COVID-19 Evidence Accelerator Collaborative

Diagnostics Evidence Accelerator #49

Thursday, July 21, 2022, 12-1 PM ET

Call Summary

Introduction to Diagnostics Evidence Accelerator Meeting #49

This week's Diagnostics Evidence Accelerator meeting consisted of 2 presentations:

1. A Systems Integrations Approach to Pandemic Response (Dr. Renee Wegryzn, Ginkgo Bioworks)
2. SHIELD Overview (Dr. Keith Campbell, FDA/CDRH)

A Systems Integrations Approach to Pandemic Response (Dr. Renee Wegryzn, Ginkgo Bioworks)

Ginkgo Bioworks was founded in 2008 with the mission to make biology easier to engineer. Ginkgo Bioworks designs, builds, tests, and ferments organisms. They envision these tools will be used for therapeutics, biosurveillance, environmental sequencing, bioinformatics and a variety of other use cases. At the beginning of the pandemic, Ginkgo launched Concentric, a division of Ginkgo which would focus on Biosecurity. They used their platform to help manufacture vaccines and scale testing through different collaborations.

Concentric by Ginkgo is positioned to enable the implementation and scaling of newly developed tests. Figure 1 shows their integrated pandemic response during the height of the pandemic. As a continued effort, Concentric by Ginkgo is layering on other population level surveillance such as waste water and air monitoring.

They have two programs which they have launched since the beginning of the pandemic: Large-scale pooled surveillance of K-12 schools and traveler-based genomic surveillance for strategic points of entry. To date, they have run 10+ million samples with 35,000+ viral samples sequenced and 5,300+ organizations supported with their tools. The traveler-based program includes a partnership with XpresCheck and the CDC in 4 key US airports. The learning from the traveler-based SARS-CoV-2 surveillance program can be viewed here and a synopsis is below. Figure 2 shows how the airport surveillance program was set up.

Figure 1: Integrated Pandemic Response

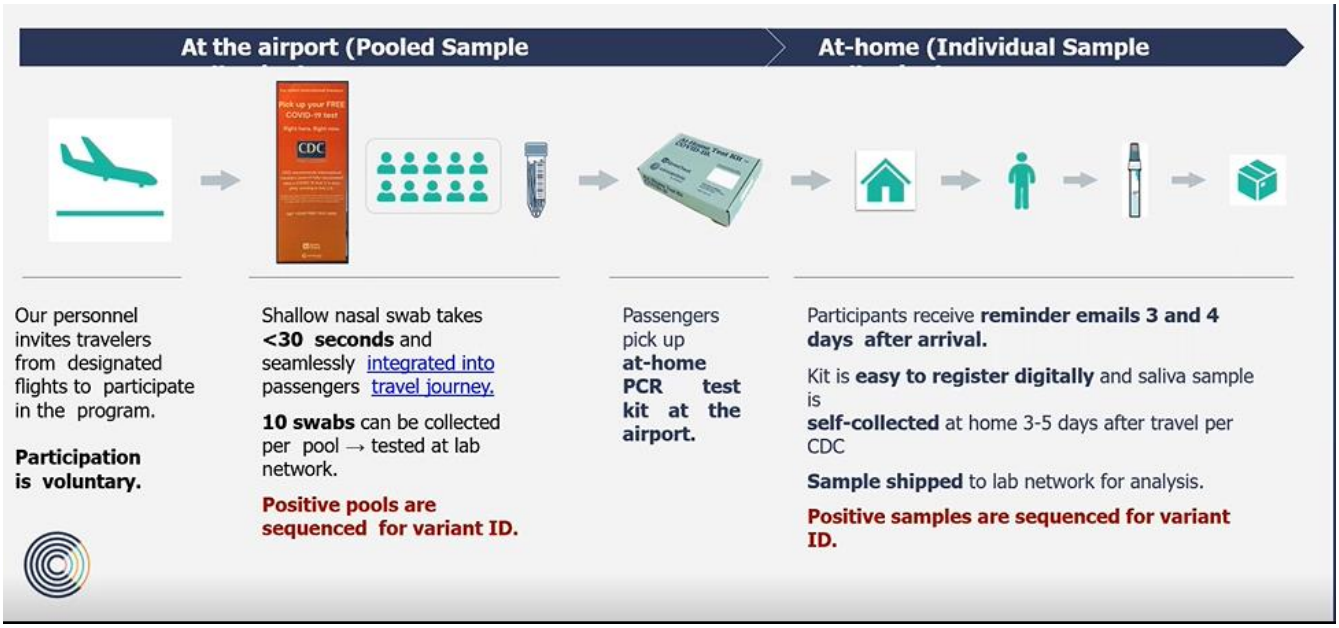

Figure 2: Traveler-based SARS-CoV-2 genomic surveillance program methodology.

