REAGAN-UDALL FOUNDATION FOR THE FDA

RAISE

REAL-WORLD ACCELERATOR TO IMPROVE THE STANDARD OF COLLECTION AND CURATION OF RACE AND ETHNICITY DATA IN HEALTHCARE

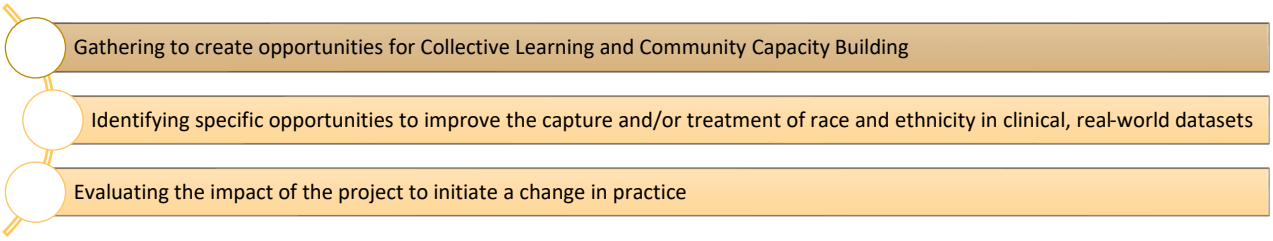
Workshop Primer and Reading List

Purpose

The Reagan-Udall Foundation for the FDA (FDA Foundation), in collaboration with FDA's Office of Minority Health and Health Equity, has launched **RAISE** to elevate the capture and curation of race and ethnicity data in health care settings to ultimately improve the quality of health care and medical products. The FDA Foundation has invited leaders in the health care space to understand incentives, challenges, and solutions to collect race and ethnicity data because the required infrastructure investments to do this work will be driven by leaders who can direct resources and institutional commitment to do so. But to do so, these leaders must see health equity as a core tenet of their system and/or see how such data adds long-term value to their patients/members and their systems.

RAISE has three specific aims grounded in collective learning, community capacity building, innovation, and research (Figure 1).

Figure 1: RAISE Specific Aims



Background

Table 1: FDA's definitions of RWD and RWE (United States Food and Drug Administration)

Real-World Data (RWD)	**Real-World Evidence (RWE)**
Data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources.	Clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD.

Real-world evidence (RWE) has increasingly become of interest to the FDA over the years as it relates to medical product development, safety and effectiveness (Table 1). Policy makers enacted 21st Century Cures Act to accelerate medical product development, improve evidence generation about product safety and effectiveness, and ensure more efficent access to those products for patients who need them.[1] With the growth of medical innovation, there is the opportunity to expand on complex analytical analysis and improve clinical trials. For safety, real-world data can aid in the post-market surveillance of medical products. One example is providing real-world performance data for medical products with limited long-term data in pre-market studies, a common constraint of clinical trials. RWE is a useful tool for increasing population safety, expanding how epidemiologic studies are conducted and assessing effectiveness studies in certain clinical cases. For more information on RWD and RWE can be applied in regulatory decision making, FDA recently released a series of guidance documents about RWD and RWE (Table 2).

Table 2: Series of FDA guidance documents about RWD and RWE

1	Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drug and Biological Products
2	Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products
3	Considerations for the Use of Real-World Data and Real-World Evidence To Support Regulatory Decision-Making for Drug and Biological Products
4	Data Standards for Drug and Biological Product Submissions Containing Real-World Data
5	Submitting Documents Utilizing Real-World Data and Real-World Evidence to FDA for Drugs and Biologics

Race and Ethnicity in Real-World Data (RWD)

Although access to health care is not equitable, once patients are able to access care, clinicians and insurers are able to collect data that can be used to answer a variety of research questions. Information from electronic health records and insurance claims data containing race and/or ethnicity can be leveraged for program evaluation to improve care, understand and improve health care coverage, and conduct broader clinical research – including medical product assessment.[2] However, as data move through a continuum from reporting to integration (see Figure 2), opportunities emerge for data loss, misclassifcation, and measurement bias of race and ethnicity.[2,3,4] For example, despite the known disparities in COVID-19 infection and sequela, only **65%** of confirmed COVID cases and 85% of COVID deaths reported to the CDC had known

race and ethnicity reported.[5] Additionally, states with gaps in race and ethnicity data generated a slower public health response to the pandemic than those with more complete race and ethnicity data - who were better able to quickly and equitably allocate COVID-19 pandemic resources.[6,7] Missing race and ethnicity data not only limits real-world disease surveillance, but the assessment of medical product utilization and performance and the efficiency to recruit for more representative clinical trials.

