U.S. FOOD & DRUG ADMINISTRATION

CTTI Diversity Project
Expert Meeting

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Disclaimer

- This presentation represents the personal opinions of the speaker and does not necessarily represent the views or policies of FDA

- No conflicts of interest to declare

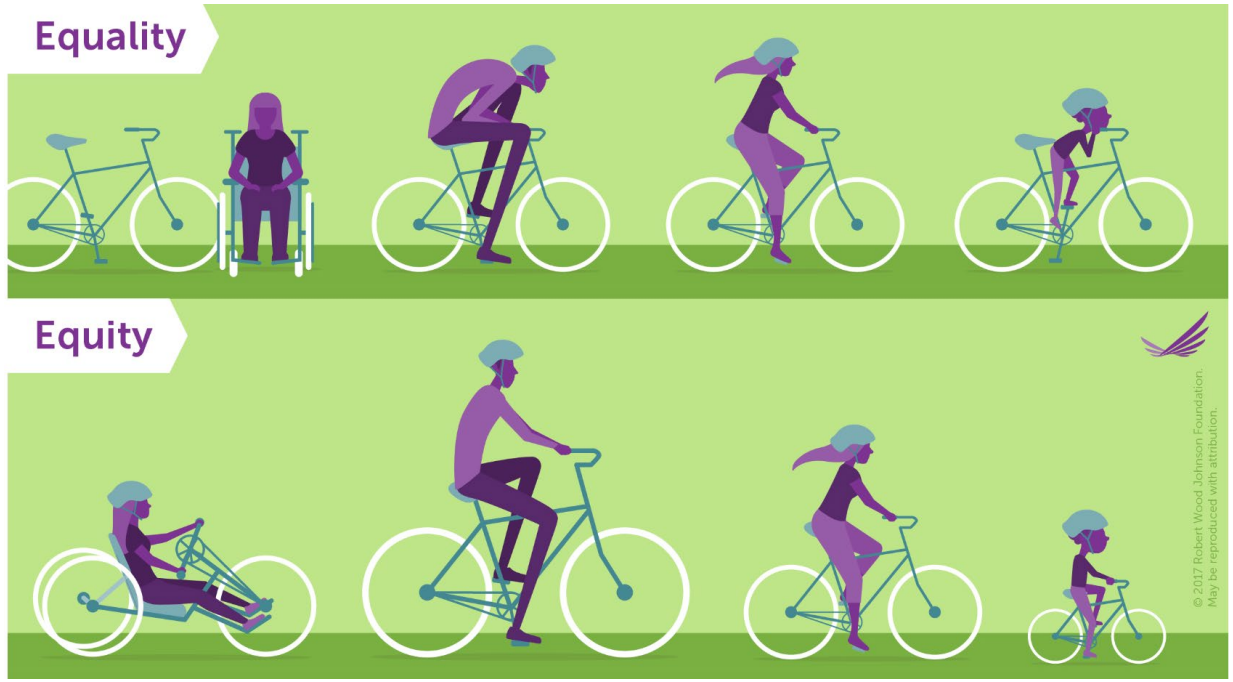
FDA Office of Minority Health and Health Equity (OMHHE)

Mission

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

Vision

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



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
- Stakeholder Input into Research Agenda

What We Do

Outreach and Communication

- Culturally and Linguistically Tailored 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
- Stakeholder Meetings/Symposiums/Exhibits
- Collaborations and Partnerships

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

PRIORITY 01

(QUALITY)

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

FDA Guidance Documents

PRIORITY 02

(PARTICIPATION)

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

Public Meetings

Tools to support diverse clinical trial participation

PRIORITY 03

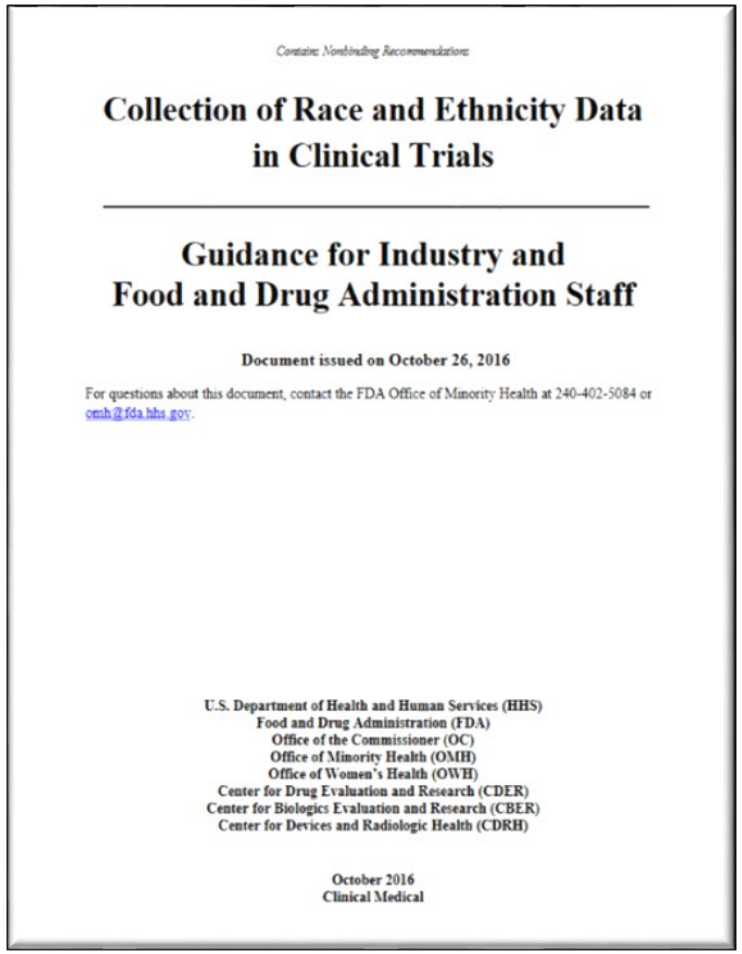
(TRANSPARENCY)

