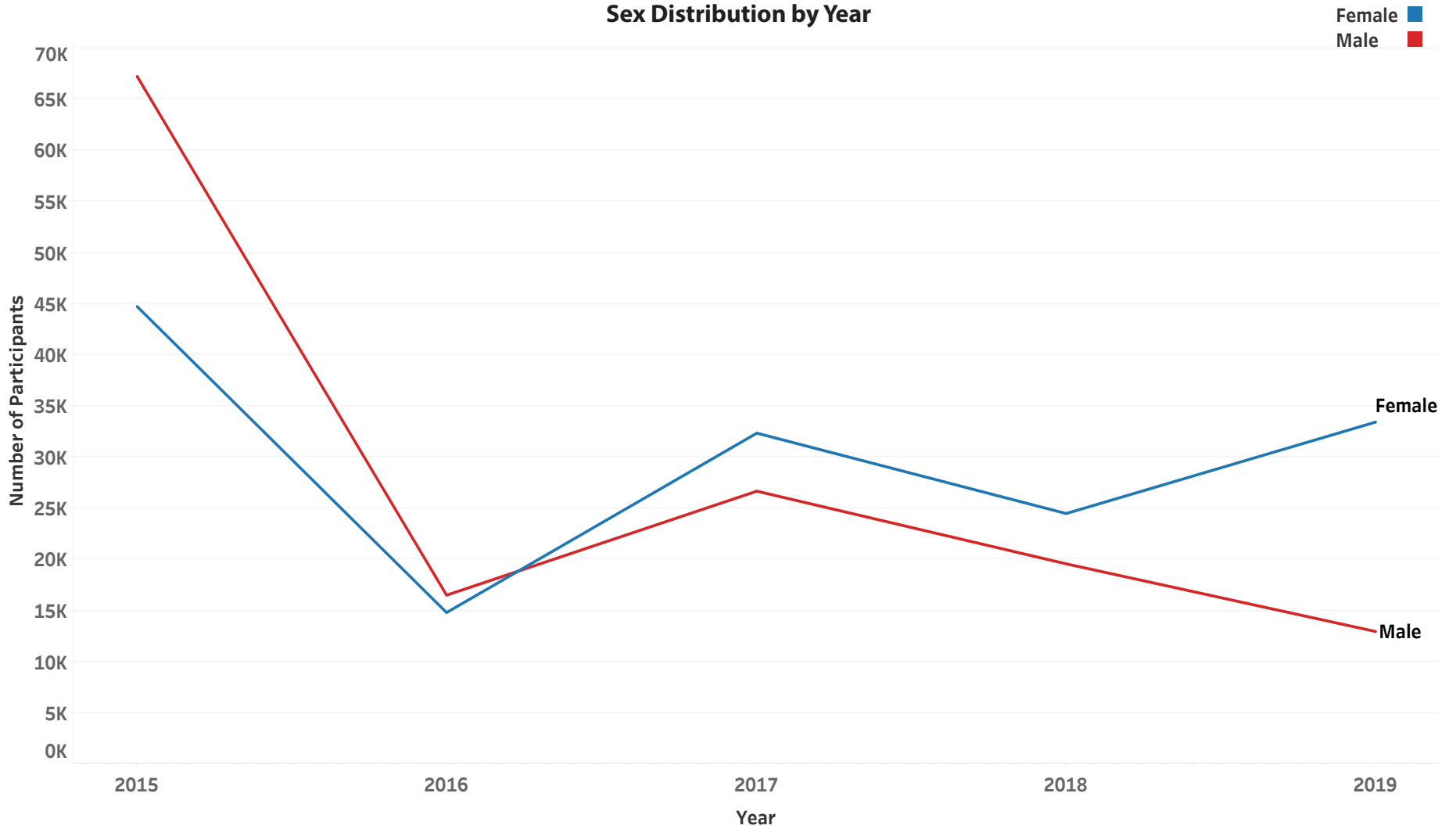
In the U.S., a greater number of females took part in the trials. World participation was more balanced.



Sex Composition

How Does Participation by Sex Differ Per Year?

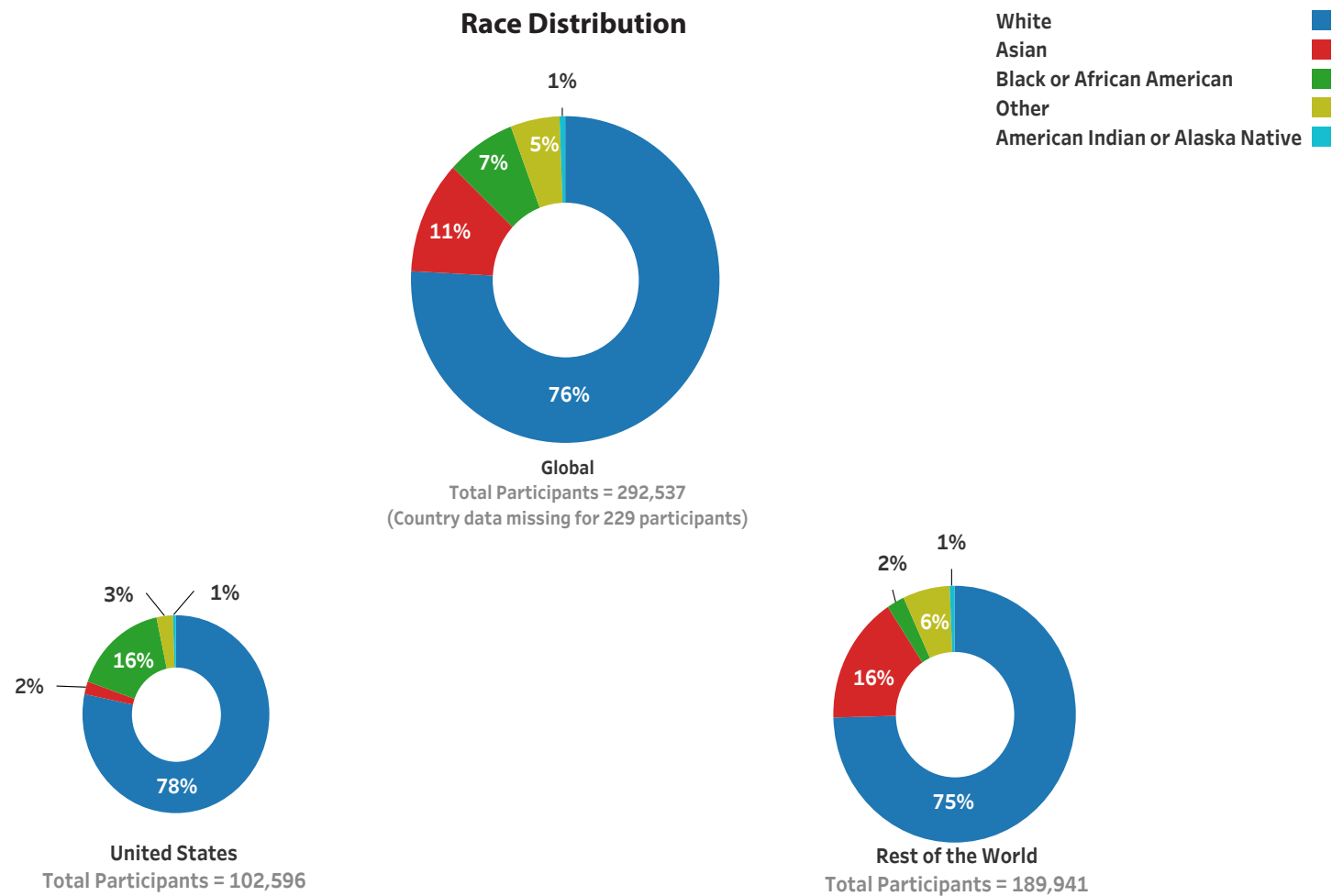
Sex Distribution by Year



Race Composition

How Does Participation by Race Differ by Geographic Location?

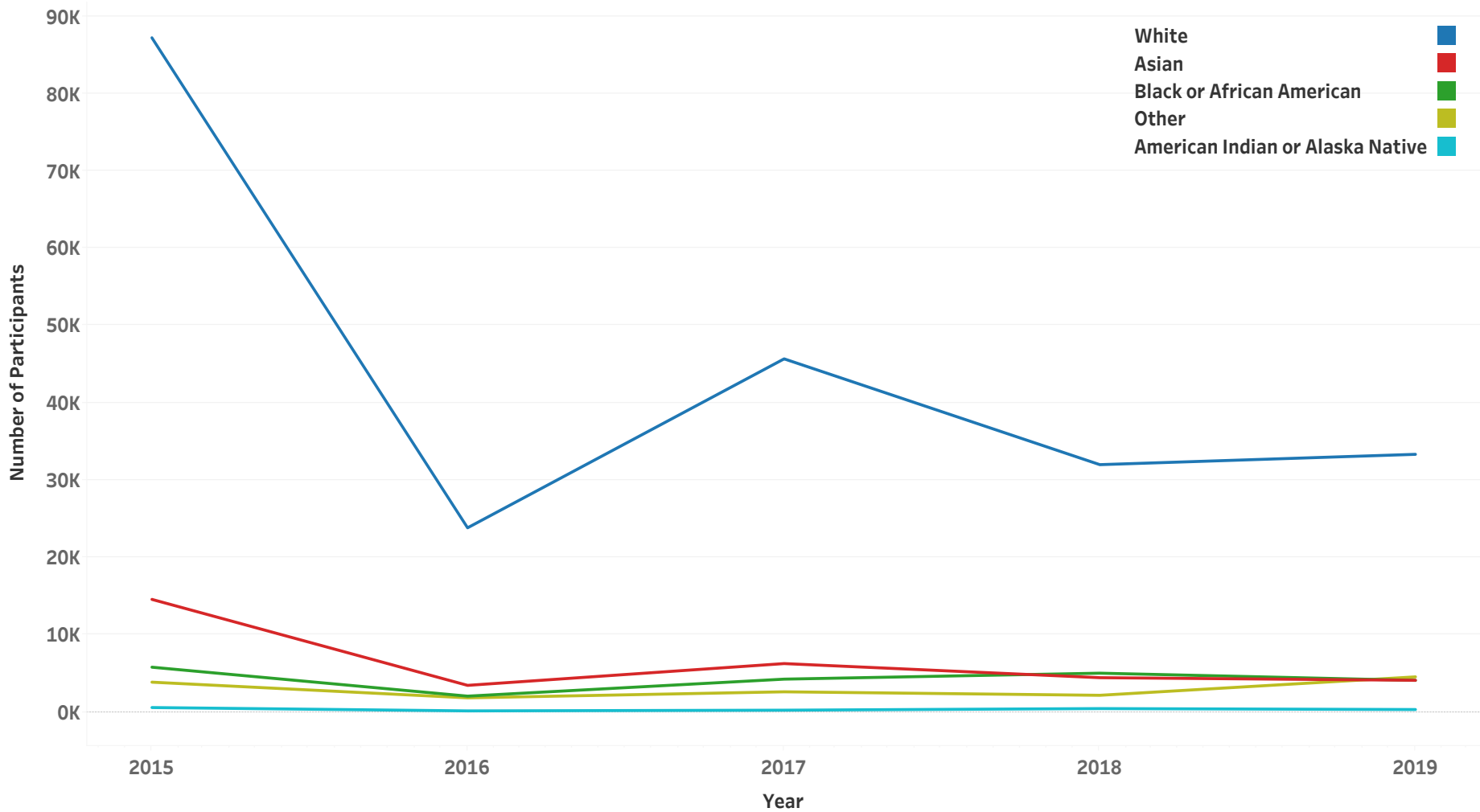
Most Asian trial participants were enrolled at non-U.S. sites; in contrast, most Black or African Americans were from U.S. sites.