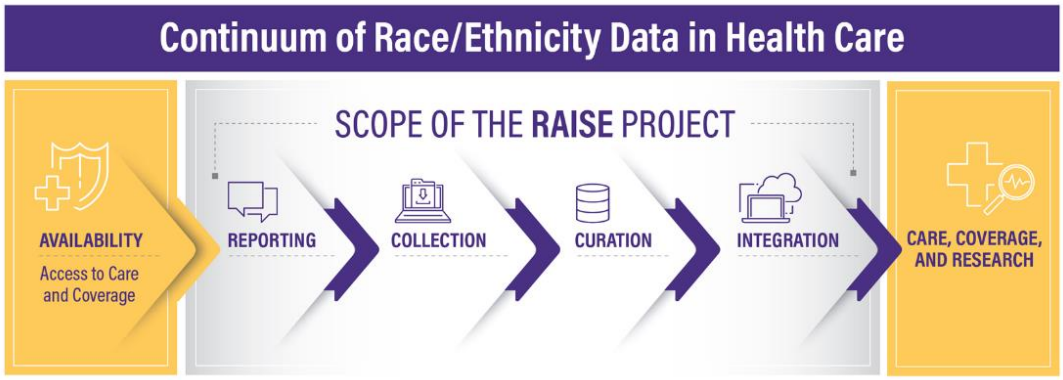


Figure 2: Continuum of Race/Ethnicity Data in Health Care

Race and ethnicity are gross social constructs imposed on a person, and thus have limitations in describing individual-level variation. Nevertheless, they are fundamental to understanding and addressing health needs at the population level. One in five recent drug approvals demonstrated differences in exposure and/or response by racial and ethnic groups.[8] The ability to identify such differences is important for hypothesis generation and to understand whether further inquiry is necessary. Given the implementation of historically race-based policies with consequences on health and well-being, it is important to understand the allocation of health resources and trends in disease status and medication response across racialized groups.[2,9] Although race does not represent biological or cultural differences between groups, assuring adequate representation across racialized groups in clinical trials is critical to closing gaps in product prescription, utilization, and effectiveness.[10,11] First, implementation of evidence-based practice in community settings may be limited when those sites are substantially different from those included in clinical research studies.[12] Furthermore, genetic variation has been linked to geographic origins of a person's ancestors (largely corresponding to Africa, Europe, Asia, Oceania, and the Americas, and thus racial categories). Current reliance on genomic studies comprised mostly by persons of European ancestry limits the understanding of the accuracy and effectiveness of precision medicine tools in non-European ancestry. [13,14,15]

Examples of initiatives to improve the capture of race and ethnicity data are highlighted in the case studies below:

Case Study: **State's largest insurer to start paying providers to address health care disparities**
Blue Cross Blue Shield of Massachusetts has signed agreements with major health groups to minimize health disparities in exchange for maximized reimbursement. Reporting race and ethnicity data is a central component of the strategy.

Case Study: **New Joint Commission requirements to include race & ethnicity for hospital accreditation**

By elevating the curation and collection of race and ethnicity data in health care, we can improve 1) real-world assessment of the utilization and performance of medical products, care, and the resulting impact of interventions and 2) the efficiency of RWD to enable more diverse recruitment for clinical trials.

Illustrative Questions
The RAISE workshop series spans topics such as interoperability, data privacy, system requirements, advanced analytics, and will highlight health system reactions. Below are a list of illustrative questions:

- Acknowledging how trust issues impact asking about (clinicians) and reporting (patients) race, how do we build community trust?
- What frameworks, incentives and/or standards exist to better collect and integrate race and ethnicity (R/E) data?
- What are common data processes, practices, and/or IT support needs? Are there any examples of implementation?
- Fostering cultural compentency and humility, what are some reporting strategies for the health care workforce? How could they better engage the community?
- How do the R/E c ategories get updated if they are outdated and seemingly do not allow people to see themselves? Despite the need for granularity in capturing R/E, how does race and ethnicity data become standardized in category roll-up across data sources?
- How can health policy better protect privacy and security of data to improve race and ethnicity reporting, capture, transmission?
- When R/E intersects with other sensitive areas: genomics, sex, SUD, LGBTQI+, disability, how do we protect vulnerable populations? How do we create the infrastructure necessary to collect and capture such data in the context of the health care system, mindful of the increasing burdens put on the system via decrease workflow burden, increase value to the system, etc.?
- How will improving R/E data in real-world datasets better shape the use of medical products and what could this synergy tell us about diversifying clinical trial?

Reading List

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