Make demographic subgroup data more available and transparent

Drug Trials Snapshots

(Center for Drug Evaluation and Research)

FDA Guidance Documents for Industry



Contains Nonbinding Recommendations

Collection of Race and Ethnicity Data in Clinical Trials

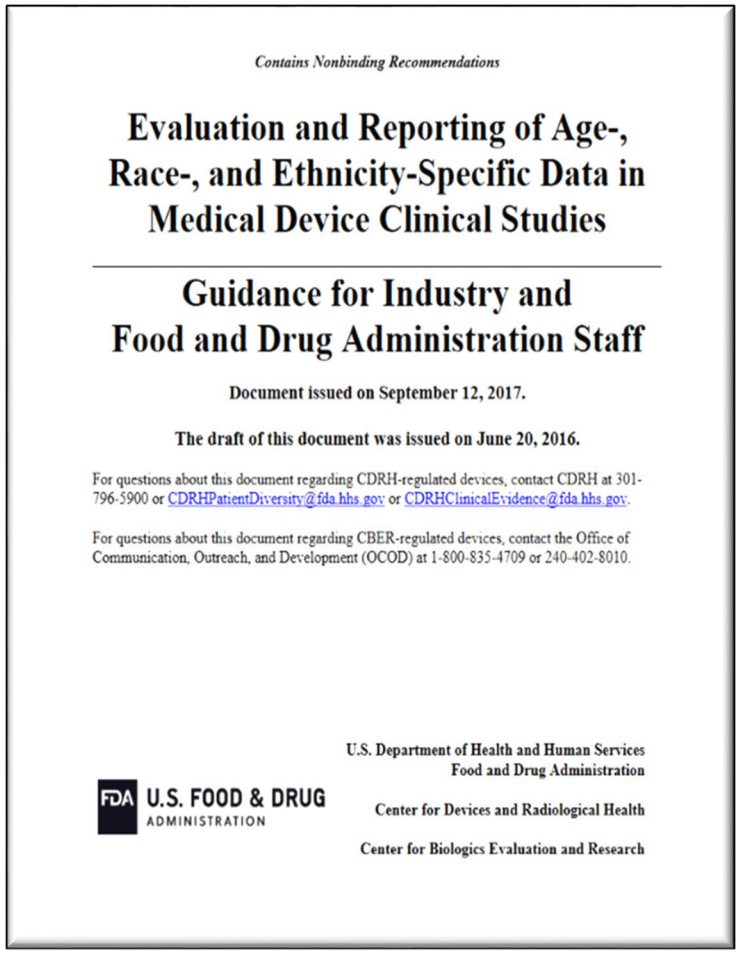
Guidance for Industry and Food and Drug Administration Staff

Document issued on October 26, 2016

For questions about this document, contact the FDA Office of Minority Health at 240-402-5084 or omh@fda.hhs.gov.

U.S. Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Office of the Commissioner (OC)
Office of Minority Health (OMH)
Office of Women's Health (OWH)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiologic Health (CDRH)

October 2016
Clinical Medical



Contains Nonbinding Recommendations

Evaluation and Reporting of Age-, Race-, and Ethnicity-Specific Data in Medical Device Clinical Studies

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 12, 2017.

The draft of this document was issued on June 20, 2016.

For questions about this document regarding CDRH-regulated devices, contact CDRH at 301-796-5900 or CDRHPatientDiversity@fda.hhs.gov or CDRHClinicalEvidence@fda.hhs.gov.

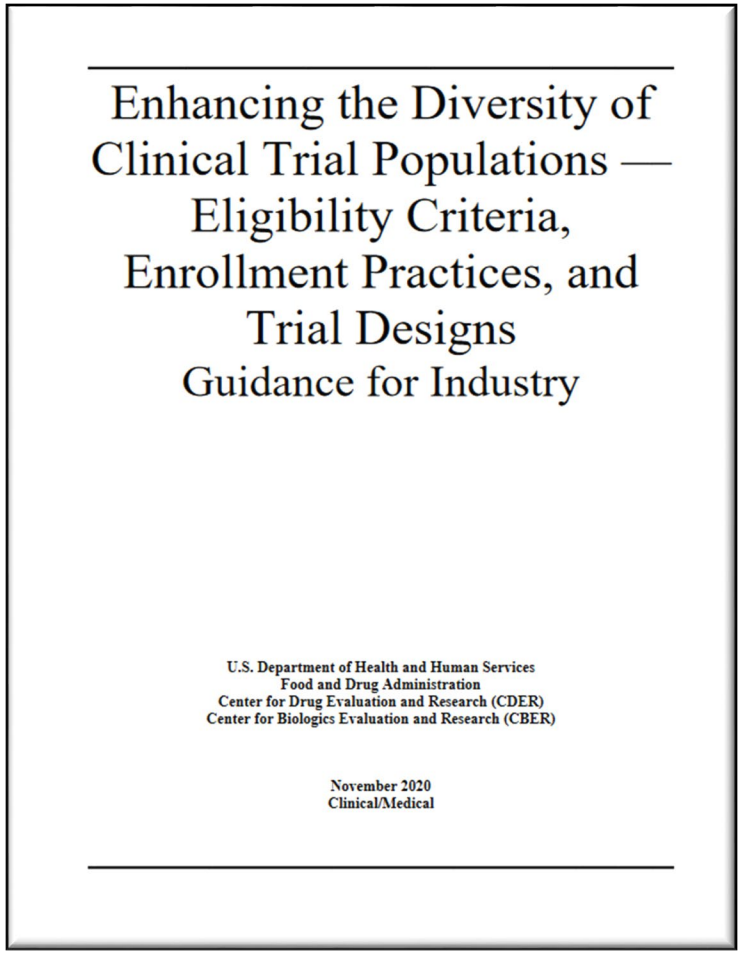
For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health

Center for Biologics Evaluation and Research



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

Guidance for Industry

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)

November 2020
Clinical/Medical

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 I Podcast

Clinical Trial Diversity Social Media Outreach

Clinical Trial Diversity Resources

CLINICAL TRIAL DIVERSITY

Fact Sheet

Clinical trials are research studies involving human volunteers to evaluate medical products like medications, vaccines, or devices for safety and effectiveness. These studies may also show which medical products or therapies work best for people with certain illnesses or for certain groups of people. Ensuring people from diverse backgrounds join clinical trials is key to advancing health equity.

