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

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 240-308-3081 or minorityhealth.hhs.gov.

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 30, 2016.
For questions about this document regarding CMS-regulated devices, contact CDHR at 301-796-3500 or CDHRProjects@hhs.gov or CDHRClinicallStudies@hhs.gov.
For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-853-4799 or 240-308-3081.

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)
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

November 2017
Clinical Medical
Clinical Trial Diversity Social Media Outreach

We all benefit from diversity in research.

Clinical trials include diverse participants like you to ensure medical products are safe and effective for everyone.

Learn about clinical trial participation.

We all benefit from diversity in research.
Clinical Trial Diversity Resources
Stakeholder and Community Engagement

- Regulated Industry
- Government
- Academia
- Nonprofits
- Advocacy Organizations
- Health Care Providers
- Tribal Groups
- Racial and Ethnic Minority Patients/Consumers
Examples of Stakeholder and Community Engagement

**MAKE YOUR VOICE HEARD!**

The FDA’s Office of Minority Health and Health Equity and the Office of Patient Affairs wants to hear from you about diversity in lupus clinical trials. Are you:

- Aged 15-44 and living with lupus or a caregiver of someone living with lupus;
- A member of a racial/ethnic minority or other diverse group; and
- Have never participated in a clinical trial.

Fill out this survey by 3/12 to be considered:
https://www.surveymonkey.com/r/Lupus_FDAListingSession

Contact PatientAffairs@fda.hhs.gov for more information about participating in listening sessions being held in late March—early April 2021.

**INCREASING DIVERSITY IN LUPUS CLINICAL TRIALS**

In honor of Lupus Awareness Month, FDA’s Office of Minority Health and Health Equity is hosting a free webinar on clinical trial diversity featuring the Lupus Foundation of America and the Lupus Research Alliance/Lupus Therapeutics.

- **Date:** Wednesday, May 26, 2021
- **Time:** 6 p.m. ET – 7 p.m. ET
- **Register on Zoom**

**OFFICE OF MINORITY HEALTH AND HEALTH EQUITY**

Albert Roy
Executive Director, Lupus Therapeutics

Dr. Joan Merrill
Chief Advisor, Clinical Development for the Lupus Foundation of America
Let’s Take Charge!

About the Let’s Take Charge! Campaign

The U.S. Department of Health and Human Services Office of Minority Health (HHS OMH) has joined forces with the U.S. Food and Drug Administration Office of Minority Health and Health Equity (FDA OMH/HE) to launch the Let’s Take Charge! Campaign, an initiative to make lupus research more inclusive and diverse.

Lupus is an autoimmune disease that has a disproportionate impact on racial and ethnic minority populations. We need diverse participation in lupus research to help ensure that products and treatments for patients living with lupus are safe and effective.

https://minorityhealth.hhs.gov/letstakecharge/
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.5

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...
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 Distribution

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

United States
Total Participants = 102,596

Rest of the World
Total Participants = 189,941
**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.

**Race Distribution**

- **Global**
  - Total Participants = 292,537
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- **United States**
  - Total Participants = 102,596

- **Rest of the World**
  - Total Participants = 189,941

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2015-2019 Drug Trials Snapshots Summary Report
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 and biologics (NMEs), and original Biological 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 areas (TA) for each drug was determined by reviewer division assignment. The demographic data were analysed and compared to U.S. census data.

Results and discussion: We examined 302,594 U.S. participants in trials of new drugs that were approved and recounted in Drug Trial 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 43% in psychiatric trials; Asian participation ranged from 0.75% in CV to 4% in dermatologic trials; and Hispanic or Latino participation ranged from 3% 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 in 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

Geographic Breakdown Across Therapeutic Areas-Overall Trials Population

**Therapeutic Area**
- **Cardiovascular Diseases**
  - United States Sites: 82%
  - Non-United States Sites: 18%
- **Endocrinology and Metabolism**
  - United States Sites: 74%
  - Non-United States Sites: 26%
- **Oncology and Hematology**
  - United States Sites: 74%
  - Non-United States Sites: 26%
- **Infectious Diseases**
  - United States Sites: 61%
  - Non-United States Sites: 39%
- **Neurology**
  - United States Sites: 49%
  - Non-United States Sites: 51%
- **Gynecology**
  - United States Sites: 70%
  - Non-United States Sites: 30%
- **Dermatology**
  - United States Sites: 49%
  - Non-United States Sites: 51%
- **Pulmonology and Rheumatology**
  - United States Sites: 69%
  - Non-United States Sites: 31%
- **Gastroenterology**
  - United States Sites: 37%
  - Non-United States Sites: 63%
- **Psychiatry**
  - United States Sites: 40%
  - Non-United States Sites: 60%
- **Ophthalmology**
  - United States Sites: 82%
- **Anesthesia and Analgesia**
  - United States Sites: 63%
- **Medical Imaging**
  - United States Sites: 0%
  - Non-United States Sites: 0%

**Number of Participants**
- 10K
- 20K
- 30K
- 40K
- 50K
- 60K
U.S. Ethnicity Breakdown Across Therapeutic Areas

Therapeutic Area:
- Neurology
- Infectious Diseases
- Cardiovascular Diseases
- Endocrinology and Metabolism
- Dermatology
- Gastroenterology
- Oncology and Hematology
- Gynecology
- Psychiatry
- Pulmonology and Rheumatology
- Ophthalmology
- Anesthesia and Analgesia
- Medical Imaging

Number of Participants:
- Hispanic or Latino
- Missing
- Not Hispanic or Latino

Number of Participants Scale:
- 5K
- 10K
- 15K
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.