



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

### **Diagnostics Evidence Accelerator #41**

*Thursday, December 2, 2021, 12-1 PM ET*

#### **Call Summary**

##### **Introduction to Diagnostics Evidence Accelerator Meeting #41**

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

1. Diagnostics: Pandemic's Next Phase – COVID and Beyond (Mara Aspinall, Health Catalysts)
2. Real World Data Survey Checklist (Dr. Gracie Lieberman, Dr. Andre Araujo)

As always, thank you to all of the analytic partners, strategic advisors, and scientific advisors that are participating in Project One of Diagnostics Evidence Accelerator.

##### **Diagnostics: Pandemic's Next Phase – COVID and Beyond (Mara Aspinall, Health Catalysts)**

With the new variants and surges, establishing mitigation techniques has become increasingly important. However, there are complications in the current mitigation techniques such that there is little interest in establishing mitigation behavior. Mitigation techniques such as vaccination rates are unlikely to rise in the US even though there are new variants, mask compliance may remain low, distancing is non-existing, travel bans are not effective or sustainable, and therapeutics may or may not be effective. Additionally, vaccine immunity wanes and there is substantial asymptomatic and pre-symptomatic spread.

The presentation highlighted five questions that we as the community need to look at answering. The questions are

1. How do we save lives from COVID in the US in the next year?
2. How do we maintain / increase economic growth amidst COVID?
3. Where do we focus resources and time?
4. When / how do we move from pandemic to endemic?
5. Do we need to redefine "fully vaccinated"? Is this the original shot or is this the original shot and the booster shot?

The answer to some of the questions is testing. We need to ensure that there is testing that is accessible and affordable by enhancing the ITAP program with high-capacity tests and ensuring more than adequate staffing at FDA for diagnostics EUA reviews. Also, we need to complement current test access through distribution in underserved communities and encourage regular screening testing for vaccinated individuals.

The reasons why we should test regularly is to:

1. Understand vaccine efficacy & duration of protection. There are no vaccines that are 100% effective and vaccine immunity wanes. Therefore, we need to test regularly to identify, quarantine, and treat individuals that are positive for COVID-19.
2. Control asymptomatic spread. There are 20-40% of cases that are asymptomatic. Additionally, asymptomatic spread is a risk between kids and teachers even if they are vaccinated. Therefore, regular testing can help identify patients that are asymptomatic.
3. Protect the non-vaccinated. Not everyone will be vaccinated due to hesitancy and eligibility. Therefore, regular testing can help control the spread of COVID-19 among the non-vaccinated and vaccinated.
4. Understand and capture mutations: The virus is known to mutate, therefore, having regular testing can help mitigate the spread of variants.

In order to prepare for the future, we need to

1. Increase genomic sequencing. This would allow the public health community to assess the different variant and how to mitigate them. Additionally, we need to increase national and international reporting. In November 2021, there was an average of 2.6% of cases that were sequenced and reported to Global Initiative on Sharing All Influenza Data (GISAID). The states that were leading the reporting were Vermont, Massachusetts, and California. In the UK, the average for sequencing and reporting to GISAID in November was approximately 10%. Currently the average in the US is 3.7% and the average in the UK is 12.7%.
2. Create a National Test Reporting Standard and create a Home Test Coding requirement. Throughout the pandemic, the number of PCR tests that are unreported is increasing. In the month of November 2021, there were 15% of PCR tests that were unreported. At the beginning of the pandemic, there were 5% of PCR tests that were unreported. This is due to many public health labs stating that they are understaffed and do not have the capacity to report the tests. Additionally, the number of antigen tests that are unreported has increased throughout the pandemic. The reason for this is due to the number of at-home tests that are not reported.
3. Creating strategic stockpile for tests.
4. Surveillance planning.
5. Create separate FDA diagnostic regulation from medical devices and create a new center called Center for Advanced Diagnostics and Research (CADER). Also, we need one system not two so that all government agencies are on one page.
6. Eliminate paternalism to allow for at-home tests and increase education in result provision for patients and providers.

From the Chat Box:

- The problem with high-sensitivity/lower-specificity antigen testing is that it feeds the disinformation/ misinformation in the data ecosystem. There are individuals that get false positive and add misinformation on social media. This makes it difficult to implement screening testing in community.
- Can you say more about what suggests that Omicron may derive from an immune-compromised patient?
  - This assumption is based on the popular media, however, there are 61 mutations and 35 of the mutations are in the spike protein. There are 24 mutations that are similar to the Beta variant and 22 that are similar to the Alpha variant. Since there are so many different

mutations in the variant, it is thought that it had to come from an immunocompromised patient which allowed for the mutations.

- The VALID act has been reintroduced in Congress to establish separate regulations for in vitro clinical tests from medical devices. Stakeholder review is in progress along with advocacy efforts on the Hill.
- Unfortunately, there are also technical barriers to moving the CT value from instrument to lab information system to clinician EHR. Therefore, this pandemic should be used as an example to mitigate the barriers that exist so that we would be prepared for future pandemics.
- Increasing Education on Data Ethics: Cimino at the recent AMIA annual meeting, described the fiduciary need to implement data ethics. “Increasingly, data scientists, analysts, and engineers are becoming fiduciarily responsible for patient safety, treatment, and outcomes, and will require training and tools to meet this responsibility”.

### **Real World Data Survey Checklist (Dr. Gracie Lieberman and Dr. Andre Araujo,TransCelerate)**

TransCelerate is a not-for-profit entity created to foster collaboration. Their mission is to collaborate across the global biopharmaceutical R&D community to identify, prioritize, design, and facilitate the implementation of solutions designed to drive the efficient, effective, and high-quality delivery of new medicines.

TransCelerate developed a Real-World Data (RWD) Audit Readiness Checklist. The focus of the work operationalizes the thought leadership stemming from Duke Margolis, FDA and many others on the use of RWD in regulatory decision-making. The team leverages Health Authority and Data/Service Provider interactions to develop documentation that supports quality management (QA, QC, and audit) for RWD sources, resulting in an “Audit Readiness Checklist” tool targeting data relevance and reliability. The Audit Readiness Checklist will help operationalize best practices in order to aid quality management oversight of RWD, including inspection readiness, in a manner suitable for regulatory decision making. The overall goal of the checklist is to build trust, reduce barriers, and demonstrate fit-for-purpose use of real-world evidence (RWE)/RWD.

The team has consulted with many stakeholders to develop this checklist. However, the voice that is missing from the development of the checklist is Data /Service Providers such as: Market Suppliers, EMRs / EHRs, Payers, Clinical Disease Registries, and Qualified Clinical Data Registry Companies. Therefore, the team developed a survey to capture the voice of data holders. Accelerators can access the survey [here](#).

### **From the Chat Box**

- Is TransCelerate linked to the SHIELD consortium regarding data provider voices and addressing interoperability as basis for reliable RWE?
  - No, however, this is an excellent avenue for exploration.
- Have you engaged sponsors/regulated industry (who may use RWD) for safety studies, for example, and who may audit researchers/data providers be in this conversation?
  - Yes, TransCelerate has engaged sponsors and regulated industry.

**Next Steps**

- Continue making data connections through the Evidence Accelerator and through [www.EvidenceAccelerator.org](http://www.EvidenceAccelerator.org).

**Next Meeting: Thursday, December 16, 2021 12-1 pm ET**