Office of Minority Health and Health Equity

5 things you should know about clinical trials

1. **Clinical trials are research studies conducted with people**—they are designed to answer specific research questions about medical products or therapies.
2. **Participation is always voluntary**—you can leave a study whenever you want.
3. Clinical trials often need **healthy volunteers** to help answer research questions.
4. **Your safety is a priority.** Researchers must follow detailed protocols and the FDA's safety requirements to make each trial as safe as possible.
5. The study will be explained to you in an **informed consent process** before you agree to join.

The importance of diverse participation in clinical trials

Participants in clinical trials should represent the patients that will use the medical products. This is often not the case—people from racial and ethnic minority and other diverse groups are underrepresented in clinical research. This is a concern because people of different ages, races, and ethnicities may react differently to medical products. To achieve health equity so all can benefit from clinical trials, we are committed to taking steps to change this.

Joining a clinical trial might be a good choice for you if:

- You and your health care provider believe a clinical trial may provide another option when standard treatments have failed.
- You want to help test new medical products or therapies in the diverse patients likely to use them.
- You want to help researchers find better ways to fight diseases.

Learn more

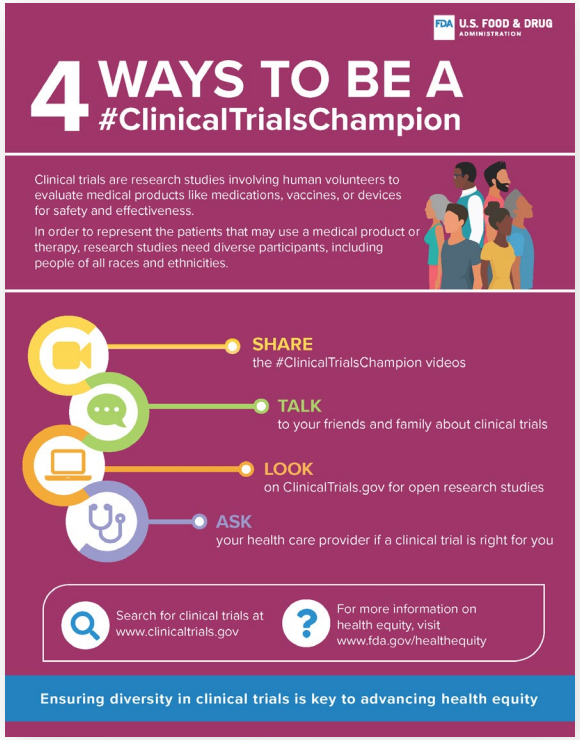
If you think a clinical trial may be right for you, talk to your health care provider. You can also search for clinical trials in your area at **www.clinicaltrials.gov**. To watch videos and view a list of questions to ask researchers, visit **www.hhs.gov/about-research-participation**.

To obtain concise information about who participated in clinical trials that supported the FDA approval of new drugs, visit **Drug Trials Snapshots** at **www.fda.gov/drugtrialssnapshot**.

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

RESEARCH NEEDS YOU

FDA Office of Minority Health and Health Equity



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4 WAYS TO BE A #ClinicalTrialsChampion

Clinical trials are research studies involving human volunteers to evaluate medical products like medications, vaccines, or devices for safety and effectiveness.

In order to represent the patients that may use a medical product or therapy, research studies need diverse participants, including people of all races and ethnicities.

SHARE the #ClinicalTrialsChampion videos

TALK to your friends and family about clinical trials

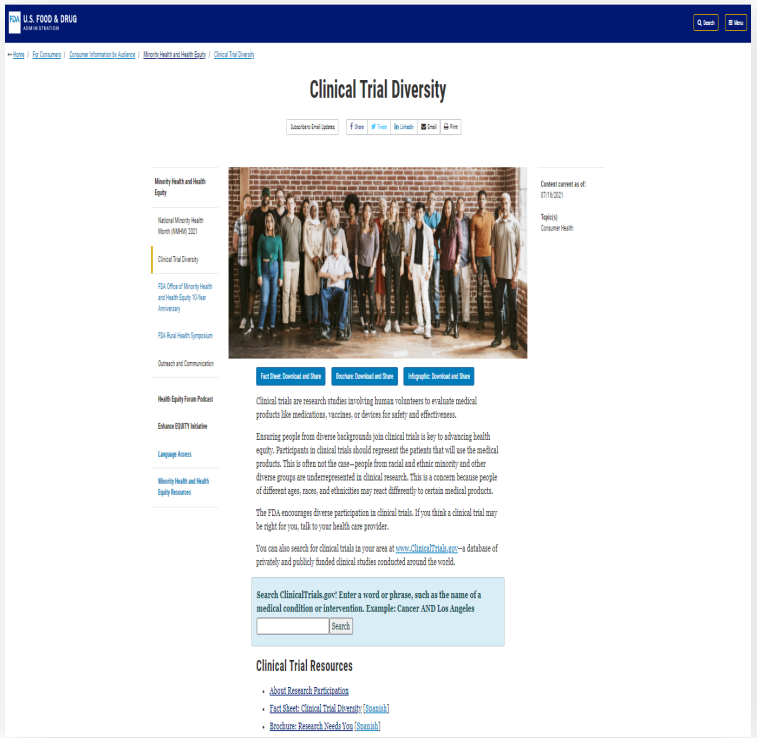
LOOK on ClinicalTrials.gov for open research studies

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



U.S. FOOD & DRUG ADMINISTRATION

Clinical Trial Diversity

Clinical trials are research studies involving human volunteers to evaluate medical products like medications, vaccines, or devices for safety and effectiveness.

