Capturing Harmonized Data from IVD Tests

U.S. Food and Drug Administration (FDA)

THE CHALLENGE – In vitro diagnostic (IVD) tests, such as SARS-CoV-2 or COVID-19 tests, are critical data sources for the healthcare ecosystem. But with the advent of new at-anywhere and non-lab based tests, capturing data these tests generate requires innovation and new digital technologies. We challenge teams to create tools that integrate emerging technologies, such as image capture and IoT, into IVD testing devices, to help easily capture and transmit this information, while doing so in accordance with best practice data standards.

THE PROBLEM – Data from IVDs, especially from tests that are not processed in a traditional physical laboratory, but rather used at the point of need, point of care (POC) and over the counter (OTC), needs to be captured in a uniform format in order to avoid ambiguities when the data is transmitted from the IVD to a health care provider or public health institution. Establishing a uniform format for data collection and transmission with logical and consistent definitions will help create a standardized data infrastructure. Multiple government agencies have attempted to tackle this issue, but without a streamlined approach, some related efforts have not yet been fully integrated.

THE OPPORTUNITY – By using specifications like RADx MARS's HL7v2 clinical messaging format and hubs like CDC's ReportStream, OTC and POC reporting systems can ensure the adoption of an established data standardization. This will lead to the faster and more accurate transfer of data through a single connection to relevant stakeholders. When paired with a process to "de-duplicate" data, ensuring that the final destination does not erroneously count the same test result multiple times, this process of cataloging data in a universally accepted format and transmitting it to a central hub will ensure the data's reliability and accuracy. Ultimately, these efforts will significantly improve patient care, as diagnostic data flows to health care systems via Electronic Health Records (EHRs), and enhance public health decision making.

VISION FOR SPRINT OUTCOMES – This TOP sprint will establish a method for seamless data collection from diagnostic testing devices through the encoding of results and associated data in a healthcare industry-standard format. This data will be transmitted to a hub which will in turn send results to physicians, healthcare providers, healthcare systems, EHRs, and downstream state and federal public health systems, all while ensuring security and "de-duplication" in order to avoid erroneously counting the same test result multiple times.

TARGET END USERS – Test users (healthcare providers, caregivers, patients and the general public); test producers (test manufacturers, pharmacies); and those utilizing the resulting data (federal, state, and local public health agencies).

RELATED DATA SETS

- ↳ COVID-19 Case Surveillance Public Use Data - Centers for Disease Control and Prevention
- ↳ Census Household Pulse Survey - U.S. Census Bureau
- ↳ DOT Cyber Security Assessment Management - Department of Transportation
- ↳ Cybersecurity and Privacy Reference Tool - National Institute of Standards and Technology
- ↳ 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

EXECUTIVE CHAMPION

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