STANFORD BYERS CENTER FOR BIODESIGN

CASE: BIOE273-4
DATE: 10/05/2017

DEMONSTRATING VALUE: EVIDATION HEALTH

"We're doing what healthcare has been trying to do for 50 years, which is to use real-life patient outcomes to facilitate better care."
– Deborah Kilpatrick, CEO Evidation Health.

Evidation Health has developed a technology platform that enables companies to more quickly, cost-efficiently, and accurately quantify the value of their health-related technologies outside of clinic walls. The company uses its connectivity to people and their data streams, as well as more traditional data sources, to run virtual trials that measure the real-world impact of a given health intervention at a scale that has never before been possible.

Background

As the United States struggles to tame its outsized healthcare spending, one solution gaining momentum is a shift from the traditional fee-for-service (FFS) care delivery to a value-based model. While FFS rewards the volume of medical interventions provided by treating each visit, test, and procedure as a separate, billable event regardless of patient outcome, value-based care favors quality over quantity, rewarding better outcomes and lower total spending.[1]

In this new environment, the need for evidence that demonstrates the value of healthcare interventions—that is, their effectiveness relative to their cost—has become increasingly important. Generating such data, however, requires a different approach than the randomized controlled trials (RCT) that historically represent the "gold standard" of clinical testing. As explained in a journal article:[2]

> Although [RCT] experimental design, if correctly applied, leads to well-controlled trials with statistically credible results, the applicability of these results to real-life practice may be questionable. Indeed, the same characteristics that contribute to the high internal validity of a trial (well-defined inclusion and exclusion criteria, blinding, controlled environment) can hamper its external validity, the ability to generalize the results in an extended population and clinical setting.

To show value in clinical practice requires different types of evaluation, often referred to as real world evidence (RWE) studies and pragmatic trials. Designed to "evaluate the effectiveness of interventions in real-life routine practice conditions," pragmatic trials test the intervention in a variety of patients, clinicians, clinical applications, and settings that reflect the real-world environment.[3] However, conducting meaningful pragmatic trials is difficult. Gathering relevant data is expensive, and the requirements placed on patients and clinicians must be kept low in order to ensure their participation over what are often long periods of time. As a result, past approaches to pragmatic studies have often resulted in minimal data collection, and difficulty characterizing subgroups of patients with differing responses, among other limitations.[4]

This case study was prepared by Samantha Madala, Stacey McCutcheon, Lyn Denend, and Marta Gaia Zanchi. Thank you to Deborah Kilpatrick for her contribution to this project.

This is where Evidation Health comes in. Evidation Health is an independent company founded in 2014 through a joint initiative of GE Ventures and Stanford Health Care. The goal of this new entity was to use digital technologies to help healthcare companies, both digital and traditional, quantify the outcomes of their interventions. Prior to its formal launch, Evidation merged with a technology company called The Activity Exchange, which aggregated data collected from health and fitness apps and devices with the goal of helping care providers, insurance companies, and employers monitor and improve the health of their patients or members. The merger provided Evidation with predictive analytic capabilities, machine learning expertise, and a sophisticated software platform that connected numerous patient-focused data streams that reflect patient behavior in the real world.

Deborah Kilpatrick signed on to the new company as the CEO. “I decided to do this because I was very interested in the new ways data and information could transform medicine,” she said.[5] With Activity Exchange co-founder Christine Lemke as President and leader of the technology functions, Evidation quickly raised $6 million in Series A funding. Then, they got to work. “We started with a technology engine that could connect to people and data, and we aimed it at health outcomes quantification,” said Kilpatrick. “We knew we could use data from patients’ real lives to measure product impact in the market.”

How it Works

In defining their offerings, Evidation embraced the emerging distinction between the traditional evidence required for regulatory clearance or approval versus the pragmatic data that proves real world outcomes. The former demonstrates safety and efficacy for regulators and answers the question, “Does your device or therapy do what your label or promotional material says it will do.” The latter are what Kilpatrick called “so what” outcomes. Are you delivering the anticipated benefit among an uncontrolled (i.e., outside of a clinical trial) user population? Does it matter clinically to the care of the patient in the standard of practice? Does it matter to the economic outcome of that care? “This is really important because pricing and value are going to be based on the outcome that you’re able to prove that you can deliver,” she said.

With this guiding focus, the team enhanced their technology platform and expanded their analytic capabilities so that they could partner with many different types of healthcare companies to help them understand the real health outcomes associated with their products and services. Evidation Health’s Real Life Study Solution is a software platform that can virtually connect to and enroll patients across the US, and quantify product impact efficiently and cost effectively, at any scale. Specifically, it can be used to help companies measure the impact of novel interventions, test new approaches, and answer research questions using data science analytics to integrate billions of points of data from both real life and traditional health data sources.

These real life data sources include electronic data being collected continuously from clinical- and consumer-grade wearables, sensors, and apps; traditional health data sources can include medical and pharmaceutical claims data alongside electronic health records from a variety of health system partners. At the center of the Evidation approach are connected patients, who have agreed to participate in these studies and provide access to their data.

These connections allow Evidation to run virtualized studies outside formal clinical trial settings. “They can still be randomized trials, or multi-armed trials, with different interventions. It’s just that all these things are happening digitally,” Kilpatrick explained. For example, to help a company prove that a fitness technology actually results in its users walking more, Evidation would design a study, recruit participants that meet the company’s inclusion criteria, secure their consent and enroll them, then connect to the applicable live, dynamic datastreams—all online. Evidation would then deploy the intervention, take participants through a protocol, and quantify the product impact based on the data streams chosen as

endpoints, such as online patient-reported outcomes or whether the technology shows they walked more. “Our platform allows all of these connections and data integration to occur seamlessly for the patient participating,” Kilpatrick noted.

