



## **COVID-19 Evidence Accelerator Collaborative**

### **Diagnostic Accelerator #6**

*Thursday, July 9, 2020, 12:00-1:00 PM ET*

#### **Call Summary**

##### **Introduction to Diagnostic Accelerator Meeting #6**

The Evidence Accelerator is a collaboration of many organizations and stakeholders working together to address issues surrounding COVID-19 through RWD. Sara Brenner from the FDA/CDRH states that it is important to understand and improve data quality and harmonization of reporting efforts as the number of cases in the United States increase. Additionally, being able to understand and use diagnostic test performance evidence as a foundation is critical to address COVID-19 as this will lead to where additional resources are required.

There were 4 presentations given during the 6<sup>th</sup> Diagnostics Evidence Accelerator meeting. Those presentations are as followed:

1. PCR and Serology Testing at Danaher (Shamiram Feinglass, CMO Danaher)
2. Verily's Baseline and COVID 19 Support (Jessica Mega, CMO/CSO Verily)
3. Exploring Different Data Sources and Connections (Amy Abernethy, FDA)
4. Moving to Parallel Analysis Question Set #1 (Jeff Allen, Friends of Cancer Research)

##### **PCR and Serology Testing at Danaher (Shamiram Feinglass, CMO Danaher)**

The main point of this presentation was that companies only transmit data to the Laboratory Information System (LIS) that is requested by their customers. Companies also are collecting additional data points that aren't requested by the customer to be transmitted to the LIS (standard for how instruments are run) and are therefore not transferred from the instrument (these data remain on the instrument; nobody accesses them). This raises the question of whether that additional data being collected can be used as RWE for COVID-19.

Cepheid (molecular diagnostics) and Beckman Coulter Diagnostics (serology) are working to answer key diagnostic questions regarding COVID-19. We also have other companies creating extraction kits (IDT and Beckman Life Sciences). PCR tests determine if a patient currently has COVID-19 and the serology test is used to see if a patient had COVID-19 and if they developed an immune response to it.

The topic discussed was where does the data go once it is collected. The data flows into a remote monitoring system and into the Laboratory Information System (LIS). The stored data alerts the company about quality issues that may arise (via the remote monitoring system). They collect many data points but only the predetermined data points indicated by the hospital, labs, and clinics will be reported into the laboratory information system (Customer requests what they need). The laboratory

information system then communicates to the patients EMR. Finally, the results are given to the patient, physician, or hospital.

There were important points raised during the discussion of this presentations. The points were as followed

- Since Danaher is collecting more data elements than they are reporting, the additional data points housed in Danaher's system might be able to be used to understand COVID-19.
- Danaher is providing the requested data elements to the customer which makes the customers responsible for reporting the data according to the new HHS reporting guidelines.
- The customers will receive the predetermined data elements that they have requested, therefore, the additional data elements collected can be reported to customers to help them fulfill the HHS guidelines.
- The customer owns the data; the company does not.

### **Verily Baseline and COVID-19 Support**

Verily's mission is to build an end to end evidence generation platform to accelerate scientific discovery and improve health outcomes. Before the COVID-19 pandemic, Verily was working on the Baseline Health Study which looked at various aspects of human life, human environment, claims data, and EHR data to understand human physiology. Through this effort, they have developed tools and technology that will accelerate clinical trials and evidence generation.

At the beginning of the epidemic, there were a limited number of screening tools. This prompted Verily to develop a program that will improve testing and screening. The objectives for this program was to optimize test allocation, reduce risk, being efficient, and have a scalable model.

Verily has developed a system for screening. First, the participant completes a screening where the participant fills out eligibility screener from the Baseline website. Next, the participant schedules the testing appointment. Then, Verily generates labels and orders through physician ordering group. Participant receives an email with their requisition ID. Verily saves and adds the requisition ID into the label sheet. The sites receive requisitions in bulk and print both labels and requisitions prior to visits. The samples are labeled and matched with the corresponding requisition and both are placed into a biohazard bag for sample collection. Then, the participant goes to their appointment. Finally, the lab processes the orders and reports the results through Verily's platform.

