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Reagan-Udall Foundation for the FDA Launches Real-World Data Initiative to Address Disparities

Federally supported project will advance solutions on race and ethnicity data for research

(December 15, 2022) The Reagan-Udall Foundation for the FDA (FDA Foundation) is launching the Real-world Accelerator to Improve the Standard of collection and curation of race and Ethnicity data in health care ([RAISE](#)). The initiative, funded by the Food and Drug Administration’s Office of Minority Health and Health Equity (OMHHE), focuses on understanding, aligning, and disseminating best practices to improve real-world reporting, collection, curation, and integration of race and ethnicity data.

“RAISE was inspired by the consistent shortcoming we have observed in health care utilization data from payors and providers to characterize the utilization and performance of medical products across all populations,” said Carla Rodriguez-Watson, PhD, MPH, Director of Research at the FDA Foundation, and the Principal Investigator of RAISE. “Missing data leads to an incomplete understanding—or worse, a biased understanding—of health care and medical product disparities in observational studies. It also limits the potential efficiency of real-world data to improve diverse recruitment for clinical trials.”

Efforts to improve race and ethnicity data collection and curation cross the domains of health disparities and health equity research, health care finance, health IT, workforce training, practice standards, and policy development. RAISE will convene a diverse group of leaders from across the health care ecosystem to collaborate on actionable solutions to improve the collection and curation of race and ethnicity data in health care settings, ultimately improving the quality of health care and medical products.

“To address health disparities, data has to represent diverse communities,” according to Rear Admiral (RDML) Richardae Araojo, Associate Commissioner for Minority Health and Director of OMHHE. “Through the Enhance Equity Initiative, our office supports innovative and collaborative projects that advance the consistent collection and reporting of race and ethnicity data, which is vital to advancing health equity overall.”

RAISE is built on three main strategies:

- Convening a series of community workshops with cross-disciplinary leaders to create opportunities for collective sharing, learning, and capacity building;

- Developing a multi-dimensional tool to assist health care systems and providers in prioritizing strategies for ease of implementation; and
- Evaluating the impact of the community workshops for initiating change in policy and practice.

RAISE will officially launch its community workshop series on January 26, 2023, with “Improving Collection of Race and Ethnicity Data in Health Care” from 2-4 PM (eastern). Keynoted by Georges Benjamin, MD, Executive Director of the American Public Health Association, the event will explore the many challenges to collecting and curating race and ethnicity data, the current regulations and guidance, and lessons from the field.

Susan C. Winckler, RPh, Esq., CEO of the Reagan-Udall Foundation for the FDA, emphasized that “for regulatory decisions and the research they are based on to be meaningful to all populations, we must address the inconsistent collection of race and ethnicity data. RAISE supports efforts to strengthen equity in pre- and post-market studies, including those leveraging real-world data, by more consistently capturing this essential demographic information.”

RAISE is supported by the Food and Drug Administration (FDA) Office of Minority Health and Health Equity of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award (FAIN) totaling \$499,514 (100% funded by FDA OMHHE/HHS).

About the Reagan-Udall Foundation for the FDA

The Reagan-Udall Foundation for the FDA is an independent 501(c)(3) created by Congress to advance regulatory science to help the U.S. Food and Drug Administration accomplish its mission. The FDA Foundation works to improve health and safety through stakeholder engagement and public-private partnerships that facilitate innovation, foster the use of real-world evidence, and identify modern tools and policies to keep pace with today’s rapidly evolving science.

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