Race Composition

How Does Participation by Race Differ Per Year?

Race Distribution by Year

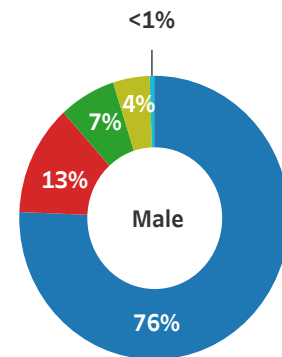
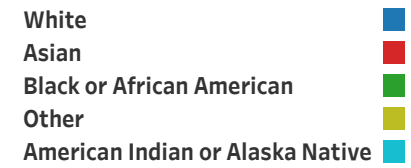
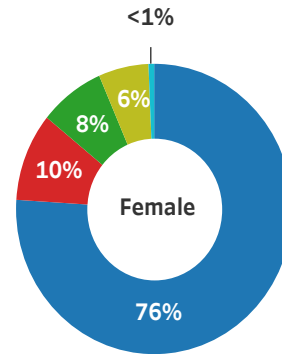


Race Composition

How Does Participation by Race Differ by Sex?

Race distribution between females and males was similar.

Race Distribution by Sex

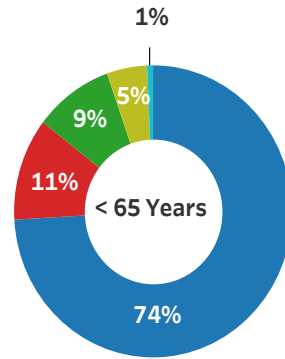


Race Composition

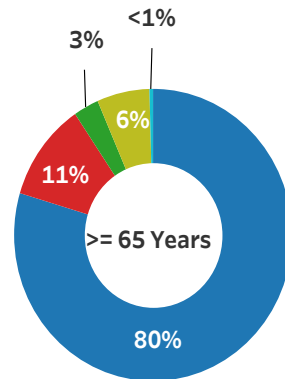
How Does Participation by Race Differ by Age?

Generally, race distribution by age was similar; however, the proportion of Black or African Americans in the 65-and-older age group is 6% lower.

Race Distribution by Age



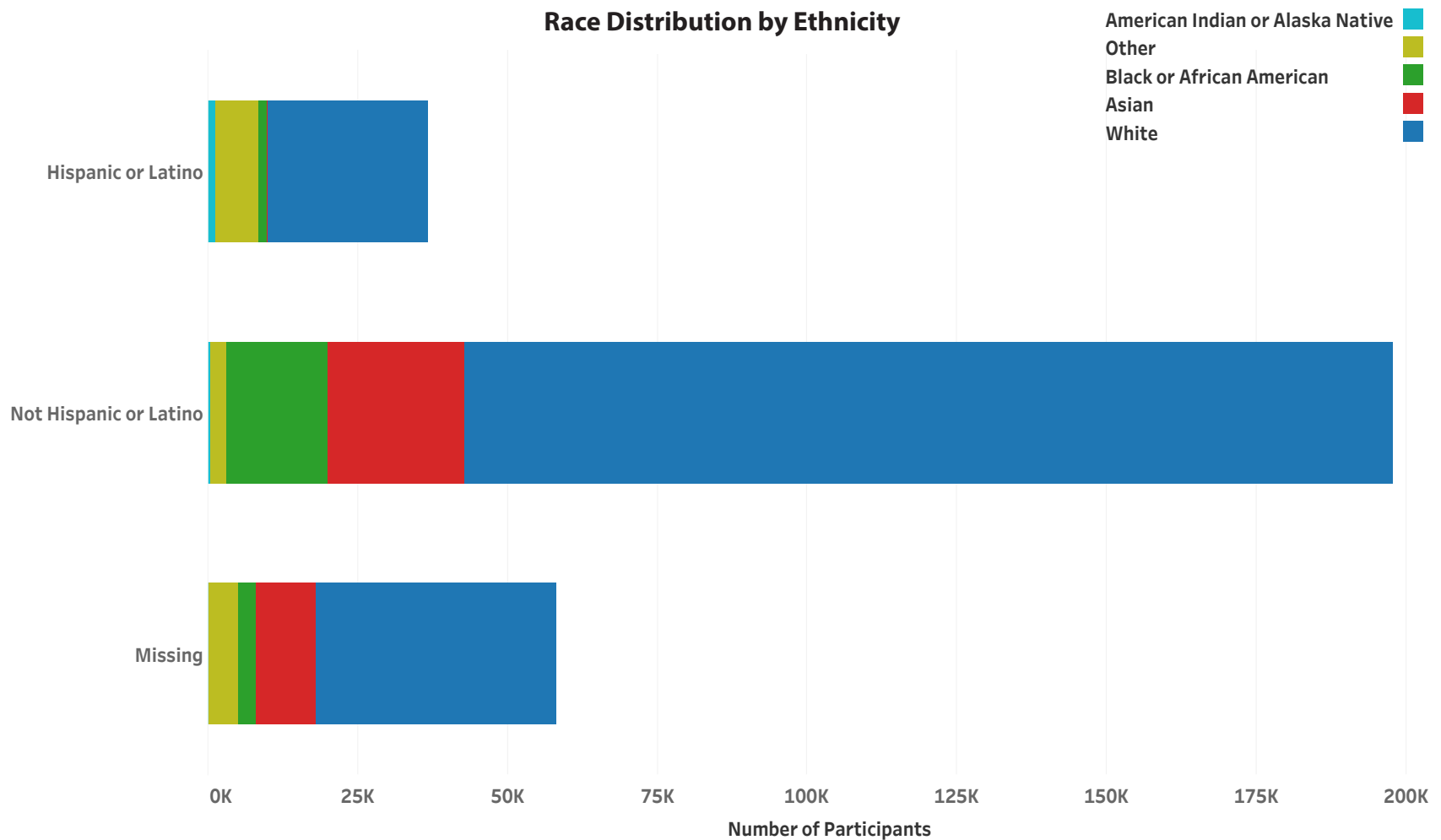
- White
- Asian
- Black or African American
- Other
- American Indian or Alaska Native



Race Composition

How Does Participation by Race Differ by Ethnicity?

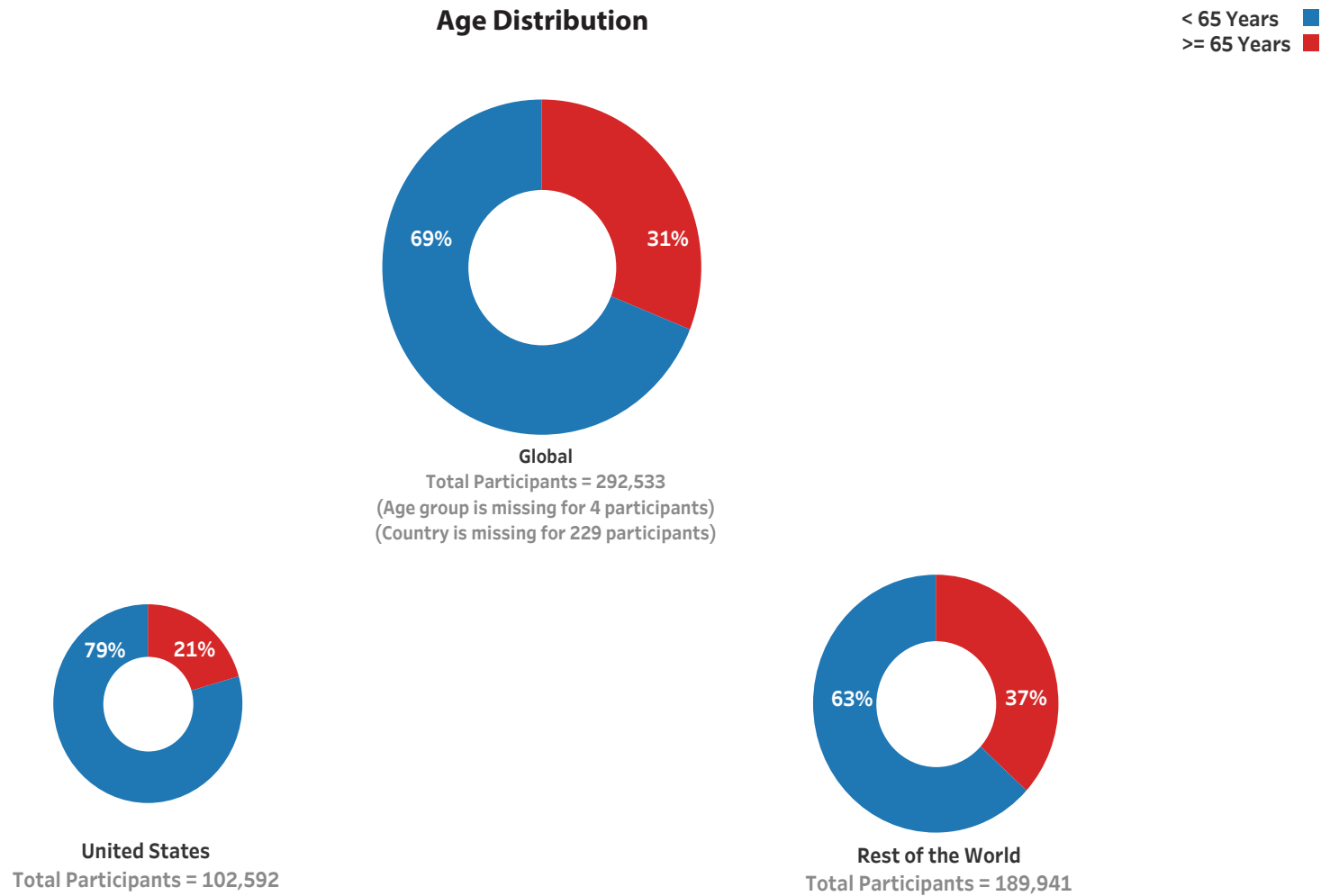
Overall, the majority of Hispanic or Latino participants identified their race as White or Other. In the Not Hispanic or Latino category, the majority of participants identified as White, Asian, and Black or African American.



