



## Novartis Commitment to Diversity in Clinical Trials

Diversity in clinical trials is integral to who we are at Novartis. Our purpose is to reimagine medicine to improve and extend the lives of all people – inclusive of race, ethnicity, gender, age, sexual orientation, disability, location and socioeconomic status.

Underrepresentation and lack of diversity in clinical trials, of both patients and investigators, is a key issue that healthcare and pharmaceutical industries must address to reduce the health disparities in society. Diverse, inclusive trials are critical to ensuring that we understand how those patients who are most likely to be treated for a disease or condition will respond to a medicine. They give healthcare providers, patients, and their caregivers the opportunity to make more informed decisions regarding current and future treatments, ultimately improving the quality of care every patient receives.

We are working hard to improve both the diversity of patients enrolled in our clinical research and the investigators involved in our trials, but we know this will take time. To achieve our long term aspiration, we understand that we need to build trust as well as identify and reduce barriers to clinical trial access and participation. We will do this by:

### *Building Strategic Partnerships*

- Expanding and strengthening relationships with patient groups, medical institutions and community organizations to develop investigators from communities of color and enable recruitment of a broader patient population
- Partnering with other companies to explore alternative recruitment models
- Improving access to our trials by expanding our engagement with clinical sites and investigators to include areas where diverse patients with a particular disease or condition may be located
- Educating policymakers to support their efforts to advocate with local authorities

### *Leveraging Data and Digital*

- Analyzing data and insights from Novartis' databank of over 2,800 worldwide clinical trials to better understand disease burden and outcomes
- Enhancing our demographic monitoring and reporting in order to identify and provide support where representation gaps exist
- Employing artificial intelligence to assess Novartis' databank of over 3 million patient-years of clinical studies data to help understand differences in patient outcomes across groups
- Exploring digital models and novel technology-enabled solutions to increase trial flexibility, reduce patient burden and democratize access to care

### *Remodeling our Process and Tools*

- Embedding diversity evaluations along the entire development continuum from early stage, to protocol-writing and site selection, to tailored recruitment strategies, as appropriate
- Incorporating the patient perspective, where appropriate, to improve and enrich clinical trial designs, access, participation, recruitment, enrollment, and retention of diverse populations
- Adopting enrollment and retention practices, where appropriate, that enhance inclusiveness and make trial participation less burdensome for participants
- Developing educational materials and toolkits for sites, patients and community partners to mitigate attitudinal and language barriers

In the short term, we are committing to first evaluating diversity and inclusion principles for 100 percent of our Phase 3 studies with US country participation starting the second half of 2021, with the goal to increase and embed this evaluation throughout our Global trials.

Our focus on enhancing diversity in our clinical trials is embedded into our [Code of Ethics](#) and our [Access Principles](#), in our dedication to bringing more of our medicines to more people, no matter where they are; and is a core component to our [Commitment to Patients and Caregivers](#), as one of the best ways we can reimagine medicines for patients is to improve their access and address healthcare inequities.