



North America Public Affairs

# Our efforts on Diversity and Inclusion in Clinical Trials

 **NOVARTIS** | Reimagining Medicine

The development of new medicines is a lengthy and complex process that depends greatly on patients volunteering to participate in clinical trials to evaluate the safety and efficacy of treatments. It is critically important to have broad-based participation in clinical trials, to help researchers find better ways to fight diseases, including those that disproportionately affect certain populations.



## The Diversity Challenge

Certain important populations are significantly underrepresented in pharmaceutical clinical trials, and this lack of diversity is contributing to disparities in care among minority groups. The COVID-19 pandemic has shone a spotlight on this issue and created a call to action for change.

### Nationally

Disparities in clinical trial participation observed across racial, ethnic and gender populations

- 1%** Typical enrollment of **Hispanic/Latinos** in oncology clinical trial populations<sup>1</sup>
- 34%** **Women** in 36 trials supporting cardiovascular new molecular entity (NME) approvals between 2005–2015<sup>2</sup>
- 9%** In 2019, **Black/African Americans** were participants in clinical trials, despite being 13.5% of the US population<sup>3,4</sup>

### Novartis

Self-reported race from 134,033 US patients participating in 965 Novartis clinical trials (1997–2017)<sup>5</sup>

#### RACE

- ~16.1%** Black/African American
- ~1.6%** Asian
- <1%** Native American/Pacific Islander
- ~4%** Other
- ~77.6%** Caucasian/ White

#### ETHNICITY

- ~12.5%** Hispanic /Latino

#### GENDER

- ~46.8%** Female

Novartis is working hard to improve the diversity of patients enrolled in clinical research globally and in the US by seeking out and implementing strategies to ensure that our trials reflect the diversity of the range of patients impacted by the diseases we are studying. We see this as an important way to meet our commitment to patients and caregivers, and address healthcare inequities.

#### References:

1. Latino/Hispanic underrepresentation. Available at: <https://www.nhcoa.org/the-importance-of-latinos-in-clinical-trials/>. Accessed August 27, 2020.
2. Participation of women in clinical trials supporting FDA-approval of cardiovascular drugs. J Am Coll Cardiol (2018).
3. US Food and Drug Administration. 2019 Drug Trials Snapshots Summary Report. Available at: <https://www.fda.gov/media/135337/download>. Accessed August 27, 2020.
4. US Census Bureau. Quick Facts. Available at: <https://www.census.gov/quickfacts/fact/table/US/RHI225219>. Accessed August 27, 2020.
5. Novartis data on file.

We are committed to drive, build, demonstrate and sustain our ongoing efforts towards diversity and inclusion in clinical trials.

The foundation of our approach is based on our enduring **Commitment to Patients and Caregivers**



**Recognizing the importance of transparency and reporting**



**Conducting responsible clinical trials**



**Expanding access to our medicines**



**Respecting and understanding the patient community perspective**

---

## **Strategic Engagement and Partnerships**

Through external strategic engagements and partnerships Novartis will enhance trial accessibility and expand our geographic reach.

- Explore alternative recruitment models
- Align with trial centers and local hospitals with dense and diverse patient populations and clinical trial personnel to expand geographic reach and trial locations
- Ensure potential patients are aware of the safeguards in place that protect the privacy of their information
- Highlight the importance of diverse patient populations in trials during investigator trainings
- Educate policymakers to support their efforts to advocate for their local constituents and support needed changes to State and/or Federal policies

## Process and Tools

Through enhanced processes and tools, Novartis will embed diversity considerations from early development, through protocol writing and site selection, ending with tailored recruitment strategies.

### Leverage strategic planning models for:

- Regional/geographical location
- Gender and ethnicity differences by disease
- Trial design and statistical analysis plan

**In collaboration with physicians and clinical staff, we will work to produce educational materials and toolkits to mitigate attitudinal and language barriers, and identify ways to mitigate practical barriers that patients face when considering participation in clinical trials, such as transportation challenges, scheduling conflicts and language barriers.**



## Data and Technology

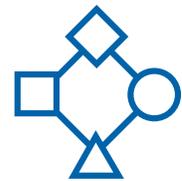
Leveraging data and technology to measure, monitor and provide support to increase outreach, recruitment and democratize access to care.

**Employ artificial intelligence to assess 2 million patient-years of clinical study data to help better manage disease and understand differences in patient outcomes:**

- Develop an inclusive gender health equity strategy
- Leverage insights from the Map of Life project to analyze data from over 2,700 worldwide clinical trials to better understand disease burden and outcomes
- Explore digital models and technology to increase recruitment and democratize access to care (e.g., home nursing and telemedicine)
- Monitor and enhance demographic reporting and provide support where representation gaps exist

---

We are accelerating our commitment to address disparities in clinical trials, improve health in underserved communities and address the underlying causes of health disparities through our participation in industry- and sector-wide collaborations.



**To learn more about:**

Novartis clinical trials: <https://www.novartis.com/clinicaltrials>

People and communities: <https://www.novartis.us/corporate-responsibility/corporate-citizenship/people-and-communities>

Privately and publicly funded clinical studies conducted around the world: <https://clinicaltrials.gov/>

## The Novartis US Foundation

The Novartis US Foundation mission is to improve health in underserved communities in the US by creating innovative and sustainable solutions to expand access to healthcare and build trust within the healthcare system.

As part of this mission, the foundation has committed:

>\$10M

to programs focused on health inequities

\$15M

to explore health inequities with a focus on diversity in clinical trials

**A key area of focus will be addressing the vast underrepresentation of minorities, including Black Americans, in clinical trials, by identifying and convening potential collaborators from the public, private, and advocacy sectors to ignite a targeted, progress-driven effort to affect change around diversity in clinical trials.**

The activities of The Novartis US Foundation are distinct and separate from commercial and development initiatives to improve diversity in Novartis clinical trials.

