

COVID-19 Evidence Accelerator Collaborative

Diagnostics Evidence Accelerator #47

Thursday, May 19, 2022, 12-1 PM ET

Call Summary

Introduction to Diagnostics Evidence Accelerator Meeting #47

This week's Diagnostics Evidence Accelerator meeting consisted of 3 presentations:

- Connecting the Pipes (Amar Bhat, Reagan-Udall Foundation for the FDA)
- IVD Sponsors' RWD Needs for Test Development and Regulatory Purposes (Nate Carrington, Roche Diagnostics)
- Introduction to Graphite Health (Dr. Stan Huff, Graphite Health)
- ONC TEFCA Recognized Coordinating Entity (Mariann Yeager, The Sequoia Project)

Connecting the Pipes (Amar Bhat, Reagan-Udall Foundation for the FDA)

At the beginning of the Evidence Accelerator series, the community wanted to understand the interrelationship between diagnostics real-world performance and outcome assessment. The community stated that we need to be able to connect the pipes between diagnostic testing and outcome. The critical aspects for the FDA was knowing test manufacturer, type of test, collection date, result date and test result. Given that there are many types of data sources to help us fill the data gaps, reality shows that connecting all of the "data pipe" is challenging. Figure 1 shows the different sources of data. This led to increased discussion into understanding the steps need to improve the data flow for interoperability.



Figure 1: Sources of data.

Additionally, in October 2021, FDA/CDRH shared four priority regulatory use cases and the minimum data elements needed to address these use cases. See figure 2 for the use cases and priority data elements.

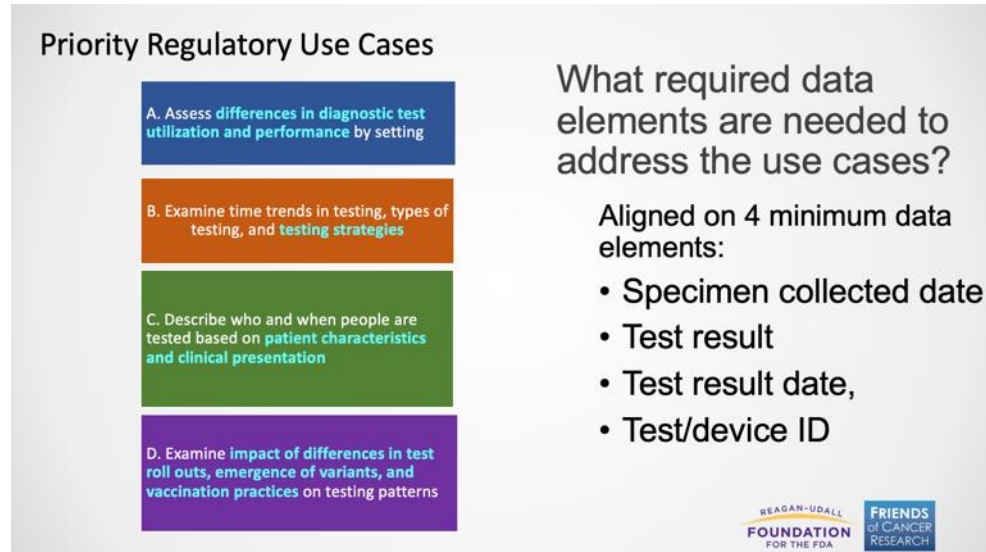


Figure 2: Regulatory use cases and priority data elements.

IVD Sponsors’ RWD Needs for Test Development and Regulatory Purposes (Nate Carrington, Roche Diagnostics)

This presentation discussed the real-world data (RWD) needs for test development and the interoperability needs. In order to use RWD and real-world evidence (RWE) for regulatory decision-making purposes, there is a need for a common digital format that enable unambiguous identification of IVD test result information. This format has to be the same across the health care ecosystem ((including providers, EHR and LIS vendors, and IVD manufacturers).

Several stakeholders proposed the an LOINC to Vendor IVD (LIVD) Digital Format Proposal v2.0 to enable the identification of IVD test results. Figure 3 shows the different components of the proposal.

