Roche Position on Race, Ethnicity, and Genetic Ancestry Application and Use in Clinical Trials and Product Development

As a research-focused global healthcare company, Roche is committed to ensuring that our clinical trials are inclusive and representative of the demographically-diverse populations* that experience disease. Responsible collection, use, and application of race, ethnicity, and genetic ancestry data in research and development is critical to our goal of delivering optimal therapeutics for all patients. Every person is distinct. Therefore, we must also understand the impact of individual characteristics on health outcomes. We believe this commitment is fundamental to our ability to conduct global, socially responsible, inclusive science that fosters equitable access and improves health outcomes for all populations.

Effective and equitable scientific advancement across our global populations is predicated on understanding the variables that are integral to human diversity. Race and ethnicity are social descriptors. Historically, race and ethnicity have been conflated and misused, contributing to discrimination and exclusion of underrepresented populations in clinical research. In contrast, genetic ancestry captures the biologic measure of genetic similarity. However, the common practice of reducing genetic ancestry to a continental-level, categorical variable compromises scientific objectivity and potentially exacerbates harmful notions of racially-defined genetic determination.

To understand differential health outcomes experienced by various populations, a complementary approach that leverages both the value of the sociopolitical and cultural contexts that individuals are subject to (e.g., self-reported race and/or ethnicity, geographic location, and socioeconomic status) and genetic similarity as a biologic measure of ancestry is needed. Therefore, the collection of comprehensive geographical, genetic, behavioral, social determinant, and environmental data may facilitate an increased understanding of the interplay between complex social histories and patterns of continuous genetic variation on patient outcomes.

Roche believes ethical and quality data collection, with appropriate safeguards, is necessary to accurately characterize patients' biological, social and environmental contexts. This practice will impact analysis, interpretation and the use of data in risk stratification of disease for patients of diverse ancestries and environments around the world.

Roche is committed to the development of standards for inclusion of social, cultural, ancestral, and other personal identifiable data in an appropriate manner. We also acknowledge that these standards will continue to evolve to accurately represent the vast and dynamic diversity of patient cohorts and populations included in scientific and medical research. Additionally, Roche pledges to implement data protection principles to advance health equity, optimize data quality, and improve our understanding of how population descriptors may be associated with disease risk.

* Population refers to a group of individuals who share specific common characteristics, as defined in their description.