

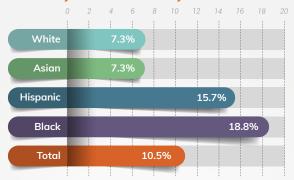


# Racial & Ethnic Diversity In Clinical Trials:

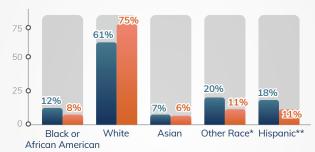
**Overcoming Socioeconomic & Financial Barriers** 

#### Socioeconomic Impact By Race & Ethnicity In Clinical Trials

#### Poverty Rates In The US By Race In 2020<sup>1</sup>



#### Racial & Ethnic Representation In Clinical Trials<sup>2,3</sup>



US Population

Clinical Trial Participants (FDA Drug Trials Snapshots Report 2020)

\*Includes American Indian or Alaska Native, Native Hawaiian or other Pacific Islander, Other, Unknown/Unreported

### **Understanding Socioeconomic Barriers And** Patients' Reluctance To Participate In Clinical Trials<sup>4</sup>

#### **Issues Impacting Patients of Lower Socioeconomic Status:**

- 1 Lack of insurance coverage for specialty care prevents patients from receiving diagnoses or being considered for clinical trials
- 2 Apprehension towards clinical trial participation due to lack of familiarity, which may stem from low health literacy
- 3 Loss of income due to time off from work, child/family care costs, transportation, lodging
- 4 Fear of adverse medication side effects and out-of-pocket medication costs during and post-clinical trial<sup>4</sup>
- 5 Lack of consistent insurance coverage and reduced income may result in a lack of access to treatment after the trial

# Increasing Racial & Ethnic Diversity in Clinical Trials<sup>4</sup>

#### **Barriers**

#### **Opportunities**

**Study Site** 

- Increase diversity and cultural competence of staff
- Recognize and overcome personal biases<sup>4</sup>



- Emphasize that participant safety is a priority, side effects will be monitored, and participation
- Provide clear information to help patients make an informed decision, allow patients to ask questions, and include friends/family members in the process if desired



Time & Resource Constraints

- · Inform participants about any expected financial burden
- Provide ethically appropriate financial assistance for expenses
- Provide additional services that will help with recruitment and retention such as travel and child care services.
- Provide flexibility in site visit hours for participants4



Language & Literacy

- Use plain language in all recruitment collateral
- Include translators and bilingual staff for patients who do not speak the primary language
- Ensure all materials are written at a 5th grade level
- Utilize pictures and graphics in



patient-facing materials

Unsure Where To Find Info.

· Community outreach to health care providers & community leaders to engage potential participants<sup>2</sup>



Strategies For Researchers To Increase Participation Among All Socioeconomic Populations:



## Recruiting

Use community resources such as schools, churches, and free health clinics and social media to recruit<sup>5</sup>



#### Be honest and assist uninsured patients regarding future medication costs, coverage, and patient assistance programs



When planning clinical trials, discuss budgets and patient reimbursement for trial expenses such as transportation5



Set up flexible hours for participants such as non-working nights, weekends, and lunch hours

# Childcare

Make childcare available or reimbursable for participants



Ensure that trial participants are covered by their state Medicaid program<sup>4</sup>

#### Legislative Efforts To Increase Diversity & Inclusivity In Clinical Trials: The Consolidated Appropriations Act of 2021<sup>5</sup>

This mandate may alleviate low representation among low-income and underrepresented patients in clinical trials. State Medicaid programs are now required to cover "routine patient costs" for items and services associated with participation in "qualifying clinical trials."

- 1. https://www.census.gov/library/stories/2020/09/poverty-rates-for-blacks-and-hispanics-reached-historic-lows-in-2019 Accessed March 2022.
- 2. https://www.census.gov/library/stories/2021/08/improved-race ethnicity-measures-reveal-united-states-population-much-machematics-reveal-united-states-rev
- acial.html/ Accessed March 2022.
- 3. https://www.fda.gov/media/145718/download/ Accessed March 2022.
- 4. Price K, et al. 2021;237:843-846. doi: 10.1159/000511889.

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