



## *Principles on*

## **Representation in Human Clinical Trials**

### **The Challenge:**

Sanofi believes that all individuals should have the opportunity to participate in clinical trials, particularly people from diverse populations who are often under-represented in clinical research. Sanofi recognizes the role and importance of trial participant diversity in our clinical research programs. Our commitment to clinical trial diversity is based on high ethical standards and norms and we abide by the relevant laws and regulations around the world where we conduct our trials.

We understand that there are many reasons why an individual may not participate in a clinical trial, including mistrust, stigma, lack of access to information about a relevant trial, financial constraints, fear of unintended consequences, geography, and narrow eligibility criteria. In addition, other important factors can play a role in excluding people from participating in clinical trials, including healthcare disparities (e.g., disparities based on ethnicity, gender, or other factors), socioeconomic status, as well as forms of unconscious bias.

We know that diverse groups do not necessarily define distinct genetic or biological subpopulations, but they can be associated with important differences in disease manifestation and treatment response. Differences in the incidence and prevalence of disease in society and treatment responses can be attributable to complex interactions between an individual's biological and genetic makeup, and other factors such as environment, access to healthcare, diet and lifestyle.

As medical science advances and these differences are identified and better understood, these factors will become increasingly critical to the success of new treatments for all patients.

### **Sanofi's Vision:**

Sanofi is working to address current challenges in the recruitment of individuals from diverse populations to clinical trials, such as using broader participant eligibility criteria. Our clinical studies are designed to identify the patient population that may benefit the most from the investigational drug. To that end, we do not exclude participants based on minority status, gender, sexual orientation or age. In addition, although comorbidities can bring increased risk

to trial participants, we have been making our trials more inclusive by not excluding patients with co-morbidities wherever we can. We are also actively working to both enhance the selection of trial sites to include more diverse population-dense communities and to involve more diverse investigators with the goal of further increasing minority participation in our trials.

In sum, Sanofi believes that to improve both social equity and human health, we should continue to increase the participation of diverse populations in clinical trials by identifying barriers to recruitment, enrollment and retention, and employing strategies that encourage participants from these diverse populations.

*Principles on Representation in clinical trials approved by Sanofi Bioethics Committee (first approval in 2020 – last review in 2024)*