The program covered 45,400 participants across 4,004 pooled samples. The program collected samples from positive cases at arrival (pooled) and 3–5 days after arrival (individual at-home). The team distributed 5,250 at-home tests to those individuals. This study included both US domestic and international flights, allowing medical intelligence regarding country of origin for outbreaks to be collected. The resulting data's positivity curve closely matched the nationwide positivity, and reflects the Omicron surge that started at the end of November 2022.

From the sequencing, they were able to map out which variant came when. Through this program, they were able to pick up the first case of BA.2 and BA.3 in the US before it was seen in clinics. In conclusion, programs like this can allow a window into the global pathogen status and allow for building a system integrator approach for the future of biosecurity.

SHIELD Overview (Dr. Keith Campbell, FDA/CDRH)

Systemic Harmonization and Interoperability Enhancement for Lab Data (SHIELD) is an initiative where stakeholders aim to improve the interoperability and quality of diagnostics data. SHIELD's mission is to "Describe the same test the same way anywhere in the Healthcare ecosystem." Figure 3 shows the timeline of events for the SHIELD initiative.

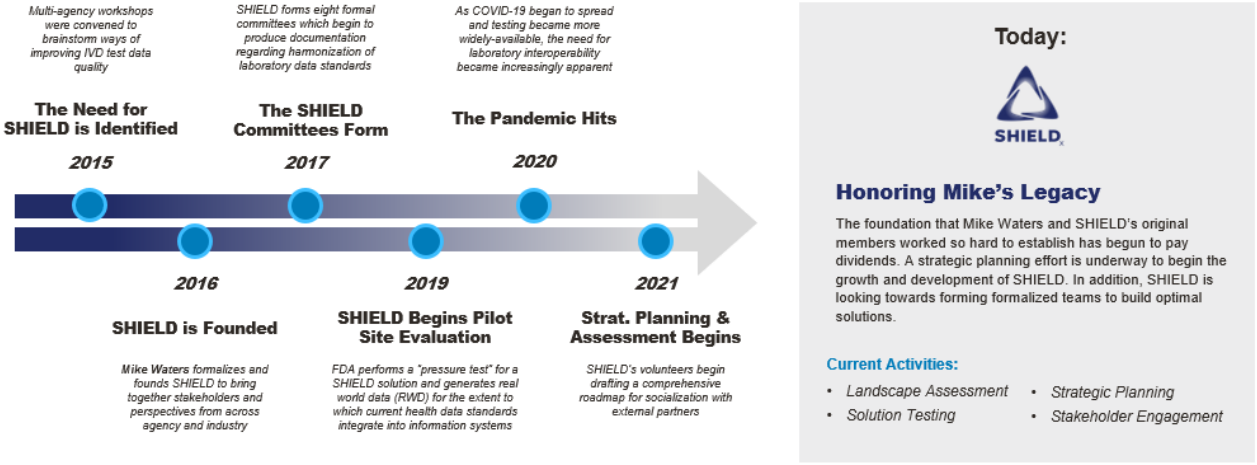

Figure 1:Timeline of the SHIELD initiative.

In order for laboratory data to be useful, it must move through numerous systems without the loss of meaning, while maintaining *data integrity** and *data agility*.* This means that data must be transformed with 100% accuracy from a laboratory analyzer, through the Laboratory Information System (LIS), and the Provider Electronic Health Records (EHRs). Finally, the data must be available to data consumers in an accurate and understandable format such that it has utility for the improvement of patient safety and care, for public health reporting, healthcare research and innovation, clinical decision support, regulatory decision making, outbreak monitoring, signal detection, and the generation of real-world evidence (RWE). However, in reality, laboratory data integrity can be severely comprised (as illustrated in published studies) as a consequence of incompatibility and variation in system implementation and localized configuration.

* *Data integrity ensures that data – from point of order to point of use – has not been altered in an unauthorized manner. Dependent on data integrity is data agility, the ability to respond to new demands for data safely, reliably, and promptly. Data integrity and data agility are foundational components for achieving highly reliable data integration, robust analytics, and enterprise-wide reporting capabilities.*

The Centers for Medicare and Medicaid Services (CMS) is responsible for the oversight of test performance in certified laboratories. They ensure that clinical laboratories maintain an acceptable performance level using several mechanisms such as laboratory inspections, oversight of personnel qualifications, and proficiency testing (Clinical Laboratory Improvement Amendments of 1988 [CLIA]). However, currently, there is no process for ensuring that test name and test context are correctly and reliably represented in the LIS, nor that they are correctly transformed from the LIS to the EHR. Efforts

by (In Vitro Diagnostic) IVD manufacturers and others to support laboratories in the correct naming of COVID-19 tests have been greatly facilitated by generation of a centralized source of test names linked to individual IVDs.

An example of a transformation error that can have a profound impact on an individual patient is illustrated below in Figure 4.

