

THE OPPORTUNITY PROJECT

FDA DIAGNOSTIC DATA EXCHANGE 2023 SPRINT PROBLEM STATEMENT

Enabling the Use of Diagnostic Testing with Telehealth Platforms

U.S. Food and Drug Administration (FDA)

THE CHALLENGE – Create tools and leverage existing platforms and technologies to ensure that diagnostic testing and telemedicine are integrated. This will help to maximize the clinical utility of expanded access to diagnostic tests by ensuring that patients and physicians can quickly use test results to inform clinical care and treatment plans.

THE PROBLEM – The use of telehealth expanded dramatically during the recent pandemic, as providers and patients sought to safely deliver and access healthcare services. As a result, attitudes toward telehealth have improved, and it is increasingly being adopted as an integral part of healthcare. However, telehealth holds other potential benefits for patients that have not yet been fully realized.

THE OPPORTUNITY – There is potential to integrate telehealth into a wider range of care, including over the counter (OTC) and point of care (POC) testing. Telehealth services may also help encourage patients to share relevant, de-identified data for public health decision-making in order to protect the safety of their communities. The [“Test to Treat” initiative](#) – which aims to help people quickly access clinical evaluation and, if appropriate, treatments for COVID-19 – can have applications beyond COVID-19 testing. This kind of model can be especially useful in addressing the OTC/POC results that relate directly to other infectious diseases, as well as to lifestyle-related chronic diseases that can be addressed through the use of telehealth for educating patients about the impact of lifestyle factors on health. Diagnostics linked to telehealth platforms also help ensure optimal use of diagnostic data to inform individual clinical management and treatment of patients as quickly as possible.

VISION FOR SPRINT OUTCOMES – This TOP sprint will encourage the adoption of telehealth as an essential component of OTC/POC testing in order to improve the utility of results and facilitate the timely clinical management of patients. Ultimately, the goal is to also create a doctor-patient relationship that centers education and knowledge-sharing and trust in order to improve the health and safety of communities.

TARGET END USERS – Telehealth companies and telemedicine healthcare providers; pharmacies; healthcare delivery organizations; patients.

RELATED DATA SETS

- ↳ [COVID-19 Case Surveillance Public Use Data](#) – Centers for Disease Control and Prevention
- ↳ [Access and Use of Telemedicine During COVID-19](#) – Research and Development Survey; Centers for Disease Control and Prevention
- ↳ [COVID-19 Hospital Data from the National Hospital Care Survey](#) – Centers for Disease Control and Prevention; National Hospital Care Survey

- ↳ [Telemedicine Use in the Last 4 Weeks](#) - Centers for Disease Control and Prevention; U.S. Census Bureau
- ↳ [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
- ↳ [Reduced Access to Care During COVID-19 Data](#) - Research and Development Survey; Centers for Disease Control and Prevention
- ↳ [CDC/ATSDR Social Vulnerability Index](#) - Centers for Disease Control and Prevention
- ↳ [Broadband Data Collection](#) - Federal Communications Commission
- ↳ [Telehealth Research](#) - U.S. Department of Health & Human Services

EXECUTIVE CHAMPION

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