Ensuring people from diverse backgrounds join clinical trials is key to advancing health equity. Participants in clinical trials should represent the patients that will use the medical products. This is often not the case—people from racial and ethnic minority and other diverse groups are underrepresented in clinical research. This is a concern because people of different ages, races, and ethnicities may react differently to certain medical products.

The FDA encourages diverse participation in clinical trials. If you think a clinical trial may be right for you, talk to your health care provider.

You can also search for clinical trials in your area at www.ClinicalTrials.gov—a database of privately and publicly funded clinical studies conducted around the world.

Search ClinicalTrials.gov: Enter a word or phrase, such as the name of a medical condition or intervention. Example: Cancer AND Los Angeles

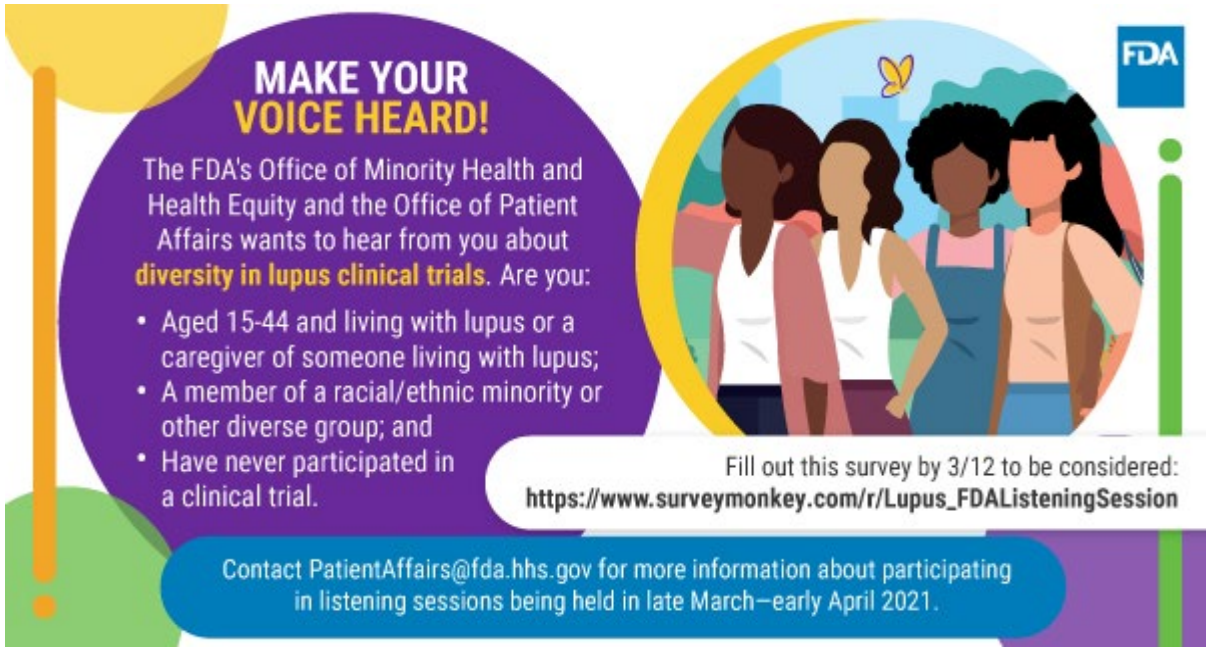
Search

Clinical Trial Resources

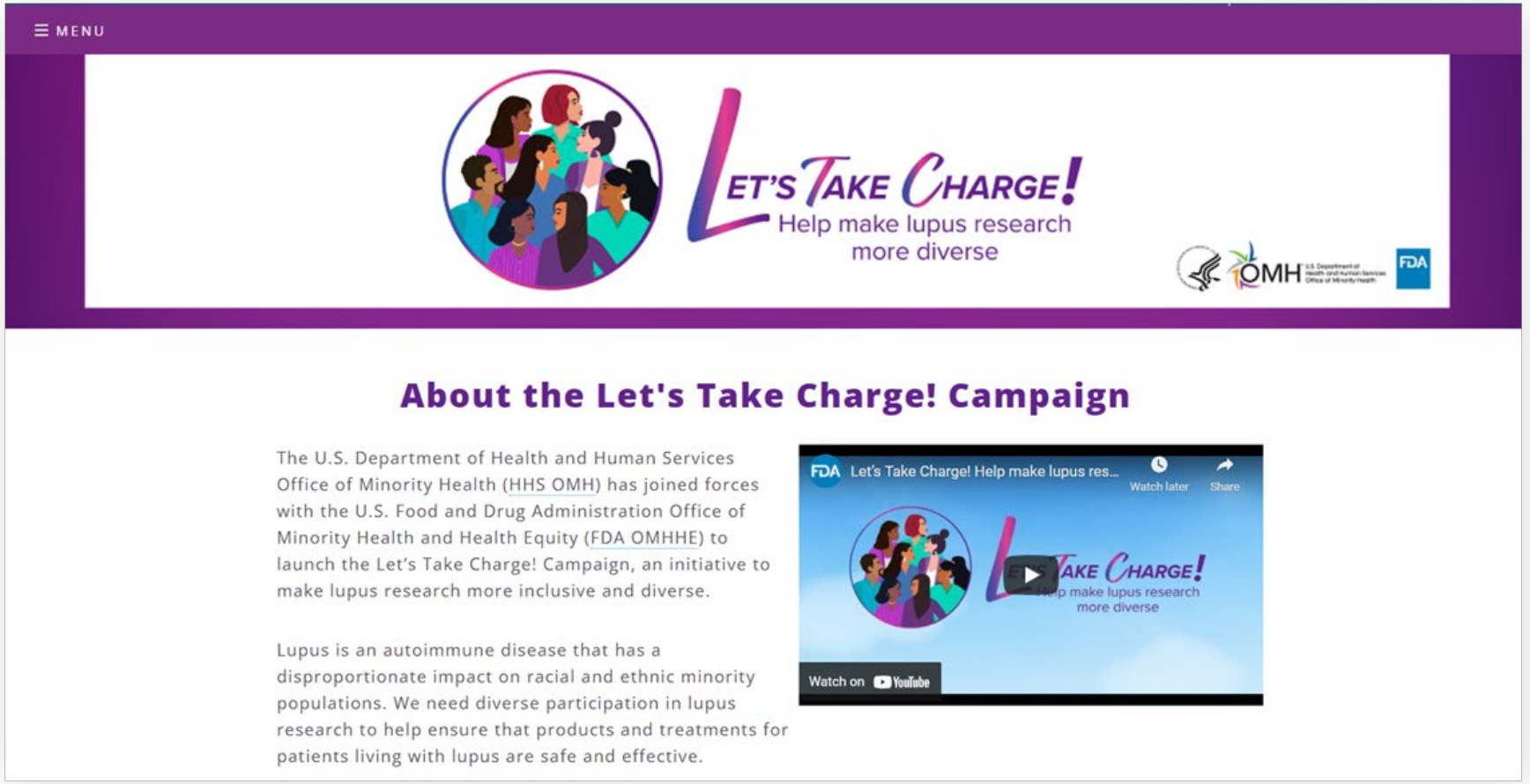
- About Research Participation
- Fact Sheet: Clinical Trial Diversity [Spanish]
- Brochure: Research Needs You [Spanish]

Stakeholder and Community Engagement

Examples of Stakeholder and Community Engagement



Let’s Take Charge!



https://minorityhealth.hhs.gov/letstakecharge/

Engaging Community Providers in Clinical Research

Perspective

Integrating Research into Community Practice — Toward Increased Diversity in Clinical Trials

Janet Woodcock, M.D., Richardae Araojo, Pharm.D., Twyla Thompson, Pharm.D., and Gary A. Puckrein, Ph.D.

Article Metrics October 7, 2021
N Engl J Med 2021; 385:1351-1353
DOI: 10.1056/NEJMp2107731
5 References