Age Composition

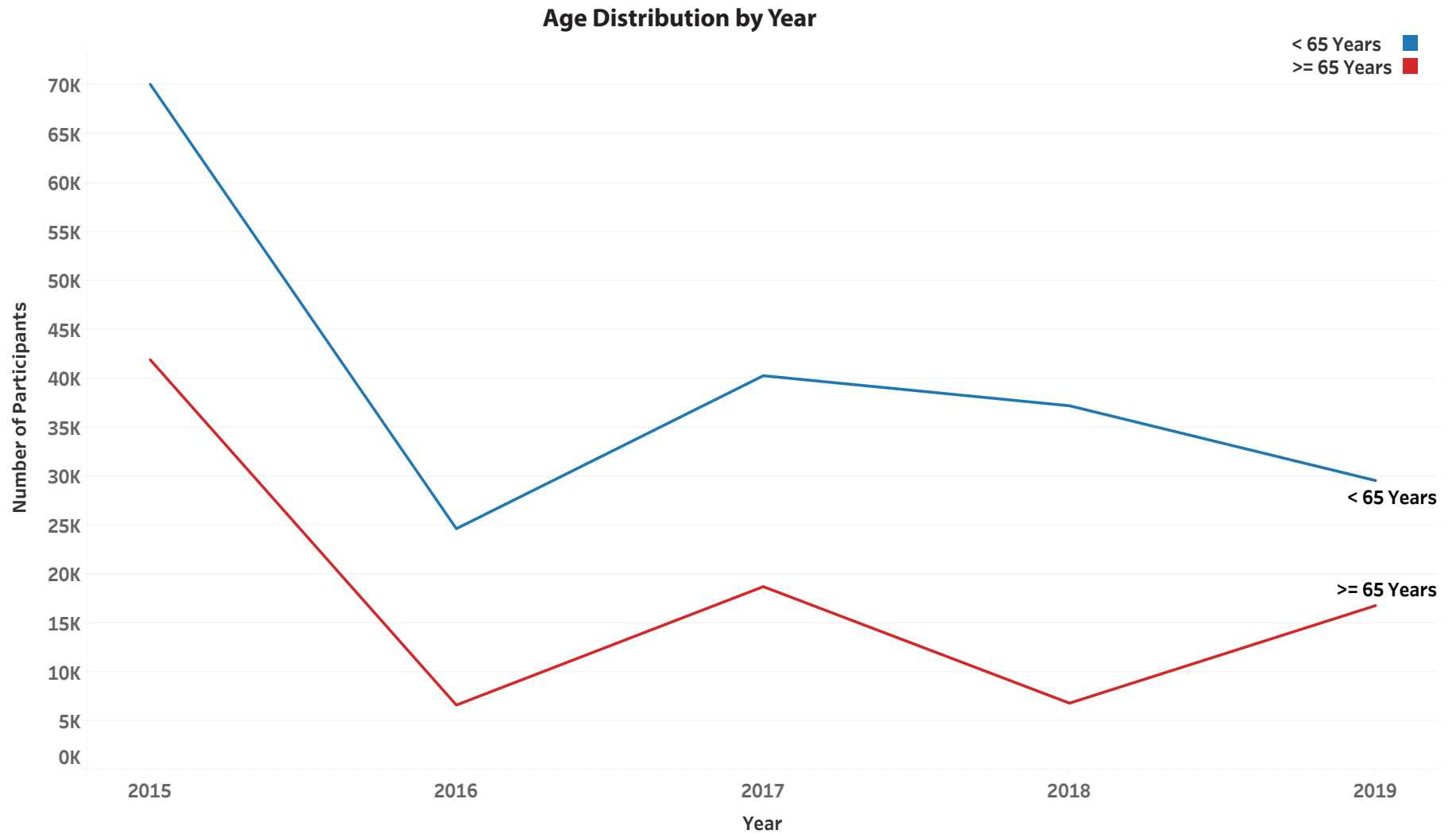
How Does Participation by Age Differ by Geographic Location?

Overall, the majority of trial participants were younger than 65 years of age. On average, participants in the U.S. tended to be younger than those in the rest of the world.



Age Composition

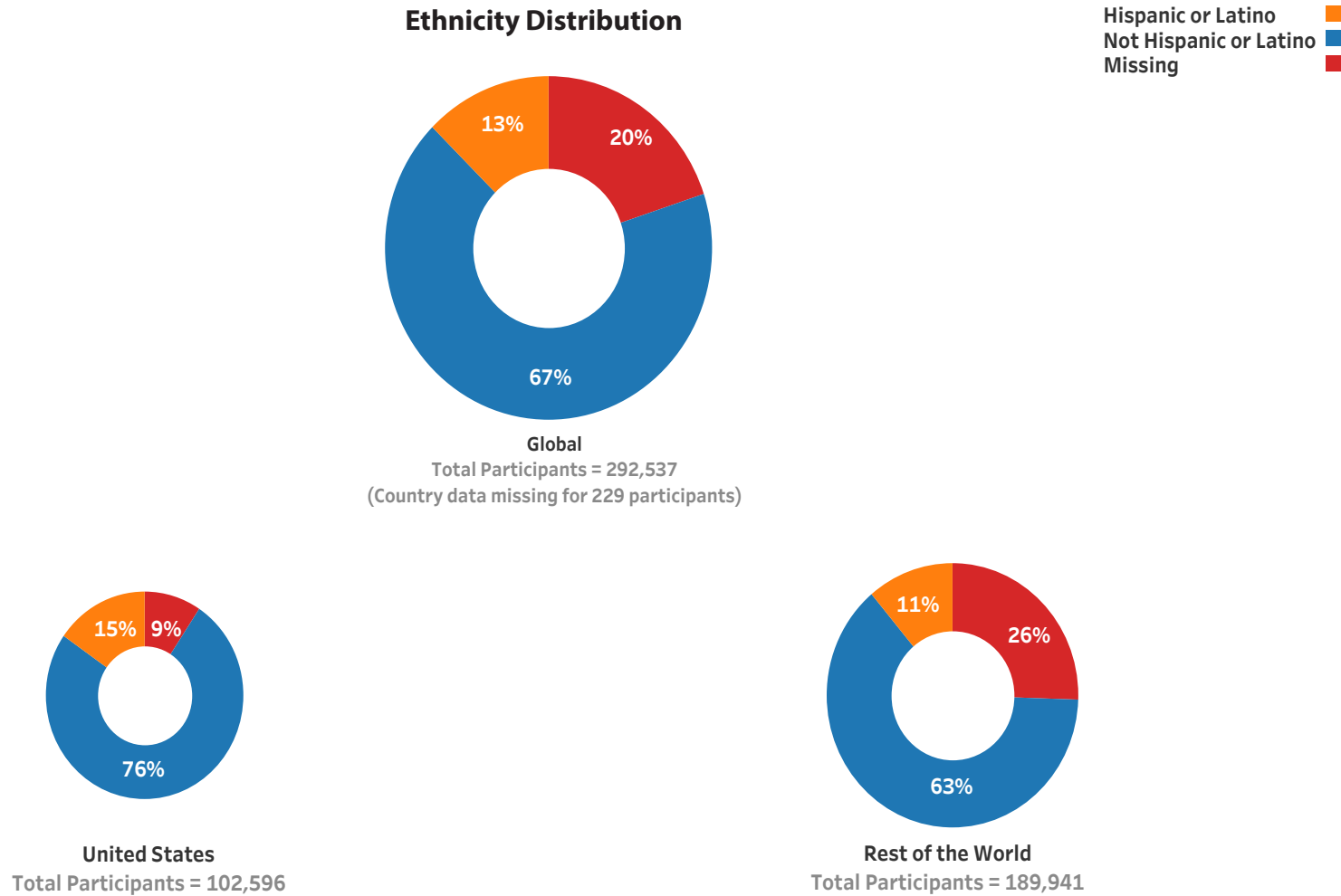
How Does Participation by Age Differ Per Year?



Ethnicity Composition

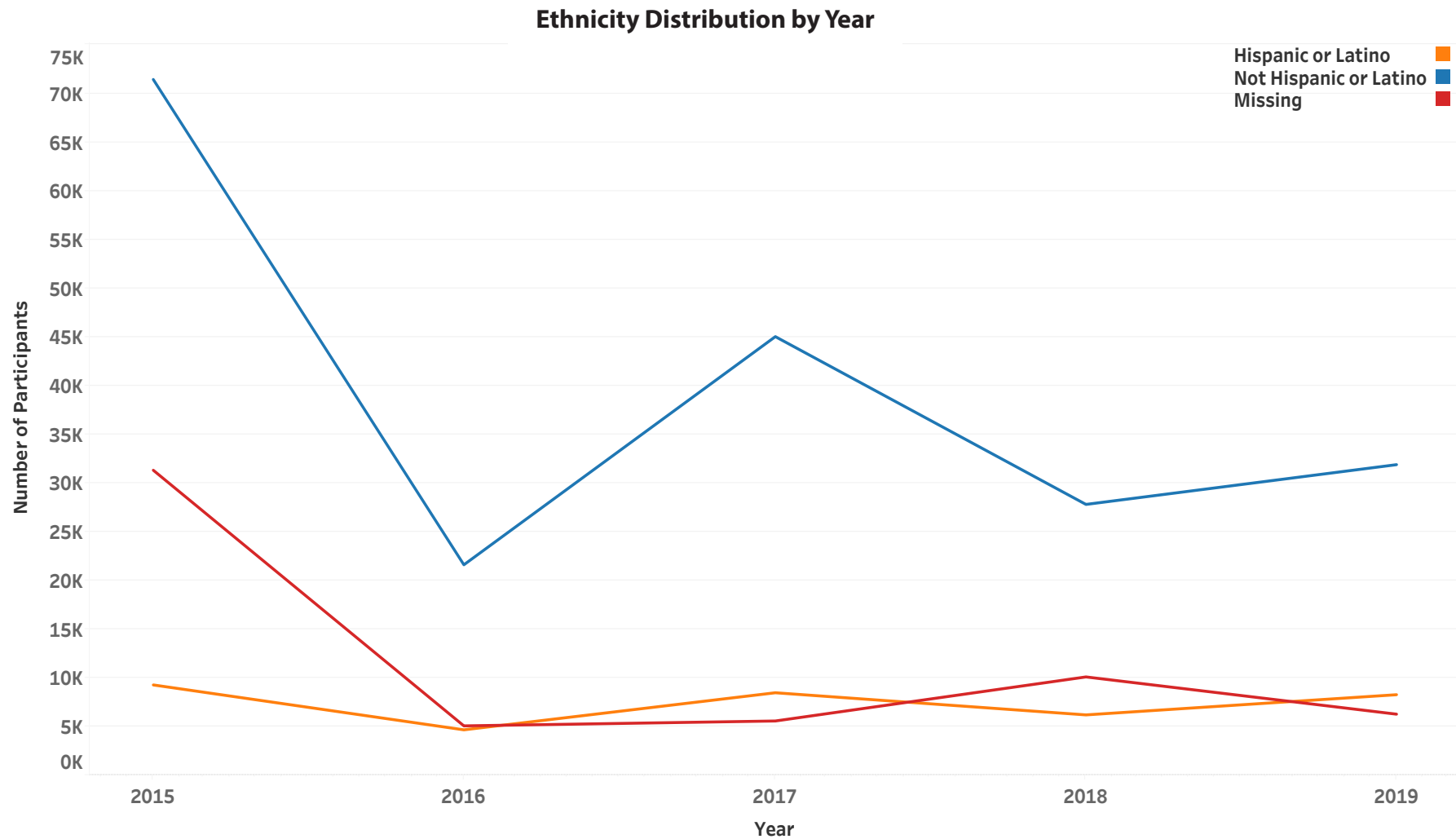
How Does Participation by Ethnicity Differ by Geographic Location?

The highest proportion of Hispanics (15%) was reported by participants from the U.S.



Ethnicity Composition

How Does Participation by Ethnicity Differ Per Year?



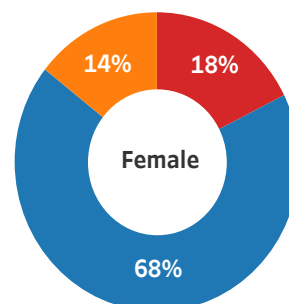
Ethnicity Composition

How Does the Ethnicity Distribution of Trial Participation Differ by Sex?