Defining a Business Model

According to Kilpatrick, this type of trial works particularly well for digital technologies because these products are easily virtualizable. For this reason, GE Ventures envisioned Evidation as initially focusing on the imperative to quantify product impact in the digital health space. With new digital health apps, tools, and other technologies flooding the market, payers, providers, and consumers were struggling to identify those that would most significantly affect outcomes for their users. At the same time, developers of digital health products needed data and clinical evidence to help them distinguish their products from competitors.

However, the Evidation team quickly realized that, “There was a tremendous opportunity in biotech and pharma to do the exact same thing we were envisioning doing for digital health,” Kilpatrick recalled. Traditional life science companies could realize a huge benefit from better understanding drug and device use and performance in the real world, in the post-market setting. “There’s a massive need for this type of evidence that can be used for value justification and pricing strategy as we move into value-based care,” Kilpatrick said.

Key questions that can be answered with this type of data could include assessing product effectiveness in different population subgroups and/or different geographies, determining whether a given price point is a barrier to uptake, or establishing the most cost-effective way to improve treatment adherence. The answers to these questions can also help biotech and pharma companies make more informed decisions about to whether or not to invest in, for example, label expansion strategies or clinical development initiatives. “So although GE Ventures was initially viewing the Evidation platform as uniquely important for digital health companies, it’s actually broadly usable as an approach across any therapeutic intervention, whether it’s a pill, a lifestyle modification, or a digital app,” Kilpatrick concluded.

Ultimately, they devised a typical software-as-service (SAS) model for customers across the healthcare sector. Clients pay a base fee for platform access and then additional fees for specific projects and use cases, in a master service agreement (MSA) approach. “There’s an underlying platform access approach, essentially, with every integration and configuration that we do,” explained Kilpatrick. “That essentially gets people and data streams hooked up in a specific configuration, in a virtual population for a given study. The MSA is the baseline for the partnership over time, and we can add study-specific statements of work that address each customer’s unique needs.”

Proving Evidation’s Own Value Proposition

To quickly demonstrate their value and product market fit after their series A, Evidation set out to acquire proof points with customers and partners by deploying their technology to quantify real world outcomes of interest. In one early project, Evidation executed a virtual study for a digital health company focused on crowd sourcing expert clinical opinions to quantify the economic impact of their platform on real world patient cases. During the same timeframe, Evidation received a DARPA grant to execute a virtual RCT in over 75,000 patients with the goal of understanding how mobile-based interventions could impact US flu vaccination rates. The team also focused on publishing their own research linking patient behaviors outside clinic walls with health outcomes. “We went out and systematically proved that the market needed what we were selling and that the platform that we had built could provide a rapid and robust solution to meet that need,” said Kilpatrick.

"One of our biggest challenges over the last couple of years has been educating the market about what we do because it's still a relatively new construct, and can feel abstract, especially to traditional healthcare companies," Kilpatrick said. She noted that digital health companies had an easier time understanding their offering when they first launched. "They fundamentally exist in a virtual world with connections to people and data streams that are part and parcel to their offerings, so doing a virtual outcomes study seems natural to them," she described.

However, as therapeutics companies become more comfortable with digital technology, Evidation's workload is shifting. "While biotech and pharma clients generated the minority of our revenue in 2015, they are a significant contributor to our revenue stream in 2017 and 2018. The tremendous growth in this channel reflects the accelerating demand for digital technologies to prove impact across all of healthcare," she said. To date, Evidation has raised over $31 million in venture funding and is growing rapidly.

Key Insights

- **The ability to clearly demonstrate value is essential…for any/every new technology**
  Now more than ever, new technologies must be supported by a strong value proposition and compelling data to back it up. Every now and then, a company "gets lucky" and generates initial interest/adoption this data. But demonstrating meaningful value is imperative for building a sustainable business.

- **Your business model and your value proposition are inherently linked**
  How (and how much) customers are willing to pay for your technology is dependent on your ability to convince them of the value your technology will deliver. Keep the cost of your technology aligned with the magnitude (and timing) of the value it delivers.

- **It's never too early to start thinking about your clinical testing strategy**
  Innovators should be thinking about the data they'll need and how they will generate it in parallel with technology development. Remember that different audiences will require different types of data for different reasons (e.g., traditional versus pragmatic data, gaining regulatory clearance versus driving adoption) and it will likely be necessary to conduct multiple trials. Plan for this early, and make updates to your approach often, as new ideas and information become available.

[1] "Value-Based Care: Better Care, Better Health, Lower Cost," Aetna, 2015, https://news.aetna.com/2015/01/value-based-care-better-care-better-health-lower-costs/ (September 27, 2017).
[2] Nikolaos A. Patsopoulous, "A Pragmatic View on Pragmatic Trials," Dialogues in Clinical Neuroscience, June 2011, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3181997/ (September 27, 2017).
[3] Ibid.
[4] Harold C. Sox, Roger J. Lewis, "Pragmatic Trials - Practical Answers to 'Real World' Questions," JAMA, September 2016, http://jamanetwork.com/journals/jama/fullarticle/2553436 (September 28, 2017).
[5] All quotations are from interviews conducted by the authors unless otherwise cited.