THE COVID-19 PANDEMIC HAS UNDERSCORED HEALTH INEQUITIES AFFECTING racial and ethnic minority and other underserved communities in the United States, highlighting, among other critical needs, the importance of increasing the diversity of participants in clinical trials. Clinical trials provide evidence of medical products' safety and effectiveness (or lack thereof). Physicians' ability to extrapolate from trial results to their own patients would be dramatically improved if a trial's participants reflected the product's intended patient population as accurately as possible. Yet in 2020, industry-sponsored clinical trials that supported Food and Drug Administration (FDA) approval of new molecular entities and original therapeutic biologics included 8% Black or African American, 6% Asian, and 11% Hispanic or Latino participants.[1]

Many strategies have been developed to increase enrollment of diverse populations, but they have produced mixed results. One strategy that has not been scaled up in a sustainable way is engaging community clinicians in research.

There is considerable evidence that clinician recommendations play an important role in helping patients to consider participating in clinical trials.[2] Yet such engagement is not widespread. Multiple barriers impede clinician engagement in research, starting with a lack of awareness and knowledge about clinical research. Many U.S. clinicians are not affiliated with large academic medical centers or

Woodcock J, Araojo R, Thompson T, Puckrein GA. Integrating Research into Community Practice - Toward Increased Diversity in Clinical Trials. N Engl J Med. 2021 Oct 7;385(15):1351-1353.

2015-2019: FDA DRUG TRIALS SNAPSHOTS
Five-Year Summary and Analysis of Clinical Trial Participation and Demographics

Ethnicity Composition

How Does Participation by Ethnicity Differ by Geographic Location?