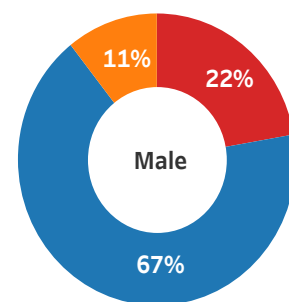
The female Hispanic or Latino population was 3% higher than the male Hispanic or Latino population.

Ethnicity Distribution by Sex

Hispanic or Latino ■
Not Hispanic or Latino ■
Missing ■



Female Participants = 149,820

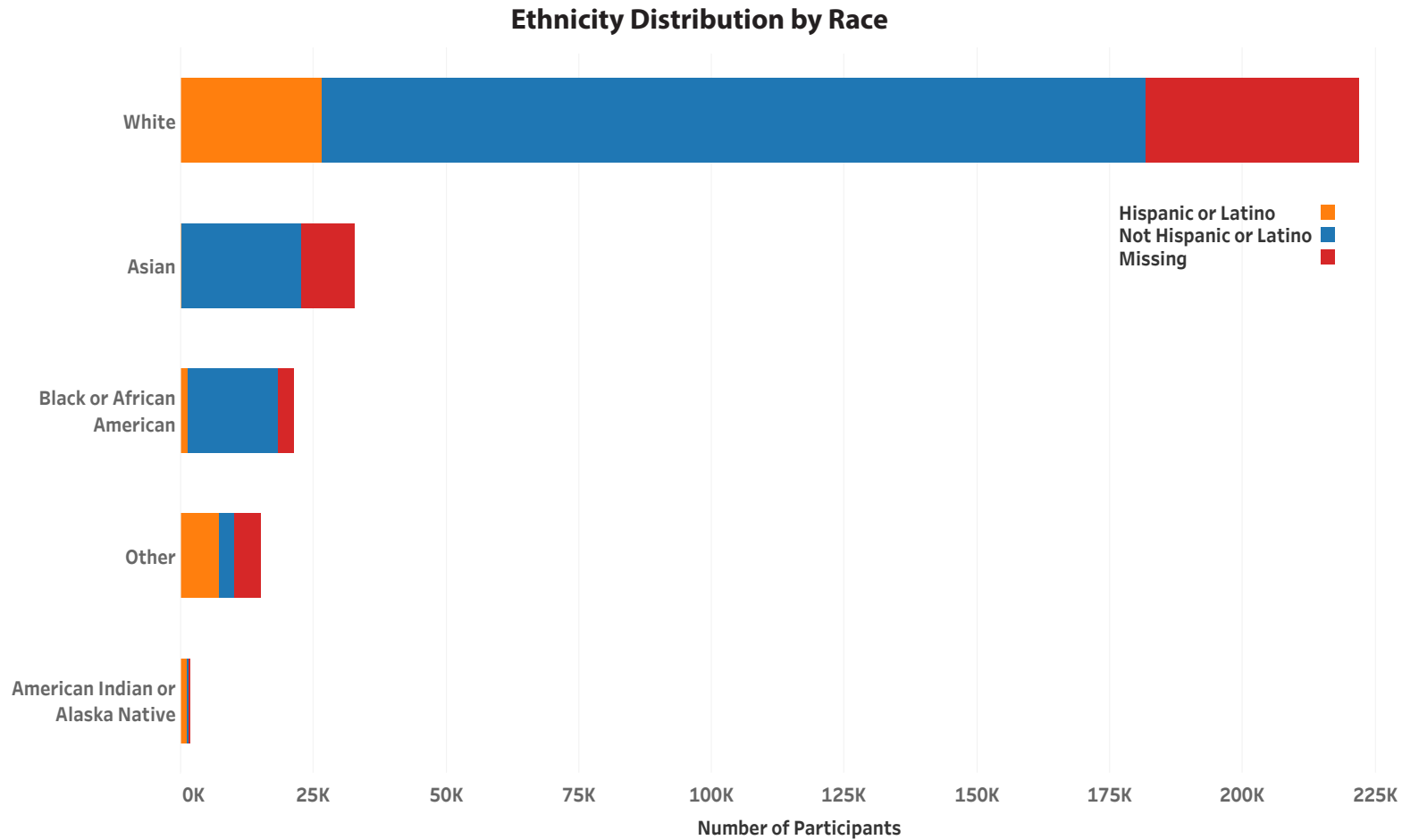


Male Participants = 142,946

Ethnicity Composition

How Does the Ethnicity Distribution of Trial Participation Differ by Race?

The White category had the highest number of Hispanic and Latino participants, while the Asian category had the lowest number of Hispanic or Latino participants. In addition, the American Indian or Alaska Native category had the highest proportion of Hispanic or Latino participants, due primarily to the high number of American Indians from South America.



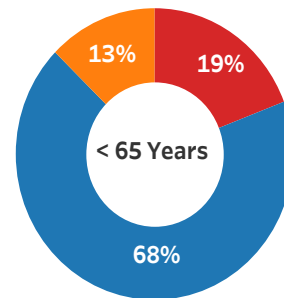
Ethnicity Composition

How Does the Ethnicity Distribution of Trial Participation Differ by Age?

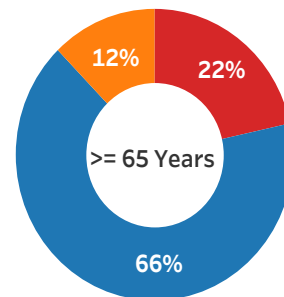
Hispanic or Latino participation was similar across age categories.

Ethnicity Distribution by Age

Hispanic or Latino ■
Not Hispanic or Latino ■
Missing ■



< 65 Participants = 201,819



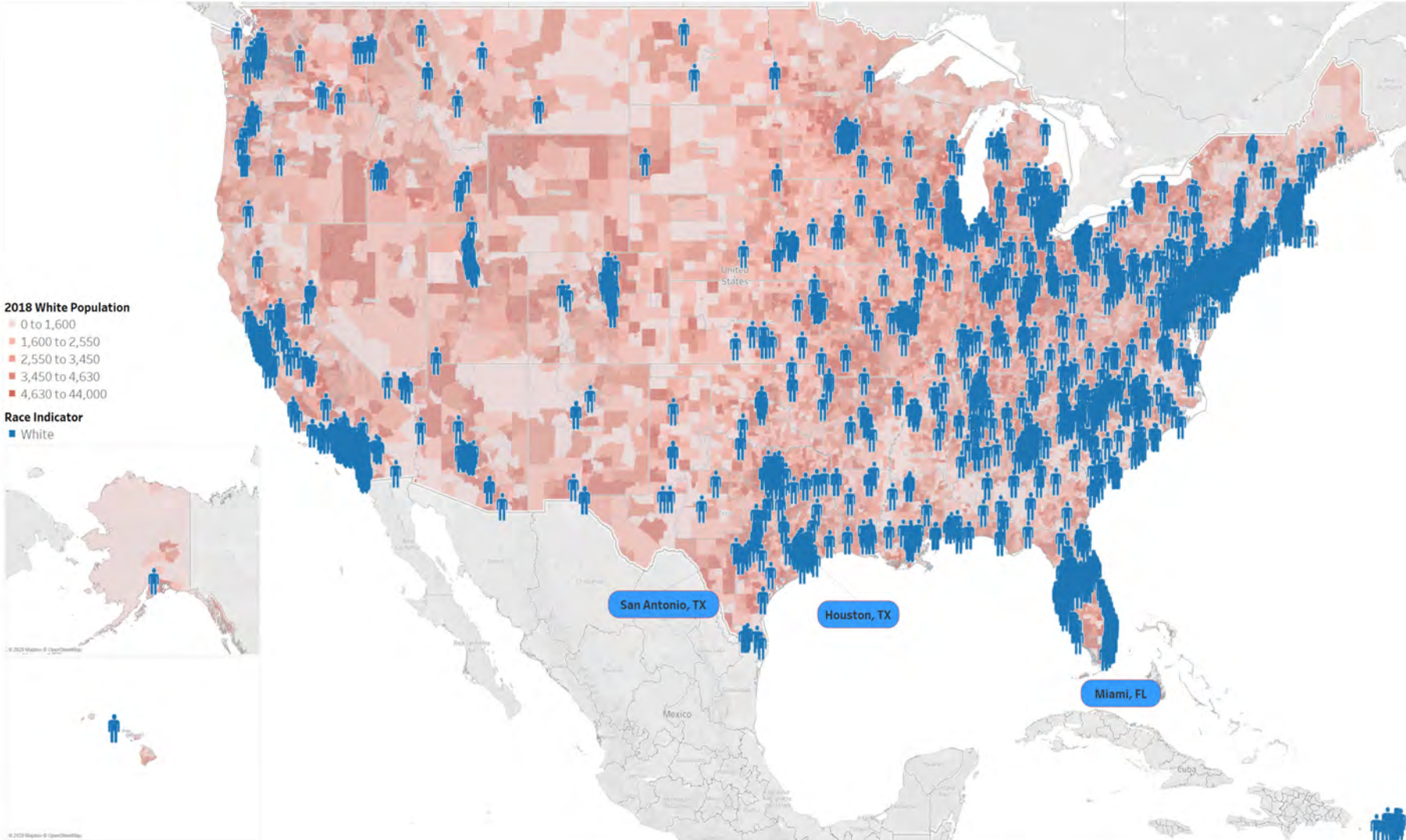
>= 65 Participants = 90,943



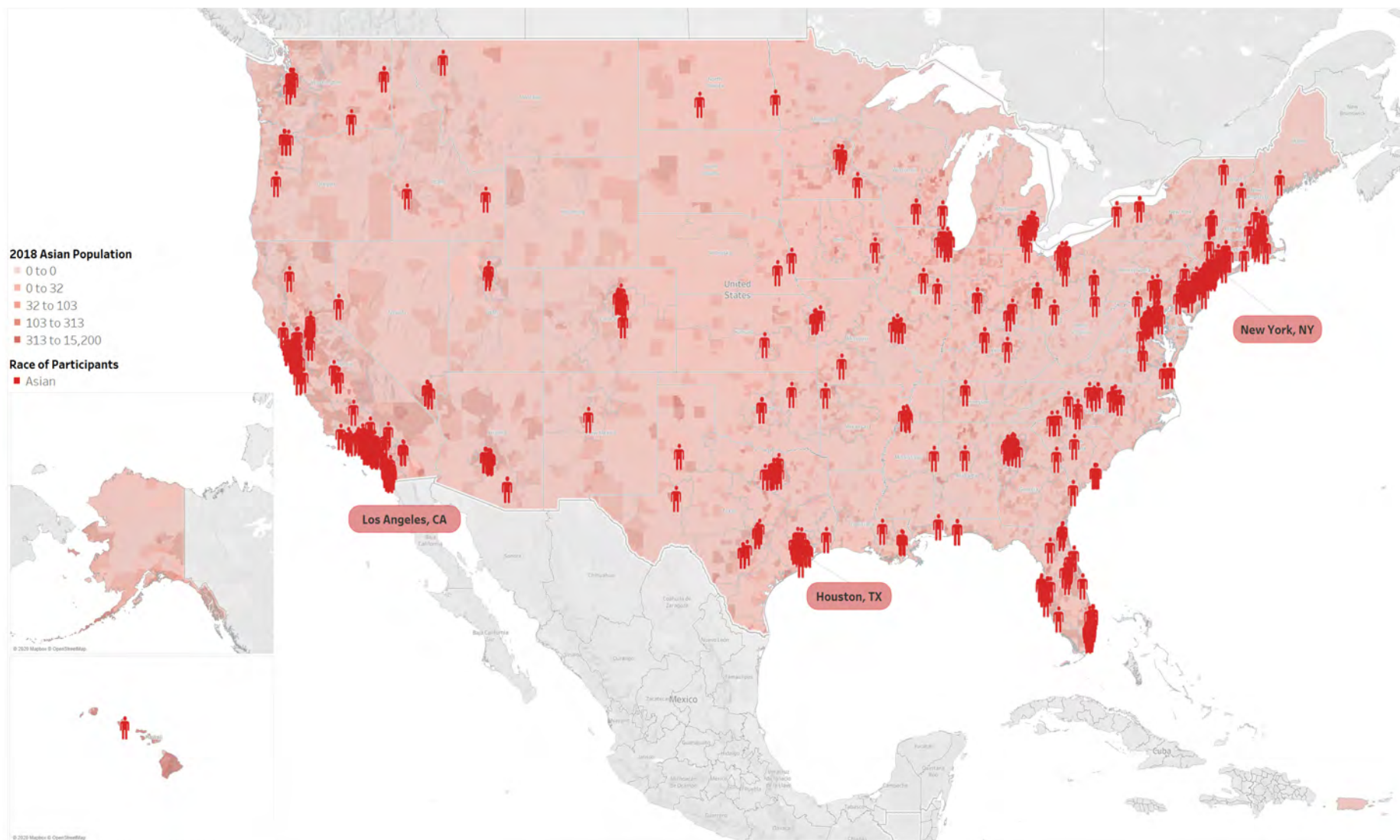
U.S. Clinical Trial Participant Distribution by Race and Ethnicity Categories