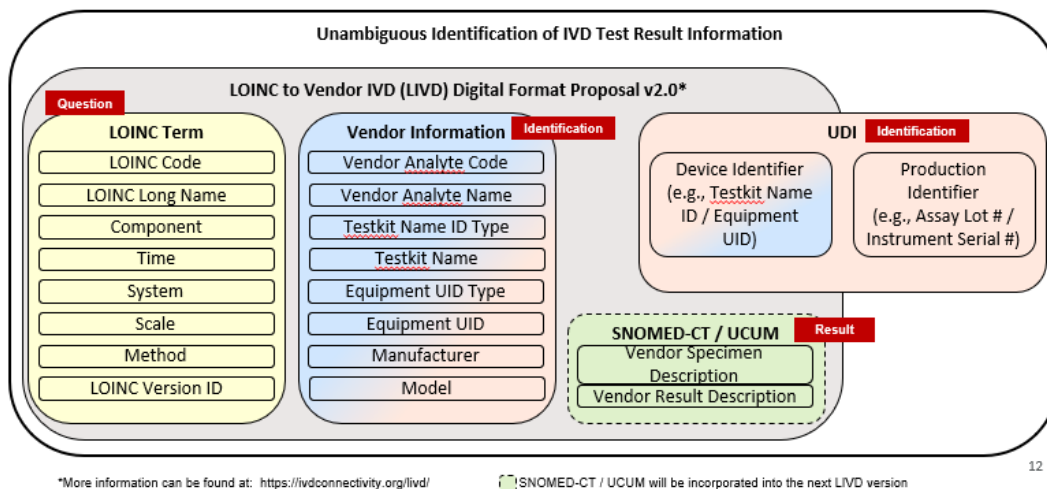


Figure 3: Component of the LOINC to Vendor IVD (LIVD) Digital Format Proposal v2.0.

The LOINC term component is intended to capture the question that is being asked in a digital format. Additionally, the proposal is intended to capture the description of the specimen and the vendor result description through the SNOMED codes. The proposal is also intended to capture the vendor information and unique device identification (UDI). There are 2 components to the UDI, the device identifier and production identifier. The device identifier is part of the proposal but the production identifier is not. However, since the production identifier is important, stakeholders are looking to add this as part of the proposal. Without having this combined, we will not be able to understand the complete picture of IVD testing and reimbursement purposes.

Introduction to Graphite Health (Dr. Stan Huff, Graphite Health)

Graphite Health is a not-for-profit company with a mission to establish a trusted digital ecosystem, composed of a plug-and-play interoperable data platform and application marketplace that will drive the advancement of healthcare for all patients. Figure 4 shows the core elements of Graphite Health.

	Data Standardization Platform	Graphite Data Standard	Marketplace	Graphite Labs Application Services
Purpose :	Ingest, organize and normalize member data via cloud agnostic infrastructure	Terminology, structure and format of health data for plug and play interoperability	Distribution, certification and billing mechanism for Graphite certified application	Tools, data, and information for app development
Ownership/ Control :	Public utility infrastructure development controlled and ownership or co-ownership	Open source with guardrails to maintain value proposition of plug and play interoperability	Graphite owned and managed due to maintenance of trust, privacy and governance	Partnerships and co-promotion
Development	Sourcing of critical parts via open source, vendors, co-development or partnership. Potential JV but complicated	Collaborations and market influence. Anticipate multiple strategic alliances	Open source, development or strategic partnership	Alliance, development, partnership.

Figure 4: Graphite Health Core Elements

The graphite standard allows for one way to standardize the data in a voluntary manner. It is open source to allow for stakeholders to collaborate. Graphite Health has models that are used to standardize the data which are then available to use in interoperability platform and application platform. The information is accessed through FHIR services. Even though there are specific standards, there are multiple ways to represent the data. the reason for this is due to convenience for input and analysis. The graphite standard is providing the exact LOINC code for stakeholders. Graphite Labs allows stakeholders to create additional applications that they might need. Once the application is developed, it can be certified as Graphite compliance and can be shared with additional stakeholders. Graphite health is working on standardizing library of FHIR profile for sharing COVID-19 test results and information. This also includes content for understanding comorbidities and exposures. There are challenges when trying to accomplish this. One challenge is that the team is having trouble finding partners that are willing to help them standardize this.

ONC TEFCA Recognized Coordinating Entity (Mariann Yeager, The Sequoia Project)

The goals of TEFCA are to: 1. Establish a universal policy and technical floor for nationwide interoperability; 2. Simplify connectivity for organizations to securely exchange information to improve patient care, enhance the welfare of populations, and generate health care value; and 3. Enable individuals to gather their health care information. There are many benefits for the state government and public health with this program. The benefits are to improve access to population health data, further advancing interoperable exchange for Medicaid, support public health reporting, facilitate bidirectional exchange, facilitate emergency preparedness, and augment state-level information exchange initiatives. Figure 5 shows how the exchange will operate.

