COVID-19 Evidence Accelerator Collaborative

Lab Meeting #16

Thursday, August 6, 2020, 3-4 pm ET

Call Summary

Introduction to Lab Meeting 16

Recognizing the need for process evaluation throughout the lifecycle of agile projects, this week's lab meeting was conducted as a "Retro," or retrospective analysis, of the COVID-19 Evidence Accelerator Collaborative. The purpose of this retro was to allow participants to reflect on their experience with the Accelerator workstreams thus far and make suggestions for process changes moving forward.

Anchoring Information

For context, a few Evidence Accelerator metrics and the original objectives of the project were shared with the group:

- The Evidence Accelerator was launched on April 16, 2020 with the goals of providing a venue to conduct parallel analyses, to gather the broader research community to share learnings, and to strategize on what additional analyses should be addressed.
- Original objectives included:
    - To develop common elements and a common data model to enable rapid work
    - To convene weekly to explore a common theme
    - To summarize each meeting, communicate regularly
    - To generate new hypotheses
    - To prioritize data elements that help inform critical data collection
- The Parallel Analysis question sets are at different stages in their lifecycles, with Question Set #1 (hydroxychloroquine) being in the whitepaper preparation stage and Questions Sets #2 and #3 in preparation and alignment stages, respectively.

Discussion

Discussion points, whiteboard, and chat contributions have been grouped generally into categories. These categories include reflections on Accelerator successes and recommendations for Accelerator improvements.

Accelerator Participants

- The Evidence Accelerator has pulled together a diverse, interdisciplinary group of representatives from across the industry. This spirit of cross-industry participation and engagement should continue to be fostered.
    - Agile collaboration with the FDA within the Accelerator community is beneficial.

- The Evidence Accelerator community is composed of independent scientists undertaking independent projects and sharing their learnings with this community. While this sharing is an important step, further effort is required to transition this into proactive collaboration.

Accelerator Goals

- Broadly, the goal of the Accelerator is to advance the understanding and adoption of decision-grade real-world evidence (RWE).
  - This is more than an academic exercise—under the 21st Century Cures Act, the FDA was tasked with exploring different clinical trial designs including the utilization of RWE.
- While the Accelerator has embraced concepts of transparency and collaboration, the Accelerator should seek to advance these principles across the broader community.

Accelerator Work Process

Lab Meeting

- Further emphasis should be placed on proactive collaboration and not just dissemination of findings. Proactive collaboration would enable organizations to work together across the community to answer COVID-19 questions.
- The creation of a "library resource" for sharing more in-depth information about projects presented in lab meeting would be useful. This library could be a place for organizations to submit code, definitions, project write-ups, and other work products for community learning.

Parallel Analysis

- The voluntary nature of Accelerator projects is of difficulty for some participants—further effort to connect these workstreams to funding is necessary.
- Avenues for the expression of high-urgency problems and a process for the prioritization of these problems for exploration by the Accelerator community or subsets of the Accelerator community should be explored.
  - FDA input on priority areas is useful.
  - Once these priority questions are established, data sources can be identified, and methods confirmed.
- The Accelerator could benefit from a more formalized "project manager/stakeholder" who serves as the decisionmaker for each project (e.g. if an additional analysis is suggested, a person to make the go/no-go decision).
- Methods for indicating when analyses are considered parallel analyses should be improved—determine 'how parallel' a 'parallel' analysis should be.
- Methods for delineating between descriptive analyses and comparative analyses should be improved.
- The opportunity to have smaller teams undertake in-depth analyses on specific topics should be considered.
- Further process refinement around the dissemination of parallel analysis project results to advance the community's understanding of COVID-19 are needed.
  - Publications
  - Public access to findings

- o Published tools
- A process for deciding when a project has been completed or when a project is no longer of interest should be established.
  - o Opportunity for a feedback mechanism.
- A value proposition which considers how the Evidence Accelerator is aiding the FDA and its decision-making, impacting the community, and advancing the development and deliverance of COVID-19 therapeutics for patients should be developed.

Areas Warranting Further Exploration

- Further effort to address upstream data pipeline pain points such as missing data, unmeasured confounding, and differential definitions is warranted.
- Standards for identifying when data are fit-for-purpose and methods for getting evidence in a credible way should continue to be explored.
  - o The creation of data and method hierarchies should be considered.
- Further emphasis among Accelerators and the broader community about the fact that not all RWE studies are of similar rigor and value is needed.
- Standardized coding efforts would greatly benefit the community.
- Consideration of how to deal with the reality that there is not a unique patient identifier is needed.
- Emphasis on the distinct goals of RWE studies and randomized clinical trials is needed. This emphasis should acknowledge that the community is not trying to replace clinical trials and the benefit of having a heterogenous population which better represents the real world.

The following Principles were discussed in an earlier Lab Meeting and refined through stakeholder input. The COVID-19 Evidence Accelerator will operate via these Principles—and continue to refine them.

*Together we will **CREATE** and **LEAD**.*

Context—Tie data to the question, address bias, explain validation strategies.

Respect—Respect for patient privacy and the patient voice is paramount.

Earn trust—Show processes. Show curation and analytic approaches. Show comparisons. Be open to input. Challenge with productive intent.

Act fast and do good work—Act with a sense of urgency, but not at the expense of quality or credibility.

Transparency—Ruthless transparency.

Embrace, and explore—Embrace and explore convergence and discordance to facilitate understanding and generate knowledge.

Learn—Continually integrate best practices from sharing. Show process, explore limitations, pitfalls, and celebrate successes.

Exercise patience—Be courageous enough to state when a research question can't be answered well enough 'right now,' yet institute action to answer it in the future.

Accessibility and traceability—Document data generation, processing, curation, and analytics.

Disseminate work—To show what good looks like. Teach, don't preach.