

# Recognize the Need for Diversity

## What should I do?

Design a person-centered strategy utilizing digital tools. Identify which digital tools are best suited for each step of the clinical trials life cycle. Focus your strategy around three principles:

1. Recognize the critical need for diversity due to the lack of equity,
2. Apply inclusivity, and
3. Demonstrate commitment through accountability.

## Why should I do it?

- Person-centered efficiencies: improve and increase engagement, enrollment and retention,
- Site-centered efficiencies: accelerate timelines and improve workflows,
- Health outcomes centered efficiencies: increase applicability of results to broader populations.

### Ethical Considerations

Much effort and resources will be needed to begin to move the needle and see improvements with diversifying clinical trial participation and developing processes for equity and inclusion. We need to recognize the current state in order to make substantial and enduring improvements. We also acknowledge that not all diversity, equity, and inclusion challenges in the clinical trial industry can be mitigated by digital technologies. We will always need innovative and empathetic leaders to interpret how these technologies should be used and evaluated.

“The U.S. population has become increasingly diverse, and ensuring **meaningful representation** of racial and ethnic minorities **in clinical trials** for regulated medical products is **fundamental to public health.**”

[Robert M. Califf, M.D., FDA Commissioner](#)

Clinical trials need to focus on...

## Diversity

**75%** of participants enrolled in trials were **White**.

**11%** were **Hispanic**.

**10%** were **Black**.

Heart disease is the leading cause of death for women in the United States.

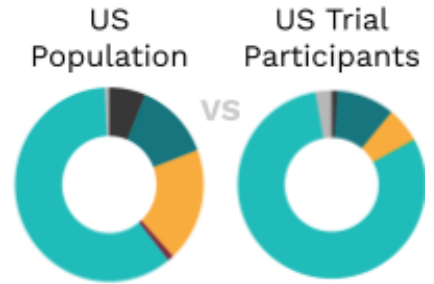
Of cardiovascular clinical trial participants:

**38%** are **women**.

**6%** are **Black or African American women**.



### Discrepancies



	US Population	US Trial Participants
White	60%	80%
Asian	6.2%	1.0%
Black/African American	13%	10%
Hispanic/Latinx	19%	6%
Native American/Alaska Native	1%	0.2%
Unknown	0.8%	2.8%

Oncology trials:



**Only 2%** of participants were **Black women**.

**84%** of participants were **White women**.

## Equity

Less than **2%** of trials over a 2-year period had a **minority group** as its primary focus.

Of **7,000** known rare and ultra-rare diseases, **10%** have a trial.



Sickle cell disease affects **>100,000 Americans**. Most are **Black or Hispanic**.



Cystic fibrosis affects about **30,000 Americans**. Most are **White**.



Cystic fibrosis research receives **10X more funding**.

## Inclusion

**86%** of clinical trials **do not reach recruitment targets**.

**50%** of clinical trial participants find it **difficult to stay enrolled**.

**<10%** of Americans **participate** in clinical trials.



**70%** of patients **live more than 2 hrs** from a research site.



To **optimize** the use of [digital tools for improving clinical trial outcomes](#), you first need to [identify where to focus your efforts](#). This starts with awareness of why there is a need for increased diversity, equity, and inclusion. Diversity encompasses several vectors which can be used to identify a specific group or population. Decades-long inequities and systemic racism drives the need to focus on race and ethnicity, however, a person-centered, **inclusive approach** requires that all vectors be considered, throughout the clinical trial life cycle, **to advance health equity**. One’s health is affected by their biology, environment, and lifestyle. Clinical trials need to be **inclusive of diverse individuals and their lived experiences** to obtain clear and comprehensive knowledge of a drug’s safety and efficacy.

## Inclusion vectors most relevant to digitized clinical trials

Inclusion Vectors	Characteristics
Age	Pediatric and adolescent populations and adults older than 65.
Annual Household Income	Individuals with annual incomes equal to or below 200% of the Federal Poverty Level.
Digital Technology Access	Communities with limited access to high-speed internet, such as broadband, and/or access to digital technology devices, such as computers and tablets.
Digital Technology Literacy	Individuals or communities not well versed with digital technology use. (e.g., inability to use the internet, download applications, connect to Bluetooth).
Disability	Individuals with either a physical or cognitive disability, including visual, auditory, and mobility.
Educational Attainment	Individuals with less than a high school degree or equivalent. Individuals with limited health literacy.
Gender Identity	Individuals who identify as a gender variant, non-binary, transgender, or something else.
Geography	Individuals who reside in rural or non-metropolitan areas. Individuals residing in areas with limited internet access. Individuals who are homeless.
Language	Individuals with limited English proficiency (written or spoken).