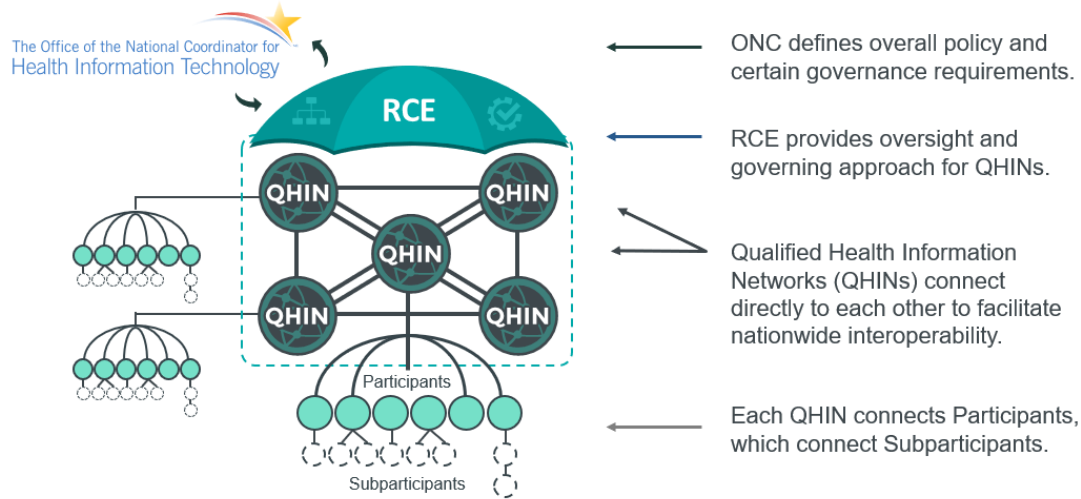


Figure 5: How the exchange will work under TEFCA.

There will be a common agreement that will be followed for anyone using the exchange. The common agreement states “Each QHIN shall voluntarily enter into a contractual agreement with the RCE by signing the Common Agreement, making all QHINs parties to the Common Agreement. The Common Agreement includes flow-down clauses for the QHIN’s agreements with its Participants and each Participant’s agreements with its Sub participants.” The required flow-down will address Cooperation and Nondiscrimination, Confidentiality, Utilization of the RCE Directory Service, Uses, Disclosures, and Responses, Individual Access Services, Privacy, Security, Special Legal Requirements, TEFCA Information Outside the U.S., and Other General Obligations.

There are two modalities for the exchange: query and message delivery. The query includes the core data elements required by HHS. The purpose of the exchange is to do the following:

- The Exchange Purpose identifies the reason for which information could be requested or shared through QHIN-to-QHIN exchange.
- Only these six Exchange Purposes are authorized under the Common Agreement.
- A forthcoming SOP will specify that Treatment and Individual Access Services (IAS) require Responses.
- Eventually, the other four Exchange Purposes will require Responses in conformance with forthcoming implementation guides. These will be rolled out with adequate time for stakeholders to prepare.
- Additional Exchange Purposes may be added over time, including whether they require Responses.

Figure 6 shows the timeline to operationalize TEFCA. If accelerator are interested in learning more, then they can view additional resources on TEFCA [here](#).

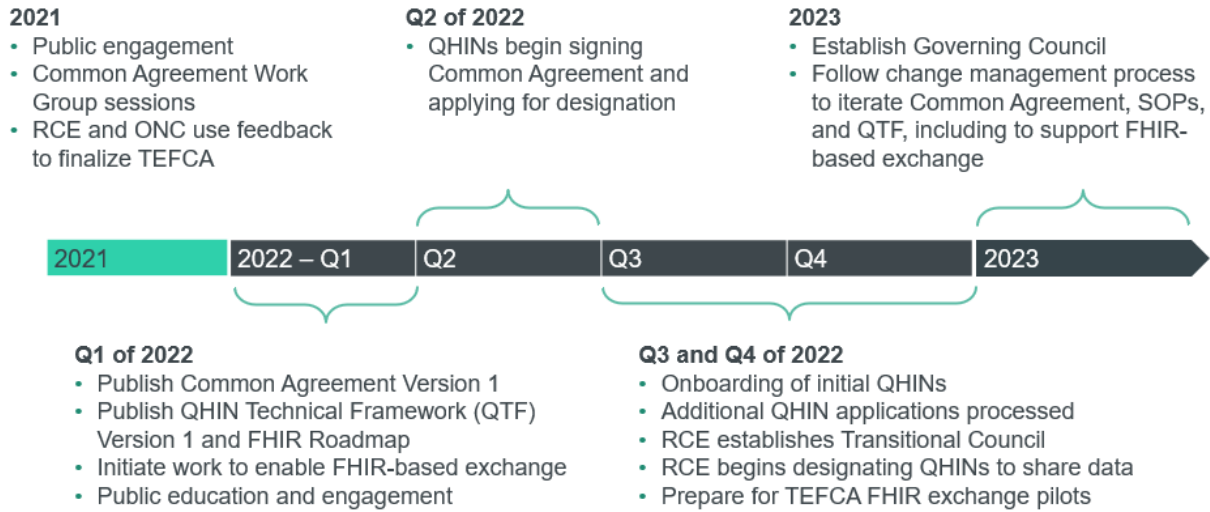


Figure 6: Timeline to operationalize TEFCA.

Next Steps

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

Next Meeting: Thursday, June 16, 2022 12-1 pm ET