The following maps show where participants of different races and ethnicities were enrolled within the United States. The background of each map represents the population distribution for the respective categories, based on 2018 U.S. Census data and one stick figure icon represents one zip code. Each map highlights the top three cities with the greatest numbers of trial participants.

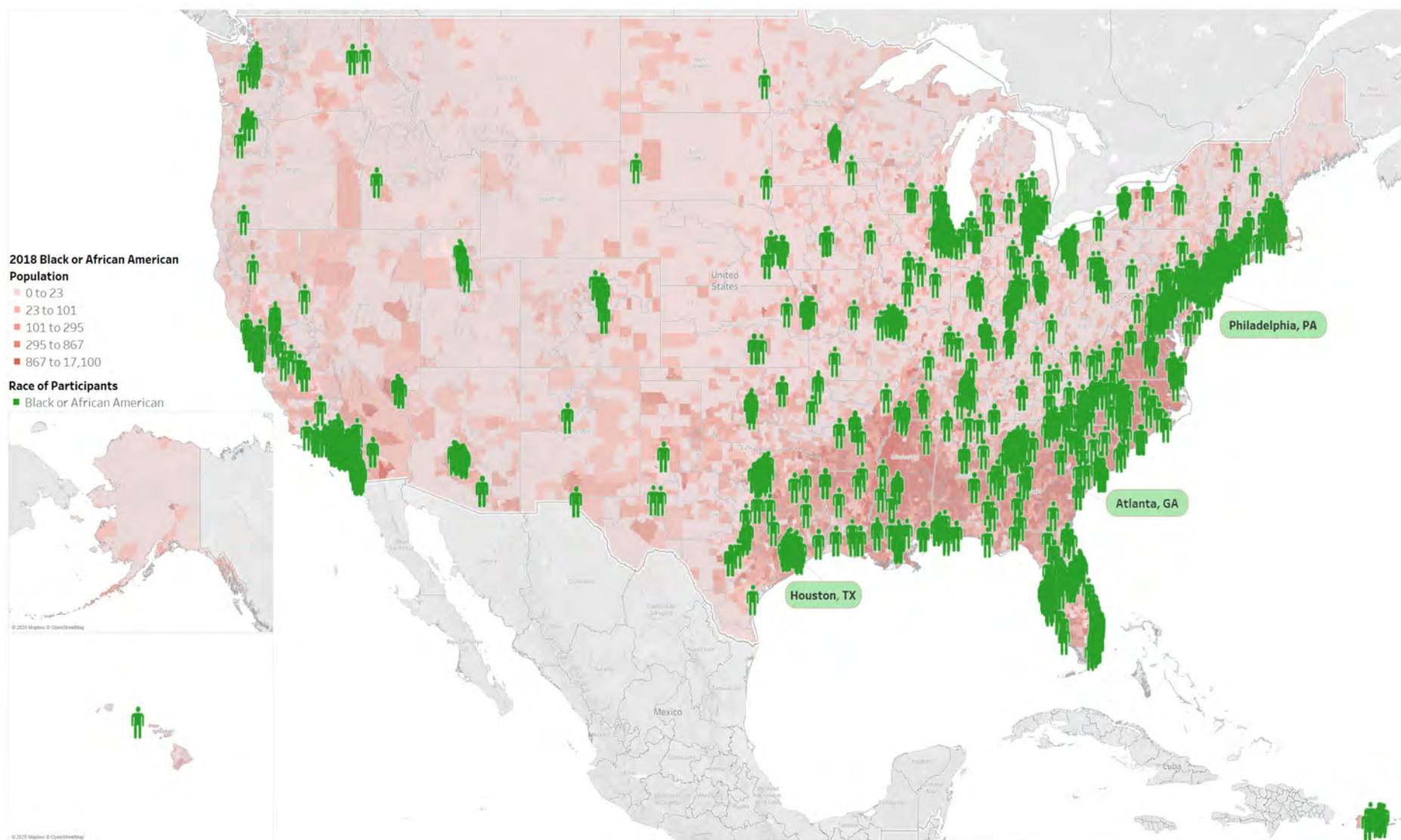
Distribution of White Trial Participants



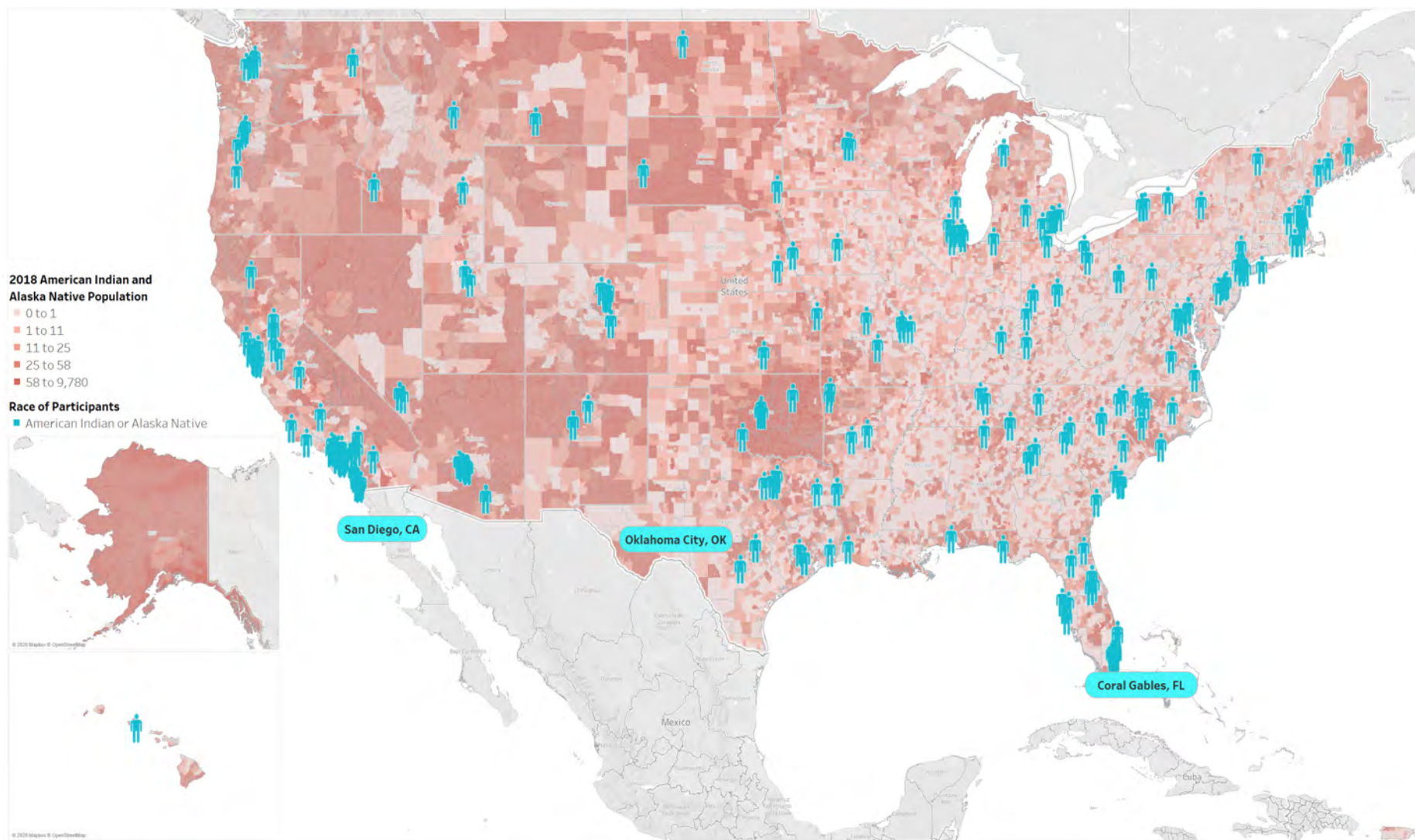
Distribution of Asian Trial Participants



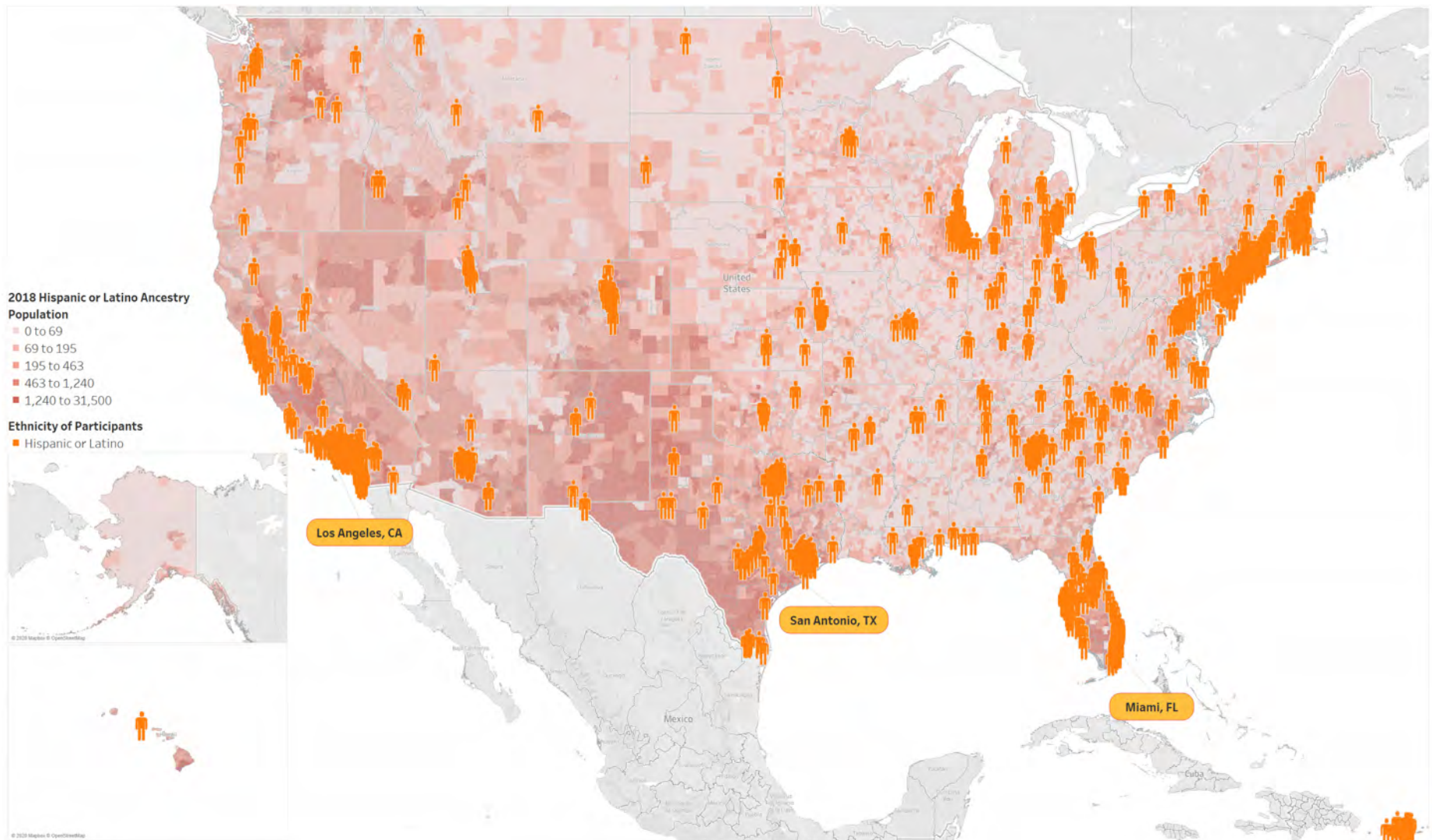
Distribution of Black or African American Trial Participants