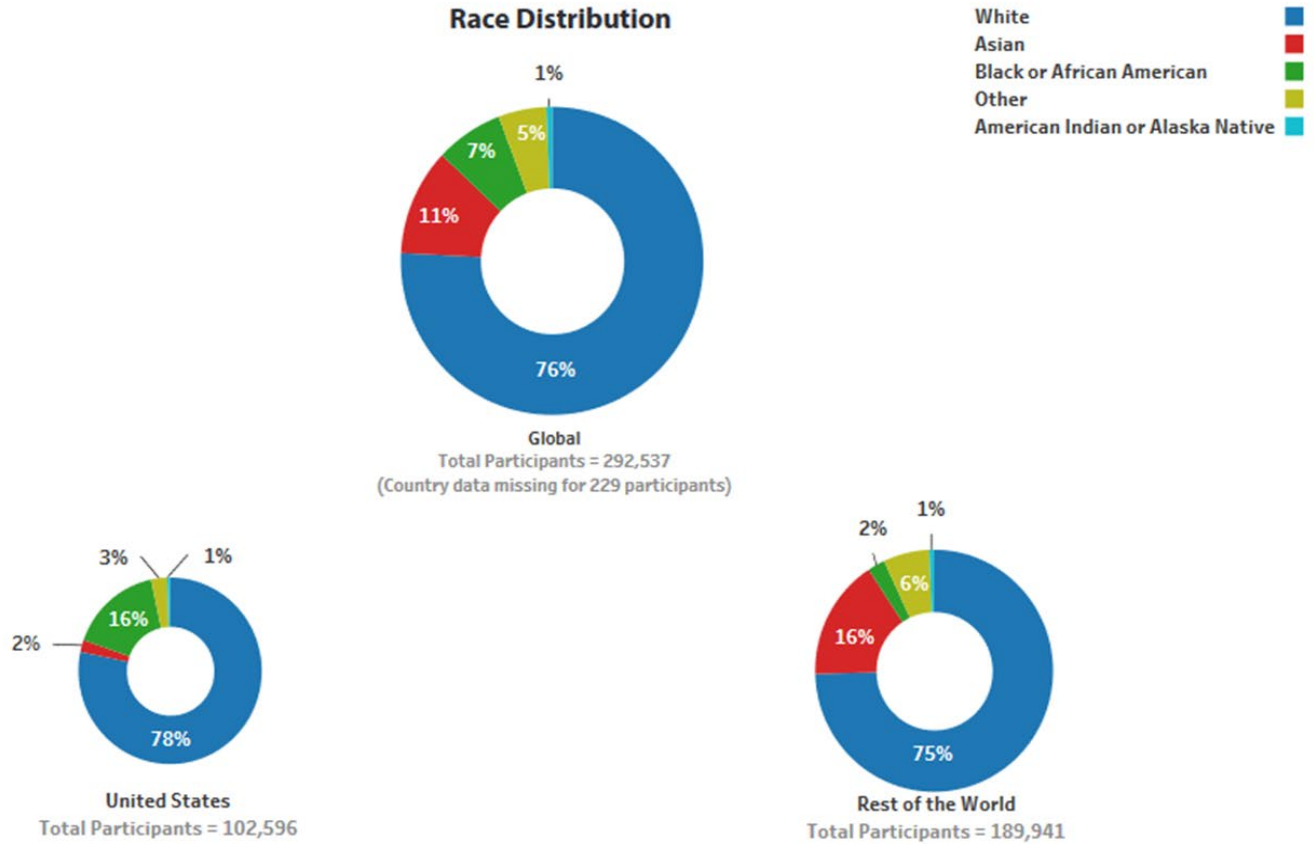
The highest proportion of Hispanics (15%) was reported by participants from the U.S.

2015-2019: FDA DRUG TRIALS SNAPSHOTS
Five-Year Summary and Analysis of Clinical Trial Participation and Demographics

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.



U.S. Racial and Ethnic Participation in Global Clinical Trials

U.S. racial and ethnic participation in global clinical trials by therapeutic areas

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Abstract

What is known and objective: The discussion about health equity in the United States frequently involves concerns over racial and ethnic minority under-representation in clinical trials and particularly in trials conducted in support of product approvals. The FDA has long worked to encourage diverse participation in clinical trials and through its Drug Trials Snapshots (DTS) program, the U.S. Food and Drug Administration (FDA) has moved to make trial demographic data more accessible and transparent. We conducted a demographic study of U.S. participants in clinical trials for FDA-approved new drugs (new molecular entities [NMEs], and original Biologics License Applications [BLAs]) from 2015 to 2019, as reported in DTS database with a purpose of understanding the extent to which U.S.-based trials used to support product approvals represent the racial and ethnic diversity of the U.S. population by therapeutic area.

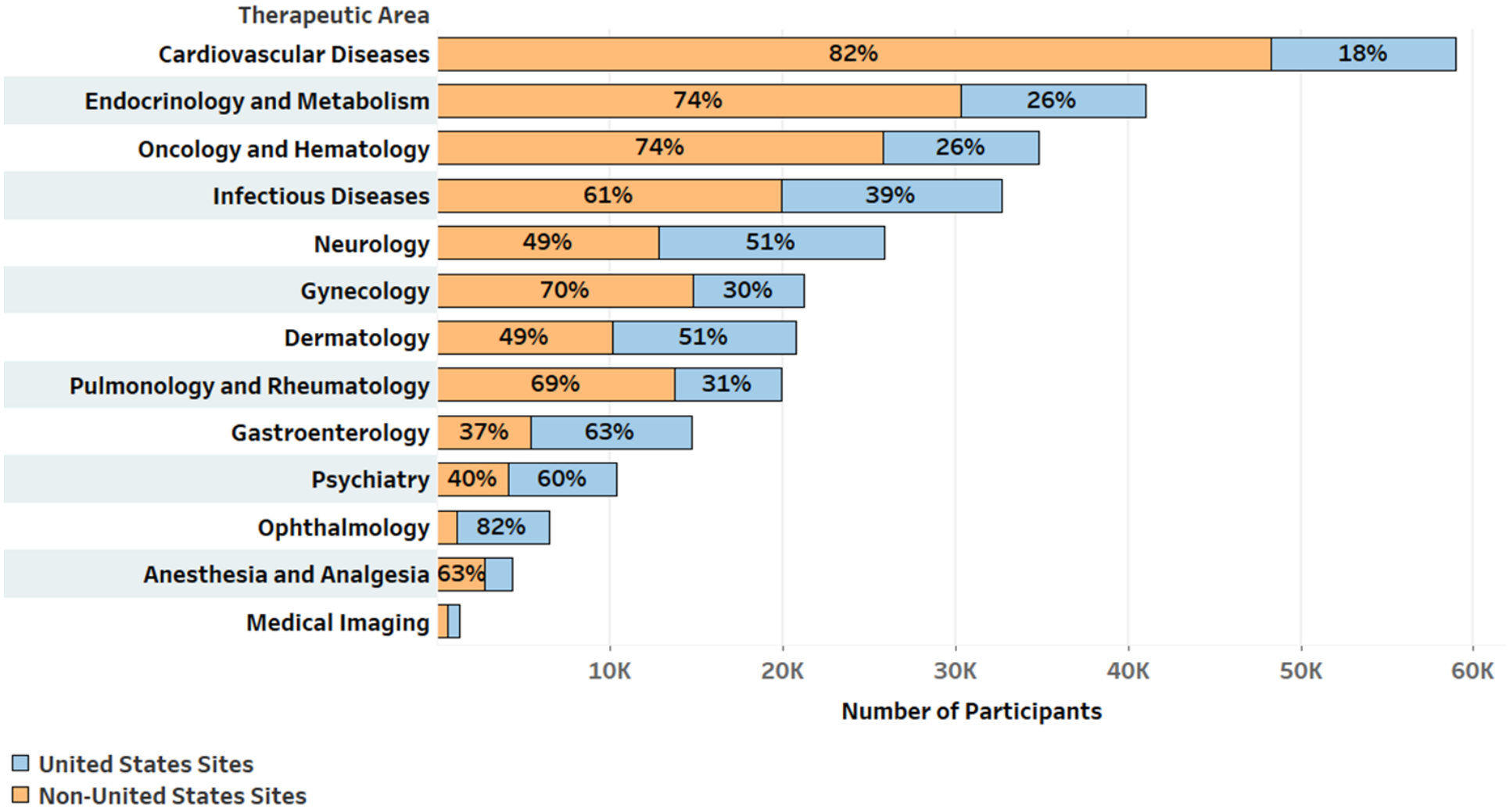
Methods: Participant-level trial data were collected by accessing the FDA electronic common technical document (eCTD), for the applications used to publish each Snapshot. The therapeutic area (TA) for each drug was determined by review division assignment. The demographic data were analysed and compared to U.S. census data.