Race and Ethnicity	Individuals who identify as other than White and non-Hispanic, based on their ancestry (e.g., African-Americans/Blacks, Asian, Hispanic/Latinx, Native Hawaiian or Pacific Islander, Middle Eastern or North African).
Cultural Practices	Individuals or communities may abstain from accessing and using digital technologies.
Sex Assigned at Birth	Individuals who are neither assigned as male or female (e.g., intersex).
Sexual Orientation	Individuals who identify as asexual, bisexual, gay or lesbian or something else.





## References & Resources

1. [Addressing Barriers to DEI in Clinical Research](#). Developing a more inclusive and equitable study and research environment will reap many benefits for the industry and establish precedent for future trials.
2. [Approaches to Increasing Diversity in Clinical Research and Addressing Health Inequities](#). This document is intended to outline some of the potential considerations and possible approaches to help research sponsors improve inclusion of under-represented groups in clinical research.
3. [CVS Ensures Equal Clinical Trial Access In Vulnerable Communities](#). Over a 2-year period, less than 2% of clinical trials had a minority group as its primary focus.
4. [Diversity, Equity, and Inclusion in Clinical Research: A Path Toward Precision Health for Everyone](#). There are several strategies that research teams can adopt to improve the diversity, equity, and inclusion of their efforts; these strategies span the totality of the research path, from initial design to the shepherding of clinical data through a potential regulatory process.
5. [Diversity in Clinical Trials Benefits Everyone](#). Racial and ethnic minority groups (REMGs) will make up the majority of the population in the near future. Lack of diversity will have serious public health consequences.
6. [How can biopharma companies challenge systemic racism?](#) The biopharma industry needs to confront the systemic and structural barriers to health equity.
7. [How Technology can Galvanize the Unrepresented Patient Population](#). Diversity initiatives are far more likely to succeed while significantly improving patient retention and engagement.
8. [Improving participant representation in the era of digital clinical studies](#). The digital clinical study model sets the stage for improved and equitable participation in biomedical research.
9. [Integrating Diversity, Equity, & Inclusion Throughout Clinical Trials](#). While it may appear obvious that the implications of DEI are especially critical within drug development and clinical trials, many organizations have struggled to mobilize their organizations to take tangible steps to reach their related DEI aims.
10. [‘It’s the disparity in who gets affected’: A sickle cell doctor tracks dollars and drug development](#). Per patient funding gap has been known for decades.
11. [Racial/ethnic differences in drug disposition and response: Review of recently approved drugs](#). Approximately one-fifth of new drugs approved in the past 6 years demonstrated differences in exposure and/or response across racial/ethnic groups,



translating to population-specific prescribing recommendations in a few cases.

12. [Racial and Ethnic Representation of Participants in US Clinical Trials of New Drugs and Biologics](#). The FDA provided but did not highlight data that only 3% of clinical trial participants for cardiovascular trials were Black or African American men younger than 65 years.
13. [Recruitment of Black Adults into Cardiovascular Disease Trials](#). Black adults are underrepresented in National Institutes of Health-funded cardiovascular trials.
14. [Reducing Disparities in Medicine: Advancing Equity in Clinical Trials](#). Clinical trial participation has not appropriately represented all patient populations.
15. [Reducing Barriers to Participation in Clinical Trials for Rare Diseases](#). The process of bringing novel drugs and therapies to market for rare and ultra-rare diseases is extremely challenging.
16. [Research Study Enrollment: Why People Do \(Or Don't\) Participate](#). Despite the energy and resources put into recruiting, enrolling study participants remains a challenge.
17. [The Opportunity Atlas](#). The objective of the Opportunity Atlas is to measure the average outcomes (e.g., earnings) of children who grow up in each neighborhood in America, by demographic subgroup (race, gender, and parental income).
18. [The Role of Diverse Populations in US Clinical Trials](#). Because people may respond differently to treatments, it is imperative to test drugs and medical products in a variety of populations.
19. [When Actions Speak Louder Than Words — Racism and Sickle Cell Disease](#). Patients with sickle cell disease (SCD) are too often marginalized and dismissed while seeking medical care when their bodies hurt and they cannot breathe.
20. [Women's Participation in Cardiovascular Clinical Trials From 2010 to 2017](#). Cardiovascular disease is the leading cause of death among women worldwide, yet, women have historically been underrepresented in cardiovascular trials.