Distribution of American Indian and Alaska Native Trial Participants

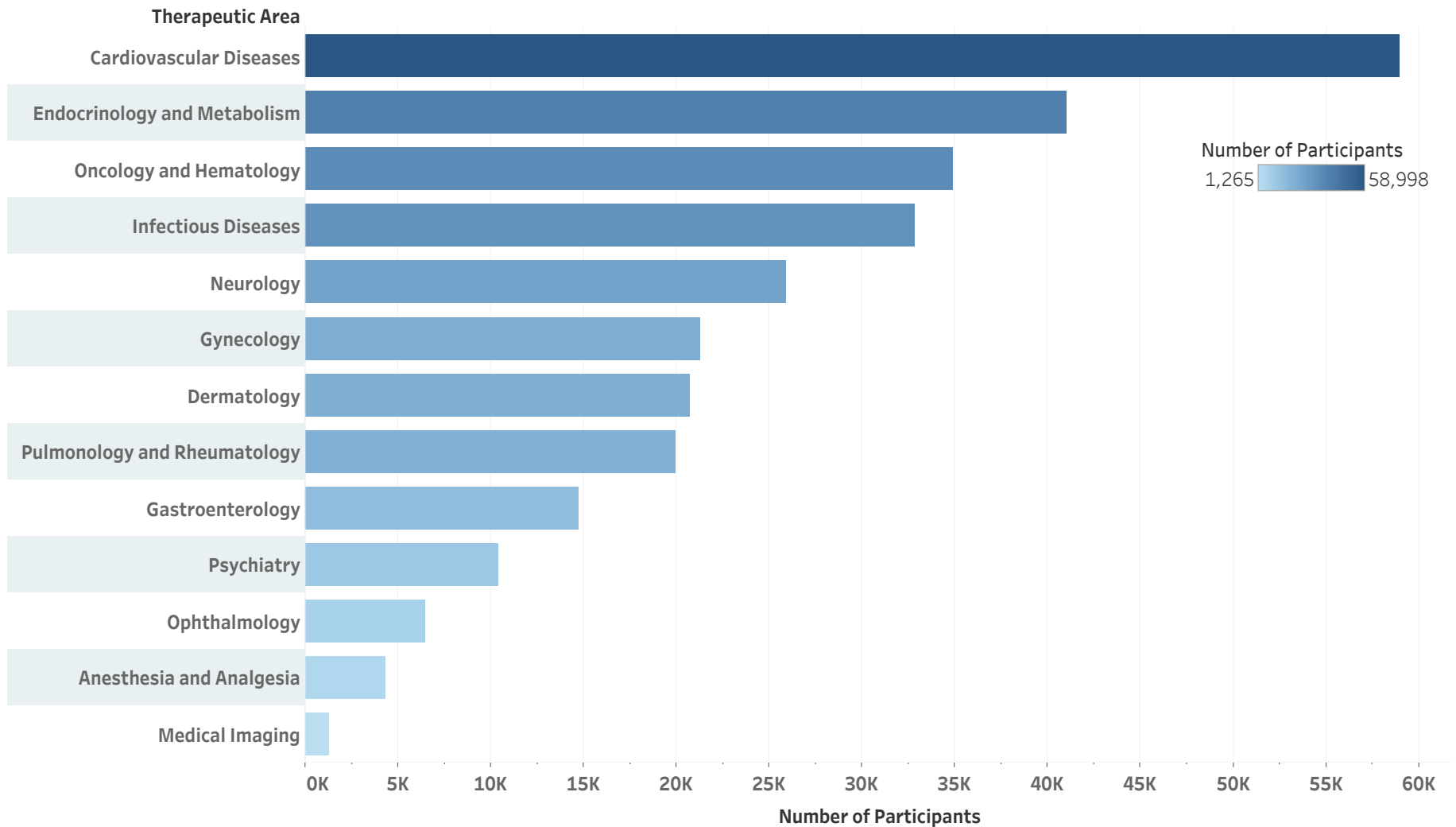


Distribution of Hispanic or Latino Trial Participants

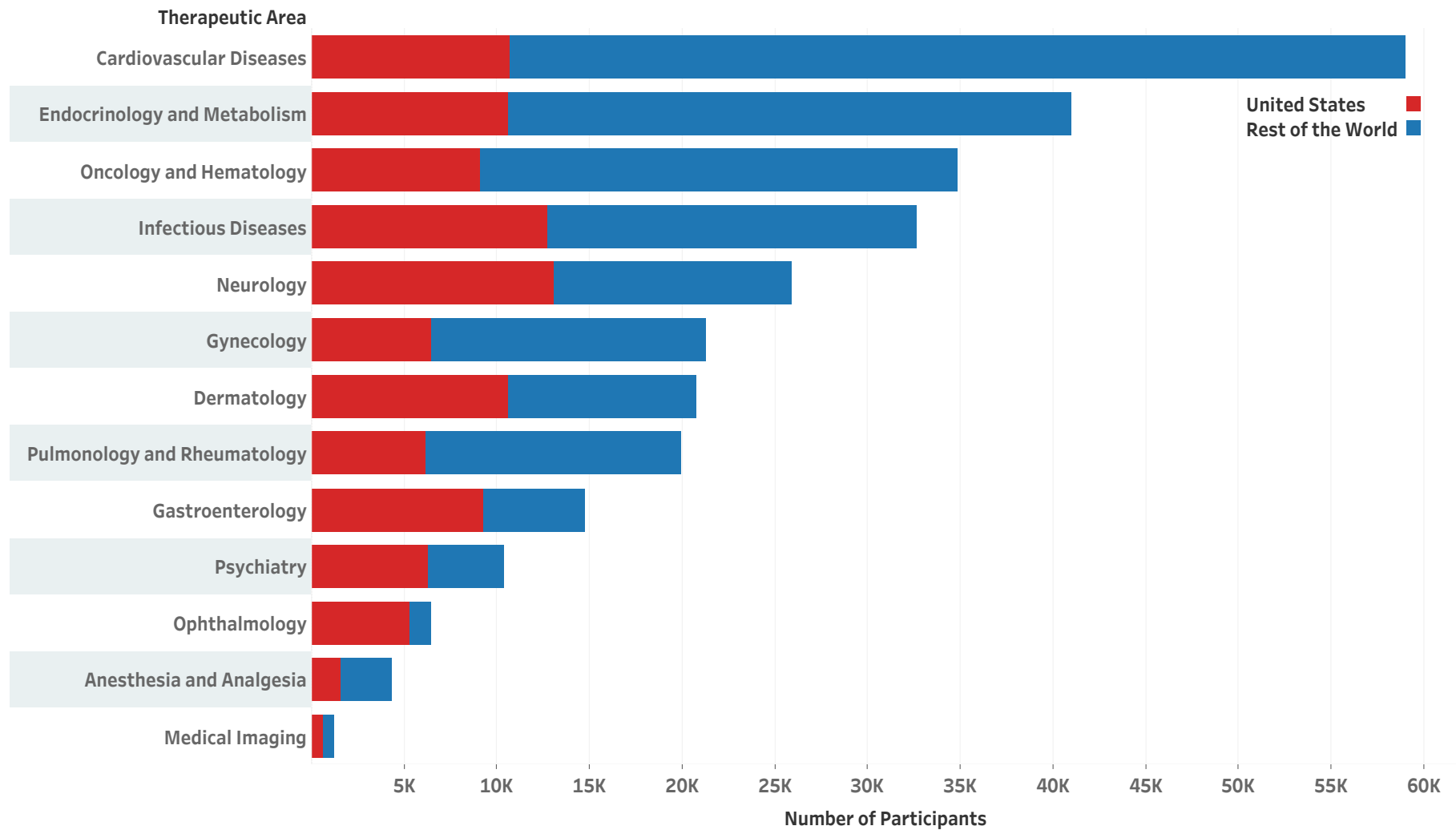


Clinical Trial Participation by Therapeutic Area

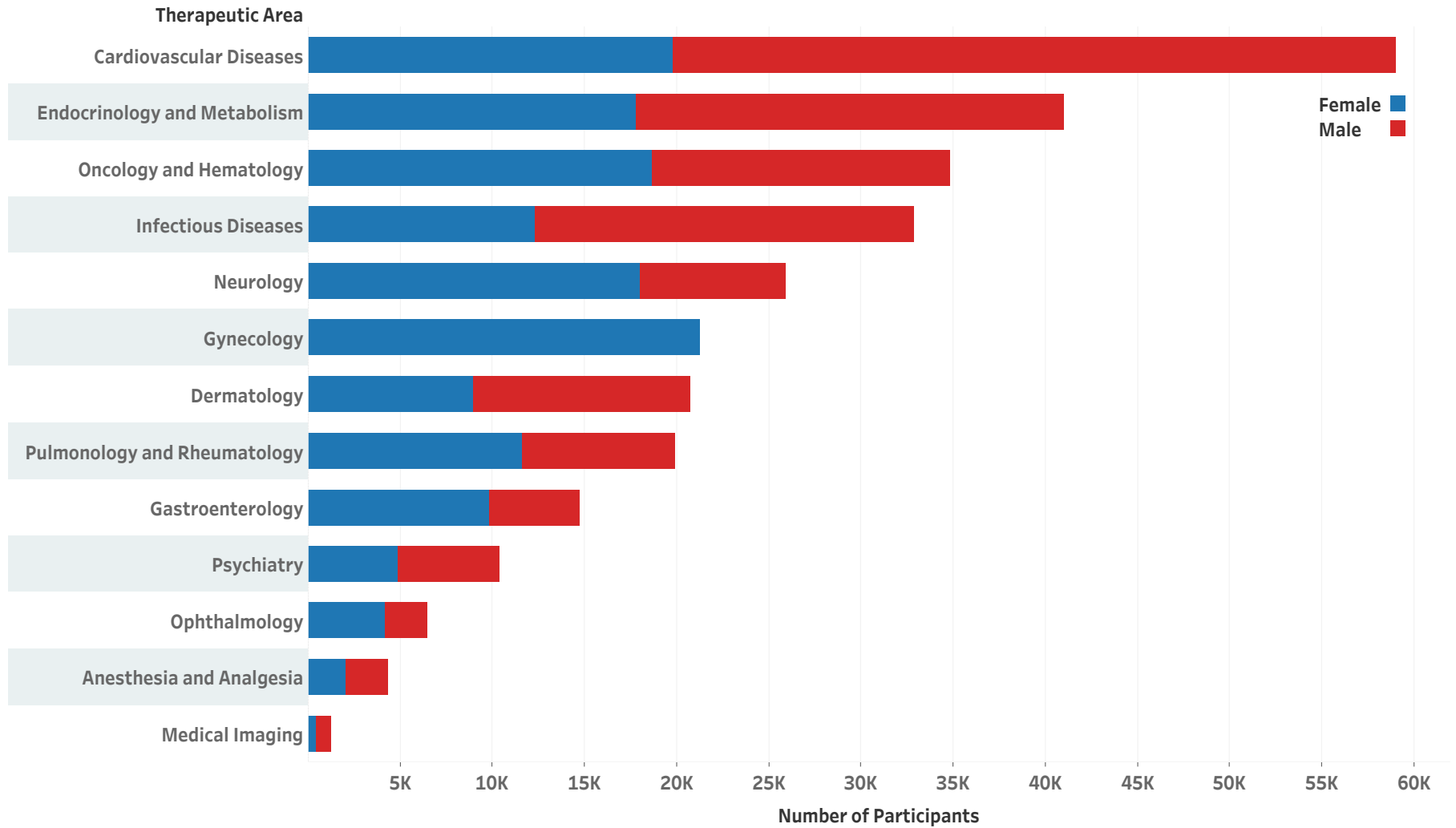
The graph below summarizes the therapeutic areas in descending order of the number of clinical trial participants. Subsequent graphs show demographic categories within each of the therapeutic areas.



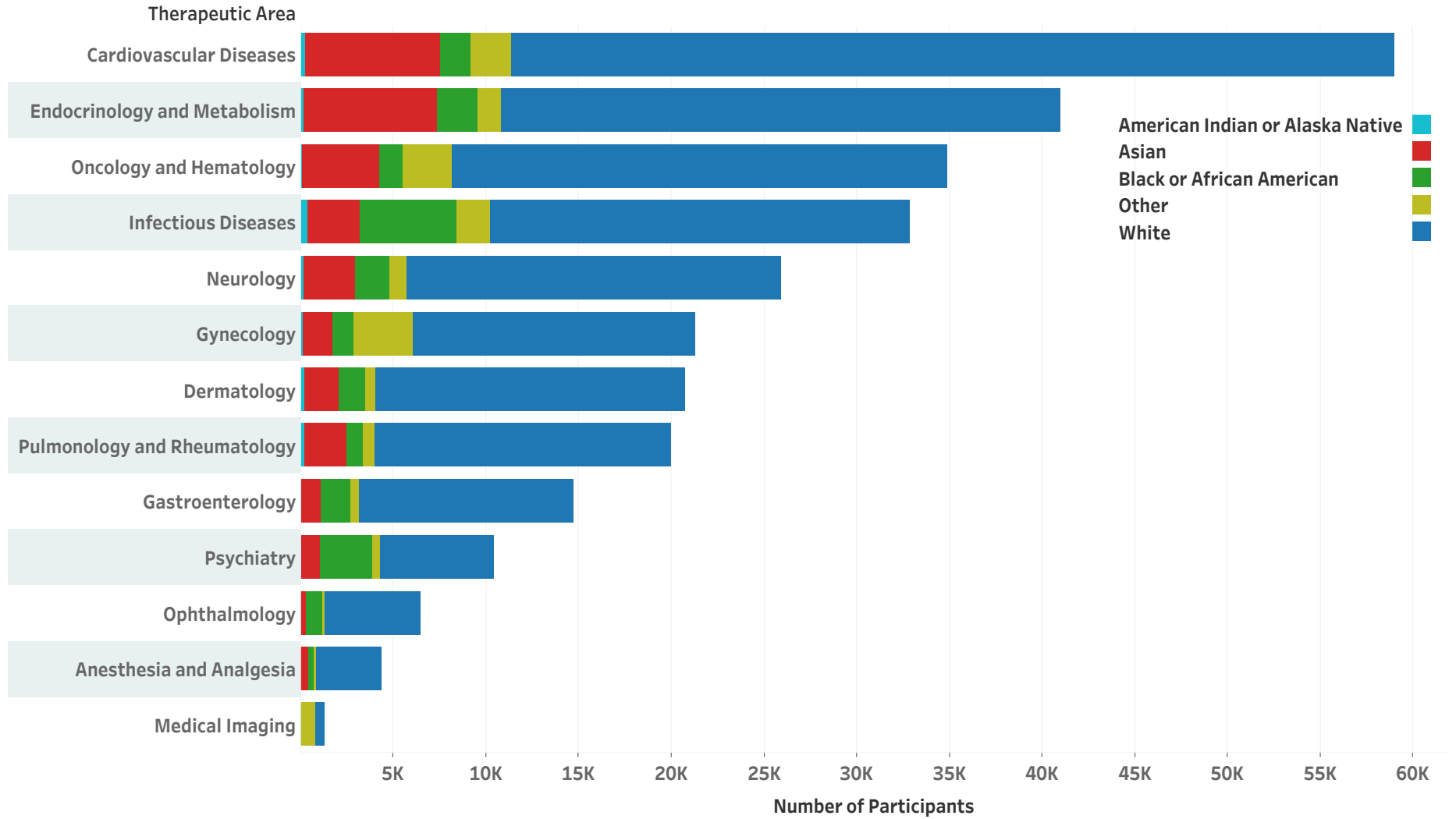
Geographic Breakdown Across Therapeutic Areas