Some of the features that they are providing for screening and testing are bilingual language support, online scheduling, configurable screener, lab workflow automation, re-screening support, re-testing support, secure return of results, and direct return of data to public health officials. Verily has over 150 testing sites in 13 states and over 350,000 tests have been completed which provides them with important data elements such as participant ID, location, demographic information, travel sites, symptoms, clinical conditions, and lab data. They have a 94% overall satisfaction rating among their participants.

Verily is allowing patients to opt in their information for epidemiological purposes. The people that do opt in to providing their information can join their patient-centric registry. Participants can participate in various research areas. So far, they have more than 39,000 accounts created and more than 31,000 individuals consented. Verily believes that this will be a great tool for researchers in the Diagnostic Accelerator to engage patients in the studies.

### **Real World Performance of Diagnostics and Outcome (Amy Abernethy, FDA)**

It is important to connect all of the information and data elements together to combat COVID-19. There is data in various sources that we need to bring together. Practically, we need to connect a few pipes instead of connecting many pipes together. By answering one question at a time, we will be better prepared in the future.

### **Moving to Parallel Analysis Question Set #1 (Jeff Allen, Friends of Cancer Research)**

Many of the questions that were proposed in the first diagnostic meeting build upon each other. One question that was proposed was to research the accuracy of testing. Finding participants that can provide linkages to answer this question and provide data on patients that are PCR positive for COVID-19 and the sensitivity for subsequent antibody testing is a step that will be taken to answer the question. It is important to link test manufacturers and test results to clinical and demographic data. The goal is to create a foundational approach with this question so in the future we are able to add additional questions to better understand the full impact of COVID-19.

In order to do this research in parallel, finding participants with multiple data sets and aligning the core questions will allow the research community to work together and learn about different approaches that can be taken to answer all of the questions surrounding COVID-19. Linking clinical information with the test the patients received, test results and timing of the results is crucial to connect the pipes.

The first step into launching the parallel analysis is to recruit participants willing to provide data to answer the question.

### **Discussion:**

Important points were raised during the discussion portion of the call:

- There is a risk of duplicate testing records. As per Quest Diagnostics, there is a way to estimate duplicate testing records which will be an important element for the research community to look into when answering these questions.
- There are more serology tests being conducted which will be a data element that we can see in the sample size.
- One challenge that will arise is that it will be difficult to link one patient's medical records since that patient can go to multiple health systems or hospitals over time.

### **From the Chat Box:**

Important points and questions raised in the Chat Box:

- According to the new HHS reporting guidelines, the party that is responsible for reporting is the performing laboratory
- Danaher is able to provide additional data elements that may be needed for future research and reporting.

- It was made clear that the data elements that can be reported back to the ordering providers are test results, test result date, unique patient identifier, test ordered, device identifier, accession number, and specimen ID.
- An important question that was asked was how we move data collected into a data linkage environment (EHR record, PCORnet, claims data, Sentinel, etc.) as nationwide interoperability is critical.
- Data from labs about device identifier, manufacturer, etc. can be accepted by health systems and clinics. The challenge is going to be how to resource it in the IT departments since most health departments are minimizing their IT department due to budget issues.
- Labs are required to report device ID and providers are recommended (but not required) to do so. Thus, unless the health system needs it for reporting, they might not request the device ID be transmitted from LIS to EHR. EHRs may/may not choose to engage that transmission because of resource issues unless they are legally required to report it.
- It may be hard to track all testing data over time since there are many different ways to get tested and many different testing locations. The solution that was suggested was to leverage linkage via lab datasets and larger claims/EHR datasets and look at the linked subsets.

**Next steps:**

- Recruit participants willing to provide data to answer the question.
- Work on gaining funding to move forward with the parallel analysis.

**Next Meeting: Thursday July 16<sup>th</sup>, 2020 12-1 pm ET**