CENSUS OPEN INNOVATION LABS

THE OPPORTUNITY PROJECT

FDA DIAGNOSTIC DATA EXCHANGE 2023 SPRINT PROBLEM STATEMENT

Enabling Health Data Aggregation for Healthcare Providers by Adopting Data Exchange Standards

U.S. Food and Drug Administration (FDA)

THE CHALLENGE – Create tools that help harmonize and aggregate diagnostic data with other information, such as data on chronic disease and social determinants of health (SDOH), to power analytics for individuals and populations. These tools should adopt Fast Healthcare Interoperability Resources (FHIR) standards for exchanging electronic health data across information systems to ensure that diagnostic data is fully integrated into medical records and public health systems.

THE PROBLEM – There has been a recent proliferation of over the counter (OTC) and point of care (POC) tests, which are generally conducted outside of physical laboratories and conventional clinical settings, disconnected from traditional reporting systems. As a consequence, consumers are now more in control of their health data than ever before. However, to inform individual patient care and for effective public health coordination and response, this data needs to be easily captured, transmitted, and analyzed with the right context by relevant stakeholders to ensure the safety of both individuals and communities. Currently, much of this health data remains underutilized: data resulting from diagnostic tests performed outside of laboratories is not connected to existing health data systems, and reports indicate that only up to 24 percent of healthcare companies currently use APIs at scale in order to exchange electronic health data across information systems. FHIR protocols lay out a path for connecting disparate information systems using an application-based approach to interoperability. Lightweight, low-cost solutions are needed to make the FHIR messages consumable and actionable by Electronic Medical Records (EMRs) and Electronic Health Records (EHRs) as well as by public health systems.

THE OPPORTUNITY – Exploring new possibilities for seamless and secure data acquisition from diagnostic testing devices can help address health issues beyond pandemics, such as chronic diseases, which make up a large portion of healthcare spending. Utilizing community-level open-source data about patients' social determinants of health (SDOH) alongside individual-level data during OTC/POC device use and other medical assessments can inform more comprehensive care and treatment for individuals, as well as population and community-level interventions.

VISION FOR SPRINT OUTCOMES – This TOP sprint will enhance prevention and disease management strategies by building upon the accomplishments and lessons learned from the 2021 TOPx COVID-19 sprint. It will expand beyond teams focusing narrowly on COVID-19 diagnostic data capture, transmission, and analytics to other medical and testing contexts, while utilizing HL7 FHIR-based approaches for the collection and sharing of information, including publicly available SDOH data.

TARGET END USERS – Community health workers; healthcare providers; academics and researchers analyzing population health and community health interventions; public health agencies.

RELATED DATA SETS

- COVID-19 Case Surveillance Public Use Data - Centers for Disease Control and Prevention
- COVID-19 Reported Patient Impact and Hospital Capacity by State Timeseries - U.S. Department of Health & Human Services
- COVID-19 Reported Patient Impact and Hospital Capacity by Facility (Raw) - U.S. Department of Health & Human Services
- COVID-19 Reported Patient Impact and Hospital Capacity by State - U.S. Department of Health & Human Services
- COVID-19 Estimated Inpatient Beds Occupied by COVID-19 Patients by State Timeseries - U.S. Department of Health & Human Services
- Reduced Access to Care During COVID-19 Data - Research and Development Survey; Centers for Disease Control and Prevention
- COVID-19 Community Vulnerability Crosswalk - Rank Ordered by Score - U.S. Department of Health & Human Services
- Census Household Pulse Survey - U.S. Census Bureau
- NIH COVID-19 Research Resources - National Institutes of Health
- Open-Access Data and Computational Resources to Address COVID-19 - National Institutes of Health
- CDC/ATSDR Social Vulnerability Index - Centers for Disease Control and Prevention
- National Health and Nutrition Examination Survey (NHANES) Questionnaires, Datasets, and Related Documentation - Centers for Disease Control and Prevention

EXECUTIVE CHAMPION

Sara Brenner, MD, MPH, Associate Director for Medical Affairs and Chief Medical Officer for In Vitro Diagnostics, U.S. Food and Drug Administration

SPRINT LEADERS

Sami Bég, MD, MPA, MPH, FACLM, Digital Health Subject Matter Expert, FDA (Lead)
Pooja D. Jani, MD, MPH, Medical Officer, Diagnostic Data Program, FDA (Co-lead)
Maya Richardson, PhD, MS, Epidemiologist, Staff Fellow, FDA (Fellow)