

ENHANCING TRIAL POPULATIONS – DIVERSITY; SEX DIFFERENCES; PEDIATRICS

CLINICAL INVESTIGATOR TRAINING COURSE

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Enhancing Diversity in Clinical Trial Populations

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Learning Objectives

- ▶ Discuss importance of diversity in Clinical Trial populations
- ▶ Identify barriers to participation in Clinical Trials
- ▶ Describe opportunities and recommendations to enhance diversity of clinical trial populations

Diversity Landscape

Clinical trial diversity includes more than the demographic categories of sex, age, race, and ethnicity

Demographic Populations	Non-demographic Populations
Age	Patients with comorbidities
Sex and Gender	Patients with disabilities
Race	Patients with rare diseases
Ethnicity	Patients at the extremes of weight range
Geographic residence (rural, urban)	Patients with organ dysfunction

Importance of Clinical Trial Diversity

The population of patients enrolled in a clinical trial should represent the population of patients who will use the drug, if approved.*

A diverse population contributes to the accurate assessment of a drug's safety and efficacy.

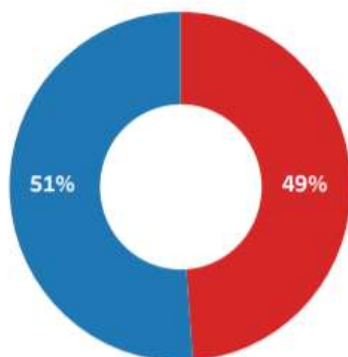
Certain characteristics (e.g., sex, age, race and ethnicity) can have an impact on how different people respond to the same therapeutic product differently.

Certain populations have a higher risk for certain diseases, so it is important that they are represented in the trial.

*See [FDA Encourages More Participation, Diversity in Clinical Trials](#)

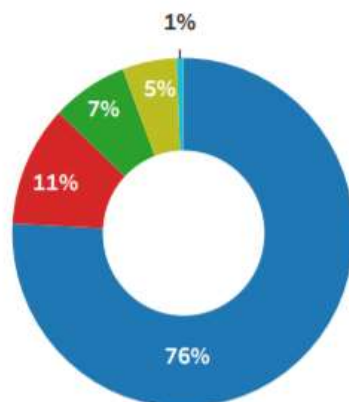
Current State of Trial Diversity*

Sex Distribution



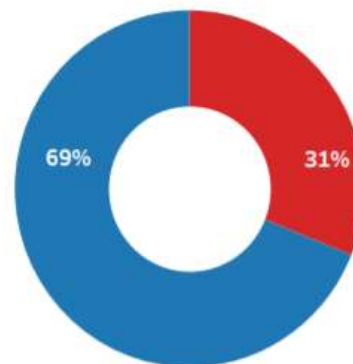
Female ■
Male ■

Race Distribution



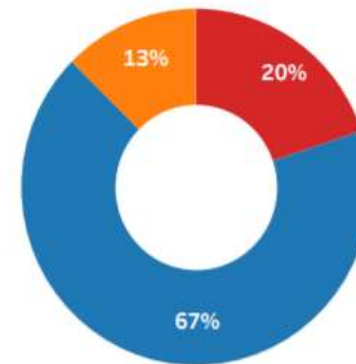
White ■
Asian ■
Black or African American ■
Other ■
American Indian or Alaska Native ■

Age Distribution



< 65 Years ■
>= 65 Years ■

Ethnicity Distribution



Hispanic or Latino ■
Not Hispanic or Latino ■
Missing ■

Opportunities to Enhance Clinical Trial Diversity

Participation Barriers	Opportunities
Distant geographic location	Decentralized trials, virtual visits, mobile medical professionals (e.g., phlebotomists), use of real-world data
Frequency of trial visits	Reduce frequency of study visits, make visit windows flexible
Financial costs	Inform participants of available reimbursements
Mistrust of clinical trials	Public outreach/education, use of non-clinical locations, community engagement
Language	Provide trial resources in multiple languages, interpreters
Lack of awareness of clinical trials	Hold trial recruitment events in non-clinical locations (e.g., salons, cultural festivals)

Examples of Recently-Issued FDA Diversity Guidances

[Collection of Race and Ethnicity Data in Clinical Trials \(2016\)](#)

[Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs \(2020\)](#)

[Cancer Clinical Trial Eligibility Criteria: Patients with HIV, Hepatitis B Virus, or Hepatitis C Virus Infections \(2020\)](#)

[Cancer Clinical Trial Eligibility Criteria: Minimum Age Considerations for Inclusion of Pediatric Patients \(2020\)](#)

Clinical Trial Diversity and COVID-19

- ▶ COVID-19 pandemic has highlighted the importance of clinical trial diversity; it has had a disproportionate impact on communities of color
- ▶ FDA guidance for industry [Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency](#) encourages sponsors to consider alternate methods for clinical assessments, such as telephone contact, virtual visits, and utilization of local laboratories

Available FDA Tools

- ▶ Beyond guidance documents, FDA promotes the following tools to encourage clinical trial diversity:
 - ▶ [Drug Trials Snapshots](#): publishes demographic data on clinical trials
 - ▶ [Consumer Update](#) webpage: provides general information on clinical trials for consumers
 - ▶ [Many Clinical trial resources](#): published by FDA's Office of Minority Health and Health Equity

Challenge Question

- ▶ True or False: Decentralized clinical trials, virtual visits, and the use of mobile medical professionals are opportunities to make trial participation less burdensome.



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