COVID-19 Evidence Accelerator Collaborative

Lab Meeting #17

Thursday, August 20, 2020, 3:00-4:00 pm ET

Call Summary

Introduction to Lab Meeting 17

The theme of this week's lab meeting was "shifting our work and mindset from an initial sprint to a longer endurance effort." Two presentations which highlighted efforts for improving longitudinal understanding of the COVID-19 patient experience were given:

1. Presentation on Bridging the Clinical and Real World (Arnaub Chatterjee, AcornAI)
2. Presentation on Social Listening: A Novel Approach to Collecting Real-World Data on Patient Experience (Maria Picone, TREND Community)

Following these presentations, Dr. Amy Abernethy (FDA) and Susan Winckler (Foundation) led the group in a discussion of proposed updates to the Evidence Accelerator. These proposed updates are based on Accelerator feedback from the Lab Meeting 16 "Retro" and are intended to help Accelerators maintain the sense of urgency needed to address the pandemic, keep the momentum, and continue to develop the tools needed for the community.

Lab Meeting Presentations

Bridging the Clinical and Real World

- The current state of COVID-19 data capture does not allow for a longitudinal understanding of the COVID-19 patient experience.
    - Once studies end on Day 28, we are in a data "white space" where we are unable to see the late effects of a drug or late effects of COVID-19.
    - Ideally, we would want a 1- or 3-year follow-up; however, in our current state, we have no exposure to any of these data.
- Data linkage is timely and allows for the development of a holistic way to capture COVID-19 data.
    - COVID-19 presents unique data challenges:
        - COVID-19 trials are not afforded the typical length/duration of a phase 3 trial and lack the requisite long-term follow-up and safety you'd expect in a typical trial.
        - Long-term safety and monitoring in the real world will be critical in better understanding patient response and improving drug performance and better understanding.
    - Data linkage presents a unique opportunity for impact:

        - Capturing early safety and efficacy signals.
        - Benchmarking late stage sequelae and enable data collection from late-effect studies.
        - Augment longitudinal follow up of trial cohorts.
        - Prospectively design new COVID-19 trials for specific patient subpopulations leveraging linked dataset to better understand clinical trial vs. real world outcomes.
- Benefits of linking clinical trial and RWD cohorts to monitor COVID-19 patients include:
    - Early safety and efficacy signals: By monitoring the RWD of trial participants, you will start to see signal data even before the treatment is launched.
    - Surveillance: Observe subsequent RWD on populations demonstrating lower efficacy or higher safety concerns during the trial.
    - Manage long-term safety with fewer risks of loss-to-follow-up: Linking RWD to clinical trial datasets does not need to replace or add workflows for patients, providers, or trial coordinators, but it can be an option for collecting data on patients that skip trial-related follow-ups.
- Potential use cases of data tokenization in COVID-19 include:
    - Link before trial/registry starts
        - Contextualize patients—pull in patient's EMR, genomics, lab results, to gain rich understanding of medical history, demographics, and background information to enrich the clinical trial
    - Link during trial/registry
        - Hybrid study—supplement clinical trial or registry data collection with HER, claims, pharmacy data, or other registries
        - In-registry trial recruiting—enrich registry data with patients' RWD to enable targeting trial recruiting
    - Link after trial/registry
        - Long-term surveillance—to monitor safety of clinical trial patients in the real world, enabling understanding of late effects of drug or disease
        - Show relationships between clinical trial outcomes with longer term outcomes in the real world
- If you are about to run a COVID-19 trial or know of a trial that is about to begin, Medidata would love to get involved. Please reach out to achatterjee@mdsol.com with any questions.

Social Listening: A Novel Approach to Collecting Real-World Data on Patient Experience

- Many patients and caregivers across disease settings are creating disease specific social networks for sharing their experiences and engaging with the community.
- These social networks can provide a wealth of information about the patient experience:
    - For example, people with COVID-19 are tracking their symptoms and posting detailed timelines of the course of their disease within public and private social media groups.
- Natural language processing and machine learning techniques have enabled us to turn the information shared on these social networks into analyzable data.
- The TREND Community Voice Report uses these methods to quantify conversations in areas such as disease burden, unmet needs, and experience treating disease.

- There are, of course, a number of limitations to this work including a limited amount of demographic data about the individuals making social media posts.
- Findings from the TREND Community's COVID-19 work are in the process of being published in Population Health Management Journal and will be shared with the Accelerator community at that time.

The Evidence Accelerator: Looking Back, Moving Forward

- Accelerator leadership has aggregated the feedback received during the Lab Meeting 16 "Retrospective" or "Retro."
- Broadly, the community likes:
    - The opportunity to drive RWE for regulatory decision-making
    - The collaborative and cooperative community
    - The opportunity to work together (and learn) in parallel analysis
- Broadly, the community thinks the following can be improved:
    - More time—time to delve deeper; more focused collaboration time
    - More detail—clear methodology; details beyond the superficial level
    - More structure—mechanisms for feedback; methods for selecting, pursuing, and concluding projects
- The new Parallel Analysis approach will:
    - Narrow the Wednesday meeting to active Accelerators for 3 out of 4 weeks; broader meeting for one Wednesday of each month
    - Accelerators commit to transparency and step-wise approach
    - Foundation/Friends leader will serve as decision-maker/driver/project manager
    - Use EvidenceAccelerator.org as a sharing venue within the Accelerator community via new password-protected portion (currently in development)
    - Continue working on funding gap
- The Accelerator will seek to expand its online community by:
    - Building a repository for tools (for parallel analysis studies and others doing real-world science) and case definitions
    - Developing a "living textbook" on COVID-19—mechanism to pool observations for a larger community
    - Modeling the OHDSI website as a quick way to access information
    - Improving collaboration beyond the meetings