Results and discussion: We examined 102,596 U.S. participants in trials of new drugs that were approved and presented in Drug Trials Snapshots between 2015 and 2019. White participation ranged from 51% in psychiatric trials to 90% in cardiovascular (CV) trials; Black or African American participation ranged from 5% in medical imaging to 45% in psychiatric trials; Asian participation ranged from 0.75% in CV to 4% in dermatologic trials; and Hispanic or Latino participation ranged from 1% in medical imaging to 22% in infectious diseases and gastroenterology trials.

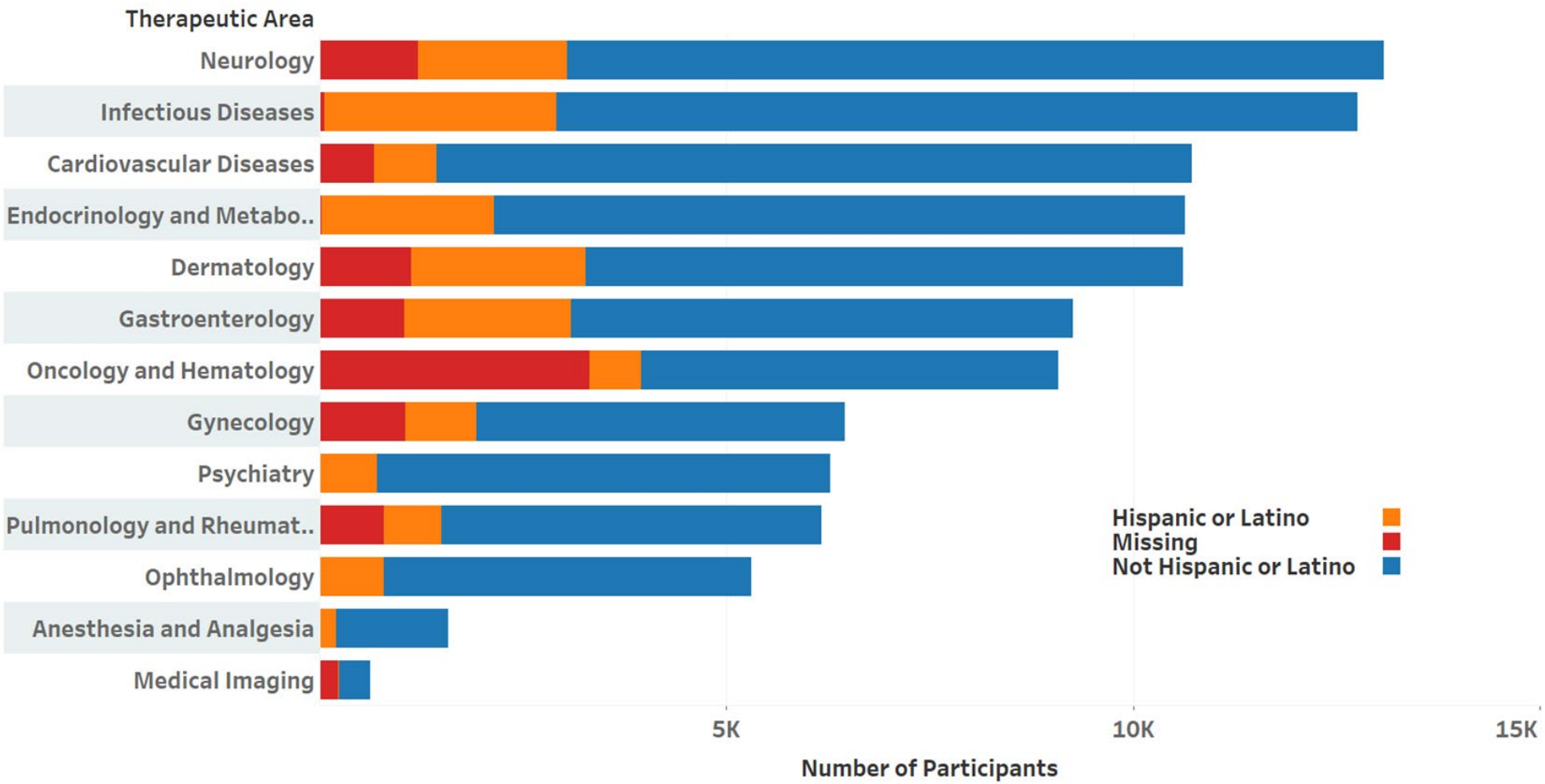
What is new and conclusion: Our data showed variable representation of racial and ethnic minorities across therapeutic areas at the U.S. sites. Blacks or African Americans were represented at or above U.S. census estimates across most therapeutic areas, while Asians and American Indian or Alaska Natives were consistently underrepresented. Hispanic or Latino participation across most therapeutic areas was below U.S. census estimates, however, more variable, and a sizable proportion of data

