Accelerating Evidence Generation by Convening Diverse Stakeholders Across the Real-World Data Ecosystem

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Abstract

The COVID-19 Evidence Accelerator is a collaborative community of engaged stakeholders from across the health ecosystem, where real-world data are put to use to address the urgent public health need.
The Evidence Accelerator approach is a model that can be adapted and refined to address further scientific and research needs.

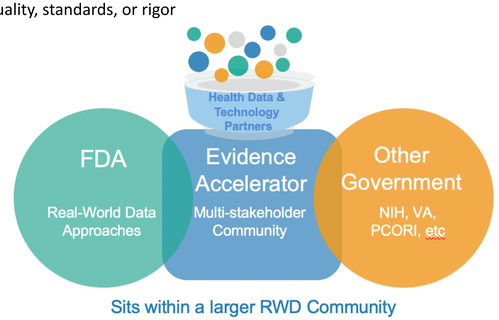
The COVID-19 Evidence Accelerator brings together leading experts in health data aggregation and analytics in a unified, collaborative effort to share insights, compare results and answer key questions. The Evidence Accelerator involves more than 200 organizations across the health data ecosystem: FDA, major health data/technology organizations, academia, professional societies, patient advocates, health systems, insurers, biopharma and medical device companies.

Background

In a situation with little historical data and a dearth of traditional sources of information, the COVID-19 pandemic required learning about the disease in real-time, from disparate data sources, in a multi-pronged approach.

- Bringing together diverse stakeholders to the (virtual) table, in an "all-hands" approach was one of the important mechanisms for advancing real-time understanding of COVID-19
- The ***COVID-19 Evidence Accelerator (EA)*** was launched in April 2020 by the Reagan-Udall Foundation (Foundation) for the FDA, in collaboration with Friends of Cancer Research (Friends)
- FDA is an active participant in the COVID-19 Evidence Accelerator and provides input on prioritized research questions and areas where RWD may provide a fuller picture to advance the understanding of COVID-19
- >200 representative organizations (as of April 2021) comprise the EA community, representing diverse contributions to the broader real-world data community **(Figure 1**):

Figure 1. Evidence Accelerator Stake holder Community
Facilitates the spirit of collaboration and learning, without sacrificing quality, standards, or rigor



Materials and Methods

Launching the Evidence Accelerator required:

- Generating core questions of relevance to the FDA; **(Table 1)**
- Identifying RWD elements of potential applicability to those questions;
- Identifying groups who hold, or analyze, such data;
- Convening those groups to understand the strengths and weaknesses of the data;
- Establishing a path forward to use data sources to address the generated questions.

Within the COVID-19 initiative, early efforts focused on the natural history of COVID, related treatments, and the model expanded to diagnostic tests and, more recently, vaccines. Routine collaboration led to the emergence of a living textbook to capture RWD efforts and understanding, a forum for online collaboration, and master protocols to explore similar questions.

Bi-monthly, one-hour, "lab meetings" focused on therapeutics, diagnostics, and vaccines provide the venue to share new data assets, analyses, challenges, and opportunities (**Figure 2)**

The community developed a set of principles to CREATE and LEAD (**Figure 3**), these are critical to advancing work in the Evidence Accelerator and for RWD writ large

- In the spirit of transparency, all meetings are documented, and public summaries are available on the website at www.evidenceaccelerator.org

Figure 2. Evidence Accelerator Work Streams: Representative participants join one or more lab meetings, parallel analysis research groups, or cross-cutting working groups

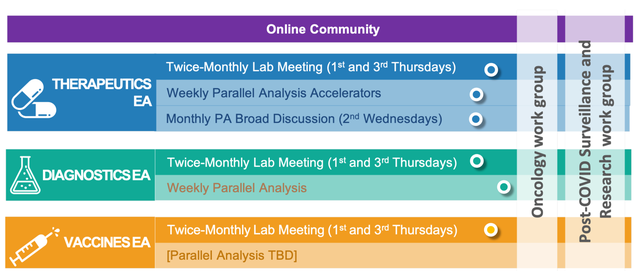
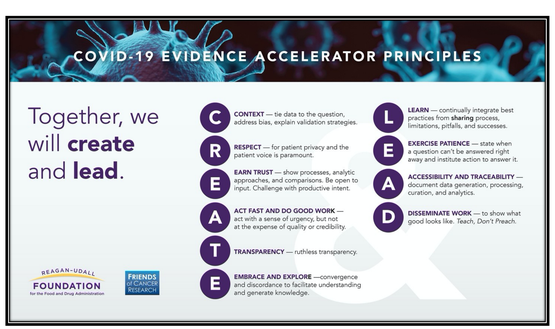


Table 1. Prioritized Research Questions: Collection of questions relevant to COVID-19 and real-world data

KEY QUESTION LIST (generated April 2020)
General epidemiology of COVID-19
Predictors of patients at risk for development of severe COVID-19 disease
Patterns of general outcomes for people with COVID-19 (e.g., death, time to disease resolution)
Patterns of COVID-19 diagnostic testing and results
Patterns of development of COVID-19 immunity across the US population
Can real world data support the evaluation of the performance characteristics of COVID-19 diagnostics?
Are there data that could help identify an evolving COVID-19 hot spot before molecular testing results become available?
What medications are doctors prescribing for COVID-19 in the real world?
What treatments are being prescribed?
Which patients are most likely to get which treatments?
Which treatments are being prescribed in the context of clinical trials?
Treatment patterns for specific subpopulations (e.g., pregnant women, underlying COPD)
Patterns of enrollment in COVID-19 clinical trials
Can real world data provide initial understanding of safety and effectiveness of therapies used for COVID-19?
In particular: safety of hydroxychloroquine and chloroquine, with or without azithromycin
Predictors of treatment safety and effectiveness
Safety for specific subpopulations (e.g., pregnancy)
Are there data that can inform risk and/or management of drug shortages (e.g., surge in demand, available drug supply)?
Can data sources be used to help identify patients who can donate convalescent plasma?

Figure 3. Evidence Accelerator Principles: Community curated guiding principles that underpin all of meetings and work efforts undertaken through the EA and empower all to *create and lead* in the real-world data space



Results and Discussion

In addition to exploring discrete research questions of interest, the effort illuminated the benefit of RWD to complement clinical trials, created a roadmap for efforts to leverage RWD for productive analyses, began developing a common language for discussing issues of relevance to the FDA and other stakeholders, and created the ability to identify the types of questions that can be answered by RWD.

Highlights

- Mechanism to keep pace with COVID-19 evolution of the infection, variants, clinical use of therapeutics, diagnostics, and vaccines
- Parallel analysis workgroups – shared analytic plan applied to different data
- Generation of new ideas – connected diverse groups to partner and research new ideas
- Share 'lessons learned' to shorten the cycle-time among myriad research efforts
- COVID-19 RWE "Living Textbook"
- Addressing complex topics such as "long-COVID" and the downstream COVID/pandemic collateral issues such as the impact on mental health
- Medication Working Group
- Launched post-acute sequelae SARS-CoV-2 infection (PASC) steering committee
- Oncology prioritized questions and data/tech -- PostCOVIDity

Conclusion

The application of rigorous analytic methods and a facility with real-world datasets offers the opportunity to rapidly evaluate changes in practice, uptake of new therapies, and the understanding of the natural history of COVID and related sequalae. Beyond addressing questions of interest to FDA within COVID-19, the Evidence Accelerator model can be adapted for other public health and regulatory use cases, such as substance use disorders.
Providing a forum for active discussion and engagement can energize participants and stimulate stakeholder collaboration.