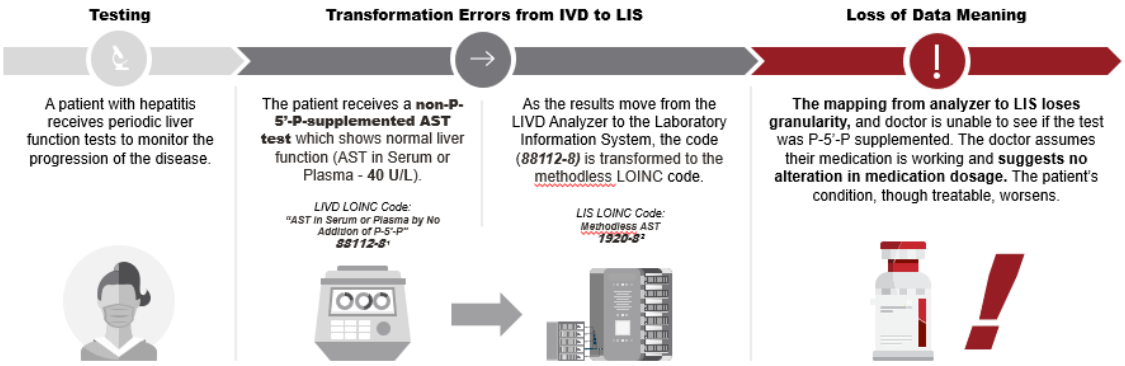

Figure 2: Real-World Example of a Transformation Error from IVD to LIS. https://www.linkedin.com/pulse/lab-result-interoperability-ast-andrea-pitkus-phd-mls-ascp-cm/

Real world data (RWD), or data collected as part of routine clinical care, is integral for decision making by public health officials, IVD manufacturers, and regulators, among many others. However, there are often silos and incompatible health IT systems that make it difficult to exchange and interpret data.

Existing challenges in the health IT ecosystem include:

- There is no systematic application of codes by device manufacturers and data standards are not harmonized;
- Existing standard interface specifications between IVDs and LISs are not implemented consistently across systems;
- There is no hierarchy of concepts in the primary laboratory data standard; and
- Not all relevant and pertinent data elements are codified or included in current laboratory systems.

These challenges limit the interoperability of laboratory data leading to negative patient, provider, and public health impact. There is a need for standardized efforts to enhance laboratory interoperability across the healthcare system.

SHIELD is a public-private partnership (Figure 5), that was formed to address these interoperability challenges. SHIELD is creating a platform to address areas of improvement, and is facilitating collaboration across government regulatory bodies, public health laboratories, private healthcare systems, and IVD device manufacturers. SHIELD's focus is to develop long term solutions that prioritize Ecosystem Engagement; Enhanced Analytic Data Storage; Systems Thinking; and Knowledge Management.

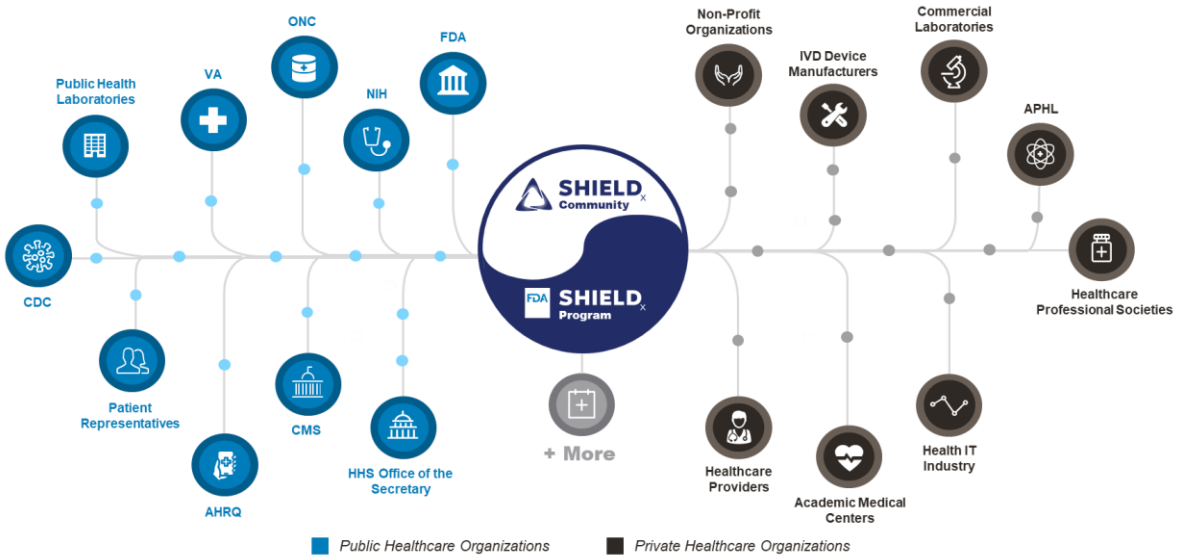

Figure 3: SHIELD: Bridging the Public-Private Gap

Next Steps

- Continue making data connections through the Evidence Accelerator and through www.EvidenceAccelerator.org.

Next Meeting: Thursday, August 18, 2022 12-1 pm ET