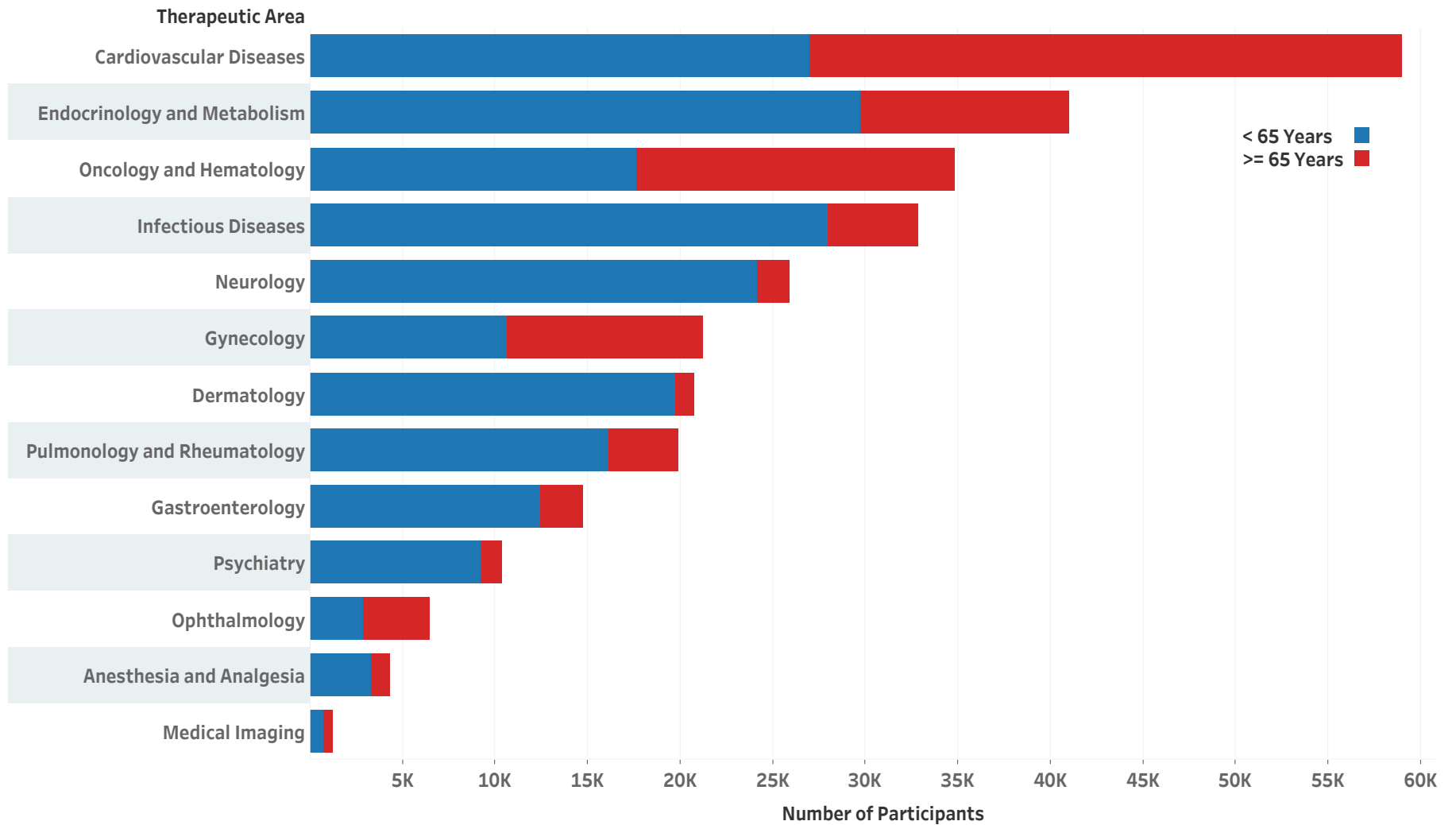
Sex Breakdown Across Therapeutic Areas



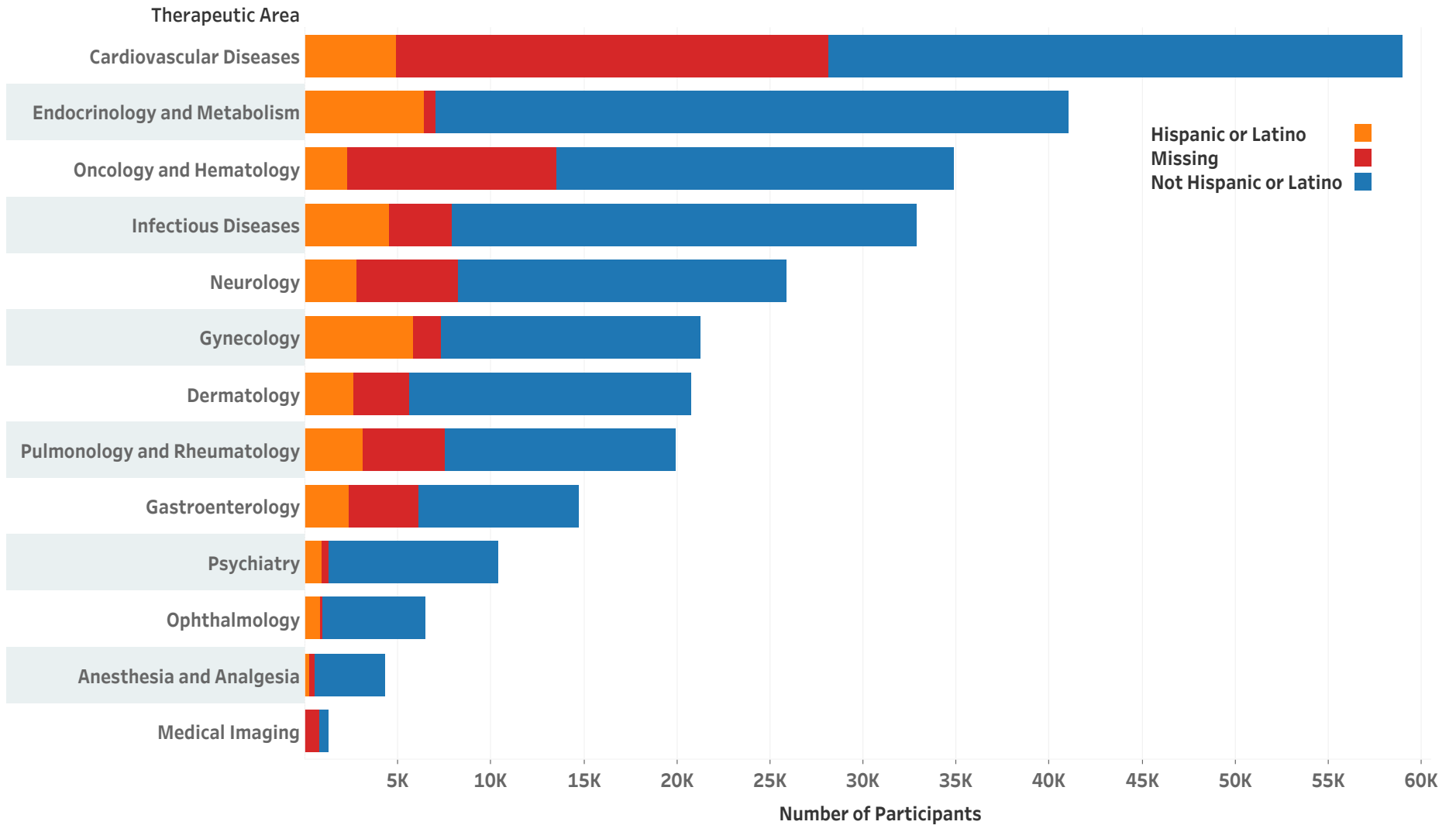
Race Breakdown Across Therapeutic Areas



Age Breakdown Across Therapeutic Areas



Ethnicity Breakdown Across Therapeutic Areas



Sex, Race, and Age Participation by Therapeutic Area

Presented below is the cross-section of sex, race, and age categories in therapeutic areas with the highest numbers of participants.

| | | Cardiovascular Diseases | | Endocrinology and Metabolism | | Oncology and Hematology | | Infectious Diseases | | Neurology | |
|-------------|----------------------------------|-------------------------|-------------|------------------------------|-------------|-------------------------|-------------|---------------------|-------------|------------|-------------|
| | | < 65 Years | >= 65 Years | < 65 Years | >= 65 Years | < 65 Years | >= 65 Years | < 65 Years | >= 65 Years | < 65 Years | >= 65 Years |
| Male | White | 79% | 84% | 72% | 79% | 71% | 82% | 67% | 83% | 75% | 51% |
| | Asian | 14% | 11% | 20% | 15% | 14% | 9% | 9% | 7% | 14% | 47% |
| | Black or African American | 3% | 2% | 5% | 3% | 5% | 2% | 17% | 8% | 5% | 1% |
| | Other | 4% | 3% | 3% | 3% | 10% | 7% | 6% | 1% | 5% | <1% |
| | American Indian | <1% | <1% | <1% | <1% | <1% | <1% | 1% | 1% | 1% | <1% |

| | | Cardiovascular Diseases | | Endocrinology and Metabolism | | Oncology and Hematology | | Infectious Diseases | | Neurology | |
|---------------|----------------------------------|-------------------------|-------------|------------------------------|-------------|-------------------------|-------------|---------------------|-------------|------------|-------------|
| | | < 65 Years | >= 65 Years | < 65 Years | >= 65 Years | < 65 Years | >= 65 Years | < 65 Years | >= 65 Years | < 65 Years | >= 65 Years |
| Female | White | 73% | 84% | 71% | 78% | 70% | 85% | 65% | 83% | 82% | 56% |
| | Asian | 16% | 10% | 17% | 14% | 16% | 8% | 9% | 8% | 6% | 41% |
| | Black or African American | 6% | 2% | 7% | 5% | 5% | 2% | 18% | 6% | 8% | 2% |
| | Other | 5% | 4% | 4% | 3% | 9% | 5% | 7% | 2% | 3% | 1% |
| | American Indian | <1% | <1% | 1% | <1% | <1% | <1% | 1% | 1% | 1% | 0% |

Sex, Ethnicity, and Age Distribution by Therapeutic Area

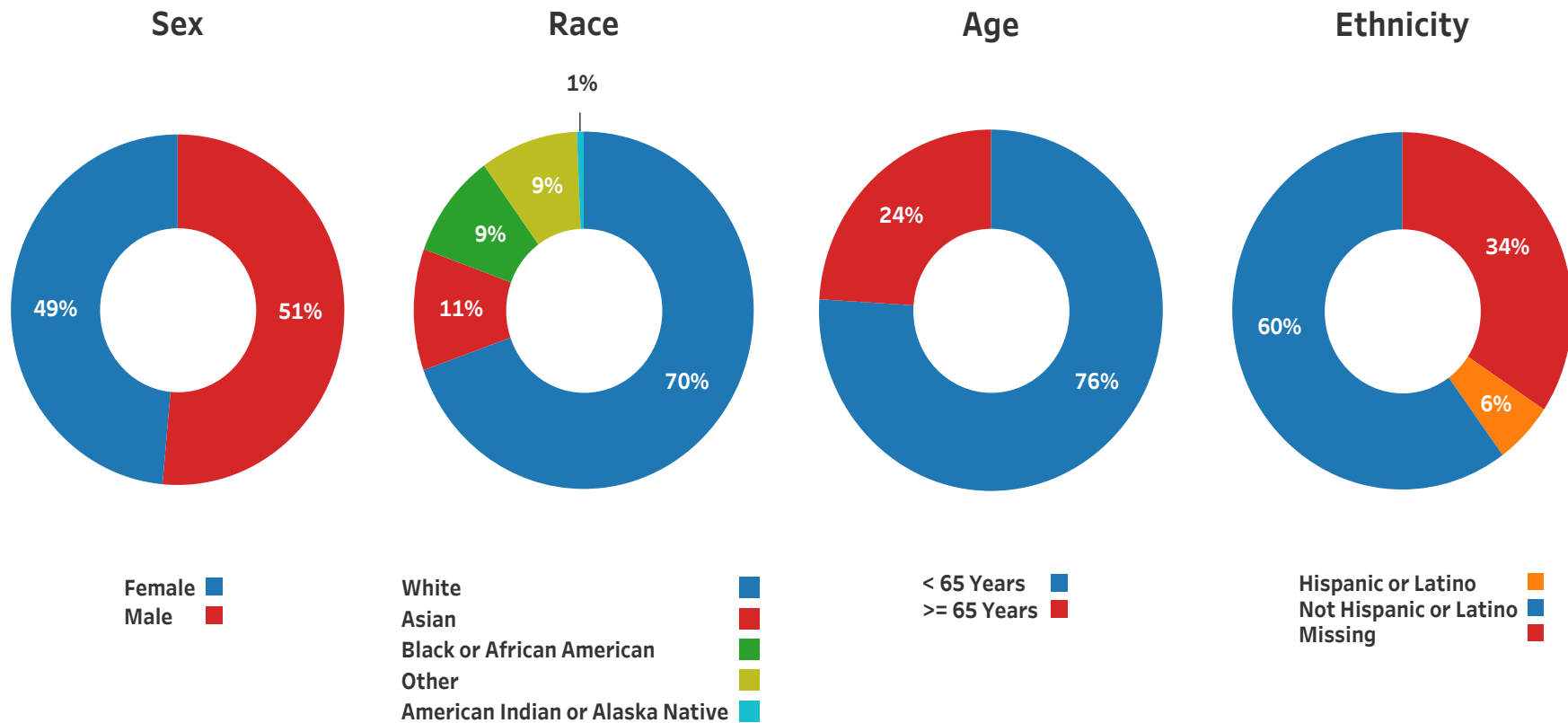
Presented below is the cross-section of sex, ethnicity, and age categories in therapeutic areas with the highest numbers of participants.

| | | Cardiovascular Diseases | | Endocrinology and Metabolism | | Oncology and Hematology | | Infectious Diseases | | Neurology | |
|------|------------------------|-------------------------|-------------|------------------------------|-------------|-------------------------|-------------|---------------------|-------------|------------|-------------|