Lolic M, Araojo R, Okeke M, Temple R. U.S. racial and ethnic participation in global clinical trials by therapeutic areas. J Clin Pharm Ther. 2021 Sep 20.

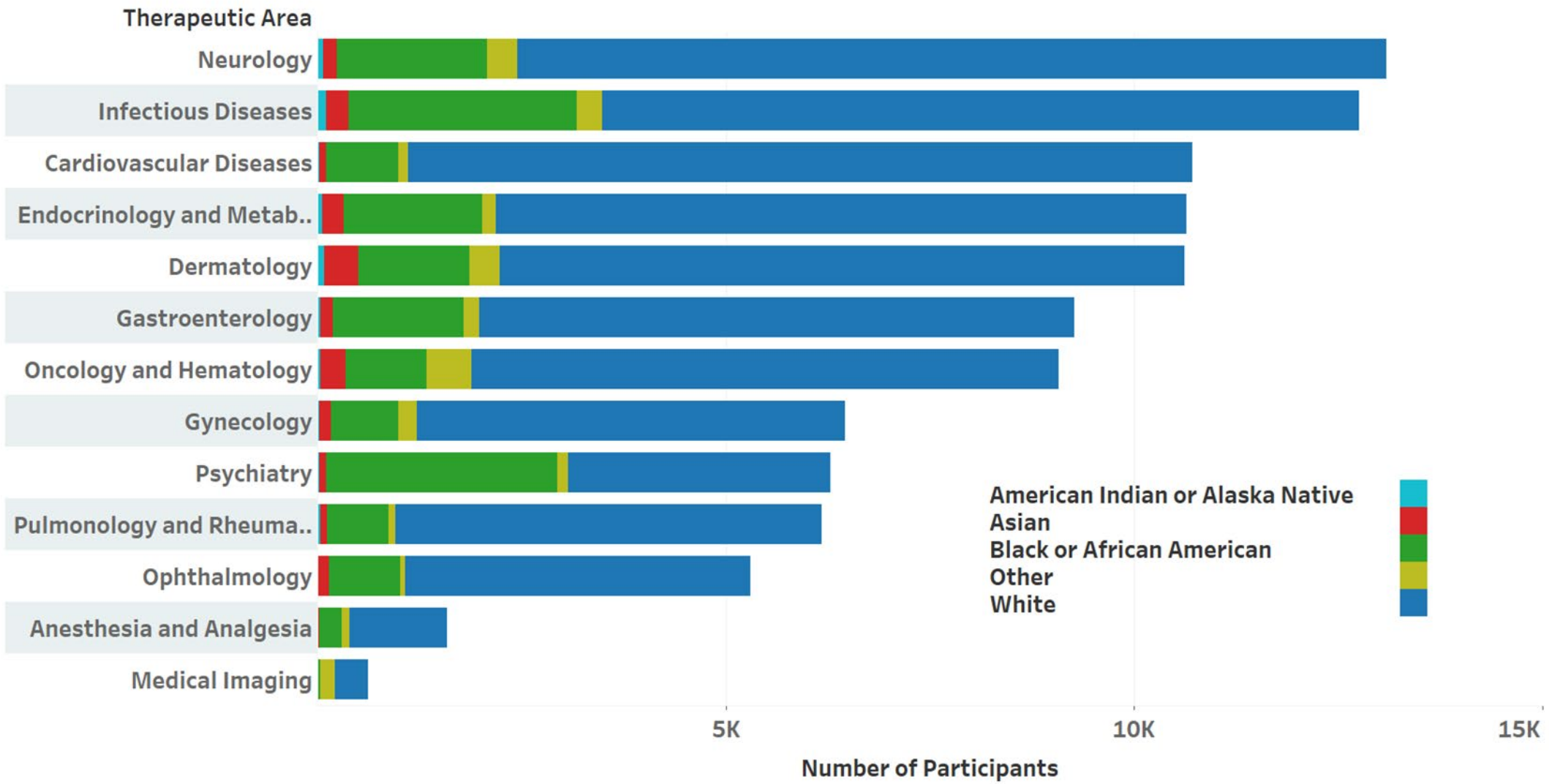
Geographic Breakdown Across Therapeutic Areas-Overall Trials Population



U.S. Ethnicity Breakdown Across Therapeutic Areas



U.S. Race Breakdown Across Therapeutic Areas



Enhance Equity Initiative

OMHHE's Enhance Equity Initiative highlights research projects and communication resources to enhance:

- **EQUITY in clinical trials** by supporting efforts to advance diversity in clinical trials,
- **EQUITABLE data efforts** by increasing data available on diverse groups including, but not limited to, ethnicity, race, age, disability and geography, and
- **EQUITY of voices** by amplifying FDA's communication with diverse groups to ensure stakeholders, including consumers, are informed about FDA's efforts and to understand diverse patient perspectives, preferences and unmet needs.

Thank You!

Follow us at: @FDAHealthEquity

Email us at: OMHHE@fda.hhs.gov

Visit us at: FDA.gov/HealthEquity

Join webinars and stakeholder calls