| | | < 65 Years | >= 65 Years | < 65 Years | >= 65 Years | < 65 Years | >= 65 Years | < 65 Years | >= 65 Years | < 65 Years | >= 65 Years |
| Male | Hispanic or Latino | 7% | 9% | 15% | 13% | 6% | 6% | 16% | 6% | 9% | 3% |
| | Not Hispanic or Latino | 48% | 55% | 83% | 86% | 64% | 65% | 74% | 88% | 62% | 57% |
| | Missing | 45% | 36% | 2% | 1% | 30% | 29% | 10% | 6% | 29% | 40% |

| | | Cardiovascular Diseases | | Endocrinology and Metabolism | | Oncology and Hematology | | Infectious Diseases | | Neurology | |
|--------|------------------------|-------------------------|-------------|------------------------------|-------------|-------------------------|-------------|---------------------|-------------|------------|-------------|
| | | < 65 Years | >= 65 Years | < 65 Years | >= 65 Years | < 65 Years | >= 65 Years | < 65 Years | >= 65 Years | < 65 Years | >= 65 Years |
| Female | Hispanic or Latino | 8% | 10% | 18% | 14% | 6% | 8% | 13% | 7% | 12% | 7% |
| | Not Hispanic or Latino | 47% | 58% | 80% | 85% | 48% | 72% | 74% | 87% | 72% | 49% |
| | Missing | 45% | 32% | 2% | 1% | 46% | 20% | 13% | 6% | 16% | 44% |

Demographics of Trial Participants in Rare Diseases

From 2015 to 2019, between 39 and 58% of all approvals were for drugs treating rare diseases, with a total of 34,209 trial participants. Clinical trial participation is broken down into four categories: sex, race, age, and ethnicity, in the figures below.



Terminology

As outlined in the Collection of Race and Ethnicity Data in Clinical Trials: Guidance for Industry and Food and Drug Administration Staff from October 2016, the FDA recommends the use of the standardized Office of Management and Budget race and ethnicity categories for data collection in clinical trials. The categories presented in this report are as follows:

Race

American Indian or Alaska Native: A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.

Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.

Black or African American: A person having origins in any of the black racial groups of Africa.

White: A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

Other: The percentages of the categories “Native Hawaiian or Other Pacific Islander,” “Unknown/Unreported/Missing,” “Other race,” and “Mixed race” were small enough that we combined them into the “Other” category for this review.

Ethnicity

Hispanic or Latino: A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term, “Spanish origin,” can be used in addition to “Hispanic or Latino.”

Not Hispanic or Latino

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